A study assessing the viability of using Fused Filament Fabrication (FFF) Additive Manufacturing (AM) technology to manufacture customised Class I medical devices

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Declaration

This is to certify that the material contained in this thesis has been produced by the author and has not been accepted in substance for any other degree and is not currently submitted in candidature for any other academic award.

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Abstract

Additive manufacturing (AM) is becoming an increasingly common manufacturing method for medical devices due to the benefits of advanced customisation, improved fit and opportunities for innovation. However, many AM medical devices remain inaccessible due to high costs of hardware and consumables, and the large infrastructural requirements required for operation. Fused filament fabrication (FFF) is a highly accessible AM technique due to its open-source nature, which has led to an extensive market of affordable desktop 3D printers. In this work FFF has been demonstrated as a potentially viable technique to fabricate low-risk medical devices in two case studies presented in this thesis: a customised daily living aid and a range of medical devices in response to the COVID-19 pandemic.

Although the potential of the technology has been demonstrated, research around the practical suitability of FFF for medical applications remained limited, with much of the research in the field focussing on proof-of-concept applications, which did not explore the necessary requirements for the integration of the technology into daily clinical practices. This thesis investigates the fundamental requirements of the FFF AM technique for it to be used for Class I medical device applications in three identified use cases: non-specialist, research and industrial use. In keeping with the ambition for FFF to provide accessible solutions, mid-range hardware aimed at professional printing applications was selected to carry out this work, which encompasses the activities present in each of the three identified use cases.

A methodology was presented to determine the repeatability and reproducibility of FFF across three potential use cases, which revealed varying process capability between the X-, Y- and Z-printing directions for individual machines, and significant variation between multiple machines of the same make and model. The repeatability and reproducibility of the FFF technique was identified as a key limitation for the widespread adoption of FFF technology for specialist and industrial use. The smallest tolerance achieved from a professional desktop FFF printer was 0.3mm in both the X- and Y- directions, and 0.4mm in the Z-direction.

Additional variable factors were studied, including the condition of filament with respect to its storage environment and duration of storage, the influence of different colours and pigments

present in filament and the use of an air management add-on unit intended to enhance the hardware. The glass transition temperature of Tough PLA remained largely unaffected from variable storage conditions, which when submerged in water decreased by around 1.4ºC from that of ambiently stored filament. The mechanical properties of printed parts were influenced by filament colour, with white filament producing parts with increased elongation and tensile strength than other colours studied. Dimensional accuracy in the Z-printing direction was affected by air management, where samples produced with air management were measured higher than the nominal value, and without air management lower than the nominal value.

This thesis is the first known work to explore the suitability of FFF technology for Class I medical devices, from the perspective of both specialist and non-specialist users. The key barriers to widespread adoption were identified as the repeatability and reproducibility of the technique, and the influence of variable factors on the process and part performance. The exploration of these continually referenced medical device regulations, whilst consideration was given to how the experimental work can be applied to real-world Class I medical device manufacturing applications.

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Nomenclature

FFF	Fused filament fabrication
AM	Additive manufacturing
FDM	Fused deposition modelling
STL file	Standard tessellation language file
3DP	Three-dimensional printing
RH	Relative humidity
ME	Material extrusion
DMA	Dynamic mechanical analysis
DSC	Differential scanning calorimetry
TGA	Thermogravimetric analysis
E’	Storage modulus
E”	Loss modulus
Tg	Glass transition temperature
SEM	Scanning electron microscopy
Micro-CT	Microcomputed tomography
UTS	Ultimate tensile strength
Tan δ	Tan delta
SD	Standard deviation
%SD	Percentage standard deviation
WB	Weight before conditioning
WA	Weight after conditioning
WC	Weight change
%WC	Percentage weight change
MMU	Manchester Metropolitan University
QMS	Quality management system
IQ	Installation qualification
OQ	Operational qualification
PQ	Performance qualification
PLA	Polylactic acid

ABS	Acrylonitrile butadiene styrene
PEEK	Polyether ether ketone
PVA	Polyvinyl acetate
HIPS	High impact polystyrene
ULTEM®	Polyetherimide
PC	Polycarbonate
PETG	Polyethylene terephthalate glycol
PET	Polyethylene terephthalate

Pa	Pascals
GPa	Gigapascals
MPa	Megapascals
mm	Millimetres
ºC	Degrees Celsius
g	Grams

Publications

Three-dimensional (3D) scanning and additive manufacturing (AM) allows the fabrication of customised crutch grips
Materials Today Communications – Volume 25
Elen J. Parry, Joshua M. Best and Craig E. Banks (2020)

COVID-19: additive manufacturing response in the UK
Journal of 3D Printing in Medicine – Volume 4
Elen J. Parry and Craig E. Banks (2020)

The rise of 3D printing in healthcare and implications for future plastic waste: constructing a Circular Economy roadmap to ensure responsible innovation
Innovative Approaches to Handle Plastic Waste and Foster Bio-based Plastics Production
Elen J. Parry, Carly Fletcher, Rhiannon Hunt and Craig Banks (2022) (in press)

COVID-19 Statement

This PhD was completed between 2019 and 2022 and was therefore undertaken during the COVID-19 pandemic. This caused some disruption to the planned work specifically relating to the supply of consumables. Stocks of 3D printing material were limited due to the increased uptake of FFF technology to produce personal protective equipment. This resulted in two colour variations of the same material being utilised in the initial pilot study, which revealed the influence of filament colour as a new line of investigation.

The narrative around the use of 3D printing in the context of the COVID-19 pandemic was particularly pertinent, and therefore became an important narrative throughout this thesis.

The findings in part one lead to a natural shift in disciple where the work became largely focussed on engineering. As a result of this, changes to the supervisory team were made mid-way through the PhD, with Dr Kirstie Andrews replacing Professor Craig Banks as principal supervisor.

Part 1

Background and context

Chapter 1

1. Introduction

1.1. Thesis structure and reading guide

Due to the complexity of the research subject the thesis is presented in three parts. Part one consists of chapters one to three, which are dedicated to the exploration of the FFF field for Class I medical devices, which was necessary to set the scene and form a baseline for part two. Chapters one to three follow the following format: introduction, body of work and conclusions, where chapter one introduces the field of study, chapter two discusses the field and its components in detail, and chapter three gives two case study examples, based on published work. Part two consists of three experimental chapters which include the design of novel experiments and the fabrication of scientific data. These chapters take the following format: introduction, literature review, methodology, results, discussion, and conclusion. Part three consists of a discussion section that ties in the key discussion points from both parts one and two, along with the impact, novelty and significance to the field, followed by recommendations for future work and overall conclusions.

Chapter three is based on two published papers: “COVID-19: additive manufacturing response in the UK” and “Three-dimensional (3D) scanning and additive manufacturing (AM) allows the fabrication of customised crutch grips”.

The work in this thesis has been granted ethical approval. The EthOS numbers are as follows: preliminary research: 17618; custom crutch accessories: 15282; material testing: 25190.

1.2. Research background and rationale

After studying inclusive design, it was made apparent that many people around the world frequently come up against barriers in day-to-day life as a result of unavailable, insufficient or poorly performing medical devices and assistive aids. These include poorly fitting devices, such as orthotics, devices with limited functionality or those causing discomfort and irritation,

such as plaster casts, and in some cases a complete lack of suitable devices entirely due to long waiting lists. Low availability and high costs of devices are key barriers to accessibility (Cropper and Zachariasen, 2017; Ferreira *et al.*, 2018). Products and devices that insufficiently meet the needs of users can often be a result of poor fit, directly influencing patient satisfaction (Graham *et al.*, 2020). An example of the importance of a well-fitting medical device is an articulated orthoses, which is a device worn to apply forces on the body which can be adjusted in the duration of its use (Ricotta *et al.*, 2020). Each of us is unique, meaning different people require different things from medical devices. Up until recently, producing customised or individual products was only common for a specific group of applications where customisable elements were critical for product functionality (Niaki and Nonino, 2016). Technological developments in the form of digital design and manufacturing techniques have set a new precedent for the manufacture of efficient and economical customised products providing optimal personalised function and comfort (Venekamp and Le Fever, 2015).

The digital manufacturing realm encompasses a wide range of techniques which are continually growing and adapting. Each technique introduces its own unique set of considerations and challenges, many of which are yet to be addressed in research, and for those that have, many remain in their infancy. The traditional manufacturing techniques used to fabricate custom medical devices largely utilise hand-crafting techniques, which are often influenced by the skill of the technician producing the device (Blij, 2019). A common method is to use flat thermoplastic sheets which are heated and manually formed around an anatomical model of the patient. The hand-crafted element can mean that sculpting devices can be a time intensive process, whilst being subject to an increased amount of human error (Cropper and Zachariasen, 2017). It is not uncommon for a technician to take multiple attempts to produce a well-fitting customised device, thus elongating timescales and increasing costs.

Individualised products produced using digital methods can be closely tailored to individuals, using software techniques that cannot be used in reality. For example, analysis tools available in digital software packages allow the user to see *through* geometry and create sectional views that would not be possible in real world fabrication scenarios. Such techniques allow for the user to fine-tune the digital geometry multiple times before it is physically fabricated. Geometry can be modified to provide increased support, ventilation, or meet other patient specific needs, meaning devices can be truly bespoke and optimised for individuals. The utilisation of digital manufacturing techniques mean design complexity is not translated into

manufacturing complexity, and the manufacturing process remains the same, meaning device variations will not affect manufacturing efficiency.

Conventional manufacturing techniques often require tooling, such as jigs or moulds which can be costly and time consuming to produce. Therefore, the products in which they produce rely on economies of scale, meaning in many cases customised designs were inefficient and uneconomical (Khajavi *et al.*, 2014). Complex geometry can also be problematic for some conventional manufacturing techniques, which in many cases require multiple techniques such as moulding, milling and drilled to be used in sequence to produce a product or part. Digital manufacturing techniques can consolidate multiple conventional techniques, resulting in reduced labour requirements and a more efficient process (Pereira *et al.*, 2019). For this reason, digital techniques have been shown to be highly suited for complex or customised products. Although, using traditional manufacturing techniques is deemed to be more cost effective for high production models (Pereira *et al.*, 2019).

Challenges associated with novel digital techniques are often amplified by the requirement of medical devices to conform to a rigorous set of standards. Medical device manufacturing is a highly complex field, even with conventional manufacturing techniques that have been used for decades, due to the extensive evidence required for the regulatory approval of medical devices as discussed in detail in Chapter two. This signifies the increased challenges associated with novel digital techniques, which are still central to many research activities aiming to understand the intricacies of the processes, to determine their full capability. At this stage, the full potential of digital techniques remains unexplored. Whilst the technology advances, considering potential applications and outlining the requirements of the technology to meet those applications can drive innovation, helping the technology to reach its full potential.

This research has identified a particular digital manufacturing technology, fused filament fabrication additive manufacturing, as having huge potential to innovate current practices for customised medical applications which are discussed in detail in Chapter two. However, critical research gaps have been identified, preventing the technique from being explored to its full potential. This research aims to address the critical research gaps and form a baseline for additional future research in this field. It is hoped that by addressing some of the critical challenges associated with fused filament fabrication technology for customised medical device applications, further research can be conducted, subsequently driving innovation from

hardware and material manufacturers to increase the suitability of the technology for this particular use application, but also drive change from a regulatory perspective. Changes in the way medical devices receive initial regulatory approval may be necessary, as well as adaptations within the approval process to support widespread use and adoption of the technology.

It is hoped that addressing some of these fundamental issues contributes to a growing understanding of how digital design and manufacturing techniques can be integrated into everyday practice. The dissemination of these findings could be used to identify future areas of development for the technique to be viable for providing improved solutions which are affordable and accessible to the widest possible range of users.

1.3. Additive manufacturing overview

Additive manufacturing (AM), or three-dimensional (3D) printing (3DP) is a wider term for a group of fabrication techniques which work by adding material, defined by ASTM as a process of joining materials to make objects from 3D model data (ISO, 2021). AM is a rapidly growing field, with a vast range of materials and technologies that is continually increasing. Currently, AM can be categorised into five groups based on material: Ceramics, cements and concretes; metals; hydrogels and bioinks; composite materials and polymers. Each of these umbrella groups have subgroups within, each containing different types of technique specific to each material. The focus of this research is on polymer AM, so for this reason, the varying techniques for other materials are not detailed in this work. Figure 1 shows the five main AM material groups on the top level, the main types of polymers AM on the second level, with details of the varying technologies for that type of AM on the third. Fused filament fabrication (FFF), a type of material extrusion (ME) is the focus technology of this work. Therefore, the lower two levels of Figure 1 detail the types of FFF technologies, and the variations within.

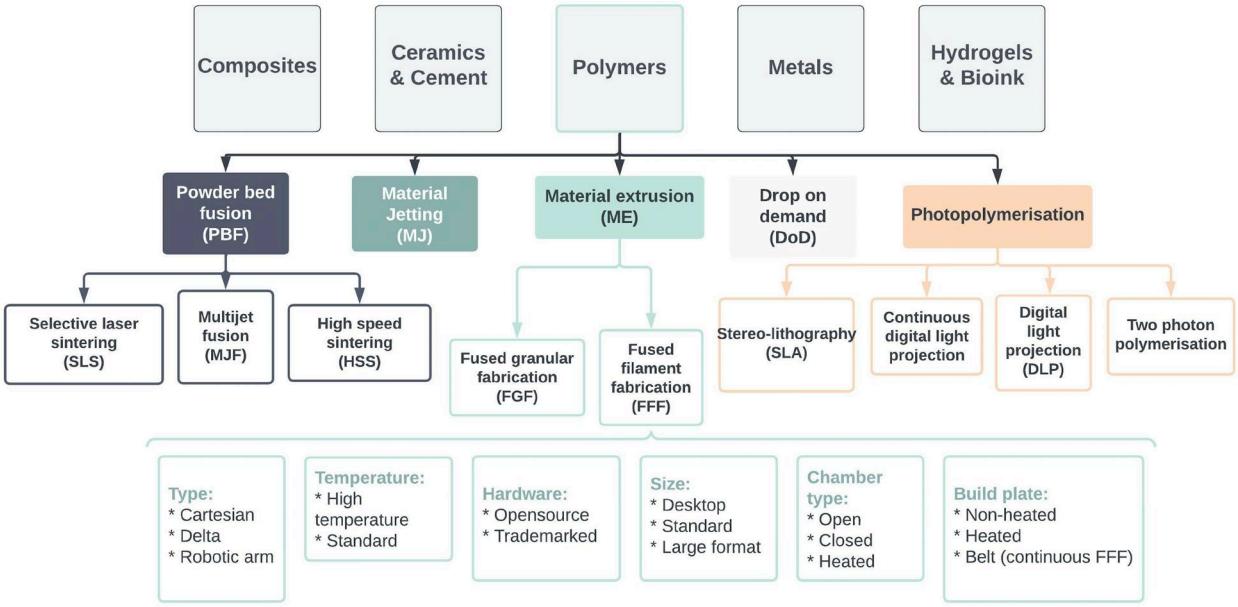


Figure 1: Additive manufacturing technologies map, focussed on polymer AM

A unique quality of AM is the ability to produce highly complex, customised geometry without the need for tooling. The technology fabricates parts based on a digital model, which can be created using multiple digital techniques. Computer aided design (CAD) is the use of computer software to create, modify or optimise a digital design (Bryden, 2014). It helps the user in the design process by offering a range of design tools and techniques to achieve their desired form and function, combined with a large set of tools aimed at aesthetic design considerations. CAD software has advanced significantly in recent years, and now offers more advanced design tools than ever before. Algorithmic processes such as topology optimisation and generative design are becoming integrated into commercially available CAD packages and can be used to optimise designs within a series of constraints, such as manufacturing method or cost constraints (Autodesk, 2022).

These advanced design techniques enable the careful and considered design of parts, making product design more flexible, productive, and innovative (Bryden, 2014). Paired with AM, CAD offers geometrical freedom, unlocking another layer of innovation and possibility within design and manufacturing industries. Functional performance can be optimised through reducing the density of parts whilst maintaining optimal performance (Briard *et al.*, 2020). Advanced lattice structures, such as non-periodic stochastic lattices, and other complex

structures can be generated using CAD software, which are only possible to fabricate physically using unconstrained methods, such as AM (Varotsis, 2022).

Once a digital file has been produced, it is prepared for AM. Usually in the form of an STL file (standard tessellation language or standard triangle language), a digital file which is imported into slicing software. This software is a necessary step in AM, which slices the digital part into thin layers and forms a G-CODE file. G-CODE is a language used to describe a set of instructions a 3D printer can read. The G-CODE is required by the printer to instruct it where to print layers of the sliced object, and therefore acts as a toolpath.

Technological advancements over the past decade have enabled continuous series of innovations across the industry, facilitating the resolve of complex problems, and in some cases permanently transforming manufacturing operations and the way things are designed and manufactured. The AM industry has seen significant growth which is projected to expand at a compound annual growth rate of 20.8% from 2022 to 2030 (Grand View Research, 2022). One of the main drivers of increased accessibility to AM techniques is the expiration of patents, which has allowed manufacturers the freedom to develop new hardware (Ngo *et al.*, 2018) as well as build on existing techniques. Democratisation of these previously constrained technologies has allowed for further innovation in hardware and materials, which in turn has driven down costs. A brief overview of the wider AM material groups is necessary to highlight the fast-paced development of the industry, and thus demonstrate the extent of the innovative work that is being done across the industry as a whole.

1.3.1. Wider AM innovations

Advanced ceramics have been used for medical and dental applications such as scaffolds for bones and teeth (Wen *et al.*, 2017). Using ceramic materials to 3D print scaffolds for tissue engineering has become a more convenient and faster method when compared with traditional methods of casting and sintering (Wen *et al.*, 2017). Ceramic materials are usually printed using inkjet technologies, powder bed fusion, paste extrusion and stereolithography (Ngo *et al.*, 2018). The extrusion of ceramic pastes is also referred to as extrusion free-forming of ceramics, or EEF, and fusion deposition modelling of ceramics, or FDC (Ngo *et al.*, 2018). Inkjet 3D printing is said to be the main method of making dense ceramic specimens, sometimes without the need for post-processing techniques (Travitzky *et al.*, 2014). Factors

currently limiting ceramic AM are visible layer lines in printed parts, and a lack of material choices.

The first residential structure printed in concrete was erected in Amsterdam in 2014 by DUS architects, using the fused deposition model (DUS Architects, 2013). Since then, cement based or concrete AM is an increasingly used technique in the construction industry, where in 2018 the AM of buildings was named as a trending application (Ngo *et al.*, 2018). The main method of fabricating structures in the construction industry is known as contour crafting (Khoshnevis, 2004). The AM of buildings has potential to revolutionise the construction industry, and has become a popular discussion point for the construction of infrastructure on the moon (Labeaga-Martínez *et al.*, 2017) to assist in space exploration and other research activities. Concrete AM also enables the rapid fabrication of shelters to provide relief for communities who have experienced natural disasters (Martys *et al.*, 2017). Another key benefit for using AM in construction is to minimise the risk to humans by removing them from hazardous construction environments (Martys *et al.*, 2017). However, the layer lines resulting from the extrusion process can lead to limitations in accuracy and precision, therefore techniques such as hybrid concrete printing (HCP), or digital hybrid printing have been developed. HCP uses 3D printing to produce an object slightly larger than desired, which is then refined using subtractive processes, removing the extra material and leaving the object in the desired size and shape (Xu *et al.*, 2022). The comprehensive range of equipment required for concrete printing, such as mixing equipment, pipes, pumps and nozzles, the robotic arm and the software to program it, could also be thought of as a limiting factor, without the additional subtractive manufacturing equipment necessary for HCP.

The AM of metals is becoming increasingly accessible since metal AM is no longer limited to industrial locations with sizeable space and infrastructure. Variations of metal AM systems are present on the market, which are distinguishable by the type of material or feedstock they use, the type of build volume, the energy source used and the way in which the material is joined. More recently, desktop metal AM has been developed, allowing users to print metal parts from an office space (Metal Powder Report, 2017). The material library for metal AM has grown considerably, and more advanced technology has allowed for improved material properties and wider functional applications (Herzog *et al.*, 2016).

Metal AM has been used to fabricate components for the automotive and aerospace industries, such as motor blades and engine exhausts, due to the increased strength and flame retardancy properties (Appleyard, 2015). Metal AM is also used for medical implants, which consolidates a process previously completed over multiple steps (Murr, 2020). Advanced customisation opportunities offered by CAD and AM, combined with materiality advancements (Geetha *et al.*, 2009; Jardini *et al.*, 2014) has enabled the fabrication of complex porous implantable structures. This enables the osseointegration, the connection between living bone and the surface area of the implant, which helps the acceptance of an implant by the human body (Yuan *et al.*, 2019), thus improving the functionality of the device by minimising rejection.

Polymer AM is considered the most common and well-known type of AM. The earliest patent filed for AM in the 1980s was for a system that cured liquid polymer using UV light (Hull, 1986), a process today known as photopolymerisation, a type of polymer AM (Quan *et al.*, 2020). The five current widely used polymer AM technologies include powder bed fusion (PBF), material jetting (MJ), material extrusion (ME), drop on demand (DoD) and photopolymerisation, as shown in Figure 1. Each of these techniques differs by technology, type of material and method of fabrication, and therefore each has different pros and cons depending on the application.

Polymer composites have been used in research aiming to address suboptimal mechanical properties of polymer AM. Advanced polymer composites became mainstream in response to the need for materials and methods of AM polymers with superior performance (Takezawa and Kobashi, 2017; Wang *et al.*, 2017). Composite printing uses additional materials, typically carbon fibre or fibreglass, to reinforce parts. Applications for composite AM include aerospace (Fasel *et al.*, 2020), automotive, architectural and medical (Ngo *et al.*, 2018), for high-functionality critical parts (Alaimo *et al.*, 2017).

Advanced polymer composites are shown to be particularly transformative for FFF polymer AM, or fused deposition modelling (FDM) which is known for the production of anisotropic parts with suboptimal mechanical performance. Thus, the addition of fibre reinforcement for the FFF technique is a promising advancement (Tian *et al.*, 2016; Ferreira *et al.*, 2017; Hou *et al.*, 2018) to strengthen the mechanical properties of printed parts (Parandoush and Lin, 2017). However, whilst the technique develops, challenges have been reported around the orientation

of fibres, the bonding between the fibre and matrix, void formation within parts (Parandoush and Lin, 2017; Wang *et al.*, 2017) and high porosity (Tekinalp *et al.*, 2014).

1.3.2. Polymer AM techniques

PBF technology uses a thermal energy source to fuse powder particles forming material to produce parts (R. Singh *et al.*, 2020). This technique is used for both polymer and metal powders. Figure 2 shows a roller spreading a thin layer of powder over the build chamber where the cross section of a part (predetermined by the CAD data) is scanned and fused. The build platform is then lowered by a controlled amount, which is known as the layer height, before the process is repeated until the full part has been fabricated. The finished part is embedded in unfused powder which acts as support material during the AM process, meaning the generation of support structures is not required (R. Singh *et al.*, 2020). The main difference between the different types of PBF technology is the method of scanning or fusing the powder. PBF typically uses a laser to solidify the material, polymer for selective laser sintering (SLS) and metal for selective laser melting (SLM). Upon completion, parts are removed from the chamber, where excess powder is removed with a bead blast which results in a more consistent surface quality, and the unused powder can be recycled in controlled quantities. The post processing of PBF parts often requires personal protective equipment (PPE) and additional hardware to collect and recycle the unused powder, which is sometimes integrated within the printer, or sometimes external hardware requiring a large footprint and intensive infrastructural requirements, making PBF more expensive and less accessible than other AM techniques.

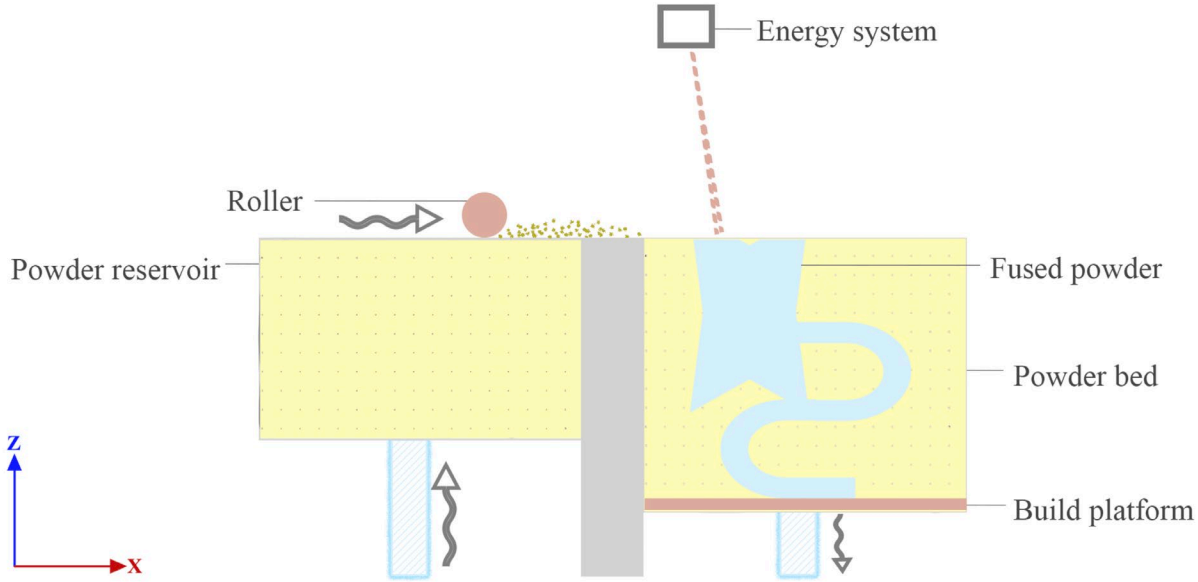


Figure 2: A schematic showing a generic version of the powder bed fusion AM process (y-axis is perpendicular to the x-axis)

MJ is the process of passing a print head across a build platform whilst the print head dispenses either a single photopolymer, or multiple photopolymers simultaneously whilst an ultraviolet (UV) light cures the material as it is deposited. The process is repeated, and each layer is cured to the previous layer until the part is complete. An extension of MJ is DoD, which instead of continuously dispensing photopolymers, it dispenses more viscous liquid materials, typically wax. Multi-material printing is enabled by multiple nozzles depositing multiple different materials simultaneously, which is a manufacturing advantage specific to this type of technology. A two material MJ process is shown in Figure 3. This technique requires the fabrication of support structures, which are usually printed using a soluble material which can be dissolved away, which is typically the only stage of post-processing required for MJ parts.

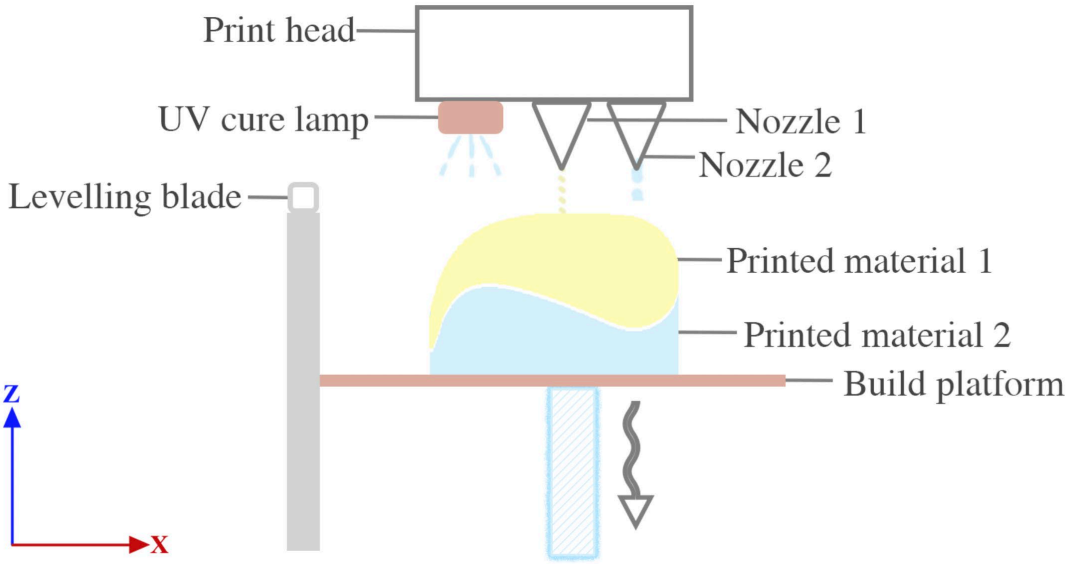


Figure 3: Schematic of the material jetting AM process (y-axis is perpendicular to the x-axis)

ME is a group of technologies which feeds thermoplastic material into a print head where it is heated to a pre-specified temperature and extruded onto a build platform along a predefined path. The most common method of ME is fused filament fabrication (FFF), which uses a spool of thermoplastic material. The other type of ME uses thermoplastic material in granular form and is known as fused granular fabrication (FGF). After a complete layer has been extruded, the build plate lowers by a controlled amount and the next layer is extruded joining the previous. FFF technology commonly uses one or two nozzles which allows for dual material printing, as illustrated in Figure 4. Modification has allowed some printers to extrude more than two materials through the use of add-on accessories, however, generally only two materials are supported by standard technology. The process requires the fabrication of support structures, which like MJ, can be printed using soluble materials when dual material printing is supported. Post-processing of FFF includes the removal of both soluble and tear-away support structures which are typically printed in the same material of the part. Soluble material can be removed with water, and tear-away support material requires removal with clipping tools, which sometimes requires additional sanding to achieve the desired surface finish.

FFF is highly popular due to its increased accessibility compared to other AM technologies. This is because of the low-cost of some hardware models and the affordability of filaments such as polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS). The benefits of the technology include a wide range of materials and colours, including flexible, transparent,

metallic in colour, and those with industry specific additives. Although the technology can produce parts with small overhangs, it cannot produce geometry with large overhangs or undercut geometry without the use of support material (Krishnanand and Taufik, 2021). Poor surface finish (Chohan *et al.*, 2017) and poor mechanical properties, some of which include modulus, tensile strength, and impact strength (Wang *et al.*, 2019), are also identified as limitations of the technology.

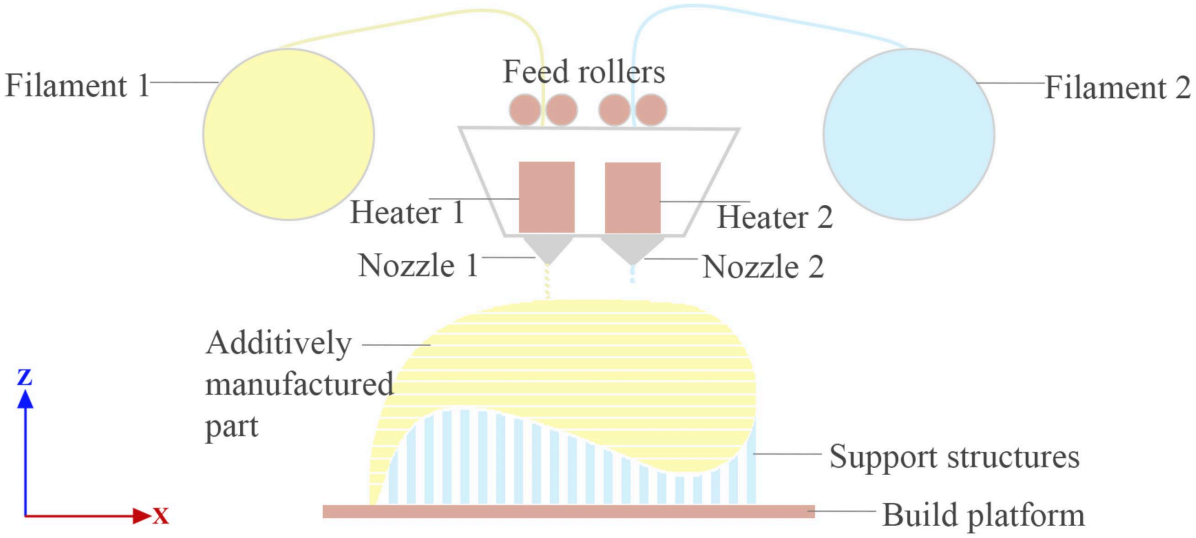


Figure 4: A schematic of dual material fused filament fabrication AM technology (y-axis is perpendicular to the x-axis)

Photopolymerisation is a process where liquid photopolymer resin is cured by a laser or light source. The two main types of vat photopolymerisation, where a build platform is lowered into a full tank of resin, are stereolithography (SLA) and digital light projection (DLP). Both techniques lower a build platform into a resin tank, where a cross section of the part is solidified. The difference between SLA and DLP is the curing technique, where SLA uses a single or multiple lasers to trace a cross section, illustrated in Figure 5, DLP flashes a full image of each layer at one time, meaning DLP is usually a faster process than SLA. The laser or light source repeats the process, bonding a new layer to the previous layer until the part is completed. The part must then be removed from the build plate, washed and post-cured.

Post-curing is a technique used to improve the part's mechanical properties where the duration and temperature of the cure depends on the chemistry of the resin used. Once printing has finished, SLA parts remain in a "green state", meaning the polymerisation reaction is not fully

completed and the part will not exhibit optimal mechanical properties. Light and heat post-curing techniques finish an SLA part increases the strength and stability, whilst curing any sticky residue left on the surface of the print from the printing process (Formlabs, no date). Specialist hardware for post curing is available on the market, usually consisting of a heated chamber with lights, often UV lights with wavelengths between 10nm and 300nm (Formlabs, no date). After curing, the support structures can be removed with clipping tools, and the surface of the part can be sanded where required for optimal surface quality.

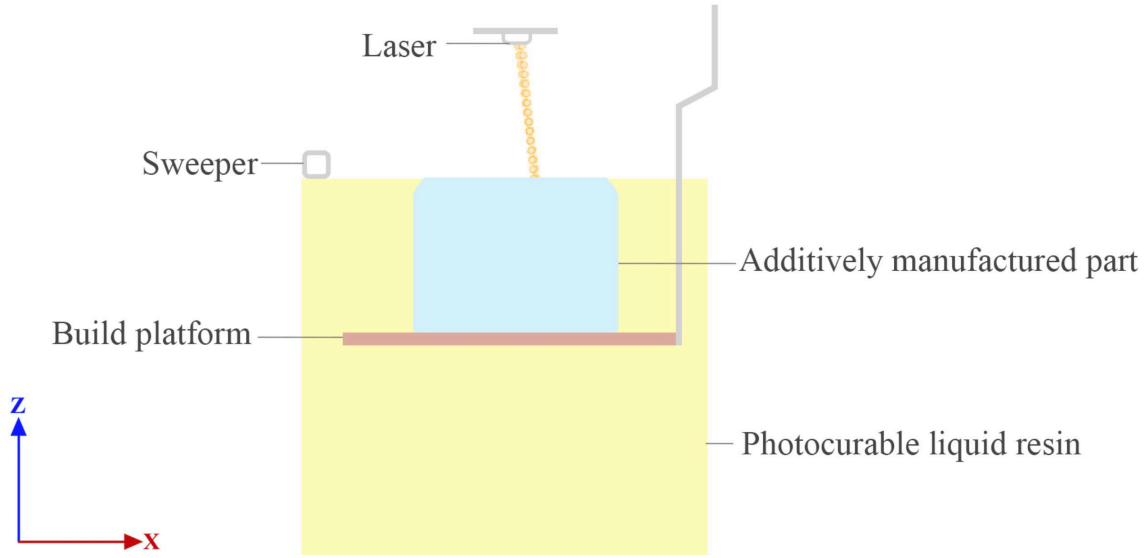


Figure 5: A schematic of the SLA vat photopolymerisation AM technique (y-axis is perpendicular to the x-axis)

This group of polymer AM technologies each include multiple hardware variations based on the same technology, which each have their own benefits and limitations. For example, within the FFF group, hardware ranges to support standard thermoplastics with low melting temperatures, up to high performance thermoplastics that have high thermal stability and increased mechanical strength. The benefits, limitations, costs and infrastructural requirements of each subgroup technology varies significantly, and therefore should be selected based on the performance requirements of AM parts. Overall, technological advancements in the AM field have formed a fast-paced industry with many exciting developments, which has created opportunities for innovation in many industries. The more sophisticated hardware ranges allow for further agility in manufacturing, such as the ability to switch between six colours of material within a single print, or the expanding material libraries across all AM technologies. AM has been particularly advantageous for applications that benefit from customisation or

personalisation such as healthcare and medical industries. Certain medical practices have been completely transformed by AM and digital technologies, as discussed in Section 1.4, and there is potential for further transformation that could benefit healthcare services and users, some with life-changing potential as a result of the increased affordability and accessibility expected through the utilisation of AM techniques, and the advanced customisation opportunities facilitated by the technology.

Table 1: Polymer AM technique comparison table

AM technique	Pros	Cons	Post-processing
Powder bed fusion	No support material required	Expensive Large infrastructural requirements	Integrated or separate post-processing equipment required
Material jetting and drop on demand	Multi-material printing	Support structures sometimes required	Soluble support offers minimal post-processing
Material extrusion	Inexpensive and accessible	Concerns around part quality and performance	Soluble support offers minimal post-processing
Photopolymerisation	High printing quality	Rigid support material is required for most parts	Two-stage post-processing requiring additional hardware, chemicals and PPE

1.4. Additive manufacturing for medical applications

The healthcare industry is one of many experiencing a technological shift. Industry 4.0 is a significant driver for digitalisation in healthcare, which uses a wide range of technologies to provide better and proactive intervention (Popov *et al.*, 2022). Due to advancements in medicine, general life expectancy of the population is increasing, and many more people are living longer than has ever been possible (Brown, 2015; Boudoulas *et al.*, 2017). As an aging population, healthcare needs are changing and chronic disorders are increasingly common (Cristea *et al.*, 2020; Schiavone and Ferretti, 2021). The healthcare system will face further

challenges in the future to meet demographic changes and meet a new paradigm of care (Schiavone and Ferretti, 2021).

AM technologies have enabled a range of innovations, specifically relating to the novel levels of advanced customisation achievable with AM technologies. AM has enabled more optimised and efficient interventions. For those people with additional needs who require medical devices and assistive aids as part of their every-day life, the functionality of the device is essential. Although, how these devices make the user feel, or how they are perceived socially can be an equally important consideration for some users. A common reason for the rejection of Class I medical devices or other assistive aids is the poorly considered aesthetic appearance of them, for example, wrist splints (Paterson *et al.*, 2015). This alone could be an access barrier for many people.

Whilst providing customised or patient specific solutions relating to anatomical fit, bespoke designs and aesthetic appearance can be introduced with little additional effort, which in turn can address the barrier of 'social accessibility', potentially increasing uptake (Shinohara and Wobbrock, 2016). As expressed by design writer Donald Norman, 'great designers produce pleasurable experience' (Norman, 2013). However, due to the complex requirements relating to clinical need and medical functionality, design elements are often neglected from the medical device development process, thus demonstrating why many examples of medical devices and assistive aids have remained relatively unchanged for decades. This is referred to as the 'legacy problem' (Norman, 2013), in which many devices follow the existing standard, or legacy of that product.

Resistance to change can be a result of numerous things, however, one of which is concern over the expense of complete innovation, or the belief that the most efficient or economical method has already been realised. When introducing new technologies and processes such as AM, an opportunity is presented to completely innovate devices and products, whilst utilising the newfound benefits associated with the technique. AM has demonstrated its suitability for complete device innovation, in terms of both aesthetics and functionality, setting a new precedent for co-design and co-creation, where users of a device can be directly involved in aesthetic decisions about their device.

1.5. AM applications in healthcare

Innovation is not limited to medical devices. AM has enabled innovation across various areas of the healthcare industry which is being reported in academic literature. This section discusses some of the wide-ranging areas where AM is showing potential for innovation. As technological developments continue and more research is reported, AM adoption is expected to increase, and innovation is expected in more areas.

A systematic review by (Martelli *et al.*, 2016) revealed that out of 158 studies around the use of AM in surgery between 2005 and 2015, the highest proportion reported using AM to produce anatomic models which are used across training, education and surgical planning applications (Martelli *et al.*, 2016). Since the publication date in 2016 an increase in publications surrounding the field indicate AM in healthcare is an active area of research. In a review of AM for abdominal surgery alone, an increase of around ten times the amount of publications were reported in the last decade (Pietrabissa *et al.*, 2020).

1.5.1. Surgical planning

Surgical planning is a process intended to improve the overall outcome of surgery, which can involve surgeons visualising, analysing, and operating on simulative models. Surgical procedures can be extremely complex; thus, the replication requires a large set of tools and equipment to replicate varied and complex environments. AM is inherently suited to the agile production of complex and unique parts, and is therefore becoming an integrated tool in pre-operative planning, and well-integrated into surgical practice (Tack *et al.*, 2016). Surgical planning models have two main functions, firstly to mimic living tissue and secondly to provide clear visualisations of affected organs or tissues before surgical procedures commence. A range of techniques can be used to meet the desired functionality, with the most commonly used techniques being FFF, PBF, MJ and photopolymerisation (Tejo-Otero *et al.*, 2020).

Multiple case studies have been presented where the use of AM for surgical planning has been successful. A study presented by (Krauel *et al.*, 2016) studied three patient cases, who each had tumours encasing major vessels. AM models were generated from CT images by a CAD engineer, radiologist and the lead surgeon, and consisted of two parts: first, an operable translucent tumour model for the surgical team to operate on prior to the surgery, and secondly

parts representing bone and other vessel components. The tumour model was required to be soft, whilst the bone models were required to be more rigid. Where increased visibility was required, the tumour was designed to be removable, enabling full visibility of the vessels.

MJ, PBF and FFF were each used in this case study and allowed the surgeon to experience what they were likely to expect during the procedure. Using sterilisation techniques such as steam formaldehyde at 60-80ºC enabled the parts to be used for reference during the surgical procedure. The 3D printed models were found to precisely predict the surgical findings, despite some technical drawbacks relating to the behaviour of materials not accurately replicating the behaviours experienced in surgical dissection, which is a limitation commonly shared across literature (Clifton *et al.*, 2020).

The case study demonstrated effective use of CAD and AM technologies to fabricate scaled models that accurately represented the scan data. Digital technologies allowed for the fabrication of complex models made of multiple components efficiently. The technique is highly flexible which is an essential requirement to meet the needs to individual use cases. A recognised barrier to the widespread adoption of such techniques is the steep upskilling required to successfully operate digital software and hardware (Clifton *et al.*, 2020), in addition to the multiple professionals required to achieve a consistent and representative model.

Concerns around the physical properties of 3D printed parts, such as the hardness and tactility, have been addressed in literature by combining AM with additional techniques, such as moulding and casting, which when combined with the wide variety of AM techniques available, allows for advanced models with separate components and varying colours, levels of transparency and shore hardness, further increasing the opportunities for customisation (Adams *et al.*, 2016; Tejo-Otero *et al.*, 2020).

1.5.2. Patient education

AM has been trialled as a tool to ease the stress and confusion of medical diagnosis, and most importantly act as an educational tool for patients to make informed decisions when consenting to a surgical procedure. This is particularly relevant in the transition between child and adult services, where young people aged 16 to 17 who demonstrate good understanding and intelligence, and can fully appreciate the extent of their treatment are known as Gillick

competent, meaning they can consent to their own treatment (NHS, 2019). By visualising the invisible, and providing patients with an exact replica of their anatomy, it is reported that patients have an improved confidence and knowledge around their condition (Biglino *et al.*, 2017) (Bernhard *et al.*, 2015; Zhuang *et al.*, 2019).

A study by (Biglino *et al.*, 2017) found that 70% of patients better understood their condition, and therefore had an improved experience when a cardiologist used a patient-specific model to communicate their condition. Participants unanimously reported they would want another model for future consultations, and would recommend having an AM model to a peer (Biglino *et al.*, 2017). Similar findings were reported by (Bernhard *et al.*, 2015), where the understanding of a planned surgical procedure increased by 44.6%. Studies report relatively small sample sizes and recognise that more research is required to confirm their findings. Another potential barrier to widespread implementation is the cost implications of the design and AM of patient-specific parts (Biro *et al.*, 2019).

1.5.3. Training

The use of training models and simulators is common practice in surgical training, as well as other industries such as the aviation industry. Technological advancements in AM and other digital techniques, namely virtual reality (VR), have made the techniques increasingly suited to applications such as surgical training (Ruthenbeck and Reynolds, 2015). Surgical simulation-based assessment is becoming increasingly common in mainstream medical training and is recognised broadly as an essential tool in surgical education (Thomas *et al.*, 2014; Atesok *et al.*, 2019). AM could be a potential solution in addressing some of the issues raised with existing tools.

1.6. Medical devices, bioprinting and pharmaceutical

Medical device (MD) applications are perhaps the most wide-reaching application for AM in healthcare, ranging from low-risk devices, known as Class I, to high-risk devices, known as Class III. A detailed overview of medical device classifications can be found in Section 2.3, where the EU medical device classifications are defined in Table 7, and the UK medical devices classifications are defined in Table 8. AM MDs range from low-risk devices, for example those used externally such as a crutch, to high-risk devices, which introduce the highest level of risk

to the user, such as medical implants. Medical devices are classified and regulated by the medicines and healthcare products regulatory agency (MHRA) in the UK, and by the food and drug administration (FDA) in the US. Low-risk medical devices (Class I) overseen by the MHRA are the focus of this thesis, however, higher classified devices by the MHRA and other regulatory bodies are lightly discussed to give context on the wider industry. A detailed review of the regulatory process and the classification of medical devices can be found in Chapter two Section 2.3. In simplistic terms, the extent of the regulatory approval process increases linearly with risk, meaning high-risk medical devices require AM techniques to meet more stringent performance requirements determined in a more rigorous assessment. Some AM technologies have been developed to produce higher risk devices than others, meaning some technologies have been successful in producing MDs that have gained regulatory approval, whilst other technologies have significant knowledge gaps which act as a barrier to regulatory approval.

Much of the published work around AM MDs is experimental, meaning it relates to the research, development and testing activities for those devices, and is not necessarily based on established practices that are used in real-world applications. The following section provides examples of AM for MD applications.

1.6.1. Implantable devices

Implantable devices come in many different forms and are generally defined as human-made devices totally or partially introduced into the human body and intended to remain after the procedure (Li *et al.*, 2015). A critical challenge in orthopaedic regenerative medicine is being able to develop implants that replicate the biomechanical properties of bone (Wang *et al.*, 2016). Before technological advancements in CAD/CAM, manual lost wax casting was used to fabricate individual customised implants, however, achieving consistent quality was challenging (Fisher, 1987). As CAD/CAM technology developed, manufacturing methods of custom titanium implants transitioned to subtractive milling from a titanium block, which initially saw costs doubling compared to generic off-the-shelf components (Fisher, 1987). More advanced methods of casting returned as techniques emerged to overcome some of the technical limitations of early milling technology where complex geometry could not be produced (Heissler *et al.*, 1998).

As CAD/CAM capabilities increased, and CNC milling machines became more advanced making higher quality custom implants available. To maximise productivity and reduce material waste, both casting and milling techniques have been used for commercial metal and alloy implants, particularly full hip and knee implants. Forged or cast-ingots have been CNC machined to patient specific sizes before being surface finished (Murr, 2020). However, more recent technological developments have enabled the design and manufacture of more advanced implants, in terms of size, shape and specifically engineered mechanical properties. AM enables customised requirements to be met for individual patients, with increased control over the internal structures of devices (Wang *et al.*, 2016). Previous manufacturing techniques only enabled randomly organised internal structures, whereas AM can fabricate complex and highly customised internal architecture.

Examples of 3DP implantable devices include a custom made tracheobronchial splint to treat tracheobronchomalaica, a condition where primary airways collapse during respiration (Morrison *et al.*, 2015), a wide range of bone implants including a clavicular implant to reconstruct a broken clavicle (Popov *et al.*, 2018), mandibular implant to treat a variety of conditions such as carcinoma (Popov *et al.*, 2018) and facial injuries causing mandible fractures (Aarthi Priyatharshini *et al.*, 2020), and implants for reconstructive surgery (Popov *et al.*, 2018) (Jardini *et al.*, 2014).

As well as improving the design and functionality of implants, AM has been found to reduce time and cost implications and optimise surgical procedures. In a case by Jardini et al. (2014) implementing an customised SLM manufactured part took approximately 3 hours less time than the surgery duration of a non-customised implant due to more efficient planning which considered the geometrical and anatomical details (Sing *et al.*, 2016).

1.6.2. Prosthetics and orthotics

AM has been shown to be particularly suitable for producing ergonomic products worn on the outside of the body due to the ability to replicate forms captured from digital scan data. This makes it an ideal technique for prosthetic and orthotic applications (Zadpoor, 2017). In 2005 (Herbert *et al.*, 2005) produced two prosthetic sockets for patients, one transtibial, meaning it was intended for use below the knee, and one transradial, meaning it was intended for use below the elbow. This was an early study that did not prove the strength or durability of 3D

printed sockets; however, it showed that the technology could fabricate comfortable prosthetic sockets and may be used for prosthetic applications. This early study acknowledged the use of low-cost accessible AM techniques in the place of high-end technologies that produce unaffordable solutions.

The use of AM is increasingly common for upper extremity prosthesis, due to the non-weight-bearing nature of most upper limb prosthesis (Campbell *et al.*, 2018). Research has been presented testing the suitability of AM for lower-extremity prosthetic sockets. Nine sockets were tested by (Campbell *et al.*, 2018) in line with ISO 10328 (ISO, 10328:2016), the standard for structural testing for lower limb prosthesis. The sockets were printed with FFF technology which showed that sockets exceeded the requirement set by the standard. The authors acknowledged that further testing was required to deem sockets fully safe and effective for patient use.

(Ennion *et al.*, 2017) discussed a non-AM solution for manufacturing prosthetic sockets in a rural community in South Africa, to alleviate the pressures on a small number of trained prosthetic staff in most developing countries. They discussed challenges with the current provision of prosthetics in rural settings as a lack of trained prosthetists, availability of materials (Wyss *et al.*, 2015) and time consuming techniques (Ten Kate *et al.*, 2017), such as plaster casting which requires multiple visits for a patient (Selles *et al.*, 2005). They found that a direct manufacturing prosthetic socket system, which consists of a hard socket being made under pressure from glass fibre and polyurethane under pressure, could be manufactured in one visit, and could provide a potential solution for the backlog in manufacturing prostheses. AM has been discussed as another potential solution for prosthetic care in developing countries (Dally *et al.*, 2015).

Glaze Prosthetics (®Krakow, Poland) took full advantage of the opportunity AM offers for mass customisation allowing their patients to choose the model, colour and finish of the prosthetics, enabling them to make design decisions in the online product order process (Caliendo, 2019). They used full colour PBF AM technology to fabricate creative and innovative solutions, such as embedded Bluetooth speakers and power banks within prosthetic limbs. They previously used SLS technology but transitioned to PBF technology to produce less expensive devices that were lighter in weight, predominantly using a Nylon 12 powder.

As a result of adopting AM technology, they found devices to be better fitting, lighter and more personalised, in turn making the user's lives more comfortable (Caliendo, 2019).

Other examples of patient specific orthotics include customised hand orthotics (Volonghi *et al.*, 2018), braces (Venkateswaran *et al.*, 2021) and casts for fractures. Traditionally made from plaster, tailor made casts have a number of drawbacks. Typically plaster casts are heavy, and due to the lack of ventilation to the affected area, skin rashes are common. This can lead to other medical conditions and complications for the user relating to the skin and soft tissues (Boyd *et al.*, 2009). To overcome these drawbacks, (Buonamici *et al.*, 2019) present a methodology for 3D printed casts for wrist fractures. They developed an adjustable scanning system that supported the hand and the elbow which could support the anatomy collection of a range of arm lengths. The methodology was tested for five case studies by clinicians who regularly performed plaster cast treatments, and the results showed incredible improvements to comfort and breathability, whilst being lighter in weight (Buonamici *et al.*, 2019). A follow-up clinical trial study was planned, to validate the entire orthoses generation procedure.

Ottobock (®Duderstadt, Germany), a leading prosthetics and orthotics company, offer a commercial service called iFab Production, which uses SLS technology to 3D print orthoses. 3D printing allows for both rigid and soft areas in the design, based on the thickness geometry design as shown in Figure 6, allowing more innovative and well-fitting solutions. These advancements allowed for the device to be more slim and elegant, making it more aesthetically considered and therefore more appealing to the user (Ottobock, no date).

Figure 6: 3D printed orthotics using SLS technology (Source: (Ottobock, no date) permissions granted)

1.6.3. Pharmaceutical

A new drug product was approved by the Food and Drug Administration in August 2015, said to indicate a new chapter for pharmaceutical manufacturing (Norman *et al.*, 2017). Tablet compression, a traditional pharmaceutical process has well-established regulatory patterns, however, the manufacturing capabilities and flexibility of the process are outdated. 3D printing drug products can offer controlled drug delivery systems (Ventola, 2014), complex and personalised solutions that can be manufactured on demand, which in turn could create opportunities for improving the safety and efficacy of medicine (Norman *et al.*, 2017). Shaqour *et al.* (2020) reviews the use of FFF technology for drug delivery systems, showing the technologies provide great potential for producing patient-specific products at a relatively low cost. Additional benefits discussed include the form optimisation of products when paired with 3D scanning, printing different geometries can be used as a strategy to help tailor the drug release profile (Shaqour *et al.*, 2020).

1.6.4. Bioprinting

Research in regenerative medicine has led to the fabrication of objects made from living cells. The development of 3D printing for biology and medicine has been categorised into four stages by (Michalski and Ross, 2014). Stage one includes structures and devices for *in vitro*, meaning biocompatibility is not required (Michalski and Ross, 2014). Stage two includes *in vivo* applications, an example of which include biocompatible implants intended for permanent use (Scheidbach *et al.*, 2004). Stage three includes degradable implants intended for *in vivo* tissue generation, again requiring good biocompatibility (Lichte *et al.*, 2011). Finally, stage four includes customised implants, tissues or organs which use extracellular matrix and cells as materials (Fedorovich *et al.*, 2007).

Bioprinting has allowed the manufacture of skin tissue (Agarwal *et al.*, 2020), cartilage (Cui *et al.*, 2012), bone (Keriquel *et al.*, 2010), artic valves and branched vascular trees (Duan, 2017), and *in vitro* or *in vivo* bioresorbable tracheal splints (Zopf *et al.*, 2013). The *in situ* generation of tissues has been used directly in the body to repair organs including skin (Cubo *et al.*, 2016; Keriquel *et al.*, 2017) and cartilage (Mouser *et al.*, 2017). Bio printing has also been demonstrated to be a useful tool for fabricating testing models, for example toxicity testing or

disease modelling (Wang *et al.*, 2014), or patient specific drug testing (Vanderburgh *et al.*, 2017).

1.6.5. Overview

AM has enabled a number of significant developments in the medical field. However, much of the work is still underway and is not yet established due to a number of challenges. The main one, being regulatory issues and the difficulties of obtaining approval for novel techniques (Morrison *et al.*, 2015). Issues with biocompatibility have also been identified. Some of the best performing materials are not biocompatible, limiting their use for medical applications (Zadpoor and Malda, 2017). Biocompatibility is the 'ability of a material to perform with an appropriate host response in a specific application' (Williams, 1999), where in the case of medical devices, biocompatibility is most commonly referred to as the compatibility of a device with a biological system, specifically the skin for externally worn Class I medical devices. Additional challenges associated with the capability of hardware, and the resultant inconsistent quality have been raised, along with material properties not being properly characterised (Campbell *et al.*, 2011).

Due to the complex regulatory approval processes required for medical applications, it has been reported that the industry was generally focussing on developing low risk medical devices, which still require stringent approval, however the regulatory approval process for low risk devices requires less evidence than that of higher risk devices (Di Prima *et al.*, 2016). It appears that there is further potential for AM in medical industries, and further developments and an increased number of approved medical devices are expected over the coming years. A cost effective 3D printing service for medical products is expected to become an economically viable and more widely used service in the coming decades (Pal *et al.*, 2021).

1.7. Significance and impact of the research

AM has been demonstrated as a highly effective process for innovation across the medical field. Although, many of the AM technologies remain inaccessible to health professionals due to the high cost of hardware and consumables, and their extensive infrastructural requirements. FFF in particular is largely a desktop-based technology, which for standard use does not require the use of toxic or flammable chemicals, or any additional hardware for post-processing.

Although advanced post-processing is not always a requirement for FFF, to achieve the desired performance qualities, such as good surface quality and mechanical properties, additional post-processing techniques may be required for part optimisation. Some techniques involve applying coatings to parts or using solvents or chemicals to smooth the surface of parts, which increases cost and infrastructural requirements. However, when compared to alternative AM techniques, such as SLA which requires parts to be washed in chemical solutions and light cured, or PBF which requires parts to be de-powdered and bead blasted, FFF requires minimal amounts of post-processing for standard use. For this reason, it is the technology most suited to providing innovations accessible to the widest possible range of users. Work is needed to determine whether FFF in its most basic state would be an appropriate technique for Class I medical device applications, and if not, whether the necessary enhancements of the FFF process, such as hardware advancements or additional post-processing techniques, would mean the FFF technique is more accessible than alternative AM technologies. If deemed suitable, FFF could be hugely impactful in facilitating highly accessible Class I medical devices, thus influencing clinical practice and the lives of users of Class I medical devices.

A large proportion of literature has been published dedicated to demonstrating the benefits of using FFF technology for healthcare and medical applications. Most published studies have been centralised around a specific class medical device, highlighting the benefits and challenges of using FFF for that particular application (Muwaffak *et al.*, 2017; Campbell *et al.*, 2018; Buonamici *et al.*, 2019). However, the practicality of the FFF technique for regulatory approved devices is limited, despite the large number of FFF AM produced medical devices in circulation. This research is significant in collating the existing specifically focussed research findings and formulating a wider narrative around the use of FFF for Class I medical devices. It considers the wider use context, focussing on the realistic and practical implementation of the technology into existing practices and use scenarios. It also discusses the technological developments observed in FFF hardware, which have been significant in the last decade. This means that frequently revised and current assessments of the field are always beneficial.

The alignment of the FFF process with the regulatory approval pathway could facilitate the widespread development and use of innovative and affordable Class I medical devices. However, to do so, a large amount of research is required to determine whether FFF is a viable technique to produce safe and effective devices. Firstly, the gaps in the field which are limiting future research must be identified, further highlighting the significance of this research. This

work intends to outline the requirements of FFF for medical applications and develop methodologies to assess whether a set of fundamental requirements can be outlined to determine safety and efficacy of FFF printing within this context.

FFF is being widely used to produce Class I medical devices currently, outside of a medical context. Therefore, this research is significant for both current and future use applications of the technology. Whilst the use of AM is increasing, and FFF technology is becoming increasingly significant, research in this area becomes critically important for the appropriate and sustainable development of the technique, whilst bringing awareness to the benefits and potential risks of the work already occurring in the field. By highlighting challenges associated with FFF for Class I medical devices, any recommendations or observations could be significant for active users of the technology and help to optimise their outputs.

The recent rollout of material markets specifically intended for medical 3D printing applications has also highlighted the significance of research in this area. The emergence of new and specific materials demonstrate that the industry is moving towards the democratised use of FFF technology for medical device applications. The development and commercial availability of a wider range of advanced materials will also be translatable across other fields interested in utilising AM technologies. Therefore, the research presented in this thesis is a highly significant contribution to the field in understanding the current and future directions of FFF technology for Class I medical device applications.

1.8. Research impact

The work produced in this thesis was designed to provide the maximum impact to the field, by relating to each of the three dominant use contexts for the FFF fabrication of Class I medical devices. For maximum research impact, methodologies were designed to be accessible and transferrable between different user groups, thus increasing the relevance of this work to the widest possible range of stakeholders. Whilst considering the impact of this research on the immediate stakeholders, consideration was also given to the wider society, including addressing some pertinent societal issues such as sustainable development, responsible consumption and production and affordable accessibility to healthcare.

1.9. Research aims and objectives

1.9.1. Research aim

The ambition of this research is to break down the current state of field for FFF manufactured Class I medical devices in a way the facilitates the analysis of each potential research area. It intends to communicate how the technology is being used currently, through identifying the main use scenarios for the technology. Through each identified use case, the work presented in this thesis intends to identify the potential benefits, challenges, and limitations of using FFF for the manufacture of Class I medical devices, revealing the knowledge gaps in the field in relation to each use context. Thus, the present knowledge gaps in the field which are thought to limit the expression of suitability or unsuitability of FFF for Class I medical device applications are addressed. The work aims to present a body of experimental work that addresses the significant knowledge gaps identified in the field which are key in drawing conclusions around the suitability of FFF for Class I medical device applications. Accordingly, this work aspires to form a baseline for future research that can underpin the further development of the FFF technique, whilst prompting the responsible and safe use of the technology in the medical field.

1.9.2. Research objective 1

Identify the significant and limiting knowledge gaps around using FFF for medical device applications.

1.9.3. Research objective 2

Design a set of methodologies to assess the under characterised process areas of FFF relating to repeatability and reproducibility, and use the developed methodologies to generate scientific results that can contribute to forming a knowledge base for future work.

1.9.4. Research objective 3

Present a series of recommendations for FFF users to optimise the suitability of FFF technology for Class I medical device applications according to each of the three use contexts, while encouraging responsible and ethical use of the technology.

1.9.5. Research objective 4

Make initial conclusions around the suitability of FFF for the repeatable production of Class I devices, through the identification of influential factors and their significance on the process. Use the initial conclusions to make recommendations for future research in the field.

Chapter 2

2. An exploration of the field

2.1. Introduction

An overview of both the additive manufacturing (AM) and medical device fields were given in chapter one, where the potential for innovation was highlighted. However, the complexities and challenges of merging two fields were not discussed in detail. The focus of this chapter is to explore the complexities in each field and their interaction within the context of using AM to manufacture Class I medical devices. Such work is novel and has only been touched on through specific medical device case studies. An overall investigation into the suitability of FFF technology for Class I medical device application is yet to be found, thus highlighting the novelty and importance of the following investigation.

Fused filament fabrication (FFF) is a complex research subject due to the vast number of hardware variations available on the market. Therefore, as the technology progresses, continuous investigation is required to maintain an understanding of the latest hardware features and the resultant part performance. Basic assumptions can be made about the technology when comparing it to alternative additive manufacturing (AM) techniques, for example, FFF parts are considered generally inferior than SLS parts (Yadav *et al.*, 2022), due to FFF parts have a rougher surface finish than SLA parts (Jani, 2018), and a lower dimensional accuracy than SLS parts (Msallem *et al.*, 2020). However, a large amount of research is ongoing, much of which considers the interaction between multiple factors, and what the outcome of such work means for FFF part applications.

Additional challenges associated with AM are the production and control of digital files and issues surrounding intellectual property, both of which are applicable in a different context to conventional manufacturing processes. Therefore, identifying each stage of the FFF process along with its recent developments and mapping it alongside the medical device manufacturing process is a critical exercise for determining the suitability of the technology for such applications.

The medical device field is extensive due to the ever-growing range of medical devices and their different use environments. The lifecycle of each medical device consists of a series of complex activities from the design and ideation stage through to regulatory approval and end-use. Complexities lie within each stage of the medical device lifecycle, which can vary considerably depending on the type of device, intended application and the context in which it is produced or sold. To gain an accurate insight into how FFF printing could be used in the manufacture of medical devices, each potential manufacturing scenario must be understood. To do so, this work maps out a typical medical device manufacturing process, whilst highlighting the key similarities and differences between each use case.

When combined with the continual research and development of the FFF technique, FFF produced medical devices form an interwoven discipline. To make conclusions around the suitability of FFF for medical device applications, a thorough understanding of the field is necessary to identify the benefits, limitations and potential challenges. This chapter aims to map out both the field of FFF AM and medical device field. The findings of which were used to identify the research gaps in the field and highlight research goals necessary to support the safe and responsible use of the technology for medical device applications.

2.2. Field exploration: Review of FFF literature

An initial scoping review was conducted to determine the key concepts present in literature around FFF AM. The first search string (("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication")) was used, limited to results from 2009-2022. 2009 was selected as the start date because the number of retrieved results was steady up until that point, however after 2009 the number of published articles increased more significantly as shown in Figure 7. Two scientific databases were searched, Pubmed and Scopus. These initial searches were used to identify the terminology and indicate how it has shifted in recent years. Initially the extrusion of molten filament through a heated nozzle was the principle behind Stratasys' trademarked fused deposition modelling (FDM®) technology. Since the expiration of patents protecting the technology, the opensource fused filament fabrication market expanded greatly, making FFF the most used terminology for the technology. The terms are still used

interchangeably in some instances, and material extrusion (ME) is another term widely used to describe the same process.

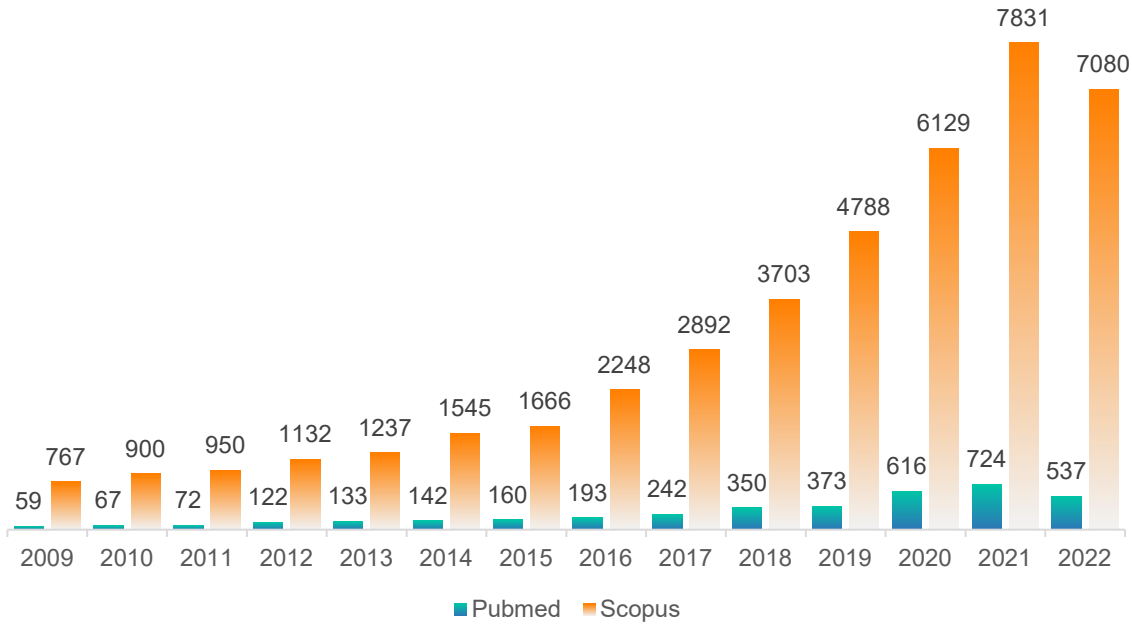


Figure 7: Pubmed and Scopus publication timelines

The initial scoping search was used to identify the key words and active research themes shown in Table 2. The search terms were used to form some preliminary search strings to explore the key areas applicable to medical device applications.

Table 2: Key words and reoccurring themes found in the initial scoping exercise

Keywords	**Quality**	**Performance measures**	**Fabrication parameters**	**Environmental parameters**
Fused filament fabrication	Repeatability	Dimensional accuracy	Infill density	Printing humidity
Material extrusion	Precision	Mechanical properties	Layer height	Material humidity
Fused filament deposition	Reproducibility	Part failure	Printing speed	Airflow

Visual inspection	Infill patter	Chamber temperature
Surface roughness	Raster angle	Build environment
Cost	Fan speed	
Time to manufacture	Material flow	
	Build plate temperature	
	Chamber temperature	

The focussed search strings shown in
Table 3 were used to identify further patterns in the research. Search strings one to five were systematically searched in Pubmed and Scopus databases, and the key factors or parameters explored in each publication were recorded. The results, presented in Figure 8, show that the largest focus areas were the process parameters present in the FFF process, which according to (S. Singh *et al.*, 2020), 80% of academic literature is based on understanding and optimising process parameters.

Printing process parameters are the measures that refer to different factors in the process. Most process parameters are given a value during the slicing stage of the FFF process, where the digital part is converted into a tool path file. The number of changeable process parameters varies significantly between hardware and software; however, it is not uncommon for slicing software to allow the configuration of upwards of 500 slicing parameters. These parameters dictate the quality and properties of the printed part, by specifying the physical attributes of the part, such as the density and the wall thickness. For example, to rapidly produce prototypes intended for visualisation purposes only, parameters could be configured as follows. To optimise the printing time, the infill density would be set to a low value which reduces print time. The layer height would be set to a low value if the surface finish is particularly important, whereas if printing time is more important, the layer height would be set to a higher value to further reduce printing time. These parameters reduce the overall printing time, meaning productivity is increased, and also use less material making the parts cheaper and lightweight.

On the contrary, if a part is intended to be functional or withstand force, the infill density would be set to a high value and the wall thickness would be increased. This increases the strength and mechanical resistance of the part, but also uses more material increasing cost and printing time.

The infill density and layer height are considered basic parameters which the user will almost always modify. However, more advanced process parameters allow for detailed modification and fine-tuning of the printing process. The process parameters and their range depend on the type of hardware components and materials used. Software for industrial hardware usually allows the user to have less control of the process parameters, with more being locked at a pre-tested value. Whereas hobbyist and mid-range software and hardware packages tend to allow more user control.

The second largest area of focus was around the performance factors, and the measures of success for the FFF process. Mechanical properties were the most studied performance factor, followed by the dimensional accuracy of printed parts, the surface quality, interlayer bonding, shrinkage, warpage, weight of parts, porosity and geometrical defects. The limiting factors of FFF was a reoccurring research theme, with efforts identifying limiting factors as the repeatability and reproducibility of the technology, the availability of appropriate standards or methods of standardisation across the industry, quality control factors, the quality and integrity of digital files and the ability of the parts to undergo sterilisation. Humidity and chamber temperature were confirmed as active research areas into the influence of environmental factors on FFF. Finally, a research category relating to the filament used in FFF was identified, which included the diameter of the filament, which also relates to quality and standardisation, and the effects of colour or pigmentation in the filament.

Table 3: Refined search strings based on the initial literature scoping exercise

Number	Search string
1	(("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND “humidity”
2	(("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND (“air” AND ("management" OR "flow")))

3	(("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND ("chamber" AND ("temperature" OR "build environment")))
4	(("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND ("repeatability" OR "precision")))
5	(("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND ("humidity" OR "moisture content")))

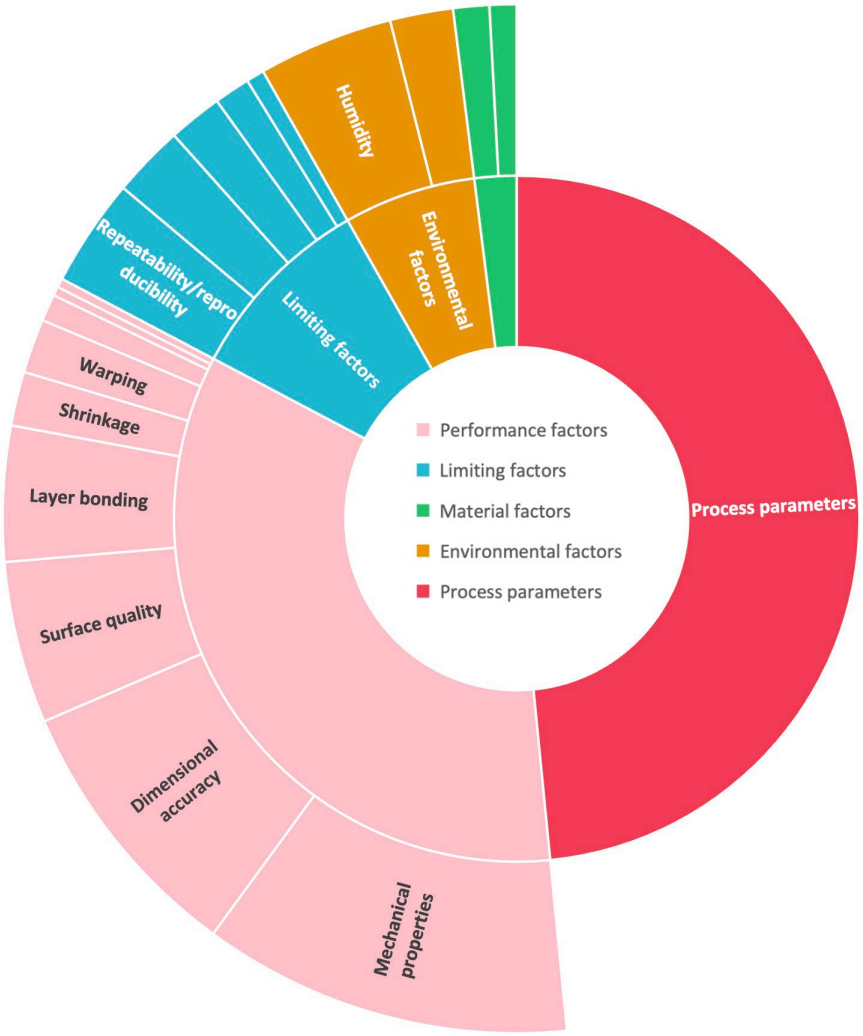


Figure 8: A sunburst diagram showing the most commonly explored themes in academic literature around FFF. Colours correspond to the themes as follows: red: process parameters, light pink: performance factors, blue: limiting factors, orange: environmental factors and green: material factors)

A breakdown of the process parameters identified are visualised in Figure 9, which shows layer height to be the most frequently discussed. The printing speed, part orientation, extrusion

temperature, build chamber environment and infill density were also commonly discussed in descending order. The parameters are discussed in relation to the performance factors outlined in Figure 8. This type of work involves testing the influence of different process parameters or a combination of process parameters on the performance factors relevant to the study. This work is highly relevant for the advancement of the FFF field, as much of the experimental work has unveiled an optimal set of process parameters for specific use applications. However, due to the uniqueness of each FFF application, as discussed, an optimal set of process parameters is generally not transferrable to any use application because of the complex trade off of desirable properties, intended functionality and geometrical requirements. Much of the literature discovered is detail orientated and is not applicable to the general use of FFF.

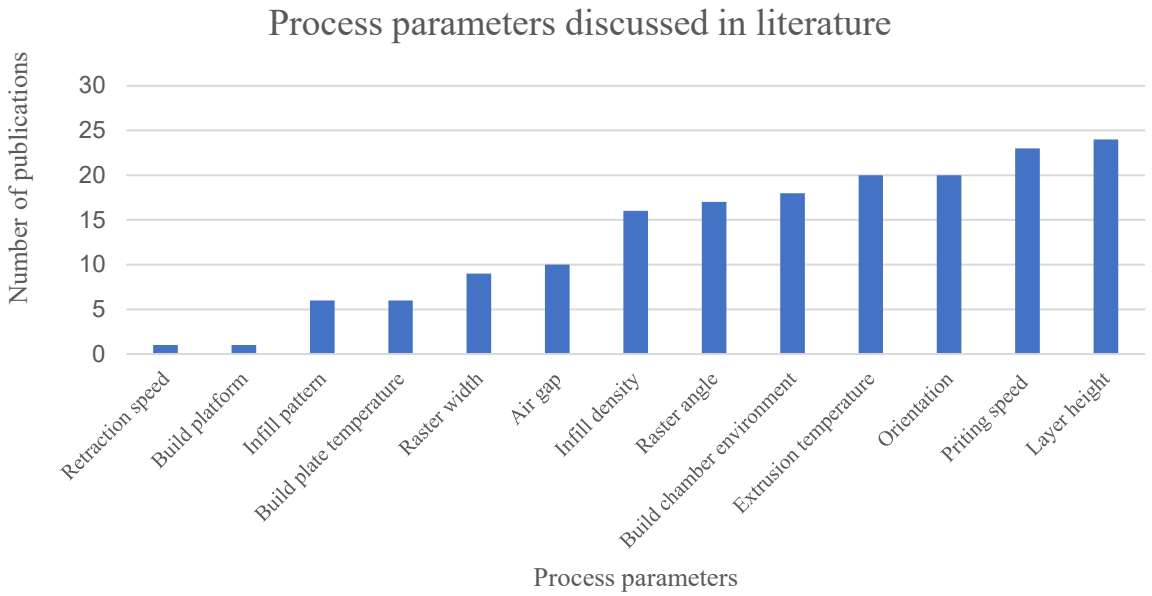


Figure 9: Frequency of the process parameters most discussed in literature

An overview of the most discussed FFF process parameters are presented in Table 4 and illustrated in Figure 10, which are typically the most common FFF parameters, suggesting they are thought to be the most influential over the FFF process. In literature, the most identified challenges of FFF have been the stability and capability of the process (Vallés, 2014), which is supported by much of the discussions in grey literature surrounding challenges associated with the FFF process. Frequently reported issues include extruder jams and blockages, which often result in print failures and low quality prints (filament2print, 2018). Multiple troubleshooting guides can be found in grey literature, intended to help users identify the cause

of poor or inconsistent quality in printed parts. Some common quality issues are identified as under or over extrusion, stringing, layer shifting, layer separation, warpage, gaps in the surface, ringing and weak infill structures (Simplify3D, no date). Each of these quality issues can result in defect parts, which could potentially be highly problematic for the production of Class I medical devices. In addition, from practical experience, the repeatability and reliability issues attributed to the FFF process often results in users of the technology opting for alternative technologies which are considered more reliable. Although reliability of the FFF technique is often criticised, many of the issues described are highly preventable through good practice, appropriate parameter selection and sufficient training.

An observation made around the literature is that the focus varies significantly depending on the type of literature, the author and the context in which it was written. Undoubtedly the literature coming from industrial stakeholders, for example 3D printer manufacturers, is highly focussed on communicating the advantages of adopting the FFF technique across educational institutions, small to medium enterprises (SMEs) and industrial settings, with the intention of promoting sales and expanding their business. Therefore, one must remain mindful of potential bias when reviewing such literature. However, with that stance in mind, it is also in the hardware manufacturers best interest to demonstrate the optimal performance of their hardware, resulting in highly tested recommendations. Information regarding the performance of FFF hardware from the manufacturer is highly optimised through detailed and repetitive testing exercises and is therefore likely to yield better results than other recommendations found in academic literature coming from a more experimental approach with varying intentions.

Table 4: Summary of the most commonly researched process parameters for the FFF printing process

Parameter	Description
Layer height	The height of each printed layer (usually in mm) measured on the Z-axis. Higher values produce faster prints with a more pronounced layered surface finish
Printing speed	The speed at which filament is deposited during the printing process (usually mm/s)

Orientation	Part orientation refers to the orientation in which the part is placed on the build platform, and therefore the direction of the printed layers in relation to the geometry of the part
Extrusion temperature	The temperature the material is heated to for printing
Build chamber environment	The environment inside the printing chamber. Where a printer has an enclosed build chamber, this is the temperature the chamber is heated to
Raster angle	Also known as raster orientation, the angle at which the direction of the deposited raster with respect to the X-axis of the build plate on the FFF machine
Infill density	The density of material inside the printed part, which can range from 0-100%
Air gap	The gap between two adjacent deposited filament rasters. Where two adjacent layers overlap the air gap is known as negative
Raster width	The diameter of the extruded filament raster which is dictated by the nozzle diameter
Build plate temperature	Where a heated build platform is used, this is the temperature it is heated to (usually in °C)
Infill pattern	The pattern of the infill material of the print. Common infill shapes and patterns include grid, triangles, concentric, cross and zigzag
Build platform	The type of material used as the build platform. Build platforms are commonly made from glass, however, build plates with special coatings or different tape coverings are commercially available
Retraction speed	The speed at which the filament is retracted and primed when the print nozzle is travelling over a non-printed area

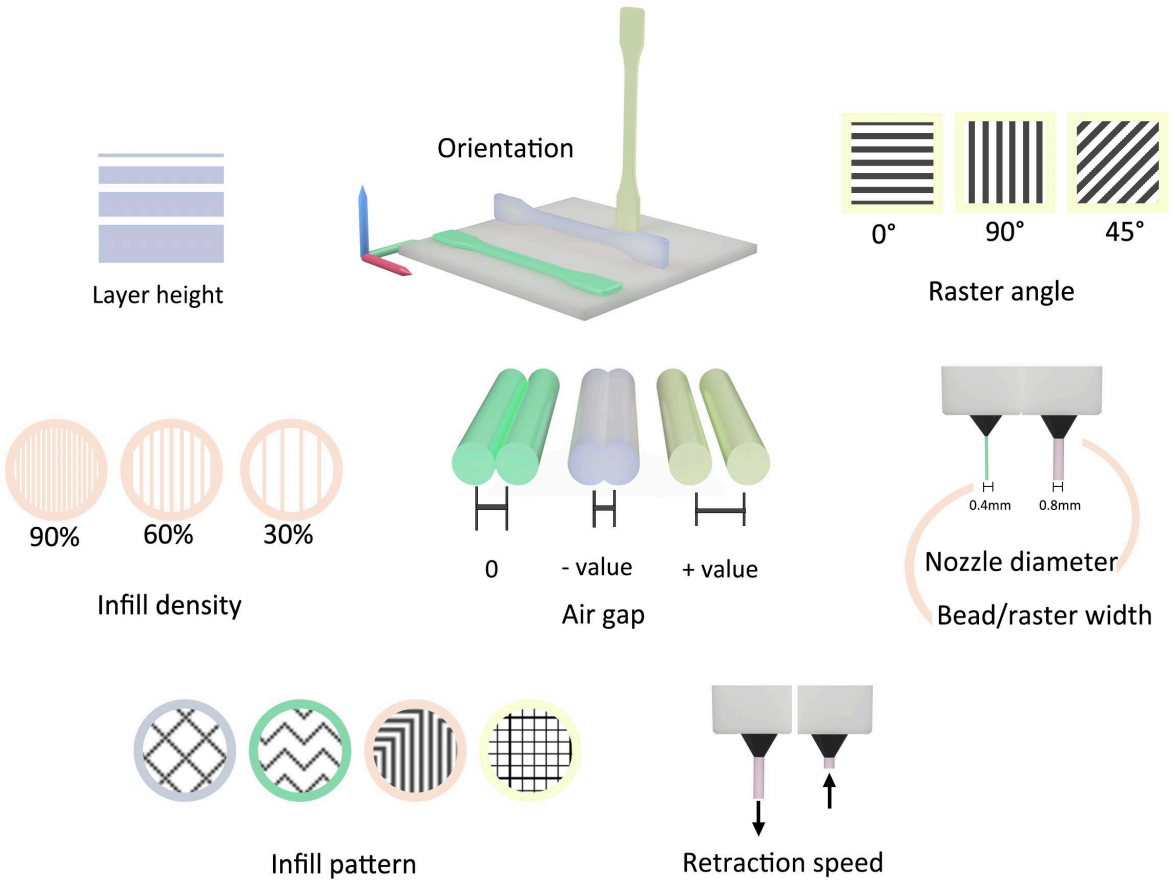


Figure 10: Schematic of the most commonly used printing parameters

(Dey and Yodo, 2019) conducted a systematic survey of published articles from 2005 to 2019 on the optimisation of FFF process parameters and the characteristics of parts printed using FFF technology. They summarised the contents of the survey in a fishbone diagram, shown in Figure 11, that shows the key measured performance factors as surface roughness, dimensional accuracy, build time, flexural strength, compressive strength and tensile strength. The research was found to be largely based on full factorial design methods; however, some were found to use various mathematical methods. This review confirmed the results of the initial scoping review conducted previously. The only performance characteristic present by (Dey and Yodo, 2019) that was not identified in the initial scoping review was the build time. However, this was identified as printing speed as a process parameter as opposed to a performance factor.

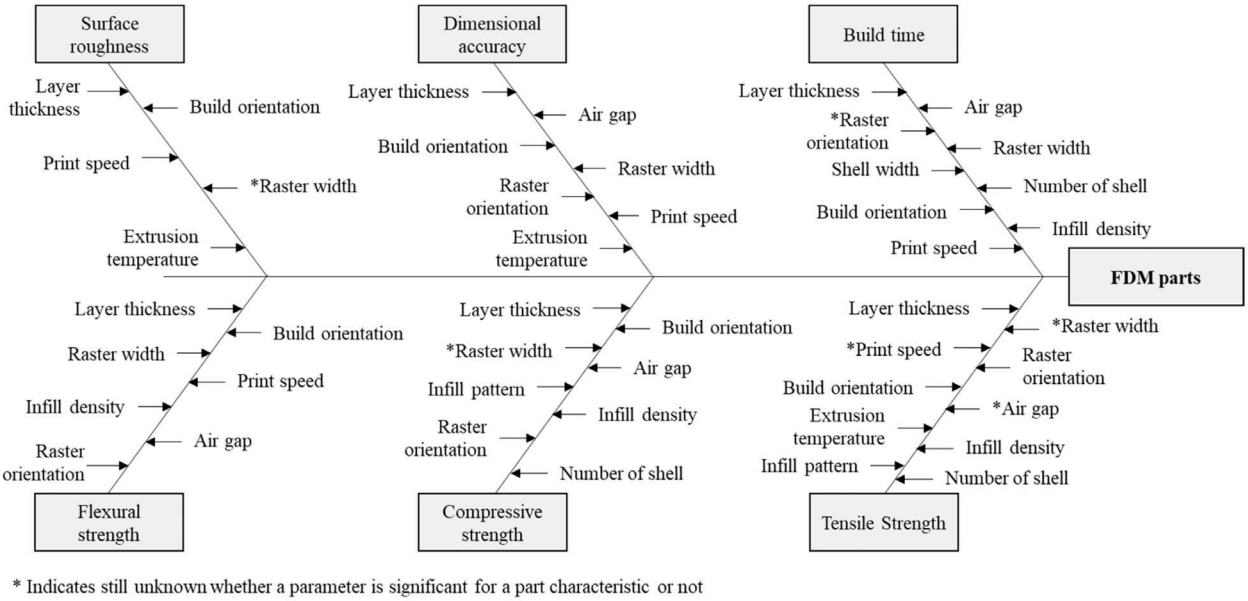


Figure 11: Reproduced with permission from (Dey and Yodo, 2019): Fishbone diagram of the results from a systematic survey of FFF parameters by (Dey and Yodo, 2019)

On dimensional accuracy, the layer thickness was one of the most analysed influential factors. Most research concluded that lower layer thickness and lower extrusion temperatures resulted in higher dimensional accuracy. The effects of raster angle and raster orientation were unknown, meaning further analysis would be required to draw conclusions. Build orientation was also determined to be an important parameter of dimensional accuracy, however the effects of extrusion temperature, number of shells, infill pattern and extrusion width on dimensional accuracy were unknown. For surface roughness, a low layer thickness was found to help with high surface finishing, along with lower extrusion temperature and print speed. The tensile properties of printed parts were found to be most significantly influenced by the build orientation. A lower layer thickness was also found to be preferable for higher tensile properties. A high infill density and higher number of outer shells were confirmed to improve tensile strength, due to the stronger bonds achieved at a higher density. The optimal raster angle for tensile strength remains unconfirmed, however colour was found to be a significantly influential factor. Research analysing the impacts of compressive strength was limited, and different researchers reported a different combination of process parameters. Initial conclusions indicate that a higher layer thickness can increase compressive properties. Similarly, research analysing the effects of process parameters on flexural strength was limited, which could be related to the complex relationship between them. Flexural strength testing exhibits both tensile and compressive force on a sample, and therefore the complexity is increased when compared to tensile or compressive strength separately. The impact of various

process parameters is unknown, due to the impact of various parameters not being widely analysed.

Build time was found to be lower at a higher layer thickness, which is a common assumption with FFF technology. It was found that the characteristics of complex parts could be improved by selecting optimised geometrical configurations (Dey and Yodo, 2019). Process parameters should be considered alongside the part geometry for part characteristic optimisation. The discussed characteristics of a part printed with FFF have been optimised by modifying process parameters. However, there are many other factors and combinations of factors that are equally important for functional parts, such as the geometry, complexity, thermal properties and other performance factors relevant to specific applications. It is unrealistic to explore every combination of process parameter due to the extensive number of variable factors present in the FFF process.

For 'optimal' performance, a trade off of relevant parameters is inevitable. The FFF process is complex, and consists of multiple integrated steps, each of which brings a different level of uncertainty (Dey and Yodo, 2019). The large number of influential parameters has highlighted the importance of determining the repeatability and reproducibility of the FFF process, and whether controlling process parameters, the FFF process can consistently produce acceptable parts. The literature review revealed that limiting factors, such as repeatability and reproducibility, quality, quality control and standardisation; environmental factors such as temperature and humidity; and material factors such as colour and varying filament diameters were significantly less studied than process parameters and performance factors. The extensive work around process parameters and their influence on performance factors indicate the interdependence between the two factors, which based on the limited findings presented suggests that the understudied factors identified are also highly likely to influence the performance of the process, further demonstrating the research gap in the field.

The repeatability and reproducibility of the technology was identified as a significant research gap which is highly relevant to medical device applications. Therefore, the aim of this review was not to find the optimal value for each process parameter to optimise performance, as this differs significantly depending on the part geometry and intended application. The focus shifted to identify the most relevant process parameters for repeatability and reproducibility of the FFF technique. Factors were deemed relevant in terms of their importance to the process. For

example, the key parameters the user must select for each part, and the factors which are inherently present in the process and are not usually considered choices. The environmental factors for example are often not physically defined by the user but may be found to affect the printing process.

For the purpose of determining the suitability of FFF for Class I medical device applications, much of the published work is detail orientated, leaving a gap for more generalised and broader reaching experimental work. To build a more holistic picture of the technological capabilities of FFF in the context of medical device applications, the inherent factors that could influence the process must be identified. The key difference is that process parameters are user selected, and inherent factors are present for every type of FFF user, unless actively controlled. For example, the environmental factors and the material factors identified in the literature could directly influence the process for every FFF user. Although within the literature identified, these are relatively unexplored when compared to the proportion of literature focussed on process parameters and performance factors, suggesting further influential factors have remained undetected in literature.

All factors influencing the FFF process must be identified, whether they are inherent, or user driven. As part of the initial scoping exercise, the FFF process was mapped out, and the variable factors at each stage of the process were identified. Figure 12 categorises the process into five groups: software, hardware, feedstock or consumables, printing and finishing. Within each of these groups, different factors can affect the part outcome, ultimately contributing to the main research question, how suitable is the FFF technique for producing Class I medical devices?

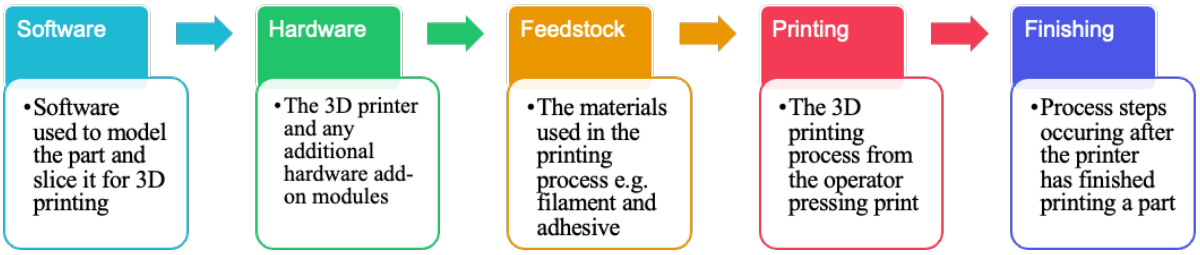


Figure 12: The FFF process presented as five groups

The five process groups contain multiple factors and sub-factors which could influence the FFF process. Based on the literature reviewed, and a grey literature search of online 3D printing forums, a map of factors that could potentially affect the end part at each stage of the FFF process was created, shown in Figure 13. Realistically, too many factors have been identified to analyse in the scope of this research, however, further work was done to compose a refined list of factors which could influence the process, most likely to be applicable to each user scenario within the context of Class I medical device manufacture.

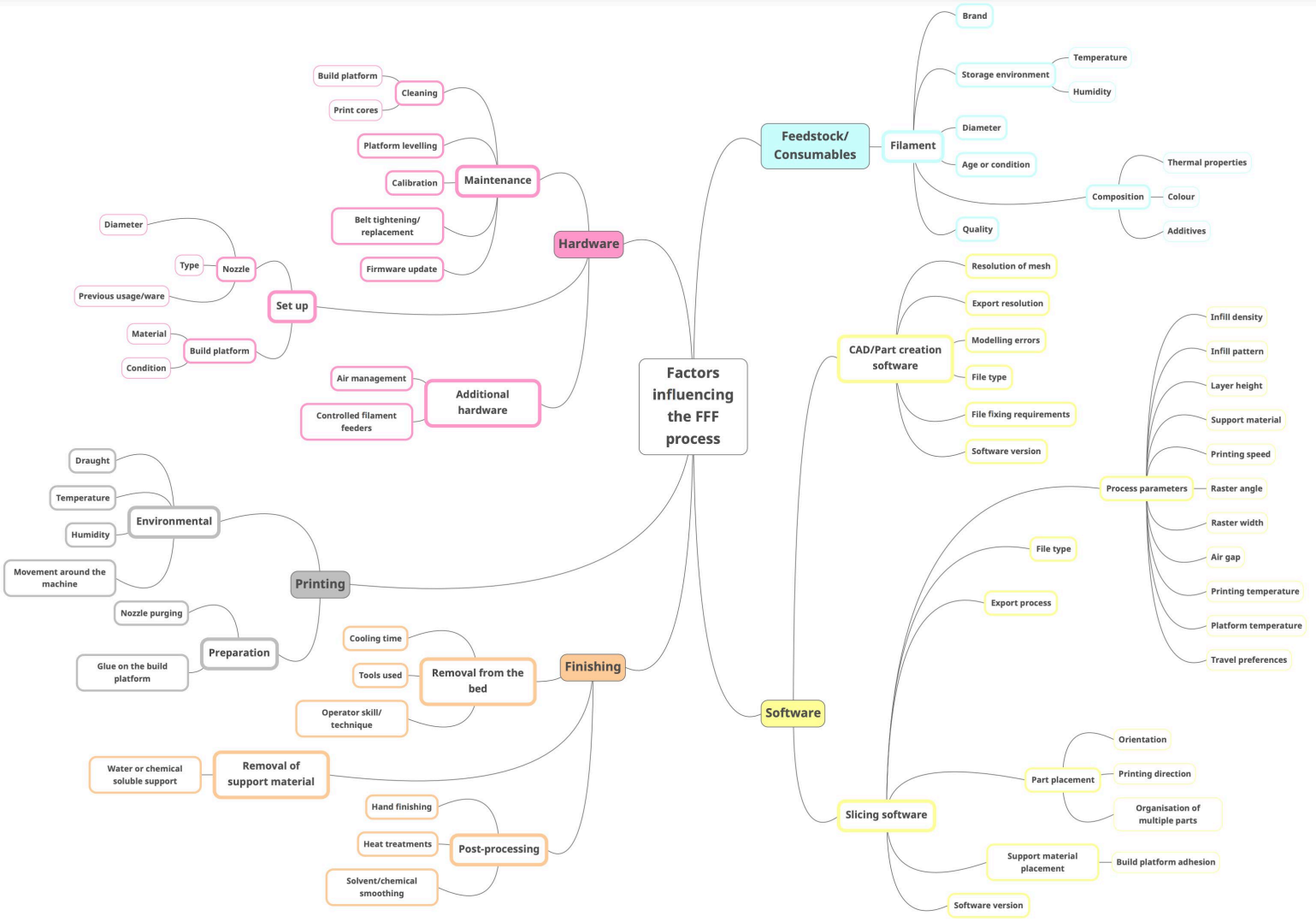


Figure 13: Potentially influential factors of the FFF process

2.2.1. Fused filament fabrication for medical applications

2.2.1.1. Medical devices

FFF, despite being one of the most popular AM techniques, is also potentially one of the most problematic due to the extensive range of printing parameters and influential factors on the process. FFF was developed by S. Scott Crump in the late 1980s under the name fused deposition modelling (FDM), which is still used today by some. The first patent (Crump, 1992) was granted in 1992 and assigned to Stratasys, Inc. who commercialised the technology and developed a series of printers. The expiration of the patent in 2009 kickstarted consumer 3D printing, allowing the formation of the RepRap Project (Jones *et al.*, 2011) by Adrian Bowyer.

RepRap was a project intended to prove the self-replication of 3D printers through printings their own parts (Hoskins, 2013), which was achieved when a 3D printer was produced by a 3D printer. This assisted an influx of start-up companies who built on the existing technology, adapting and innovating, which lead to the formation of many successful companies, including Prusa (®Prague, Czech Republic) and MakerBot (®New York, US), both still highly relevant names in the FFF market. Recently (September 2022) MakerBot merged with another successful FFF company, Ultimaker, to form UltiMaker (Ultimaker, 2022b). These developments caused the cost of the technology to be driven down, and provided many variations of the technology, ultimately making it more suited to a wider range of users. The FFF market is vast, and covers extremely low-cost solutions, up to high-end industrial hardware. Table 5 gives examples of entry level (hobbyist) hardware, mid-range (professional) hardware and top-of-the-range (industrial) hardware. Although the characteristics and features of each type of FFF printer vary significantly between manufacturers and third-party suppliers, hobbyist, professional and industrial machines can generally be differentiated by a set of features relating to the software, hardware and printing materials.

Table 5: A table detailing the typical attributes of hobbyist, professional and industrial FFF printers *these are typical observations and do not apply to every FFF 3D printer*

	Hobbyist	Professional	Industrial
Cost	Low	Medium	High
Build chamber	Open	Closed	Heated
Software	Open source	Dedicated software offering open-source and pre-set profiles	Dedicated software locked to pre-set profiles
Materials	Third-party and experimental. Only really suited for low temperature 'easy to print' materials such as PLA Poor quality materials (deviations in diameter, fillers or other additives may affect performance)	Compatible with third-party materials but optimised for manufacturers own material. Configurable for more advanced materials (abrasive, higher temperature) Allows use of poor quality and high-quality materials	Manufacturer approved quality materials More likely to support high temp/high-performance materials Approved materials for specific applications (food safe, biocompatible etc.)
Extrusion type	Single extrusion	Double extrusion (support material)	Double extrusion (support material) End-use performance parts and components
Application	Model making and prototyping	Prototyping and functional prototypes	
Resolution	Low/medium	Medium/high	High
Performance	Unreliable, poor repeatability and reproducibility	Improved reliability depending on the user choices	Strong repeatability and reproducibility, consistent quality delivered

Varying hardware features and characteristics include the cost of the machine, heat sources within the build chamber, the number of sensors or calibration tools and more recently, compatibility with add-on hardware modules. Industrial printers have capabilities for what are known as "performance materials", which have more extreme characteristics including high heat resistance. To accommodate these printing materials, industrial hardware will have an enclosed build chamber as a minimum, and usually a fully climate-controlled chamber that can enable high-temperature FFF. A patent for heated build chambers was also held by Stratasys (Swanson *et al.*, 2004), meaning the development and sale of printers with motion control components which were segregated from the rest of the build chamber was restricted. This

made the production of printers with high-temperature capabilities difficult. The patent was expected to expire in 2021, which is thought to prompt a technological shift to high-temperature and temperature controlled FFF printing. The size of the build chamber is also an indication of the intended user group. 'Mini' printers are usually intended for beginners, or educational settings, unless the size reflects a specific function, for example intricate jewellery design or dental applications.

If a printer has its own dedicated software, it is likely that the software has been optimised to work with the hardware. Pre-set profiles, or default settings available in software has usually been subject to hours of testing which hardware manufacturers use to provide performance information about the hardware and optimised materials. The software generates the instructions for the hardware to follow, dictating the movement and speed of the print head, along with many other instructions. Therefore, good alignment of software and hardware can produce improved results through reducing vibrations by tailoring movement to the hardware capabilities. Open source slicing software is available for those printers without dedicated software; however, this involves a more experimental approach requiring the user to input large amounts of information. The amount of information required almost certainly requires some guess work unless extensive testing has been conducted for a specific material and configuration.

The compatibility of printing materials can indicate the intended user group of an FFF printer. Industrial machines usually support a smaller range of materials than hobbyist printers. Again, this is due to testing and optimisation, because a smaller number of material profiles can be monitored, tested, and optimised more closely than an extensive range. Some industrial machines will only work with manufacturer branded filament, for example, the Markforged (®Massachusetts, US) 3D printers are only compatible with Markforged materials. This is due to print parameters such as the nozzle temperature and the build plate being optimised and locked down. This ensures a certain level of quality is obtained, due to the printing parameters locked down by the software, the hardware and the materials being fully aligned, and the process being fine-tuned to deliver a set of results.

Professional or mid-range printers sometimes facilitate two approaches, open-source compatibility for the user to select any material and customise the printing profiles in the dedicated software for experimental work, but also specific materials made by the

manufacturer, which align with specific profiles in the dedicated software which have been tested and engineered for optimal performance. Professional machines do not tend to have the same restrictions as industrial machines, for example, a user can select a recommended pre-set and make tweaks and changes to suit a specific application or experiment. Allowing the user to modify settings could result in damage to the hardware, which for more expensive, industrial machines is not recommended.

FFF as a technique is widely used, but examples of where the technique has been optimised for industrial applications are extremely limited. When compared with other technologies, FFF is often considered inferior due to the reliability and performance concerns discussed, and therefore alternative AM techniques have been selected specifically for medical device applications by manufacturers. For example, the benefits of SLA printing, such as the production of isotropic parts, has led to the technique being developed and optimised specifically for medical applications. Techniques such as SLA, as an example, are not subject to the same level of user-modification as FFF, meaning the parameters are naturally more constrained. This makes the fine-tuning of the process easier due to an already reduced level of variability resulting from the technique.

The open source origins of FFF has naturally facilitated a large amount of variation in the technology, which can be difficult and time consuming to manage and reduce into an optimal set of process controls. More variables result in more testing, which can be time consuming and expensive. Additionally, the extensive range of research around the optimisation of FFF and the influence of each process parameter on the process can lead to confusion. This is due to a large amount of research being inconclusive and highly dependent on a range of interacting parameters or factors. For these reasons, among others relating to the performance of parts, FFF has not been prioritised as a technique for final use parts in demanding or critical applications such as medical, aerospace or other regulated fields, meaning development in this area is limited and slow-moving.

When comparing the amount different AM technologies are used for regulated applications, FFF is lacking. It is a widely used technique, however, the number of opportunities for experimental work, including the availability of extensive material ranges, has broadened the scope of the technology. The use has been so widespread with so many variable factors, it is more difficult to select some of those variable factors and refine the technology for a specific

purpose. This has led to the scope of FFF being more widespread and less specific, whereas other techniques are less widespread but more specialist for specific areas. Other technologies have resulted from different growth strategies, where the technique was identified and developed by one or two companies who have championed a particular technology for a specific technique. For example, Formlabs (®Massachusetts, US) created a range of SLA printers specifically for medical applications. This type of development is yet to be seen with FFF, likely due to the large number of knowledge gaps which require significantly more effort and learning to work with, thus requiring more time and capital investment. Other technologies that had a more solid baseline through working within a more constrained model would be preferable to many. This is an expected reason why FFF has only slowly and hesitantly advanced into functional part industries.

There is strong justification for pushing the boundaries of FFF technology due to the huge potential it has to create positive change as a result of its accessibility. When discussing the accessibility of FFF, many factors come into play. Firstly, the cost. The affordability of FFF hardware and materials is essential for widespread adoption. High costs create access barriers, similarly to some high-cost medical devices that remain inaccessible to many of the people who would benefit from them. The materials and consumables must also be affordable to be able to operate a printer and produce low-cost parts, which are ultimately affordable to the intended user. The infrastructural requirements of a 3D printer also affect its accessibility. For example, SLA and SLS technologies require additional hardware, such as chemical wash stations and curing stations for SLA, and powder removal and recycling stations for SLS, which can be problematic to an organisation without appropriate chemical storage, ventilation and disposal facilities. Post-processing equipment is sometimes integrated into a larger unit and is sometimes a separate unit requiring more space. Appropriate personal protective equipment (PPE) is also an additional requirement for post-processing and finishing techniques. Desktop machines are preferable to many, due to their ‘plug in and go’ nature, as well as the minimal infrastructural requirements.

Professional FFF was selected as the most appropriate hardware type to investigate the FFF process for Class I medical applications. It was selected due to its increased suitability over hobbyist FFF, due to the larger build platform and improved hardware quality which is expected to deliver the maximum amount of impact relating to performance, but also retaining the accessibility factors professional FFF provides.

2.2.1.2. Materials

Material development projects have increased with the rise in filament research specialists, in turn offering new opportunities. Numerous specialist filaments have been developed for specific applications, including material specifically engineered for medical device applications. Zinc, copper and silver nanoparticles have been incorporated into polymers to produce filament for 3D printing with antimicrobial properties. Antimicrobial metals have been incorporated into a polycaprolactone (PCL) (Muwaffak *et al.*, 2017), PLA and thermoplastic polyurethane (TPU) (®Copper 3D, Nebraska, US). These materials are specifically designed for printing antimicrobial medical devices, as a response to antibiotic resistance and pandemics (Copper3D, no date). PC-ISO polycarbonate is another material developed for biomedical applications, which has been cleared for biocompatibility for use in the biomedical industry (Gómez-Gras *et al.*, 2021). Its use for applications such as bone scaffold has been investigated, however currently it is not strong enough, suggesting further development of combining it with other materials to increase its strength.

A recent and significant material development is the 2022 release of a material collective named 'Varioshore prosthetic', which is specifically designed for prosthetic and orthotic applications by a company called ColorFabb. ColorFabb is a tech and 3D printing company founded by Rudd Rouleaux in 2012-2013 (colorFabb, 2022a), which started by producing PLA and Polyhydroxyalkanoates (PHA) filaments. They now produce innovative ranges of filament, such as 'Varioshore prosthetic' shown in Figure 14, which is a TPU base material, with variable shore hardness and variable skin colour. By increasing the printing temperature from 200ºC to 250º the material will start to expand to around 1.5 times its original volume, meaning the material flow rate can be reduced to between 60-70% resulting in softer parts.

The formula includes silver, known for its beneficial properties for medical applications. The filament is commercially available in three colours, pale pink, medium brown and dark brown. Each of these colours can be fine-tuned by changing the printing temperature and speed to create more or less intense skin tones. Their marketing material shows four skin tones for each of the filaments, overall giving 12 colour variations. Printing at a lower temperature results in a higher density part with more intense colours. When the printing temperature is increased,

the foaming agent in the TPU is activated which results in reduced density, reduced weight, and less intense colours.

Figure 14: colorFabb Varioshore prosthetic filament (Source: (colorFabb, 2022b) permission granted)

In addition to Varioshore prosthetic, engineered for both function properties and aesthetic appearance, a wide range of materials have been developed for aesthetic purposes alone. The aesthetics of medical devices have become an increasing priority for users in recent years, partially as a result of the shift in cultural attitude towards disability. Materials have been formed to support this movement, now available in an extensive range of colours and finishes including neon colours, metallics, glitters, iridescent and gradient finishes, as well as a range of environmental responsive materials, such as glow in the dark and thermochromic capabilities. Filaments replicating other materials are also available. Some examples of which include stone, marble, wood, and metal effect.

2.2.1.3. Prosthetics

Prosthetic limbs are perhaps the most discussed type of 3D printed medical device, particularly prosthetics for infants and children. There have been multiple news stories and media reports around innovative prosthetics that play a significant role in changing people's lives. Prosthetic limbs range from medically approved MDs to make-shift limbs. Commercially available 3D

printed prosthetics are available on the market from Open Bionics (®Bristol, UK), Hulotech (®Groningen, Netherlands), ProsFit (®Sofia, Bulgaria) and Glaze prosthetics (®Krakow, Poland) which now provides 3D printed prosthetics for children with Ambionics.

The most well-established manufacturer of prosthetics is Open Bionics, which was founded in 2014 (Open bionics, no date). Their flagship product is now the 'Hero Arm' which is an advanced myoelectric device intended for children over the age of eight years, and adults. They describe the key features of the arm as adjustable, breathable and lightweight, with versatile multi-grip functionality powered by high-performance batteries and microprocessors. They describe the aesthetics of the device as empowering, with character inspired designs including Iron Man, Star Wars, Marvel and Frozen.

The latest device, the Hero Arm, is the world's first clinically approved 3D printed bionic hand, which is medically certified and an FDA registered Class I medical device. However, this version of the device is not manufactured using FFF technology, it is made using SLS technology and tough Nylon 12 material. A web post by open bionics explains that in 2020, the company switched to another printing process, which was more robust and water resistant, which we can now assume was SLS due to the disclosure of the use of SLS technology for their latest device (Gibbard, 2021). Prior to SLS, it is believed that they used FFF technology, specifically Ultimaker (®Ultimaker, Netherlands) brand FFF printers. In 2017, a video posted on Ultimaker's YouTube channel features Joel Gibbard, CEO of Open Bionics, describing the manufactured parts inside the hand, all manufactured using an Ultimaker 3D printer (Ultimaker, 2017).

The switch from FFF to SLS could be due to a number of reasons, including the improved suitability of SLS for medical approval. SLS parts are typically more robust due to their isotropic properties when compared with FFF parts (Jani, 2018). Of the commercially available 3D printed prosthetics and orthotics available, all of the identified examples are manufactured using with PBF AM techniques (Crispin orthotics; Ottobock, no date). One example suspected to use FFF technology is a cast and splint company called ActivArmor (®Colorado, US). A video showing their production method shown a cast being printed using the FFF technique, although they do not provide any specific details on the manufacturing techniques or materials used. The material used is described as a high temperature thermosetting plastic. They also discuss using a variety of coatings to improve the device properties, such as increasing the

strength or give it antibacterial or antimicrobial properties. Their casts, have a smooth and glossy appearance, which could be a result of the coatings applied, or as a result of solvent or chemical smoothing postprocessing techniques.

ActivArmor communicate that they are FDA registered, and ISO 10993 (BSI, 2018) certified, which refers to the standard for the biological evaluation of medical devices. The device is claimed to be biocompatibility tested, listed with the FDA as a Class I splint, and microporosity tested for cleanability. The device is supported by two research publications as well as a range of case studies.

The first publication (Graham *et al.*, 2020) investigates the functionality of 3D printed orthoses. The study included 12 research participants who were fitted with both a 3D printed cast and a conventional fiberglass cast in separate sessions. Tests were performed relating to functionality and dexterity, and any skin complications that occurred with use. Results indicated that there was no significant difference in function between the two casts, although one third of participants could perform tasks in a normal time, which they could not in the fiberglass cast. Minor skin irritation was noted in 42% of participants in the fiberglass class due to insufficient fit. The authors concluded that patient satisfaction, comfort and perceived function were found to be superior in 3D printed casts. The second publication by (Chen *et al.*, 2017) focussed specifically on the treatment of distal radius fractures, which were typically managed by using a plaster cast, splint or synthetic material cast. This study involved 10 research participants who were involved in a clinical trial. A follow-examination was conducted by an orthopaedic surgeon after six weeks of use which showed superior clinical outcomes. The ventilated structure was shown to increase patient comfort and satisfaction and was shown to support and maintain the alignment of fracture bones.

On the opposite end of the spectrum, charitable organisation e-NABLE works with a network of volunteers, many of them non-specialists, to manufacture upper limp prosthetics. e-NABLE are a registered charity of around 40,000 volunteers (E-NABLE, 2020), which is a two-fold increase since 2020, where an estimate of 20,000 volunteers was published on their website. In 2022, the charity estimate between 10,000-15,000 prosthetic hands and arms have been delivered to participants, which in 2020 was 8000 (E-NABLE, 2020). High demand for low-cost, or free, prosthetics is in response to patients experiencing difficulties accessing prosthetics

due to the increased costs and timescales associated with conventional manufacturing techniques (Cropper and Zachariasen, 2017; Ferreira *et al.*, 2018).

Combined with digital data acquisition techniques, such as 3D scanning, the devices are designed to be highly customisable, often resulting in an ergonomic fit. The ability to customise the appearance of the devices is an additional benefit, making it even more desirable to children and young people. Assistive technology and medical devices are often rejected by users based on their aesthetic appearance (Paterson *et al.*, 2015). Thus, the facilitation of advanced customisation is a highly desirable feature of 3D printed devices.

The devices, shown in Figure 15, are updated regularly as a result of continuous innovation by the network of volunteers. The latest design, the Kinetic Hand, was created by Mat Bowtell and made open source to encourage further innovation in the field and improve global access to assistive technology. e-NABLE are known for their devices being 'body powered', meaning they use movement from the wrist to open and close the fingers. As open-source devices, the advanced technology used in other devices, such as the Hero Arm, is not accessible or feasible for use in this model. Devices are designed to be accessible, rather than high-performance. The Kinetic Hand is available on Thingiverse, an open-source file sharing website, where it is listed as 'experimental' with the description disclosing it is not classified as a medical device and is therefore for evaluation purposes only.

Figure 15: collection of e-NABLE prosthetic hands and arms (Source: (Owen, 2019) (permission granted))

Aside from commercial and publicly available 3D printed prosthetics, experimental work has been conducted in a research context. Zuniga (2018) conducted a study to describe the development of 3D printed prosthesis using antibacterial filament, and to verify the antibacterial properties of the printed devices. The finger prosthetics were given to two adults who tested them for usability satisfaction. Results showed that the manual gross dexterity was improved using the prosthesis, with participants reporting to be "quite satisfied" to "very satisfied". A bacterial analysis of the prosthesis was performed, which revealed that the device was up to 99.99% effective against *Staphylococcus aureus* and *Escherichia coli*. Zuniga concluded that antimicrobial filament can be used for the development of functional and effective antibacterial prosthetics.

2.2.1.4. Surgical tools

In a systematic literature review of AM in a medical setting, out of 227 publications over half were on the AM of surgical guides, followed by models for surgery planning (Tack *et al.*, 2016). FFF is reported to be one of the main techniques used for manufacturing surgical planning prototypes (Tejo-Otero *et al.*, 2020).

Surgical uses include the manufacture of models for surgical planning, external parts, surgical guides and distractors, and internal implants (Tejo-Otero *et al.*, 2020). The use of additive techniques could help to improve a surgeons' preoperative performance by providing them the opportunity to train and prepare with physical printed models, therefore decreasing the operation time and reducing risk (Tejo-Otero *et al.*, 2020). Benefits of using FFF over other AM techniques include the low-cost of prototypes, however they are mainly used for visual purposes. The ability to use multiple colours during printing helps the surgeon to identify different anatomical structures.

Examples in research include (Anderson *et al.*, 2016) who manufactured a rigid but hollow intracranial aneurysm model out of PLA material. They found a good agreement between the printed geometry and the source anatomy, with a level of accuracy acceptable for producing models for comparing computational fluid dynamics. Farooqi *et al.* (2016) printed cardiac models for preoperative surgical planning purposes using ABS material. They discuss multiple clinical examples through patient case studies and acknowledge that FFF has been proven to be a promising technology. The main barriers of widespread FFF adoption were identified as technical and knowledge based, largely relating to the accessibility of software and the skill to operate it. Increased accessibility and standardisation of the technique were also identified as being key in the future of FFF for anatomical evaluation for disease management (Farooqi *et al.*, 2016). Clifton *et al.* (2020) conducted *ex vivo* investigations of spinal instrumentation techniques using FFF printed models, finding that FFF was an accurate and cost-effective technique for studying spinal instrumentation. They described potential limitations relating to the materiality and lacking representation of soft-tissue structures. The learning curve necessary to effectively operate the 3D software packages required was also identified as a potential limitation, which is directly linked to the potential for error, distortions and inaccuracies in the printed parts (Clifton *et al.*, 2020).

2.2.1.5. Other FFF printed device examples

Some early work has been conducted by (Rimington *et al.*, 2017), who observed the biocompatibility of AM polymers manufactured with FFF technology, which could potentially provide the opportunity to improve the efficiency of making anatomical models, through offering design freedom, the rapid production of design iterations and the ability to enhance the biomimicry of skeletal muscle cells *in vitro* (Rimington *et al.*, 2017).

A comparison of AM technologies for producing customised wrist splints was conducted by (Paterson *et al.*, 2015), who compared FFF, SLS, SLA and MJ. This is particularly relevant as wrist splints would be typically classified as a Class I medical device. Their findings did however indicate that FFF was considered the least suitable for upper extremity splinting due to poor surface quality which exhibited obvious layer steps affecting the aesthetic appearance of the splint. This is also considered to be a potential factor increasing discomfort for the patient around the edges of the splint. The recesses between layers could also collect waste products, causing potential hygiene issues. The material studied, ABS, was found to be relatively robust and is thought to withstand daily use including mechanical cleaning with mild detergents. SLA was found to have a good surface quality, whereas SLS and MJ both showed aesthetic and functional advantages, meaning they were named as preferable over the FFF technique.

Studies have investigated the dimensional accuracy and trueness of various anatomical models (Msallem *et al.*, 2020). Accuracy is identified as one of the main aspects of medical AM, due to inaccuracies leading to the wrong assumptions, which could potentially cause harm to patients. FFF was found to have the lowest mean and median values in trueness analysis but had a higher variability in standard deviation than other techniques, meaning it did not perform as well in the overall root mean square, which was the method used to calculate the square root of the mean square between two parts. Yap *et al.* (2017) also studied the resolution of FFF for bio-models for medical applications. They found that the data acquisition process affects the overall printing resolution, and therefore a key limitation of using FFF to produce anatomical models was the inherent noise data present from the data acquisition techniques. Hatz *et al.* (2020) compared a low-cost desktop FFF machine with an industrial SLS machine when producing mandibular models and found that both technologies were found to produce highly precise models. The literature in this area generally agrees that 3D printed anatomical models have had inaccuracies of less than 1mm, which make them an accurate but cheaper alternative to professional grade models.

Although limitations of FFF were identified meaning it was labelled inferior to other AM technologies, steps can be taken to improve surface quality, and additional process steps such as solvent smoothing and/or medical coating techniques could be used. The accuracy and trueness of FFF has been shown to have potential, and when combined with the key benefits of FFF, the high accessibility and low cost, it would still be considered a promising technique

for low-risk medical device applications. Further, as demonstrated in Section 2.2.1.3, FFF devices are already in use, so any explorative work in this field would be beneficial.

2.2.2. Fused filament fabrication for medical applications: Use settings

2.2.2.1. Research

Class I medical devices produced in a research context are usually subject to numerous control measures. It is important to highlight that research can occur in many settings where standards and general practices will vary, however, for the purpose of this study, a research setting refers to a typical research institution, such as a university or another established research organisation. The differentiation between this type of research, and research conducted independently is the number of regulations research activities must adhere to, and the number of control measures in place to ensure this adherence.

Research ethics are in place to ensure research is carried out responsibly, minimising risk and ensuring the safety of any participants involved, the researchers themselves and the wider society. They are also in place to establish and maintain the public's trust of the discipline and the institution in which it is being carried out. The importance of adhering to good research ethics procedures is widely agreed upon, as they work to ensure truthful outcomes which could be jeopardised by deliberate or accidental error. Research ethics are in place to prohibit the fabrication or falsification of findings, whilst minimising the chances of misinterpretation of data or other errors communicated. Ethical adherence also works to ensure that researchers can be held accountable, and that their work is fair, free of conflicts of interest, and is therefore supported by the public.

Research governance frameworks promote good research practice, ensuring that the research activities are accompanied by the correct procedures. The research activities are outlined, details around the rationale, aims and objectives, intended methodologies including information regarding timescales and locations for data collection and any additional areas of concern relating to risk, intellectual property and data protection. There is usually a multi-stage approval in place, where research is first approved by the principal investigator, followed by the institution's research ethics committee. During these approval phases, any concerns relating

to research integrity, safeguarding and risk to researchers and participants would be identified, ensuring high standards are upheld and research is ethically sound.

The rationale, aims and objectives are also reviewed to ensure the research will be beneficial and will not replicate work that has already been done. The rationale must be justified, further enforcing that the research is purposeful and will provide a contribution of knowledge. Methodologies are often supported by other approaches in literature, which can help ensure the research is pitched to yield the most meaningful and impactful outcome. Therefore, devices produced within a research environment are often calculated and well thought out. The research is often planned around characteristics relevant to a pre-defined narrative.

In the context of medical device research, the research protocols required for ethical approval are expected to include details of the data collection, for example, which process parameters are locked down. A principal investigator, research supervisor or experienced researcher would be likely to spot any flaws in the research protocol which could invalidate the research or create uncertainty or ambiguity in the results. This means that meticulous attention to detail is given, and the research is expected to produce credible results. In addition, the equipment available in a research environment is likely to be properly maintained with cleaning, servicing, and calibration schedules in place.

The type of equipment available is also a differential factor to other use applications. Research environments usually have a good range of equipment covering all different types of analysis. For example, equipment relevant to AM and the manufacture of Class I medical devices could include a wide range of 3D printing equipment and accessories, laboratories for thermal analysis, metrology, mechanical testing and microscopy. Access to a broad range of equipment allows the scope of experiments to be extended, which may not be possible in an industrial setting, and even more so for non-specialist users.

2.2.2.2. Industrial

Industrial manufacturing settings often have a commercial focus, meaning the goals of an industrial organisation are likely to differ significantly than from a solely research-based environment, even when research is conducted in an industrial context by an organisation. The focus of a Class I medical device manufacturer in an industrial context is often based around

the production of high-quality products. Commercial success is heavily reliant on good quality products. Poor-quality is likely to drive a manufacturer to failure, especially in the case of medical device manufacture where high quality is a critical requirement.

To ensure quality, industrial manufacturers must have a well-defined set of quality management procedures. They will be well rehearsed with the standards and regulations in the industry, and their operating procedures will be formed to meet the regulations. Operators of equipment or machinery will be highly trained and expected to adhere to thorough standard operating procedures (SOPs). These control measures are in place to ensure that parts produced fall within specification and meet the relevant quality standards. The manufacturing set up and SOPs are usually well-established and have undergone numerous stages of repeatability and/or reproducibility testing, meaning there is a large amount of certainty that the product outcome would be as intended.

The equipment available in an industrial setting is more likely to be limited to the direct activities of the organisation, however this equipment will be strictly maintained and have specific operating procedures. A key difference between the use of equipment in a research and industrial environment is the types of activities different equipment is used for. For example, a larger range of equipment would be available in a research environment, however, this equipment is likely to be used for a much wider range of activities by researchers in different disciplines. The activities will be more experimental than those in an industrial environment, where although the range of equipment is smaller, it's use will be constrained to specific approved activities. This is to mitigate risks like contamination, or to ensure the workload of a machine is tracked to record wear for maintenance schedules. The equipment in an industrial environment is typically held to the highest of standards, as this directly influences the quality of the product outcome.

As well as quality and performance standards, it is increasingly common for industrial organisations to push for sustainable innovation, driven by the increasing awareness of contemporary society. Especially where plastic products are concerned, companies are under increasing pressure to operate in a more sustainable manner through using recycled and bio-based plastics where possible. This creates further challenges in terms of quality control, however, push from research and industrial users can help to ensure positive and sustainable growth of the technology.

2.2.2.3. Non-specialist

Non-specialist users of the technology will have different access to equipment than research and industrial users. It must be stated that each scenario of non-specialist user will be different, and generalisations will be made to represent most users in this user group. Typically, a non-specialist user would have access to a single FFF machine within the hobbyist to professional range. The machine is likely to be a desktop machine that is set up in a home environment. Home 3D printers are commonly set up in garages or home workshops, which typically do not have the same ambient environment as an office or laboratory. Non-temperature-controlled spaces will experience harsher temperature changes, whilst being subject to other external factors such as increased draughts. The ambient humidity is also likely to be a differing environmental factor, due to there being less environmental control measures in place than the other discussed printing environments. Additional contamination may also be a factor, where increased amounts of dust and debris could be present potentially affecting the outcome of a printed part.

As discussed, the success of an FFF printed part is likely to be influenced by environmental factors, such as temperature, humidity, draughts and contamination, which could result in warping, poor layer adhesion and non-uniform parts (May *et al.*, 2021). Environmental factors have been said to affect other factors in the FFF process, aside from the actual printing process. The storage of filament and 3D printing consumables could also be a factor that affects the process. Filament stored in different locations, for example a laboratory, office or home garage could mean that the properties of the filament differ when exposed to different environmental conditions, and the timescales at which exposure occurs. This is especially relevant for non-specialist users who are likely to store filament in the most extreme conditions for the longest period of time. Industrial users are likely to have process controls on filament that dictates a 'use by' date, whereas it is probable that non-specialist users would store filament for longer, due to the reduced output volume.

The ability to conduct testing is a significantly limiting factor for non-specialist users, as these are the users most likely to have the largest variation between parts, however they are often unable to test parts. As well as restricted access to scientific sample testing, non-specialist users will have access to a different type of measuring equipment. A non-specialist user might have access to a Vernier calliper, whereas standard measuring equipment in a laboratory or industrial

environment is typically required to be more accurate and precise, usually taking the form of a micrometer, probe, or coordinate measuring machine (CMM).

The training a non-specialist user receives is also likely to differ significantly from research and industrial users. As discussed, much of the training a researcher receives is from an experienced and highly skilled researcher. A large amount of knowledge obtained in a research environment comes from academic literature and other scientific sources. Where a researcher might base their decisions for the process on this kind of knowledge, such as the printing parameters or manufacturing control measures, a non-specialist user is more likely to base their manufacturing decisions on grey literature sources, such as web pages or web-based forums.

Where non-specialist users are manufacturing Class I medical devices as part of a wider group or organisation, guidance may be available to promote a level of consistency between individuals working towards the same cause. For example, charity group e-NABLE provide an extensive set of resources for manufacturers, which includes CAD files, specific instructions relating to print parameters such as orientation, as well as other tips for printing successful parts. They also provide a basic quality specification, which sets out to maintain the quality of prints across a wide range of different FFF printers. Comparing a non-specialist specification against a research or industrial specification illustrates a clear difference between the measures considered within each environment. A non-specialist specification for a 3D prosthesis is taken from the e-NABLE website. It specifies that no large gaps should be left between parts, the layer height should be set between 0.1mm and 0.25mm, no experimental, scented, or chemically treated filament should be used, parts should be fabricated according to detailed guidelines for orienting parts, and the printer must be properly calibrated to "achieve the dimensional tolerances necessary for functioning hands" (Simon, 2021).

An industrial quality specification is explored in detailed in Section 2.3, which outlines the steps required in a quality management system for Class I medical devices intended for regulatory approval. However, it is highly unlikely for a non-specialist user to be working towards producing a medical device intended for regulatory approval, due to the time, cost, and knowledge intensive nature of achieving regulatory approval for medical devices. A non-specialist user would not usually be required to prove that a fabricated device meets a certain level of quality due to it usually being directly given to the user, outside of a medical context. This type of product release is unique to non-specialist users, due to the research ethics and

governance constraints in place for research institutions. Industrial use cases where the product is intended to be sold must ensure that the relevant product supply laws and legislative requirements to be sold in the intended region. In the UK, medical devices must be approved and show the UKCA mark which is discussed further in the following section.

The differences in equipment, environment and training between each use scenario inherently means that if the same part was produced in each of the discussed use cases, the outcomes are likely to be significantly different. The connecting factor between each scenario is that the device could end up in use by a user. However, the path the device takes to the user differs substantially. The ethical and regulatory checkpoints for researchers and industrial users are unavoidable, which means the device has undergone a process to consider the safety and efficacy of the device, whether that is through ethics and governance policies or through the regulatory requirements. Non-specialist users are usually either connected to an end user directly, or through the charity or organisation they are working with. Where basic observational assessments of the device may be conducted, there is unlikely to be a thorough assessment of risk to the user, thus leading to concerns around safety and risk.

2.3. Regulatory scope

2.3.1. Transition from the Medical Device Directive to Medical Device Regulation

Medical device regulations vary in different parts of the world, but most countries have a regulatory body which requires devices to undergo a conformity assessment, demonstrating the devices is safe and effective, and that it meets the legal requirements of that country. Each country has their own regulations and system for enforcement for their markets. Some countries or islands have no formal medical device regulatory approval processes. However, most countries have established organisations responsible for medical device and pharmaceutical regulation. Some of the larger medical device markets and regulatory enforcement authorities include Canada, with the Medical Device Single Audit program, Australia with the Australian Government Department of Health Therapeutic Goods Administration, China with the China Food and Drug Administration, Africa with the World Health Organisation, Brazil with Anvisa, the US with the Food and Drug Administration, Europe with the European Medicines Agency, and the UK with the Medicines and Healthcare products Regulatory Agency.

The three markets covered in the scope of this study are the UK, EU and US due to the high levels of research activities present in these markets. The pathway to medical device regulation is well-established in each of these regions and remains the same regardless of the manufacturing methodologies used to produce medical devices. However, specific process steps within the wider regulatory pathway, such as determining appropriate manufacturing controls can be challenging due to the reliance on new and unestablished workflows, which in many ways differ significantly from conventional manufacturing techniques. AM workflows are complex, varying between technologies, and even between hardware using the same technology. Therefore, care must be taken when adapting novel techniques to established regulatory pathways to ensure important factors unique to AM technologies are considered within the process.

2.3.1.1. United Kingdom leaving the European Union

Up until January 2020, when Britain left the European Union (EU), medical devices sold in the UK were required to hold a CE mark, meaning the route to conformity was the same in the UK as the rest of the EU. The UK medical devices directive (UK MDR, 2002) gave effect in UK law to the EU MDD (Council Directive, 93/42/EEC) prior to the end of the transition period. This meant that after the UK left the EU, the route to market and UKCA marking requirements were derived from the EU legislation.

However, regardless of the UK leaving the EU, other major changes were made to the regulation of medical products in Europe. The medical device directive (MDD) (Council Directive, 93/42/EEC) was introduced in 1993, and its purpose was to regulate medical devices sold in the EU, harmonising laws relating to medical devices. On the 26th May 2021, the new medical device regulation (MDR) (Council Regulation, 2017/745) was put in place following a four year transition period which allowed organisations to make the switch.

The MDD had 58 legislative procedures, with 23 articles. Comparatively, the MDR has 101 legislative procedures with 123 articles. The annexes which detail the requirements, are shown in

Table 6. The additional five annexes in the MDR, show the increased number of requirements necessary to gain regulatory approval. The MDR is now the regulation for medical devices in the EU.

*Table 6: Annexes in the MDD (Council Directive, 93/42/EEC) and MDR (Council Regulation, 2017/745) * Unique device identifier (UDI) is a grouping name that a particular device fits into*

Annex	MDD	MDR
Annex I	Essential requirements	General safety and performance requirements
Annex II	EC declaration of conformity (full quality assurance system)	Technical documentation
Annex III	EC type-examination	Technical documentation on post-market surveillance
Annex IV	EC verification	EU declaration of conformity
Annex V	EC declaration of conformity (production quality assurance)	CE marking of conformity
Annex VI	EC declaration of conformity (product quality assurance)	Information to be submitted upon the registration of devices and economic operators; core data elements to be provided with to the UDI* database
Annex VII	EC declaration of conformity	Requirements to be met by notified bodies
Annex VIII	Statement concerning devices for special purposes	Classification rules
Annex IX	Classification criteria	Conformity assessment based on a quality management system and assessment of the technical documentation
Annex X	Clinical evaluation	Conformity assessment based on type examination
Annex XI	Criterial to be met for the designation of notified bodies	Conformity assessment based on product conformity verification
Annex XII	CE marking of conformity	Certificates issued by a notified body
Annex XIII		Procedure for custom-made devices
Annex XIV		Clinical evaluation and post-market clinical follow-up
Annex XV		Clinical investigations

Annex XVI	List of groups and products without an intended purpose
Annex XVII	Correlation table

2.3.2. EU regulations

Medical devices sold on the EU market require a CE mark to demonstrate they comply with the EU MDR (Council Regulation, 2017/745), which requires the classification of medical devices according to Table 7. A quality management system (QMS) complying with the requirements outlined in the MDR is necessary requirement. (ISO, 13485:2016) is the standard used worldwide for specifying the requirements of quality management systems for medical device manufacturers and suppliers to comply with regulatory requirements. It can be used at one or more of the following stages of the life cycle of a medical device: design and development, production, storage and distribution, installation, servicing, final decommissioning, and disposal. It can also be used for the design and development or provision of associated activities, such as technical support. ISO 13485 is a stand-alone standard, however, it is based on ISO 9001 (ISO, 9001:2015), the internationally recognised standard for quality management. The standard presents the requirements in five overall steps presented in Figure 16.

Table 7: Classification of medical devices in the EU according to the EU MDR (Council Regulation, 2017/745)

Classification	Examples	Requirement
Class I (generally regarded as low risk)	Adhesive bandages, medicine spoons	Self-certification
Class I with added functionality (generally regarded as low risk)	Devices with additional measuring functionality, sterile devices or reusable surgical instruments	Notified body approval required
Class IIa	Standard hearing aids, suture needles	Notified body approval required
Class IIb (generally regarded as medium risk)	Surgical lasers, ventilators	Notified body approval required

Class III (highest risk) (generally regarded as high risk)	Breast implants, pace-makers	Notified body approval required

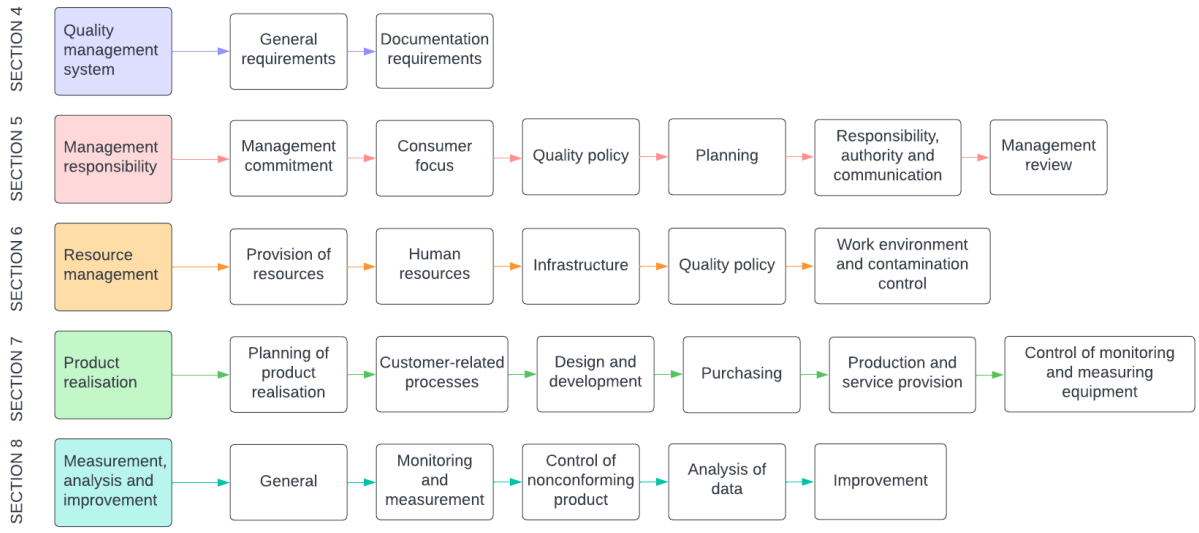


Figure 16: A visualisation of the stages of a quality management system (based on (ISO, 13485:2016))

The QMS feeds into EN ISO 13485 certification and the technical file feeds into CE compliance. Both of these components together are usually sufficient to demonstrate compliance. In addition to the regulatory steps discussed, EU legislation requires notified bodies to perform unannounced audits of medical device manufacturers and their critical subcontractors or suppliers at least once every five years (BSI, no date).

2.3.3. UK regulations

In the UK, the rules differ across the dissolved nations. Different rules apply for Northern Ireland, and Great Britain (GB), which includes England, Wales and Scotland. The UKCA mark is the product marking used in the UK, however it is not recognised on the Northern Ireland market where the CE or UKNI (a new conformity marking for products placed on the market in Northern Ireland) market is required. The requirements of the UKCA mark are based on the three main types of medical devices, and their part in the UK medical devices regulations 2002 (UK MDR, 2002). All medical devices must be registered with the medicines and

healthcare products regulatory agency (MHRA) before being placed on the market, and must conform to the UK MDR 2002, or the EU MDR until 30th June 2023. CE marked devices under the EU MDD are also accepted on the (GB) market until 30th June 2023. From this date, EU certification will no longer be accepted, and a UKCA mark will be required to place a device on the GB market (Gov-UK, 2020a).

To place a UKCA mark on a medical device, a manufacturer is required to demonstrate the device meets the UK MDR requirements by passing a conformity assessment, which depends on how the device is classified. The classification of general medical devices in the UK is categorised into four groups shown in Table 8. The UK MDR 2002 specifies that devices can be classified in accordance with classification criteria outlined in Annex IX of the MDD. The UK MDR:2002 references the annexes of other directives: Directive 93/42/EC (EU MDD for medical devices), Directive 98/79/EC (EU AIMDD (active implantable medical device directive) for *in vitro* diagnostic medical devices) and Directive 90/385 (EU IVDD (*in vitro* diagnostic directive) for active implantable medical devices).

Table 8: Classification of medical devices in the UK according to the UK MDR (UK MDR, 2002)

Classification	Examples	Requirement
Class I (generally regarded as low risk)	Adhesive bandages, medicine spoons	Self-certification
Class IIa (generally regarded as medium risk)	Standard hearing aids, suture needles	Approved body assessment
Class IIb (generally regarded as medium risk)	Surgical lasers, ventilators	Approved body assessment
Class III (generally regarded as high risk)	Breast implants, pace-makers	Approved body assessment

The MHRA are the government agency which is responsible for regulating medicines, medical devices and blood components for transfusion in the UK. They are responsible for designating and monitoring the conformity assessment bodies in the UK, which oversee the conformity assessment for Class IIa to Class III devices. The MHRA has enforcement powers to prohibit the sale or supply of medical devices which are considered unsafe, or do not comply with UK regulations, as well as issuing notices of warning, suspension or requests for information. Many compliance activities are conducted in writing, however in some cases on-site inspections are required. MHRA officers have powers to enter premises to conduct inspections. Inspections could include an examination of medical device documentation, as well as the examination of manufacturing and product testing procedures.

The conformity assessment bodies, or more widely known as notified bodies, conduct conformity assessments based on the relevant directives of regulations. The assessment typically involves a review of the technical documentation supporting the claims of safety and performance for the medical device under assessment. An audit of the quality management system may also be required, depending on the classification of the device. There are currently four approved bodies for medical device assessment which are approved by the MHRA and permitted to issue the UKCA certification. These are DEKRA Certification UK Ltd (®High Wycombe, UK), SGS UK Ltd (®Cheshire, UK), UL International UK Ltd (®Hampshire, UK) and BSI Assurance UK Ltd (®Milton Keynes, UK) (Gov-UK, 2020b). The scope of each approved body differs meaning not every assessment body is authorised to certify every type of medical device, therefore the manufacturer should choose an assessment body qualified and experienced with the type of medical device under assessment (BSI, no date).

Similarly to the EU, a production quality assurance system, or QMS, is a requirement stated in part II of the UK MDR, referring to Annex II of the MDD. Although the regulations or directives do not specify specific standards for a QMS, the most widely used and accepted standard is (ISO, 13485:2016). In addition to a QMS, a medical device manufacturer must provide technical documentation, Part I Section 17 of the UK MDR references the technical documentation referred to in Section 6.3 of annex II, or Section 7.4 of Annex III of the MDD 93/45. Technical documentation must cover the wide range of aspects detailed in Table 9, which is compiled to form a technical file (TF). Technical documentation requirements vary between device classifications.

Table 9: UK technical documentation requirements for Class I medical devices (adapted from (Gov-UK, 2016)

Technical documentation requirement	**Description/example**
Description	A description of the device, including variants (for example names, model numbers and sizes)
Raw material and component documentation	Specifications including details of raw materials, drawings of components and/or master patterns, quality control procedures
Intermediate product and sub-assembly documentation	Specifications including appropriate drawings and/or master patterns, circuits, formation specification, relevant manufacturing methods and quality control procedures
Final product documentation	Specifications including appropriate drawings and/or master patterns, circuits, formation specification, relevant manufacturing methods and quality control procedures
Packaging and labelling documentation	Specifications for packaging and copies of all labels and any instructions for use
Design verification	The results of qualification tests and design calculations relevant to the intended use of the product, including connections to other devices in order for it to operate as intended
Risk analysis	Looks at whether risks associated with the use of the product are compatible with high-level protection of health and safety and are acceptable when weighed against the benefits to the patient or user
Compliance with essential requirements	Demonstrate that the relevant essential requirements in Part II of the UK MDR 2002 or Annex I of the MDD 93/42. Not all essential requirements apply to every device, so these must first be identified before finding evidence to demonstrate they have been met. It is recommended that devices are developed in accordance with the relevant standards. Technical documentation must include a description of how each relevant essential requirement has been complied with, including a list of relevant standards that have been applied concerning the manufacture and design of the product.
Clinical evaluation in accordance with Annex X MDD 93/42	A clinical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device is required under Part II of the UK MDR 2002. This section of the technical documentation must

	demonstrate that the product fulfils its intended purpose, which includes any claims made as part of the marking material supplementary to those made in the technical file
Declaration of conformity	To place a UKCA mark on a medical device, the EC declaration of conformity procedure described in Part II of the UK MDR 2002 or Annex VII of the MDD 93/42 must be followed. This must be done before the device is placed on the market. Technical documentation must be kept for at least five years after the last product has been manufactured, allowing the MHRA to investigate any device problems even if it is no longer on the market.

For the clinical evaluation, in cases where there is not enough pre-existing evidence that demonstrates that the device conforms with essential requirements, a specifically designed clinical investigation may be necessary. In this case, the MHRA must be notified in advance of doing the investigation (Gov-UK, 2016). In addition to the TF requirements for Class I medical devices detailed in Figure 17, sterile devices or those with additional measuring functionality must meet a series of extra requirements. Post-market surveillance procedures must be in place for when a device is placed on the market, and the MHRA must be informed immediately if the device has been involved in an incident that led to a serious injury or serious deterioration in health or death. Any technical or medical reasons resulting in the recall of a medical device must also be reported to the MHRA. To summarise, Figure 17 illustrates the process for regulating medical devices in the UK.

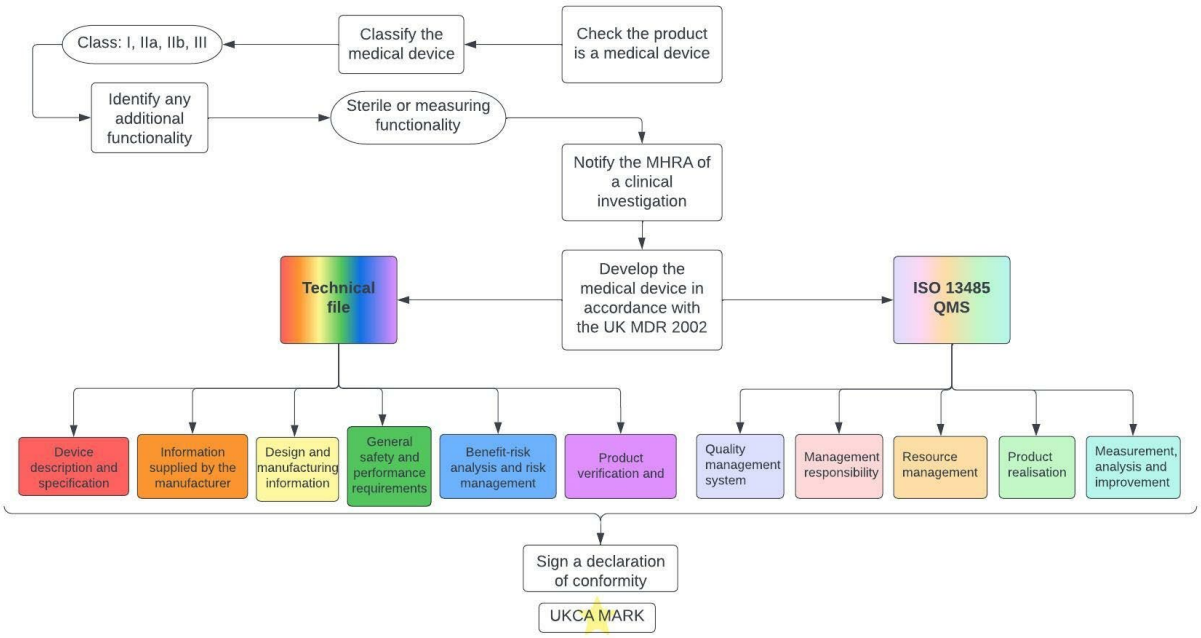


Figure 17: Process for regulating Class I medical devices for the GB market

2.3.3.1. Custom-made medical devices in Great Britain

The guidance on custom-made medical devices differs to general medical devices, and they are not required to be UKCA marked. A custom-made device is defined as the following:

> *(a) manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his [their] responsibility, specific characteristics as to its design; and*
> *(b) intended for the sole use of a particular patient*
>
> *From the UK MDR 2002*

It does not include mass-produced devices that require adaptation to meet the specific requirements of the medical practitioner or professional user. Examples of professional users include optometrist, prosthetists, orthotists and orthopaedic shoe fitters. Written prescriptions for custom-devices are often in letter form, however, they could also take the form of a moulded impression of the shape of the required device with the order specifying customer details and the request to 'make as pattern' (MHRA, 2020b). An example of a patient-specific device is a prosthetic socket, which is typically prescribed by a medical consultant or prosthetist and manufactured by a prosthetist. Conformity assessment requirements still apply, and manufacturers must meet the relevant Annexes, which for medical devices are in Part II of the

UK MDR 2002. This includes a statement containing information about the device and the keeping of the device documentation. Examples of necessary information include identification data (i.e., a serial number or order number), the name of the person who prescribed the device, and a statement that the device conforms to all the relevant essential requirements. An exception is a custom-made Class I medical device, which does not require a statement.

Post-market surveillance is another requirement applicable to custom-made devices and requires manufactures of custom-made devices to review and document experience gained in the post-production phase. They must also set up a post-market vigilance system of reporting to the MHRA. Manufacturers must report any incidents resulting from the constituents or design of the device if it poses a serious risk to public health. The manufacturer must also be registered with the MHRA, which includes a description of the devices (MHRA, 2020b).

For a non-specialist manufacturer, medical device regulations in the UK can be complex and difficult to understand. The current UK regulation, the UK MDR 2002, references the MDD, whilst discussing the requirements of CE marking, which is no longer accepted in the UK. The amalgamation of multiple rules and regulations alone can cause confusion to someone inexperienced in the medical device regulatory field. The outdated regulations can cause some confusion between the MDD and the MDR, as well as references being made to CE marking as the MDD is no longer relevant in the EU, and the new UKCA mark is not referred to in the MDD, it is only referenced in the government's up-to-date guidance webpages. An updated UK MDR would be helpful for medical device manufactures and those non-specialist users producing medical devices.

2.3.3.2. Clinical investigations

In many cases, a clinical investigation is required as part of the process to obtain a UKCA or CE mark in the UK or Europe respectively. In the UK, the MHRA must be informed about a clinical investigation at least 60 days prior to beginning the investigation where necessary. Usually, where the medical device will be patient contacting with human participants, and the device is not already CE marked, notification to the MHRA is required. Applications must be made through the integrated research application system (IRAS), which includes a required clinical investigation application. The clinical investigation application is extensive, and includes the components listed in Table 10.

Table 10: Essential components in the clinical investigation application through IRAS based on (MHRA, 2021)

Clinical investigation plan	The clinical investigation plan should be in line with ISO 14155:2020 (BSI, 14155:2020) and should detail the investigation parameters and design and the data collection, analysis and statistics.
Participant information sheets and consent forms	The participant information sheet should identify and explain all of the risks to the participants. Consent forms intended for participants should be included.
Device details	The depth of information supplied within the notification should be appropriate to the classification of the device, the novelty of the design, the materials used, and the overall risk associated with the device.
Essential requirements / general safety and performance requirements checklist	The essential requirements checklist should detail how the requirements have been addressed, including the references to designated or harmonised standards, and evidence of how these standards have been met. It should also include copies of all the test reports and other documents referenced in the essential requirements checklist.
Risk analysis	A risk analysis should be provided, preferably to the EN ISO 14971:2019 (BS EN ISO, 14971:2019) standard. The risk analysis should cover the compatibility of all device components.
Instructions for use and device labels	Instructions and labelling is required for all investigational device components. Instructions should include where relevant information on the setup of the equipment for use with a patient and include and pre-use checks that may be necessary. The labelling should state that the device is 'Exclusively for clinical investigations'.
Summary of all bench testing and pre-clinical testing conducted	Bench testing and pre-clinical testing reports should be included, with results and the manufacturer's conclusions referenced to the device model and version involved. Testing standards should be referenced where relevant, and any adaptations to test standards should be detailed. The results of design calculations, acceptance of criteria for testing and confirmation of whether each device will be individual tested for conformance to the design criteria after manufacture. A summary of any

	testing conducted to address human factors and usability engineering should be included.
Summary of all clinical experience with the device to date	All clinical experience should be summarised, including adverse events seen and performance related cases. If the device differs from the investigational device, full details on how the new device differs should be outlined. Information relating to changes in the design, material, intended use and the rational should be detailed.
List of standards met	All designated or harmonised standards that the device complies with should be listed, including the year of issue. Full justification for where standards met have been superseded should be given. The application of designated or harmonised standards is voluntary, and applicants may choose alternative methods of demonstrating compliance with the essential requirements. Full justification should be given where alternative methods have been chosen.
Sterilisation validation report and software information	The MHRA requires manufacturers of sterile devices, either provided sterile or sterilised at the point of use, to submit suitable documentation demonstrating that the methods of sterilisation renders the device sterile. Devices that include a software component should be addressed in the notification.
Biological safety assessments of patient contacting materials where relevant	All devices that are patient contacting require a biological safety assessment. It should include a detailed description of how biocompatibility and biological safety have been addressed. A description of how biological safety has been evaluated should be included, with information around the identity of the person(s) responsible for the risk assessment, a summary of the data examined and the basis for the judgement that the materials and suitable for the proposed use.
Research ethics committee opinion	A copy of the ethics committee opinion should be included, whether this is a fully or partly approved opinion. If it is approved with conditions, these conditions should be provided to the MHRA at the time of submission if available, otherwise to follow.

All project-based research taking place in England and Wales requires health research authority (HRA) approval, which brings together an assessment of governance and legal compliance with the independent research ethics committee (REC) opinion, which is provided through the UK research ethics service. HRA approval is the process for the NHS in England and Wales to research in healthcare, which involves NHS organisations. The HRA and REC provide a service intending to protect the rights, safety, dignity and wellbeing of research participants. Due to the nature of medical device research, to ensure the safety of participants, HRA approval is required.

2.3.4. US regulations

In the United States (US), medical devices are regulated by the food and drug administration (FDA). Within the FDA, the centre for devices and radiological health (CDRH) is the centre responsible for regulating firms involved with the manufacture, packaging and labelling and/or import of medical devices sold in the US. The code of federal regulations (CFR) is a publication of general and permanent rules published in the federal register (FR), which is divided into 50 titles representing the areas subject to federal regulation. Most medical device regulations are in title 21 (food and drugs) of the CRF in parts 800-1299 (21 C.F.R., 2022).

As in the UK and EU, the US assign medical devices to one of three regulatory classes based on the necessary control steps to assure the safety and effectiveness of the device. The device classification is risk based. It depends on the intended use of the device, but also the indications for use which can be specified in the labelling and communication around the device. The three classifications and regulatory controls are detailed in Table 11.

The regulatory controls are referred to as either general, special, or premarket approval controls, which describe the appropriate level of scrutiny to ensure a device is safe and effective. The general controls apply to all the medical device classes, and control things like the quality system, device labelling and reporting, and premarket notification. Special controls are required for some Class II medical devices which could include special labelling requirements, design characteristics or specifications, performance standards or guidance documents. General and special requirements alone are insufficient to ensure the safety and effectiveness of Class III devices, and therefore premarket approval is required.

Table 11: FDA classes and requirements of medical devices based on (FDA, 2020a)

Classification	Type	Requirement
Class I	With exemptions Without exemptions	General controls
Class II	With exemptions Without exemptions	General controls and special controls
Class III	-	General controls and premarket approval

A 510(k) is a technical dossier which acts as a premarket notification submitted to the FDA to demonstrate a device is safe and effective. For devices which do not require premarket approval, a 510(k) must be submitted to the FDA unless the device is exempt from 510(k) requirements. Most Class I devices are exempt from 510(k), however some can require it. Most Class II devices require 510(k) clearance. In some cases, Class II devices can be exempt from 510(k), as long as they comply with special controls defined by the FDA. Class III devices require premarket approval (PMA) applications, which are the most stringent type. The requirements of a PMA are outlined in the CFR under Section 814 (21 C.F.R. § 814, 2022).

Although the EU and US processes for medical device regulation differ in some ways, they share similarities, such as the compliance with ISO 13485 and many of the documentation requirements. The key differences between the MDR and CFR are the classification systems, and the way devices are classified. There are also some minor differences in requirements and reporting processes. The MDR categorises devices into four categories: non-invasive, invasive, active, and those with special rules. Section 4 of chapter III in the EU MDR details the specific rules for each type of device, based on whether they are invasive or non-invasive. These rules dictate their classification shown in Table 7. The FDA classifies devices in three groups as either Class I, Class II or Class III, which is identified using a classification database where the device name or device panel is searched. In most cases the database will identify the classification regulation in the CFR. Classified devices have a seven-digit number associated with them which is used to describe the device.

Another key difference is the clinical testing procedures, which in the US is done under the 510(k) process. Under the MDR, Class I devices are evaluated based on Annex IV and V and

are exempted from conformity assessment for CE marking. Some Class I devices with increased risk, and all Class IIa devices may need to undergo conformity assessments. Class IIb and Class III devices are required to have robust technical documentation that proves the conformity with basic safety and performance requirements. They are required to undergo conformity assessments with notified bodies.

All non-invasive devices are Class I unless specific rules apply, which are found in parts 862-892 of the CFR (U.S. Food & Drug Administration, 2020) with each part ending in xxx.9, for example 862.9. Invasive devices can be classified as either Class I I, IIa, or IIb. Invasive devices intended for transient use are Class I I. Invasive devices intended for short-term use are Class I IIa, with some exceptions falling under Class I I, and Class I IIb if they are intended for long-term use, with some exceptions classifying as Class I IIa. All surgical invasive devices intended for transient use or short-term use are classified as Class I IIa, unless they come under the exception categories listed in rule 6 (Section 5.2) and rule 7 (Section 5.3). All implantable devices and long-term surgically invasive devices are Class I IIb, unless they meet the exceptions list under rule 8 (Section 5.4). Active devices are either Class I IIa, IIb or Class I III, decided in rules 9-13 (in Sections 6.1-6.5). Finally, special rules apply to devices not covered by the above rules.

Prior to COVID-19, the FDA published guidance for 3D printing for medical devices in 2017 (FDA, 2017), which included the considerations outlined in Table 12. The guidelines for AM introduced in response to COVID-19 are discussed in more detail in Chapter three. The overall process steps for 3D printing medical devices are described as (1) design, (2) software workflow, (3) material control and build, (4) post processing and (5) final testing considerations. Fulfilment of the quality system requirements by the FDA require consideration of each of the factors included in the design and manufacturing process considerations. This is not an exhaustive list, and medical device manufacturers should always refer to the CRF.

Table 12: The design and manufacturing process and device testing considerations for 3D printed medical devices based on FDA guidance (FDA, 2017)

Design and manufacturing process considerations	Overall device design	▪ Introduction of variability not present when using other manufacturing techniques ▪ Design for AM is a skill, designs should be optimised for the AM process ▪ Feature sizes should be carefully considered to account for the process tolerances ▪ Desired dimensional specifications must be reliably met using the technology ▪ Requirements for surface finishing should be outlined in the product specification.
	Patient-matched device (PMD) design	▪ PMD may be produced within a defined design envelope, which is determined before patient-matching can be initiated ▪ The design envelope describes the minimum and maximum dimensions, mechanical performance limits and other clinically relevant factors ▪ The PMD inputs may be acquired form measurements, clinical assessment, patient imaging or a combination thereof ▪ Alterations to the device may have direct consequences to the patient, therefore clinically relevant design parameters should be clearly identified ▪ Use of imaging techniques (such as laser scanning) ▪ Complex design files ▪ Cybersecurity and the management and care of personally identifiable information
	Software workflow	▪ Consideration of variability or inconsistencies from file format conversions ▪ Digital device design to physical device o Build volume placement

	○ Addition of support material ○ Slicing ○ Build paths ○ Machine parameters and environmental controls ▪ Validating and automating software processes
Material controls	▪ Starting material, the following information is required: ○ The material name (chemical name, common name, trade name, recognised material standard etc. ○ Material supplier ○ Incoming material specifications with material certificates of analysis and the test methods used. Material standards should be referenced ▪ Material reuse
Post-processing	▪ Postprocessing steps of AM could include removing residue, heat treatments to remove residual stresses and final machining processes ▪ All post-processing techniques should be documented and include the effects they have on the final device ▪ Procedures for monitoring and control of process parameters must be established to ensure specified requirements continue to be met.
Process validation and acceptance activities	▪ Validation of the printing process to ensure the quality is the same. Where the results of a process cannot be fully verified by inspection and testing, the process must be validated with a high degree of assurance and approved according to established procedures

	▪ Process validation must be performed to ensure quality is maintained for devices or components produced within a single build cycle, between build cycles and between machines where the results of a process cannot be fully verified by inspection and testing ▪ Revalidation is required where any changes to the device, manufacturing process or process deviations are made, to identify and analyse any risks they could potentially introduce. ▪ Some examples of changes require revalidation include: o Software changes (changes or software updates) o Changes in material (supplier, material specification, new formulation) or handling o Changes in the spacing or orientation of devices or components in the build volume o Physically moving the machine to a new location o Changes to post-processing steps or parameters ▪ Acceptance activities are sometimes required for induvial devices or components to verify the geometry, morphology and some performance characteristics. Some examples are ultrasound, computer tomography (CT) or micro-CT, X-ray and confocal microscopy ▪ Test coupons are representative test samples of the device or component. Coupons can be shapes for destructive mechanical testing or they may contain multiple structural features. Coupons are recommended to be used within the process validation, and to identify the worst-case conditions of the manufacturing process.
Quality data	▪ Analysing sources of quality data is an essential part of any quality system, and can identify existing and potential causes of nonconforming product or other quality problems ▪ It is important to consider whether it is necessary to keep track of the build volume location. This will depend on the information obtained during process validation activities and design specifications

		▪ A high level of specificity is required to identify possible causes of failure when multiple components are made in the same build volume at the same time. Quality data relating to the build volume location should be analysed to enable the proper identification of quality problems and investigation of the cause of nonconformities.
Device testing considerations	Device description	▪ AM facilitates the creation of customised device sizes, specifically PMD. Since these devices may not have discrete sizes, the range of dimensions for the device should be identified. ▪ Design variation should be described, and critical dimensions and features intended to be matched to a patient should be clearly identified. ▪ The AM technology used to build the device should be described due to the different technical considerations of different techniques. ▪ Critical features of the device should be clearly described in the device description and identified in technical drawings. All components manufactured using AM should be identified.
	Mechanical testing	▪ The type of performance testing is generally the same as if the device was manufactured using traditional manufacturing methods ▪ Depending on the device type, performance testing may include material property testing (such as modulus, yield strength, ultimate strength, fatigue or abrasive wear) ▪ Performance testing should be conducted on final devices subjected to all post-processing, cleaning and sterilisation steps ▪ The device orientation and build location should be considered during mechanical testing.

Dimensional measurements	▪ Device dimensions may also be affected by orientation and location within the build chamber. Therefore, the dimensional tolerances should be specified and the dimensional measurements should be performed for the worst case AM devices or components ▪ To demonstrate consistency and reproducibility between build cycles, dimensional measurements should be made on samples from multiple build cycles.
Material characterisation	<u>Chemistry</u> ▪ The final material may be an altered version of the starting material which is altered during the build processes. Therefore, all materials involved in the manufacturing of the device should be identified, including the source and purity of each material used. ▪ Certificates of analysis and material data sheets can facilitate the review of each material. ▪ The material composition of the final finished device should be documented. <u>Material physical properties</u> ▪ Interlayer bonding determines the ultimate structural integrity of the final finished device and therefore material properties known to affect the interlayer bonding should be characterised. ▪ The microstructure of metal or ceramic parts should be characterised. ▪ For polymer AM devices, the consistency of the technology in producing a device or components that meets the specification must be ensured.
Removing manufacturing material residues and sterilisation	▪ Complex geometries are expected to increase the difficulty in removing manufacturing material residues, making them more difficult to clean and sterilise. Therefore, validation of the reduction of the manufacturing material residue should be done to levels that do not adversely affect the quality of the device. The

		sterilisation process validation should account for the complex geometry of the device under worst-case conditions. ▪ Residual materials should be removed, and the process of doing so should be described to ensure the removal of materials is done to a safe level where the safety and effectiveness of the devices is not affected. ▪ Where a manufacturing material could be expected to have an adverse effect on the device quality, the manufacturer must establish and maintain procedures for the use and removal of such material. ▪ An overview or summary of the manufacturing residue removal process information should be included in the premarket submission.
	Biocompatibility	▪ The biocompatibility of the final finished device should be evaluated using ISO 10993.
Labelling	General labelling	▪ Labelling should be developed in accordance with applicable regulations, device specific guidance documents and consensus standards
	Labelling considerations for PMD	▪ PMD should include additional labelling information due to the potential modification of the device by clinical staff or device manufacturers. ▪ Each AM PMD should have healthcare practitioner labelling included in the packaging, including a patient identifier, the intended use of the device and the final design iteration or version used to produce the device ▪ The expiration date may be driven by the patient imagine data rather than the standard methods of determining shelf life.

The additional considerations presented by AM technology can add complexities that are typically not present when using manufacturing techniques. An example of which is the optimisation of a single design parameter is likely to influence another, and therefore critical design parameters must be carefully controlled and validated. This is an example of one of the many trade-offs that musts be considered for AM processes. The design and process parameters may directly affect the function and performance of the printed device or component. Therefore, the type of information necessary for research applications to the HRA, including the details surrounding the manufacturing and performance of parts required investigation.

2.4. Exploration of HRA approval in the UK: "HRA" readiness of FFF devices

One of the preliminary objectives of the PhD was to specifically investigate additively manufactured prosthetics for children. The device under investigation was an upper limb transradial prosthetic device for infants. As one of the original objectives of the PhD, the viability of conducting a device specific study was considered, through the formation of a study protocol intended for HRA ethical approval, which would allow the research and investigation of the medical device. This exercise was intended to highlight the necessary requirements of a HRA research project and allow the identification of underdeveloped project areas or any potential grounds for rejection.

To investigate the HRA approval process for a medical device research project in the UK, two main activities must be completed: a full research protocol must be formed, followed by a clinical investigation application through IRAS, as discussed in Section 2.3.3.2 and detailed in Table 10. Firstly, a study protocol was formed which comprised of the background and rationale, study objectives, information about the study design, research setting, and the eligibility criteria of participants. To clarify, the prosthetic device used to form the HRA research application was not produced as part of this PhD and was used as an example to explore the HRA process, therefore details of the device were not included in this study.

The second part of gaining HRA approval was to complete an IRAS application form. One of the earliest questions in the application was to detail whether the study was

sponsored or funded by a device manufacturer or another commercial company. For this question, the type of study must be specified, with the two most relevant options being '*clinical study of a non-UKCA/CE marked device where commercialisation of the product is intended'* or *'pre-clinical device development or performance testing'.* Although the intention of this research was to identify the steps necessary to create a Class I medical device that would be suitable for UKCA/CE marking to demonstrate that FFF technology can produce safe and effective medical devices, a prior exercise of completing a full research protocol revealed that the device fell into the pre-clinical device development or performance testing, because the performance of the device was unknown.

The application for pre-clinical device development or performance testing differs from the applications for UKCA/CE marked and non-UKCA/CE marked devices. The pre-clinical application consists of the sections listed in Table 13. Part B: Section 2 requests information about the device and the manufacturing arrangements of the investigational device. Details of the quality assurance system should be given, in addition to details of any collaborations with commercial manufacturers or other sub-contractors. The application goes on to ask what safety and performance testing has been undertaken on the investigative device. This should include details of the appropriate tests and the outcomes of each test, with given examples of mechanical, electrical, biological, toxicological and sterilisation testing. The following question asks for the sponsor's plans for further development and use of the device, which should indicate whether the plans include making it available to other legal entities or working with a device manufacturer to commercialise the product. Finally, a declaration must be authorised by the head of clinical engineering or equivalent at the institution developing the device. The declaration declares that the head of clinical engineering takes '[…] full responsibility for ensuring that the device has been manufactured to the standards expected of an equivalent UKCA/CE marked device and that all relevant testing to demonstrate compliance with these standards has been undertaken.'

Table 13: IRAS application sections (version 6.3.3) for pre-clinical device development or performance testing. The application form and required sections were based on the project information given in the initial IRAS project filter section.

Section	Questions	Content
IRAS project filter	1-11	Filter questions used to create the form
PART A – Core study information	1	Administrative details
	2	Overview of the research
	3	Purpose and design of the research
	4	Risks and ethical issues
	5	Scientific and statistical review
	6	Management of the research
Part B: Section 2	1-7	General information
Part B: Section 7 - Children	1-4	Information relating to participants who are children
Part C: Overview of research sites	1	Details of host organisations

For pre-clinical device development or performance testing an extensive range of product development and testing is required. Before any patient-based study could be considered, sufficient evidence must be provided which demonstrates appropriate biological safety and clinical or technical effectiveness of the device. The medical device under investigation must be well-developed to an acceptable stage, which includes having an established device name, model number, description, and established manufacturing procedures. In addition, the requirement of quality assurance systems in the manufacturing process implies that the device has been developed to meet the relevant regulations specified in Section 2.3, which confirms that an extensive amount of additional product development and testing would be required to apply for HRA approval in this case.

The largest knowledge gap identified preventing the HRA application was the lack of bench and pre-clinical testing. The device intended for use in the research project should have undergone bench and pre-clinical testing, however, the expectation of the device was largely unknown, due to the general lack of understanding of the capability

of the technology to produce test specimens. Before bench testing, an acceptance criterion should have been developed, which at this stage was unknown. If the baseline capability of a novel technology was unknown, the expected performance of a device during testing was also unknown.

Further to the technical and process limitations, additional members of the study management team would be required, specifically the appointment of a clinical lead and project statistician. The clinical lead would be necessary to incorporate patient groups and conduct the necessary clinical assessments relating to the trial of a new medical device. A study statistician would be necessary to manage the study size calculations and the planned recruitment rate, in addition to a statistical analysis plan and any other statistical considerations. However, it would be highly impractical to appoint a full research team without the fundamental knowledge identified.

Due to the novelty of the technology for such applications, it was realised that initial research should focus on the capability of the technology whilst identifying factors specific to AM, and the subsequent implications these might have on the manufacture of medical devices. This information is necessary to define the expectations of a part produced with this technology, which in turn would form an appropriate and realistic testing criteria for a specific type of medical device. The findings resulting from the "HRA" readiness of medical devices section highlighted the requirement to perform baseline testing for the technology, which could be used to determine the baseline performance of professional FFF, allowing for the further development and testing of specific devices which could then be developed towards the route for HRA ethical approval.

2.5. Pilot study

Based on the findings from the initial scoping review and other findings relating to the current state of progress in the field, a pilot study was conducted to form a baseline of knowledge around the capability of professional FFF hardware. This work was intended to reveal the typical range of capability for the technology, whilst indicating how much or how little the process and environmental factors identified in literature

affect the FFF process in practice, under typical user conditions. It is known that the FFF process is susceptible to the influence of multiple factors, however, the extent of which is not known. It is also acknowledged that results were found to vary significantly between different types of hardware, use cases, environments and materials, so the variation observed in similar studies may not be representative of the work conducted in this study.

Although the effects of process parameters on performance factors are heavily studied, little research exists mapping the capability of the process to the practical requirements of regulated medical devices. Without realistically considering the requirements of the technology within the context of regulated Class I medical device applications, the suitability of the technology remains unknown. For this reason, the experimental work in this study focusses on the wider context of FFF suitability, based on the factors most likely to be relevant to the key user groups, research, industrial and non-specialist. Much of the regulatory landscape is focussed on quality management and complying to the ISO 13485 quality management system, a significant part of the approval process. At this stage, quality management has been identified as potentially the largest barrier prohibiting the widespread use and adoption of FFF technology for regulated medical devices.

To assess the repeatability of professional FFF technology, an initial testing protocol was formed, which involved the manufacture, analysis and mechanical testing of dog bone samples. The main purpose of this pilot was to learn the expected behaviours of the technology, and to use these findings to build appropriate and realistic methodologies for the remaining experimental work in this thesis. From literature, three initial areas for investigation were determined: the baseline capability of professional FFF hardware, the environmental effects of the build environment and the effects of humidity exposure on the filament, and their subsequent effects on the 3D printed part.

Additional curiosity relating to the batch production of medical devices arose from considering the process validation requirements in the regulatory approval process. In most cases the production cycles present in FFF differ significantly from conventional manufacturing methods, in the sense that multiple parts can be produced in different

ways. For example, multiple parts can be produced within a single build, separate builds and over single or separate builds on different machines. To ensure process validation, any differences in part quality resulting from different production cycles must be identified and accounted for in the process. Therefore, the pilot study was designed to consider three replicates of each part produced in the same build, which could then be compared to parts produced in a different build, and over different print cycles.

To test the influence on these factors, a systematic study was designed to reveal the influence of the discussed parameters on some of the key performance factors identified in literature. These were selected as mechanical properties in the form of tensile strength, dimensional accuracy and surface quality, as each of these performance factors are particularly relevant to the manufacture of Class I medical devices across all three discussed use cases. The scope of the pilot study included preliminary work only, and therefore does not include any detailed statistical analysis of results.

2.5.1. Methodology

2.5.1.1. Sample production

A dog bone sample was produced to the dimensions shown in Figure 18, in line with ISO 3167:2014 (BS EN ISO 3167:2014: Plastics. Multipurpose test specimens, 2014) in Fusion 360 software (®Autodesk, California, US). The digital part file was sliced in CURA slicing software (®Ultimaker, Netherlands) with the process parameters specified in Table 14. Initial literature searches suggested that higher dimensional accuracy could be achieved with lower layer thickness values. However, when considering the wider context of this research, the digital manufacturing process must be as efficient, or more efficient than conventional manufacturing methods. For this reason, a mid-range layer height of 0.15mm was selected, although it is not the lowest and therefore may not yield the most optimal dimensional accuracy, increasing the layer height from 0.06mm to 0.15mm reduced the printing time by more than half (one hour, 43 minutes). Where the effects of certain process parameters were found to be

inconclusive in literature, either the default parameter values were used, or the values were based on successful printing from prior experiences.

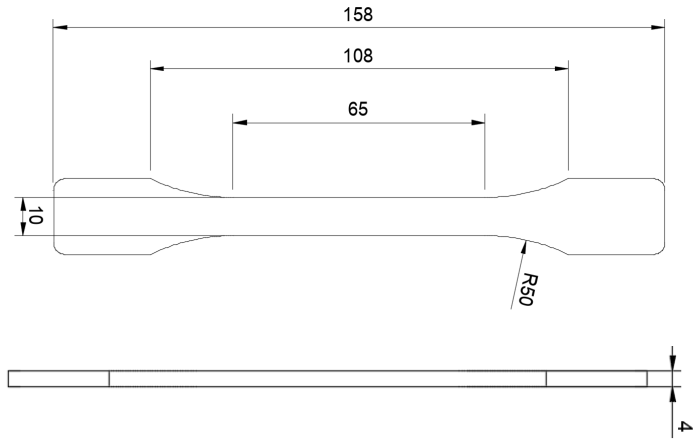


Figure 18: Dog bone sample dimensions (units: mm)

Table 14:Process parameters for pilot study sample production

Parameter	Value
Layer height	1.5mm
Infill pattern	Triangles
Infill density	80%
Wall thickness	1.2mm
Support material	None
Build plate adhesion	None
Raster angle	None
Air gap	Default (0)
Orientation	Flat to bed (short edge parallel with XY)
Nozzle diameter	0.4mm
Printing speed	70mm/s
Printing temperature	200ºC

A total of 48 dog bone samples were produced on an Ultimaker S5 (®Ultimaker, Netherlands) under the conditions specified in Table 15. Each group consisted of four cycles, which represent a “shut down” cycle of the printer, meaning between each

cycle the printer was powered off and restarted. “Build” refers to a production run, in which single or multiple parts could be produced within a single run. Between each build, the glass build platform was cleaned, and a single later of Elmer’s (®Columbus, Ohio) purple glue stick was applied. Two types of print file, known as GCODE, were produced for the two different cycles. Cycles A-C consisted of three samples per build, and three samples were produced in separate builds within cycle D, as illustrated in Figure 21. Upon completion, samples were removed from the build platform using a large scraper in a top-to-bottom motion and stored in an air-tight sample bag until tensile testing.

Table 15: Pilot sample production grid. Material marked with an (*) was stored in humidity-controlled conditions immediately after the manufacturer's seal was broken. Material without an (*) was exposed to ambient conditions

Groups	Printer shut down cycle	Build	Sample #	Material	Material Storage	Air management	Humidity control
Group 1	Cycle A	1	1a	PLA-N	Uncontrolled	None	None
			1b	PLA-N	Uncontrolled	None	None
			1c	PLA-N	Uncontrolled	None	None
	Cycle B	2	2a	PLA-N	Uncontrolled	None	None
			2b	PLA-N	Uncontrolled	None	None
			2c	PLA-N	Uncontrolled	None	None
	Cycle C	3	3a	PLA-N	Uncontrolled	None	None
			3b	PLA-N	Uncontrolled	None	None
			3c	PLA-N	Uncontrolled	None	None
	Cycle D	4	4a	PLA-N	Uncontrolled	None	None
		5	5a	PLA-N	Uncontrolled	None	None
		6	6a	PLA-N	Uncontrolled	None	None
Group 2	Cycle E	7	7a	PLA-N	Uncontrolled	In and out	None
			7b	PLA-N	Uncontrolled	In and out	None
			7c	PLA-N	Uncontrolled	In and out	None
	Cycle F	8	8a	PLA-N	Uncontrolled	In and out	None
			8b	PLA-N	Uncontrolled	In and out	None
			8c	PLA-N	Uncontrolled	In and out	None
	Cycle G	9	9a	PLA-N	Uncontrolled	In and out	None
			9b	PLA-N	Uncontrolled	In and out	None
			9c	PLA-N	Uncontrolled	In and out	None
	Cycle H	10	10a	PLA-N	Uncontrolled	In and out	None
		11	11a	PLA-N	Uncontrolled	In and out	None
		12	12a	PLA-N	Uncontrolled	In and out	None
Group 3	Cycle I	13	13a	PLA-N* New	Sealed <40%	None	<40%
			13b	PLA-N* New	Sealed <40%	None	<40%
			13c	PLA-N* New	Sealed <40%	None	<40%
	Cycle J	14	14a	PLA-N* New	Sealed <40%	None	<40%
			14b	PLA-N* New	Sealed <40%	None	<40%
			14c	PLA-N* New	Sealed <40%	None	<40%
	Cycle K	15	15a	PLA-N* New	Sealed <40%	None	<40%
			15b	PLA-N* New	Sealed <40%	None	<40%
			15c	PLA-N* New	Sealed <40%	None	<40%
	Cycle L	16	16a	PLA-N* New	Sealed <40%	None	<40%
		17	17a	PLA-N* New	Sealed <40%	None	<40%
		18	17b	PLA-N* New	Sealed <40%	None	<40%
Group 4	Cycle M	19	19a	PLA-N* New	Sealed <40%	In and out	<40%
			19b	PLA-N* New	Sealed <40%	In and out	<40%
			19c	PLA-N* New	Sealed <40%	In and out	<40%
	Cycle N	20	20a	PLA-N* New	Sealed <40%	In and out	<40%
			20b	PLA-N* New	Sealed <40%	In and out	<40%
			20c	PLA-N* New	Sealed <40%	In and out	<40%
	Cycle O	21	21a	PLA-N* New	Sealed <40%	In and out	<40%
			21b	PLA-N* New	Sealed <40%	In and out	<40%
			21c	PLA-N* New	Sealed <40%	In and out	<40%
	Cycle P	22	22a	PLA-N* New	Sealed <40%	In and out	<40%
		23	23a	PLA-N* New	Sealed <40%	In and out	<40%
		24	24a	PLA-N* New	Sealed <40%	In and out	<40%

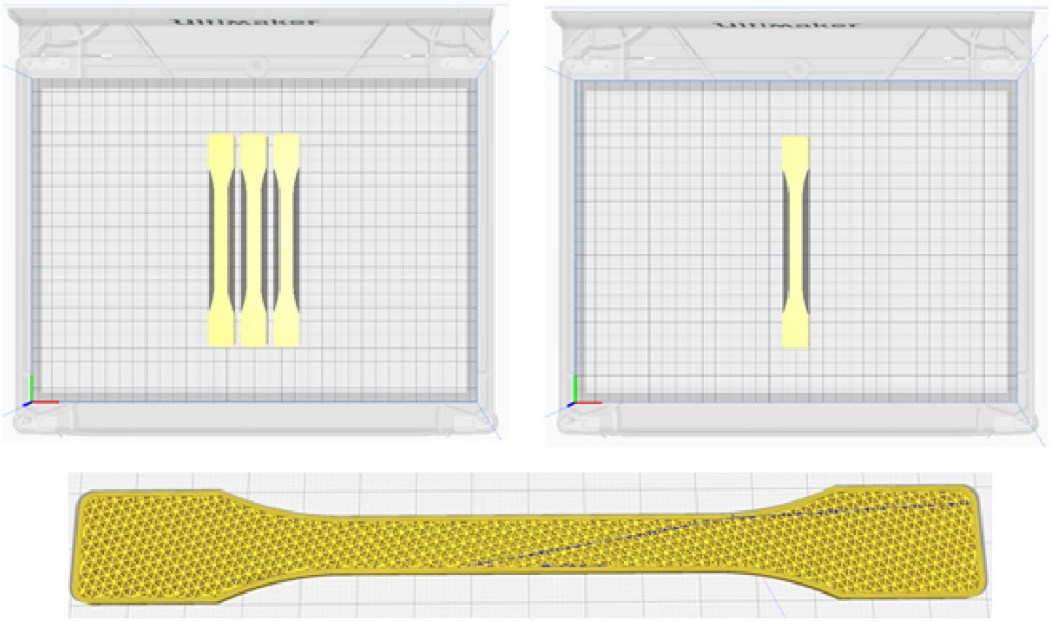


Figure 19: GCODEs for sample production. Three dog bone samples (left), a single dog bone sample (right) and the triangular infill structure present within the samples (bottom)

Sample ‘group 1’ was manufactured with the typical FFF hardware set up, which consisted of an Ultimaker S5 printer with no additional hardware installed. Samples in ‘group 2’ were manufactured with an air management module known as an ‘Air manager’ shown in Figure 20, which controls the airflow within the build chamber. ‘Group 3’ was manufactured with the “material station” shown in Figure 20, which is a humidity-controlled material storage unit that feeds filament directly into the printer. Finally, ‘group 4’ was manufactured with an air manager and material station installed, which together with the printer make up the “Ultimaker S5 Pro Bundle”. The pro bundle is marketed as being suitable for professional FFF and end-use part manufacture.

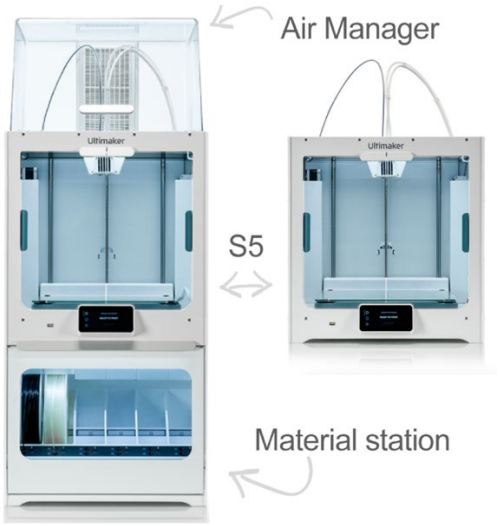


Figure 20: Ultimaker S5 Pro Bundle (left) and Ultimaker S5 (right) (Source:(Ultimaker, 2020))

Other variable factors were present in the study; however, these were not tested systematically. Material condition and colour were additional factors, that have been identified as potentially influential to the FFF process in literature, however, were found to be significantly less researched than the environmental factors identified as systematic variables. Samples were manufactured using PLA-N (®Filkemp, Portugal), a modified PLA engineered to deliver superior mechanical properties comparable with ABS, whilst remaining biodegradable and non-toxic. Two different shades of white filament were used, Sample ‘group 1’ and ‘group 2’ were produced using natural coloured filament, and ‘group 3’ and ‘group 4’ were produced using signal white. The two colours of filament are shown in Figure 21 and were used because of supply chain issues during the COVID-19 pandemic as discussed in the COVID-19 statement (p. xvii).

Figure 21: A visual comparison of the colour difference between PLA-N Signal White (left) and PLA-N Natural (right)

2.5.1.2. Evaluation and testing methods

Each sample was measured using a single set of digital callipers. Three width and three depth measurements were taken at the top, middle and bottom of each sample's gauge length. The dimension of the end width was taken at the top and bottom of each sample, as well as the length dimension at the left and right side. Each sample was weighed using a Sartorius AC210P analytical balance (®Göttingen, Germany). Samples were inspected by eye and any defects, such as discolouration or surface imperfections, were recorded through a written description and standard photography. Samples were inspected before and after tensile testing under a standard optical microscope to identify any changes in surface structure. An image was captured of the surface structure of a sample from each batch. For tensile testing, samples were loaded into a Hounsfield H10KS universal testing machine (®Surrey, UK) fitted with a 10KN loadcell. Tests were carried out at a speed of 50 mm/min using an extensometer shown in Figure 22. The testing speed was deemed appropriate based on the number of samples that required testing.

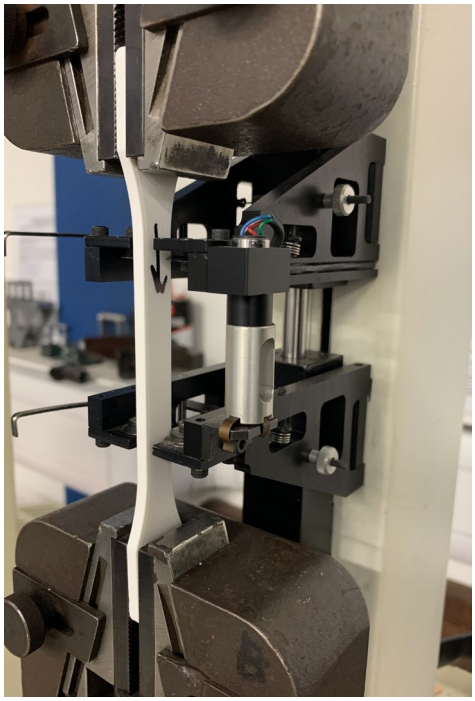


Figure 22: Dog bone sample loaded in a testing machine with extensometer positioned along the sample gauge length

2.5.2. Results and discussion

2.5.2.1. Dimensional evaluation

Due to the additional material variables, colour and exposure to ambient conditions that were not considered systematically, sample groups could not be directly compared due to the presence of multiple variables. To identify any differences between the samples produced with different variable factors, a dimensional and weight evaluation of each sample was conducted.

An initial difference in weight was observed between groups one and two, and groups three and four as illustrated in Figure 23. A larger weight variation was observed between groups three and four, and groups one and two. At this stage, the reason for this weight variation was unidentified, however, these findings revealed that further investigation is required to determine the effects of filament colour and exposure of filament to ambient environmental conditions. Group four showed the best consistency between samples, which was an expected result of the additional control measures used during the manufacturing stage.

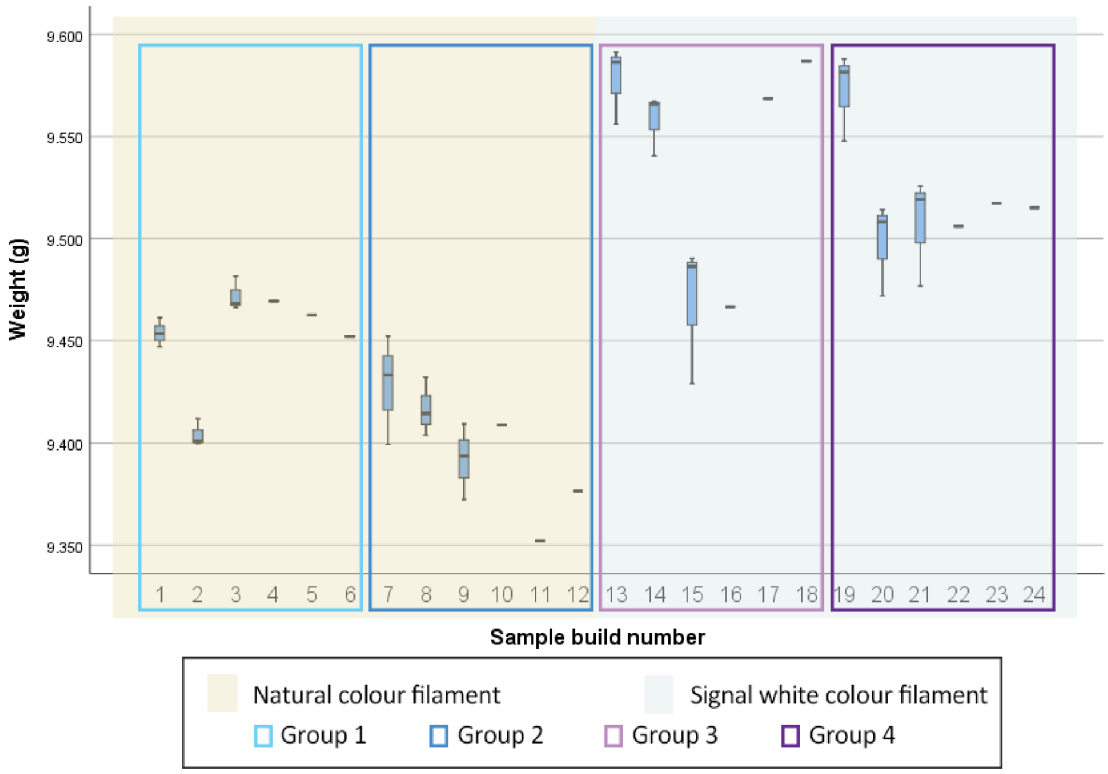


Figure 23: Chart showing the variance in weight between samples (N=48) and groups (Boxes represent interquartile range of 3 samples with marked median, error bars show confidence interval)

The chart in Figure 24 showed that there was variability in the measured depth of the samples within all groups. However, the largest variation in depth was observed in group one for cycles A-C, and the least variation was observed in group one for cycle D for samples 4a-6a, although it must be noted that the variations are relatively small, and the y-axis in Figure 23 covers a small range of 0.25mm. No correlation was observed between the measured depth and the positioning on the build platform, which can be concluded by the measured values not being consistently higher or lower for samples 1-3, 7-9, 13-15 and 19-21. Although this finding may vary when more extreme placement options are considered. No significant correlation between air management and measured depth was observed, which was also shown to be the case for humidity-controlled material, and for air management and humidity control combined.

The measured values for sample width shown in Figure 25 showed that the variability was similar across all sample groups. No significant corelation was observed for any

of the variable factors studied. Width variation was shown to be larger that depth variation across all groups, indicating that dimensional repeatability in the Z direction could be stronger than the XY printing direction. This may be considered in when deciding the orientation and printing direction of a printed part.

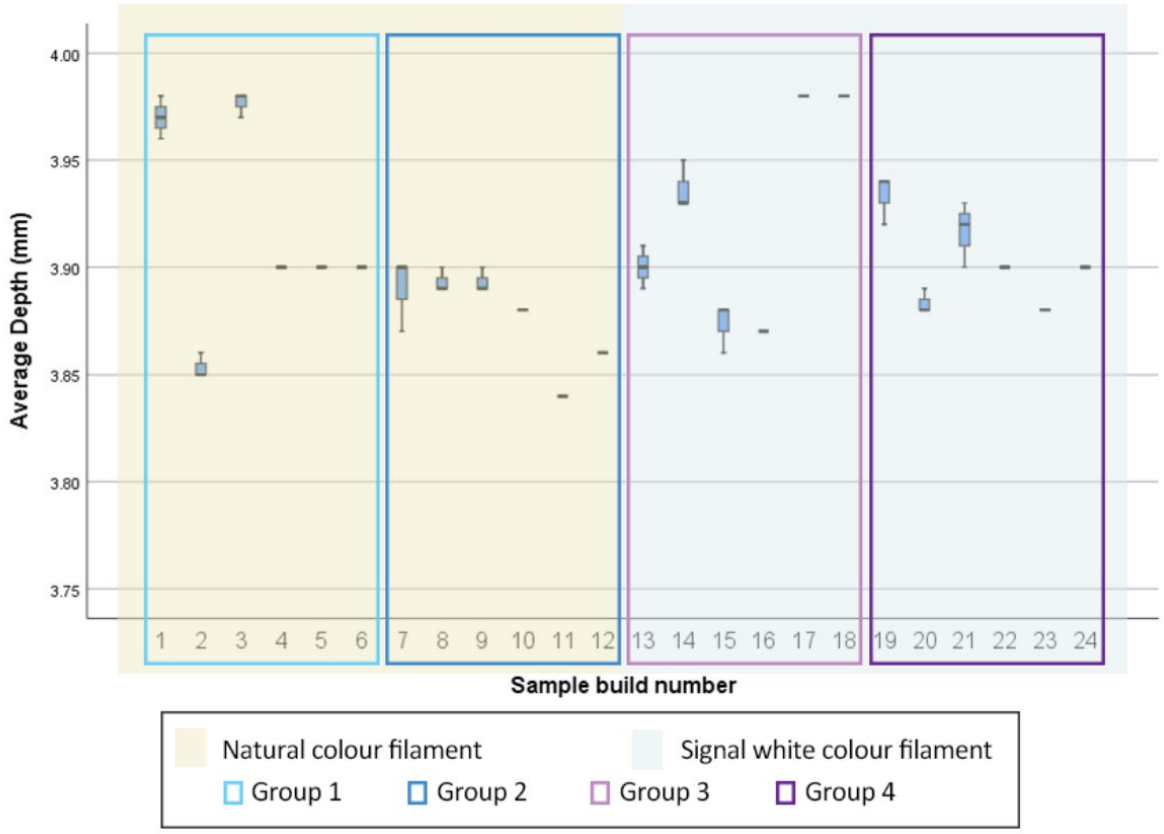


Figure 24: Chart showing the variance in dimensional depth between samples (N=48) and group (Boxes represent interquartile range of 3 samples with marked median, error bars show confidence interval)

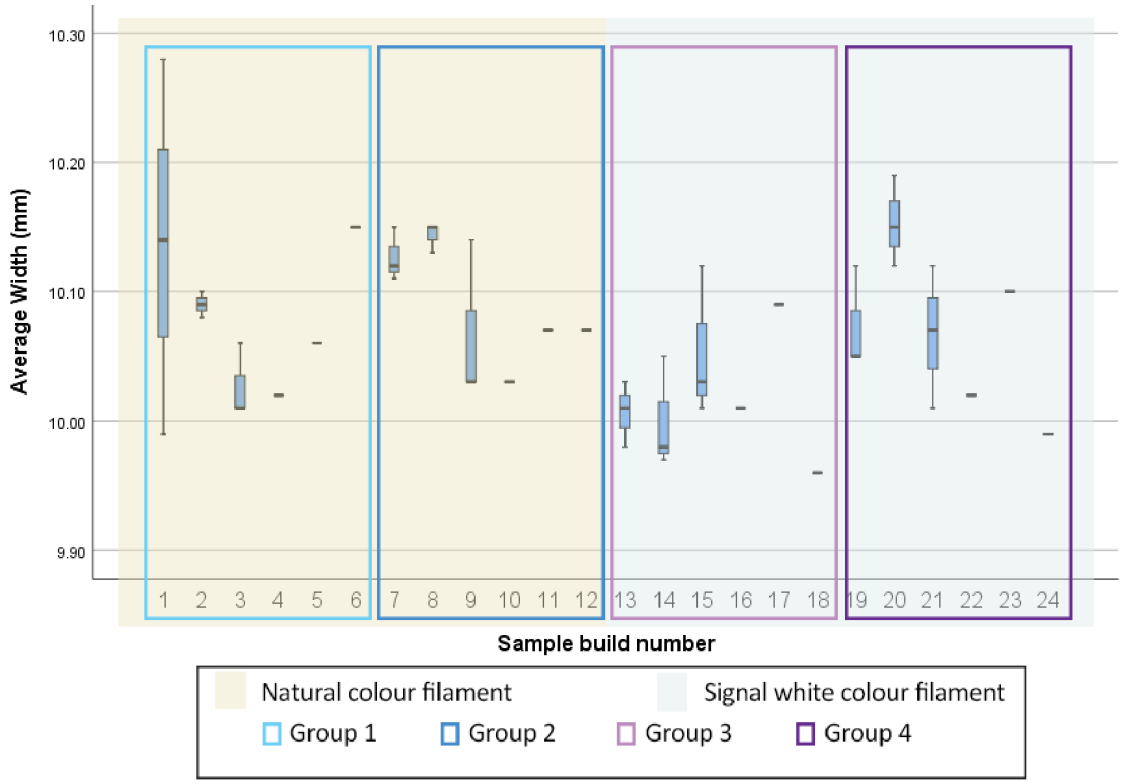


Figure 25: Chart showing the variance in dimensional width between samples (N=48) and groups (Boxes represent interquartile range of 3 samples with marked median, error bars show confidence interval)

To analyse the dimensional deviation between samples, a set of mean standard deviations (SD) and percentage standard deviations (%SD) were calculated using the following process: Three measurements were taken for the width and depth for each sample. The SD and %SD were calculated for each sample, followed by the mean of each group, average SD of each group, and mean %SD of each group. The values of which are shown in Table 16. The highest %SD for both width and depth values were identified within group one. This was an expected finding, due to the absence of all environmental control measures. When considering the overall variance within each group, the smallest width variance was observed in group 3, and the smallest depth variance was observed in group two. This indicates that the dimensional accuracy in the XY direction could be more influenced by humidity-controlled material storage, and accuracy in the Z direction could be more influenced by air management, although due to the relatively small variations observed, the outcome was not deemed significant.

Table 16: Data representing the average group means, mean group standard deviations and mean group percentage deviations based on width and depth dimensional values for each sample

Natural colour filament Signal white colour filament
Group 1 Group 2 Group 3 Group 4

	Width (mm)			Depth (mm)		
Build Number	Average Group Mean	Average Group SD	Average Group %SD	Average Group Mean	Average Group SD	Average Group %SD
1	10.14	0.16	1.58	3.97	0.07	1.66
2	10.09	0.03	0.33	3.86	0.02	0.53
3	10.03	0.02	0.21	3.98	0.03	0.66
4, 5, 6	10.08	0.05	0.53	3.90	0.02	0.61
7	10.13	0.03	0.30	3.89	0.02	0.56
8	10.14	0.04	0.38	3.89	0.01	0.33
9	10.07	0.01	0.14	3.90	0.02	0.60
10, 11, 12	10.07	0.01	0.13	3.86	0.02	0.53
13	10.01	0.01	0.15	3.90	0.02	0.50
14	10.00	0.01	0.11	3.94	0.02	0.42
15	10.05	0.02	0.24	3.87	0.02	0.43
16, 17, 18	10.02	0.04	0.37	3.94	0.02	0.40
19	10.08	0.03	0.29	3.93	0.02	0.50
20	10.15	0.04	0.40	3.88	0.02	0.43
21	10.07	0.07	0.72	3.91	0.02	0.61
22, 23, 24	10.04	0.03	0.26	3.89	0.02	0.57

2.5.2.2. Visual inspection

The most common visual defect was discolouration, which was believed to be caused by excess material burning during the process. This was visible on 20 of the 48 samples produced, with the most severe example being shown in Figure 26. Visual defects could be reduced by cleaning the extruder or reducing the printing temperature. Slight warpage was also observed on the edges of five samples, however none of these defects were severe and all prints were successful with no failed or aborted prints. When observed under an optical microscope, the outer surface of all samples appeared to be similar with clearly distinguishable layer lines. The most significant difference was observed between sample 7A which showed minimal defects, and sample 22A showing the most significant defects, as illustrated in Figure 27.

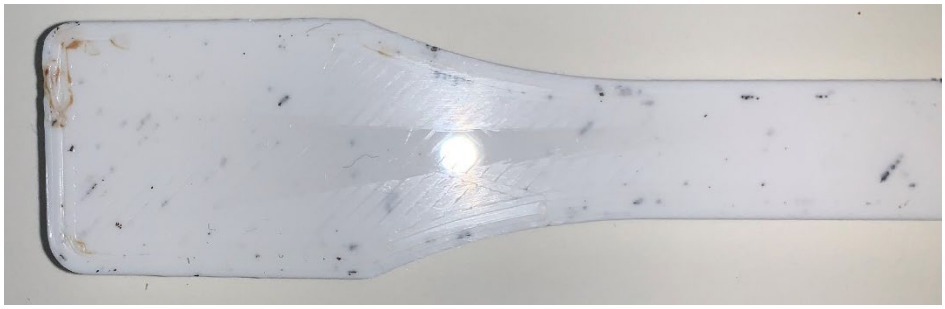


Figure 26: Burning and discolouration of sample 21C which appears to be randomly occurring

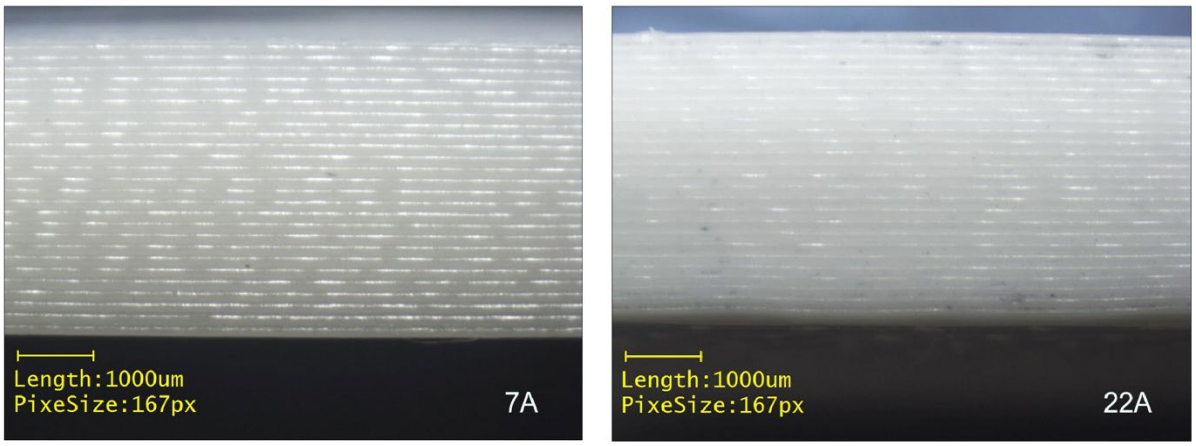


Figure 27: Images of the end of two samples captured from a standard optical microscope. (Left: sample 7A showing minimal defects) (Right: sample 22A showing the most noticable defects)

Sample 22A shows layer lines with varying thickness, most noticeable on the bottom layers. The dark flecks are likely to be burned filament or dust particles and appear to be cosmetic and not cause any severe structural defects in the part. This is supported by no correlation being observed between the tensile strength of parts and the defects observed.

2.5.2.3. Mechanical evaluation

The tensile strength of samples is shown in Figure 28, excluding samples 8B and 10A due to a machine fault during testing. Upon analysis, findings showed a difference in tensile strength between groups one and two, and three and four. Higher tensile strength values were observed for groups three and four, which could be a result of the differences between the two material factors, the filament colour, or the exposure to

different environmental conditions. It could also be a result of the variable factors of air management and humidity-controlled material storage during printing. Less variance was observed within groups three and four compared with groups one and two.

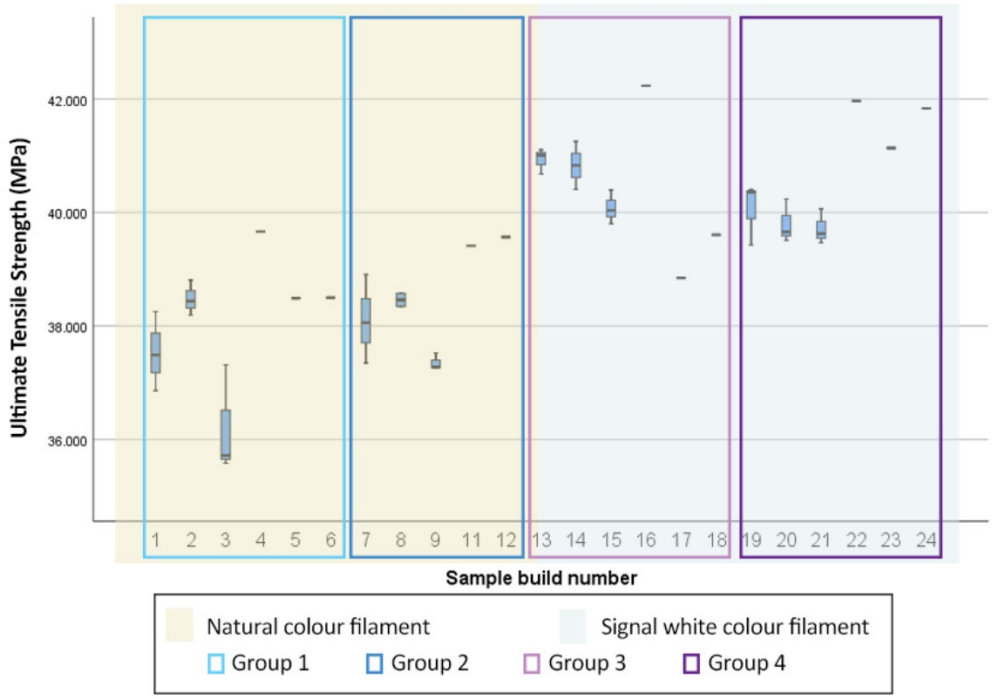


Figure 28: A graph showing samples recorded ultimate tensile strength of 46 samples within 24 builds. (Boxes represent interquartile range of 3 samples with marked median, error bars show confidence interval)

2.5.3. Discussions and lessons learned for future work

The results were not conclusive enough to determine whether the build plate positioning was shown to be an influential factor on the dimensional repeatability of the FFF process. A potential limitation of this pilot study was the placement of the three repeat samples in the same build. The three samples were positioned in close proximity towards the centre of the build platform, and therefore conclusions could not be made about the effects of part placement on the wider build platform. For this reason, build plate positioning should be a factor considered in a dedicated and more detailed repeatability and reproducibility study with locked down variable factors.

This would allow conclusions to be made about the dimensional repeatability across the build plate. Although not conclusive, based on the results shown in this pilot study, the significance of air management and humidity-controlled material storage as variable factors are not expected to be significantly influential for the intended use context of this study. A more influential factor related to the volume production of Class I medical devices using FFF technology would be the method in which production runs are considered, relating to the build cycles and use of multiple 3D printers.

Although not conclusive, the visual defects observed in some samples were not shown to affect the dimensional or mechanical properties of the parts. Defects were more common in groups one and two, which could either indicate that PLA-N in natural colour is more susceptible to burning than PLA-N in signal white, or that the material storage humidity control measures applied in groups three and four helped to mitigate the burning and visual defects observed. The dimensional evaluation revealed repeatability between builds and cycles, however, a more detailed study is necessary to quantify the level of repeatability and reproducibility, which can then be used to establish manufacturing tolerances and be useful to each of the three discussed user groups. Although not conclusive, differences in tensile strength were observed between groups, which showed that the issue of variance connected either to environmental control measures or pigmentation was possible to have an impact upon the produced part, and hence needed wider investigation to determine conclusive answers that are not currently available in literature or known in the wider field.

Monitoring the part-to-part variation of performance factors, such as tensile strength, is essential to determine the repeatability and reproducibility of 3D printed parts. However, when the research focus is on the Class I medical device field holistically, it is unrealistic to specify a range of acceptable variation relating to specific performance characteristics, due to these being highly specific to each type of medical device. Every device should have a product specification, which specifies how the product should be used, and therefore how it should perform under those conditions. Therefore, instead of working to achieve a minimal tensile strength value which would have to be derived from the intended use of the device, the focus of results is on the part-to-part variability between the mechanical properties. Although the acceptable

level of variability is yet to be determined, as it is believed to be a result of multiple factors, such as the part geometry.

Medical devices standards often specify the level of mechanical performance required for a device, and the corresponding testing standards to ensure the device performs to standard. An example of a product testing standard for a Class I medical device is ISO 11334, which details the requirements and test methods for elbow crutches (ISO, 11334-1:2007). It specifies that static loading tests should be conducted, as well as pulling forces which form a separation test to ensure the upper and lower part of the crutch will not come apart. In this case, a pulling force of 500 N should be applied, and maximum force should be held for at least 10 seconds. A loading force of 1000 N should be applied, and maximum force should be held for 10 seconds. These testing forces are for a user mass of 100 kg, which would be detailed in the manufacturer's device specification. Instead of aiming for a specific tensile or impact strength value, the force applied in this test method is based on the mass of a user and is therefore tested to that requirement and inspected for any defects. Whereas in this study, the samples have been tested to find their maximum mechanical properties, and mechanical variability between samples, which would be more useful in future research to understand the mechanical performance and variability of Tough PLA manufactured using FFF. Detailed testing specifications can then be constructed based on a device and its intended use.

Printing in different cycles, i.e., powering off and restarting the printer between different builds, was not shown to influence the process in anyway, and therefore this was not considered as a variable factor in any future work within this thesis. The dimensional repeatability was lightly assessed in this pilot study, however, further work is required to understand the repeatability and reproducibility of the technology in multiple printing directions, as indicated by the differences in variability between the XY (width) and Z (height) printing directions. A full repeatability and reproducibility study was conducted, analysing the repeatability and reproducibility of the process, applicable to each of the three use cases identified in Chapter two, Section 2.2.2. In addition, material storage conditions and colour were identified as potential variable factors. For this reason, a detailed systematic study was conducted for each of those variable factors, with Chapter five focussing on material storage conditions

and the effects of humidity exposure on the printing process, and Chapter six focussing on the effects of pigmentation in filament.

This chapter has indicated that although literature around the optimisation of FFF process parameters is plentiful, the cross over between the complexities of FFF and its application for medical devices is minimal. Discussions around challenges relating to dimensional accuracy and other key performance factors have been found, however, they focus on a specific device or application and neglect the wider suitability of the technology. Moving forwards, it has been recognised that key factors that could influence the FFF process, and therefore affect its suitability for medical device application have been unexplored within the medical and regulatory landscape. To form a baseline for future work in this area, it is necessary to explore the repeatability and reproducibility of the FFF process. The influence of material storage and pigmentation in filament have also been identified as key areas for exploration due to their relevance to each of the three potential cases, non-specialist, research and industrial manufacturing environments.

2.6. Additively manufactured medical equipment in light of COVID-19

COVID-19 presented an opportunity to investigate the use of FFF AM for medical device applications in the context of the COVID-19 pandemic, providing insights into the complexities of using FFF for medical applications across each of the three use contexts presented in chapter two Section 1.2.2.; non-specialist, research and industrial.

The COVID-19 pandemic was a pivotal point for the additively manufactured medical device industry, where unprecedented demand for agile manufacturing techniques pushed the experimental work out of laboratories and into clinical practice, expediating research and development that otherwise could have taken years. Therefore, it provided the perfect landscape to explore the interact between FFF medical devices and the societal acceptance of a relatively novel technique, whilst also prompting urgent changes to advice and guidance's around medical device regulations.

2.6.1. Introduction

In December 2019, severe acute respiratory syndrome coronavirus 2 (COVID-19), a novel coronavirus caused severe global disruption impacting most aspects of everyday life. By January 2020, the virus had quickly spread prompting the declaration of a public health emergency, and by March 2020, was officially declared as a pandemic (WHO, 2020b). The number of infections grew quickly, resulting in a huge spike in hospitalisations and deaths. This resulted in the closure of many facilities, including schools, places of work, factories, and most other non-urgent services. This inevitably placed a huge amount of strain on the demand for essential services and equipment, which rose at an unprecedented rate.

Staff shortages and facility closures left many supply chains unable to operate resulting in extreme shortages of essential tools, equipment, and personal protective equipment (PPE). Conventional linear supply chains are highly reliant on the additional steps or processes in the wider supply chain, therefore when one silo in that chain went down, the whole chain was severely affected, an in many cases left unable to operate. The COVID-19 pandemic was key in exposing the vulnerabilities in the linear supply networks that are relied on daily, and therefore presented a need to build more resilient supply networks and methods of producing essential goods (Kilpatric and Barter, 2020).

Whilst supply chains were failing, demand was still at an unprecedented high, meaning governments and world leaders were desperately looking for alternative methods of meeting demand for essential tools and equipment, which were required to save lives. The world health organisation (WHO) called for a manufacturing increase of 40% (WHO, 2020a), which meant manufacturing facilities had to adapt, and in some cases completely transform their work to manufacture medical devices, medical testing equipment and PPE. An overwhelming number of firms offered their support and began producing in-demand products. A global effort of innovation and collaboration was seen as a response to help gain control of and mitigate the damage of the COVID-19 pandemic.

Some challenges were very specific, for example the shortage of ventilators or medical breathing equipment were desperately needed in UK hospitals. This prompted a movement of openness, support and collaboration, which to many was surprising for such a highly regulated and competitive industry. The UK Medicines and Healthcare products Regulatory agency (MHRA) provided the government with a specification and blueprint for ventilators, for anyone who could get involved (MHRA, 2020a). This allowed a range of companies, such as automotive and fashion companies, to work with the UK government (GOV-UK) to assist with the design and manufacture of essential equipment (Great Britain. Department of Health and Social Care, 2020).

Tools and resources which are usually held behind paywalls, such as standards, were made publicly available by the International Standards Organisation (ISO) to support the design and manufacture of these products. Undoubtably, risks were presented by non-specialist medical device manufacturers adapting their process to manufacture critical equipment and medical devices. Therefore, the release of official standards was necessary to streamline efforts and promote safety (MHRA, 2020c). New guidance was also published, outlining some of the steps taken to speed up the medical devices regulatory process, which is usually an extremely thorough and time extensive process as demonstrated in Chapter two Section 2.3. Guidance was published specifically for new-to-field manufacturers by the notified body in the UK, the British Standards Institution (BSI) (MHRA, 2020c). This was to ensure that where possible, manufacturers obtained the appropriate certification, providing confidence that safety standards were met.

Whilst every intention was made to support and work with large and established manufacturing facilities to promote safe and effective products, another level of contribution was seen from smaller manufacturers, organisations, and individuals where contributors worked independently to meet demand. This introduced a new set of challenges relating to the control and distribution of products which by-passed the official channels of support. This meant that many of the contributors did not have contact with the relevant authorities. AM was a key technology in facilitating the independent production of products and devices, also referred to as the ‘citizen supply chain’. This term was used to describe the collaboration of individuals and smaller

organisations, who mostly consisted of non-specialist users, to independently produce PPE and medical equipment.

Some of the key benefits of AM, including its accessibility and manufacturing flexibility, made it a highly suitable technique to produce parts on demand, and therefore fill gaps left by conventional supply chains. The democratisation of AM has meant there is a large number of 3D printers and 3D printing organisations distributed globally. Distributed manufacturing systems were shown to be highly resilient compared to centralised manufacturing systems, many of which were unable to remain operational. 3D printers were used to produce parts locally, where they were required, eliminating the requirement of transportation links, storage warehouses and other elements typically found in linear supply chains. There were numerous examples of AM parts and products created for the COVID-19 response, some of which include PPE (Dorfman, 2020; Jaguar Land Rover, 2020), rapid testing equipment (Resolution Medical, 2020) and components for respirators (Kleinman, 2020).

Universities, design studios, and makerspaces used their AM capabilities to respond to local demand. This resulted in the formation of direct communication channels between organisations like hospitals and care homes, and people with 3D printers, forming the “citizen supply chain”. At this local scale, one of the most common parts produced was the face shield, a form of PPE designed to protect those working in people-facing contact roles, for example shop assistants and care home staff, to prevent the spread of the virus. Within a short space of time, face shields were 3D printed and handed directly to the people who needed them. In most cases, official channels were bypassed, and there was no way of knowing whether these products conformed to safety standards. This inevitably raised concerns over the safety and efficacy of the products being manufactured and put into use.

As discussed in chapter one, there are numerous AM technologies available, each of which have their own strengths and weaknesses. AM is used as a production method for regulated and medically approved medical devices, as discussed in Chapter two Section 2.2.1. Regulatory approval was obtained through manufacturers demonstrating and documenting the safety and efficacy of the product. However, in most cases in the citizen supply network is made up of non-specialist users, not

medical device experts, meaning they are largely unaware of the detailed processes required for regulatory approval. The benefits of using polymer AM in healthcare are widely discussed in academic literature as discussed in Chapter two, however concerns around safety, performance and standardisation are expressed (Paterson *et al.*, 2015). The huge number of complexities and challenges that polymer AM presents, especially in terms of regulated applications discussed in Chapter two, Section 2.2.1. are often not understood by a typical user (Yeong and Chua, 2013). As well as being an expert of the technology, a user producing critical devices must also be an expert on the requirements of the critical devices, and how they can be achieved specific to that manufacturing process, which is a seemingly unrealistic expectation for non-specialist users.

The exceptional circumstances presented by the COVID-19 pandemic created a grey area for the polymer AM of regulated products, which was not a reflection on standard practice in many ways. Firstly, the movement was a result of an overwhelming response to help, and in many ways desperation. A large quantity of the devices produced in this movement were not sold, they were donated. Technically, regulatory approval clears devices to be *sold* on specific markets. Ultimately, the legal responsibility of medical devices lies with the manufacturer, to ensure the products they are producing are fit for purpose (BSI, 2020). Parallels can be seen between the COVID-19 response and the e-NABLE charity response discussed in Chapter two. Both involve volunteers working to provide people with devices that were otherwise inaccessible or unavailable to them, to help improve their quality of life, or in the case of COVID-19 protect lives. The workflows were also similar, where designs and digital products were created and shared online through open-source platforms.

The urgency of COVID-19 did force AM into the media and raise awareness of the high adoption rates of AM for such applications to authorities, such as notified bodies, standards organisations, and governments. This type of exposure would have been unlikely without such a huge global response, forcing industry leaders to take action and implement steps to try and manage the movement. This movement highlighted the different process steps to consider whilst using AM for medical applications, demonstrating that many factors contribute to a product's success. The design,

material, manufacturing process and product testing are all essential steps that when combined, *could* result in a device being deemed suitable for regulatory approval.

2.6.2. Coordination of the AM response

A guide on manufacturing PPE with no prior experience was released specifically for schools and universities by BSI (BSI, 2020). In a time of crisis, where the combined goal was to help and support in whatever way possible, a popular belief relating to the production of medical equipment and PPE was that "something is better than nothing", meaning that even if the devices were not regulatory approved, they were still better than nothing. The statement released form BSI specifically contradicted that thought process, communicating that they could cause more harm than good, by giving people a false sense of security, meaning less care could be taken resulting in higher risk (BSI, 2020).

The guide outlined streamlined processes for the certification process of PPE, and the technical specification requirements. It covered potential risks like ensuring the parts had no sharp edges or defects, and ensuring the materials used were not known to cause skin irritation. Guidance does, however, have limited reach, and the extent it was followed would vary between organisations and remain largely unknown to officials. For this reason, many regulatory bodies expressed that despite providing guidance and support for the production of PPE for non-specialist users, it should only be used as a last resort when no other options were available (FDA, 2020b).

In an attempt to coordinate the masses of designs produced by the citizen supply chain in the US, a non-profit AM innovation institute called America Makes (®Ohio, US) collaborated with the FDA, Department of Veteran's Affairs (VA) and the National Institutes of Health (NIH). Their process, outlined in Figure 29 shows America Makes as a central hub which acted as a "match maker", identifying the needs of organisations and communicating those with the manufacturing capabilities of the community. They set up a review process, initially starting with the NIH who progressed successful designs to a clinical review stage, which resulted in three possible outcomes: (1) designs were authorised for emergency use by the FDA, (2) designs were optimised

for community use, or (3) returned with a warning of safety implications (America Makes, 2020).

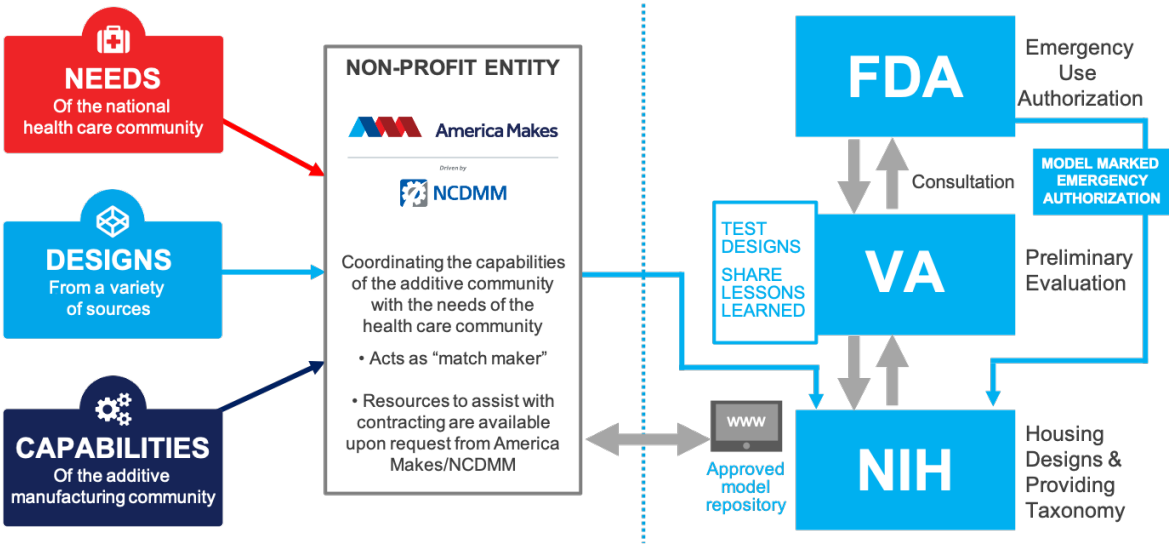


Figure 29: America Makes 3D Printing Response to COVID-19 (Source: (Fighting COVID-19 with 3D Printing: America Makes Responds, 2020))

Similar initiatives were facilitated by smaller organisations in the UK, including the 3D Printing Media Network (3DPMN) (®Surrey, UK) and the Knowledge Transfer Network (KTN) by Innovate UK (®Swindon, UK), which offered the exchange of information, parts, and services in response to COVID-19 shortages. Although, this practice appeared cautious. Many disclaimer statements were published, for example, 3DPMN states that they could not verify or advise on any information posted in their online forum (3D Printing Unite for COVID-19, 2020), and the KTN signposted users to the official guidance released (InnovateUK, 2020).

Of the many examples of 3D printed medical equipment and PPE, some were able to quickly obtain medical certification as a result of their prior familiarisation of the regulatory approval process and requirements, and the systems they already had in place. Examples of regulated devices produced specifically for the COVID-19 response included 3D printed swabs for testing. An example of an AM swab was produced by Resolution Medical (®Minnesota, US) using Carbon™ technology (Resolution Medical, 2020). Another example was a collaboration with Concordance Healthcare Solutions (®Ohio, US) and Formlabs (®Massachusetts, US), which was

produced using the already established Formlabs medical range which uses SLA technology (Worth, 2020). Using a single SLA printer, 650 swabs were produced in 24 hours as shown in Figure 30, demonstrating volume production.

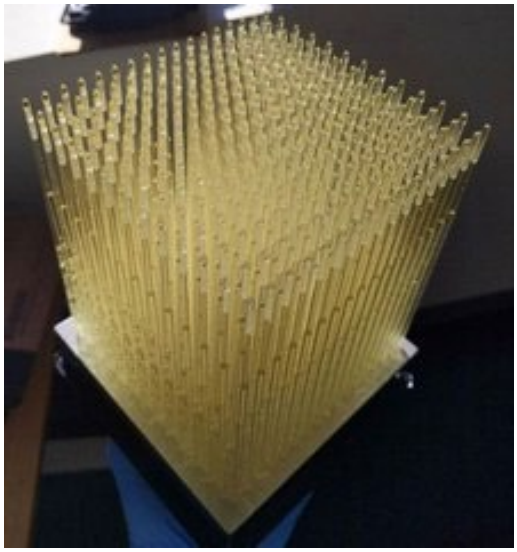


Figure 30: Test swabs manufactured on a Formlabs 3D Printer (Source:(Formlabs, 2020) (permission granted))

Filament and 3D printer manufacturers encouraged their communities to 3D print medical devices and equipment. Prusa (®Prague, Czech Republic) created a face shield design approved by the Czech Ministry of Health, which was downloaded 200,000 times within its first month of publication. The design was modified and adapted for American and European use due to the original design specification referring to materials, components and measurement units meeting different cultural/geographical requirements. This highlighted the importance of understanding the difference between the regulatory requirements in different geographical locations. The participation of large AM organisations and suppliers undoubtedly encouraged participation and provided an element of trust and confidence in the process, perhaps downplaying some of the risks of such activities.

2.6.3. Discussion

Valuable lessons were learned from the COVID-19 AM response. Firstly, it was learnt that the scope of AM is wide-reaching, and the citizen supply chain is a powerful force. A study investigating the impact of social media on the COVID-19 support effort

found that between 1st January 2020 and 14th April 2020, the approximate total reach of 7.2 billion social media responses with more than 18,000 individuals contributing to the AM effort (Vordos *et al.*, 2020). Between 2020 and 2022, the number of AM volunteers in the e-NABLE charity increased by 20,000, and their output of devices is expected to have nearly doubled. One would expect that the extensive media and social media coverage of AM parts and equipment in response to COVID-19 inspired users to volunteer their time and equipment to help people, thus increasing the number of active volunteers for charities like e-NABLE. These statistics indicate the significance of this work, and that there is both a high demand and offering for AM medical devices.

Successfully approved devices demonstrated gaining regulatory approval is possible, and reinforced it is an attainable goal. Although these examples were with technologies already established for medical applications., with further research, other technologies may be able to offer similar levels of confidence, providing further opportunity for timely device development and approval. No examples of approved devices produced using FFF technology were found, however, examples of FFF being used for functional (but unregulated) applications were found, showing there is potential for technology, and further research and investigation is warranted.

Additional concerns relating to the environmental sustainability of the widespread adoption of FFF and other polymer AM techniques were raised. Masses of disposable medical devices, such as swabs and other PPE items were produced using a range of different polymers and composites. The disposal of these parts was identified as an issue due to the insufficient guidance on how to appropriately dispose of such items. However, even with published guidelines on the responsible disposal of AM produced parts, a more significant challenge would be identifying the material used. Labelling and material identification factors have been highlighted as a sustainability concern in AM (Hunt *et al.*, 2015). Low-risk waste that could potentially be re-processed is likely to be missed and disposed of with other generic waste products. Further research is necessary to develop a material and/or product identification system to ensure the sustainable growth of the technology. Additional complexities specific to medical waste include the problems associated with infection control, which makes the implementation of circular economy principles difficult without the added

complexities presented with AM (Kane *et al.*, 2018). Methods of cleaning or sterilising AM waste must be explored, and the implementation of circular economy principles could support the sustainable growth of AM in healthcare.

Intellectual property (IP) has been historically identified as a potential issue with AM (Khoury, 2016). The COVID-19 AM response also highlighted IP as a concern in relation to specific medical equipment and components. The venturi valve design was central to discussions around copyright infringement. However, the unusual circumstances added an element of morality to the debate, as the component was critical for some breathing apparatus which were being used to save lives (Tino *et al.*, 2020). Legal action was unpractical in these particular circumstances, due to the high volume of parts and components being produced, which was amplified by the social media response and extensive number of online repositories for digital part files. IP issues have been highlighted as a potential concern for manufacturers using AM techniques, however, steps may be taken to limit the unauthorised reproduction of parts or products similarly to those used for conventional products. Changes to rules and regulations may be necessary if widespread adoption increases.

2.6.4. Regulatory updates in response to COVID-19

The attention COVID-19 brought to the regulatory landscape prompted further clarity in guidance around medical devices. As discussed in Chapter two Section 2.3.4, the FDA had previously published guidance on the use of AM for medical device applications. The EU guidance specifically published for AM used in the context of COVID-19 stated that 3D printers are 'harmonised products', for which EU product harmonisation legislation is in place, and therefore must comply with the applicable essential health and safety requirements in the Machinery Directive (Council regulation, 2006/42) and be CE-marked before being placed on the EU internal market (European Commission, 2020). The guidance specified that the medical devices manufactured using 3D printers must meet the medical device requirements in EU legislation, as discussed previously in Chapter two Section 2.3. No harmonised standards were specifically applied to AM parts within the medical devices sector; however, the guidance recommends using other safety standards relating to the

manufacture and use of other components or devices, regardless of the manufacturing method used to produce them.

The guidance did however address issues relating to the materials used in AM as discussed, specifying that it is essential that materials used are safe, performant and tested for the intended use of the 3D product for its final use, i.e., mechanical or thermal resistance. In addition, the guidance noted that the qualification of the printing process should be updated to confirm that the correct geometry is achieved, and that process parameters for subsequent mass production of 3D printed parts should be identified and confirmed (European Commission, 2020).

2.6.5. Conclusions

Although steps were taken to clarify the rules, regulations, and safety considerations around the use of AM for medical device applications, a detailed and robust guidance document was not produced for EU and UK markets, unlike the guidance provided by the FDA for the US market. The complexities of the medical device approval process were publicised, and AM users were made more aware of the risks of both manufacturing and using AM medical devices. Clarification on the legal responsibilities of manufacturers were somewhat communicated, however, users were shown to be very much in support of voluntarily manufacturing medical devices for a good cause. The coordination of a central hub appeared to be the most appropriate method for taking steps to ensure that where AM is being used for medical applications, it is done so in the most safe and effective way.

Future work will dictate what research is required for the technical aspects of AM for medical applications. However, from a social perspective, the formation of a central hub with official guidance and approved design files appears to be a sensible approach. Of course, the medical device industry is vast, and making a central hub applicable to all applications would be challenging and perhaps unrealistic. However, for individual organisations working within a specific area, for example the e-NABLE charity for prosthetics, a collated set of guidance, standards, good practices and tips and tricks would be a recommended outcome. Although this would be unlikely to result in the

production of regulatory approved devices, it may help to make people aware of the risks and be aware of steps that can be taken to minimise those risks.

Part one of this thesis has explored the benefits of AM for the production of Class I medical devices, and specifically the potentially large impact FFF could have on society as a result of the increased accessibility to the technology. Chapters one to three have explored the current status of the field, and the use of FFF for medical device applications, in conjunction with a thorough analysis of the medical device rules and regulations in the UK, EU and US markets. Section one has formed a baseline for the current state of the field, which has revealed the significant research gaps limiting further use and more widespread adoption of the technique. Observations of the potential limitations and considerations identified through first-hand research in the pilot study and case studies, combined with concerns raised in literature, have been used to identify the relevant focus of experimental work required, forming the basis of part two of this thesis, which will provide novel contributions to the field, and provide the largest impact to the widest possible range of users.

Chapter 3

3. Case study

3.1. FFF for daily living aids

Multiple examples of FFF for medical device applications were given in chapter two, and the key benefits of using FFF were identified. These include manufacturing freedom, advanced customisation through digital data acquisition techniques, low cost and high accessibility of the technology, and the material freedom available through the opensource nature of the technology. To explore these benefits in more detail, whilst providing the opportunity to identify the process steps, challenges and limitations first-hand, a medical device case study was conducted for a Class I medical device, as classified by MHRA.

The case study is a customised daily living aid, which explores the process from the initial design phase to additive manufacturing a prototype daily living aid. Under the UK MDR (UK MDR, 2002), a crutch grip would be classed as a medical device accessory, where '"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device…' and should therefore be classified in its own right as a medical device. Therefore, this case study was deemed an appropriate example to focus specifically on the experimental nature of the FFF process, along with the potential challenges associated with digital data acquisition, digital file creation and manipulation, and the physical FFF process.

3.2. Additively manufactured daily living aids

3.2.1. Introduction

The potential benefits of using FFF for the manufacture of low-risk Class I medical devices have been discussed in Chapter two. This section aims to walk through the process of using FFF technology to manufacture a customised daily living aid, with

the aim of identifying or reaffirming the necessary process steps to create a digital custom device and fabricate it using FFF technology. Throughout the design and manufacturing process, the digital design and AM workflow remained under scrutiny, to identify any factors or considerations that might be significant in the regulatory approval process. The viability of using a range of digital techniques, including digital data acquisition techniques, digital design and modification tools, and digital manufacturing processes is explored. The type of device studied in this section has been selected to represent the largest impact area of FFF, by catering for an underrepresented user group where current solutions may not meet the user's needs, whether that is in terms of affordability, accessibility, aesthetics, or functionality. This case study was also intended to explore the use of FFF for non-specialist users outside of a clinical context, to reflect the type of hobbyist work that is currently happening within the FFF community.

The demographic shift we are experiencing as an aging population has prompted a desire to create more inclusive design solutions (Clarkson and Coleman, 2010). An outcome of this demographic shift is that many more people are likely to require daily living aids (DLA) as assistive devices to carry out activities in daily life. DLA and assistive products are frequently discussed in literature as having high rejection rates (Mann *et al.*, 2002). Device abandonment can be due to a number of reasons; however, the main reason is believed to be relating to the device not effectively meeting the needs of the user (Verza *et al.*, 2006). A typical issue with standard DLA is that they are designed generically. Although they are intended to be useful for the widest possible user group, needs of individuals are often complex and can vary significantly from person-to-person. In addition to needs varying between people, the needs of a user are often likely to vary over time.

Previously, using traditional manufacturing techniques, customised and bespoke devices were often not efficient to produce or affordable to the user. In many instances, people 'hack' everyday products and devices to improve their functionality or aesthetic appearance, through traditional hand crafting techniques, which has also been applied to medical devices and DLA. More recently, 3D printers have been used for multiple 'quick fix' applications, with users of the technology frequently producing parts to modify everyday objects. These are shared in online part libraries for members

of the AM community to download and manufacture locally. Some examples are shown in Figure 31.

Figure 31: Assistive technologies and non-specialist product improvement solutions produced using FFF technology. (left: a bottle holder by user 'hobb3s', top: bottle opener by user 'makersmakingchange', bottom-middle: a key turner by user 'ivan_gee', and bottom right: bag holder by user 'ivanseidel' (source: (MakerBot Thingiverse, 2022) (images made opensource))

The utilisation of digital technologies could mean fully customised and bespoke devices or modular accessories could become an affordable reality. Many product examples have been given in Chapter two, most of which have been complete devices as opposed to modular components. In addition to a fully customised 3D printed device, combinations of customised components intended to be used with generic products or devices could be a promising solution, leading to better performing products and devices.

3.2.2. Case study rationale

A case study has been selected as an appropriate method of research based on the open nature of the study. At this point in the thesis, some process stages in using FFF for low-risk medical devices remain undefined, and therefore this experimental exercise was necessary to define the process steps users might adopt to achieve the outcome of a 3D printed medical device. A single case study was deemed sufficient in identifying the process steps at this preliminary stage, as this provided an adequate rationale for demonstrating the potential activities of a non-specialist user producing low risk medical devices. Further justification for a single case study was the revelatory nature of this work, where the investigation of low-risk medical devices being produced by non-specialist users has not occurred in academic literature, and has predominantly been reported in grey literature sources which have provided limited information on the process steps and specific considerations for the FFF process. The single case study was constructed with a single unit of enquiry, meaning it took the form of a single holistic case study.

3.2.3. Design problem

A design problem was identified which formed the basis of the case study. Arthritis is a common condition that causes pain and inflammation in the joints. Osteoarthritis (OA) and Rheumatoid Arthritis (RA) are the two most dominant forms of arthritis in the UK. A total of 8.75 million people were requesting treatment for OA (Arthritis Research UK, 2013), and approximately 387,000 adults have RA in the UK (Symmons *et al.*, 2002). The number of people with arthritis is expected to double to 17 million by 2030 (Arthritis Care, 2012), which indicates a significantly growing market, and a growth of 48500 annually (Symmons *et al.*, 2002). There are 12,000 new cases of RA reported every year (Symmons *et al.*, 2002). Hence, a total of approximately 497,00 people are diagnosed with RA or OA annually.

This large number of cases requires effective solutions to improve the day-to-day experience of people suffering with the condition. Numerous ‘off the shelf’ products are available to help people live with arthritis, however few tailored solutions are

available to specifically meet individual people's needs. Crutches or walking sticks are hugely popular assistive aids, however, the highly economical method of manufacture means there have been trade-offs with the design and usability of the devices. Consequently, for people suffering from arthritis, or in many cases crutch users who do not suffer with arthritis, interacting with standard crutches is uncomfortable for a variety of reasons relating to manual dexterity, grip and impact during use (Arthritis Research UK, 2013).

Crutch use differs significantly between users; however, the majority are susceptible to pain and discomfort through the hand for weightbearing crutch use due to a significant proportion of weight being absorbed by the forearm during use (Hügle *et al.*, 2017). Further investigation into axillary crutches suggested that forces of up to 44.4 percent of the entire body weight can be experienced through the palm of the hand during crutch use (Goh *et al.*, 1986). These findings relate to general crutch use, meaning those with more complex needs will likely experienced intensified symptoms. Techniques or 'hacks' to improve the comfort of using crutches are commonly used, which usually includes wrapping and securing foam or soft textiles around the crutch handles.

An analysis of solutions already available on the market in the UK revealed that products specifically made for arthritis sufferers were ergonomically designed substitutes for daily tools and equipment. Product extensions were available; however choice was limited and costly, with basic foam tubing costing £7.78 (Essentialaids.com, 2022). This case study therefore seeks to explore the feasibility of digital design and manufacturing techniques to produce a tangible customised outcome that could potentially better cater to the needs of individuals who use crutches, or more specifically suffer from arthritis in the hand.

Products that require a high degree of flexibility may be easier to facilitate through modular accessories, as opposed to the design and fabrication of multiple different versions of the same device. Pairing custom components with mass produced DLA is thought to potentially reduce costs, meaning accessibility to these devices could be increased. The longevity of DLA and medical devices should also be considered here. User needs are complex and progressive, and over time will place different demands

on DLA. 3D printing is a solution that can be used to iterate quickly in a cost-effective way, combined with rapid digital workflows, this technical solution could consistently adapt to the ever-changing needs of the end user (Bogers *et al.*, 2016).

3.3. Protocol and research question

A case study protocol was defined based on the rationale of exploring the effectiveness of FFF technology for producing a simplistic customised Class I medical device. This was explored through the identification of process steps necessary to design and fabricate the device, which allow for the effectiveness of the process to be evaluated against the product design specification (PDS) included in Appendix 1. The PDS is broken down into four sections: general considerations, the design process, the manufacturing process, and the methods of evaluation for the study.

The overarching research question for this case study was 'Can FFF technology be used to produce a simplistic customised Class I medical device?'. The following sub-questions were defined to answer the overarching question, and to form the baseline of the study protocol.

1. What are the process steps required to fabricate a simplistic customised Class I medical device using FFF technology?
2. How well does the printed part perform against the product design specification in Appendix 1?

To address the questions above, a device was designed, developed, and manufactured based on the user need outlined in the introduction section of this chapter. The device was used as the unit of analysis for this study and evaluated based on the following consideration areas: the surface finish, the physical fit of the device to an elbow crutch, the overall part quality (in terms of deviation from the digital part model), the ease of the manufacturing process and the cost or viability of using FFF in this instance.

For clarification, the focus of this case study was not on the clinical performance of the device to meet the medical needs of a user or a group of users. This was intended

to be a qualitative study (n=1) where the medical functionality of the device was not considered, and the device was used as a mechanism for answering the research questions above. For this to be a realistic and representative case study, the device was designed to meet the user needs outlined, and process steps for collecting and using scan data were intended to be as realistic as possible.

After identifying the design problem and the user group that could potentially benefit from the solution, the case study entered the product design and development phase. This took the form of a typical design and development process for conventional devices. This phase highlighted the benefits and added functionalities AM combined with a digital workflow could offer, relating to design, materials and a combination of design and material optimisation.

3.3.1. Methodology

An overview of the methodology used in this case study is presented in Figure 32, which categorises the workflow into four stages: data collection, digital data acquisition and manipulation, hardware configuration and AM.

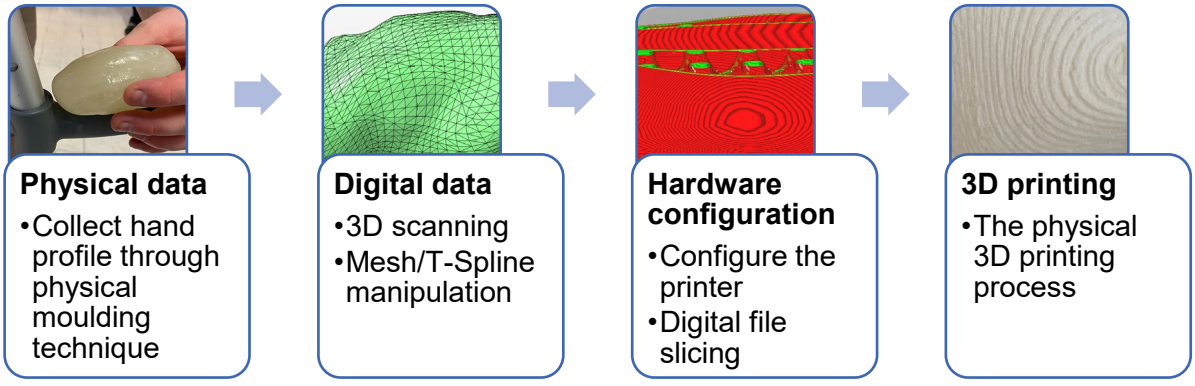


Figure 32: Methodology overview showing step 1: physical data collection, step 2: digital data collection and manipulation, step 3: hardware configuration, and step 4: 3D printing.

3.3.1.1. Physical data collection

Viability assessments of physical data collection methodologies were conducted at an early stage in order to determine an effective and appropriate data collection method

that considers the interaction with an end user. Typically, within a medical context, this would be done by a clinician or professional user for specialist applications. However, as demonstrated previously, the democratisation of digital techniques, in this case 3D scanning or other form of digital data acquisition, is no longer limited to specialist users, and therefore these types of manufacturing activities are being conducted by non-specialist user groups. To fully explore the potential of this new way of manufacturing medical devices, consideration was given to the target user group who were likely to be unfamiliar with the technological advancements surrounding digital data acquisition. This meant the designed methodology was required to maximise accessibility through utilising non-technical and non-invasive methods.

Establishing an effective data collection methodology is complex and requires careful consideration of the route to market for that particular product or device. In specialist use cases, where the intention is to embark on the route to regulatory approval, this step would be required to comply with the rules stated in the relevant regulation. As established previously, this type of device or accessory would likely be classified a Class I device accessory under the UK MDR. The customisation element means that in a clinical context, such device would typically be prescribed with specific characteristics to meet a documented clinical need. In this instance, compliance with the necessary standards such as a quality management system (ISO, 13485:2016) should be demonstrated. However, AM technologies are not widely used in clinical practice for such devices, and therefore currently this work would most likely represent the type of development happening within a non-specialist use context.

To replicate the perspective of a non-specialist AM user, and to demonstrate proof-of-concept, a basic and non-technical method was used for data collection in the form of a "data collection kit" which could be sent to the user for them to provide an impression of their hand grip. In this case, data collection was based on n=1 for proof of concept. This was simulated by the author, who took a hand grip impression using a polycaprolactone thermoplastic called Coolmorph ™ (®Thermoworx, UK), which was selected due to its non-toxicity and safe melting temperature of 42ºC. The material was re-usable, meaning in theory it could provide a circular solution for collecting grip profiles where each sample could be reused and re-formed by different users. The

specific set of instructions detailed below were followed to capture the hand grip. The specific instructions were designed with the intention to capture a hand grip impression that represented a typical 'in use' scenario, as opposed to a passive grip profile that was taken during a non-weight baring activity. To reiterate, this methodology of data collection was not based on clinically approved methodologies and was a simplistic method of capturing a hand grip profile, typical of a non-specialist user.

- *Heat the thermoplastic in warm to hot water (~ 42ºC) until it has turned transparent*
- *Form it to fit this shape (oval drawn out to scale)*
- *Place the thermoplastic atop the handle (closest to the cylindrical shaft)*
- *Sit down in a chair, placing the crutch close to the chair*
- *Use the crutch (with the thermoplastic atop the handle) to move from as seated position to a standing position, and take three steps forwards using the crutch*
- *Allow 10 minutes for the moulded thermoplastic to cool before removing it from the crutch*
- *Package it in the packaging provided and return it to the researcher*

This method of data collection was found to accurately capture a grip profile. It was demonstrative of a non-invasive, minimal contact interaction that could be done at home without any specialist tools or equipment. Thus, similar data collection methodologies could make a technical solution more accessible to the wider market and overcome barriers such as geographical location or physical and/or social barriers.

3.3.1.2. Digital data acquisition

3D scanning is a widely used digital data acquisition technique, commonly in the form of laser or light scanners, which digitally capture shapes and surfaces, often with high precision and speed (Lee *et al.*, 2013). Some current applications of 3D scanning include for quality control purposes, reverse engineering, and assembly applications. The democratisation of such technologies has led to a rise in dental, prosthetic and orthotic industries using 3D scanning in their day-to-day activities (Golovin *et al.*, 2018; Jin *et al.*, 2018). Prosthetists have praised 3D scanning technologies due to them

removing the need for invasive plaster casts which were traditionally required to capture the form of a limb (Volonghi *et al.*, 2018; Haleem and Javaid, 2019). Scanning was found to be preferable to the patient, more environmentally friendly and significantly faster than other techniques (Herbert *et al.*, 2005; Shiyo *et al.*, 2020), due to the ability of high-quality scanners to collect scan data in minutes.

In many cases digital data acquisition techniques are used in the place of physical data collection where a custom fitting device is required. However, in the case of a crutch grip, complexities arose due to the non-static functionality. A static scan of a body part is often sufficient for custom fitting devices, however, placing a patient's hand in the static position of how they would expect to hold a crutch would give an unrepresentative and likely unrealistic scan model, hence the development of a specific physical data collection methodology. However, capturing the shape of a body part, for example a wrist or a residual limb, would be an ideal use case for direct digital data acquisition.

In addition to the many benefits of digital data acquisition techniques, potential challenges and concerns have been identified. The storage and handling of digital data could potentially raise concerns around the security of personal data. Other concerns raised include the quality of scan data and whether it is a true and accurate representation of the patient's anatomy. Errors and inaccuracies could be present from the initial scan data, or they could arise from the data processing or post-processing. The use of multiple software packages, or even multiple versions of the same software, could present problems when used for regulated applications. The digital data acquisition process would be required to be included and validated in the QMS and documentation relating to that device, demonstrating it is a valid and representative technique.

In this case study, the mould representing a user's grip profile was scanned using a ROMER Absolute Arm from Hexagon Manufacturing Intelligence (® Telford, UK), combined with Geomagic Wrap scanning software from Artec (®Senningerberg, Luxembourg). Some simple steps were taken to optimise the scanning process, which included ensuring sufficient lighting, and using a light powder to mattify and remove any shine from the surface of the hand grip impression. A point cloud was captured

using the scanner which the scanning software converted to a mesh model. Mesh models are made from vertices, edges, and faces that are represented either through triangles or polygons (Autodesk, 2015), and is typically more versatile than a point cloud, meaning it can be read and manipulated in a wider range of software packages.

Following physical and digital data collection, the next stage involved post-processing the data, which was done using a set of mesh 'cleaning tools' available in Geomagic Wrap software. It is common for mesh models to have holes and imperfections. Most meshes formed from scan data require some level of post-processing to repair and tweak the mesh. Again, this could raise some concerns around the software operator changing or modifying a patient's anatomical data, thus affecting the fit or functionality of the device. In a specialist use context, to limit the possibility of over-manipulation, tolerances of the scanner and software should be investigated prior to the data processing stages, and clear guidelines around acceptable levels of modification should be clinically judged. In a non-specialist context, any inconsistencies or over manipulation would be more likely to be spotted during use of the final physical device, and an iterative method of modification and printing would be more likely to be adopted.

Basic mesh modifications involved softening any sharp or well-defined lines that may cause discomfort to the user. This process was done by eye, and therefore the extent the geometry was relaxed was unquantifiable, which would likely be unacceptable within a clinical context. For this particular application, it was thought that the relaxation of geometry may improve the suitability of the crutch grip allowing a wider range of movement for the hand whilst still providing support in the critical areas. For many applications, this may need to be done in a more precise manner. In critical applications, insufficient mapping of the geometry to the patient's anatomy could reduce the functionality of a device, or in a worst-case scenario cause discomfort or harm to the user.

The mesh model was exported as a standard tessellation language (STL) format file, which is a widely used file type in AM. The STL file was imported into Fusion 360 CAD software by Autodesk (®California, US) which was used to optimise the model for 3D printing. Steps were taken to unify, reduce and close the mesh which resulted

in a smoother and more organic form. It was realised that the digital data processing stage is open ended. It could be done quickly in a few steps, or it could be done extensively using a wide range of software and tools. The extent of digital data processing is likely to depend on the functionality and specific requirements of individual devices and the skill of the software user.

Due to the way the data was collected, the digital grip form did not resemble an accessory or device per-se. It required some additional modification to make the form more appealing, making it look like a crutch handle support, but also to modify it to fit on a crutch handle and work with the device. To tweak the aesthetics a freeform surface modelling tool called “sculpt” was used in Fusion 360 software which can be used to mould and manipulate a digital mesh. However, to use this tool, the mesh model needed to be converted into a geometry type known as a “quad mesh”, which is a conversion required for freeform surface modelling. The “sculpt” command uses T-splines, a type of geometry used for free-from modelling, which could only be based of the “quad mesh” model type. Netfabb, an additional software package by Autodesk, was used to convert the standard mesh into a quad mesh, this process is shown in Figure 33. The sculpt space shown in Figure 34 allowed the manipulation of the model using arrows and handles, which simulated the physical activity of moulding clay.

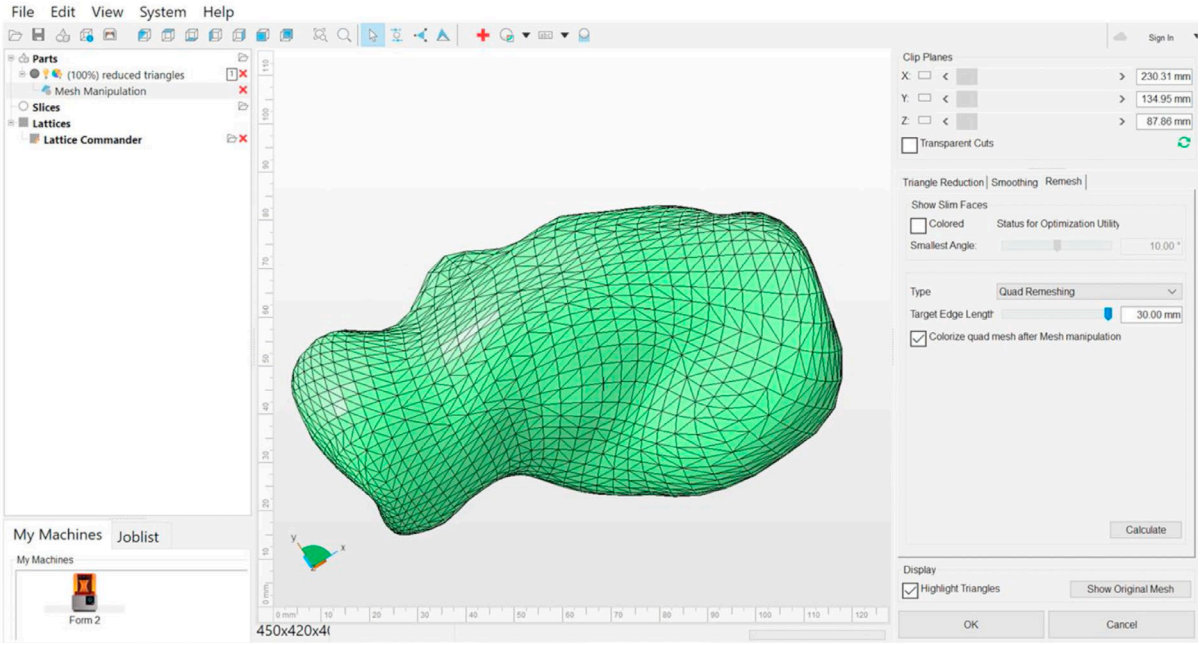


Figure 33: Quad remeshing workflow actioned in Autodesk Netfabb

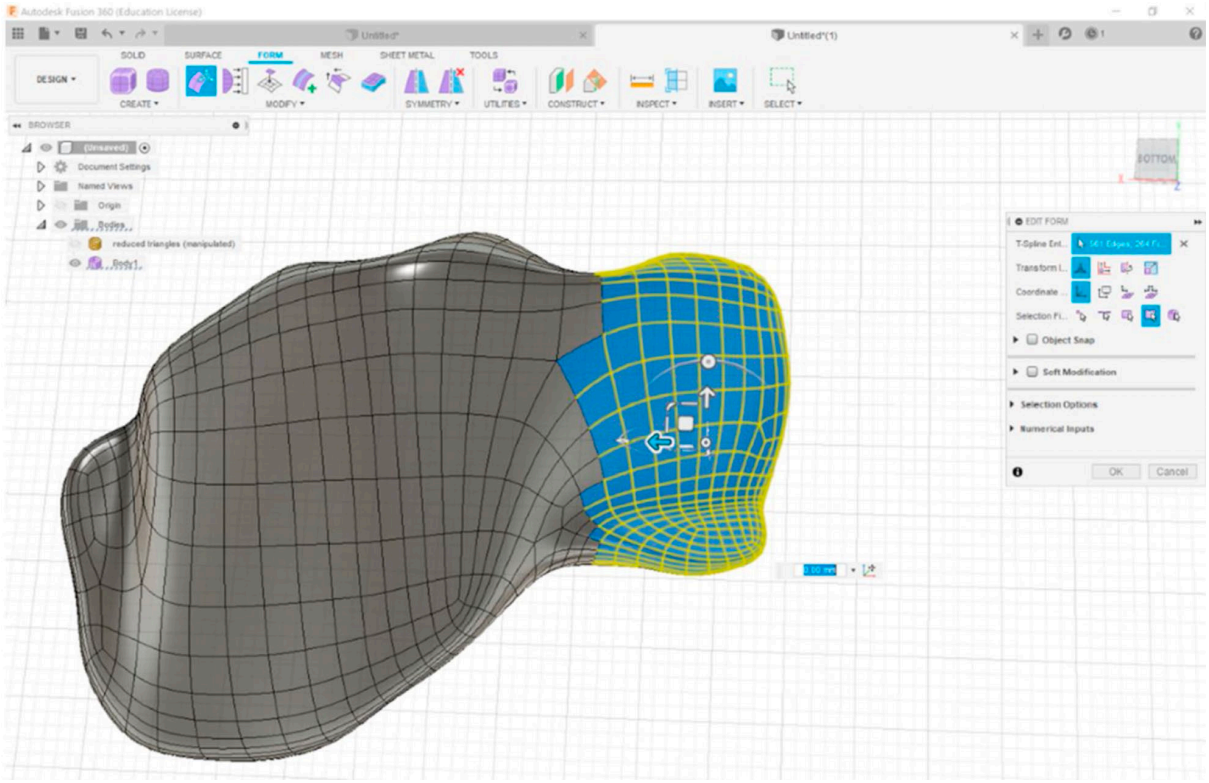


Figure 34: T-spline manipulation in the sculpt space of Autodesk Fusion 360

This step may not have been necessary but felt beneficial in terms of the aesthetic appearance of the part. An alternative method may be preferable to a different CAD technician, as this stage represents the typical 'crafting' element present in conventional moulding techniques. The amount of manipulation required for this part meant the two conversion steps were necessary. Without them, the modification of the mesh was limited. T-spline manipulation allows the CAD user a larger amount of control over the aesthetics, which is seen as important attribute of the part to encourage use and minimise rejection rates.

Next, the digital part was converted into a boundary representation (BRep) of a form, which represents a solid body, thus facilitating the conventional parametric modelling techniques used in typical CAD work. A subtractive Boolean operation was performed using a digital model of the crutch handle which was reverse engineered. This operation, shown in Figure 35, theoretically created a perfectly fitting intersection between the two parts as shown in the sectional view. A digital visualisation of the fully customised crutch grip can be seen in Figure 36.

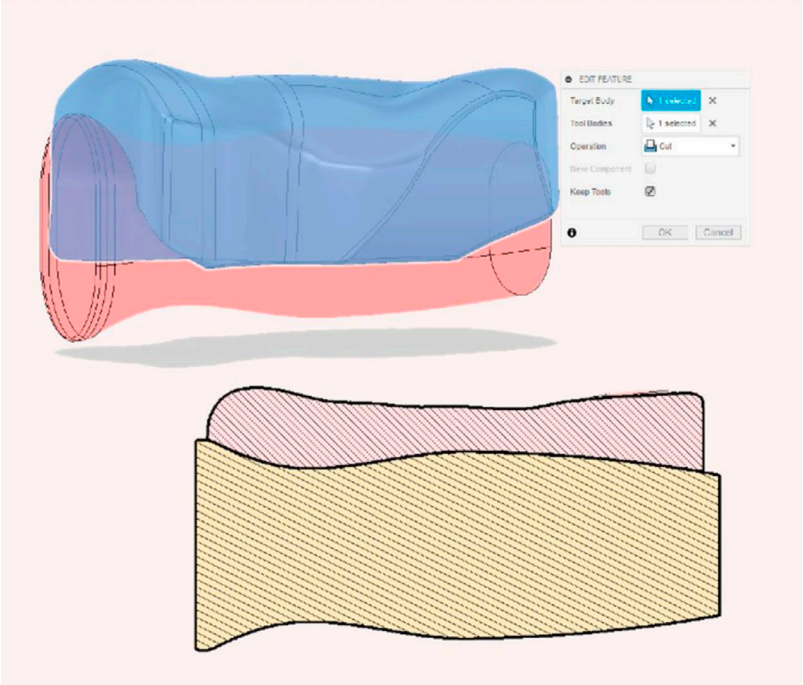


Figure 35: Subtractive Boolean extraction to remove geometry with a cross-sectional analysis view of the feature in Autodesk Fusion 360.

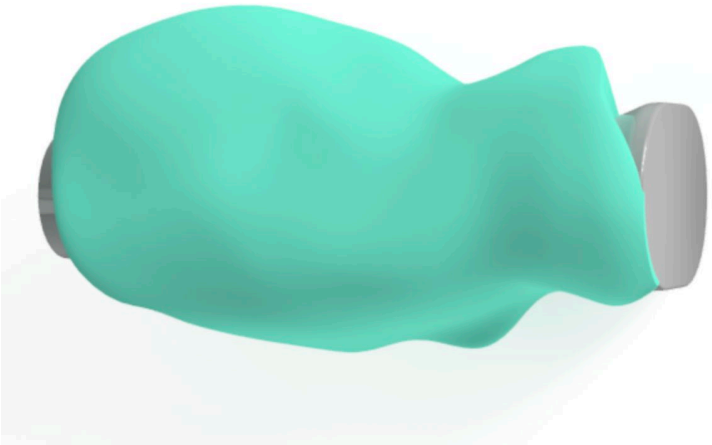


Figure 36: Digital visualisation of a customised crutch grip (top view)

3.3.1.3. Hardware configuration and 3D printing

Preparation for 3D printing, in the form of slicing and hardware configuration, were the next steps necessary to determine which set of print configurations yielded the optimum outcome. The material selected for this component was Varioshore, a thermoplastic Polyurethane (TPU) by ColorFabb due to its innovative properties and the opportunities it provides for advanced customisation, as detailed in Chapter two,

section 2.2.1.2. The chosen 3D printer was an Ultimaker S5, aligning with the objectives set out for the wider thesis. The selection of printing parameters required an experimental approach, especially due to the experimental nature of Varioshore filament.

Several iterations were required to fine-tune the printing process. During this stage factors attributed to a successful print were identified. In the interest of demonstrating that a custom component could be delivered quickly, printing time was considered a factor when determining the process parameters. Printing time can be influenced by multiple factors, including the orientation of the part, or extrusion parameters such as the nozzle width, extrusion speed and movement speed of the print head. A nozzle diameter with an extrusion width of 0.8mm was selected, as opposed to the more commonly used 0.4mm nozzle that comes as standard with the machine, which reduced the printing time by one hour and 46 minutes to nine hours and 23 minutes, whilst providing minimal difference to the surface quality.

The placement of support material was also deemed as an important factor, as support placement is known to influence the surface quality of the part. As the part is intended for direct contact with the hand, the surface must be smooth and comfortable. The compatibility of Varishore material with other support materials was problematic. The removal of support material caused tears to the Varioshore material on many occasions. Decisions around support placement combined were made whilst considering the surface finish, which was the most challenging part of the hardware configuration. A decision matrix was formed to evaluate the success criteria, including the printability, comfort of the DLA, configurability and the surface quality, as shown in Figure 37. This criteria was used to create multiple printing strategies with varied printing temperatures, flow rates and support structure generation.

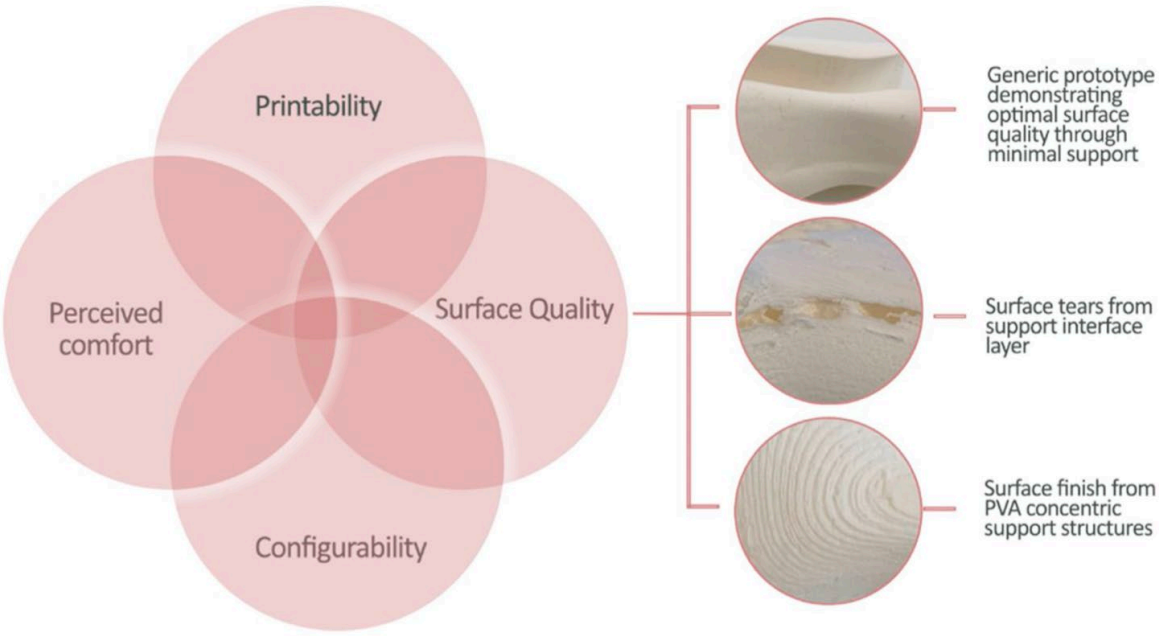
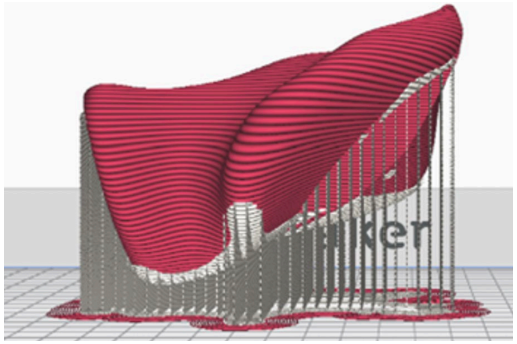
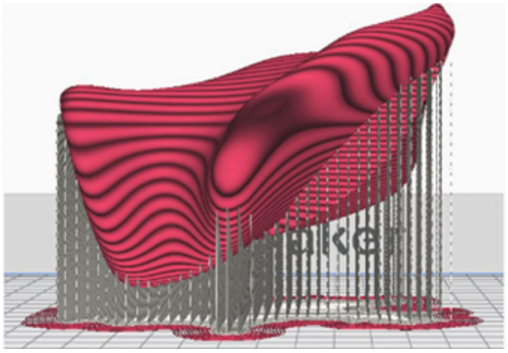
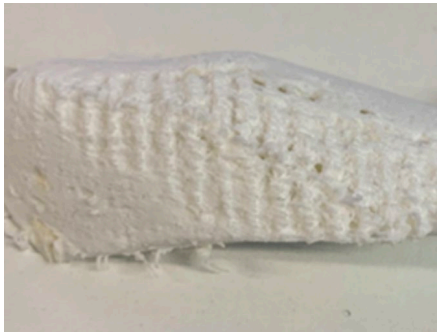


Figure 37: Success criteria decision matrix

Table 17 shows the effects of three tested support structures. The surface finish was found to be inadequate on most occasions due to the requirement of support structures to build an organic and non-self-supporting form. Sacrificial support material was necessary to enable the part to print using FFF technology, which is a widely discussed consideration and sometimes limitation. The issue regarding support material was largely a result of the foaming properties of the Varioshore, which may not have been as problematic with other materials. However, the properties of Varioshore TPU were well-suited for this application, meaning a trade-off was necessary.

The careful removal of support material was both time consuming and labour intensive, which were direct contradictions to the key benefits of using the FFF technique initially. A generic prototype demonstrated an excellent surface finish through minimising support material. The desired surface quality was achievable with overhanging geometry that did not exceed 60 degrees on the outer surface. 60 degrees is the maximum critical support angle, meaning the software will only generate support structures that are absolutely required for the part to print. This factor may limit the suitability of FFF for fully customised devices, and as a proposed solution it should perform effectively with many geometrical variations.

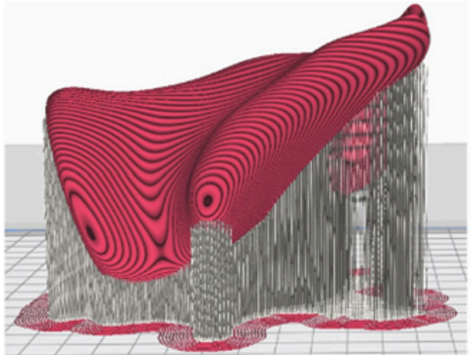
Table 17: Tested support structures with a visual represnetnaion of support placement and an image of the resulting surface finish, with additional coments and observations for each method of support used

Type of support structure	Visual representation of support placement	Surface finish	Comments
Support interface layer A dense interface between the model and support material. • Support roof thickness from 1mm to 0.5mm • Support roof density from 100% to 25%			Breakaway support material has bonded to the Varioshore TPU, making it difficult to remove The Varioshore part has breakaway support fused into the outer surface which could potentially cause injury or discomfort to the user
Support pattern variation Line distance from 3.5mm to 3mm • Support interface layer features to reduce the chances of both materials fusing • Line infill pattern was selected because generally it is easier to remove than a grid pattern			The distance between each support structure is too large The foaming properties of Varioshore mean the material is expanding between support struts leaving an uneven surface finish with defined ridges

Support pattern variation

Support line distance from 3mm to 1mm

- As a response to the 3mm distance above being too wide, the distance has been reduced to 1mm
- Reducing the distance between supports could remove the need for an interface layer



Surface finish remains uneven with Varioshore still expanding between support structures

As well as an uneven surface finish, the amount of support material required an increased amount of material from the previous by 69g

Other materials were trialled as support materials including PLA, recommended by the manufacturer, which showed similar characteristics to the breakaway support. Water soluble polyvinyl acetate (PVA) was trialled based upon the author's experience. Initially it was found to produce parts of a worse quality than PLA and breakaway support material. However, after repeating the experimental approach with PVA, the benefits and limitations of using the material were discovered. Initially, PVA demonstrated poor results, with sharp points and an uneven and unpredictable surface finish. Using the same techniques outlined previously, specifically the support interface layer, provided an efficient way to guarantee a smooth surface area, however, the difficulty experienced previously was the removal of the support material. Utilising the soluble properties of PVA it was dissolved in water which was found to be the best method of removing the support structures with minimal labour.

The PVA support material printed in a concentric pattern was found to produce a satisfactory surface finish, which could likely be improved with further testing and experimentation. The final prototype, illustrated in Figure 38, showed a smooth surface finish. Table 18 shows a detailed breakdown of each process step, and the skill level, time and cost required for each stage. Excluding the automated manufacturing process which could be left to run autonomously, the time taken to create a digital file of a customised crutch grip could be as little as 20 minutes. The data collection, required to be completed by the user, was estimated to be 30 minutes which is comparable of many other fitting procedures.

Figure 38: Additively manufactured customised crutch grip installed on a crutch

Table 18: A labour, time and cost breakdown for each process step in the proposed digital workflow

	Data collection	3D scanning	Mesh/T-spline manipulation	3D printing
Labour intensity	Low, minimal skill level	Low, semi-automated data collection, minimal skill level	Medium to advanced skill level, semi-automated data processing depending on the device requirements	Low skill level, automated production, some manual post processing
Approximate time to complete	30 minutes	10 minutes	From 10 minutes up to hours**	10 hours 5 minutes
Materials cost*	£2.50	N/A	N/A	£4.92

* This assumes hardware is readily available. Prices obtained January 2020. Note that there is no comparative workflow for ergonomic grips currently available.

** Timescales depend on skill level of the user, level of manipulation required and the requirement to work to specific protocols or meet specific requirements

3.3.2. Discussion

This case study was effective in demonstrating that FFF technology can be used to fabricate a customised Class I medical device through the physical outcome of the case study being a fabricated customised Class I medical device. This study qualitatively demonstrated a workflow including digital data acquisition, CAD and AM, and was extremely effective in highlighting problematic aspects of the workflow which would need to be considered for use of the technology in a regulated medical device context, for example ensuring the scan data was maintained enough to accurately represent the patient, and not overly distorted through mesh manipulation tools. By working through the process methodically and evaluating the success of each stage of the process, the case study was able to reveal the limitations of the manufacturing technique, such as the requirement of support structures and the material factors surrounding the use of a support material.

The wide range of material choices is a positive of FFF printing, however it has been shown to cause some disjoin and compromise in performance between manufacturers. The best preforming support material was found to be Breakaway support by Ultimaker, which was not intentionally designed to be compatible with Varioshore materials, hence the problems experienced.

In addition to highlighting limitations, the study was also effective in highlighting further opportunities for innovation through the unique material qualities available through using FFF technology. The variable density and shore hardness of Varioshore were both properties key to this application. A more established material such as PLA may have been a more user-friendly alternative, due to its compatibility with breakaway support material being validated by the manufacturer, however, the rigidity of PLA would have made the device uncomfortable to use and inadequate. Other variations of flexible materials were trialled, which were thought to be too firm and unlikely to provide comfort to the user. Potential has been demonstrated for increased technical customisation. The generation of variable lattice structures, which is highly achievable using current software packages, when combined with varying material density offers huge potential for advanced customisation if it was to be taken further. This could be hugely innovative for a range of medical device applications, as well as customised safety or sporting equipment designed to work with the body.

A limitation of this study was n=1, meaning the study cannot be used to make general conclusions around the suitability of FFF to produce multiple customised medical devices varying between intended functionality and intended users. Additionally, the manufacturing skill level of the author may not be representative of the general non-specialist FFF user group. External validity assessment of this study was challenging due to the revelatory nature of the case study. Although devices have been produced and discussed publicly, the methodologies and process steps have not been reported on in any similar academic studies. The unit of analysis, the fabricated crutch grip, may be compared to existing device solutions to provide insight on the potential cost and user benefit of using FFF for low-risk Class I medical devices.

To assist in discussions around the success of the proposed workflow, a minimal viable product was defined, intended to act as a comparative tool when discussing results. Based on the solutions available on the market, a cost of £30 or less would be considered a cost-effective solution to DLA, without the added element of customisation. The total manufacturing time was 10 hours and five minutes, with a baseline consumable cost of £4.92. When considering overheads and machine depreciation, excluding labour, an expected cost per part would be approximately £9.50, which was quoted by a competitive 3D printing bureau, Additive-X (®Ripon, UK). There is not currently a definitive service which provides users with customed accessories for DLA. Customised crutch grips specifically are known to have been hand-crafted by individuals who recognised the need for such solutions, due to their own needs not being met by products available on the market. A solution crafted by an individual involved stitching leather around an internal structure, however this is not a widely adopted technique and was identified as a singular case.

Online craft shops were identified as the most comparable service available to provide this type of daily living aid. They offer customised products; however, the customisation element is based around aesthetic appearance only, and the functionality of the product is similar to generic foam tubes. Users could select different fabric colours or patterns for handle covers. This may be important in increasing the desirability and social acceptance of DLA for some users; however, the functionality remains limited.

The repeatability of this case study is expected to be low due to the subjective nature of this type of work, especially within non-specialist communities. In professional or industrial use

cases, a standard operating procedure would be used for each of the stages identified in the methodology: physical data collection, digital data handling and manipulation, hardware configuration and the 3D printing process. The process is highly subjective, and is likely to differ between people, further highlighting the potential for inconsistency and quality discrepancies in designs and printed part outcomes. Sources of error could occur in the data collection phase around the working temperature of the modulable polymer, variations in technique and the pressure and position of the hand. Similarly, digital data work can be highly subjective, with individuals adopting different workflows for modelling and mesh manipulation. The design of the device would be likely to differ between users who will have a different preference of aesthetic form, but also subjective bias of the optimal device shape to support the user. As discussed, the FFF process has an extensive number of variables, which again, is likely to create variation between users. Further, the process stages are interdependent, meaning the optimal manufacturing considerations should be based on the design and material considerations. Therefore, the reliability of this case study in terms of repeatability is low, however with respect to the method, the conclusions are representative of the type of use case constructed.

3.3.3. Conclusions

This proof of concept has shown FFF technology is capable of producing low-cost customised DLA. The collection of an individual's anatomical data was found to be a straight-forward process step. However, it is acknowledged that this may only be the case where n=1 and may not be the case for a larger participant group who have wider and more complex needs. A wider range of more complex grip profiles could introduce further challenges related to the orientation of the grip and other patient specific considerations. Complexities arose during the digital data manipulation stage for the single participant (n=1) observed in this study. The additional complexities expected from a wider participant group could translate into further complexities in the digital data manipulation stage, which could be seen as significant challenge to widespread adoption for both non-specialist and clinical specialist use contexts.

To manipulate digital models, a strong understanding of the different types of digital data was required, which included being able to understand and differentiate between the terminology used. This process step appeared to be particularly complex when considered in relation to the regulatory landscape. The documentation of the multiple intangible process steps involved with

mesh manipulation could be problematic. Measures such as setting quantifiable limits to the extent a mesh could be manipulated may be necessary to maintain process control in this area. However, to enforce this, a highly skilled operator would be required. The file exportation and importation process must also be reviewed, ensuring that no significant changes to the file go undetected during this stage of the process. Additional measures to manage the storage and usage of personal data would also be necessary.

Additional challenges were experienced during the 3D printing preparation stages, relating to the hardware characterisation and selection of process parameters. Optimising the printing process to accommodate the geometry and material choices was time consuming and labour intensive. A significant amount of investment of both time and resource was required to achieve an acceptable outcome. Issues relating to the requirement of sacrificial support material and the resulting implications to the surface finish were amplified by the use of an experimental material, where few examples of good practice have been determined. The repeatability of the technique was also found to be problematic, on multiple occasions the print failed. To overcome these issues further research would be required to develop and optimise a manufacturing protocol for a particular type of geometry, material, support type and set of process parameters.

The justification, testing and validation of each of the discussed process decisions would be necessary for regulated use cases, indicating a large amount of future work would be required. Clinical studies would also be recommended to test the use of such products, where the clinical safety and effectiveness must be proven. User testing managed by appropriate risk assessments would typically be incorporated into the design and development stage of the process.

Part 2

Experimental

Chapter 4

4. Repeatability and reproducibility of fused filament fabrication

4.1. Introduction

Previous work in part one of this thesis has demonstrated that due to technological and material developments, and advancements in research, fused filament fabrication (FFF) technology is improving and becoming more capable of producing functional parts, which is an active occurrence in the AM community. Previously FFF was predominantly used for prototyping and other non-functional applications. However, as the technology progresses, and its use for functional applications becomes an increased reality, the technology must undergo the same kind of scrutiny as any other mainstream manufacturing process where its performance, capabilities and limitations are understood.

FFF AM is used widely in multiple industries by a range of user groups including non-specialist, specialist, and research users as discussed. However, one of the largest identified barriers to the widespread adoption of FFF is its consistency and reliability as discussed in Chapter two. Uncertainty around how a process performs can act as a significant limitation to its use and adoption for functional part applications. For the advancement of FFF technology, and to increase its suitability for wider-reaching applications, a method of determining the basic repeatability of the process is required. This is particularly important for regulated applications, where stringent process control and validation activities are required to be conducted and validated by external quality standards, such as ISO 13485 (ISO, 13485:2016), as discussed in Chapter two. The validation activities are highly specific to the medical device specification and its intended use case, which can be assessed under the following groups based on the device description and specification: design inputs vs the general safety and performance requirements, the product verification and validation activities, which are specific to the device and consists of functional testing, lifetime testing, usability engineering, clinical studies and clinical evaluations.

When evaluating the “performance” of AM techniques, even for specialist users who are well rehearsed with typical manufacturing performance evaluations, in the context of AM

understanding performance can be a complex task. AM technologies are not universally capable. Each technology is unique, and each piece of hardware has a unique combination of features, leading to unique capabilities, thus increasing the complexity of performance determination. It is widely understood that different makes and models of 3D printers have different capabilities, and therefore the characterisation of these capabilities must be a unique activity. For this reason, some well-established AM technologies are being used in regulated fields for functional applications, and others remain at early stages of research. FFF for example, is largely being used for prototyping and other non-functional applications, or for research activities due to the challenges discussed relating to repeatability of the FFF technique and/or the quality of FFF printed parts. Few companies are using FFF technology for industrial applications, despite its potential being widely discussed. The use of FFF for functional applications is currently more common within non-specialist communities, due to the lack of meticulous monitoring, control and inspection processes present in most specialist or research use contexts.

In the context of FFF for medical applications, FFF is used in the three discussed scenarios, for research and for both specialist and non-specialist production. FFF use for functional parts across all industries is limited, and when compared to other AM techniques, such as SLS and SLA, FFF is less established. This has been attributed to a number of factors, including poor mechanical performance in terms of surface finish, part isotropy and the corresponding reduction in tensile strength (Bikas *et al.*, 2016; Ngo *et al.*, 2018; Allum *et al.*, 2020; Kristiawan *et al.*, 2021; Rouf *et al.*, 2022), build inconsistencies (Campbell *et al.*, 2011; Bähr and Westkämper, 2018) and the heavy influence of external factors (Valerga *et al.*, 2018; S. Singh *et al.*, 2020). As discussed in previous chapters, FFF is thought of as an opensource process, which allows for the use of infinite materials, both commercial and experimental, an extensive range of input parameter modifications, and many machine modifications. Each of these can result in performance changes, which if not locked down and properly controlled, could be causing poor performance and part inconsistencies, thus impeding the use of FFF for functional applications and making understanding the performance of FFF a convoluted task.

Examples of functional applications of FFF have been demonstrated, although not in high numbers. One of the most pertinent examples of functional FFF parts in recent times is in the COVID-19 pandemic response, as presented in Chapter three, which discussed the FFF AM of functional components for ventilators and PPE, which were commonplace across organisations

globally. Other examples of functional FFF parts include prosthetics, replacement components for household appliances and jigs, and fixtures and tooling across the manufacturing industry (Brenken *et al.*, 2018). The use contexts in which these parts are manufactured vary, meaning that work in this area must be both applicable and accessible to each user group, and not limited to specialist manufacturers with advanced equipment and knowledge. Realistically, the practice of managing performance of FFF between user groups will differ, however, a baseline methodology that is specific to the FFF process, not the wider use context of an organisation, is expected to be more useful to the wider industry. Typically, with any process, specialist users, such as industrial manufacturers, will incorporate their own modifications to tweak their processes based on the specific requirements of the industry or application they are manufacturing for.

The performance of both a manufactured part or a manufacturing process can be assessed independently. It can therefore also be related to the performance process, which can be determined by analysing the performance of a part. In the case of FFF, when assessing the performance of functional parts, multiple part attributes could be considered. These could include things like its mechanical properties, durability, surface finish, aesthetic appearance, or any other factor important to its functional use. These performance factors are determined based on the design, development and manufacturing stages which involve making decisions to ensure the performance specification is met. In manufacturing, part performance assessments typically take place at more than one stage in the process. Usually, a sample set of parts will be inspected initially after a manufacturing process has been set up, to ensure that the process can produce parts to the required specification. Sampling will be conducted throughout the process and before shipment of parts as part of an established quality control schedule.

For a manufacturing process to consistently produce capable parts, within an agreed tolerance limit, it must be stable. The tolerance limit will be different for each parameter; however, a commonly critical parameter would be the allowable dimensional tolerance. This means that the manufacturing process must be able to achieve dimensional tolerances outlined in the product specification. Too much part variation caused by the manufacturing process means the process is unstable and not capable. The consequences of an unstable and uncapable manufacturing process could include financial losses, time losses (due to troubleshooting, maintenance/improvement or remanufacture time), part failure and customer dissatisfaction. Proving that a manufacturing process is stable and capable is often a requirement for regulated

products, where compliance is enforced though quality management system standards. Aside from being an essential requirement in many cases, a well-performing process can have many benefits to a manufacturer, including time and cost benefits, sustainability benefits through reducing waste and resource consumption, improved efficiency, and increased capacity.

In most cases, a defective part or one that does not meet its product specification would never reach a customer, as it would be identified by quality control procedures before leaving the manufacturing facility. In instances where non-specialist manufacturers are producing functional products, it is unlikely a system would be in place to identify defective or non-conforming products. Perhaps a more relevant issue would be how a non-conforming product would be identified by a non-specialist user, without strict performance specifications established by specialist manufacturers. Without following an established protocol, which could include a basic set of checks for each part, not necessarily utilising specialist equipment and complex procedures, quality control in a non-specialist scenario would be difficult and inconsistent.

A common performance evaluation technique is to check that the dimensions of a part repeatedly conform to its specification, which usually includes acceptable limits or allowable tolerances. By definition, repeatability refers to the amount of variance observed over a set of parts or products produced with the same equipment (Drozda *et al.*, 2020). Determining specification limits for AM parts can be more complex than traditional manufacturing techniques due to the lack of established standards and procedures. Other potential barriers include inconsistencies throughout the wider industry. For example, the quality of filament and consumables for FFF have been reported as inconsistent by some (Cardona *et al.*, 2016), perhaps due to the lack of industrial FFF use it is not yet seen as an essential requirement by upstream suppliers.

Due to the individualised nature of FFF, and 3D printing generally, it is likely that multiple printers would be used to produce parts within the same batch. Compared to other manufacturing techniques, the FFF process is considered slow, especially when printing larger parts. Therefore, to print a batch of products, or parts at volume, it is common for multiple printers to be used simultaneously, known as a print farm. Using multiple machines within the same batch adds an additional level of complexity where quality is concerned, which introduces the concept of reproducibility. Reproducibility refers to the variance observed within a

manufacturing system, which in this case would be a print farm (or a group of 3D printers). It is the ability of a system, or a collective of machines, to regularly reproduce the same part under the same conditions (Mohamed *et al.*, 2018). Where repeatability or reproducibility is not demonstrated, excessive variation between parts could be problematic and result in an unstable and not-capable process.

Where multiple machines are used, quality control (QC) processes become increasingly important, as more opportunities for variable factors are introduced at each stage, as illustrated in Figure 39. The highest level of process control is present in scenario one, where a single set of hardware and material is used by a single operator. In scenario 2 print cycles cannot be run at the same time, meaning environmental conditions could vary between cycles. Varying environmental conditions are thought to affect the properties of printed parts (Sun *et al.*, 2008; Coogan and Kazmer, 2017), which could directly influence the reproducibility of FFF printed parts. Scenario 3 introduced multiple additional levels of variance, including varying hardware and hardware components such as build plates and print heads. Multiple spools of filament would also be required, shifting an element of responsibility onto the QC requirements of the filament manufacturer. A print farm is likely managed by different operators, again introducing further opportunity for variance.

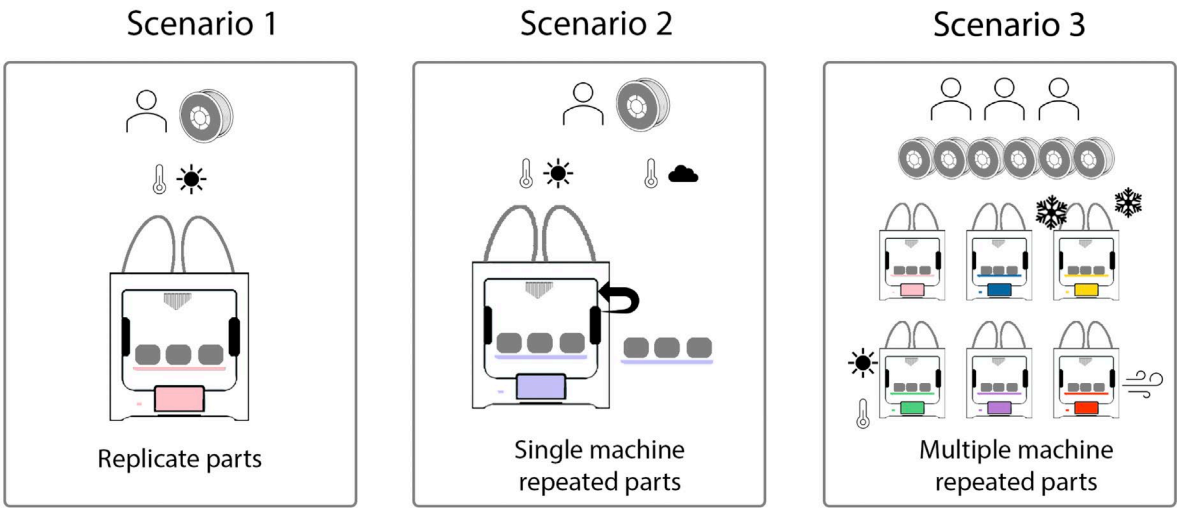


Figure 39: An illustration of the increased number of variable factors from using (1) a single printer and single build cycle, (2) a single printer and multiple build cycles, and (3) multiple printers

4.1.1. Evaluating performance

To understand how variance can occur in the FFF process, it is first necessary to refer to the intricacies of the FFF process and identify the human or non-human factors which could influence the process and therefore the part outcome. This section builds on the identification of FFF process groups discussed in Chapter two section 2.2 (Figure 12), which were presented as software, hardware, feedstock, printing and finishing. However, for the purpose of evaluating performance of the process, the stages have been categorised into the following four process stages: the initial FFF hardware set up, inputs (filament, process parameters), process conditions during printing (environmental factors), and outputs (removing from the build, post-processing), which is detailed in Figure 40. The following section discusses each process stage in detail, and how each of these specifically relate to the process capability of FFF.

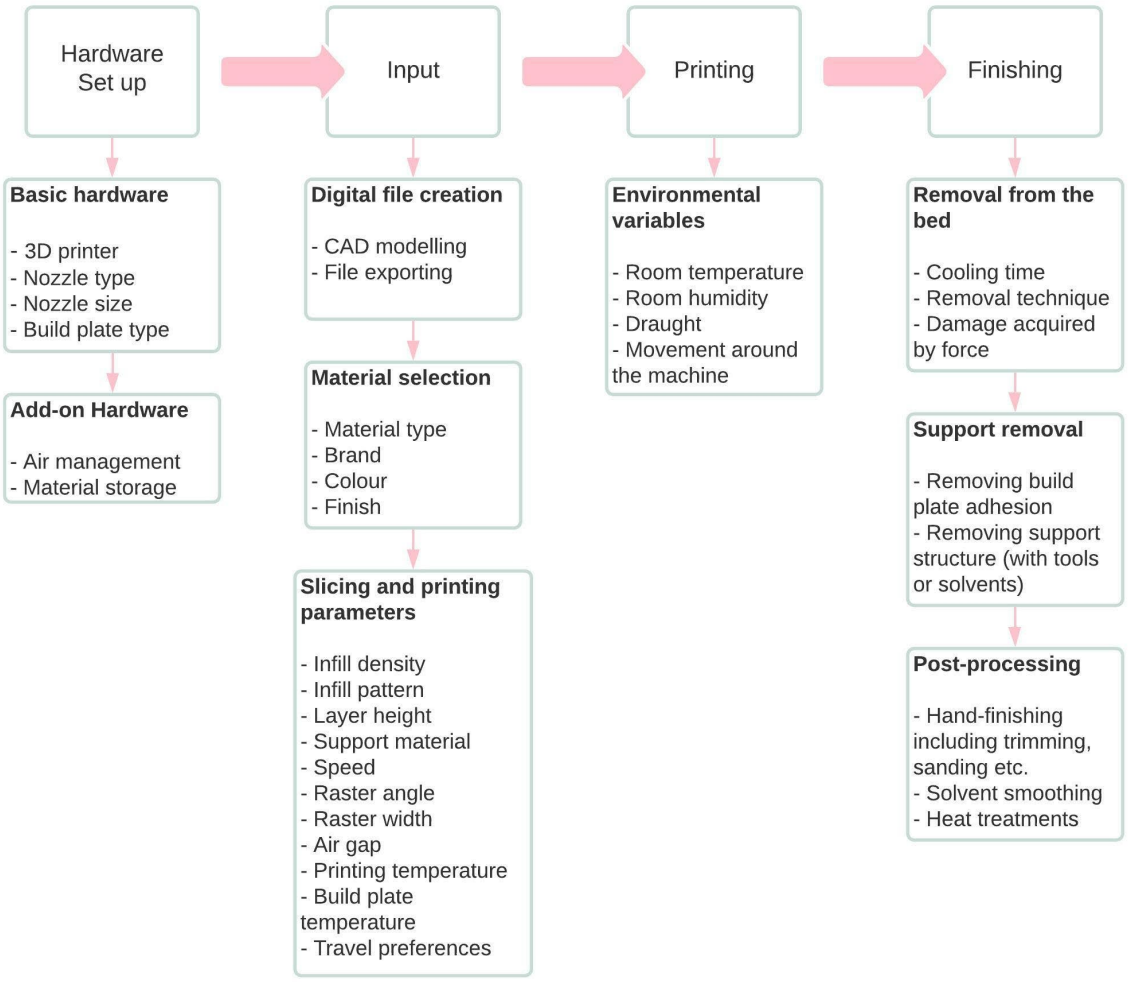


Figure 40: Flow chart showing factors that could influence repeatability and reproducibility at each process stage

4.1.1.1. FFF hardware

FFF hardware is considered the 3D printer module which physically prints a part, including the basic components required to operate the machine. The main components of any FFF printer are the build plate and print cores, shown in Figure 41 (A). As standard, the printer of choice for this study, the Ultimaker S5 (®Utrecht, Netherlands), comes with a glass build platform, two standard print cores and a material spool holder. The default print cores are an "AA 0.4" core and a "BB 0.4" core. "AA" is the label for standard non-abrasive printing materials and 'BB' is specifically for polyvinyl acetate (PVA) filament. "0.4" references the extrusion diameter of 0.4mm. PVA is predominantly used as a "support material" which enables the printing of overhanging or complex geometries. It requires a dedicated nozzle with different internal geometry due to the flow characteristics of the material, although this is not necessary for the study, as a standard core in the machine, it will remain installed but unused. Other specialist print cores are available from the manufacturer and some third parties, which include larger and smaller extrusion diameters, and reinforced internal channels designed for more abrasive materials such as composite materials for high strength parts.

In addition to interchangeable components, FFF hardware is often compatible with add-on modules which are intended to improve the printing process or provide additional capabilities to the standalone 3D printer. For example, the Ultimaker S5 is sold either as a standalone 3D printer, or an 'Ultimaker S5 Pro Bundle' which includes an air management module, named an "air manager", and material station shown in Figure 41 (B). The air manager encloses the 3D printer and allows an inside-out airflow trapping ultrafine particles (UFP) in the built-in E10 filtration system. The material station is an additional base unit which stores up to six spools of filament. The material station directly feeds the 3D printer and can switch materials or material colours mid-print, allowing additional manufacturing flexibility. Although, another key benefit of using the material station is said to be the humidity control aspect, which actively maintains a <40% relative humidity (RH) environment. The significance of humidity-controlled material storage is discussed in more detail in Chapter five. In addition to Ultimaker branded modules, third-party modules exist, including other variations of environmental control chambers and multi-material splicing machines.

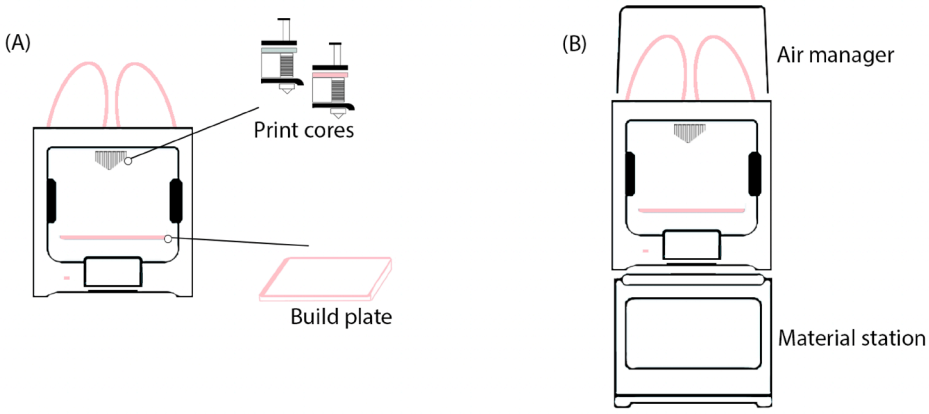


Figure 41: FFF 3D printer components (for Ultimaker S5). (A) shows hardware as standard, (B) shows optional 'add-on' hardware which forms the 'Ultimaker S5 Pro Bundle'

4.1.1.2. Input

Input factors include anything that is "put in" to the process, from physical material to print files. Firstly, the material which is loaded into the printer in filament form. Filament comes in an extensive range of materials, colours, and finishes, and like many scenarios, the quality of the filament is likely to influence the quality of the part produced. Some indications of poor-quality filament include inconsistent filament diameter, poor packaging or impurities or debris in the plastic. Filament that fluctuates in diameter could lead to irregularities in material flow, potentially resulting in over-extrusion or under-extrusion in places (Cardona *et al.*, 2016). For this reason, quality filament should have ± tolerance values, and the entire length of the filament should have a diameter within this value. Insufficient packaging is a sign of low-quality because unless filament is fully sealed, preferably vacuum sealed, it has the potential to be exposed to contaminants in the air such as moisture and dust which can affect the printing, discussed in detail in Chapter five. Finally, impurities in the plastic can lead to issues with material viscosity which can affect print quality through under-extrusion, but also cause nozzle blockages.

After the material has been loaded, the next component to "put in" to the FFF process is the digital file to be printed. Preparing the file consists of multiple stages, all of which can influence the quality of a part. Firstly, the design of the part can affect the quality of a print. A series of minimum requirements that are specific to the technology and printer must be met. These include considerations like the minimum printable feature size or wall thickness of a part. If the geometry does not align with the printer's capabilities, certain geometry may not print, or

print poorly. Non-manifold geometry is geometry that cannot exist in the “real world” which will cause problems when printing. This can occur when digital objects are not connected properly, or where faces or surfaces do not have a realistic volume and therefore cannot exist physically. Non-manifold geometry will not be recognised by the printer and will therefore not be printed because it cannot be physically supported in the real world, which could significantly affect the printing or other valid geometry present in the same part.

After the digital file has been created, it must be exported as a standard tessellation language file (STL), also referred to as a standard triangle language file, which describes the geometry of a three-dimensional object. Printers cannot directly read STL files, meaning they require an additional process step called slicing. Slicing takes an STL file, along with a set of predefined preferences and values, and converts this information into a set of instructions for a 3D printer. A part is separated into layers, or “slices” which the printer can produce one-by-one. Many of these preferences are selected by the user and are known as printing parameters, which are discussed in more detail in Chapter two.

Parameters must be altered to match the hardware set up, meaning there is a specific set of settings that the user must define to indicate the types of print cores, nozzle sizes and information about the material. The user must specify the type of material or the printing temperature for that material, along with the filament diameter. Additional material related parameters include the print bed temperature, and fan or cooling speed which will differ between materials. The parameters should be configured to optimise printing performance for the material used. Suboptimal printing parameters could cause issues with material flow or the part lifting away from the print bed during printing.

The remaining parameters are related to the geometry or intended properties of a part. Depending on the slicing software, there are usually hundreds, if not thousands of parameters to modify. Some of the main parameters identified in Chapter two are as follows: layer height, printing speed, part orientation, extrusion temperature, build chamber environment, raster angle, infill density and air gap. Within each of these parameter settings lie multiple sub-settings where the input values can be tailored to specific layers, or multiple groups of layers which allows the printing behaviours to change multiple times throughout a single print. Chapter two contains discussions around the considerable amount of research done around

modifying parameters to optimise performance which concludes that by modifying different combinations of parameters, different properties and performance attributes can be achieved.

4.1.1.3. Printing

Environmental changes during the printing process are suggested to influence the part outcome, as discussed in Chapter five. It is generally agreed that 3D printers with enclosed build chambers that can regulate and maintain temperature relate to improved properties and process repeatability (Shelton *et al.*, 2020). The effects of environmental temperature changes on printing are suggested to be more severe with some materials than others, particularly those requiring high printing temperatures (Kuo *et al.*, 2019), however particularly cold or draughty environments are thought to result in print irregularities for most materials. Any extreme movements or vibrations around a 3D printer whilst printing is likely to impact the print, particularly on the surface. Vibrations, judders or severe movement can cause oscillations on the surface of the print, which is known to the 3D printing community as surface "ringing". Although changes in environmental factors in many cases need to be quite severe to impact the print, they can. Being aware of, and carefully monitoring and controlling all factors that could introduce variance will improve the chances of obtaining repeatable results.

4.1.1.4. Finishing

Once the printing process has completed, the part must be removed from the print bed. Prints are usually securely fixed to the build plate requiring some force to remove them. Standard practice is to use a flat scraper to prise the print off the plate, however, sometimes the first layers can be damaged using this technique, and if the scraper is not flat to the bed, the user could be applying force between bonded layers. The geometry and part functionality should be considered when forming removal protocols to ensure minimum damage and consistent technique. For example, minor damage to one area of a print may be insignificant, whereas similar minor damage to another area of the print could be critical to its functionality. Removing support material or applying any additional post-processing techniques such as solvent smoothing can all introduce variability when completed by hand, and therefore steps must be made to ensure any actions performed in the finishing stage are as repeatable and reproducible as possible through the implementation of control measures.

4.1.2. Ensuring repeatability and reproducibility

Manufacturing control measures are a regulatory requirement for many types of products and parts. Where goods are placed on the market, they must conform with the applicable requirements for products in that country to display a conformity marking. All medical devices sold on the UK market require a UKCA mark as discussed in Chapter two, which is granted when a specific set of standards are met. For regulatory requirements to be satisfied, it is not uncommon for every part of a manufacturing process to be carefully considered, tested and validated. The specific manufacturing process stages will vary between manufacturing processes, but the types of activities conducted to ensure conformity remain similar.

4.1.2.1. Regulatory requirements

In the case of FFF, upstream and downstream processes must be considered, from material sourcing through to postprocessing. The stages of FFF manufacture have been discussed, and the most likely factors to introduce variance have been identified. Next, for the manufacture of Class I medical devices within a specialist use context, it is necessary to ensure that the process meets the regulatory requirements which are specified in the relevant medical device regulations for the intended market. The regulatory approval process for medical devices, detailed in Chapter two section 2.3, requires the use of a quality management system (QMS) which covers all aspects of design and manufacture. A QMS is required to ensure manufacturers meet the requirements set out by ISO 13485; Quality management system for medical devices (ISO, 13485:2016) for the UK and EU, and US FDA QSR: quality system regulation for medical devices (U.S. Food & Drug Administration, 2020). These standards require the manufacturing process to be validated, which includes assessing all production equipment that can affect product quality.

Validation is an essential aspect of approval. In ISO 13485, section 7.5.6 ‘Validation of processes for production and service provision’ states the procedures for validation of processes that should be documented. They include defining the criteria for review and approval of the processes; qualification of equipment and personnel; use of specific methods; procedures and acceptance criteria; statistical techniques with rationale for sample sizes; requirements for records; revalidation, including criteria for revalidation and approval of changes to the process. This also applies to the application of any computer software used in production.

The qualification of equipment includes both the manufacturing equipment, and the equipment used to qualify the manufacturing equipment, such as the measuring and/or testing equipment. The MDR states that "*[…] it shall be possible to trace back adequately the calibration of that test equipment"*. This forms the requirement relating to the control of monitoring and measuring equipment under section 7.6 (ISO, 13485:2016). To ensure valid results, measurement equipment must be calibrated or verified against measurement standards, and where these do not exist, the basis used for calibration or verification must be recorded.

Monitoring and measuring of both the process and the product are required (specified in sections 8.2.5 and 8.2.6 of ISO 13485 respectively). Suitable methods for monitoring and measuring the QMS must be in place, demonstrating the ability of the process to achieve planned results. To verify product requirements have been met, the characteristics of the product should be monitored and measured at applicable stages of product development. The organisation must evidence conformity to the acceptance criteria for that product, which would require a product to be fully refined to a stage where the capability of the FFF process is known.

A method of verifying a manufacturing system is to conduct a system performance capability study. In manufacturing, it is common for process capability analyses to include installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ), which are sequential activities. IQ is the process of ensuring equipment is installed correctly and is configured according to the product requirements. In the case of an FFF printer, this would include installing the specified components, such as the print core and build platform, and any add-on modules detailed in the manufacturing specification. Calibration and maintenance schedules for equipment should also be established prior to validation activities, and usually defined in the product development stage according to specific information for that part, i.e., the build time of a part, and the level of precision required. The OQ process validates that equipment operates as it should. This process can be used to determine an acceptable window which ensures a reproducible process that can consistently produce parts to meet specified requirements. PQ is the final step of the validation process which is necessary to validate the stability of a process over time.

Any changes or modifications to the hardware, input parameters, process conditions or finishing techniques could introduce variability in the process. Repeatability evaluations can

be applied to study this variability, either observing a particular process step, or the entirety of the process. The hardware set up is particularly influential, as the addition of any add-on modules are designed to influence the printing process in some way by nature. To understand the repeatability of the FFF hardware without considering the influence of add-on modules, the hardware configuration and any user-driven variable factors must remain constant for the entirety of a study. This will allow conclusions to be made about the repeatability of the process by analysing printed parts produced under the same conditions.

A fundamental quality criterion is dimensional accuracy, which sees that all parts are dimensionally similar and within the acceptable tolerance range defined in a part's specification. The limits of acceptable dimensional tolerances vary significantly between different types of medical devices, which are usually defined in device specific standards. These standards are used to form device specifications that manufacturers must ensure their manufacturing process can meet through regular quality control processes. Two examples of standards specifying tolerances include (BS EN ISO, 22523:2006) for external limb prosthesis which specifies an allowable tolerance of ±1mm for linear dimensions, and (BS EN ISO, 9173-1:1996) for dental extraction forceps, which specifies varying allowable tolerances for different features on the device which range from ±0.25mm to ±3mm.

Dimensional inspection is particularly important to verify a new or modified manufacturing process, and by thoroughly inspecting a part, and comparing the manufactured object to its digital file, information will be given about the manufacturing process including whether the equipment was properly installed, configured and calibrated. Dimensional analysis at this early stage is critical to determine achievable tolerances and verify the manufacturing technology complies with the product specification. After initial inspections have been completed, routine dimensional analysis is an expectation in the quality control process for regulatory compliance.

4.1.3. Measurement system analysis

As discussed, regulatory requirements include the calibration or verification of measurement equipment. This provides confidence that the variation identified can be attributed to the manufacturing process, and not unwanted variation introduced by the measurement system, by the measurement system variation being known and accounted for. A common method of gauge validation is to conduct a measurement system analysis (MSA), which is defined as a

mathematical method of identifying components of variation within the measurement process. Many manufacturing industries are required to conduct statistical studies for their measurement systems as a part of their QMS. For example, the standard for automotive quality management (IATF 16949:2016) requires a statistical study for each type of measurement system (Pop and Elod, 2015).

Sources of variation in a measurement system can be due to a number of factors, including the process, operators, equipment, parts to be measured, or environmental factors (Automotive Industry Action Group, 2010). Figure 42 shows possible sources of variation in a measurement system. Different types of MSA are capable of determining different types of error. Two of the most common MSA techniques are a gage repeatability and reproducibility study and a type 1 gage study ('gage' is the most commonly referred to terminology, 'gauge' is also used in this context but less commonly).

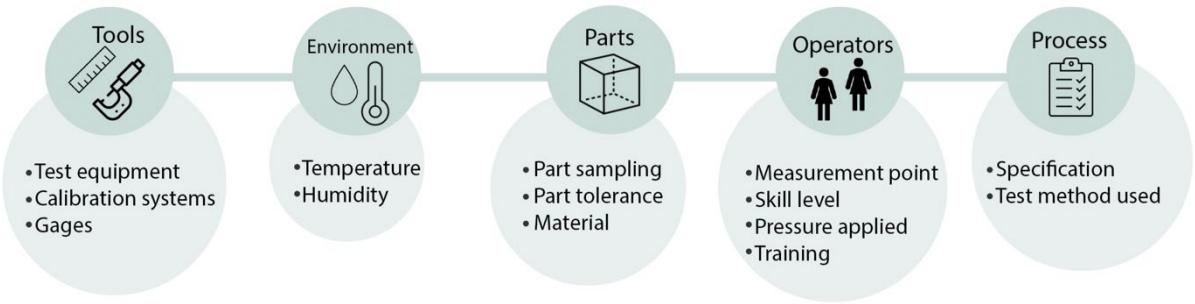


Figure 42: Measurement system sources of variation

Several terms are used when discussing measurement system verification. To ensure clarity, the following terms are defined: repeatability, reproducibility, accuracy, precision, and trueness.

Repeatability is defined as the variation in measurements taken by the same person, using the same measurement system, under the same conditions (Drozda *et al.*, 2020). Reproducibility is the variation in measurements taken by different operators, using different measurement systems or under different conditions (Mohamed *et al.*, 2018). Accuracy is a general term used to refer to both trueness and precision (ISO, 5725-1:1994). Precision refers to how close measurements of the same dimension are to each other (ISO, 5725-1:1994). Finally, trueness refers to the closeness of agreement between the mean of many test results and the true or accepted reference value (ISO, 5725-1:1994).

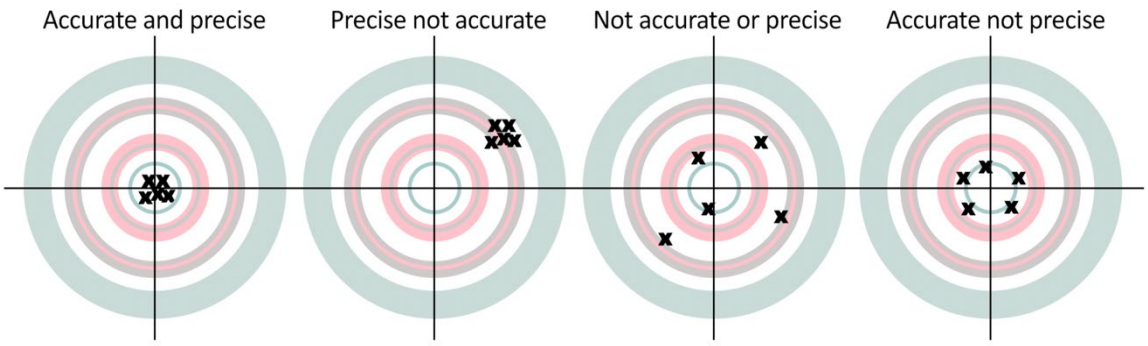


Figure 43: Precision and accuracy visualisation

4.1.3.1. Gage studies

A gage repeatability and reproducibility (gage R&R) study is an MSA technique which assesses the amount of variability caused by a measuring system, with the gage being the measurement tool. A gage R&R study can be performed in three ways; the range method which provides an approximation of measurement variability, however through only focussing on the range between measurements, this method does not compute repeatability and reproducibility separately; the average and range method, which provides information on measurement variability providing repeatability, but also reproducibility between operators and part variation (Cepova *et al.*, 2018); and finally the analysis of variance (ANOVA) method which quantifies the variance in the measurement system, variance between parts, reproducibility between operators, and the interaction between the operator and parts (Zanobini *et al.*, 2016).

The chosen method of gage R&R will depend on the type and availability of the data. Firstly, a nested gage R&R study would be used where two factors are nested, where the levels of one factor are similar (Minitab, no date). For example, if two operators were measuring a set of parts each operator would measure a different set of parts, which would represent a scenario where parts need to be destructively tested. Secondly, a crossed gage R&R study would be used when each level of one factor occurs in combination with each level of the other factor, for example when each operator measures each part is an expanded gage R&R (Minitab, no date). Visualisations of both nested and crossed gage R&R studies are shown in Figure 44. Finally, an expanded gage R&R study would be used where the inclusion of multiple factors is required, for example, an operator, gage and part. This means the expanded gage R&R

method is suitable for a study which includes both crossed and nested factors (Minitab, no date).

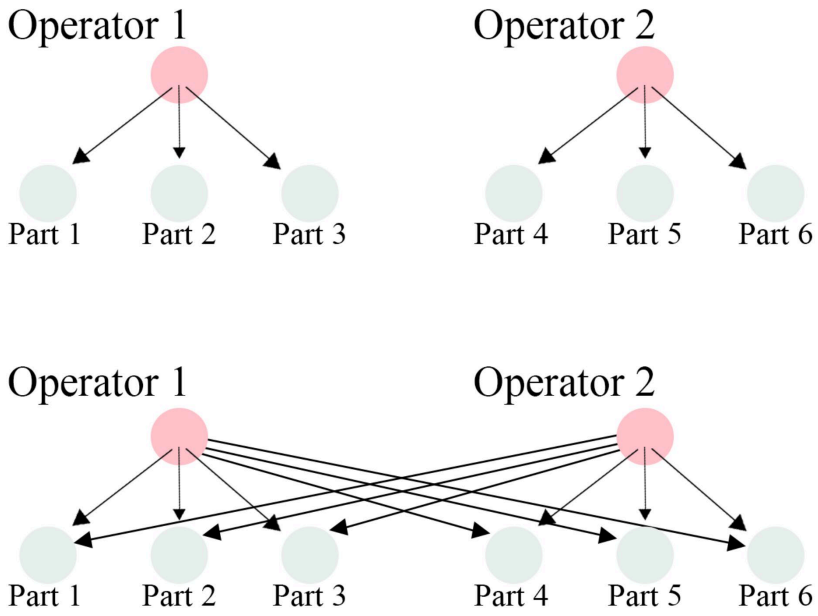


Figure 44: Visualisation of different types of gage R&R study (top: nested, bottom: crossed)

The most widely used and accurate method of gage R&R is the two-way ANOVA method, which is based on a crossed gage R&R (Mohamed *et al.*, 2018). A typical gage R&R study has three operators and 10 parts, where each operator measures the part three times, and the measurements are recorded. The measurement data is then used to calculate a gage R&R percentage, usually using statistical software, which can be interpreted using the following guidelines. If the gage R&R percentage value falls below 10%, the measurement system is considered acceptable. If the score is between 10% and 20%, the measurement system *may* be acceptable depending on the importance of the application. A score of over 30% generally means the measurement system is unacceptable and requires improvement.

A type 1 gage study assesses only the variation from the gage and does not consider variation from different sources such as the operator(s). A type 1 gage study allows the operator to quickly assess any variation and bias that comes from a measurement tool. An analysis of measurements taken form one reference part by a single operator will determine whether a gage is capable of measuring with small variation (Zanobini *et al.*, 2016).

Both type 1 gage studies and gage R&R studies require a known tolerance value of the reference part. Currently, realistic geometrical tolerance values are not known for AM in literature, nor in standards (Lieneke *et al.*, 2016). The multiple environmental and process factors have been shown to influence dimensional accuracy of FFF parts, which will impact upon the achievable tolerances. The dimensional accuracy and subsequently achievable tolerances could also be influenced by part geometry, particularly the infill percentage, meaning it is likely that manufacturing tolerances can only be calculated on a part-by-part basis (Drozda *et al.*, 2020). Due to the uncertainty of tolerances, a preferable option would be to use a calibrated reference part, where the tolerance values are known and well-established.

4.1.4. Process capability analysis

Process capability can be defined as the range over which the output of a process varies (Spiring, 2010). To estimate the capability of a process, a process capability analysis (PCA) can be performed, which is a systematic method involving the measurement and assessment of natural variation in the quality characteristics of a process (Siraj and Bharti, 2020). PCA remains the most known type of capability analysis and most referred to in literature, however additional techniques can be completed within a PCA, including a system capability analysis (SCA). PCA and SCA are differentiated by the stages of manufacturing they cover. The conditions for each analysis are different, however the index calculations are principally similar (Udroiu and Braga, 2020). For example, SCA assesses the performance and quality outputs of a single machine or 3D printer, as an isolated stage in the wider process. This would be done by producing multiple parts in a single batch, by a single operator. On the other hand, a PCA is typically a long-term study on a stable manufacturing process (Udroiu and Braga, 2020). This includes taking samples from different batches, often three, where the process has been managed by different operators.

A capability analysis can be done using either historical data, or data collected specifically for a PCA. However, the process capability concept can only be used when a process is in a state of statistical control. Where a process is not in a state of statistical control, the variable being measured does not have a normal distribution. Data must first be charted and analysed with control charts to identify whether the process is in statistical control. Where statistical control is indicated, the data can be used to estimate the mean and standard deviation of the process (Ryan, 2011).

Literature around PCA is rising in complexity as more techniques are developed. For this reason, the process capability study used in this work will use the fundamental concepts of a PCA or SCA. These are process capability indices (PCI) and process performance indices (PPI) in relation to process sigma which is introduced in lean six sigma (Arcidiacono and Nuzzi, 2017). Lean six sigma is a philosophy geared towards continuous improvement, through driving waste out of an organisation at every level and improving product quality (Carreira and Trudell, 2006). Essentially, it is a data-driven improvement process, through applying a methodical approach to measure a process against metrics in order to create improvement (Carreira and Trudell, 2006).

4.1.4.1. Capability indices

Process capability indices (PCI) are used to indicate quality by calculating the deviation of the process mean from the target mean. There are multiple indices for quality control, like capability and performance indices (Arcidiacono and Nuzzi, 2017). Different indices represent different things, however, the four indices generally used are Cp, Cpk, Pp and Ppk. Cp and Cpk are referred to as capability indices, and Pp and Ppk are referred to as performance indices (Peña-Rodríguez).

Cp and Cpk represent the process capability ratio and process capability index respectively. They indicate how well the outcome of a process conforms to a specification, by comparing the natural variability of a process to the specification. Cp, also referred to as "precision index" does not take into account where the process mean is located, meaning Cp indicates only the spread of the specification relative to the process spread (6σ), providing information on only the theoretical capacity of the process, not the actual process performance (Arcidiacono and Nuzzi, 2017). The Cpk index was introduced to directly respond to this short fall. The addition of '*k*' quantifies the amount the distribution is centred. Where the distribution is perfectly centred, the Cpk value would be the same as the Cp value (Peña-Rodríguez, 2013). Cpk is used to relate process variability to its specification with reference to the mean. Therefore, it indicates how well a process conforms to its specification limits (Arcidiacono and Nuzzi, 2017). The Cp and Cpk can be calculated using the following formulae.

$$C_p = \frac{USL - LSL}{6\sigma}$$

$$C_{pk} = min\left[\frac{USL-\mu}{3\sigma}, \frac{\mu-LSL}{3\sigma}\right]$$

Where σ = standard deviation and μ = average of mean

Pp and Ppk are used for long term capability analysis. In order to select the appropriate indices, the user must first be able to differentiate between a long term and short term process study. A short-term study would be where some of the process variables are shown, for example, if a new batch of material is loaded in that particular process cycle. A long-term study would be held over a timescale where all of the variables for that process would appear. For example, it would include the change of material or other consumables, the typical number of operators that appear in the typical process duration, any planned or scheduled maintenance, or any other variable present in that process. In the case where all of the variables are captured, the Pp and Ppk indices would be used.

The difference between Cp and Cpk, and Pp and Ppk is the way in which process variation, or sigma (σ) is calculated. Cpk is calculated using the equation for σ_1, which is a way of estimating standard deviation using the range, whereas Ppk is calculated using the full formula for standard deviation (σ_2) (Peña-Rodríguez).

$$\sigma_1 = \frac{\bar{R}}{d_2}$$

$$\sigma_2 = \sqrt{\frac{\sum(x_i-\mu)^2}{n-1}}$$

The Pp and Ppk can be used when a process is new, or not under statistical control because the equation for standard deviation is based on the whole population of studied data. Pp uses sampling, where the estimated standard deviation within that sample is calculated. The Cp and Cpk indices can be used when the process is under statistical control, and sample deviation or deviation mean can be used. It assumes the process is stable and will likely have enough data to calculate a true standard deviation.

Additional indices referred to include Cm and Cmk, the machine capability index. These are used for SCA, as opposed to PCA, to describe machine capability where 'm' represents the machine. The calculations for Cm and Cmk are the same as Pp and Ppk, where between 30-50 measurements are taken from consecutively produced parts. A SCA should be conducted before a PCA, preferably at new product introduction, to identify the machine capability in isolation, without the influence of additional factors present in the wider process, such as different batches of material, changes in operators, set up or maintenance and equipment deterioration.

Once process capability indices have been calculated, they can be interpreted to gauge the capability of a system or process. Table 19 details the interpretation of indices Cp and Cpk, however the same approach can be used for Pp and Ppk. The acceptable value, or "benchmark" differs between industries, but the most common industry target value is ≥1.33 (Peña-Rodríguez). Although this does vary between industries, for example, in the automotive industry, the target value is 1.67, and an excellent value would be considered between 1.67 and 2 (Arcidiacono and Nuzzi, 2017).

Table 19: Interpretation of capability and performance indices (based on (Peña-Rodríguez))

Cp value	Cpk value	Capable?	Centred?
Cp = 0.82	Cpk = 0.82	Not capable	Centred
Cp = 1.33	Cpk = 0.95	Capable	Not centred
Cp = 0.95	Cpk = 0.75	Not capable	Not centred
Cp = 1.33	Cpk = 1.33	Capable	Centred

The values in Table 19 are based on the industry target value of 1.33, where a system or process is deemed capable with a Cp value of 1.33 or more. As discussed, the Cpk value indicates the closeness to the centre of the specification. An ideally centred process would be indicated by the Cp and Cpk values being the same. In scenario one, where Cp = 0.82 and Cpk = 0.82, although the process is not capable (because Cp is <1.0), it is centred. In this case the variation is the issue, and improvement would require either the specification limits being widened, or the spread of the process being reduced. On the other hand, where Cp = 1.33 and Cpk = 0.95,

the process is capable, but not centred, which is indicated by the Cp and Cpk values being different. This means improvement must be made to the centring of the process.

4.1.4.2. Determining specification limits

To calculate capability and performance indices, upper standard limits (USL) and lower standard limits (LSL) must first be established. This has been done in different ways depending on the process stage, examples include establishing appropriate tolerance limits at the design stage, experimentally estimating the limits for new processes where the achievable limits are unknown or unconfirmed, and using tolerance systems and standards to comply with other parts.

Engineering tolerances are defined and communicated using a system called geometric dimensioning and tolerancing (GD&T). The system is made up of standards which define language and symbols to communicate and describe products, parts, and drawings standards. A heavily referred to GD&T standard is ISO 286 (ISO, 286-1:2010) which is a standard for international tolerance (IT) grades. IT grades refer to an internationally accepted code system for tolerances on linear sizes based on the size of the feature, meaning larger feature sizes have larger tolerances. ISO 286 (ISO, 286-1:2010) is usually used for metal parts (Udroiu and Braga, 2020), where lower IT grades imply better dimensional accuracy. It covers general tolerance ranges for cylinders, shafts and holes. A more general standard is ISO 2768-1 (ISO, 2768-1:1989), which covers general tolerance ranges for linear and angular dimensions

4.2. Literature review

4.2.1. Dimensional accuracy in AM

There is a need to obtain a better understanding of dimensional repeatability and reproducibility using AM, which is a question often raised by industry (Mohamed *et al.*, 2018). This is particularly important for FFF due to frequent reports of dimensional variability in literature (S. Singh *et al.*, 2020). As FFF moves from a hobbyist technology into an industrial space, dimensional variation will be a more significant issue leading to a higher demand for improved solutions. Alternative well-established manufacturing techniques used for industrial applications are better understood. For example, standards specifying tolerances and acceptable conditions are available for plastic moulded parts (ISO, 20457:2018). The standard details IT

grades, which identify what tolerances a process is capable of producing for a given dimensions. Such information for AM processes is limited (Minetola *et al.*, 2020).

Dimensional accuracy can be defined as an indication of the closeness between a physical 3D printed part and the nominal value (Δd), in most cases the CAD reference value. Jin *et al.* (2018) use the term "trueness" as the measure of deviation from the given reference. Dimensional variation refers to the capability of the manufacturing process to consistently reproduce parts under the same conditions with the same dimensional measurements. Variation can be broken down into repeatability and reproducibility. The term "precision" is used by some as the measure of deviation from repeated measurements in the same group (Jin *et al.*, 2018). In this work, the term dimensional accuracy will be used to indicate the closeness of a part to the nominal value, and dimensional variance will be used to indicate the spread of deviation across repeated measurements in either the context of repeatability or reproducibility.

Multiple studies have investigated the dimensional accuracy of FFF, most comparing how a printed part's measurements differ from the dimensional values of the original digital model (Hanon *et al.*, 2021). This is particularly important to produce customised medical devices, models, and surgical tools, where the part geometry is based on anatomical data. Dimensional accuracy is essential in many cases to ensure patient compatibility. In one study (Hatz *et al.*, 2020) concluded that desktop FFF printers can provide sufficient accuracy for medical models that are suitable for daily clinical practice. They found the overall mean difference between FFF models and their digital STL files of -0.036 ± 0.227mm.

Many studies have focussed on the optimisation of dimensional accuracy of parts compared to the nominal value through modifying process parameters. The most commonly studied parameters are raster width (Kaveh *et al.*, 2015), raster angle (Kaveh *et al.*, 2015), extrusion temperature (Kaveh *et al.*, 2015; Valerga *et al.*, 2018), flow and feed rate (Kaveh *et al.*, 2015), part orientation (Górski *et al.*, 2013; Abdelrhman *et al.*, 2019) and filament colour (Valerga *et al.*, 2018). Valerga *et al.* (2018) also investigated the influence of the relative humidity of filament storage environments on the dimensional accuracy of printed parts.

Dimensional accuracy can be important for individual parts, but equally important between part batches in replicate or repeat parts. Dimensional variance, characterised by batch to batch

dimensional variation whilst all other parameters remain the same Mohamed *et al.* (2018), is less frequently studied compared with dimensional accuracy. Assessing dimensional variability will help to make conclusions about the repeatability and reproducibility achievable with FFF. It is also necessary to draw conclusions around achievable tolerances expected within a batch of parts. Mohamed *et al.* (2018) identify the source of dimensional variability as either the manufacturing process, or the measurement system. Within the measurement system, two sources of variation exist: the measurement device (gage) or the operator(s) of the measurement device.

Although the influence of process parameters on part accuracy has been studied in detail, few have considered the variance attributed to the measurement system in their findings. Instead, a number of parts are measured and these values are compared to the nominal value as a reference, thus providing an accuracy percentage for each specimen (Hanon *et al.*, 2021). In this case, repeatability can be determined through standard deviation calculations. However, the values obtained using this methodology may not represent the true dimensional accuracy or variation of the printing process due to additional sources of variation present in the measurement system used. Understanding the source of this variance is essential to make accurate conclusions about the true capability of a manufacturing system.

4.2.2. Process capability analysis

Researchers have conducted process capability analyses on different AM techniques, including PolyJet printing for plastic components (Singh, 2011; Udroiu and Braga, 2020), FFF for polylactic acid (PLA) (Preißler *et al.*, 2017; Mansour *et al.*, 2020; Siraj and Bharti, 2020) and ABS (Singh, 2014; Sing Rathor *et al.*, 2018), and AM as a casting solution for non-ferrous alloys (Kumar *et al.*, 2016). Their methods vary significantly and will therefore be discussed in more detail.

(Sing Rathor *et al.*, 2018) set out to calculate the capability of a part through three linear dimensions (length, hight and thickness) and the diameter of a hole centred in the cuboid. 20 parts were printed using FFF technology, then measured using a CMM. Measurement data was collected, and X-bar and R-charts were plotted. Findings indicated that all the length and width dimensions (in the XY plane) were underdeveloped, and hight dimensions (in the Z direction) were larger than the nominal value. The error in the Z direction was around two to three times

larger than the error in the XY directions. The diameter of the hole was also found to be smaller than the nominal value, with the hole diameter showing the greatest error of all four dimensions. Cp and Cpk values were found to be larger than 1.33 in all four areas. Due to the upper and lower limits specified by the authors, which allowed a measurement range of 600 microns, the study concluded that the process capability was approximately 300 microns and therefore acceptable.

(Mansour *et al.*, 2020) investigated the process capability of an Ultimaker 2 Extended FFF machine using PLA, through printing parts with different heights and infill patterns. Samples were printed in four rows where the height of samples varied for each row ranging from 20mm to 150mm. Dimensional measurements were taken from the top, middle and bottom of each part and the process capability was calculated. The Cpk value for all samples was less than one, and significantly less than the Cp value, meaning the process was both incapable and uncentered. The Cpk was found to decrease as the z direction (height) of a part increased, demonstrating that process capability is unique to geometrical factors, in this case height and infill, there were discrepancies in the capability values. In all but two cases, the Cp values were less than 1.33, indicating the process was not capable. Therefore, the authors advised that the geometry of the parts should be considered when evaluating process capability.

(Preißler *et al.*, 2017) also conducted a study using FFF technology with an Ultimaker 2 Extended machine. They manufactured 25 parts in PLA and found shrinkage in all dimensions. Similarly to (Mansour *et al.*, 2020), they found very few measured dimensions were higher than the nominal value, although the printing direction was not specified in this study. The process was found to not be in statistical control, where most values were lower than the lower limit. The authors suggested calibration should place all values within the USL and LSL, which was 25±0.2mm, which suggests a Cp value of >1 combined with a lower Cpk value. They concluded that geometrical deviations were within tolerance, suggesting that with improved centring, FFF was capable as an industrial tool.

(Siraj and Bharti, 2020) identify PCA as a popular tool in AM to ascertain how well the process can meet specification limits. They use PCI to determine the level of quality achieved by the FFF process using PLA. Unlike previous work that has focussed on only the Cp and Cpk indices, the authors of this study compute six PCIs, describing the extended number of PCIs as the novelty of the work. 50 samples were produced under the same environmental conditions

with the same process parameters. Measurements were taken of all 50 samples and the allowed tolerances were identified using GD&T standards. The data was analysed to find 6 PCIs which gave Cp values of 1.14, 1.55 and 0.8821 for length, width, and thickness respectively. The Cp value for length was lower than the 1.33 benchmark, although the authors discuss that because it was larger than one, the process was deemed capable of producing accurate dimensions and was therefore thought to be capable. All Cpk values were below one, showing the process was uncentered. The width value of 1.55 was deemed capable, whilst the thickness value was of larger concern due to it being less than one.

The Cpk for length width and thickness were 0.9935, 0.3307 and 0.2394, all below one indicating the process was not centred. Additional indices including Cpm and Cpmk were used. Cpm is the measurement of the ability of the process to cluster near the target, and Cpmk combines Cp, Cpk and Cpm. The percentage of mean quality loss (Pql%) of process output is a statistical tool for the evaluation of quality characteristics of a component. It was calculated to show the mean quality loss, which was 11.67% for length, 5.78% for width and 14.50% for thickness. The Pql% value should be low to show a high-quality product. These methods give additional information about a process and may be more relevant after initial capability studies have been conducted.

(Singh, 2011) set out to investigate process capability of PolyJet printing. They list the key considerations for determining a part to study, stating that the part should be manufactured commercially, and the design should be subject to frequent changes, thus representing batch production. They prepared the component in three different orientations using three different materials. The orientation parameters were selected based upon a pilot study where the dimensional deviation from the nominal value was found to be the smallest in the horizontal orientation. The standard tolerance was calculated to determine the classification of IT grades according to ISO 20286-1 (ISO, 20286-1:1993) (ISO, 20286-1:1993), and an IT grade was assigned to each measured feature. IT grades for each critical dimension were between IT5 and IT13.

They conducted the process capability analysis for four critical dimensions of each part. 16 parts were produced in the same material and orientation, each part was measured for four critical dimensions (D1-D4). Statistical analysis was performed on the four critical dimensions and Cp and Cpk indices were calculated for each. The Cp values were above 1.33 for each

dimension. The Cpk values were similar, with all being greater than one. These values indicate that PolyJet printing was a highly capable process, and the tolerances obtained align with the permissible range of tolerance grades as per ISO 20286-1(ISO, 20286-1:1993).

(Singh, 2014) conducted a PCA on FFF technology as a pattern making solution for plastic components, with the intention of being used in casting or moulding applications. The aim of the study was to understand whether FFF parts provided sufficient replicas. Input parameters included part orientation, material, support material, production cost and production time. Output parameters were dimensional accuracy and part hardness. Horizontal parts were shown to use less support material, along with reduced production time and cost, therefore the horizontal orientation was used for the experiment. 16 parts were produced, and four critical nominal dimensions were identified which were measured using a CMM. Dimensions were statistically analysed where Cp and Cpk values were calculated. The Cp values for each critical dimension were above 1.33 with Cpk values all relatively close to the Cp value for each dimension. These findings indicated that FFF under these parameters was a highly capable process.

(Kumar *et al.*, 2016) investigated the process capability of the ZCast 3D printing process for six different non-ferrous alloy components. Cp and Cpk values were both found to be <1.33, meaning the process was successful in meeting the upper and lower specification limits.

A study by (Udroiu and Braga, 2020) presented a methodology for system performance and process capability in AM, with the main objectives being to define statistical quality tools for assessing the variability of the measurement system, and determining the AM repeatability, AM system capability or performance, and the process capability. They first defined the AM process, considering the digital file type, file conversion process, the type of geometry, material, sample size and process characteristics, like the part placement and build orientation, recognising that each of these factors can directly influence process performance. Firstly, an MSA was performed to identify the variability introduced by the measurement system itself.

The authors then conducted a system capability study by a single operator producing 50 parts in one batch. The variation of the material batch or any variation attributed to the user was not considered in the given variation of the process. A tolerance for ±0.1mm was selected for the parts, based on the ISO 2768-1 (ISO, 2768-1:1989). Initially the Cm capability index was

calculated, giving the number of times the machine variation fits into the tolerance interval. The Cmk value was then calculated which indicated the position of the process spread in relation to the tolerance interval. The requirements for Cm and Cmk were met for the diameter but not for the height.

The second part of capability analysis was the process capability, where three batches of 50 parts were produced. The authors identify the target capability indices as 1.67 in the automotive industry, where excellent capability is between 1.67 and 2 (Arcidiacono and Nuzzi, 2017). The Cp and Cpk values for the height dimension were lower than the target of 1.67 and lower than the other commonly accepted target of 1.33. Cp and Cpk values were both met for the diameter dimension.

The results of the study were then used to identify the IT grade for the parts. The IT grade was IT10 for the height dimension, for 86% of the specimens. The IT grade for the diameter dimension was 22% IT10, 58% IT9 and 20% IT8. Additional microscopy work was completed on critical features for quality inspection purposes. The study concluded with the capable upper and lower limit deviations of the specified artefact using PolyJet technology.

The standard used by (Singh, 2011), ISO 20286-1 (1993), which is related to ISO 286-1, is the system of limits and fits for machined workpieces to address the inherent inaccuracy of the manufacturing method. It was created when “exactness” was found to be unnecessary, and therefore permissible limits, or tolerances, would deduce what variation in size is necessary in manufacturing. The standard refers to fit, which is the relationship between two different parts to be assembled, and tolerance, the permissible variation in size is outlined for different geometrical features, such as shafts and holes. Again, this standard is usually used for metal parts, and these tolerances are unlikely to be achievable with plastic, due to significantly larger deviations with respect to dimension, form and location (ISO, 20457:2018). The standard used by (Udroiu and Braga, 2020), ISO 2768-1 (ISO, 2768-1:1989), is more general, covering linear and angular dimensions, and is therefore more appropriate to use for most AM plastic parts. Although, the need is recognised for new standards specifically for AM processes that are diverse in technique and materiality (Udroiu and Braga, 2020).

4.3. Methodology

4.3.1. Measurement system analysis and verification: Type 1 gage study

An initial measurement system analysis was conducted to select an appropriate measuring tool and validate it for use in the system and process capability studies. Before taking dimensional measurements, a range of appropriate measuring tools were selected. Factors of consideration for the identification of measurement tools included the appropriate level of precision for the manufacturing process under investigation, which should usually be one decimal place more precise than what is necessary. The manufacturing system under investigation, the Ultimaker S5, has a horizontal (XY) resolution of 6.9 microns which refers to the smallest movement of the print head within a layer. Although, it is worth noting that the resolution of the stepper motor does not necessarily reflect the feature resolution of a part, which can only be as small as the nozzle diameter. It has a vertical (Z) resolution of 2.5 microns which refers to the smallest vertical step the print head can move. This enables a layer resolution of 200-20 micron with a 0.4mm nozzle and 600-20 micron with a 0.8 nozzle.

A commonly used measurement tool amongst FFF users generally is a vernier calliper, usually to a resolution of 0.01mm. Measurement systems are classified into grades in ASTM 52902-19 (ISO/ASTM DIS 52902, 2021), which lists hand-held callipers and micrometers as measurement grade A. A calliper is a simplistic and inexpensive measuring tool widely used for both day-to-day and research activities and is usually sufficient for measuring parts produced with FFF technology. Although, when making conclusions about the repeatability of a manufacturing technology in an industrial context, to comply with regulatory requirements, a higher level of precision is necessary, which allows for the identification of process sensitivities which may influence the performance or efficiency of the process. Investigating a range of measurement systems ranging from 0.01mm resolution to 0.001mm will indicate which is the most appropriate tool for the characterisation of FFF dimensional variation, and the potential variation between different manufacturing contexts.

A gage R&R study is suited to a more established manufacturing process where multiple process factors must be considered. Thus, a gage R&R study is usually conducted after a type 1 gage study which assesses the variation from the gage only. A gage R&R provides a more detailed understanding of the variation in both the process and the measuring system, whilst

considering additional factors in the manufacturing process, such as multiple operators. For this study, and in the case of many AM operations, the process was managed by a single operator, making a type 1 gage study an appropriate type of MSA. In a scenario where either an individual printer, or a print farm is managed by multiple operators, a full gage R&R study would be recommended to follow an initial type 1 gage study.

A Type 1 gage study was carried out using three measurement tools. It was an analysis of measurements taken from one reference part by a single operator to determine whether a gage was capable of measuring with small variation (Zanobini *et al.*, 2016). The reference part selected was a calibrated gauge block (calibration was completed using a micrometer calibrated to BS 870:2008 (BSI, 2008).

The three types of measurement system were selected to cover the range of tools typically found across the three identified use contexts for the FFF of Class I medical devices: research, industrial and non-specialist. Firstly, a standard digital vernier calliper with a resolution of 0.01mm was used due to its low cost and high accessibility. As a commonly used measurement tool in most workshops and makerspaces, analysing this tool will indicate the level of measurement error obtained by a lay user under non-specialist conditions. The second tool was a portable measuring arm by Hexagon Manufacturing Intelligence (®Montoire, France), which was expected to be significantly more accurate and precise than the calliper. The arm is compatible with a series of touch probes for metrology and inspection, commonly used in an industrial context. For this study a 3mm ruby tip probe was used with Autodesk (®California, US) PowerInspect 2021 software. Finally, a digimatic micrometer by Mitutoyo (®Kanagawa, Japan) with a resolution of 0.001mm was used, calibrated to BS 870:2008 where the maximum error in the traverse of the micrometer screw was one micron. Details of each study and the reference part used are shown in Table 20.

Table 20: Type 1 gage study variables

Measurement tool	Resolution (mm)	Reference part
Digital vernier calliper	0.01	50mm slip gauge block
Hexagon Romer measuring arm	0.001	50mm slip gauge block
Digimatic micrometer	0.001	15mm slip gauge block

Each measurement tool was used to take 50 measurements of a calibrated reference part. The measurement data was taken and used in a type 1 gage study using statistics software Minitab 19 (®Pennsylvania, US) for each measurement tool. Statistical analysis was conducted, indicating the variability introduced by each measuring tool. A Cg metric was calculated, indicating the spread of the gauge's measurement representing the ratio of precision to tolerance, and a Cgk value which represents the ratio of accuracy to tolerance.

4.3.2. Process capability analysis

4.3.2.1. System capability analysis (SCA)

A SCA was conducted in line with the "hands off" approach, where the indices Cm and Cmk describe the machine capability. Firstly, a part was identified to conduct a SCA. The part needed to be small enough to produce between 20-50 parts per print (batch), therefore a cube with the dimensions 20x20x22mm has been produced. The measurement tool selected, a 25mm micrometer, means the part size was limited to 25mm. The height of the cube was extended to 22mm so the orientation and printing direction could be easily identified. A single STL file was produced and replicated 30 times on the build plate using automatic part placement using CURA (®Ultimaker, Netherlands) slicing software, and the parts were printed using an Ultimaker S5 with Tough PLA (®Ultimaker) filament. The printing parameters are detailed in Table 21, where a 10% infill was selected to reduce the overall printing time of parts, minimising the influence of environmental variability on the printing process. A reduction in mechanical performance would be expected for parts with a lower infill density, however, for the purpose of this exercise which focusses on dimensional accuracy, the mechanical properties are not considered.

Table 21: Printing parameters for system capability analysis of Ultimaker S5

Parameter	Value
Layer height	0.2mm
Infill pattern	Concentric
Infill density	10%
Wall thickness	1.2 mm
Support	None
Build plate adhesion	None
Raster angle	±45°
Air gap	Default (0)
Nozzle diameter	0.4mm
Material	Ultimaker Tough PLA Black
Printing temperature	215ºC
Build plate temperature	60ºC

After printing, parts were marked with chalk marker whilst on the build plate, to identify the X, Y and Z printing directions. Parts were removed by a single operator and measured with the calibrated micrometer which was validated by the MSA. Measurements were taken by a single operator in a temperature-controlled environment of 20±0.5ºC. Three critical features were measured (D1, D2 and D3), the edge lengths of the cube in the X, Y and Z directions, indicated in Figure 45. Measured dimensions for each feature were recorded. The data was plotted on an Xbar control chart using Minitab 19 software to confirm the dataset was normally distributed. A statistical analysis was then completed, and Minitab software was used to compute Cp and Cpk values for each critical feature.

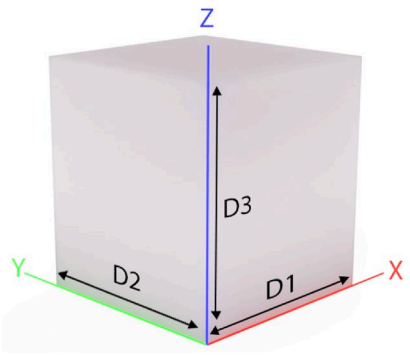


Figure 45: Visualisation of the printing direction of the part indicating the three critical features

Initial process capability was determined with a USL of 20.5 and LSL of 19.5, allowing a ±0.5mm tolerance, experimentally selected as a large tolerance range in relation to the nominal value. Further analysis was conducted, incrementally decreasing the allowable tolerance limit to indicate the lowest possible tolerance the system can operate within that predicts an acceptable level of process capability. A tolerance of mm would be considered appropriate for this type of AM technology, where sub-micron accuracy would not reflect the resolution of the technology. Typically, FFF users would have access to standard measurement devices, such as a micrometer or Vernier calliper, therefore the introduction of more specialist measurement devices would not reflect a realistic use scenario.

4.3.2.2. Process capability: Individual machine (PCA-1)

Process capability of a single 3D printer was evaluated over the production of five batches of 30 parts. No changes to the printer's hardware were made for the duration of the study. To minimise variation occurring from material, a new spool of filament was used for the initial print and the same spool was used for subsequent batches. The location of the printer remained the same, and each batch was manufactured and measured within a two-week period. The build platform was manually levelled before the first batch and between batches, the build platform was clean, and a fresh single layer of glue was applied. The same STL file was used for each batch.

Each completed batch was numbered and labelled to identify the X, Y and Z printing directions before being removed from the build plate, as shown in Figure 46. Measurements of the three critical dimensions were taken using the same verified measurement tool, in a temperature-controlled environment between 20±0.5ºC. Measurements for each were recorded for statistical analysis.

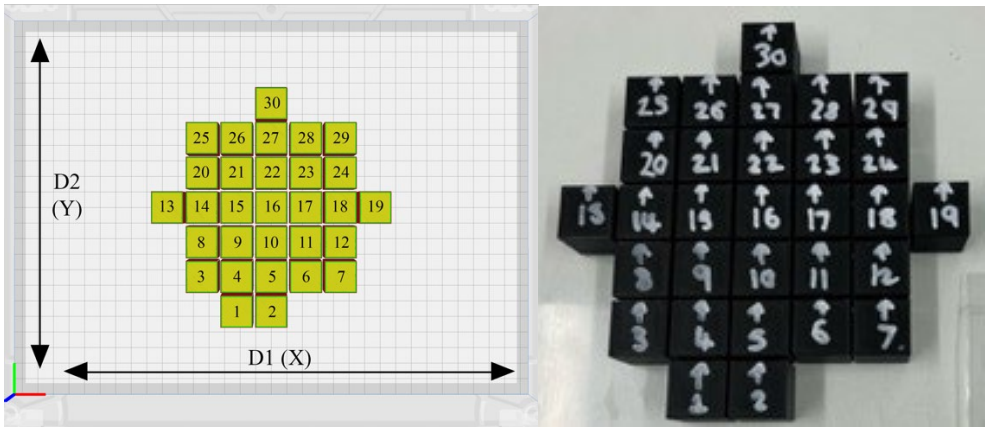


Figure 46: Layout and numbering of 30 parts (left) and 30 printed parts labelled before being removed from the build plate (right)

4.3.2.3. Process capability: Print farm (PCA-2)

Process capability across a group of 3D printers representing a print farm was evaluated. Each printer, numbered 1-5, was an Ultimaker S5 printer configured with a glass build plate and an AA 0.4mm print core. Again, to minimise variation occurring because of filament inconsistencies, a single spool of Tough PLA was opened from sealed and distributed evenly between the five printers. The printers operated in the same room near one another in a stable ambient temperature, representative of the conditions this kind of desktop printer would typically operate, as shown in Figure 47. All operational activities were completed by the same operator, again to minimise operator variability. Each machine was manually levelled before the print beds were cleaned, a layer of glue was applied, and each was actively levelled before printing. A single STL file, identical to the file used for the SCA and PCA-1 was used on each of the machines. Parts were numbered and labelled before removal then measured in a temperature-controlled environment between 20±0.5ºC.

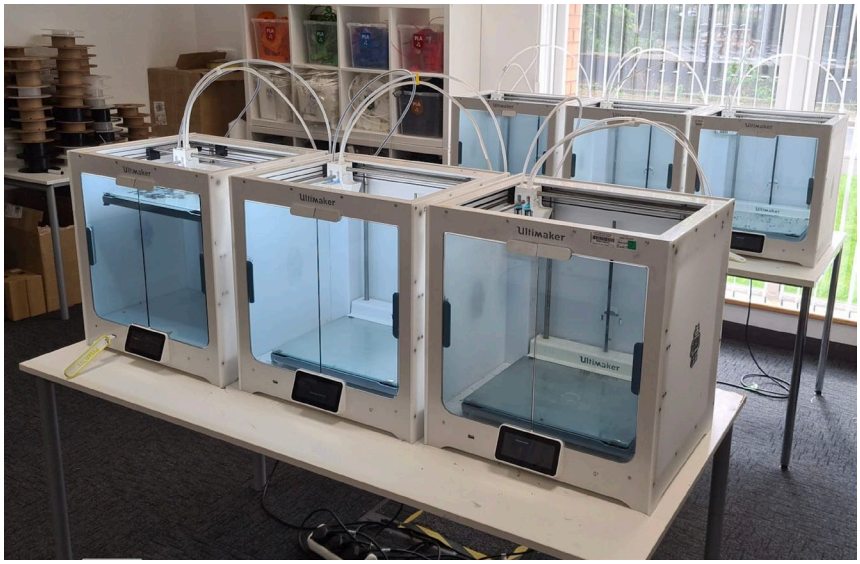


Figure 47: Printing set up for the printers used in PCA-2

4.3.2.4. Statistical methods (PCA-2)

Dimensional data was processed using Minitab19 (®Pennsylvania, US) statistics software. The process must be stable and in control for a process capability analysis to adequately estimate the capability of a process (Kotz and Johnson, 2002). Therefore, an initial I-MR chart was plotted with each set of dimensional data to monitor process stability. A process is deemed stable where all data points lie within three standard deviations from the centre line. Stability evaluations were completed with individual continuous data points and subgroup data points.

The data for each printing direction was plotted to identify the distribution pattern. The data must be normally distributed for normal capability analysis, as the test is fitted to a normal distribution for the process data to estimate the capability. The normality plot and Anderson-Darling test were used to evaluate the normality of data where $p \geq 0.05$ indicated normally distributed data.

Dimensional data was analysed separately for D1, D2 and D3 dimensions. For PCA-1 and PCA-2 all data was entered and grouped in subgroups of 30 representing each batch due to each measured part being produced under the same input conditions close together in time. By analysing the data in subgroups, the natural or inherent variation of the process could be estimated.

4.4. Results

4.4.1. Measurement system analysis and verification: Type 1 gage study

The reference part, a 15mm slip gauge block, was measured as shown in Figure 48. The range of measured dimensions for each reference part is shown in Table 22. The vernier calliper and micrometer performed as expected, however the measuring arm showed a measurement range significantly larger than expected. During calibration testing, the arm measured a length accuracy of ±25µm and achieved a point repeatability of 17µm, which was considerably more precise than the initial measurements taken with the instrument for this gage study at 533µm. During a troubleshooting process, the equipment was relocated to an area with solid flooring and used with a granite table to minimise any measurement error introduced by environmental movement. After re-calibrating (measuring arm*) in the new location, 50 measurements were taken and a range of 45µm was achieved.

Figure 48: 15mm slip gauge block measured with a micrometer

Table 22: Dimensional range over 50 measurements for each measurement tool

** Values obtained after location change and recalibration*

Measurement tool	Reference	Dimensions over 50 measurements (mm)	Range (µm)
Callipers	50.000	40.99-50.04	50
Measuring arm	50.000	49.533-50.265	533
Measuring arm*	50.000	50.001-50.046	45
Micrometer	15.000	15.000-15.001	3

A Cg metric was calculated, which indicated the spread of the gage's measurement representing the ratio of precision to tolerance, and a Cgk value which represents the ratio of accuracy to tolerance. Both values must be higher than 1.33 (Cg>1.33, Cgk>1.33) to show a gage is both repeatable and accurate. Values for %Var (repeatability) and %Var (repeatability and bias) should be 15%. Where this value is higher, it suggests the variation due to the measurement system is large. A type 1 gage study was conducted for each measurement tool considered (excluding the uncalibrated measuring arm) and summary of the results can be seen in Table 23, where every tool was shown to be inadequate by the Cg and Cgk values, and %Var repeatability and %Var repeatability and bias values. This is due to the fine tolerance of 3 microns, which would be unrealistic based on the resolution of the measurement tools selected. Higher resolution measuring tools are available, however these would be inappropriate for the resolution of the 3D printed parts polymer parts being produced.

Table 23: Summary of type 1 gage study results

Measurement tool	Reference (mm)	Tolerance (μm)	Cg	Cgk	%Var (repeatability)	%Var (Repeatability and bias)
Callipers	50	3	0.01	-0.17	2996.60	-116.75
Measuring arm*	50	3	0.01	-0.96	2069.63	-20.74
Micrometer	15	3	0.25	-0.41	80.81	-48.49

Type 1 gage study guidelines state that the resolution should not be greater than 5% of the part tolerance. On the report shown in Figure 49 where the gage resolution was inputted, it was shown to be greater than 5% of the tolerance (0.00127 > 5% of 0.003). The tolerance value is multiplied by the software by 0.10, giving an acceptable tolerance range of 0.0003mm, which is unachievable using a 0.001mm micrometer. This suggests a Cg of greater than 1.33 could only be obtained using a nanometer, which would be unsuitable for FFF parts up to 330 x 240 x 300mm on a standard professional FFF printer. Therefore, to create a realistic scenario representative of the measurement tools available, the tolerance was inputted as30 microns, which yielded the acceptable Cg and Cgk values shown in Table 24 for the micrometer.

Table 24: Type 1 gage study results for the calibrated micrometer with the tolerance adjusted to 30 microns

Measurement tool	Reference (mm)	Tolerance (µm)	Cg	Cgk	%Var (repeatability)	%Var (Repeatability and bias)
Mitutoyo calibrated micrometer	15	30	1.98	1.66	10.09	12.02

The Cg and Cgk values with the allowable tolerance were both greater than 1.33, meaning the spread of the gauge's measurements can be deemed adequately narrow in relation to the tolerance range which is illustrated by the run chart in Figure 49.

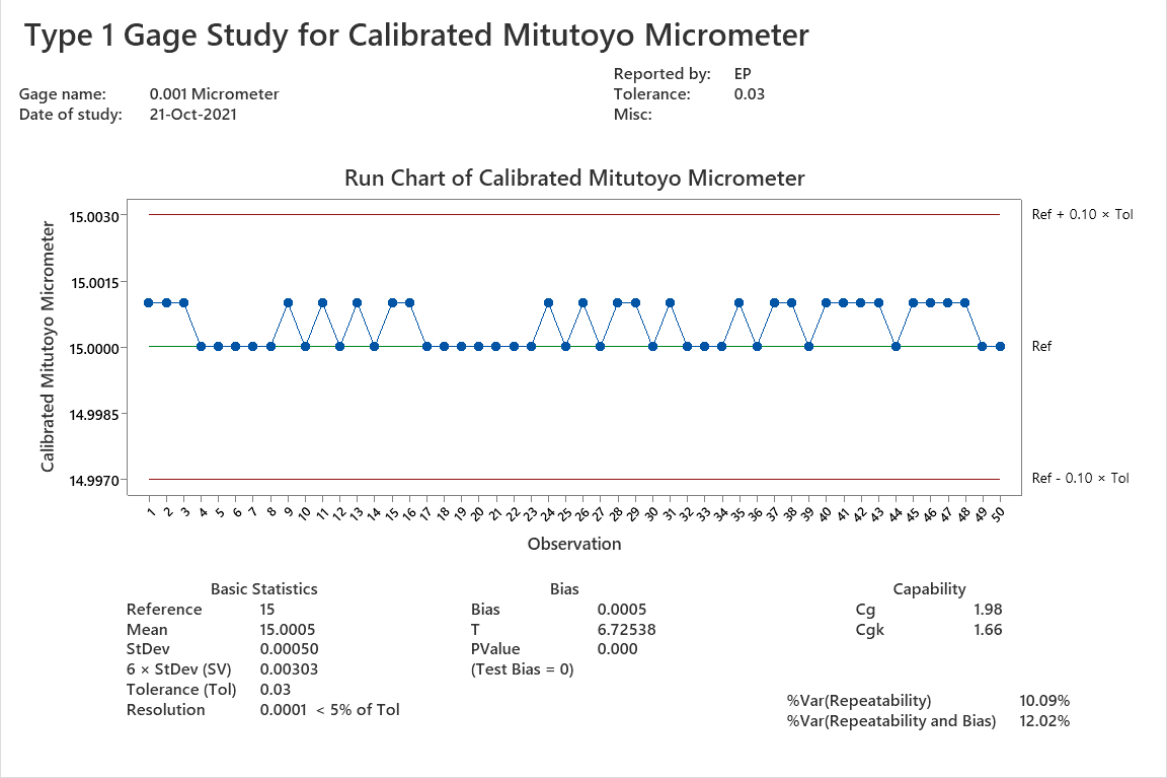


Figure 49: Run chart of Type 1 Gage study for the micrometer and slip gauge part

4.4.2. System capability analysis

The measurement data of 30 parts from a single build cycle was collected and plotted on control charts to visualise the distribution of the data. The control charts, shown in Figure 50 indicate that the process was stable in the X, Y and Z directions respectively by each of the data points lying within the control limits. The calculation of the control limits was done using Minitab software as three standard deviations above and below the mean. This shows that the dataset falls within the tolerance ranges identified, giving confidence of a stable process.

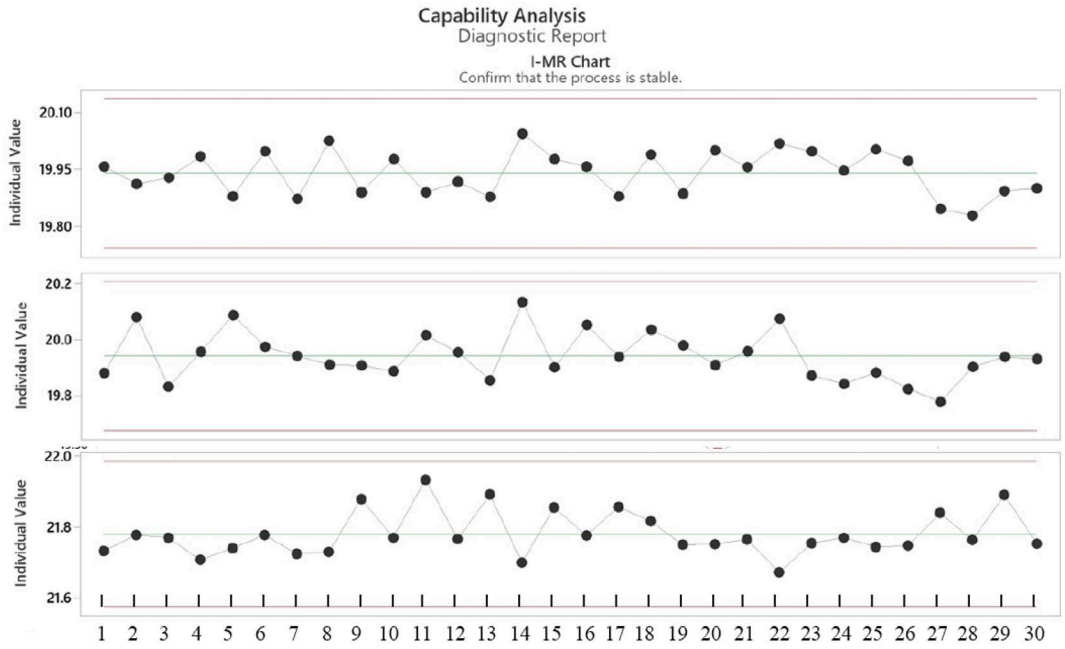


Figure 50: Control chart of D1 (top), D2 (middle) and D3 (bottom) measurements showing individual values

After confirming the stability of the dimensions, the model distribution of dimensions D1-D3 was plotted, as shown in Figure 51. The data was tested for normality using the Anderson-Darling normality test, where D1 and D2 dimensions passed the test ($P \geq 0.05$) and therefore showing a normal distribution, and D3 failing the test ($P \leq 0.05$) showing a non-normal distribution. Normal distribution is a critical assumption of a normal system capability study, meaning normal indices Cm and Cmk cannot be used to predict system capability, due to the assumption that the data is normally distributed, which was not shown to be the case for the D3 dimension. In this case, where data is not normally distributed, or it is not shown to be stable by falling within stable control limits, it can be assumed that the system is not performing adequately, and therefore must be modified to fit the criteria before a normal system capability study can be conducted. It can be assumed in this case that in the D3 direction the process is

not capable. Although, different process capability models exist for datasets that follow a different distribution shape for those with a particular interest in the nuances of data distribution and process capability. However, this falls outside of the scope of this study.

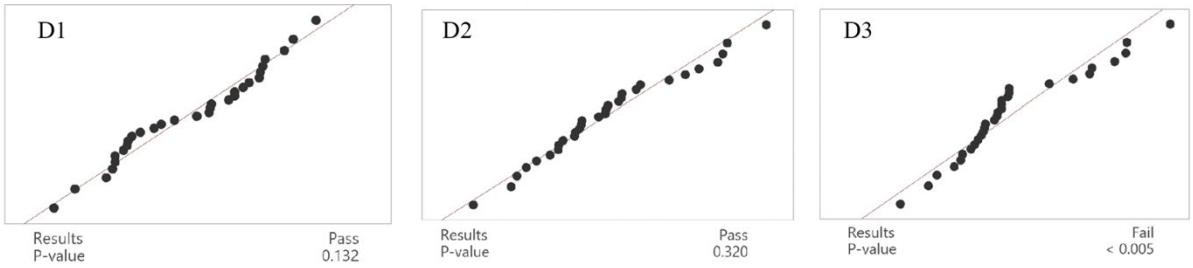


Figure 51: Model distribution plots for dimensions D1 (left), D2 (middle) and (D3) with Anderson-Darling test results (x-axis: process data, y-axis: percent)

The system capability was calculated over three printing directions with a ±0.5mm tolerance, the Cm and Cmk values for each dimension are shown in Table 25. The system showed higher capability in the X-direction than the Y-direction, although with an allowable tolerance of ±0.5mm, the system was deemed capable in the X and Y directions.

Table 25: Machine capability analysis for D1, D2 and D3 dimensions

Dimension	Nominal values		Collected values		Statistics	
D1	ΔD	20	n	30	StDev Overall	0.058048
	LSL	19.5	x_{min}	19.829	StDev Within	0.065358
	USL	20.5	x_{max}	20.044	Cm	2.85
	Tol	1	x_{mean}	19.940	Cmk	2.50
D2	ΔD	20	n	30	StDev Overall	0.086213
	LSL	19.5	x_{min}	19.778	StDev Within	0.088438
	USL	20.5	x_{max}	20.133	Cm	1.88
	Tol	1	x_{mean}	19.941	Cmk	1.66
D3	ΔD	22	n	30	StDev Overall	0.062581
	LSL	21.5	x_{min}	21.672	StDev Within	0.068446
	USL	22.5	x_{max}	21.933	Cm	2.44
	Tol	1	x_{mean}	21.780	Cmk	1.36

The smallest acceptable tolerance ranges for each printing direction were calculated, through reducing the tolerance range until an acceptable Cm and Cmk value was given. The smallest acceptable tolerance value in the X-direction was ±0.3mm, whereas the smallest tolerance

range for capability in the Y direction was +0.3/-0.5mm. As discussed, the Z-direction was deemed not capable based on the distribution of the data and therefore an acceptable tolerance value could not be calculated. These findings suggest that parts can confidently be produced at 20mm ±0.3mm in the X-direction and +0.3/-0.5mm in the Y direction. The actual dimensional range for D1 (ΔD1=20mm) was 0.215mm with a relative standard deviation (RSD) of 0.25, D2 (ΔD2=20mm) was 0.355mm with RSD of 0.43, and (ΔD3=22mm) was 0.344mm with RSD of 0.32.

Whilst indicating the acceptable tolerance of a given process, information around the location of process distribution can also be extracted. Figure 55 shows the distribution of the process data in each printing direction, which was closer to the LSL than the USL on all occasions. Despite the system being most capable in the X direction, the Y direction was the most centred between the USL and LSL. Due to the D3 data following a non-normal distribution, the capability could not be accurately estimated using a normal process capability study. Therefore, the potential and actual process capability for the D1 and D2 dimensions is shown to be capable of operation within a tolerance of 0.6mm (±0.3mm) in the X-direction, and 0.8mm (-0.5mm, +0.3mm) in the Y-direction.

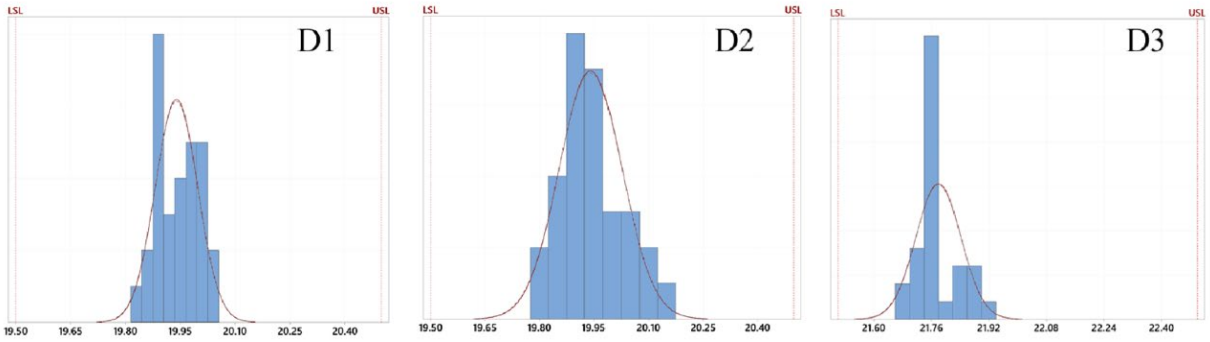


Figure 52: Histograms showing the location of process distribution for measurements D1/X-direction) (left), D2 (Y-direction) (middle) and D3 (Z-direction) (right). X-axis: process data, y-axis: frequency.

4.4.3. Process capability 1 – Individual machine

As for the SCA, the stability of the data was analysed through plotting control charts for each dataset as shown in Figure 53 and Figure 54. Figure 53 shows each individual datapoint (n=150), which were collected across five different build cycles, each containing 30 parts. Figure 54 shows the mean of each subgroup (n=5) of each batch of 30 parts. This approach

would be useful where a process is considered with identifiable subgroups, in which case the process was shown to be stable in the D1 and D2 directions. Stability was not shown in the D3 direction between individual parts, or between subgroups of 30 parts.

The control charts of individual values showed the process to be stable in the D1 direction only, with D2 and D3 datasets not showing stability within the calculated control limits. This meant that for D2 and D3 datasets, one or more of the recorded data points was more than three standard deviations from the centre. The control chart for D3 showed a repeated trend for the five different subgroups, which was identifiable through the numbering system of each part based on its build platform position. This directly indicated a correlation between the parts build location, and the dimensional accuracy in the Z direction. D3 dimensions were smaller than the nominal direction for the lower-numbered parts placed towards the front of the build plate. Towards the middle and back of the build plate, measured values were closer to the nominal value and the final part numbered 30 was measured to be larger than the nominal value. This could be a result of drift in the system, perhaps related to the tension in the belts.

The location of the part on the build platform was shown to directly influence the process capability of the FFF printers studied. This is a particularly relevant finding for specialist users and manufacturers who rely on dimensional accuracy as a quality indicator over multiple parts which would be produced in the same build. To minimise variance attributed to the parts position on the build plate, a single print file should be used where possible which will ensure parts are printed in the same exact location. This finding demonstrates consistent build plate positioning as good standard practice when manufacturing replicate and repeat parts, especially for closely monitored applications or regulated fields.

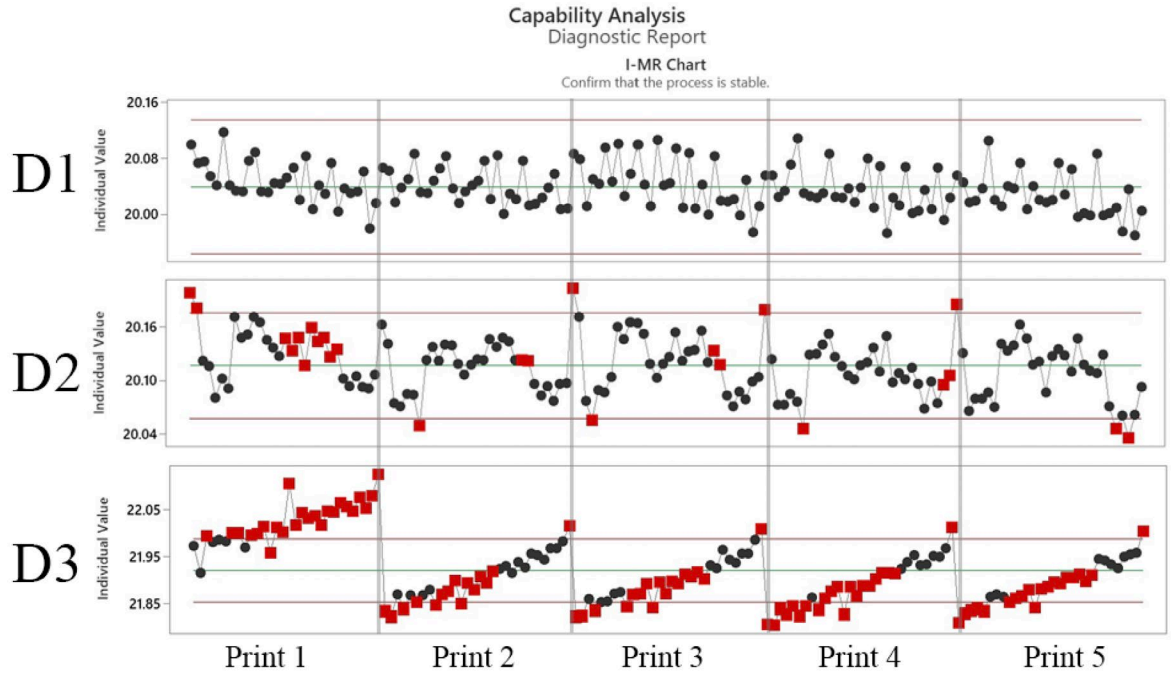


Figure 53: Control chart of D1 (top), D2 (middle) and D3 (bottom) measurements showing individual values. Red markers indicate specific patterns in the dataset, highlighting data points outside the control limits, shifts or consecutively increasing/decreasing trends in the data.

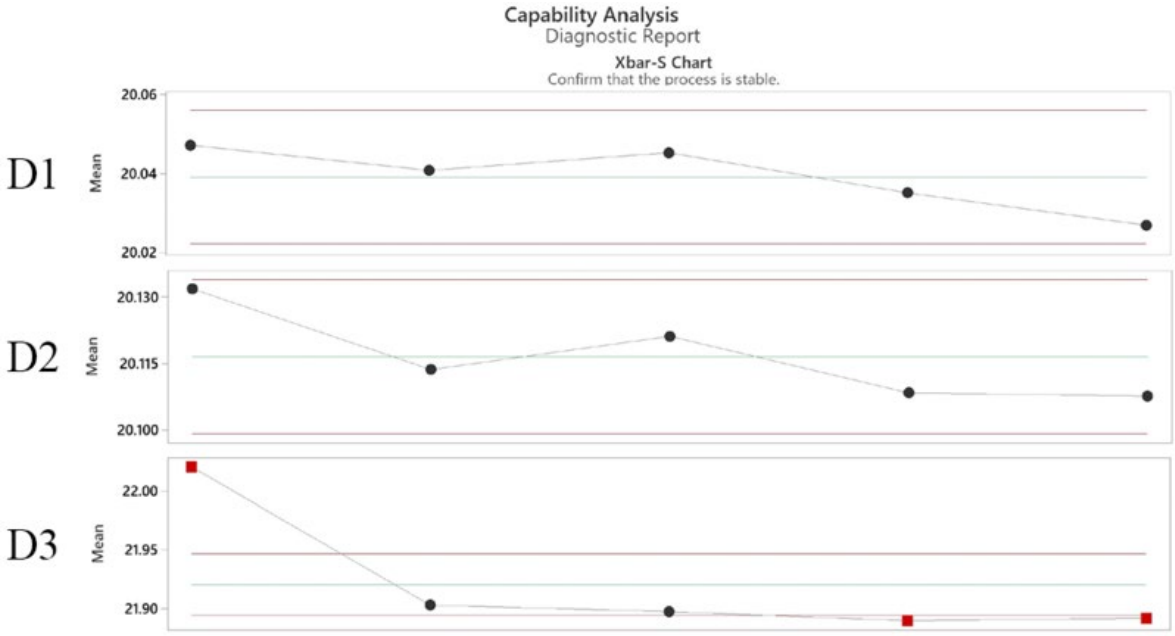


Figure 54: Control chart of D1 (top), D2 (middle) and D3 (bottom) measurements showing the mean values for each subgroup of 30 data points. Red markers indicate data points outside the control limits.

The distribution of the data was tested using the Anderson-Darling normality test as shown in Figure 55. D1 and D2 values failed the normality test ($p \leq 0.05$), showing a non-normal distribution, and the D2 values passed ($p \geq 0.05$) showing a normal distribution. Due to the process showing poor stability and non-normally distributed data, the process capability could not be accurately estimated, and therefore, in a manufacturing scenario, steps should be taken to minimise the instability.

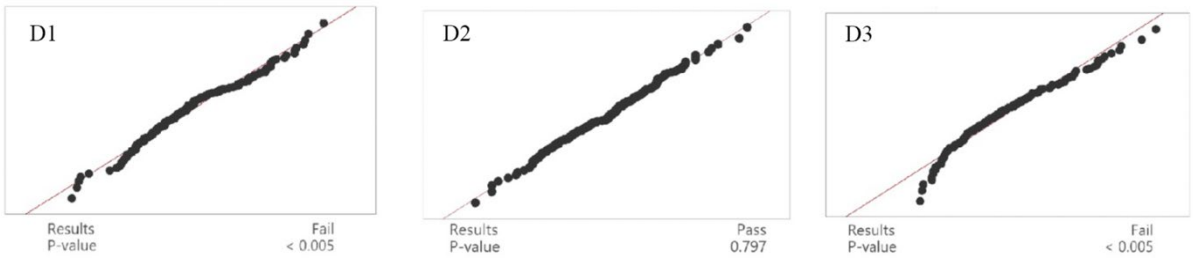


Figure 55: Model distribution plots for dimensions D1 (left), D2 (middle) and (D3) with Anderson-Darling test result

Although the process capability could not be accurately estimated using a normal capability analysis that assumes the data is normally distributed, the data was plotted as histograms to visualise the process distribution location between the upper and lower process limits, as shown in Figure 56. On all occasions, the data was located between the USL and LSL, which resulted in acceptable Cp and Cpk values as shown in Table 26.

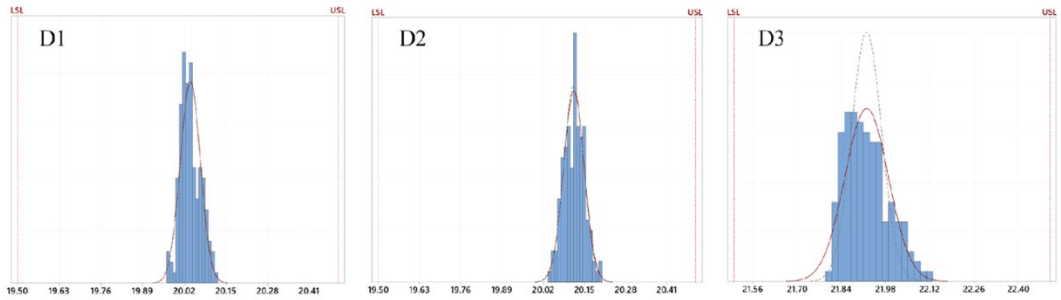


Figure 56: Histograms showing the location of process distribution for measurements D1 (left), D2 (middle) and D3 (right). X-axis: process data, y-axis: frequency.

Table 26: Process capability statistics for D1, D2 and D3 dimensions

Dimension	Nominal values		Collected values		Statistics	
D1	ΔD	20	n	150	StDev Overall	0.031262

	LSL	19.5	x_{min}	19.970	StDev Within	0.030847
	USL	20.5	x_{max}	20.117	Cp	5.40
	Tol	1	x_{mean}	20.039	Cpk	4.98
D2	ΔD	20	n	150	StDev Overall	0.032515
	LSL	19.5	x_{min}	20.203	StDev Within	0.031705
	USL	20.5	x_{max}	20.036	Cp	5.26
	Tol	1	x_{mean}	20.117	Cpk	4.03
D3	ΔD	22	n	150	StDev Overall	0.068869
	LSL	21.5	x_{min}	22.124	StDev Within	0.047759
	USL	22.5	x_{max}	21.808	Cp	3.49
	Tol	1	x_{mean}	21.921	Cpk	2.94

Where a tolerance of 1mm was specified, the printer was estimated to be capable in the X, Y and Z directions. The varying capability indices indicated a different level of capability in each printing direction, meaning the achievable tolerances in the X, Y and Z printing directions were different. The Cp and Cpk indices indicated that the process was most capable in the X-direction and least capable in the Z-direction when the tolerance is centred from the nominal value.

The 1mm tolerance allowance meant that each capability index was found to be significantly larger than the acceptable value of 1.33, indicating it is likely that a smaller tolerance would be achievable for the process. The smallest acceptable tolerance for the D1 dimension was 0.3mm (ΔD -0.1mm, ΔD +0.2mm), resulting in a Cp value of 1.62 and Cpk of 1.5. The D2 dimension had an acceptable tolerance value of 0.3mm (ΔD -0.05mm, ΔD +0.25mm), giving a Cp of 1.58 and Cpk of 1.40. The low standard deviation observed (Table 26) for D1 and D2 is a strong indication of a more stable process that will produce parts more consistently. The smallest acceptable tolerance in the D3 dimension was 0.5mm (ΔD -0.3mm, ΔD +0.2mm), which also had a larger standard deviation indicating lower stability in the Z direction than the X and Y directions.

Finally, the dimensional deviation from the nominal value was plotted in five separate groups for each print cycle as shown in Figure 57. The deviation ranges were comparable across all five print cycles for each dimension, except for print one for the D3 dimension. Whilst prints two to five for the D3 dimension were below the nominal value, most measurements were shown to be higher than the nominal value. The reason for the larger measurements in the Z direction for print one was unknown. In this case, it would be recommended to check for any

issues with the machine, specifically the components relating to the Z- printing direction, such as the belts. After taking steps to mitigate any issues, a PCA should be re-run to see whether the steps maintenance steps taken have resolved the issue. If an unexplained difference still occurs, a more thorough troubleshooting processes should be conducted. The importance of these findings is the awareness it brings to this particular type of issue with FFF hardware, which would have otherwise remained undetected.

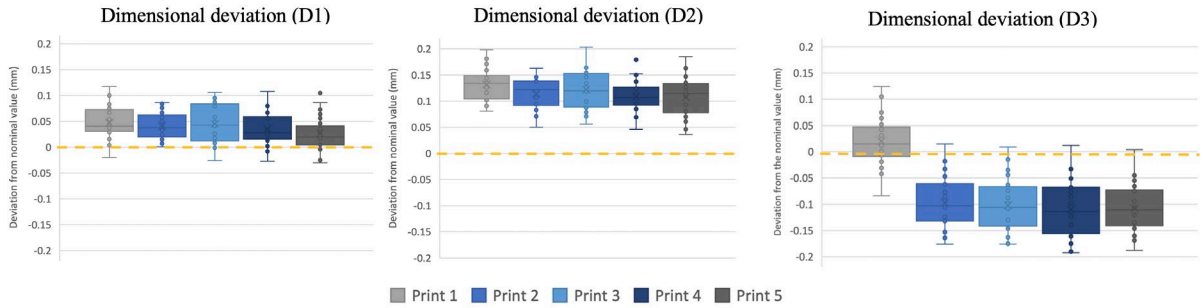


Figure 57: Charts showing dimensional deviation from the nominal value for dimensions D1, D2 and D3

4.4.4. Process capability 2 – different machines (print farm)

The dimensional data collected from 30 parts printed simultaneously on five different machines (n=150) was plotted on control charts, as shown in Figure 58. The machines, as a collective process, were not shown to be stable in the X, Y or Z printing directions. In all cases, the parts produced using the fourth printer appeared to be significantly smaller than those printed on the other printers, in both the D1, D2 and D3 directions. The variability between the measurement data collected from each printer was illustrated by the control charts. Initial observations indicated that the process spread in the D3 direction was larger than observed in the D1 and D2 directions.

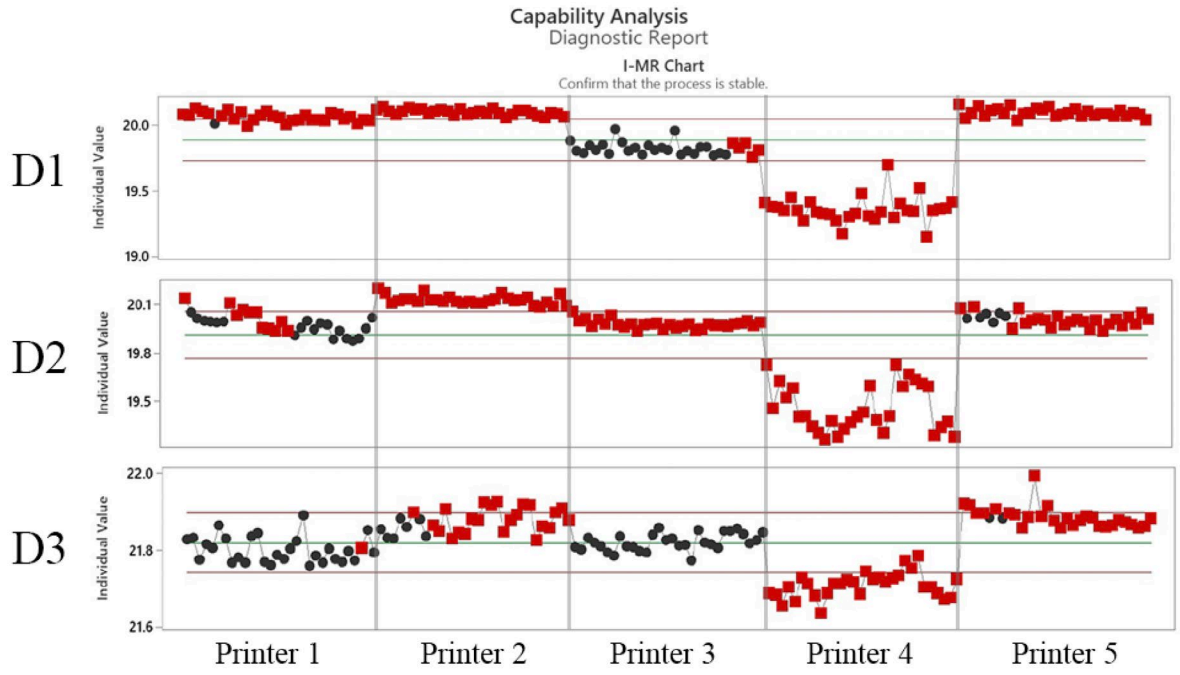


Figure 58: Control chart of D1 (top), D2 (middle) and D3 (bottom) measurements showing individual values. Red markers indicate specific patterns in the dataset, highlighting data points outside the control limits, shifts or consecutively increasing/decreasing trends in the data.

The data was tested for a normal distribution using the Anderson-Darling normality test, plots are shown in Figure 59. Data collected from all printing directions showed a non-normal distribution. The initial stability and normality tests indicate that there was a large amount of variation present in the production process which used multiple 3D printers. Therefore, the process capability could not be accurately estimated, and therefore steps should be taken to minimise variation.

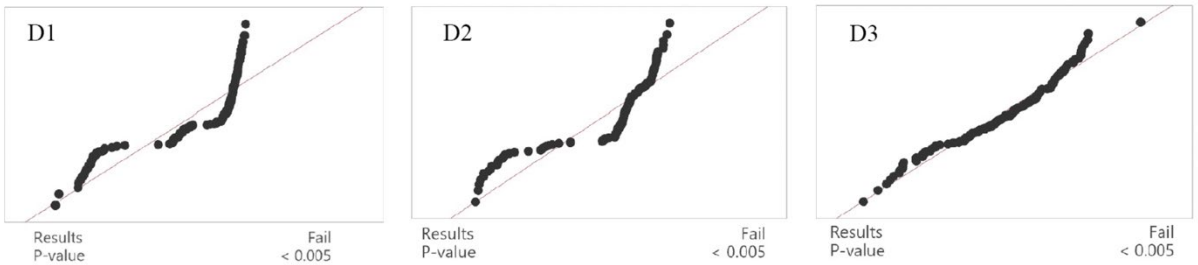


Figure 59: Model distribution plots for dimensions D1 (left), D2 (middle) and D3 (right) with Anderson-Darling test results

Although the process was not shown to be stable, the Cp and Cpk values were calculated based on the dimensional data for each printing direction, shown in Table 27. The distribution (X_{max}-

X_{min}) was considerably larger across five machines than the data collected from parts printed on a single machine. The data range for D1 measurements for parts printed on a single machine was 0.147mm, and over parts printed on five machines was 1.01mm as shown in Table 28. A similar difference was identified for the D2 dimension with parts printed on a single machine ranging 0.167mm and parts printed on five machines ranging 0.926mm. The range of dimensions in the D3 direction was larger than D1 and D2 for samples produced on a single machine at 0.316mm, whereas the parts printed on five printers was 0.356 which was significantly smaller than the reported range for D1 and D2 measurements. This indicated that a larger tolerance was required in the Z-direction, however, across multiple machines it was shown to be more consistent. Significantly more variance was observed in the X- and Y-directions.

Table 27: Process capability analysis statistics for D1, D2 and D3 dimensions based on an allowable tolerance of ±0.5mm

Dimension	Nominal values		Collected values		Statistics	
D1	ΔD	20	n	150	StDev Overall	0.29028
	LSL	19.5	x_{min}	19.151	StDev Within	0.054967
	USL	20.5	x_{max}	20.161	Cp	3.03
	Tol	1	x_{mean}	19.888	Cpk	2.35
D2	ΔD	20	n	150	StDev Overall	0.24489
	LSL	19.5	x_{min}	19.273	StDev Within	0.073949
	USL	20.5	x_{max}	20.199	Cp	2.25
	Tol	1	x_{mean}	19.911	Cpk	1.85
D3	ΔD	22	n	150	StDev Overall	0.069810
	LSL	21.5	x_{min}	21.637	StDev Within	0.029743
	USL	22.5	x_{max}	21.993	Cp	5.60
	Tol	1	x_{mean}	21.818	Cpk	3.57

Table 28: A table showing the range of recorded measurements for each printing direction on each printer

Dimensional range (DR)	P-1 DR (mm)	P-2 DR (mm)	P-3 DR (mm)	P-4 DR (mm)	P-5 DR (mm)	Overall DR (mm)
D1	0.135	0.085	0.214	0.546	0.127	1.01
D2	0.259	0.114	0.117	0.454	0.146	0.926

D3	0.13	0.101	0.085	0.148	0.135	0.356

The Cp and Cpk values indicated that the process was capable with a tolerance of 1mm (±0.5mm), although as discussed, these estimations of process capability were not accurate based on the instability of the data. The process capability histograms shown in Figure 60 visualise the location distribution of the data. Some data points were located below the LSL for both D1 and D2 dimensions, however, all data points were shown to fall within the USL and LSL for the D3 dimension.

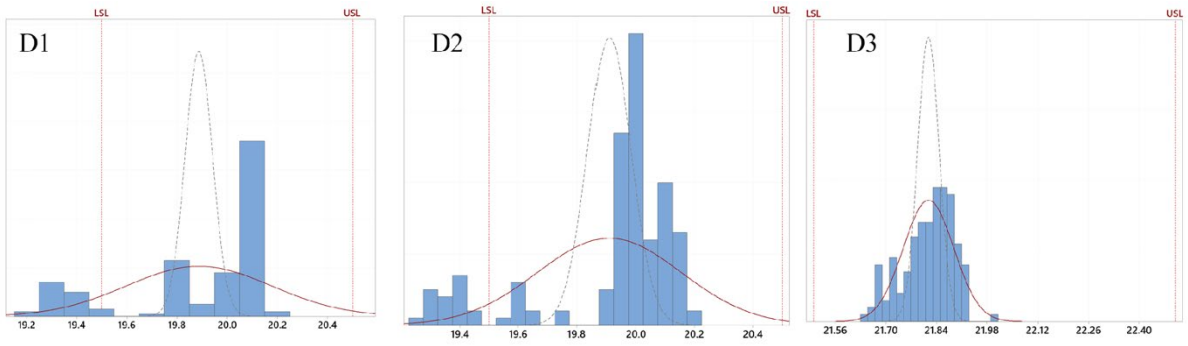


Figure 60: Histograms showing the location of process distribution for measurements D1 (left), D2 (middle) and D3 (right). X-axis: process data, y-axis: frequency.

The measurement deviation from the nominal value for each different printer is visualised in Figure 61. Printer four was shown to produce smaller parts in each printing direction when compared to the other printers used. In the X and Y printing directions, some printers were producing parts smaller than the nominal dimension, and some larger. In the D3 dimension parts were consistently smaller than the nominal value which was also seen in most cases for the individual machine system capability study. Findings indicated that most of the parts produced on six Ultimaker S5 3D printers (one for PCA-1 and five for PCA-2) were smaller than the nominal dimension in the Z-direction. In the other printing directions, the trend was less apparent, and parts were shown to be smaller or larger than the nominal dimension which was expected to be a result of wear and printer maintenance. Further research would be necessary to determine whether replacement and calibration of machine components could improve the accuracy and better meet the nominal target.

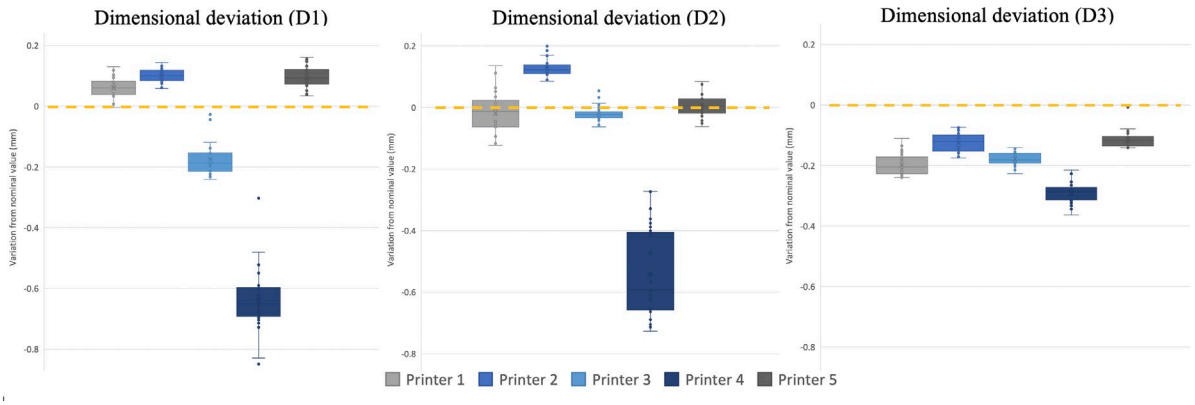


Figure 61: Charts showing dimensional deviation from the nominal value for dimensions D1, D2 and D3

4.5. Discussion

4.5.1. Measurement system analysis

Although a type 1 gage study was deemed the most appropriate in this instance, due to the process being managed by a single operator, in more industrial contexts where multiple variables are present, a full gage R&R study would be recommended. This, however, typically uses parts produced using the process intended for analysis in the PCA, which means the parts being measured for the gage R&R study would be parts printed with FFF technology. In this case, it is important to highlight any additional variation that could be presented through the measurement technique of an FFF produced part specifically. Therefore, an additional set of dog bone samples were produced, which were measured with each of the three measuring systems identified in the type 1 gage study.

A slight brim was noticed on the first print layer of the sample which could directly influence the measured values. This is a common occurrence for FFF due to the first print layer being maintained at a higher temperature through direct contact with the 60°C print bed and spreading under the pressure applied by the subsequent layers. The brim was found to be one layer thick, in this case meaning it was 0.2mm thick, which meant it was extremely fragile, and that contact from the measuring tool damaged and in some cases removed the additional material. The unintentional brim is shown in Figure 62. A thorough inspection of FFF parts should therefore be conducted before a gage R&R study, and any inconsistencies in the parts outer surfaces should be accounted for in the measurement protocol.

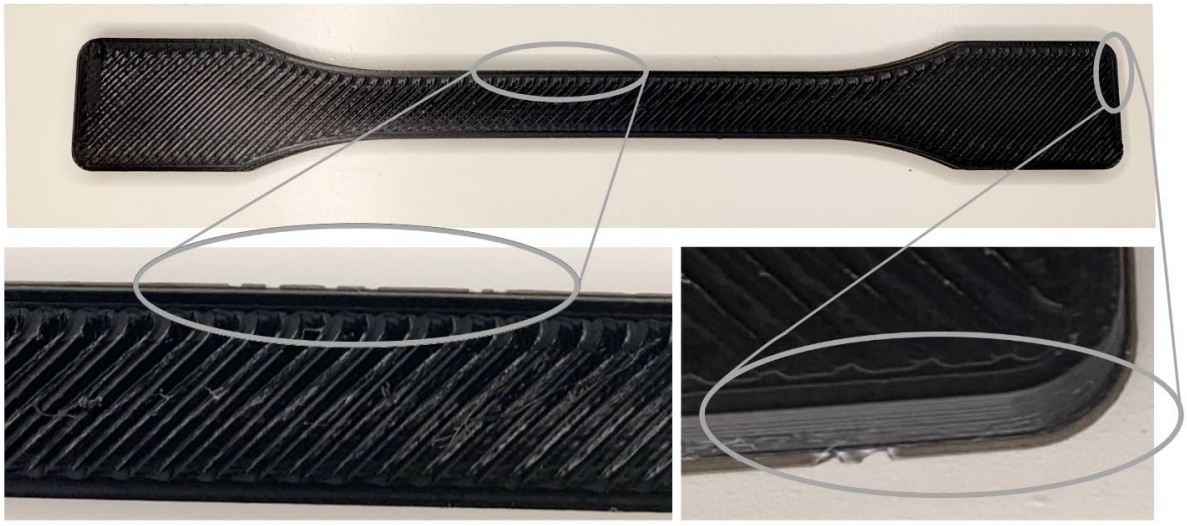


Figure 62: Images showing the single layer brim around the base of the sample

Due to the additive nature of the technology, layer lines naturally exist in the XZ and YZ directions of the part, which again could introduce measurement error depending on whether the gage makes contact with a raised or lowered surface of the part, as illustrated in Figure 63 (A). For this reason, the direction of the layer lines will influence the point of measurement. When a gage with fine contact points is used, particularly a probe with a small diameter, the value would be expected to be inconsistent depending on the positioning of the gage in relation to the layer lines. For an instrument with measurement faces significantly larger than the layer steps, a reliable width measurement can be taken, shown in Figure 63 (B). The geometrical characteristics of FFF parts mean attention must be given to the orientation of a part, and the measurement points which are selected for inspection.

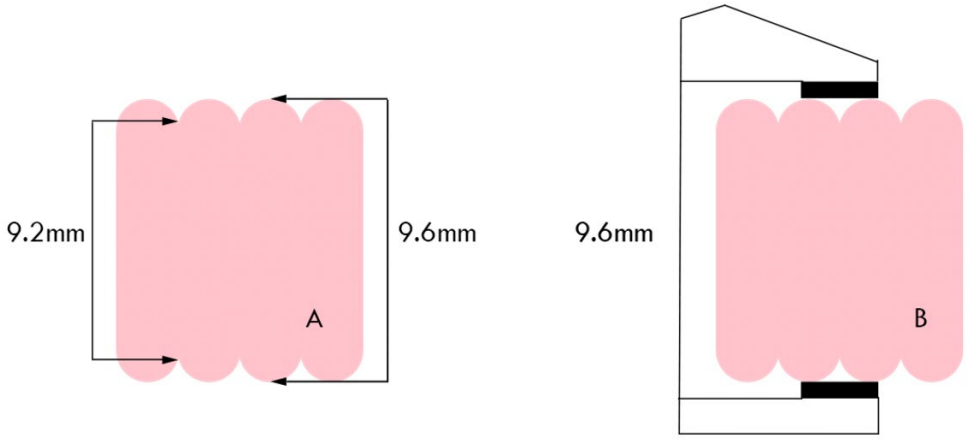


Figure 63: An illustration of the upper and lower measuring points in the XZ and YZ directions (A: point-to-point variation with a probe or calliper; B: micrometer measuring faces make contact with raised surface area).

The importance of measurement system analysis activities has been demonstrated. Advanced metrology equipment, such as the Hexagon Romer Arm, failed to give adequate results, and demonstrated significantly more variability than a standard digital calliper. After a series of troubleshooting activities, the range of measurements was five microns smaller than the range obtained by the digital calliper, still significantly larger than expected. Although the Cg and Cgk values obtained from the dimensions taken using the micrometer were considered unacceptable by general guidelines, a range of 3 microns over 50 measurements is a small variation within the context of FFF technology. This measurement system was deemed as valid, and therefore an appropriate measurement tool to conduct process capability studies on FFF technology.

4.5.2. Process capability analysis

The dimensional variability differed between each of the X, Y and Z printing directions within a single cycle and build, meaning the process capability varied depending on the printing axis. The variability between printing directions occurred randomly between printers, which suggests that the amount of variability was specific to each printer, as opposed to the type or model of the printer. It is therefore expected that the dimensional variability attributed to the printing direction could be a result of wear on the machines. Although no obvious signs of machine wear were observed, the use nature of the printers meant that the types of part produced varied considerably, meaning the workload of each printer and the corresponding running time was expected to vary considerably. Further, it was shown that the process

capability between print cycles and printers of the same make and model could not be assumed. Differences in process capability were observed between multiple parts printed within a single print cycle, but also between print cycles on the same printer. Therefore, it was expected that differences in process capability would be observed between build cycles on different printers, as shown.

The printers used in this study were put into use at around the same time and have been used heavily by multiple users. The printers belong to PrintCity (®Manchester, UK), a university manufacturing facility where students, staff, researchers, and specialist operators frequently use the machines. Therefore, the machines experience heavy use, as well as varied and experimental printing activity which often utilises a wide range of materials. The machines were maintained as and when necessary, and no strict maintenance procedure was adhered to throughout the use period of these printers. This scenario therefore represents the most variable use case where the monitored use and the according maintenance of the machines has been minimal. Consequently, tolerances achieved in this study are likely to represent the largest range of tolerances occurring from the Ultimaker S5 FFF printer.

The presented methodology provided a large amount of information about the printing process in each of the three FFF use scenarios. These activities were particularly useful in identifying whether performance was lacking in a single printing direction compared to others. In addition to this methodology being used as an optimisation tool for functional part manufacturers, it could also function as a troubleshooting tool, both in the manufacturing field and for general use of FFF. It provides a detailed analysis that could potentially be used to identify components that are worn and need replacing. For example, if the capability in the X direction is significantly poorer than the capability in the Y or Z directions, it is likely that maintenance should be focussed on the components controlling that axis on the printer. It could also be a result of poor control of the print head positioning. To overcome this uncertainty, the same study could be repeated on a new printer, which would confirm the variability is a result of use, wear, and/or maintenance.

A widely discussed challenge of FFF printing in general is the determination of tolerances. Generic tolerances published by 3D printer manufacturers can be a useful starting point, however tolerances for machines of the same make and model have been shown to differ significantly in this study. Thus, to obtain tolerances for specific machines, and more so fine

detailed tolerances in each printing direction, this method is expected to be a tremendously useful tool for all users of FFF working with connecting parts. In the SCA a balanced capable tolerance (CT) of ±0.3mm was achieved in the X-direction and an unbalanced CT of +0.3/-0.5mm in the Y-direction. Whereas in the PCA-1, the CT was unbalanced in each printing direction with X as +0.2/-0.1mm, Y as +0.2/-0.05mm and Z as +0.2/-0.3mm. The overall tolerance across five machines studied in PCA-2 was ±0.5mm, which is significantly higher because of the introduction of additional machines.

Overall tolerances can be determined by evaluating the performance of a system or process. However, dimensional accuracy was shown to vary significantly depending on the build plate location of the parts for one of the printers observed, which would directly influence the achievable tolerance of that particular system or process where multiple printers are used. Therefore, careful consideration of the build plate positioning, among other factors, could result in the fine-tuning and reduction of tolerance limits where high dimensional accuracy is critical. Without this type of analysis, the varying dimensional accuracy depending on build platform location would have likely remained undetected. Therefore, the presented methodology was shown to be useful for finding the optimal printing position on the build plate, which gives the best dimensional accuracy.

The reason for variation attributed to the part location on the build platform could be a result of inconsistencies in the drive system, thus affecting positional accuracy. Additional research would be required to determine whether fine-tuning a printer through tightening drive belts and other calibration activities can result in consistent capability for parts produced anywhere on the build plate. The geometry of the part could be an influential factor as it dictates the movement of the print head. A detailed study monitoring the relationship between movement of the print head and dimensional accuracy would be necessary to confirm whether directional changes in the toolpath are related.

Where good repeatability and reproducibility are required, the implementation of strict operating procedures around the use, maintenance and repair of machines is likely to reduce the level of achievable tolerances and therefore increase the capability of an individual printer or print farm. By ensuring controlled use of machines, one would expect wear on components to be similar, further contributing to reducing part-to-part variation. Control measures could include activities such as dedicating print cores to specific materials, eliminating contamination

and ensuring similar wear. Some materials are known to be more abrasive than others, meaning nozzle wear may be inconsistent between machines. This may lead to varying extrusion diameters, thus increasing the potential for dimensional deviation. The full use history of the print cores used in PCA-2 were unknown, which was perhaps a contributing factor to the large variance observed. PCA-1 used a new print core which was used for each of the five print cycles. This could have contributed to minimising dimensional variation between parts compared with those in PCA-2. A systematic approach to replace all components that may introduce variation may be an appropriate step to minimise variation in an already established process.

The variation patterns observed support the recommendation to include process capability in volume FFF manufacturing. This may not be necessary for all users of the technology and should reflect the manufacturers intentions. Using the techniques outlined in this chapter, dimensional capability can be determined, thus providing opportunities for the improvement and optimisation of FFF manufacturing. Optimisation on a local scale is impactful, however such activities could support manufacturing on a wider scale, for example distributed manufacturing.

A key benefit of AM technology is its suitability for distributed manufacturing activities. Digital part libraries are becoming increasingly common, where spare parts can be downloaded from a digital cloud-based repository and manufactured locally. This does however raise concerns over part quality, and whether the physical 3D printed parts meet the intended product specification. A process capability study would be an appropriate tool for benchmarking machines to ensure the manufacturing process can produce parts within the required limits. Note that process capability requirements are highly dependent on the intended application and part functionality, and this methodology is intended to be adapted by including USL and LSL relevant to the application.

4.6. Conclusions

Process capability analysis techniques were applied to three real-word AM scenarios. A SCA is an appropriate first step of determining the process capability of FFF and should be completed prior to a SCA. A PCA of a single machine over five builds was conducted, followed

by a PCA of five different machines was conducted representing a print farm scenario. The novelty of this work relates to the three manufacturing scenarios considered, as to the authors knowledge, this is the first study of its kind to consider process capability across a print farm, which is a highly relevant use scenario in industrial AM fields.

The findings in this chapter are highly relevant to each considered FFF user group, although are thought to be particularly beneficial to manufactures working within an industrial use context. The presented methodologies contribute to the FFF manufacturing field by detailing appropriate methods to both troubleshoot for concerns around dimensional variability, and to determine a range of tolerance ranges for FFF printing. A key finding relevant to every part produced with FFF technology is that process capability can vary significantly between the three printing directions, which could be directly linked to the selection of process parameters, specifically the part placement and printing orientation.

Variability between parts was shown to be lower when batches were produced on the same machine, and larger variance was shown in the Z-direction than the X- and Y-directions. Significantly larger variation was observed for parts printed on different printers, although the variability in the Z-direction was less when compared to X- and Y-directions. Therefore, careful consideration should be given to process capability when using multiple printers within the context of a wider process. A part's location on the build plate was shown to affect the dimensional accuracy and process capability.

The methodology presented is an appropriate method to evaluate the process capability of FFF AM for replicate and repeat parts. The findings were validated through the methods in which the variance was calculated, which analysed the inherent variance from this chapter attributed to different aspects of the hardware. The inherent process variance was calculated through constraining all other potentially influential variables, which were then investigated in isolation in subsequent chapters.

Based on the findings of this study, a series of recommendations can be made to minimise variation and maximise capability, which is a common goal in batch production. For the smallest possible dimensional deviation where tight tolerances are required, parts should be printed using a single printer, in separate build cycles using the same print file to ensure the build platform position is replicated. If multiple parts are being produced within the same cycle,

a basic system capability study should be performed prior to production, so any dimensional deviation attributed to build plate positioning can be identified and minimised, with the appropriate maintenance, fine-tuning and calibration of the machine. To obtain the largest possible range of information about a process, with the intention to fully maximise process capability, a SCA should be conducted on each machine initially, followed by a between batch PCA (PCA-1). Finally, that process should then be repeated for any additional machines introduced into the process, before a final PCA (PCA-2) is conducted for the process in its entirety.

Chapter 5

5. Influence of material storage on fused filament fabrication

5.1. Introduction

The quality of consumables used with fused filament fabrication (FFF), particularly the filament, are thought to directly influence the quality of printed parts. This is due to the extrusion temperature remaining constant throughout a print, which assumes the composition of the filament is consistent throughout, as discussed further in section 5.3.1 . Filament is the term used for threads of thermoplastics which are spooled into a reel to be fed into a FFF 3D printer. Filament is available in an ever-growing range of materials and colours which offer an extensive range of material properties. The composition of different thermoplastics has been engineered for specific applications and usage, which is becoming increasingly common for a wider and more innovative range of applications. 3D printing filament can generally be grouped into the following types of material: standard, engineering (including composites), soluble, recycled and aesthetic.

Standard materials include polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS), the most widely used filaments are available in a wide range of colours. Recent developments in colour include advanced colour matching the globally recognised PANTONE Matching System, a service offered by FiberForce (®Treviso, Italy) (Pantone, 2019). Commonly used engineering filaments include nylon, polyetherimide (ULTEM®) and polyether ether ketone (PEEK). Some are reinforced with additional materials or additives to engineer improved properties such as increased impact strength, stiffness, durability, the capability of withstanding higher temperatures or chemicals, or other specific properties like self-extinguishing. Many of the engineering materials are varying chemical blends of standard materials, for example PLA variations include Tough PLA, PLA plus, metal-filled PLA and carbon fibre infused PLA. These variants are said to improve PLA properties for specific applications by improving their mechanical properties. Soluble materials include polyvinyl acetate (PVA) and high impact polystyrene (HIPS) which can be dissolved in water or d-Limonene respectively. Applications for such materials include parts requiring support structures, specifically in hard-to-reach areas

or enclosed geometry. When used effectively, soluble filaments can enable working features, such as 3D printed hinges. Recycled materials include those which have been manufactured from non-virgin plastics and can include a percentage of recycled material up to 100%, although the blend of virgin and recycled materials varies considerably between suppliers. Materials developed for aesthetic applications include those with specific visual qualities, including glow-in-the-dark pigment; flecks of glitter; wood, stone or metal particles; metallic, iridescent or pearlescent appearance, with more becoming available. Aesthetic materials are commonly developed using a PLA base. This is due to its popularity for prototyping applications as a result of it being non-toxic, easy to print and low-cost.

Manufacturers claim that some filament variations improve the performance of printed parts in terms of dimensional stability, layer adhesion and surface finish. Although, in most cases these claims are not supported by scientific evidence, and the printing conditions to achieve such characteristics are not detailed by the manufacturer. López *et al.* (2015) acknowledge that little information related to achievable quality attributes of a printed part is provided by the manufacturer. Information around dimensional tolerances and surface finish are not provided, nor the comprehensive list of machine configurations required to achieve those performance characteristics.

Despite the fast-paced material advancements and hardware innovations, the use of FFF technology is limited. FFF is not completely industrialised yet due to the large quantity of influential parameters on the process, in addition to limited research, lack of standardisation and communication (Valerga *et al.*, 2018). A number of technological challenges associated with AM generally, identified by the European Commission in 2020, are highly relevant to FFF, including the challenges of process stability, capability and productivity, and the industrialisation of AM technologies (Vallés, 2014). As demonstrated in Chapter four, stability and capability are particularly relevant, to increase productivity and facilitate the industrialisation of FFF.

Multiple complexities are foreseen in providing information about improved performance through filament variation, some of which are demonstrated by the findings from Chapter four which suggests that performance can vary under identical conditions due to additional variability factors. Therefore, a manufacturer would be unable to accurately specify this kind of information. In addition, the storage and handling of the material are said to affect the quality

of printed parts, which will be the focus of investigation in this chapter. Thus, specific information based on an extensive amount of future research would be necessary to guarantee certain quality attributes.

Guaranteeing quality attributes is important for many applications, however, it is absolutely critical for medical device applications, the focus of this work. For medical device applications, especially those intended for regulatory approval, variation should be minimised in every aspect of the manufacturing process to ensure performance is consistent between components within a device or between devices. Variation attributed to material storage conditions would typically be controlled and minimised through using a quality management system (QMS), which should evidence that the manufacturing activities are capable of producing a safe and effective medical device, that conforms to the specification. However, complexities occurring as a direct result of the FFF process, such as the interaction of multiple printing parameters and other factors can make characterisation challenging. For non-specialist Class I medical device applications, not intended for regulatory approval, it is likely that variation attributed to material storage conditions would remain unknown, due to it being undifferentiable from other sources of variation which would not be controlled.

Filament is usually supplied in 750g spools for professional desktop hardware. Due to the build volume limitations of desktop FFF, most individually printed parts are unlikely to use a full spool of filament. In most cases where production is not continuous, especially for the production of small parts, it can take a user up to weeks or months to use 750g of material. As the range of colours and materials options increase, users are more likely to have larger amounts of surplus stock that is rotated to suit different applications or user preferences. For some specific Class I medical device applications, specifically non-specialist applications that are focussed on aesthetic appearance, the use of colour, material and finish is a compelling incentive to use the technology. Although aesthetics would not be the primary consideration for medical devices generally, especially for specialist manufactures, aesthetic factors such as material colour are often an important consideration for non-specialist users in particular, who are producing devices for children. It is therefore important that consideration is given to stock storage methods, and that it is stored appropriately to avoid potential degradation.

For specialist users intending to produce regulated devices using FFF technology, material identification, storage, and stock rotation are all factors that require consideration. Protocols

for such activities are a requirement under ISO 13485 where the manufacturer is required to 'determine the criteria and methods to ensure that both the operation and control of […] processes are effective', and 'implement actions necessary to achieve planned results and maintain the effectiveness of […] processes' (ISO, 13485:2016). Records for traceability of materials should also include the conditions for the work environment used. To implement appropriate procedures, the manufacturer must first determine the susceptibility of material to factors which may cause degradation or cause deviation from the intended result. Once the optimal working conditions for the material are found, relevant steps can be put in place to ensure activities related to material storage and handling are monitored and controlled.

For FFF to remain accessible, and for its use in wider industrial applications, the process must be as efficient as possible. This research intends to investigate variation occurring in printed parts where filament has been exposed to different humidity conditions during storage. Filament is likely to be exposed to different humidity conditions depending on its use and storage environment. For example, non-specialist users with non-specialist equipment are more likely to store material in extreme environments that are too hot, cold, humid or are affected by contaminants like dust. Specialist and research users are more likely to have access to climate-controlled areas, specifically designed for material storage. This research will indicate the effects of storage conditions on the filament and printed parts, so manufacturers and different types of FFF users can make informed decisions about where to store their stock for optimum performance, whilst providing evidence that can be used to create any relevant quality management procedures and documentation, expected to be of particular interest to specialist users of the technology.

Current guidance on material storage varies between manufacturers, with many manufacturers not providing any storage recommendations (Valerga *et al.*, 2018). Most commercial filaments are supplied in vacuum sealed packaging with desiccant to stop the filament from absorbing moisture from the air. When filament cannot be stored in low-moisture environments, (Zaldivar *et al.*, 2018) suggest it is good practice to dry polymeric filaments before use. Solutions include independent vacuum sealable storage boxes, powered humidity-controlled storage solutions and automated multi-material feeding stations with powered dehumidifiers. There does however seem to be some ambiguity around the optimal humidity range for storing 3D printing filament. The DryBox 3D from Essentium (®Essentium, Texas) specifies a storage range of <1% relative humidity (RH) (Essentium, 2021), PolyBox Edition II by Polymaker

(®Polymaker, Shanghai) maintains <15% RH (Polymaker, 2021), whilst the Material Station from Ultimaker (®Ultimaker, Netherlands) maintains <40% RH (3DGBIRE, 2021) and others not specifying a humidity range.

The aim of this chapter is to determine whether varying storage conditions for filament, relating to moisture exposure, affect the quality and performance of FFF 3D printed parts. In the case that quality was affected by storage conditions, recommendations for enhanced filament labelling may be necessary, including the specific storage and usage conditions required for the material to perform as intended. Information as such may play a pertinent role in improving the stability and therefore capability of the FFF process, increasing its suitability for industrial applications.

5.2. Characterisation techniques

To understand the impact filament storage might have on the material, printing process and end-use printed parts, materials must be analysed to understand whether humidity exposure changes any of their properties or behaviours. To do this, a number of techniques can be utilised. Techniques to investigate the properties and behaviour of raw 3D printing filament include thermal analysis and geometrical analysis. Techniques to investigate the influence of humidity exposure on the printing and performance of 3D printing of parts include mechanical testing, geometrical analysis, and observational analysis.

5.2.1. Thermal Techniques

In order to aid the reader in their understanding in the following literature review of this topic, which looks into research aspects which have not been commonly investigated in the field, the most commonly used and referenced characterisation techniques and the associated meaningful parameters are included here.

Thermal analysis is used to explore the thermal properties of polymers. The most commonly discussed thermal properties of polymers include glass transition temperature (T_g) and melting temperature (T_m) amongst others. T_g is the temperature of polymers without clearly defined structures, amorphous polymers, that causes changes to occur in the thermal properties as a

result of molecular mobility (Campo, 2008). Below the T_g, physical properties change to a crystalline state where the molecules have little mobility. Above the T_g, they have rubbery behaviour (Ebnesajjad, 2016). The melting temperature (T_m) describes the transition of a solid phase into a liquid phase. Other properties include thermal expansion, thermal conductivity, heat absorption, decomposition temperature and density. Thermal analysis can also indicate ageing processes of materials, and how they change after exposure to specific conditions.

This information is often an essential contribution to the quality control process where testing can verify whether a polymer will behave or perform as expected for specific applications. There are four commonly used thermal analysis techniques: differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), thermomechanical analysis (TMA) and dynamic mechanical analysis (DMA). Three of which, DSC, TGA and DMA, are used frequently in literature for the characterisation of polymers after exposure to moisture.

A dynamic mechanical analyser is the instrument used to carry out the DMA technique, which is used to characterise the viscoelastic behaviour of most polymers. A material sample is held in position whilst a force motor within the instrument subjects it to controlled stress or strain. This is done sinusoidally, meaning it is varied according to a sinusoidal wave, or sine wave. The DMA process measures stiffness and damping, where stiffness is the ability of a material to resist elastic deformation, and damping describes the energy that is dissipated. These behaviours are reported as modulus and tan delta, respectively. The modulus can be expressed as in-phase modulus and out-of phase modulus when under sinusoidal vibrations. In-phase modulus is expressed as storage modulus (E') which reflects the energy stored, and loss modulus (E") is the out-of phase component reflecting the energy lost. The loss modulus curve (E") indicates the polymers transition from solid-to-rubber, which can be identified as the glass transition temperature (T_g) by the peak of E" (Zaldivar *et al.*, 2018).

A higher E' value indicates greater elasticity of the material when a sinusoidal force is applied, which refers to the materials ability to resist deformation under force. A higher E" value indicates a higher amount of energy is lost from the specimen. Tan delta (Tan δ) is the difference between the storage modulus and the loss modulus (E'/E"). This determines the dampening characteristics of the specimen, indicating the viscoelastic properties of the material. Increasing tan δ value indicates a material has more energy dissipation potential.

Decreasing tan δ implies more elastic behaviour, meaning there is more potential to store and return energy rather than dissipating it.

The DSC technique measures the heat flow in or out of a sample whilst being exposed to a controlled temperature program. The technique allows the analysis of multiple properties of a material, including thermal stability, T_g, T_m, crystallization and specific heat capacity. There are two types of commercially available DSC instruments: a heat flux type and a power compensation type. A heat flux DSC works by varying the temperature of a sample unit, which includes the sample to be tested and a reference material, in a specific program. This allows for the temperature difference between the sample and the reference material to be measured as a function of temperature. Secondly, The power compensation method applies thermal energy to both the sample and reference material chambers which are separate and measures the thermal energy change of the sample holder as a function of time.

TGA is a process that determines the mass of a sample whilst being heated. TGA is carried out using a tool called a thermogravimetric analyser, which consists of a sample pan on a precision balance which are located inside a furnace which can be heated or cooled. A purge gas either oxygen, argon or nitrogen, or in some cases a specialty gas is used to control the sample environment that the sample only reacts to temperature. The data collected from the process forms a TGA thermal curve, which can reveal the mass loss related to volatile components, in this case moisture. The data provides insight into the decomposition of the material, and the separate components within.

5.2.2. Mechanical Techniques

Mechanical analysis techniques are used to characterise the behaviours of materials or parts under specific conditions. The most commonly used technique in the literature is tensile testing, which records a series of force and elongation data while force is applied to a dog bone sample. This method generates a force-elongation curve, which with added dimensions can be used to plot a stress-strain curve from the data. This can then be used to derive basic material properties. The stress-strain curve, an example is shown in Figure 64, indicates the three main types of behaviour of a material, which are separated by yield points. Firstly, the material demonstrates elastic behaviour, during this stage the material has the ability to return to its original form once the force has been released. Secondly the material enters a stage of plastic behaviour, at which

point the sample becomes permanently deformed at will not return to its original form (Figure 64-B-C). If force applied is larger than what the part can withstand, it will rupture and break. At this point, the ultimate strength (Figure 64-C) of a sample is given. Commonly discussed properties include the modulus, elongation, and max stress and strain.

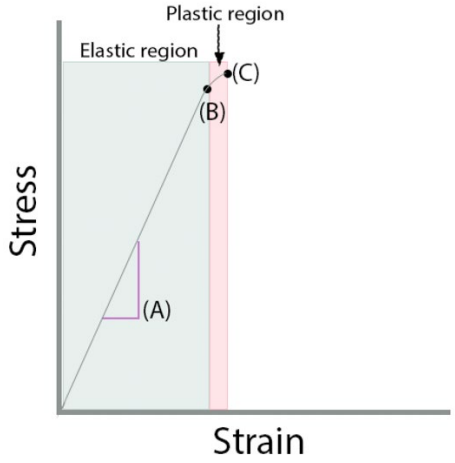


Figure 64: A typical stress-strain curve for brittle plastic showing (A) modulus, (B) yield strength, (C) ultimate tensile strength followed by fracture

Samples printed in two orientations are commonly tested. Samples printed horizontally (XY orientation) are used to test the tensile strength in the longitudinal direction, where the applied force is parallel with the direction of layer lines. Vertically printed dog bone samples (XZ orientation) are used to test tensile strength in the transverse direction where the force applied is perpendicular to the layer lines. Vertical dog bone samples can be used to indicate the layer adhesion strength, or how well adjacent layers have bonded. Figure 65 shows a visual representation of the layer line directions.

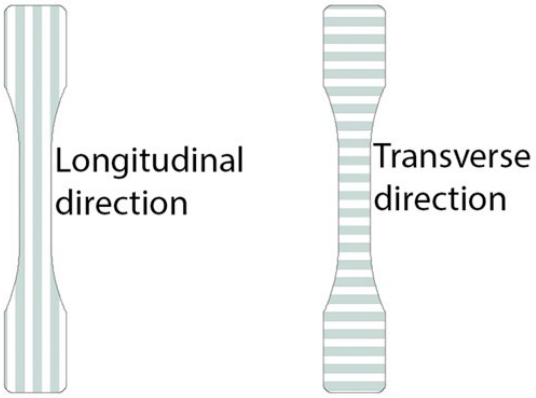


Figure 65: A visual representation of the layer direction for vertical and horizontal printed samples

By analysing the mechanical properties of parts, observations can be made on the effects of moisture on the overall strength of a part, changes to its elastic or plastic behaviour, as well as all other changes to the part's condition.

5.2.2.1. Elongation

The elongation of a sample is a type of deformation which can indicate the behaviour of a sample when force is applied. As with the Young's modulus, elongation is a relevant property to investigate, helping to build a picture of how that material will perform when force is applied.

5.2.2.2. Maximum stress and strain

Maximum stress is the maximum amount of stress that can be applied to a material before it breaks, giving the tensile strength, or sometimes referred to as the ultimate tensile strength (UTS), of that sample. Strain is a measure of the deformation of a material as a result of applied stress.

5.2.2.3. Modulus

The modulus, or elastic modulus, is a property that represents stiffness when normalised to the dimensions of the material. Modulus is defined by the ratio of stress to strain during the elastic stage of deformation. There are different types of moduli which are differentiated by the way in which they are calculated. Young's modulus, one of the most common types of moduli, is the slope of the curve in the elastic behaviour stage shown in Figure 64.

The modulus and stiffness are relevant properties to consider across research and real-life applications. In many cases, a material or part may be subjected to a force as part of their application, especially parts intended to be functional. Therefore, understanding how that 3D printed part will perform when force is applied is essential. Printed parts that are undergoing stresses in their use application may perform differently depending on the storage conditions of the materials used, it is therefore important to understand if there is any difference in performance and use this information to reflect on what this means in the context of end-use FFF parts.

5.2.3. Visual techniques

Typically, two types of microscopes are used to assess the surface and structure of printed samples or specimens of raw material, or in the case of FFF, samples of printing filament. Firstly, standard optical microscopes, sometimes referred to as light microscopes (typical maximum magnification of 1,000x), have been used to identify any voids or defects in the structure of samples. Scanning electron microscopes (SEM) are also used, providing a higher magnification power (typical maximum magnification of 100,000,000x) and greater depth of field, resulting in improved image resolution. SEM works by scanning with electron beams to create an image. SEM also has additional capability to view three-dimensional structures of sample surfaces whilst offering greater depth of field. A micro computed tomography (micro-CT) scan is another imaging method used to produce high-resolution 3D images using X-rays. Micro-CT scans are particularly useful to see inside a part without using any destructive techniques.

5.2.4. Geometrical techniques

Geometrical analysis techniques among literature commonly refer to taking dimensional and weight measurements. These are widely used techniques to characterise geometrical changes as a result of modifying input or process parameters. Additional topographical characterisation techniques have been used to evaluate surface quality. These studies have used a contact profilometer to determine surface roughness, another indication of quality which is more applicable to some applications than others.

Parts should be characterised using techniques relevant the part's intended functionality. They can be used initially to identify a performance range a part is expected to perform within, before being used for more detailed testing, such as to identify the effects of moisture. Material and part characterisation is a necessary step to demonstrate a part can meet the performance specification requirements, which is a critical part of developing a Class I medical device intended for regulatory approval.

5.3. Literature review

A systematic literature review on the effects of humidity and environmental moisture on aspects of the FFF printing process was carried out to identify all relevant literature. The search

was kept broad to identify literature related to the printing process, but also the effects on the printed parts and printed part performance. Firstly, grey literature sources were identified by searching through troubleshooting steps from 3D printer and filament manufacturers. Sources were found to include websites, forums and community user channels. The methodology used to form a systematic literature review included two Boolean search strings: (("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND “humidity”, and (("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND (“humidity” OR “moisture content”). They were used to search both PubMed and Scopus databases. The total number of results retrieved was 747. Table 29 details publication excluded by abstract, excluded by full text and retained for review. The inclusion-exclusion criteria applied to the three appraisal stages included: (1) articles must be written in English, (2) full text versions of the articles must be available (either through institutional or open access), (3) must be focussed on polymer FFF; publications focussed on composite or metal FFF were excluded. To identify additional relevant sources of literature, further exploratory research was conducted using the backward snowballing technique (Wohlin, 2014). Here, reference lists from retained publications were used to identify additional relevant sources.

Table 29: Search terms and results retained for PubMed and Scopus databases

Search term	Database	No. of records	Excluded by abstract	Excluded by full text	Final no. retained
(("FDM" OR "fused deposition modelling") OR ("FFF" OR "fused filament fabrication") OR (“ME” OR “material extrusion”)) AND (“humidity” OR “moisture content”)	PubMed	150	140	4	6
	Scopus	597	572	10	7

The effects of moisture on 3D printed parts have been studied, although the literature does not present a comprehensive picture of the effects of moisture on multiple performance

characteristics. The literature can be categorised generally into two areas, firstly studying the effects on the filament as a material, and secondly studying the effects on a printed part. A third area of interest is the performance of printed parts when used in high moisture environments. Although this is not directly relevant to the effects of filament storage, it is relevant more widely to the use of FFF for functional parts. Considering the lifecycle of FFF medical devices is important due to the wide range of use environments. Worn devices, such as casts or splints, could experience frequent and prolonged moisture exposure, and therefore any degradation over time must be considered. The natural anisotropic structure of FFF parts changes the water absorption and potential degradation of parts (Moreno Nieto *et al.*, 2021). A review of literature in this area will help to define future research directions necessary to advance the field further.

The effects of humidity on FFF filament during storage, and the FFF process itself, have been insufficiently studied (Fang *et al.*, 2020), despite a number of reports indicating that moisture exposure could significantly influence printing quality and performance parameters (Halidi and Abdullah, 2012; Valerga *et al.*, 2018; Fang *et al.*, 2020). Fang *et al.* (2020) recognise humidity as a primary source of printing defects in FFF.

Grey literature sources suggest filament exposed to moisture can lead to weakened interlayer adhesion, undesirable surface finish (Landry, 2016), weakened filament due to micro-breaks, extruder jams/blockages and low quality prints (filament2print, 2018). PLA is said to have 'moderate' resistance to moisture (filament2print, 2018), although, what does moderate mean to FFF users, and what steps to they need to take to prevent material degradation as a result of moisture exposure? Before understanding the effects of moisture for highly controlled industrial FFF applications, they must first be understood for FFF printing generally, for users of the technology to make informed decisions around their material storage protocols and decisions around purchasing hardware with humidity control capabilities.

5.3.1. Effects of moisture exposure on filament

Zaldivar *et al.* (2018) investigated both the absorption characteristics of ULTEM® 9085, and how it affects the FFF process for 3D printed parts. On assessing moisture absorption, the weight gain of five filament specimens placed in each relative humidity (RH) environments (50, 72, and 100% RH) were periodically measured and recorded, and the moisture content was calculated versus time compared to initial dry mass until stabilization was achieved. Tests were

performed at the following temperatures: 25ºC, 65ºC and 100ºC. Findings indicated that the moisture uptake of ULTEM® 9085 was significantly higher in the first 25 hours of moisture exposure, which plateaued at maximum saturation content.

Similar findings were reported by (Fang *et al.*, 2020) when dry polycarbonate (PC) filaments were exposed to four different humidity levels (10%, 30%, 50% and 70%RH) for 24 hours, which resulted in four different uptakes of moisture given as a percentage by mass (0%, 0.05%, 0.1% and 0.15% mass) which were measured using a lab balance. The initial absorption rate was very high before gradually levelling out and reaching a plateau. The filament with the highest moisture content (0.15% by mass) held up to 11.7% porosity by volume.

Two studies utilised thermal analysis techniques to observe the effect of moisture on the T_g of ULTEM® 9085 and ABS respectively (Halidi and Abdullah, 2012; Zaldivar *et al.*, 2018), finding that moisture increases resulted in a decrease in T_g.

Zaldivar *et al.* (2018) analysed the melt flow characteristics of ULTEM® 9085 to evaluate changes in the flow characteristics when moisture was present. They tested dry material and material with a moisture concentration level of 0.2%. The 0.2% moisture material indicated a higher index value, which suggested that it had a higher flow rate and therefore reduced viscosity. This can be problematic for 3D printing, due to the programming of an FFF printer being set mostly based on the manufacturer's specification. For example, each material has advised print settings, including extrusion temperature, build plate temperature, flow rate, fan speed etc. Therefore, the presence of moisture in a material can mean the material is no longer optimised for printing in line with the manufacturers recommendation and will flow excessively based on the pre-programmed settings for dry material.

The most concerning factor here is that typical visual inspection tests could indicate a quality part, failing to show issues or defects in the part. In an end-use part, unexpected mechanical properties due to moisture content in filament could lead to performance and safety failings. There appears to be a window where a certain level of moisture content is acceptable. As mentioned previously, 0.1% moisture showed improved consolidation, which could result in porosity decreasing 15.7% which would often be desirable. Whereas 0.16% moisture content resulted in unwanted porosity, an approximate increase by 20%, or trapped volatiles, which could potentially lead to bonding degradation (Zaldivar *et al.*, 2018).

Nozzle blockages and extruder jams have been reported in grey literature sources (filament2print, 2018). A single study investigated the effects of moisture on filament diameter. Halidi and Abdullah *et al.* (2012) observed the diameter of ABS filament samples over prolonged exposure to moisture. The diameter increased in line with prolonged moisture exposure, but the expansion was not large enough to constrict material flow inside the nozzle which had an allowable tolerance of 1.8mm in diameter.

5.3.2. Effects of filament moisture exposure on FFF printed part

This section focusses on literature around the performance characterisation of FFF printed parts as a result of filament being exposed to different moisture levels. Valerga *et al.* (2018) demonstrated that temperature changes were shown to influence the dimensions of printed PLA specimens and increase the amount of air bubbles between layers. Higher extrusion temperatures showed extruded filament rasters were smaller in height and wider in width, which is believed to be a result of increased material viscosity at higher temperatures combined with longer cooling times, thus allowing the filament to spread further (Valerga *et al.*, 2018). In turn, this results in larger dimensional deviation at increased temperatures in both the XY and XZ planes. Whilst it is generally agreed that higher printing temperatures decrease material viscosity (Signori *et al.*, 2009; N. Turner *et al.*, 2014; Valerga *et al.*, 2018), combined with reduced T_g of materials, the effects of dimensional deviation could become more significant. The dimensional deviation reported by Valerga *et al.* (2018) was around 0.35mm at the highest tested temperature, 240ºC.

3D printed samples of different materials were visually analysed using microscopy by Zaldivar *et al.* (2018). Surface analysis of ULTEM® 9085 samples printed with filament with >0.4%wt moisture content revealed significant irregularities in the surface finish due to the large quantity of voids. As moisture content increased, it was difficult to identify layer lines, or even printing orientation, due to the increased porosity and void formation. The authors believe that surface irregularity is a possible result of evaporation of moisture from the filament during the extrusion process. Lower moisture contents of 0.16% gave a typical surface finish, however upon closer inspection inconsistencies were observed. 0.1% moisture filaments gave nearly identical results to dry filament, and upon further investigation seemed to improve consolidation when observed through an optical microscope. Dry material showed significant gapping, which was reduced with a small amount of moisture present (Zaldivar *et al.*, 2018).

Similarly, a micro-CT scan of PC sample surfaces showed geometry increased in non-uniformity as moisture content increased. The authors also believe that water was vaporised during the printing process, thus creating pores in the sample. As moisture content increased, more frequent and larger pores were observed (Fang *et al.*, 2020). PLA samples showed similar behaviour where changes were observed in the microstructure. Defects, mainly in the form of bubbles, occurred in samples produced with filament stored in a higher relative humidity environment (Valerga *et al.*, 2018).

It is agreed by all who observed the structure of FFF printed parts that higher humidity storage environments increased the formation of bubbles, causing voids (Valerga *et al.*, 2018; Zaldivar *et al.*, 2018; Fang *et al.*, 2020). Another implication of air bubbles is insufficient overlap between rasters causing cavities (Valerga *et al.*, 2018). These reported findings provide good scientific insight into the effects of filament exposed to moisture. However, the methodology for identifying moisture content within filament, through storing material in conditions with specific RH percentages for set timescales, or until a specific weight percentage of the material is moisture content, which cannot be easily replicated without specialist tools and equipment.

Therefore, relating these findings to real-world use cases, specifically for non-specialist users, or users without access to scientific equipment is unrealistic. Matching real world humidity environments where fluctuation in RH is common, to the artificial environments presented in literature is almost impossible, therefore comparisons cannot be made, meaning the scientific research is not directly useful to users outside of a research environment. The literature review has identified a gap in the literature of studies focussing on in-context use of FFF. Real-world use cases unlikely involve storing material in humidity-controlled chambers for a set amount of time to achieve a specific moisture content. Therefore, additional research applicable to non-specialist users and realistic use contexts is required. Conditioning environments should include room conditions where the temperature and relative humidity is likely to fluctuate. These findings will be more applicable to the user and could be used to inform standard operating procedures for a wider range of FFF users.

Future research may also be necessary to inform the operating procedures and quality control of filament suppliers. A supplier of ULTEM® 9085 suggested the material should have a maximum moisture level of 0.04% when sealed. A freshly opened spool of filament was found to contain moisture in the range of 0.12% to 0.18%, showing the 0.04% moisture level was

exceeded after one hour of opening in a room temperature environment (Zaldivar *et al.*, 2018). This study suggests that material storage with moisture control is necessary to prevent changes to the materials flow characteristics and resulting macrostructure of FFF parts, and therefore specific storage guidance is necessary for ULTEM® 9085 material.

Mechanical properties were the most analysed performance characteristic in literature. Zaldivar *et al.* (2018) tensile tested dog bone samples manufactured with ULTEM® 9085 filament with different moisture contents. Samples were manufactured in both the horizontal (XY) and vertical (XZ) orientations. XY samples with a 0.1% moisture content showed gradual increases in ultimate tensile strength (UTS). However, as moisture content increased over 0.1%, a significant decrease in UTS was observed. This aligns with the findings of improved consolidation between rasters, which appeared to strengthen mechanical performance. Upon analysis of the fracture modes, dog bone samples printed with material with 0.1% moisture content appeared to show less detail between filaments, with increased coalescence between rasters. Voids were observed in the fracture surface of samples with 0.16% moisture contents and higher, which appears to correspond with the significant decreases in tensile strength >60% and failure strain >50%. Samples printed in the XZ orientation showed a similar trend, with the behaviour somewhat amplified compared with the XY samples, although only three of the samples produced could be tested due to quality issues, commonly seen with samples printed in the XY orientation due to decreased printing stability.

PC dog bone samples were tensile tested by (Fang *et al.*, 2020), where samples with higher moisture content showed around a 30% loss in tensile strength in the longitudinal direction (printed in XY orientation). It is thought that the reduction in tensile strength is due to larger pores within the sample structure which helped to propagate cracks. In the transverse direction (printed in the XZ orientation), mechanical performance was reduced further by up to 70%. Samples became brittle shown by UTS being the same as fracture strength. Both fracture strength and strain initially decreased, but as water content increased further, both fracture strength and strain increased. As this only happened in the transverse direction, it was suggested that it could be a combined effect of printed geometry and pore defects. For example, the randomly distributed pores may have deviated the crack and let it propagate along a longer path, seemingly the bond between two layers, suggesting to the authors it may have introduced extra ductility.

The mechanical properties of PLA were investigated by (Valerga *et al.*, 2018) where they found higher relative humidity exposure directly corresponded with lower tensile strength. This is thought to be due to the degradation the material undergoes by the uptake of moisture, which when heated during the extrusion process boils the water, resulting in air bubbles. The accumulation of these bubbles formed the propagation of cracks in mechanical testing (Valerga *et al.*, 2018). The fracture surfaces of the samples were analysed, revealing most 'dry' samples had a clean fracture. This is believed to be due to few distributed air bubbles, which initiated cracks simultaneously at different locations within the sample. Specimens stored under ambient conditions had an uneven fracture, which showed they usually broke in a single place, believed to be caused by defects spread throughout the entire section. Humid specimens showed a similar fracture, but the crack was much more pronounced. The bubbles were more frequent and larger in size, and cracks appeared along the length of the sample (Valerga *et al.*, 2018).

Upon analysis of the first two literature groups, effects of moisture exposure on filament and effects of filament moisture exposure on FFF printed parts, general conclusions can be made. High moisture storage environments seemed to directly affect the T_g of filament material, with higher moisture content resulting in a lower T_g. Analysis of melt flow characteristics showed a higher flow rate, likely linked to the reduced T_g and therefore higher material viscosity. Filament storage was shown to directly affect FFF printed samples, with high relative humidity environments causing defects in the structure of parts and reduced UTS of printed samples.

5.3.3. Performance of FFF printed parts used in high-humidity conditions

The third and final part of the literature review focuses on the use of FFF printed parts in high moisture environments. Although this is not directly related to this study, it is important to recognise the work done in the wider field, and effectively distinguish the difference between material and part performance as a result of moisture, and part degradation by moisture exposure after printing.

(Moreno Nieto *et al.*, 2021) studied the absorption and degradation behaviours of two polymers, PLA and polyethylene terephthalate glycol (PETG), both printed using FFF technology. The authors recognise that limited research has been found for product applications where AM parts are used in high moisture environments or are submerged in water. Recycled materials, such as PLA and PETG are increasing in popularity due to the increasing awareness

of sustainability with plastic production, therefore this literature remains particularly relevant and important in a wider context.

In this study, the authors 3D printed 15 square shaped samples of each material and submerged them in three solutions: distilled water, fully saturated distilled water with maritime salt and distilled water fully saturated with white sugar. Water absorptions were quantified, with the main water absorption occurring in the first two or three days which is expected to be due to the sample defects caused by the manufacturing process. Water is believed to have penetrated the sample through all the defects, micro holes and bonding defects of the external layers. PETG became stable after 9 weeks, with subtle weight changes of 0.3%, whereas the mean weight increase of PLA specimens was 2.5% after 8 weeks. The degradation of samples reflected these results, with PLA showing signs of degradation after two weeks, and PETG withstanding four weeks without change. Degradation indicators for both materials were brownish dots appearing in the specimens, which expanded within the interior of the specimen and to the surface. Samples then started to change in colour, some yellowing, before slowly becoming transparent, which was believed to be due be a result of the change in crystallinity of the polymer.

(Kim *et al.*, 2016) investigated the water absorption behaviours of FFF printed ABS, along with the mechanical properties of FFF printed ABS samples according to water absorption and temperature conditions. The authors studied the weight of samples in two-hour intervals over the first 12 hours, followed by every 12 hours over 100 hours, and finally every 24 hours over 300 hours. The process was repeated in water at 60ºC. They concluded that high temperatures accelerated the diffusion rate, although the maximum water absorption rate was not affected. Samples printed in three orientations were analysed, with the sample printed in the vertical orientation showing the highest rate of water absorption at 7.879%. Horizontally printed samples showed absorption rates between 5.121% and 9.972% depending on infill structure. In comparison, an injection moulded sample showed an absorption rate of 0.339%.

The effects of environmental conditions on mechanical properties were then analysed. Tensile strength was shown to decrease linearly as temperature and water absorption rates increased, which was true for all samples. Under high temperature and high moisture conditions, the tensile strength was 67.6% less for vertical samples, and between 68.4% and 71.6% less for

horizontal samples with differing infills. The injection moulded part showed a similar reduction in tensile strength, 67.5% less than under dry room temperature conditions.

(Kariz *et al.*, 2018) studied the effects of humidity on FFF specimens printed with wood-PLA filament. They investigated PLA with different wood ratios: 0% (commercial PLA), 10%, 20%, 30%, 40% and 50%. Samples printed with standard PLA had a moisture content of 0.8% when stored in humid conditions (87% RH), compared with wood-PLA (50% wood content) which had a moisture content of 5.2% under the same conditions. Specimens were also seen to swell in all directions, with the higher wood content specimens showing the highest expansion (0.3% for 50% wood-PLA in 87% RH). This work indicates the influence additives have on the behaviour of FFF parts in different environmental conditions.

A particularly relevant finding was the varying filament diameter depending on the wood content. Filaments were produced under the same temperature conditions with the same extrusion speed, meaning the diameter deviation was a result of increasing viscosity due to wood mixtures, requiring higher extrusion forces. Filaments with higher wood content had a smaller diameter, in the most significant case, 0.21mm variation was observed, with a filament diameter of 1.51mm. FFF 3D printing software calculates extrusion based on filament diameter, which in this case was 1.75mm. These changes in diameter result in FFF printed parts with higher wood content being fabricated with less material, which in turn influenced the mechanical properties of the part. The authors calculated that 50% wood-PLA parts were printed with 23% less material when comparing the cross section of filaments with a smaller diameter (Kariz *et al.*, 2018).

This finding may be applicable to filament moisture absorption under varied storage conditions. As discussed previously, reports of filament swelling are associated with moisture absorption (Halidi and Abdullah, 2012), and although in the discussed case, increased filament diameter did not result in nozzle blockages, diameter changes could affect the deposition rate of material. Diameter changes combined with thermal property changes could result in the amplification of part inconsistency and subsequent quality concerns.

The analysis of mechanical properties showed that modulus of elasticity was lower with wood-PLA than commercial PLA. 10% wood filament decreased the modulus of elasticity by almost 47%. It is unclear whether the result of these mechanical property changes was a result of a

smaller, thinner diameter, and therefore less material, or other possible factors such as the wood particles acting only as a filler, poor layer fusing, wood particles not being fully encapsulated with polymer and non-homogenous printing due to nozzle clogging. Effects of environmental humidity has been shown to vary significantly between different materials, and the different hygroscopic properties of each.

In summary, moisture is shown to affect material both before, during and after printing. The effects of moisture are shown to directly influence quality attributes of parts; however, most findings are specific to a definitive set of environmental conditions. Existing literature is useful for indicating findings relating to specific conditions, however, few studies relate these findings to daily practice and real-world use cases for the technology. Therefore, the relevance of this research to key user groups is limited.

Few studies considered the effects of moisture on physical part attributes at a holistic level, such as the overall dimensional accuracy. Dimensional variation of 3D printed parts, as a key quality indicator in manufacturing, is a beneficial area of investigation which has been insignificantly covered in literature. The effects of filament storage conditions on the dimensional accuracy or variation between parts is relevant to each user group producing end-use parts, particularly those working in regulated fields. Further, the influence of material storage conditions on the repeatability and reproducibility of end-use parts has not been considered in any of the publications identified. Quality indicators such as accuracy, repeatability and reproducibility are essential considerations for regulated applications, but also for any end-use part required to meet a specification. Through identifying each of the sources of variation present in FFF parts, appropriate steps can be taken to minimise variation, minimising the number of defect parts and therefore optimising the process.

The further reaching studies, such as (Valerga *et al.*, 2018) provide a useful insight into the effects of exposing filament to moisture on a range of key quality and performance characteristics of a 3D printed part, however, it did not consider the effects on the properties of the filament before extrusion, meaning conclusions around the effects of moisture exposure on the thermal properties of filament could not be validated. Due to the focussed nature of existing literature, few studies draw relevant conclusions in the three key areas of investigation: the effects of moisture on the material, the printing process and the subsequent effects on the printed part. As a result, this chapter intends to consider the effects of filament storage in

relatable storage environments, as opposed to specific temperatures, relative humidity's, and moisture contents, and measure the effects of this against key performance indicators through a range of geometrical, mechanical, and visual techniques useful to users of FFF technology. This study has been formed to address some of the gaps in literature and present a comprehensive picture of the effects of moisture across a wide range of quality and performance attributes necessary for regulated applications.

Additional questions around the effects of moisture on FFF printed parts during use have been raised by the systematic literature review. This highlights the need for future research around the long-term performance of FFF parts in different environmental conditions. It has also highlighted the importance of appropriate packaging for FFF parts intended to be used in a regulatory approved context. It is a requirement to specify product shelf-life and care instructions, which could both be influenced by high-humidity environments. It is also noted that defects in the manufacturing process, such as pores in the part structure due to filament storage, could potentially affect the long-term performance of parts under different environmental conditions. This is due to increased numbers of cavities and pores, and potentially reduced layer adhesion, meaning long-term part testing is required in addition to initial quality testing.

5.4. Methodology

5.4.1. Experimental methodology

The experimental methodology for this chapter is presented in five stages, where stage one is material conditioning for thermal analysis, stage two is thermal analysis, stage three is material conditioning for sample production, stage for is the manufacture of dog bone samples and stage five is the inspection of printed samples, all of which are illustrated in Figure 66.

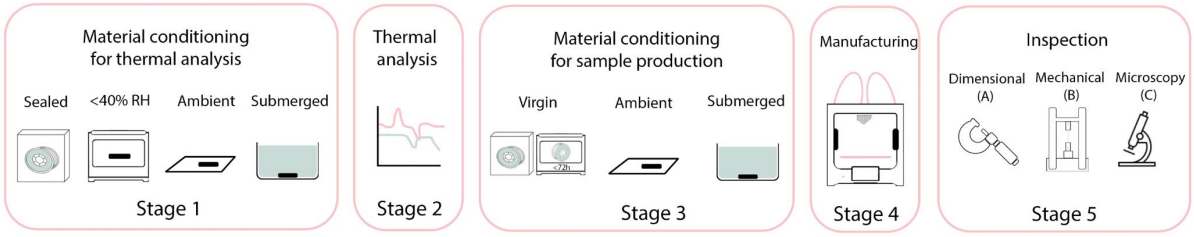


Figure 66: Schematic of the chapter methodology in stages one to five

5.4.1.1. Stage 1: Filament conditioning for thermal analysis

To fit the context of the wider study, material storage conditions that replicate day-to-day use were selected. Published studies have focussed on conditioning material to contain a specified amount of moisture, which does not represent a realistic use case for FFF. It is likely the time, resource or costs implications of using laboratory equipment to characterise material moisture content would be unattainable and unrealistic in many industrial or non-specialist use environments. For this reason, material has been conditioned first to reflect a standard use case of research, industrial and non-specialist, and the typical use environments where the technology would be situated. Research and industrial environments likely have access to humidity-controlled storage facilities; therefore, an Ultimaker Material Station (®Ultimaker, Netherlands) was used to maintain a <40% RH storage environment. The material station is a mid-range piece of hardware for humidity control, specifically intended for professional FFF.

Access to humidity-controlled storage chambers is increasing as more manufacturers are introducing them into their hardware ranges, specifically those that have been made more accessible for intended use in professional FFF scenarios. Ambient conditions reflect use conditions of a lay-person or non-specialist user, or in many cases research and industrial contexts where humidity-controlled storage has not been used. This may be due to commonly used materials remaining unaffected by moisture, knowledge gaps around the implications of moisture on certain materials, lack of resources or just poor practice. Submerged filament specimens represent an extreme use case where filament has come into direct contact with water, indicating the potential implications this could have on the material, printing process and performance of a part.

Specimens of Ultimaker brand Tough PLA filament (®Ultimaker, Netherlands) were conditioned in the storage environments detailed in Table 30 for the corresponding durations. Upon removal from the conditioning environments, specimens were measured and stored in a

sealed bag to limit any unwanted changes before undergoing thermal analysis. For clarification, storing samples *after conditioning* in a sealed bag was to preserve their state following the conditioning period, and was not related to the sealed condition. The sealed condition specifically refers to filament in its original packaging sealed by the manufacturer.

Table 30: Sample storage conditions

Group number	Storage conditions	Conditioning timescales
1	Sealed (by the manufacturer)	-
2	<40% relative humidity	72 hours, 3 months
3	Ambient room conditions	72 hours, 6 days, 2 weeks, 3 months
4	Submerged in water (room temperature)	72 hours

5.4.1.2. Stage 2: Thermal analysis of filament

Thermal analysis was not conducted by the author. Samples were submitted to Manchester Metropolitan University (MMU) for thermal analysis. MMU used the DMA 800 model (Perkin Elmer, Massachusetts, US) according to ISO 6721-11:2019 (ISO, 6721-11:2019) and TGA 4000 model (Perkin Elmer, Massachusetts, US) according to ISO 11358-1:2014 (ISO, 11358-1:2014) to collect thermal analysis data for each conditioned filament specimen. Three specimens for each condition were tested.

The T_g was identified using two methods, the E' drop and the peak of the tan δ curve. The T_g is a range of behaviour, where scientists have agreed to accept a single temperature as an indicator depending on different industry standards. Different industries have used indicators that can vary considerably between different values, which is expected due to DSC and DMA measuring different processes, meaning numbers are likely to vary.

5.4.1.2.1. Statistical analysis of thermal data

Analysis of variance (ANOVA) was used to identify which sample's T_g were significantly different from others. Firstly, the data was tested for equal variances which is one of the assumptions of parametric statistical testing. Levene's test was used to determine a common variance between all of the populations. A general linear model was used to restore the residuals, identifying how much higher or lower each observation was from the group mean.

The residuals were checked for normality using the Anderson-Darling normality test, which indicates normality through a P-Value of >0.05. Finally, post hoc tests were done to compare the tan delta peak temperature of each condition. Comparisons were made through grouping information using the Tukey method. Data was plotted as an interval plot to illustrate the standard deviation between samples, and which means were significantly different.

5.4.1.2.2. Determination of conditioning environments for filament to manufacture samples

Based upon the initial thermal analysis findings for filament samples, conditioning environments and timescales were selected for the filament to be used to manufacture dog bone samples. No significant difference was observed between sealed material and material stored in <40% RH conditions for up to 72 hours. To ensure the observations from the thermal analysis were supported, and that no significant changes in the material were likely to occur towards the end of the 72-hour cycle, additional tests were conducted.

Ultimaker brand black Tough PLA filament was conditioned from sealed condition in a <40% relative humidity environment for between 60 and 72 hours and used to 3D print three dog bone samples on an Ultimaker S5 3D printer. Samples were printed as repeats (one sample per build) due to the influence of build plate positioning identified in Chapter four. Changes in the diameter and weight were observed, followed by a comparison of tensile strength of samples printed in the horizontal orientation. Printed dog bone samples were measured at multiple points using a digital calliper with 0.01mm resolution and weighed using a Sartorius AC210P analytical balance (Sartorius, Göttingen, Germany). Samples were tested using a Hounsfield H10KS universal testing machine (Hounsfield, Surrey, UK) and tested with a load range of 3000N.

5.4.1.3. Stage 3: Filament conditioning for sample production

A small specimen of filament was taken and measured, before it was placed with lengths of Ultimaker brand black Tough PLA filament in the storage environments detailed in Table 31 for the corresponding conditioning timescales. Upon removal from the conditioning environments, the specimen was measured, and filament was used to print. Conditioned filament was used immediately to print to prevent any additional environmental influence between conditioning and printing.

Table 31: Filament conditioning environments and timescales for sample manufacture

Group number	Storage conditions	Conditioning timescales
1	Virgin	<72 hours
2	Ambient room conditions	72 hours
3	Submerged in water	72 hours

5.4.1.4. Stage 4: Sample manufacturing

Dog bone samples were 3D printed for mechanical testing using conditioned filament according to the dimensions shown in Figure 67. Samples were manufactured on an Ultimaker S5 FFF printer with an air manager installed (®Ultimaker, Netherlands). Based upon the initial thermal analysis findings, and the unrealistic practicality of using an unopened spool of material for each part, three conditions were selected: Sealed material, including filament stored in a humidity-controlled unit below <40%RH for less than 72 hours. To differentiate between the initial sealed condition for thermal analysis, and sealed including low moisture storage for <72h, this condition will be referred to as 'virgin' from herein; Ambient, which has been stored in ambient room conditions for 72 hours; And submerged filament which has been immersed in water for 72 hours. Specimens of Tough PLA filament were weighed using a Sartorius AC210P analytical balance (®Göttingen, Germany) and the diameter was measured (three times to obtain a mean) using a digital calliper with a resolution of 0.01mm before and after conditioning to see whether there was any corelation between diameter and printing performance.

Three samples in both the horizontal (XY) orientation and vertical (XZ) orientations were manufactured for each condition, using the printing parameters shown in Table 32. Two standard tessellation language (STL) files were used to print all samples, one for horizontal samples and one for vertical. To ensure quality, vertical samples had a reduced gauge length and were printed in pairs, with a central support structure to improve print quality. Samples can be seen in Figure 68. A glass build plate was washed between each sample, and a single layer of glue was applied to improve adhesion and aid removal. Filament was loaded onto the spool mount on the reverse of the printer in all cases, and an air manager unit was installed for all prints enclosing the print chamber. Upon completion, samples were removed from the build plate with a large scraper and stored in an airtight sample bag until testing.

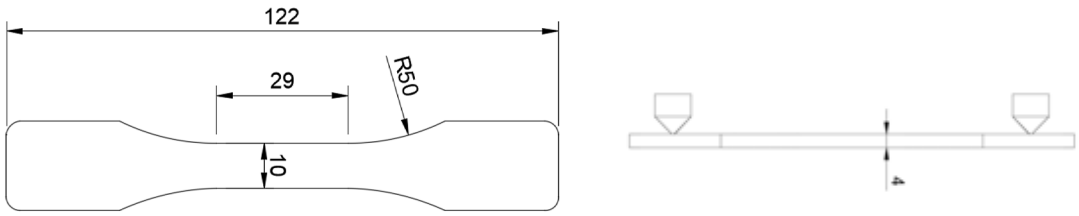


Figure 67: Nominal dimensions of printed dog bone samples

Figure 68: Images of dog bone samples (top: vertical printing orientation, bottom: horizontal printing orientation)

Table 32: Printing parameters for 3D printed dog bone samples

Parameter	Horizontal	Vertical
Layer height	0.2mm	0.2mm
Infill pattern	Triangles	Triangles
Infill density	100%	100%
Wall thickness	0.8mm	0.8mm
Support material	None	None
Build plate adhesion	None	Brim
Raster angle	±45°	±45°
Air gap	Default (0)	Default (0)
Orientation	Flat to bed	Vertical
Nozzle diameter	0.8mm	0.8mm
Support	Disabled	Enabled
Support wall line count	-	4
Support overhang angle	-	50º
Support pattern	-	Lines

5.4.1.5. Stage 5: Sample inspection

5.4.1.5.1. Stage 5(A): Dimensional analysis

Dog bone samples were measured using a digital calliper with 0.01mm resolution. Measurements were taken of the gauge width and thickness, grip section width at the top and bottom of the sample, and the entire sample length on the left and right side. Three measurements of width and thickness were each taken along the gauge length at the top, middle and bottom of the dog bone. The mean width and thickness of each dog bone was then calculated along with the mean of each sample group. The standard deviation (SD) and percentage standard deviation (%SD) were calculated as a means to compare the influence of material storage condition on the dimensional repeatability of FFF parts.

5.4.1.5.2. Stage 5(B): Mechanical evaluation

Samples were loaded into a Hounsfield H10KS universal testing machine (®Surrey, UK). Horizontal samples were tested with a 50mm extensometer, and vertical samples were tested with a 25mm extensometer. The horizontal testing program had a load range of 3000N and the vertical program had a range of 2500N. Both tests were carried out at a speed of 50mm/min.

An operational range could not be selected, therefore an elastic region comparable across all the samples was selected for each of the horizontal and vertical oriented samples. Modulus was calculated between the 0.3-0.7mm extension for horizontal samples, and between 0.1-0.25mm for vertical samples. This modulus calculation was selected to keep the data relevant and comparable between different machines and test programs, whilst making the methodology reproducible. By not starting at zero, the beginning and end data points are not considered as they were more likely to be subject to machine errors.

5.4.1.5.3. Stage 5(C): Microscopy

After mechanical testing, the dog bone samples were dissected according to Figure 69, providing two specimens for analysis. The surface and fracture sections were removed for examination.

Following specimen preparation, visual analysis was done using SEM with a TM4000Plus Tabletop Microscope (® Hitachi, Tokyo, Japan). All samples were analysed under vacuum at reduced pressure to maintain the integrity of the electron beam. Samples were mounted onto aluminium pin stubs using adhesive carbon tabs and loaded into the SEM. A backscattered electron detector was used to obtain images of the sample and images were taken using an acceleration voltage of 15kV. Images were taken at four magnification levels: 500x, 250x, 100x and 50x of two randomly selected areas on the surface and fracture surface of each sample, printed in the horizontal and vertical orientation, as shown in Figure 69.

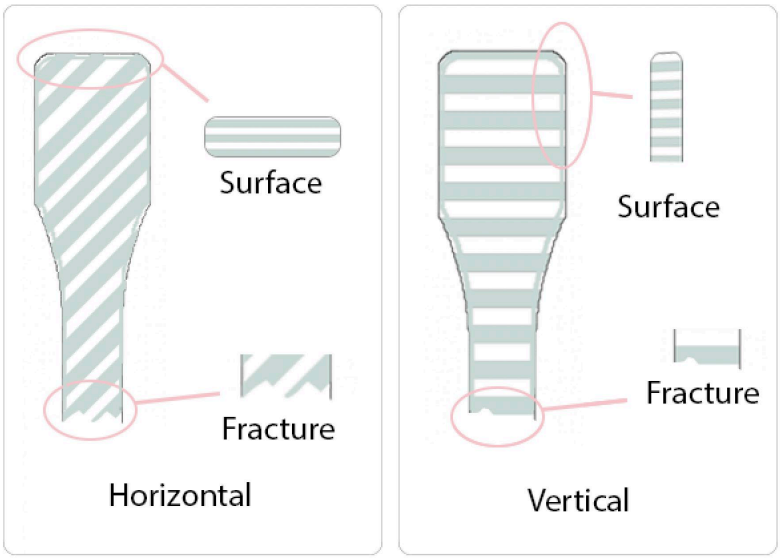


Figure 69: Dissection of dog bone samples into surface, cross-sectional and fracture specimens for SEM

5.5. Results

5.5.1. Specimen dimensions and weight changes

Figure 70 shows the mean diameter (of three repeats) for each specimen stored in different conditions over the specified timescales. The diameter specified by the manufacturer is 2.85mm ±0.05mm. Filament submerged in water for 72 hours showed a larger diameter than other specimens with an average increase of 0.04mm from sealed to submerged specimens. The mean diameter of submerged specimens was 2.88mm, which remains within the manufacturer's tolerance specification.

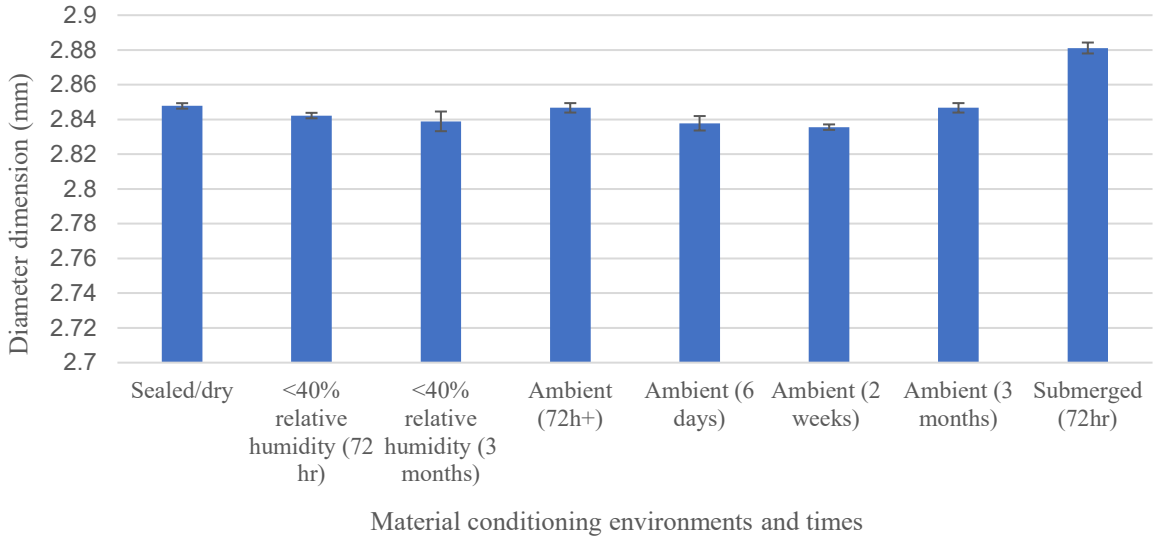


Figure 70: The effects of environmental condition on diameter of conditioned filament. Values are means with error bars showing standard deviation over three repeats

Due to submerged samples showing a larger diameter than other samples, filament specimens were measured again before and after conditioning, according to the three conditioning environments determined for sample production, due to the first set of results showing no significant difference between the other conditions. The larger diameter observed for submerged samples could have been a combination of a larger initial filament diameter and the result of moisture absorption.

Figure 71 shows the mean diameter of virgin, ambient, and submerged filament specimens before and after 72 hours of conditioning. Virgin specimens were sealed or stored in a low-humidity environment and therefore do not show "after conditioning" data. Specimens conditioned in an ambient environment showed a larger increase in diameter than those submerged in water, although this increase was relatively small at 0.04mm. An average increase of 0.008mm was observed for specimens after they were submerged in water. The recorded dimensions after conditioning showed a small increase for both conditions, although the increase falls within the manufacturer's acceptable tolerance level.

By comparing the three specimen groups before conditioning, variability in filament diameter is demonstrated, meaning the hardware is already expected to perform within a tolerance range. The range specified by the manufacturer is 2.85 ± 0.05mm, which was only exceeded for

samples before conditioning. This could have been due to human error when measuring, or the filament exceeding the given tolerance range in places. The slight increase of diameter observed because of moisture exposure is unlikely to significantly affect the FFF process for most use cases, due to it falling consistently within the acceptable range specified by the manufacturer. Any affect the filament diameter has on the printing process and final part performance will be present already because of the natural deviation occurring in the filament manufacturing process. Whilst the deviation occurring as a result of moisture absorption falls within the accepted tolerance range from the manufacturer, the process should remain unaffected.

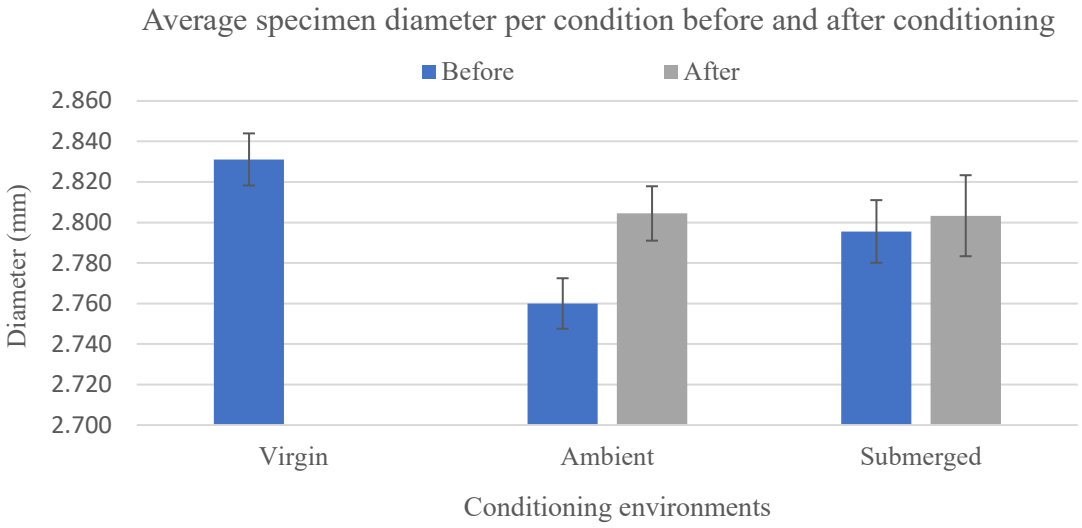


Figure 71: A chart showing the deviation in diameter before and after conditioning. Error bars show standard deviation.

The weight of specimens before conditioning (WB) and the weight of specimens after conditioning (WA) are displayed in Table 33, with weight change (WC) and percentage weight change (%WC). Each of the three submerged specimens appeared to slightly increase in weight, whilst ambient specimens showed a very slight decrease. This was an expected finding for submerged samples, due to the observation of weight increases or decreases being used widely as a methodology to identify moisture content of a material, as demonstrated by (Zaldivar *et al.*, 2018) and in section 5.5.2.2 of this chapter.

Table 33: Specimen weight before and after conditioning. (WB: weight before; WA: weight after; WC: weight change; %WC: percentage weight change)

Condition	Specimen #	WB (g)	WA (g)	WC (g)	%WC
Ambient	4	0.2012	0.2009	-0.0003	-0.15%
	5	0.1649	0.1645	-0.0004	-0.24%
	6	0.1701	0.1697	-0.0004	-0.24%
Submerged	7	0.1653	0.1656	0.0003	0.18%
	8	0.1844	0.1858	0.0014	0.76%
	9	0.1619	0.1624	0.0005	0.31%

5.5.2. Thermal analysis

Thermal analysis was done by MMU Chemistry Technical Services Team using *DMA*, which provided data for a range of properties including the storage modulus (E'), loss modulus (E") and tan delta (tan δ).

5.5.2.1. Glass transition temperature (T_g)

The T_g of tough PLA under different storage conditions is a particular area of interest due to the close relationship between the programming of the printer and the thermal properties of the polymer used. In industry, the value reported as the T_g varies. The most commonly used values are the onset of the E' drop, the peak of the tan δ curve, and the peak of the E" curve.

The mean E' for each conditioned material is shown in Figure 72. The onset of the large drop in E' indicates the T_g of each material, with the submerged specimen appearing to transition around 5-7ºC before the other conditioned materials. The difference in E' between the other conditions was marginal, aside from sealed specimens, ambient 72h and ambient 3 months specimens showing a higher initial storage modulus, and a slightly delayed drop. A higher initial storage modulus could be a result of the samples being denser, or slightly different in size. Larger samples tend to have a delayed thermal response, due to the sample taking longer to heat. For example, whilst one sample has been heated to past the thermal transition phase, the temperature scan would have proceeded further than for a smaller sample, thus indicating the transition has occurred at a higher temperature for the larger sample.

As discussed previously, by inputting specific information to a slicing software, the flow rate and printing speed are calculated based on the optimal printing temperature of a particular material, which is directly related to the T_g. Typically, manufacturers provide information on the optimal printing temperature for each material, although the storage conditions of that material are not accounted for. This could result in misaligned printing parameters such as suboptimal extrusion or bed temperatures, in turn leading to inconsistencies in printed parts where the same extrusion temperature has been used.

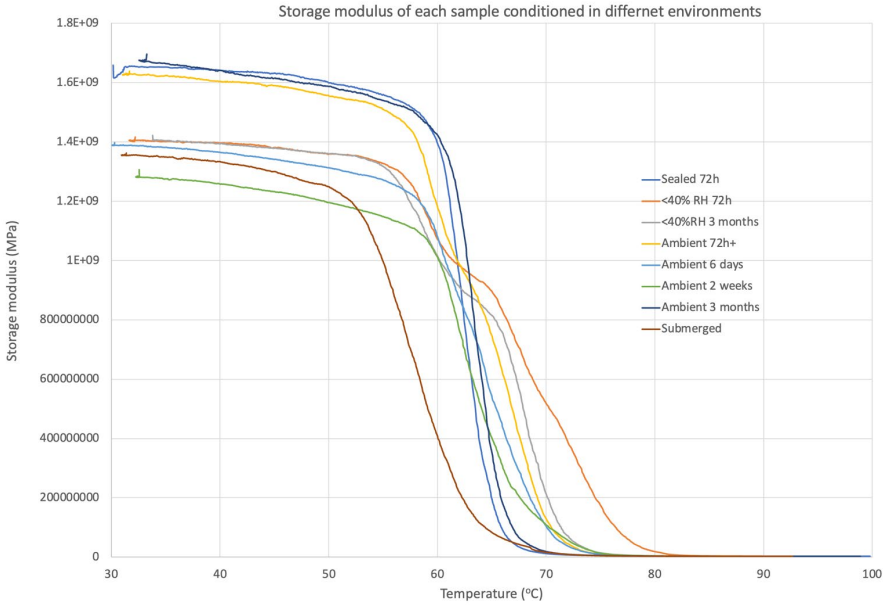


Figure 72: Storage modulus curves from DMA for each conditioned material

A second method of identifying T_g is through the peak of the tan δ curve. Figure 73 shows the tan δ curves for each repeat. On two occasions, the submerged specimens showed the lowest tan δ peak, again supporting the conclusion that extreme exposure to moisture over 72 hours results in a lower T_g than other conditioned specimens. The curves for repeat three show multiple peaks for specimens stored in <40% RH for three months and specimens stored in ambient conditions for two weeks. They do not conform to typical gaussian or voigt profiles, and due to their sudden occurrence, and only for some data points, these are classed as anomalies. The reason is unknown; however, this could be a result of building work in close proximity to the testing laboratory.

The mean T_g indicated by the tan δ curves is detailed in Figure 74. Submerged specimens showed the lowest mean T_g of 68.725ºC and had the smallest standard deviation (SD) between repeats (0.087). This result might be expected due to the addition of absorbed molecules, which can increase the free volume inside the polymer, hence reducing the T_g. This concept is known

as free volume theory (Young and Lovell, 2011). These findings align with other published studies which suggest high levels of moisture exposure result in decreasing T_g. The second lowest mean T_g was observed for sealed specimens at 69.733ºC, with a relatively small standard deviation (0.189). No trend was observed between the T_g of humidity-controlled specimens and ambient specimens over the range of studied timescales, suggesting the studied timescales have no effect on the T_g of Tough PLA. The total range of T_g over all material storage conditions was around 1.6ºC which is relatively low.

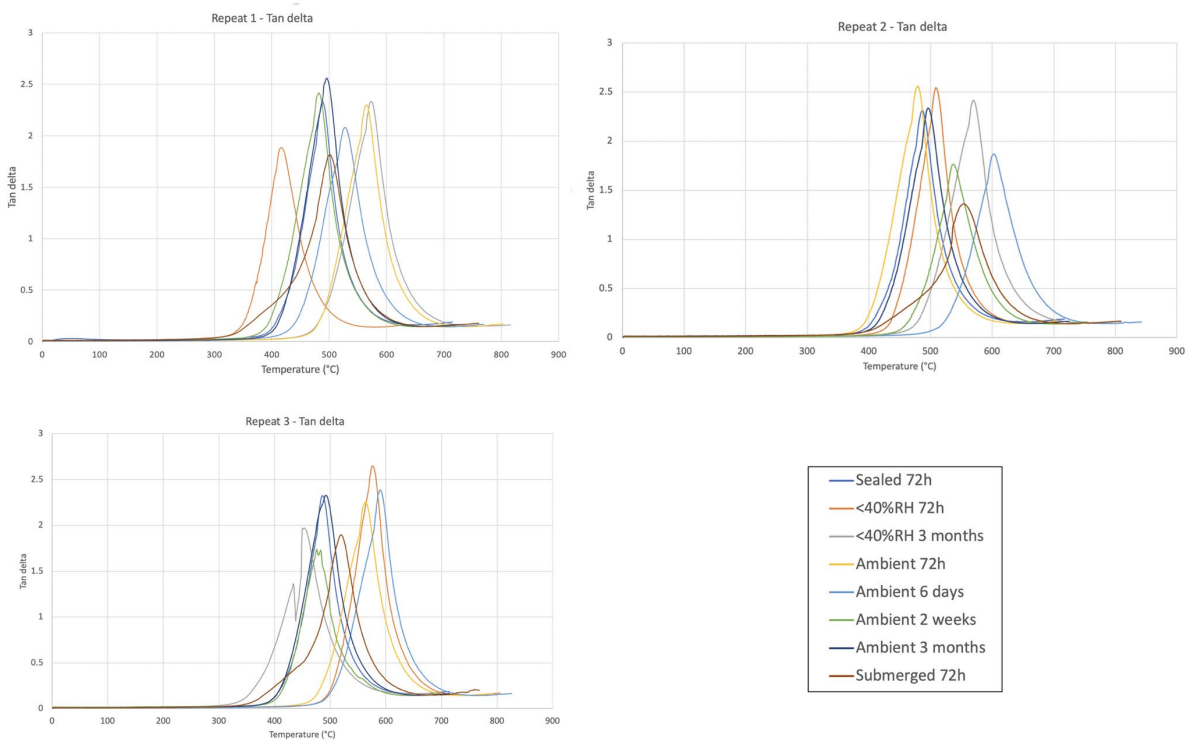


Figure 73: Tan delta curves (repeats 1-3) for each conditioned material

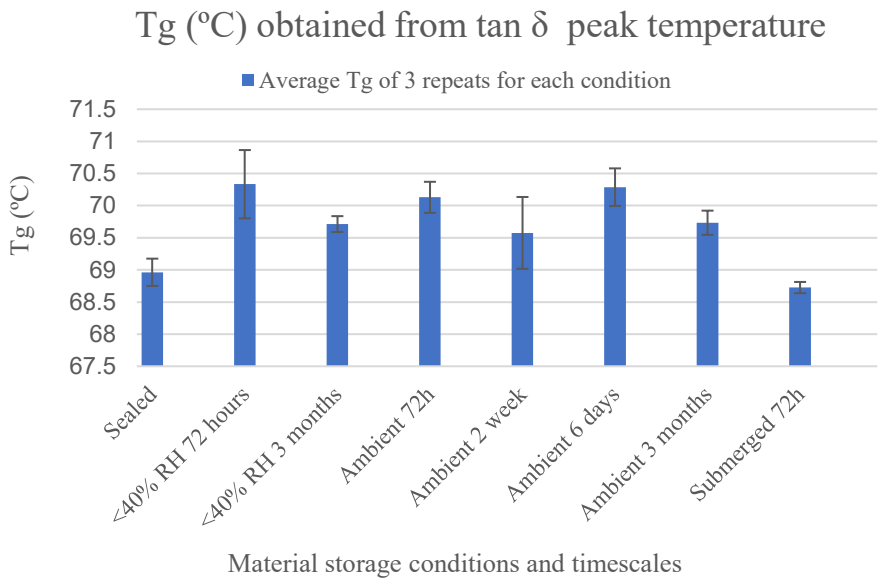


Figure 74: A chart showing the mean T_g of Tough PLA stored under different moisture conditions. Error bars show standard deviation.

5.5.2.1.1. Analysis of variance of Tg from tan delta peak temperature

To confirm the significance of these findings, ANOVA was performed on the tan δ peak temperature of each of the tested conditions. An interval plot of each condition is presented in Figure 75, which includes groupings calculated using the Tukey method. Groupings indicate that sealed and submerged samples are statistically significantly different from the rest of the tested conditions, showing a significantly lower tan delta peak temperature compared to the other conditions. The thermal properties, specifically the T_g of samples conditioned in a <40% RH chamber were not significantly different from samples conditioned in an ambient environment. Varying timescales of exposure were also shown to insignificantly affect the T_g of Tough PLA for up to three months, meaning filament open for 72h should have a similar T_g to filament opened for three months. These findings suggested that using a humidity-controlled chamber to store Tough PLA is not necessary for up to three months after the seal has been broken.

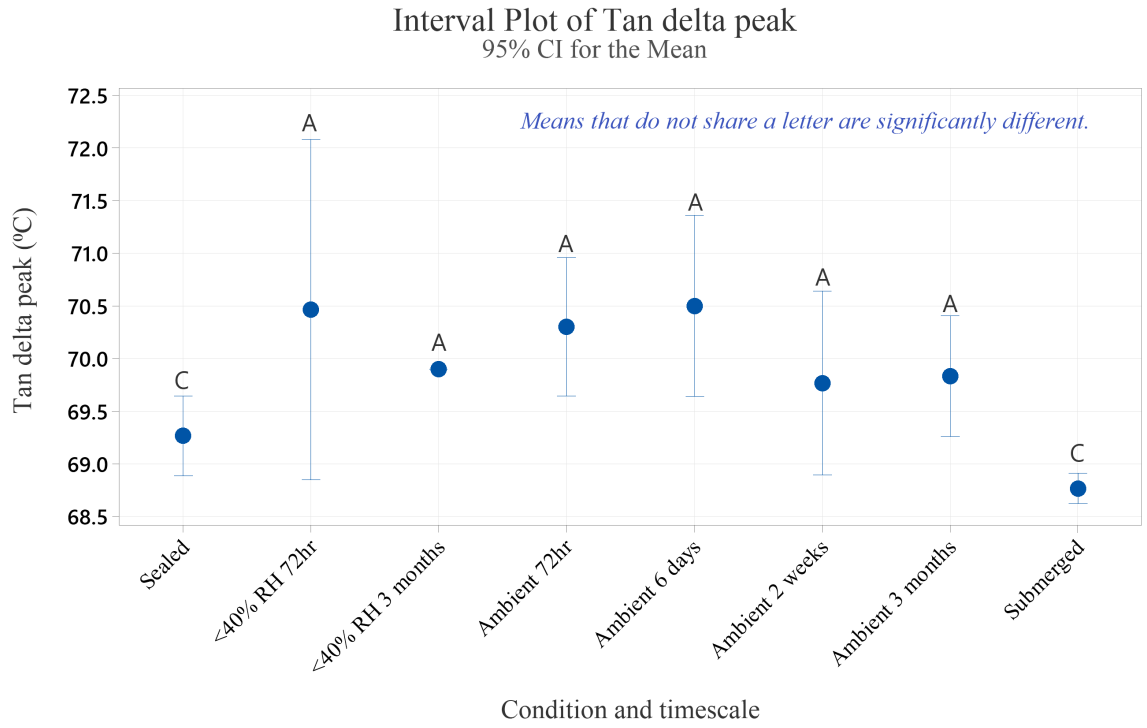


Figure 75: Interval plot of tan delta peak temperature (error bars show 95% confidence intervals for the mean)

Findings suggested that thermal properties of Tough PLA were altered when the filament was exposed to varying environmental conditions once the filament seal was broken. The thermal transition phase was altered by prolonged contact with water, returning the thermal transition phase closer to that of sealed filament before it was exposed to controlled or ambient environmental conditions. The data shows the specimens exposed to room conditions and <40% RH environments have a slightly higher T_g than both sealed and submerged conditions, although they do not differ significantly from each other. This data implies that lower humidity storage is not necessary for the timescales studied, and material can be stored in ambient room conditions without affecting the T_g.

The T_g of sealed filament is statistically significantly lower than that of all other conditions, apart from submerged. Submerged and sealed samples were shown to be statistically significantly different from all the sample conditions, but not different from each other. Extreme contact with moisture, as replicated by the submerged condition, may be shown to transition at a similar temperature to the sealed condition with respect to T_g, although wider testing is required to identify any other implications in different performance areas. This data

should not be used in isolation due to the wide number of factors and parameters associated with FFF AM.

An observed benefit of using sealed material is the lower T_g, which is ~69ºC. The T_g specified by the manufacturer for Tough PLA is 59ºC. Although this is ~10ºC lower than observed, sealed, and submerged material is closer to the manufacturer's specification than filament stored in humidity controlled or ambient conditions. As discussed, in the pre-set printing profiles the parameters such as the extrusion temperature are pre-set by the manufacturer, based on the properties of each material. Unless these parameters are modified by the user during the slicing stage, the printer will assume the T_g is the same. This could potentially lead to under extrusion issues if the optimal melting temperature is not reached.

However, using sealed material for every print is unpractical, uneconomical, and unsustainable, and therefore is an unrealistic option for non-specialist, specialist, and research users. As a result, changing the starting point of the material to include 72 hours of the seal being broken, may be a solution to ensuring consistency between printed parts. This would allow filament to reach a level of consistency suitable for the production of multiple parts, ensuring that the first printed part and the last printed part were consistent within the three-month timescale. This is as opposed to printing the first part where the material seal has been broken immediately before use, and the rest of the parts after 72 hours of the seal being broken where significant differences in T_g were observed.

5.5.2.2. Moisture content

Different methods have been used to quantify the water absorption of materials, most of which calculate moisture absorption through weight gain/loss. This study used TGA to gain insights into the loss of water through evaporation through the controlled increase of temperature, shown in Figure 76.

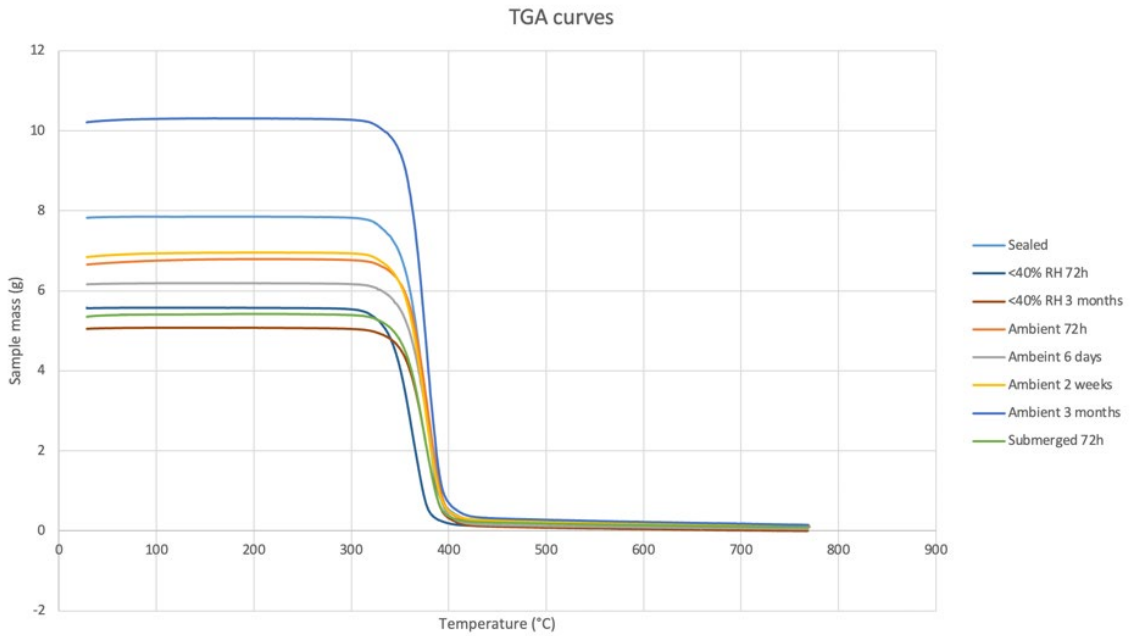


Figure 76: TGA curves for all conditioned specimens

The weight changes between 30ºC and 140ºC were investigated to identify the evaporation of any solvents. Between the specified temperature range, no polymetric changes will be observed meaning any weight changes can be attributed to the evaporation of solvents, such as water. Three repeats were conducted for each specimen condition/timescale. On all but one occasion, specimens were seen to increase in weight slightly, averaging between 0.069g and 0.015g. A single specimen submerged in water for 72 hours was shown to lose -0.012g on one occasion, however, this behaviour was not observed for the other two repeats of the submerged specimens and is therefore considered an anomaly.

Table 34 shows the weight change, and Table 35 shows the % weight change, recorded for each specimen, with the largest mean weight change being attributed to specimens stored in ambient conditions for 3 months. However, it is important to note this was a weight increase, which does not align with the expected weight decrease as moisture evaporates.

Table 34: Table showing the weight difference (g) of specimens over a heating period of 30ºC and 140ºC (indicates an anomalous result)*

Condition environment and timescale	Weight change (g)			
	Repeat 1	Repeat 2	Repeat 3	Mean
Sealed	0.02346	0.02982	0.04758	0.03362
Ambient 72h	0.12103	0.01272	0.01403	0.04926
Ambient 6 days	0.02631	0.01272	0.01250	0.01718
Ambient 2 week	0.09998	0.04429	0.02522	0.05650
Ambient 3 months	0.08990	0.10525	0.01206	0.06907
<40% RH 72h	0.01206	0.06709	0.06095	0.04670
<40% RH 3 months	0.02785	0.02916	0.03113	0.02938
Submerged 72h	0.05547	-0.01162*	0.00241	0.01542

Table 35: Table showing the % weight change of specimens over a heating period of 30ºC and 140ºC

Condition environment and timescale	Weight change (g)			
	Repeat 1	Repeat 2	Repeat 3	Mean
Sealed	0%	0%	1%	1%
Ambient 72h	2%	0%	0%	1%
Ambient 6 days	0%	0%	0%	0%
Ambient 2 week	1%	1%	0%	1%
Ambient 3 months	1%	2%	0%	1%
<40% RH 72h	0%	1%	1%	1%
<40% RH 3 months	1%	0%	0%	0%
Submerged 72h	1%	0%	0%	0%

5.5.2.3. Determination of conditioning environments for filament to manufacture samples

Data obtained from each of the thermal analysis techniques was plotted and compared. E" peak temperature, E', moisture content and tan δ peak temperature were compared. Most data points, excluding tan δ were comparable between sealed samples and <40% RH samples. This indicated a largely insignificant difference between sealed filament and <40% RH. For this

reason, in addition to the unrealistic practicality of using a sealed spool of filament for every part, the two conditions were combined forming the 'virgin' condition. Although thermal data showed similarities, additional mechanical tests were conducted to ensure the performance was comparable, and the material properties were not significantly different for sealed and <40%RH filament.

The results shown in Figure 77 indicated no significant difference between sealed and conditioned filaments. The observed differences can be attributed to error of the measurement tool, as discussed in Chapter four, and the slight fluctuations in filament diameter which are a known and declared by filament manufacturers. The largest recorded weight change from sealed condition to <40%RH for between 68-72 hours was -0.0001g indicating no significant weight change that would be unlikely to be detectable by any of the considered users.

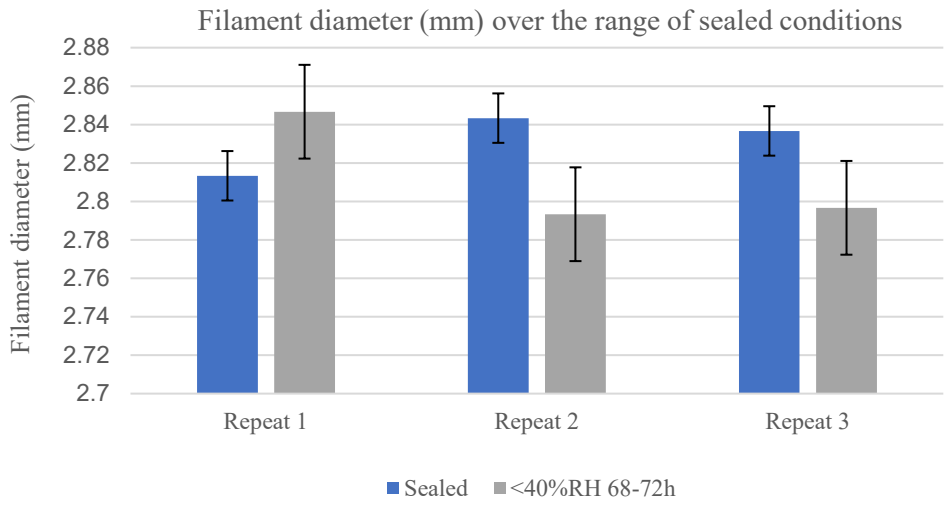


Figure 77: Mean filament diameter of sealed material and material stored in <40% RH conditions for between 68-72 hour. Error bars show standard deviation.

Tensile data showed similar elongation strain values between the two conditions, but samples stored in <40% RH environments for between 68-72 hours showed a slightly higher tensile strength as shown in Figure 78. At this stage, it was unknown whether these values were significant compared to the other conditions. Due to the only observed difference being a slight increase in tensile strength, it was assumed that including the <40%RH conditioning environment was not likely to provide any extra contribution to the research. Therefore, the rest of the study was conducted with sealed material including <40% RH for between 68-72 hours. Due to there being no significant differences in the thermal data for ambient samples

between 72 hours and three months, ambient conditions for 72 hours were considered acceptable for the mechanical testing.

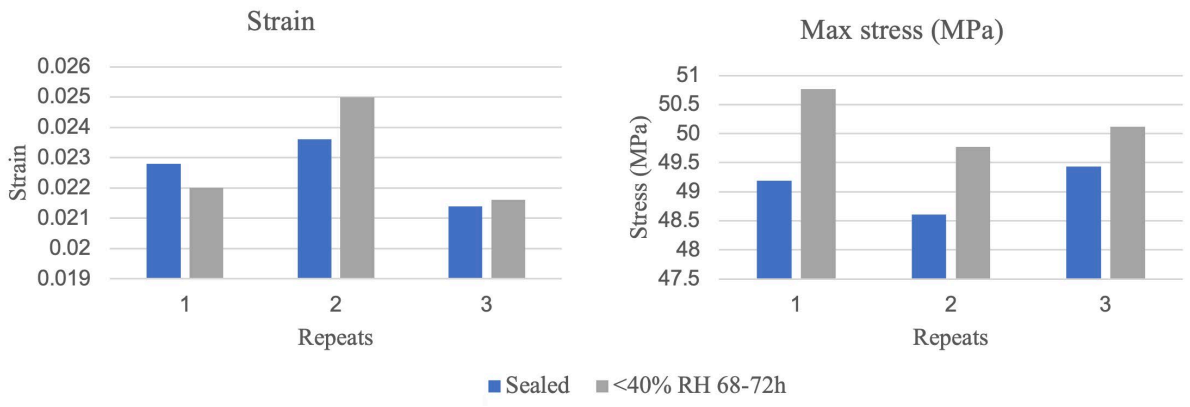


Figure 78: Tensile data for samples produced with sealed and <40% RH for 72-hour conditioned material.

By combining the sealed and <40% RH for 72-hour conditions into a single condition, and introducing ambient conditions for 72h, comparisons could be made to support the decision to exclude the <40%RH environment. In the case where a significant difference can be seen between virgin and ambient conditions, additional conditions and timescales may need to be reintroduced in additional research. The 'submerged' condition for 72 hours was included as an extreme scenario to indicate any changes for direct and prolonged moisture contact. Although this is not representative of a real-world scenario as filament is unlikely to be stored in water at any point, it will give an indication of how severe moisture exposure could be, and what the most severe effects of moisture might be in a worst-case scenario.

5.5.3. Geometrical

Dimensional data shown in Table 36 suggests there was no direct correlation between material storage conditions and the dimensional variance of 3D printed parts in the vertical orientation. Conversely, dimensional data for samples printed in the horizontal orientation suggests that across all the geometrical features measured (width, thickness, and length), the lowest amount of dimensional deviation between samples was observed for virgin filament. The largest

amount of dimensional deviation between samples was shown between samples printed with ambient filament.

Every measured dimension for submerged samples was larger than the nominal value. In most cases, samples produced with ambient conditioned filament were larger than the nominal values, with one exception. On three occasions, samples produced with virgin filament were measured to be smaller than the nominal value. This could suggest that virgin filament has a slightly lower extrusion rate or a reduced flow rate due to increased viscosity than ambient filament, which spreads out more due to a higher extrusion rate or increased flow rate. Although this does not link with the thermal analysis data, which suggests that more moisture exposure, i.e., submerged conditions, results in a lower T_g, which would be an expected result for over extrusion due to the increased viscosity at lower temperature.

Table 36: Dimensional data of dog bone samples printed in horizontal and vertical orientations using conditioned filament

Condition	Sample	Vertical						Horizontal					
		Gauge width (mm) (Δd=10 mm)	**SD (%)**	**Gauge thickness (mm)** (Δd=4mm)	**%SD**	**Sample length (mm)** (Δd=122 mm)	**SD %**	**Gauge width (mm)** (Δd=10m m)	**SD %**	**Gauge thickness (mm)** (Δd=4mm)	**SD %**	**Sample length (mm)** (Δd=158m m)	**SD %**
Virgin	1	10.06	0.38	4.09	1.09	122.075	0.06	10.84	0.27	3.99	0.90	158.25	0.05
	2	10.15		3.98		122.24		10.85		3.92		158.44	
	3	10.07		4.03		122.11		10.79		4.00		158.27	
Ambient	4	10.18	0.51	4.01	0.43	122.19	0.04	10.90	1.63	3.96	1.49	158.70	0.12
	5	10.07		4.05		122.065		10.74		4.04		158.38	
	6	10.08		4.05		122.11		10.47		4.10		158.24	
Submerged	7	10.17	0.75	4.05	0.49	122.23	0.09	10.64	1.30	4.12	1.18	158.15	0.11
	8	10.01		4.01		121.97		10.58		4.14		158.04	
	9	10.01		4.01		122.18		10.90		4.03		158.46	

Table 37 shows weight data for dog bone samples 3D printed with conditioned filament. The least amount of weight deviation between samples was observed for those printed with virgin material, and the largest deviation was for those printed with ambient material.

When looking at the actual sample weight, and not the weight deviation, both horizontal and vertical samples printed with virgin material were the lightest of the group. Horizontal samples increase in weight linearly with filament moisture exposure. A weight change of 0.0853g was observed from virgin to ambient filament, and 0.1541g from virgin to submerged filament. This increase in weight could be a result of moisture absorption lowering the T_g of ambient and submerged filament more so, meaning the material is less viscose and therefore more material is deposited, increasing the weight of the sample. This was not however reflected by the dimensional measurements, suggesting the additional material deposition occurred within the sample. A similar trend can be observed between virgin and ambient samples with a weight increase of 0.0240g, however, submerged samples showed a weight increase of 0.0227g from sealed, which was marginally less than ambient by 0.0012g.

Table 37: Weight data of horizontal and vertical dog bone samples from conditioned filament

Condition	Sample #	Vertical			Horizontal		
		Weight (g)	Mean weight (g)	%SD	Weight (g)	Mean weight (g)	%SD
Virgin	1	9.0472	8.8949	1.25	10.5644	10.5240	0.50
	2	8.7842			10.4502		
	3	8.8532			10.5574		
Ambient	4	8.8724	8.9188	0.80	10.4841	10.6093	1.07
	5	8.8647			10.584		
	6	9.0194			10.7597		
Submerged	7	9.048	8.9176	1.03	10.7522	10.6781	0.73
	8	8.8511			10.7123		
	9	8.8537			10.5698		

5.5.4. Mechanical

Mechanical properties of samples produced with conditioned materials were observed through tensile testing. The maximum stress, or tensile strength of samples was investigated, revealing that on all occasions horizontally printed samples with ambient material showed the highest tensile strength, samples manufactured using virgin material consistently showed the lowest tensile strength. The vertically printed samples were consistently weaker than horizontally printed samples as expected, however the differences in tensile strength were smaller between the conditioning environments, indicating that storage conditions had a lesser effect for samples printed in the XZ orientation. On average, the vertical data showed slightly more variation than the horizontal samples illustrated by the error bars in Figure 79.

Ultimaker, the material manufacturer, state the tensile stress at both yield and break are 37MPa. This was achieved using white Tough PLA, where samples had a 90% infill and is therefore not directly comparable to the data recorded in this study, where black Tough PLA was used with a 100% infill.

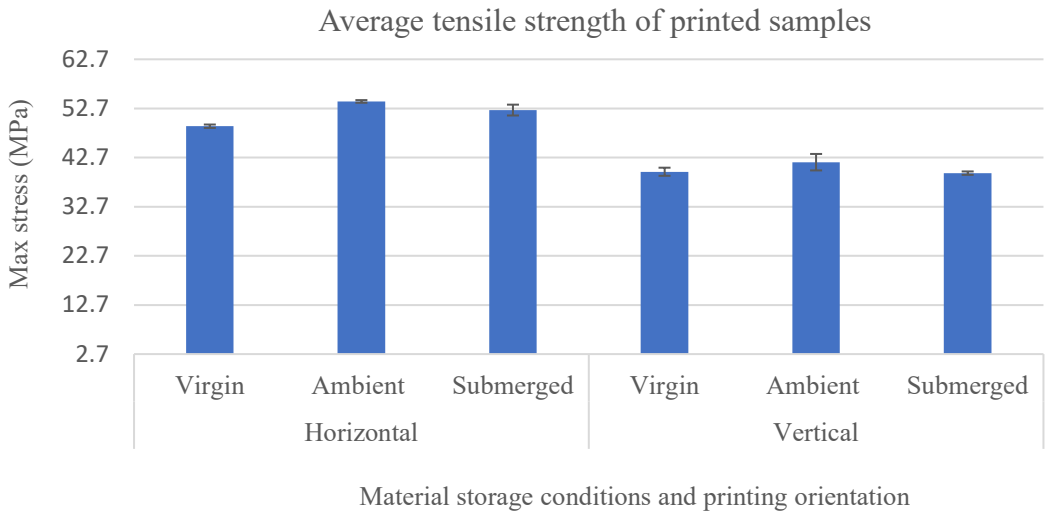


Figure 79: Chart showing the max stress of 3D printed samples with error bars showing standard deviation (mean taken from three repeats of each condition/orientation)

Figure 80 shows the mean elongation for each sample with the corresponding force. There was a clear and expected difference between elongation of samples tested in the horizontal and vertical orientations. It is widely known that FFF parts have a higher elongation in the longitudinal direction than the transverse direction, due to the inherent anisotropy present in the FFF process. In the transverse direction, force is applied parallel to the layer bonds and perpendicular to the filament direction, meaning the primary failure mode is delamination of layer bonds. In the longitudinal direction, filaments have higher elongation due to the filament being able to resist more change than the weaker layer bonds.

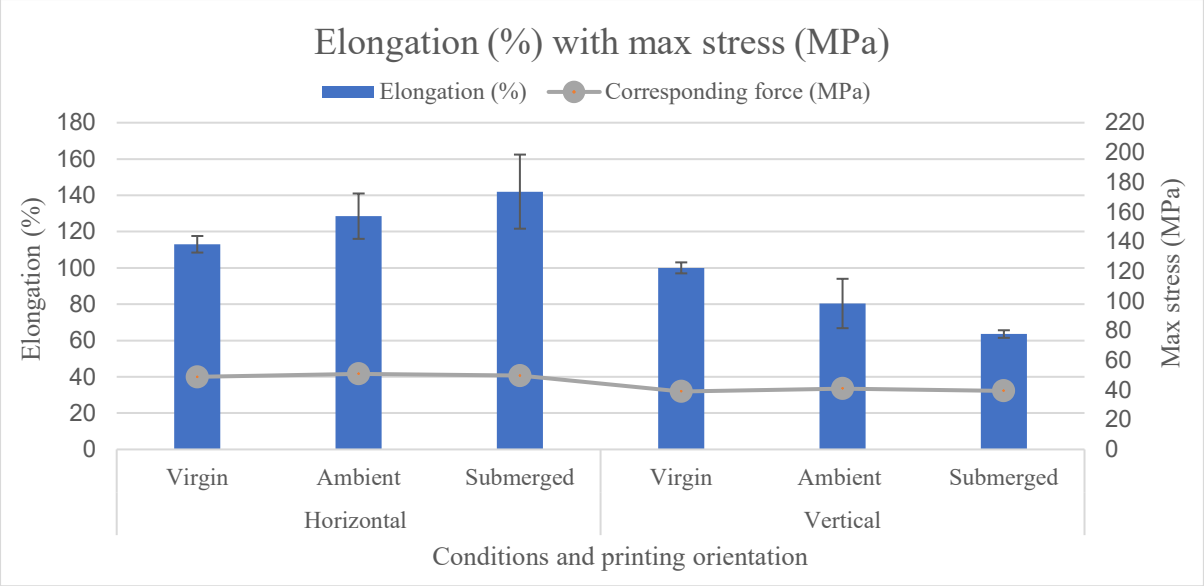


Figure 80: Chart showing the mean percentage elongation calculated from three repeats for each sample/condition. Secondary axis shows the corresponding force. Error bars show standard deviation.

The similarity between the force applied to each sample, in relation to the percentage elongation for each samples suggests that the difference in elongation is caused by the filament storage conditions, the variable under investigation. For horizontal samples, the elongation of dog bone samples was shown to increase linearly where filament exposure to moisture increased. Conversely, in the vertical orientation, elongation decreased linearly where filament was exposed to increased moisture levels.

The low tensile strength and elongation values indicate Tough PLA is brittle. Moisture exposure appears to linearly increase the ductility in horizontally printed samples, although the increase range is small at 0.44%. Samples printed with virgin material showed the lowest percentage elongation in the horizontal orientation. However, in the vertical orientation, submerged samples showed the lowest percentage elongation. Vertical samples produced using filament stored in virgin and ambient conditions show similar elongation, with submerged samples appearing to be slightly more brittle. This could be a direct consequence of the increased number of voids in the sample structure where layer bonding was reduced. This is only seen in vertically printed samples due to the smaller surface area where layer bonding can occur, which could amplify the effects of voids in the structure.

Figure 81 suggests that no significant difference in Young's modulus was observed across the samples investigated. Virgin samples printed in both the horizontal and vertical orientations showed a slightly larger standard deviation between repeats than the other samples. This could be a result of the virgin conditioning group being made up of sealed material, and material that has been stored in a <40%RH environment for less than 72 hours. As shown with the tan δ peak temperature, where there was a significant difference between sealed and <40% RH conditions for 72 hours, the Young's modulus property could be another property that shows a more significant difference over the initial phase of the filament seal being broken, thus resulting in a larger standard deviation than for other conditions.

On both occasions, material exposed to ambient conditions produced samples with the smallest standard deviation between repeats, suggesting that ambient filament storage conditions could reduce variation in Young's modulus between samples. Material storage conditions were not shown to significantly affect the Young's modulus of printed parts; no direct correlation was observed with the material storage conditions.

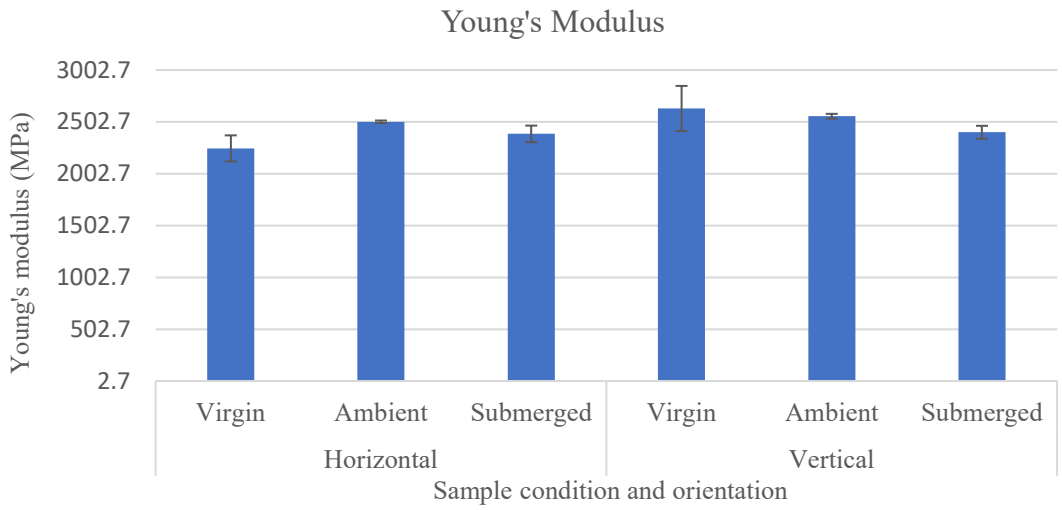


Figure 81: A graph showing the mean Young's modulus (calculated between an extension range of 0.7mm and 0.3mm) for three repeats of each sample condition/orientation. Error bars show standard deviation.

5.5.5. Observational

Figure 82 indicates the internal structures in both the vertical and horizontal printed samples, where (A) and (B) shows a ±45º raster angle which alternates each printed layer. (C) and (D)

show the internal structure of horizontal samples with a ±45º infill. Due to the samples both being printed with 100% infill, no internal structure can be seen, and the ±45º raster angle is used to generate a solid fill. This is the default method for Ultimaker hardware generated by CURA software (®Ultimaker, Netherlands). Both samples have perimeter layers (shown in red in Figure 82) which generate the conventional layered surface finish attributed to FFF technology.

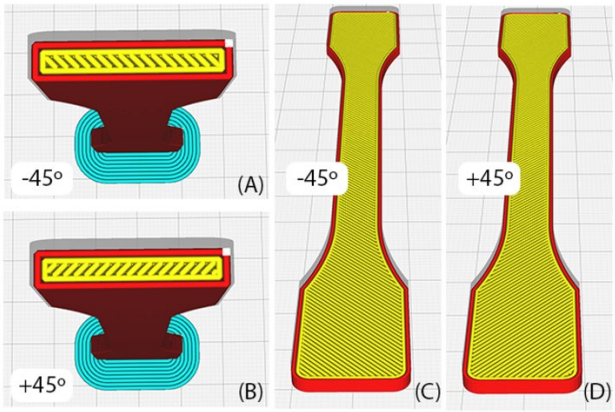


Figure 82: Alternating ±45º infill for vertical (A+B) and horizontal (C+D) samples

5.5.5.1. Surface observations

Figure 83 shows the layered surface of horizontally and vertically printed samples produced from material stored in different conditions. Firstly, when comparing the horizontal samples, the layered structure appeared to reduce in uniformity where material was exposed to a higher level of moisture. Minor pores and defects can be seen in samples printed with virgin and ambient materials. The ambient samples appeared to have slightly less uniformed layer lines visible by the slightly wavy appearance of layers, whereas virgin material shows straighter and more consistent layer lines. Samples manufactured from submerged material show further inconsistencies, with visible pores identifiable between layer lines. Figure 84 shows closer magnification, which confirmed the presence of pores and non-uniform layers. Pores were smaller and less frequent in the submerged sample than expected, compared with some of the images in literature for PLA (Valerga *et al.*, 2018). This could suggest that Tough PLA is more resistant to moisture absorption than PLA, or that exposure for 72 hours is not long enough to detrimentally affect the layer structure of printed parts.

Pores and air bubbles have been identified in literature and are believed to be caused by moisture evaporating during the extrusion process. These voids are not identifiable by eye, and

therefore one could assume the samples are like-for-like in structure. In most cases, the air bubbles appeared to be situated along the surface of the layers, not encapsulated within the material raster. This could influence bonding behaviour between rasters due to the reduced contact area, which may influence the mechanical properties. A larger number of pores could also result in increased porosity of a sample, which depending on the intended application, could affect performance, as discussed in section 5.3.3.

The surface of vertical samples shown in Figure 83 appear less consistent than the horizontally printed samples. This is expected, due to the poorer surface finish observed when comparing the two samples by eye. Surface defects can be observed in samples manufactured with material from all three storage environments. Pores are less visible on the surface of vertically printed samples, however defects in the form of distorted layers were observed, which appeared to affect the following three layers. Samples printed with submerged material appeared to be less linear overall, with more variation in layer thickness and therefore an increasingly turbulent structure.

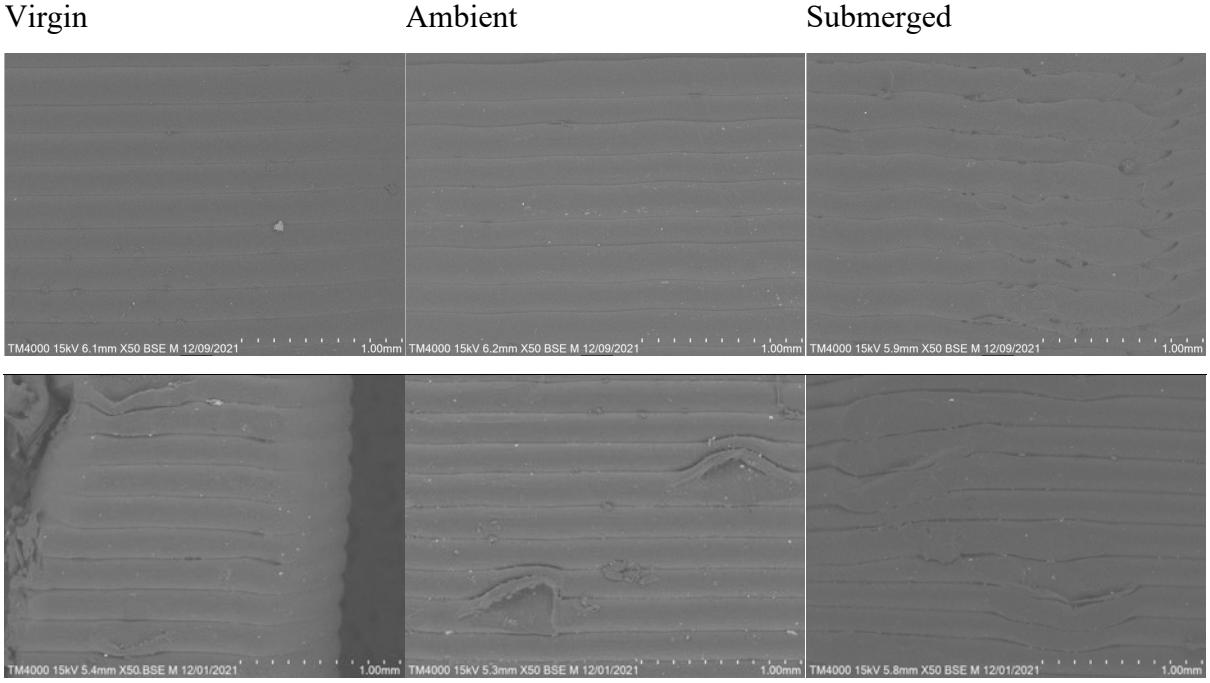


Figure 83: Surface analysis of horizontally printed (top) and vertically printed (bottom) samples with filament stored under different conditions (left: virgin, middle: ambient for 72h, right: submerged for 72h). Repeats shown in appendices (1).

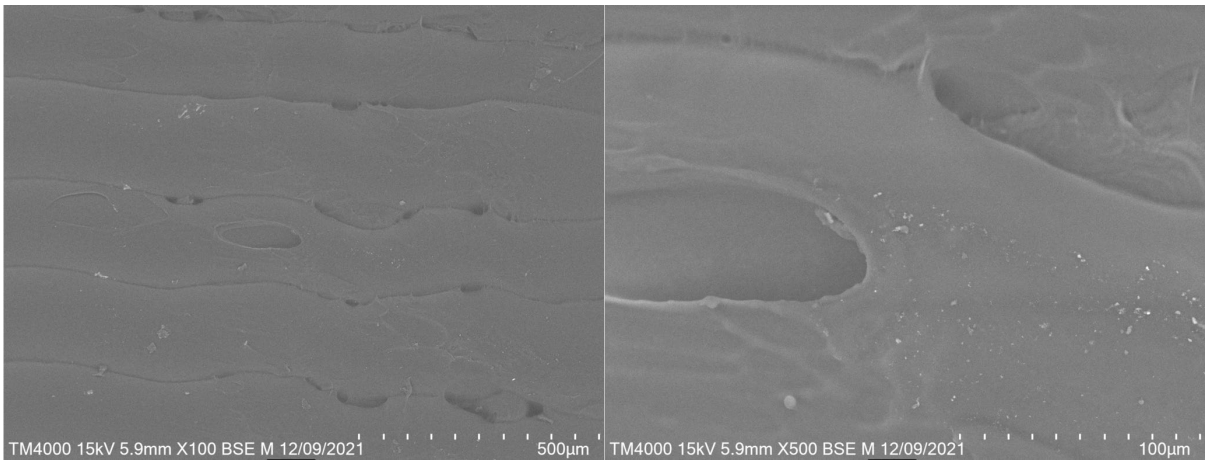


Figure 84: 100x magnification (left) and 500x magnification (right) of horizontal samples printed with submerged material showing pores in the sample structure

5.5.5.2. Fracture observations

After tensile testing, the fracture surface was removed from each sample and analysed with SEM. Figure 85 shows the fracture surface of samples printed with conditioned materials. Virgin and ambient images show the cavities between subsequent filament deposits which occurs naturally during the FFF process. Where filament rasters are deposited next to each other, they do not overlap, meaning there is often a small air gap between rasters. The air gap is a parameter that can be reduced further during the slicing stage. Figure 86 shows the internal structure caused by the ±45º raster angle on alternating layers, which can partly be observed in Figure 85. The fracture shows the layer structure within the sample in both the virgin and ambient material samples. The layer structure is less defined in the submerged samples which could be a result of the less defined layers seen on the surface in Figure 83, or due to slightly increased viscosity of submerged material which is a direct result of a decreased T_g. These observations, however, are not statistically significant.

All images of the vertical samples show the fracture is not a clean break between layers. The depth seen in the fracture surface indicates the fracture has separated multiple bonds over different layers. There is no apparent difference between material stored in each of the observed conditions.

Virgin Ambient Submerged

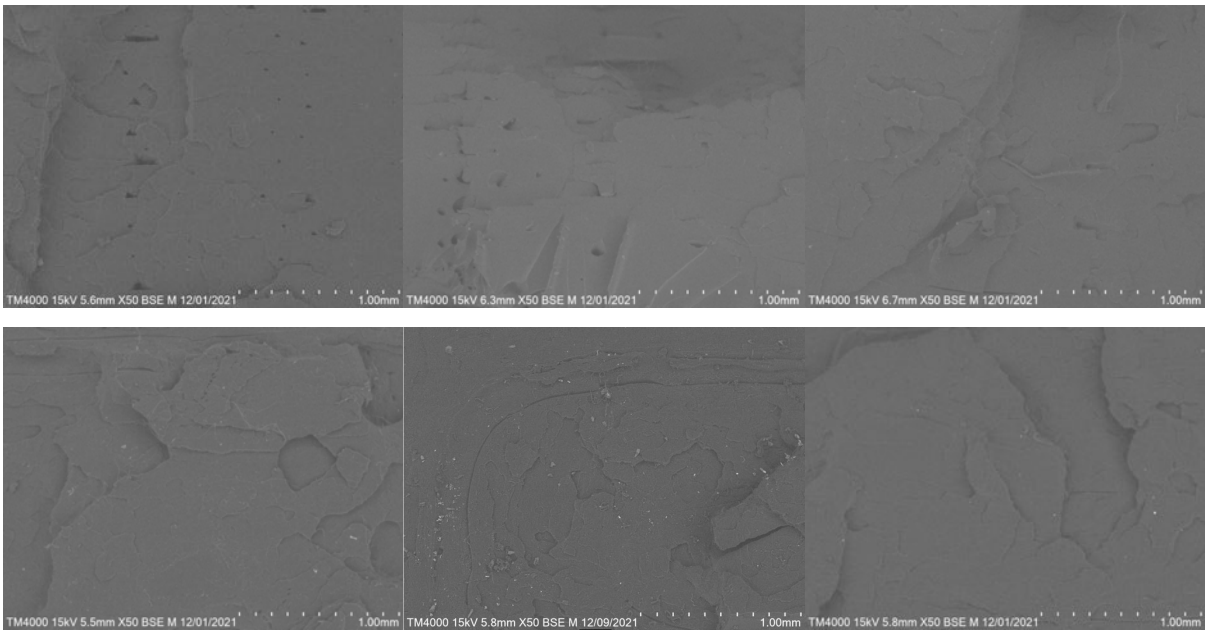


Figure 85: Fracture analysis of horizontally printed (top) and vertically printed (bottom) samples with filament stored under different conditions (left: sealed, middle: ambient for 72h, right: submerged for 72h).

Figure 86: Digitally generated image of the layer structure within horizontal samples with ±45° infill

5.6. Discussion

The purpose of this experimental work was to determine whether the storage conditions for Tough PLA filament, and/or the timescales in which it is stored, influences the suitability of FFF AM technology for the fabrication of Class I medical devices. The suitability of FFF for regulated applications can be assessed against changes in environmental conditions. These effects were categorised into two groups: structural and mechanical properties, and variability occurring between filament specimens and printed samples.

5.6.1. Structural and mechanical properties

Filament specimens submerged in water were shown to have a larger diameter than samples conditioned in other environments, which was believed to have no effect on the printing process. This provides the first quantitative evidence to contradict popularly held opinion that the swelling of commonly used filament as a result of moisture absorption, in this case Tough PLA, can be problematic in the printing process, causing issues like blocked nozzles. However, the largest measured diameter falls within the manufacturer's tolerance specification, meaning increases of such are likely to have been tested and show no impact on the printing process. Increased moisture uptake causing nozzle blockages, as suggested in some grey literature sources (filament2print, 2018), appears to be unlikely for Tough PLA within the studied timescales. No printing issues or nozzle blockages were seen during any of the printing for this study. It is likely that increased diameter due to moisture uptake is more concerning for materials with higher sensitivity to moisture. Future research across a wide range of materials would be required to identify possible cases where swelling may cause printing problems due to moisture uptake. Additional research may also be necessary to make conclusions around the temperature of the storage conditions, and whether prolonged temperatures higher than room temperature increases swelling.

When studying the diameter change of filament specimens stored under virgin, ambient (72h) and submerged (72h), the findings were somewhat unexpected. They did not correlate with the previous diameter findings where submerged specimens were consistently measured to have a larger diameter than specimens stored in other conditions. The mean weight change diameter did show an increase of 0.008mm for submerged samples, although the increase in submerged filament was significantly smaller than the increase of ambient conditioned filament, which was 0.04mm.

Two measured diameter dimensions did not fall within the manufacturer's specification of 2.85 ±0.05mm, measuring at 2.78 and 2.79mm. These measurements were taken before conditioning on both occasions, potentially indicating a poor-quality batch of filament. However, the highest recorded value before conditioning was 2.84mm, indicating the diameter was below the nominal value in all cases. Diameters for both datasets were calculated using three measurements at different points of each specimen, therefore the difference in range and more varied results is unknown.

It was generally agreed in literature that higher moisture exposure resulted in reduced T_g (Halidi and Abdullah, 2012; Zaldivar *et al.*, 2018). This was also found to be true for Tough PLA. For the other studied storage conditions, aside from the sealed condition, there was no significant difference in T_g. The T_g calculated from tan δ peak temperature reflected these findings, with the T_g being lowest for submerged samples, which was statistically similar for sealed samples. Sealed samples having the second to lowest T_g was an unexpected result, and the reason for this is unknown. Although, within the context of this work, the results show that once the filament seal is broken, the shift in T_g was clearly demonstrated. Further work in materials chemistry could be conducted to elucidate the reason for these differences in thermal properties, however the lack of conclusive reasoning did not affect the validity and impact of these results in the general use contexts of FFF. These findings indicated that there was no significant thermal change to materials in ambient conditions for any length of time up to three months. Specimens in direct contact with water for 72 hours showed a slight increase in filament diameter and weight, and a reduction in T_g. To understand the impact of these material changes and therefore what effect these have on the user, further analysis observing their implications on the geometrical accuracy of printed samples and the performance of those samples would be required.

Although there was no direct correlation between material storage conditions and the dimensional accuracy over the gauge width, gauge thickness and sample length of printed parts in the vertical orientation, a clear correlation was observed in the horizontal printing orientation. Although, when put in the context of Class I medical device manufacturing, the difference in dimensions and weight were small, with dimensional deviations of no more than 0.10mm in the horizontal printing orientation and 0.1g in weight.

Whether this level of deviation is acceptable will depend on the application, however, a tolerance of 0.10mm is relatively small, and seemingly insignificant especially for non-specialist users who are not required to meet the stringent specifications that specialist users might. The decreased T_g of submerged material did not appear to influence the geometrical accuracy of printed parts against the nominal value, only the dimensional variance between repeated parts as discussed. The significance of the variation was determined in two ways, firstly the statistical significance is presented through ANOVA, and secondly the variability was considered within the context of FFF use. The significance in this instance would be based

on the user and intended use of the technique, whilst considering the wider context such as the capability of the hardware and measurement tools used.

For dimensional analysis, conclusions were based predominantly on data for horizontal samples due to the improved printing quality. Samples were more consistent and uniform when printed in the horizontal orientation compared to vertical. It is common for FFF printers to print higher quality parts closer to the build plate, because whilst extruding further from the build plate there is a smaller surface area to secure the part and prevent movement from the printing head. Vertical samples were visibly lower in quality than horizontally printed samples. Thus, variation shown in the horizontal samples is more likely to be attributed to the variable factors studied, i.e., the moisture exposure of filament, than naturally occurring variance from poor printing quality.

The data on the mechanical properties of horizontally printed samples showed the virgin samples to have the lowest tensile strength, and ambient samples have the highest. This was also seen in two of three repeats for vertical samples. These findings are consistent with those in literature (Zaldivar *et al.*, 2018), which suggests that sealed material shows more pronounced gaps between rasters, in turn reducing the tensile strength. A slight increase in moisture exposure could potentially be reducing gaps between rasters, improving consolidation, and therefore increasing tensile strength. However, this was not shown to be the case by the SEM images in Figure 85 which showed virgin and ambient samples had similar internal structures. SEM images of the internal structure of the dog bone samples were difficult to obtain, aside from using the fracture surface, due to Tough PLA being a difficult material to polish. Due to the tensile strength data, and findings in literature, it is believed that more apparent gaps between rasters would likely be seen in the internal structure of samples printed with sealed material.

The reduced T_g observed for sealed and submerged material conditions were loosely reflected by the tensile testing data, with ambient conditions which had a higher T_g, showing the highest tensile strength. This suggests that the initial increased viscosity of ambient samples did not result in under extrusion. Controversially, the weakest samples, printed with virgin filament, would have been expected to have increased consolidation between rasters due to the decreased viscosity. This could indicate that the T_g is not a significantly influential factor for the performance of printed parts. Analysing the melt temperature may have shown less of a gap

between sealed and submerged conditions, and ambient conditions, potentially explaining the increased tensile strength of ambient parts. Based on these findings, storing filament in ambient conditions is not likely to negatively affect the performance of printed parts.

To understand how much the significant difference in T_g, identified by the tan δ peak temperature, affected the material properties of printed parts, a tensile strength comparison was set up to compare sealed material and <40%RH material for 68-72 hours. Samples printed with filament conditioned in <40% RH environments showed similar thermal properties (apart from tan δ T_g) to samples produced with sealed filament, also showing similarities in dimensional and weight measurements. When comparing tensile strength data across all samples (see Figure 87), samples stored in <40% RH environments showed a slight increase in tensile strength. This data conclusively implied that virgin material has the lowest tensile strength, and incrementally, as the packaging seal is broken, strength increases to a certain point recorded in this study as ambient room conditions. A small standard deviation implies the data was consistent across repeats for sealed, <40% RH and ambient conditioned material.

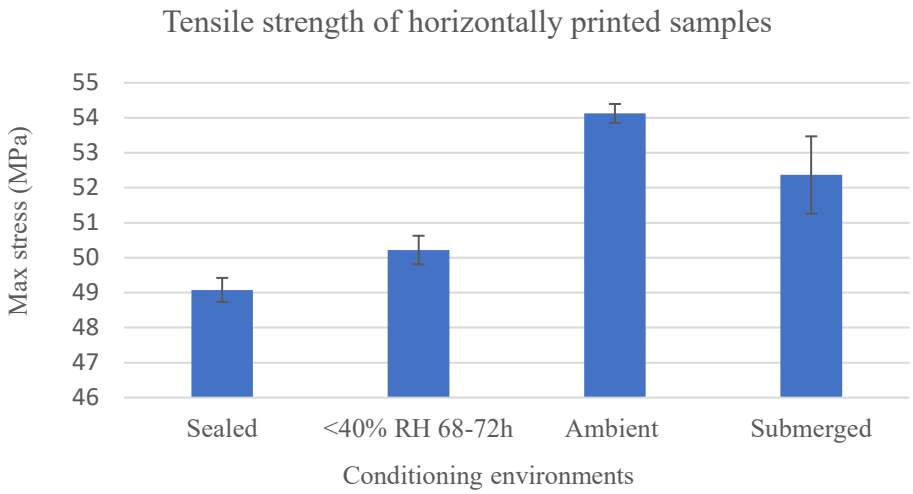


Figure 87: Tensile strength of all horizontal samples, including samples stored in a <40% RH environment for less than 72 hours

This fully supports the theory of increased consolidation between rasters where filament has been exposed to moisture levels found in ambient room conditions. In the context of Class I medical device manufacture, the findings most transferrable to daily practice were the use of sealed material to minimise dimension and weight variability between printed samples, and the use of material stored in ambient conditions for slight improvements in tensile strength. Using

virgin material for every print is highly unpractical for non-specialist users, as well as research and industrial users of the technology, and due to the small benefits shown for repeatability and reproducibility, is not likely to be a viable approach to FFF AM.

5.6.2. Variability occurring between filament specimens and printed samples

Firstly, variability between repeats was measured for the material in filament form and for the 3D printed sample. The variability between diameter for filament specimens was not found to be significantly affected by the conditioning environments. Variability between repeats was relatively similar across all filament samples. Variability between the T_g of filament specimens from different conditioning environments was shown to be the smallest for submerged samples, however the variance between the repeats within other sample conditions were less significant and did not directly correspond with the level of moisture exposure. At the raw filament stage, moisture storage conditions were not seen to be significant in increasing variability between filament specimens.

However, when analysing the variation between samples, moisture conditioning environments were found to have a more profound effect. The dimensional variance between repeat dog bone samples showed that in all cases, samples produced from virgin filament had the lowest percentage standard deviation (%SD) between repeats for all measured points. The highest %SD was observed for samples produced with ambient material. These findings indicate that using sealed filament can result in printed parts being more geometrically consistent, with a higher level of repeatability achieved. Ambient materials increased the geometrical deviation, showing less consistency across width, thickness and length values. Similarly, the weight of the printed samples also showed virgin material giving the smallest %SD, and ambient material showing the highest. These findings indicate that where high levels of repeatability and reproducibility are required, using material that has had minimal amounts of moisture exposure is more likely to reduce variability between repeat parts.

The variability between the mechanical properties of repeat samples was not shown to be influenced by material storage conditions for the tensile strength and elongation properties with no distinct trends being observed. Young's modulus, however, did show that samples produced from virgin material showed a larger range of variance than the other conditions, which as discussed, could have been a result of the virgin condition being made up of a combination of

sealed conditions and <40%RH for <72 hours, which showed a larger range of results for this mechanical property.

To summarise, storing filaments in different moisture environments did not appear to reduce the variability between raw filament specimens, however, filament exposed to increased levels of moisture did increase the dimensional and weight variability between 3D printed samples. The variability between mechanical properties remained unaffected by filament storage conditions for the most part, however, Young's modulus showed increased variability for virgin conditions. For the user, these findings indicate that filament exposure to different moisture environments is not likely to significantly cause increased variation between repeat parts. Although, for the specialist users, intending to produce regulatory approved parts, where improved repeatability and reproducibility is more critical than increased mechanical performance, sealed filament, or filament exposed to minimal moisture levels should be used for optimal results.

5.7. Conclusions

To the author's knowledge, this is the first study to consider the effects of filament storage conditions on the material properties, microstructure of printed parts, and the geometrical and mechanical performance of 3D printed parts in relation to quality control aspects such as part-to-part variation. This study therefore provides valuable insights to FFF users working with Tough PLA which can be used to inform daily practice. This work concludes that storing filament in ambient conditions for up to three months is unlikely to negatively impact the material properties, printing process and part performance. Ambient storage conditions are likely to slightly increase the tensile strength of 3D printed parts.

The tensile strength of horizontally printed samples increased linearly with moisture exposure levels before peaking at ambient room conditions for 72 hours. After this peak, maximum tensile strength began to decrease, but remained higher than the max stress values for sealed filament. When considered alongside the small variation in tensile strength between vertically printed samples, it can be concluded that exposing filament to ambient conditions over the considered timescales did not negatively influence the tensile strength of 3D printed parts. For applications prioritising mechanical properties, this research dispels the need to purchase humidity-controlled chambers for storage of Tough PLA material. By maintaining mechanical

properties and not requiring additional equipment to store material, the technology remains highly accessible to users creating functional parts. This is particularly relevant to non-specialist users, who are unlikely to have financial access to professional equipment such as humidity-controlled storage stations.

On the other hand, the humidity-controlled chamber discussed maintained relative humidity levels below 40%. A wide range of hardware options offer storage at much lower humidity levels, down to <1%. Future research is necessary to determine whether a more advanced humidity-controlled chamber, maintaining lower levels of RH would offer the same advantage of reduced part-to-part variability, whilst showing mechanical property improvements. For specialist users preparing a device for regulatory approval, more stringent control measures may need to be explored to uncover further optimisation of the FFF process. Where high accuracy and precision are a priority, for example for a surgical guide, research should be geared around optimising control measures that will produce the most accurate physical part of a representative digital model. In this case, research should specifically focus on a wider number of input variables, for example the extreme end of low humidity material storage environments (<1% RH), and their effect on accuracy and precision as performance characteristics. For a different type of medical device, such as a weight baring prosthetic limb, an extensive study focussed on the mechanical performance would be required, demanding more in-detail testing of those particular performance characteristics by opening the study up to a wider range of input variables.

Storing material in ambient conditions did however increase dimensional variance, thus reducing the repeatability of part dimensions. Dimensional variance was smallest in virgin samples and largest in ambient samples, around double the percentage standard deviation for each measured feature. These findings may be particularly relevant for FFF applications obtaining regulatory approval, or in any other scenario where precision levels of repeatability and reproducibility are required. A manufacturer who would prioritise precision may choose to only use sealed filament or filament stored below <40% RH for a relatively short time. Alternatively, a manufacturer looking to produce parts with optimum tensile strength, based on these findings, would opt to store filament in ambient room conditions.

To conclude, the storage conditions of Tough PLA filament for FFF did not appear to significantly affect the material properties, printing process or performance of 3D printed parts.

The results indicated that by fine-tuning the storage of filament to achieve specific material characteristics is possible. Slight variations in T_g, dimensional and weight variance, tensile strength, and observed microstructure can be achieved under specific filament storage conditions, however, in the context of day-to-day applications of FFF, none of the observed conditions are likely to significantly influence the FFF process or part outcome.

Where a particular medical device is concerned, which has a defined performance specification, testing could be more focussed around the desired performance areas and be used as a way to optimise the FFF technique for specific devices. For example, variations in elongation may be more critical to one device than another, and therefore testing can be focussed around optimising that specific characteristic.

Chapter 6

6. Influence of pigmentation and air management on fused filament fabrication

6.1. Introduction

Colour is a particularly relevant variable when considering medical applications. As discussed in Chapter two, a key benefit of using FFF technology to produce bespoke Class I medical devices, such as prosthetics and orthotics, is the advanced customisation opportunities it offers. Examples from e-NABLE include prosthetic devices produced in a single colour, multiple colours and specialist colour variations including glow in the dark pigments, glitter flecks and metallic fillers to name a few. Quality is more difficult to control where multiple material variations are present. Any differences in part performance, whether that is the dimensional accuracy or the mechanical properties of a part, could result in assembly issues or weaknesses in an area of the part. Colour could also be a problematic variable for single colour parts if parts with duplicate geometry are produced in different colours as part of the same production batch. For example, if a user has two prosthetic devices (based on one single digital part file), one orange and one blue, they would be expected to fit the same and perform the same. In the event of the orange device being more brittle, damage or injury could occur if the user continued to use both devices in the same way or for the same activities. Colour now becomes an important variable to investigate for both safety and quality reasons.

Colour is often overlooked as a variable factor. This is likely due to suppliers not differentiating between colours. Most filament manufacturers provide the same material data sheet for all colour variations of the same material. The data sheet includes information about the optimal print settings for that material, the thermal properties and the mechanical properties of the filament when printed. For this reason, users expect variations of the same material to perform the same, despite the different chemical composition of material responsible for giving it a different colour. Combined material data sheets are likely to be based on the less critical applications of FFF seen previously, such as prototyping or visual model making, where these variables may not significantly influence the process. As the technology, materials and

applications have become increasingly sophisticated, additional research is required to justify the continued combination of material information or documentation, or to prompt the development of an updated system meeting the requirements for the current usage of the technology.

Chapter four focussed on the capability of baseline FFF hardware without additional hardware add-ons. It is becoming increasingly common for manufacturers to release additional hardware modules with the intention of improving the FFF process in some way. As discussed in previous chapters, two additional hardware modules for the Ultimaker S5 were released in late 2019, which when combined form the "Ultimaker S5 Pro bundle". An air management unit, called the "air manager", and the humidity-controlled storage chamber call the "material station" discussed in Chapter two, are the additional hardware modules compatible with the Ultimaker S5. The additional hardware which converts a standard machine to a "pro" machine is said to be in response to some of the challenges faced by FFF users. The units were released to address research and development (R&D) challenges raised by users of the technology. Some of the challenges reported by customers included material degradation, safety of ultrafine particles (UFPs) produced during printing, general productivity, and the influence of environmental factors on the printing process.

The module of interest in this chapter is the air manager, which is a unit placed on top of the Ultimaker S5 to enclose the print chamber. The safety concerns over UFPs being released into the air was recognised by the hardware manufacturer, which became an R&D challenge. Driven by technological advancements and sophistication of the technology, FFF has been used for volume production where multiple printers are operating within the same enclosed environment. Print farm is a term used to describe a group of 3D printers that run simultaneously, which is becoming increasingly common practice. This heightened concerns around the safety of having multiple printers operating simultaneously in an office environment with limited ventilation. Increased printing volume results in increased amounts of UFPs, therefore a primary feature of the air manager is the 95% filtration (Ultimaker, 2019) of all UFPs from polymer printing.

For effective filtration, the air manager must enclose the print chamber. This is also said to protect the printed parts from the environment around them. Research in this area compares open build chambers to a range of methods used to close or control the build chamber. Methods

include make-shift chambers, such as plastic boxes made from acrylic or Perspex which are placed over the top of a printer, up to industrial climate-controlled chambers. The method of air management under investigation is a purpose-built system which encloses the chamber. However, air is still circulated in and out of the chamber using the combined fan and filtration system. The hardware does not include any heating or cooling elements to control the temperature of the chamber like some of the more sophisticated systems.

Some research suggests that draughts or irregularities in temperature can negatively affect the quality of printed parts. However, little to no research exists that describes the effects of hardware such as the air manager on printed parts. In addition, there is a lack of research on the effects of air management or enclosing the build chamber in combination with other variable factors. It may be seen that air management is more beneficial when coupled with other printing parameters or variable factors. For example, air management may be more influential for parts printed in the horizontal orientation than the vertical orientation, or it may have more of an effect on some material colours than others.

For high performance materials such as polyether-ether-ketone (PEEK) which is printed above 350ºC (Geng *et al.*, 2019), the thermal processing conditions play a crucial role in the prevention of printing issues or defects in the part (Sharma *et al.*, 2021). Higher printing temperatures result in more extreme temperature gradients, which then result in unwanted defects. For this reason, most industrial 3D printers intended for use with high performance materials have a fully enclosed, climate-controlled build chamber. For other less specialised or standard materials, working to stabilise a printing environment is good practice. However, the exact steps required to stabilise a printing environment, and the benefits of doing so are unknown, especially to non-specialist users who do not have access to equipment or facilities to conduct their own experiments. This research therefore aims to quantitatively present the effects of air management on three quality attributes: dimensional and weight variability, dimensional accuracy, and mechanical performance. These findings can then be used by individuals to make informed decisions around the investment of air management hardware in relation to their product requirements.

The effects of air management on quality attributes such as part repeatability is likely to be of interest to those pushing the boundaries of FFF printing to find the optimal performance of professional FFF technology. This could be directly relevant to determining the suitability of

FFF technology for the manufacture of medical devices or other regulated products by specialist users. High-end industrial hardware would be preferable for ensuring quality, due to the increased control factors built in. However, a promising and potentially powerful benefit of mid-range FFF technology is the low cost and high accessibility it offers to a wide range of users. If an acceptable level of quality can be achieved through implementing control measures, more specialist, non-specialist and research entities will benefit from low-cost solutions. This in turn enables increased accessibility for customers and users of FFF produced parts.

The aim of this chapter is to determine whether investment in air management technology would be beneficial to the FFF printing process in relation to its suitability for low-risk Class I medical device manufacture in relation to the quality requirements necessary for the use context. Although, the relevance of this research applies to users in a similar working environment of an air conditioned, indoor office. These findings are not as relevant for severely different settings, such as a non-insulated garage area which is more susceptible to changing environmental conditions. In this scenario, the use of air management could potentially show different findings.

6.2. Literature review

6.2.1. Air management

Enclosing a printing chamber has two main benefits. Firstly, the fumes produced when melting plastics can be both unpleasant and dangerous, so using an enclosed chamber with a filtration device can minimise safety concerns. Secondly, the quality of FFF parts in terms of their geometrical and mechanical performance are said to be influenced by the thermal effects of the FFF printing process, which is said to be mitigated by enclosing the build chamber and regulating the printing environment.

Anisotropic behaviour of FFF parts and part deformation are commonly discussed limitations of FFF. Anisotropy in FFF printed parts is a result of the bonding or welding of adjacently deposited material in a directional manner (Ahn *et al.*, 2002; Kim *et al.*, 2016), and is said to be the weakest and most critical link in FFF parts (Sun *et al.*, 2008). Deformation of FFF parts occurs where inner stresses are released from a printed plastic part (Wang *et al.*, 2007). Both limiting factors are a result of thermal effects of FFF printing where the heating and cooling of polymers occur.

Minimising anisotropy and deformation is an important objective to many FFF users. Part deformation is a form of part failure that can be costly, time consuming and wasteful. Minimising the number of defect parts is an important priority for individuals and organisations to maintain an efficient manufacturing operation. Minimising anisotropic behaviour is important for functional applications where parts are intended to withstand significant amounts of stress, which is also likely to be the case for most FFF produced medical devices. Anisotropic parts, where physical properties vary according to the printing direction, must be carefully considered to ensure the part is resistant to the stresses in the loading directions the part will be exposed to in use. This can often add design complexity and in some cases require alternative manufacturing methods capable of producing isotropic parts.

Improving the bonds between deposited material can reduce anisotropy. Firstly, the mechanism of raster bonding is addressed. Strands of filament are extruded from a heated nozzle. These strands are referred to as rasters and are deposited on a build platform along a predefined path. Upon completion of a full layer, the next layer is deposited adjoining the previous. Two types of bonding occur; the adjacent bonds between rasters deposited in the same layer and the directional bond between two rasters as illustrated in Figure 88.

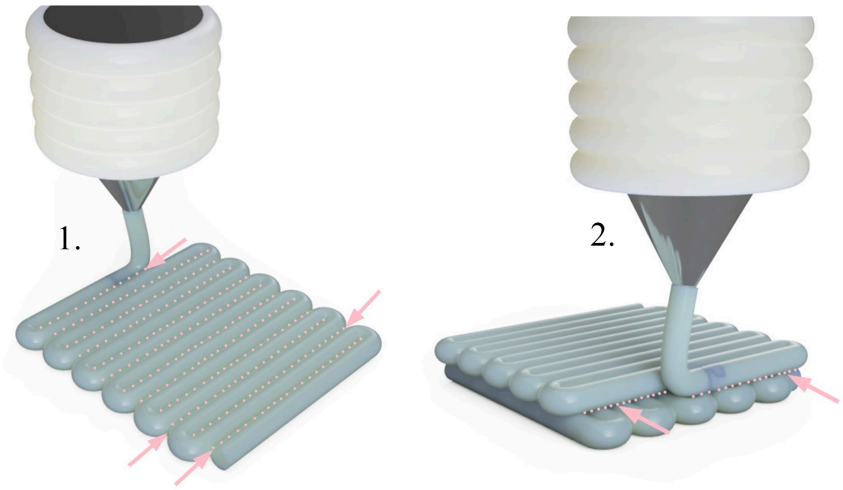


Figure 88: Illustration of layer bonding in FFF where bonds are indicated by a dotted line (1. showing adjacent bond in the same layer, 2. showing the bond between layers in the Z direction)

Contact between molten (liquid) polymer and solid surfaces is known as the wetting phenomenon (Rios *et al.*, 2007), which is the bonding stage where neck growth occurs (Bellehumeur *et al.*, 2004). Neck growth is described as the merging between two rasters, as illustrated in Figure 89 which is said to dictate the quality of the bond between individual filaments (Bellehumeur *et al.*, 2004; Sun *et al.*, 2008). Molecular diffusion dictates the bonding quality of filament, which in turn plays an important role in establishing the mechanical properties of printed parts (Thomas and Rodríguez, 2000; Sun *et al.*, 2008). The bonding behaviour between rasters can be influenced by a number of factors which have been explored in literature.

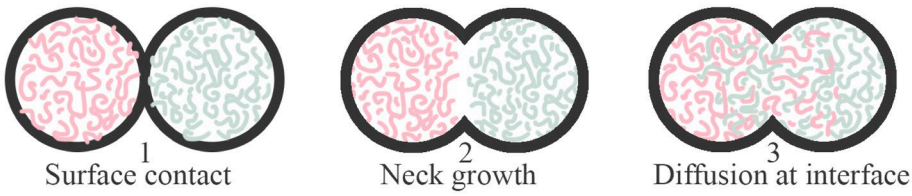


Figure 89: The bond formation process between two deposited filaments (adapted from (Bellehumeur et al., 2004))

A comparison of the tensile strength of PLA was conducted by (Spoerk *et al.*, 2017) who tested the tensile strength of compression-moulded PLA and the tensile strength of FFF printed PLA. They found that with optimised printing parameters, 85-90% of the tensile strength of the moulded PLA was achieved with FFF.

Bulk material strength of PLA was achieved by (Allum *et al.*, 2020) with samples printed in the longitudinal and transverse directions when printed with an FFF printer with a fully enclosed build chamber, paired with a ventilation system which allowed a consistent temperature to be achieved. The effects of varying printing parameters were studied, these included layer height, extrusion width and volumetric extrusion rate. The authors found that varying these parameters had little effect on the strength of the samples. They found that anisotropy was a result of the geometry of extruded filament and localised strain, not insufficient bonding between layer interfaces.

(Coasey *et al.*, 2020) also suggested that bulk strength could be achieved for ABS when very high printing temperatures were used. Although, they did recognise that defects formed during the printing process are inevitable, acting as failure points and therefore not allowing

characterisation of the bond strength. By increasing the printing temperature from 204ºC to 224ºC, a substantial effect on the degree of healing was observed which increased by more than a factor of two. The time at which the material took to cool to the glass transition temperature (T_g), was also substantially affected by the 20ºC temperature increase.

When investigating the bonding strength of ABS, (Coogan and Kazmer, 2017) found that 95% of filament tensile strength was found in the longitudinal direction, and the bond strength ranged between 40 to 85% of the filament strength, depending on the printing parameters. The parameters studied include build plate and nozzle temperature, print speed, fibre width and layer height. Higher bond strengths were found to be a result of increasing build platform temperature and nozzle temperatures, faster print speeds, smaller layer heights and larger fibre widths.

It is generally agreed that the mechanical properties of FFF parts were negatively influenced by insufficient filament bonding between rasters (Sun *et al.*, 2008). Although the challenges around characterising bond strength were noted, and that bond strength could wrongly be attributed to defects from the printing process. High variable bond strengths were reported. A range of 45% reported by (Coogan and Kazmer, 2017) is significant and could heavily influence a parts' functional performance. Therefore, understanding which factors influence the bond strength is essential for optimisation of the FFF technique.

Temperature is shown to be a key factor in influencing the bonding of rasters (Sun *et al.*, 2008). Ko *et al.* (2019) suggests that for optimal bonding, two polymetric interfaces should be heated above either their T_g or melting temperature (T_m) and brought into immediate contact due to the number of polymer chains that move into the next deposit is increased at these temperatures.

The three main heat sources in FFF are the heated nozzle, a heated build plate and a heated build chamber. Most FFF printers have a heated build plate, however few have a heated build chamber. Numerous studies have evaluated how each of these heat sources, among other parameters can influence the bonding strength between filament rasters. The nozzle temperature is the primary source of heat where it melts the material to the desired extrusion temperature. After filament has been extruded from the heated nozzle it immediately begins to cool. At this point, additional heat sources such as a heated build platform and heated build

chamber can be used to control the cooling of deposited rasters for optimum bonding conditions.

It is agreed that nozzle temperature is thought to influence the bond strength between filament rasters (Coogan and Kazmer, 2017). Basgul *et al.* (2021) found that nozzle temperature had the most significant effect on neck growth in the bonding zone, more so than chamber temperature. They suggest that improving the control of cooling conditions for deposited material can influence the mechanical properties of a part. This is agreed by Thomas and Rodríguez *et al.* (2000), who discuss that slower cooling rates during the solidification phase of deposited material can promote stronger bonding between rasters. Additionally, Costa *et al.* (2017) found that lower extrusion temperatures resulted in poorer adhesion between layers. The literature generally reported a direct correlation between nozzle temperature and bonding strength of rasters.

As well as directly influencing the bonding temperature, higher nozzle temperatures are thought to influence the chamber temperature in hardware that does not actively control the build chamber temperature (Coogan and Kazmer, 2017). This is due to the higher nozzle temperature acting as a more powerful heat source which transfers to the printing environment. A less powerful heat source is a heated build platform; however, it's influence on the overall chamber temperature and the bonding of layers should be considered.

Using a heated build platform has been shown to increase the bonding of layers (Coogan and Kazmer, 2017; Basgul *et al.*, 2021). A heated build platform is also thought to reduce warping; however, this only applies to the first layers of the print due to the poor heat conduction of plastics. Compared with other printing parameters explored by (Coogan and Kazmer, 2017), the build plate temperature was not statistically significant in affecting the bond strength, although a trend was observed where higher build plate temperatures indicated stronger bonds. They noted that the vast majority of printed samples failed at locations furthest away from the heated build platform, suggesting the higher temperatures closer to the build platform formed the strongest bonds.

Similar findings were reported by (Basgul *et al.*, 2021) where higher temperatures were exhibited closer to the heated build platform, increasing the healing of layers. This study was conducted using PEEK which is printed at around 440ºC, significantly higher temperatures

than PLA. Expectedly, the platform temperature was maintained at a higher temperature of 130ºC. A decrease in specimen temperature as the distance from the build plate increased was reported by (Fang *et al.*, 2020) for polycarbonate samples.

The cooling time of a deposited layer before the next layer is deposited depends on the movement of the nozzle which is dictated by the geometry. Larger parts take longer to print, resulting in longer cooling time between layers than observed for smaller parts. This movement of the heated nozzle, a powerful heat source, creates non-isothermal conditions when the build chamber is not enclosed, and temperature controlled.

A number of studies have analysed the movement of heat within an enclosed build chamber, however few have focussed on the effects of an open build chamber, or closed/semi-closed chambers without active temperature control systems. Ahn *et al.* (2002) recognised that different temperature pockets are present in different locations within the build chamber, however it was neglected as a parameter in Ahn's study due to the fluctuation of chamber temperature and a general lack of precise control over this parameter. They also state that build chamber temperature was shown to have an insignificant effect on parts produced in previous work.

The temperature of the build chamber, or the air around the part(s) being printed is not consistent across all regions of the chamber due to the movement of heat sources discussed. The nozzle temperature is much higher than the chamber temperature, and therefore causes temperature changes within the chamber (Sun *et al.*, 2008). Temperature changes within the build chamber affect the cooling rate of deposited filament, subsequently affecting the bonding strength.

The effect of part geometry on building temperature was investigated by Sun *et al.* (2008), who found that laterally built parts (in the XZ printing direction) had a higher mean building temperature than longitudinally built parts, with a difference of 12.3ºC. This is due to the print head travelling longer distances around the chamber, allowing longer cooling times before the next printing path. Laterally build parts have a shorter print path which results in the build head being positioned in the same region for longer time periods. As a result, the recorded peak temperatures were higher.

Temperature profiles were found to vary greatly at different locations within the build chamber (Sun *et al.*, 2008). The printer used in this study was equipped with a temperature-controlled build chamber which heated and circulated enclosed air. They found the temperature management to be homogeneous, but the airflow not. This supports the notion that build chamber location has a strong effect on the thermal characteristics of a part. A 31% larger neck growth was reported between two parts produced in the same build chamber in different locations (Sun *et al.*, 2008). These findings conclude that build chamber temperature was found to have strong effects on the mesostructure, overall affecting the quality of the bonds between rasters.

The effects of build chamber temperature for polycarbonate (PC) were analysed by (Fang *et al.*, 2020), who tested four different build chamber temperatures: 30, 50, 70 and 90ºC. The chamber was heated and maintained at the four temperatures with a fluctuation of ±5ºC due to the limited insulation in the chamber. The temperature field was evaluated using infrared thermography, which saw that material rapidly cooled immediately after leaving the nozzle. The authors discuss that actual material temperature was around 15% less than the specified printing temperature. They observed a thermal gradient of up to 5.4ºC/mm when printing with an open-chamber printer with a heated build platform. Increasing build chamber temperatures was reported to result in a slight increase in ultimate tensile strength and fewer geometrical defects however this was not statistically significant. Across the 60ºC temperature range studied, the authors concluded that defects could be mitigated by 50%.

A similar study conducted by (Thomas and Rodríguez, 2000) investigated bonding strength of ABS at three chamber temperatures: 50, 60 and 70ºC. Based on their findings, the authors predicted that when the chamber temperature is raised to 80ºC, the bond strength would be ~5% higher. Additional methods of increasing bond strength were also discussed, including doubling the extrusion size and annealing parts post fabrication.

A study conducted by (Casavola *et al.*, 2019) set out to verify the use of a heated build chamber for producing ABS parts. They compared two FFF printers, one with a fully heated and enclosed chamber, and the other which had an open build chamber and heated bed. Findings indicated that samples printed in an open chamber with a heated build plate had higher residual stresses. To measure thermal stress, they used a hole-drilling method presented by (Casavola

et al., 2017) which involves drilling a hole in a specimen and using an optical technique to measure surface displacement around the hole caused by stress.

Thermal stresses occur as a result of thermal expansion. The coefficient of thermal expansion is a property that indicates the extent a material expands upon heating. A lower coefficient improves the printability of the material. As discussed, when thermal stresses are released from plastic parts deformation occurs (Wang *et al.*, 2007). When the cooling temperature ranges between the T_m (melting temperature) and T_g, larger deformation can affect the polymer with less force. This is due to the temperature having less capacity to resist outside force when the material is hot, therefore internal stresses are not accumulated.

(Wang *et al.*, 2007) found that increasing the temperature of the build chamber decreases the warp deformation of printed parts linearly. They found that by heating the build chamber to the materials' T_g, deformation is eliminated. However, increasing the chamber temperature reduces the cooling time for deposited filament which may affect the quality of the layers as a result of the previous layer not completely solidifying. The deformation due to thermal stresses may be reduced, but fibre rippling could occur where new deposits are fused with molten material. Allowing the material to cool enough to form a 'crust' is important for maintaining quality. Therefore, (Wang *et al.*, 2007) suggest finding a chamber temperature that balances optimum bonding temperature and sufficient cooling.

(Fang *et al.*, 2020) observed deformation caused by residual stresses in PC parts. They found that warping occurred in layers furthest away from the heated build platform which was a result of larger temperature changes between specimen temperature and the T_g. PC showed less shrinkage and therefore less deformation in the warmer layers closer to the build plate which acts as a permanent heat source for the duration of the print. Higher temperatures surrounding the part were shown to lower the thermal gradient, thus resulting in less warpage and deformation.

As mentioned, faster print speeds are thought to improve bonding strength due to the reduced time for cooling the previous layer before the next layer is deposited (Coogan and Kazmer, 2017). When studying the influence of printing parameters on the temperature field and gradient variation, (Zhang *et al.*, 2017) predicted that higher printing speeds lead to improved mechanical properties of parts. This is through thermal coalescence due to the lower amount

of cooling time between layers. Deposited rasters were also found to be reheated by a freshly deposited raster occurring mainly in the Z direction. They also predict that increasing the layer thickness lowers the overall cooling rate, due to the larger deposits of material taking longer to cool. On the other hand, (Allum *et al.*, 2020) found that varying the print speed, and modifying the time taken to print each layer had no influence on the interlayer bonding strength.

6.2.2. Pigmentation

Pigmentation in 3D printing filament is an under evaluated characteristic (Valerga *et al.*, 2018). The exact filament composition is rarely provided to the end user (Tymrak *et al.*, 2014), and as discussed, the properties established by the manufacturer are often presented the same, regardless of colour. The influence of colour is often neglected in reporting results in scientific literature (Ramian *et al.*, 2021). There is a lack of standardisation and communication around material characteristics in AM (Valerga *et al.*, 2017).

6.2.2.1. Effects of colour on dimensional accuracy

(Hanon *et al.*, 2021) investigated the effects of colour on the dimensional accuracy of PLA. Three colours, white, grey and black, were studied combined with a set of printing parameters which included the build orientation, raster angle and layer thickness. The authors found that white samples weighed more than black samples with a difference of almost 7.4%. The dimensional accuracy was reported as a percentage of accuracy to the nominal value. Most samples showed similar dimensional accuracy, ranging between 98.36% and 99.72%. A 45º raster angle appeared to result in poorer dimensional accuracy. The best overall dimensional accuracies were obtained with black coloured filament and a set of process parameters. Conversely, lighter or natural coloured PLA was found to have less dimensional deviation and be closer to the nominal value than more intense colours in two other studies (Soares *et al.*, 2018; Valerga *et al.*, 2018).

A study investigating the warpage of ABS parts printed with FFF was conducted by (Ramian *et al.*, 2021). The variables investigated were the length and height of a part, the surface area, nozzle temperature, bed temperature and filament colour. The colour variables were black, grey, blue, green and white. Results showed that properties of printed parts were influenced by the filament composition, specifically the addition of pigment. The type of dye used combined with other parameters, such as the printing temperature, can influence the properties of printed

parts. For this reason, the authors expected results obtained from coloured filament to vary between different companies. The authors found that brighter colours showed the most amount of warpage, although darker coloured parts had more cracks (Ramian *et al.*, 2021).

6.2.2.2. Effects of colour on physical properties

A preliminary study investigating the geometrical deviations of samples using different pigmentation was conducted by (Valerga *et al.*, 2017). The colours used were pink, grey, translucent green and transparent. Their results showed that pigment and temperature were both factors shown to affect the viscosity of materials. The pink material was also shown to be more resistant to air bubbles within the printed structure. Green material showed a higher density of air bubbles and voids. The dimensional deviations were small and were therefore not shown to be influenced by colour in the initial temperature range. However, as the printing temperature increases, so does the fluidity of the material, which causes pronounced intensification of these dimensional deviations. Some colours differed from the nominal value more than others when printed at the same temperature. Grey and transparent were not as strongly affected by temperature.

A full study using the same filament used in the preliminary study by (Valerga *et al.*, 2017) was conducted by (Valerga *et al.*, 2018) to determine whether pigmentation modifies the properties of printed parts. The colours investigated were pink, grey, translucent green and transparent from the same manufacturer. Variations in dimensional deviation were observed in relation to the printing temperature, indicating that pigmentation had a direct influence on the properties of printed parts. The lighter coloured parts were closer to the nominal value than darker colours. Green material produced parts of worse dimensional quality, despite the green material being translucent. The translucent green filament was found to behave very differently to the transparent material. It is thought that translucent green material would behave much better in terms of dimensional tolerance than opaque green according to (Aydemir *et al.*, 2017) who studied transparent white and opaque white inks.

Wettability is said to be more pronounced in material with translucent or transparent pigmentation (Aydemir *et al.*, 2017). This is due to translucent pigment have increased ability to adhere to already solidified layers, reducing the appearance of imperfections. This is thought to be the reason behind parts produced with translucent materials being measured closer to the

nominal value. The transparent PLA had the lowest roughness value when compared to other materials because its viscosity was much higher. A smoother and more homogeneous surface is believed to be a result of a lack of pigment (Valerga *et al.*, 2018). When investigating the mechanical properties however, translucent material resisted less tensile strength than those characterised by their brightness and opacity. The translucent green filament showed the worst mechanical properties, suggesting that green pigmentation was shown to significantly modify the polymer properties, making it an unsuitable material choice for some applications.

Although transparent material was one of the least resistant to force, its elongation was greater for the same increase in change. Reduced amounts of pigmentation in PLA made the material more plastic and malleable, meaning its molecular structure was more modifiable to relieve internal tensions (Valerga *et al.*, 2018). To summarise (Valerga *et al.*, 2018)'s findings, the lighter colours were found to be closer to the nominal value than those more concentrated with pigmentation. Parts produced with translucent filament with added pigmentation and parts produced with transparent filament showed the lowest mechanical properties but a higher elongation.

The material properties of PLA parts produced in different colours was also investigated by (Wittbrodt and Pearce, 2015), who studied five colours of material; white, black, blue, grey/silver and natural. Each colour of PLA was from the same supplier, and the authors ruled out any variation from material condition by using material from a new and sealed condition. White samples were printed with varying extruder temperatures from 190-215ºC which showed that percent crystallinity was strongly related to extrusion temperature. They also tested the crystallinity of each colour, which was clearly shown to be colour dependent. Natural PLA with no pigmentation contained the lowest percent of crystalline regions with 0.93%. White material had the highest percentage of crystalline regions at 5.05%. The authors present a possible explanation for the changing crystallinity is the different pigments used to colour the PLA material.

The tensile strength was shown to change significantly according to the percentage of crystallinities. Each sample produced at 190ºC showed differences in tensile strength. The Young's modulus was consistent between all samples. Natural material showed the highest stress/strain values whilst grey showed the lowest. The findings suggested quite a significant change in ultimate tensile strength vs. strain for different colours. The standard deviation

between samples was deemed low and acceptable for all coloured samples apart from black, which had a higher standard deviation of 3.72.

The colourant was shown to affect the gap size between rasters in the internal structure of the samples in a similar way that temperature does. The addition of dyes, strengthening agents or other agents are explained to be the contributing factor for the different crystallinity percentages seen in the coloured samples. The results indicate that the flow of material could be restricted by some colourants, as seen with lower extrusion temperatures, which in turn increases the gap size. Smaller triangular shaped gaps between rasters were observed for natural material than for white material. This is thought to explain the difference between the strength of the different coloured samples. The authors acknowledge that future work is necessary to characterise a wider range of colours as a function of temperature, however initial findings show that consideration of the filament colour and corresponding printing temperature can be used to tailor the FFF printing process to a specific application.

The mechanical strength of parts produced with clear and black PLA was investigated by (Spina, 2019). The percentage of additives present in the filament were between 1-5% for black, and 0-5% for clear which was not reflected in the manufacturer's specification of thermal properties. The author used DSC to determine the thermal properties of the material, finding that black and clear materials had the same T_g of 64.5. The cold crystallisation melt temperature differed with black being 28.7ºC higher, supporting (Wittbrodt and Pearce, 2015)'s findings that crystallinity is colour dependent.

The viscosity variation field was higher for the clear coloured material than black for all materials tested. Higher filament viscosity led to under-extrusion, resulting in missing layers, thin layers, or layers with defects indicating that colour additives can significantly influence the thermal and rheological properties of filaments. Interestingly, this finding contradicts that of (Wittbrodt and Pearce, 2015), who suggested that increased levels of pigmentation increased viscosity and restricted flow.

Samples were 3D printed with a range of infill densities. Infill was presented as the distance between each infill line, where 0.5mm was the densest, followed by 1.5mm, 5.25mm and 10mm, which was the least dense part. Parts were tested based on the uniaxial compression test. Clear filaments exhibited better mechanical performance in compression tests than black

filament for samples printed with 0.5mm and 5.25mm infill distances. Clear samples also showed better performance in terms of elastic modulus. Clear samples showed improved tensile strength compared with black samples, directly contrasting (Wittbrodt and Pearce, 2015)'s findings.

Samples produced with 0.5mm infill distance showed black material was more defined and the gaps were more uniform. Clear material expanded and covered gaps between adjacent rods. This behaviour was in accordance with the lower melting point that could have caused re-melting of previously deposited layers. The smaller gaps could have resulted in the higher elastic modulus and yield strength than those shown for black samples. Samples produced with an infill distance of 2.5mm however showed a different result. The most uniform internal part structure was also observed in clear samples. Poor gap uniformity was observed for black samples which was thought to be a result of the higher viscosity.

Natural, green and black coloured PLA was investigated by (Soares *et al.*, 2018) who discovered that the degradation temperatures and T_g varied depending on the colour of PLA. Black PLA had the highest T_g at 70.29ºC, green had a T_g of 67.83ºC and transparent had the lowest T_g at 61.13ºC. The colour was also shown to affect the finishing quality of the parts. Natural PLA parts were finished to the best quality and showed a lower amount of deviation to the reference. Black parts were larger showing increased deviation between the sample and reference. With a 45º raster angle, black samples had finish defects, although green material produced parts with the worst finishing quality. The best surface quality was found in natural parts, due to a more suitable printing temperature. TGA and DMA confirmed that the colour of the material affected its thermal properties. Black and green material presented greater layer height variations when observed using SEM, as well has showing some voids in the structure.

6.3. Methodology

Findings from previous chapters were used to determine a set of control factors to minimise variation occurring as a result of these identified factors. Chapter four detailed the process capability of a standard FFF 3D printer, which revealed that different printers, despite being the same make and model, introduced large amounts of variability between printed parts. It also indicated that the location of a part on the build plate was a source of variability. For that

reason, this study was designed to use a single FFF printer to produce every sample, and each sample was positioned in the same location in the centre of the build plate to eliminate variability from those factors.

Chapter five detailed the effects of filament storage on printed parts. This work identified that once the airtight seal of a filament spool is broken, the dimensional variability between samples increased for those printed in the horizontal direction. The tensile strength of samples was also shown to be influenced by the storage conditions and the duration of filament storage. Therefore, to eliminate variability occurring as a result of material condition, a new (sealed) spool of filament was used for each day of printing, meaning each sample was produced with filament exposed to room conditions for less than eight hours.

6.3.1. Printing

A systematic sample production grid was formed to investigate three printing variables: colour, orientation, and air management. Table 38 details the variable factors for each sample. Two dog bone samples were modelled in Fusion 360 (® Autodesk, California, USA), exported as STL files and separately sliced for printing using CURA software (® Ultimaker, Utrecht, Netherlands). Four repeats of each sample were produced, giving a total of 48 dog bones. 24 were printed in the horizontal orientation (XY direction) and 24 were printed vertically (Z direction). The width and thickness of the dog bone samples are shown in Figure 90 and were based on the BS EN ISO 527-2 (ISO, 2012). The gauge length was based on a smaller extensometer (25mm) suitable for the vertically printed samples.

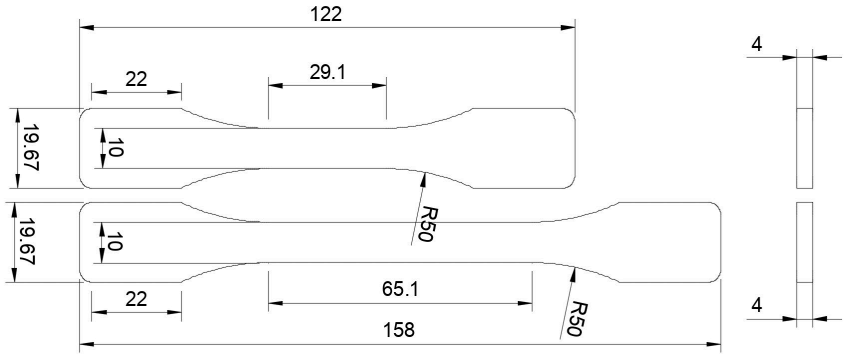


Figure 90: Engineering drawing showing the dimensions of 3D printed dog bone samples (top: vertical, bottom: horizontal)

Due to the lack of stability in the Z direction, samples were printed with a support tower connected to the dog bone sample at two points. However, to mitigate any influence the tower might have on the mechanical testing, the two connection points were 1mm in diameter and placed on the grip section of the sample so not to influence the testing results. The printing position and orientation of both dog bone samples is shown in Figure 91.

Table 38: Dog bone sample production grid of variable factors

Sample group	Orientation	Build chamber	Colour
1	Horizontal	Closed (air management)	Black
2	Horizontal	Open	Black
3	Vertical	Closed (air management)	Black
4	Vertical	Open	Black
5	Horizontal	Closed (air management)	White
6	Horizontal	Open	White
7	Vertical	Closed (air management)	White
8	Vertical	Open	White
9	Horizontal	Closed (air management)	Green
10	Horizontal	Open	Green
11	Vertical	Closed (air management)	Green
12	Vertical	Open	Green

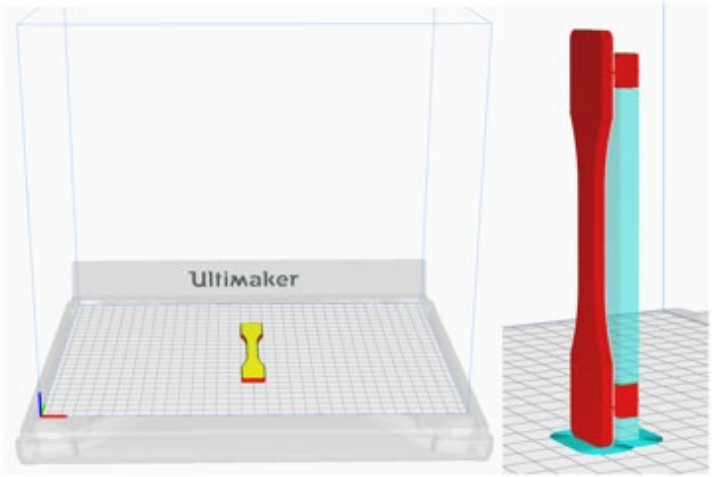


Figure 91: GCODE generation of horizontal (left) and vertical (right) dog bone samples

All samples were produced on a single Ultimaker S5 FFF printer (®Ultimaker, Utrecht, Netherlands) configured with an AA 0.4 print core and a glass build platform. The print core

was used for Tough PLA only (®Ultimaker, Utrecht, Netherlands), meaning no abrasive materials could have damaged the internal structure, thus modifying the extrusion diameter. To close the build chamber, an Air Manager (®Ultimaker, Utrecht, Netherlands) was installed as shown in Figure 92. Colour was introduced using a single material, Ultimaker branded Tough PLA, in black, white and green. According to the manufacturer's instructions, each of the colours align with the same technical data sheet and should be printed with the same parameters, detailed in Table 39.

Figure 92: Ultimaker S5 printer (left) and S5 printer with air management unit installed (right) (Source: 3dgbire.com)

Table 39: Printing parameters for horizontal and vertical dog bone samples

Parameter	Horizontal	Vertical
Printing temperature	215	215
Build plate temperature	60	60
Infill	100%	100%
Printing speed	50mm/s	50mm/s
CURA version	4.1.3	4.1.3
Support	None	15% density (everywhere)
Build plate adhesion	None	Brim
Time	56 minutes	1h 33 minutes

Temperature and humidity readings were taken at the start and end of each print. Upon completion, the part was removed with a flat scraper, the build platform was wiped clean, and a single layer of glue was applied for the next print. The support material and brim were

removed from vertical samples, and samples were stored in a sealed sample bag with a desiccant sachet to eliminate any influence moisture in the air might have on the sample between printing and testing.

6.3.2. Measuring and weighing

The gauge width and thickness were measured using a Mitutoyo micrometer (®Kanagawa, Japan) with a resolution of 0.001mm calibrated to BS 870 (BSI, 2008). Due to the 25mm maximum measuring range of the micrometer, a digital calliper with a resolution of 0.01mm was used to collect length measurement data. Three measurements for each feature were taken to obtain a mean. All measurements were taken at a temperature of 20±0.5ºC. Samples were weighed using a Sartorius AC210P analytical balance (®Göttingen, Germany).

6.3.3. Tensile testing

Tensile testing was carried out using a Hounsfield H10KS universal testing machine (®Surrey, UK). The test program used a 25mm extensometer, with a load range of 3000N and a test speed of 50mm/min. Elastic modulus values were calculated using QMAT software by Tinius Olsen (®Redhill, UK).

6.3.4. Microscopy

6.3.4.1. Scanning electron microscopy with energy dispersive X-ray analysis (SEM-EDX)

A Surpa 40VP scanning electron microscope manufactured by Carl Zeiss Ltd. (®Oberkochen, Germany) was used with SmartSEM software by the same manufacturer. The EDX sensor was the Apollo 40 SDD model by EDAX Inc. (®New Jersey, US) with Genesis software by the same manufacturer. Filament samples of Tough PLA in three colours, black, white and green, were taken and mounted on aluminium pin stubs with carbon tape. The samples were inserted into the microscope and put under vacuum. The working distance (distance between the lens and the sample) was ~15mm and a low magnification was used to analyse a larger sample area. Software was used to collect an image, select an area to scan and detect the energy of the x-ray, providing information on what elements were present, and their quantities, in the scanned area of the sample. Three areas of each coloured sample were analysed, and element quantities were presented as a mean from the three sample areas studied.

6.3.4.2. Scanning electron microscopy (SEM)

SEM was completed according to the methodology detailed in Section 5.4.1.5.3.

6.3.4.3. Optical microscopy

The fracture surface of a sample from each specimen group was observed using a S1000 industrial stereo microscope. Images were taken at the 0.8 and 2.0 zoom positions on the optical system.

6.3.4.4. Raman microscopy

A Raman microscope is a laser-based microscope that combined with software can give information about the chemistry of a sample through analysing the scattering of light. The depth resolution was approximately 1µm below the surface of the sample. A DXR Raman microscope with OMNIC software by ThermoFisher Scientific (®Massachusetts, US) was used. The program ran for 2.5 seconds and was repeated 20 times to generate more data and smooth the curves. Three areas on each sample were observed to check for consistency within the results.

6.3.4.5. Statistical analysis

A three-way factorial ANOVA was conducted with multiple levels using Minitab software (® Pennsylvania, US). A linear regression model ANOVA was done, followed by main effect plots and interaction plots which were included where appropriate. The three independent factors, A, B and C, represent colour, air management and orientation respectively. Factor A (colour) had three levels, black (A1), white (A2) and green (A3), which were analysed separately as subgroups. Factor B (air management) had two levels, with air management (B1) and without air management (B2). Factor C (orientation) also had two levels, horizontal (C1) and vertical (C2). For each set of results the total number of treatment groups was 12, and the number of observations within each group was four (four repeats), meaning the total number of observations was 48 (n=48). The ANOVA was based on the data presented in Table 40.

Table 40: ANOVA set up for sample weight data, where for example W= weight measurement

	Horizontal (C1)		Vertical (C2)	
	AM (B1)	NAM (B2)	AM (B1)	NAM (B2)

Black (A1)	W1, W2, W2, W4	W1, W2, W2, W4	W1, W2, W2, W4	W1, W2, W2, W4
White (A2)	W1, W2, W2, W4	W1, W2, W2, W4	W1, W2, W2, W4	W1, W2, W2, W4
Green (A3)	W1, W2, W2, W4	W1, W2, W2, W4	W1, W2, W2, W4	W1, W2, W2, W4

6.4. Results

6.4.1. Dimensional evaluation

6.4.1.1. Sample weight

Vertical samples were approximately one gram lighter than horizontally printed samples as shown in Figure 93. This is likely due to gaps in the central structure of vertical samples shown in Figure 103 (Section 6.4.3.1) when observed with an optical microscope. On average, green samples weighed slightly less than black and white samples and black samples weighed the most. The range between the highest weight and lowest weight samples within each category were calculated. Overall, black horizontally printed samples with air management had the largest weight range of 0.21g. The second and third largest ranges were seen in black and white samples printed horizontally without air management. The smallest weight range of 0.03g was seen within the green vertically printed with air management sample group. ANOVA indicated that the difference between means for the colour and air management factors were not shown to be statistically significant.

The use of air management is said to improve printing consistency between samples through reducing temperature changes and other varying environmental conditions. There could be a loose corelation between air management and weight variance, although it is not strong enough to be conclusive.

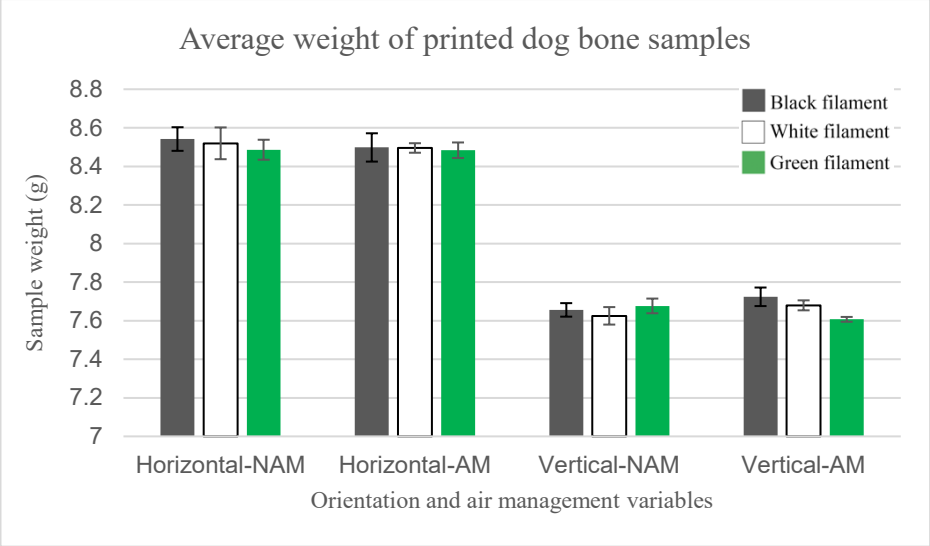


Figure 93: Mean weight of samples printed with the following variables (calculated from three repeats): Horizontal-NAM (horizontal orientation, no air management), Horizontal-AM (horizontal orientation with air management), Vertical-NAM (vertical orientation, no air management) and Vertical-AM (vertical orientation with air management. Error bars show ± standard deviation. Graph is coloured according to the filament colour of each sample as black, white and green respectively.

6.4.1.2. Gauge width

6.4.1.2.1. Air management on variance

Three gauge width measurements were taken for each sample and were used to calculate the mean gauge width for each sample. The means were used to calculate the mean gauge width for each sample group (four repeats of each sample formed a sample group) which are shown in Figure 94. The range of dimensional variance was calculated for each sample group and were compared to identify trends linked to two factors, air management and material colour.

Firstly, when looking at the effects of air management, there was no direct correlation between air management and dimensional variance. For black samples printed both horizontally and vertically, slightly less dimensional variance was observed between samples printed with air management than those printed without. For white horizontally printed samples, those printed without air management showed the smallest dimensional variance between samples, whilst white vertically printed samples showed the largest dimensional variance with air management. Vertically printed green samples showed the smallest dimensional variability when printed without air management. The variation between groups is small and statistically insignificant.

Therefore, these findings indicate there is no direct relationship between air management and dimension variance of sample gauge width, which was confirmed with ANOVA.

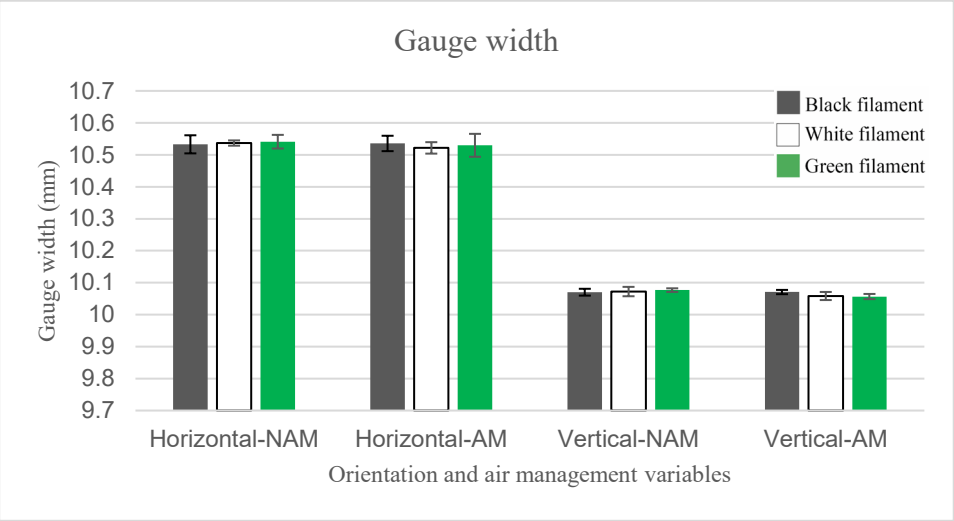


Figure 94: A chart showing the mean gauge width of each sample group (calculated from three repeats). Error bars show ± standard deviation

6.4.1.2.2. Colour on variance

To make conclusions on the effects of colour on the dimensional variability of the gauge width, data was analysed within three colour groups for the horizontal and vertical orientations. The horizontal and vertical groups with the largest range of dimensional values were black and white respectively. The horizontal and vertical groups with the smallest range of dimensional variance was white and black respectively. These findings indicated that material colour had no significant influence on the dimensional variability between the gauge width of printed samples.

6.4.1.2.3. Air management on accuracy

Dimensional accuracy is discussed as the closeness to the nominal value, which in the case of the gauge width is 10mm. The error from the nominal value was calculated for each sample before being grouped according to the variable groups for analysis. In all cases there was a significant difference in error percentage between horizontally and vertically printed samples, with horizontal samples showing a much larger error percentage. The sum of error percentage was calculated for samples grouped by air management. Horizontal samples printed with and without air management had a combined error percentage of 15.07% and 15.29% respectively.

Vertical samples printed with and without air management had a combined error percentage of 1.85% and 2.16%. In both cases, sample groups printed with air management had a slightly lower combined error percentage, although the differences of 0.22% for horizontal and 0.31% for vertical are small.

6.4.1.2.4. Colour on accuracy

Comparing the error percentage between colour groups as shown in Table 41 showed the difference in error is small. The largest differences were observed for vertical samples printed with air management. Green and white samples showed error percentages 0.56% and 0.58% respectively, whereas black showed 0.7%. This was the largest difference in error at 0.14% which indicates that the colour variable did not significantly influence the accuracy of printed parts.

Table 41: Mean percentage error for gauge width dimensions

Orientation	Colour	Air management?	% error	Dimensional range
Horizontal	Black	N	5.06	0.069
Horizontal	Black	Y	5.08	0.05866667
Vertical	Black	Y	0.70	0.017
Vertical	Black	N	0.70	0.028
Horizontal	White	N	5.09	0.021
Horizontal	White	Y	4.96	0.04633333
Vertical	White	Y	0.58	0.03366667
Vertical	White	N	0.72	0.03666667
Horizontal	Green	N	5.13	0.05033333
Horizontal	Green	Y	5.03	0.09866667
Vertical	Green	Y	0.56	0.02066667
Vertical	Green	N	0.74	0.014

6.4.1.3. Gauge thickness

6.4.1.3.1. Air management on variance

The variability of measurements taken of the gauge width of samples was calculated for samples in each colour and orientation variable group and compared in terms of air

management. Black horizontally printed samples and black vertical printed samples showed a smaller range of measurements when printed with air management. White samples printed in the horizontal and vertical orientations, and green samples printed in the horizontal and vertical orientations all showed a smaller range of measurements when printed without air management. The measurement range difference between air management and no air management was small for every group, with the largest difference between sample means in each group being 0.02mm. The ANOVA of the gauge thickness of dog bone samples is presented in Table 42. The statistics show the P-value ≤ α for air management and orientation, meaning the alternative hypothesis was accepted and interaction was observed between factors B (air management) and C (printing orientation) (H_a: $\mu_{B1} \neq \mu_{B2}$ and H_a: $\mu_{C1} \neq \mu_{C2}$).

Table 42: ANOVA table for gauge thickness measurements

Source of Variation	***DF***	***SS***	***MS***	***F-Value***	***P-Value***
Air management	1	0.004163	0.004163	22.11	0.000
Colour	2	0.000507	0.000254	1.35	0.273
Orientation	1	0.092079	0.092079	489.08	0.000
Air management*Colour	2	0.000192	0.000096	0.51	0.605
Air management*Orientation	1	0.002347	0.002347	12.47	0.001
Colour*Orientation	2	0.000025	0.000012	0.07	0.937
Air management*Colour*Orientation	2	0.000414	0.000207	1.10	0.344
Error	36	0.006778	0.000188		
Total	47	0.106505			

6.4.1.3.2. Colour on variance

The range of dimensional variance between printed samples was categorised and analysed in colour groups and printing orientation groups to indicate any influence of colour on variance in the gauge thickness of samples. In the horizontal printing orientation white samples had the largest range of dimensional values, followed by green then black. In the vertical orientation black and white samples had the same range of variance, whilst green samples showed less dimensional variance illustrated in Figure 95. As with the findings around the effects of colour on dimensional deviation for the gauge width of samples, no significant relationship between colour and dimensional variance of the gauge thickness was shown between samples.

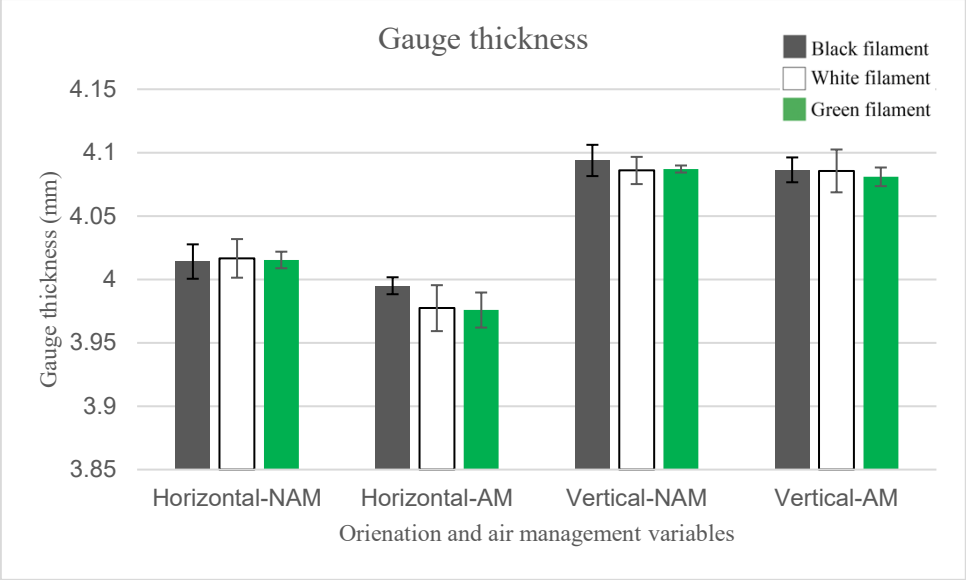


Figure 95: Mean gauge thickness of each sample group (calculated from three repeats). Error bars show ± standard deviation.

6.4.1.3.3. Air management on accuracy

The nominal gauge thickness of the samples was 4mm. The error percentage above or below the nominal value was calculated and compared considering the air management variable to make conclusions around the effects of air management on dimensional accuracy of the gauge thickness. Horizontally printed samples without air management had a positive error value for each colour, with a total error percentage of 1.14%. Horizontally printed samples with air management had a negative error value for each colour, with a total error percentage of -1.31%. These findings indicated that air management did directly influence the dimensional accuracy of horizontally printed parts, and by printing with air management, the sample thickness was less than the nominal value.

In the vertical orientation, samples produced without air management had an mean percentage error of 6.52% and those printed with air management had a 6.19% error. In all cases, the mean dimensional error was larger than the nominal value. Air management appeared to have less of an influence in the vertical printing orientation. It was deduced that a likely cause could be the increased distance from the heated build plate resulting in a smaller change in temperature or air movement than for horizontally printed samples which are printed at most 4mm away from the heated build plate. At this small distance, it could be assumed that the air management

system slowed the dispersion of heat, thus reducing the thermal expansion of the material upon cooling, resulting in lower dimensional values.

6.4.1.3.4. Colour on accuracy

Dimensional accuracy, presented as mean error percentage from the nominal value as shown in Table 43, was analysed in terms of colour. Each colour was grouped by either horizontal or vertical printing orientations. In the horizontal orientation, the black samples had a mean error of 0.11% over the nominal value, and green samples had a mean error of -0.11% under the nominal value. White samples had an error of -0.08%. In the vertical orientation, black samples showed the largest mean error at 2.20%, whilst green showed the smallest mean error at 2.06%. These findings indicated that colour did not affect the dimensional accuracy of sample thickness in the horizontal or vertical orientations.

Table 43: Mean percentage error for gauge thickness dimensions

Orientation	Colour	Air management?	% error	Dimensional range
Horizontal	Black	N	0.35	0.0316667
Horizontal	Black	Y	-0.13	0.018
Vertical	Black	Y	2.11	0.0256667
Vertical	Black	N	2.29	0.0343333
Horizontal	White	N	0.41	0.03966667
Horizontal	White	Y	-0.57	0.04733333
Vertical	White	Y	2.09	0.04066667
Vertical	White	N	2.10	0.027
Horizontal	Green	N	0.38	0.017
Horizontal	Green	Y	-0.61	0.03766667
Vertical	Green	Y	1.98	0.01966667
Vertical	Green	N	2.13	0.007

6.4.2. Mechanical testing

6.4.2.1. Tensile strength

The mean tensile strength of each sample group is shown in Figure 96. Samples were first analysed in six groups: horizontal without air management and horizontal with air management for black, white, and green samples; and vertical without air management and vertical with air

management for black, white and green samples. Samples printed without air management showed higher tensile strength than those printed with air management excluding one group. Every group except black vertically printed samples were slightly stronger when printed with no air management. When excluding colour as a variable, horizontally printed samples were approximately 1MPa stronger than samples printed with air management. Vertical samples were approximately 0.6MPa stronger than samples printed without air management. The small difference indicates there was no significant correlation between air management and tensile strength of samples. As in previous chapters, the determination of the significance of these findings was based on statistical analysis, and the consideration of how significant the effects would be in the considered use context of polymer FFF for the manufacture of simple Class I medical devices.

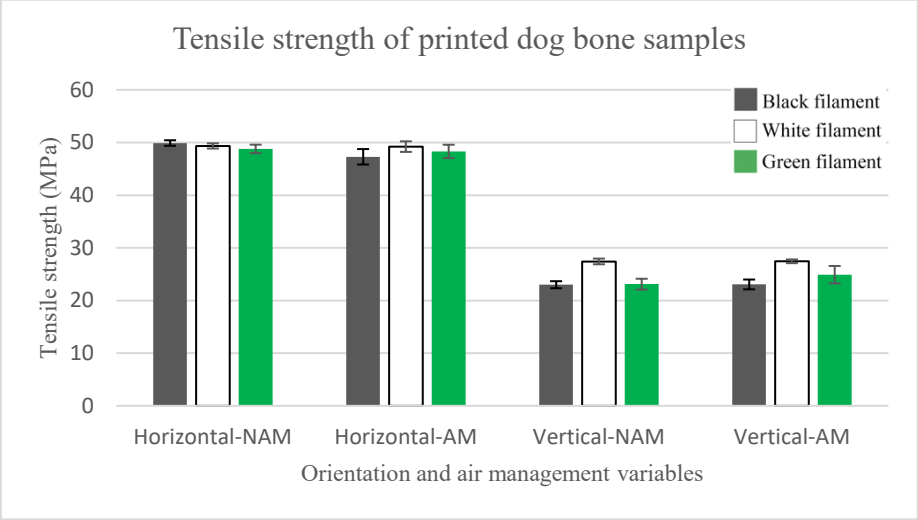


Figure 96: A chart showing the mean tensile strength (MPa) of each sample group (calculated from three repeats). Error bars show ± standard deviation

When looking at the range of tensile strength within each group, five out of six groups had the largest range when printed with air management. These findings indicated that printing with an air management unit did not result in increased tensile strength or did not reduce variability between samples.

The ANOVA of the tensile strength of dog bone samples is presented in Table 44. The influence of colour and orientation were shown to be statistically significant (P-value ≤ α) and therefore the null hypothesis for factor A and C were rejected ($H_0: \mu_{A1} = \mu_{A2} = \mu_{A3}$ and

$H_0: \mu_{C1} = \mu_{C2}$). Air management was the only factor shown not to be statistically significant in affecting the tensile strength of parts.

Table 44: ANOVA table for tensile strength of samples

Source of Variation	***DF***	***SS***	***MS***	***F-Value***	***P-Value***
Air management	1	0.59	0.59	0.62	0.435
Colour	2	58.79	29.39	30.80	0.000
Orientation	1	6905.57	6905.57	7237.29	0.000
Air management*Colour	2	7.74	3.87	4.06	0.026
Air management*Orientation	1	8.60	8.60	9.02	0.005
Colour*Orientation	2	29.50	14.75	15.46	0.000
Air management*Colour*Orientation	2	3.66	1.83	1.92	0.161
Error	36	34.35	0.95		
Total	47	7048.81			

The main effects plot shown in Figure 97 illustrates that samples produced with white filament specifically was shown to differ from black and green filament. White material printed in the vertical orientation was shown to influence the mechanical properties of samples, showing a higher tensile strength than black and green. White material also showed the smallest amount of variance between samples within the same group in both orientations with and without air management. Green material showed the largest amount of variability between samples in three of four groups.

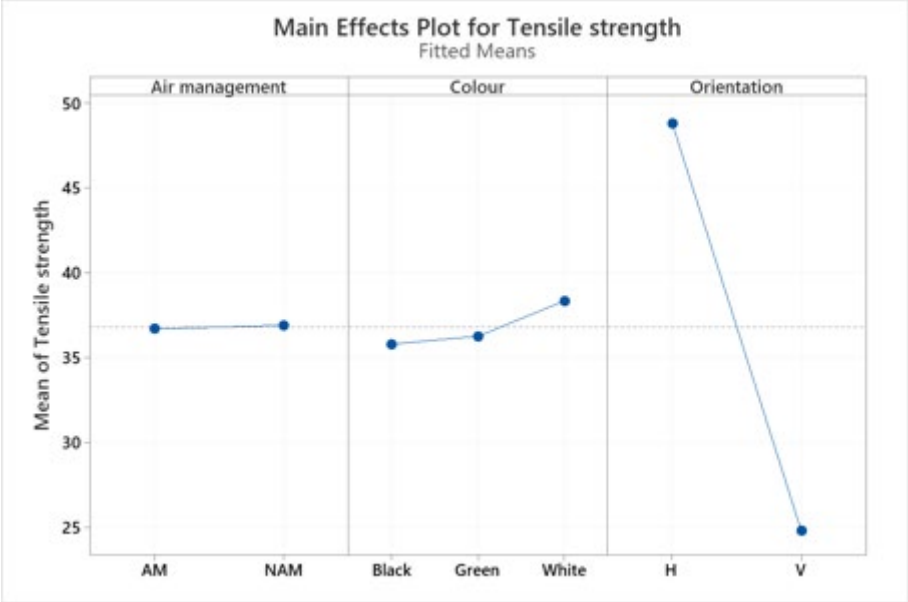


Figure 97: Main effects plot using data means for tensile strength

6.4.2.2. Elongation

The elongation values for each sample group shown in Figure 98 indicate that in most cases samples printed with white material had a higher elongation that black and green samples, showing that white material was more ductile. Green and black materials were shown to be similar in terms of ductility. Vertical samples printed without air management showed slightly lower elongation values for each colour tested. Vertical samples printed with air management were slightly more ductile than those printed without.

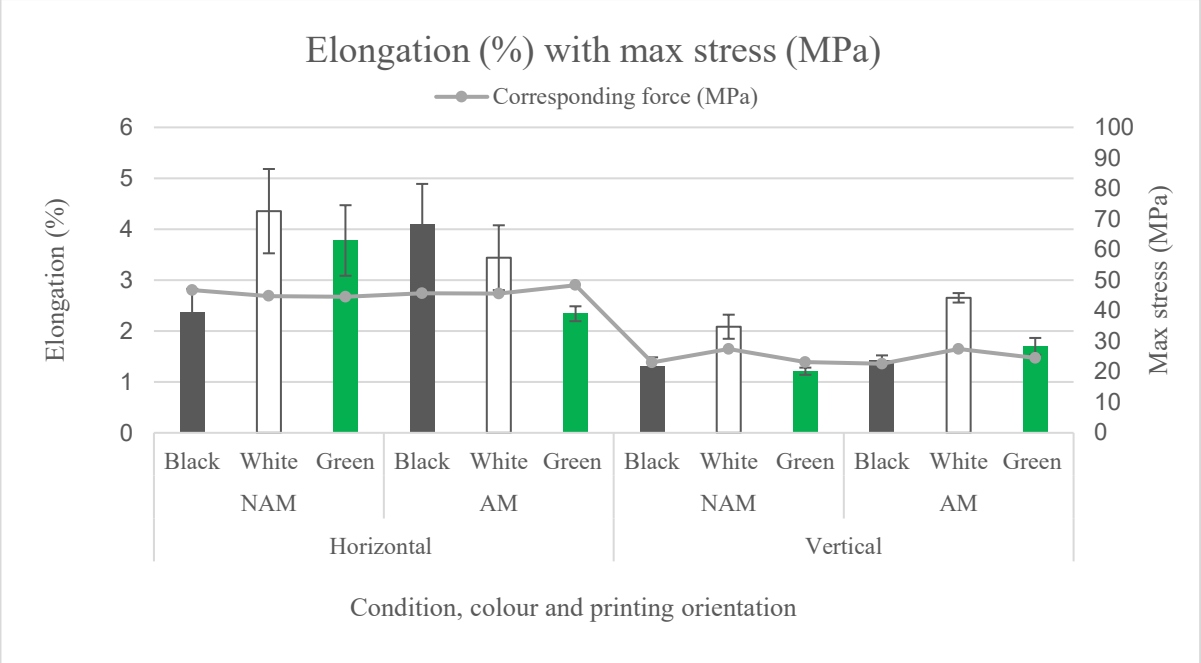


Figure 98: A chart showing the mean percentage elongation of each sample group (calculated from three repeats). Error bars show ± standard deviation

The ANOVA statistics shown in Table 45 revealed that each factor studied was shown to be statistically significant in affecting the elongation of printed dog bone samples. The main effects plot shown in Figure 99 illustrates the influence of each factor on the elongation mean, showing that the mean of elongation percentage was higher without air management, higher for white material, and higher in the horizontal orientation. The interaction plots shown in Figure 100 show limited interaction between air management and orientation and colour and orientation, however interaction was observed between black and green filament colours and air management, which showed elongation to be higher for black when air management was used compared to without air management. Elongation was shown to be higher for green when air management was not used, and lower when it was.

Table 45: ANOVA table for elongation measurements

Source of Variation	***DF***	***SS***	***MS***	***F-Value***	***P-Value***
Air management	1	2.8111	2.8111	9.82	0.003
Colour	2	7.7999	3.9000	13.62	0.000
Orientation	1	33.2600	33.2600	116.18	0.000
Air management*Colour	2	0.7955	0.3978	1.39	0.262
Air management*Orientation	1	9.1386	9.1386	31.92	0.000
Colour*Orientation	2	0.2416	0.1208	0.42	0.659
Air management*Colour*Orientation	2	0.1089	0.0544	0.19	0.828
Error	36	10.3065	0.2863		
Total	47	64.4621			

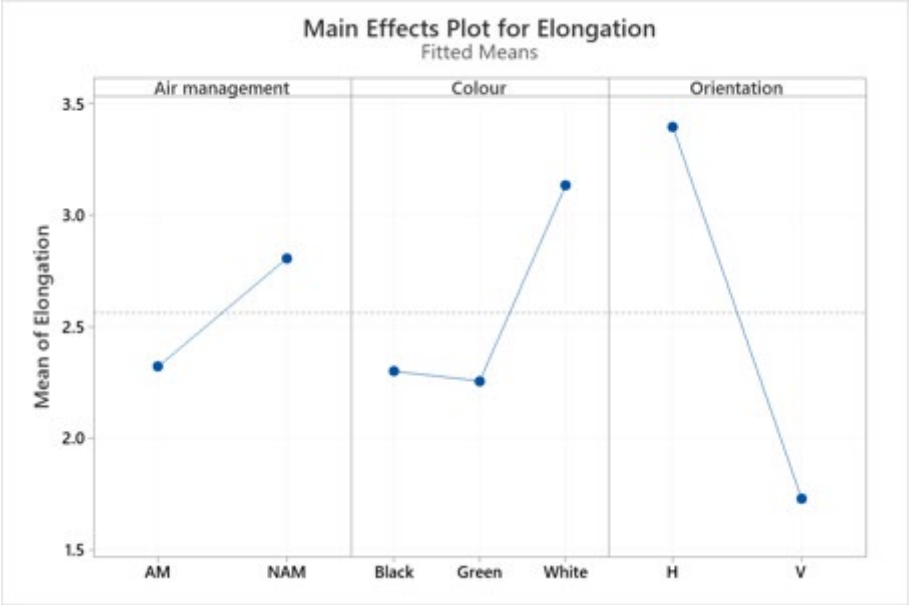


Figure 99: Main effects plot using data means for elongation

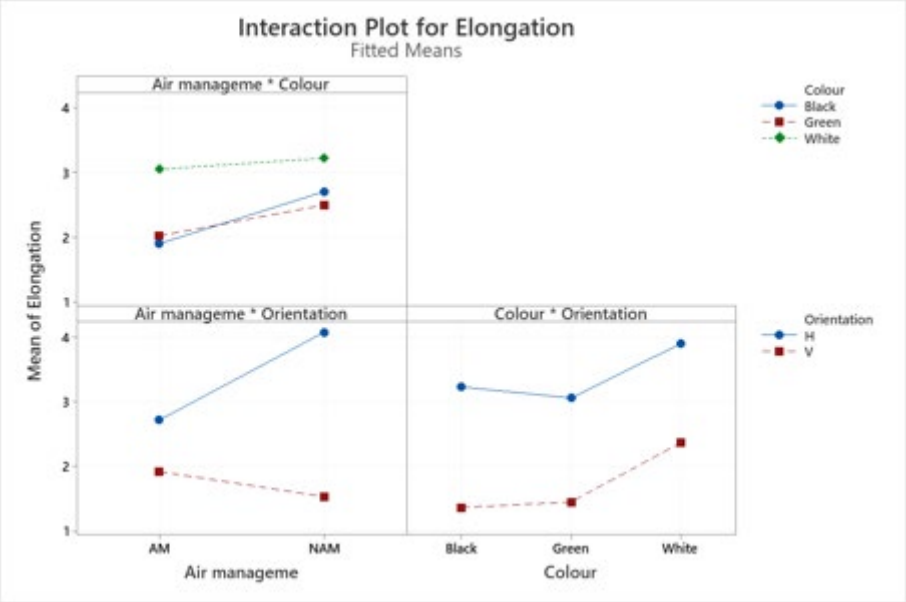


Figure 100:ANOVA interaction plot for elongation

White material was shown to provide up to a ~2% increase in elongation and would therefore be the most appropriate material choice where ductility is a desired property. Force was relatively consistent for horizontal samples; however, white samples required more force to break, indicating that the higher elongation may be directly linked to the larger force required to break, not necessarily resulting from changes to the composition of the white material.

6.4.2.3. Elastic modulus

White samples printed without air management showed a lower elastic modulus than those printed with air management. Air management was only shown to be an influential factor for white samples and did not show any effect on the black and green samples. Aside from the influence of air management on white material, there was no significant difference in elastic modulus between the colours. Green samples showed a slight increase, however the overlap of error bars shown in Figure 101 show this difference as insignificant.

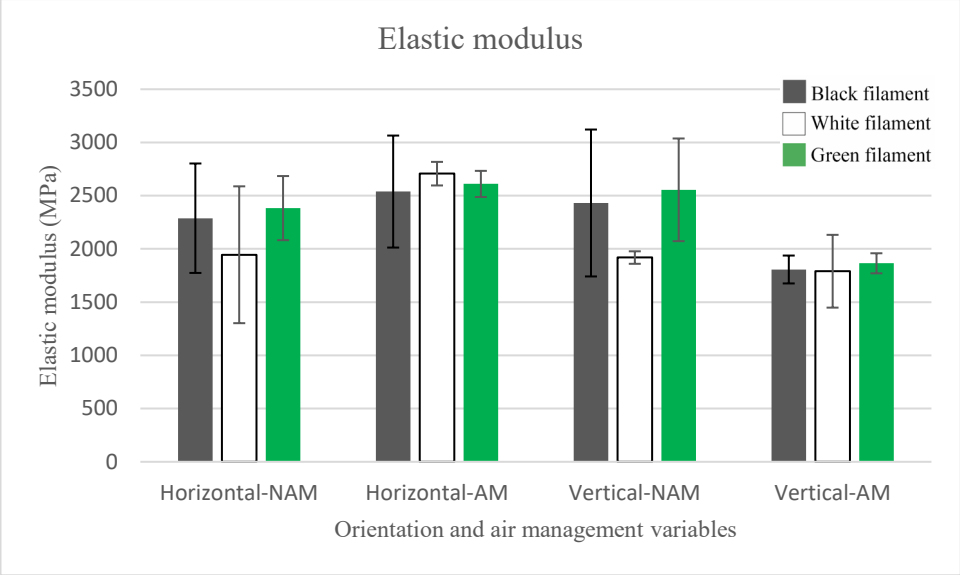


Figure 101: A chart showing the mean elastic modulus (MPa) of each sample group (calculated from three repeats). Error bars show ± standard deviation

The statistics shown in Table 46 suggested that orientation, and the interaction between air management and orientation were the only factors shown to be statistically significant in affecting the elastic modulus of printed dog bone samples. The interaction plots shown in Figure 102 show the significance of air management and orientation, where vertical samples with air management had a lower elastic modulus, whereas horizontal samples with air management had a higher elastic modulus. Interaction between the white filament and air management was also observed in Figure 102, although it was shown to be insignificant by the P-Value.

Table 46: ANOVA table for elastic modulus

Source of Variation	***DF***	***SS***	***MS***	***F-Value***	***P-Value***
Air management	1	13917	13917	0.06	0.800
Colour	2	575142	287571	1.34	0.274
Orientation	1	1477761	1477761	6.90	0.013
Air management*Colour	2	741679	370840	1.73	0.191
Air management*Orientation	1	2399208	2399208	11.20	0.002
Colour*Orientation	2	87245	43622	0.20	0.817
Air management*Colour*Orientation	2	924	462	0.00	0.998
Error	36	7709538	214154		
Total	47	13005413			

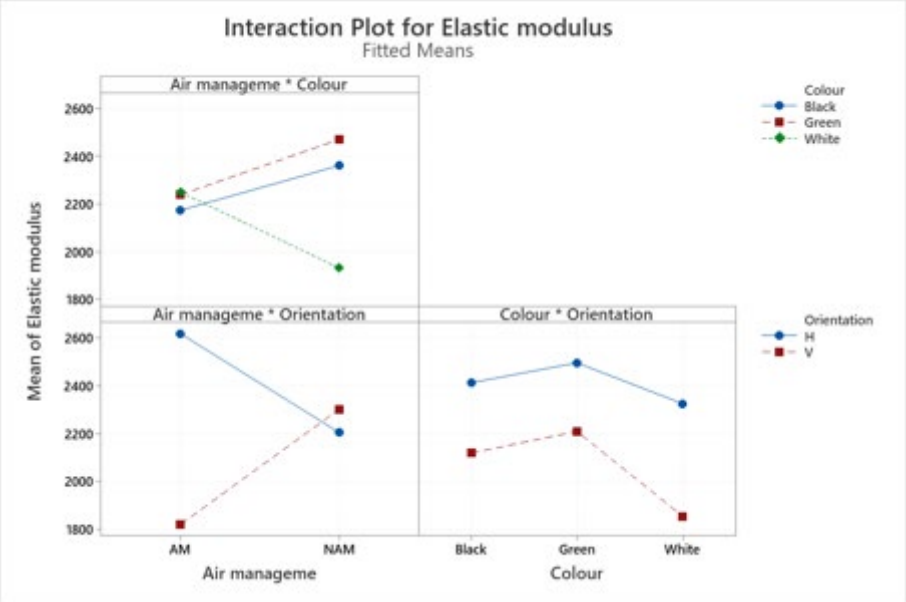


Figure 102: ANOVA interaction plot for elastic modulus

6.4.3. Microscopy

6.4.3.1. Optical microscopy and SEM of dog bone samples

The fracture surface of one repeat of each sample was observed and photographed using an optical microscope, findings are shown in Figure 103. This section is based on a qualitative assessment of the images, which were captured under the same conditions with the same lighting and magnifications, meaning they can be compared like-for-like. Vertical samples shown in the right two columns showed a large air gap in the central structure of the sample which provides an explanation for the difference in weight between horizontally and vertically printed samples discussed in Section 6.4.1.1. Horizontal samples were denser, indicated by the more tightly bonded rasters. Upon initial analysis, there did not appear to be any major differences between the internal structures of samples printed with or without air management in both the horizontal and vertical orientations. However, upon closer inspection, comparing the air gaps between rasters revealed that samples printed without air management showed slightly larger air gaps than those printed with air management in the horizontal orientation shown in Figure 104.

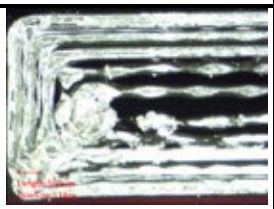
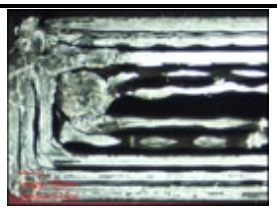
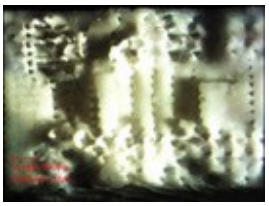
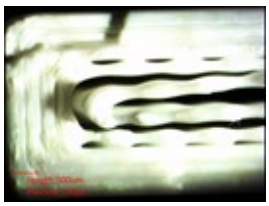
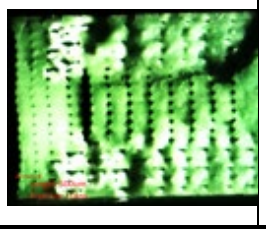
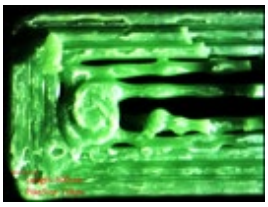
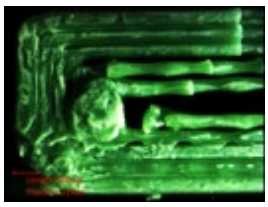
Horizontal		Vertical	
No air management	Air management	No air management	Air management
			
			
			

Figure 103: Images taken of the fracture surface of one sample from each sample group with an optical microscope for black (top row), white (middle row) and green (bottom row) samples

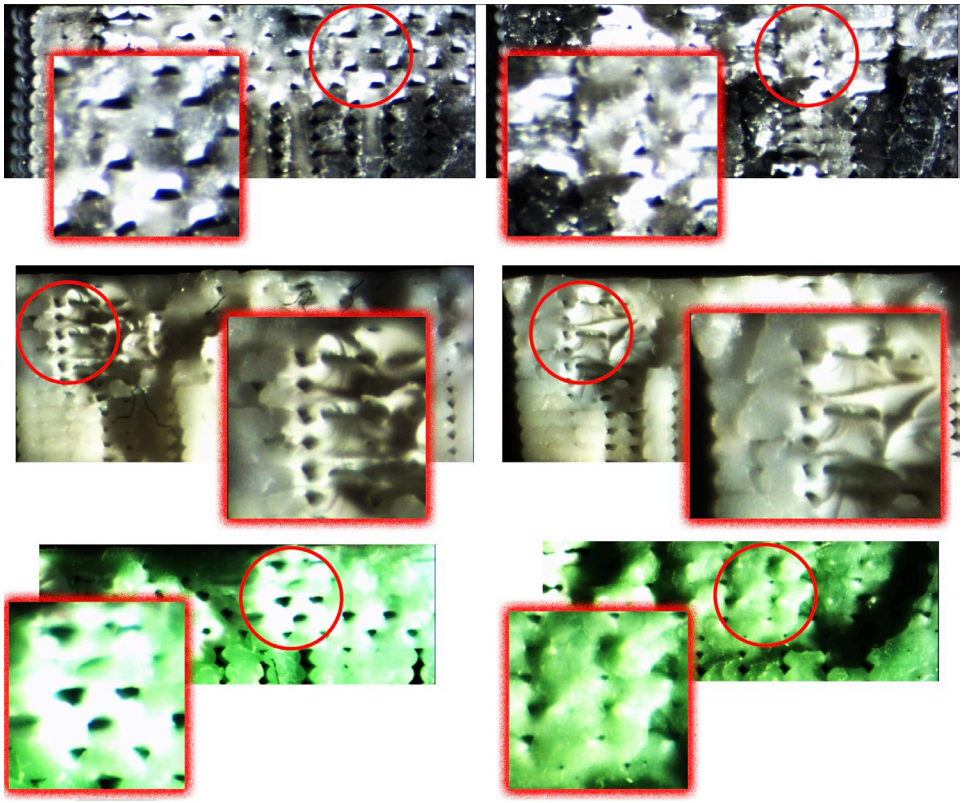


Figure 104: Detail images of air gaps within horizontally printed samples printed without air management (left) and with air management (right) for black (top), white (middle) and green (bottom) samples

6.4.3.2. SEM of dog bone samples

SEM images were captured of the edge and fracture surfaces of each dog bone sample in black, white and green, printed with and without air management. The interior structures of samples did not differ significantly as a result of colour or air management. Air gaps were not shown to be larger for samples printed without air management, as previously suggested from the images captured using an optical microscope. A comparison of the fracture surface for white samples printed horizontally is shown in Figure 105, which shows a multi-level break for both samples.

Air management

No air management

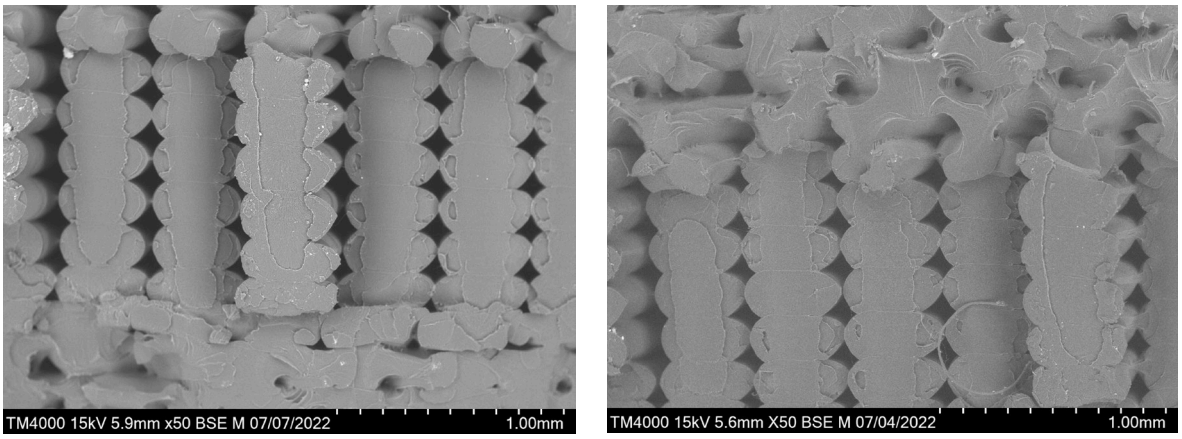


Figure 105: SEM images of horizontally printed white dog bone samples printed with air management (left) and without air management (right)

The fracture surface of vertically printed samples, shown in Figure 106, confirm the large air gaps between rasters suggested by the optical images. The outer layers were more tightly bonded than the inner layers, with the central ring connecting to the rest of the sample structure at the short edge, which was not shown to be consistent for each layer.

Air management

No air management

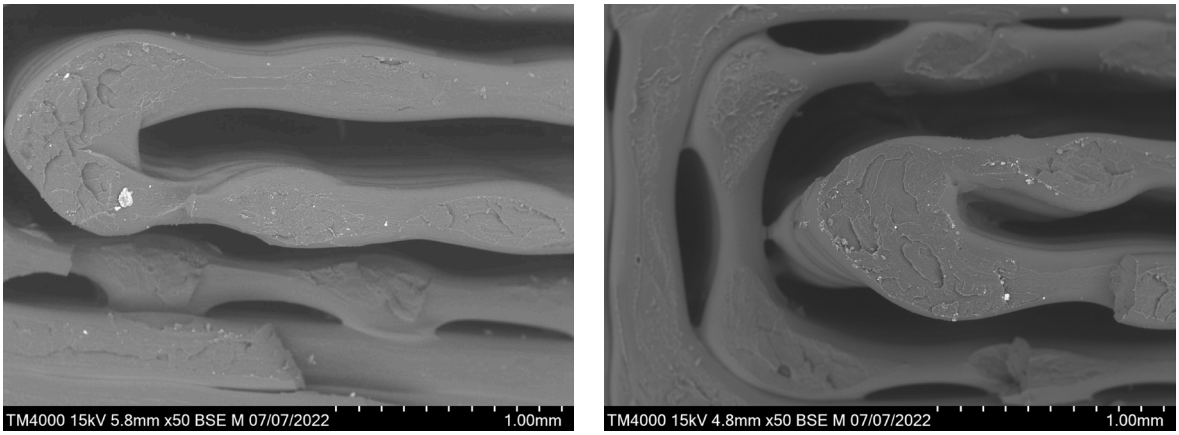


Figure 106: SEM images of vertically printed white dog bone samples printed with air management (left) and without air management (right)

Air management was not shown to affect the structure of the samples internally or externally. The outer surface was analysed by SEM, showing no significant difference between samples printed with or without air management, nor between colours. All layer lines were shown to be consistent with few defects, as shown in Figure 107. The scattering of particles visible on the

surface of the samples is likely to be dust or debris, not surface defects. These images conclude that air management was not shown to affect the surface structure of printed dog bone samples.

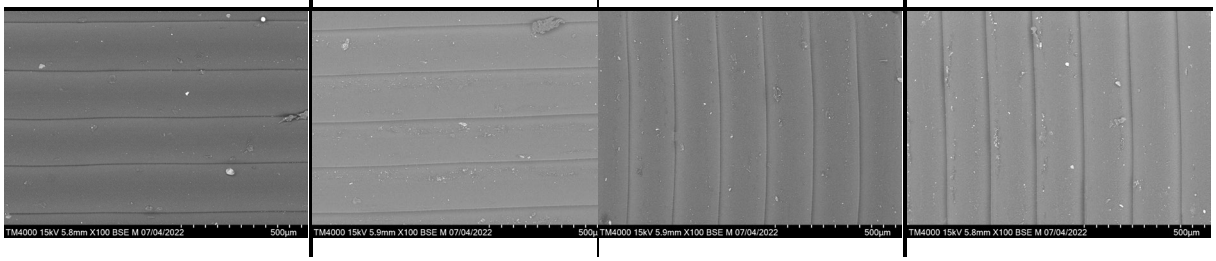
Horizontal		Vertical	
No air management	Air management	No air management	Air management
			

Figure 107: SEM images of the outer surface of black dog bone samples

6.4.3.3. SEM-EDX

Energy dispersive x-ray (EDX) analysis indicated that the main elements present in Tough PLA were similar in black, white and green filament, largely consisting of carbon and oxygen as illustrated by the peaks in the analysis graphs in Figure 108. Trace quantities of aluminium, silicon and titanium were also present in each of the materials.

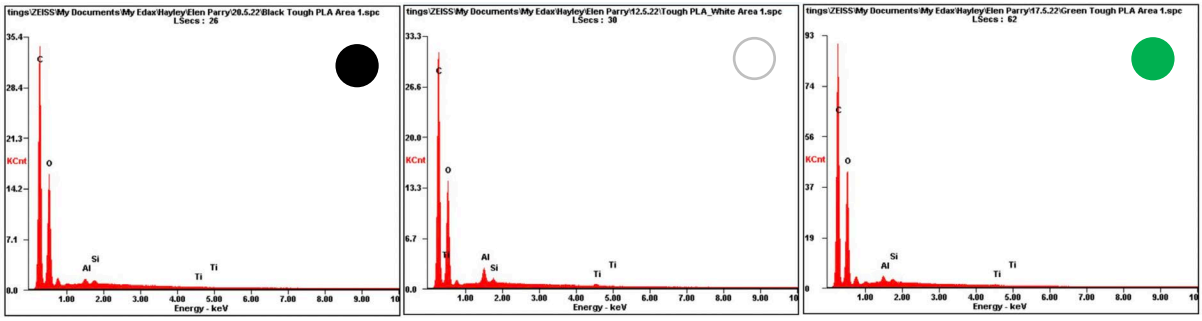


Figure 108: SEM-EDX analysis graph showing the elements present in black (left), white (middle) and green (right) tough PLA filament samples

The same elements were present across all three samples; however the quantities were shown to vary. White material was shown to have the most carbon and the least oxygen, with larger amounts of aluminium and a larger trace of titanium than the other colours as shown in

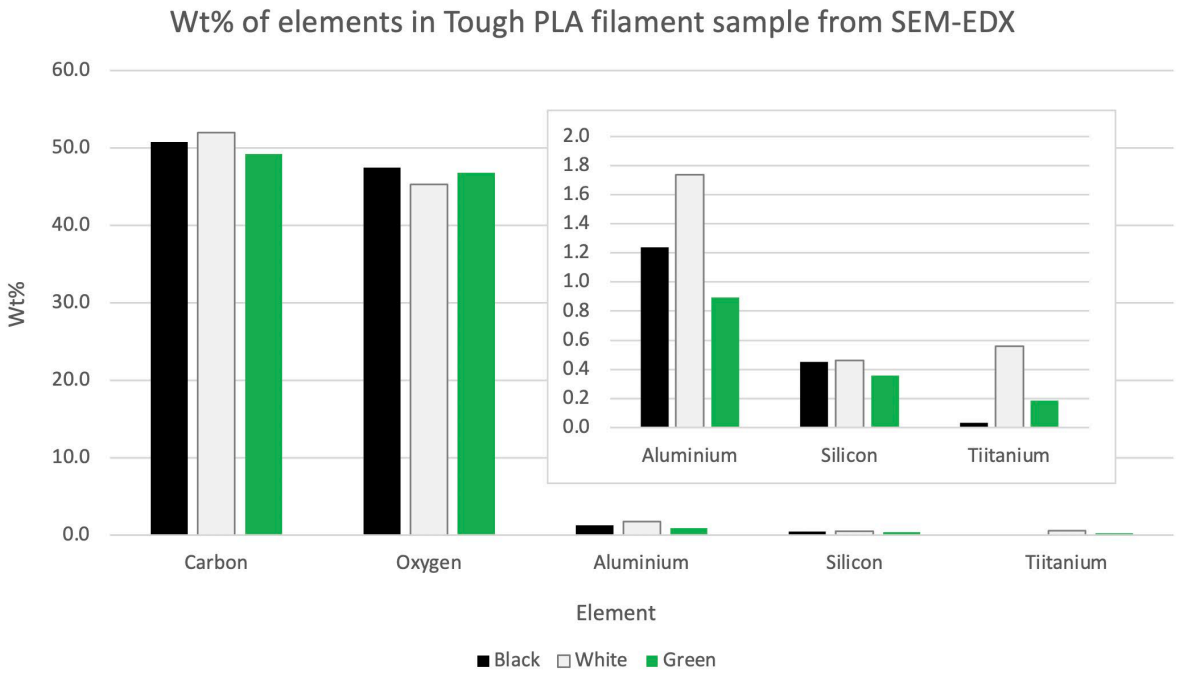


Figure 109. Green material had a trace of aluminium (<1 wt%), whereas black and white materials showed larger quantities.

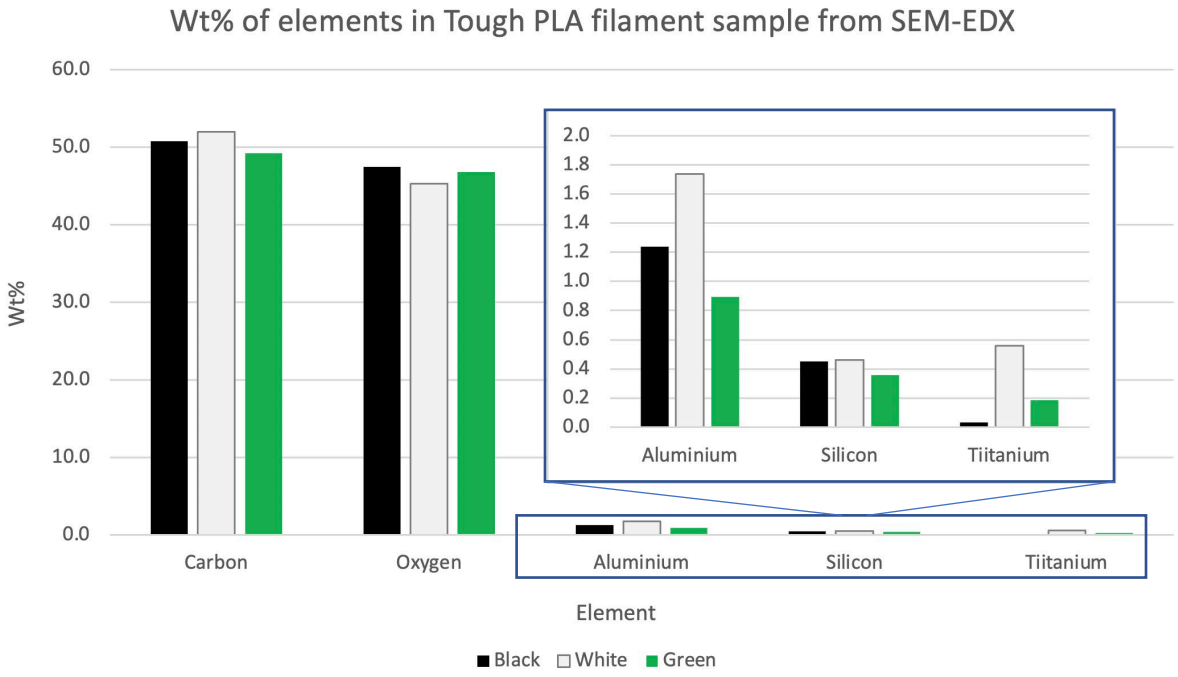


Figure 109: Graph showing the weight percentage of each element present in black, white and green Tough PLA samples

6.4.3.4. Raman spectroscopy

The Raman spectra of black, white and green materials was captured, shown as the intensity of the scattered light (y-axis) and energy (frequency) of light (x-axis). The unit of frequency is traditionally measured in wavenumbers written as the number of waves per cm/cm-1. The Raman spectrum gives information about a material which is interpreted through identifying different features which relate to different aspects of the material. The peaks on a Raman spectrum are referred to as bands or Raman bands which represent different molecular environments in the studied material which refers to the atoms present and the bonds between them. Heavy atoms and weak bonds have low Raman shifts, whereas light atoms and strong bonds have high Raman shifts. The Raman shift and their relative intensities can be used to identify the material, and additional information such as variations in crystallinity and stresses in the sample can be identified through changes in the individual bands, for example narrow or broad bands.

Three areas of each sample were analysed and are presented as area one, two and three for each coloured sample in Figure 110. Repeats carried out over three different areas of each sample show similar results for all colours. Although area three of the black tough PLA sample was offset slightly, the peaks were consistent across all areas analysed. The offset curve for area three was a result of the signal collected being a different intensity, likely due to a slight difference in the focus or the orientation of the sample. After confirming the consistency between each area of each sample, conclusions can be made that the Raman shift presented is an accurate representation of each material and is not due to contamination.

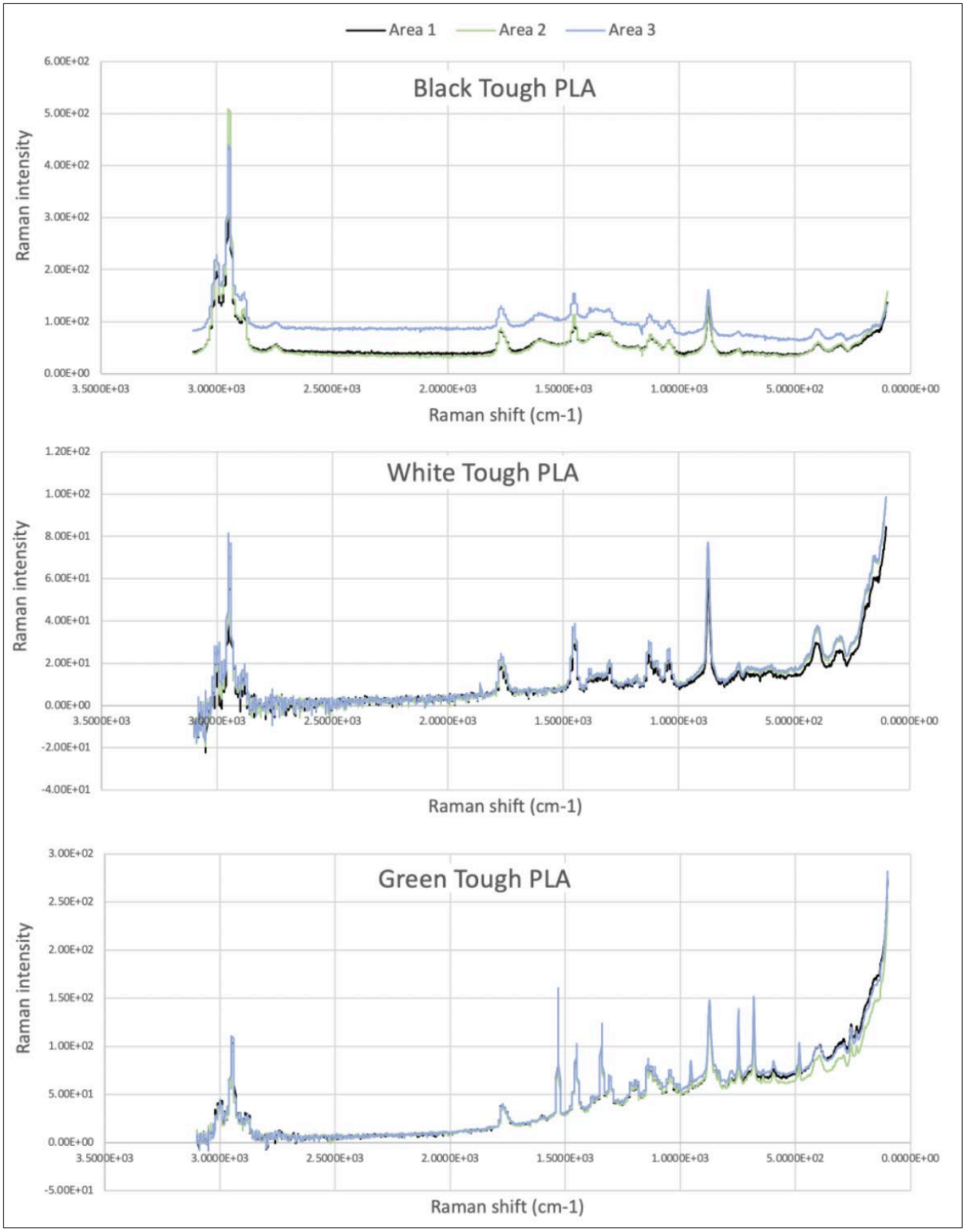


Figure 110: Raman spectrums for black (top), white (middle) and green (bottom) tough PLA filament in three different areas of the sample

Data from 'area 1' of black, white, and green filament was plotted in a stacked graph for comparative purposes shown in Figure 111. The spectra illustrate that bands were consistent for black and white specimens. The intensity peaks present for black and white material were

also present in green material, however, green material showed six additional intensity peaks that were not present in the other coloured materials. The consistencies between black, white, and green specimens demonstrated the material base of Tough PLA was the same across each colour. However, the bands highlighted with numerical labels and shaded vertical lines are unique to the green coloured material. This indicates there is a clear difference between the black and white filament when compared to the green filament. Raman reference libraries were searched for any spectra that matches the additional peaks; however, no matches were found. The most promising way to identify the additional peaks would be to search for the Raman spectrum of the suspected additive, which in this case would be the green dye or pigmentation used to colour the material. Finding a match for the additional peaks would be unrealistic without identifying a way of narrowing the search, and due to the limited information provided by the manufacturer, searching for a match would be unfeasible.

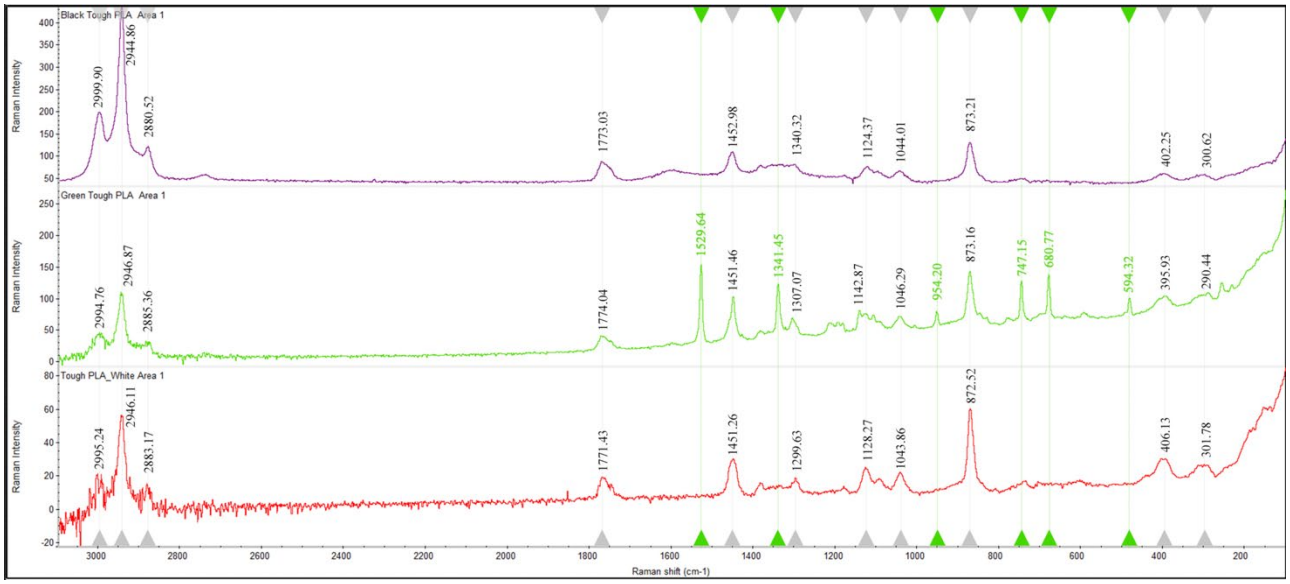


Figure 111: Raman spectra of black, white and green filament sample

6.5. Discussion

A loose corelation was observed between the weight variance of printed samples and the use of air management during printing. However, findings were not significant enough to be conclusive. Similar findings were reported for the dimensional variance of gauge width where variation was statistically insignificant with respect to air management as a variable factor. This indicates that the slightly smaller air gaps observed with optical microscopy for horizontal samples printed with air management did not significantly affect the overall external

dimensions of the dog bone samples in the XY direction. Colour was also shown to be an insignificant factor on the dimensional variability of gauge width between samples.

On the accuracy of the gauge width, samples printed with air management had a slightly lower combined error percentage than those printed without air management. Colour was not shown to significantly affect the dimensional accuracy of gauge width, which did not correspond with findings by (Hanon *et al.*, 2021), who reported that black filament had the best overall dimensional accuracy.

For gauge thickness, the dimensional variance was not shown to be affected by the colour of the filament or the use of air management during printing. The accuracy of the gauge thickness was however influenced by the use of air management during printing in the horizontal orientation, with air management resulting in a positive error value for all colours, and no air management resulting in a negative error value for all colours. This trend was not reflected in the vertical orientation, where all error values were larger than the nominal value. Colour as an independent variable was not shown to significantly affect the dimensional accuracy or the dimensional variance of the gauge thickness, again not aligning with findings reported in other studies by (Soares *et al.*, 2018) and (Valerga *et al.*, 2018) who reported that lighter or natural colours were shown to have less dimensional variance than brighter or more intense colours.

The variation in gauge thickness due to air management, where air management resulted in an error value larger than the nominal value, was an unexpected result. Based on the literature findings, where chamber temperatures were higher, the spread of the filament in the XY direction was expected to be larger as a result of the increased material flow at higher temperatures, thus reducing the hight in the Z direction. The gauge thickness is the result of Z directional printing. Where air management was not used, the thickness was lower than the nominal value. It was deduced that a possible reason for this could be that a slightly lower, or more variable chamber temperature could have caused slight under extrusion.

The weight, dimensional variance and dimensional accuracy remained largely unaffected by colour. Air management was more influential, specifically for the dimensional accuracy of the gauge width. Air management led to a gauge thickness larger than the nominal value by approximately 1.1%, whilst no air management led to a gauge thickness smaller than the nominal value by approximately 1.3%. In practical terms, the small increase or decrease may

not significantly limit the suitability of the technology to produce dimensionally accurate parts. However, in terms of quality control for parts produced in an industrial context, a range of over 2% for part thickness could be significant for repeatability and reproducibility and thus limit the suitability of FFF for industrial applications. Therefore, air management should either be consistently used, or consistently not used batches of the same product.

Dimensional accuracy will be a more critical performance factor in some applications than others. For example, the main functionality of a 3D printed prosthetic socket is to fit the user well and act as a connection point for a prosthetic device. Well-fitting devices must fit tightly enough to prevent unwanted rubbing, movement or the device falling off; however, it must be a comfortable fit with allowable tolerances for the patient's anatomy whilst allowing for movement. Therefore, dimensional tolerances become a critical performance factor in this scenario when compared to other devices, such as an ergonomic handle for a walking aid where dimensional accuracy is less critical. Dimensional accuracy is also deemed a critical performance factor by medical device regulations where dimensions are specified in the product specification. An allowable tolerance range must be specified in the technical documentation for the device, which would be based on the importance of dimensional quality in relation to the intended functionality of the device. Medical device standards and regulations also govern dimensional tolerances, meaning producing devices within a specified tolerance range becomes a critical requirement for the regulation of that device.

The tensile strength of printed dog bone samples was not shown to be significantly affected by the air management. This result was unexpected based on the assumption that air management helps to keep the printing chamber at a slightly higher and more stable temperature than an open build chamber, thus leading to improved bonding between rasters resulting in increased tensile strength of parts. This assumption was based on findings in literature; however, it may be that enclosing the build chamber does not maintain temperature enough to improve raster bonding and may require a fully heated and temperature-controlled build chamber to affect the bonding behaviour of rasters. The tensile strength was also shown to be unaffected by the colour variables tested, despite findings in literature suggesting that white or lighter colour filament had higher tensile strength when compared with other colours (Wittbrodt and Pearce, 2015).

The variability of tensile strength between samples was also shown to be unaffected by air management. Filament colour was however shown to influence the variability of tensile strength between repeats. White filament resulted in the smallest amount of variation between groups in both the horizontal and vertical orientations, and green filament resulted in the largest variability. In terms of the tensile strength values, in the horizontal orientation the relationship between filament colour was less significant than in the vertical orientation. Vertically printed samples with white material showed the highest tensile strength, and samples printed in black material showed the lowest tensile strength. Samples printed in white material also showed elongation ~2% higher than other colours. Additionally, the elastic modulus of white samples was shown to be influenced by air management more so than other colours when printed in the vertical orientation, where samples printed without air management showed a lower elastic modulus than those printed with air management. This trend was not observed for any of the other coloured samples suggesting that white dye or pigment did affect the mechanical properties of printed parts.

This observed difference in mechanical properties could introduce variability between batches of parts where different coloured filament is used, potentially causing quality issues for specialist manufacturers producing regulated medical devices. It is likely that these differences would remain undetected for devices manufactured by non-specialist users due to their limited access or need to perform mechanical testing. However, colour being shown as an influential factor on tensile strength and elongation has raised further questions around the influence of other colours or pigments used in aesthetically varied filaments on the mechanical performance of printed parts. Due to the differences in filament composition raised by the spectra results, it would also seem likely that additions of more obviously different chemicals or extra fillers to the materials, for example glitter flecks, would exacerbate this effect.

Microscopy showed that vertical samples were less dense than horizontal samples, evidencing the weight difference between the two. Optical microscopy showed slightly smaller gaps between rasters in samples printed with air management than without, however, these findings were not replicated using SEM, which showed no difference between the interior or exterior structures of samples between colour and air management variables. Qualitative analysis of the SEM images revealed there was no significant difference in the structure of any of the dog bone samples, aside from those printed in different orientations.

The effect of colour and air management on the internal structure of samples was thought to be insignificant for potential Class I medical device use cases. Where devices are produced by a non-specialist user, the slight variations in elongation and elastic modulus due to colour, and dimensional variability due to air management are likely to remain undetected due to there being no identifiable differences between printed parts. The differences resulting from printing orientation are more significant to every type of user, as they are often visible, with vertically printed samples showing a more turbulent surface finish than horizontally printed samples.

The weight difference between vertically and horizontally printed samples is likely to be the largest factor of variability most noticeable to all three user groups. Further research is necessary to determine whether the weight differences and type of voids present in samples printed in the vertical orientation translates to different types of geometry, and whether the weight difference becomes increasingly apparent in larger parts which could be more problematic. However, this is unlikely to be a limiting factor of FFF technology because variance resulting from printing orientation can be eliminated through specifying the printing orientation in the manufacturing specification. It is widely known and common practice in AM to select the same printing parameters, including orientation, to promote consistency between replicate parts.

A limiting factor in this research would be the basic nature of the geometry produced. It was shown that air management affected the accuracy of the gauge thickness for parts printed in the horizontal direction. However, the dog bone part produced for this study is not likely to be representative of the parts produced in an industrial context, especially within the medical device field. As discussed in previous chapters, customised medical devices are often tailored to the patient's anatomy, meaning the geometry of such parts are more likely to be organic forms, as opposed to the linear forms with distinct dimensions investigated in this study. However, the potential range of geometry is vast and a single form or a group of forms would not be a fully representative sample of the types of geometry produced in practice. For this reason, it is recommended that the key research questions relating to the repeatability and reproducibility of a process, paying special attention to the relevant variable factors, in this case colour and air management, are tested for each type of device in production.

The level of detail in these testing procedures would be highly dependent on the manufacturing context. A lay-user or non-specialist could perform some basic quality and repeatability tests,

such as weighing and measuring parts, and performing visual inspections to identify any obvious surface or structural defects. For research users, the level of testing required would be dictated by the research questions, and for specialist users by the regulatory requirements, which as discussed in Chapter two, involves rigorous scrutiny of the manufacturing process and part outcome, coupled with extensive recording and reporting procedures.
SEM-EDX showed the elements present in each of the coloured filaments were the same, however the quantities of each element differed slightly. Raman spectroscopy showed the largest difference in material composition was within the green filament, which showed six additional intensity peaks when compared to the other colours tested. This was an unexpected finding based on the other testing results, which showed the performance of parts printed with white filament to differ the most with respect to the mechanical properties. Findings by (Valerga *et al.*, 2018) reported that green filament behaved very differently to the other colours studied. The chemical composition of green was found to differ when compared to black and white filament when tested in this study, however it was the samples produced with white filament which were found to show different behaviours.

To support the use of FFF in a regulated context, where differences in part performance are a result of pigmentation used to colour the filament, improved testing and labelling of filament by the manufacturer would be beneficial. Manufacturers reporting on the effects of colour combined with other variables would be unrealistic due to the high number of variable factors in the FFF process. However, by assessing the material properties for different coloured filaments under the same conditions, filament labelling could reflect the differences varying chemical compositions have on printed part performance, thus raising awareness of colour as a variable factor, and allowing users to conduct the level of testing appropriate to ensure quality where multiple colours of filaments are required.

Based on the possible difference observed for the mechanical properties, the use of pigmentation to colour filament is an interesting issue that has not been widely reported on in literature, and with respect to the potential significance for AM needs wider investigation. It is acknowledged that filament labelling, and individual data sheets may not be a desirable outcome for filament manufacturers who are unwilling to divulge their material ‘recipes’ or specific chemical composition. In addition, the creation of individual data sheets would require increased amounts of testing, which could be a time and cost intensive investment for filament

companies. This may not be considered a viable investment when the range of data values given is considered acceptable by the general AM community.

6.6. Conclusion

The influence of filament colour and air management on the properties and performance of printed parts was found to be complex and interrelated. In conclusion, it is important to highlight that findings presented in this chapter are not standardised to fit a single generic use case. The findings show that both filament colour and air management can influence the performance of FFF printed parts. However, the significance of this influence is highly unique to the specific medical device application and the context in which it is being produced.

Filament colour was shown to influence the weight of samples, with green samples weighing less than white or black. However, as with the dimensional variability of the gauge width and gauge thickness, the differences were shown to be statistically insignificant. Colour combined with air management and printing orientation showed the smallest amount of dimensional variance in gauge width with the following parameter combinations: White printed horizontally without air management and green printed horizontally and vertically without air management. Black filament produced samples with the largest dimensional variance for gauge width when printed horizontally, and white filament produced the largest dimensional variance when printed vertically. An ANOVA showed interaction between colour and air management for gauge thickness, where samples produced with black filament showed less variance when printed with air management than without. The exact reasoning for the observed interaction between colour and air management falls outside the scope of this thesis, however, a systematic experiment with filament colour and air management, with a large number of repeats, could provide further insight into the interaction between these two parameters. Where orientation is considered an important variable, the study could be extended to include orientation as a variable factor.

The filament colour was not shown to significantly affect the accuracy and variance of gauge thickness of printed dog bone samples. Findings around filament colour are relevant to the medical device industry for two reasons. Firstly, the potential implications of colour on the other performance aspects of the device, such as the dimensional accuracy, should be considered. Secondly, the use of colour for medical devices can be considered important for

social and desirability factors for patients, and thus influence the uptake and continued use of some medical devices. The use of a broad range of colour and materials must be supported by evidence that performance factors of devices are not compromised.

The most notable effects of filament colour were observed in the mechanical properties of printed parts. White material specifically showed a higher elongation for samples printed in the vertical orientation. Samples produced with white material in both the horizontal and vertical orientation showed the smallest amount of variation in tensile strength between groups, whereas green filament resulted in the largest variability. Although not conclusive, a possible reason for the differences in mechanical properties shown for white filament could be a result of larger quantities of carbon, and the smallest quantities of oxygen observed when compared with black and green filament samples. The slightly different chemical composition shown by Raman spectroscopy for green filament was not shown to have a drastic influence on the performance of printed parts for any of the quality attributes analysed.

Air management was shown to influence the accuracy of the gauge thickness of printed dog bone samples. When printed in the horizontal direction with air management, the measured value was higher than the nominal value for all colours and without air management, the measured value was lower than the nominal value. On accuracy of the gauge width, samples produced with air management showed a slightly lower combined error percentage than those printed without. The tensile strength and the variability between tensile strength values for sample repeats were shown to be unaffected by air management. However, the elastic modulus for white samples printed vertically was higher when printed with air management and lower when printed without.

Air management was conclusively shown to affect the dimensional accuracy of the thickness of the printed parts and improve the elastic modulus for a particular combination of printing parameters (white filament printed in the vertical orientation). With further investigations on varied geometries, it may be concluded that for particular medical device applications where dimensional accuracy is a critical performance characteristic, air management could improve the suitability of the technology for specific applications. For any medical device produced within a regulatory context by a specialist user, the use of air management would be recommended based on its suggestion to reduce overall dimensional error percentage. Within the use context of a specialist medical device manufacturer, the cost implication of investing

in air management technology is largely insignificant when compared with the additional costs required to develop a medical device for regulatory approval. Thus, air management would be a worthwhile investment to limit the contamination of a part through dust and debris in the air, and the UFP filtration functionality, without any additional benefits relating to minimising variability and improving dimensional accuracy.

Similarly, the effects of colour on the performance of parts are likely to be more relevant to specialist users where thorough testing is a requirement of the regulatory approval process. The differences in accuracy, variability and mechanical performance seen are likely to remain undetected in devices produced by a non-specialist user, where stringent testing protocols are not required, and the facilities required for such testing are not accessible. However, for FFF to advance as a technology and become more suited for industrial applications, steps should be taken by filament manufacturers to make users aware of the differences in chemical composition between varying filament colours, as well as the effects these have on the mechanical performance of printed parts. It is recommended that this is done through more detailed labelling, and the creation of technical data sheets for each individual material to replace the current method of labelling, which consists of a single technical data sheet for every colour of material within the same category, for example tough PLA, standard PLA, ABS etc. The technical data sheets should include standardised test methods which indicate the differences in mechanical performance between the variations of each material. This would help specialist users of the technology, and those working to produce regulated products to create product specifications and tolerance ranges that are a true representation of the material being used.

This chapter has highlighted the importance of including variable factors such as colour and air management in device testing for specialist users. By systematically testing combinations of variable factors, different performance characteristics can be achieved. In turn, these findings could be used to fine-tune the process, optimising it to meet the critical performance factors required by a specific application. More importantly, information relating to the repeatability and reproducibility of the process, along with quality testing and reporting are a regulatory requirement. Such information is necessary to prove the safety and efficacy of medical devices during this process.

Part 3

Discussions, future work, impact/significance to the field, and conclusions

Chapter 7

7. Discussion

There are many cases where medical devices remain out of reach from users who would benefit from them due to issues with accessibility, stemming from high cost, low availability and extended timescales to manufacture customised devices using conventional methods, or a combination of multiple limitation factors. AM was identified as a technology shown to revolutionise conventional customised AM processes, which traditionally require a highly skilled technician to craft each customised device. This method of production is both time and resource intensive, thus limiting the availability of some devices such as customised prostheses. However, many of the widely used AM technologies require high investment and complex infrastructural requirements, making them difficult to adopt in many clinical settings. In addition, the high running costs prompted by expensive consumables and the additional tools and hardware required mean the cost of customised AM medical devices can be high, still leaving them out of reach for many patients.

Many customised low risk medical devices are intended for either single or short-term use, which makes the high cost of some AM devices more unjustifiable in some instances. For example, a patient specific surgical tool or medical communication model might only be intended for a single use and would be disposed of immediately after that use. In this case, a cost benefit analysis would be required in each use case to compare an AM produced device with one produced using conventional methods, and a decision would have to be made about the benefits of using AM techniques in that particular situation. If it presents valuable benefits that significantly improve the surgical success rate, or minimises risk to the patient, higher investment costs may be justified. It may also mean that AM is unsuitable in some cases, and alternative methods may be deemed more appropriate. This type of economical consideration would likely only be relevant for specialist users where volumes of devices would be required, and no alternative method was suitable. For non-specialist users who would be more likely to produce one-off devices, an alternative is not usually available, thus justifying the use of the technology.

A short-term device, as opposed to a single use device, may be a more appropriate use of a costly AM technique due to the increased longevity. Examples of short-term devices could include casts or splints, or prosthetic sockets for infants. Casts and splints are often only used for a limited amount of time during the healing process. Similarly, prosthetic sockets specifically for infants or children will only remain functional for a limited amount of time due to the growth and changing needs of the individual. There have been known instances where children have almost immediately grown out of customised prosthetic sockets. In the timescale between the initial consultation and the fitting appointment, a child's anatomy could have changed significantly. This is an example that would benefit significantly from a rapid and semi-automated production process that can operate out of hours.

Where cost and accessibility are the largest barriers, the introduction of a more accessible technique, namely FFF, could provide a cost-effective alternative to the more established but expensive AM techniques. FFF was identified as a technology that could provide similar benefits of the well-established AM techniques whilst remaining accessible to a wider range of clinicians and patients. However, it was established that in terms of technical development, FFF was lacking in some areas that raised concerns relating to the repeatability of the technology and the part quality and performance. The opensource nature of FFF was discussed to be significant in prompting the open-endedness of the technology, which has subsequently led to high levels of variability reported in literature.

The large number of variable factors present in the FFF technique introduced a range of complexities. This presented additional challenges related to the regulation of FFF produced parts. The contrasting factors between each type of AM technique mean that knowledge relating to the regulation of a medical device produced with one type of AM, is not likely to be transferrable to a different type of AM. Similarly, even when focussing on the FFF technique alone, a lot of the research findings cannot be transferred due to the large number of variable factors. For specialist and industrial users, this means they are often required to conduct their own testing, alongside the development of their protocols, standards, and other documentation.

The excessive FFF market, which has a large and continually increasing number of FFF hardware, was identified as a factor that added complexity to understanding the process. The extreme variation meant that making sense of the published findings in the area and applying them to a different application was challenging. This means that critical research gaps were

identified in the field. It was realised that the focus of this work should relate to the FFF process generally, and that unlike much of the published work in the field which was based on a single device, product, or application. The findings related to specific studies, for example those that found FFF was a promising technique based on its ability to produce accurate models, did not consider the wider context of using FFF. Although a specific performance area may have been evaluated, the suitability of FFF in the context of the wider field was something not often discussed in literature. Therefore, evaluating the practicality of utilising FFF in a real-world use case, not just within a controlled research environment, was identified as a key approach within this work. The complexity of the regulatory landscape was discussed in detail, which is critical for most research, industrial or other specialist use case, like a clinical environment.

To reflect on the current status of FFF AM for medical applications in society, perhaps the most crucial area for consideration was the non-specialist use of FFF. The non-specialist use of FFF was identified and discussed in two main use cases; firstly, the charity work conducted by the e-NABLE organisation who are producing a significant number of FFF prosthetic limbs, and secondly, the non-specialist uses of FFF in response to the COVID-19 pandemic. The significance here was the scale of use in both cases. FFF is currently being used on a large and impactful scale, meaning there is a significant volume of FFF devices being produced and making their way into society.

Non-specialist use was not however limited to the discussed applications. In many instances, individuals and organisations are using FFF technology to produce a range of functional parts in the form of citizen supply networks. Some examples include research projects like the Interreg North-West Europe project Sharepair (Sharepair, 2021-2022), which is a large project (€ 8.23 m) representing a community of over 1500 repair clubs. The project aims to support the citizen supply chain by developing a digital infrastructure to facilitate the repair of consumer goods to divert them from entering waste streams where possible, prompting a more circular approach. The digital infrastructure involves producing online digital part libraries, which can be used to download files that can be manufactured to form physical replacement parts. Consumer products in this context largely refer to electrical and electronic equipment (EEE) waste, and not medical products, however, EEE products are also regulated, thus presenting parallels between most types of parts and devices coming out of citizen supply chains.

The safety and effectiveness of parts coming out of a citizen supply chain remains largely unknown. Challenges relating to the trueness of parts within a specialist context were discussed, meaning these issues are likely to be amplified in a non-specialist use environment where control measures are lacking. The multiple steps to creating a physical part using AM were discussed, and the concern around accumulative error building at each process stage was discussed. Therefore, the effectiveness of parts produced from the citizen supply chain remains a concern. The suggestions presented to mitigate variability in the FFF process could be beneficial to FFF users generally, across all three use contexts. The use of FFF across a wide range of industries, not just medical, highlights the significance of the dissemination of the research findings in this study. Increased awareness of the potential risks, or even to help users understand the potential scale of variation could be helpful in prompting the introduction of basic control measures to manage the FFF process.

The full effects of the citizen supply chain were explored in Chapter three, which revealed examples of both good and poor practice. The risks of using AM to manufacture medical devices which are not controlled or regulated were highlighted, which prompted the formulation of systems to manage the potential risks and mitigate them where possible. The most thorough and effective response from authorities was seen in the US, which combined the FDA, Department of Veteran's Affairs and National Institutes of Health as officials, with America Makes (the Department of Defence's national manufacturing innovation institute), to coordinate the citizen supply chain response. Designs went through a tiered approval system where some were approved for emergency authorisation, and those successful designs were made publicly available from an online repository in an attempt to encourage use of effective designs, and limit use of ineffective or dangerous designs. Part of the approval process involved design testing, which is a critical element in evaluating performance. However, as demonstrated within the work presented in this thesis, the performance of parts can differ significantly depending on the type of hardware, process parameters and other factors present in the process.

The collaborative initiative provided an excellent first step in mitigating risk through promoting the use of safe and effective designs. This model could be adapted and used across the citizen supply chain for Class I medical devices, as well as wider initiatives such as the repair network discussed. However, to enhance this model further, guidance on printing, in the form of a specific set of instructions, could be introduced. The instructions could be based on work such

as that presented in this thesis. However, it has been acknowledged that the printing and testing of samples was time and resource intensive. Therefore, applying a similar model to medical devices would increase time and resource intensity considerably. Forming and funding an operation as such could be challenging, however it could be highly beneficial if the uptake of FFF AM for low-risk medical devices and assistive aids continues as projected.

The approach in the UK was less involved, and directed people to rules, regulations, and official guidance. This approach was applicable and relevant to industry specific manufacturers who could understand and interpret the regulations, however to the non-specialist FFF community was a largely unhelpful response, and one which was less likely to influence their process of designing and manufacturing medical devices. Although the approach was less involved, it did help to raise awareness around the potential for AM in the medical field, and therefore was expected to help advance the industry, as seen by the increased number of volunteers in charitable organisations using AM to make medical devices in recent years.

The unauthorised reproduction of parts was also highlighted as a potential issue in FFF, as discussed in Chapter three with the Venturi valve. The production and control of digital file occurred as a potential issue in multiple areas. Firstly, the ease of sharing digital files was illustrated through the popularity of online part repositories. Where these files are used by the citizen supply chain, it is likely that their use will remain undetected due to the lack of traceability. However, where digital files are being used within a commercial environment, for example by private companies producing AM medical devices, the risk of IP and legal challenges increases significantly.

The challenge of storing and sharing patient data was also discussed as a critical area for consideration. At this stage, it is uncertain whether a consent protocol exists and is being used by medical AM providers. The only use context where appropriate consent and data protection procedures will almost certainly be enforced is through research, and the requirement of reputable research organisations to enforce stringent ethics and governance regulations for all research conducted. Private organisations, for example specialist customised medical device manufacturers are required to comply with the relevant data protection acts by law. However, the enforcement of these regulations across a range of digital platforms could be unclear. An investigation into the storage, use and sharing of digital patient data should be studied in future research.

As with many of the regulatory issues associated with non-specialist manufacturing activities, the storage and sharing of personal data would be much more difficult to control. However, the context in which the data is being shared is slightly different to that in a specialist manufacturing context. For example, a non-specialist user will likely be in direct communication with a manufacturer, and by sending over their own data are consenting for it to be used in that process. Although, the user may not be aware of where their data may end up. For example, networks utilise the skills of specialists, which due to the nature of digital data is not limited by geographical location. Therefore, it is not unlikely for a digital mesh file to be sent to a data processing volunteer somewhere else in the country, or even the world, for them to modify the mesh into a printable format, before sending it back to a volunteer with manufacturing capability locally. Where consent is obtained, this is unlikely to be an issue. However, ensuring that the use and potential sharing of data is communicated with the patient would be good practice.

Issues around the storage and sharing of personal data also translate up to industrial and specialist users through the collection of scan data from a significantly larger range of patients. The modification and manipulation of the data is also likely to occur between different technicians and clinicians. Within a specialist context, the appropriate management of personal data would be expected in line with the adherence to medical device regulatory processes and approval processes, which require detailed information on these aspects of custom medical device fabrication. Therefore, this could result in patients carrying the same expectations into a non-specialist environment, which may not always be the reality of how data is handled outside of a regulated scenario.

Multiple material related factors were raised throughout this thesis. The introduction of new lines of material specifically for medical device applications was unexpected, due to the premature state of the technology. However, it is a telling sign that FFF for medical applications is expected to become increasingly common in coming years. Two of the most popular filaments were identified as the antimicrobial filament for medical applications by Copper3D, and the skin coloured Varioshore range by ColorFabb. The introduction of these materials is expected to prompt an increased confidence in non-specialist users that the technology is suited to medical applications, due to the dedicated range of materials. However, many factors associated with the filament were shown to influence the printing process.

Issues relating to FFF printing materials, and the regulatory process have been highlighted during this study. Firstly, the requirement of all skin-contact devices to undergo biocompatibility testing is a known hurdle by FFF medical device manufacturers. As discussed, ActivArmor, a 3D printed cast company, adopted medically approved coating techniques to improve the device properties while helping to overcome barriers relating to skin contact. However, device coating, along with all other types of post-processing must be included in the technical documentation and quality management system for that device for specialist users.

The material identification of FFF parts has been discussed as an issue throughout, specifically relating to the appropriate disposal of FFF produced parts. Adding coatings could introduce further difficulties to the sustainable disposal of printed parts, further contributing to concerns around AM and sustainability. The traceability of materials used in printed parts is important for the appropriate disposal of FFF products, and for quality purposes critical for regulated industries. Varying material quality has been shown to affect the printing process. Inconsistencies in filament diameter can directly affect the extrusion behaviour of an FFF printer, pushing a larger volume of material through the print nozzle at the same printing rate as a smaller volume of material, will create extrusion inconsistencies, which can lead to changes in the dimensions, weight, and mechanical properties of a part. Further, any contamination in the filament, or changes in the filament composition, can also directly influence the quality of printed parts.

The extrusion temperature of a filament is based on a particular material composition and remains constant throughout the printing process. Therefore, if the material composition changes through inconsistent quality, the extrusion temperature will not adjust accordingly. A subsequent result of this could be changes to the melt flow characteristics of the material, and as with inconsistent filament diameter, result in deposition variation introducing additional levels of variability within printed parts. The likelihood of significantly varied filament quality within a single spool of filament is unlikely. However, inconsistent quality between batches of filament could be more likely, and could result in unwanted, and in a non-specialist use environment where material testing and quality control activities are not common practice, undetected variability between printed parts.

The influence of material quality on part quality was an important factor to highlight due to the increasing number of filament manufacturers emerging on the market. Historically, material quality may not have been of concern to most users, due to the FFF technique being used largely for prototyping applications. The shift towards functional applications, specifically within the regulatory context has increased the expectations of manufacturers to provide high-quality filaments consistently. The dissemination of guidance relating to basic practices, such as the appropriate and consistent selection of filament suppliers could be important for non-specialist users. A layperson could be under the assumption that all types of a single material, for example standard PLA, will perform the same. However, each supplier is likely to vary the material composition, if only slightly, which could affect the quality and performance of printed parts.

Specialist manufactures will be familiar with the basic principles of quality control and will be equipped to manage variation between material batches. Filament variability could be problematic in a scenario where multiple devices have been produced with different brands of PLA, which could mean the devices have slightly differing properties or performance. Such activities could be minimised through the appropriate dissemination of good practices. Although it may not be practical to suggest that all non-specialist manufacturers use the same filament, raising awareness as to why could be helpful.

For the reasons outlined, responsibility lies with filament manufacturers to ensure that a thorough and effective traceability methodology is employed in their production processes. In the event of poor-quality batches of filament reaching manufacturers, it should be identifiable and traceable. The quality management requirements discussed in Chapter two include the requirement to use approved and trusted suppliers, which must be routinely approved in line with the risk level associated with the device being produced. Filament would be deemed as a critical material, and therefore the supplier would be considered a critical supplier, meaning frequent reviews and audits would be necessary.

Filament storage is a factor that every user of FFF technology must consider, therefore it was a pertinent factor to explore. The results illustrated that the storage conditions of Tough PLA did have some slight effects on the dimensional variability and mechanical properties of parts, but to a typical manufacturer of Class I medical devices, these differences were likely to remain insignificant. Although the influence was shown to be small, being aware of the potential influence the variable factors discussed in this work have on the part outcome could be useful

for the fine-tuning of functional specific applications. For example, where optimal tensile strength is required, a manufacturer might choose to store material in ambient conditions which showed slight improvements in mechanical strength. Where elongation is an important property, geometry printed in the horizontal direction would be expected to benefit from filament being exposed to moisture, whereas for geometry printed in the vertical direction, where in-use forces would be applied perpendicularly to the layer lines, sealed material provided the optimal elongation. Further, samples printed with white filament in the vertical direction showed the highest tensile strength, and samples printed with white material showed higher elongation than other colours. Where dimensional accuracy is important, and dimensional variability between parts must be minimal, the manufacturer might choose to use sealed material because of the reduction in dimensional variability shown between printed parts printed with sealed material when compared to material stored in ambient conditions.

Typically, for most users, storing material in different environments to prompt changes in performance would be unrealistic, due to the expected small scale of the impact. However, knowing that moisture exposure to ambient conditions is not likely to cause significant performance limitations is a valuable finding. The main limitation to this research was the range of material investigated. It is acknowledged that the hygroscopic properties change significantly between materials and are also thought to be affected by material quality and composition which as discussed, can vary significantly between manufacturers. To make conclusive recommendations about filament storage for PLA materials generally, a more extensive range of materials would need to be tested, and a wider range of conditioning environments should be considered.

For non-specialist users, material storage conditions are likely to be more extreme for longer timescales, and the nature of the manufacturing environment means resultant changes to a part's properties and performance is more likely to remain undetected. Where variability is introduced as a result of one factor, and remains undetected, the likelihood an accumulative combination of error is likely. Whether this cumulative error could be significant or not remains unknown, due to it being highly dependent on the process factors introduced, and the effects on a part within the context of its intended application.

Extreme moisture exposure through filament being submerged in water for 72 hours was shown to reduce the T_g. The change to the thermal properties of material has been discussed as an

important consideration in FFF, due to much of the deposition behaviour being based on the concurrence of the melting temperature of the material, and the extrusion temperature defined in the slicing software. A small difference in weight was observed for samples produced with moisture exposed filament of around 0.1g. This was expected to be a result of slight over extrusion related to the decreased material viscosity. A small weight change of 0.1g could however be attributed to multiple factors in the process, which would make it unidentifiable for non-specialist users. Realistically, in practice, the most common way to identify significant issues with 3D printing for most users is observing the printing process. Visual indications, such as blobbing or stringing which cause poor surface quality and the deformation of prints, are likely to be the most common indication of printing defects. This would usually prompt a process investigation, which for many non-specialist users will likely be the only time they look for factors that are influencing the FFF process and the resulting quality of printed parts.

The influence of colour on the FFF process is a particularly significant factor when considering the benefits colour options bring to the FFF process. A commonly discussed benefit of using FFF technology for wearable Class I medical devices was the expression of personality through colour and aesthetic design. Although from a scientific and functional point of view, the colour of a device might be considered unimportant, from a social perspective it is a key factor for the adoption of medical devices and assistive aids for many users. Medical devices and assistive aids were discussed to have significant rejection rates, largely due to them not meeting user needs both medically and socially. Expressive prosthetics for example have gained significant media attention due to the positive impact they have made on the acceptance of medical devices for users, especially children and young people. Adherence to medical devices is key for adoption, which can be influenced hugely by the user's perception of their device. The ever-growing library of experimental FFF printing filament makes aesthetic customisation an increasingly relevant factor, and therefore it was highly appropriate to be considered a variable factor in this study. The devices produced by non-specialist users are often designed based upon the preference of the end user. In many cases, a user can request any colour or combinations of colours for FFF printed parts.

The mechanical properties observed indicated that the pigment used to colour white filament did have an effect on both the elongation, which was ~2% higher for white samples than other colours, and elastic modulus, which was shown to be ~20% lower for white samples than black and green, combined with a specific set of factors which were vertically printed without air

management. The lower elastic modulus was only shown to be true for white samples printed in a vertical orientation with air management, meaning it was highly specific. To determine these types of perturbations between specific combined factors, a systematic study must be conducted. This, however, is unrealistic for most users apart from those working within a research context. Industrial users may be likely to perform this type of systematic study in the development or early manufacturing stages when optimising the manufacturing process for a specific application, however, non-specialist users would be unlikely to conduct such activities, again due to the small, and for general use insignificant, influence on the performance of printed parts. This type of analysis of variation between the mechanical properties of part repeats would be relevant to the repeatability testing of a manufacturing method. However, specific mechanical tests, such as testing for maximum pushing or pulling forces, would be based on the testing standards available to assess the functionality of a feature of a particular medical device, such as the operating forces for the operation of a manual wheelchair, as in BS EN ISO 12183 (BS EN ISO, 12183:2022).

Although findings in literature reported connections between filament colour and performance factors, such as surface quality and dimensional accuracy, the results in Chapter six indicated that dimensional accuracy, dimensional variability and surface quality remained largely unaffected by colour. The weight of green samples was slightly lower than black and white samples, although, the difference was small. In all but one case, the mean difference in weight between green samples and other colours was less than 0.1g, showing the weight difference as a result of colour was largely insignificant. Although, a limitation of this study was that it covered three colours of Tough PLA, which were all fully opaque. Recommended future work would be to study a wider range of materials, including translucent and transparent materials, as well as those with exotic fillers and additives such as flecks of glitter or metallic fillers.

Analysis techniques such as SEM-EDX and Raman spectroscopy showed the quantity of elements differed for each colour of material. Green filament was shown to be the most compositionally different filament, although this was not reflected in the dimensional or mechanical analysis against other samples. Although in this case the filament composition was quite similar, it would be expected to vary more for exotic materials as discussed, and therefore communicative practices around the labelling of filament would be an appropriate step for filament manufacturers to take when appealing to a more industrial market of FFF users. Filament suppliers were found to be reluctant to share information about the filament composition due to the competitive nature of the field. Currently, technical data sheets (TDS)

exist for each type of filament, for example Tough PLA, PLA, ABS etc. However, when pigmentation or other aesthetic fillers have been shown to affect the properties or performance of parts, the industry would benefit from providing technical data for each filament (colour) variation.

The largest notable difference observed in the results for Chapter six was the difference in weight between horizontally and vertically printed samples. Observations of the internal structure of the samples indicated that vertically printed samples had a central void, thus resulting in a significant reduction in sample weight. Orientation is a known factor to influence the performance and properties of a part, and it is common practice to orientate a part based on its geometry for optimised printing or intended functionality. However, both horizontally and vertically oriented samples were printed with a 100% infill which meant the ~1g weight difference was an unexpected result, and at $1/7^{th}$ to $1/8^{th}$ of the sample's weight, was deemed significant.

The effects of air management were shown to be minimal for weight and gauge width variation. However, they were shown to influence the gauge thickness accuracy of the printed dog bone samples, only when printed in the horizontal orientation. Where air management was used, the thickness of specimens was larger than the nominal value for all filament colours. Where air management was not used, the thickness was smaller than the nominal value for all colours. In the horizontal direction, sample thickness was dictated by the Z printing direction, which was shown to be the most variable printing direction in terms of process capability. To understand the full effects of air management on accuracy within the context of a production cycle, the methodology for system capability could be repeated twice, both with and without air management. This would provide further conclusions around the effects of air management on dimensional accuracy both generally, and particularly in the Z printing direction.

The benefits of conducting process capability studies were demonstrated in Chapter four, which showed that the dimensional variance was directly linked to the X, Y and Z printing directions. It also showed the capability of each machine differed, despite being the same make and model of machine. This highlighted the importance of conducting process capability studies to identify the level of machine-to-machine variation, particularly for manufacturers who use multiple machines in a volume production scenario. The context of manufacturing is

highly relevant when deciding which type of process capability studies to conduct, along with the MSA activities relevant to the process, operations, and variable process factors.

Process capability findings indicated that the positioning of a part on the build platform directly affected the dimensional accuracy of the part. It was recommended that maintenance steps were implemented in an attempt to reduce variation across the build platform. However, if this was unsuccessful, the manufacturer may wish to use this information to inform standard practices during the slicing stage of manufacture. For example, if a manufacturer was producing four different types of parts, as illustrated in Figure 112, if locational printing accuracy was a persistent issue, the production schedule could be modified to print parts in batches of multiple parts, where the positioning of replicate parts remains the same across builds, as shown in build 3 and build 4 (Figure 112). Typically, production cycles resembling build one and build two (Figure 112) are more efficient in maximising printing productivity, however, the methodologies presented in Chapter four can be used to quantify the dimensional variation attributed to locational positioning, and the subsequent effect on achievable production tolerances, and adjust the process accordingly.

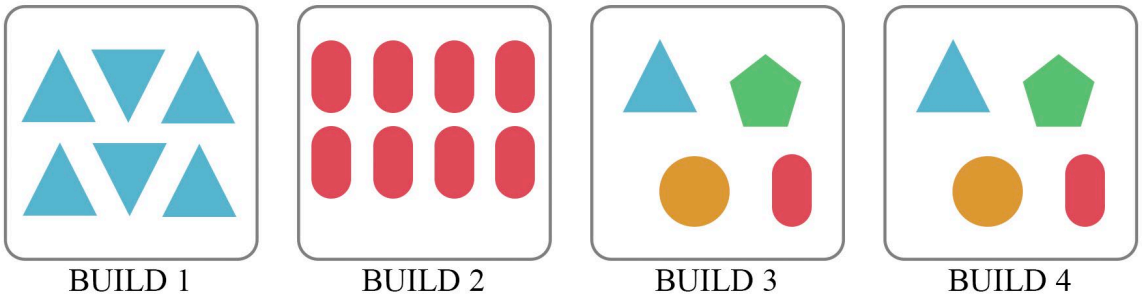


Figure 112: Visualisation of different build configurations for the production of multiple parts

For a manufacturer, being able to demonstrate process capability through process validation activities is common practice. However, for a non-specialist user, this type of analysis would not typically be done, due to non-specialist activities not being required to meet specific standards and quality levels. However, as identified, with basic equipment, this type of study could be conducted by every type of user to provide them with useful insights about the technology. This methodology is thought to be highly significant to the FFF field generally, through its applicability to every industry that manufactures parts that are dimensionally significant, especially those required to meet certain tolerances.

The achievable tolerances are another heavily discussed topic in the field of FFF, specifically in non-specialist communities, which in this case includes makerspaces such as university AM facilities. The determination of tolerances is typically done through experience, which has often been a result of *trial-and-error* practices over an extended timescale. Therefore, paired with a basic type 1 MSA study, a SCA could be integrated as an essential tool for the determination of printing tolerances for FFF hardware in many use cases, making it a significantly impactful area of research. Knowing tolerances can help users to design appropriately for the limitations of a technique, thus reducing the need to print iterative parts consecutively whilst modifying the dimensions between each print. This method of trial and error can be time consuming and contributes to the excessive production of defect parts, increasing the levels of AM waste.

This work also helped to highlight the importance of conducting MSA activities on measurement systems being used for process capability. Of the three measurement tools investigated in this study, the tool expected to be the most accurate and precise, the portable measuring arm with a ruby tip probe, was shown to have the lowest dimensional accuracy. From the studies analysed in the literature, the inclusion of MSA activities in PCA studies was lower than expected. However, when a significant amount of variation is attributed to a measurement system, this variation can be detrimental to the results of a SCA or PCA, especially where the system/process variation is small compared to that of the measurement system.

Implementing process capability protocols from the initial set up of a machine would be an appropriate way to identify the initial capability of the machine and monitor and observe the process capability over use intervals. One would expect the continual PCA of a machine to indicate potential issues and wear on the machine's components. These activities, combined with adhering to the maintenance schedules recommended by the manufacture will help to optimise the performance of machine over short term and long-term use periods. PCA could also be a useful tactic to manage the performance over multiple machines, which could be in different geographical locations. One of the benefits of AM is its suitability for distributed manufacturing. In the context of Class I medical device manufacturing, an organisation or manufacturer could operate in a manner where their core activities, such as design and development, occur in one location and the manufacturing of end-use parts could be distributed globally. In this scenario, a method of benchmarking machines would be an essential activity in a wider group of quality activities to ensure the machines operate as intended, within the

allowable tolerance limits for a particular part of device. SCA or PCA could be used to benchmark the performance of multiple machines, which is applicable for the manufacture of medical devices, but also for the wider FFF industry where both distributed and central manufacturing activities are being carried out.

Within the context of FFF printed Simple Class I medical devices, the findings presented in this thesis mean different things for different users. For non-specialist users, scientific findings in relation to the mechanical performance of FFF printed parts would likely be irrelevant to their AM activities, based on the lack of required testing and accountability within the citizen supply chain model, alongside the lack of equipment or resources to test for the properties of printed parts. Due to the differences in properties being sometimes deemed insignificant based on their influence on the FFF process within the relevant use context, aside from the statistically significant differences which are unlikely to be detectable by eye, or with basic equipment available to non-specialist users, the discussed level of detail surrounding performance factors is unlikely to be directly transferrable to non-specialist practices. However, much of the work is highly relevant to non-specialist users, such as the identification of factors which introduce variation to the process, and the potential risks of manufacturing medical devices to be aware of, which were highlighted by the response to the COVID-19 pandemic through the widespread adoption and real-world use of FFF printed parts.

The findings surrounding the process capability of FFF are highly beneficial to all FFF users. The process capability findings contradicted the widely adopted assumption that the capability of FFF technology is consistent in the X-, Y- and Z-printing directions. The methodology presented for system and process capability analysis is highly advantageous to the wider field of FFF printing generally. It allows the determination of manufacturing accuracy, which is a critical aspect of any industrial application for FFF. Many of the devices produced by both specialist and non-specialist users consist of multiple printed parts or components, which require assembly, and therefore heavily rely on acceptable tolerances, which can be deduced from the presented work.

The translation of scientific data into this accessible discussion format provides non-specialist users with a series of recommendations to optimise their practices, such as the confidence to store filament in ambient conditions for up to three months without expecting to experience problematic effects on the printing process and part performance. The detailed scientific data

presented in this thesis is highly relevant to specialist, industrial and research users of FFF who would be expected to present such data for medical devices in line with the regulations discussed. The findings can be used as a baseline to formulate thorough manufacturing protocols to record and optimise the capability of the FFF process within the context of Simple Class I medical device manufacturing, providing a significant contribution to aid the progression of the field.

7.1. Impact, novelty and significance to the field

This study is the first of its kind to examine the current status of the FFF field for Class I medical device applications, collating the key points of consideration from a wide range of stakeholders. This in itself is novel work, due to the current literature focussing on specific industries or use applications, which present a lack of holistic work. The FFF process has been approached from the point of view of three relevant and current identified use cases, whilst identifying and exploring specific considerations for each of these use cases. A multidisciplinary approach to this work has allowed the work to take multiple forms, including reviewing, conducting practical case studies and scientific experimental work. The current research activities in the field were identified as largely being specific to individual device applications, which prompted this work to consider the wider context of FFF for medical device applications, thus widening the impact and significance to the field as a whole. Detail orientated work in the form of experimental systematic studies were completed in response to specific challenges identified in part one, further strengthening the impact of the thesis.

Considerations to non-specialist manufacturers were identified through the formation of a customised Class I medical device case study, which both confirmed considerations raised by literature, and identified new areas for consideration regarding the process steps and potential challenges. These discoveries highlighted most beneficial focus of the experimental work. The rapidly increasing number of volunteers working with organisations such as e-NABLE to manufacture medical devices, combined with the release of specific material ranges for FFF medical device applications demonstrate the significance of this work to the field currently, and in the future where the growth and adoption of the technique is expected to increase further.

This is the first known work to explore the process capability of FFF through the analysis of both a single machine, and a print farm, which is a highly relevant use application for FFF

technology. The use of a measurement system analysis highlights further novelty, due to this not being included in current literature surrounding FFF. Further, the experimental work surrounding the storage conditions of filament combined analysis techniques from chemistry, design, engineering and inspection approaches to address a wide range of potential effects on the FFF process and part performance. This makes the work relevant to the widest possible range of users, creating the largest impact. It was also the first body of work to quantitatively dispel popular belief from the AM community that moisture absorption leads to swelling and blockages in the FFF process for PLA based material. Another novel area of research was to investigate the effects of enclosing a non-heated build chamber. Published literature was limited to heated, or partially heated chambers, leaving a large gap in the literature relevant to non-specialist and professional FFF users without access to heated build chambers. The context in which this research has been conducted has allowed a highly explorative approach, which responds directly to the needs of key stakeholders and the wider field of FFF for medical device applications.

7.2. Future work

The use of FFF AM technology for medical device applications is expected to be an up-and-coming field, which will gain further research interest over the coming years. The results from this work have raised additional questions and potential areas for exploration, which are presented in accordance with each experimental chapter, followed by recommendations for future research for the field generally.

7.2.1. Repeatability and reproducibility of fused filament fabrication

Most of the individual processes studied in Chapter four, which looked at the repeatability and reproducibility of FFF, were found to be unstable due to the inherent variation in the FFF process. This was shown by measured data points falling outside of the calculated control limits. To improve the reliability of a PCA, the stability of the FFF process required improvement in multiple cases. However, the process of improving the stability of an FFF printing process falls outside of the remit of this study, and therefore future work would be required to understand the steps necessary to improve the process stability of FFF. An expected initial approach in reducing the data spread would be to action a full maintenance schedule for the printer.

The recommended maintenance schedule for the Ultimaker S5 can be seen in Table 47, and is likely to have many similarities to the maintenance requirements of other FFF hardware. The maintenance schedule is based on 1500 hours of printing per year, which is expected to vary between different user cases and use patterns. In scenarios where maintenance schedules were not adhered to for the duration of printer use, a full maintenance assessment for the printer should be conducted. For printers that have been frequently maintained, additional troubleshooting activities may be necessary. For example, the use of calibration and test parts, which can be downloaded and printed to check for particular hardware errors. As demonstrated, a process capability analysis is required as the first step to identify and analyse the performance of an FFF printer. The results obtained from a SCA or PCA should then be used as the initial starting point for troubleshooting and possible machine maintenance tasks.

Table 47: Ultimaker S-line 3D printer maintenance schedule (Source:(Ultimaker, 2022a)

Timescale	Action	Details
Every month	Clean the printer	Keep the printer clean for optimal printing results. This includes the glass plate, nozzles, Bowden tubes, and the inside of the printer.
	Lubricate the axles	Apply a small drop of oil to the X, Y, and Z axles. Move the print head and build plate to equally distribute the oil.
Every three months	Check for play on the axles	The X and Y axles in the frame should only rotate, not move back and forth. Firmly attempt to move the axles individually.
	Check the tension of the short belts	The short belts attached to the X and Y motors should be tight to correctly transfer the movement to the print head.
	Clean the front fan	Thin strands of filament could end up in the fan. Check this regularly by opening the front fan bracket. Remove any strands of filament with tweezers.
	Check the nozzle cover	The nozzle cover shields the print cores from cold airflow from the fans. Check both sides of the cover for tears or damage from heat. If it is damaged, replace the nozzle cover.
	Lubricate the lead screw	Apply a small amount of grease to the lead screw of the Z motor. Move the build plate up and down to equally distribute the grease.
	Clean the feeders	Small filament particles can gather on the feeder's knurled wheel. Unload the materials and open the feeders to clean the inside with a small brush.
	Clean the print cores	Preventively clean the print cores to remove any degraded material from the inside of the print core. Use Ultimaker cleaning filament or PLA for applying hot and cold pulls.
Every year	Lubricate the feeder gear	Remove the feeder from the back panel to access the feeder gear. Clean it first, then apply a small amount of grease to the gear.

Check the Bowden tubes	Materials can slightly scratch the inside of the Bowden tubes and the ends of the tubes can get damaged by the tube coupling collets. Check them once a year and replace them when they are damaged.
Clean system fans	Check the fans at the back of the printer for dust and blow on the blades to clean them.
Lubricate door hinges	Apply a small drop of oil to the door hinges to ensure the door(s) continue to open and close smoothly.

An additional recommendation for future research would be to conduct a gage R&R study, in addition to a type 1 gage study where multiple operators are involved in the production process. This activity will allow for the variation in the measurement system, which includes the measuring tool and operator, whilst indicating what level of variation is attributed to the part. This stage would likely only be relevant for industrial manufacturers and as demonstrated in Chapter four, would not be applicable to an individual researcher or non-specialist user of FFF technology.

Further, a similar process capability study should be conducted with representative geometry of a typical production process. Although it is possible for a manufacturer to produce linear cubic parts, it is likely that the geometry produced within a real use environment would be more complex. Although process capability is a unique process, and should be specific to a certain process application, the introduction of more complex geometry may reveal additional trends or areas for consideration that were not identified in this chapter. Another step to strengthen the process capability study when used in practice would be to repeat the study at specified intervals, for example one a week, month or year depending on the production output and level of process. This would allow for continuous improvement, and would help to provide confidence in the process, which would be beneficial for the validation of manufacturing processes of regulated products, such as Class I medical devices.

7.2.2. Material storage

To make more general conclusions about the effects of filament storage on the FFF process and the quality and performance of parts, a wider range of materials should be considered.

Material variations should include commonly used printing materials such as standard PLA, ABS, nylon, polyethylene terephthalate (PET) and polyethylene terephthalate glycol (PETG). In addition to each material type, variations of material within each group should be considered, for example, different colours of PLA, including solid colours, translucent colours, and commonly used PLA filament with a modified composition for aesthetic purposes, such as iridescent, metallic or glitter filaments. By exploring a wider range of materials and colours, more general conclusions can be made about the effects of filament storage for FFF printing generally.

In addition to expanding the material range, investigating the effects of extended conditioning timescales would be beneficial to provide insights into the maximum life of Tough PLA filament stored in different conditions. By analysing conditioned material and parts printed using conditioned material at specified time intervals over an extended period, perturbations in the printing process could be observed, potentially indicating an acceptable maximum storage period for each material before any signs of degradation in quality were observed. In turn, this research could prompt the introduction of "best before" guidance on packaging, if found to be necessary, which could help to prompt users to be more aware of using filament when it is likely to perform at its best. This information could be used to form good stock rotation practices which, for industrial FFF users, and manufacturers of regulated FFF medical devices, would be valuable information for manufacturing quality management systems.
The timescales used in this study were perhaps more relevant to industrial users, or some non-specialist users who have a high production output. The longest observed timescale in the initial work was three months, which is a realistic maximum timescale for filament to be used in a high-volume setting. Non-specialist users however, or those with reduced output volumes, could potentially store filament for years before using it. This is particularly relevant when considering the growing material libraries. Where users are switching between different aesthetic variations of filaments, it is likely that they will remain in storage longer before a full spool of filament is used, further enforcing the rationale for increasing the timescales in future work.

To be more representative of non-specialist FFF users, the type of ambient conditioning environments could be extended to represent a wider range of use environments in different locations. For example, the literature review made apparent that changes in temperature could influence the uptake of moisture in filament. Ambient conditions in a warmer and more humid

climate may yield different results, potentially having a more significant effect on the FFF process. Additionally, ambient conditions in the same geographical location may differ according to the use environment. Within this work, ambient conditions represented an indoor space with air conditioning, which is likely to be an accurate representation of use environments for most research and industrial applications, however, for non-specialist users, specifically in the UK where air conditioning units are not commonly installed in home environments, an ambient space is likely to differ significantly, commonly taking the form of a garage or shed, which is more susceptible to the outside climate. A study of users storing filament in different locations could provide insights into any varying levels of moisture update depending on location and varying environmental conditions.

7.2.3. Effects of variable factors

Based on the results in Chapter six around the effects of pigmentation in filament, it is recommended that future research including a wider and more diverse range of material is discussed. As recommended for Chapter five, increasing the material range to include more exotic materials, as well as including those from different filament manufacturers, will help to build a more general picture for the wider field, which is increasingly applicable to every type of user. The increasing number of materials is a highly desirable aspect of FFF printing, which is often limited with other AM technologies. The effects of pigmentation and fillers should be tested on the effects they have on dimensional accuracy and mechanical performance, as well as considering the amount of variability between repeats and replicates with respect to each performance characteristic.

To extend on the work completed, an additional range of material properties could also be studied. The mechanical property requirements are specific to different types of device applications. For example, for a lower extremity prosthetic socket, or any device that is likely to have for exerted onto it, compression and impact properties will be more applicable for that type of device.

In addition to the work around the use of air management, recommendations for research would include further observing the effects of air management on the dimensional accuracy in the Z-printing direction, based on the observed effect it had for the gauge thickness of printed

samples. To have the widest possible impact, future work should include a range of different types of geometry, for example larger parts with more complex geometrical features. It may be possible that the use of air management is more prominent for larger and more complex parts, based on the findings related to the thickness of dog bone samples, which remained constant throughout this study.

7.2.4. General recommendations for future work

Reference has been made to the sustainability of FFF as a manufacturing technique throughout this thesis, which is applicable to much of the work discussed. However, the testing and implementation of sustainable practices fell outside of the scope of this thesis and would therefore be recommended as future work. Much work is necessary to ensure the responsible and sustainable growth of the technology, however an issue that has been identified as particularly pertinent is the identification of material for 3D printed parts. This is essential for the implementation of any type of material recovery or recycling scheme. The practicality of this must be addressed, as well as how it is implemented across each of the different use contexts discussed. Slicing software could be used to embed an identification number, code, or symbol, which could also be used for traceability and quality control purposes for industrial manufacturers. Complexities would however lie with the location and positioning of the marking, as well as the potential affect it could have aesthetically.

This approach towards material identification may not be applicable for non-specialist users, especially those using opensource software packages. A body of research investigating the potential methods for material identification and how they could be implemented field wide would be a highly beneficial contribution to the field. This work, followed by the establishment of an infrastructure to manage 3D print waste, whilst considering the complexities introduced specifically to the medical field, such as hygiene and contamination, is critical to ensure responsible growth if the technology is implemented more widely as predicted.

Additional steps through the implementation of good printing practices could also be useful in reducing the environmental impact of the technology. As discussed, steps could be taken as part of the decision-making process when printing to reduce the overall consumption of consumables through reducing the amount of defect or unsuitable parts. By developing

protocols for good practice, such as maintaining machines and efficiently identifying printing tolerances through planned activities, as opposed to a trial-and error style of printing, the environmental impact could be reduced further. Similarly, if long term effects of moisture exposure were shown to affect filament quality, especially for the more hygroscopic materials not considered within this work, conscious choices to use filament responsibly could reduce volumes of waste further.

The inherent low-cost of FFF printing filament means the reduction of waste is often not a priority to many users, due to the cost of consumables being insignificant to many individuals or organisations. Therefore, the trial-and-error approach is one commonly adopted for the teaching and use of FFF, and although this does have some benefits, the 3D printing community as a whole should take responsibility for the environmental impact these methods have on a larger scale. A body of future work relating to the volumes of waste as a result of FFF use could help to raise awareness in 3D printing communities. The dissemination of such work could be particularly impactful, and provides opportunities for a creative and visual approach, such as art or sculpture as a method of visualising impact.

The lack of standardisation in the AM field has been noted by many. The introduction of standards to reflect the performance of hardware, and quality of material would be beneficial to the field. It would be thought to help build confidence in the technology, thus prompting more functional use of the technology. The development of standards relating specifically to the storage, use and sharing of personal data in the form of CAD and mesh models would also be beneficial, as well as further work to test the security of storage and sharing methods used currently. Many digital software packages have collaboration capabilities, which makes it easy for digital data to be shared via the software, web browser and some mobile applications. The ease of collaboration also raises concern for the potential of security breaches. Additional work in this field would be beneficial to understand the security of digital data trails, whilst highlighting any additional measures necessary to protect patient confidentiality, thus reducing risk of unauthorised sharing and other similar breaches of data protection regulation.

Further, the controlled modification of personal data requires additional work. Mechanisms should be developed to ensure the controlled and appropriate modification of anatomical patient data collected from 3D scans. During the customised daily living aid case study in Chapter three, the under/over modification of digital scan data was identified as a potential

issue. Within a medical context the data manipulation could be critical to the functionality of a device, and therefore mechanisms should be developed to ensure free-hand modification is done within acceptable limits which should be determined in conjunction with a clinical professional. The level of control required would be highly dependent on the device, and therefore this type of work would be most beneficial on a case-by-case basis. Manufacturers of regulated medical devices would be expected to demonstrate control of this type of process. However, consistent and efficient methods of doing so could be a result of future research. Although these types of research activities may appear insignificant in relation to the wider field, the implementation of effective control measures throughout the process will likely promote an optimised and more efficient model for the FFF manufacture of Simple Class I medical devices.

Chapter 8

8. Conclusions

FFF technology was identified as a rapidly developing technology which could be hugely impactful to the customised Class I medical device industry. Hardware was categorised as either hobbyist, professional or industrial based on its features, cost, infrastructural requirements and the types of material it supports. Professional or mid-range FFF was suggested to be a highly suitable manufacturing method due to its low cost and high accessibility. Most professional FFF hardware is desktop based, making it suitable for use in home, office, industrial and clinical environments, acting as an advantage over some of the other more infrastructurally demanding technologies, such as powder bed fusion, a popular choice for medical device manufacturing.

The complexity of the FFF technique was explored, followed by how these complexities combined with those present in the medical device industry. The amalgamation of process complexities demonstrated the challenging nature of applying FFF methodologies to medical device fields. The regulatory landscape was explored, and an investigation of how the fused filament fabrication process could align with regulatory requirements was conducted, revealing the suitability of 3D printing materials for skin contact, general quality control, and process verification, as the most potentially challenging areas.

The literature relating to the use of FFF for medical device applications was reviewed. Initial scoping exercises revealed the literature on FFF as a process generally was plentiful, however it was similarly focussed on optimising the printing process through the modification of process parameters. The FFF process was shown to be highly influenced by input parameters, such as process parameters, and environmental factors. A large and growing amount of published literature was found to relate to the use of FFF for medical applications, however these were mostly in the form of device specific case studies. The fundamental limitation of published literature in the field was identified as its lack of reference to real-world use contexts. Although much of the work is being completed in a research or clinical research environment, for it to

progress out of that environment, there must be a level of engagement with the measures in place in society to regulate medical devices.

The three main use cases of FFF in society were identified as non-specialist, industrial and research. The significance of the non-specialist use context was highlighted by the large volume of devices being manufactured and put into use by the citizen supply chain, further highlighting the importance of research relating to FFF medical device applications to be put into context, maintaining relevance to the real-world use scenarios. Two case studies were presented, exploring use cases for FFF in society, which confirmed the potential of the technology, but also highlighted challenges and risks relating to the complexity occurring in each of the process stages, the risk associated with use, and challenges the widespread use of FFF could present in relation to social issues, such as sustainability.
An initial pilot study into the susceptibility of professional FFF to the influence of external factors was conducted, revealing that detailed and thorough assessments of process capability were necessary. It indicated that the use of different coloured filaments and additional hardware add-ons could affect the key performance indicators of printed parts, which were the dimensional accuracy, dimensional variability, and mechanical properties. The influence of the identified factors was observed through systematic studies to provide insights on the level of control necessary to optimise the stability, an important indicator of manufacturing suitability of the FFF process.

The process capability of professional FFF hardware was found to vary depending on the printing direction, where the dimensional accuracy was shown to vary between the X-, Y- and Z-directions of the same printer. The directionality associated with inferior dimensional accuracy varied between printers and was not consistently inferior in a single direction for all printers. This was a significant finding that is expected to be highly impactful for all FFF users who require dimensional accuracy of parts. The placement of parts on the build platform was also found to be a factor influencing the dimensional accuracy of printed parts. The methodology presented was effective in identifying the capability of the FFF process between builds and cycles and was shown to be an appropriate method of identifying manufacturing tolerances in each of the three printing directions. Results indicated that the smallest achievable tolerance in each printing direction on the machines tested were 0.3mm in both the X- and Y-printing directions, and 0.4mm (rounded to the nearest 0.1mm) in the Z-direction. These values were observed across different machines, showing the significance of machine-to-machine

variation. The use of multiple machines in a print farm scenario was shown to reduce capability, which was an expected result of extending the process.

The effects of storing filament in variable conditions were studied to examine potential defects or degradation caused by moisture exposure. Storing filament in ambient conditions for up to three months was not found to significantly affect the material properties, printing process or the properties of printed parts. The dimensional variance between printed samples was slightly smaller for those printed with sealed material when compared to those printed with material stored in ambient or submerged conditions. Slight variations in tensile strength of printed samples were observed, where filament conditioned in an ambient environment for 72 hours showed a slight increase in tensile strength. Tough PLA remained largely unaffected even when submerged in water for 72 hours and was only found to have a slightly lower glass transition temperature (~1.4ºC) than material stored in ambient conditions.

The effects of different coloured filaments as a result of the added pigmentation were studied, revealing that the colour of the filament was slightly influential on the weight of printed samples, with samples produced using green material weighing slightly less than those printed with black or white material. The dimensional variability of printed samples as a result of filament colour was shown to be insignificant, however the mechanical properties were shown to be influenced. The variability between the tensile strength of samples printed with green filament was shown to be higher than other colours. The mechanical properties of samples printed with white material differed from the other colours, with white samples showing an increased elongation and decreased elastic modulus when combined with printing orientation and air management variables. Interactions between the use of air management, filament colour and printing orientation as variable factors were also observed. Air management was shown to influence the dimensional accuracy of the gauge thickness of dog bone samples printed with white filament in the vertical orientation. This combination was also shown to yield the highest elastic modulus value of all colour/orientation/air management combinations. Overall, the use of air management was shown to reduce the dimensional error percentage slightly.

In each systematic study where variable factors were analysed, the findings demonstrated complex relationships between variable factors and other parameters such as the printing orientation. Being aware of the complex relationship occurring between variable factors in the FFF process is important, however, the details and quantification of these relationships is less

relevant to the field generally due to their uniqueness to the specific hardware used, and all other process factors considered. Much of the variances attributed to technical factors, such as the modification of printing parameters and process factors, is more relevant to specialist manufacturers, and those producing devices intended for regulatory approval. FFF has been confirmed as a highly variable process, and a large number of control measures are required to be in place to achieve consistent quality.

The pathway to regulatory approved Class I medical devices has been demonstrated as complex, although with the implementation of stringent process control and validation measures, paired with comprehensive part testing, regulatory approval is thought to be an achievable goal. Efforts from stakeholders in the wider field could contribute to easing the adoption of FFF within industrial use cases, through ensuring the quality and traceability of printing material and other consumables, thus ensuring the stability of the wider process.

The FFF process has been confirmed as a highly situational process, which is influenced significantly by the capability of the hardware used. The accumulative effects of multiple other process and environmental factors is thought to potentially influence the process, and the subsequent performance of printed parts. Recommendations for specialist manufacturers producing Simple Class I medical devices would include dedicating the necessary amount of time and resource for research and development exercises, to fine-tune the FFF process to best meet the device specification and the performance requirements specific to that device. After optimising the process, control measures should be employed and the capability of the process should be tested using the methodologies presented in this study, followed by continuous monitoring and quality control testing throughout production.

For non-specialist communities, recommendations would include the implementation of a central hub for approved design files, presented in conjunction with recommendations for good practice when printing. Some of the charitable organisations discussed have similar initiatives in place, however the guidance was found to be limited and outdated, and based heavily on grey literature sources. Updating these resources based on scientific findings and combining them with simplified and collated versions of the relevant regulatory guidance for AM for medical applications could be a beneficial resource to non-specialist users. Recommendations for users to conduct basic quality assessments of printed parts, for example visual inspections and basic measurement activities including weight and dimensional analysis. Differences in

the weight or dimensions of parts could indicate potential defects, such as under extrusion in the internal structure of the part, which could in turn significantly affect the part's performance.

In conclusion, FFF has huge potential to democratise customised Simple Class I medical devices that currently remain inaccessible to many. However, the implementation of the technology remains specific, and highly individual to each use case. The manufacture of custom Class I medical devices that can be prescribed is thought to be a more achievable route to conformity, through the requirement of an individualised risk assessment as opposed to the relevant conformity marking. However, as confidence in the technology increases, and wider testing, such as skin biocompatibility and toxicity testing, is demonstrated as successful, the potential for generically classified devices is expected to increase. This thesis for the first time has investigated the viability of using fused filament fabrication technology to manufacture Class I medical devices, through the identification of the fundamental requirements of the technique within specialist, non-specialist and research medical device manufacturing contexts.

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Appendices

1. Product design specification: Chapter three

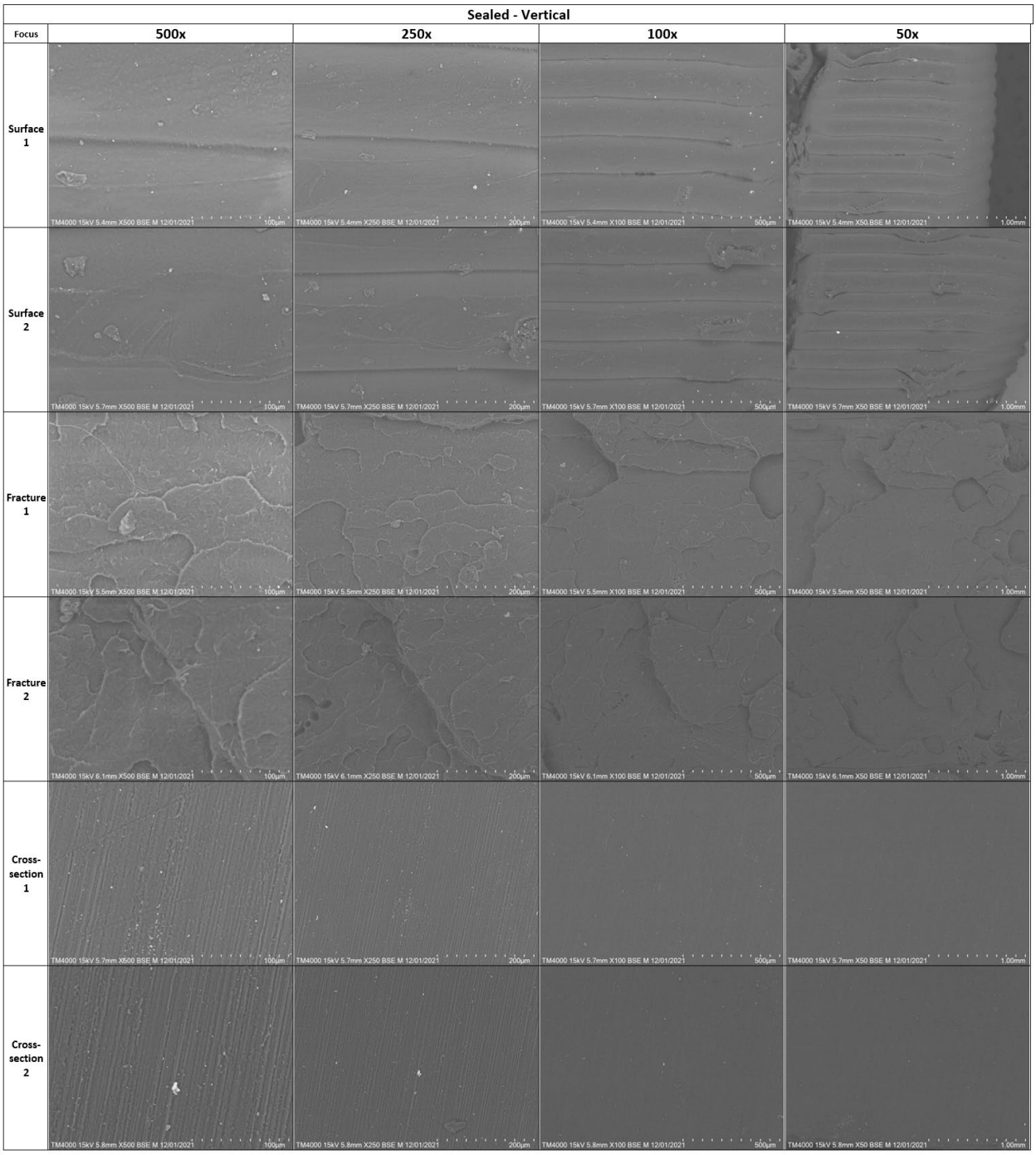
Overview		
A 3D printed customised crutch handle grip intended to fit a regular elbow for sufferers of arthritis. It should be fully 3D printed using professional FFF technology and should not require any professional finishing or post-processing at this stage. The product will be assessed upon standard non-specialist 3D printing post-processing methods. The crutch handle grip should be manufactured from a soft material that would be comfortable to hold, grip and apply pressure to. It should therefore have no sharp edges or design features or textures that could cause discomfort to the user. The device must be manufacturable with professional range FFF technology and should be designed and manufactured using low to mid-range affordable filament (costing no more than £50) that is commercially available. The manufacturing process will take an experimental form, and The device's performance will be assessed against the functional requirements of the manufacturing method, with minimal emphasis on the medical functionality of the device or its ability to meet the clinical needs of a user.		
General	Quantity	A single device should be produced as a proof-of-concept (POC).
	Size and weight	The size should be relative to a standard elbow grip. The device should take a snug fit atop the crutch handle. Weight should be minimised through reducing the density of the part where possible to reduce costs and maintain accessibility of the process and technique.
	Aesthetics	The part should be organic in form, aesthetically pleasing and where possible not resemble a clinical

		medical device. For POC no specific colour or aesthetic considerations are required.
	Ergonomics	The part should have a smooth and organic surface that is comfortable to grip and apply pressure to.
	Safety	The part should have no sharp surfaces or ages and should be fitted securely atop the crutch handle to prevent slippage and injury.
	Cost consideration	The part should be produced as cheaply as possible to demonstrate the use of the technology to produce low cost and accessible devices. Filament and consumables should be low to mid-range costing less than £50, ensuring the device can be produced for under £30 which is considered a cost-effective solution.
Design process	Data collection	Hand grip data should be collected through providing an impression in a malleable material through dynamic movement of using a crutch. Collecting data from a static grip may not represent the hand grip of the user when the crutch is in use.
	User considerations	Data should be collected in a way which is safe and familiar for the user. Digital or complex data collection methods may not be appropriate and cause confusion; therefore, data collection methods should be as simplistic and user friendly as possible.
	Accessibility	Equipment required for data collection should be available to each intended user to ensure accessibility and avoid exclusion through inaccessibility.
Manufacturing process	Manufacturing skill level	To represent a non-specialist scenario, parts should be produced by an operator who is familiar with digital data acquisition, CAD and slicing software. However, to provide a representative insight, the operator should not be a 3D scanning or CAD specialist.
	Hardware	An Ultimaker S5 unit limited to use with pro bundle accessories only.

	Software	Due to the experimental nature of this project, specific software packages have not been defined. Appropriate software should be used for the collection and manipulation of mesh scan data, followed by mesh manipulation and slicing.
	Materials	The device must be made from a soft material that can absorb impact and feel comfortable under the hand when pressure is applied. Variable density material should be used where possible to provide further control over the properties of the device.
	Digital file	The digital file may be formed of any type of mesh during the design/development phase. Upon completion, the file should be prepared for slicing by converting it into a high resolution STL file format.
	Slicing	CURA software must be used for part slicing, and the print file must be in G-CODE format.
	Printing parameters	As an experimental POC, the manufacturing parameters will be tested and defined as part of the manufacturing process. They should be configured to promote fast printing and a quality surface finish where possible.
	Number of process steps	The number of process steps is undetermined at this stage, however to minimise time and cost, the number of process steps should be limited to those that are necessary for the design and fabrication of the device.
	Post-processing	Post-processing can include general clean-up of the part including the removal of support material and shaving of surface imperfections. Post-processing tools should include typical professional FFF tools such as a scalpel and snips.
Evaluation	Surface review	The materiality and printed surface of the device should be reviewed against the safety requirements considerations detailed.

	Physical testing	The part should fit atop an elbow crutch handle and should remain in place when dynamic pressure is applied through use. Physical testing should be scored against the fit of the device to the crutch. The medical performance and functionality to ease symptoms fall outside of the scope of this study and should not be evaluated.
	Observational review	Printing defects and major quality issues should be identified through observing the part.
	Manufacturing review	The product should be reviewed by the ease of manufacturing process, the issues that arose during the process and any other limitations resulting from the manufacturing process
	Cost/viability assessment	The proposed workflow should be compared against the requirements for a minimal viable product considering consumable costs, manufacturing costs and machine depreciation.

2. SEM images: Chapter five



Sealed - Horizontal				
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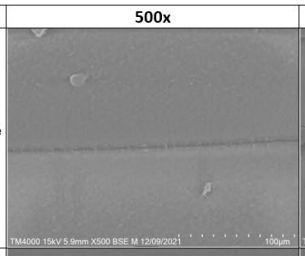
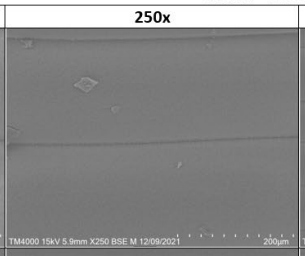
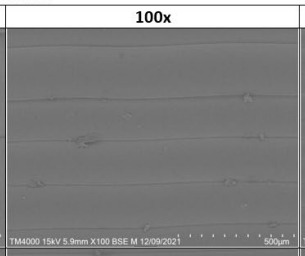
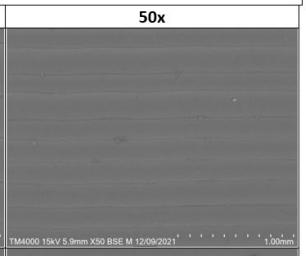
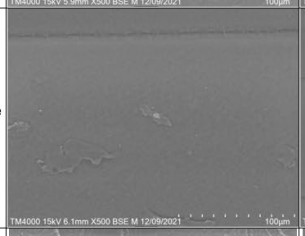
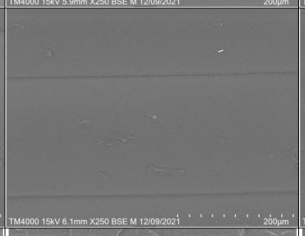
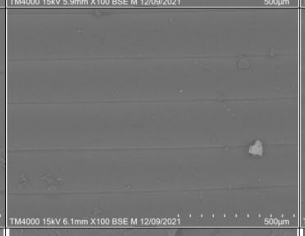
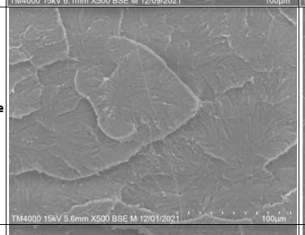
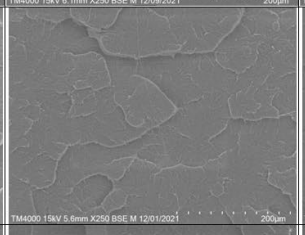
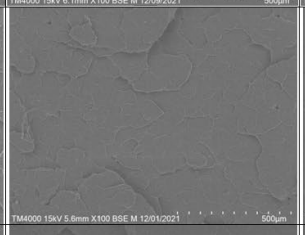
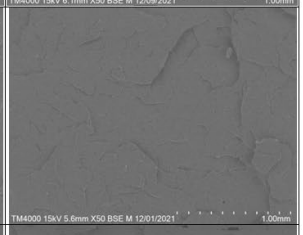
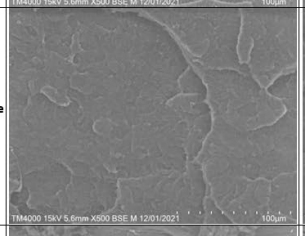
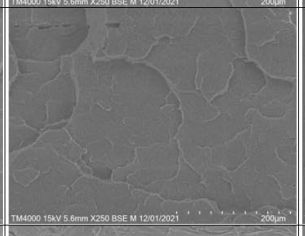
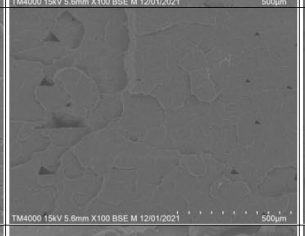
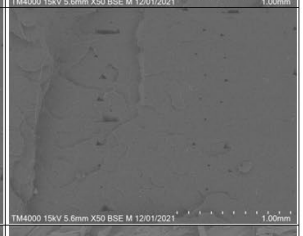
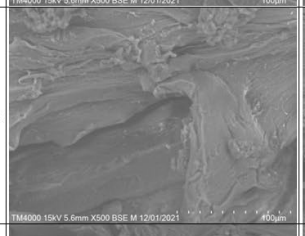
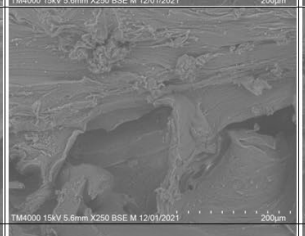
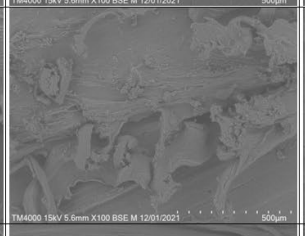
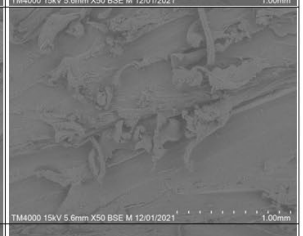
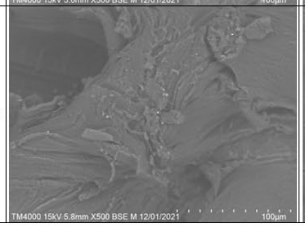
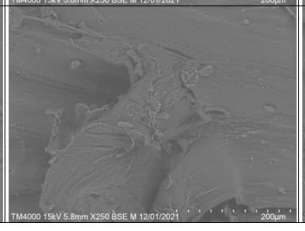
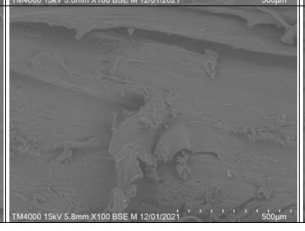
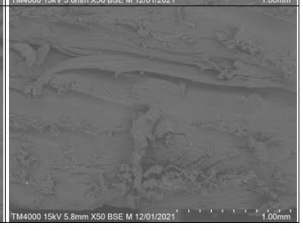
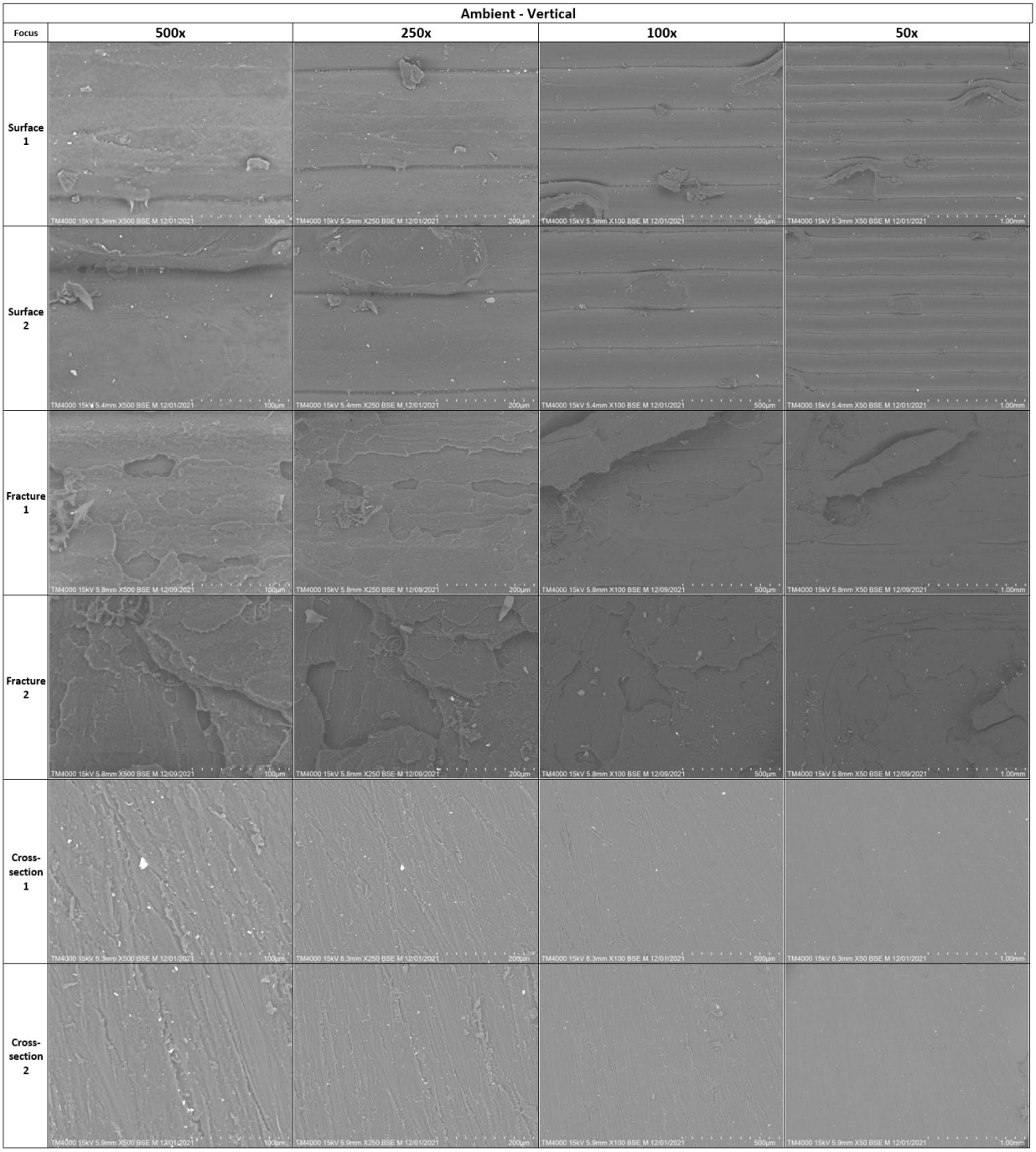
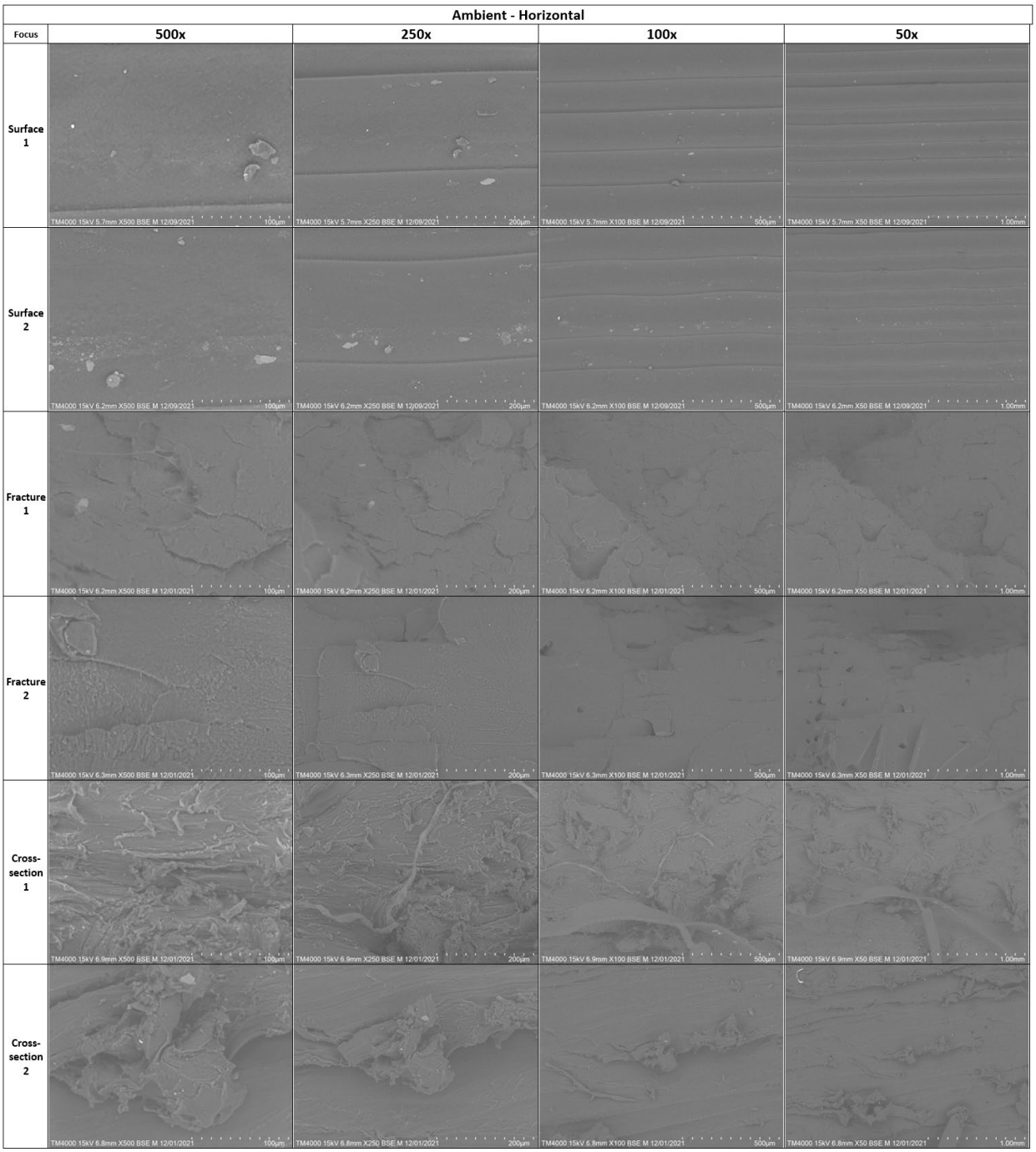
Surface 1				
Surface 2				
Fracture 1				
Fracture 2				
Cross-section 1				
Cross-section 2				


Ambient - Vertical
Focus
500x
250x
100x
50x
Surface 1
Surface 2
Fracture 1
Fracture 2
Cross-section 1
Cross-section 2


Ambient - Horizontal
Focus
500x
250x
100x
50x
Surface 1
Surface 2
Fracture 1
Fracture 2
Cross-section 1
Cross-section 2

Submerged - Vertical				
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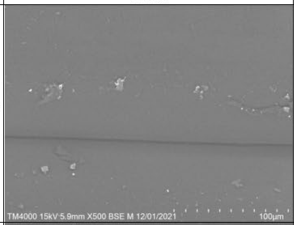
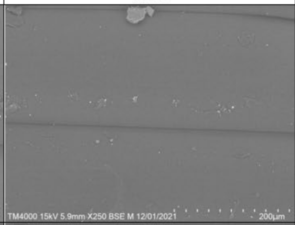
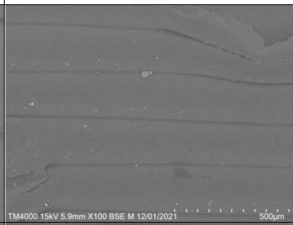
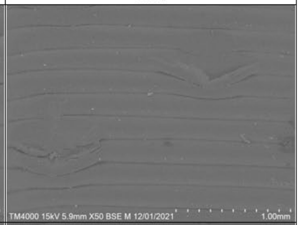
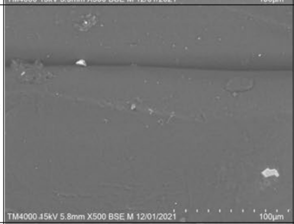
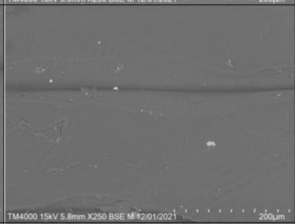
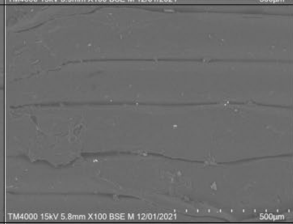
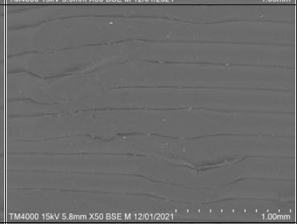
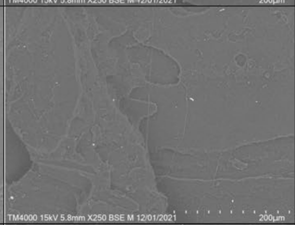
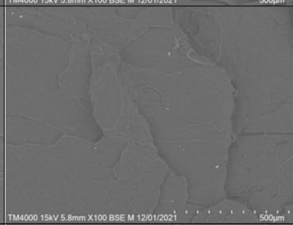
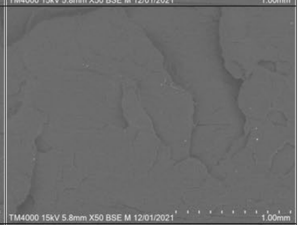
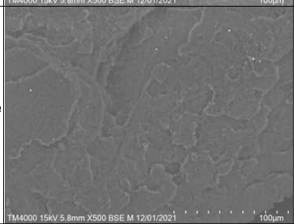
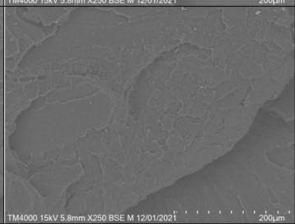
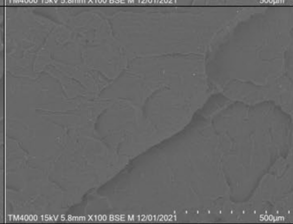
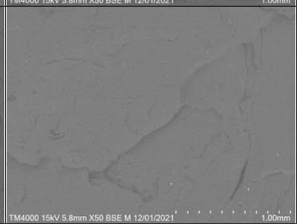
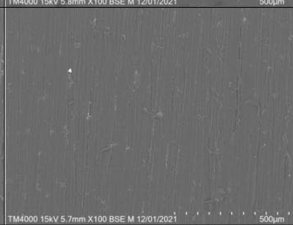
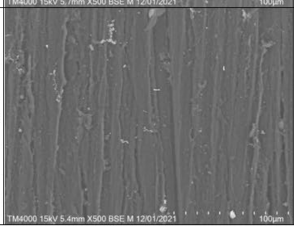
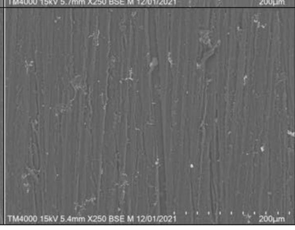
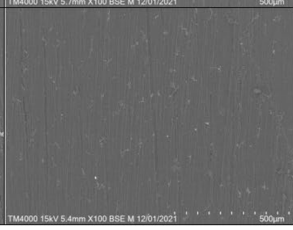
Surface 1				
Surface 2				
Fracture 1				
Fracture 2				
Cross-section 1				
Cross-section 2				

Submerged - Horizontal				
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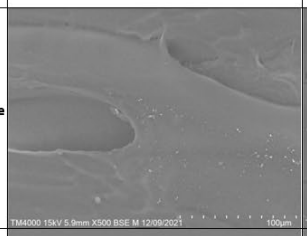
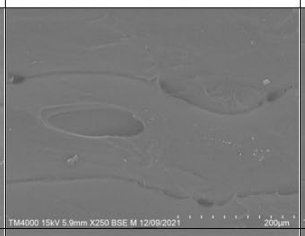
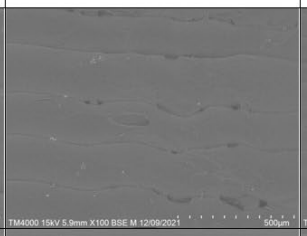
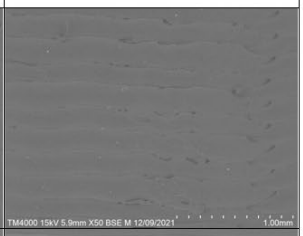
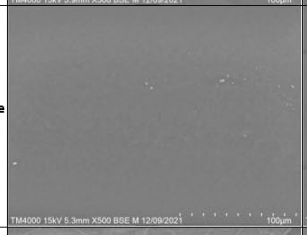
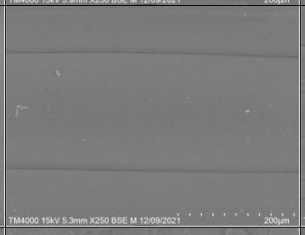
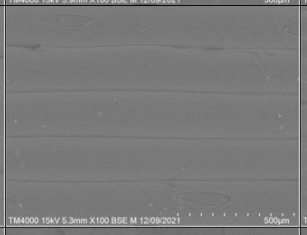
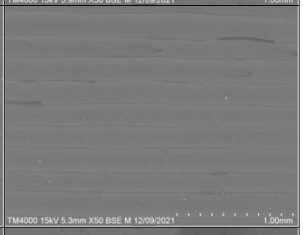
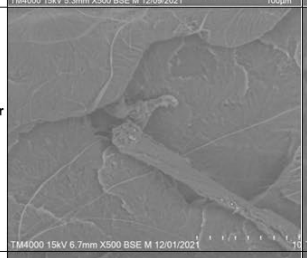
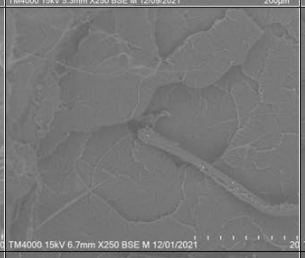
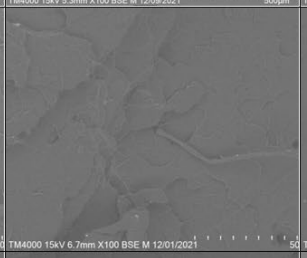
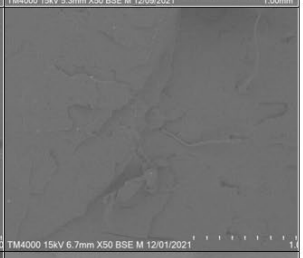
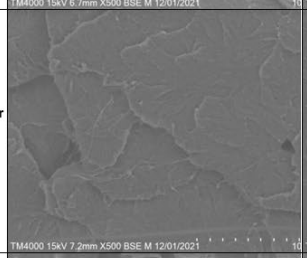
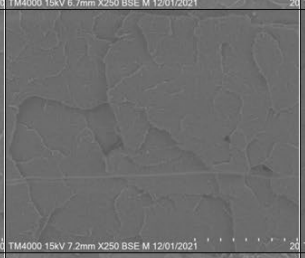
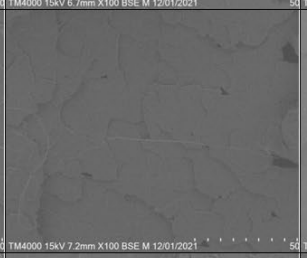
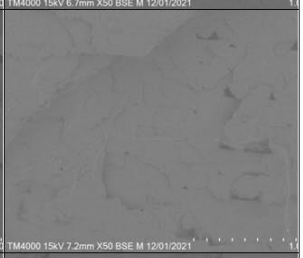
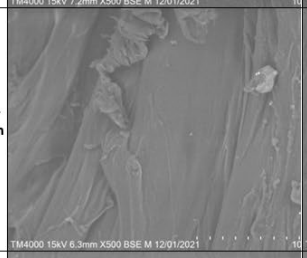
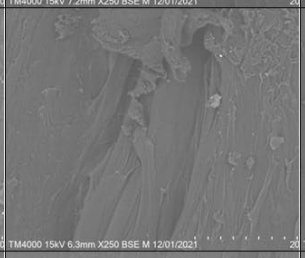
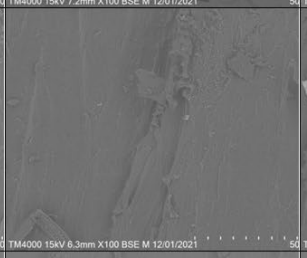
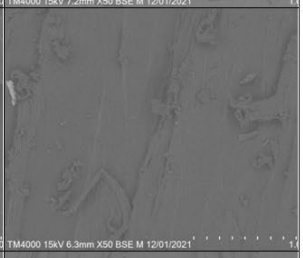
Surface 1				
Surface 2				
Fracture 1				
Fracture 2				
Cross-section 1				
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