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'Socksess' - Smart Sensing Socks for Monitoring Diabetic Feet and Preventing Ulceration (EP/X001059/1)

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Project Vision

Diabetic neuropathy (nerve damage) causes a loss of sensation in the foot, which is one of the major risk factors for developing diabetic foot ulcers. This loss of foot sensation removes people's ability to 'naturally' self-regulate their foot pressures and over time this causes tissue breakdown and ulceration, with subsequent limb amputation, or death as ultimate consequences, with NHS costs >£1billion annually. This presents an opportunity for a health technology solution to support and empower people with their foot health.

Current solutions include smart insole systems constrained by footwear requirements and presenting barriers to adoption and adherence. A crucial engineering-based innovation gap is that no system is capable of measuring shear stress, increasingly recognised as an important contributor to diabetic foot ulcer development.

The 'Socksess' project vision is to develop 'smart-sensing socks' addressing innovation gaps and providing a novel solution for daily monitoring and prevention of diabetic foot ulcers.

Project Aims

The project **aim** is to co-design, develop and test an ambitious new healthcare monitoring technology focused on preventing diabetic foot ulcers through **'reconnecting people with their feet'**.

Specific project objectives are:

1. To understand the needs and preferences of people with diabetes, their carers and clinicians, to co-design a smart-sensing sock.
2. Develop and evaluate candidate sensor technologies for measurement of shear stress and to integrate these within stretchable sock fabric with electrical connectivity.
3. Test and validate the smart-sensing socks in a cohort of people at high-risk for diabetic foot ulceration.
4. Co-design with relevant stakeholders a highly accessible feedback system to alert the user when they are at risk of foot ulceration.

Key Outcomes and Results

Co-Designing the Technology with Stakeholders

A qualitative study was undertaken with key stakeholders including 20 people with diabetic neuropathy (n=16 with history of diabetic foot ulcers), carers (n=2) and podiatrists (n=6). Three main themes were generated.

1. **Patient buy-in:** challenged by lack of awareness of risk, and potentially addressed though using the device to collect and record evidence to enhance clinical messaging.
2. **Effective engagement:** challenged by difficulties accepting and actioning information, requiring simple, specific and supportive instructions in line with podiatrist advice.
3. **Sustained use:** challenged by difficulties coping, with the possibility to gain control with an early warning system.

Design & Development of Socks Material

We used an industry-grade socks knitting machine (with integral toe closure) at Manchester Fashion Institute, to fabricate our custom-designed socks.

We explored novel sock designs, the composition of sock material, knit structure, yarn type, and fibre composition to optimise performance and incorporation of sensing elements within the sock. The development process has been guided by stakeholder input, qualitative research, and garment design factors (Fig. 1).

Socks were made using 78 dtex recycled nylon yarns, 44 dtex Lycra/nylon blended yarns, 30/1 Ne combed cotton yarns and elastic filament.

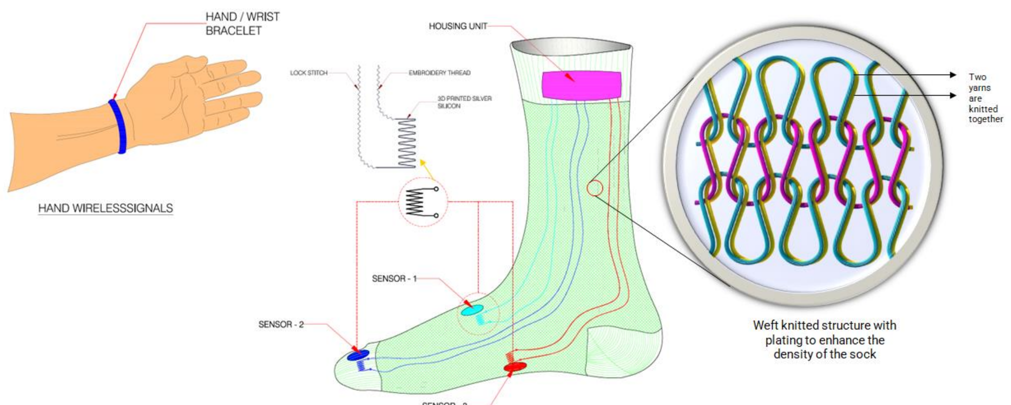

Figure 1. Initial concept design for the Socksess project.

We have developed socks with embroidered conductive yarns to connect with flexible resistance-based strain sensors. Following extensive development work, we have refined our shortlist to two types of socks (Fig. 2).

The conductive thread embroidery pattern can be seen in the supplementary material (scan QR code below).

Figure 2. Final versions and key features of sock design 1 and 2.

Shear Sensor Design and Development

Manufacture: Sensors were produced using a Workbee CNC coupled to a Nordson dispensing system, allowing for the 3D printing of our sensors (Fig. 3).

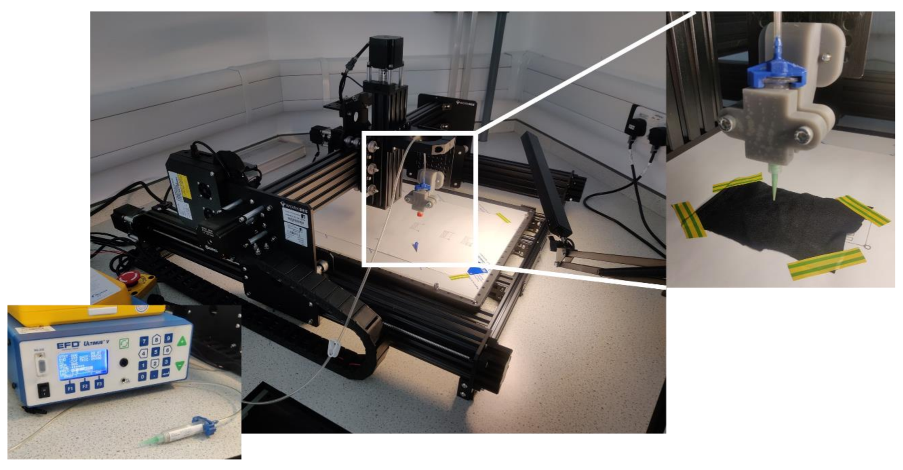

Figure 3. System used for 3D printing the shear sensors.

Parametric Study: After extensive investigation of potential materials, a silver adhesive by Dycotec was selected. Parametric testing was initially undertaken on a Lycra substrate before integration with sock material. This approach enabled development prior to the additional challenges introduced with 3D printing onto knitted structures (Fig. 4).

Sensor Integration: conductive yarns allowed for sensor signals to be passed to the socks welt area in a flexible manner. Sensor signals were collected through an Arduino based microcontroller in combination with a MAX31865 resistance temperature detector amplifier. Traditionally the chip is used to measure temperature, however, we have applied it as a high-resolution method of measuring resistance. Additionally, the 4-wire thermocouple method enabled us to account for the resistance induced by the conductive yarns. Custom connectors were produced to form an interface between sock and electronic components (Fig. 5). A custom PCB was designed to house two of the MAX31865 breakouts by Adafruit supporting the placement of two sensors on the sock (Fig. 5).

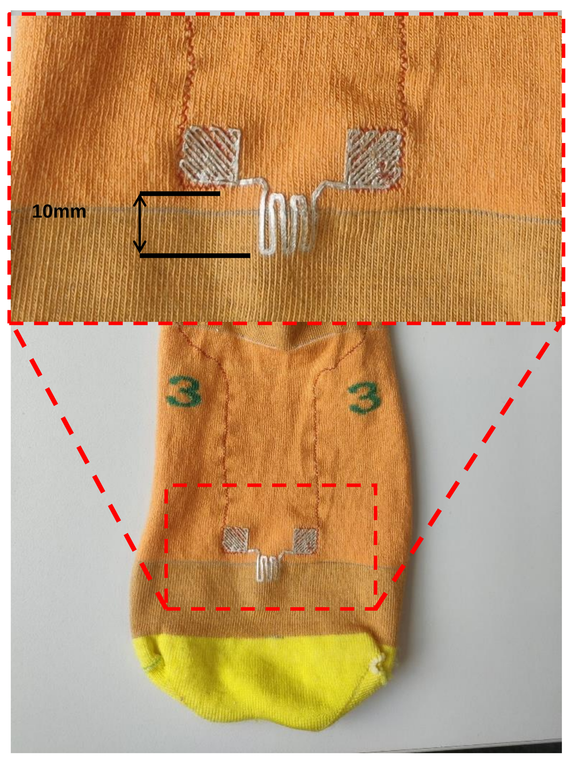

Figure 4. Silver adhesive sensors 3D-printed onto the sock material, connecting up with the embroidered conductive fibres.

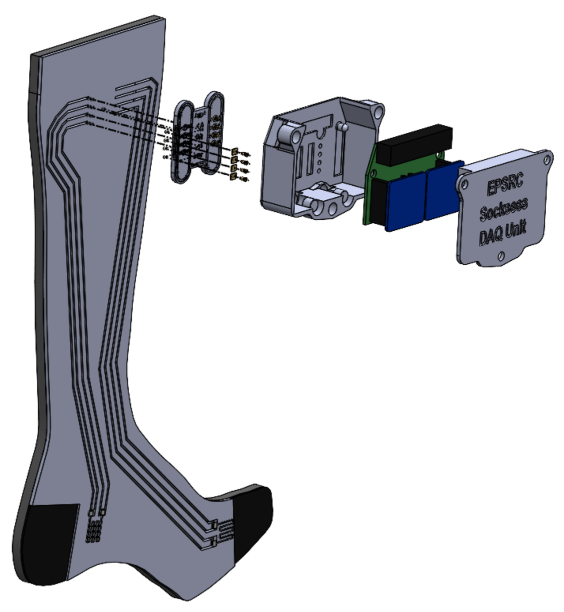

Figure 5. Exploded diagram showing sensor placement, embroidered conductive yarn paths and custom electronic connector components.

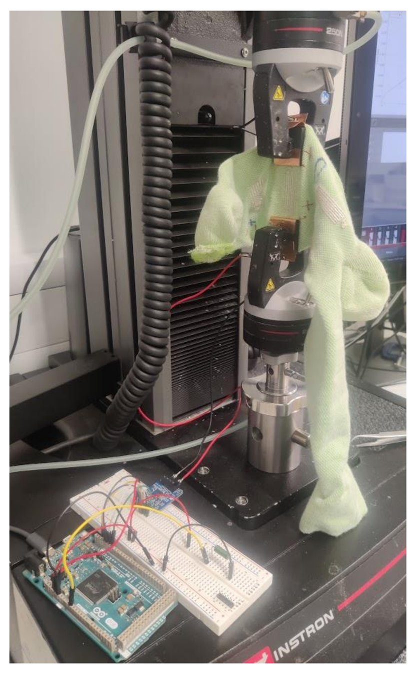

Figure 6. Intron machine and sensor testing environment.

Sensor Assessment: samples were loaded (quasi-static and cyclic) on an Instron (Fig. 6) to determine strain gauge performance and inform final design based on parametric results. The knitted structure improved performance by acting as a new composite structure. Sensor reinforcement with a silicone coating allowed us to tune responsiveness while also protecting from the local environment.

Next Steps

Additional project information

We are embarking on human user trials to test the smart-sensing socks in people with diabetic neuropathy (Fig. 7).

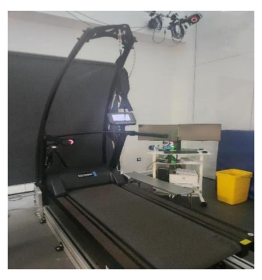

Figure 7. Treadmill to be used for user trials with embedded force and pressure platforms.

Further technology development: This project has produced major innovations, driven by co-production and novel research.

The team are now planning to further develop the technology by refining key features, advancing TRL and developing a route towards commercialisation. Funding routes to support this are being explored.