AN INVESTIGATION INTO THE OCCURRENCE AND EFFECTS OF SPORTS INDUCED MAXILLOFACIAL INJURIES: MOUTHGUARDS AS PROTECTIVE MODALITIES.

TIMOTHY ALAN BILL FARRINGTON

A thesis submitted in partial fulfilment of the requirements of the Manchester Metropolitan University for the degree of Doctor of Philosophy.

Institute for Performance Research

Department of Exercise and Sport Science

the Manchester Metropolitan University

January 2015

Abstract.

In England and Wales, up to 1.4 million people attend emergency departments, each year, with head injuries. A number of these derive from sporting activities, which have an inherent risk of facial injury from traumatic impacts against fellow competitors, projectiles, posts or the ground. Monitoring the incidence and aetiology of sports injuries can enhance the understanding of head injuries, and the development of more effective protective modalities. This thesis starts with a questionnaire survey, which systematically describes the interplay between the types of sport, the sex of the players, the anatomical site, and the regularity of incidence of fractures. Alongside, the contribution of protective devices in common usage and the technology behind the materials used. A question often arises how thick should a mouthguard be for an individual. Through a series of manufacturing assessments, this thesis investigates the finished mouthguard thickness from a large sample group of experienced participants in relation to manufacturing thickness. Subsequently, this thesis proposes a new mouthguard manufacturing technique, whereby it was found that increasing the anterior angulation of the dental model by varying degrees (15°, 30° & 45°) produces a redistribution of thinning patterns of the 4 mm EVA mouthguard material and increases thickness. By rotating the anterior section of the dental model by 45°, there was a 75% increase in anterior thickness, from a mean of 1.6mm (SD: 0.34), with the model on a flat plane, to 2.8mm (SD: 0.16), with the model held at a 45° angle. Finally, this thesis explores how bone density either by ageing or individuality may affect the impact performance of the mouthguard from the values obtained from both studies. Thus, highlighting the question does the mouthguard need to be more bespoke for the individual in terms of bone density as well as what sport they play.

Declaration.

I declare that whilst registered as a candidate for the University's research degree, i have undertaken a programme of supporting studies in accordance with the Institutional Practice and Research Degree Regulations. I declare that no material contained in this thesis has been used in any other submission for another award. I declare that i have maintained professional integrity during all aspects of my research degree and have complied with the Instututional Code of Practice and Research Degree Regulations.

Timothy Alan Bill Farrington.

Publications derived from this thesis.

FARRINGTON, T., ONAMBELE-PEARSON, G,, TAYLOR, R. L,, EARL, P. & WINWOOD, K. 2012. A review of facial protective equipment use in sport and the impact on injury incidence. British Journal of Oral and Maxillofacial Surgery, 50, 233-8. (Appendix A).

FARRINGTON, T., ONAMBELE-PEARSON, G,, TAYLOR, R. L,, EARL, P. COWARD, T & WINWOOD, K. 2014. An investigation into the relationship between thickness variations and manufacturing techniques of mouthguards. Accepted for publication in the Journal of Dental Traumatology. (Appendix B).

FARRINGTON, T., ONAMBELE-PEARSON, G,, TAYLOR, R. L., EARL, P. COWARD, T & WINWOOD, K. 2014. The effect of model inclination during fabrication on mouthguard calliper-measured and CT-scan assessed thickness. Under review in the Journal of Dental Traumatology awaiting outcome from referees. (Appendix C).

Acknowledgements

Firstly and most importantly, my sincerest gratitude goes to Dr. Keith Winwood for his support, inspiration and encouragement in those dark PhD moments. I couldn't have wished for a better Director of Studies. I would also like to thank Dr. Gladys Onambele-Pearson (my statistics Guru), Dr. Rebecca Taylor and Mr. Phillip Earl (Consultant Maxillofacial Surgeon, Worcester Royal Hospital) for all their advice and guidance. I would like to thank all the Maxillofacial Consultants who took part in the questionnaire study, for their participation identifying and facilitating the collection of data used in Chapter 2 of this thesis. I would like to thank both Dr. Trevor Coward, Reader in Maxillofacial and Craniofacial Rehabilitation, Kings College, London, and Dr. Zioupos, Reader in Biomechanics of Materials, Cranfield Forensic Institute, for the use of their facilities and fountain of knowledge and being an inspiration for the future. I would also like to thank Robin Hill for his support.

On a personal note, to my Dad, thank you for giving me the work ethic that has driven me on. Finally, my two beautiful children, Xavier and Jasmine to whom I now give my free time in lieu of their patience, and hope this in some way encourages them to push their own limits xx.

I Am A Lucky Man ! ! ! !

List of Contents

Abstract……………………………………………………………………...ii

Declaration…………………………………………………………………iv

Publications derived from this thesis v

Acknowledgements.. ………………………………………………………vi

List of Contents……………………………………………………………vii

List of Figures……………………………………………………………...xii

List of Tables……………………………………………………………...xvii

Glossary……………………………………………………………………xix

Chapter 1 : A review of facial protective equipment use in sport and the impact on injury incidence.. 1

1.1 Introduction 1

1.1.1 Facial protective equipment within sports 8

1.1.2 Helmets/Headgear. 11

1.1.3 Mouthguards.. 15

1.2 Conclusion.. 20

Chapter 2: An investigation into the occurrence and effects of Maxillofacial injury due to sport 22

2.1 Introduction 22

2.2 Methodology 24

1.2.1 Questionnaire 26

2.3 Results 27

2.3.1 Clinical Information: (Questions 1-4) 28

2.3.2 Patient and Incidence: (Questions 5-12) 30

2.3.3 Lifestyle and Medical History: (Questions 13 - 20)........... 32

2.4 Discussion 33

2.4.1 Aetiology of fracture (Question 9) 36

2.4.2 Gender and Age (Questions 5 & 6) 37

2.4.3 Anatomical site of fracture (Questions 2&3) 38

2.4.4 Rehabilitation period (Question 4) 39

2.4.5 Protective modality (Question 12) 39

2.4.6 Supplementary questions (Questions 13 to 20).................. 40

2.5 Conclusion 43

Chapter 3: An investigation into the relationship between thickness variations and manufacturing techniques of mouthguards 45

3.1 Introduction 45

3.2 Materials & Method 52

3.2.1 Model selection 52

3.2.2 Model accuracy by CT Scan 55

3.2.3 Model accuracy 59

3.2.4 Possible reasons for distortion... 59

3.2.5 Fabrication of Mouthguards 60

3.2.6 Measurements of the processed mouthguards..................... 61

3.2.7 CT scanned measurements of mouthguards 63

3.2.8 CT scanned comparison of two surfaces of the finished mouthguards……………………………………………..65

3.3 Statistical analysis ………………………………………67

3.4 Results 68

3.4.1 Questionnaire Results.. 68

3.4.2 Comparison of measurement techniques, CT scan against calliper results……………………………..…………..75

3.4.3 CT scanned images of both the thickest and thinnest mouthguard…………………………………………………77

3.5 Discussion 81

3.5.1 Factors that may affect mouthguard material thinning 86

3.6 Conclusion.. 89

Chapter 4: An Investigation into the Degree of Model Inclination on Custom Made Mouthguard Thickness 91

4.1 Introduction. ………………………………………………91

4.2 Materials & Method 96

4.2.1 Fabrication of Angle Blocks... 97

4.2.2 Dimensional Measurements 100

4.2.3 CT Scans . …………………………………………….…101

4.3 Statistical Analysis .. ………………………………………..102

4.4 Results 103

4.4.1 Gross measurements 103

4.4.2 CT scans of mouthguards 108

4.5 Discussion 110

4.5.1 Influence of the Degree of Inclination on Thickness 112

4.6 Conclusion 117

Chapter 5: An investigation into the mouthguard performance in relation to an ageing bone model 119

5.1 Introduction 119

5.1.1 Testing Modalities 121

5.1.1.1 Artificial skull and jaw model 130

5.1.1.2 Bone Tissue 131

5.2 Materials & Method 135

5.2.1 Bone Sample Preparation 135

5.2.2 Artificial Ageing of the Bone Samples 136

5.2.3 Mouthguard Sample Preperation 139

5.2.4 Custom Designed Testing Bath 141

5.2.5 Experimental setup 142

5.3 Statistical Analysis 149

5.4 Results 150

5.4.1 Bone model 150

5.4.2 Varied levels of Mouthguard Protection 153

5.5 Discussion 167

5.5.1 Testing methodology design considerations 171

5.5.2 Bone model 172

5.5.3 Ageing of the samples 174

5.6 Conclusion.. 178

Chapter 6 : General Discussion and Conclusion 180

6.1 Study One (Chapter 2): An investigation into the occurrence and effects of Maxillofacial injury due to sport....................................... 181

6.2 Study Two (Chapter 3): An investigation into manufacturing thickness variations of mouthguards. ……………………………………188

6.3 Study Three (Chapter 4): Proposed model inclination technique…………………………………………………………...…….192

6.4 Study Four (Chapter 5): Mouthguard thickness levels in an older bone tissue model …………………………………………………196

6.5 Overall conclusion…………….......................................202

References……………………………………………………………..205

Appendix…………………………………………………………………238

List of Figures

Figure 2-1: Percentage of fractures at each anatomical site........................ 28

Figure 2-2: Breakdown of the mandible anatomical site in relation to fracture……………………………………………………………………..29

Figure 2-3: Incidence of orofacial fracture by age group 30

Figure 2-4: Breakdown of responses into geographical regions.................. 31

Figure 3-1: Shows the five measurement points used for the model selection……………………………………………………………....53

Figure 3-2: Colour representation of dimensional changes between duplicated models (A-D)……………………………………..……..…...58

Figure 3-3 Markers placed onto the mouthguards (black points: original permanent marker anatomical measurement points, white points: barium markers)…………………………………………………………………64

Figure 3-4 A-C: Three measurement points on the mouthguard with barium marker highlighted (bulge); A = Anterior, B = Occlusal, and C = Posterior lingual………………………………………………………………....65

Figure 3-5: Degree of variation in the manufacture of the finished mouthguard thickness between all 5 sample mouthguards within the group, using a Coefficients of Variation (site A = Anterior, site B = Occlusal & site C = Posterior Lingual)... 69

Figure 3-6: Mean finished thickness (mm) of mouthguards, with error bars denoting standard deviation, in the labial anterior sulcus (Site A)………73

Figure 3-7: Mean finished thickness (mm) of mouthguards, with error bars denoting standard deviation, at the occlusal anterior lingual cusp of the first upper right molar (Site B) 74

Figure 3-8: Mean finished thickness (mm) of mouthguards, with error bars denoting standard deviation, at the lingual sulcus (Site C)......................... 74

Figure 3-9: A calibration chart showing the measurement discrepancies between the measurement techniques used, CT scan and digital gauge…...77

Figure 3-10 A-E: CT scanned images of the two surface areas within the five thinnest mouthguards 79

Figure 3-11 A-E: CT scanned images of the two surface areas within the five thickest mouthguards 80

Figure 4-1: The gradient angulation blocks (15°, 30°, & 45°) used to incline the anterior section of each of the dental models 97

Figure 4-2: Dental model flat on the "cone plate" prior to forming (A). Images B-D show the dental model held at a 15°, 30° & 45° angles, respectively, in the "F insert" using the modified plate and angle blocks with 10mm gap between incisai tip and plate 98

Figure 4-3: Comparison of the finished anterior thickness of the mouthguards after varying anterior model inclinations…………………..104

Figure 4-4: Comparison of the finished occlusal thickness of the mouthguards after varying anterior model inclinations…………………..105

Figure 4-5: Comparison of the finished posterior-lingual thickness of the mouthguards after varying anterior model inclinations……………………107
Figure 4-6: CT scan of the finished mouthguard formed flat on the forming platform (A), positioned at angles of 15° (B), 30° (C), and 45° (D) ..... …109
Figure 5-1: Schematic of a drop-weight tower setup as used by Kennedy et al (2006) in eye impact validation tests 125
Figure 5-2: Schematic of a proposed pneumatic impactor setup, as used by Kennedy et al (2006) in eye impact validation tests 127
Figure 5-3: Schematic representation of a pendulum device for the impact testing mouthguard material... 127
Figure 5-4: Structure of the mandible, (a) cortical bone on the outer surface and (b) trabecular internally, (Image obtained from Isen, 2009) 133
Figure 5-5: Polycarbonate template used to mark the position of the holes (A & B) on the aged bone specimens……………………………………..…137
Figure 5-6: Schematic diagram of the experimental testing bath set-up used to impact test the bone samples with and without mouthguard protection…………………………………………………………………142
Figure 5-7: Servo-hydraulic Dartec® series HC10 testing machine with custom designed testing bath……………………………….................143
Figure 5-8: Steel impactor tip and dimensions (mm)................................ 144
Figure 5-9: Custom designed testing bath with bone sample held into position………………………………………………………………...145

Figure 5-10: Illustrates the loading principal employed in the current study design……………………………………………………………………..145
Figure 5-11 : Shows the build-up of speed and the motion of the tip against time to demonstrate how impact was achieved (stroke vs time)…………147
Figure 5-12: Profile of the force applied on a sample versus time 148
Figure 5-13: Bone strength of both the unprotected young and artificially aged/lower bone mineral density bone 151
Figure 5-14: The ultimate impact force prior to fracture of all groups and for both bone tissue models (young and old)………………………………...155
Figure 5-15: Traces of force versus time to fracture for the three protection levels. Sample data recording during tests using, none, 1.6mm MG and 2.8mm MG, in the young bone model……………………………………156
Figure 5-16: Traces of force versus time to fracture for the three protection levels in the 'aged' bone samples. Sample data recording during tests using, none, 1,6mm MG and 2.8mm MG, in the old bone model…………………………………………..……………………157
Figure 5-17: Traces of force versus time to fracture for the three protection levels and for both 'young' and 'old' overlapped. Sample data recording during tests using none, 1.6mm MG and 2.8mm MG, in both the young and old bone models…………………………………………………………..158
Figure 5-18: The correlation between BMD of the young and old bone model against the force required to break each sample……………………………………………………………….....159

Figure 5-19: The impact energy absorption of the grouping model when analysed with the mouthguard and bone model are combined .... .161

Figure 5-20: The impact material displacement of the grouping model when analysed with the mouthguard and bone model……………...…………...162

Figure 5-21: The impact stiffness of the grouping model when analysed with the mouthguard and bone model…………………..……………………165

List of Tables

Table 1-1: Incidence and type of facial sports injuries from the published literature……………………………………………………………….3
Table 1-2: The incidence risk level of orofacial injuries within sport 7
Table 1-3: Protective devices of the head and face in sports for adults in the United Kingdom. Regulations set through sports' governing bodies……….9
Table 1-4: Property values for materials used for mouthguards from past to present……………………………………………………………...17
Table 2-1 : Clinicians suggested rehabilitation time post fracture............... 29
Table 2-2: Type of sport played when injury occurred 32
Table 3-1: Maxillary arch width measurements used in the present study...54
Table 3-2: Anatomical measurement reference points (Points A-C)............ 62
Table 3-3: Number of years' experience of each participant........................ 68
Table 3-4: Statistical differences between technicians at each anatomical site with Bonferroni corrections 72
Table 3-5: Comparison between the two measurement techniques (callipers and CT scan) of the five thickest and thinnest mouthguards 76
Table 4-1: Descriptions of anatomical measurement reference points (Points A-C)…………………………………………………………….....100

Table 4-2: Mean thickness of the formed mouthguards at each anatomical site. Site A: Anterior sulcus thickness, Site B: Occlusal thickness, Site C: Posterior lingual thickness.. 103

Table 5-1 : Previous impact testing studies testing methodologies 128

Table 5-2: Post hoc pairwise Mann Whitneys of bone model with varying levels of mouthguard protection and displacement…..……………………164

Table 5-3: Post hoc pairwise Mann Whitneys of the bone model with varying degrees of mouthguard protection and stiffness…….….……...166

Table 5-4: Summary table showing examples of orofacial research animal models……………………………………………………………….173

Glossary

The following terminology relates to this thesis:

Anterior: Describing a location towards the front of the oral cavity or infront.

Buccal: Relates to the surface of the dental arch situated close to or facing the cheek.

Distal: Furthest away from the midline of the dental arch or jaw.

EVA: Ethylene Vinyl Acetate

GDC: General Dental Council

Gingiva: a strong protective cuff of connective tissue and overlying keratinized mucosa the surrounds the neck of the teeth.

Labial: defined as situated close to or facing the lips.

Labial Flange (of the mouthguard): the part of the mouthguard that is positioned between the lips and the anterior dentition, extending into the labial sulcus.

Lingual: defined as situated close to or facing the tongue.

Mandible: Lower jaw bone.

Maxilla: Upper jaw.

Mesial: Near the midline of the dental arch or jaw.

Occlussal: Relating to the grinding surfaces of the premolar and molar dentition.

Orbicularis oris: The sphincter muscle encircles the mouth, forming part of the lips.

Orofacial: The facial and oral regions.

Posterior: Describing a location towards the back of the oral cavity or behind.

Sulcus: A deep pocket that forms between the mucous membranes of the maxillary and mandibular arches where it meets the lips and cheeks.

Zygoma (Zygomatic arch): Commonly known as the cheek bone, formed by the union of the zygomatic process of the temporal bone and temporal process of the zygomatic bone.

CHAPTER 1: A REVIEW OF FACIAL PROTECTIVE EQUIPMENT USE IN SPORT AND THE IMPACT ON INJURY INCIDENCE.

1.1 Introduction

Facial injuries can be both physically and emotionally disfiguring for the individual. Gassner et al, (2003) identified five main causes of facial injury; these were work related, traffic, assault, sport, and incidences due to daily activities. The severity of traumatic facial injury has been shown to affect the return time back to work which will also be the case for sport (Girotto et al., 2001). This may be due to the fact that facial injuries are associated with injury-related disability including visual impairment, alteration to smell, dysfunction in mastication, respiratory problems, and psychological problems, particularly if reconstructive surgery is required (Girotto et al., 2001, Glynn et al., 2003, De Sousa, 2008, Glendor, 2009). The most common associated facial fracture sites are the mid and lower two thirds of the skull, more specifically the nose, zygoma, and mandible (Table 1.1). In general, sports injuries tend to be associated with impact forces against the ground, equipment, or a fellow participant (Maladiere et al., 2001, Gassner et al., 2003, Mourouzis and Koumoura, 2005). Therefore, the development of preventative protective measures to reduce this occurrence is of utmost importance.

There is a scarcity of studies on the recorded occurrence rates of facial injuries in sport, particularly annually or nationally in the United Kingdom (Hill et al., 1998, Hutchison et al., 1998). A one-week study by the British Association of Oral and Maxillofacial Surgeons (BAOMS) on the incidence and aetiology of facial trauma in association with alcohol consumption also recorded sporting activities. Whilst their findings showed that 21% of the recorded injuries resulted from sporting activities, the manuscript did not discriminate fully between the types of injuries (Hutchison et al., 1998). Walker et al, (2012a) carried out a one week multicentre prospective study in the West of Ireland, observing facial injuries presenting at emergency departments. Their results showed, of the 325 recorded patients, 8.9% sustained fractures due to sports, of these 79% were male. The 15-24 yrs age group had the highest rate of fractures caused by sports. There is a breadth of research from other countries pertaining to sporting facial injuries (Table 1.1).

Reference	Sex (male:female)	Site of injury	Incidence (%)	Major sports responsible for fractures	Incidence (%)	Country of origin
Exadaktylos *et al*, 2004.	6.5:1	Zygoma	30%	Skiing	25.6%	**Switzerland**
		Mandible	25.5%	Cycling	21.1%	
		Orbit	20%	Soccer	13.3%	
		Nasal	14%	Ice Hockey	8.9%	
		Other		Mountain climbing	6.7%	
				Other		
Chao *et al*, 2008.	Not specified	Nasal	50%	Basketball		**USA**
		Zygoma	10%	American football	1.4%	
		Mandible	10%			
		Other				
Tanaka *et al*, 1996.	5.5:1	Mandible	60.2%	Rugby	23%	**Japan** (Tokyo)
		Alveolar	22.4%	Skiing	23%	
		Maxilla	6.1%	Basketball	13%	
		Other		Soccer	11%	
				Other		
Gassner *et al*, 2003.	2.1:1	Midface	71.5%	Skiing	31.8%	**Austria**
		Mandible	24.3%	Cycling	23.6%	
		Supraorbital and Frontobasal	4.2%	Soccer	8.6%	
		Other	*	Other		
Mourouzis *et al*, 2005.	9:1	Mandible	45.9%	Soccer	64%	**Greece**
		Zygoma	35.1%	Basketball	13.6%	
		Alveolar	9.4%	Tae Kwon Do	4.8%	
		Other		Skiing	3.2%	
				Other		

Delilbasi *et al*, 2004.	19:1	Mandible Midface Alveolar Other	56% 31% 12%	Baseball Rugby Soccer Other	44% 28% 18%	**Japan** (Osaka)
Bataineh, 1998.	3:1	Mandible Maxilla Zygoma Alveolar Other	74.4% 13.5% 10.7% 1.4% *	***		**Jordan**
Maladiere *et al*, 2001.	7.2:1	Mandible Zygoma Nasal Other	34.4% 23.4% 15.6%	Soccer Rugby Mountain biking In-line skating Other	25% 15% 10% 8.6%	**France**
Hill *et al*, 1998.	8.2:1	**	**	Rugby Cycling Soccer	26% 23.9% 13.7%	**UK**
Walker et al, 2012b.	4:1	Nasal Maxilla Zygoma Mandible	50% 1.2% 11.8% 25% *	Gaelic Football Hurling or Camogie	45% 34%	**West Ireland**
Elhammali et al, 2010.	3.9:1	**	**	Soccer Handball Horse riding Inline-skating	59.2% 8.2% 6.8% 6.8%	**Germany**

* Percentages were for all causes of fracture such as traffic, domestic violence, and sport.
** The data recorded on anatomical sites of fracture were not recorded in a compatible format i.e. Upper third, mid-third and lower third.
*** The type of sport was not recorded as part of their study.

Table 1-1: Incidence and type of facial sports injuries from the published literature.

It has also been suggested that the rise in sports injuries may be attributed to an overall increase in participation in sports and leisure activities (Hutchison et al., 1998, Mourouzis and Koumoura, 2005). Many of the previous studies examining maxillofacial injuries generally focus on one specific sport e.g. rugby or squash (Chapman, 1985, Sane et al., 1988, Gassner et al., 1999a, Gassner et al., 1999b, Eime and Finch, 2002, Capao Filipe, 2004, McIntosh et al., 2008, Papakosta et al., 2008) and these generally are at regional/national level. Larger clinical based studies tend to be either retrospective (Mourouzis and Koumoura, 2005), over a short period of time (Hutchison et al., 1998, Walker et al., 2012a), or from one geographic site (Hill et al., 1998, Maladiere et al., 2001). These do not give a holistic overview of the incidence and aetiology of facial injuries at all levels of sport.

When comparing results from different countries, care should be taken to consider differences such as geographical factors, socioeconomic attitudes to physical activity, and the political environment, including local rules or regulations (Williams et al., 1997, Motamedi, 2003). Geographic differences in sporting injuries can be observed in most studies; with specific countries having more injuries in certain sports due to the popularity of the sport in that country. For example, skiing is popular in Switzerland however it is a major contributor to sports injuries accounting for 25% of total incidents (Exadaktylos et al., 2004), whereas football and rugby are popular sports in Britain (accounting of 13.7% and 26% of sporting injuries, respectively (Hill et al., 1998), and baseball is most popular in Japan, accounting for 44% of injuries (Delilbasi et al., 2004) (Table 1.1).

American Football illustrates effectively how such differences are linked to type, level or quality of protective wear, in addition to regulatory rules, and attitudes to wearing the protective headwear (Exadaktylos et al., 2004). Eime and Finch, (2002) reported that the reason for not using protective headgear in squash, in the form of goggles, was the lack of knowledge of the risk of injury. The ratio of incidence of injuries between sexes are also shown in Table 1.1. Male participants are typically at greater risk of injury, as a relatively greater number participate in ball sports (Delilbasi et al., 2004). They in generally have higher body mass, and their masculinity compels them to apply high levels of force against their fellow players or opponents (Smith, 1974, Messner, 1990, Delilbasi et al., 2004). Football (Soccer) has consistently been shown to be a major contributing sport where facial fractures or other injuries occur, followed closely by rugby (Maladiere et al., 2001) which are predominately a male dominated sport worldwide. The British Standards Institute deem sports such as rugby, football, American football, field hockey, ice hockey, skating, ski jumping and martial arts, as “high risk” sports when considering the incidence of orofacial injuries, whereas basketball, cycling, horse riding, gymnastics, and squash are considered to be medium risk (British Standards Institution., 2007), as shown in Table 1.2.

High risk	Medium risk
Rugby	Basketball
Association football	Cycling
American football	Horse riding
Field hockey	Gymnastics
Ice hockey	Squash
Skating	Diving
Ski jumping	Parachuting
Martial arts	Water polo
Lacrosse	
Boxing	

(American Dental Association, 2006, British Standards Institution., 2007).

Table 1-2: The incidence risk level of orofacial injuries within sport.

Many injuries in sport, whether body or facial are often not reported (Birrer and Birrer, 1983, Kujala et al., 1995). Birrer and Birrer, (1983) from a study survey over three training sessions in a two week tournament period reported a figure as high as 63% of injuries in martial arts go unreported. They suggest this may be due to the fact that athletes are reluctant to report injuries for fear of instructors'/coaches' perception, forgetting minor injuries, becoming tolerant to pain, and denial of their own vulnerability and severity of the injury. However, simple relatively easily obtainable protective equipment, such as helmets, goggles and mouthguards can be used to reduce the risk of orofacial injury occurrence. From a socioeconomic perspective, Williams et al, (1997) examined socioeconomic status and risk of injuries, they observed that families from more affluent areas had a greater appreciation of protective equipment used in sport, e.g. the use of helmets in bike riding.

1.1.1 Facial protective equipment within sports.

Facial protective equipment is designed to reduce the risk of potential injury; however it is still not a fully preventative measure. The equipment can be in the form of protective headgear (e.g. scrum caps), mouthguards (boil and bite, stock and custom made), helmets (hard and soft), protective goggles/glasses, and specialist face masks. The main focus of this chapter will highlight helmet and mouthguard protection within sport.

Sport	**Protective Equipment**	**Governing body**	**Is it mandatory to wear device?**	**Ruling of governing body** (Quote/Comment)
Squash	Eye protection	World Squash Federation (2014).	No	The World Squash Federation recommends players should wear protective eyewear, to an appropriate standard, during play, inclusive of warm-up.
Boxing	Mouthguard	British Boxing Board of Control (2007).	Yes	A Boxer is required to wear throughout the contest a properly fitted mouthguard.
Kick boxing	Mouthguard, Helmet.	International Sport Kickboxing Association UK (2010)	Yes	It is compulsory for competitors to wear a helmet and mouthguard.
Rugby	Mouthguard, Head guards	The Rugby Football Union	No	The RFU strongly recommend that mouthguards are worn for any contact rugby sessions – it is also recommended that such mouthguards should be custom fitted. Mouthguards are compulsory for all school players involved in rugby activities above school level (County, Division and England Representative Squads)
Football	Mouthguard, Protective headgear.	The Football Association.	No	No form of head protection is required by any of the Football governing bodies.

Cricket	Helmets	The England and Wales Cricket Board (2010).	No	The ECB has only issued guidance as to the level of protective headwear, mainly aimed at Juniors i.e. under 18 - young players are not allowed to bat or stand up to the stumps when keeping wicket against a hard ball without wearing appropriate protection (helmet with a faceguard), compliant with British Standard – BS7928:1998.
Hockey	Mouthguard, Protective headgear.	The International Hockey Federation, (2013).	No	Are recommended to wear shin, ankle and mouth protection. Protective headgear incorporating a helmet with fixed full-face protection and cover for the entire head and throat is recommended for goalkeepers and players with goalkeeping privileges.
Cycling	Helmets	British Cycling (2010).	Yes	A rider whilst racing or training in any cycling discipline, with the exception of training on the open road shall wear properly affixed protective headgear which must be of a hard/soft shell construction.
Paintball	Eye protection and Ear defenders and/or Face mask.	United Kingdom Paintball Sports Federation (2009).	Yes	It is a mandatory insurance stipulation that paintball sites in the UK, insist on players wearing goggles, face masks and ear protection.

Table 1-3: Protective devices of the head and face in sports for adults in the United Kingdom. Regulations set through sports' governing bodies. Data obtained through the sports official websites or by personal communication with governing bodies.

Table 1.3 illustrates head/facial protection regulations for some of the most popular sports in the United Kingdom from an adult prospective. However, some sport governing bodies that only recommend the use of protective headwear for adult's state that it is of mandatory usage for junior players (Rugby Football Union., The England and Wales Cricket Board, 2010, World Squash Federation, 2014). Other sports that are also considered to be of medium to high risk of injury, but were not included in the chart, are: horse riding, water polo, parachuting, basketball, gymnastics, ice hockey, diving, ski jumping, skating, fishing and lacrosse (MacEwen, 1987, British Standards Institution., 2007).

1.1.2 Helmets/Headgear.

The use of protective helmets in sport is important to reduce head or facial injuries. This is achieved by the redistribution of load and the attenuation of energy from impact forces (Vetter et al., 1987). It is common to see sports played in the USA with specifically designed protective helmets, which may be in no small part, linked to the culture of litigation (Classe, 1988, Napier et al., 1996). President Theodore Roosevelt threatened to ban American football due to its appalling safety record in 1904, when 19 players were either killed or paralysed. Over a time period of 73 years, at least 1000 deaths can be directly attributed to American football, averaging approximately 13 per year;

over half of these can be attributed to head injuries (Cantu, 1996, Mueller and Colgate, 2011). The earliest versions of helmets in American football were called "head harnesses" and were merely a soft leather cap that fastened under the chin, covering the player's ears. These evolved during the 1930's, using harder leathers and fabric as cushioning for greater protection. In 1939, John T. Riddell Company of Chicago introduced the first plastic football helmet, which proved to be stronger and more durable than the earlier leather helmet. In 1959 the use of protective headwear became mandatory in the USA; prior to this 50% of injuries in American Football involved facial and dental regions (Chao et al., 2008). Presently, the construction of modern helmets consist of polycarbonate plastic/high quality composites and high-tech cushioning systems (Gaffney, 2008). Helmet liners are generally fabricated from Expanded Polystyrene (EPS) foam, which is used for its cushioning properties, this in turn dissipates energy from traumatic impacts, and raises the level of protection (Bicycle Helmet Safety Institute., 2009a). Other materials such as Expanded Polypropylene (EPP) and Expanded Polyurethane (EPU) are being incorporated into the design of some helmets due to their material properties, i.e. rate-sensitive slow rebound foams (Bicycle Helmet Safety Institute., 2009a). The performance of the helmet has been shown to be dependent on the lining material, and the thickness, density, and stiffness of the shell (McIntosh and Janda, 2003). Vetter et al, (1987) used a nonlinear finite element modelling computer system to examine how a helmet's materials and structure can influence the performance of American football helmets. They found that increasing the helmet thickness only marginally increased its impact absorbency. When the shell was increased by 50% from 3.94 mm to 5.92 mm, this only had a 5-10% effect on the absorption of impact energy. Some helmets have been designed to incorporate grates, polycarbonate visor or half shield, which offers protection against violent impact to the player’s nose and mouth. However, these incorporated features must have a minimal impact on functionality, and thermal comfort/regulation and field of vision for the athlete/sports person (McIntosh and Janda, 2003). McIntosh and Janda, (2003) evaluated cricket helmet performance against baseball and ice hockey helmets, and found that at lower impact speeds, all the helmets offered the desired level of head protection. They observed that the cricket helmet reduced the headform acceleration by 80% at speeds of 19 m/s, falling to 40% at 27 m/s (McIntosh and Janda, 2003). However, when the speed of the projectile was increased the risk of head injury increased substantially with impacts greater than 27 m/s. As highlighted in a study, a cricket ball can reach speeds of more than 30–45 m/s at club and elite levels (Stretch et al., 2000). McIntosh and Janda, (2003) referred to a “multiuse” helmet that could be used in most sports to reduce cost, but this could be difficult to implement as each sport has their own unique requirements for protection and use. For example, helmets for cycling and downhill skiing must not only protect the head against violent impact, but must also be aerodynamic to maximise drag resistance (Alam et al., 2008), whereas baseball helmets need to protect against high velocity impacts to the side of the head.

Wilson, (1998) theorised that players who use headgear in contact sports, such as rugby, place themselves and other players at greater risk of injury, because of altered psychological behaviour the use of greater force under the assumption that they are protected. Many helmets in common use protect only the cranium, and not the mid and lower face, with the exception of sports like American football, cricket, and bobsleigh. This could call into question why full-face helmets are not used more often in sports that have high numbers of mid to lower facial fractures for example, road cycling which accounts for as much as 23.9% of injuries in some studies (Table 1.1) (Hill et al., 1998, Gassner et al., 2003, Exadaktylos et al., 2004). Such protection might minimally increase the weight of the helmet but would offer a physical guard against direct impact, so the "pros" far outweigh the "cons" in this instance.

Cycling is one sport where it is becoming more acceptable, even mandatory whilst racing and training (British Cycling., 2010), to use a helmet to protect the head in the event of an accident. However, in some competitions where there have been complaints about the extra weight, the event organisers have allowed participants to remove their helmets for the final hill climb, thus negating the purpose of the helmet at probably the most crucial phase of the competition (Bicycle Helmet Safety Institute., 2009b). Both the British

Medical Association (BMA) and the World Health Organization (WHO) recognize the protection of the cranium by the use of helmets within cycling, and actively promote the use of helmets in sporting activities (Bicycle Helmet Safety Institute., 2009c, British Medical Association., 2009). The incidence of head injuries in cycling has been reported to be 85% lower for those who wear helmets than those who do not (Thompson et al., 1989). Scuffham et al, (2000) examined the effects of helmet laws in respect to head injuries in New Zealand between 1988-1996. From 1st January 1994 it was a requirement to wear an approved cycle helmet for on-road cycling. Their findings observed a 19% reduction in head injuries in the first 3 yrs. Marshall *et al*, (2003) analysing a national database for compensation insurance claims in baseball, during 1997-1999, highlighted an association between the use of helmets with faceguards and a reduced the risk of facial injuries.

1.1.3 Mouthguards

The primary function of a mouthguard is to prevent the violent contact between the upper and lower dentition. The earliest recorded mouthguards used in boxing which were little more than a horseshoe shaped piece of leather or rubber loosely fitting between the teeth (Knapik et al., 2007).

Rubber in this application has lower impact absorbency, hardness, and tensile and tear-strength properties than the ethylene vinyl acetate (EVA) or polyurethane which is commonly used today (Knapik et al., 2007). Modern custom-made mouthguards use materials such as polyvinyl acetatepolyethylene or ethylene vinyl acetate (EVA) copolymer. Other materials that have been used are: polyvinylchloride, latex rubber, acrylic resin, and polyurethane (Knapik et al., 2007, Maeda et al., 2009), examples of materials and properties used for the fabrication of mouthguards are shown in Table 1.4.

Material	**Tensile Strength (Mpa)**	**Elongation (%)**	**Density (g/cm^3)**	**Modulus (Mpa)**
Leather (Cool Conservation Online., 2011)	Between 13.8 – 41.3*	**	**	**
Natural latex rubber (The Rubber Foundation Information Center for Natural Rubber., 2003)	31.0	1050	0.93	1.3
Silicone rubber (Matbase, 2009)	5 – 8	200 – 800	1.25	**
Polyvinylchloride (The Rubber Foundation Information Centre for Natural Rubber., 2003)	13.8	500	1.25	4.5
Polyurethane (The Rubber Foundation Information Center for Natural Rubber., 2003)	41.4	675	1.25	3.8
Ethylene Vinyl Acetate (EVA) (Polymerweb.com, n.d.)	13.8	800	0.93	**

* Many factors affect the tensile strength of leather, i.e. species and age of the donor animal, degree of splitting and type and length of tanning.

** Not recorded.

Table 1-4: Property values for materials used for mouthguards from past to present.

The mouthguard generally covers the upper dentition of the maxillae, at least as far back as the distal of the first molars, and over the soft tissue extending into the maxillary sulcus. Dual mouthguards are sometimes used as it is thought that they may improve performance, due to increased air flow. The material acts like a shock absorber, dissipating the impact force through the surrounding orofacial structure. Impact forces from punching have been recorded as high as 4741 N for some super heavyweight boxers (Walilko et al., 2005) and fractures of the mandible have been reported to occur between 685-5400 N (Nahum, 1975, Hampson, 1995, Viano et al., 2004, Kennedy et al., 2006, Cormier et al., 2010). In relation to impact testing the majority of research into head and orofacial protective devices use simple drop-weight impact test apparatus in a laboratory environment to induce and measure the force of impact on the guard/device (Patrick et al., 2005, Knapik et al., 2007). However, these cannot fully mimic real life impacts through muscles, joints, and connective tissue of the head and neck.

Custom made mouthguards in comparison to market "boil and bite" mouthguards, generally are more accurate in relation to fit and are more comfortable (Gawlak et al., 2014). The looser fit of the boil and bite mouthguard could be a potential choking hazard (Newsome et al., 2001). Zadik and Levin, (2009) investigated the compliance in use of boil and bite mouthguards within formal team sport participation using a population representative sample of 630 male soldiers from the Israel Defence Forces. A total of 272 participants received a boil and bite mouthguard and 358 did not receive a mouthguard. Their study observed only 34.2% (n= 93) of the group that received boil and bite mouthguards reported use during sporting activity. (Zadik and Levin, 2009) highlighting that mouthguards are not always used even if readily available.

UK sports governing bodies specify the mandatory use of mouthguards in some sports including ice-hockey, fencing, boxing and lacrosse (Holmes, 2000, British Boxing Board of Control., 2007). Mandatory use in martial arts tends only to be at international level (Holmes, 2000). In all other sports, the sporting associations and governing bodies make vague recommendations as to the use and level of protection used within the sporting activity, leaving the decision directly with the individual (Holmes, 2000), Table 1.3. However, from a dental perspective there is a financial impact on the player, as many dental insurance companies now make exclusions for sporting injuries where a mouthguard or other recommended protection is not worn during matches and including training (Denplan, 2009). The risk of an orofacial injury is 1.6-1.9 times higher when a mouthguard in not worn when compared to those wearing a mouthguard (Knapik et al., 2007). Due to these observed benefits of the use of mouthguards in both medium and high risk sports, Table 1.2, there should be a mandatory requirement for all levels of sport (junior/senior) played in the UK. Within both helmet and mouthguard protection there appears to be more technology advancements in the helmet sector than mouthgaurds.

1.2 CONCLUSION

This chapter found a distinct lack of assessable published information upon which participants could make an informed decision about the type and level of protective headwear for their given sport. UK governing bodies' statements on the mandatory (or otherwise) use of protective headwear for adults and children varies between the type of sport. Whilst there have been several studies on craniofacial sporting injuries, there is a sparse number of supporting studies in certain sports within the UK.

Simple preventative measures to reduce the occurrence of facial injuries (helmets, goggles, and mouthguards) can easily be implemented. Sporting participants still sustain injuries because either they decide not to wear them, or do not know which is best, or choose a poorly fitting device. Despite the availability of such items, there are still no guarantees that an orofacial injury can be prevented; the risk of injury can only be reduced, and is dependent (in many ways in terms of the magnitude of force, source, and anatomical site) on the individual who plays the sport in the first instance.

The following chapter will investigate the occurrence of injuries in craniofacial injuries due to sport within the United Kingdom. The study will be qualitative by the use of questionnaires to 156 Maxillofacial departments in the NHS within the United Kingdom. The questionnaire will examine the incidence of sports injury to site-specific areas of the facial skeleton e.g. zygoma, maxillae, mandible, frontal bone etc, and the type of sport played to occur such injury. The questionnaire will also provide information on gender, age and physical activity level of the participant, thus giving an up to date picture of orofacial injuries derived from sport and whether protective headwear was used.

CHAPTER 2: AN INVESTIGATION INTO THE OCCURRENCE AND EFFECTS OF MAXILLOFACIAL INJURY DUE TO SPORT.

2.1 INTRODUCTION

There is a limited amount of published data in relation to maxillofacial related injuries, concussion and traumatic head impacts in sports within the United Kingdom (Hill et al., 1998, Hutchison et al., 1998, Kemp et al., 2008, Walker et al., 2012a). The majority of papers relating to traumatic head impacts and concussion within sport predominately focus on highly physical active sports such as American football, rugby, soccer and hockey (Guskiewicz et al., 2000, Naunheim et al., 2000, Withnall et al., 2005, Agel and Harvey, 2010, Hollis et al., 2011, Levy et al., 2011, Kroshus et al., 2014).

Hutchinson et al, (1998) examined the occurrence of maxillofacial injuries over a one week period (12th-19th September 1997) in 163 Accident and Emergency (A&E) Departments. They reported that the total number of injuries that occurred during sports and other recreational activities was 16%. From their findings only 13% of all the sources of injuries (not only sport) were maxillofacial fractures the rest were made up of 45% facial bruising, 59% lacerations, and 5% damaged teeth. However, the study by Hutchinson et al, (1998) would have been unrepresentative of a twelve month cycle of sporting activity, whereby the peaks and troughs in the sporting seasons could be observed. Hill et al, (1998) conducted their study over a one year period;

patients were also recruited on presentation to A&E. Their findings showed that the majority, i.e. 80.7% of injuries were soft tissue lacerations, 10.6% being dento-alveolar fractures and only 8.5% were fractures of the facial skeleton. Walker et al, (2012a), over a one week period ran a multicentre (11 A&E departments) study, and collected data on facial injuries. Their study used a modified version of the data collection form devised by the British Association of Oral and Maxillofacial Surgeons (Hutchison et al., 1998), it was modified to record more detailed data on sporting injuries. A total of 325 patients were reported with facial injuries during this timeframe. The gender split was 68% (n = 222) male compared to 32% (n = 103) female, giving a male to female ratio of 2.15:1. The highest incidence of head injury from sport was reported in the 1-15yrs age group, followed closely by the 15-25yrs age group. The main cause of injuries were accidental falls 39%, followed by sports 29%, assault 17% and vehicle crashes 11%. A follow up study by Walker et al, (2012b) focused in part on the aetiology of fractures with regard to sport. Of the 325 patients presenting with facial injury, only 84 were fractures and 29 were caused through sport or physical activity. From this cohort 79% were male with the peak age group of 15-24yrs. Gaelic football accounted for 45% of these injuries. From the 84 fractures sustained from all causes, the most common site of fracture was the nasal bone 50% (n = 42), 25% (n = 21) sustained fractures of the mandible and 17.9% had zygomatic-orbital complex fractures. The previous aforementioned studies by

Hutchinson et al, (1998), Hill et al, (1998) and Walker et al (2012a & b) were initially run within A&E departments at the participating hospitals.

There are a number of other factors which could potentially contribute to an increased risk of bone fracture, irrespective of playing sport. These factors can be both genetic and lifestyle, for example, gender, age, body type, ethnic origin, low testosterone levels in men, levels of oestrogen, onset of menarche, menopause in women and a family history of fractures (Boot et al., 1997, Lane, 2006, McArdle et al., 2009). In addition, controllable lifestyle factors such as smoking, excessive alcohol consumption, insufficient calcium consumption and also some medications can also increase the risk of fracture incidence rates (Boot et al., 1997, Lane, 2006, McArdle et al., 2009). The aim of the present research study was to give an up-to-date overview of sports related maxillofacial/orofacial injuries seen in maxillofacial hospital departments in the UK and not those within Accident & Emergency during a year long study.

2.2 METHODOLOGY.

Full ethical approval for the study was obtained both, from the National Research Ethics Service (NRES Reference Code: 09/H1016/89), and the ethics committee at the Department of Exercise and Sports Science, Manchester Metropolitan University, Cheshire (MMU Ethics Code:18.12.09) prior to the commencement of the study. A total of 156 Maxillofacial units within the United Kingdom were approached through a postal mail campaign, enquiring whether they would be interested in partaking in this UK-wide study. A total of 29 units (or 18.6% of the units approached) expressed an interest. Ethical approval was then obtained from each hospitals Research and Development (R&D) Department. As with any study there were many factors to consider when designing the questionnaire, i.e. clinical time, patient ethics, no questions that could cause embarrassment, patient's time and interest, informed consent, data protection, etc, thereby safeguarding the patients' "dignity, rights, safety and wellbeing" (Department of Health., 2005). National Research Ethics Service (NRES) guidelines were followed for the taking and holding of such data i.e. NRES ethics, code of conduct, liability insurance, etc.

Once approval had been granted from each NHS Trust unit, they each received patient packs which contained a copy of the questionnaire and a participant information sheet (Appendix D), and a return stamped addressed envelope. The study's aims were to collect data for a one year period at Maxillofacial Departments rather than an Accident and Emergency. Although a number of studies have run such data collections, exercises such as this have been predominately in A&E departments (Hill et al., 1998, Hutchison et al., 1998, Walker et al., 2012a, Walker et al., 2012b). It was thought the cost of logistics would be too high as this has been previously highlighted in an analysis of logistics running costs in the second UK National Facial Injury Survey (unpublished) covering a one week period (Ganpot et al., 2009). Also, by approaching Maxillofacial departments directly this would focus on potential fractures rather than lacerations, concussion and bruising etc. commonly seen within an A & E department. Last but not least, the questionnaire at this phase of treatment would provide a more in-depth view of the patient's history highlighting the usage of protective headwear/facial protection.

1.2.1 Questionnaire

The questionnaire was designed as a pro-forma document for ease of completion which was predominantly a tick box exercise. The first section was completed by the clinician recording the patient's oral health, the anatomical site of fracture, any previous fractures, and rehabilitation time (Appendix D: Questions1-4). The second section was completed by the patient and recorded basic information i.e. gender, age, and geographical region. Information on the type of sport played which included level, how many hours training per week, and whether any form of head protection was worn (Appendix D: Questions: 5-12). The last section was concerned with the patient's lifestyle factors that may have a bearing on fracture rates and healing of bone tissue. This included smoking status and quantity, alcohol consumption, calcium consumption, medication, age of menarche and history of osteoporosis or arthritis in the family (Appendix D: Questions: 13-20). The patient returning the completed questionnaire assumed consent for participation in the study, this was in compliance with protocols agreed under the REC ethical approval. All completed questionnaires were returned to the university in a stamped addressed envelope, ready for data collection and analysis. The study was anonymous, no identifiable patient data was recorded, codes were assigned for individual units which were only privy to the author of this thesis, in accordance with NRES prior recommendations. All documents were stored in compliance with NRES and data protection protocols.

2.3 RESULTS

The data collection phase ran over a period of one year between 2009-2010 (there were multiple start dates due to R&D approval process differing between Trusts). From the 29 units that showed an initial interest in the study, only 13 units returned a total of 26 questionnaires.

2.3.1 Clinical Information: (Questions 1 – 4).

From the cohorts treated for maxillofacial fractures, 92% of respondents were deemed by the clinician to be of good oral health at the time of fracture. The most common sites of fracture recorded were the Mandible (25%), Zygoma (25%) and Maxillary sinus (25%), as shown in Figure 2.1. The mandible was further scrutinized into anatomical site with the angle of the mandible being the most susceptible to fracture (45%), followed by the body and condoyle (Figure 2.2). Only 27% (n=7) of the cohort had a previous history of fractures elsewhere within the body.

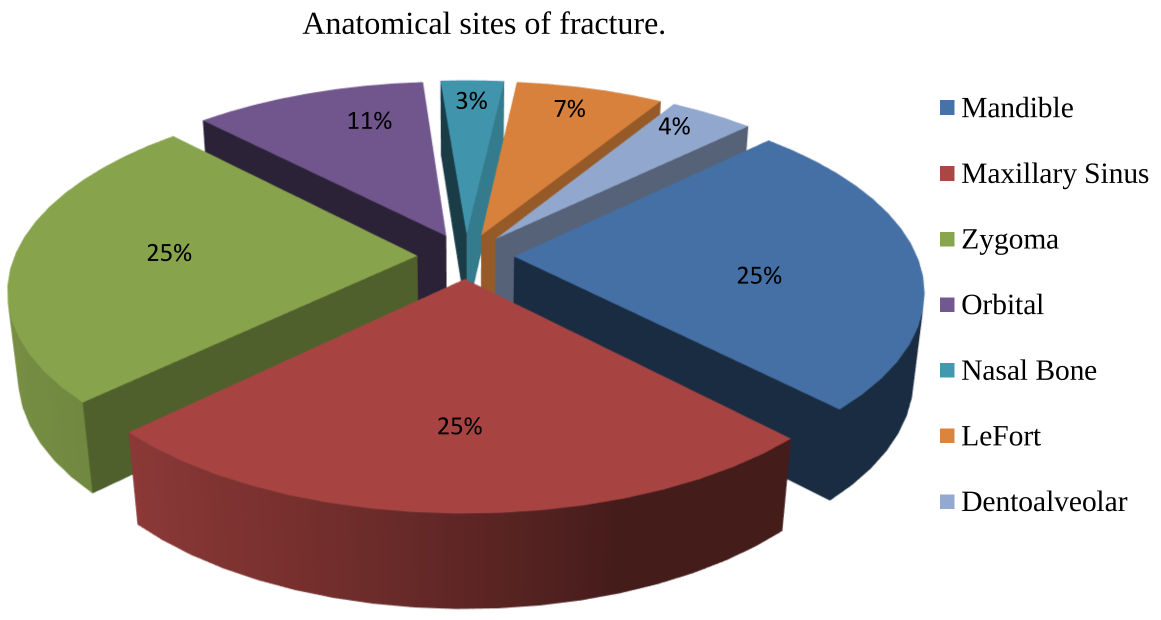


Figure 2-1: Percentage of fractures at each anatomical site.

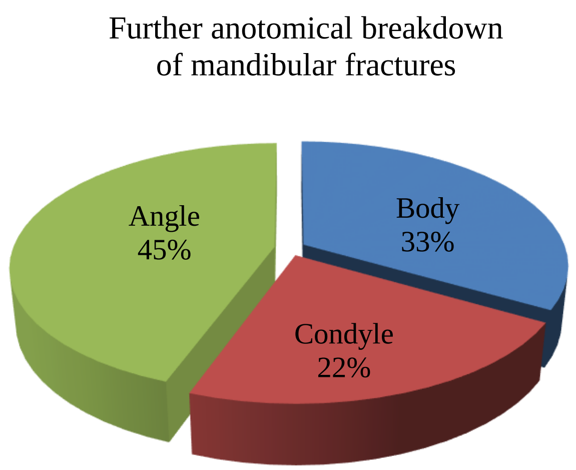


Figure 2-2: Breakdown of the mandible anatomical site in relation to fracture.

The mean suggested time by the clinician for post fracture rehabilitation was 6wks, and ranged from 1-12wks dependent on the extent of injury (Table 2.1).

Number of recommended weeks to refrain from sport	**Frequency**	**%**
1	1	3.8
2	1	3.8
3	1	3.8
4	4	15.4
6	15	57.7
8	2	7.7
12	1	3.8
Total	25	96.2
Missing	1	3.8
Total	26	100.0

Table 2-1: Clinicians suggested rehabilitation time post fracture.

2.3.2 Patient and Incidence: (Questions 5 -12).

The study showed there was a gender incidence ratio of 12:1 (male:female). The age range of respondents was <16-65yrs, with a mean of 33.5yrs (SD: 1.38), The highest incidence range of orofacial injury within the present study was observed in the 16-25 year group (Figure 2.3).

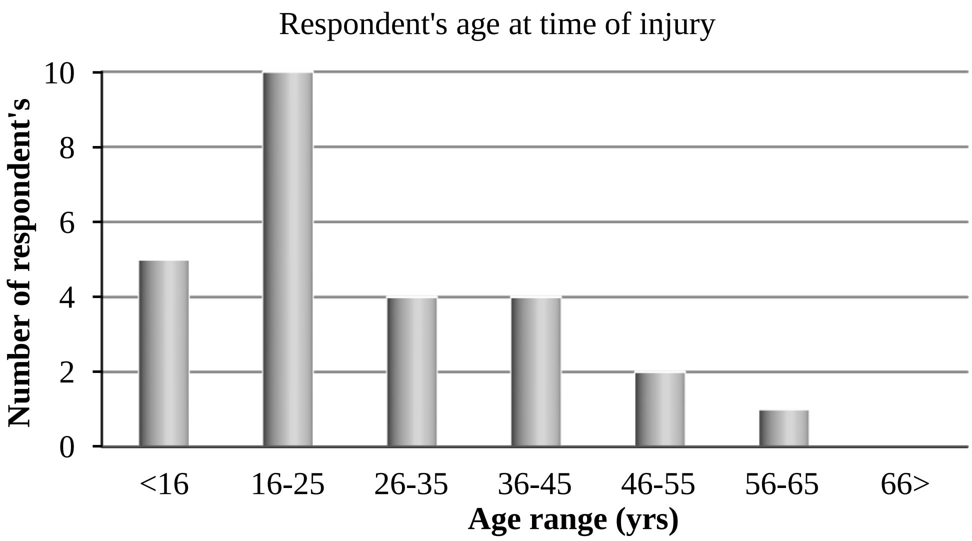


Figure 2-3: Incidence of orofacial fracture by age group.

The highest number of Maxillofacial units responses was from the North West of England at 29%, followed equally by South East, North East and West Midlands, all at 19% (Figure 2.4).

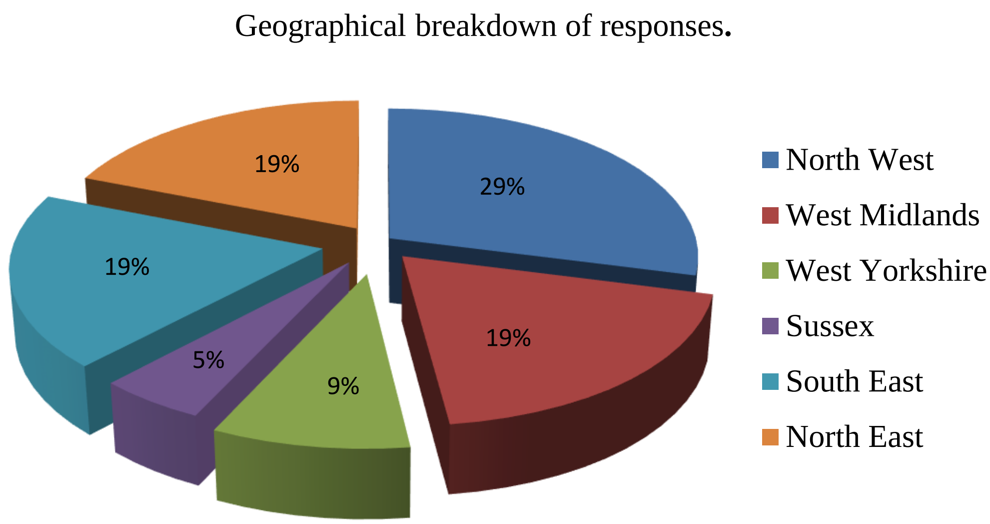


Figure 2-4: Breakdown of responses into geographical regions.

Table 2.2 shows in ascending order the sports reported from the present study which had the greatest incidence of facial injuries; Football 46%, Rugby 23%, Cycling 15%, Hockey 4%, Squash 4% Gymnastics 4% and Cricket 4%. Of these the majority, 63% of sport was played recreationally, 29% were at county level and 8% at national level. The mean number of hours each respondent trained per week was 6 hrs with a range from 0-40hrs. In total 73% of the participants reported to not to have worn any form of head protection at the time of the fracture.

Sport	Frequency	Percentage (%)
Football	12	46.2
Rugby	6	23.1
Cycling	4	15.4
Hockey	1	3.8
Squash	1	3.8
Gymnastics	1	3.8
Cricket	1	3.8
Total	26	100.0

Table 2-2: Type of sport played when injury occurred.

2.3.3 Lifestyle and Medical History: (Questions 13 – 20).

When questioned on lifestyle factors which have been associated with a greater risk of bone fracture and rehabilitation, 23% of the cohort were smokers, all smoking between 1-10 cigarette(s) per day. The majority of respondents n=15 reported only drinking 1-10 units, n=1 drinking 11-20, n=2 drinking 21-30, and n=1 drinking 31-40 units of alcohol in a typical week. Within the cohort, 96% of the respondents considered their calcium consumption to be average or above. However, this question is subjective in that the answer would have been the patient's own perspective on calcium intake and as such cannot be relied upon to be entirely accurate. There are also a number of medical factors that could have a bearing on a person's risk of bone fracture.

2.4 DISCUSSION

Worldwide, the main causes of maxillofacial type injuries are road traffic accidents (RTA), assault, falls and sport (Tanaka et al., 1994, Bataineh, 1998, Kotecha et al., 2008, Gerber et al., 2009, Kostakis et al., 2011). However, in the UK a large percentage of maxillofacial injuries are caused by interpersonal violence, with alcohol playing a large part in this phenomenon (Laverick et al., 2008, Gerber et al., 2009, Elledge et al., 2011). The present study's primary focus was principally the incidence and aetiology of maxillofacial bone fractures obtained from participation in sport, where a patient had been admitted to a maxillofacial unit. This is a very specific subject to obtain data on and specifically other studies have focused collecting data from A&E departments. This current study used the maxillofacial department as a point of recruitment to the study. A limited response was expected and indeed was obtained 26 completed questionnaires returned over a one year period, corresponding to an average of 2 injuries per 13 units a year.

Hutchinson et al, (1998) surveyed 163 A&E departments in the UK over a one-week period, they showed that the majority of maxillofacial injuries arose from falls (40%) and interpersonal violence (24%) plus a large number of those were alcohol related. Sport/other accidents were reported as 21%, with the remainder being 9% unreported and 5% road traffic accidents. Of the initial 6114 patients presenting to A&E with a facial injury only 21% (all types of injury) of those were then referred to the maxillofacial specialty for further treatment. A similar study by Hill et al, (1998) also using A&E as a point of contact, over a twelve month period looked more specifically at maxillofacial sports injuries. They identified 790 patients with injuries sustained from sport, of these 64 were facial fractures, 80 dento-alveolar fractures with the majority 604 being soft tissue lacerations, this represents only 18% of those being orofacial fractures. The initial figure of 790 patients with maxillofacial sports injuries only accounted for approximately 1% of all A&E attendances in the 12 month time period. Hill et al, (1998) in their study were concerned in part on service demand, whereas the present study focused on the causality of orofacial injuries in sport. Hill et al, (1998) also concluding their paper by stating the need for "*better protective headgear and the increased use of mouthguards*". Other studies have reported higher figures to those found in the present study (Hill et al., 1998, Walker et al., 2012a). This may be due to the fact that these studies have included soft tissue damage, bruising and/or abrasions or are not solely focused on sports injuries in relation to incidence of fracture. Earlier studies sourced their data from Accident and Emergency (A&E) attendances, whereas the present study's first contact was at the patient's first referral to the maxillofacial department. In this study much of the superficial soft tissue lacerations and bruising would most likely have already been treated by A&E medical staff, and therefore would not appear at the stage of data collection. It also must be considered that minor facial skin abrasions, bruising or tooth avulsions may have been treated by other healthcare specialties e.g. GP or dentist respectively and self-administered at home, instead of presenting to a maxillofacial department or A&E. The area of interest for this study was only in the recording of bone and tooth fractures in the facial regions.

In a study by Maladiere et al, (2001) the authors illustrated the diverse success of previous studies in recording the incidence of facial fractures and sport. In a review of similar studies they reported the highest study participation as 368 cases over a 7 year period and the lowest as 46 cases over a 2 year period, which is comparable with this study. However, given the amount of units involved in the present study, it was hoped there would be a greater response. Due to the manner in which this study was required to be carried out, a definitive percentage for the incidence of sporting injury, against all other forms of maxillofacial injury could not be identified. NRES specified for this current study, that patients must be allowed to take the information pack away with them, to digest the information. Originally it was this study's aim that the patients were to fill out the questionnaire whilst waiting for their appointment, then the clinician would fill in their relevant section and would return the questionnaire. It was thought the latter would provide greater compliance, as it would not be reliant solely on the patient's interest in the study and good will. Hutchison et al, (1998) and Walker et al, (2012a) collected data from their respective participant hospitals A&E departments over a one week period. The study by Hill et al, (1998) was a single site study over a twelve month period. In these previous studies, the pertinent data was recorded by the medical staff as part of the patient's treatment records, and not as with this current study that was reliant on the patients filling out the questionnaire and sending back in their own time, which would have inevitably effected the number of responses.

2.4.1 Aetiology of fracture (Question 9).

Football was reported to be the greatest contributor to facial injuries within this study; this is in agreement with previous authors' findings such as Maladiere et al, (2001) and Mourouzis & Koumoura, (2005). With regards to the present study's findings it may be due to the popularity of football within the UK. Sports England performed a survey of sport participation, defined by weekly attendance in their "Active People Survey" over a period of a year. Their findings reported that 17.16% of people aged between 14-25yrs played football weekly (Sports England, 2014). Paradoxically, football is one of the sports that do not require the participants to wear any form of protective headwear as shown in the previous chapter Table 1.3. Rugby was the second major contributor to facial injuries within sport, followed closely by cycling. The Sports England survey estimated weekly participation in rugby union to be 2.26% and cycling 5.84% in 14-25 yrs (Sports England, 2014). Mourouzis & Koumoura, (2005), suggests that the incidence and aetiology of maxillofacial fractures are very much influenced by the popularity of each sport in each individual country.

2.4.2 Gender and Age (Questions 5 & 6).

This study recorded a gender ratio of 12:1 (male:female), this trend of males suffering greater injury rate in sport has also been observed in other studies of this kind (Tanaka et al., 1996, Hill et al., 1998, Maladiere et al., 2001, Delilbasi et al., 2004, Exadaktylos et al., 2004, Mourouzis and Koumoura, 2005). Delilbasi et al, (2004) reported a male to female gender ratio as high as 19:1. They theorised that a possible explanation to this observation could be males generally have a higher body weight and more aggressive attitude to the playing of sports, or simply that males play more ball sports that involve greater levels of interpersonal contact e.g. rugby and football.

In relation to age this study showed that 16-25 yr olds had the highest incidence rates. A number of studies have reported similar results between rate of injury and age 20-29 yrs (52%) (Tanaka et al., 1996), 21-30 yrs (43.2%) (Mourouzis and Koumoura, 2005), 10-19 yrs (48%) 20-29 yrs (approx.33%) (Delilbasi et al., 2004), 15-24 yrs in males and 5-14 yrs in females (Walker et al., 2012b). One possible reason for these age range incidence rates could be younger people of this age range simply play more sports therefore are at a greater risk of injury. In a previous survey by Sport England (2011), the age group 16-34 yrs represented the highest level of sporting activity (at least 12 sessions of 30+ minutes of moderate activity each month).

2.4.3 Anatomical site of fracture (Questions 2 & 3).

The most common sights of fracture were the mandible, zygoma and maxillary sinus. These common sites of fracture form the outer "T" bone section of the mid and lower face are more susceptible to adverse violent contact (Chao et al., 2008). The mandible was further scrutinized in this study showing the mandible angle (45%) was more prone to fracture followed by the body (33%) and condyle (22%). Maladiere et al, (2001), Delilbasi et al, (2004) and Mourouzis & Koumoura, (2005) also found similar patterns of fracture. Interestingly, both Maladiere et al, (2001) and Mourouzis & Koumoura, (2005) also recorded football (soccer) as the major maxillo-facial injury contributor, with 25% and 64% prevalence respectively. The current study recorded an incidence rate of 46%, these high incidence rates are comparable with the previous mentioned studies and maybe indicative of common fracture patterns seen within this sport.

2.4.4 Rehabilitation period (Question 4).

The mean recovery time was 6 wks, and ranged from 1-12 wks before returning back to sport. This is in complete accord with findings by Mahmood et al, (2002) who also found 6 wks to be the most common length of time advised by surgeons to refrain from sport. They reported this advice is commonly based on traditional practice and common sense. However, Fowell and Earl (2013), using a prospective study of 20 cases of sportsmen with facial fractures, 12 zygomatic complex, 4 orbital, 3 mandible and 1 suffering multiple fractures, proposed that “return-to-play” schedule should gradually re-introduce the patient back into competitive selection after 3 wks, for players who sustain maxillofacial fractures.

2.4.5 Protective modality (Question 12).

Protective headwear and mouthguards are readily available to all levels of sporting participants, yet 73% of cohorts were not wearing any form of head protection, i.e. mouthguard, glasses/goggles or helmet at the time of injury within the present study. A study by Eime *et al*, (2004) suggested that a possible reason for this phenomena is either a poor awareness of the injury risk associated with given sports and/or a lack of knowledge as to the appropriate protective equipment that should be worn. In their study of a sample of 1163 squash players only 8% used appropriate protective eyewear whilst playing squash. There is a lack of scientific evidence based information as to the correct form of protective headwear or oral device to reduce such risks (Maeda et al, 2009), and/or a lack of enforcement at club and governing body level, Table 1.3.

2.4.6 Supplementary questions (Questions 13 to 20).

When questioned about smoking status only 23% of the respondents indicated they smoked on a regular basis (all smoked between 1-10 per day). This is relevant in the context of this study as smoking has been shown to compromise bone strength. Some cigarettes can contain as many as 4000 chemicals (American Cancer Society., 2014), some of which may have a detrimental effect on bone metabolism and bone parameters, including diaphyseal marrow cavity expansion and epiphyseal trabecular bone reduction, which could be a contributory factor to fracture (Wust et al., 2010). Smoking also has a detrimental effect on bone quality and healing time post fracture (Adams et al., 2001, Sloan et al., 2010). Adams et al, (2001) studied recovery times of open tibial fractures, they found a statistically significant ($P < 0.05$) difference between the mean time for bone union in smokers 32 wks in comparison to a mean of only 28 wks for non-smokers.

From the present study's cohort, 91% of responders were deemed to have good oral health by the consultant. This is relevant as osteoporosis has been potentially linked to bone loss in the jaw (Horner et al., 1996). This to a greater extent is an age-related factor, but is an important indicator of possible risks of fracture. Also there has been reported an association between chronic periodontal disease/tooth loss/reduction in mandibular bone mineral density and osteopenia/osteoporosis in some age and gender groups (Horner et al., 1996, Wactawski-Wende, 2001, Horner et al., 2002, Dutra et al., 2006, Lindh et al., 2008, Kyrgidis et al., 2011, Sultan and Rao, 2011). Females who experience a late menarche and enter puberty later or have an early onset of menopause are at a greater risk of reduced bone mineral density (Boot et al., 1997). Oestrogen protects bone and is required for osteoblast remodeling of bone, the oestrogen inhibits osteoclast activity, protecting the bone from excessive bone resorption (Kneale and Davis, 2005, Jester et al., 2011). Therefore at the onset of menopause when the production of oestrogen is greatly reduced, women are at higher risk of osteoporotic fractures (Kneale and Davis, 2005, Jester et al., 2011, National Osteoporosis Foundation., 2011). There were only two female respondents in this study, aged 36 and 55 yrs, therefore statistical analysis with regards to menarche and menopause was unfeasible.

Sports participants should also be made aware of the importance of nutrition in relation to health, even more so in terms of calcium consumption (Kaye, 2007). Therefore, each of the participants were requested to assess their own level of calcium consumption. This question was subjective since it relied on how qualified or knowledgeable the individual would be regarding their own level of calcium consumption, although the recommended daily allowance (RDA) is now stated on most processed food packaging. A good level of calcium in the diet is integral to bone health, maintaining bone density and strength. Both the average male and females, aged between 19-50 yrs of age are meant to have a recommended dietary allowance (RDA) of 1,000 mg of calcium, this increases to 1,200 mg for females 51+ yrs and for males 71+ yrs. A total of 73% of the cohort considered themselves to have an average calcium consumption, 23% reported they had an above average calcium consumption, however it must be highlighted this question is subjective. A prolonged deficiency in calcium consumption could cause osteopenia and left untreated could lead to osteoporosis (McArdle et al., 2009, Institute of Medicine of the National Academies., 2011, Office of Dietary Supplements., 2011), making bone more susceptible to fracture.

2.5 CONCLUSION

Football was identified as the most prevalent sport in terms of its contribution to maxillofacial type injuries, with males aged between 16-25 yrs to be at greater risk of orofacial injury. Although protective head protection is readily available the majority 73% of the questionnaire responses still did not choose to wear any form of protection. In both this current study and previous studies, maxillary and mandibular fractures have been shown to be highly prevalent within sporting activities Table 1.1. Mouthguards are a cheap, easy to implement and relatively effective way of reducing a percentage of the orofacial injuries observed within this study.

As a recommendation, with the aim of reducing the amount of serious facial injuries in all sports shown to have a medium to high incidences rate of facial injuries, these high risk sports should be subject to a comprehensive risk assessment; which dependant on the outcome should lead to possible regulatory changes. A comprehensive history should be taken of the individual participating in the given sport, and the type and level of protection should be based on this information. There needs to be a review into the mandatory use of protective headwear in high risk sports also a more affective education strategy, at club level, as to the correct protective headwear to be worn for each sport differing needs, due to the incidence of mandible fractures shown in the present study and many other studies, Table 1.1. The following chapter will focus on mouthguard design and manufacturing processes of custom made mouthguards. Custom made mouthguards are an effective way of reducing orofacial fracture; however their effectivity is linked to their thickness over key anatomical sites i.e. the anterior of the mouth, were the majority of orofacial sports injuries occur. Mouthguards, EVA, material is known to thin during the fabrication process. Older sports participants and those with a reduction in bone density may require a thicker mouthguard to provide adequate protection. The following chapters investigate the manufacturing processes of custom made mouthguards and how to improve in terms of thickness dimensions, in addition to test two level of bone tissue models (young and old) in impact with both dimensional values. An aged model would represent a cohort with reduced bone density in ageing or those weight restricted sports where lower levels of bone density are reported thus highlighting as to whether a more bespoke mouthguard is required.

CHAPTER 3: AN INVESTIGATION INTO THE RELATIONSHIP BETWEEN THICKNESS VARIATIONS AND MANUFACTURING TECHNIQUES OF MOUTHGUARDS.

3.1 INTRODUCTION.

Mouthguards are used as an intervention against trauma from violent impact between the upper and lower dentition, transferring forces to the surrounding structures. A mouthguard blank, when used for a sports mouthguard, is fabricated from a predetermined thickness of material typically ranging between 3-6 mm. Ethylene vinylacetate (EVA), which is commonly used for mouthguard production, is a random copolymer of ethylene and vinyl acetate. The homopolymer of ethylene is a semicrystalline thermoplastic. Random incorporation of vinyl acetate along the chains adds irregularity to the chain structure that hinders chain packing and hence reduces crystalline content and crystalline melting point (T_m). Therefore as the level of vinyl acetate in EVA copolymers increases the latter parameters decrease in value until at about 40 - 50 % vinyl acetate no crystallisation can occur and the copolymers are amorphous elastomers. In EVA used for mouthguards the vinyl acetate level is such that the T_m is around 84 °C (Gilby, 1982). The EVA thermoplastic material has a linear and branched molecular spatial structure, which have relatively weak physical bonds. When heated, as with the thermoforming process, these weak bonds break allowing the molecular chains slip past each other, resulting in the softening of the material, which can be reshaped over a mould using vacuum pressure or air pressure forming technique and held under pressure till cool. On cooling, the material returns to its manufactured stable state (O'Brien, 2002). The mouthguard is formed using a thermoforming process, where the EVA material is heated between 80-120 °C (Patrick et al., 2006, Yamada and Maeda, 2007), allowing the material to sag by 15-25 mm (American Dental Association, 2006, Geary and Kinirons, 2008). After this phase it is then either pulled down (in the case of vacuum forming) or forced down (in the case of the pressure forming technique) over the dental model. The mouthguard material itself must possess properties such as the ability to absorb and dissipate impact energy effectively, must be easy to clean, non-leaching, and resistant to the uptake of fluids.

During the fabrication process there is also an inherent thinning of the mouthguard material on heating and during the forming of the mouthguard (Del Rossi and Leyte-Vidal, 2007). A mouthguard’s performance (i.e. energy absorbency) has been linked to it thickness (Westerman et al., 1995, Maeda et al., 2009). Therefore the greater the thickness of the finished mouthguard the greater the ability to dissipate any impact force it may potentially encounter. There are many production factors that could influence the degree of thinning. For example, height and orientation of the model, duration of heating, degree of material sag prior to forming, operators level of experience, model size, palatal depth, model position on platform, and model temperature (Westerman et al., 2002a, Geary and Kinirons, 2008). Del Rossi and Leyte-

Vidal (2007) examined the correlation between dental model height and thinning. Their study found that when using a 3 mm blank with a model height of 20 mm the material thinned to 1.6 mm; thus equating to the material thinning by approximately

47%. Similarly, at a model height of 25 mm, the material thinned to 1.4 mm (i.e. thinning by 53%), and a model height of 30 mm gave rise to material thinning to 1.2 mm (i.e. thinning by 60%). Interestingly, during all test conditions the molar cusp (occlusal) region thickness remained constant at 1.6 mm. Geary and Kinirons, (2008) also investigated model height in relation to material thinning. They found by increasing the model height by 10mm (from 25 to 35 mm) this had a corresponding additional thinning of the EVA material of 21% (from 1.53 to 1.21 mm) when using a 3 mm blank. In the case of the 25 mm model the mouthguard material thinned to 1.53 mm or by 49%, and with the model at 35 mm to1.21 mm or 60% respectively. Both Geary et al (2008) and Del Rossi et al (2007) concluded that by keeping the dental model height low, the degree of material stretching observed during the thermoforming process is minimized.

Del Rossi et al, (2008) examined colour in relation to infra-red (heat) energy absorption, they found that darker colored mouthguard blanks had greater adaption and firmer fit to the finished mouthguard. Their findings suggest that darker blank materials will absorb greater amounts of heat (infra-red energy) over the same time period. It is the opinion of the author of this thesis that it would be expected that the more efficient heating of the blank would translate to the greater the degree of sagging of the material prior to forming which, in turn, reduces the thickness of the preformed material.

Therefore, the superior fit, obtained by using darker materials, may be at the detriment of the finished mouthguard thickness, as heating and material thinning seems to be inextricably linked. Geary and Kinirons, (2008) also investigated prolonging the heating interval of the EVA material prior to forming and its effect on the finished mouthguard thickness. They found increasing the duration of heating by 30 sec actually decreased the amount of thinning in the material. Initially this seems counter-intuitive, however, they postulated an explanation relating to the proximity of the sagging EVA material with the dental model, whereby the sagging EVA material contacts the model, transforming from its elastic plasticised state to its plastic state, prior to the pressure being introduced.

Mizuhashi et al. (2013a) examined the thickness and fit of a 3.8mm blank during two different thermoforming conditions. The conditions being (i) sheet lowered over the model when vacuum applied and (ii) sheet lowered over the model prior to vacuum applied. They measured anatomical points at both the incisal and first molar region and found that there were differences in thickness between anatomical points. However, there were no significant differences between thickness and condition. The thinning patterns observed within these conditions equate to 40-42% (incisal region), 32% (molar region) and 23-24% occlusal region. They also found that the fit differed between the two conditions.

Mizuhashi et al. (2013b) also examined four heating conditions in relation to thickness and fit, they found again that there was a difference in fit, which was dependant on the heating method, but no difference was reported between method and thickness between conditions. Thinning reported within this study ranged from 26-45% and was dependent upon the anatomical site measured. A study by Takahashi et al. (2013b) examined the effects of six conditions, which varied in relation to height of the model and heating procedures they reported that within conditions there was up to a 26% variation in thickness difference. Holding conditions of the mouthguard blank during the heating process has also been investigated, and this has been demonstrated to have an increase in thickness of the processed material especially when the mouthguard material is held at four points during heating (Mizuhashi et al., 2012). Thus, from the mentioned literature it shows that technique plays an important crucial factor within the fabrication process.

Kojima et al, (2014) investigated mouthguard material thinning during the thermoforming process using both vacuum and pressure forming, in conjunction with angled surfaces of 0º, 45º and 90º. They fabricated a custom made hexahedron model (20 mm x 65 mm x 60 mm) in dental stone. The model had a flat top (0º), a 45º angled surface and the back of the model served as the 90º surface.

They used both vacuum and pressure forming techniques. A total of three mouthguard blanks were formed per test condition. Each mouthguard blank was measured four times using a digital gauge, at the centre point of each surface. Their study reported a greater degree of material thinning at 45º and 90º than the 0º surface. At 90º the material thinned by 36% (1.09 mm) using vacuum forming and 66% (1.98 mm) using the pressure forming technique. At 45º the material thinned by 17% (0.51 mm) for vacuum forming and 20% (0.60 mm) when pressure forming. However, on a flat surface (0º) the EVA material only thinned by 11% (0.33 mm) with vacuum forming and 2% (0.06 mm) with pressure forming. Thus, highlighting material thicknesses differences between both the vacuum and pressure technique, and also model angulation.

Previous studies have used callipers to record thickness measurements. Geary et al, (2008) sectioned their mouthguard samples and measured at 12 points using a digital micrometer (resolution 0.001 mm). Del Rossi et al, (2007) used a spring-loaded calliper gauge (resolution 0.01 mm) and measured the mouthguard thickness occlusally at each cusp of the first molars and labial from the central incisors, and both right and left canines. Mizuhashi et al, (2013) states they used a measuring device to measure the thickness of the mouthguard. However, they state they removed the spring on the measuring device to prevent distortion of the material on placement.

Mizuhashi et al, (2013) recorded 10 incisal measurement points (three at incisal edge, four at the central and three at the cervical side), also six points of the first molar (the cusp, central, and cervical part of the mesiobuccal and distobuccal cusp). Takahashi et al, (2013) also just state that they used a measuring device. They measured at five points in the incisal region, ten points at the labial surface and nineteen points in the first molar region. Previous studies have predominately used one operator to form the mouthguards (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Mizuhashi et al., 2012, Mizuhashi et al., 2013a, Mizuhashi et al., 2013b, Takahashi et al., 2013a, Takahashi et al., 2013b). The primary focus of this present study was to examine the reproducibility of the thermoforming task between a larger cohort of operators producing a single identical mouthguard. The author of this thesis then examined the degree of both intra and inter-individuals variability of the mouthguards by both caliper and CT scanning technology. The objective was to highlight how the reproducibility of the thermoforming task fared in relation to mouthguard thickness and production consistency.

3.2 MATERIALS & METHOD.

Ethical approval was sought and obtained, prior to commencement of the study taking place, from the ethics committee at the Department of Exercise and Sport Science, Manchester Metropolitan University (MMU Ethics Code:18.12.09)

3.2.1 Model selection

A suitable average generic model was selected from demonstration models on which appliances were made for training purposes for clinician's. The average model was verified firstly by a study carried out by Mills, (1964) whereby 230 males aged between 17-21 yrs from mixed European ancestry were assessed. They reported a mean maxillary arch width of 35.13 ± 0.20 mm in the inter-canine region (b), 41.60 ± 0.17 mm in the region of the first premolars (c), 47.05 ± 0.18 mm in the region of the second premolars (d), and an arch length of 32.79 ± 0.20 mm (a) (Mills, 1964) Figure 3.1 & Table 3.1. In addition, a study by Uysal et al, (2005) examined a mixed gender cohort of 150 participants (72 male, 78 female. mage, 21.6 ± 2.6 yrs) with normal occlusion. They reported the mean arch width in the inter-canine region was 34.4 ± 5.9 mm (b), 42.1 ± 10.7 mm in the first pre-molar region (c) and 50.7 ± 8.7 mm in the maxillary inter-molar width (e). The selected master model used in the present study (Figure 3.1 and Table 3.1) had an arch width of 34.5 mm (b), 40.5 mm (c), 46 mm (d), 49 mm (e) and arch length is 32 mm (a), at the same measurement points respectively. From a combined cohort of the two previous studies mentioned, the current studies maxillary model measured within ± 1.7 mm at the same measurement points. Therefore, it could be deemed that the current study model is a fair representation of the average maxillary arch. In addition, the selected model had a good sulcus depth, before the reflection of lip tissue of 14 mm.

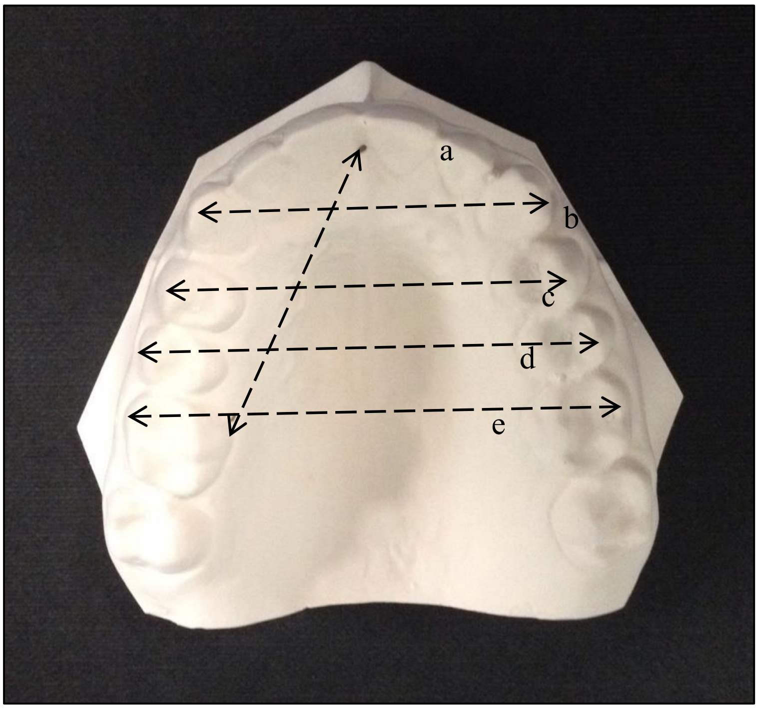


Figure 3-1: Shows the five measurement points used for the model selection.

A	Arch length	The distance between the lingual aspect of the midline of the central incisors and the gingiva of the mesio-palatal first molar cusp.
B	Maxillary inter-canine width	The distance between the cusp tips of the right and left canines.
C	Maxillary inter first premolar width	The distance between the cusp tips of the right and left first premolars.
D	Maxillary inter second premolar width	The distance between the cusp tips of the right and left second premolars.
E	Maxillary inter-molar width	The distance between the mesio-buccal cusp tips of the right and left first molars.

Table 3-1: Maxillary arch width measurements used in the present study.

Model Preparation Procedure

A thermo-reversible hydrocolloid duplicating gel (Dentaurum Dublipast® Type 1, DIN EN ISO 14356 – LOT 20805 – REF 165-500-00) was used to reproduce identical copies of the master dental model. These were then used to produce subordinate duplicate models. The gel was heated to 93 °C/199.4 °F using a duplicating machine (Bego Gelovit 200 - model No 26179). The gel was then cooled to 50 °C / 122 °F (± 1 °C / 1.8 °F) and poured into standard duplicating flasks (Foster Dental Equipment, Model: DF78 Flat base), the ambient room temperature when pouring the gel was 20°C (± 1 °C / 1.8 °F). The models were cast using a Crystacal R® mix, with a plaster to water ratio of 2.86:1, this equates to for every 1 litre of water 2.86 kg of powder, as specified by the manufacturer's instructions.

For statistical validity it was determined that the sample group should have 20 participants each required to repeat the task five times therefore a large number (n=100) of the same model was required for the study design. In dentistry, the most cost effective way of mass producing models is by the duplication technique. However, distortion can occur during the duplication process, so for good research practice, the models were tested as a matter of study accuracy and continuity. To determine the accuracy of all the duplicate sample models, five master models and five randomly selected subordinate duplicate models were selected. Each were CT scanned to examine any discrepancies between each model. If a large amount of distortion between the duplicate models was identified, thus this would have a corresponding effect on the finished mouthguard.

3.2.2 Model accuracy by CT Scan.

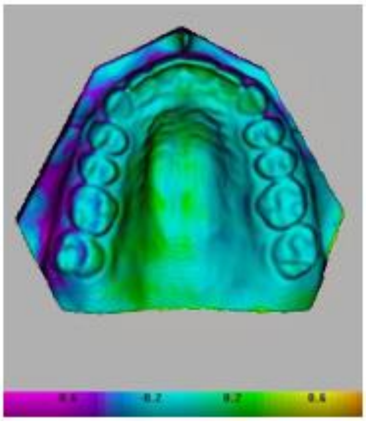
All model scans were performed at Kings College London Dental Institute under the supervision of Dr Trevor Coward, Reader in Maxillofacial and Craniofacial Rehabilitation. The models were scanned using a CT scanner (Make & Model:- Scanner: GE Medical Systems.) With the following settings: - Light Speed 16, Mode of Capture – Helical, Gantry Tilt – 0 Voxel

Size – 0.7031 x 0.7031 x 0.5, Matrix Size – 256 x 256, kV – 120, Ma – 90, Reconstructed in 0.625 mm axial slices).

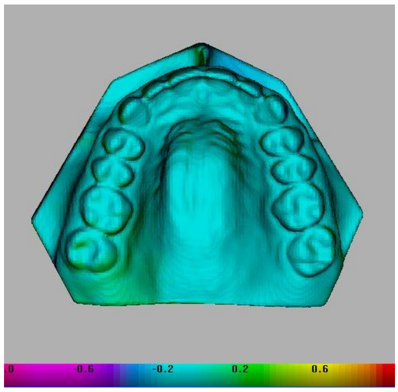
The scanned images were then transferred for further analysis using Robin's 3D - 3D Editor Software (Robin Richards, London, UK). The computer software program used an established algorithm technique to calculate the least square fit points between the two images surfaces (Knuth 1997). Essentially, the program fits the two images as closely as possible to an average number of points (200) with the difference between the two surfaces viewed as a colour that was assigned a numerical value which can be set between 0.001-10 mm. A cursor is then placed onto the surface to confirm the difference between the two surfaces.

The background noise (unwanted scanned information i.e. the surface the mouthguard was scanned on) from the image was also removed using the programs edit suite. Then, dimensional reference points and measurements were taken from the original scanned model, and the Hounsfield threshold of the scanned images were then scaled to this measurement. The Hounsfield unit (HU) is the numerical information contained in each pixel of the CT image. The threshold for this study was set approximately half way between the minimum and maximum intensity of the CT scan output, this was then finely adjusted to correlate to the measurement taken from the same anatomical sites of the corresponding model using the digital callipers, giving continuity between both the model and the scanned image. Finally, the image was then converted and saved as a 3D STL image file that could be rotated and sized as required.

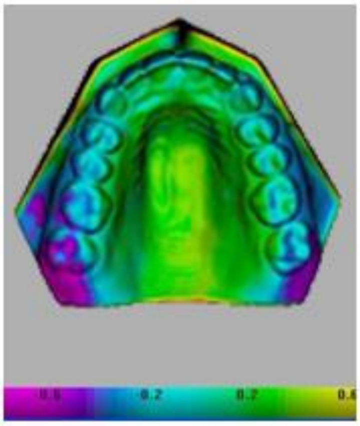
Robin's surface scan software – Cloud - polygon mesh manipulator (V3.0.7) was used to interpret the image. Twenty nine easily identifiable anatomical points were selected and marked onto the first scan to act as plot points; which were also identified on all the other scanned models. The plot points on the comparison models were mapped and compared against each other to give the degree of distortion between the duplicate models, this was represented by a picture of the two models superimposed, giving a picture colour map of different distortion points between all of the models. The degree of error/variability can be shown as a visual assessment of the two comparable surfaces; the differences between the models are assigned colour codes, which indicate the discrepancy in mm as shown in Figure 3.2. The master models were all compared against each other alongside the subordinate duplicate models.



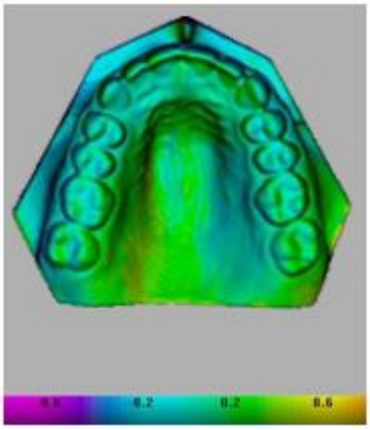
(A): Master model one compared to master model two.



(B): Master model one compared to master model three.



(C): Master model one compared to master model four.



(D): Master model one compared to master model five.

(E)

Figure 3-2: Colour representation of dimensional changes between duplicated models (A-D). Measurements expressed at a range of +/-0.6mm. (Image Colour key codes are; Purple: -0.6mm, Blue: -0.2mm, Green: 0.2mm, Yellow: 0.6mm (E)).

3.2.3 Model accuracy.

There was a slight distortion, as expected in the production of the duplicate models used for this study; a ± 0.2 mm discrepancy between the duplicated models was observed in the anatomical region from where the thickness measurements were taken which is deemed to be within acceptable tolerances within dentistry (Anusavice and Phillips, 2003). There were slightly higher distortion patterns observed on the master model four scan (0.6mm ± mm) in the posterior bucco-distal region, Figure 3.2. However, none of the measurement points used in this study were associated in that specific region. This distortion is comparatively very small and could simply be inherent anomalies associated with the duplication technique or a plot point scan error. All measurements were taken three times and the mean value recorded.

3.2.4 Possible reasons for distortion

Duplication by the use of a thermo-reversible agar hydrocolloid (Dubliplast®) was the most cost effective way of mass producing the models which is used in many dental laboratories. However, this type of material is prone to be slightly dimensionally unstable i.e. shrinkage (O'Brien, 2002, Shen, 2003). Also, the duplicate models were cast using Crystacal R ($CaSO_4.½ H_2O$) which is a high strength dental stone which was mixed to the manufacturer's specifications at a plaster to water ratio of 2.86:1. At this ratio Cyrstacal R has a maximum linear expansion of 0.55%, which could also be a contributing factor (BPB Formula, 2000). These relatively small levels of expansion and/or shrinkage can occur as part of the duplication process and are readily accepted within everyday dental technology as having a minimal effect on the accuracy (Shen, 2003) of the duplicated model or the subsequent mouthguards that will be formed over these models.

3.2.5 Fabrication of Mouthguards.

A total of 20 boxes were distributed to General Dental Council registered dental technician participants, each containing five identical duplicated dental models (total study cohort n=100) and 5 × 4 mm, EVA, 120 mm Ø (diameter), clear mouthguard blanks (Bracon Dental Laboratory Products, East Sussex, UK). Each box contained an information sheet regarding the study and they were informed that by returning the completed task they were consenting to take part in the research study. Participants were asked to complete a short questionnaire, which encompassed their level of experience, the type and age of the mouthguard formation machine, the size of blanks used, and any further details on the technique each employed in manufacturing mouthguards. A single technician, blind to the identity/questionnaire answers of individual technicians, then collected all the questionnaires and mouthguards. The study was blind to avoid selection bias and to guarantee the anonymity of any participant. The study was designed to be blind due to that participants may not want to be involved if they were to be compared against each other or subject to individual scrutiny. In the selection of the mouthguard material for the present study: (1) EVA has been recorded as the most commonly used material (Tran et al., 2001, Westerman et al., 2002a, Wicks et al., 2009). Personal communications with material suppliers indicated that 4-6mm EVA blanks were the most common thickness used in the construction of mouthguards within the United Kingdom.

3.2.6 Measurements of the processed mouthguards.

Following the return of the mouthguards each box was assigned a code and each model was given a numeric identification code for reference purposes. Anatomical plot points were marked on the master model, which indicated where all the subsequent mouthguards were to be measured. These plot points were then transposed onto the mouthguard using a permanent medium tipped marker pen to ensure consistency. Three anatomical measurement points were selected and marked on the finished mouthguards (Table 3.2 & Figure 3.3), allowing for precise comparisons to be made both within and between participants.

	Anatomical regions of measurement plot mark.
Point A	The upper anterior labial sulcus, at a point 5 mm, perpendicular to the occlusal plane, in line with the gingival, located at the interdental space between the upper permanent central and lateral.
Point B	The apex of the upper mesio-palatal cusp of the first upper right permanent molar.
Point C	The upper palatal aspect, at a point 5 mm, perpendicular to the occlusal plane, in line with the gingival, between the first and second permanent premolars.

Table 3-2: Anatomical measurement reference points (Points A-C).

An electronic calliper gauge (External Digital Calliper 442-01DC Series, Moore & Wright, UK) was used to measure the thickness of all the finished mouthguards. This type of gauge, was chosen for ease and level of range of action, giving easy access to the occlusal cusp areas of the mouthguard. The callipers had a resolution range of ± 0.01 mm. Anatomical points on each mouthguards were measured three times for consistency and a mean value obtained, after each measurement the gauge was zeroed. Callipers were calibrated by the use of a 4 mm steel calibration block, grade 1, ISO-DIN-BS (Cen Dev µm +0.02, Max Dev +0.02, Min Dev -0.11, Variation 0.13) (Alan

Browne Gauges Ltd, Leamington Spa, UK) and were frequently used to check the accuracy of the gauges between the measurements sessions.

3.2.7 CT scanned measurements of mouthguards

Five finished mouthguards from the group that produced the thickest dimensions and five from the group that produced the thinnest were selected to be CT scanned. This was to give a holistic visual overview of the thickness of the finished mouthguards. Barium markers were placed above the original three anatomical site markings (Table 3.2 and Figure 3.3). Barium is radio opaque and shows up on CT scans, this facilitated onto the mouthguard provided accurate placement of the plotting cursers used for the scanning/measuring software. The markers were created by placing a small amount of barium sulfate (E-Z-HD™, Bracco UK Limited) mixed with Cyanoacrylate adhesive (Procure-PC24 20G) into a paste and placed into position immediately onto the mouthguard (Figure 3.3).

Figure 3-3 Markers placed onto the mouthguards (black points: original permanent marker anatomical measurement points, white points: barium markers).

The CT procedure followed that as described with regard to the process of CT scanning the duplicate dental models (Section 3.2.2.) Robin's surface scan software (cloud - polygon mesh manipulator, V3.0.7, Robin Richards, London, UK) was used to interpret the scanned image. Dimensional reference points and measurements were taken this time from the scanned mouthguards using digital calipers at an easily identifiable point. The Hounsfield threshold was then set to this measurement, which was approximately halfway between maximum and minimum exposure, this gives continuity between the mouthguard and the scanned image. The background noise was removed.

Barium markers had been placed just above the marked points as previously mentioned in Table 3.2. The permanent marker points do not show up on the scanned image, hence the Barium markers showed up on the scans as a small lump on the image (Figure 3.4).

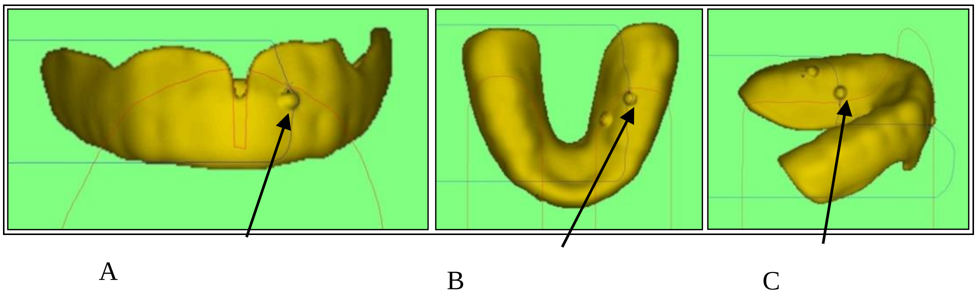


Figure 3-4 A-C: Three measurement points on the mouthguard with barium marker highlighted (bulge); A = Anterior, B = Occlusal, and C = Posterior lingual.

Measurement markers were placed onto the outermost surface of the mouthguard image. The image was then rotated/flipped showing the fit side of the mouthguard scanned image, the corresponding marker was placed directly over the previous marker in that anatomical site. The first marker point was designated as the "Set Ref Point" the software then calculated the thickness between the two points. Each measurement was performed three times for study accuracy and the mean value was recorded.

3.2.8 CT scanned comparison of two surfaces of the finished mouthguards.

Five of the thickest and thinnest mouthguards were further analysed by CT scans. This will show a visual representation of the thinning patterns over the whole mouthguard that arise from variations in the fabrication technique. The same CT scanning protocols and settings were the same as used to determine the model accuracy.

The scanned images were transferred for further analysis using Robin's 3D - 3D Editor Software (Robin Richards, London, UK). The image was scaled and the extraneous image noise (unwanted scanned information i.e. the surface the mouthguard was scanned on) was removed using the programs edit suite. Hounsfield threshold of the scanned images was then scaled against the original measurements of the corresponding mouthguard and the image was saved as an STL data file.

The desired STL image was opened in Robin’s Cloud - Polygon Mesh Manipulator program (V3.0.7) (Robin Richards, London, UK), the image was sized and rotated to the desired orientation. A second copy of exactly the same STL image was opened. The surface of interest on the first image was highlighted using the 3D edit function within the program. The foreground was discarded.

In the program's options the 'difference of surface' command was selected “*The difference of surface function calculates the shortest distance of each point on one surface from a second surface”* (Robin Richards, London, UK), which compared the background of the edited image (first) against the foreground of then second image, effectively comparing the fit side of the mouthguard against its outer most surface, giving a single image containing a colour map of thickness of the mouthguard (Figures 3.10 & 3.11). The comparison range on the output image was set at 4.000 mm, as this is the initial thickness of the unformed mouthguard blank. Finally the comparison image output was captured using Photoshop® and saved as a jpeg file.

3.3 STATISTICAL ANALYSIS

Statistical analyses were performed using PASW® Statistics 18 (SPSS Inc., Chicago, IL, USA). Parametricity checks were carried out using the Kolmogorov-Smirnov (for normal distribution) and Levene's (for equal variance) tests. The statistical analyses to identify the variability in mouthguard characteristics within participant groups were tested through computing the Coefficients of Variation and Intraclass Correlation Coefficients (2-way random model, absolute agreement). Between participants groups differences were tested using factorial ANOVA (with appropriate post-hoc Independent Bonferroni corrected 2-tailed *t*-tests). Where data did not obey the parametric assumption, Kruskal Wallis analyses (with appropriate post-hoc Mann Whitney pairwise comparisons) were run. The degree of association between dependent and independent pairs of variables was investigated using correlations (Pearson or Spearman's- depending on whether the data set was parametric or not). Data are presented as Mean ± STDEV, with α set at ≤ 0.05.

3.4 RESULTS

3.4.1 Questionnaire Results.

The questionnaire showed that 70% of the participants generally used 4 mm blanks for their mouthguards, 25% used 3 mm, and only 5% used 5 mm blanks. The vast majority (i.e. 75%) of the participants did not usually laminate the mouthguard material to increase the finished thickness. In total 90% used pressure forming machines to make their mouthguards. Furthermore, 70% of the respondants had 20 yrs or more experience as technicians, Table 3.3. The age of the thermoforming machines ranged from 1-20 yrs with a mean age of 6.6 yrs.

Years of experience	Frequency	Total (%)
6-10	3	15
11-15	1	5
16-20	2	10
21-25	3	15
26-30	5	25
30+	6	30
Total	20	100

Table 3-3: Number of years' experience of each participant.

Research Question: How consistent were the participants at the task of forming mouthguards within and between groups at three anatomical measurement points?

A total of 20 of the 22 boxes were returned completed, which equates to a response rate of 91%.

PARAMETRIC status of data:

The Kolmogorov-Smirnov test showed that the data measurements at sites A and C were normally distributed ($P>0.05$) but not for four participants at site B (5,12-13, & 19). The Levene's test reveals that site A had equal variance ($p > 0.05$) but not sites B ($p = 0.003$) and C ($p = 0.004$).

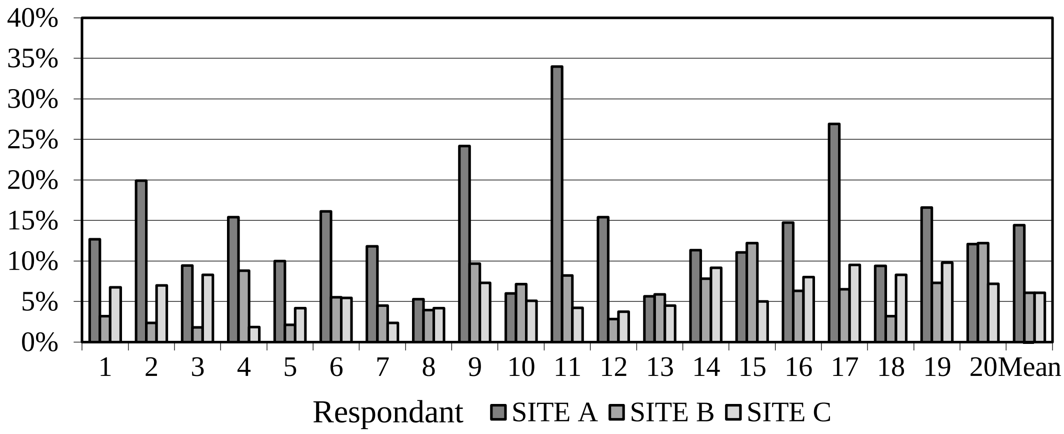


Figure 3-5: Degree of variation in the manufacture of the finished mouthguard thickness between all 5 sample mouthguards within the group, using a Coefficients of Variation (site A = Anterior, site B = Occlusal & site C = Posterior Lingual).

When setting a threshold of 5% for maximal acceptable coefficients of variation in repeated mouthguard manufacture thicknesses (Figure 3.5), it was observed that at Site A, all the participants (to a lesser extent participants 8, 10 & 13) showed a significant degree of variation, with CVs reaching up to 34%. At site B participants 4, 6, 9-11, 13-17, 19-20; and Site C participants 1-3, 6, 9, 10, 14, 16-20; also showed significant variations in manufacturing thicknesses, though variations here were less pronounced than those measured at Site A, reaching 12.2% in Site B and 9.8% in site C respectively. Kruskal Wallis tests was used to compare the mean mouthguard thickness difference observed between participants; this showed that there was a significant participant effect ($p < 0.001$) at all three sites.

Research Question: Did any of the following variables i.e. type and age of thermoforming machine or level of experience of the participant have a significant influence on the finished thickness of the mouthguards?

It was shown that the make/model of the moulding machine and the average mouthguard thickness were not significantly associated, regardless of the anatomical site (A-C) under consideration ($p > 0.05$). Similarly, there was no significant correlation between the approximate age of the forming machine and the finished thickness of the mouthguard ($p > 0.05$). Also there was no significant correlation between the number of years' experience of the participant and the finished thickness of the mouthguard. Between participants at each site, using intra-class correlation coefficient (2 way random model, absolute agreement) there was an interaction effect between participants at each site ($p < 0.05$). In a comparison of the mean thickness between participants, using a Kruskal Wallis main effect tests if data non-parametric. The results showed there was a significant participants effect ($p < 0.001$) for sites A, B and C.

Comparison technician group \ Technician	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
20																				
19																				§
18																			† §	† §
17																			† §	† §
16																			† §	† §
15																		§	† §	† §
14															† §	†	†	†	† §	† §
13															†	†	†	†	† §	† §
12													† §	† §	§	§	† §	† §	† §	† §
11												† §		§		†		§	† §	† §
10												§	†	† §				§	† §	† §
9												§	†	† §					† §	† §
8										§	§	† §	†	†		†			† §	† §
7										§	§	† §	†	†		†			† §	† §
6							§	§					† §	† §				§	† §	† §
5						†	†	†	†	† §		† §			†	†		†	† §	† §
4					†	§	†	†		§	† §	§	†	†	§				† §	† §
3				†	†	† §			†			† §	†	†		†			† §	† §
2				§	†							†	†	† §				§	† §	† §
1				†	†							† §	†	† §		†		§	† §	† §

Technician

[shaded box] Site A – (non parametric) Independent *t*-test (2 tailed) (P<0.05).

† Site B - (parametric) Mann Whitney (2 tailed) (P<0.05).

§ Site C - (parametric) Mann Whitney (2 tailed) (P<0.05).

Table 3-4: Statistical differences between participants at each anatomical site with Bonferroni corrections.

There was a statistically significant difference in mouthguard thickness within and between, subsamples/groups of participants at the assigned measurement points as shown in Figures 3.5-3.8 & Table 3.4. This was observed to a greater extent in the anterior region (Figures 3.5 & 3.6) where the greatest degree of material stretching/thinning was noted.

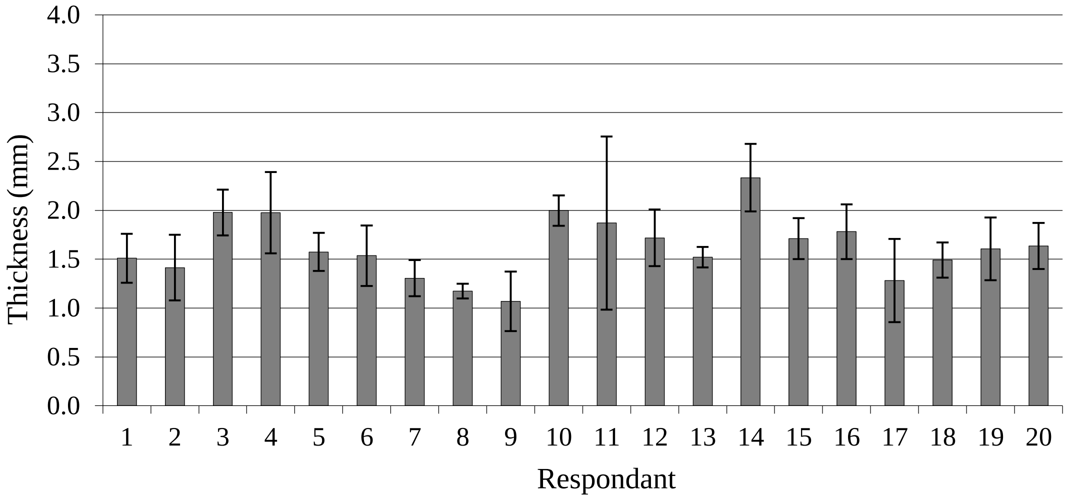


Figure 3-6: Mean finished thickness (mm) of mouthguards, with error bars denoting standard deviation, in the labial anterior sulcus (Site A). Overall group mean thickness 1.62 mm (SD 0.38).

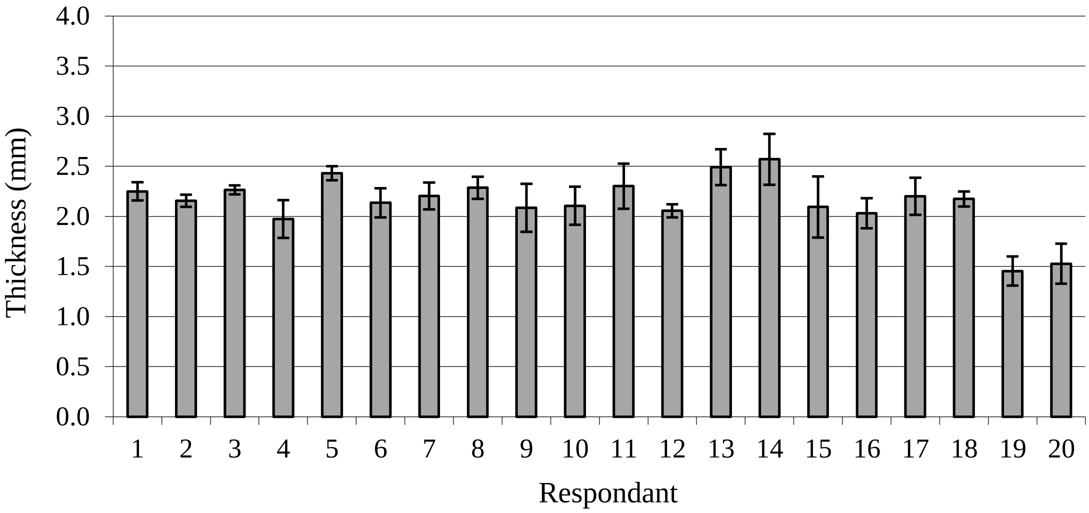


Figure 3-7: Mean finished thickness (mm) of mouthguards, with error bars denoting standard deviation, at the occlusal anterior lingual cusp of the first upper right molar (Site B). Overall group mean thickness 2.14 mm (SD 0.29).

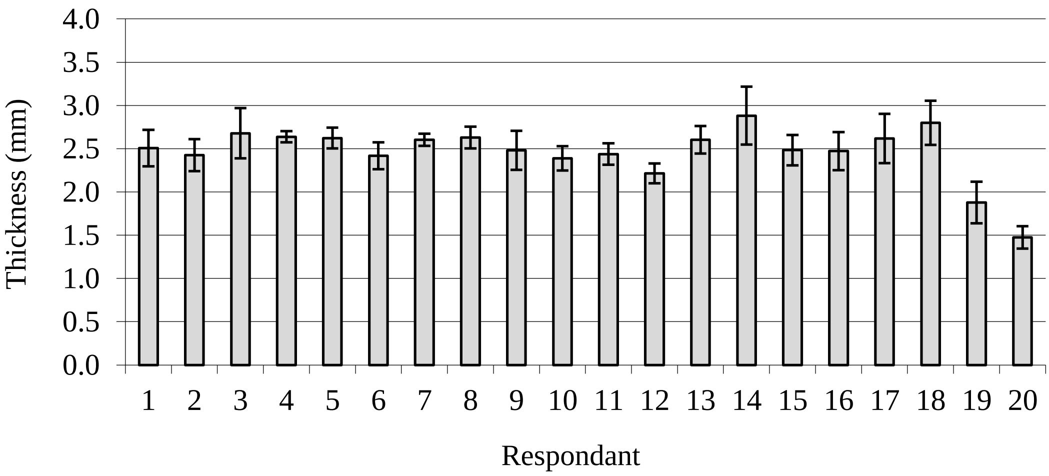


Figure 3-8: Mean finished thickness (mm) of mouthguards, with error bars denoting standard deviation, at the lingual sulcus (Site C). Overall group mean thickness 2.46 mm (SD 0.34).

Some participants showed greater consistency within their group than others, (e.g. respondents 3 and 10), when measuring the finished mouthguards in the anterior region (Figures 3.5 & 3.6). At the other end of the consistency spectrum, there were some with higher variability in mouthguard manufacturing whilst using the same model, material and machine. A case in point was respondent 11 who showed a 63% thickness variation (Figure 3.6). The mean thickness of the mouthguards, from all samples, in the anterior region was 1.62 ± 0.38 mm with a range of 0.77-2.80 mm. The reduction in thickness on forming from 4 to 0.77 mm, in the most extreme case represents an overall thinning of 81%. From this cohort 52% had a greater material thinning than 1.62 mm at the anterior region measurement point, with the mean thickness equating to an overall thinning of 59.5% in a single 4 mm EVA blank.

3.4.2 Comparison of measurement techniques, CT scan against calliper results.

For study validity and calibration both measurement techniques; CT scanned images and calipers were compared against each other, Table 3.5, to observe the degree of accuracy of each system.

Mouthguard Code	Point A Scan (mm)	Point A Gauge (mm)	Difference (mm & %)	Point B Scan (mm)	Point B Gauge (mm)	Difference (mm)	Point C Scan (mm)	Point C Gauge (mm)	Difference (mm)
G14 M1	2.73	2.33	0.40 (14.6%)	2.72	2.47	0.25 (9.1%)	3.15	3.17	-0.02 (-0.6%)
G14 M2	2.56	2.37	0.19 (7.4%)	2.86	2.91	- 0.02 (-1.7%)	2.83	2.78	0.05 (1.7%)
G14 M3	2.79	2.75	0.04 (1.4%)	2.88	2.49	0.39 (13.5%)	2.88	2.88	-0.00 (0%)
G14 M4	2.27	2.16	0.11 (4.8%)	2.76	2.58	0.18 (6.5%)	3.23	3.08	0.15 (4.6%)
G14 M5	2.30	2.06	0.24 (10.4%)	2.69	2.40	0.29 (10.7%)	2.51	2.50	0.01 (0.3%)
G9 M1	1.19	1.25	-0.06 (-2.7%)	2.12	2.22	- 0.10(-4.7%)	2.48	2.46	0.02 (0.8%)
G9 M2	1.65	1.42	0.23 (13.9%)	1.97	1.77	0.20 (10.1%)	2.35	2.25	0.10 (4.2%)
G9 M3	0.99	0.88	0.11 (11.1%)	2.72	2.25	0.47 (17.2%)	2.95	2.62	0.33 (11.1%)
G9 M4	0.94	0.81	0.13 (13.8%)	2.42	2.00	0.42 (17.3%)	2.63	2.38	0.25 (9.5%)
G9 M5	0.97	0.98	-0.01 (-1.0%)	2.34	2.19	0.15 (3.4%)	2.80	2.70	0.10 (3.5%)
Mean (mm)			0.14 (7.3 %)			0.22 (8.1 %)			0.09 (3.5 %)

Table 3-5: Comparison between the two measurement techniques (callipers and CT scan) of the five thickest and thinnest mouthguards.

There was a mean combined measurement point difference of 0.15 mm (6.3%) between the CT scan and digital calliper technique as shown in Table 3.5 and illustrated in Figure 3.9.

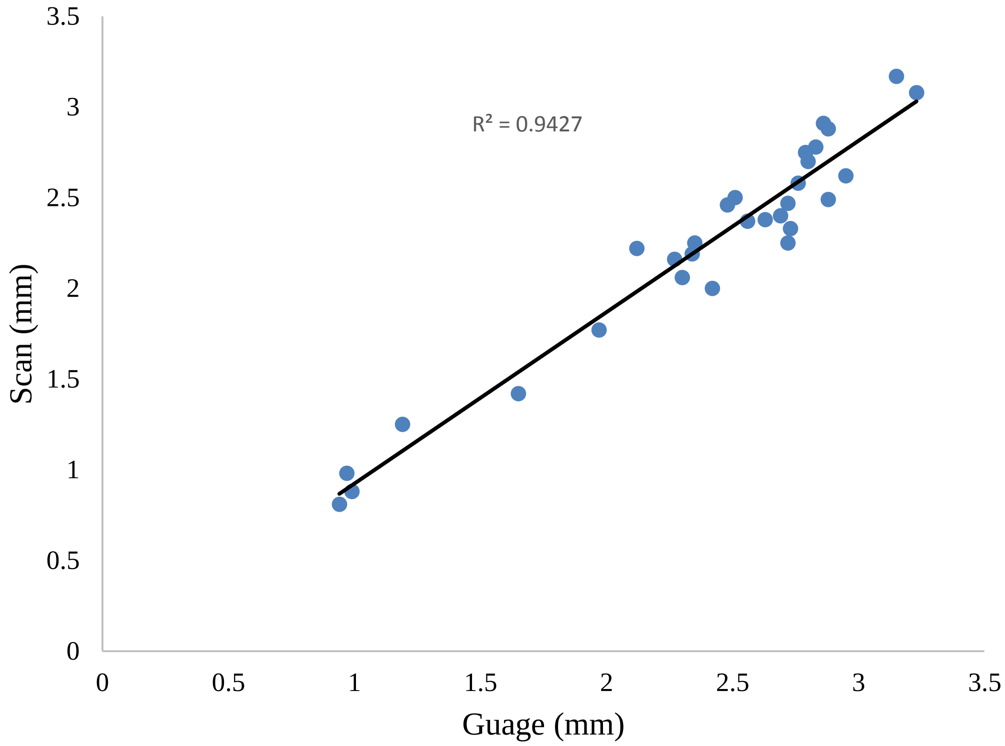


Figure 3-9: A calibration chart showing the measurement discrepancies between the measurement techniques used, CT scan and digital gauge.

3.4.3 CT scanned images of both the thickest and thinnest mouthguards.

The scanned images act as a visual assessment tool for the thickness patterns observed over the whole of the finished mouthguard, not just at the pre-selected measurement points. The blue/green colour denotes 1 mm+/-

and the orange/red colour denotes 3-4 mm as shown on the measurement range bar at the bottom of each image (Figures 3.10 & 3.11). Figure 3.10 show an example of the thinnest anterior labial flange of the mouthguards which is shown in green, denoting the material has thinned to less than 2 mm, which fully concurs with the previous gauge measurements. This means the mouthguard could have lower levels of protection to the individual at this point. The section labial to the anterior teeth in most of the anterior view is yellow, indicating the material is 2 mm or above. Figure 3.11 shows an example of the thickest mouthguard, there was a marked colour change towards the yellow to red spectrum in the anterior region, showing the mouthguard thickness increasing towards 3 mm around the anterior teeth. The occlusal surface of this second set of images has a greater proliferation of red and darker (Black) sections, where it forms into the deeper fissures of the posterior teeth, indicating the mouthguard is thicker in these sections also.

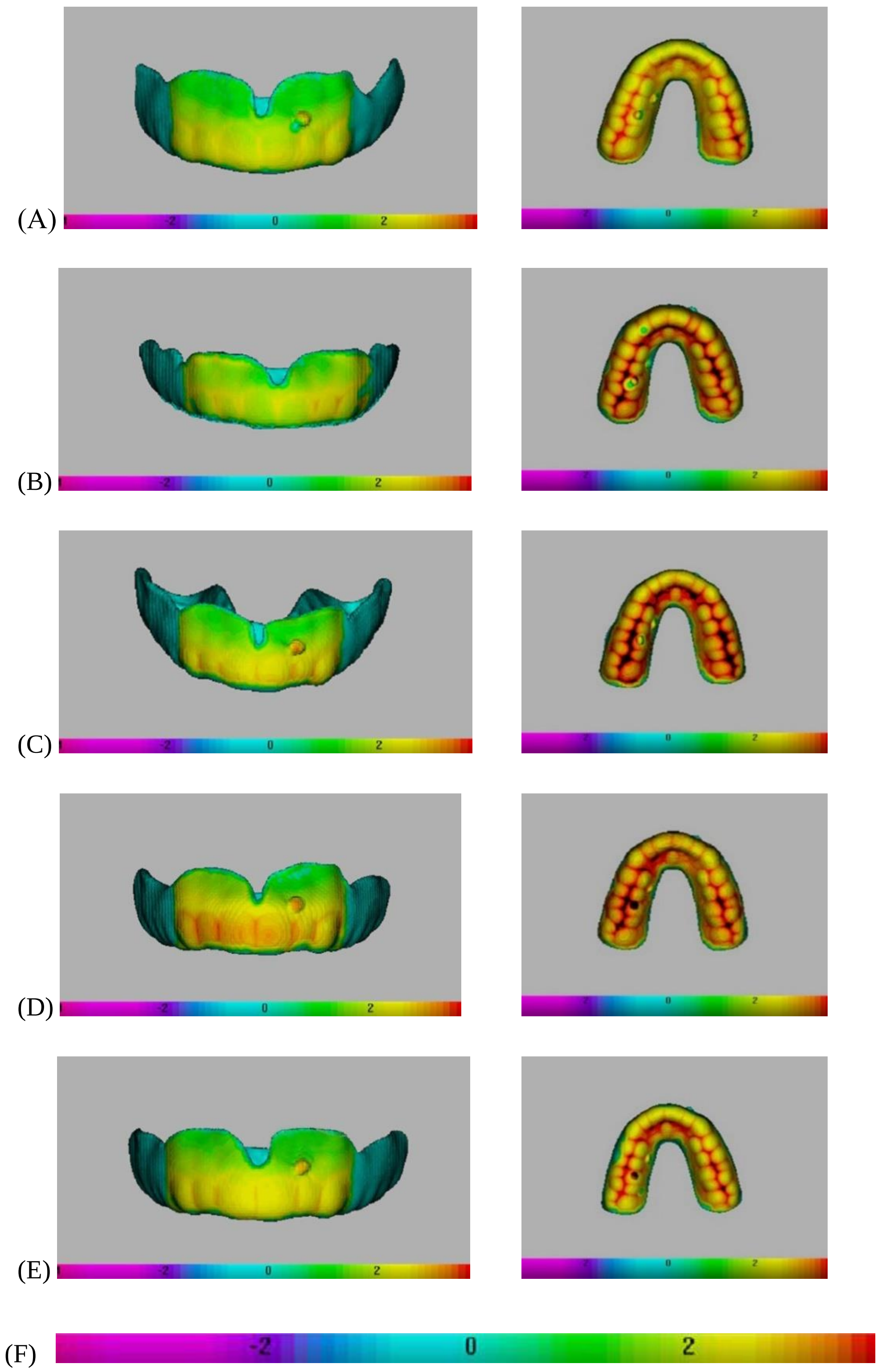


Figure 3-10 A-E: CT scanned images of the two surface areas within the five thinnest mouthguards. (F) Shows an enlarged thickness/colour key, 0 mm to ± 4 mm.

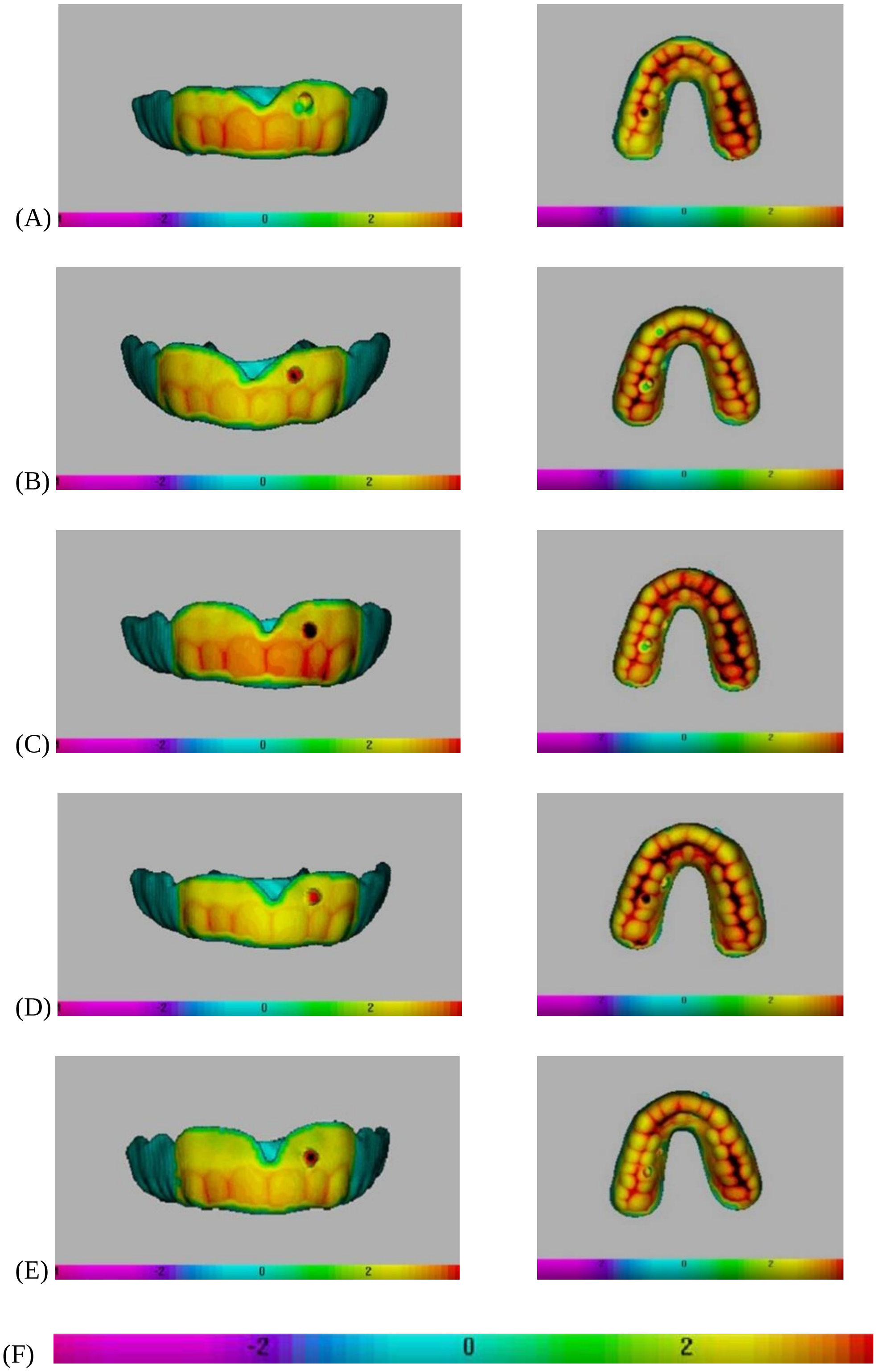


Figure 3-11 A-E: CT scanned images of the two surface areas within the five thickest mouthguards. (F) Shows an enlarged thickness/colour key, 0 mm to ± 4 mm.

3.5 DISCUSSION

The CT scan results showed that there was a small difference of +\- 0.2 mm between the sample of duplicate models. This is not a major significance as there is a commonly accepted shrinkage and expansion distortion, respectively, with duplication of dental models (O'Brien, 2002, Anusavice and Phillips, 2003). There were three modes of measurement employed for this study, digital engineering gauge, plot points from CT scans and visual analysis of the images of the CT scan, giving unique thickness morphology over the whole surface of the mouthguard. The initial measurements were taken using the calibrated digital gauge at the three predetermined anatomical sites, the gauge gave an accuracy of 0.01 mm. Care was taken to calibrate the digital gauges between each measurement. CT scans were carried out on the five thinnest and five thickest groups for further analysis. CT scanning of all 100 mouthguards would have been very expensive, thus it was chosen to have mouthguards from both ends of the dimensional spectrum. The CT plot point scans when compared against the initial gauge measurements were comparable to a mean of 0.15 mm (SD: 0.15). Finally, the CT scans were converted to a colour image map of the thicknesses of each of the finished mouthguards. This gives a greater picture of the material thinning observed over the whole of the mouthguards and not just at the three preselected measurement points, thus allowing a greater visual analysis of material thinning patterns.

The main focus of the current study was to investigate consistency/variability in the thermoforming procedure in relation to dimensional characteristics. The additional aim being to ascertain which parameters would be associated with decreased reproducibility in the thermoforming procedures either machine or human-related. The participants were left to prep the models as they would normally. Most participants did not prep the model, only one participant using a vacuum forming machine drilled a hole in the base of the models. This technique has been reported to increase the vacuum pressure to inaccessible regions of the dental model i.e. the palatal volt (Naval Education and Training Professional Development and Technology Center, 1999). The current study showed 52% of the 100 mouthguards had a greater material thinning of 1.62 mm at the anterior region measurement point, with the mean thickness equating to an overall thinning of 59.5% in a single 4 mm laminate blank. A single 4 mm blank was used to see thickness changes at the lower end of the mouthguard thickness spectrum. Excessive thinning may be addressed by the use of a lamination technique, whereby two or more layers of mouthguard materials are bonded together to create a thicker finished blank, with the aim of absorbing greater energy (Patrick et al., 2002, Westerman et al., 2002a). This study showed that the majority (i.e. 75%) of the participants did not usually laminate the mouthguard material to increase the finished thickness of the mouthguard. Westerman et al, (2002a) found that a 1 & 2 mm thickness of EVA offered little/lower protection with regards to energy absorption. Indeed they reported that with 2 mm, transmitting 15.70

kN, this was more than three times less effective as the 4 mm material, that transmitted only 4.38 kN. The same study observed that there was only a marginal increase in material performance, i.e. force transmission, through increasing the material thickness beyond 4 mm, with 5 and 6 mm blanks reducing transmission forces to 4.03 kN and 3.91 kN respectively. Thus, with the results obtained from this study, if sport-induced impact occurred, and was to be greater than the above values then the material might not absorb the full impact and the potential occurrence of fracture/periodontal injury risk could be increased within these individuals if the guard was made from a single 4 mm EVA blank.

The results showed notable variability in the manufacturing of custom-made mouthguards in relation to a single 4 mm blank, in particular with respect to thickness, in the anterior region, both within and between participant groups as shown in Figures 3.5, 3.6 & Table 3.4. The greatest degree of material thinning and thickness inconsistency was observed in the anterior sulcus region of the finished mouthguard (Figures 3.6 & 3.10). The occlusal and posterior lingual regions were much less of a problem (Figures 3.7 & 3.8). This study found there was up to an 81% thinning of the processed mouthguard material in the most extreme case, from 4 to 0.77 mm. This degree of thinning is marginally higher than that described in the study by Geary et al, (2008) who reported thinning of 72% when using a 3 mm mouthguard blank. The mean thickness of the mouthguards, from all samples, in the anterior region, was 1.62 ±0.38 mm with a range of 0.77-2.8 mm. At

1.62 ± 0.38 mm the mean degree of thinning would be 59.5% of the original blank thickness of 4 mm, which is similar to studies by Del Rossi et al (2007) who reported thinning as high as 60% in the labial surface of the incisal and canine dention, when using 3 mm mouthguard blanks. Geary et al, (2008) reported thinning in the anterior labial sub gingival region of 49%, which is a comparable measurement point to the anterior site as used in this study. They also recorded thinning as high as 72% in the incisal region using 3 mm blanks (Geary and Kinirons, 2008). However, within the present study, 4 mm blanks were used showing that even the thicker blanks still have significant variations in thinning. The study showed that 70% of cohorts commonly used 4 mm blanks for their mouthguards either for single or dual laminate guards this is in accordance with the earlier personal communication with dental material suppliers. However, studies by Geary et al, (2008) and Del Rossi et al, (2007) used 3 mm blanks, as their personal preference.

When researching for the ideal mouthguard thickness with regard to mouthguard protection against impact forces, a number of papers advocate the use of a 4mm thickness of EVA as providing the most comprehensive protection without compromising functionality (Westerman et al., 2002a). However the test samples derived at, were of 4 mm thick piece unformed material, which inherently has different properties than a post formed blank (Patrick et al., 2006). Patrick et al, (2006) showed a significant difference in impact properties between processed and unprocessed EVA mouthguard material. Their results showed there was a greater degree of displacement (centre) observed in the heat treated EVA sample – 30 mm, on impact testing, when compared to untreated EVA -18 mm. They also recorded a reduction in peak impact force in the heat treated EVA sample <140 N from 160 N for the untreated sample. Many studies, for simplicity, have used unprocessed mouthguard material as part of their study design, Patrick et al, (2006) stated their results could be misleading due to the differing properties of unprocessed material properties. Their study showed by the use of photoelastic analysis, that when the mouthguard blank was received from the supplier there is an inherent internal stresses, simply by heat treating the blank to its thermoforming temperature of 84±3 ºC for 10 mins, these stresses can be virtually eliminated. This disparity in the reporting on ideal thickness of mouthguard from published works, whereby some papers are reporting unprocessed material thickness and others are reporting on the finished mouthguard can be confusing. Once the material has been formed and has been subject to the inherent thinning observed as part of the process in this study, it will be a fraction of the initial thickness and the uniform unprocessed material and therefore unrepresentative of its actual usage. All mouthguard thickness recommendations should only be reported as finished processed material thicknesses.

3.5.1 Factors that may affect mouthguard material thinning.

Another key novel aspect of the present study design was the large sample size in terms of participants and the total number of formed mouthguards. In general, most earlier studies the mouthguards were formed by an individual study investigator (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Mizuhashi et al., 2012, Mizuhashi et al., 2013a, Mizuhashi et al., 2013b, Takahashi et al., 2013a, Takahashi et al., 2013b). This study incorporated participation from twenty GDC registered dental technicians, which is more representative of the current mouthguard production market. To add to which, the participants were requested to complete an accompanying questionnaire, which collected data on participants individual material thickness preference, the age/make/type of forming machine used, the participants level of experience (in numbers of years in practice), which may have had a bearing on the finished thickness of the mouthguards.

The age of the thermoforming machines ranged from 1-20 years. This is relevant as in most cases the thermoforming machine uses a halogen heater to heat the blank. Over time the heaters may become less efficient and may not heat the blank evenly. Pressure forming machines are shown to be the most widely used to make mouthguards even though they are the most expensive to purchase. Only two of the twenty-strong cohort used vacuum forming machines making a true statistical comparison unfeasible with regard to a comparison between vacuum and pressure forming machines. Statistically there were no correlations between the thickness of the finished mouthguard and either the years of experience of the participant or the age, make or type of machine used. Accepting this, other possible reasons for the observed discrepancies within groups could be: different positioning of the models i.e. orientation, as discussed previously in a study by Geary et al, (2008), and/or distance from the heat source, fluctuations in environmental temperature i.e. open window cooling the blank or technique.

Some of the more modern machines (such as Dreve-Drufomat Scan) that are used to blow down mouthguards utilise scanning technologies whereby the bar code from the box of the material can be scanned by the machine. This code sets the controls/times on the machine to the settings specified by that give material manufacturer, an audible marker sounds when the material is ready to be formed, with the intent of maximising the materials properties and reducing the anomalies of manufacture that may occur due to operator interpretation.

The level of experience of participants ranged from 6-30+ yrs; arguably it might have been assumed that with greater experience one would have seen less variation. Indeed, statistically there was no significant difference ($p > 0.05$) between the levels of experience of the groups of participants in this task. It could therefore, be proposed that the reason for this lack of influence of number of years' experience on the participants results may be that different participants will allow the material to heat for indeterminate amounts of time and showing technique being a factor. Consequently, since the amount of time heating correlates to the degree of sag (amount the heated blank is allowed to slump), ultimately this will have impacted on the degree of thinning of the material prior to forming.

The present study showed that 70% of respondents used 4 mm mouthguard blanks for construction of their custom-made mouthguards. Following the inherent thinning observed in the processing of the given cohort 52% had a greater material thinning of 1.62 mm within the anterior region point and an overall thinning of 59.5% in a single 4 mm laminate blank. All in all the present study shows the differences in consistency within, and between, groups of participants in the manufacture of this single custom made mouthguard (Figures 3.5, 3.6 & Table 3.4). This degree of material thinning is comparative to that of previous researchers. The mean thickness obtained from the anterior measurement of all the sample mouthguards was 1.6 mm, this measurement value will be used in Chapter 5 of this study.

3.6 CONCLUSION

The current production methods showed 52% of produced mouthguards had a material thinning greater than 1.62 mm within the anterior region point, and an overall thinning of 59.5% for a single laminate 4 mm mouthguard blank, at the chosen point at the anterior sulcus, irrespective of the participant's level of experience or type/age of the thermo-forming machine. It is recommended that prior to any mouthguard being sent to the dentist, it should be measured in the thinnest section of key anatomical points, i.e. anterior sulcus. The dental technology community also needs to be aware of these issues in relation to the thermoforming technique, and not take it at face value that the mouthguard's thickness would be consistent throughout the manufacturing process. This recommendation applies regardless of the initial thickness of the blank as there are variations within the degree of thinning between individuals. Differences in thickness may affect the absorption of force to the guard (Tran et al., 2001, Westerman et al., 2002a, Patrick et al., 2005). However, it must be emphasised here that any form of mouthguard protection regardless of thickness is better than wearing none at all even with the lower levels of thickness (Hoffmann et al., 1999, Maeda et al., 2009, Ozawa et al., 2014). Also, as previously suggested by Patrick et al, (2005) a grading, based in part on the thickness of the finished mouthguard whether by lamination, design or blank selection, could be awarded to the mouthguard as to the level of protection the mouthguard affords to an individual's chosen sport. This study highlights, the need for a definitive and readily available guide for both the dentists and members of the public, to show the correct thickness of mouthguard, so that an informed decision as to the adequacy of the mouthguard to perform the expected function in relation to the selected chosen sport.

This chapter demonstrated that the excessive thinning of the finished mouthguard is predominantly in the labial flange, as previously shown within previous published studies. Technique plays a key part thus by tilting the anterior section of the model would inevitably increase the thickness at this point. Thus, the following chapter will examine how by altering the forming machine plate by varying degrees i.e. 15°, 30° & 45° would reduce the amount of material thinning, as observed in this current study with the same 4 mm blank thickness to make a comparative analysis.

Chapter 4: An Investigation into the Degree of Model Inclination on Custom Made Mouthguard Thickness.

4.1 Introduction

The primary function of a mouthguard is to protect the dentition and some of the surrounding structures from violent traumatic impacts during sporting activities (Finch et al., 2005, Patrick et al., 2005, Maeda et al., 2009). Of all the types of mouthguards, stock, boil & bite and custom-made, it has been proposed that custom mouthguards provide a superior fit (Patrick et al., 2005). However, in the process of construction, when forming the mouthguard material over the dental model thinning occurs (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Takahashi et al., 2013a) which was also reported in Chapter 3 of thesis. A common site of excessive material thinning has been reported in the anterior region of finished custom-made mouthguards, using current single layer techniques (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Maeda et al., 2009, Takahashi et al., 2013a).

Reduction in thickness of EVA has been shown to affect the ability to dissipate impact forces, as it has been shown that there is a direct correlation between material thickness and attenuation of force (Park et al., 1994, Westerman et al., 2002a). Westerman et al, (2002a) found that both 1 mm and 2 mm thickness of unformed ethylene vinyl acetate (EVA) offers lower protection in relation to energy absorption. They reported that a 2 mm thickness of mouthguard material was more than three times less effective of absorbing force than a 4 mm piece of material, (15.70 kN in comparison to 4.38 kN). Increasing the material thickness beyond 4 mm, with 5 and 6 mm blanks reducing transmission forces to 4.03 kN and 3.91 kN respectively, showing marginal differences and hence evidence of a plateau occurring in relation to force absorption.

Del Rossi et al, (2007) and Geary et al, (2008) observed material stretching and thinning of EVA when forming over the dental cast. Del Rossi et al, (2007) examined model height and jaw size from impressions taken of the maxillary dentition of fifteen subjects. For each subject three duplicate models were fabricated, and model heights created of 20 mm, 25 mm, and 30 mm. A single 3 mm mouthguard blank was formed over each testing condition, and measurements were taken. In the anterior and canine region of the mouthguard they observed a mean material thinning of: 47% (mean thickness 1.6 mm) with the model at 20 mm in height, 53% (mean thickness 1.4 mm) at 25 mm and 60% (mean thickness 1.2 mm) at a model height of 30 mm. At the molar cusp measurement point, the thickness was reported as 1.6 mm and independent of all three model heights. Their findings suggested, as the model gets higher, the mouthguard material thins' in the labial (incisal) region thus to reduce these factors the model height should be kept as low as possible.

Geary et al, (2008) examined more widely the variations in the manufacturing process that may cause stretching (thinning) of the EVA material, i.e. model height, shape, position on thermoforming platform, plasticizing time and dental model inclination. With relation to model height, Geary et al, (2008) observed when the model height was increased from 25 to 35 mm there was an additional thinning of the EVA material of 21% (from 1.53 to 1.21 mm) when using a 3 mm blank. This translates to an overall thinning of the material e.g. in the case of the 25 mm model height a mouthguard material thinning to 1.53 mm or by 49%, and with the model height at 35 mm with a material thinning of 1.21 mm or by 60%, this is comparable to findings observed by Del Rossi et al, (2007) previously mentioned. Geary et al, (2008) also altered the dental model position on the mounting platform (insert bowl) from the centre (1.53 mm), with the labial and then the distal aspects of the model placed on the outermost edge of the mounting platform, in two separate testing conditions. They observed that the model position on the mounting platform significantly ($p < 0.01$) increased the stretching of the mouthguard material, from 3 mm to a mean of 1.53 mm for the control (centred model) and 1.31 mm for the model at the edge of the mounting platform, which represents a 49% and 56% material thinning respectively. Geary et al, (2008) studied the heating of the EVA material during the thermoforming process with regards to material thinning. They reported that by increasing heating time by 30 seconds, the amount of thinning in the material was in fact reduced, theorising that the EVA material transforms from its elastic plasticised state to its plastic state, on contact with the dental model, earlier than it would have with a shorter heating time.

A number of studies have investigated variations in heating conditions, in relation to mouthguard thinning, when using a vacuum forming machine (Mizuhashi et al., 2013a, Takahashi et al., 2013b, Mizuhashi et al., 2014). Here, the mouthguard material is heated on both sides prior to forming (Takahashi et al., 2013b, Mizuhashi et al., 2014), the distance from the heat source is increased (Takahashi et al., 2013b) and the heat source is turned off for a short duration prior to forming (Takahashi et al., 2013b) and the mouthguard material is lowered over the model in two test conditions: (a) before (b) after the vacuum in applied (Mizuhashi et al., 2013a). Mizuhashi, Koide & Takahashi (2013a and 2014) reported no significant change ($P > 0.05$) in finished mouthguard thickness in the anatomical measurement sites of interest, i.e. anterior (central incisor) and posterior (first molar), regardless of the thermoforming conditions. However, these authors did report a *"superior fit"* and retention of the mouthguards, using the following adaptions to recommended heating methods: when the vacuum is applied before the mouthguard material is lowered over the dental model (Mizuhashi et al., 2013a), when the heated surface comes in contact with the surface of the dental model, in the case of the material being heated to a 1.5 cm sag on both sides prior to forming (Mizuhashi et al., 2014), and the mouthguard blank is lowered 50 mm from the heat source than ordinarily used, when the blank reaches a 10 mm sag, the heat source is turned off until the blank reaches a 15 mm sag before forming. Takahashi et al, (2013b) hypothesised by slightly lowering the mouthguard material from the heat source, this would create slower raise in material temperature which leads to a more uniform softening of the mouthguard blank prior to forming, their results reported this final test condition also had a 26% reduction in thinning, when using a 4 mm mouthguard EVA blank.

As variations in model height and heating methods have been previously examined, the present study investigated how manipulation of the inclination of a dentate model would modulate the distribution of the EVA material which was visually seen by CT scanning. It was hypothesised that by systematically increasing the anterior angulations of the dental model during the thermoforming process, there would be an increase in the thickness of the anterior sulcus section throughout the mouthguard which could increase the impact protection.

4.2 MATERIALS & METHOD.

Ethical approval was sought and obtained prior to commencement of the study, from the ethics committee at the Department of Exercise and Sport Science, Manchester Metropolitan University (MMU Ethics Code:18.12.09).

The same master models were used in this study, as used in Chapter 3 for continuity. The models were duplicated using the same principles and there reproduction accuracy was checked as per procedures within Chapter 3 producing 60 identical dental models. A total of 60 mouthguards were segregated into four inclination conditions (n=15 per group) which consisted of 0° (flat), 15°, 30°, & 45°. The mouthguards were fabricated using 4 mm thick, EVA, 120 mm Ø (diameter) clear mouthguard blanks (Bracon Dental Laboratory Products, East Sussex, UK). A Drufomat Scan (Dreve Dentamid GMBH, Unna/Germany) was used for the pressure thermoforming process. This was used due to its audible marker that indicates when the mouthguard is to pressure formed. This feature gives the study consistency as each blank is heated and blown down at the same point in time, thus reducing variability and potential error.

4.2.1 Fabrication of Angle Blocks.

Angulation blocks were fabricated using vacuum mixed Crystical R dental stone (BPB Formula, Nottinghamshire, UK). These were then trimmed on a Wehmer trimming machine (Model 108; Wehmer corporation, IL, USA), which is often used for orthodontic study models, due to the precision calibrated engraved protractor on the trimming table and an angulation tool for precision trimming of dental stone. The blocks were trimmed to gradients of 15°, 30° and 45° (Figure 4.1), and then inserted into the machine as shown in Figure 4.2. The angulation blocks inclinations were checked using a Cephalometric protractor/template (Ortho-Care Ltd, West Yorkshire, UK).

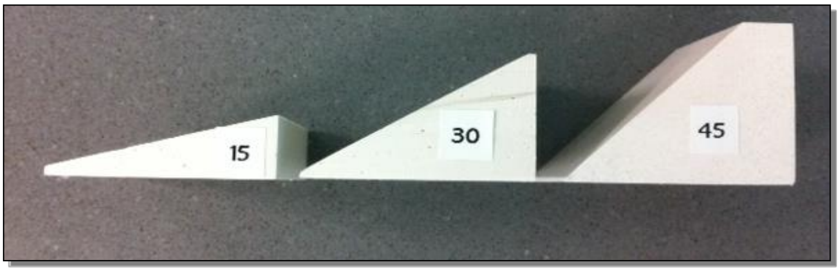
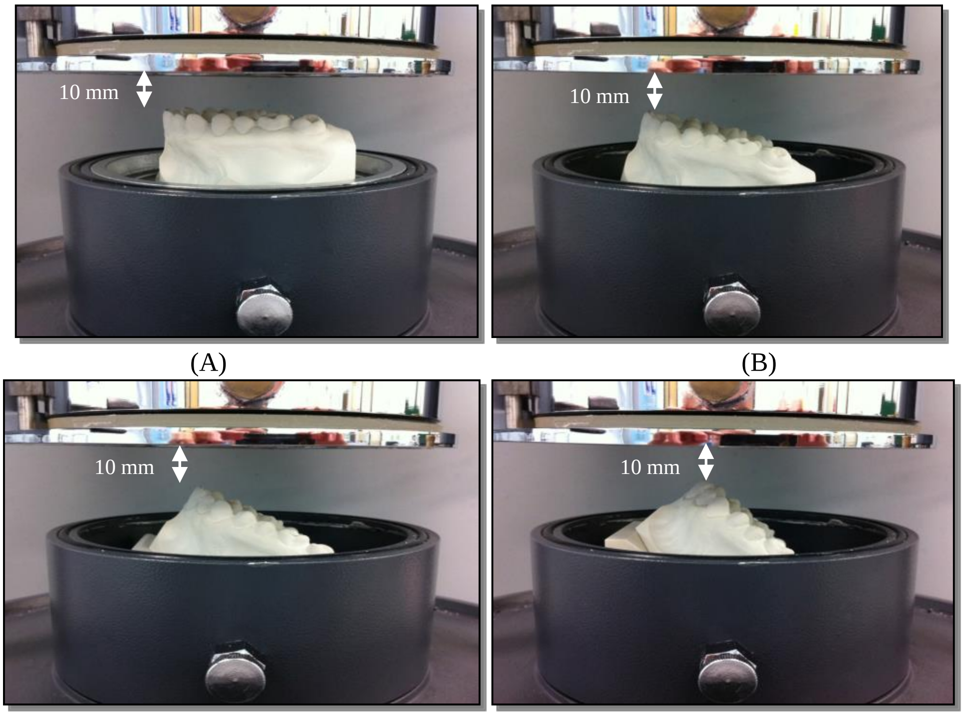


Figure 4-1: The gradient angulation blocks (15°, 30°, & 45°) used to incline the anterior section of each of the dental models.

The insert bowl on which the model is normally placed during the forming process was removed to allow for the rotation of the model by 15°, 30°, and 45°, as the current system did not allow enough depth for inclination of the anterior section. For the purpose of this study, three removable plates were cast (Crystacal R) into the base of the “F insert” vessel, to form a stable base on which the models and angulation blocks could be seated. The new plates were made to heights of 27 mm for the 15º, 16 mm for the 30º and 12 mm for the 45º. Thus accommodating the rotation of the model in the “F insert”, creating a constant 10 mm gap for each testing procedure between the incisal tip of the dental model and the underside of the “plate reception” (Figure 4.2).



(A) (B) (C) (D)

Figure 4-2: Dental model flat on the “cone plate” prior to forming (A). Images B-D show the dental model held at a 15°, 30° & 45° angles, respectively, in the “F insert” using the modified plate and angle blocks with 10 mm gap between incisal tip and plate.

Care was taken not to cover the vent hole in the F insert, which allows the air to escape during the thermoforming as this may alter the function of the pressure forming process. All models were treated with an isolating layer of sodium alginate (Isolant Cold Mould Seal, Dentsply, DeTrey GMBH, Germany) prior to forming the mouthguard, to allow easier removal of the formed EVA blank from the dental model once cooled.

The Drufomat Scan provides a barcode programing system that stipulates material specific heating and cooling times, dependant on blank thickness. Amongst the available settings, the 'Drufosoft 4,0' program was selected, which involves 2.10 mins heating, 7.00 mins cooling at a 4.5 bar pressure, as it was comparable to the size and thickness of the 4 mm blank selected for this study. The audible beep by the machine indicated when to apply the pressure and how long to leave the mouthguard material to cool prior to releasing the pressure. All test samples were produced by the same operator and thermoforming machines manufacturers suggested program (as detailed above) to minimise any potential errors and variability during the forming process.

4.2.2 Dimensional Measurements

Reference point.	Anatomical measurement site of each reference point.
Point A	The upper anterior labial sulcus, at a point 5mm, perpendicular to the occlusal plane, in line with the gingival, located at the interdental space between the upper permanent central and lateral.
Point B	The apex of the upper mesio-palatal cusp of the first upper right permanent molar.
Point C	The upper palatal aspect, at a point 5mm, perpendicular to the occlusal plane, in line with the gingival, between the first and second permanent premolars.

Table 4-1: Descriptions of anatomical measurement reference points (Points A-C).

An electronic calliper gauge (External Digital Caliper 442-01DC Series, Moore & Wright, UK) was used to measure the thickness of the finished mouthguards. This type of gauge was chosen for ease, and level of range of action, giving viable access to the occlusal cusp areas of the mouthguard. The callipers had a range resolution of 0.01 mm. Each anatomical point on the mouthguard, Table 4.1, was measured three times for consistency with a mean value obtained the same as those reported in Chapter 3. After each measurement the gauge was zeroed. Callipers were calibrated by the use of a 4 mm steel calibration block, grade 1, ISO-DIN-BS (Cen Dev µm +0.02, Max

Dev +0.02, Min Dev -0.11, Variation 0.13) (Alan Browne Ltd) and were used at every measurement session to check the accuracy of the gauges.

4.2.3 CT Scans

A mouthguard from each condition (Control, 15º, 30º & 45º) was scanned using a CT scanner (Make & Model: Scanner: GE medical Systems.) (Light Speed 16, Mode of Capture – Helical, Gantry Tilt – 0, Voxel Size – 0.7031 × 0.7031 × 0.5, Matrix Size – 256 × 256 × 97, KV – 120, Ma – 90, Reconstructed in 0.625 mm axial slices). The scanned images were then transferred for further analysis using Robin's 3D - 3D Editor Software (Robin Richards, London, UK). Each image was scaled and the extraneous image noise (unwanted scanned information i.e. the surface the mouthguard was scanned on) from the image was also removed using the program's edit suite. The Hounsfield threshold of the scanned images were then scaled against the original measurements of the corresponding mouthguard, and the image was saved as an STL data file. The desired STL image was opened in Robin's Cloud - Polygon Mesh Manipulator program (V3.0.7). The image was sized and rotated to the desired orientation. A copy of each STL image was simultaneously opened. The surface of interest on the first image was highlighted using the 3D edit function within the program, and the foreground discarded.

Difference of surface command compared the background of the edited image (first) against the foreground of the second image, effectively comparing the fit surface of the mouthguard against its outer most surface, giving a single image, containing a colour map of thickness of the mouthguard (Figure 4.6). The comparison range on the output image was set at 4.000 mm. Finally, the comparison image was captured using Photoshop® and saved as a JPEG file. Figure 4.6 served purely as a visual comparison of the thickness changes over the whole of the anterior section of the mouthguard in each testing condition.

4.3 STATISTICAL ANALYSIS

Statistical analysis was performed using PASW® Statistics 18 (SPSS Inc., Chicago, IL, USA). Sphericity checks were carried out using the Mauchly's test and Greenhouse-Geisser corrections applied where the assumptions were violated, i.e. sphericity not assumed. To identify any impact of dental model anterior inclination on the variability in mouthguard thickness, a repeated measures ANOVA was performed at each discrete anatomical measurement site. Post-Hoc pairwise comparisons, with Bonferroni corrections, were carried out where a main effect was identified. Data are presented as mean ± STDEV unless otherwise specified. Statistical significance was accepted at $\alpha \leq 0.05$. Z-score analyses were also carried out on the outliers in Figures 4, 5 and 6.

4.4 RESULTS

4.4.1 Gross measurements

Model angle (degrees)	n	Mean Anterior sulcus thickness (mm (SD))	Mean Occlusal thickness (mm (SD))	Mean Posterior Lingual thickness (mm (SD))
0°	15	*1.6 (0.34)	*2.2 (0.09)	*2.5 (0.21)
15°	15	*2.1 (0.10)	1.8 (0.06)	2.3 (0.18)
30°	15	*2.4 (0.14)	1.9 (0.15)	2.1 (0.14)
45°	15	*2.8 (0.16)	*1.5 (0.10)	*1.6 (0.15)

∗ Significantly different ($P < 0.05$).

Table 4-2: Mean thickness of the formed mouthguards at each anatomical site. Site A: Anterior sulcus thickness, Site B: Occlusal thickness, Site C: Posterior lingual thickness.

Anterior Section (Site A, Table 4.1):

The results showed that there was a highly significant difference, ($p< 0.0001$), in anterior mouthguard thickness, between the varying degrees in anterior inclination of the dental model (Figure 4.3). Post-hoc pairwise comparisons showed a significant difference greater than $p< 0.005$ in the anterior mouthguard thickness, between all four groups, when inclining the anterior region dental model by 15°, 30° and 45°.

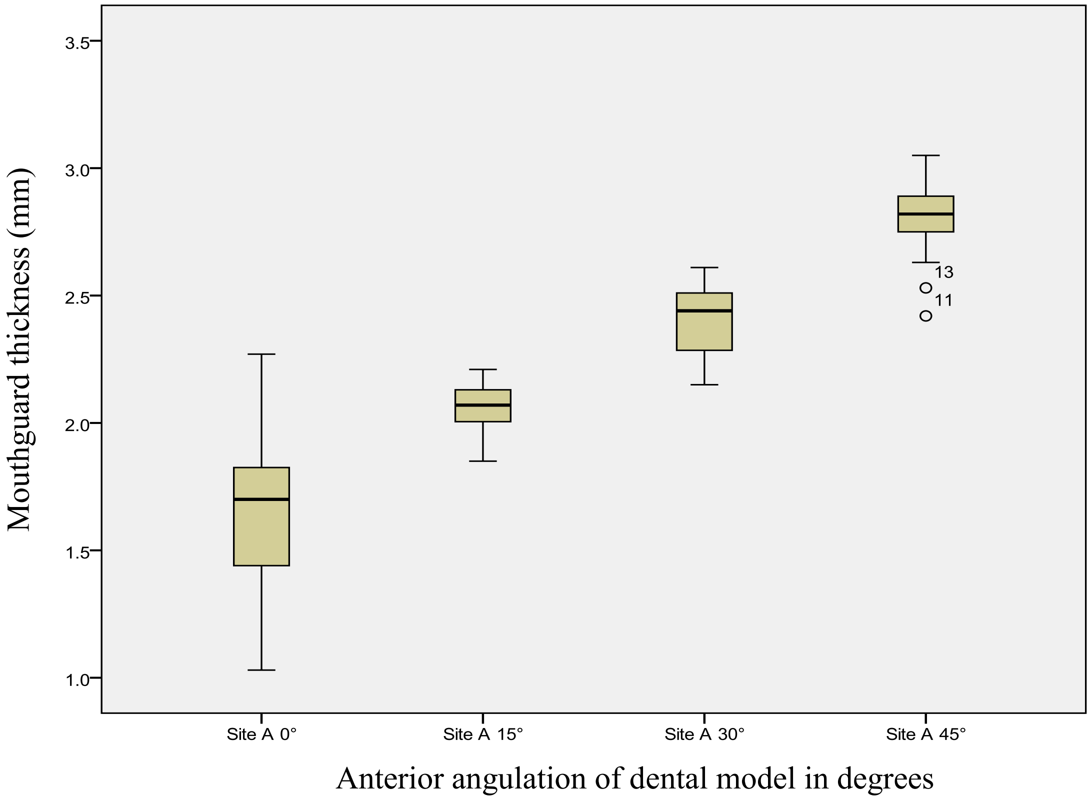


Figure 4-3: Comparison of the finished anterior thickness of the mouthguards after varying anterior model inclinations.

Figure 4.3 shows at site A models 11 & 13 of the 45° group are considered outliers, falling outside of the expected range of rest the samples within the group and were subjected to further inspection. Z-score analyses revealed the apparent outliers (highlighted in the stem-and-leaf plot) in fact belong within the sub-sample and so all data was included in the group analysis.

Occlusal Section (Site B, Table 4.1):

The results showed that there was a highly significant difference, $p < 0.0001$ in the occlusal mouthguard thickness, between the varying degrees of anterior inclination (Figure 4.4). An ANOVA showed a significant difference of $p < 0.0001$ between all groups but the post hoc tests were used to identify where those differences were and showed non-significance for inclination groups 15° and 30° (Table 4.2 and Figure 4.4).

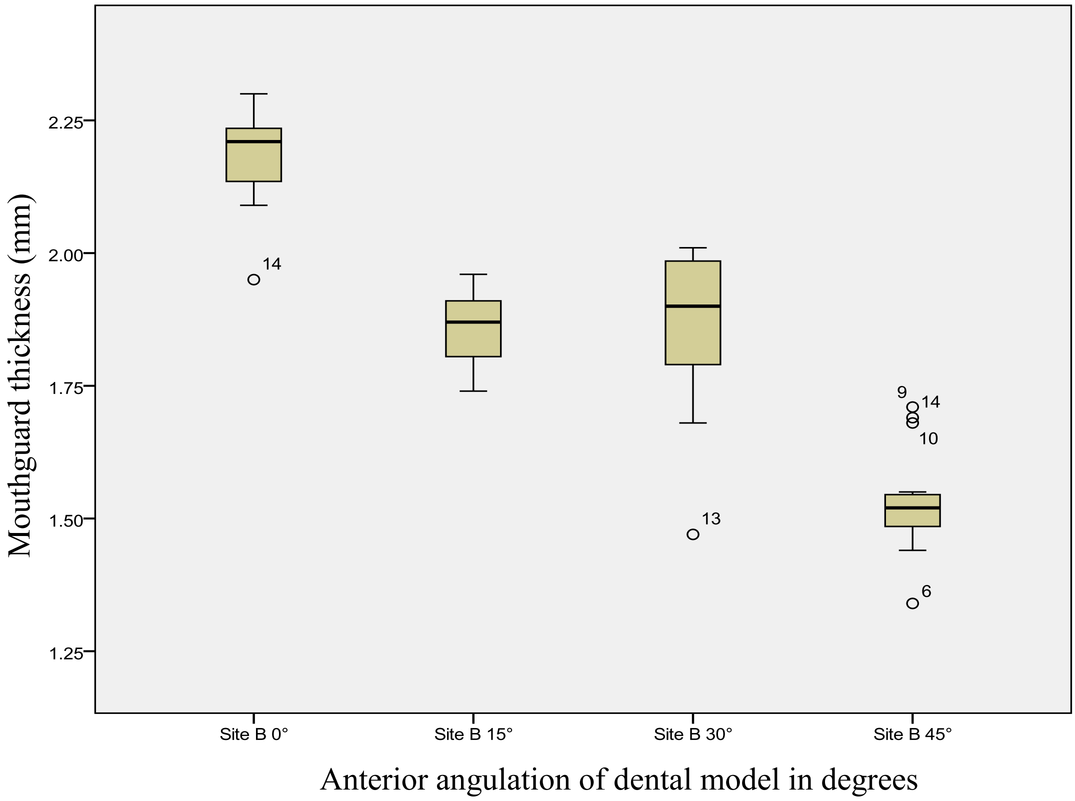


Figure 4-4: Comparison of the finished occlusal thickness of the mouthguards after varying anterior model inclinations.

Figure 4.4 shows at site B models 14 in the 0° group, 13 of the 30° group and model 6, 9,10 & 14 of the 45° group are considered outliers, falling outside of the expected range of rest the samples within the group and were subjected to further inspection. Z-score analyses revealed the apparent outliers (highlighted in the stem-and-leaf plot) in fact belong within the sub-sample and so all data was included in the group analysis.

Posterior-Lingual Section (Site C, Table 4.1)

The results showed that there was a significant difference, ($p < 0.0001$) in posterior-lingual mouthguard thickness, between the varying degrees in anterior inclination of the dental model (Figure 4.5). An ANOVA showed a significant difference of $p < 0.05$, in posterior-lingual mouthguard thickness between all groups but the post hoc tests were used to identify where those differences were and showed non-significance for inclination groups 15° and 30° (Table 4.2 and Figure 4.5).

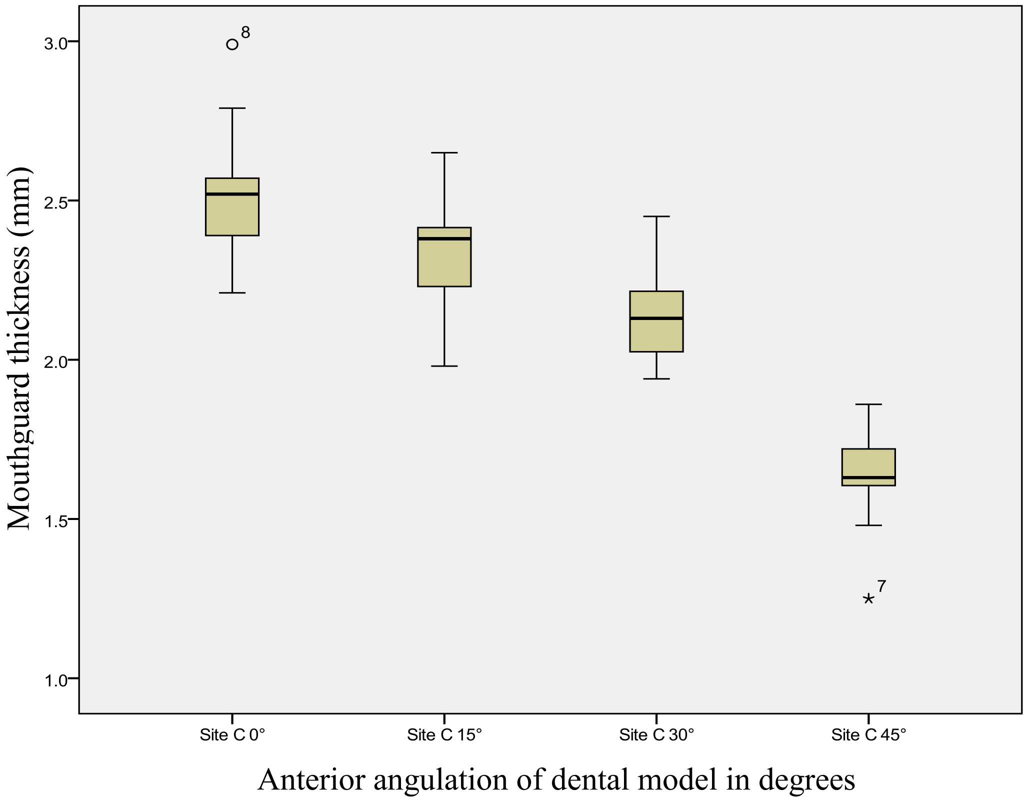


Figure 4-5: Comparison of the finished posterior-lingual thickness of the mouthguards after varying anterior model inclinations.

Figure 4.5 shows at site C models 8 in the 0° group and 7 of the 45° group are considered outliers, falling outside of the expected range of rest the samples within the group and were subjected to further inspection. *Z*-score analyses revealed the apparent outliers (highlighted in the stem-and-leaf plot) in fact belong within the sub-sample and so all data was included in the group analysis.

4.4.2 CT scans of mouthguards

The four typical CT scanned images (Figure 4.6) show the thickness typography of the finished mouthguards for each angulation group. As the mouthguard thickness increases, the mouthguard image changes from a light blue, denoting approximately 1.6 mm to a red which denotes a thickness of 2.8 mm (Figure 4.6). The scanned images are purely visual representations to illustrate the thickness distribution, over the whole anatomy of the finished mouthguard, for each test variable and degree of anterior inclination. The scanned image was scaled to the thickness of each of the selected mouthguards to set anatomical measurement points in the anterior sulcus and posterior occlusion.

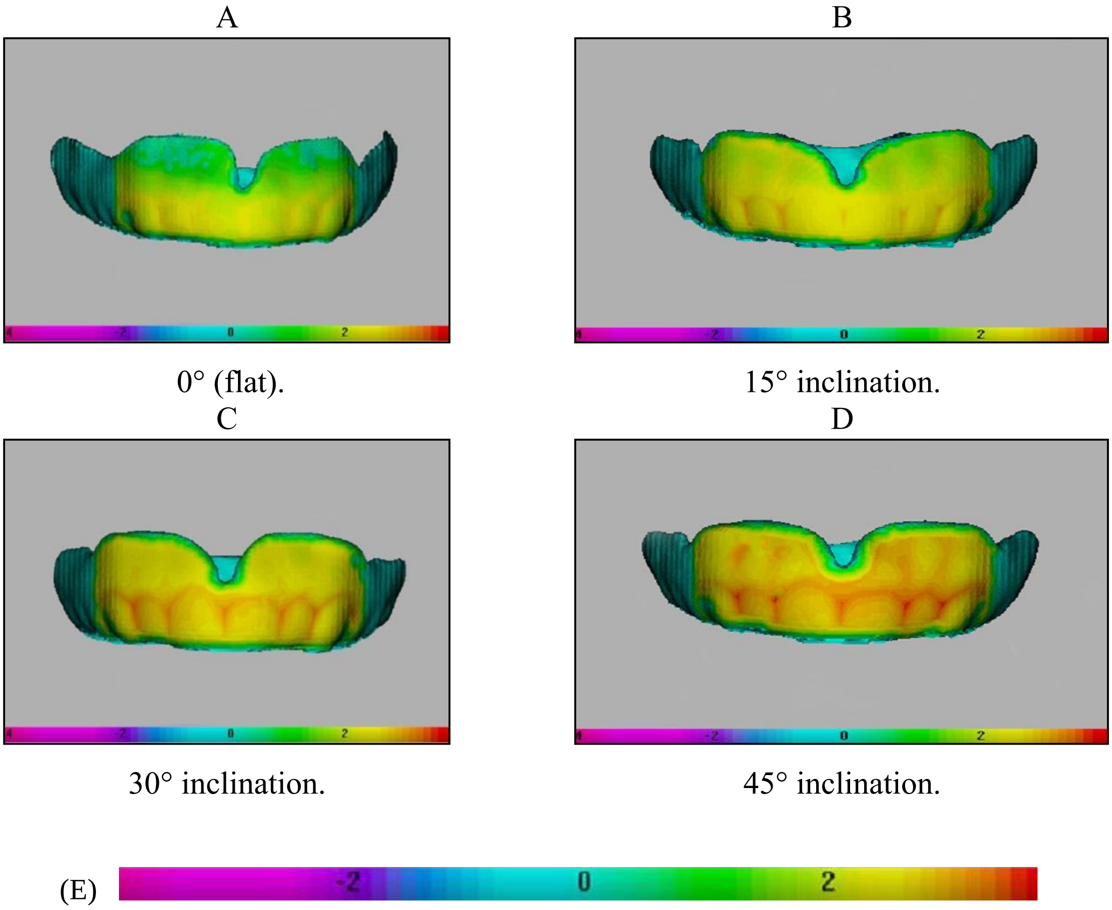


Figure 4-6: CT scan of the finished mouthguard formed flat on the forming platform (A), positioned at angles of 15° (B), 30° (C), and 45° (D). (E) Shows an enlarged thickness/colour key, 0 mm to ± 4 mm.

4.5 DISCUSSION

The thickness of a mouthguard has been shown to directly correlate with the rate at which energy is absorbed (Park et al., 1994, Westerman et al., 2002a), therefore it is imperative to obtain the optimal material thickness when manufacturing custom-made mouthguards and thereby increase their protective potential against orofacial trauma from impact in sport.

A proposed solution to address the thinning problem, seen with finished mouthguards, is to laminate the material using one or more layers to increase the finished thickness of the mouthguard (Patrick et al., 2002, Geary and Kinirons, 2008). However, the lamination technique, where a second mouthguard blank is formed over the initial formed mouthguard, can suffer from poor bond strength between two layers of mouthguard material, leading to delamination of the finished mouthguards, especially with vacuum formed mouthguards (Newsome, 2010).

Model selection for this study was verified by two studies, that of Mills, (1964) and Uysal et al, (2005). Mills, (1964), in a study where 230 males aged 17-21 yrs were assessed. They reported a mean maxillary arch width of 35.13 ± 0.20 mm in the inter-canine region, 41.60 ± 0.17 mm in the region of the first premolars, 47.05 ± 0.18 mm in the region of the second premolars and an arch length of 32.79 ± 0.20 mm. Uysal et al, (2005) also examined a mixed gender cohort of 150 participants (m 72, f 78) with a normal occlusion, the mean arch with in the inter-canine region was 34.4 (SD: 2.1) mm, 42.1 (SD: 2.5) mm in the first pre-molar region and 50.7 (SD: 3.7) mm in the maxillary inter-molar width. The selected master model used in this study, had an arch width of 34.5 mm maxillary inter-canine, 40.5 mm maxillary inter first premolar width, 46.0 mm maxillary inter second premolar, 49.0 mm maxillary inter-molar width and arch length from the midline of the central incisors and the gingiva of the mesio-palatal first molar cusp is 32.0 mm, at the same measurement points respectively. From both Mills, (1964) and Uysal et al, (2005) studies the maxillary model measured within ± 1.7 mm at the same measurement points.

In Chapter 3, a total of twenty technicians were asked to form five mouthguards on an identical model using their usual technique. The study showed there was a thinning of 59.5% in the 4 mm mouthguard blank in the anterior region equating to a mean thickness of 1.62 mm. It showed thickness differences, both between individuals and inconsistencies within individual participants.

The results from the present study show that by changing the orientation of the working model on the forming plate, the order of contact between the model and material can be redistributed with the aim of altering the thinning patterns observed in the mouthguard during processing.

4.5.1 Influence of the Degree of Inclination on Thickness.

By elevating the anterior section of the model by 15°, 30° and 45° there was a statistically significant ($p < 0.005$) reduction in thinning in the anterior region of the mouthguard material during the forming process, Table 4.2 and was illustrated in Figures 4.3 and 4.6. A 45° anterior angulation of the dental model produced the thickest mouthguards in the anterior region 2.8 mm (SD: 0.16). However, the anterior increase in thickness came predictably at the expense of the occlusal mouthguard thickness which reduced to 1.5 mm (SD:0.10), and in the posterior-lingual region which reduced to 1.6 mm (SD: 0.15).

When the model was kept flat on the forming platform, the anterior flange of the mouthguard can be seen to be predominantly green, turning to blue towards the edge of the mouthguard flange. This indicates that the material is less than 2 mm thick in this region, and in the case of the blue, less than 1 mm. With the model held at a 15° angle, there is a greater proliferation of yellow, denoting that the thickness has increased to greater than 2 mm in this region. However, the edge of the anterior flange of the mouthguard is still green and therefore less than 2 mm in this region.

When the model is placed at a 30° angle the lingual anterior flange of the finished mouthguard is generally yellow, showing the mouthguard is above 2 mm in this region. Also, there is a greater degree of red in the gingival and inter dental spaces, indicating the material thickness has increased to approximately 3 mm in this region. Finally, if the model is placed at a 45° angle, Figure 4.6d, a greater prevalence of red/orange is seen denoting the finished mouthguard has increased thickness between 3-4 mm within this region (Figure 4.6).

It has been postulated that mouthguards could offer protection against concussion, through the shock absorbency quality of the mouthguard between the occlusion, preventing or lowering the transmission of traumatic impact forces from the mandible to the maxilla and subsequent cranial vault (Takeda et al., 2005b). However, Knapik et al, (2007) and Benson et al, (2009) report there is no strong evidence to support whether mouthguards do reduce the risk of concussion. The current new technique reduced the mean occlusal thickness of the mouthguard from 2.2 mm, with the model flat on the forming table (0º), to 1.5 mm with the anterior of the model inclined to a 45º angle.

The posterior lingual/palatal section of the mouthguard is a region of the oral cavity that would be at a much reduced risk of impact due to its inaccessibility. Therefore, it is considered that the thickness of the mouthguard in this region could be 'sacrificed' and redistributed to the anterior region of the mouthguard where the majority of the thinning is normally observed. What is more, anterior orofacial injuries are highly prevalent in sport, with this region most at risk of a traumatic impact from an opponent, via a punch, kick, elbow, or equipment i.e. ball, bat, handlebars, racquet (Hill et al., 1998, Hutchison et al., 1998, Maladiere et al., 2001).

The thinning of the mouthguard material in specific anatomical regions may reduce the protective efficiency of the mouthguard and leave the wearer more susceptible to orofacial injury (Geary and Kinirons, 2008). Conversely, the increase in material thickness in the anterior region would increase the protective potential of the finished mouthguard (Westerman et al., 2002a). Therefore, the 45° angulation of the model seems to be the optimum model rotation as it increases the anterior region of the mouthguard to a mean thickness of 2.8 mm, and the mean occlusal reduced thickness of 1.5 mm. In other words, with increased angulation, despite the 'sacrificed' thickness in the posterior lingual/palatal region, the mouthguard's ability to dissipate commutable impact forces between the mandibular and maxillary dentition and substructure is still maintained.

In the current study the thicknesses in the anterior region of the finished mouthguards were more consistent, (mean Coefficient of Variation = 5.9%) when the model was inclined at 45º (Figures 4.3 – 4.5). Figure 4.3 shows at 0° there is a large variation between the upper and lower ends of the whiskers of the box plot chart. In contrast, with angles 15°, 30° & 45°, there is a much closer gap between the upper and lower extremes of the whiskers of the box plot, indicating greater consistency in these samples. This leads to the assumption that the inconsistency of anterior mouthguard thickness could decrease if the proposed technique of angling the anterior section of the dental model by 45° is employed.

There seems to be very little published data on this subject matter for comparative analysis. Geary et al, (2008) as part of their study examined model inclination and orientation variables that can affect mouthguard thinning. Geary et al, (2008) took measurements in twelve anatomical regions, five in the anterior and seven posteriorly. They examined both inclination of the anterior and posterior sections of the model by trimming copies of the control models (25 mm) anteriorly by 10 mm and 20 mm, which had the effect of increasing the posterior inclination of the model by approximately 9° and 18° respectively. This had the effect of stretching the material to 1.26 mm ($P < 0.001$) in the first instance and to 1.17 mm ($P < 0.001$) in the second. They reported a significantly higher degree of material thinning in the incisal anterior and cuspal posterior region of the finished sample mouthguard.

As one of their testing conditions, Geary et al, (2008) also trimmed the dental model posteriorly by 10 mm, effectively rotating the model, increasing the elevation of the anterior section of the dental model, as seen within this current study. Geary et al, (2008) also inclines the anterior of the model, by trimming the posterior by 10 mm. Geary's study (Geary and Kinirons, 2008) and this current study, a model from the present study, that is believed to be a fair representation of the average size of maxillary dentition, was subjected to the same preparation technique by reducing the posterior portion of the models by 10 mm. When using an orthodontic cephalometric protractor (Ortho-Care Ltd, West Yorkshire, UK) this would equate to a 9° inclination of the anterior section as opposed to the much higher angulation of 15°, 30° and 45° used in the current study.

The technique used in the current study used removable plates and angulations blocks, which employed greater accuracy and consistency during the manufacture of the test samples. However, this technique cannot be easily incorporated on all vacuum-forming machines. The dental model may therefore be placed in lead shot at the proposed angle of 45°, or alternatively when the initial model is cast, the angle of the impression tray can be based to achieve a 45° anterior inclination to save time and materials. In future thermoforming machine manufacturers may wish to include a forming table that can be angled, by as high as 45º.

4.6 CONCLUSION

Excessive thinning of the mouthguard material has been observed in a number of studies (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Mizuhashi et al., 2012) could be redistributed to areas at less risk of direct impact, through the angulation of the anterior section of the dental model. Correspondingly, the thickest section of mouthguard is created over the anatomical site of the dental model that is at greater risk of direct impacts i.e. the anterior sulcus. There is a significant increase in difference in thickness of mouthguards ($P < 0.05$) when the anterior section of the dental models are elevated by varying degrees. The optimum increase of dental model angulation, in the anterior section, was by 45°, increasing the finished thickness of a mouthguard by as much as 75% in the anterior sulcus region, where the majority of orofacial injuries from sport occur. Even though there were slight reductions in other measurement sites these could possibly increase by using a thicker mouthguard blank. This technique whereby the dental model should be held with an anterior inclination can easily and at no extra cost be implemented to maximise the protective function of the mouthguard in the anterior region. This technique can be implemented on all thicknesses of mouthguard blank. The thickness values from this Chapter (i.e. 2.8 mm) by the inclination technique and Chapter 3 (i.e.1.6 mm) will be tested in a representative bone tissue model. Bone tissue will be subjected to density changes creating two models that of a young and an old/reduce bone mineral density model representative of an older athlete or a sports person with lower than normal bone density values. This tissue will then be tested with both thickness values reported within the previous two chapters and examine how they perform during impact loads that are commonly seen within sport and previous craniofacial research studies.

Chapter 5: An investigation into the mouthguard performance in relation to an ageing bone model.

5.1 Introduction.

With an ageing population, it is encouraged that people partake in sport and exercise into later life to reduce the medical risks associated with the ageing process. Those highlighted as being depression, high blood pressure, coronary heart disease, stroke, type 2 diabetes, colon and breast cancer (Sui et al., 2008, World Health Organization, 2011). The World Health Organization (WHO) recommends adults from 18-64+ yrs to partake in at least 150 mins of moderate physical activity or 75 mins of vigorous-intensity physical activity per week (World Health Organization, 2011). Older people (over 35yrs) are participating in sport at both a recreational and competitive level, these are sometimes referred to as master or veteran athletes (Reaburn and Dascombe, 2008, British Masters Athletics Federation, 2014). However, typically the same mouthguard blank thicknesses for custom made mouthguards are commonly prescribed regardless of age. Boil and bite mouthguards do however come in a relation to size, junior and adult, although this type of guard can potentially be ill fitting (Newsome et al., 2001). The thickness of the mouthguard is generically associated with the type of sport played, the higher the risk, the greater the protection needed, for example, rugby or boxing with a high degree of inter-personal violent contact would require the high degree of mouthguard protection. Conversely, lower to medium risk sports, Chapter 1; Table 1.2, where violent impacts are more accidental, the degree of protection in mouthguard thickness is reduced. The perspective of this chapter was to focus on the results obtained in relation to thinning of a 4 mm EVA blank in Chapter 3 and the associated changes in material thickness in Chapter 4 (via the inclination technique) and examining how these thickness values would compare during impact on a young and old bone tissue model. As the human body ages there is a natural steady reduction of bone mass and thereby bone strength, as a result the rate of bone resorption increases, this process can start from middle age once reached peak bone mass (Tortora and Derrickson, 2009). Therefore, are current levels of mouthguard thickness adequate for the older population who partake in sport? Or does the design need to be taken into consideration for these individuals, thereby making the mouthguard more bespoke for the individual.

In relation to sport, impact forces vary due to the environment i.e. hard or soft surface, intensity to which the sport is been played, gender, and finally, the weight and/or construct of the offending opponent, projectile or equipment. In football head injuries are usually obtained either by "direct contact", (for example, head vs. head, head vs. knee, head vs. the ground) or whilst heading the ball (Levy et al., 2011). The majority of the research and published data, concerning head impacts in sports focus predominately on concussion (mild traumatic brain injury) (Withnall et al., 2005, Levy et al., 2011, Clay et al., 2013). The following section of this chapter investigates how previous studies have replicated such forces within an experimental model and the various methodologies employed.

5.1.1 Testing Modalities

Head-forms, mannequins or more colloquially known crash test dummies are predominately used by the automotive industry. Kennedy et al (2006) in their initial assessment investigated the design of the advanced Hybrid-III head-form, for the United States Army, with the aim of developing a system of predicting eye and facial injury resulting from blunt impacts. They recommended various impact methodologies, Figure 5.1 and 5.2, to replicate blunt trauma force to the head-form. They stated that the head-form would allow for an accurate assessment of protective headwear, for example, faceshields, goggles and other protective devices, in the prevention of serious eye and facial injury. They also recommend its use for impact scenarios in the evaluation of sporting injury.

Head-forms have been used in relation to sports injury/impact research (McIntosh and Janda, 2003, Walilko et al., 2005, Withnall et al., 2005, Viano et al., 2007). Atha et al, (1985) measured the force of a professional heavy-weight boxer's punch, using a test rig comprising of a padded target, suspended as a ballistic pendulum, to replicate the head and neck of a heavyweight opponent. The punch reached a velocity of 8.9 m/s on impact and the study recorded peak contact forces of 4096 N with an estimated maximum force to the head of 6320 N. Smith et al, (2000) investigated punch force in 23 male boxers (n=7 elite, n=8 intermediate & n=8 novices) each participant had to deliver straight punches at maximum effort. Their results showed that the elite boxers recorded a mean punch force of 4800 ±227 N, intermediate 3722 ±133 N and novice 2381 ±116 N. Walilko et al, (2005) conducted a study using seven Olympic boxers to deliver three straight punches to the jaw region (lower third) onto a Hybrid III dummy head-form. Their results reported an average peak force of 2625 ±543 N for middleweight boxers and a force of 4345 ±280 N for the super heavyweights. Falco et al, (2009) examined impact forces in experienced and novice Taekwondo players aged 16-31 yrs. They reported a mean impact force of 1994 ±537 N (Max 3482 N) for experienced competitors and a mean impact force of 1477 ±679 N (Max 3339 N) for novice competitors.

Viano et al, (2007) investigated concussion biomechanics in American football. Twenty-five real head (helmeted) impacts were replicated using Hybrid III dummies. The study recorded a mean impact force of 7642 ±2259 N at a mean velocity of 9.3 ±1.9 m/s and the highest impact force being 11680 N at 10.3 m/s. As shown, the range of forces observed in sports can differ greatly, from as low as 158 N for novice participants (Falco et al, 2009) up to as 11680 N (Viano et al, 2007) in professional competitors. Head-form devices cannot fully replicate the interaction of soft tissue, musculature, and joint movement of the human head. However, these type of head-forms are a good substitute for a human hard and soft tissue model (Cormier et al., 2010).

Previous testing methodologies have incorporated variables that may have an influence on the testing of mouthguards. Takeda et al, (2004b) examined the characteristics of the impact object (impactor) used in mouthguard performance research. They considered the use of a steel ball, which is commonly used for impact testing of mouthguard materials studies, for example by Park et al, (1994) and Auroy et al, (1996), is not fully representative of the sorts of projectiles or bats that would be encountered within sport. Their study examined seven types of impact objects; steel ball, baseball, softball, field hockey ball, ice hockey puck, cricket ball, and wooden bat. The steel ball invoked the greatest peak transmitted force at 4719.68 N. In contrast, the ice hockey puck only induced a force of 459.62 N. In their study, impact tests were carried out both with and without mouthguard protection; in the case of the steel ball, there was a 61.3% difference between with and without mouthguard protection. In the case of the wooden bat, this reduced by 38.3%, and the other objects ranged from 2.4 - 6.0% respectively. They reported a direct correlation between the material hardness and the peak force transmission, leading to the conclusion that the projectile is absorbing some of the impact energy. Takeda et al, (2004a) also examined sensor types used to measure impact absorption. They used a pendulum device apparatus with four interchangeable impact object heads, steel ball, wooden baseball bat, baseball ball, and a field hockey ball. The study compared the mean impact values by three modes; load cell, accelerometer, and a strain gauge. The study observed discrepancies between the three

recording systems when using the different impact objects. For example, for the steel ball there was an 80.3% impact absorption with the strain gauge and the accelerometer, but only 62.1% absorption was recorded when using the load cell. The baseball recorded 46.3% absorbency with the strain gauge and only a 4.36% change with a load cell. They concluded that the strain gauge was the most appropriate and sensitive method to measure shock absorbency at the point of impact, whereas an accelerometer would be better suited for taking measurements further from the point of impact and they suggested that a standard sensor type should be agreed for all similar experimental testing.

Greasley & Karet, (1997) & Greasley et al, (1998), in an attempt to develop a standard testing procedure for mouthguard assessment, used an upright testing assembly and a simulated jaw made from rubber, dental stone and/or a light cured composite. The impactor assembly was situated on a track of a predetermined height, a weight was selected to a mass that would induce the required test conditions, and this was attached to the impactor assembly. The test specimen was positioned on the platform, and the impactor assembly was released allowing it to fall, guided on its track and hitting the test specimen as required. An example of a typical test procedure is shown in Figure 5.1.

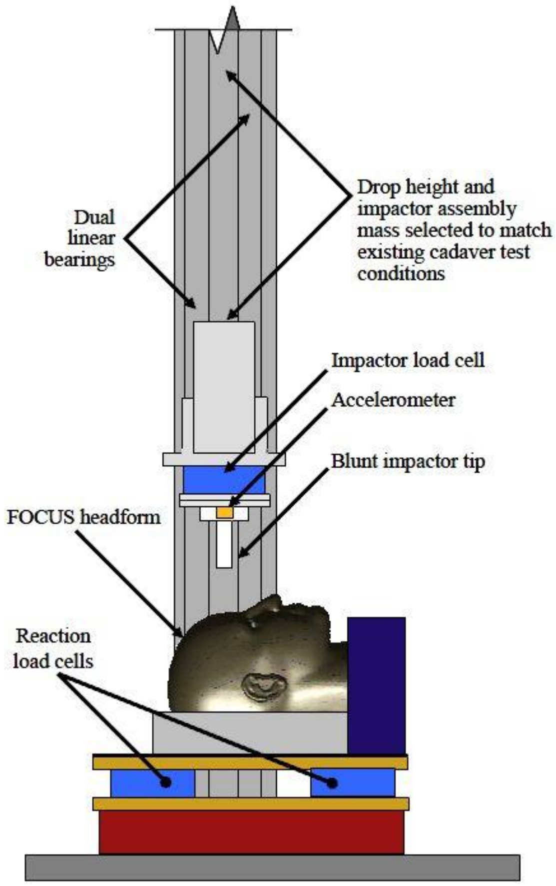


Figure 5-1: Schematic of a drop-weight tower setup as adapted from Kennedy et al (2006) in eye impact validation tests.

Patrick et al, (2002) when investigating laminated mouthguard structures devised a combined impact and static indentation test. They used a modification to the drop weight testing technique, whereby the laminated test samples were retained in a circular clamping mechanism, rather that impacting testing on a formed and fitted mouthguard, as with the two previous testing methodologies. They then used an infrared LED/phototransmitter reflective transducer to determine the degree of displacement of each test specimen on impact, in support of their hypothesis that states, the lesser the degree of displacement, the greater the degree of protection. Their testing model also included an accelerometer and a strain-gauge load cell. They used a drop height of 0.5m to produce an impact velocity of 3 m/s (Patrick et al., 2002). Patrick et al, 2002 considered the instrumented drop-weight impact test appropriate for mouthguard impact testing, as it utilises both force-time and displacement-time characteristics that can be utilised to analyse the energy absorbance of the mouthguard material in variation of thicknesses (Patrick et al., 2002). Table 5.1 shows both dropweight and variations on pendulum testing which have been employed by the majority of previous research studies, as the preferred method of delivering the impact event.

A pneumatic ram could also be employed to induce the impact force to the experimental model, Figure 5.2. This method of testing allows the test rig to be set up transversely. A ram/impactor tip is forced out of a barrel at high speed, usually by the use of compressed air. The air is controlled by means of a pressure regulator and a solenoid valve. The site of interest on the test specimen would be positioned directly in front of the barrel. As before, the output data was recorded by the means of a load cells and an accelerometer. This method has been suggested by Patrick, (2005) in his thesis summarisation for further work into mouthguard research, stating a pneumatic setup would be versatile in this application; however cost and complexity of the gas/liquid delivery mechanism may prove prohibitive (Patrick, 2005).

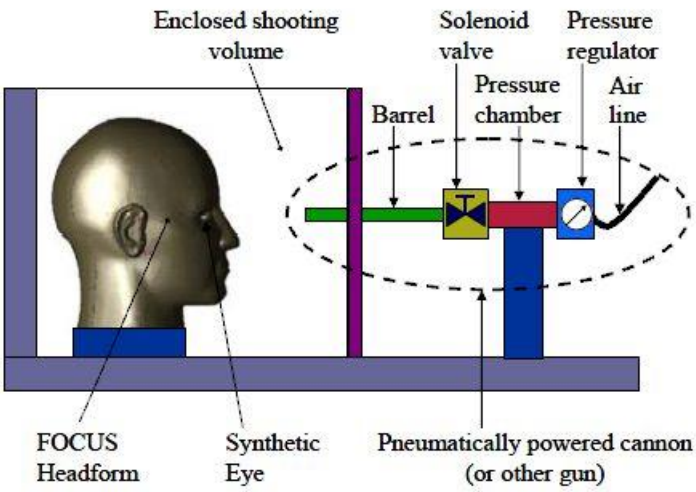


Figure 5-2: Schematic of a proposed pneumatic impactor setup, as used by Kennedy et al (2006) in eye impact validation tests.

Pendulum impact machines, an example shown in Figure 5.3, have also been used for inducing impacts to the orofacial region, especially in mouthguard research testing (Tiwari et al., Hoffmann et al., 1999, Westerman et al., 2000, Westerman et al., 2002b, Takeda et al., 2005a).

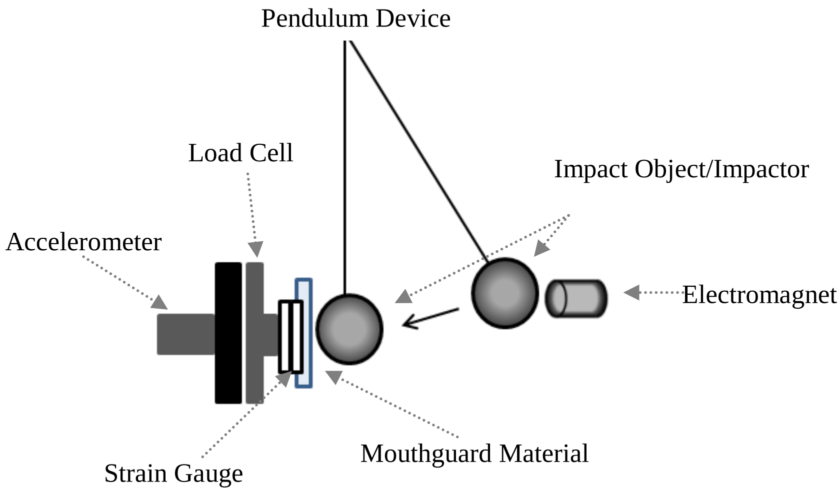


Figure 5-3: Schematic representation of a pendulum device for the impact testing mouthguard material.

Study	Impact machine type	Impactor	Force applied (N or g)	Recorded variables i.e. Acceleration, Height or Angle	Sample model	Sample size (number of impacts)	Absorption of impact force
Greasley et al, (1998)	Drop weight	Conical ended 0.51 kg projectile		Impact velocity 6.25 m/s (10 J energy)	Artificial dental model comprising of rubber arch with a replaceable ceramic teeth and jaw bone assembly.	2 impacts per experimental setup × 8 testing variations + control (table 1).	No impact data was recorded, only the number of teeth broken.
Park et al, (1994)	Drop weight	Steel ball × 2	66.8gm 473.4gm	33.75 inches 10 inches	EVA material	*	50.4%↓ rebound
De Wet et al, (1999)	Pendulum	Impact hammer			Artificial skull	5 mouthgaurds	25.7-33.3%
Hoffman et al, (1999)	Pendulum	*	250 N, 350 N & 500 N	5000g (? diagram)	Artificial dental model comprising of metal teeth set in a silicone and resin jaw assembly.	5 impacts per experimental setup.	34%↓ ** 46%↓ ** 52%↓ **
Westerman et al, (2000)	Pendulum (similar Izod)	Circular flat face of 12.75mm	Impact energy of 1.05 joules	Impact velocity of 3 m/s	*	10 impacts per sample thickness (n = 5) (new material surface per impact).	Results compared against the control, not as an overall reduction in impact force.

Craig and Godwin, (2002)	Pendulum (Charpy)	Impact surface of 1 × 1.5cm	113 N-cm		High strength stone dental models or cast high strength dental stone disc base. A mix of materials, thicknesses, products and applications i.e. lamination.	*	73-93%↓ rebound
Patrick et al, (2002 & 2006)	Drop weight			Impact velocity 3 m/s, from a height of 0.5 m		2 & 4 sample designs were tested	
Takeda et al, (2005a)	Pendulum (similar to Charpy or Izod)	Steel Ball	300g (grams)	Axis length 50cm	Artificial skull (resin)	3 Impacts × 3 Mouthguard's	54.7%↓ (approximate) total reduction in distortion to the mandible
Takeda et al, (2008)	Pendulum (similar to Charpy or Izod)	Steel ball Baseball	172.5g (grams) 147.3g (grams) 30 kg	Axis length 50cmat an angle of 90°	Acrylic dental model	3 Impacts × 3 Mouthguard setup's	57%↓ 26%↓

* Not stated in paper. ** Values only expressed in a chart (Figure 4), therefore these figures are purely a visual approximation.
*** ↓ Reduction in transmitted impact force

Table 5-1: Previous impact testing studies testing methodologies.

5.1.1.1 Artificial skull and jaw model

A number of studies have attempted to recreate the orofacial dentition. Greasley & Karet, (1997) devised an artificial upper jaw comprising of a horse-shoe design of rubber and a light-cured composite to increase rigidity which included teeth cast from dental stone. Mouthguards were formed and were mounted on a spring loaded device and subjected to impact from free falling projectiles at an impact velocity of 6.25 ms^{-1}. Three strike surfaces were employed, flat ended to replicate impacts with walls or ground, Hemispherical (40 mm radius): small ball or puck sports and rounded cone (5 mm tip radius) for bat and racket sports. However, it is the opinion of the author of this thesis that the arch and cast stone teeth would have very different impact properties than those of natural dentition or surrounding bone tissue.

Takeda et al, (2005a) when testing the hypothesis that mouthguards may prevent mandibular bone fractures and concussions from traumatic impacts to the chin, employed an artificial skull model. The impacts were induced using a pendulum and were recorded via strain gages and accelerometers. They reported a 54.7% total reduction in distortion to the mandible and an 18.6% total reduction in head acceleration, measured at the parietal and temporal regions, when the mouthguard was used. The advantages of this test model are that the skull is anatomically and morphologically correct and that there are no complex ethical issues. However, the composition of a resin skull will react very differently to bone and soft tissue, therefore this testing model will only be able to give an indication to the level of protection afforded by the mouthguard.

Previous testing methodologies have generally used materials to construct the model on which the mouthguard is formed and sub-sequentially tested, that have little representation to the orofacial structure in terms of impact properties (Greasley and Karet, 1997). The force observed in other studies tends to be very quick with a relatively large blunt force, for example, a boxing glove, ball, boot, etc. This current study design was to be as close as possible to replicate the natural orofacial composition (e.g. a tooth or bone model), the variation during individual in terms of bone density of the same age and of an older athlete could inevitably effect the performance of the mouthguard. The next section will focus on the types of bone tissue and its structure within the orofacial region and how it is affected by ageing.

5.1.1.2 Bone Tissue.

Human bone tissue comprises of two types of bone, cortical (compact) bone which forms the outer shell of bones and trabecular (cancellous or spongy) bone the inner structure. Cortical bone is highly resistant to torsional and bending stress and makes up approximately 80% of the human skeleton (Tortora and Derrickson, 2009, Jester et al., 2011). Trabecular bone the remaining 20% is found beneath the cortical bone specifically within the epiphysis section of bone, which is made of fine sheets of trabeculae that are arranged in relation to stress distribution, both of these two bone structures are found within the craniofacial skeleton Figure 5.4. Bone is a dynamic tissue which adapts to its structure during mechanical stress or loading (Pocock and Richards, 2006).

The majority of the bones forming the craniofacial skeleton are flat or irregular bones (Waugh et al., 2010). Irregular bones are complex and irregular in shape. They consist of a thin layer of compact bone covering a spongy bone interior. Some of the bones in the skull are irregular bone, such as the mandible, ethmoid and sphenoid bones (Tortora and Derrickson, 2009, Waugh et al., 2010). Bone in nature is dynamic, continually responding to mechanical stress and damage, removing old bone and replacing with new bone tissue by osteoblastic and osteoclastic activity in the form of modelling. Osteoclasts, which are multinucleate cells responsible for bone resorption, remove fragments of dead bone by the production of enzymes capable breaking down the collagen in the bone material. New bone is then formed by an increase in osteoblastic activity which then deposits onto the bone surface, transforming into an osteocyte (bone cell) (Winwood, 2003, Ireland, 2010, Jester et al., 2011). With age, the process of bone repair becomes less efficient due to a decreased blood supply and cellular activity (Kneale and Davis, 2005).

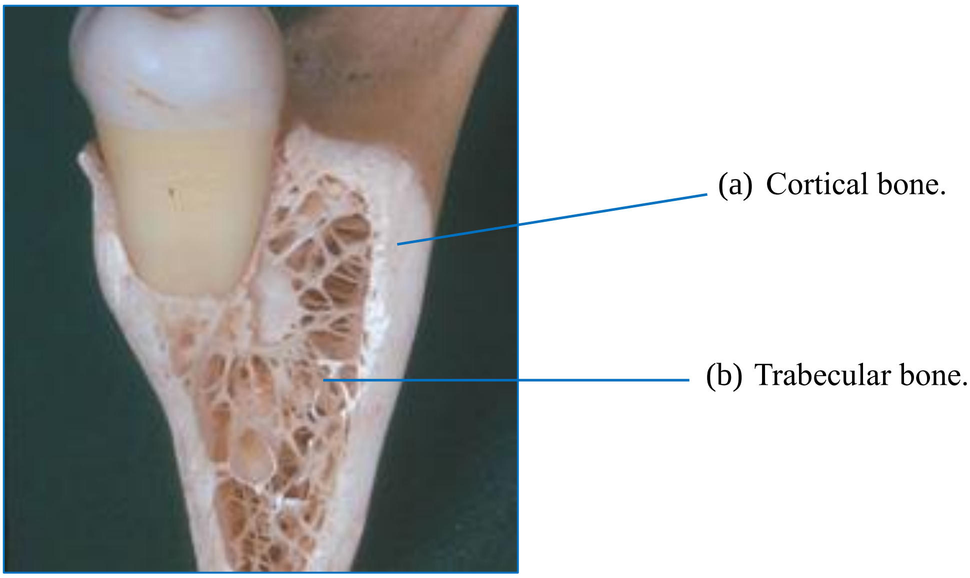


Figure 5-4: Structure of the mandible, (a) cortical bone on the outer surface and (b) trabecular internally, (Image obtained from Isen, 2009).

Craniofacial skeletal change is an inevitable process of human ageing, which involves tooth loss; constant bone resorption and remodeling that can cause dentoalveolar and sagittal shape changes, which results in horizontal and vertical facial height changes throughout an adult lifespan (Albert et al., 2007, Mendelson and Wong, 2012). However, bone changes are not uniform; factors that can affect the rate at which these changes occur include age, gender, genetics, menopause, diet and drug therapies, as previously highlighted in Chapter Two.

During ageing bone becomes weaker with age due to a reduction in bone mass which creates an increased risk of fracture. The reduction in bone mass is predominantly through changes in bone mineral density (BMD), which is more pronounced in females normally after 30 yrs of age, peaking around age 45 yrs when oestrogen production reduces, until age 70 yrs whereby as much as 30% of the calcium in the bone could have been lost. Brittleness derives from a reduced rate of protein synthesis, which affects the bones collagen fibres and thereby reduces the bones tensile strength (Tortora and Derrickson, 2009).

Within the current study, bovine tissue will be used as it shares many attributes to that of human bone. Yacker and Klein, (1996) examined bovine bone by computerized tomography scanning; the cortical bone was reported to be 1,400 Hounsfield units and the medullary bone to be 470 Hounsfield units. The cortical bone in the average human mandible would be between 1,400 to 1,600 Hounsfield units and between 400 to 600 Hounsfield units for the medullary bone. Their study therefore recognised comparative similarities, in terms of density measurement, between a bovine bone sample and the bone density of the average human mandible (Yacker and Klein, 1996). Interestingly, bovine and humans share approximately 80% of their genome (Tellam, 2009). With this taken into account bovine bone tissue will be used to mimic a young bone model and an artificially aged model for the older bone tissue within the present study.

The emphasis of this phase of the thesis was focused on empirical data, collected from previous Chapters 3 & 4 in terms of thickness dimensions and to see the effects of impact on bone and that of an ageing bone model. The aim of the present study was to compare a young and an aged bone tissue model in three impact test scenarios; (i) unprotected, (ii) mouthguard of 1.6 mm (mean thickness reported in Chapter 3 from a single 4 mm mouthguard), and (iii) 2.8mm Mouthguard protection reported in Chapter 4, whereby the anterior of the dental model was angled by 45°.

The hypothesis being the new inclination technique of mouthguard production will offer the greater level of protection in both test conditions, young and old. Secondly, the older bone samples will be more prone to damage mechanisms and therefore require a greater degree of protection reflecting the need that custom mouthguards should be made to the individual regardless of the material.

5.2 MATERIALS & METHOD.

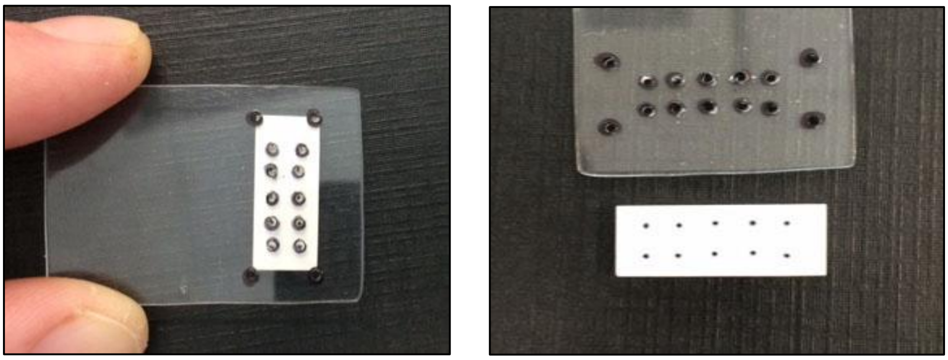
Ethical approval was sought and obtained, prior to commencement of the study taking place, from the ethics committee at the Department of Exercise and Sport Science, Manchester Metropolitan University (MMU Ethics Code:18.12.09).

5.2.1 Bone Sample Preparation

Bone samples were prepared from bovine femurs in accordance with University protocols for preparation and storage. Two complete femurs from the same bovine carcass were obtained (food chain by product). The femurs were placed into frozen storage (-20ºC) until required for sectioning. Bone specimens were cut under water irrigation, due to bone collagen denatures when heated, thus affecting the bones material properties (Todoh et al., 2009). An autopsy powered isolating saw, Medezine 4000 Autopsy and Orthopaedic saw (Medezine Ltd, Sheffield, England) sectioned the specimens. The femurs were cut into oversized pieces allowing for the refined sizing of each sample. From a 45cm femur approximately 40 cortical bone samples of 8mm × 19mm × 3mm were obtained. Each of the cortical bone samples were trimmed down to their specified dimensions, width 8mm ± 0.16mm, length 19mm ± 0.93mm and thickness 3mm ± 0.13mm, using a water cooled/irrigated carborundum sanding wheels (Wehmer Corp, Illinois, USA). The samples were then finely sanded using 1200 - 2500 grit waterproof silicon carbine paper (English Abrasives & Chemicals Ltd, Stafford, England, UK) and polished to a mirror finish using alumina slurry (0.05µ Alumina suspension Alpha) and a specialist polishing pad (MetPrep) prior to testing. A total of 60 samples were obtained and segregated into six groups which consisted of, 10 young (control), 10 young 1.6mm MG (mouthguard) protection, 10 young 2.8mm MG protection, 10 old (control), 10 old 1.6mm MG protection and 10 old 2.8mm MG protection.

5.2.2 Artificial Ageing of the Bone Samples

From the original 60 samples, a total of 30 samples were artificially aged to represent an older experimental cohort or that of lower bone mineral density. The physical properties of the bone were initially artificially altered to imitate the ageing process by the introduction of small holes in the back of the samples thus replicating porosity, which is seen in the ageing process and osteoporosis. This was achieved by 10 holes being drilled into the back surface of two thirds of the specimens, 2 mm ±0.1 mm deep, using a Kavo K9 hand piece (KaVo Dental Ltd, Bucks, UK.) and a 0.80 mm rose head titanium bur (Busch & Co, Germany), at a perpendicular angle to the specimen. The hand piece was set to 15000 rpm. All samples were submerged under water during drilling, to avoid excess heating and damage occurring to the specimens. For consistency, prior to drilling a polycarbonate template was fabricated for 10 located predetermined holes. On each specimen the template was positioned and the holes were transposed onto the back surface by the use of a mechanical pencil, Figure 5.5 (A, B).



(A) (B)

Figure 5-5: Polycarbonate template used to mark the position of the holes (A & B) on the aged bone specimens.

Specimens were then subjected to chemical treatment by Ethylenediaminetetraacetic acid (EDTA). EDTA has been used in dental applications to clean, remove inorganic debris and lubricate the root canal in endodontics (Garberoglio and Becce, 1994, Hulsmann et al., 2003). It has also been used in research for the demineralisation of bone to create an osteoporotic model (Lee et al., 2011, Wallace et al., 2013) and also for gene and protein analysis associated with tooth and bone disease (Cho et al., 2010). EDTA disodium salt LR (Timstar laboratory suppliers Ltd, Crewe, UK) was dissolved in distilled water at a concentration of 3.72% to create the demineralization 0.1M EDTA solution. A total of 30 bone specimens, with the holes drilled in the back, Figure 5.5, were placed in separate 50 ml specimen tubes filled with the 0.1M EDTA solution. Care was taken to keep all the samples in the correctly identified tube, marked with the anatomical site details from where the bone samples were harvested. The 50 ml tubes containing the bone specimens were placed onto a rotating specimen roller at room temperature (21ºC). The samples were subjected to a demineralisation period of 14 days and the solution replaced every other day, this methodology follows work by Cho et al, (2010), however, the time was adjusted to the required level of demineralisation for this current study. Cho et al, (2010) investigated methods to rapidly demineralise bone and tooth tissue for analysis of cell morphology. They used a 0.1M EDTA solution over a period of 3wks for the demineralisation of mice skulls.

All cortical bone samples were then individually stored in freezable 50ml specimen pots (Reliance Medical Ltd, Cheshire, UK) in a 15 ml solution of 10% Thymol and Ethonol (2 g Thymol dissolved in 10 ml Ethonol and 90 ml water). Each specimen pot was labelled and then assigned a code in relation to anatomical site of the host bone. The samples were then stored frozen at -20ºC until testing.

5.2.3 Mouthguard Sample Preparation.

All the EVA blanks for the final study were ordered from the same manufacturer (Bracon Dental Laboratory Products, East Sussex, UK) for continuity. Individual squares of EVA material were cut 19 mm x 19 mm. With regard to the experimental thicknesses, “Mouthguard blanks tend to be a little generous, in thickness, by about 0.1 mm or 0.2 mm”. The 1.5 mm blanks fortuitously, when they were precisely measured using the calibrated gauge, were 1.6 mm, the required thickness. Each of the 3.0 mm mouthguard samples were trimmed to 2.8 mm, in accordance with the new mean thickness of mouthguard by using the proposed technique of elevating the anterior section of the dental model. The trimming of the mouthguard material was by a dental hand motor and an abrasive band (Schleifbänder, 120/50), typically used for the trimming and finishing of custom made mouthguards. Each samples dimensions where checked using Vernier callipers (Electrontic Digital Callipers, RadioShack®, Texas, US. Range: 0-150 mm, Resolution: 0.01 mm, Accuracy: ±0.02 mm).

When designing the final testing methodology it was considered that each of the test specimens should be ‘heat treated’ to remove any residual strain (‘Fringe’) that the unprocessed material blank may be subject too which has previously been highlighted and reported by Patrick et al, (2005), and therefore making the testing more representative of the material usage. Heat treatment, as described by Patrick et al, (2005), is the process whereby the EVA material is heated to its thermoforming temperature, 84±3ºC for EVA, with the aim of removing the internal strain within the EVA material that occurs in it manufacture. Patrick et al, (2005) used photoelastic analysis and impact testing on the effects of heat treating mouthguards, they observed a reduction in the “fringe” from as high as 1.0 fringe in unprocessed material to a zero fringe order in heat treated samples, thereby highlighting that heat treated EVA materials significantly react differently. This dispels the assumption that definitive conclusions can be drawn from unprocessed material impact testing samples used in some other studies. The methodology for the mouthguard preparation emulates work carried out by Patrick et al, (2005). Each sample was invested in dental stone (Crystacal R) to create a matrix pattern, designed to avoid dimensional changes of the material whilst in its plastic state at a temperature of 84±3ºC. A dental wax furnace (BEGO Herbst GmbH. Model: Miditherm 200 MP) was used to heat the EVA material, it was bought up to a temperature of 84ºC and held for 10 minutes, as specified by Patrick et al, (2005) as the optimal time and temperature for this process. Furnace temperature was collaborated and checked by the use of an independent thermometer (Thermometer range -20 to + 150 ºC, 305mm, Brannan, England) which was placed at the same level in the furnace as the mouthguard samples. The time that the samples were in the furnace was timed using a standard stopwatch. The samples were then removed from the furnace and left to cool for two hours at room

temperature, 23ºC, prior to removal from the stone matrix, to avoid distortion of the material. Each test specimen was measured pre and post heat treating using Vernier callipers, no significant dimensional thickness changes were observed as part of this process.

5.2.4 Custom Designed Testing Bath

A testing bath was specially designed by the author of this thesis with design input from Dr. Winwood (MMU, Cheshire) who had used a similar design in his PhD thesis, Dr. Zioupos (Reader in Biomechanics of Materials, Cranfield Forensic Institute) and Mr. Richards (MMU, Cheshire). The main body of the testing bath was custom milled from a solid block of Polyurethane with location prongs. A liquid inlet and outlet fittings were incorporated into the design of the testing bath, to allow the circulation of liquids using a heated circulating bath (Grant Instruments, Cambridge, UK) to replicate temperature of the human body (37 ºC) as shown in Figure 5.6.

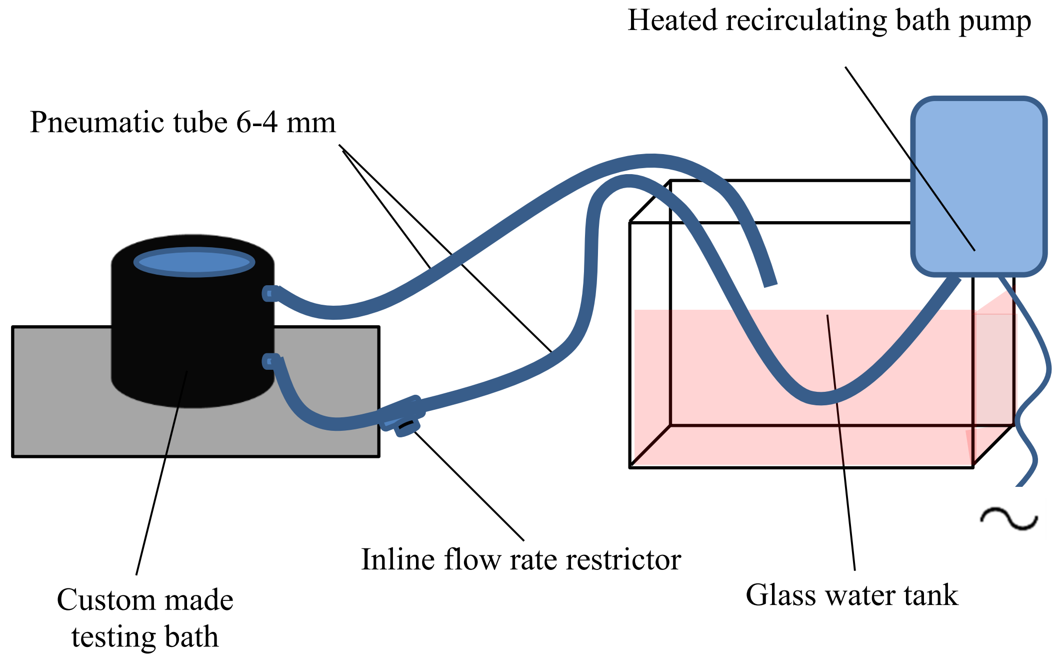


Figure 5-6: Schematic diagram of the experimental testing bath set-up used to impact test the bone samples with and without mouthguard protection.

5.2.5 Experimental setup

All impact testing procedures were carried out by the author at Cranfield University, Cranfield Forensic Institute. A servo-hydraulic Dartec® series HC10 testing rig was employed for this study, the force was applied to the test sample in compression by a 25 kN load cell (Sensotec® Ohio, USA) as shown in Figure 5.7.

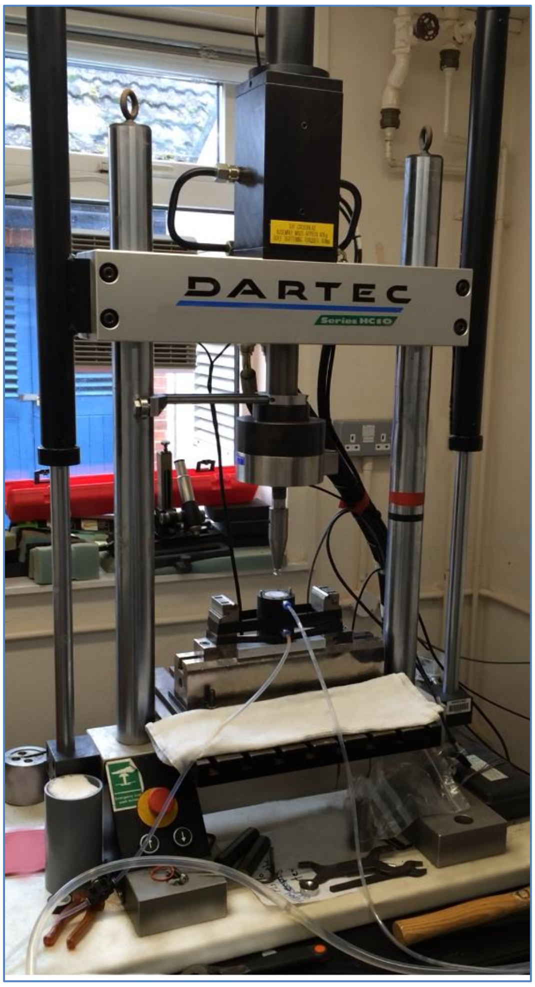


Figure 5-7: Servo-hydraulic Dartec® series HC10 testing machine with custom designed testing bath.

A custom designed impactor tip was constructed in steel (Figure 5.8) which fitted directly into the Dartec® testing machine. Higher impact values have been obtained from a punch scenario (Atha et al., 1985, Walilko et al., 2005), it was considered that a blunt slightly rounded tip to the impactor, would be more representative of traumatic impacts in sport. Therefore, the impactor tip was designed to have a relatively large contact surface area, to the test specimen set-up, to prevent damage to the EVA material during the impact event.

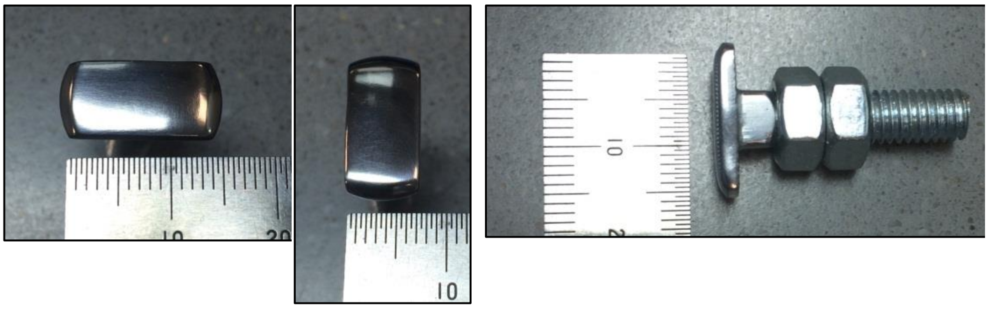


Figure 5-8: Steel impactor tip and dimensions (mm).

Each sample was then positioned onto the internal platform (ledge) (Figures 5.9 and 5.10). For the relevant testing groups a prescribed thickness of EVA material was placed over the bone sample (1.6 or 2.8 mm). The testing bath was designed to allow liquid to circulate freely around the bone sample. Water was pumped into the testing bath at 37ºC, thus simulating the oral environment with respect to temperature and saliva. The temperature of the water could have an influence on the performance of the EVA material. The water had a 10% infusion of Fluorescein, this was incorporated to highlight damage mechanisms in the bone in relation to microcrack damage during sample preparation and also after fracture.

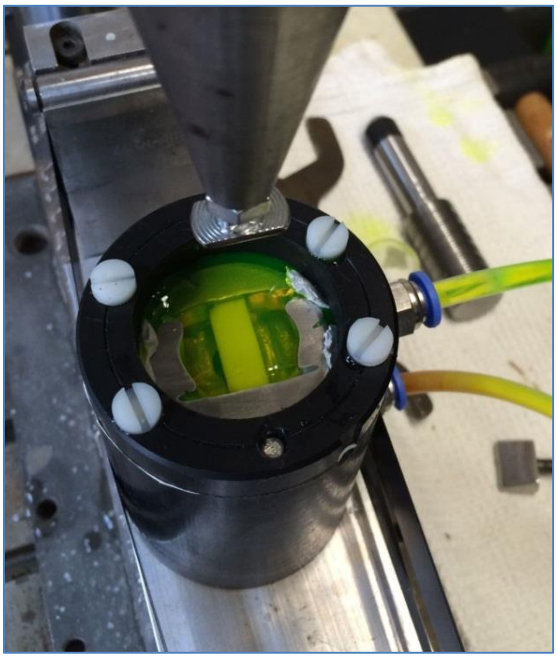


Figure 5-9: Custom designed testing bath with bone sample held into position.

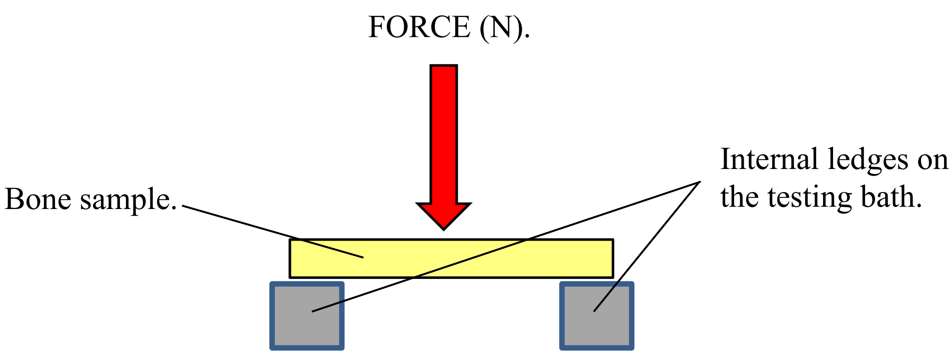


Figure 5-10: Illustrates the loading principal employed in the current study design.

All the prepared samples were then loaded in a DARTEC (Zwick-Roell) servohydraulic material testing machine. The machine had a maximum load capacity of 25 kN and a maximum stroke speed of 200 mm/s. Each sample was only loaded once in a single stroke from zero load till beyond its maximum load point (complete rupture) in a 3 point bending mode (3pb). 3pb means that the samples, which were in the form of beams, were supported at either end and were pressed in the middle by a blunt impactor (tip). The tests were carried out in the presence or absence of mouthguard material to examine the effects that these mouthguard protective layers may offer under these circumstances. Data acquisition was obtained using the Dartec® software (Toolkit 96) at 10 kHz (sampling frequency). The maximum stroke speed at the loading phase only lasted 20-50 ms simulating thus impact loading in conditions that resemble physiological circumstances. The piston with its impacting tip at the end moved from a resting position and achieved its maximum cruising speed (which was set at 200 mm/s) within 0.050 mm (50 micron), or in terms of time within 5 ms. After this very short accelerating phase, the piston/tip reached the maximum travelling speed and it was recorded to move at 170-190 mm/s. The loading phase with the tip in contact with the sample (either with or without the mouthguard material on it) lasted 20 ms (in all cases under 50 ms) which also resembled physiological loading profiles.

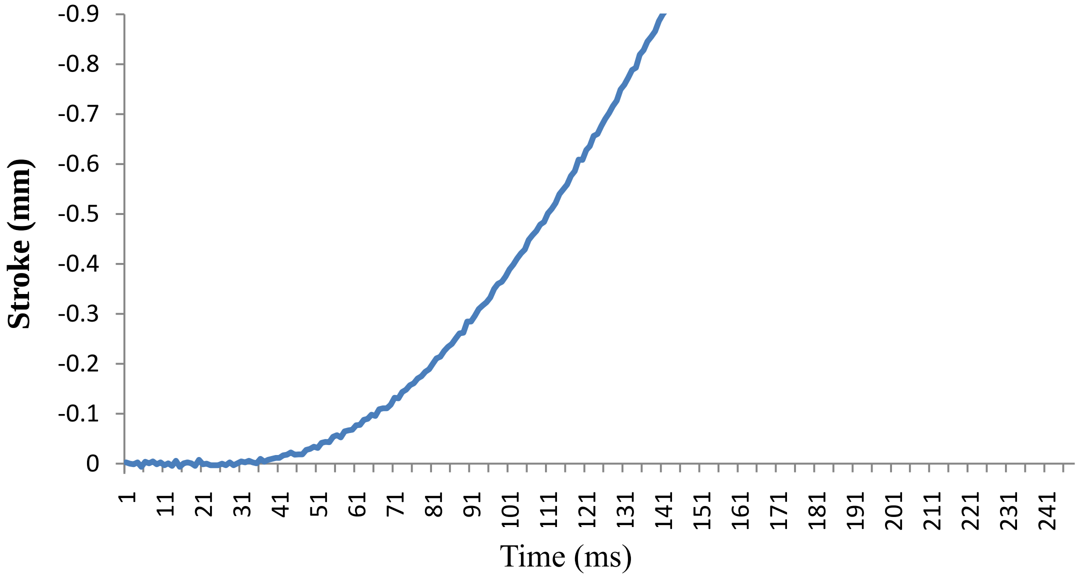


Figure 5-11: Shows the build-up of speed and the motion of the tip against time to demonstrate how impact was achieved (stroke vs time).

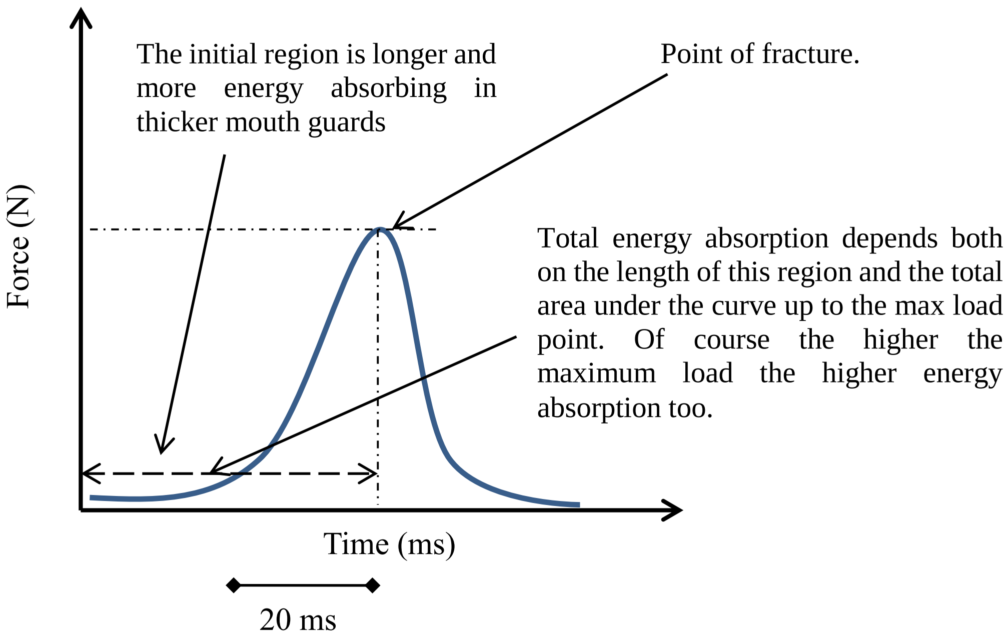


Figure 5-12: Profile of the force applied on a sample versus time.

Figure 5-12 demonstrates the loading principal used within this current study. The loading lasted milliseconds and the maximum load point was reached within 20-50 ms maximum, this was designed to mimic a real time impact event. The traces showed a period at the start where force rises slowly as the mouthguard is compressed and then the sample is fully compressed (linear fast loading region of the curve) and it then reaches a maximum load point where it fractures. After that the load dropped rapidly (the sample snaps in two and can sustain no load any further). The overall energy absorption is a result of both the initial rise from zero load (longer region due to wearing a mouthguard) and the maximum load point. See examples in Figure 5.11 and 5.12.

As bone strength is related to bone density. The bone mineral density values (g/cm^2) were obtained for the all of the samples inclusive of both the young and old cohort, using a Discovery QDR dual energy x-ray absorptiometry (DXA) scanner (Hologic Inc, USA). Each experimental group (10 specimens per group) were placed onto the calibration block (Hologic DXA quality control phantom spine; Area 54.4 cm^2, BMC: 51.2, g). The scans were then performed using the Hologic Discovery DXA systems forearm sub-region scan software. The fractured bone samples were reconstructed and scanned, to achieve a holistic record of BMD, both the halves of the fractured specimen were scanned and measured and a mean value was assigned in g/cm^2.

5.3 STATISTICAL ANALYSIS

Statistical analysis was performed using PASW® Statistics 21 (SPSS Inc., Chicago, IL, USA). Parametricity checks were carried out using the Kolmogorov-Smirnov (where n.50) or Shapiro-Wilk for normal distribution, and the Levene's test to check for homogeneity of variance. Log-transformation of non-normally distributed raw data (absorption) were carried out. Force and LOG (absorption) achieved parametricity, whereas stiffness and displacement were non-parametric. To identify any impact of mouthguard thickness in the level of protection against bone fracture, a UNIVARIATE 2×3 FACTORIAL ANOVA was performed on the parametric data (FORCE and LOG_ABSORPTION) with the BONE MODEL and level of MOUTHGUARD PROTECTION being the fixed factors. Post-Hoc pairwise comparisons, with Bonferroni corrections, were carried out where a main effect was identified. Non parametric data, STIFFNESS and DISPLACEMENT, were analysed using 1: Mann Whitney for AGE effect 2: Kruskall Wallis test for MOUTHGUARD effect (with appropriate post hoc pair wise man whitneys) 3: Kruskall Wallis for combined AGE-MOUTHGUARD effect (post hoc pair wise man whitneys), hence a pseudo-interaction analysis. Data are presented as mean ± STDEV unless otherwise specified. Statistical significance was accepted at $\alpha \leq 0.05$. Study power ($\beta \geq 0.8$), and effect size ($p\varepsilon^2 \geq 0.2$), are also specified for the factorial analyses. Distribution of data was assessed with a Kolgomorov Smirnov test. Pearson's linear correlation was used to reveal any association between bone mineral density and bone fracture strength. Statistical significance was defined at α = .01.

5.4 RESULTS.

5.4.1 Bone model.

A control group was used without mouthguard protection to highlight the difference in strength between the two experimental bone models, both young and old, Figure 5.13. The results showed that there was a highly significantly ($p < .0001$), reduced bone strength in old bone compared to the young bone tissue model.

The mean fracture rate for the young bone without any form of protection was 630 ±247 N compared to the aged old bone tissue without any form of protection was 225 ±127 N (Figure 5.13). This equates to a 64% reduction in strength between the young and the artificially aged bone/lower bone mineral density tissue. The BMD analysis of the samples showed a BMD reduction of 14.9% from a mean BMD of 0.423 g/cm^2 in the young model to 0.360 g/cm^2 in the old model.

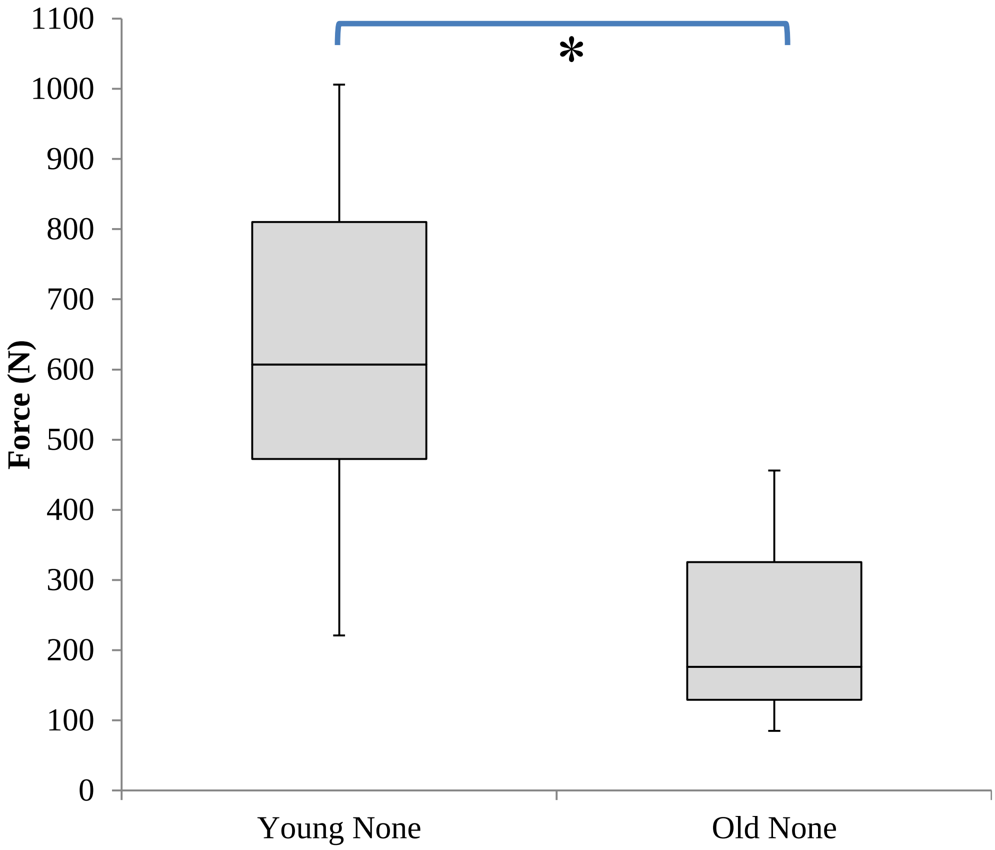


Figure 5-13: Bone strength of both the unprotected young and artificially aged/lower bone mineral density bone. Error bars included to indicate the level of significance (*p< 0.0001).

There was a highly significant positive linear correlation between the fracture point of the specimens and the degree of density ($r(58) = 0.50$, $p = 0.0001$), Figures 5.13 and 5.18. This bears out the study hypothesis, the higher the bone density the higher the force required to fracture the bone sample, Figure 5.18. Conversely, the lower the bone density, the lower the force required to fracture the bone samples. This was used in the study design to provide an example of an older experimental model (older sports participant or an individual with lower bone mineral density)

5.4.2 Varied levels of mouthguard protection.

When the mouthguard was incorporated within the set up for both young and old model the behaviour exhibited was as shown in Figures 5.14 – 5.17 and 5.19. An ANOVA analysis showed the maximum force (N) sustained by each sample exhibited a clear effect for mouthguard protection. Post-hoc pairwise comparisons showed there was a significant difference ($p < .001$) in the level of protection the 2.8 mm mouthguard offered compared to the unprotected sample group in both bone models, young and aged (Figure 5.14). Whereas, there was no significant effect between the unprotected group and the 1.6 mm mouthguard sample group, and the 1.6 mm to the 2.8 mm groups ($p > .05$), Figure 5.14. In the young bone model the control (without any mouthguard protection) the mean fracture point was 631 N (SD: 247 N), with the 1.6 mm mouthguard protection it took a mean force of 723 N (SD: 196 N) to fracture the samples and with the 2.8 mm mouthguard protection, the mean fracture point was 836 N (SD: 241 N). This correlates to a 14.6% increase in force to fracture for the 1.6 mm sample group, compared to without mouthguard protection and 32.5% increase in force to fracture in the case of the 2.8 mm sample group compared to without mouthguard protection, equating to a 15.6% increase in protection for the 2.8 mm over the 1.6 mm young group. Within the old bone tissue model the control (without any mouthguard protection) the mean fracture point was 225 N (SD: 127 N), with the 1.6 mm mouthguard protection had a 419 N (SD: 199 N) fracture point and the 2.8 mm mouthguard protection had a mean fracture point of 506 N (SD: 222 N). This correlates to an 86.2% increase in force to fracture for the 1.6 mm sample group, compared to without mouthguard protection and a 124.8% increase in force to fracture in the case of the 2.8 mm sample group, equating to a 20.7% increase in protection for the 2.8 mm over the 1.6 mm older group. In terms of percentage change between the young and old groups, without mouthguard protection there was a 64% decrease in force required to fracture the older sample, from a mean of 631 N in the young bone model and 225 N in the old bone model. With the 1.6 mm mouthguard sample in situ, there was a 42% decrease in force required to fracture the older sample, from a mean of 723 N in the young bone model and 419 N in the old bone model. Finally, using the 2.8 mm mouthguard protection, a 39% decrease in force required to fracture the sample was observed, from a mean of 836 N in the young bone model and 506 N in the old bone model.

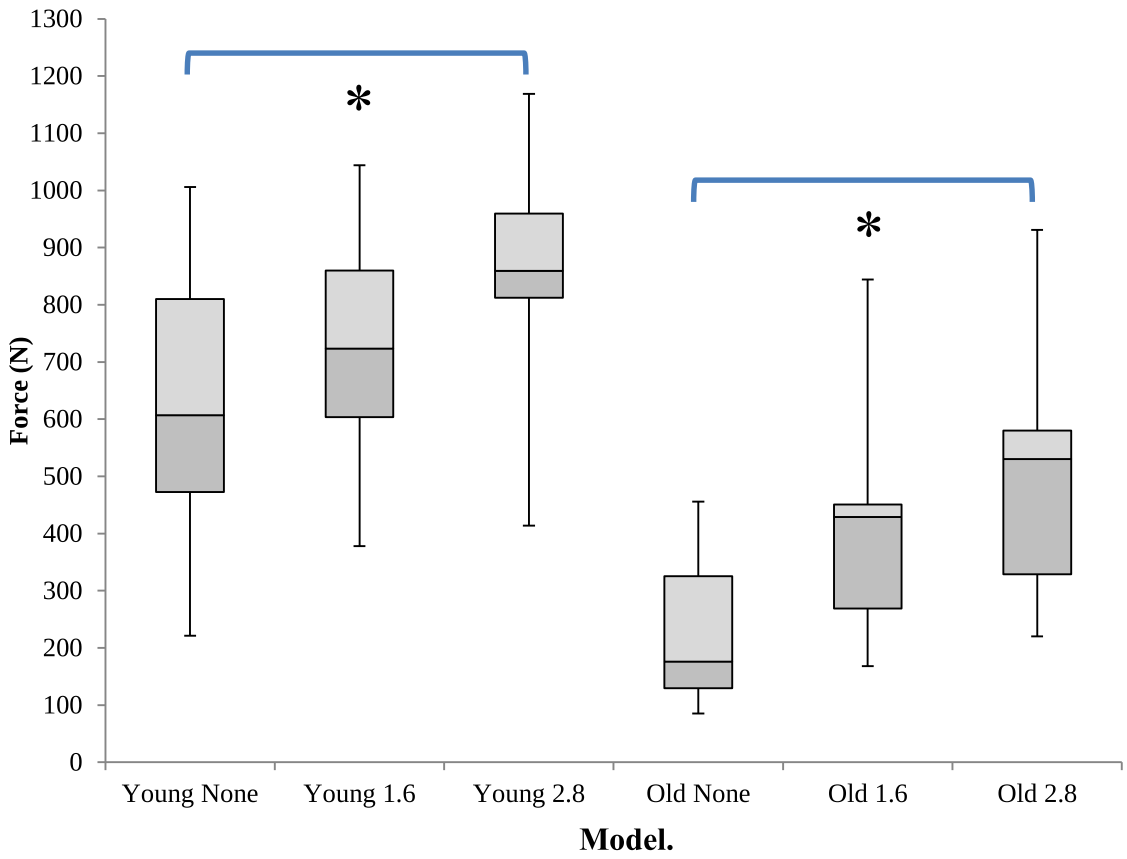


Figure 5-14: The ultimate impact force prior to fracture of all groups and for both bone tissue models (young and old). (* = $p < .001$)

Figure 5-14 demonstrates both the effects of ageing and the beneficial effect of the guard in both young and old in a very similar fashion (noticeably better for the thicker mouthguard). The boxplot chart shows the median value, the quartiles show the upper and lower 25% of the data set and the interquartile range shows the spread of the middle 50% of the data values.

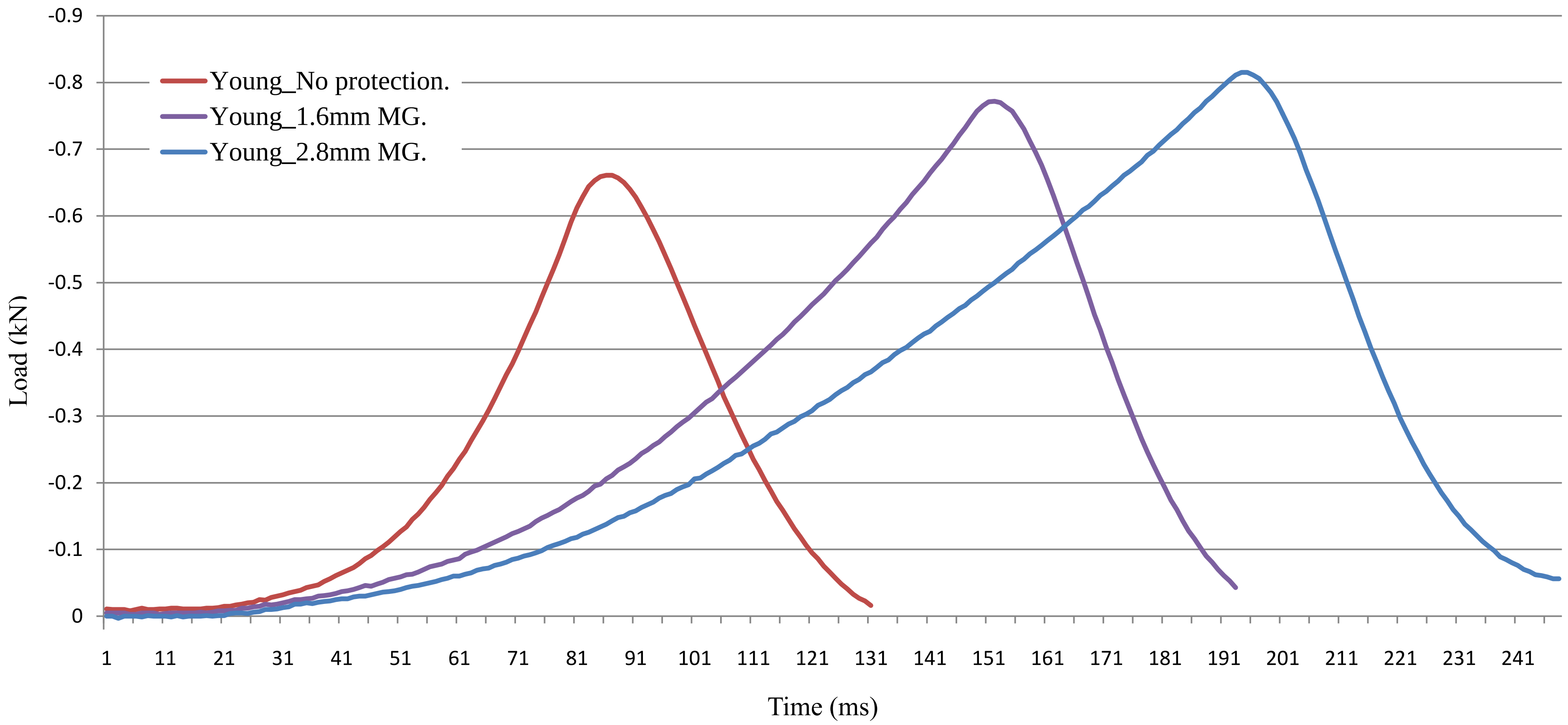


Figure 5-15: Traces of force versus time to fracture for the three protection levels. Sample data recording during tests using, none, 1.6mm MG and 2.8mm MG, in the young bone model.

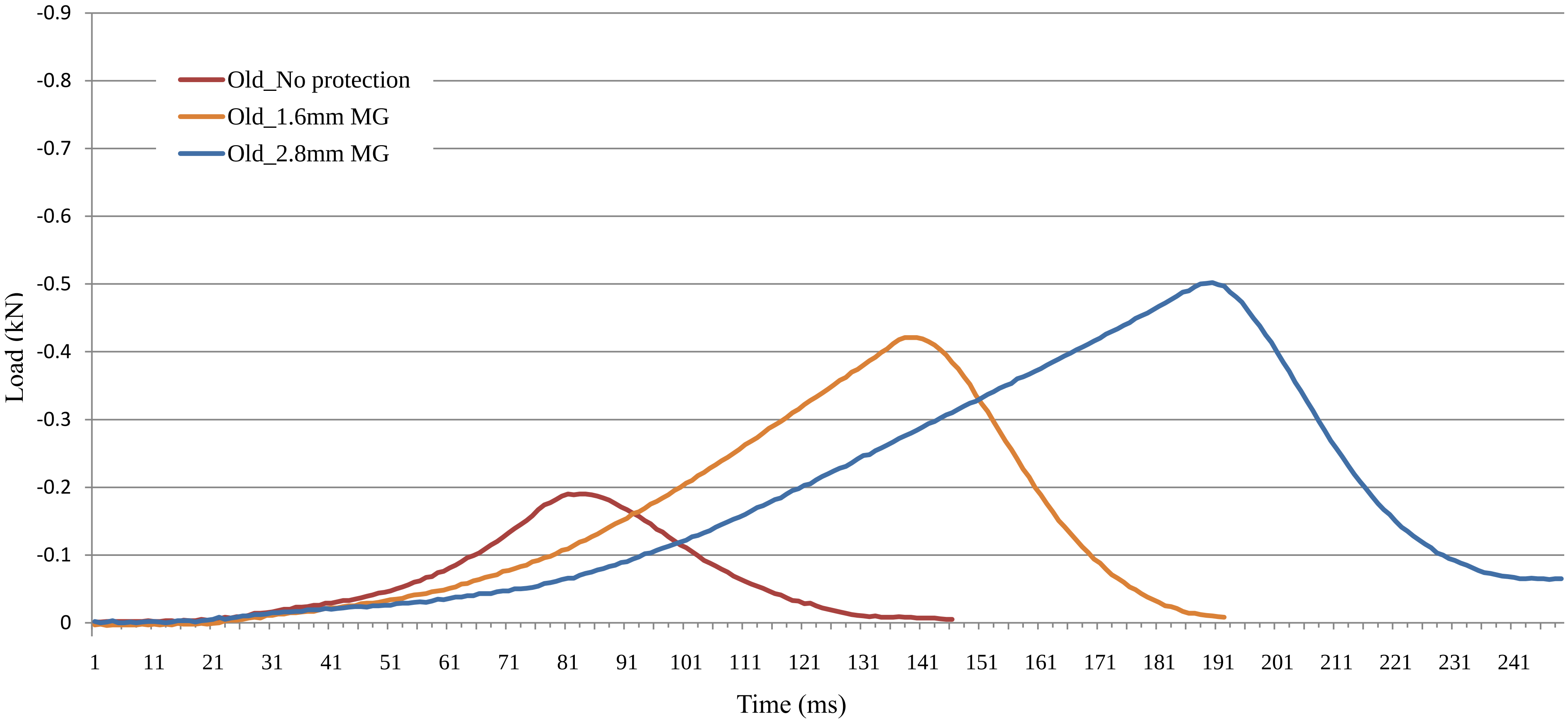


Figure 5-16: Traces of force versus time to fracture for the three protection levels in the 'aged' bone samples. Sample data recording during tests using, none, 1.6mm MG and 2.8mm MG, in the old bone model.

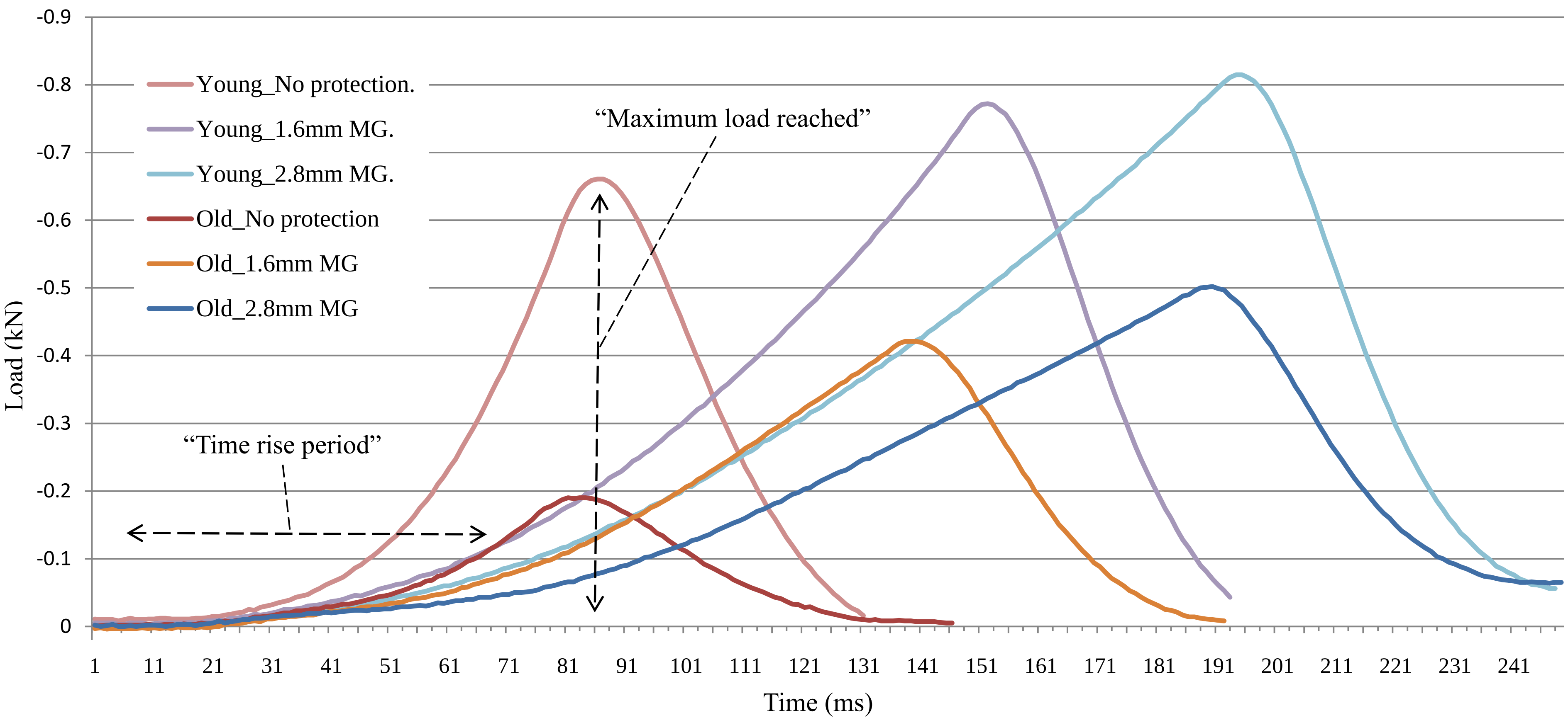


Figure 5-17: Traces of force versus time to fracture for the three protection levels and for both 'young' and 'old' overlapped. Sample data recording during tests using none, 1.6mm MG and 2.8mm MG, in both the young and old bone models.

Figure 5-17 demonstrates the beneficial effect of the mouthguards are twofold: (1) the compression of the mouthguard extends the initial load region (time rise period) and thus softens the blow and in this way the structure (bone and guard) absorbs extra energy; then (2) the rise to maximum load point is delayed by the protective layer and the bone can sustain higher loads (maximum load reached) because it is somehow protected from the sharp rise in force. Both these factors together show, that the area under the curve is higher for the thicker mouthguards and for the younger bone material.

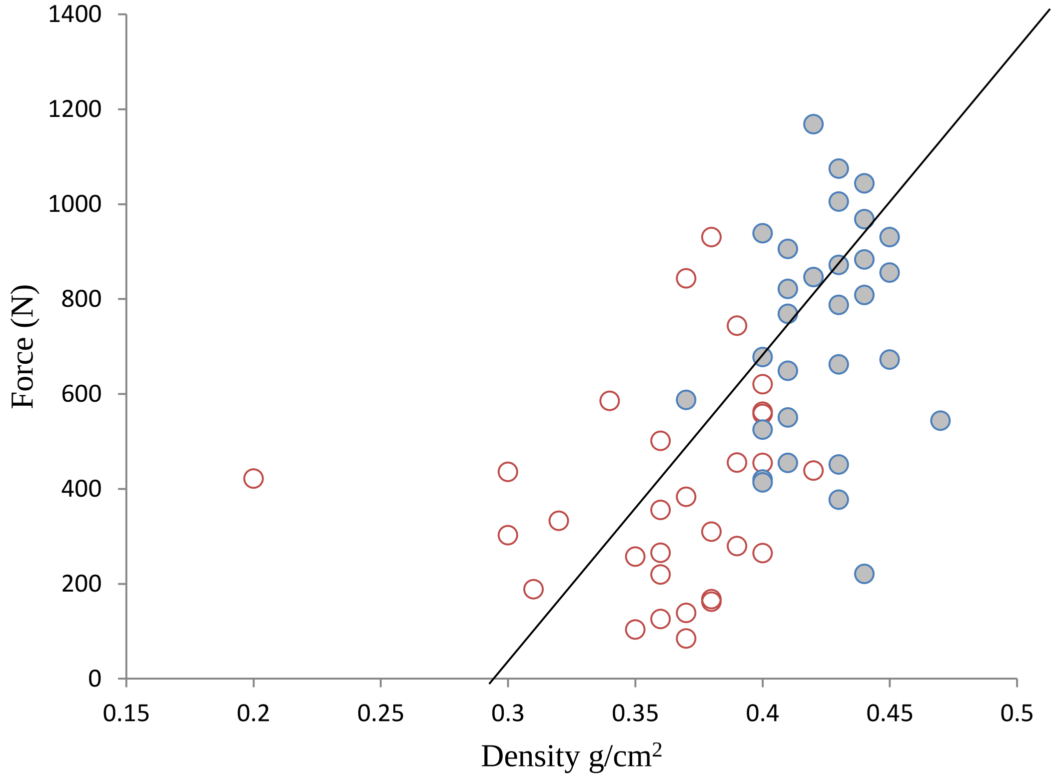


Figure 5-18: The correlation between BMD of the young (●) and old (○) bone model against the force required to break each sample. The trend line indicates the general pattern of the data series.

There is a highly significant positive linear correlation between the fracture point of the specimens and the degree of density ($r\ (58) = 0.50$, $p = .0001$). This bears out the study hypothesis, the higher the bone density, the higher the force required to fracture the bone sample, Figure 5.18. Conversely, the lower the bone density, the lower the force required to fracture the bone samples. This was used in the study design to provide an example of an older experimental model (older sports participant or an individual with lower bone mineral density). The correlation between bone density and force at fracture is only evident when the data set is pooled. Indeed when looking at the young and old bone model separately, there is no association between bone density and force at fracture. Thus confirms that the effects described are due to the ageing process.

Mouthguard - Absorption:

In terms of energy absorption there was a main effect of mouthguard in the ANOVA analysis. A Post-hoc pairwise comparisons showed there was a highly significant difference (p <.0001) in the energy absorbance between the unprotected groups and those protected by the 1.6 mm and 2.8 mm mouthguard (Figure 5.19). However, there was no significant effect difference in absorption between the 1.6 mm and 2.8 mm mouthguard protected samples (p>0.05).

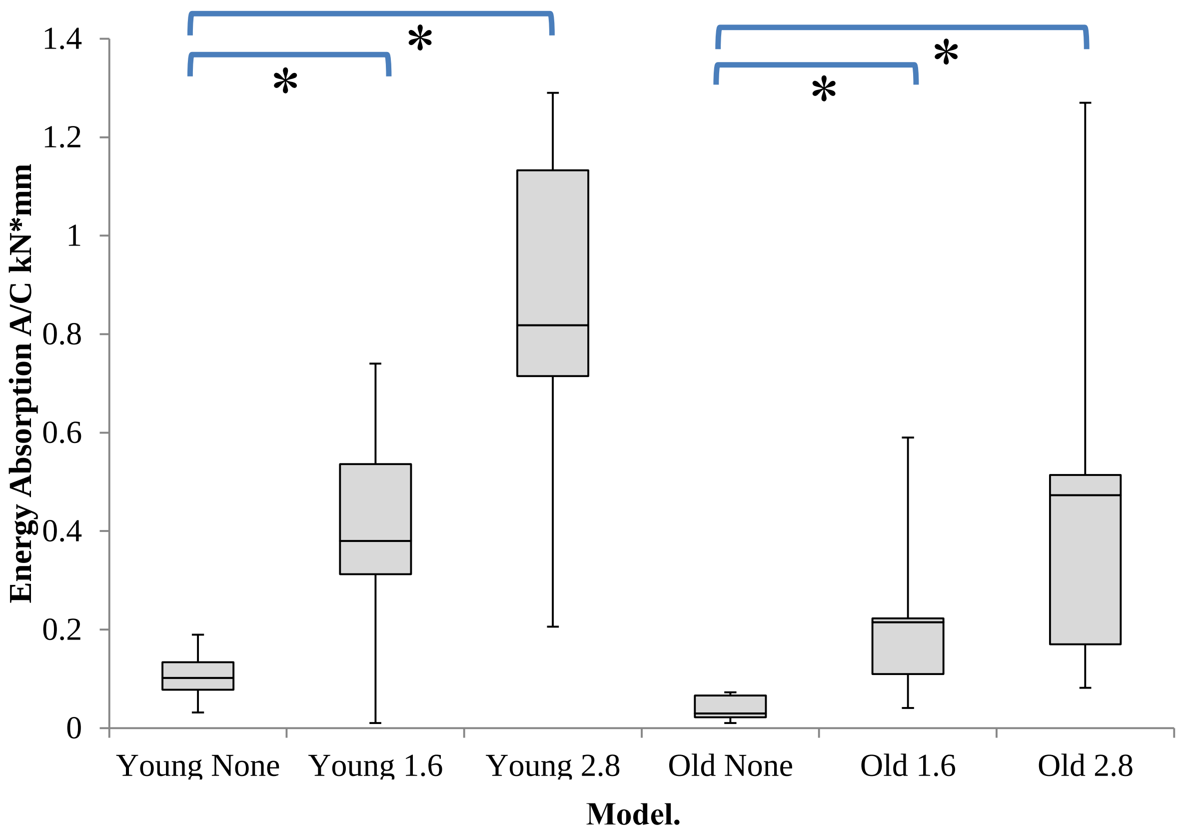


Figure 5-19: The impact energy absorption of the grouping model when analysed with the mouthguard and bone model are combined (* $p < 0.0001$).

Figure 5-19 illustrates both the effects of ageing and the beneficial effect of the guard in both young and old in a very similar fashion (noticeably better for the thicker mouth guard). The greatest degree of energy absorption was observed in both bone models, young and old, when protected by the 2.8 mm mouthguard material.

Mouthguard - Displacement

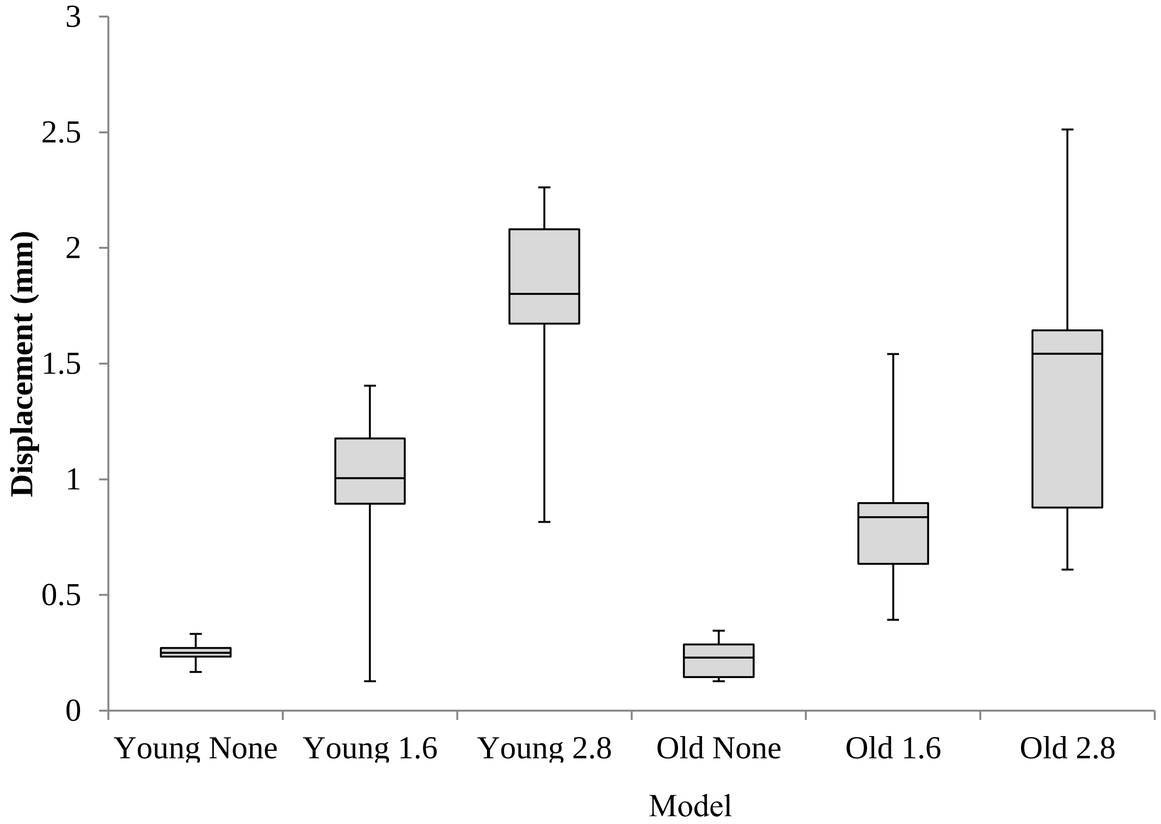


Figure 5-20: The impact material displacement of the grouping model when analysed with the mouthguard and bone model.

In terms of Displacement (kN/mm) a Post-hoc pairwise comparisons showed there was a significant difference ($p < .001$) as shown in Table 5.2 and illustrated in Figure 5.20. The greatest degree of displacement was observed in both bone models, young and old, when protected by the 2.8 mm mouthguard material. This chart demonstrates both the effects of ageing and the beneficial effect of the guard in both young and old in a very similar fashion (noticeably better for the thicker mouth guard). The boxplot chart shows the median value, the quartiles show the upper and lower 25% of the data set and the interquartile range shows the spread of the middle 50% of the data values.

	Young no protection	Young 1.6mm MG	Young 2.8mm MG	Aged no protection	Aged 1.6mm MG	Aged 2.8mm MG
Young no protection		*	*		*	*
Young 1.6mm MG			*	*		
Young 2.8mm MG				*	*	
Aged no protection					*	*
Aged 1.6mm MG						
Aged 2.8mm MG						

* <.001. Mouthguard (MG).

Table 5-2: Post hoc pairwise Mann Whitneys since there is a main effect of ‘bone model with varying levels of mouthguard protection and displacement’.

Mouthguard - Stiffness:

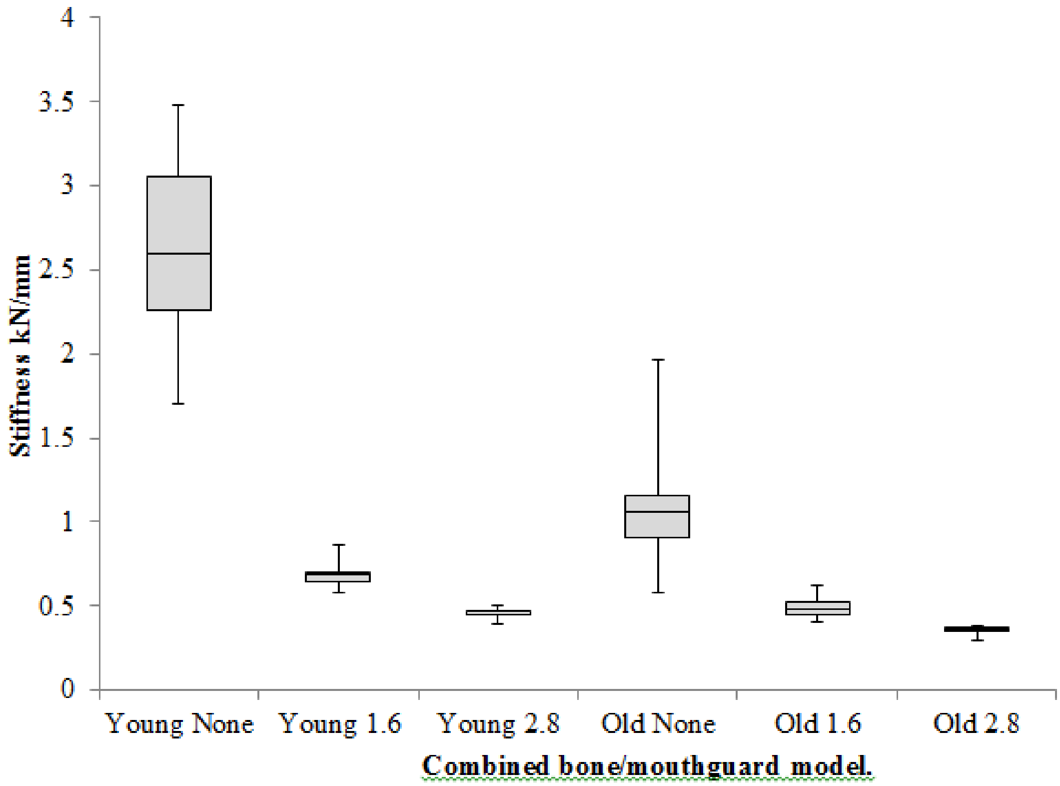


Figure 5-21: The impact stiffness of the grouping model when analysed with the mouthguard and bone model.

In terms of Stiffness (kN/mm) a Post-hoc pairwise comparisons showed there was a significant difference ($p < .001$) as shown in Table 5.3 and illustrated in Figure 5.21. The boxplot chart shows the median value, the quartiles show the upper and lower 25% of the data set and the interquartile range shows the spread of the middle 50% of the data values. The unprotected young bone model exhibited the greatest degree of stiffness. As expected, the old unprotected bone model exhibited a decreased level of stiffness. Both the bone models, young and old, were comparatively similar in terms of stiffness when protected by the 1.6 mm and 2.8 mm mouthguard material.

	Young no protection	Young 1.6mm MG	Young 2.8mm MG	Aged no protection	Aged 1.6mm MG	Aged 2.8mm MG
Young no protection		*	*	*	*	*
Young 1.6mm MG			*	*	*	*
Young 2.8mm MG				*		*
Aged no protection					*	*
Aged 1.6mm MG						*
Aged 2.8mm MG						

* <.001. Mouthguard (MG).

Table 5-3: Post hoc pairwise Mann Whitneys of the bone model with varying degrees of mouthguard protection and stiffness.

5.5 DISCUSSION

The results of this study showed that the 2.8 mm mouthguard, proposed in Chapter 4 (model inclination study) offers statistically ($p < 0.001$) more protection this would be a consequence of the increase within thickness. In terms of fracture strength there was no statistical difference ($p > 0.05$) between the current mean manufacturing thickness for custom made mouthguards, of 1.6 mm (Chapter 3) and not wearing a mouthguard at all as there was not enough thickness of mouthguard material to dissipate sufficient energy. In the young bone tissue model without mouthguard protection, the mean fracture impact force was 631 N (SD: 247 N). The old unprotected bone model had a mean fracture value of 225 N (SD: 127 N), which represents a 64% reduction in bone strength between these groups. This reduction in strength correlates with the reduced density of the older samples. In relation to the young bone model, without any mouthguard protection the mean fracture point was 631 N (SD: 247 N), with the 1.6 mm mouthguard protection in-situ it took a mean force of 723 N (SD: 196 N) to fracture the samples and with the 2.8 mm mouthguard protection, the mean fracture point was 836 N (SD: 241 N). This correlates to a 14.6% increase in force to fracture for the 1.6mm sample group compared to no mouthguard protection and 32.5% increase in force to fracture in the case of the 2.8 mm sample group compared to no mouthguard protection. Thus, equating to a 15.6% increase in protection for the 2.8 mm over the 1.6 mm younger group. The older bone tissue model exhibited the same relative increase in force to fracture as seen in the young tissue model; however the initial unprotected fracture point was much lower. The old bone model, without any mouthguard protection the mean fracture strength of 225 N (SD: 127 N), with the 1.6 mm mouthguard protection having 419 N (SD: 199 N), and the 2.8 mm mouthguard protection had a mean fracture of 506 N (SD: 222 N). Which correlates to an 86.2% increase in force to fracture for the 1.6 mm sample group, compared to no mouthguard protection and a 124.8% increase in force to fracture in the case of the 2.8 mm sample group, equating to a 20.7% increase in protection for the 2.8 mm over the 1.6 mm older group. This highlights, in an older bone model, a mouthguard on 2.8 mm offers more than double the protection against impact fractures than no mouthguard at all. As shown in Figures 5.15 – 5.17, as the thickness of the mouthguard increases not only does the protection against force increase, but also the level of absorption the material exhibits becomes greater. In terms of impact energy absorbency, in both bone models young and old, both the 1.6 mm and 2.8 mm mouthguard material significantly ($p < 0.0001$) absorbed a greater degree of force over a much longer period of time than no mouthguard at all, Figures 5.15 - 5.17. The results follow that of previous studies by Westerman et al, (2002) and Maeda et al, (2008) in that the mouthguards performance linked to its thickness. Westerman et al, (2002) using a pendulum impact machine, tested EVA material using an impact energy of 4.4 J at 3 m/s. They found that a 1 and 2 mm thickness of EVA offered lower protection with regards to energy absorption when tested in the laboratory. They reported that 2 mm thick mouthguard transmitted 15700 N, a 3 mm thickness transmitted 11400 N, whereas the 4mm mouthguard only transmitting 4380 N, giving the 3 mm mouthguard thickness 61% reduction in energy than the 2 mm thickness, and the 4 mm mouthguard thickness has a 72% reduction in energy when compared against the 2 mm thickness. However, within the present study a bone tissue model was incorporated in two thicknesses, each of the sample groups were subjected to force to fracture loading and the point of fracture was recorded (N).

Maeda et al, (2008) also tested a series of mouthguard thicknesses ranging from 1-6 mm, they also employed a pendulum impact testing machine. The study employed three different types of sensor, a load cell, accelerometer and a strain gauge that was incorporated into an acrylic resin back plate. Their pendulum had interchangeable impact heads, a 172.5 g steel ball and a 147.3 g baseball. However, this current study is only concerned with the data from the steel ball, as it is comparative in material used with its own impact head design. As an omission by Maeda et al, (2008), “clearer results were obtained for the steel ball sample”. In total three samples were produced and impacted per experimental variable (1-6 mm MG thickness). Maeda et al, (2008) states in their method, that the samples were heated for 150 secs as part of their sample preparation; whereas, this current study heated the mouthguard samples to temperature of 84°C and held for 10 minutes, in accordance with previous research by Patrick et al, (2005). Maeda et al, (2008) included a control group without mouthguard protection, which just involved an impact against their acrylic resin mounting plate, which incorporated measurement sensors, so comparative analysis between thicknesses could be better understood. They reported the initial impact without mouthguard protection at 1307.3 N, the 1 mm mouthguard decreased the impact force by 48.3% (673.2N), 2 mm by 63.1% (482 N), 3 mm by 68.7% (410 N), 4 mm by 72.9% (355 N), 5 mm by 73.2% (351N) and 6 mm by 74.6% (332 N). Their methodology differs in design from the current study, as a bone tissue model both young and old was employed with and without mouthguard protection making it more representative of the oral cavity structure. Both Westerman et al, (2002) and Maeda et al, (2008) observed little increase in energy absorption in mouthguards thicker than 4mm. Direct comparisons between results in terms of bone fracture force (N) would be difficult as the current study uses a bone tissue model, alongside different testing methodologies and mouthguard thicknesses (1.6 mm & 2.8 mm), plus also some of the previous studies samples were not heat treated (Westerman et al., 2002a). In terms of energy absorption, in the young bone model, of this current study, there was a 74% absorption of energy between no mouthguard and the 1.6 mm mouthguard and 87% between none and the 2.8 mm guarded samples. In the old bone model there was an 85% absorption of energy between no mouthguard and the 1.6 mm mouthguard and 93% between none and the 2.8 mm guarded samples, Figure 5.19. However, the general trend is the same, the thicker the mouthguard material, the greater the energy absorbed (Westerman et al., 2002a, Maeda et al., 2008) and level of protection against impact fracture. This current study differs from previous research in this area as it employs a bone tissue model with a heated testing bath, which shows the performance of the mouthguard material in a testing methodology that is more representative of the orofacial structure in a traumatic impact scenario.

5.5.1 Testing methodology design considerations.

Ethylene vinyl acetate (EVA) physical properties are influenced by temperature, the higher the temperature the softer the material becomes (Rawls, 2003). Therefore, to make material testing methodology as representative as possible, a uniquely designed testing rig was developed to create a constant temperature of 37ºC to be pumped around the sample during the impact, thus in this event mimicking the effects of saliva found in the intra oral environment. In addition, temperature has been known to effect bone mechanical properties (Carter and Hayes, 1976). As previously stated, the majority of traumatic impacts within sport are quick and from a relatively blunt object (ball, opponents head, floor, etc.) therefore it was considered that a blunt, slightly rounded impactor tip would the most representative of this type of impact force, Figure 5.8. Patrick (2005), examined laminated structures for sports mouthguards, in which they recommend a force of between 320-800 N which would be representative of hockey and cricket projectile frontal impacts (Patrick, 2005). Given the thickness of the bone sample, the magnitude and delivery time of the impact force were designed to be as representative as possible. This is comparable of the forces observed in this current study, that the mean fracture rate for the young bone samples without any form of protection was 630 ±247 N. In comparison to the aged bone samples without any form of protection at 225 ±127 N, which were designed to represent an older sporting cohort or an individual with lower bone density.

5.5.2 Bone model

In this current research design a bone model was incorporated which is unique and has not previously been demonstrated in relation to this environment. The previous published study designs properties were mimicked by the use of plastics, dental stone and metals (Greasley and Karet, 1997, Hoffmann et al., 1999, Takeda et al., 2005a), these materials are not fully representative of the anatomical structures found within the oral cavity. Previous animal models have been well established as a bone research model which have used canine, ovine and more favoured in orofacial research porcine (Vodicka et al., 2005, Oltramari et al., 2007, Pearce et al., 2007, Wang et al., 2007, Gahlert et al., 2010), Table 5.4. For the present study three of the animal bone tissue models; porcine, equine and bovine were considered and comparisons of the relative merits and disadvantages of each are discussed in Chapter 6 of this thesis.

Animal models	**Research area**	**Anatomical site**	**Age**	**Author**
Porcine (including mini pig)	Dental implant	Mandible	12mths	Stadlinger et al, (2008)
		Mandible	"Dentally mature"	Bousdras et al, (2007)
		Mandible and maxilla.	18-21mths	Neugebauer et al, (2009)
		Maxilla	18mths	Gahlert et al, (2010)
Canine	Dental implant	Mandible	"Skeletally mature"	Salmoria et al, (2008)
		Mandible and maxilla	"Adult"	Chen et al, (2008a)
		Maxilla	6.5 mths	Asscherickx et al, (2008)
		Mandible	13-15 mths	Chen et al, (2008b)
Monkey	Dental implants	Mandible	*	Hammerle et al, (1998)
		Maxillary sinus	8-12yrs	Quinones et al, (1997)
Rabbit	Dental implant	Tibia		Seong et al, (2013)
		Femur	12mths	Tsetsenekou et al, (2012)
		Mandible	*	Shafer et al, (1995)
		Tibia	"Skeletally mature"	Mori et al, (1997)
		Tibia	"Mature"	Meredith et al, (1997)
Ovine	Dental implants	Maxillary sinus	"Adult"	Haas et al, (1998)
		Maxillary sinus	"Adult"	Jakse et al, (2007)
		Pelvis (iliac bone)	2-3 yrs	Langhoff et al, (2008)
Bovine (Cow)	Dental Implants	Mandible	*	Benington et al, (2002)
		Rib	*	Oliveira et al, (2012)

Table 5-4: Summary table showing examples of orofacial research animal models.

*Information not recorded in the paper.

5.5.3 Ageing of the samples

It was the intent of this current study to use a young and old cohort, to determine if the mean current thickness of mouthguard, 1.6 mm, offers sufficient protection against traumatic orofacial impacts, for senior sporting participants or those with lower bone density. Due to the lack of age providence and the relatively young age of slaughter for the food chain, Chapter 6, a suitable pre-existing young/old bone model from an animal source proved unobtainable. With the use of EDTA solution, the young bone samples could be sufficiently aged to replicate BMD values observed in previous research in this area. Wallace et al, (2013) examined the risks of low energy fractures in an ageing/osteoporotic bone model. To achieve this they subjected 20 untreated ovine femurs to three-point bone testing at high (17.14 s^{-1}) and low (8.56 s^{-1}) strain rates, then another 20 femurs from the same group were artificially aged through demineralisation of the bone by EDTA. They determined the level of demineralisation by radiographic imaging; the untreated bone had a mean value of 2.47 ±0.45 g/cm^3 compared to the demineralised samples that had a mean value of 1.86 ±0.28 g/cm^3, which equates to a mean reduction of 25%. Their study observed a reduction in fracture toughness at a slow load rate, a mean of 3.7 ±1.4 MJ/m^3 for untreated samples and 2.8 ±0.9 MJ/m^3 for the demineralised samples. These were whole bone tissue samples, whereas the samples for this current study had been reduce in dimensions of 8 mm wide × 19 mm long × 3 mm thick, considerably thinner than the study by Wallace et al, (2013), therefore this would be reflected in the BMD values. Holes (n=10) were placed into the back of the EDTA treated samples, to replicate an osteoporotic model and allow a full depth penetration of the EDTA solution. A DXA analysis of the samples showed a BMD reduction of 14.9% in the EDTA treated samples from a mean BMD of 0.423 g/cm^2 in the untreated samples compared to 0.360 g/cm^2 in the treated samples. This equated to a 64% reduction in strength with between the untreated bone samples compared with the treated sample. The mean fracture rate for the untreated bone samples without any form of protection was 630 ±247 N compared to the EDTA treated bone samples without any form of protection at 225 ±127 N.

The human jaws have different levels of bone mineral density (BMD) dependant on the anatomical site of measurement. Gulsahi et al, (2010) evaluated differences in BMD of both the maxilla and mandible in participants by using dual energy X-ray absorptiometry (DXA) compared to panoramic radiomorphometric indices. Measurements were made in the anterior, premolar and molar regions of 49 healthy edentulous patients (18 males and 31 females with a mean age of 60.2 ±11.04 yrs). The mean BMD in both the maxillary anterior and premolar regions was 0.31(SD: 0.13) g/cm^2, maxillary molar region was 0.45 (SD: 0.15) g/cm^2. The mean BMD in the mandibular anterior region was 1.39 (SD: 0.36) g/cm^2, the mandibular premolar region was 1.28 (SD: 0.3) g/cm^2 and 1.09 (SD: 0.33) g/cm^2 in the mandibular molar region. Their mean BMD in the maxillary anterior and premolar regions of 0.31 g/cm^2, for an sample group with a mean age of 60.2 ±11.04 yrs, is comparable to the EDTA treated bovine samples used in this current study that had a mean BMD of 0.36 g/cm^2. They found the BMD was lowest in the maxillary anterior and premolar region and highest in the mandibular anterior region. Their study highlighted the differing BMD throughout both jaws. As the mandible is imbued with different bone densities at differing anatomical sites i.e. incisor, premolar, molar and angle, these sites would have different impact strengths and impact absorbency, which would make likewise comparisons inaccurate. In relevance to this current study, the majority of custom made mouthguards are formed over the maxillary dentition. Using a ovine mandibular bone model (3 yrs of age), Kovan, (2008) impact tested four anatomical regions of a full thickness of the mandible using an Izod impact tester under two impact loading directions, lateral and ventral. They found that the molar region of the mandible was the strongest under ventral and lateral loading conditions, whereas, under ventral loading the premolar region was the weakest as was the angle region under lateral loading (Kovan, 2008).

Crawford et al., (2014) investigated facial bone mineral density as a potential indicator for the risk injury in sport. They asssessed a cohort of 26 males from two ethnic backgrounds; Caucasian (n=14) and African Caribbean (n=12), the cohort had a mean age of 21 ±1.7 yrs. Participants were subjected to BMD measurements using a DXA scanner of the mandible. Their results showed a mean BMD for the ramus were 0.65 ±0.28 g/cm^2 in the Caucasian cohort and 0.92 ±0.25 g/cm^2 in the African Caribbean cohort, which equates to a 29% lower BMD in the Caucasian cohort than the African Caribbean cohort, in the ramus. The mandibular body showed a 1.40 ± 0.34g/cm^2 for the Caucasian cohort and 1.45 ±0.36 g/cm^2 in the African Caribbean cohort, which equates to a 3% lower BMD respectively. Their study highlighted that BMD can differ between ethnic groups of relatively the same age, but also between the anatomical sites of the jaw, i.e. the mandibular body and the ramus. Their findings highlight that some individuals may be more susceptible to facial injury and therefore, therefore the level of facial protection in sport should be more bespoke to the individuals risk of injury, in terms of bone density. Lower bone density occurs not only older athletes but athletes of different ethnicity and within groups (Crawford et al., 2014), and athletes where diet restrictions occur, e.g. horse racing be important, boxing, gymnastics (O'Brien, 2001, Dolan et al., 2012). Osteoporosis has also been linked to bone loss in the jaw (Horner et al., 1996). This to a greater extent is an age related factor, but is an important indicator as to possible risks of fracture. It is believed there is an association between tooth loss/chronic periodontal disease/reduction in mandibular bone mineral density and osteopenia/osteoporosis in some gender and age groups (Horner et al., 1996, Wactawski-Wende, 2001, Lindh et al., 2008, Kyrgidis et al., 2011, Sultan and Rao, 2011). Intra-oral signs of bone disorders may be apparent at the patient's annual dental check-up (Kaye, 2007), and could be used in the future to give an indication of the level of risk a sports participant is at of other types of fracture and the level of head/facial protection.

5.6 CONCLUSION

The aim of this study was to test the mean thicknesses of mouthguards observed in Chapter 3 of 1.6 mm and the values obtained from the technique discussed in Chapter 4 of 2.8 mm. An experimental model was devised to closely replicate the intra oral cavity. This comprised of a custom designed testing bath which allowed the circulation of water at 37ºC around both the bone sample and mouthguard material, during the impact event thus mimicking an intraoral environment. A bone model was chosen to represent a young and older sporting cohort. The older bone model was partly demineralised by EDTA solution equating to a young model having a mean BMD of 0.423 g/cm^2 and 0.360 g/cm^2 for the older/lower bone mineral density. This observed reduction in BMD, as expected had a reduction in bone strength, from a mean fracture for the young bone without any form of protection of 630 ±247 N compared to the aged old bone tissue, without protection, of 225 ±127 N, equating to a 64% reduction in strength with between the young and the artificially aged bone tissue. The results of this study highlight: (i) the current mean manufactured thickness, of 1.6 mm, for custom made mouthguards statistically offers no more protection against impact fractures than not wearing a mouthguard at all, however, more research on this is required. (ii) The mouthguard thickness of 2.8 mm offers statistically ($p <.001$) greater protection against traumatic impact fractures in both a young and old bone model.

There should not be a one fits all mentality when it comes to custom made mouthguards, in terms of thickness. Specifically in older sports participants with decreased bone density, or athletes/individuals who have their weight restricted, for example boxing, gymnastics and horse jockeys who have sometimes being reported at risk of osteoporosis (O'Brien, 2001, Dolan et al., 2012). Bone mineral density could be determined by the incorporation of a dental X-rays, highlighting that some participants may require thicker level of mouthguard to achieve the same levels of protection as a younger cohort or those with higher bone mineral density as shown in this study. Given there are differences in finished thicknesses they need to be measured at the key anatomical sites after moulding, specifically the anterior sulcus and occlusal sections. In addition, when prescribing the dentist should take the age and medical history into account before determining the correct thickness of mouthguard for that individual to make it more custom made for the individual.

CHAPTER 6: GENERAL DISCUSSION AND CONCLUSION

Head injuries have been identified as the most common cause of death and disability in people aged 1–40 yrs in the United Kingdom. A total of 1.4 million people attend emergency departments, each year, in England and Wales with head injuries. Of the 200,000 people that required admission to hospital, one-fifth had skull fractures or some degree of brain injury (National Institute for Health and Care Excellence, 2014). The aim of the present thesis was to investigate maxillofacial type injuries sustained from sport. In addition, how protective modalities at the current standard could affect injury specifically within those who have differences in bone density and ageing populations. Custom made mouthguards have been identified as a relatively effective method of reducing orofacial fracture. However, excessive material thinning has been observed in the manufacturing of custom made mouthguards (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Takahashi et al., 2013a), this may have a detrimental effect on injury rates within certain participants in sport with a lower bone density (e.g. horse jockeys and master athletes). This discussion will highlight the main findings from the four studies, what the outcomes were, the limitations of the studies and finally, suggestions as to improve future research in this subject area.

6.1 Study One (Chapter 2): An investigation into the occurrence and effects of Maxillofacial injury due to sport.

Sports facial injuries account for quite a considerable amount of hospital attendances throughout the world (Tanaka et al., 1996, Bataineh, 1998, Hill et al., 1998, Gassner et al., 2003, Delilbasi et al., 2004, Exadaktylos et al., 2004, Mourouzis and Koumoura, 2005, Chao et al., 2008, Elhammali et al., 2010, Walker et al., 2012a). Some of these injuries can be complex and can leave the patient with impairments in masticatory function, vision, respiration, sense of smell and psychological problems in cases of disfigurement (Girotto et al., 2001, Glynn et al., 2003, De Sousa, 2008, Glendor, 2009). There are a limited number of studies, in the United Kingdom recording the occurrence rates of orofacial injuries deriving from sport, particularly annually or nationally (Hill et al., 1998, Hutchison et al., 1998, Walker et al., 2012a). Therefore, the aim of this study was to give an up to date overview of sports related maxillofacial/orofacial injuries seen in maxillofacial hospital departments in the UK during a one year duration (2009 – 2010). A questionnaire methodology was employed to provide a qualitative tailored analysis of recorded data that is current and interest specific to the subject matter. For example, it identified the types of sports played, anatomical sites of fracture, age range, gender ratio, geographic region, and other anomalies etc. The questionnaire was initially completed by the clinician and then passed to the patient with a study pack, which consisted of a patient information sheet and a franked envelope. The patients consent was assumed by the completion and return of the questionnaire.

The results from the questionnaire study showed that maxillofacial injuries were predominately in young adult males (16-25 yrs), which is concurrent with previous studies that show a similar age ranges between 15-30 yrs (Tanaka et al., 1996, Delilbasi et al., 2004, Mourouzis and Koumoura, 2005, Walker et al., 2012b). The trend of young males being at a greater risk of injury in sport has also been observed in previous studies (Tanaka et al., 1996, Hill et al., 1998, Maladiere et al., 2001, Delilbasi et al., 2004, Exadaktylos et al., 2004, Mourouzis and Koumoura, 2005). It was shown that the maxilla, mandible and zygoma being of equal risk (25% for each site) of orofacial fracture. Irrespective that protective headwear and mouthguards are readily available to all levels of sporting participants 73% of the cohort of sports participants did not wear any form of head/facial protection during their given sport.

The data collection phase of this study was not as effective as expected with only a total of 26 replies. Other studies have reported higher figures to those found in the present study (Hill et al., 1998, Walker et al., 2012a). This in part may be due to the fact that these studies were run in Accident and Emergency departments and have included bruising, abrasions and soft tissue damage, not solely in relation to fractures as with this study, however, these other studies were allowed to collect data via a proforma document completed by the clinicians. Under the current study design taking account of NRES advice/recommendations, the participants were asked to take the questionnaire pack away with them to consider at their leisure rather than complete under perceived time constrained conditions during their time in hospital. The protocol as prescribed by NRES ethical guidelines may have affected the number of returns, as some participants may have not bothered returning the information as they simply forgot. The low rate of return to the study may be explained by a number of factors including: a restricted use of the patient's time in the waiting room and therefore collection method having to change to postal, and a lack of patient interest, post appointment.

Initially, the questionnaire and patient information sheet was designed to be given to the patient on their first arrival to the Maxillofacial department, with the consultant filling out their own section last, thereby allowing the consultant to collect in all the completed questionnaires. It was felt that the time the patient was in the waiting area prior to their appointment could be utilised to look at the 'patient information sheet' and complete the very short questionnaire. This was however, rejected by NRES on the grounds that it would not allow the patient sufficient time to digest the questionnaire and PIS and for consent to be given for inclusion to the study. The questionnaire was therefore revised in accordance with NRES stipulations; the consultant first completed his section and then the patient took the questionnaire away to read and fill out in their own time. This was then sent back in the self-addressed franked envelope. The effect was that the collection of the data was very much at the mercy of the patient's interest in the study. This returning of questionnaires by postal response has been acknowledged as having the potential to be severely detrimental to the amount of data collected (Hicks and Hicks, 1999).

Other studies of this kind have employed a historical/retrospective form of data collection through past patients' notes (Bataineh, 1998, Delilbasi et al., 2004, Mourouzis and Koumoura, 2005). However, this type of data gathering is reliant on the information that has previously been recorded in patient notes and hence a limitation, in that such data cannot be revisited or improved upon in terms of level of detail recorded. Indeed such retrospective work may miss facts that are pertinent to the study/participant for example; sport type or as to whether protective equipment was worn or not etc. Studies over a long period of time would have different operatives inputting data and there is currently no uniform database pre-existing recording data, of the kind recorded for this study within hospitals in the UK as a whole. Direct access to patients notes for a retrospective study over the same time period (1 year) using the same amount of sites would be unfeasible due to the need for retrospective consent for access to patient private notes. Informed consent from each individual patient to use their data, as with a retrospective study, would have been required, as all patient data therein are subject to NHS ethical approval and thereby written patient consent should/must be sort prior to its use for any form of publication. This would have been logistically impossible; as consent of this kind is not recorded in the patient's notes as a matter of course. In contrast, with the present questionnaire study, by following guidance from NRES, informed consent was assumed by the patient returning a completed questionnaire, also all participants data remained non-identifiable as not to contravene their confidentiality. Studies by Hill et al., (1998), Hutchison et al., (1998) and Walker et al., (2012a) all employed a a proforma document design that was filled out by the clinicians at the time of the appointment.

As a recommendation for the future and to give a true picture of patient/medical/trend/service needs, there should be greater continuity in computing operating systems nationally, in this case within the NHS, and also internationally, as advocated by American Dental Association (2006) and trialed at a unit level in Switzerland, with the aim of establishing a Swiss maxillofacial database (Exadaktylos et al., 2004). This would require a central database throughout the NHS as a whole that can be used to record standard predetermined patient information by each specialty within the NHS which can be centrally updated and monitored by the relevant authorities.

Limitations

Since the end of the data collection phase of this study (2009 to 2010) a review of public service was commissioned by the Government, as part of this review process. NHS research governance was to be scrutinized (Munn, 2011), in a comprehensively holistic manner with a focus on effectiveness from the standpoint of the patient, the researcher, society and economy. One such report from the Academy of Medical Sciences (2011) stated:

> *"A 'one-size-fits-all' approach to regulation damages us all. Access to patient data for research is currently hampered by a fragmented legal framework, inconsistency in interpretation of the regulations, variable guidance and a lack of clarity among investigators, regulators, patients and the public"*(The Academy of Medical Science, 2011).

The report also includes the following statements which are pertinent to this study:

> *"The current process for obtaining research permissions across multiple NHS sites is inefficient and inconsistent, characterised by NHS Trusts reinterpreting assessments already undertaken by regulators such as the National Research Ethics Service and duplicating checks that could be done once across a study. Local negotiation of research contracts and costings are a further source of delay. Together with the lack of agreed timelines within which approval decisions are made, the governance arrangements within NHS Trusts are the single greatest barrier to health research"* (The Academy of Medical Science, 2011).

Following the report by the Academy of Medical Sciences, the UK Government acknowledged that *"National regulation and local governance* *of health research are too complex and scattered across too many different bodies"* [Andrew Lansley MP, Secretary of State for Health] (The Academy of Medical Science, 2011).

In September 2011 the Department of Health announced their intent to establish a new department, the Health Research Authority (HRA) that will rationalise the older systems of NHS research governance by streamlining and unifying the approval process.

At the time of this study the author was restricted to act only within the confines of the ethical approval that had been granted. It is the author's opinion that the study may have had a greater number of respondents under recommended service changes suggested by the Academy of Medical Sciences (2011). Research of this kind is relevant and important as it could lead to a better understanding of the incidence and aetiology of maxillofacial injuries and the subsequent regulatory changes or protective equipment development used to reduce said injuries and highlight to specific sports governing bodies.

6.2 Study Two (Chapter 3): An investigation into manufacturing thickness variations of mouthguards.

Findings from Chapter 2 emphasized that both the mandible and maxilla were greatly at risk of orofacial injury during sporting activities. Mouthguards are one of the most effective, cheapest and readily available methods of combating/reducing the occurrence of orofacial injuries (Finch et al., 2005, Patrick et al., 2005, Maeda et al., 2009). Within mouthguard research the question has arisen on several occasions as to how thick a mouthguard should be and for what type and level of sport. It has been shown during the manufacturing process of custom made mouthguards, there is an inherent thinning of the mouthguard material during heating and forming over the dental model (Del Rossi and Leyte-Vidal, 2007). The finished thickness of the mouthguard has been shown to effect performance, particularly in terms of protection i.e. the thicker the mouthguard the more energy that can be dissipated (Westerman et al., 1995, Maeda et al., 2009). Westerman et al, (2002a) observed a thickness of 4 mm to be the optimal thickness for mouthguards, with only a marginal increase in performance with 5-6 mm thicknesses, however this was not formed material. Previous studies investigating mouthguard thinning have focused predominately on single operator (author) to form the mouthguard test samples (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Mizuhashi et al., 2012, Mizuhashi et al., 2013a, Mizuhashi et al., 2013b, Takahashi et al., 2013b, Takahashi et al., 2013a). This current study employed a large independent operator cohort of technicians (n=20), giving a more representative sample of current mouthguard manufacturing. Given this observed thinning of mouthguards during manufacturing, it highlighted the research question are current thicknesses of custom made mouthguards suitable for an ageing sports participant, or for those with lower bone density values? This warranted further investigation. Using a sample cohort of General Dental Council registered dental technicians to investigate thickness in the manufacturing of custom made mouthguards. A total of 20 boxes were distributed each containing five identical duplicated dental models (n=100) and 5 × 4 mm thick, 120 Ø, clear EVA mouthguard blanks (Bracon Dental Laboratory Products, East Sussex, UK). A 4 mm mouthguard blank was chosen as this is the most popular thickness used for custom made mouthguards and it is one of the lowest thicknesses with respect to the 3 mm that has been used in previous studies. A short questionnaire was also enclosed, which encompassed the participants level of experience, age of the machine, type of machine, size of blanks commonly used and any personal techniques. The study design was single-blind to avoid selection bias and to guarantee the anonymity of any participant. Each participant was required to produce mouthguards on the models provided using the mouthguard blanks, also provided, in the manner they normally would.

Results from this study highlighted current manufacturing processes for mouthguards, using a single 4 mm mouthguard blank which is representative of current practice. They had a mean finished thickness of 1.6 mm (SD 0.38), which represents a 60% reduction of the original material thickness in the chosen anatomical point of the labial anterior sulcus, with some finished mouthguards measuring as low as 0.77 mm or an 80% reduction in thickness. However, this thinning was less pronounced in the occlusion with a mean thickness of 2.1 mm (SD: 0.29) and the posterior lingual region that had a mean thickness of 2.4 mm (SD: 0.34), these thinning patterns are concurrent with previous studies (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008). The study used CT scanning and the interpretive software was a novel application which highlighted surface typography of the mouthguard as a whole. The majority of previous studies have employed caliper/gauges as their preferred method of measuring the mouthguard thickness (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Kojima et al., 2014). However, this only shows that specific area of interest, the CT scanning technique gives a holistic view of the whole mouthguards thickness.

The study within in Chapter 3 of this thesis used a uniquely large sample group to determine the variability of the construction of custom-made mouthguards, the study observed large differences between individuals and in some cases between five samples within a single individual. The differences between the participants could be explained by techniques employed, i.e. model placement, machine preference, heating and cooling timing. However, given all the initial models and mouthguard blanks were supplied by the author, and all post fabrication measurements were made by the author, to maintain consistency. It would be expected that an individual operator should be relatively consistent in repeating the production task given the same machine, material and environment were used by each individual. Therefore it can only be concluded that there was a lack of consistency in heating and forming timing, through variations are also due to a participants own technique or interpretation of instructions from the material manufacturers.

It would be interesting to observe the variables that cause these discrepancies by eliminating one variable at a time, for example, model placement. Three square steel blocks of different heights could be placed in a jig on the forming platform on a new Dufomat scan machine, that uses a preselected timer and an audible beep to instruct the user when to form the blank. In theory all the finished mouthguards at each height should not be statistically different in thickness, which may reduce production anomalies; this hypothesis may form a future study. It is noted that not all laboratories have such a machine, but if it can be shown to be affective, it may guide others in their selection when purchasing a thermoforming machine.

Novel elements of Chapter 3:

- This study primarily highlights issues within mouthguards and their thickness. The thinning of mouthguards during manufacturing and the inconsistency, in individual groups and between participant groups, in the task of manufacturing is investigated.
- A large current representative sample of the manufacturing levels of custom made mouthguards, in terms of technicians, but also the total number of formed mouthguards; with earlier studies only using one investigator/operator to form the mouthguards (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008, Mizuhashi et al., 2012, Mizuhashi et al., 2013a, Mizuhashi et al., 2013b, Takahashi et al., 2013b, Takahashi et al., 2013a)
- A particularly novel aspect is the CT scanning technology to give a visual representation of material thinning over the whole of a custom made mouthguard.

6.3 Study Three (Chapter 4): Proposed model inclination technique.

Chapter 4 expands on the observations and findings reported in Chapter 3 in relation to thinning and dimensional changes during the fabrication process. The study highlighted variability in current custom mouthguard fabrication, within and between individual participants. In the analysis of the findings, patterns were observed that led the researcher to hypothesise that the material thinning could be controlled and even redistributed by changing the orientation of the working model on the forming plate. Thereby the order of contact between the plasticised mouthguard material and the dental model reduces excessive stretching of the material in key anatomical sites i.e. the anterior sulcus. Material thinning during the thermoforming process occurs in within all blanks, regardless of their initial thicknesses, therefore, the forming technique needs to be optimised to achieve the thickest mouthguard possible at the required anatomical sites i.e. anterior sulcus. Previous studies have used a variety of techniques to reduce the thinning of the mouthguard material during fabrication, these have included, altering the model height (Del Rossi and Leyte-Vidal, 2007, Geary and Kinirons, 2008), posterior inclination (Geary and Kinirons, 2008), mouthguard blank colour effect on heating (Del Rossi et al., 2008), variations in heating conditions (Mizuhashi et al., 2013a, Takahashi et al., 2013b, Mizuhashi et al., 2014) and variations of holding techniques (Mizuhashi et al., 2012).

The order in which the plasticised mouthguard material comes in contact with the dental model seems to dictate the thickness ratios of the finished mouthguard in the key anatomical regions, anterior sulcus, occlusally and posterior lingual. The author of this current study devised a technique to change the angulation of the anterior portion of the dental model by 15, 30 and 45 degrees; this resulted in controlled alteration in the thinning patterns during the mouthguard fabrication. This technique within this study did not require the model to be altered thus reducing any specific angulation issues. Observing each anatomical site against the degree of model anterior inclination, the mean anterior sulcus thickness at 0° was 1.6mm (SD: 0.34), 15°- 2.1 mm (SD:0.10), 30°- 2.4 mm (SD:0.14) and 45°- 2.8 mm (SD:0.16). The mean occlusal thickness 0° was 2.2 mm (SD: 0.09), 15°- 1.8 mm (SD:0.06), 30°- 1.9 mm (SD:0.15) and 45°- 1.5 mm (SD:0.10). The mean posterior lingual thickness 0° was 2.5 mm (SD: 0.21), 15°- 2.3 mm (SD:0.18), 30°- 2.1 mm (SD:0.14) and 45°- 1.6 mm (SD:0.15). Presumably, the use of thicker mouthguard blanks e.g. 5-6 mm, would not only increase the thickness in the anterior, which is desirable, but also in the occlusion which can affect comfort and usability. With the use of CT scanned technologies, a visual representation of the whole thickness of the finished custom made mouthguard could be observed. The results from this study showed a significant difference ($p < 0.005$) in the anterior mouthguard thickness between the four levels of anterior inclination, with the 45° inclination producing the thickest mouthguards. Increasing the mean anterior thickness by 75% (2.8 mm, SD:0.16) relative to the model being on a flat plane. By increasing the thickness of custom mouthguards in the anterior region, where the majority of traumatic impacts are observed (Hill et al., 1998, Hutchison et al., 1998, Maladiere et al., 2001), this would be expected to offer a greater level of protection against impact fracture. Anterior model inclination of 30º and 45º inclinations increased consistancies between the thickest and thinnest mouthguards in the anterior region of these sample groups. This novel technique is easy to implement without extra additional cost in time, equipment or material. It is therefore the recommendation of the author of this study that the new technique whereby the dental model is angulated, elevating the anterior of the dental model by as much as 45 degrees, should be implemented.

Limitations

This study design was only a single operator (the author) forming the mouthguards, for a more holistic statistical analysis, a larger cohort of operators would improve the design of the study. For a possible further research project, it would be interesting to observe the use of thicker mouthguard blanks, 5 mm or 6 mm, in conjunction with the proposed anterior model inclination technique may also offer a more enhanced finished thickness in the desired regions. It is a recommendation by the author that each custom made mouthguard needs to be measured before being sent to the prescribing dentist, this measurement should be required on the statement of conformity, now required by the GDC with all new dental appliances.

Novel element of Chapter 4:

- A new technique that increases the finished anterior thickness of custom made mouthguards by 75%, from 1.6mm to 2.8mm, thereby increasing their impact protection potential.
- This proposed technique of inclining the anterior section of the dental model by 45° can easily, at no extra cost in time or specialist equipment, be implemented to increase the finished thickness of the mouthguard in the anterior region.

6.4 Study Four (Chapter 5): Mouthguard thickness levels in an older bone tissue model.

Older people are encouraged to participate in sport later in life, for the associated health benefits (Sui et al., 2008, World Health Organization, 2011). Bone mineral density (BMD) can reduce as part of the ageing process which has a reduction on bone strength (Tortora and Derrickson, 2009). This bone density variability within people could make some sports participants with lower bone density at greater risk of orofacial fractures. BMD not only differs with age but can be associated with ethnicity (Crawford et al., 2014), gender (Horner et al., 1996, Wactawski-Wende, 2001, Lindh et al., 2008, Kyrgidis et al., 2011, Sultan and Rao, 2011), diet (Tortora and Derrickson, 2009) and anatomical site (Kovan, 2008, Crawford et al., 2014). This calls into question, whether current levels of mouthguards protection are adequate in an older cohort or participants with lower BMD?

An ideal scenario would have been to have human cadaveric mandibular male test models, aged approximately 23-65+ yrs, to give a comparison as to how the human orofacial region reacts to sports fractures and subsequent mouthguard protection, for both the current and new technique. A cadaveric model has the obvious advantages of the correct morphology (Paterson, 2005), plus the providence of the specimen (i.e. age and general health of the donor) is more accurate. To obtain a consistent mandibular bone model from a human cadaveric source, with the specimens of approximately the same

BMD for each group (young and old), would have required a large number of donors and further NRES ethical clearance, therefore an animal model was used.

Animal bone models are well established in dental research (Benington et al., 2002, Stadlinger et al., 2008, Neugebauer et al., 2009, Oliveira et al., 2012, Tsetsenekou et al., 2012, Seong et al., 2013). This study considered three specimen groups; porcine, equine and bovine. A number of published orofacial studies promote the use of a porcine bone specimen for dental and orofacial research, as they possess a similar physiology and anatomical size, to that of a human skull (Gahlert et al., 2007, Oltramari et al., 2007, Wang et al., 2007). More specifically, Wang et al, (2007) states that the posterior section of a miniature pig mandible, temporal mandibular joint, body and ascending ramus are comparable to that of a human. Pigs have a lifespan of 12–18 yrs (Vodicka et al., 2005). However, within the food chain the majority of pigs are sent to slaughter at approximately 3-6 mths of age (Royal Society for the Prevention of Cruelty to Animals., 2009), at this age the bone would be considered green stick. Green stick injuries is a medical term meaning that the bone would be adolescent tissue which is less brittle, softer, flexible and prone to plastic deformation, this type of bone is more prone to bend and crack rather than fracture completely into two pieces (Solomon et al., 2005). Sows were also considered as these are slaughtered between 4-6 yrs, however there is little in way of age comparison information to give an appropriate older bone model in relation to human bone tissue. A substitute animal model in relation to ageing is that of an equine model. Horses have a longer life span when compared to that of a pig, horses can live up to 36 yrs of age (Equine Resources., 2003).

It is mandatory in England, as of 2004, for every horse to have a passport (P10 passport) that records date of foaling (birth), species, sex, colouring and markings and a record vaccination. This information is recorded to monitor vaccinations and prevent horse meat from entering the human food chain (Department for Environment Food and Rural Affairs, 2011, Horse Passport Agency., 2013). Additionally, as of 2009 it became compulsory to micro-chip foals and previously non-identified horses (Department for Environment Food and Rural Affairs, 2011). Samples were not selected from the equine model as at the time of death or slaughter their body is disposed of through licenced abattoirs, making the acquisition of suitable bone tissue difficult.

Bovine tissue shares many attributes to that of human bone in terms of BMD, the cortical bone has values between 1,400 to 1,600 Hounsfield units which is consistent with the average human mandible (Yacker and Klein, 1996). Benington et al, (2002) compared temperatures generated with external and internal irrigation systems during bone preparation for dental implants. They used a bovine model due its easy availability. All mandibles were cut into sections that measured approximately 6 cm x 6 cm, and were stripped and frozen. Eighteen drilling procedures were undertaken and assessed using a conventional dental hand-piece at a speed of 2500 r.p.m. The drilling procedure was recorded thermographically, allowing the continuous monitoring of the temperatures. Their results confirm there is no benefit to investing in a more expensive internal irrigation system as the simple flood irrigation was as efficient at thermal insulating the bone during the drilling of implant holes.

A bovine femur was chosen as the desired bone tissue model, as the mandible of the bovine would have different bone densities throughout its anatomy for example where the various muscles attach and tooth loss. This would make the like for like comparison of impacted samples needlessly convoluted or would require a very large sample of many mandibles, with samples obtained from exactly the same anatomical site, to provide a holistic sample group. The femur provides one long bone that is consistent with the mandible in composition but also relatively consistent in density throughout the majority of its length.

Using a bovine femur as a bone model, individual samples (n = 60) were created from the cortical bone. Half of the bone samples (n = 30) had 10 small (pinhead size) holes placed in the back and were treated with EDTA which reduced the bone samples BMD from a mean 0.423 g/cm^2 by 14.8% in the control to 0.360 g/cm^2, successfully creating an aged or reduced bone density model. The samples were impact tested using a servo-hydraulic testing rig and a custom made testing bath. Each sample was subjected to force (N) to fracture. Six bone sample groups were created: young no protection, young

1.6 mm MG protection, young 2.8 mm MG protection, aged no protection, aged 1.6 mm MG protection and aged 2.8 mm MG protection. The results of the impact test showed the 2.8 mm MG protection provided a significantly ($p < 0.001$) greater level of protection against fracture, than both the young and aged bone model without mouthguard protection and the 1.6 mm mouthguard protection. The unprotected young bone model exhibited a mean fracture of 631 N; the 1.6 mm mouthguard protection had a mean fracture of 723 N, and the 2.8 mm mouthguard protection a mean fracture of 836 N. The unprotected old bone model exhibited a mean fracture of 225 N, the 1.6 mm mouthguard protection had a 419 N fracture point and the 2.8 mm mouthguard protection had a mean fracture of 506 N. In terms of the absorptive qualities of the mouthguards in each bone model, the Post-hoc pairwise comparisons indicated there was a highly significant difference ($p < 0.0001$) in the energy absorbance between the unprotected groups and those protected by the 1.6 mm and 2.8 mm mouthguards. However, there was no significant effect difference in absorption between the 1.6 mm and 2.8 mm mouthguard protected samples ($p > 0.05$). These findings highlight that a sports participant with a lower bone density may require a greater degree of protection against impact fractures. The 2.8 mm mouthguard thickness offered the highest degree of protection in both bone models.

Limitations

In previous mouthguard studies little consideration has been given to the role played by the surrounding muscularity system in orofacial and mouthguard impact research in sport, as the muscles such as the Orbicularis oris, and the vermillion and dermis form an additional layer over the mouthguard. The thickness of the soft tissue will inevitably dampen the impact force exerted onto a participant or that of an experimental model; therefore it would have been of benefit to have expressed this within the study design. The use of cadaveric animal tissue to simulate the lip has its drawbacks as it lacks some of the vitality seen in living tissue. For example, a lack of circulation may cause tissue to become flaccid, a reduction in weight and volume and a lack of skin and muscle tone. This will inevitably have an effect on the tissues response and impact values gained during testing (Paterson, 2005). Initially, the use of porcine soft tissue was considered, however, the use of this tissue directly onto the testing equipment was considered unfeasible. The present study considered using layers of Chamois leather to a thickness of 12 mm which is concurrent with the dimensions associated in the maxillary anterior lip (Lehman, 1987). However, the proposed leather lamination would not have any of the musculature or vitality seen in a human model but could represent an alternative approach to an experimental model.

Novel elements for Chapter 5:

- The use of a bespoke testing setup, using a bone tissue model and heated bath, to closely replicate the physiological material properties within the oral cavity i.e. 37ºC in a wet environment closely mimicking saliva.
- A bone model was used which is more representative of the physiology found in the orofacial region than previous resin skulls and non-biological designs.
- The study examines the level of force (N) and energy absorption required to induce fracture in a young and old bone model with varying degrees of mouthguard protection.
- Sports participants with lower BMD values may require a greater level of mouthguard protection.

6.5 OVERALL CONCLUSION.

This thesis examined the incidence and aetiology of orofacial impact fractures with special focus on the production and effectiveness of custom made mouthguards. Study one highlights the need for a generic statistics database to accurately collect data pertaining to the incidence and aetiology of head and neck injuries as a whole. However, more specifically to this study such data is of paramount importance in terms of the prevention and treatment of facial injuries sustained during sports. Such information can be used to guide health service provision and inform regulatory controls on sports and protective strategies, for example, as to the level of protective equipment that should be utilised for each individual sport.

With respect to sports mouthguard protection, examining the current manufacturing practices, it was considered that an improved method for increasing the anterior thickness of the custom made mouthguard and testing was needed. The proposed new technique of inclining the anterior section of the dental model by as much as 45º has a positive effect on the finished thickness of the finished mouthguard in the anterior sulcus. The new technique can be easily implemented by manufacturing technicians without extra cost implications or specialist equipment. Chapter 5 replicated an aged bone model to represent differences in bone density associated with ageing and potentially for senior athletes and at risk groups (e.g. horse jockeys). Therefore, an older sports participant requires a greater level of impact protection. The results obtained were found to support the hypothesis that the thicker a mouthguard is, the more protection it offers which should be considered within the populations mentioned (Park et al., 1994, Westerman et al., 2002, Maeda et al., 2009).

There are many factors that affect fracture risk; this must be taken into account when prescribing the appropriate level of protective headgear for individual sports participants. More research is required in the area of extraneous environmental and biological factors that make up each individuals unique risk of fracture seen within sport, such as, bone density.

These considerations should inform the clinician as to the level of protection prescribed to the individual. All mouthguards need to be measured in key anatomical sites i.e. anterior sulcus and occlusion. These measurements need to be recorded on a statement of conformity, thereby giving a representation to the level of protection that mouthguard affords. This thesis concurs with Patrick et al, (2005) in the recommendation that mouthguards require a universal thickness grading system, but also being bespoke to the individual.

REFERENCES

THE ACADEMY OF MEDICAL SCIENCES. 2011. A new pathway for the regulation and governance of health research. London, UK: The Academy of Medical Sciences.

ADAMS, C. I., KEATING, J. F. & COURT-BROWN, C. M. 2001. Cigarette smoking and open tibial fractures. *Injury,* 32**,** 61-65.

AGEL, J. & HARVEY, E. J. 2010. A 7-year review of men's and women's ice hockey injuries in the NCAA. *Can J Surg,* 53**,** 319-23.

ALAM, F., SUBIC, A. & AKBARZADEH, A. 2008. Aerodynamics of Bicycle Helmets (P68). Estivalet, M & Brisson, P. (ed.) *The Engineering of Sport 7.* Springer Paris, 337-344.

ALBERT, A. M., RICANEK, K., JR. & PATTERSON, E. 2007. A review of the literature on the aging adult skull and face: implications for forensic science research and applications. *Forensic Sci Int,* 172**,** 1-9.

AMERICAN CANCER SOCIETY. 2014. *Questions About Smoking, Tobacco, and Health - What in tobacco smoke is harmful?* [Online]. American Cancer Society. Available: http://www.cancer.org/cancer/cancercauses/tobaccocancer/questionsaboutsmokingtobaccoandhealth/questions-about-smoking-tobacco-and-health-cancer-and-health [Accessed 11.09.14].

AMERICAN DENTAL ASSOCIATION 2006. Using mouthguards to reduce the incidence and severity of sports-related oral injuries. *J Am Dent Assoc,* 137**,** 1712-20.

ANUSAVICE, K. J. & PHILLIPS, R. W. 2003. *Phillips' science of dental materials,* St. Louis, Mo. ; [Great Britain], Saunders.

ASSCHERICKX, K., WEHRBEIN, H. & SABZEVAR, M. M. 2008. Palatal implants in adolescents: a histological evaluation in beagle dogs. *Clin Oral Implants Res,* 19**,** 657-64.

ATHA, J., YEADON, M., R., SANDOVER, J. & PARSONS, K., C. 1985. The damaging punch. *British Medical Journal,* 291**,** 1756-1757.

AUROY, P., DUCHATELARD, P., ZMANTAR, N. E. & HENNEQUIN, M. 1996. Hardness and shock absorption of silicone rubber for mouth guards. *J Prosthet Dent,* 75**,** 463-71.

BATAINEH, A. B. 1998. Etiology and incidence of maxillofacial fractures in the north of Jordan. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod,* 86**,** 31-35.

BENINGTON, I. C., BIAGIONI, P. A., BRIGGS, J., SHERIDAN, S. & LAMEY, P. J. 2002. Thermal changes observed at implant sites during internal and external irrigation. *Clin Oral Implants Res,* 13**,** 293-97.

BENSON, B. W., HAMILTON, G. M., MEEUWISSE, W. H., MCCRORY, P. & DVORAK, J. 2009. Is protective equipment useful in preventing concussion? A systematic review of the literature. *Br J Sports Med,* 43 Suppl 1**,** i56-67.

BICYCLE HELMET SAFETY INSTITUTE. 2009a. How Bicycle Helmets are Made. Arlington, USA.

BICYCLE HELMET SAFETY INSTITUTE. 2009b. Helmet Briefs - UCI to Require Helmets. Arlington, USA.

BICYCLE HELMET SAFETY INSTITUTE. 2009c. Helmet Laws for Bicycle Riders. Arlington, USA.

BIRRER, R. B. & BIRRER, C. D. 1983. Unreported injuries in the Martial Arts. *Br J Sports Med,* 17**,** 131-3.

BOOT, A. M., DE RIDDER, M. A., POLS, H. A., KRENNING, E. P. & DE MUINCK KEIZER-SCHRAMA, S. M. 1997. Bone mineral density in children and adolescents: relation to puberty, calcium intake, and physical activity. *J Clin Endocrinol Metab,* 82**,** 57-62.

BOUSDRAS, V. A., SINDET-PEDERSEN, S., CUNNINGHAM, J. L., BLUNN, G., PETRIE, A., NAERT, I. E., JAECQUES, S. & GOODSHIP, A. E. 2007. Immediate functional loading of single-tooth TIO2 grit-blasted implant restorations: a controlled prospective study in a porcine model. Part I: Clinical outcome. *Clin Implant Dent Relat Res,* 9**,** 197-206.

BRITISH BOXING BOARD OF CONTROL. 2007. Rules of Boxing. Cardiff.

BRITISH CYCLING. 2010. Technical Regulations General & for Road, Track & Roller Racing. Manchester, UK.

BRITISH MASTERS ATHLETICS FEDERATION. 2014. *Welcome to the British Masters Athletic Federation website* [Online] [Accessed 29.12.2014] http://www.xchangecms.co.uk/index.php?option=com_content&view=article&id=12&Itemid=192.

BRITISH MEDICAL ASSOCIATION. 2009. Improving and protecting health - Transport - Promoting safe cycling. London, UK.

BRITISH STANDARDS INSTITUTION. 2007. *Mouthguards for use in sport and recreation. Requirements and test methods.* British Standards Institution. London, UK.

CANTU, R. C. 1996. Head injuries in sport. *Br J Sports Med,* 30**,** 289-96.

CAPAO FILIPE, J. A. 2004. Soccer (football) ocular injuries: an important eye health problem. *Br J Ophthalmol,* 88**,** 159-60.

CARTER, D. R. & HAYES, W. C. 1976. Fatigue life of compact bone--I. Effects of stress amplitude, temperature and density. *J Biomech,* 9**,** 27-34.

CHAO, M. T., C. PALETTA & GARZA., J. R. 2008. *Facial Trauma, Sports-Related Injuries* [Online] [Accessed 29.12.2014] http://emedicine.medscape.com/article/1284288-overview

CHAPMAN, P. J. 1985. The prevalence of orofacial injuries and use of mouthguards in Rugby Union. *Aust Dent J,* 30**,** 364-67.

CHEN, Y., SHIN, H. I. & KYUNG, H. M. 2008a. Biomechanical and histological comparison of self-drilling and self-tapping orthodontic microimplants in dogs. *Am J Orthod Dentofacial Orthop,* 133**,** 44-50.

CHEN, Y. H., CHANG, H. H., CHEN, Y. J., LEE, D., CHIANG, H. H. & YAO, C. C. 2008b. Root contact during insertion of miniscrews for orthodontic anchorage increases the failure rate: an animal study. *Clin Oral Implants Res,* 19**,** 99-106.

CHO, A., SUZUKI, S., HATAKEYAMA, J., HARUYAMA, N. & KULKARNI, A. B. 2010. A method for rapid demineralization of teeth and bones. *Open Dent J,* 4**,** 223-9.

CLASSE, J. G. 1988. Legal aspects of sports-related ocular injuries. *Int Ophthalmol Clin,* 28**,** 211-4.

CLAY, M. B., GLOVER, K. L. & LOWE, D. T. 2013. Epidemiology of concussion in sport: a literature review. *J Chiropr Med,* 12**,** 230-51.

COOL CONSERVATION ONLINE. 2011. Bookbinding and the Conversation of Books, A Dictionary of Descriptive Terminology - Tensile Strength. [Online] [Accessed 14.1.15] http://cool.conservation-us.org/don/dt/dt3469.html.

CORMIER, J., MANOOGIAN, S., BISPLINGHOFF, J., ROWSON, S., SANTAGO, A., C., MCNALLY, C., DUMA, S. & BOLTE, J., H. 2010. Biomechanical Response of the Human Face and Corresponding Biofidelity of the FOCUS Headform. *SAE Int. J.,* 3**,** 842-859.

CRAIG, R. G. & GODWIN, W. C. 2002. Properties of athletic mouth protectors and materials. *J Oral Rehabil,* 29**,** 146-50.

CRAWFORD, S., BURDEN, A., YATES, J., ZIOUPOS, P. & WINWOOD, K. 2014. OC1 Facial Bone Mineral Density: A Potential Indicator For At Risk Injury Groups. *British Journal of Sports Medicine,* 48**,** A1.

DE SOUSA, A. 2008. Psychological issues in oral and maxillofacial reconstructive surgery. *Br J Oral Maxillofac Surg,* 46**,** 661-64.

DE WET, F. A., HEYNS, M. & PRETORIUS, J. 1999. Shock absorption potential of different mouth guard materials. *J Prosthet Dent,* 82**,** 301-306.

DEL ROSSI, G. & LEYTE-VIDAL, M. A. 2007. Fabricating a better mouthguard. Part I: factors influencing mouthguard thinning. *Dent Traumatol,* 23**,** 149-54.

DEL ROSSI, G., LISMAN, P. & SIGNORILE, J. 2008. Fabricating a better mouthguard. Part II: the effect of color on adaptation and fit. *Dent Traumatol,* 24**,** 197-200.

DELILBASI, C., YAMAZAWA, M., NOMURA, K., IIDA, S. & KOGO, M. 2004. Maxillofacial fractures sustained during sports played with a ball. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod,* 97**,** 23-27.

DENPLAN 2009. Supplementary Insurance Policy 2009 (and Insurance Services Information) - Exclusions. Winchester.: Denplan Limited.

DEPARTMENT FOR ENVIRONMENT FOOD AND RURAL AFFAIRS. 2011. *Horse passports questions and answers.* [Online] [Accessed 15.07.2013] http://archive.defra.gov.uk/foodfarm/farmanimal/movements/horses/horses_qa.htm.

DEPARTMENT OF HEALTH. 2005. Research Governance Framework for Health and Social Care,. *In:* Health, D. O. (ed.) Second Edition ed.

DOLAN, E., CRABTREE, N., MCGOLDRICK, A., ASHLEY, D. T., MCCAFFREY, N. & WARRINGTON, G. D. 2012. Weight regulation and bone mass: a comparison between professional jockeys, elite amateur boxers, and age, gender and BMI matched controls. *J Bone Miner Metab,* 30**,** 164-70.

DUTRA, V., DEVLIN, H., SUSIN, C., YANG, J., HORNER, K. & FERNANDES, A. R. 2006. Mandibular morphological changes in low bone mass edentulous females: evaluation of panoramic radiographs. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod,* 102**,** 663-68.

EIME, R., OWEN, N. & FINCH, C. 2004. Protective eyewear promotion: applying principles of behaviour change in the design of a squash injury prevention programme. *Sports Med,* 34**,** 629-38.

EIME, R. M. & FINCH, C. F. 2002. Have the attitudes of Australian squash players towards protective eyewear changed over the past decade? *Br J Sports Med,* 36**,** 442-45.

ELHAMMALI, N., BREMERICH, A. & RUSTEMEYER, J. 2010. Demographical and clinical aspects of sports-related maxillofacial and skull base fractures in hospitalized patients. *Int J Oral Maxillofac Surg,* 39**,** 857-62.

ELLEDGE, R. O., ELLEDGE, R., AQUILINA, P., HODSON, J. & DOVER, S. 2011. The role of alcohol in maxillofacial trauma: a comparative retrospective audit between the two centers. *Alcohol,* 45**,** 239-43.

EQUINE RESOURCES. 2003. *Age Relationship Chart Reveals More about Humans and Horses.* [Online] [Accessed 13.09.2012] http://www.equineresources.com/pfizer-animal-health/259-pfizer-horse-human-age-chart.

EXADAKTYLOS, A. K., EGGENSPERGER, N. M., EGGLI, S., SMOLKA, K. M., ZIMMERMANN, H. & IIZUKA, T. 2004. Sports related maxillofacial injuries: the first maxillofacial trauma database in Switzerland. *Br J Sports Med,* 38**,** 750-53.

FALCO, C., ALVAREZ, O., CASTILLO, I., ESTEVAN, I., MARTOS, J., MUGARRA, F. & IRADI, A. 2009. Influence of the distance in a roundhouse kick's execution time and impact force in Taekwondo. *J Biomech,* 42**,** 242-48.

FINCH, C., BRAHAM, R., MCINTOSH, A., MCCRORY, P. & WOLFE, R. 2005. Should football players wear custom fitted mouthguards? Results from a group randomised controlled trial. *Inj Prev,* 11**,** 242-46.

FOWELL, C. J. & EARL, P. 2013. Return-to-play guidelines following facial fractures. *Br J Sports Med,* 47**,** 654-56.

GAFFNEY, A. 2008. *10 Steps in the High-Tech Evolution of Pro Football Helmets.* [Online]. [Accessed 13.09.2012] http://www.popularmechanics.com/outdoors/sports/football/4281378.

GAHLERT, M., GUDEHUS, T., EICHHORN, S., STEINHAUSER, E., KNIHA, H. & ERHARDT, W. 2007. Biomechanical and histomorphometric comparison between zirconia implants with varying surface textures and a titanium implant in the maxilla of miniature pigs. *Clin Oral Implants Res,* 18**,** 662-68.

GAHLERT, M., ROHLING, S., WIELAND, M., EICHHORN, S., KUCHENHOFF, H. & KNIHA, H. 2010. A comparison study of the osseointegration of zirconia and titanium dental implants. A biomechanical evaluation in the maxilla of pigs. *Clin Implant Dent Relat Res,* 12**,** 297-305.

GANPOT, L., L., HUTCHINSON, L., RIDOUT, F. & MAGENNIS, P. 2009. The difficulties and logistics of running a National Facial Injury Survey (NFIS). *British Journal of Oral & Maxillofacial Surgery,* 47**,** e57.

GARBEROGLIO, R. & BECCE, C. 1994. Smear layer removal by root canal irrigants. A comparative scanning electron microscopic study. *Oral Surg Oral Med Oral Pathol,* 78**,** 359-67.

GASSNER, R., HACKL, W., TULI, T. & EMSHOFF, R. 1999a. Facial injuries in skiing. A retrospective study of 549 cases. *Sports Med,* 27**,** 127-34.

GASSNER, R., TULI, T., EMSHOFF, R. & WALDHART, E. 1999b. Mountainbiking--a dangerous sport: comparison with bicycling on oral and maxillofacial trauma. *Int J Oral Maxillofac Surg,* 28**,** 188-91.

GASSNER, R., TULI, T., HACHL, O., RUDISCH, A. & ULMER, H. 2003. Cranio-maxillofacial trauma: a 10 year review of 9,543 cases with 21,067 injuries. *J Craniomaxillofac Surg,* 31**,** 51-61.

GAWLAK, D., MIERZWINSKA-NASTALSKA, E., MANKA-MALARA, K. & KAMINSKI, T. 2014. Comparison of usability properties of custom-made and standard self-adapted mouthguards. *Dent Traumatol,* 30**,** 306-11.

GEARY, J. L. & KINIRONS, M. J. 2008. Post thermoforming dimensional changes of ethylene vinyl acetate used in custom-made mouthguards for trauma prevention--a pilot study. *Dent Traumatol,* 24**,** 350-55.

GERBER, B., AHMAD, N. & PARMAR, S. 2009. Trends in maxillofacial injuries in women, 2000-2004. *Br J Oral Maxillofac Surg,* 47**,** 374-77.

GILBY, G. W, 1982. Developments in Rubber Technology-3, Chapter 4, Applied Science Publishers Ltd, UK. 101-144.

GIROTTO, J. A., MACKENZIE, E., FOWLER, C., REDETT, R., ROBERTSON, B. & MANSON, P. N. 2001. Long-term physical impairment and functional outcomes after complex facial fractures. *Plast Reconstr Surg,* 108**,** 312-27.

GLENDOR, U. 2009. Aetiology and risk factors related to traumatic dental injuries--a review of the literature. *Dent Traumatol,* 25**,** 19-31.

GLYNN, S. M., ASARNOW, J. R., ASARNOW, R., SHETTY, V., ELLIOT-BROWN, K., BLACK, E. & BELIN, T. R. 2003. The development of acute post-traumatic stress disorder after orofacial injury: a prospective study in a large urban hospital. *J Oral Maxillofac Surg,* 61**,** 785-92.

GREASLEY, A., IMLACH, G. & KARET, B. 1998. Application of a standard test to the in vitro performance of mouthguards. *Br J Sports Med,* 32**,** 17-19.

GREASLEY, A. & KARET, B. 1997. Towards the development of a standard test procedure for mouthguard assessment. *Br J Sports Med,* 31**,** 31-35.

GULSAHI, A., PAKSOY, C. S., OZDEN, S., KUCUK, N. O., CEBECI, A. R. & GENC, Y. 2010. Assessment of bone mineral density in the jaws and its relationship to radiomorphometric indices. *Dentomaxillofac Radiol,* 39**,** 284-89.

GUSKIEWICZ, K. M., WEAVER, N. L., PADUA, D. A. & GARRETT, W. E., JR. 2000. Epidemiology of concussion in collegiate and high school football players. *Am J Sports Med,* 28**,** 643-50.

HAAS, R., DONATH, K., FODINGER, M. & WATZEK, G. 1998. Bovine hydroxyapatite for maxillary sinus grafting: comparative histomorphometric findings in sheep. *Clin Oral Implants Res,* 9**,** 107-16.

HAMMERLE, C. H., CHIANTELLA, G. C., KARRING, T. & LANG, N. P. 1998. The effect of a deproteinized bovine bone mineral on bone regeneration around titanium dental implants. *Clin Oral Implants Res,* 9**,** 151-62.

HAMPSON, D. 1995. Facial injury: a review of biomechanical studies and test procedures for facial injury assessment. *J Biomech,* 28**,** 1-7.

HICKS, C. & HICKS, C. R. F. P. 1999. *Research methods for clinical therapists: applied project design and analysis,* Edinburgh, Churchill Livingstone.

HILL, C. M., BURFORD, K., MARTIN, A. & THOMAS, D. W. 1998. A one-year review of maxillofacial sports injuries treated at an accident and emergency department. *Br J Oral Maxillofac Surg,* 36**,** 44-47.

HOFFMANN, J., ALFTER, G., RUDOLPH, N. K. & GOZ, G. 1999. Experimental comparative study of various mouthguards. *Endod Dent Traumatol,* 15**,** 157-63.

HOLLIS, S. J., STEVENSON, M. R., MCINTOSH, A. S., LI, L., HERITIER, S., SHORES, E. A., COLLINS, M. W. & FINCH, C. F. 2011. Mild traumatic brain injury among a cohort of rugby union players: predictors of time to injury. *Br J Sports Med,* 45**,** 997-99.

HOLMES, C. 2000. Mouth protection in sport in Scotland--a review. *Br Dent J,* 188**,** 473-74.

HORNER, K., DEVLIN, H., ALSOP, C. W., HODGKINSON, I. M. & ADAMS, J. E. 1996. Mandibular bone mineral density as a predictor of skeletal osteoporosis. *Br J Radiol,* 69**,** 1019-25.

HORNER, K., DEVLIN, H. & HARVEY, L. 2002. Detecting patients with low skeletal bone mass. *J Dent,* 30**,** 171-5.

HORSE PASSPORT AGENCY. 2013. *Identity Horse Passport Application 2013.* [Online] [Accessed 15.07.2013] http://www.horsepassportagency.co.uk/org/forms/horse_passport_registration_2013-a.pdf.

HULSMANN, M., HECKENDORFF, M. & LENNON, A. 2003. Chelating agents in root canal treatment: mode of action and indications for their use. *Int Endod J,* 36**,** 810-30.

HUTCHISON, I. L., MAGENNIS, P., SHEPHERD, J. P. & BROWN, A. E. 1998. The BAOMS United Kingdom survey of facial injuries part 1: aetiology and the association with alcohol consumption. British Association of Oral and Maxillofacial Surgeons. *Br J Oral Maxillofac Surg,* 36**,** 3-13.

INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES. 2011. *Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Calcium and Vitamin D.* , National Academy Press.

INTERNATIONAL SPORT KICKBOXING ASSOCIATION UK. 2010. ISKA Rules - Clothing and outfit. Birmingham, UK.

IRELAND, R. 2010. *A dictionary of dentistry,* Oxford ; New York, Oxford University Press.

ISEN, D. A. 2009. An effective method to achieve profound local anesthesia: two case reports. *Dent Today,* 28**,** 148, 150.

JAKSE, N., PAYER, M., TANGL, S., BERGHOLD, A., KIRMEIER, R. & LORENZONI, M. 2007. Influence of low-level laser treatment on bone regeneration and osseointegration of dental implants following sinus augmentation. An experimental study on sheep. *Clin Oral Implants Res,* 18**,** 517-24.

JESTER, R., SANTY, J. & ROGERS, J. R. G. N. 2011. *Oxford handbook of orthopaedic and trauma nursing,* Oxford, Oxford University Press.

KAYE, E. K. 2007. Bone health and oral health. *J Am Dent Assoc,* 138**,** 616-19.

KEMP, S. P., HUDSON, Z., BROOKS, J. H. & FULLER, C. W. 2008. The epidemiology of head injuries in English professional rugby union. *Clin J Sport Med,* 18**,** 227-34.

KENNEDY, E., DUMA, S., DEPINET, P., MORGAN, C., BEEBE, M., ROLLER, R., CROWLEY, J. & BROZOSKI, F. 2006. Design of an advanced headform for the prediction of eye and facial injuries.: Virginia Polytechnic Inst Blacksburg.

KNAPIK, J. J., MARSHALL, S. W., LEE, R. B., DARAKJY, S. S., JONES, S. B., MITCHENER, T. A., DELACRUZ, G. G. & JONES, B. H. 2007. Mouthguards in sport activities : history, physical properties and injury prevention effectiveness. *Sports Med,* 37**,** 117-44.

KNEALE, J. D. & DAVIS, P. S. 2005. *Orthopaedic and trauma nursing,* Edinburgh, Churchill Livingstone.

KNUTH, D. E. 1997. *The art of computer programming. Volumes 1-4a,* [Upper Saddle River], Addison-Wesley.

KOJIMA, I., TAKEDA, T., NAKAJIMA, K., NARIMATSU, K., KONNO, M., OZAWA, T. & ISHIGAMI, K. 2014. Thinning factors influence on custom-made mouthguards thermoforming. *Dent Traumatol*, 1-10.

KOSTAKIS, G., STATHOPOULOS, P., DAIS, P., GKINIS, G., IGOUMENAKIS, D., MEZITIS, M. & RALLIS, G. 2011. An epidemiologic analysis of 1,142 maxillofacial fractures and concomitant injuries. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology*. In press 1-5.

KOTECHA, S., SCANNELL, J., MONAGHAN, A. & WILLIAMS, R. W. 2008. A four year retrospective study of 1,062 patients presenting with maxillofacial emergencies at a specialist paediatric hospital. *Br J Oral Maxillofac Surg,* 46**,** 293-96.

KOVAN, V. 2008. An assessment of impact strength of the mandible. *J Biomech,* 41**,** 3488-91.

KROSHUS, E., DANESHVAR, D. H., BAUGH, C. M., NOWINSKI, C. J. & CANTU, R. C. 2014. NCAA concussion education in ice hockey: an ineffective mandate. *Br J Sports Med,* 48**,** 135-40.

KUJALA, U. M., TAIMELA, S., ANTTI-POIKA, I., ORAVA, S., TUOMINEN, R. & MYLLYNEN, P. 1995. Acute injuries in soccer, ice hockey, volleyball, basketball, judo, and karate: analysis of national registry data. *BMJ,* 311**,** 1465-68.

KYRGIDIS, A., TZELLOS, T.-G., TOULIS, K. & ANTONIADES, K. 2011. The Facial Skeleton in Patients with Osteoporosis: A Field for Disease Signs and Treatment Complications. *Journal of Osteoporosis*, 1-11.

LANE, N. E. 2006. Epidemiology, etiology, and diagnosis of osteoporosis. *Am J Obstet Gynecol,* 194**,** S3-11.

LANGHOFF, J. D., VOELTER, K., SCHARNWEBER, D., SCHNABELRAUCH, M., SCHLOTTIG, F., HEFTI, T., KALCHOFNER, K., NUSS, K. & VON RECHENBERG, B. 2008. Comparison of chemically and pharmaceutically modified titanium and zirconia implant surfaces in dentistry: a study in sheep. *Int J Oral Maxillofac Surg,* 37**,** 1125-32.

LAVERICK, S., PATEL, N. & JONES, D. C. 2008. Maxillofacial trauma and the role of alcohol. *Br J Oral Maxillofac Surg,* 46**,** 542-46.

LEE, C. Y., CHAN, S. H., LAI, H. Y. & LEE, S. T. 2011. A method to develop an in vitro osteoporosis model of porcine vertebrae: histological and biomechanical study. *J Neurosurg Spine,* 14**,** 789-98.

LEHMAN, J. A., JR. 1987. Soft-tissue manifestations of aesthetic defects of the jaws: diagnosis and treatment. *Clin Plast Surg,* 14**,** 767-83.

LEVY, M. L., KASASBEH, A. S., BAIRD, L. C., AMENE, C., SKEEN, J. & MARSHALL, L. 2011. Concussions in soccer: a current understanding. *World Neurosurg,* 78**,** 535-44.

LINDH, C., HORNER, K., JONASSON, G., OLSSON, P., ROHLIN, M., JACOBS, R., KARAYIANNI, K., VAN DER STELT, P., ADAMS, J., MARJANOVIC, E., PAVITT, S. & DEVLIN, H. 2008. The use of visual assessment of dental radiographs for identifying women at risk of having osteoporosis: the OSTEODENT project. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod,* 106**,** 285-93.

MACEWEN, C. J. 1987. Sport associated eye injury: a casualty department survey. *Br J Ophthalmol,* 71**,** 701-705.

MAEDA, M., TAKEDA, T., NAKAJIMA, K., SHIBUSAWA, M., KUROKAWA, K., SHIMADA, A., TAKAYAMA, K. & ISHIGAMI, K. 2008. In search of necessary mouthguard thickness. Part 1: From the viewpoint of shock absorption ability. *Nihon Hotetsu Shika Gakkai Zasshi,* 52**,** 211-19.

MAEDA, Y., KUMAMOTO, D., YAGI, K. & IKEBE, K. 2009. Effectiveness and fabrication of mouthguards. *Dent Traumatol,* 25**,** 556-64.

MAHMOOD, S., KEITH, D. J. & LELLO, G. E. 2002. Current practice of British oral and maxillofacial surgeons: advice regarding length of time to refrain from contact sports after treatment of zygomatic fractures. *Br J Oral Maxillofac Surg,* 40**,** 488-90.

MALADIERE, E., BADO, F., MENINGAUD, J. P., GUILBERT, F. & BERTRAND, J. C. 2001. Aetiology and incidence of facial fractures sustained during sports: a prospective study of 140 patients. *Int J Oral Maxillofac Surg,* 30**,** 291-95.

MARSHALL, S. W., MUELLER, F. O., KIRBY, D. P. & YANG, J. 2003. Evaluation of safety balls and faceguards for prevention of injuries in youth baseball. *JAMA,* 289**,** 568-74.

MATBASE. 2009. *Mechanical, physical and environmental properties of material, Silicone Rubber.* [Online] [Accessed 29.3.2012] http://www.matbase.com/material/polymers/elastomers/silicone-rubber/properties.

MCARDLE, W. D., KATCH, F. I. & KATCH, V. L. 2009. *Sports and exercise nutrition,* Philadelphia, Pa. ; London, Lippincott Williams & Wilkins.

MCINTOSH, A. S. & JANDA, D. 2003. Evaluation of cricket helmet performance and comparison with baseball and ice hockey helmets. *Br J Sports Med,* 37**,** 325-30.

MCINTOSH, A. S., MCCRORY, P., FINCH, C. F. & WOLFE, R. 2008. Head, face and neck injury in youth rugby: incidence and risk factors. *Br J Sports Med*, 188-93.

MENDELSON, B. & WONG, C. H. 2012. Changes in the facial skeleton with aging: implications and clinical applications in facial rejuvenation. *Aesthetic Plast Surg,* 36**,** 753-60.

MEREDITH, N., SHAGALDI, F., ALLEYNE, D., SENNERBY, L. & CAWLEY, P. 1997. The application of resonance frequency measurements to study the stability of titanium implants during healing in the rabbit tibia. *Clin Oral Implants Res,* 8**,** 234-43.

MESSNER, M., A. 1990. When bodies are weapons: Masculinity and violence in Sport. *International Review for the Sociology of Sport.,* 25**,** 203-220.

MILLS, L. F. 1964. Arch Width, Arch Length, And Tooth Size In Young Adult Males. *The Angle Orthodontist,* 34**,** 124-129.

MIZUHASHI, F., KOIDE, K. & TAKAHASHI, M. 2013a. Thickness and fit of mouthguards according to a vacuum-forming process. *Dent Traumatol,* 29**,** 307-12.

MIZUHASHI, F., KOIDE, K. & TAKAHASHI, M. 2013b. Thickness and fit of mouthguards according to heating methods. *Dent Traumatol*, 60-64.

MIZUHASHI, F., KOIDE, K. & TAKAHASHI, M. 2014. Thickness and fit of mouthguards according to heating methods. *Dent Traumatol,* 30**,** 60-64.

MIZUHASHI, F., KOIDE, K., TAKAHASHI, M. & MIZUHASHI, R. 2012. A method to maintain the thickness of the mouthguard after the vacuum forming process: changes of the holding conditions of the mouthguard sheet. *Dent Traumatol,* 28**,** 291-95.

MORI, H., MANABE, M., KURACHI, Y. & NAGUMO, M. 1997. Osseointegration of dental implants in rabbit bone with low mineral density. *J Oral Maxillofac Surg,* 55**,** 351-61; discussion 362.

MOTAMEDI, M. H. 2003. An assessment of maxillofacial fractures: a 5-year study of 237 patients. *J Oral Maxillofac Surg,* 61**,** 61-64.

MOUROUZIS, C. & KOUMOURA, F. 2005. Sports-related maxillofacial fractures: a retrospective study of 125 patients. *Int J Oral Maxillofac Surg,* 34**,** 635-38.

MUELLER, F., O. & COLGATE, B. 2011. *Annual Survey of Football Injury Research 1931-2010.* [Online] [Accessed 26.12.14] http://nccsir.unc.edu/

MUNN, H. 2011. *A new pathway for the governance of health research.* [Online] [Accessed 01.04.12] http://www.newscientist.com/blogs/thesword/2011/01/a-new-pathway-for-regulation-a.html.

NAHUM, A. M. 1975. The biomechanics of facial bone fracture. *Laryngoscope,* 85**,** 140-56.

NAPIER, S. M., BAKER, R. S., SANFORD, D. G. & EASTERBROOK, M. 1996. Eye injuries in athletics and recreation. *Surv Ophthalmol,* 41**,** 229-44.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE 2014. Head injury: Triage, assessment, investigation and early management of head injury in children, young people and adults. NICE clinical guideline 176. London, UK.: © National Institute for Health and Care Excellence 2014.

NATIONAL OSTEOPOROSIS FOUNDATION. 2011. *About Osteoporosis: Factors that Put You at Risk.* [Online] [Accessed13.4.14] http://www.nof.org/aboutosteoporosis/bonebasics/riskfactors

NAUNHEIM, R. S., STANDEVEN, J., RICHTER, C. & LEWIS, L. M. 2000. Comparison of impact data in hockey, football, and soccer. *J Trauma,* 48, 938-41.

NAVAL EDUCATION AND TRAINING PROFESSIONAL DEVELOPMENT AND TECHNOLOGY CENTER 1999. Fabricating Mouthguards - Preparing the Cast. Dental Technician - Dentist training manual for military dentists. FL, USA, *Naval Education and Training Professional Development and Technology Center.*

NEUGEBAUER, J., IEZZI, G., PERROTTI, V., FISCHER, J. H., KHOURY, F., PIATTELLI, A. & ZOELLER, J. E. 2009. Experimental immediate loading of dental implants in conjunction with grafting procedures. *J Biomed Mater Res B Appl Biomater,* 91, 604-12.

NEWSOME, P. O., S. REANEY, D. 2010. The dentist's role in the prevention of sport-related oro-facial injuries. *International Dentistry-Australasian Edition,* 5, 64-77.

NEWSOME, P. R., TRAN, D. C. & COOKE, M. S. 2001. The role of the mouthguard in the prevention of sports-related dental injuries: a review. *Int J Paediatr Dent,* 11**,** 396-404.

O'BRIEN, M. 2001. Exercise and osteoporosis. *Ir J Med Sci,* 170**,** 58-62.

O'BRIEN, W. J. 2002. Dental materials and their selection, London., Quintessence. 90-112.

OFFICE OF DIETARY SUPPLEMENTS. 2011. *Dietary Supplement Fact Sheet: Calcium - Recommended Intakes.* [Online] [Accessed 5.11.13] Dietary Supplement Fact Sheet: Calcium - Recommended Intakes Available: http://ods.od.nih.gov/factsheets/calcium/.

OLIVEIRA, N., ALAEJOS-ALGARRA, F., MAREQUE-BUENO, J., FERRES-PADRO, E. & HERNANDEZ-ALFARO, F. 2012. Thermal changes and drill wear in bovine bone during implant site preparation. A comparative in vitro study: twisted stainless steel and ceramic drills. *Clin Oral Implants Res,* 23**,** 963-69.

OLTRAMARI, P. V., NAVARRO, R. L., HENRIQUES, J. F., CAPELOZZA, A. L. & GRANJEIRO, J. M. 2007. Dental and skeletal characterization of the BR-1 minipig. *Vet J,* 173**,** 399-407.

OZAWA, T., TAKEDA, T., ISHIGAMI, K., NARIMATSU, K., HASEGAWA, K., NAKAJIMA, K. & NOH, K. 2014. Shock absorption ability of mouthguard against forceful, traumatic mandibular closure. *Dent Traumatol,* 30**,** 204-10.

PAPAKOSTA, V., KOUMOURA, F. & MOUROUZIS, C. 2008. Maxillofacial injuries sustained during soccer: incidence, severity and risk factors. *Dent Traumatol,* 24**,** 193-96.

PARK, J. B., SHAULL, K. L., OVERTON, B. & DONLY, K. J. 1994. Improving mouth guards. *J Prosthet Dent,* 72**,** 373-80.

PATERSON, N. 2005. *An experimental and finite element study of the protective mechanisms of sports mouthguards.* PhD 1 v; 31 cm. The Open University.

PATRICK, D. G. 2005. *Laminated Structures for Sports Mouthguards.* PhD, University of Sheffield.

PATRICK, D. G., VAN NOORT, R. & FOUND, M. S. 2002. Laminated structures for sports mouthguards. *Key Engineering Materials,* 221-222**,** 133-144.

PATRICK, D. G., VAN NOORT, R. & FOUND, M. S. 2005. Scale of protection and the various types of sports mouthguard. *Br J Sports Med,* 39**,** 278-81.

PATRICK, D. G., VAN NOORT, R. & FOUND, M. S. 2006. The influence of heat treatment on the impact performance of sports mouthguard materials. *Composites Part A: Applied Science and Manufacturing,* 37**,** 1423-1427.

PEARCE, A. I., RICHARDS, R. G., MILZ, S., SCHNEIDER, E. & PEARCE, S. G. 2007. Animal models for implant biomaterial research in bone: a review. *Eur Cell Mater,* 13**,** 1-10.

POCOCK, G. & RICHARDS, C. D. 2006. *Human physiology : the basis of medicine,* Oxford, Oxford University Press.

POLYMERWEB.COM. n.d. *Comparative Properties of Plastic Materials – EVA Ethylene Vinyl Acetate.*[Online] [Accessed 23.5.13] http://www.polymerweb.com/_datash/eva.html.

QUINONES, C. R., HURZELER, M. B., SCHUPBACH, P., ARNOLD, D. R., STRUB, J. R. & CAFFESSE, R. G. 1997. Maxillary sinus augmentation using different grafting materials and dental implants in monkeys. Part IV. Evaluation of hydroxyapatite-coated implants. *Clin Oral Implants Res,* 8**,** 497-505.

RAWLS, R. 2003. Dental Polymers *In:* ANUSAVICE, K. J. & PHILLIPS, R. W. (eds.) *Phillips' science of dental materials.* 11th ed. ed. St. Louis, Mo. ; [Great Britain]: Saunders.

REABURN, P. & DASCOMBE, B. 2008. Endurance performance in masters athletes. *European Review of Aging and Physical Activity,* 5**,** 31-42.

ROYAL SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS. 2009. *The Welfare of Pigs*. RSPCA Farm Animals Department. Manchester, UK.

RUGBY FOOTBALL UNION. *What protective kit can players wear?* [Online]. [Accessed 22/12/09] http://www.rfu.com/TakingPart/PlayerHealth/FAQs.

SALMORIA, K. K., TANAKA, O. M., GUARIZA-FILHO, O., CAMARGO, E. S., DE SOUZA, L. T. & MARUO, H. 2008. Insertional torque and axial pull-out strength of mini-implants in mandibles of dogs. *Am J Orthod Dentofacial Orthop,* 133**,** 790 e15-22.

SANE, J., LINDQVIST, C. & KONTIO, R. 1988. Sports-related maxillofacial fractures in a hospital material. *Int J Oral Maxillofac Surg,* 17**,** 122-24.

SCUFFHAM, P., ALSOP, J., CRYER, C. & LANGLEY, J. D. 2000. Head injuries to bicyclists and the New Zealand bicycle helmet law. *Accid Anal Prev,* 32**,** 565-73.

SEONG, W. J., GRAMI, S., JEONG, S. C., CONRAD, H. J. & HODGES, J. S. 2013. Comparison of push-in versus pull-out tests on bone-implant interfaces of rabbit tibia dental implant healing model. *Clin Implant Dent Relat Res,* 15**,** 460-69.

SHAFER, D. M., ROGERSON, K., NORTON, L. & BENNETT, J. 1995. The effect of electrical perturbation on osseointegration of titanium dental implants: a preliminary study. *J Oral Maxillofac Surg,* 53**,** 1063-68.

SHEN, C. 2003. *Impression Materials.* Anusavice, K. J. & Phillips, R. W. (eds) *Phillips' science of dental materials,* St. Louis, Mo. ; [Great Britain], Saunders. 9, 205-254.

SLOAN, A., HUSSAIN, I., MAQSOOD, M., EREMIN, O. & EL-SHEEMY, M. 2010. The effects of smoking on fracture healing. *Surgeon,* 8**,** 111-16.

SMITH, M., D. 1974. Hockey Players Significant others' Influence on the Assaultive Behavior of Young. *International Review for the Sociology of Sport.,* 9**,** 45-58.

SMITH, M. S., DYSON, R. J., HALE, T. & JANAWAY, L. 2000. Development of a boxing dynamometer and its punch force discrimination efficacy. *J Sports Sci,* 18**,** 445-50.

SOLOMON, L., WARWICK, D., NAYAGAM, S. & APLEY, A. G. 2005. *Apley's concise system of orthopaedics and fractures,* London, Hodder Arnold.

SPORTS ENGLAND. 2014. *Once a week participation in funded sports amongst people aged 14 years and over (April 2013 – April 2014).* [Online] [Accessed 12.10.2014] http://www.sportengland.org/research/who-plays-sport/by-sport/.

STADLINGER, B., PILLING, E., HUHLE, M., KHAVKIN, E., BIERBAUM, S., SCHARNWEBER, D., KUHLISCH, E., ECKELT, U. & MAI, R. 2008. Suitability of differently designed matrix-based implant surface coatings: an animal study on bone formation. *J Biomed Mater Res B Appl Biomater,* 87**,** 516-24.

STRETCH, R. A., BARTLETT, R. & DAVIDS, K. 2000. A review of batting in men's cricket. *J Sports Sci,* 18**,** 931-49.

SUI, X., HOOKER, S. P., LEE, I. M., CHURCH, T. S., COLABIANCHI, N., LEE, C. D. & BLAIR, S. N. 2008. A prospective study of cardiorespiratory fitness and risk of type 2 diabetes in women. *Diabetes Care,* 31**,** 550-55.

SULTAN, N. & RAO, J. 2011. Association between periodontal disease and bone mineral density in postmenopausal women: a cross sectional study. *Med Oral Patol Oral Cir Bucal,* 16**,** e440-47.

TAKAHASHI, M., KOIDE, K. & MIZUHASHI, F. 2013a. Difference in the thickness of mouthguards fabricated from ethylene-vinyl acetate co-polymer sheets with differently arranged v-shaped grooves. *J Prosthodont Res,* 57**,** 169-78.

TAKAHASHI, M., KOIDE, K. & MIZUHASHI, F. 2013b. Variation in mouthguard thickness due to different heating conditions during fabrication. *J Prosthodont Res,* 57**,** 179-85.

TAKEDA, T., ISHIGAMI, K., JUN, H., NAKAJIMA, K., SHIMADA, A. & OGAWA, T. 2004a. The influence of the sensor type on the measured impact absorption of mouthguard material. *Dent Traumatol,* 20**,** 29-35.

TAKEDA, T., ISHIGAMI, K., SHINTARO, K., NAKAJIMA, K., SHIMADA, A. & REGNER, C. W. 2004b. The influence of impact object characteristics on impact force and force absorption by mouthguard material. *Dent Traumatol,* 20**,** 12-20.

TAKEDA, T., ISHIGAMI, K., HOSHINA, S., OGAWA, T., HANDA, J., NAKAJIMA, K., SHIMADA, A., NAKAJIMA, T. & REGNER, C. W. 2005a. Can mouthguards prevent mandibular bone fractures and concussions? A laboratory study with an artificial skull model. *Dental Traumatology,* 21**,** 134-140.

TAKEDA, T., ISHIGAMI, K., HOSHINA, S., OGAWA, T., HANDA, J., NAKAJIMA, K., SHIMADA, A., NAKAJIMA, T. & REGNER, C. W. 2005b. Can mouthguards prevent mandibular bone fractures and concussions? A laboratory study with an artificial skull model. *Dent Traumatol,* 21**,** 134-40.

TAKEDA, T., ISHIGAMI, K., NAKAJIMA, K., NAITOH, K., KUROKAWA, K., HANDA, J., SHOMURA, M. & REGNER, C. W. 2008. Are all mouthguards the same and safe to use? Part 2. The influence of anterior occlusion against a direct impact on maxillary incisors. *Dent Traumatol,* 24**,** 360-65.

TANAKA, N., HAYASHI, S., AMAGASA, T. & KOHAMA, G. 1996. Maxillofacial fractures sustained during sports. *J Oral Maxillofac Surg,* 54**,** 715-9; discussion 719-20.

TANAKA, N., TOMITSUKA, K., SHIONOYA, K., ANDOU, H., KIMIJIMA, Y., TASHIRO, T. & AMAGASA, T. 1994. Aetiology of maxillofacial fracture. *Br J Oral Maxillofac Surg,* 32**,** 19-23.

TELLAM, R. 2009. *Bovine genome decoded - Similarities between cow and human DNA.* [Online]. Commonwealth Scientific and Industrial Research Organisation. [Accessed:30.01.2014] HTTP://WWW.CSIRO.AU/OUTCOMES/FOOD AND-AGRICULTURE/BOVINE-GENOME-DECODED/SIMILARITIES-BETWEEN-COW-AND-HUMAN-DNA.ASPX.

THE ENGLAND AND WALES CRICKET BOARD. 2010. *Non First Class Rules and Regulations 2010 - ECB Safety Guidance on the Wearing of Cricket Helmets by Young Players.* England. patent application. The England and Wales Cricket Board. London, UK.

THE INTERNATIONAL HOCKEY FEDERATION 2013. Rules of Hockey - Players' clothing and equipment. Lausanne, Switzerland.

THE RUBBER FOUNDATION INFORMATION CENTER FOR NATURAL RUBBER. 2003. *Latex technology part 2, Tube Extrusion - Typical values obtained on dipped products or alternative sheet materials.* [Online] [Accessed 21.01.2012] The Rubber Foundation Information Center for Natural Rubber. Available: http://www.rubber-foundation.org/docu/Natuurrubber_31.pdf.

THE RUGBY FOOTBALL UNION. *Frequently Asked Questions - First Aid - What protective kit can players wear?* [Online] [Accessed 14.11.10] www.rfu.com.

THOMPSON, R. S., RIVARA, F. P. & THOMPSON, D. C. 1989. A case-control study of the effectiveness of bicycle safety helmets. *N Engl J Med,* 320**,** 1361-67.

TIWARI, U., MISHRA, V., BHALLA, A., SINGH, N., JAIN, S. C., GARG, H., RAVIPRAKASH, S., GREWAL, N. & KAPUR, P. Fiber Bragg grating sensor for measurement of impact absorption capability of mouthguards. *Dent Traumatol,* 27**,** 263-68.

TODOH, M., TADANO, S. & IMARI, Y. 2009. Effect of Heat Denaturation of Collagen Matrix on Bone Strength. *In:* LIM, C. & GOH, J. H. (eds.) *13th International Conference on Biomedical Engineering.* Springer Berlin Heidelberg. PG

TORTORA, G. J. & DERRICKSON, B. 2009. *Principles of anatomy and physiology,* Hoboken, N.J., Wiley ; [Chichester : John Wiley, distributor].

TRAN, D., COOKE, M. S. & NEWSOME, P. R. 2001. Laboratory evaluation of mouthguard material. *Dent Traumatol,* 17**,** 260-65.

TSETSENEKOU, E., PAPADOPOULOS, T., KALYVAS, D., PAPAIOANNOU, N., TANGL, S. & WATZEK, G. 2012. The influence of alendronate on osseointegration of nanotreated dental implants in New Zealand rabbits. *Clin Oral Implants Res,* 23**,** 659-66.

UNITED KINGDOM PAINTBALL SPORTS FEDERATION. 2009. Paintball - The Law - Masks and Barrel Plugs/Condoms Rochdale, Lancashire, UK.

UYSAL, T., USUMEZ, S., MEMILI, B. & SARI, Z. 2005. Dental and Alveolar Arch Widths in Normal Occlusion and Class III Malocclusion. *The Angle Orthodontist,* 75**,** 809-813.

VETTER, L., VANDERBY, R. & BROUTMAN, L. J. 1987. Influence of materials and structure on performance of a football helmet. *Polymer Engineering & Science,* 27**,** 1113-1120.

VIANO, D. C., BIR, C., WALILKO, T. & SHERMAN, D. 2004. Ballistic impact to the forehead, zygoma, and mandible: comparison of human and frangible dummy face biomechanics. *J Trauma,* 56**,** 1305-11.

VIANO, D. C., CASSON, I. R. & PELLMAN, E. J. 2007. Concussion in professional football: biomechanics of the struck player--part 14. *Neurosurgery,* 61**,** 313-27; discussion 327-28.

VODICKA, P., SMETANA, K., JR., DVORANKOVA, B., EMERICK, T., XU, Y. Z., OUREDNIK, J., OUREDNIK, V. & MOTLIK, J. 2005. The miniature pig as an animal model in biomedical research. *Ann N Y Acad Sci,* 1049**,** 161-71.

WACTAWSKI-WENDE, J. 2001. *Periodontal Diseases and Osteoporosis: Association and Mechanisms.* , Annals of Periodontology. 197-208.

WALILKO, T. J., VIANO, D. C. & BIR, C. A. 2005. Biomechanics of the head for Olympic boxer punches to the face. *Br J Sports Med,* 39**,** 710-19.

WALKER, T. W., BYRNE, S., DONNELLAN, J., MCARDLE, N., KERIN, M. J. & MCCANN, P. J. 2012a. West of Ireland facial injury study. Part 1. *Br J Oral Maxillofac Surg,* 50**,** 631-35.

WALKER, T. W., DONNELLAN, J., BYRNE, S., MCARDLE, N., KERIN, M. J. & MCCANN, P. J. 2012b. West of Ireland facial injury study. Part 2. *Br J Oral Maxillofac Surg,* 50**,** e99-e103.

WALLACE, R. J., PANKAJ, P. & SIMPSON, A. H. 2013. The effect of strain rate on the failure stress and toughness of bone of different mineral densities. *J Biomech,* 46**,** 2283-87.

WANG, S., LIU, Y., FANG, D. & SHI, S. 2007. The miniature pig: a useful large animal model for dental and orofacial research. *Oral Dis,* 13**,** 530-37.

WAUGH, A., GRANT, A. & CHAMBERS, G. 2010. *Ross and Wilson anatomy and physiology in health and illness,* Edinburgh, Churchill Livingstone Elsevier.

WESTERMAN, B., STRINGFELLOW, P. M. & ECCLESTON, J. A. 1995. Forces transmitted through EVA mouthguard materials of different types and thickness. *Aust Dent J,* 40**,** 389-91.

WESTERMAN, B., STRINGFELLOW, P. M. & ECCLESTON, J. A. 2000. The effect on energy absorption of hard inserts in laminated EVA mouthguards. *Aust Dent J,* 45**,** 21-23.

WESTERMAN, B., STRINGFELLOW, P. M. & ECCLESTON, J. A. 2002a. EVA mouthguards: how thick should they be? *Dent Traumatol,* 18**,** 24-27.

WESTERMAN, B., STRINGFELLOW, P. M., ECCLESTON, J. A. & HARBROW, D. J. 2002b. Effect of ethylene vinyl acetate (EVA) closed cell foam on transmitted forces in mouthguard material. *Br J Sports Med,* 36**,** 205-8.

WICKS, R. A., COCO, S. & AHUJA, S. 2009. A mouthguard fabrication technique for contemporary sports dentistry. *J Tenn Dent Assoc,* 89**,** 32-3; quiz 34-35.

WILLIAMS, J. M., CURRIE, C. E., WRIGHT, P., ELTON, R. A. & BEATTIE, T. F. 1997. Socioeconomic status and adolescent injuries. *Soc Sci Med,* 44**,** 1881-91.

WILSON, B. D. 1998. Protective headgear in rugby union. *Sports Med,* 25**,** 333-37.

WINWOOD, K. 2003. *An experimental investigation into the effects of cyclic fatigue on ageing human cortical bone.* PhD, Cranfield University

WITHNALL, C., SHEWCHENKO, N., GITTENS, R. & DVORAK, J. 2005. Biomechanical investigation of head impacts in football. *Br J Sports Med,* 39 Suppl 1**,** i49-57.

WORLD HEALTH ORGANIZATION 2011. Global Recommendations on Physical Activity for Health. *In:* WORLD HEALTH ORGANIZATION (ed.). Geneva, Switzerland.: World Health Organization,.

WORLD SQUASH FEDERATION 2014. WSF Singles Rules, Documents & Regulations - Protective Eyewear. St Leonards, East Sussex.

WUST, R. C., WINWOOD, K., WILKS, D. C., MORSE, C. I., DEGENS, H. & RITTWEGER, J. 2010. Effects of smoking on tibial and radial bone mass and strength may diminish with age. *J Clin Endocrinol Metab,* 95**,** 2763-71.

YACKER, M. J. & KLEIN, M. 1996. The effect of irrigation on osteotomy depth and bur diameter. *Int J Oral Maxillofac Implants,* 11**,** 634-38.

YAMADA, J. & MAEDA, Y. 2007. Thermoforming process for fabricating oral appliances: influence of heating and pressure application timing on formability. *J Prosthodont,* 16**,** 452-56.

ZADIK, Y. & LEVIN, L. 2009. Does a free-of-charge distribution of boil-and-bite mouthguards to young adult amateur sportsmen affect oral and facial trauma? *Dent Traumatol,* 25**,** 69-72.

Appendix

A

A review of facial protective equipment use in sport and the impact on injury incidence.

Timothy Farrington [a], Gladys Onambele-Pearson [a], Rebecca L. Taylor [b], Philip Earl [c], & Keith Winwood [a].

a. Department of Exercise and Sport Science/Institute for Performance Research, Manchester Metropolitan University, Crewe Green Rd, Crewe, Cheshire CW1 5DU, United Kingdom.
b. School of Healthcare Science, Faculty of Science and Engineering, Manchester Metropolitan University, Chester Street, Manchester M1 5GD, United Kingdom.
c. Worcestershire Royal Hospital, Charles Hastings Way, Worcester, Worcestershire WR5 1DD, United Kingdom

Abstract.

Sporting activities have an inherent risk of facial injury from traumatic impacts from fellow competitors, projectiles, and collisions with posts or the ground. This retrospective review systematically describes the interplay between the type of sport (including the level at which specific sports are played), the sex of the players and their musculoskeletal characteristics, the technology behind the materials used, the protective devices commonly used, the anatomical site, and the regularity of incidence of fractures. We describe how variations in sporting activities induce different orofacial fracture patterns, and critically consider the methods used to test protective headgear against more contemporary techniques. Facial injuries can have a profound psychological effect on those injured, can take a long time to heal, and have been known to end promising careers. Use of properly fitted protective head or facial equipment could reduce the number of facial fractures commonly seen in sports. We recommend that individual sports should have full risk

assessments, and that mandatory standards should be agreed about protective devices that would be appropriate.

B

An investigation into the relationship between thickness variations and manufacturing techniques of mouthguards

Timothy Farrington[1], Trevor Coward[2], Gladys Onambele-Pearson[1], Rebecca L.Taylor[3], Philip Earl[4], & Keith Winwood[1].

1. Department of Exercise and Sport Science/Institute for Performance Research, Manchester Metropolitan University, Crewe Green Rd, Crewe, Cheshire CW1 5DU, United Kingdom
2. Department of Prosthetic Facial Rehabilitation, Guys Hospital, London Bridge, London SE1 9RT, United Kingdom
3. School of Healthcare Science, Faculty of Science and Engineering, Manchester Metropolitan University, Chester Street, Manchester M1 5GD, United Kingdom
4. Worcestershire Royal Hospital, Charles Hastings Way, Worcester, Worcestershire WR5 1DD, United Kingdom

Abstract.

Background: The aim of the present study was to measure the finished thickness of a single identical 4mm laminate mouthguard model from a large fabricated sample group and to evaluate the degree of material thinning and variations during the fabrication process.

Materials & Methods: Twenty boxes were distributed to dental technicians, each containing 5 duplicated dental models (n=100), alongside 5 × 4 mm mouthguard blanks and a questionnaire. The mouthguards were measured using electronic callipers (resolution: ±0.01 mm) at three specific points. The five thickest and thinnest mouthguards were examined using a CT scanner to describe the surface typography unique to each mouthguard, highlighting dimensional thinning patterns during the fabrication process.

Results: Of the three measurement points, the anterior sulcus point of the mouthguard showed a significant degree of variation (34% coefficient of variation), in finished mouthguard thickness between individuals. The mean thickness of the mouthguards in the anterior region was 1.62 ± 0.38 mm with a range of 0.77 to 2.80 mm. This inconsistency was also evident in the occlusion and posterior lingual regions but to a lesser extent (12.2% and 9.8% variations respectively).

Conclusion: This study highlights variability in the finished thickness of the mouthguards especially in the anterior sulcus region measurement point, both within and between individuals. At the anterior region measurement point of the mouthguard, the mean thickness was 1.62mm, equating to an overall material thinning of 59.5% when using a single 4mm EVA blank. This degree of thinning is comparative to previous single operator research studies.

C

The effect of model inclination during fabrication on mouthguard calliper-measured and CT-scan assessed thickness.

Timothy Farrington[1], Trevor Coward[2], Gladys Onambele-Pearson[1], Rebecca L.Taylor[3], Philip Earl[4], & Keith Winwood[1].

1. Department of Exercise and Sport Science/Institute for Performance Research, Manchester Metropolitan University, Crewe Green Rd, Crewe, Cheshire CW15DU, United Kingdom
2. Department of Prosthetic Facial Rehabilitation, Guys Hospital, London Bridge, London SE1 9RT, United Kingdom
3. School of Healthcare Science, Faculty of Science and Engineering, Manchester Metropolitan University, Chester Street, Manchester M15GD, United Kingdom
4. Worcestershire Royal Hospital, Charles Hastings Way, Worcester, Worcestershire WR51DD, United Kingdom

Abstract.

Aim: Excessive material thinning has been observed in the production of custom-made mouthguards in a number of studies, due to production anomalies that may lead to such thinning. This study investigated the effect of thinning material patterns of custom made mouthguards when the anterior angulation of dental model was increased during the thermoforming process.

Materials & Methods: A total of 60 samples of mouthguard blanks were thermoformed on identical maxillary models under four anterior inclination conditions (n=4×15); control 0°, 15°, 30°, and 45° . Each mouthguard sample was measured, using an electronic calliper gauge, at 3 anatomical points (anterior labial sulcus, posterior occlusion and posterior lingual). Mouthguards were then CT scanned to give a visual representation of the surface thickness.

Results: Data showed a significant difference ($p < 0.005$) in the anterior mouthguard thickness between the four levels of anterior inclination, with the 45° inclination producing the thickest mouthguards, increasing the mean anterior thickness by 75% (2.8mm, SD: 0.16) from the model on a flat plane (1.6mm, SD: 0.34). Anterior model inclination of 30º and 45º inclinations increased consistancies between the thickest and thinnest mouthguards in the anterior region of these sample groups.

Conclusion: This study highlights the importance of standardising the thermoforming process, as this has a significant effect on the quality and material distribution of the resultant product. In particular, greater model inclination is advised as this optimises the thickness of the anterior sulcus of the mouthguard which may be more prominently at risk from sport-related impact.

D

Participant Information Sheet.

We would like to invite you to take part in our research study, in conjunction with Manchester Metropolitan University.

Title of study.
"An investigation into the occurrence and effects of Maxillofacial injury due to sport".

Aim of study.
The objective of this study is to determine the amount and type of facial injuries currently in the UK due to sports, looking at geographic regions, gender, age, and the type of fracture.

Do I have to take part in this study?
No, participation in this study is totally voluntary, but your time and input would allow a greater understanding of Sports Injuries sustained in the UK.

The questionnaire:
The Questionnaire is designed to be relatively short, all information is anonymous and will be held in strict confidence; NHS data protection and indemnity protocols will be enforced throughout this study. The processed information (no identifiable information will be used) could be used for future publications in relevant medical/sport journals.

If you wish to participate:
You the patient are required to fill in the second section of the questionnaire as indicated; the questionnaire is designed to be relatively short, as not to take up much time.

Finally…Thank you for taking your time to consider this study.

Further information is available from:

Timothy Farrington, Manchester Metropolitan University,
Hassall Road, Alsager, Stoke-on-Trent ST7 2HL.

08988901@stu.mmu.ac.uk

MMU Ethics Code 18.12.09 NRES Reference: 09/H1016/89

D

V2.2

Facial Sports Injury

"An investigation into the occurrence and effects of Maxillofacial injury due to sport".

Questionnaire

First section to be completed by the Clinician.

Q1 Oral health of patient Good ❑ Poor ❑

Q2 Anatomical site of fracture

Maxillary Sinus	❑	Zygoma	❑	Orbital	❑	Nasal bone	❑
Le Fort I, II, III	❑	Dento-alveolar	❑	Tooth evulsions	❑		
Mandible	❑	Body	❑	Angle	❑	Condyle	❑

Q3 Has the patient had any previous fractures:

Radius/Ulna	❑	Femur	❑	Tibia	❑	Humerus	❑
Skull	❑	Metatarsal	❑	Other			

(If other please specify) ______________________________

Q4 How long is the expected time for rehabilitation? ______________________

This second section is to be completed by the Patient.

Q5 Gender Male ❑ Female ❑

Q6 Age

16-25	26-35	36-45	46-55	56-65	66 +
❑	❑	❑	❑	❑	❑

Q7 Geographic region

England ❑ Ireland ❑ Scotland ❑ Wales ❑

Timothy Farrington, Manchester Metropolitan University, Hassall Road, Alsager, Stoke-on-Trent ST7 2HL

MMU Ethics Code 18.12.09 NRES Reference: 09/H1016/89

D

V2.2

Q8 **Geographical area** (e.g North West, West Midlands) ________________________________

Q9 **Type of sport** (please specify) e.g. Rugby, Football ____________________________________

Q10 **At what level is the sport played** (please circle) Recreational County National International

Q11 **How many hours training per week?** __________

Q12 **Was any form of headwear or mouthguard worn at the time of the facture?**

Yes ☐ No ☐ Unknown ☐

Q13 **Smoker** Yes ☐ Never smoked ☐ Past smoker ☐

Q14 **Quantity smoked** (per day)

1-10	11-20	21-30	31-40	41-50	51+
☐	☐	☐	☐	☐	☐

Q15 **During a typical week, how many units of alcohol do you consume?**

1-10	11-20	21-30	31-40	41-50	51+
☐	☐	☐	☐	☐	☐

Q16 **Calcium consumption**

Poor ☐ Average ☐ Above average ☐

Q17 **Are you on any long term medication?** (please specify) ____________________________

Q18 **Age of Menarche (first period)** (female participants only) ______

Q19 **Patients age at Menopause** (female participants only/if relevant) _______

Q20 **Is there a history of Osteoporosis or Arthritis within your family?**

Yes ☐ No ☐ Don't know ☐

Thank you for your time and co-operation, it is greatly appreciated.
Please return the questionnaire within the self addressed envelope, once again thank-you.

Timothy Farrington, Manchester Metropolitan University, Hassall Road, Alsager, Stoke-on-Trent ST7 2HL

MMU Ethics Code 18.12.09 NRES Reference: 09/H1016/89