OedaSock Group Report

Henry Adams
MEng Design Engineering
Imperial College London
London, UK
hka21@ic.ac.uk

Jasper Ferguson
MEng Biomedical Engineering
Imperial College London
London, UK
jf1322@ic.ac.uk

Anish Mariathasan
MEng Biomedical Engineering
Imperial College London
London, UK
ajm322@ic.ac.uk

Bowen Zhi
MSc Human Robotics
Imperial College London
London, UK
bz1424@ic.ac.uk

Xuanyun Qiu
MSc Human Robotics
Imperial College London
London, UK
xq124@ic.ac.uk

Abstract

This report details the development of an initial prototype of OedaSock. OedaSock is a smart sock designed to detect leg swelling, oedema, and apply targeted pneumatic compression to help manage water accumulation. Developed in collaboration with lymphoedema specialists, a working prototype was developed and integrated with a partner app for real-time monitoring and control. Initial testing, including feedback from medical professionals and a patient trial, indicated a positive reception and highlighted the device's potential benefits. This report documents the design, construction and testing of the prototype as well as future development plans.

I. Background

Ideas and concepts

Oedema is a condition characterized by the build-up of excess fluid in tissues, leading to swelling. It affects over 250 million individuals worldwide [1] and up to 80% of pregnant women [2]. While a healthy diet and exercise can help swelling over time, compression garments are commonly used to stimulate lymphatic drainage and provide short-term relief [3].

Current compression garments rely on manual mechanisms such as fastening straps or inflation systems, which require patient intervention. These solutions often provide constant pressure, which is uncomfortable when worn for long durations. For individuals with limited mobility, these garments are difficult to put on and adjust due to their tight fit. Through discussion with lymphoedema specialists, Rebecca Elwell (Accelerate Clinic, London) and Saskia Krijgsman (Guy's and St Thomas' NHS Foundation Trust, London), the need for an automated system to provide a low-resting, high-working pressure was identified. These conversations guided OedaSock development, a smart compression garment designed to actively manage oedema and transmit key data to clinicians for improved monitoring and treatment.

II. Outreach

This project was aided by lymphoedema specialists: Rebecca Elwell and Saskia Krijgsman. After developing an initial prototype, we conducted a user trial on Ms. Mary Higgins at Cross Deep Surgery, Twickenham.

Insights from Rebecca Elwell

Rebecca advised targeting OedaSock to healthy patients with pitting oedema, such as pregnant women, sedentary individuals, post-surgery, MS, varicose veins, and stroke patients. She noted current compression garments are bulky, expensive, hard to wash, and apply constant pressure, whereas OedaSock only applies pressure as needed. She stressed its potential if it could monitor blood flow in the lower limbs [4].

Insights from Saskia Krijgsman

Saskia warned OedaSock may be unsuitable for diabetics with reduced foot sensation, and mentioned technologies like Limbstat and porometer for measuring foot volume and circumference.

User Trial Feedback – Ms. Mary Higgins

Mary, with over a decade of severe oedema, experienced discomfort and mobility issues with her stockings. She found OedaSock comfortable, valued its phone-controlled pressure, and recommended a slimmer electronics module and a knee-length design.

For the full version, please see the Appendix B.

III. High Level System Design

OedaSock is designed specifically to manage oedema by dynamically monitoring and controlling foot swelling using an integrated system of sensors and actuators. At its core, the device uses a stretch-sensitive variable resistance band, strategically placed to measure real-time changes in foot swelling. As the foot swells, the resistance band stretches, causing a measurable change in electrical resistance, which the device interprets to determine the degree of swelling.

The embedded software continuously monitors resistance values from the stretch-sensitive band, interpreting an increase of resistive values as an indication of swelling beyond an acceptable threshold. When such swelling is detected, the system activates an air pump, inflating a compression cuff wrapped around the foot. This inflation provides controlled compression, effectively reducing the swelling.

Once the swelling diminishes by a predetermined safe range, indicated by a decrease in resistive values, the software opens a solenoid valve to release the air pressure within the cuff. This automated release ensures compression is only applied when necessary, enhancing patient comfort and safety by preventing over-compression.

This closed-loop automated system ensures precise and responsive management of oedema. The software logic provides a reliable operative system through integrating continuous feedback and automated adjustments.

Design Objectives:

1) **Maximum inflation time:** The device should be able to fully inflate within a reasonable amount of time to effectively treat the condition.
2) **Maximum Pressure:** Through our conversations with clinicians, we determined that for some important metrics, such as the relationship between the stretch sensor and pressure applied, there is not a determined relationship. However, for severe swelling, 40 mmHg is a well researched figure [5].
3) **Device weight:** Although the device is not intended to be worn while walking, it is crucial for it to be lightweight to ensure the user can move their leg with ease.
4) **Maximum foot size:** The device must be designed to easily accommodate the user's foot, with a target size of the largest standard UK shoe size, 12. This ensures it can fit most users, even those with swollen feet.
5) **Stretch sensor accuracy:** The sensor needs a reasonably high level of accuracy to detect any slight changes in swelling. 1% increase allows for a $1mm$ change in diameter of the foot, based on 3 loops around the foot over 1m.
6) **Battery life:** The device needs to run for longer than the duration that a user could reasonably be expected to sit.

TABLE I: Design objectives and Specifications

Metric	Target Value
Maximum inflation time	1 minute
Maximum pressure	$> 40mmHg$
Device weight	$< 500g$
Maximum Foot size	12 (30cm)
Stretch sensor accuracy	$\pm 1\%$
Battery life	6 hours

IV. Hardware Design

The hardware design of the OedaSock device integrates the stretch-sensitive resistance sensor, an electronically controlled air pump, a solenoid valve for pressure release, and Bluetooth Low Energy (BLE) communication modules all controlled by an ESP32S3. The design focuses on simplicity, to ensure a reliable and responsive device.

Electronics layout

1) **ESP32 Microcontroller (XIAO ESP32S3)**: Acts as the central control unit, handling sensor data acquisition, processing, and actuator control (air pump motor and solenoid valve). It provides BLE for wireless monitoring and manual control.
2) **Variable Stretch Resistor (R2)**: Functions as the primary sensor, detecting swelling by measuring resistance changes when stretched due to foot swelling.
3) **10 kΩ Fixed Resistor (R3)**: Creates a potential divider with the variable resistor, allowing precise voltage measurement corresponding to resistance changes through the ESP32's analog input (D1 pin).
4) **3.7 V Li-Po Battery (B1)**: Supplies a portable and stable power source to the entire system.
5) **Physical Button Switch (SW1)**: Allows manual disconnection of the battery, ensuring safe maintenance, storage, and preventing battery drainage.
6) **3.3 V to 5 V Level Shifters (U2 for Air Pump Motor, U3 for Solenoid Valve)**: Elevate the microcontroller's 3.3 V output signals to 5 V required by high-power components. They feature an enable (EN) pin for switching them on and off with a

true electrical disconnection, providing protection against voltage spikes and preventing unintended current flow.

7) **Air Pump Motor (M1)**: Inflates the compression cuff, delivering therapeutic pressure to actively reduce foot swelling.
8) **Solenoid Valve (M2)**: Releases air from the cuff, precisely controlling the deflation process.
9) **Capacitor (470 μF, C1)**: Connected in parallel with the motor to smooth voltage spikes and stabilize motor operation.
10) **1 A Diodes (D1, D2)**: Provide protection against reverse voltage spikes (flyback currents) from inductive loads like the motor and solenoid valve, safeguarding the electronic components.
11) **Resistor (10 kΩ, R1)**: Collaborates with the capacitor and diode in a spike suppression network, protecting the motor circuit against transient voltage fluctuations.

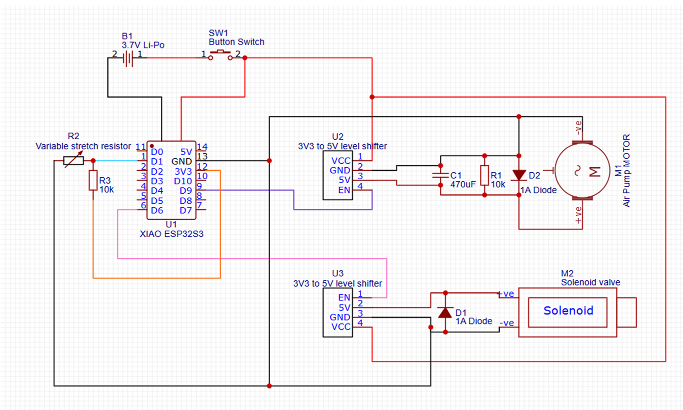

Fig. 1: Electronics wiring schematic

CAD Schematic

The CAD model in figure 2 shows how each component has been organised within a compact and durable 3D printed casing. The arrangement has been designed for ease of assembly and maintenance, with all components accessible and laid-out to minimise wire length. Press fits were used to hold all components in place to allow for rapid development and stop short circuiting from"free floating" parts. Appendix 1 shows exploded views with labelled parts.

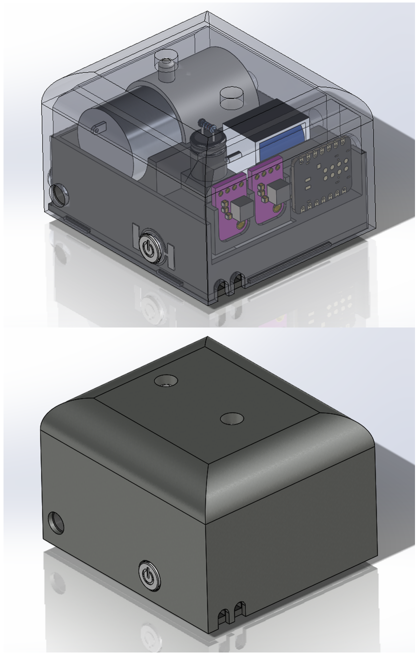

Fig. 2: CAD model of the device

V. Software Design

Microcontroller Control System

The control system is designed using five different states within the code, written in Arduino to be compatible with the Xiao Seeed Studio ESP32S3 microcontroller.

1) *Initialisation*: The device initialises the relevant microcontroller pins, sets up Bluetooth Low Energy (BLE) communication and enters a calibration state.

2) *Calibration*: During calibration, the device takes multiple readings from the stretch-sensitive resistive band to establish a baseline resistance value. This value represents the unswollen state of the foot and is crucial for detecting subsequent swelling. A new baseline reading is taken after each time the cuff inflates or deflates.

3) *Monitoring and Control*:
   - For automatic control, the device continuously compares real-time sensor readings against the calibrated baseline resistance.

   - If a reading indicates swelling beyond a predefined threshold (typically 10% above the baseline), the system automatically initiates inflation of the compression cuff. This is achieved by activating the motor controlling the air pump for 4 seconds, as advised by Ms.

Mary Higgins.

- If the sensor indicates a reduction in the resistive reading below the baseline threshold (10% below), this suggests a decrease in foot swelling. This initiates the microcontroller deflation cycle to relieve the applied pressure by activating the solenoid valve for 2 seconds, as advised by Ms. Mary Higgins.

- Users can manually adjust inflation and deflation levels via BLE commands from their phone, allowing individualised control and immediate response to user comfort or clinical needs.

4) *Inflation/Deflation Management*: The inflation and deflation processes are precisely timed and managed through incremental adjustments. The system periodically updates the inflation level until the desired target pressure is reached, ensuring gradual and comfortable changes for the user. It sets the system to a "Motor Running" state that halts all other processes so that full power can be diverted to the motors. Additionally, it ensures other signals do not interfere with the inflate/deflate process. Any readings from the resistive band or BLE commands are disregarded, preventing the system from mistakenly issuing multiple inflation calls.

5) *Safety and Emergency Handling*:
   - Users can initiate an "Emergency Stop" from the OedaSock app. Upon activation, the device immediately ceases inflation and opens the solenoid valve for 30 seconds to completely alleviate the applied pressure. The device is then safely reset to a recalibration state.

   - Comprehensive debug features allow for detailed diagnostics and parameter adjustments. This is particularly important during testing and refinement to ensure the systems flexibility and robustness. It also allows the OedaSock team to easily incorporate user feedback.

App Development

The partner app to accompany the OedaSock device was designed to be effective and simple for users. This was important as many individuals in the target market are from a less technologically driven generation. We built the first prototype on Android as it is well documented and has the largest market share [6]. Developed in Android Studio, and written in Kotlin for the easiest integration with external libraries. Figure 3 shows the home screen of the app after connecting to the device, with the manual inflate, deflate and emergency stop buttons clearly visible.

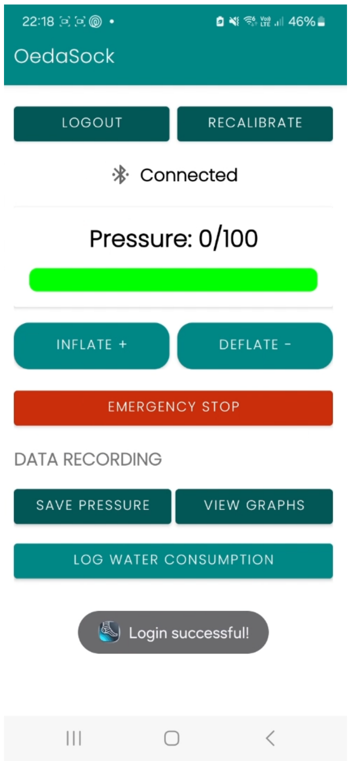

Fig. 3: Home page after logging in

Bluetooth Low Energy (BLE): The development process prioritised creating a user interface intuitive for both clinicians and users. BLE connectivity used to communicate between OedaSock and phone was chosen due to its lower latency and power consumption compared to Bluetooth. Wi-Fi was considered, however, the inability to use it outside a secure home network would render the device useless for a mobile user. Our use of BLE wireless technology enables real-time pressure readings from the microcontroller to be displayed on the user's smartphone [7] and Nordic Semiconductor BLE-Kotlin wrapper library [8] was used to reduce the connection failure rates.

User login functionality: User authentication was implemented through a secure login system. Important metrics including weight, age, gender, and email address (Figure 4) are captured. Once the user has logged in, the ability to save pressure and input their water consumption, as shown in Figure 5, is available on the home screen. This data, recommended by R. Elwell and S. Krijgsman, is critical for understanding compression therapy and tracking patient progress over time. The app's interface was designed with larger text elements and simplified navigation to accommodate users with varying levels of technological proficiency [9].

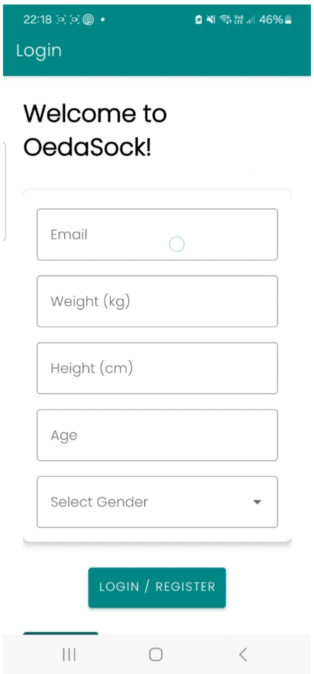

Fig. 4: Login page

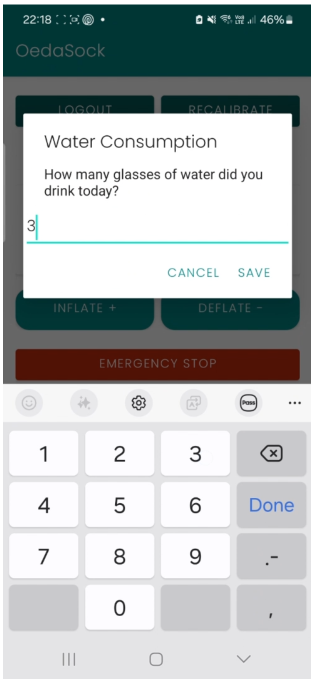

Fig. 5: Water consumption input field

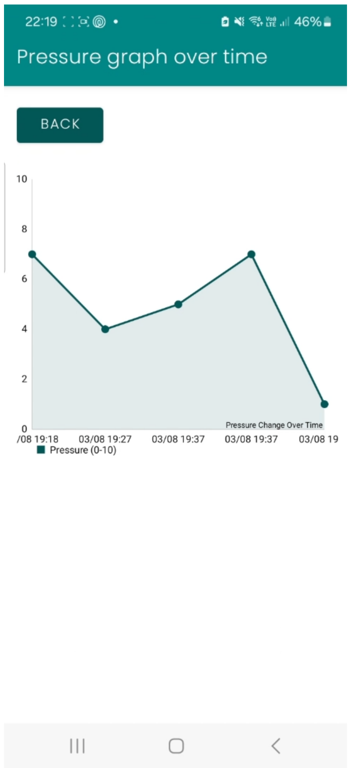

Fig. 6: Graph generated within the app

Graphical visualisation: The app's data visualisation feature enables patients to track pressure measurements over time. This provides information into the individualised pressure required to effectively manage swelling. This feature proven beneficial for patient engagement and treatment adherence, as users can observe tangible evidence of swelling reduction [13]. By saving their pressure periodically, the app automatically generates a time-dependent pressure graph as shown in Figure 6.

Data storage: Data storage and management presented significant challenges, particularly regarding patient privacy and data security. Google Firestore was selected as the backend database solution due to its robust security features, real-time synchronisation capabilities, and scalability. Unlike traditional SQL databases, Firestore's NoSQL structure allows for flexible schema design. This accommodates the data collection requirements across different clinical settings [10]. Firestore's built-in authentication and encryption protocols ensure compliance with healthcare data protection standards [11] [12]. This allows clinicians to securely download patient data in standardised formats tofacilitate a deeper analysis of the relationship between pressure applied and the patient's level of swelling.

VI. Prototypes and Evaluation

After building the device was evaluated against the predefined metrics, see table I. Final comparison shown in table II.

1) **Maximum inflation time:** Testing found OedaSock to inflate in around 30 seconds dependent on external pressure.
2) **Maximum Pressure:** Our motor pump was rated to achieve 400mmHg or 55Kpa, with the cuff able to withstand this pressure.
3) **Device weight:** On weighing final device was around 225g, well below the target.
4) **Maximum foot size:** The open strap design allowed for users to easily put their foot in. On testing OedaSock accommodated a size 12 foot.
5) **Stretch sensor accuracy:** The sensor was easily able to detect the 1% change, this was validated

both through code output and with a multimeter. In the final code the required accuracy was adapted so it could deal with any potential noise for a more robust experience.

6) **Battery life:** The device was tested to run for an hour continuously, this is expected to increase to over 20 hours during normal use as the motor, the main source of power consumption, will run rarely as it is only required for active inflation, when a swelling change is detected.

TABLE II: Design objectives and Specifications

Metric	Target Value	Achieved
Desired inflation time	1 minute	$\approx 30 seconds$
Maximum pressure	$> 40 mmHg$	$400 mmHg$
Device weight	$< 500 g$	$\approx 225 g$
Maximum Foot size	12 (30cm)	12 (30cm)
Stretch sensor accuracy	$\pm 1\%$	$\pm 1\%$
Battery life	6 hours	20 hours est

VII. Conclusion

OedaSock has established its relevance in the compression garment industry with support from experts in the field. Additionally, a functional prototype was developed for the Imperial College London HCARD competition, where it secured first place.

Despite these successes, the current prototype of OedaSock has some practical limitations which are to be addressed in future iterations.

1) Designing a bespoke garment would improve the functionality. Currently, the inflatable sock used is an off-the-shelf component. A specifically designed longer sock, with the ability to apply a compression gradient up the leg, would be more practical. Additionally, slimming the electronics module down, through using smaller pumps and a PCB board, would help reduce size and weight.

2) The sensitivity of the stretch sensor could potentially be compromised if the patient walks due to the resistive band short-circuiting. Integrating the stretch sensor into the sock so it is completely isolated could resolve this. However, using porometer technology for increased accuracy would be preferred.

3) Integrating a press and hold inflate feature for the app to enable finer control.

4) Implementation of predictive algorithms to help apply pre-emptive pressure before swelling onsets.

5) Increase the number metrics recorded directed such as heart rate, blood pressure and measures of blood flow.

If implemented, these future changes would improve both the functionality and usability of OedaSock.

VIII. Appendix

A. Testing and validation

Images from our testing and validation sections.

Fig. 7: The final packaged device

Fig. 8: Testing working principles with real users

Fig. 9: Showing the device to Ms. Mary Higgins

Fig. 10: Testing maximum foot size

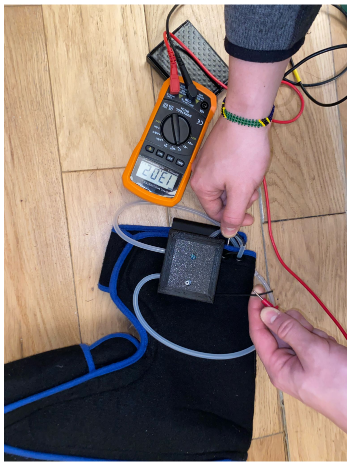

Fig. 11: Testing sensor accuracy

CAD design

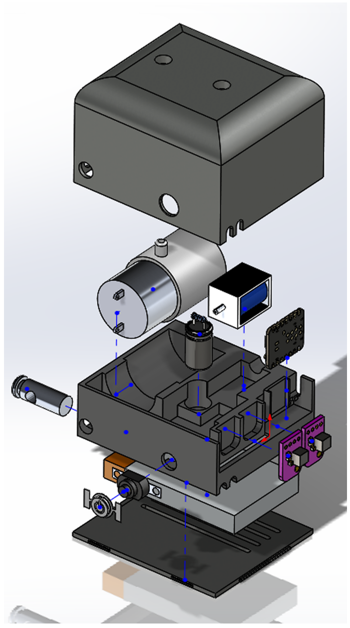

Fig. 12: Exploded view of the device

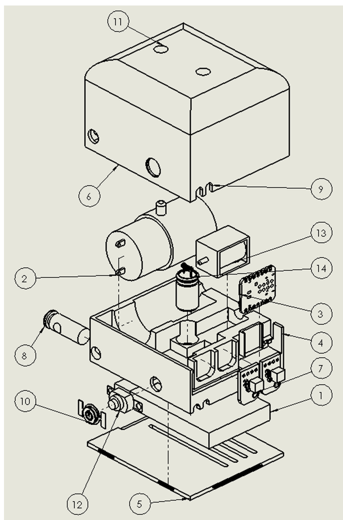

Fig. 13: Exploded drawing of the device

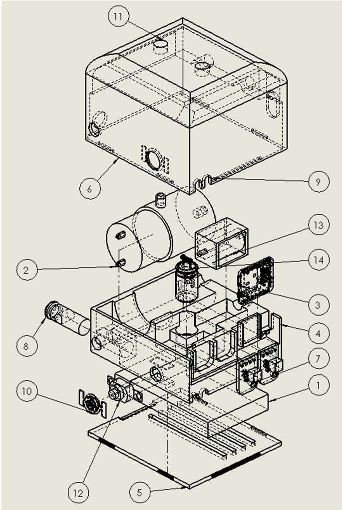

Fig. 14: Exploded drawing of the device showing the hidden lines

Figure 13 and 14 are labelled:

1) 3.7V Li-Po battery.
2) Motor Pump.
3) Xiao Seed Studio ESP32S3 microcontroller.
4) Central casing which holds all of the components.
5) Base Plate, which uses an interference fit to grip the cover and hold the components together.
6) Cover, protects all of the internal components and gives a seamless finish to the design.
7) Two level shifters.
8) Spring catch for holding and adjusting one end of the variable resistor.
9) Entrance holes for the variable resistive cord.
10) On-Off button cover with a 3D printed complient mechanism design
11) Outlets for tubing to inflate and deflate the cuff
12) On-Off button
13) Solenoid valve
14) Capacitor and resistor circuit for smoothing the motor

B. Full Insights and Trial Feedback

Insights from Rebecca Elwell

Rebecca provided clear direction regarding our target market. She recommended targeting OedaSock towards “healthy” patients with pitting oedema, including:

- Pregnant women
- Individuals with sedentary jobs
- Post-surgery
- MS patients
- Patients with varicose veins
- Stroke patients

Rebecca shared insights into existing compression garments, such as compression stockings and intermittent pneumatic compression devices. Our discussions highlighted key limitations of these garments, including cost, bulkiness, and difficulties with washing. When we introduced the concept of low resting pressure and high working pressure, Rebecca expressed strong confidence in OedaSock’s potential.

Current compression garments apply constant pressure to the foot, which many patients find uncomfortable. She confirmed OedaSock’s novel approach, providing pressure only when necessary, would be a valuable innovation. Rebecca outlined key metrics that clinics would require from such a device, which we incorporated into our app. She emphasized that if the device could eventually monitor blood flow through the lower limbs and track how oedema affects circulation, it could be ‘revolutionary’ [4].

Insights from Saskia Krijgsman

Our conversation with Saskia focused on the potential limitations of the device and measuring techniques used in clinical settings. One key discovery was that OedaSock would be unsuitable for diabetic patients, as they often experience reduced sensation in their feet. This could pose a serious risk, as they might not feel the applied pressure. However, through the use of our predefined mechanical and software pressure limits, the patients will not experience compression pressures which pose a risk to their health.

Saskia introduced us to existing technologies such as Limbstat, which could assist in calculating foot volume. We also explored porometer technology as a potential method for measuring foot circumference in future designs.

User Trial Feedback – Ms. Mary Higgins

Mary has suffered from severe oedema for over ten years and has tried multiple compression garments. She currently wears compression stockings but reported significant discomfort and mobility issues due to the constant pressure, which has caused foot deformation. She highlighted difficulty washing these garments, as the fabric must retain its structural integrity to function properly.

Mary provided valuable feedback on OedaSock:

- **Comfort** – She was pleasantly surprised by how comfortable the device felt. She suggested slimming the electronics module to reduce its size and weight. Additionally, the 3D-printed clip slightly dug into her leg at high pressures, so she recommended attaching the module completely externally.

- **Functionality** – She was impressed by how much pressure was applied, stating: ‘it’s a lot more than my stockings.’ To improve functionality, she suggested extending the sock’s length to around knee height, a common length for compression garments.

- **Pressure Control** – The highlight for Mary was the ability to control the pressure applied to her foot directly from her phone. Her current compression garments do not have this feature, and it allowed her to adjust the pressure as needed.

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