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Project No.: 825429 SocketSense

SOCKET:SENSE
A TAILORED FIT OF THE FUTURE

Advanced sensor-based design and development of wearable prosthetic socket for amputees

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For further information please contact the SocketSense project coordinator:

Dr. Dejiu Chen
Mechatronics Division, Department of Machine Design,
School of Industrial Engineering and Management,
KTH Royal Institute of Technology
Brinellvägen 85, SE-100 44 Stockholm,
Sweden
chen@md.kth.se

Authors

Document manager: Siu-Teing Ko, Magnús Oddsson & Freygarður Thorsteinsson

Contributors: Valter Dejke

Josephine Charnley

Suranjan Ottikkutti

Wenyao Zhu

Sharon Brown

Joe Miller

Paula Algarín Sánchez

Mike Karamousadakis

Reviewers: Josephine Charnley & Zulf Ali

Content

Executive Summary

BACKGROUND	GOALS
This deliverable describes the lessons learned through system testing during the early prototyping phase through to user testing during the clinical trials investigation.	The aim of this deliverable is to provide a high-level summary of the testing performed throughout the development of the SocketSense system.
APPROACH AND COURSE OF ACTION	
Iterative testing was undertaken throughout the development of the SocketSense system. At each instance, technology and procedures were enhanced based on the discoveries. The process to reach readiness for clinical investigation was an important part of the success of the project. Throughout the clinical investigation, as new findings arose, continuous improvements were made to the system. These were documented and are described in this deliverable.	
FINDINGS AND RESULTS	
Iterative testing during the early development phase is extremely important for the success of a functional prototype. The application procedure for clinical investigation approval from the healthcare regulatory bodies should not be underestimated. Well prepared documentation and protocols for clinical trial investigations is of great value for the success of the study.	
IMPACT	**PLANNED DISSEMINATION AND EXPLOITATION**
The purpose is to provide insights and advice for management regarding testing and application process for clinical investigations in other projects, as well as for future developments of SocketSense.	This deliverable is public.

ACRONYMS

AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
AI	Artificial Intelligence
CE	Conformité Européenne
Covid19	Coronavirus Disease 2019
EU	European Union
HRA	Health Research Authority
Hz	Hertz
ICT	Information and Communication Technologies
KTH	Kungliga Tekniska Högskolan
Li-Ion	Lithium-ion
MDD	Medical Devices Directive
MDR	Medical Device Reporting
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
PCB	Printed Circuit Board
PET	Polyethylene terephthalate
PIC	Patient Identification Centre
Q&A	Question & Answer
QA	Quality Assurance
QTSS™	Quantum Technology SuperSensors ™
REC	Research Ethics Committee
RISE IVF	Research Institutes of Sweden
SAS	Servicio Andaluz de Salud
SD	Secure Digital
Sensel	Sensing element
STH	South Tees Hospitals NHS Foundation Trust
TU	Teesside University
TWI	The Welding Institute
UI	User Interface
UK	United Kingdom

1. Introduction

This document provides a high-level overview of the lessons learned from the system testing and user evaluation throughout the SocketSense project.

Document Structure

Section 2 introduces the SocketSense system and explains the interaction of the subsystems – to provide context to the subsequent sections of the deliverable. These sections are ordered based on sequence of events – from bench-top testing during the early prototyping phase (Section 3) to the clinical investigation application process, and the continued evolution of the system as the clinical investigation trials were conducted with amputees in Spain and the UK (Section 4). This includes a summary of the user evaluation report from the perspective of clinicians and amputees who tested the system (Section 5). Finally, a retrospective review of the project events and outcomes are listed to advise the management and conduct of subsequent projects.

2. SocketSense Project Overview

SocketSense is project funded by the European Union's Horizon 2020 Research and Innovation Programme, as part of the ICT-02-2018: Flexible and Wearable Electronics call, under the grant agreement No 825429. The purpose of this call is to overcome manufacturability challenges that come with lightweight, flexible, printed, and multifunctional electronic products. The scope is to seek opportunities and benefits for use of such technologies in existing and emerging markets.

The SocketSense project aimed to develop an innovative advanced sensor-based system for prosthetic sockets that will enable comfortable socket manufacturing tailored to amputees' needs. The goal of the system was to measure pressure and shear stresses exhibited on the inner surface of the prosthetic socket during activities of daily living with the ultimate goal of improving socket fit and comfort and reducing further damage to the residual limb. Flexible, lightweight, and low-cost printed pressure and shear sensors, as well as artificial intelligence (AI) methods were among the technologies developed.

2.1. Consortium Roles

Nine partners from across Europe participated in the project, bringing together expertise from a range of fields. The consortium members along with their respective roles in the project are listed in Table 1.

Table 1 Consortium Roles

Partner	Role
Kungliga Tekniska Högskolan (KTH) Project coordinator & technical manager	Mechatronics and Embedded Control Systems Electronics and Embedded Systems
Teesside University (TU)	Healthcare Innovation and biomechanical modelling Clinical investigation
RISE IVF	Sensor development, testing, and manufacture
Össur Commercilisation manager	Design and Development process and biomechanical modelling
LussTech Innovation manager	Sensor and sensor material development, testing and manufacture
Nuromedia	Software development
South Tees Hospitals NHS Foundation Trust (STH)	Clinical investigation lead
Servicio Andaluz De Salud (SAS)	Clinical investigation lead
TWI Hellas	System integration and biomechanical modelling

2.2. The SocketSense System

The aim of the system is to enable prosthetists to achieve a good socket fit with fewer visits to the clinic.

Design aspects of the system include:

- Soft, flexible, and lightweight 3D pressure and shear sensors based on an environmentally friendly Quantum Technology Supersensors™ (QTSS™) which can achieve functionality that has otherwise been unattainable
- Simple, low cost, low power processing, multi-sensel and multi-functional electronic sensors that are easy to assemble and manufacture large-scale
- Sensor system capable of providing a three-dimensional pressure map in real time for better prosthetic fit
- Advanced biomechanical analytics model to analyse the interaction of residual tissue and sockets
- Advanced data analytics and artificial intelligence algorithms to enhance the accuracy of data analysis

The SocketSense system is comprised of seven interacting subsystems:

- Main data acquisition
- Power supply
- QTSS sensing
- Gait monitoring
- Environment sensing
- Central processing and data storage
- Mobile/tablet device

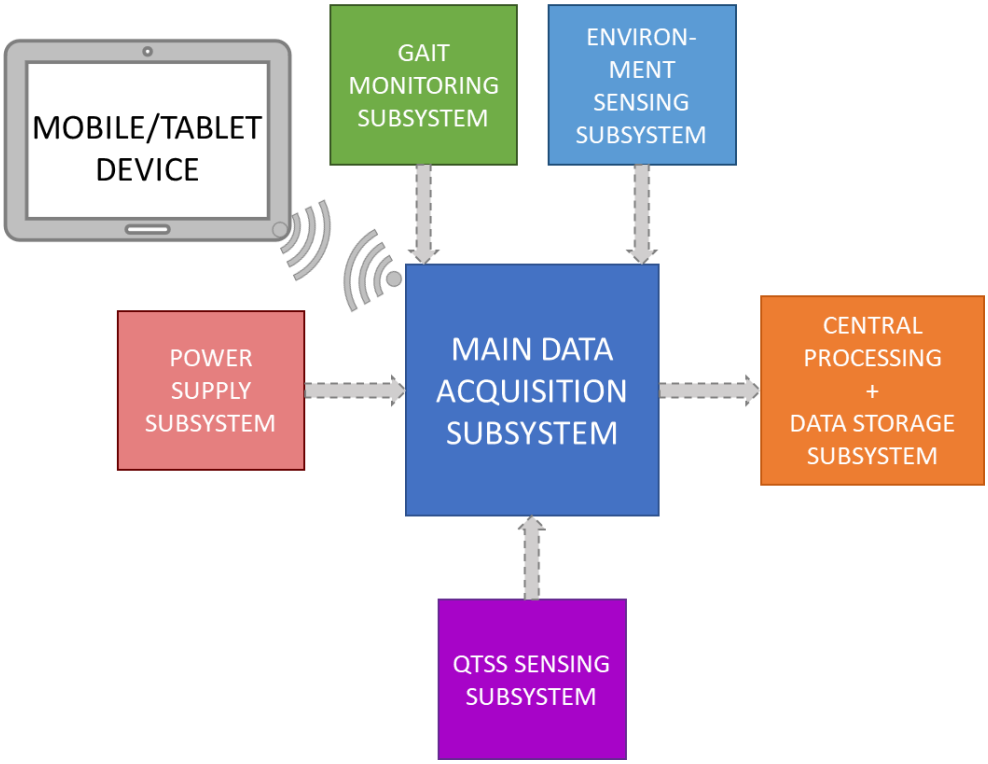

Figure 1 Block diagram of the interactions between the subsystems of the SocketSense system

A high-level overview of the system architecture is depicted in Figure 1, and the corresponding physical prototype in Figure 2. The *main data acquisition* subsystem receives power from the *power supply* subsystem and data input from the *QTSS sensing*, *gait monitoring*, and *environmental sensing* subsystems. These subsystems measure pressure/shear at the inner surface of the prosthetic socket; gait events (heel strike, mid-stance, toe-off, mid-swing); atmospheric temperature/pressure, respectively. Data is then output from the *main data acquisition* subsystem to the *central process and data storage* subsystem. The central processing and data storage subsystem is also referred to as the software in this document. The software also includes the user interface (UI), which is the platform on which the information gathered and curated from the sensing subsystems is visualised, an example is shown in Figure 3. The mobile/tablet device is used to initialise and stop recording of measurements. In the context of the clinical trials, the mobile/tablet device was also used to input tag identification numbers on the exercises being performed by the participants, such as level ground walking, stair ascent/descent etc.

A more detailed description of the SocketSense system can be found in the publication by Lu et al. [1].

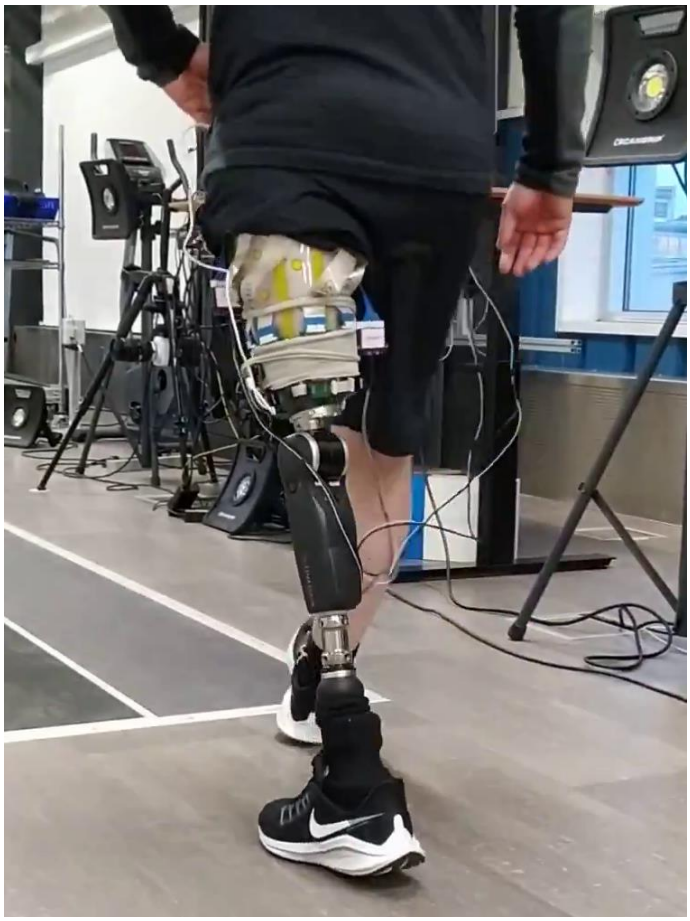

Figure 2 Amputee walking with SocketSense system integrated with their prosthesis.

The QTSS sensing subsystem consists of pressure and shear sensor strips that are attached to the inner surface of the socket with removeable double-sided adhesive (Figure 4). The pressure sensor strips can be cut between sensels to accommodate different socket sizes. The gait monitoring, environment sensing, power supply, and main data acquisition subsystems are all temporarily attached to the outside of the socket (Figure 2).

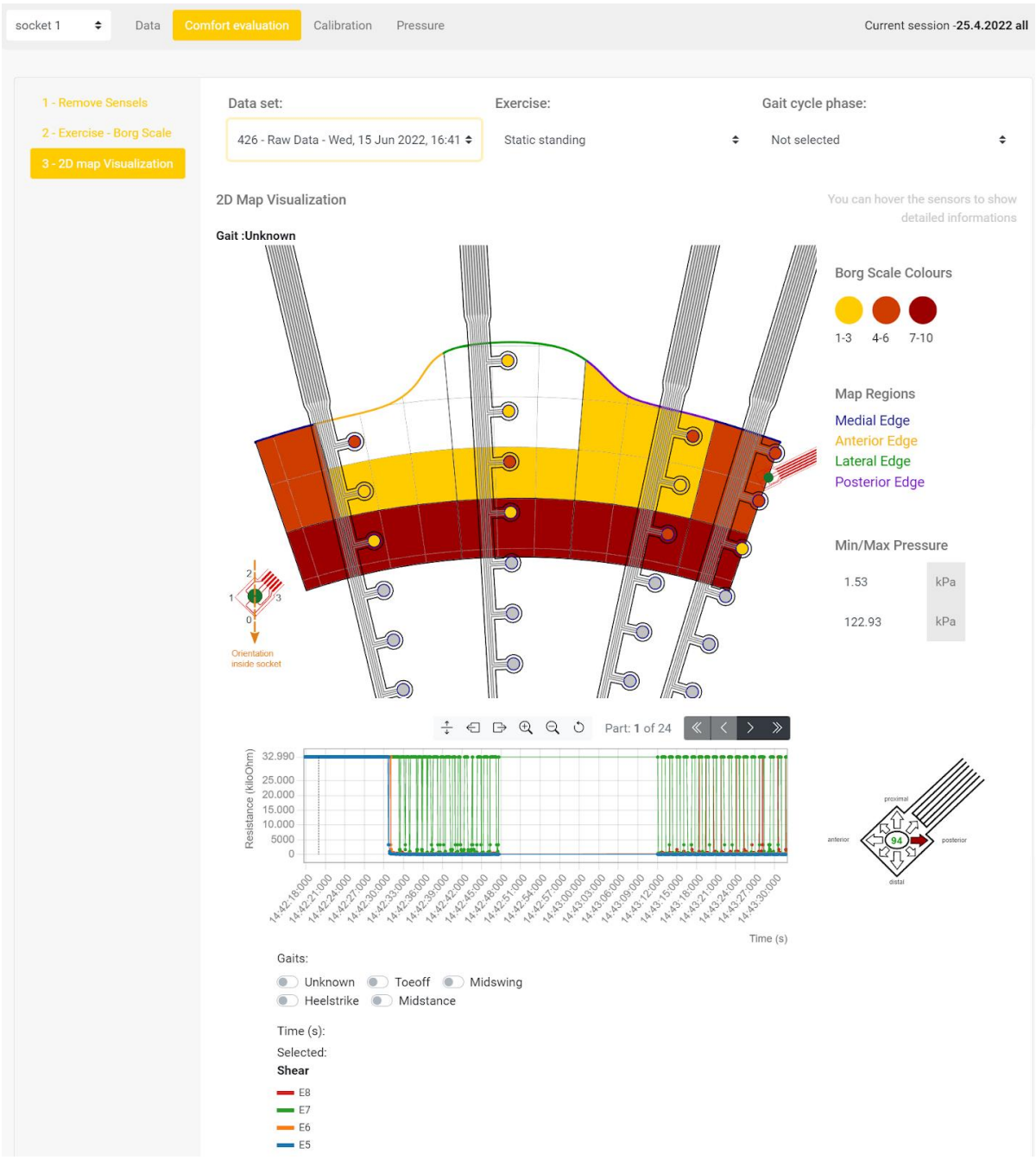

Figure 3 Screenshot of the "2D map Visualization" feature of the SocketSense software (UI)

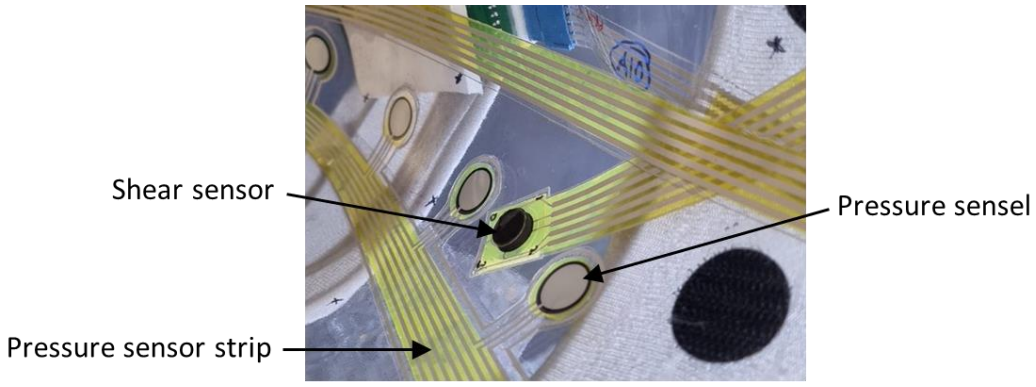

Figure 4 Pressure and shear sensors adhered to inner surface of a prosthetic socket.

3. Lessons Learned from Pre-Clinical Investigation Testing

Four phases of testing took place prior to the clinical investigation, see Figure 5. Benchtop tests were a part of the design and development process, particularly for the QTSS sensors and data acquisition subsystems. The realistic use-case environment of the sensors is inside a prosthetic socket, which has curved surfaces. In-socket testing was therefore performed to characterise the sensors in realistic conditions. A pilot study was held with one transfemoral amputee to evaluate the feasibility of the prototype. After the pilot study, design iterations were made and tested in the Stewart Platform to ensure functionality prior to the clinical investigation.

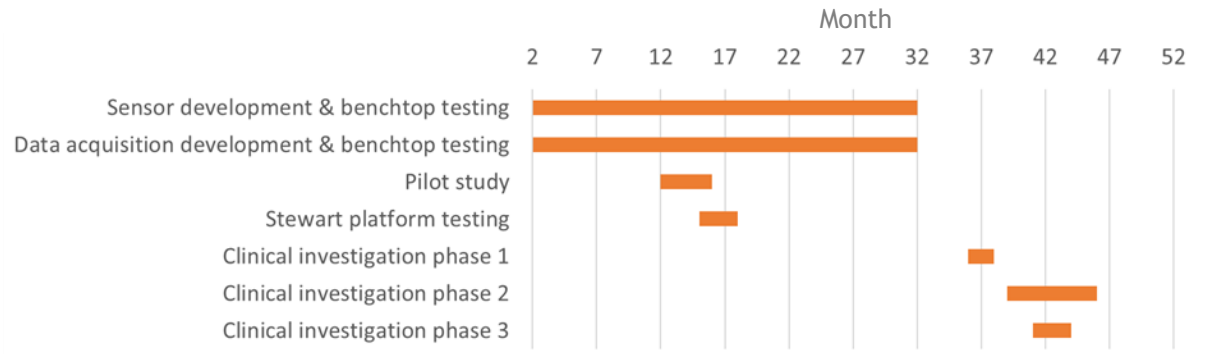

Figure 5 Gantt Chart of system testing (benchtop and clinical investigation)

3.1. Bench-top Testing

Although a typical part of the development process, bench-top testing is valuable to ensure the correct sensor characteristics are achieved in a controlled conditions before introducing a more complex test environment. Bench-top tests for development of the SocketSense system were initially separated to focus individually on the sensing subsystem and data acquisition subsystem, and tested together to ensure compatibility.

3.1.1. Sensing Subsystem

The sensing subsystem was continuously and iteratively developed and tested. Primary testing took place on a flat surface to first characterise the sensors and evaluate the functionality. Secondary testing was performed inside a socket to test the feasibility of measurements in a more realistic environment, i.e., on curved surfaces.

Flat Surface

Sensor functionality, validation and characterisation testing was carried out in the lab on the bench top flat surface (Figure 6) and the following lessons were learned:

1. As the soft silicone liner is a key component of the prosthetic system and is the interface between the skin of the residuum and the hard socket in pin-suspension systems, it is important to use a liner interface when performing characterisation and validation tests to replicate realistic use conditions.
2. The lab testing equipment electronic circuitry can significantly affect the measurements, therefore for final sensor testing it was important to use the SocketSense main data acquisition subsystem electronics that would be used in the clinical investigation.
3. A shear test rig was built to carry out initial validation of the shear/slippage sensor, however, it was quickly decided to evaluate the sensor under more realistic

conditions - in the prosthetic socket of an amputee. The sensor was therefore tested in a pilot study (discussed in section 3.2) to test the real-life movement of the residuum on the shear/slippage sensors.

4. Lab testing procedures were important as the basis for establishing simple QA procedures for product manufacture in the future.

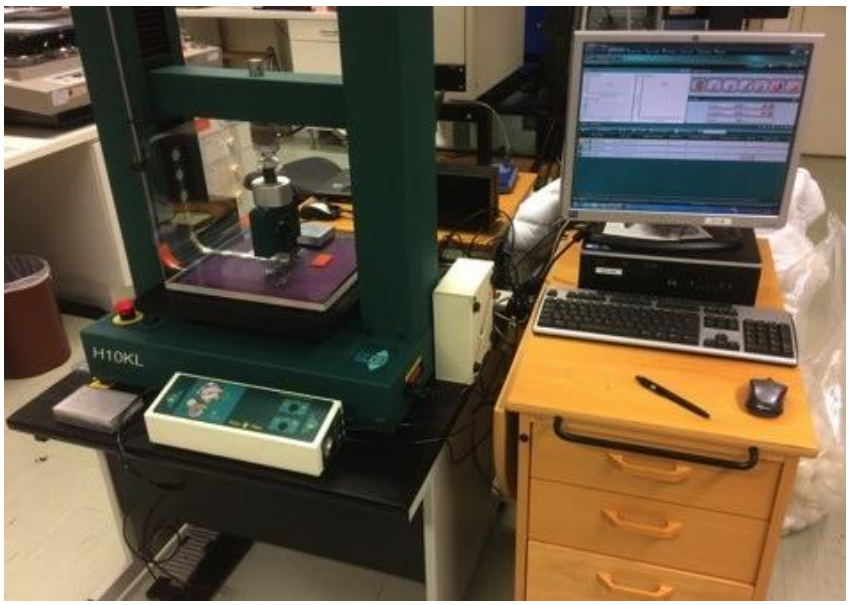

Figure 6 Pressure sensor characteristic testing on flat surface

In-Socket

The next step in development process was to test the sensors under more realistic conditions. In-Socket testing was therefore carried out in the lab using an in-socket test rig set up. An inflated liner balloon was used in the test-socket to recreate the residuum application of pressures on the sensor strips (Figure 7).

The following lessons were learned:

1. A socket coordinate system and coordinate marking rig were needed to be able to segment the socket to allow individual sensor sensels to be placed in known and identifiable locations for testing (Figure 8).
2. Insufficiencies of the in-socket test rig led to the realisation that a handheld calibration device was needed that would fit inside a socket to calibrate the sensors in their final positions. This would be performed during the clinical investigation.
3. A calibration protocol was established in conjunction with the User Interface to allow ease of use of the calibration device and entry of results into the User Interface during use.
4. A sensor integration protocol was developed for placement of sensors within a patient's socket.
5. Extra strong (yet removable) adhesive would be required to ensure the sensors were held firmly in place in sockets on highly contoured regions in the socket.

As evaluated from the literature [2], the importance of designing sensors for the specific application is crucial to achieve meaningful data. Testing the QTSS sensors inside a socket led to the creation of the handheld calibration device that would be utilised in the clinical investigation, and likely supplied as part of the final product. It also verified the sensor substrate selection due to its good flexibility performance to fit to socket contours.

Figure 7 Liner inflated inside a prosthetic socket to apply specified uniform pressure on the sensors integrated in the socket

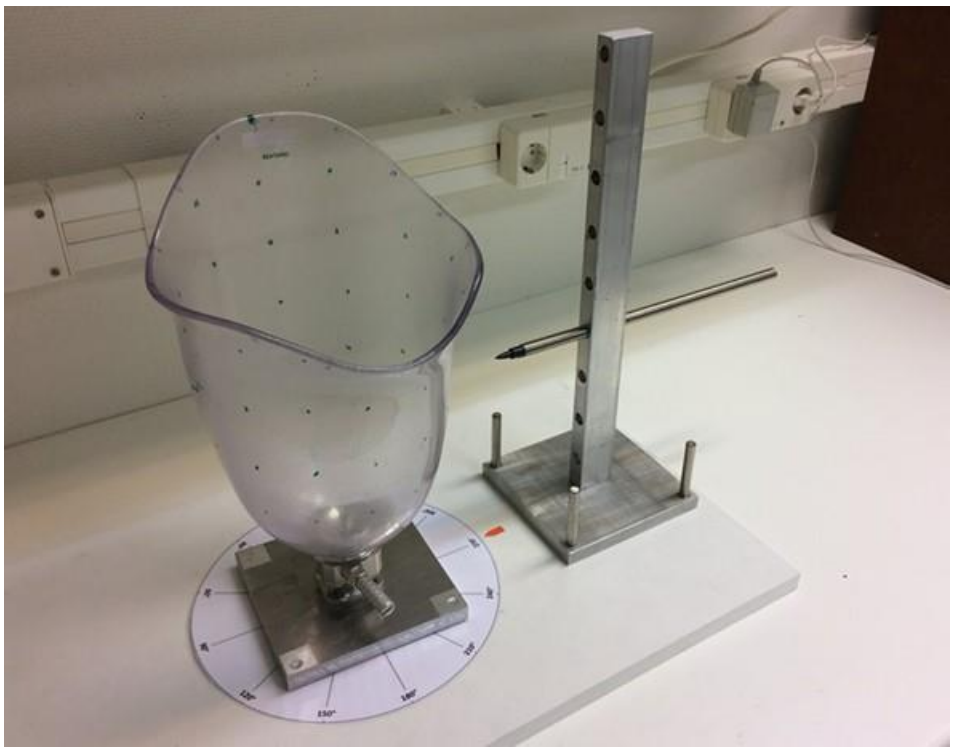

Figure 8 Socket coordinate system and marking rig to discretise prosthetic sockets into 30-degree segments radially and 50mm increments along the longitudinal axis.

3.1.2. Data Acquisition Subsystem

The testing of SocketSense electronics was done at the lab scale to validate its functionality and show its performance to fulfil the requirements laid out at the start of the project. The following lessons were learned:

1. The accurate reading of input voltages is the key function for sensor data acquisition. It is important to use known resistance fixed and adjustable resistive loads to test the system. Self-testing PCB boards were used to test the QTSS sensor reading function. After that, the gait monitor and environmental sensors were also tested.
2. The test of the data transmission function is needed to ensure the data is safely stored in the desired places. Under the lab situation with stable network connection, the wireless transfer and local storage could work together with no data loss. While in further tests with more complex network situations and a remote server, the wireless communication was not robust enough to handle latency and some data was lost. In later user trials, the local SD card storage was enabled but the wireless transfer was disabled to avoid risk of data loss.
3. The system performance was also tested from the power consumption part. Initially, a small Li-Ion battery powers the system in the lab as the system power consumption is quite low. While for the clinical investigation, a larger off-the-shelf power bank was selected since it lasts much longer and can be exchanged and recharged easily. Most importantly, the selected power bank was also CE marked and included relevant safety certifications.
4. A sampling frequency of 20Hz of the QTSS sensor sampling frequency was deemed sufficient to capture gait events. A higher frequency was also tested to validate the system performance and may be applied in future iterations of the system.

3.2. Pilot Study

A pilot study was held in Össur, Iceland, with a fully functional SocketSense system integrated with a transfemoral amputee's prosthetic socket. The primary purpose of the study was to evaluate the feasibility of the system with an amputee under real-use conditions before proceeding further with the design. With regards to system design, the primary outcome measures were to ensure the system did not interfere with the normal socket fit nor affect the functionality of the prosthesis under normal use conditions. Additionally, the study required a test protocol to be designed – defined exercises to be performed, number of repetitions, and duration of execution, etc., which was further utilised as input for the clinical investigation protocol.

The study was conducted in compliance with Icelandic regulations and guidelines and in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and the protocol, CII2020121754, was approved by the Ethics Committee IRB VSN 19-083.

3.2.1. Pressure Sensors

The first pilot study tested the system with five pressure sensing strips – no shear sensor was present. The following lessons were learned:

1. The pressure sensors did not have any effect on the socket comfort or fit perceived by the test subject.
2. The entire system integrated with the subject's prosthetic socket did not have any perceivable impact on the ability to perform tasks such as level ground walking, ramp and stair ascent/descent, but did have some impact when sitting due to the bulkiness of the data acquisition subsystem attached to the outside of the socket. The impact was deemed minimal as the subject was still able to sit comfortably, however, it was assessed necessary for electronic enclosures to be manufactured for the next phase of user testing (i.e., clinical investigation).
3. Issues with simultaneous real-time data transmission to a remote server, for real-time data visualisation and data writing to a local storage, led to data dropouts in the local storage. The issue was not identified until the first pilot study took place,

which resulted in insufficient data collection. It was decided to exclude real-time monitoring and only locally store data on an SD card instead. With this change, a second trial took place, and all data was acquired as expected.

4. Sensor integration in the socket was a lengthy process. The study led to the next sensor design iteration to include the double-sided adhesive pre-installed; ready for direct attachment to the socket surface.
5. The combination of the socket co-ordinate system and marking rig and the 2D map of the residual limb overlaid with sensors positioned as desired, was of great use when integrating the sensors in the prosthetic socket; particularly for non-clinicians (Figure 9). This led to the creation of template maps representing residual limbs of a selection of sizes on which sensor strips could be overlaid to aid systematic and repeatable sensor strip positioning in the physical socket for the clinical investigation trials.
6. A series of silicone pads and straps were required to hold the data acquisition subsystem electronic hardware components in place on the outside of the socket.
7. To organize the external cables and reduce the risk of cables mechanically interfering with the environment, availability of different cable lengths to accommodate different socket circumferences was desired for the clinical investigation trials.
8. For smoother data evaluation, a tagging system was introduced to split the data based on each exercise performed by the amputee. The tagging system that was developed is a remote system via Bluetooth, which can also trigger start/stop data recording.

More information on the benchtop tests and pilot study can be found in the publication by Dejke et al. [3].

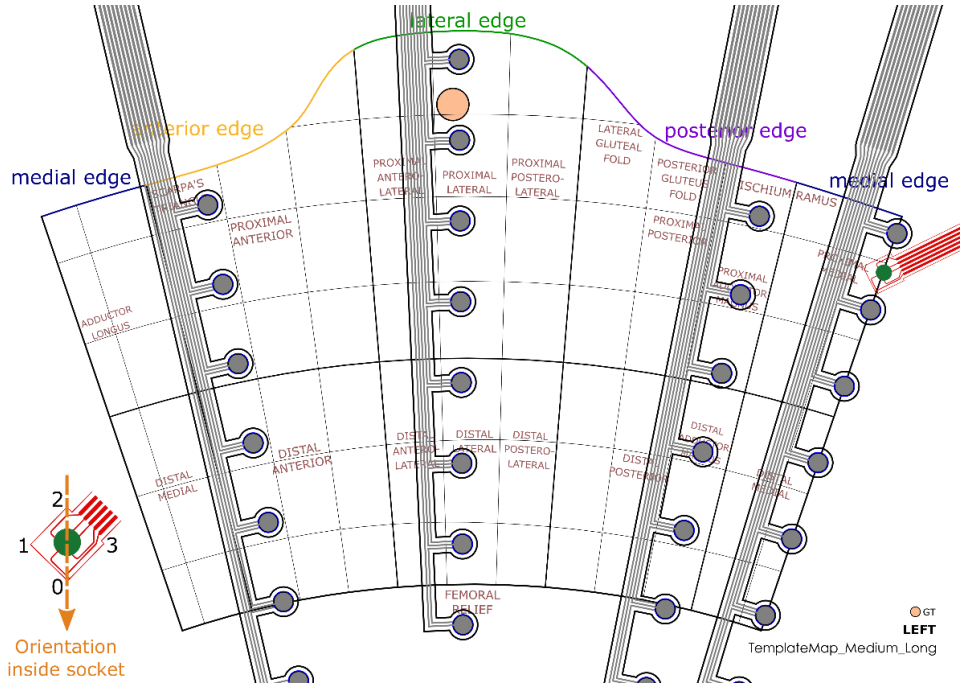

Figure 9 Example template map of residual limb and corresponding sensor strip positionings

3.2.2. Shear Sensors

The second pilot study focused on testing the system with three shear sensor designs to assess which design provided optimal measurement signals. Three different anatomical locations of interest were identified from the literature; therefore, each shear sensor was

tested in each of these locations to determine the best location for the shear sensor for the purpose of the clinical investigation. The SocketSense prototype system version, used in the clinical investigation, is capable of measuring from up to five sensing strips, whereby one shear sensor is considered one sensing strip. To acquire pressure measurements from each quadrant (anterior/posterior/medial/lateral) of the socket, one pressure strip was placed in each quadrant, thus space for only one shear sensor was available. The following lessons were learned from the shear demonstration study:

1. The shear sensor did not have any effect on the socket comfort or fit perceived by the test subject.
2. Best shear sensor design – based on material selection and puck thickness.
3. Anatomical location selection of the shear sensor for clinical investigation.
4. Orientation of shear sensor inside the socket is of great importance to facilitate extraction of shear information, which includes direction of shear occurrence. A guidance on how to orient and integrate the shear sensor inside the socket was created and included in the protocol for the clinical investigation.

The pilot study was particularly valuable as it gave the consortium an early insight into the use of the prototype by an amputee in real-life. It also ensured small details were not overlooked, such as method of attachment of the data acquisition subsystem on the outer surface of the socket. The trial was successful for several reasons - primarily that the system did not alter the fit or comfort of the amputee's socket; and the acquisition of visibly repetitive intra-socket pressure patterns aligned with the gait phases, which were identified using the gait monitoring subsystem.

3.3. Stewart Platform

The Stewart platform enabled an automated testing of in-socket sensors with high repeatability in load conditions. By replicating the real test conditions as closely as possible, in a well-controlled environment, the actual sensor behaviour could be better observed and analysed (Figure 10). Using the test-rig offered the possibility of identifying system errors and erratic system behaviours and allow correction prior to moving on to the clinical investigation. In addition, those conducting the tests gained familiarity with the sensor system. This allowed the clinical investigation to be conducted in a smoother, less error-prone, and more efficient manner.

3.3.1. Calibration

The tests conducted at KTH with the Stewart platform allowed the researchers at KTH to gain hands-on experience with the calibration device. Tests were conducted in an online workshop to ensure the usage of the device was according to protocol. This allowed thorough preparation before the clinical investigation. Consequently, significant time and effort was saved during the clinical investigation conducted at SAS, Spain and TU, UK.

3.3.2. Simulations of Clinical Investigation Session

To support the justification of time required for clinical investigation test duration, an estimation was to be made. Firstly, a preliminary protocol containing various activities to be conducted during the clinical investigation was created. An attempt was made to replicate each step of the clinical investigation and form a conservative duration for each activity. The various activities were replicated in the Stewart platform by simulating closely the dynamic conditions between the socket and residual limb. The tests were shown to replicate the dynamic conditions and reflect sensor performance closely to the

Pilot Study previously conducted at Össur. The protocol was then adjusted and finalised for use in the clinical investigation.

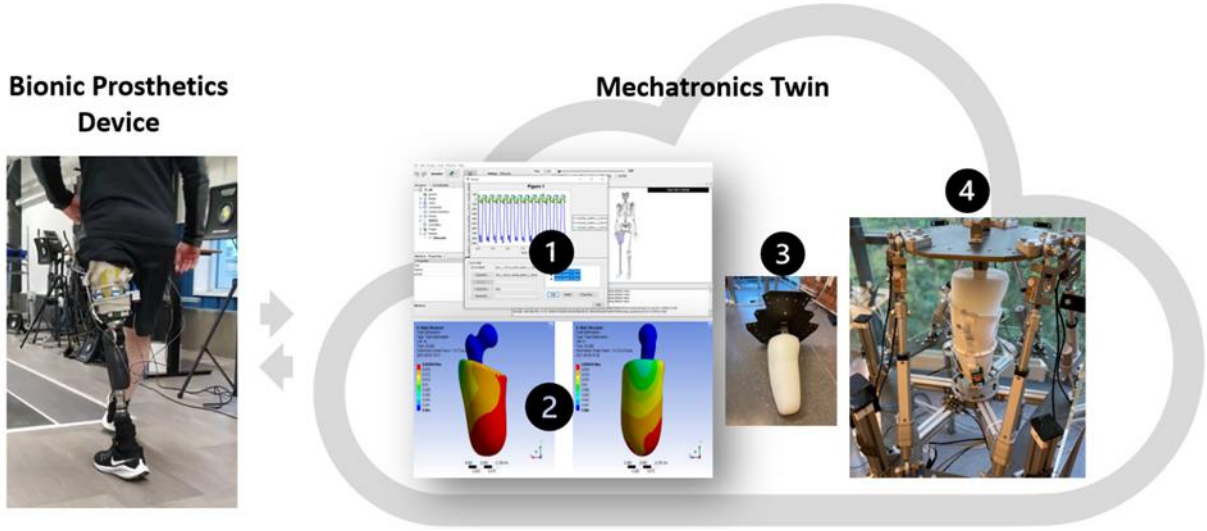

Figure 10 Overview of the mechatronics-twin that allows both virtual and physical replications of prosthetic device. The virtual replication is supported by (1) biomechanical modelling and simulation; (2) FEA; the physical replication is supported by (3) 3-D printing; which is finally tested in the Stewart platform (4).

Further information on testing conducted with the Stewart platform can be found in the publication by Chen et al. [4]. The publication describes the adaptation of the Stewart platform for testing the complex interaction between the residual limb and the socket, and the framework that integrates advanced modelling, simulation, and data analysis.

3.4. Software Testing

Software development and testing is a continuous and iterative process. In the SocketSense project, software development took place concurrently with the hardware development and testing. It was, however, not until preparation for clinical investigation began that software development rapidly advanced as the needs and requirements became clearer. Although data acquisition from the SocketSense system is not reliant on the software, for the purpose of the clinical investigation, the software was required to validate the success of sensor calibration. This particular functionality was verified and validated prior to the start of the clinical investigation.

4. Lessons Learned from Clinical Investigation

One of the primary outcome measures of the clinical investigation was to assess and report any adverse events that arise during testing of the system with amputees. A second primary outcome measure was to determine the success of integration of the system in the prosthetic socket and usefulness of the data output from the system.

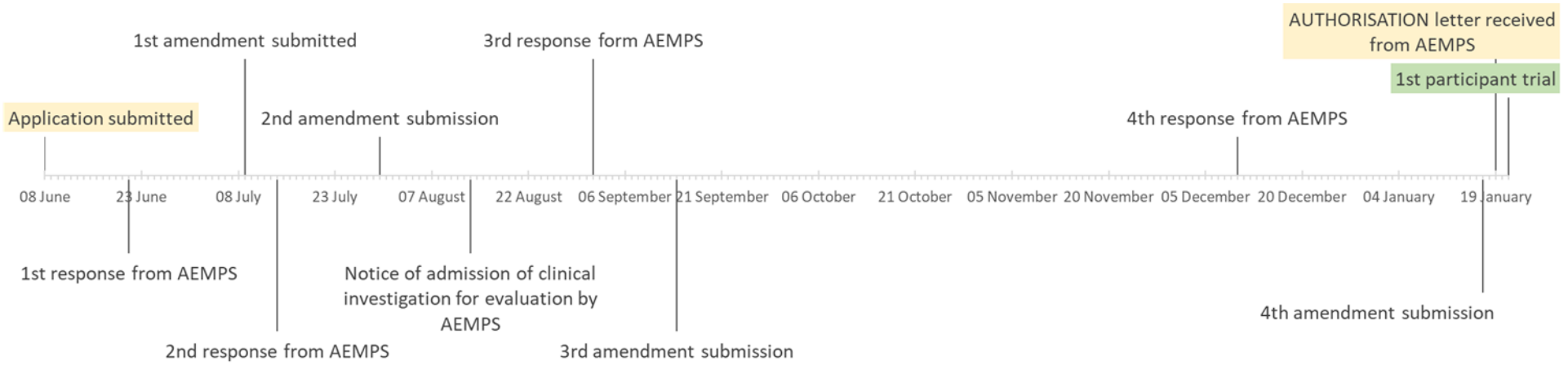

Figure 11 AEMPS application timeline

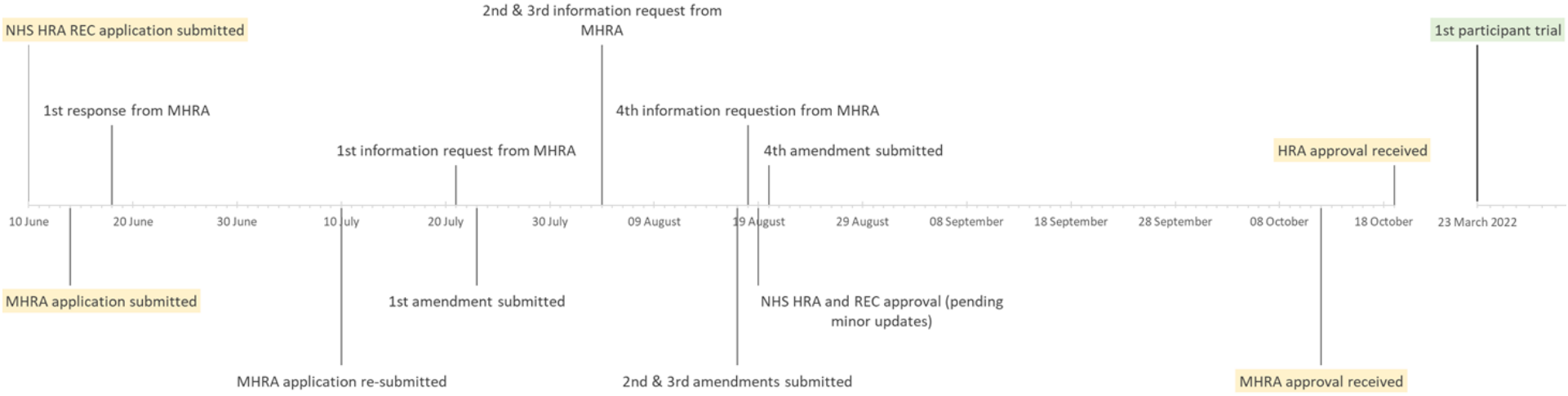

Figure 12 MHRA application timeline

4.1. Application Process

The application process to hold a clinical investigation in both Spain and the UK was a considerable undertaking. The clinical investigation cannot begin until approval has been formally received from the medical authorities from the respective country that the study will be held. In Spain, an authorisation letter is required from *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS), and in the UK *Health Research Authority Research Ethics Committee* (HRA REC) and *Medical Health Research Authority* (MHRA) approvals are required. Many detailed documents describing the medical device, such as, the hazard analysis, software development plan, the intent of the study, and many more were required by the authorities; a full list can be found in Appendix A. As depicted in the timelines for approval from the Spanish and UK authorities, Figure 11 and Figure 12, respectively, several application revisions were required, and can be common even for Class I medical devices*. Overall, the process can be lengthy before the final approval and authorisation letter is received.

In addition, the SocketSense project experienced unexpected delays due to Covid19, which affected healthcare around the world and therefore priorities in both healthcare sites were diverted away from research unrelated to Covid19. More positively, the SocketSense consortium developed and maintained a couple of useful documents to aid the development and oversight of the clinical investigation trial protocol and trial delivery plan. One of these was a 'clinical claims' document which summarised the full list of intended outcomes for the study, acting both as a useful summary to aid understanding and as focal point for the development of the protocol to ensure this closely tied into the project's essential end goals. A second document was a 'project development and delivery - key actions and deadlines' plan which was reviewed and updated at monthly meetings. These documents were created in response to the funding body's advice at a funding review meeting to use simple high-level overview documents to help maintain progress.

*According to the European Medical Device Reporting (MDR) and UK Medical Devices Directive (MDD) the SocketSense prototype under investigation is a Class I medical device as it is non-invasive and does not touch the patient or contacts only intact skin, and the software, in this instance, will not be used to administer diagnoses or therapeutic decisions [5].

4.2. Clinical Investigation Trial Conduct and Management

There were several delays in the conduct of the clinical investigation trials both in the UK and Spain as Covid19 further significantly impacted in taking the clinical investigation forward. In the UK, due to restrictions to activity onsite, it was agreed with partners to change the venue from a hospital location to a university location which could accommodate the needs of the clinical investigation.

In addition to compromising with Covid19 restrictions and limitations, a lesser impact in the UK was caused by industrial action which curtailed travel opportunities for key partners from both within and outside of the UK who were delivering the clinical investigations. In Spain, there was a delay as the regulatory authority required the hospital to provide insurance cover for the investigation trials. These all contributed to a delay in starting the investigations with trial participants.

Other challenges were faced with regards the clinical investigation. The initial SocketSense prototype was designed with considerations for pin-suspension systems only to avoid interfering with vacuum suction systems, therefore, the inclusion criteria for the clinical investigation were limited to only amputees using pin-suspension sockets. As recruitment started it became apparent, especially in the UK, that the numbers of patients with pin

suspension who met all other criteria were limited. In the STH recruitment cohort, there were only 18 amputees who met the criteria; of these, five were recruited. Other prosthetic services in the UK were contacted to recruit the rest of the participants and become Patient Identification Centre (PIC) sites. This again led to delays as each PIC site must approve the documentation before releasing information to their patient cohort. Nine sites were engaged with, of which three were able to provide participants, however, the requirement for pin-suspension socket users remained a limitation.

Although the delays due to Covid19 and industrial action could not be foreseen and considered prior to the start of the project, timelines should be planned for to accommodate unexpected delays. The limitations due to the inclusion/exclusion criteria of the participants could have been prepared for, by adopting PIC sites earlier in the recruitment process.

4.3. Clinical Investigation

The most successful trials were considered those where the test session ran smoothly with regards to system integration, system performance once integrated, and length of test session duration. To elaborate, if the system performed exactly as expected with no additional interventions such as no loose cables/connections or data losses, this led to minimal stress on the clinical investigator and technical team. It also allowed the test session duration to be kept to a minimum, benefitting the welfare of the test participant.

4.3.1. First Phase of Trials at SAS

The welfare of the test participant is of utmost importance during the test session, therefore any steps that could be taken to minimise the duration of the time volunteered by the participant were valued. Adjustments to the test protocol were made in consideration of this, for example, combining exercises such as sit-to-stand and stand-to-sit, as well as ramp ascent and descent, although this led to more work for the technical team, it meant the participant did not have to perform more tasks than was required.

Preparation day

The team involved in the clinical investigation met a day before the test day with the first participant. The team became familiarised with the test protocol and the SocketSense system – the hardware and software. A test run of system integration was undergone with practise sensor strips and prosthetic socket, including calibration and data upload to the user interface. A mental exercise of the full test protocol was also performed. This helped the team prepare and manage expectations for the first trial. The first trial ran unexpectedly smoothly – the trial duration was not prolonged in any way, and the participant did not experience any discomfort throughout the session. It is likely the preparation helped reduce the trial time, which decreased as the team became more experienced after each test session.

Remote controlling implementation

The tagging system utilized an Android application to label the test session data with proper tags according to the trial protocol. The physical button on the electronics was used to control the start/pause of recording. It was sometimes inconvenient for technical team to reach the physical button after the system is mounted to the socket, such as, when the subject is standing on top of the stairs. To improve the ease of use, the Bluetooth tagging app was updated to include control of recording, enabling fully remote control of the system.

Functionality checks of the hardware

In order to minimise clinical investigation trial time and identify any hardware issues it was realised that it was important to pre-test all the hardware to be used in each clinical investigation trial in advance by setting the full system up on a benchtop before each trial and functionality testing each element of the connected hardware, for example by sequentially pressing each sensel whilst recording the data. The data was then visually checked to ensure each sensel produced a signal. This allows any issues with hardware to be identified in advance and addressed.

Change of firmware to pair gait monitor

The firmware of the data acquisition subsystem and gait monitoring subsystem were both updated prior to the start of the clinical investigation. An oversight, however, meant the communication between the two subsystems with their newer firmware versions was not tested. This led to data loss during the first phase of the trials in Spain. The problem was identified and rectified prior to any further test sessions. Although the data loss is significant, it led to the development of machine learning algorithms to detect gait events based on the pressure signals only. If the algorithms prove effective, it could reduce the need for the gait monitor, resulting in a simpler device with fewer subsystems.

4.3.2. Second Phase of Trials at TU

After the first phase of trials in Spain, all flagged issues were resolved prior to starting the trials in the UK. As a result, only one technical issue arose during this phase of the clinical investigation. A faulty cable in the data acquisition subsystem was eventually found. Although a minor fault, it led to some data loss, and delays during the test session. The problem was easily rectified by purchasing cables from a certified distributor, rather than self-manufactured units. The error did not arise again for the remainder of the trials. It has been noted that future developments of the device should include a failure notification system that can immediately inform the user of the root cause such that the error can be easily rectified.

4.3.3. Third Phase of Trials at SAS

During the final phase of the clinical investigation, two technical issues arose that led to data loss. The first issue was due to improper implementation of the gait monitoring subsystem for one participant, resulting in insufficient gait phase information. This was a human error, which should be easily avoided. The cause of the second issue is still under investigation.

4.4. Conclusion from Clinical Investigation

Although it was not intended for the clinical investigation held at SAS and TU to run sequentially, the project greatly benefitted from the later start date of the trials at TU. This enabled the consortium to evaluate and rectify issues that arose during the first phase of trials. The outcome of the clinical investigation could have been strengthened with a second pilot study to test the prototype version that was planned for use in the clinical trials. This could have resulted in identification and rectification of some errors prior to the clinical investigation. The importance of firmware compatibility tests for all version updates is crucial. For the early prototyping stage, it may be beneficial to use off-the-shelf components wherever possible; this helps minimise problems arising from hardware that has not undergone QA. Additionally, the reduced likelihood of off-the-shelf componentry breakdown expedites the debugging process should a malfunction in the system occur.

All paperwork for use during the test sessions were well prepared in advance, including other equipment that was required. The value of good organisation should not go unnoticed as it ensured smooth management during the trials, minimised data losses and improved the efficiency of the test sessions.

4.4.1. Hardware and Firmware Review

Qualitative review of the data acquired from the clinical investigation found there could be benefits to increasing the sampling frequency of the system, for example from 20Hz to 50Hz. This may provide greater insights when evaluating the signal patterns of individual gait events, for instance. The duration of the toe-off phase, for example, is typically very short, therefore a higher sampling rate may be desired for analysis of stress signals during short-lived events.

To evaluate the pressure sensor strip design, the number of sensels per strip for all participants in the clinical investigation were summarised (Figure 13). No participants needed to utilise the full length of the pressure sensing strips (eight sensels). Although the participant size was small, this showed that the length of the strips were appropriate, however, there is opportunity for future developments in sensor strip designs to utilise the full capabilities of the system.

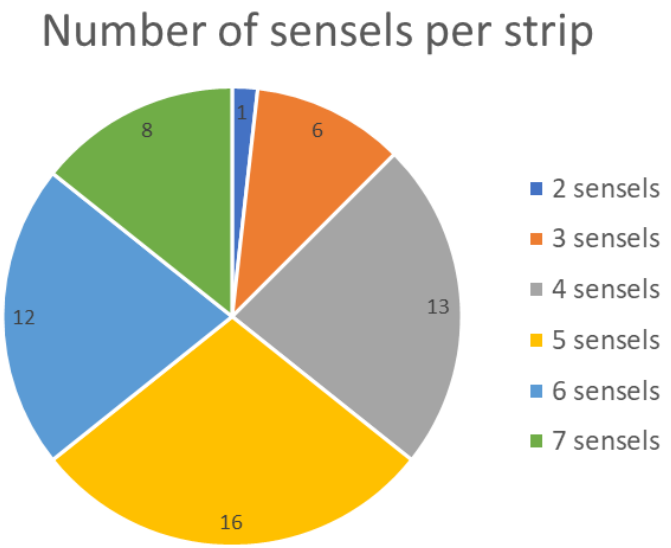

Figure 13 Pie chart reflecting ratio of sensels used per sensing strip for all participants in the clinical investigation

4.4.2. User Interface Review

Many creative and innovative ideas with regards to the data visualisation techniques evolved after conducting the clinical investigation. This was challenging to prepare for prior to the trials due to the large variety of different data types and the unknown quality of data that could be obtained during the clinical investigation from the SocketSense prototype. Significant advancements to the user interface were therefore accomplished during and after the clinical investigation. This also meant time constraints as the project timeline closes, many features of the user interface may not be accomplished prior to the end of the project. It would have been beneficial to allocate more time after the closure of the clinical investigation to data analysis and data visualisation development.

5. User Evaluation

Feedback from the end-user is invaluable during product development. In the case of SocketSense, the end-user is both the clinician and the amputee. Comfort and safety are the key concerns when regarding the amputee. The clinician is expected to interact with the device much more than the amputee – the clinician should install the device in the socket and operate the user interface, which also presents the data (e.g., pressure, shear, etc.). A software evaluation questionnaire was designed and feedback from the prosthetists were collected to gain insights regarding the user interface.

5.1. Clinicians' Perspectives

The clinicians provided their feedback on the use of the SocketSense system during the clinical investigation but the software evaluation questionnaire (Appendix B) was completed separately afterwards. This was in part due to some further updates to the software, including the user interface, that were made after completion of the clinical investigation. Furthermore, a UI user manual was also produced after the updates were made.

5.1.1. System Setup

During the clinical investigation, a technical team was present alongside the clinician(s). The technical team installed the system in the participant's socket. A report from the clinician highlighted the need to improve the usability of the system with regards to installation, even with the detailed instructions manual, some unexpected complications can arise. A seamless procedure for system integration is desired and should be heavily considered in future design developments.

5.1.2. Using the device

After initial setup, the clinician reported that the system was easy to run. There were some instances of disconnection/non-functioning elements that led to interruptions. It is expected that as development continues, these minor teething issues will lessen.

On a separate note, the clinician felt that some exercises performed during the clinical trial, such as sitting and standing, were unnecessary as these activities do not often lead to problems with the soft tissue of the residual limb. In future, careful selection of the exercises with guidance from a clinician can help reduce the trial time, and therefore the duration the participant is required to spend in the test session.

5.1.3. Using the User Interface

The user interface (UI) has two functionalities: 1) input participant information, including data upload; 2) output data visualisation and the Socket Rectification Assistant feature, which intends to recommend an optimal socket design for the individual amputee.

From the software evaluation questionnaire, the following comments were highlighted:

- General layout was logical, easy to read, and easy to navigate
- The interface made it easier to complete tasks
- The information provided was mostly appropriate and informative; all relevant information is included
- Some unnecessary details were provided, such as calibration data, raw data, and hardware issues

The following suggestions for improvement were highlighted:

- Automated calibration
- Simplification of terminology; visual aids are more informative than literary descriptions
- Integration of the UI with other existing CAD/CAM software, for example, to allow upload of 3D scans of the residual limb

Overall, the clinicians reported the UI is simple and easy to understand, with a good level of detail and space for inputting the amputee's medical history. There are high hopes and expectations of the Socket Rectification Assistant to provide scientifically based suggestions for socket design. It is noted that the UI was initially developed as an aid for the clinical investigation as well as the final product that the clinician would use. It is therefore understood that some technical features included in the UI could be removed in the final product and further optimisation completed for improved user experience.

5.2. Amputees' Perspective

Question & Answer (Q&A) session took place with an amputee contact identified through the NHS and the consortium attendees. The Q&A session was useful in providing the Consortium with an independent and ground-level perspective on prosthetic services and challenges that amputee service users may face (both within and outside of the healthcare service). A key learning point that arose from this discussion was the need to maintain a nuanced view of 'patient comfort' regarding their socket and prosthesis fitting as a person's perception of comfort is subjective and can vary according to a wide range of factors (e.g., activity being undertaken, environmental factors such as temperature). This feedback emphasised the need to incorporate a broad range of sensors that were built into the SocketSense technology.

During the clinical trial all participants reported no discomfort or pain after donning their socket with the SocketSense system integrated. The majority of participants did not notice the sensors inside the socket. This confirms the sensor design is optimal in regard to user comfort.

The importance of minimising the time taken to complete a single trial is highlighted by a few participants mentioning the lengthy test session.

6. Conclusion

The active and highly motivated participation of the consortium throughout the project enabled rigorous testing at numerous stages of development of the SocketSense system. The team were available and hands-on when it came to live debugging as the clinical investigation were taking place. Nonetheless, some key takeaways were noted:

1. Preparation time and efforts required for clinical investigation applications should not be underestimated. Sufficient time should be accommodated for when applying for clinical investigation approval from healthcare regulatory bodies.
2. The level of work required to prepare and assemble all the documentation for the clinical investigation application should not be underestimated.
3. Benchtop testing is typically done as part of the development process; starting with the simplest test conditions as the foundation, that can be of benefit in the next steps of further testing under more realistic/complex conditions.
4. Gain as much experience under realistic use conditions as possible with the product under development prior to the clinical investigation.

5. System functionality checks prior to test sessions are valuable for debugging and will likely save time during the participant testing.
6. Good organisation and preparation of paperwork prior to clinical investigation trials will result in the smooth running of test sessions and minimise time, confusion and data losses.

7. References

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8. Appendices

Appendix A. Documents required by health authorities

Below is a list of documents the required by medical health authorities (AEMPS and MHRA) for the application to run a clinical trial investigation for SocketSense.

- Application cover letter
- General application form
- Promoter’s contact details
- Sponsor's statement
- Declaration of designation of representative of the promoter
- Declaration of a designation of a contact person of the promoter
- Favourable report on a biomedical research project (CEI)
- Application for a favourable report on a biomedical research project (CEIm)
- Centres participating in clinical research
- Dates of the clinical research
- Authorisation processing status in other countries
- Statement of the current regulatory situation
- Manufacturer's declaration (Annex I)
- Promoter's declaration (Annex II)
- Economic memory
- Insurance policy
- Cambridge International ESOL Level 1 Certificate (Level B2) of the prosthetic
- technician
- Diploma of higher technician in orthopedics, prosthetics and support devices of the
- CPO involved in the project
- Economic contract for the completion of an observational post-authorisation study
- with medicinal products
- Researcher's handbook
- Clinical Research Plan
- Clinical study presentation letter
- Informed consent
- Patient information sheet
- Patient recruitment letter
- Clinical Investigator's Brochure
- Design Overview Document
- General Safety and Performance Requirements
- Hazard Analysis Document
- Risk Management Report
- Instructions For Use
- Device labelling

Appendix B. Software Evaluation Questionnaire

System user-friendliness questionnaire

This questionnaire will collect feedback from you, the system user, in order to check the design of the user interface and make improvements, where necessary. Questions are either scaled 1-5 or Yes/No. Please answer all questions and provide as much information as possible.

1. Screen presentation

a. Are the characters on the screen easy to read?	
Yes	No
If No, what could be improved?	

b. Is the layout logical and easy-to-navigate?	
Yes	No
If No, what could be improved?	

c. Is the information on the appropriate screens?	
Yes	No
If No, what could be improved?	

d. Are all required resources easy to find?	
Yes	No
If No, what could be improved?	

e. Did you miss any relevant information?	
Yes	No
If No, what could be improved?	

f. Does the interface display unnecessary information that can appear confusing or overwhelming?	
Yes	No
If No, what could be improved?	

2. Task Management

a. Does the interface make it easy to complete key tasks?	
Yes	No
If No, what could be improved?	

b. Is the terminology used on the software appropriate?	
Yes	No
If No, what could be improved?	

c. Does the system keep you informed as to what it is doing?	
Yes	No
If No, what could be improved?	

g. Are related tasks put together and unrelated tasks separated?	
Yes	No
If No, what could be improved?	

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3. Learning

a. How easy was it to learn to use the system?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

b. How intuitive is the use of the system?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

c. How straightforward is it to perform tasks?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

4. System

a. Is the system fast enough?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

b. How reliable is the system?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

c. How easy is it to correct mistakes/go back to a previous point?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

5. Usability

a. Overall how would you rate the system?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

b. How would you rate the system response to errors?

(LOW) 1 2 3 4 5 (HIGH)

Comment (optional):

c. Are there unnecessary items that you consider better placed elsewhere?

Yes No

If Yes, what could be better?

6. Use of the software in clinical care

a. Are there any additional features or changes to the software that could make the software more useful in terms of its use in clinical care? (in particular when the software is used by prosthetist services during a patient appointment)

Comment:

b. Are there any aspects of the software that may inhibit or negatively affect the delivery of clinical care? (in particular when the software is used by prosthetist services during a patient appointment)

Comment:

c. What do you feel would be the most effective ways to provide training and guidance for prosthetist services staff in terms of using this software in clinical care? (in particular when the software is used by prosthetist services during a patient appointment)

Comment:

7. Any other comments?

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