PRESSFIT

DESIGN OF A PRESSURE-SENSING TEXTILE TOOL TO DIGITISE EXPERT INTUITION IN THE FITTING OF BELOW-KNEE PROSTHESES

Graduation Thesis by Erin Dooley

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GYROMOTICS
MOVE BETTER

PREFACE

I would like to express my gratitude towards everyone who has given me a "leg up" throughout this project. As an individual graduation project, involving others made the project more meaningful academically, and mentally.

Thank you to my chair, Arjen, and my mentor, Hilbrand, for inspiring me by posing interesting questions and offering fresh perspectives on my conclusions along the way.

Thank you to everyone at Gyromotics for supporting me and reminding me that a graduation project should be fun. Thank you especially to Bas and Guido for your guidance and reassurance, and to Mo and Tamara for helping with photoshoots and pilot testing. And, of course, for the very important bouldering sessions!

To the team at Frank Jol, thank you for welcoming me in Amsterdam and for the help organising interviews and participating in testing sessions. Thank you Ivo for offering so much help and insight early on in the project, and for your enthusiasm in the many discussions and brainstorms we had. And thank you to Marly for stepping in during the last phase of my project to assist with planning my final evaluations.

Thank you to Linda, Kaspar and the staff at the Applied Labs for showing me around and offering consult in the realm of smart textiles.

To my friends and family, thank you for everything. Maria and Niyaz, thank you for always lending a listening ear at our booth sessions in the faculty. Thank you to the GCP for providing a network of graduation students for sharing advice, struggles and small victories. Thank you to my friends I solicited to read through my disorganised drafts and offer outsider insights to help me put on paper what was stuck in my head.

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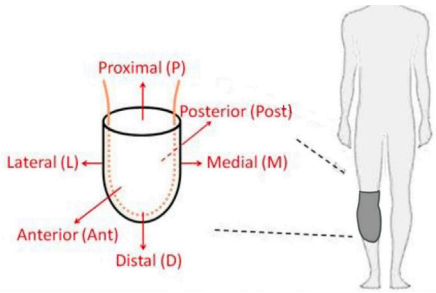
Anatomical Directions



Build height: the distance between the distal end of the stump and the ground; the space in which the CPO has to "build out" the prosthesis including adapters, piston and foot

CPO: certified prosthetist and orthotist (Dutch: instrumentmaker)

Donning/doffing: the processes of putting the prosthesis on and taking it off, respectively

Pistoning: relative (vertical) movement of the residual limb with respect to the socket

Proprioception: the sense that one can perceive the location, movement, and action of parts of the body

Prosthetic/prosthesis: unless stated otherwise, refers to the transtibial prosthetic, specifically the socket-liner interface

Suspension: the method by with the prosthesis is fixated to the residual limb

Stump: the remaining part of the amputee's limb, specifically that which interfaces with the prosthesis. Also referred to as the residual limb.

Transtibial: describing an amputation through the lower leg (below the knee)

Activity Levels

Industry standard terms used to categorise mobility level:

K0: sedentary

K1: limited indoor walker

K2: limited outdoor walker

K3: unlimited outdoor walker

K4: totally unlimited

EXECUTIVE SUMMARY

Prostheses and orthoses are trending towards digital methods and automation. Adopting these methods is especially a challenge at Frank Jol, a clinic where patients' wide variety in residual limb characteristics and high activity demands pose a challenge for digital workflows which utilise 3D scanning to arrive at a final prosthesis. This is because certified prosthetists and orthotists (CPOs) who design and produce prostheses, apply a series of tactile adjustments to the residual limb using plaster that result in a more optimal fitting and distribution of weight in the socket, which cannot easily be captured and digitised. In collaboration with Gyromotics, a high-tech prosthetic foot start-up, and Frank Jol, this graduation project is an exploration into the potential for a pressure-sensing textile tool to capture the tacit knowledge of CPOs in the fitting of below-knee prostheses.

The project begins with a detailed analysis. First, the clinical situation of the residual limb and the biomechanics of transtibial prosthesis is studied to understand what factors influence prosthesis fit, and how CPOs manipulate the residual limb to that effect. Then the process towards producing a prosthesis is analysed as it is executed at Frank Jol, in order to then compare to alternative processes that incorporate digital methods to understand the barriers and opportunities for intervention. Finally, CPOs and patients are interviewed to uncover their needs and values in the process. This analysis reveals the need for an intervention that captures and standardises the stump modification process in a digital way, while retaining CPO control and tactility, and keeping the patient in the communication loop.

The design result is PressFit: a pressure-sensing textile tool to be worn by the patient, which registers CPO applied pressures and provides visual feedback during stump measuring and plastering. PressFit is introduced as it fits into an envisioned future prosthesis prescription workflow. PressFit is developed through iterative technical development of the physical prototype, alongside development of the interaction for both measuring and plastering use cases. A co-design method with a CPO is followed throughout this development.

An evaluation is conducted with 5 CPOs at Frank Jol to assess the prototype's performance against design drivers. Results show that PressFit standardises the measurement process. All participants agreed PressFit is a helpful tool with potential to improve patient-CPO communication and bring traceability to the plastering process. Additionally, the tool shows promise for us as a training tool for new CPOs. As this thesis serves as a proof-of-concept for the application of pressure-sensing textile in the prosthesis prescription process, it concludes with recommendations for further development in physical prototyping (textiles), software, and user interaction.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Introduction

This chapter begins by introducing the problem area and the project context in terms of the two main stakeholders, Gyromotics and Frank Jol. Then the design challenge and design assignment are introduced, after which the research questions are posed which frame the following Analysis chapter. Finally, research methods are discussed and the design method applied to the project is outlined.

PROBLEM INTRODUCTION

For millions of people worldwide, donning a prosthesis is a part of getting ready for the day. In the Netherlands alone, 3,300 amputations are carried out each year (Federatie Medisch Specialisten, 2020). Of lower-limb amputations, 28% are transtibial, making it the most common (Paterno et al., 2018). A fitting prosthesis is integral to being able to stand, walk, work, and exercise. With a well-fitting prosthesis and rehabilitation, an amputee has the potential to enjoy the activities and lifestyle of someone with an intact limb.

Just as a poorly fitting shoe can limit movement and cause skin problems, so can an ill-fitting prosthesis. At the least, pistoning and movement within the socket is an annoyance. In worse cases it can inhibit one's activity potential and lead to painful skin irritations and even infections. Even in a well-fitting prosthesis, amputees experience issues such as excessive heat and sweating in their residual limb, as well as having to monitor and adjust for changes in stump volume with time of the day, weather, and activity.

Certified prosthetists and orthotists (CPOs) design, manufacture, and fit the prosthesis. The quality of the prosthesis, and therefore the patient experience, lies in the expertise of that specific CPO. Making a prosthesis is a labour and material intensive process. Furthermore, the industry standard follows a completely analogue process, where all (stump shape) data is stored in multiple physical plaster models, visible at the bottom in Figure 2. This process is difficult to trace and replicate. Furthermore, these models takes up valuable physical space in orthopaedic clinics (Figure 1 at left). Therefore models are only kept for set periods of time, sometimes as short as months or even weeks (G. Hendriks, 12 May 2023). As a result, patient data is lost and often the prosthesis fitting process must be reworked from the beginning, increasing costs and running the risk of a less ideal end result.

Figure 1. Physical data storage at Frank Jol

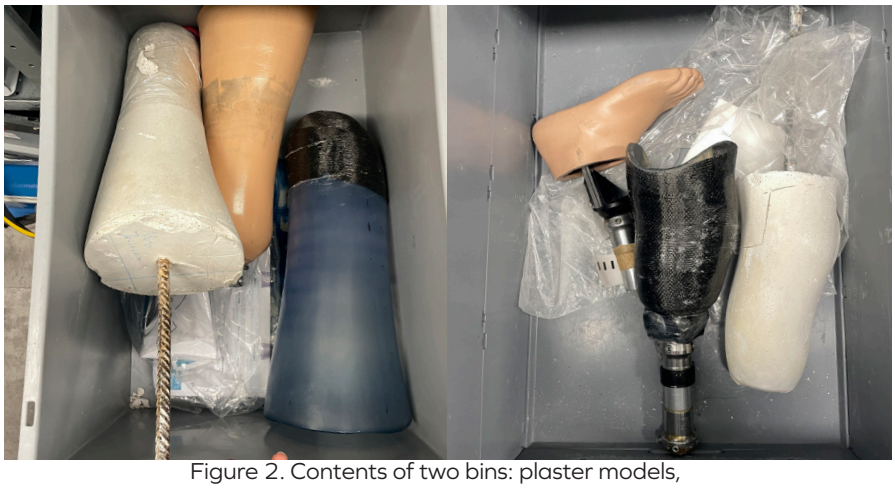

Figure 2. Contents of two bins: plaster models, diagnostic sockets, prosthetic feet

PROJECT INTRODUCTION

Project Context

The graduation project has been completed at Gyromotics, but also in close collaboration with Frank Jol. These two main stakeholders and the reason for the collaboration are described below.

Gyromotics

Gyromotics is a small start-up based in Delft which produces a prosthetic foot with an adjustable ankle joint, meaning the user can adjust the angle at which the foot sits in relation to the ground (Figure 3 at right). Prior to the kickoff of the project, Gyromotics received a grant from the Dutch government to, in collaboration with Frank Jol B.V., digitise and automate the below-knee prosthesis fitting and production. including the socket and liner, within approximately three years from the project kickoff.

Figure 3. Gyromotics' ArcX product

Frank Jol

Frank Jol B.V. is an orthopaedic and prosthetic clinic in Amsterdam, founded by Frank Jol (seen at right in Figure 4). They are a small family-run clinic, with around five CPOs and additional production and adminstrative staff. Frank Jol's client base varies in age, gender, and reason for amputation. However, what unites their target user is ambition for high activity level. While the standard process for prescribing a prosthesis is to match the patient where he or she is currently in terms of activity level (Stuurgroep PPP, 2022), Frank Jol challenges this to assert that every patient has the potential to be a K4 level (I. Schouten, personal communication, March 17, 2023). Frank Jol is involved in the project as co-client and case study. CPOs at Frank Jol were also often involved in design activities. A more thorough analysis of Frank Jol can be found in Chapter 2: Analysis.


Figure 4. Frank Jol modifying a positive plaster model

Design Challenge

There is a growing trend among prosthesis and orthopedic industries to bring digital methods into the workflow as tools like 3D scanning become more accessible and accuate. 95% of amputations in the Netherlands are necessitated by the consequences of vascular disease incurred from diabetes, (Federatie Medisch Specialisten, 2020). These patients generally have low activity lifestyles and therefore demand less from prosthesis performance than those outside the 95th percentile. These patients' stumps also bode well for workflows which automate the prosthesis prescription process, such as a 3D scan-to-3D print process, as patterns can clearly be identified and automated in similar stumps.

The interesting challenge for this design project comes hand-in-hand with Frank Jol's unique clientele. Frank Jol differentiates itself by specialising in the 5% of patients with higher activity levels. Amputees with diverse, high activity level demands also present difficult-to-fit stump shapes, which also creates a very difficult-to-automate dataset.

However, there are many shortcomings with 3D scanning. It requires significant time and attention to remap scans into editable 3D models. 3D scans do not give a picture of the composition of the limb in terms of soft tissue, imperative for predicting optimal socket fit (Safari et al., 2020). Scans do not account for the manual adjustments to the limb that the CPO applies. And finally, CPOs struggle to adjust from a completely physical workflow to a completely digital one. This process and these shortcomings are elaborated in detail in Chapter 2: Analysis.

Assignment Definition

The assignment definition as stated in the project kickoff was: to develop a method for producing a personalised liner and socket for below-knee prostheses. This method can be applied to a given set of stump data to prescribe a comfortable and secure liner and socket.

This project addresses the assignment by defining the clinical, technical and human-centered factors that are important in producing a prosthesis when integrating digital methods, and proposing a future workflow which is validated through development of a prototype of a tool to be used throughout the prosthesis prescription process.

Research Questions

Research questions were formed based on the components of the assignment definition. The goal of defining research questions was to guide exploration of the problem space and refine the scope to arrive at a well-substantiated design problem definition. The first two questions aim to explore how prosthesis are currently designed and prescribed. The second two questions go beyond this basic knowledge to investigate the situation at Frank Jol specifically.

RQ1. What are the components of a below-knee prosthesis? What is the state-of-the-art in the Netherlands?

RQ2. What are the characteristics of the residual limb, and how does the prosthesis interface with it to create a good fit? What are the challenges in achieving this?

RQ3. What process does Frank Jol follow to produce a prosthesis? What are the bottlenecks in this process? What technologies can be applied to improve this process?

RQ4. Who are the main stakeholders in the prosthesis prescription process, and what are their main needs and pain points?

Research Methods

Approaching the research questions was done with a variety of research methods. Literature research was used to obtain background in technical and clinical areas. Interviews and observations were conducted to gain insight into stakeholder perspectives and process details. Co-design was also used during research by developing process visuals as communication tools with involved stakeholders.

Project Approach

The open nature of the design brief presented a broad range of possible directions for the project to take. It was important therefore that designing was approached with flexibility, curiosity and frequent communication between project stakeholders in order to discuss and evaluate design decisions. To this point, a co-design method was often applied, involving CPOs at Frank Jol in brainstorming sessions and prototype interactions.

To provide structure to the design project, the double diamond model was applied. This model was not seen as a binding, restrictive format but rather a flexible reference frame within the constrains of the 20 week graduation project. Furthermore, within each phase, multiple iterative loops often took place. This is illustrated in Figure 5 below. Through this model the project can be seen as having two consecutive phases of diverging and converging. The first phase being the research phase and the second the design phase.

The **discover** phase is detailed in Chapter 2: Analysis and consisted of investigating the design challenge from the angles of clinical context, technology and process, and stakeholders involved.

The **define** phase is detailed in the first half of Chapter 3: Design Drivers and Ideation and consisted of synthesising the research findings into key insights and themes, and stating a refined design vision.

The **develop** phase is covered in the latter half of Chapter 3 and consisted of ideating and clustering ideas into concepts.

The **deliver** phase is covered in Chapters 4, 5, and 6, and consisted of iterative prototyping to arrive at a prototype of the chosen concept, evaluating this concept with users, and drawing conclusions for further work.

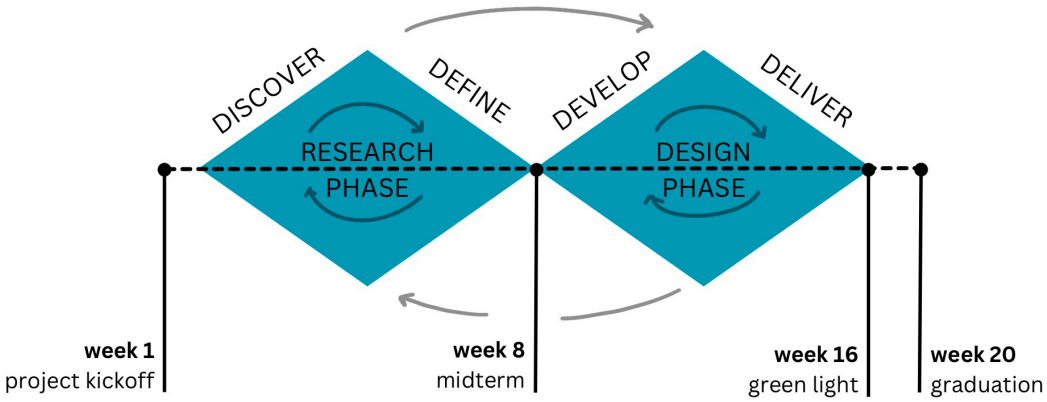

Figure 5. The double diamond model of design

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Analysis

This chapter follows the research process through answering the research questions posed in the Introduction. First, a clinical analysis is conducted into transtibial prostheses, the residual limb, and the interface between them, including the role of the CPO. Then, the process towards producing a prosthesis is analysed in detail, with attention on the pre-diagonstic phase. An investigation into alternative processes which involve digital methods is also conducted. Finally, a stakeholder analysis is presented, investigating the role and needs of CPOs and amputees in the prosthesis prescription process.

RQ1: What are the components of a transtibial prosthesis?

CLINCIAL ANALYSIS

TRANSTIBIAL PROSTHESES

As introduced in Chapter 1, the socket and liner is the subsystem of the below-knee prostehsis within the scope of analysis for the design project. The following describes the standard socket and liner systems provided in the Netherlands.

Socket

The transtibial socket (Figure 6 at left) is a rigid component responsible for providing secure attachment to the stump, bearing the user's body weight, withstanding impact, and protecting the stump. Sockets are produced custom for each patient by laminating layers of carbon fibre with epoxy resin atop an adjusted[1] positive plaster model of the patient's stump. Patients with mature[2] residual limbs can use the same socket for two to three years (Feenstra, 2023). Because carbon fibre is extremely durable, the reason for receiving a new socket is usually due to a change in needs or stump shape, not mechanical failure of the socket.

[1]The CPO applies adjustments to the stump to create an optimal socket fit. These adjustments are elaborated in the following sections.

[2]A residual limb is generally considered mature after 12-18 months post-operation (Paterno et al., 2018)

Figure 6. Transtibial socket and foot assembly

Figure 7. Transtibial liner

Liner

The liner serves many purposes. From a technical perspective, the liner ensures an air-tight fit between the residual limb and the socket, minimizing relative movement and enabling the suspension methods discussed in the following section. From a user comfort perspective, the liner protects and cushions the residual limb within the socket. It also promotes hygiene as it is more easily cleaned and replaced than the socket itself. Liners are made of elastomeric materials, to provide comfort and cushioning, coated in a knit textile outer layer, to protect the liner from wear against the inside of the socket. Most liners are made of silicone, urethane, or thermoplastic elastomer (TPE) as found by Cagle et al. in an analysis of over 25 types of liners (2018). However, the properties of liners vary greatly even within the same material. Liners are differentiated with variances in thickness profiles, skin-conditioning additives, or multi-hardness profiles. The lifetime of a liner depends highly on patient activity level, fit of the socket (minimization of friction), and care of the liner. Some users wear holes in their liners after a few months, while others are able to use the same liner for a year. Insurance providers in the Netherlands usually cover two liners every six months. An example of a liner is shown to the left in Figure 7.

Suspension types

The method by which the prosthesis adheres to the stump can be categorized into mechanical pin-lock attachments, and passive or active vacuum attachments. A hybrid pin-lock and vacuum system may also be implemented in a case where a patient requires extreme security (a very difficult-to-fit stump, detailed in following sections). The two categories of suspension systems and their benefits and drawbacks are summarized at the bottom of the page in Table 1.

Pin-lock

A pin-lock system (Figure 8 at right) consists of a liner with a straight metal pin at the distal end (Figure 10 at bottom right). This pin engages with a lock integrated into the base of the socket to adhere to the stump. A push button on the base of the socket allows the user to disengage the lock to doff the prosthesis.

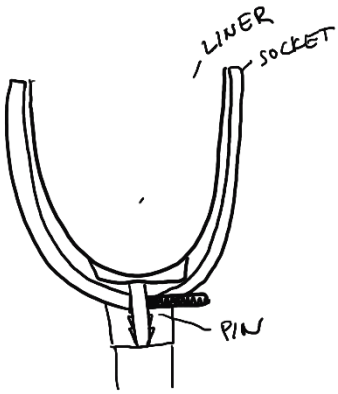


Figure 8. A pin-lock system

Vacuum

Vacuum suspension systems rely on the seal created by the liner adhering to the inner surface of the socket. Liners used with vacuum systems do not have a metal pin at the distal end. Instead, vacuum liners often feature silicone sealing rings, as can be seen to the right in Figure 9 and below in Figure 10. In passive vacuum systems, a one-way valve at the base of the socket allows air to escape when the user dons the socket. In active vacuum systems, a pump is installed at the base (distal end) of the socket to actively create a vacuum in the socket. Vacuum systems are preferred by active users because of their lower bulk, more secure fit (less pistoning), and more even distribution of pressure throughout the socket.

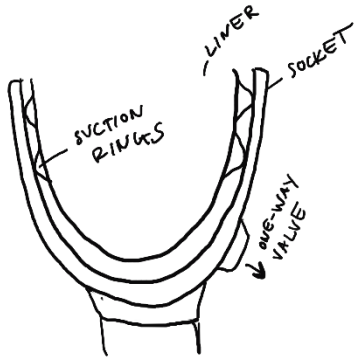


Figure 9. A (passive) vacuum system

Table 1. Comparison between suspension systems

	Pin-lock	**Vacuum**
Principle	Mechanical lock of liner pin into socket	Passive or active vacuum
Use case	Recent amputees	Mature amputees, sensitive stumps
Potential for activity	Low activity	High activity
System bulk/weight	Higher	Lower
Ease of donning/ doffing	Easier	More difficult
Other benefits	Auditory/physical cue of security	Less pistoning, less stump problems

Figure 10. A liner with sealing rings for a vacuum system (left) and a distal mount for a pin (right)

RQ2: What are the characteristics of the residual limb, and how does the prosthesis interface with it to create a good fit?

THE RESIDUAL LIMB

A properly fitting socket reflects the unique composition of a patient's residual limb, or stump. The residual limb is a complex component to fit a socket against. The following sections analyse the two main ways in which stump complexity creates a challenge and need for crafting a well-fitting prosthesis.

Geometric Variety

The first way in which stump fitting is complicated is through stump shape variations. As introduced in Chapter 1, especially at Frank Jol, patients span the spectrum of possible stump shapes and characteristics. The profile of the stump can be a result of how the amputation is performed and healed. For a more complete overview of the amputation procedure, see Appendix 2.

A glance into a storage cabinet at Frank Jol quickly reveals the variety of stump shapes to be accommodated (Figure 11a). Pulling from two ends of the spectrum, a comparison between a short, bony stump and long, smoother stump has been made by examining the plaster models of two patients, seen below in Figure 11b and 11c, respectively. The patient of Figure 11b presents a more challenging case for fitting than the patient of Figure 11c, due to the bony protrusion of the fibula (on the left side of the photo) in combination with the short length.

Figure 11a. Some variety of stump shapes (and other models)

Figure 11b. A short, bulbous, bony stump

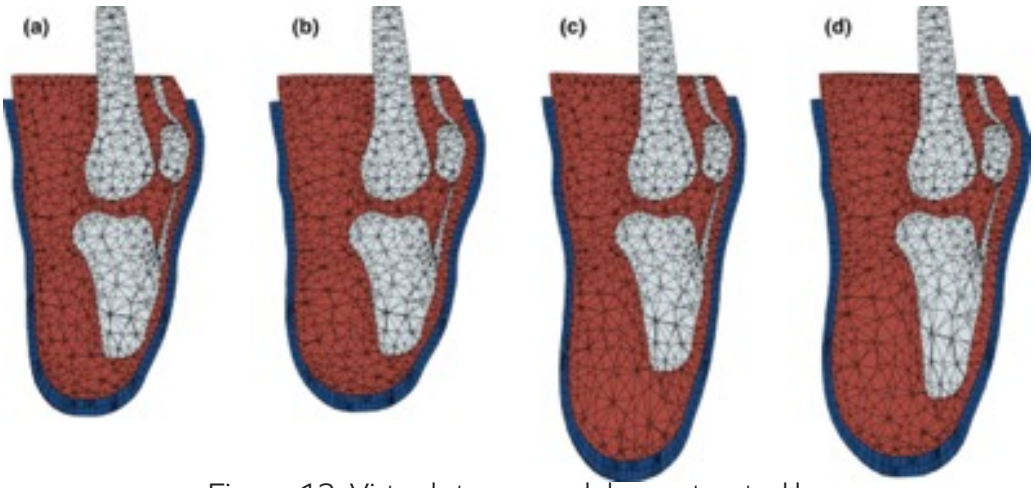
Figure 11c. A long, conical stump

To gain a more thorough, analytical understanding of stump variability, additional literature was consulted. The variances identified in Frank Jol patients align with the four independent modes of variability transtibial amputees as identified in a statistical analysis of 30 stump scans conducted by Steer et al. (2020). These modes are short/long, conical/bulbous, short tibia/long tibia, stiff/soft and can be seen at the bottom of the page in Figure 12. The relation between these four modes and difficulty of socket fit are detailed below in Table 2.

Table 2. Overview of difficult-to-fit stump characteristics

Mode (from Steer et al., 2020)	**More difficult to fit**	**Reasoning**
Short/long	Short	Less surface area for contact
Conical/bulbous	Bulbous	Difficult to don prosthesis over bulbous region
Short tibia/long tibia	Long tibia	More sensitive distal region to consider
Stiff/soft	Stiff	More prominent bony regions to consider

The conclusion from this investigation into stump variability at Frank Jol is that although certain patterns exist between amputees, each patient is treated as a unique case, solidifying the challenge of automating such a process.



(a) short, conical, short tibia, stiff;

(b) short, bulbous, short tibia, stiff;

(c) long, conical, short tibia, stiff;

(d) long, bulbous, long tibia

Figure 12. Virtual stump models constructed by Steer et al. to represent the modes of variance (2020)

Compositional Complexity

The residual limb is not close to uniform with regards to softness and therefore sensitivity. The anterior face of the residual limb has many areas where bone is close to the surface, resulting in much higher sensitivity for the user and low tolerance to pressure. However, at the posterior side, there are large amounts of soft tissue which can easily be manipulated and tolerate much larger amounts of pressure. The CPO who fits the prosthesis must have a thorough understanding of this anatomical composition.

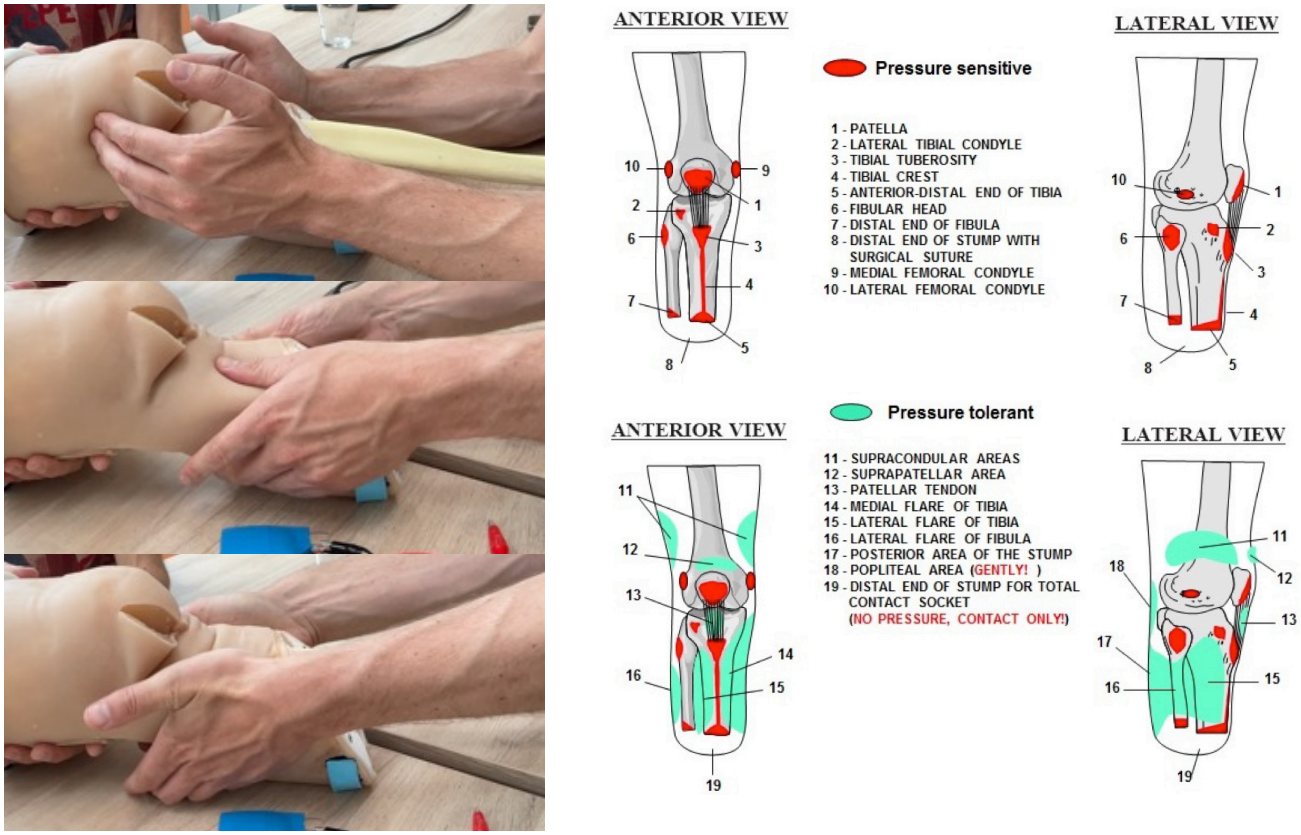


Figure 13. Pressure sensitive and pressure tolerant regions of residual limb, corresponding to stump manipulations

FITTING PROSTHESIS TO RESIDUAL LIMB

Socket suspension methods are named as such because, due to the sensitive nature of the distal region of the residual limb as evident in Figure13 on the previous page, one goal of socket fitting is to avoid putting pressure on this region, thus effectively suspending the limb inside the socket. Sockets have been produced from plaster models and carbon fiber shaping since the 1980s. Throughout the decades, different methods of shaping the socket against the limb have been developed. These methods produce different mechanical situations in how the weight of the patient is distributed within the socket, and this has a great effect on socket comfort, security, and freedom of movement.

The two most common theories of socket fitting are patellar tendon bearing (PTB) and total surface bearing (TSB) (Yiğiter et al, 2002). As the names imply, PTB sockets are designed such that the user bears the majority of his or her weight at the patellar tendon, whereas TSB sockets aim to more evenly spread the wearer's weight across all pressure-tolerant regions of the socket. TSB socktets have gained popularity within the past decades due to their superior security and comfort, and go hand-in-hand with vacuum suspension methods. Figures 14 and 15 to the right indicates the general difference in applied pressures throughout the socket for these two fitting types. Note that in the TSB socket, pressure is still applied to the patellar tendon, but to a lesser degree than in the PTB socket.

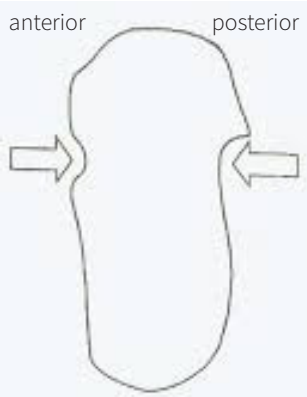


Figure 14. PTB socket

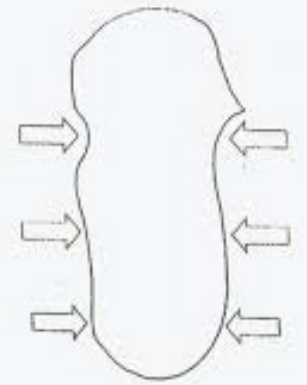


Figure 15. TSB socket

Stump Adjustments

To achieve the correct pressure distributions in the socket for TSB fit, the CPO applies a set of critical adjustments to the limb during the plastering phase. These are:

Shaping the 'box': This adjustment is applying pressure to the femural condyles and patellar tendon (areas 11 and 13 in Figure 13 on the previous page). Even in a TSB socket, extra security is needed around the patellar region.

Shaping the 'triangle': One CPO described this adjustment as shaping the cross-section of the residual limb below the knee into a triangular shape - with one point at the anterior region, allowing space for the sensitive tibia and fibula, while pushing pressure-tolerant soft tissue towards the posterior side of the limb. This adjustment corresponds to applying pressure at regions 14-18 in Figure 13. The resulting 'triangle' is illustrated at the right in Figure 16.

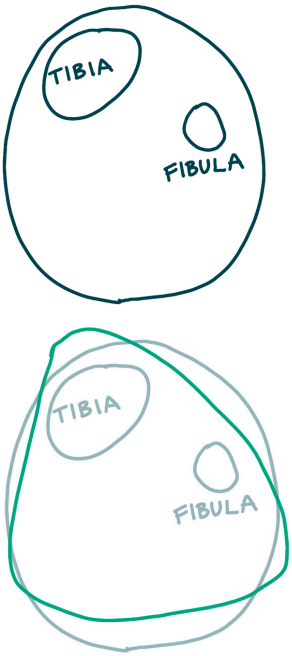


Figure 16. Cross-sectional simplification of residual limb below knee (above) and the triangle manipulation (below)

RQ2: What are the challenges in creating a good fit?

THE DYNAMIC RESIDUAL LIMB

Even in mature residual limbs, volume fluctuates throughout the day, and over longer periods of time with such factors as body weight and weather. Active users might experience daily volume fluctuations within +/- 5%. To quantify this, it was found that a 5% volume change in a 90mm diameter residual limb corresponds to approximately 1mm of radial difference (Yang et al., 2019). Although one milimeter may seem to be an insignifcant change, it is enough for a patient using a vacuum system to "lose vacuum", or break the seal keeping the prosthesis on.

To accommodate for small fluctuations in volume throughout the day, users add layers of stump socks to their limb. Depending on preference or suspension type, users may add the socks underneath the liner, or between the liner and socket. Socks are available in varying ply of 1mm thickness per ply. Some socks provide additional features such as anti-sweat.

In Figure 17 below, one patient dons two layers of cotton stump sock atop her liner before donning her socket.

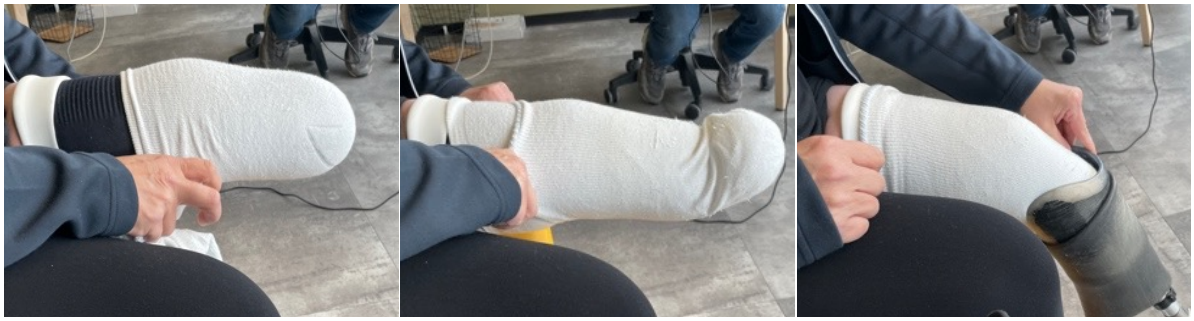


Figure 17. Patient demonstrates donning her layers of stump stock

Frank Jol considers the socket fit acceptable if patients use less than 3 layers of socks. Beyond this, the socket is considered too large and the patient must return to the clinic for reassessment and depending on the assessed change in stump volume, a plastering for a new socket.

Stump volume fluctuation presents a case for the importance of monitoring prosthesis fit at multiple moments throughout the day, not just during appointments. Olsen et al. support this claim in an overview of current prosthesis evaluation frameworks, arguing that assessment of comfort and discomfort should happen over larger periods of time than just the assessment moment (2022).

RQ3: What is the current process to produce a prosthesis at Frank Jol?

What are the bottlenecks?

PROCESS ANALYSIS

In the Netherlands, prostheses are prescribed according to the Prothese Prescriptie Protocol (PPP) (Stuurgroep PPP, 2022). In the case of a newly amputated patient, this process can be considered as two-phased, only the second of which involves the CPO, for the production and fitting of the prosthesis. An overview of the entire process is given in Appendix 3.

The current process of prescribing a prosthesis as practiced at Frank Jol was analysed to identify pain points and bottlenecks. This investigation was conducted through conversations with a CPO, observation of a plastering session, and developing process maps as communication tools to check if the process was understood correctly. Notes from discussing these process maps with a CPO are available in Appendix 3.

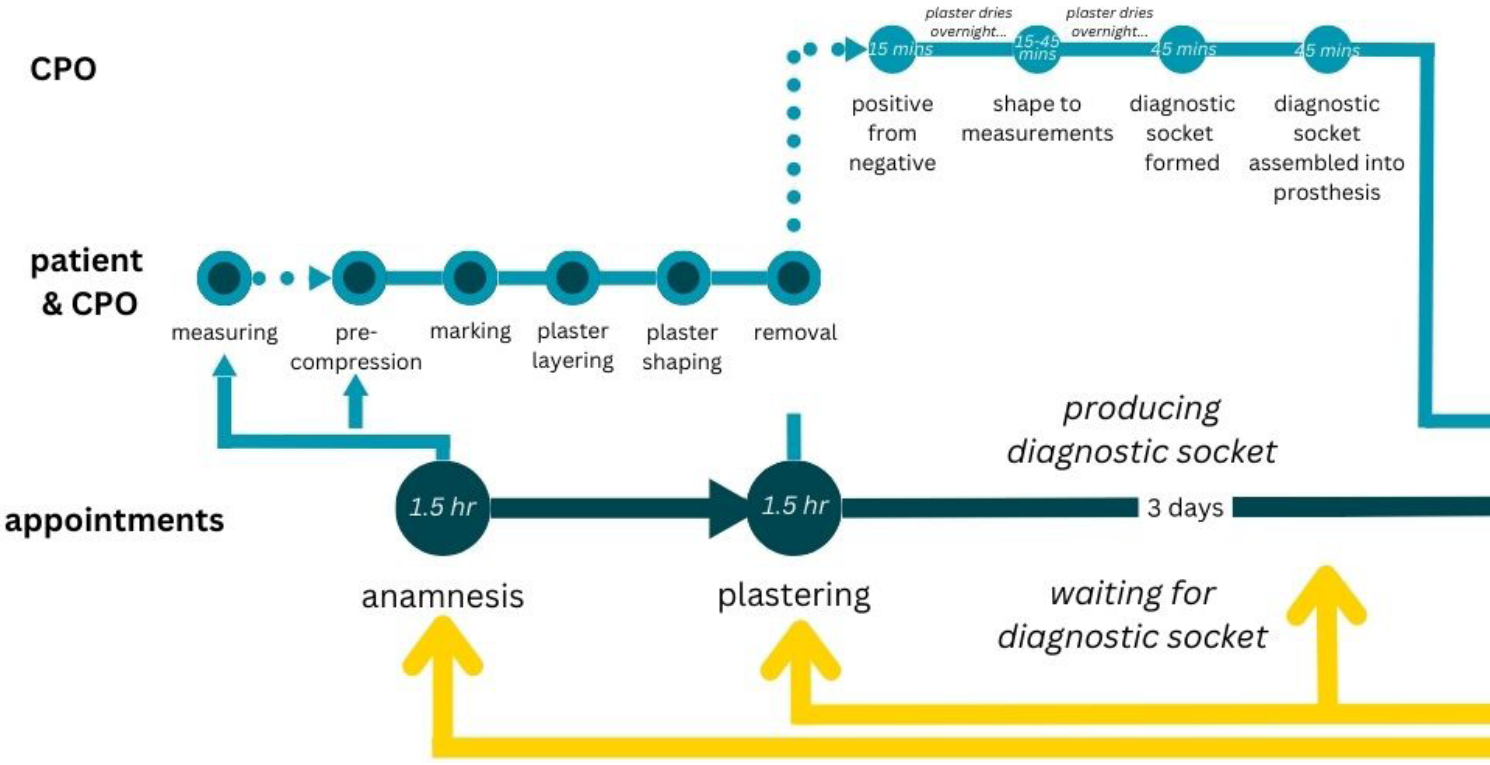
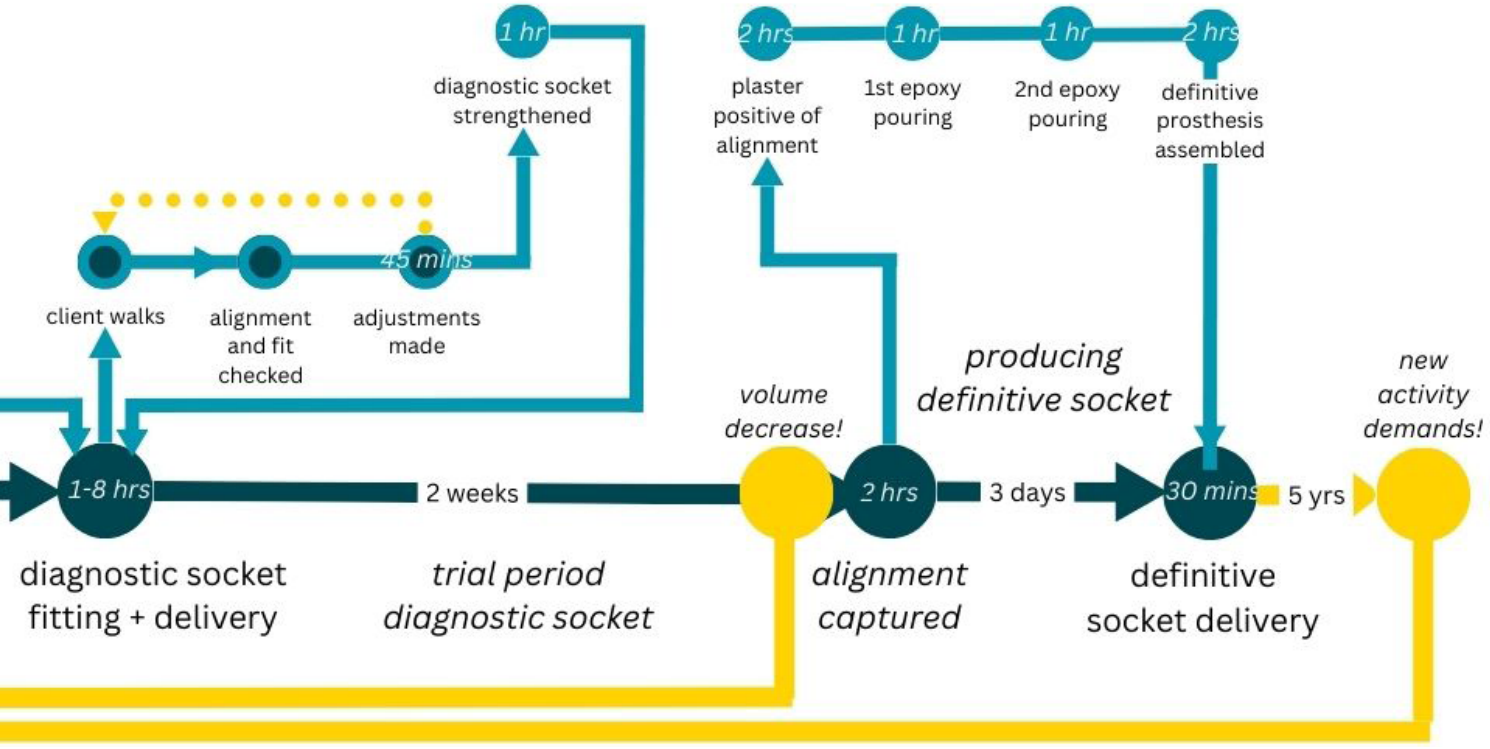


Figure 18. The prosthesis prescription process at Frank Jol

For someone receiving their first prosthesis, the process towards a prosthesis can be divided into three phases. The pre-diagnostic phase, the diagnostic phase, and the definitive phase. The pre-diagnostic phase encompasses needs assessment and collecting stump shape data and modifications (as discussed in the previous section). The diagnostic phase is when a temporary, or diagnostic socket, is produced to test and refine the fit. The definitive phase includes production and delivery of the final, definitive socket, and the long-term wear of this. This process is mapped below in Figure 18. In yellow are noted the major inefficiencies identified in the current process which require significant re-working.



CPO only activities

patient + CPO activities

separate patient appointments

interruptions/inefficiencies in process

Pre-diagnostic socket phase

The pre-diagnostic phase encompasses the anamnesis and plastering appointments. Analysis of the diagnostic and definitive stages was also conducted, but these are considered out-of-scope. Diagrams of these phases can be found in Appendix 3.

Anamnesis

The first meeting between Frank Jol and the patient is the anamnesis, in which familiarity is made with the client's situation, his or her activity wishes are discussed, and initial measurements of the stump without a liner are taken. Specific features of the stump are also noted, such as if the patient has particularly sensitive areas. Frank Jol also uses this moment to analyse the position of the stump with relation to the intact limb. These considerations all inform the CPO on an appropriate suspension method for the patient. The CPO then orders a fitting liner with these factors in mind.

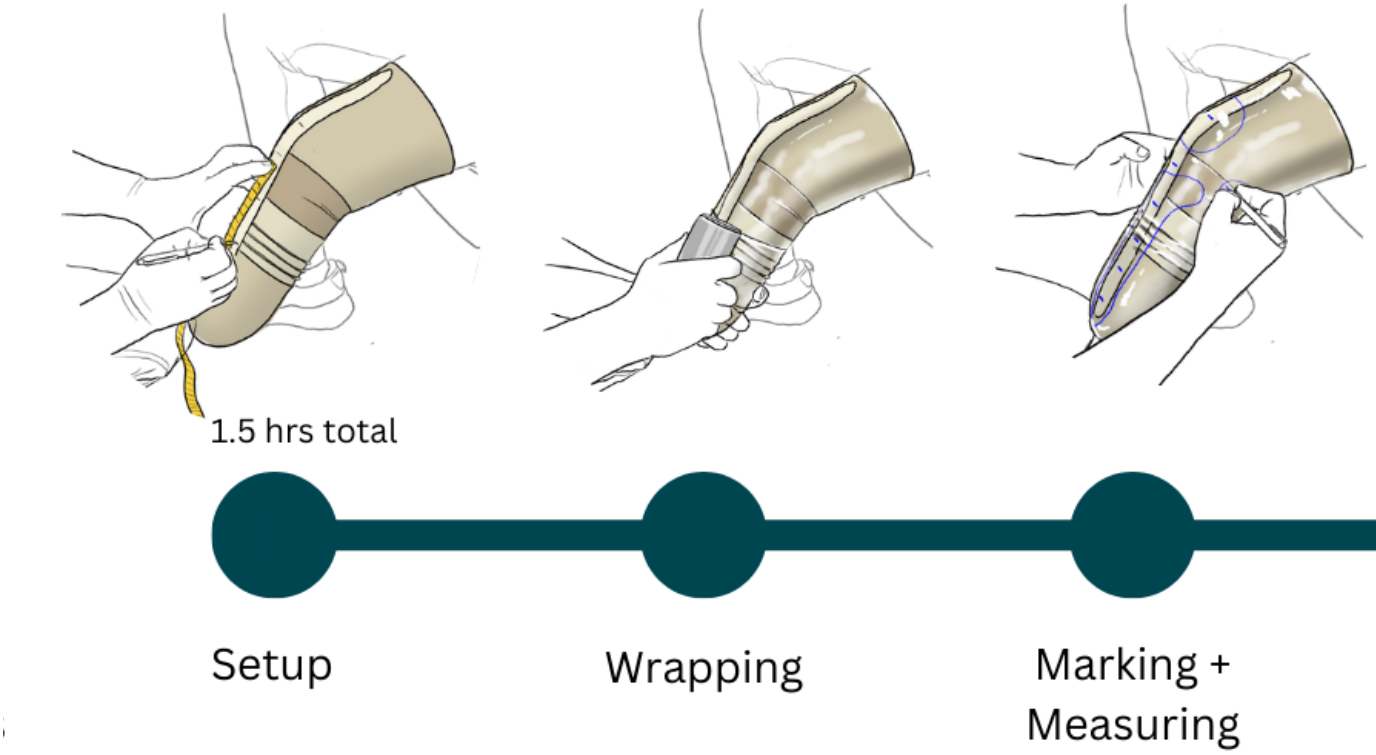
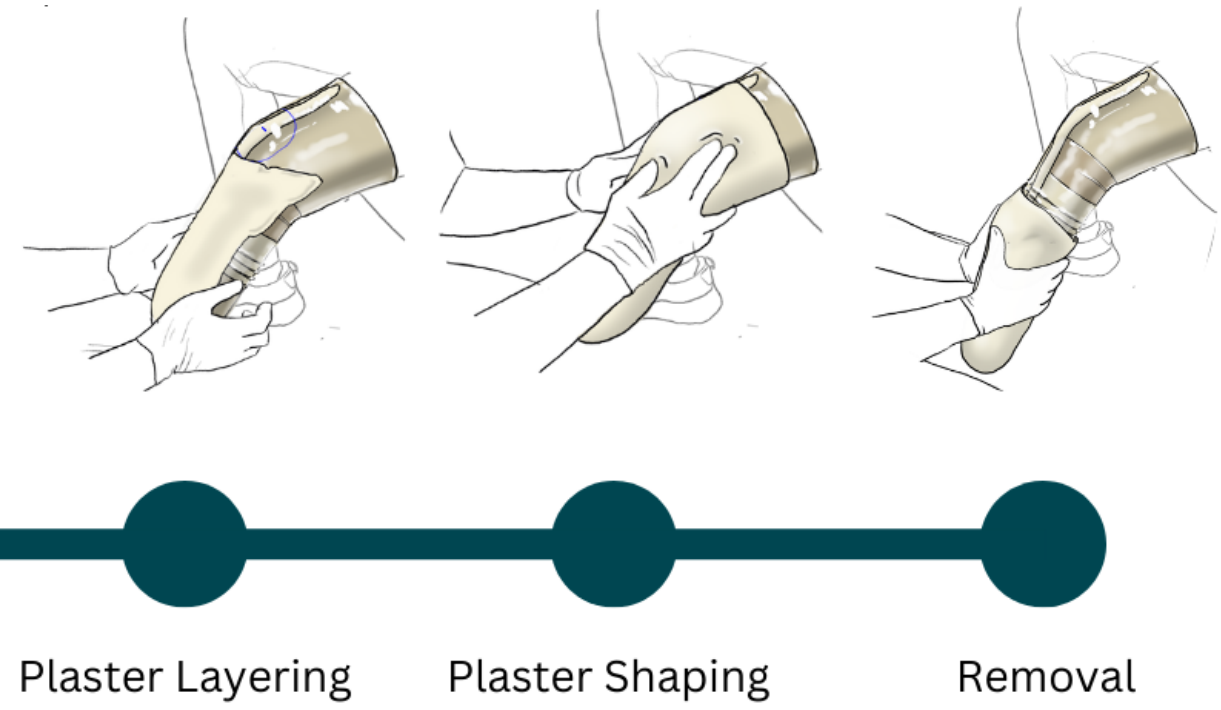


Figure 19. The pre-diagnostic phase

Plastering

The next appointment between the patient and CPO is the plastering session. The aim of the plastering session is to capture the shape of the stump in the optimal position for a well-fitting result. Frank Jol schedules plastering sessions in the afternoon as stump volume tends to decrease throughout the day.

The plastering process is outlined below in Figure 19. First, a liner is donned and the CPO marks intervals at which he or she will later take circumference measurements (normally every 5 cm). Then, plastic wrap is applied to protect the liner from plaster and provide pre-compression. Then the CPO draws on the stump to indicate bony regions and specific bone markers. The CPO also measures the circumference of the stump at the marked intervals. Then it is time to layer plaster onto the stump. The CPO applies the stump adjustments at this moment, applying pressure and holding to shape the plaster using the 'box' and 'triangle' approaches to TSB socket design as explained in the Clinical Analysis. After about 10 minutes, the plaster has dried and the negative model can carefully be removed.

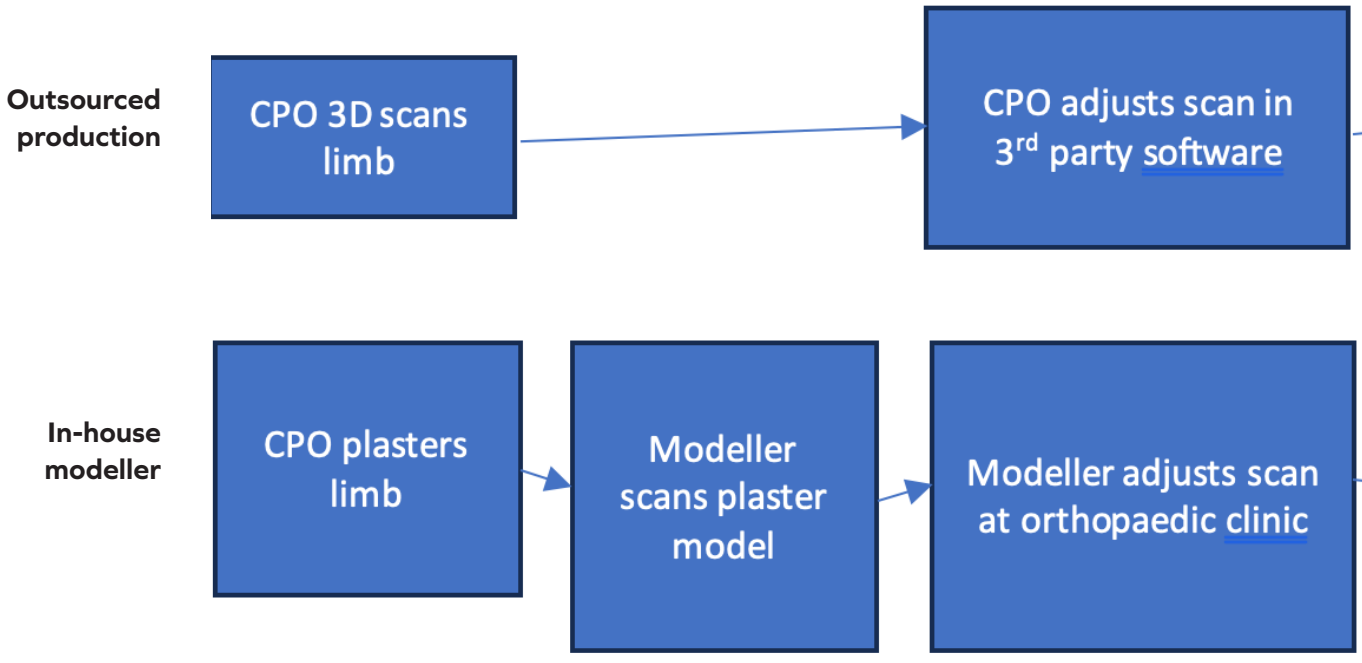


RQ3: What technologies can be applied to improve this process?

ALTERNATIVE PROCESSES

Another key aspect of the analysis phase was placing Frank Jol within the greater prosthetic market context, and identifying potential technologies which could be applied in the design process. Companies and organizations offering below-knee prosthesis solutions were found by checking large medical device distributors (Ottobock and Össur), from mention by Gyromotics employees and Frank Jol CPOs, and reference in academic literature. A full analysis of types of socket and liners identified in the search is available in Appendix 4. Most relevant to the scope of the project were the workflows identified which presented alternative steps towards achieving definitive socket are discussed below, and the benefits and drawbacks of their methods are outlined, as discussed with a Frank Jol CPO. These alternative methods are outlined below in Figure 20.

The Ottobock MyFit TT system involves the use of a proprietary 3D scanner and software. This workflow keeps the CPO at the front of the initial fitting and adjustment process. However, the CPO must make the difficult adjustment from working entirely from tactile experience to digitally, and he or she loses autonomy at the production stage as the production is outsourced to the 3rd party.



LIVIT and OIM are two large groups of orthotic and prosthetic clinics across the Netherlands which practice workflows similar to the second outlined below. The CPO maintains plastering the limb and producing the end socket, but the plaster model is handed off to in-house 3D modellers who execute a set of modifications to the scanned plaster model. In this process, the CPO loses control over what modifications are made. One Frank Jol CPO with experience at one such clinic criticised this process for giving the modification step off to someone who was isolated from the patient's experience, and another commented that often, the sockets produced this way met a much lower standard of fit, and often had to be reworked, than sockets produced completely by the CPO.

The conclusion from the analysis into workflows which incorporate digital methods reflects the recommendations of a study by Ngan et al. of CPOs' experiences with and perspectives on digital workflows that digital methods should be framed as complementary to the traditional workflow and not as a replacement thereof (2022). This is also reflected in the views of the CPOs which can be seen in the following section, Stakeholder Analysis.

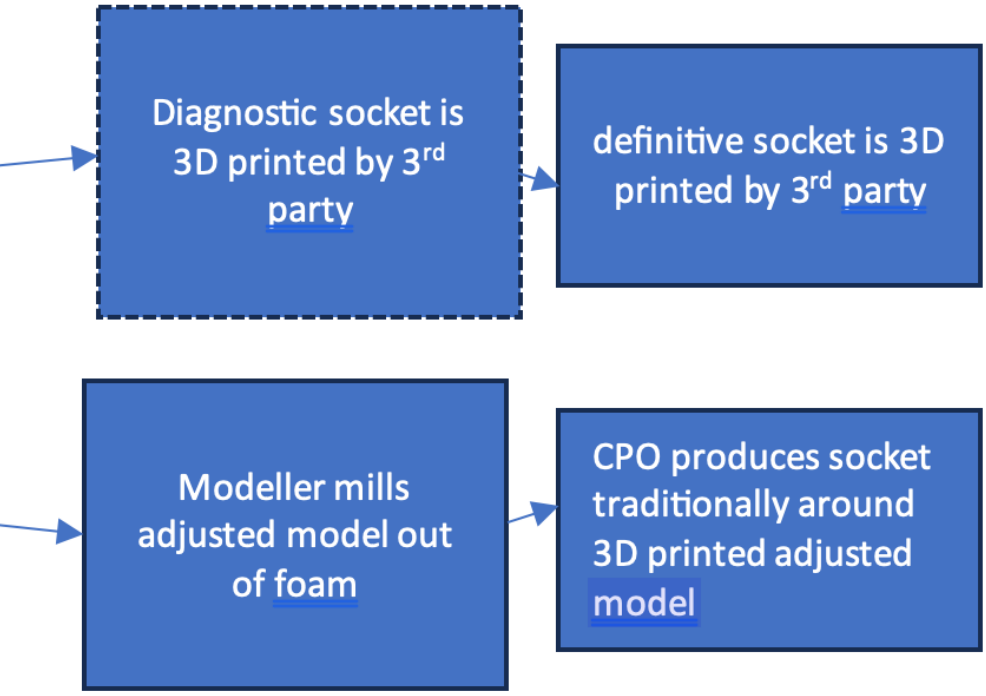


Figure 20. Identified prosthesis workflows incorporating digital methods

RQ4: Who are the main stakeholders in this process at Frank Jol? What are their needs and values?

STAKEHOLDER ANALYSIS

Understanding the clinical situation of below-knee prostheses and the process towards producing, fitting, and living with one were approached from an objective perpsective. At the same time, it was important to also appreciate the subjectivity around the product and process. This necessitated a human-centered method: involving the main stakeholders in semi-structured interviews. This allowed for discovering of previously unseen user needs and pain points by allowing the user to guide the conversation, and for comparing how potential issues found in desk research were experienced in actuality at Frank Jol.

The patient and CPO were identified as key stakeholders (holding both high interest and influence), after a broad investigation into all project stakeholders (available in Appendix 5). The conclusions of these interviews was the extraction of both stakeholder values and pain points within the current process, after considering results with the findings of the process analysis.

Interviews were analysed by identifying commonalities, and points of difference, across responses. The questions for both series of interviews are available in Appendix 6.

Table 3. CPO participants by experience

Participant ID	Experience level
1	> 30 yrs
2	> 10 yrs
3	> 10 yrs
4	< 2 yrs

CPO Interviews

4 CPOs were interviewed. Although all interviewed CPOs were employees of Frank Jol, most had experience working at other clinics and could speak to the differences in work environment, philosophy and process across clinics. Their experience in years is given to the left in Table 3. The interview framework was centered around first discussing experience in the industry, followed by a focus on perspectives on digital methods being used in the industry, in order to understand the perceived barriers to adoption as they saw them, and to uncover CPO values.

CPO Interview Themes

"There is less direct contact with the patients . . . and you exprience less freedom to make your own choices [at a bigger company]."
- P2

CPOs value acting autonomously and being able to exercise their handicraft. One CPO explained how his favourite part of the job was the variety presented by Frank Jol's unique clientelle, which he didn't find in employment at a larger company. A large range of stump profiles and activity types creates exciting challenges and decisions to make regarding building an approparite prosthesis. Furthermore, CPOs enjoy the tactile nature of their job, and being able to build systems with their hands.

Inconsistencies between CPOs are costly. A prothesis being produced by one CPO may need to be handed to another CPO at one point, but not all CPOs follow the same procedure for measuring, and this can get lost in translation, resulting in having to do the same work twice, such as having to start over with shaping a plaster positive model.

Experience as a CPO fosters confidence in providing a good fit. Between the CPOs interviewed, those with less than a few years of experience in fitting prostheses expressed uncertainty about how they know when a fit is considered good enough, whereas those with decades of experience were proud of how consistently they believed they could provide a good fit.

"If I measure it again, it will be the same!"

– P1

CPOs associate digital tools with loss of control over the production process. Two of the interviewees spoke of their experience working at larger clinics which implemented direct 3D scan-to-print workflows, and how they did not like handing their handiwork off to a modeller to apply a standard set of adjustments, to receive a socket to give to a client that ultimately would not fit well. However, CPOs still see value in adding digitisation to their workflow, as one participant stated he sees great potential in digital workflows in improving patient-client relationships.

"Some of the [3D modellers] had never seen an amputee before. They were just clicking buttons. I would want to do it myself."

- P3

A common frustration among CPOs is the difficulty of having fully transparent communication with the client. One CPO emphasised the importance of the client keeping in close contact during the definitive socket phase, in order to inform the CPO of any fit issues which, if gone unchecked, can develop into painful blisters and infections, resulting in the client being unable to wear the prosthesis until they heal or, at worst, require surgical intervention. The CPOs explained, however, that patients often do not realise that certain sensations are problematic and they should alert their CPO[3].

"If there is pressure, there's going to be a wound."

- P4

[3]For diabetic patients, the situation is even worse, as patients lose much sensation in their residual limb and therefore are not able to detect problematic areas on their own.

Patient Interviews

6 patients were also interviewed. Demographics of the patients can be seen to the right in Table 4. Patients were categorised as "experienced" if they had been wearing a prosthesis for more than 2 years. "Recent" patients had been wearing a prosthesis for less than 2 years.

Table 4. Patient participants by experience

Participant ID	Experience level
1	recent (< 2 yrs)
2	experienced (3 + yrs)
3	recent (< 2 yrs)
4	experienced (10+ yrs)
5	recent (< 2 yrs)
6	exprienced (5+ yrs)

"... with the plastering, that sort of hurt. I thought, huh... I don't know!!"

- recent amputee (P3)

"My old CPO was always a little too tight on me. Last time I couldn't even put my finger in [my socket]. I trust [my new CPO]."

- experienced amputee (P4)

Patient Interview Themes

Recent amputees lack trust in their CPO at Frank Jol. Adjusting to life as an amputee means experiencing many new, unfamiliar, and often uncomfortable sensations and situations. One of the first of these on the path towards their first prosthesis is the plastering process. Patients expressed the strangeness of experiencing this process for the first time: they must expose their residual limb to the CPO, and endure the cold, wet plaster, and the sometimes painful pressing of the CPO. Because they do not yet understand how the CPO's gestures translate to a good fitting prosthesis, they may leave the plastering appointment nervous about whether their socket will fit or be too tight.

First-time clients at Frank Jol are sometimes too nervous to express their unease and discomfort during the first plastering processing directly to the CPO. This was revealed through a conversation with the desk manager at Frank Jol, during which she mentioned that clients often call her while at home waiting for their diagnostic socket, questioning whether the plastering had been done correctly.

Experienced amputees trust their CPOs at Frank Jol. Through years of working with them, patients see and feel first-hand how certain decisions made by their CPO--whether to change liner type or fit the socket tighter in certain areas--create a better prosthesis experience in the long run. One interviewee even expressed that she trusted her CPO blindly with the decisions he made, and even

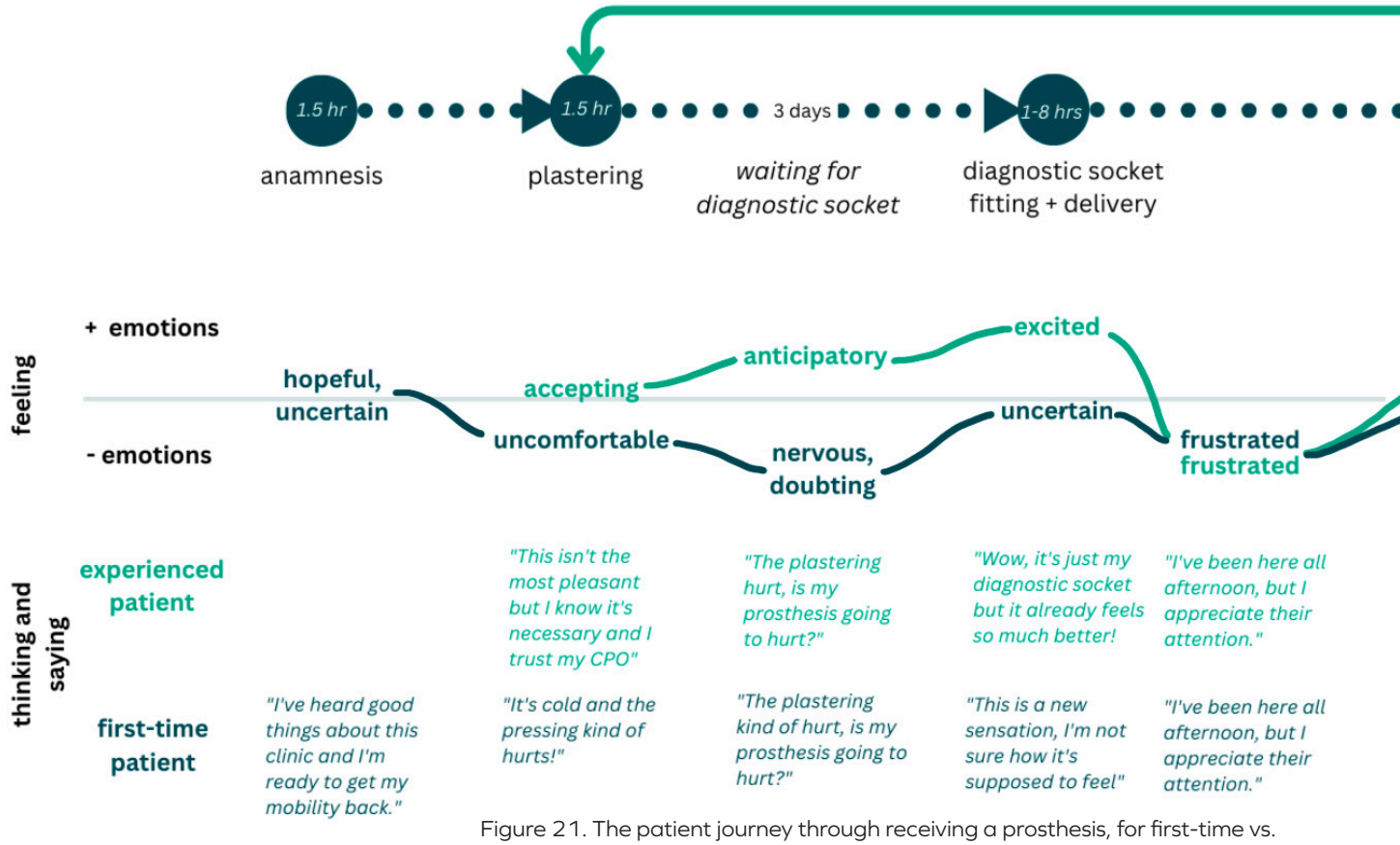


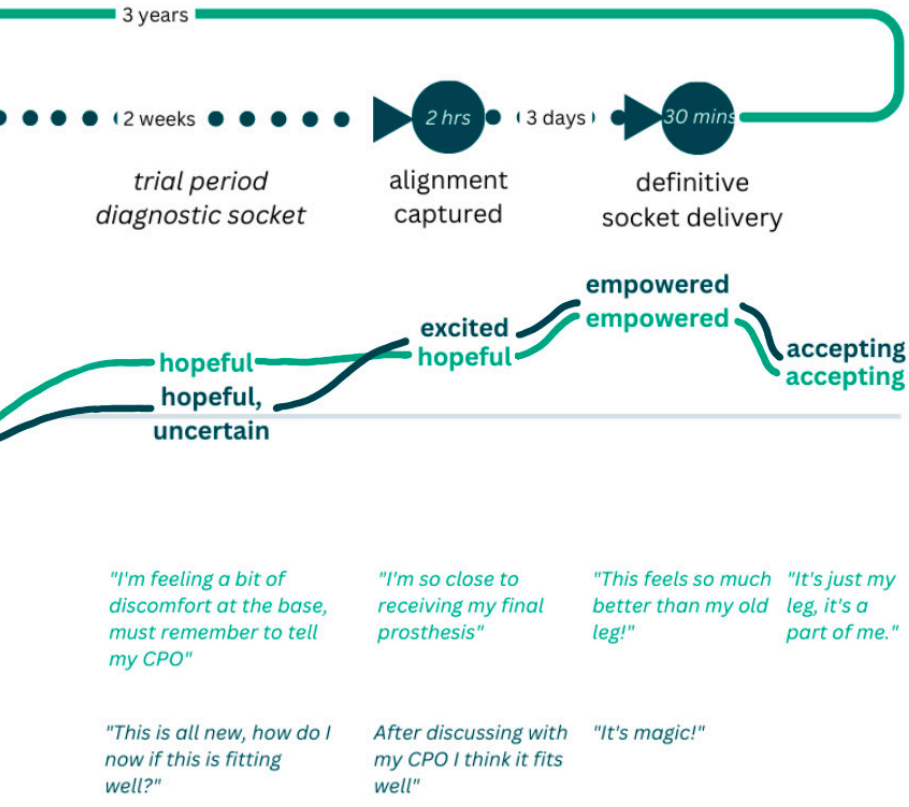
Figure 21. The patient journey through receiving a prosthesis, for first-time vs. experienced patients

if he had tried something that didn't end up working, she would not loose trust.

Face-to-face time is important for building trust. Not only does evidence of a good fit increase patient-CPO trust, but face-to-face time also fosters this relationship. A study conducted by Mayo et al. revealed that many patients appreciated face-to-face interactions with their prosthetist, enjoyed watching them work, and that these human interactions increased their trust in their prosthetic (2022). One interviewee stated how she admired the passion her CPO had for his job which was evident during their appointments.

Attitude and emotion towards their prosthesis. Recent amputees expressed great enthusiasm and excitement upon trying on their prosthesis and discovering it fit well and allowed them to stand or walk without pain. One interviewee even exclaimed it was like magic. Experienced amputees had a more subdued view, considering their prosthesis as merely a part of their body. Still, this shows the close relationship that amputees form with their prosthesis, even if they are modest in expressing it.

Patient experience has been represented in a journey map below in Figure 21, with the more negative experience of a first-patient being shown in navy.



"There was no active choice on my side, to trust [my CPO]. But it worked out well. And if it hadn't worked out, that wouldn't be an issue also I think. He loves his job really well."

- experienced amputee (P4)

"I feel so euphoric that I can walk for so long without pain… magic!"

- recent amputee (P3)

"For me it's just my leg, it feels like my leg."

– experienced amputee (P1)


CAST WITH LEG RAISED → let gravity shape?
soft tissue naturally goes back
PRESSURE SENSING FABRIC
ARRAY
OR
PATCHES FOR SPECIFIC REGIONS
injection liners (ski boots)
HOW TO:
CAPTURE AND MODIFY STUMP SHAPE FOR OPTIMAL SOCKET FIT?
TOP VIEW STUMP
CPO MOD
slap wristband for stump
lead screw
proximity sensor
AR + video record movements

3

Design Drivers & Ideation

This chapter first presents the conclusions of the analysis phase in the form of design drivers, before framing a design vision. Then, ideation and concept development are elaborated. Finally, the concepts are evaluated using a combination of methods and a choice made for the concept(s) to bring into the realisation phase.

DESIGN DRIVERS

The analysis insights were synthesised into the following design drivers which would guide the ideation and concept selection phase.

Capture stump data

The design should integrate capture and storage of patient stump data digitally. This includes not only the neutral, resting form of the stump, but also the modifications that the CPO makes. In future scenarios, this also includes capturing data not only during the plastering, but also during the use phase of the definitive socket.

Value and utilise CPO craftmanship

CPOs' tacit knowledge is of utmost value to creating a successful prosthesis within the target group of active users. Therefore the design solution should take advantage of CPO's tactile, hands-on expertise and strive to make this knowledge explicit, traceable, and productive towards digitalisation.

Simplify production process

To be appealing to and adaptable by CPOs, the design should improve the efficiency of the prosthesis prescription process and be intuitive to implement. The design should reduce the number of meeting moments needed between the CPO and patient in the journey towards a prosthesis, as well as minimizing the need for starting over. Simultaneously, the design should reduce the CPO's labour time in production.

Standardise production process

In making the process more traceable and explicit, the design should also make the process more standardised. This will enable better communicaiton between CPOs, and increase flexibility within a clinic as the possibility for mismatch of practices or measurement techniques is eliminated.

Improve communication between patient and CPO

As discovered through stakeholder interviews and literature research, maintaining quality face-to-face time and communication is critical to not only patient-CPO trust, but also ensuring the socket fit is monitored properly. Moving towards digital, automated processes creates the potential for a largely remote process. It is therefore imperative to the design that even if steps are automated, the patient still feels that they are personally cared

for and attended to, and the CPO feels in-the-loop. Furthermore, improved contact between the patient and CPO will allow for more transparency and quick addressing of any issues the patient may face.

DESIGN VISION

The vision is a tool to be used by the CPO which captures stump shape and modification during the prosthesis prescription process. This tool keeps him or her in control of the prosthesis fitting process, and will inform the beginning of the journey towards a standardised, automated prosthesis prescription at Frank Jol.

IDEATION

After research was synthesized into design drivers, these were grouped to two general opportunity areas based on the phase of the production process at which they intervened (during the pre-diagnostic phase, or during the diagnostic phase).

Opportunity area 1: Pre-diagnostic phase

Opportunity area 2: Diagonstic phase

To kick-off the ideation, a brainstorming session was held with Gyromotics colleagues (Figure 22 at right). Prompts for this session were derived from a function breakdown of the prosthesis journey from pre-diagnostic socket, to diagnostic socket, to definitive socket in the form of blank morphological charts (available in Appendix 7). Along with this, the opportunity areas were phrased as how-to questions to prompt ideation. Results of the brainstorm were collected into two idea maps, one for each opportunity area. From these idea maps, clusters were formed according to four themes: developing a smart casting material, tracking socket fit during the diagonstic phase, creating a smart measuring tool, and capturing stump data using a sensing ring. These four themes were then further elaborated into concepts, discussed in the following section. Sketches from ideation are also available in Appendix 7.

Figure 22. Brainstorming session with Gyromotics employees

CONCEPTS

Pressure-sensing Casting

This concept consisted of a prosthetic liner with a force-sensing matrix embedded in it which registers the location and intensity of the CPO's applied forces during the plastering process and stores these in a digital file. The modifications can then be applied to a 3D scan of the limb to create the the optimised socket shape (either positive to directly 3D print) or negative (to 3D print for construction of the socket using traditional carbon fibre methods). Potentially, the data could eventually be used to construct a 3D model of the residual limb, circumventing the need to 3D scan if digitisation is the goal. The pressure-sensing casting concept is illustrated below in Figure 23.

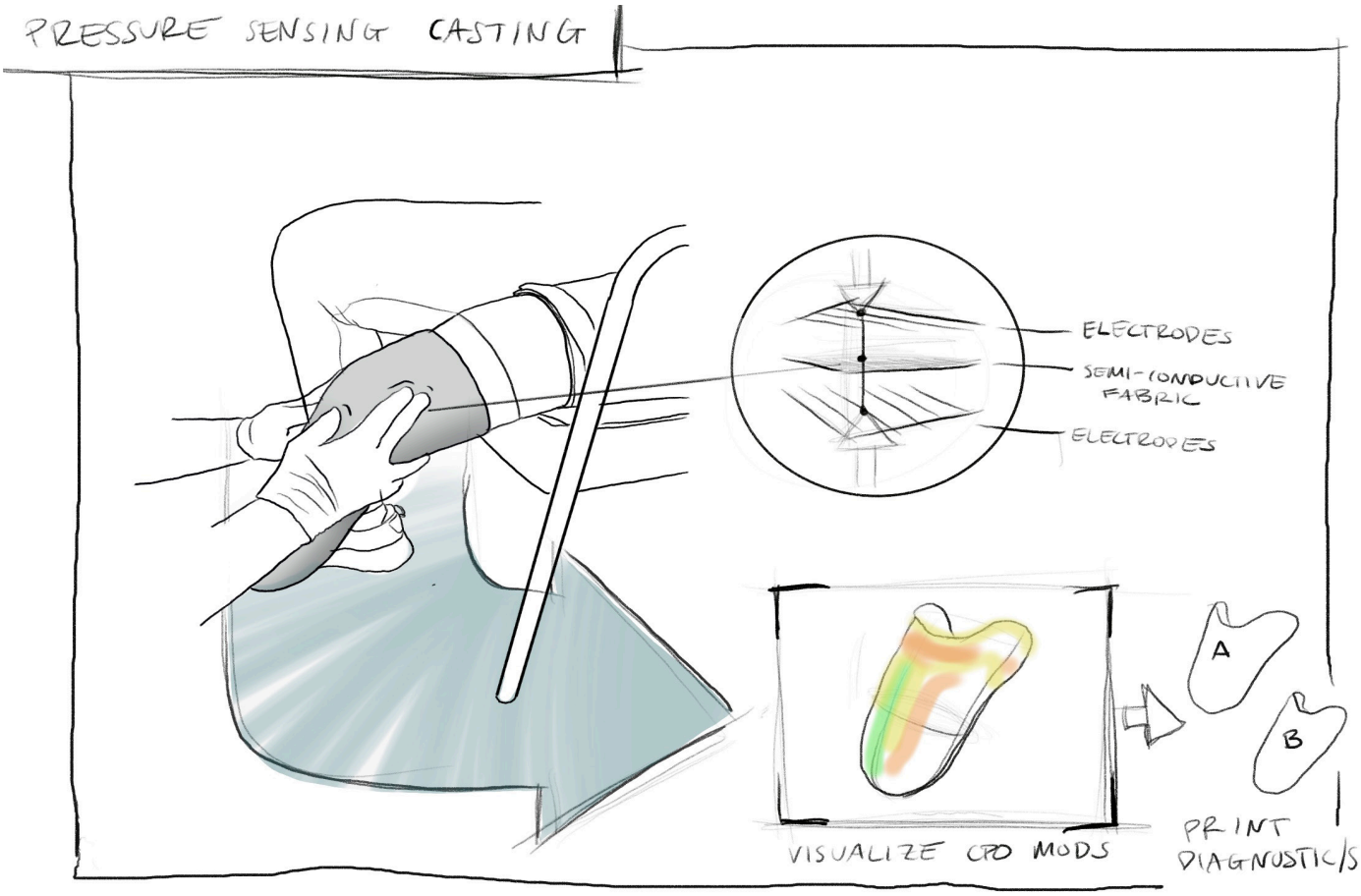


Figure 23. Pressing-sensing casting concept sketch

Connected Diagnostic Socket

The connected diagnostic socket features pressure sensors integrated into it at areas which tend to cause pain or lead to problems. In conjuction with an app, this concept keeps both patient and CPO informed of how the diagnostic socket is fitting after he or she leaves the fitting appointment. This could allow for catching pain points before they develop into blisters or infections, therefore reducing the potential for costly re-work within the process. Furthermore, this pressure data would build a valuable dataset for later automation. The connected diagnostic socket concept is detailed below in Figure 24.

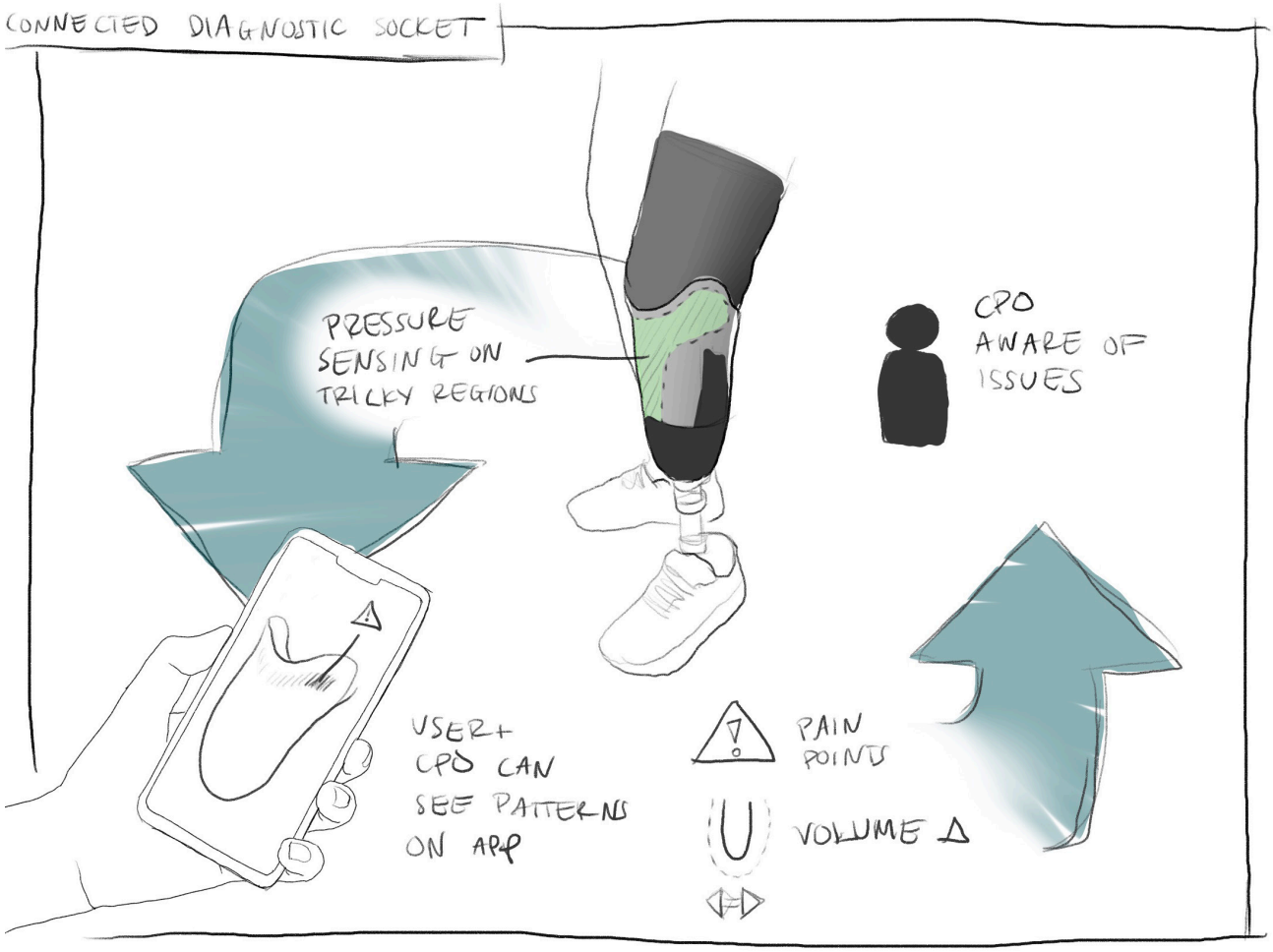


Figure 24. Connected diagnostic socket concept sketch

Smart Measuring Tape

The smart measuring tape concept propsed a device to standardise the taking of stump measurements. This device would be used during the anamnesis and plastering appointments when circumference measurements are taken. It would provide visual or haptic feedback to alert the CPO when appropriate tension had been reached as he or she took measurements on the stump. The smart measuring tape is illustrated below in Figure 25.

This concept's strength was its simplicity and technical feasability, along with its strong potential to standardise a step of the process. However, this concept missed capturing any modifications made to the stump.

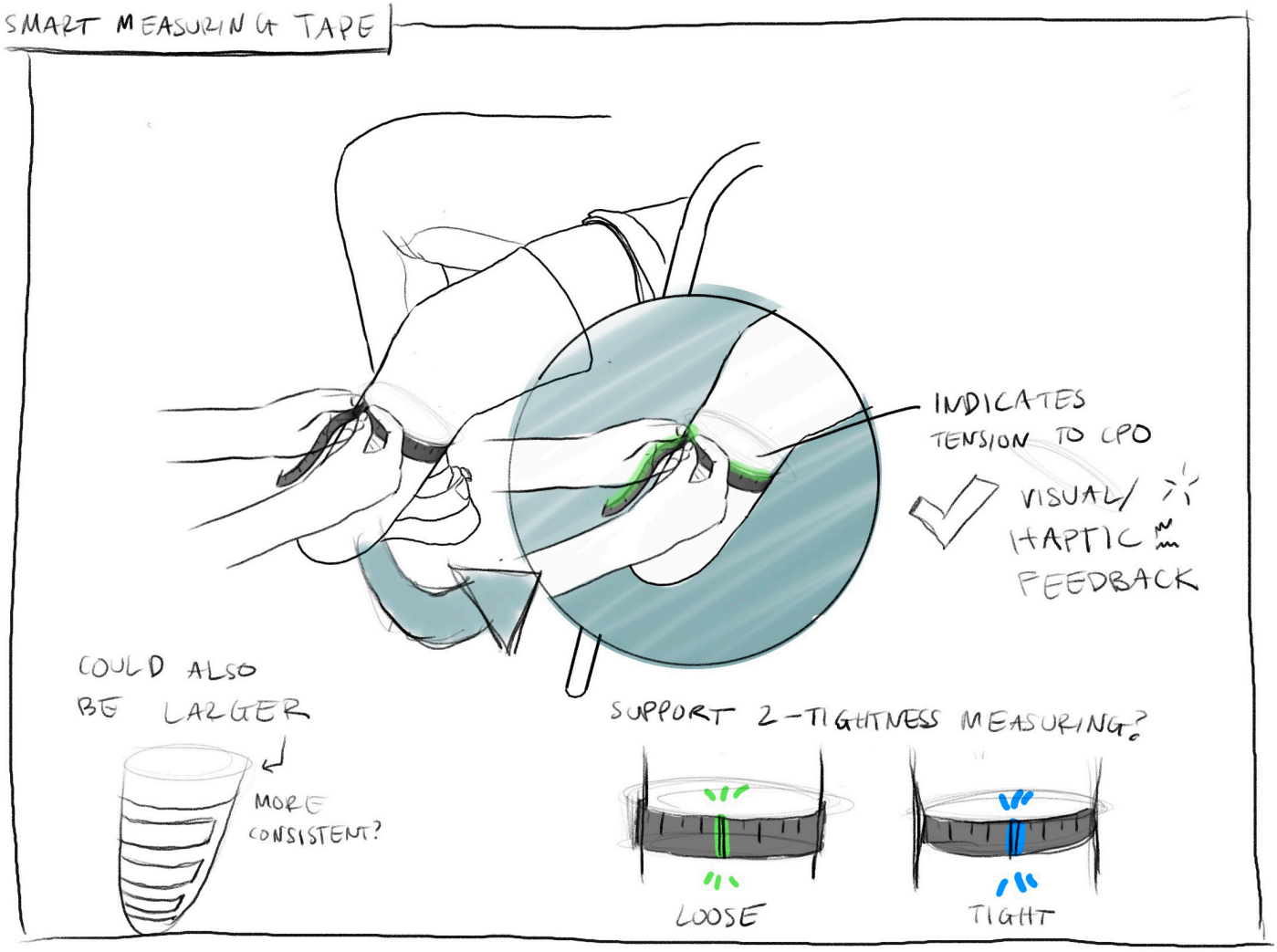


Figure 25. Smart measuring tape concept sketch

Measuring and Sensing Ring

The measuring and sensing ring concept consisted of a radial setup of proximity sensors (ultrasonic or other), which when moved along the proximal-distal axis of the stump, could capture enough data to construct a 3D model of the stump. This concept can be seen below in Figure 26.

This concept did not make use of the CPO's handiwork; rather, it replaced the manual plaster manipulaiton. As it was a key design driver to capture and track the CPO's manual adustments, this concept was not further considered for this reason. However, it could be of interest to revisit this concept once a large enough dataset of manual stump manipulations has been built and closer to maturity for automation.

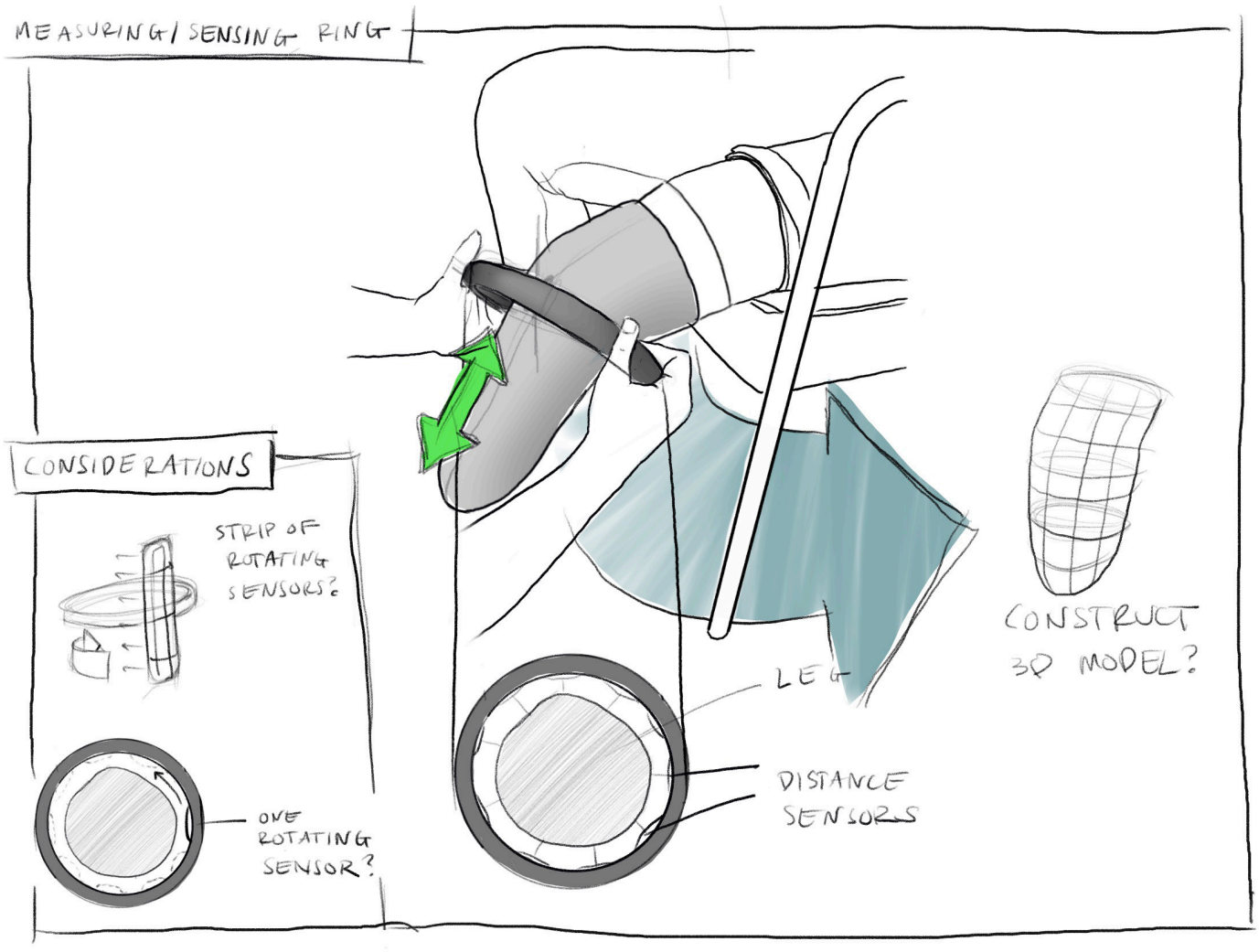
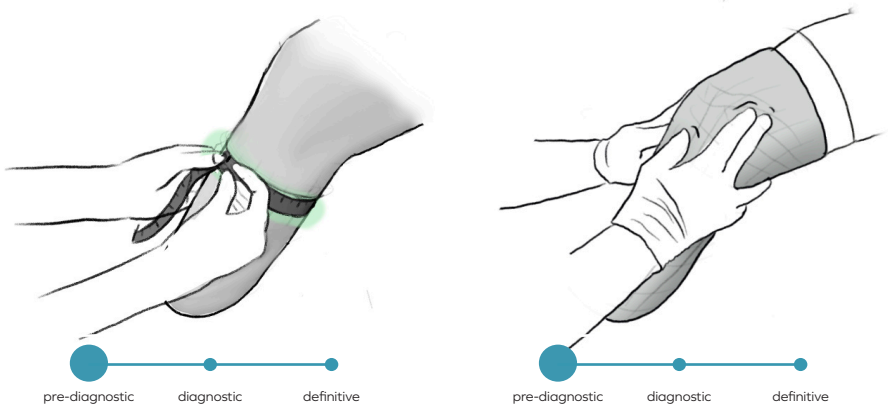


Figure 26. Measuring and sensing ring concept sketch

CONCEPT SELECTION

Selecting the concept to continue into the development and delivery phases was accomplished through a combination of design evaluation methods and dicussions. These concepts and their benefits and drawbacks were discussed with coworkers at Gyromotics, with the project supervisory team, and with a CPO at Frank Jol. These discussions brought up that one of the most intriguing elements of the pressure-sensing liner and smart measuring tape was the ability to extract the tacit knowledge of the CPO.

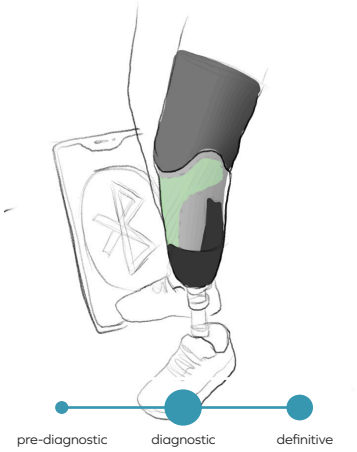
In addition to these insights from project stakeholders, the design concepts were compared against the project design drivers in the Harris profile shown below. Pressure-sensing casting performed well across all design drivers, specifically capturing stump data (specifically modifications made to the stump), and

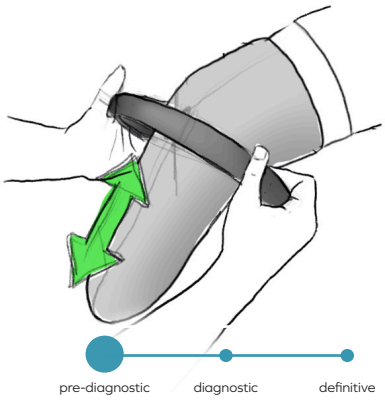


Design Driver	Smart Measuring Tape				Pressure-sensing Casting			
	--	-	+	++	--	-	+	++
capture stump data			■				■	■
value CPO craftmanship		■					■	■
standardise production process			■	■			■	
improve patient-CPO communication			■				■	
simplify production process		■					■	

therein valuing CPO craftmanship. It was interesting to note that the direct feedback element of the smart measuring tape scored highly on standardising the production process for minimising error between CPOs, and the connected diagnostic socket scored well on improving patient-CPO communication through use of a shared interface and monitoring system.

Sorting the concepts by the phase of the prosthesis prescription process in which they intervene led to the realisation that these positive interaction aspects from the smart measuring tape and connected diagnostic socket could be incorporated within the frame of a pressure-sensing liner which is used by patient and CPO over the entire process This envisioned future workflow and the proposed concept to be designed are introduced and elaborated in detail in Chapter 4: Development.





Connected Diagnostic Socket				Measuring and Sensing Ring			
--	-	+	++	--	-	+	++
		■	■			■	
	■				■		
	■					■	
		■	■		■		
	■					■	

4

Realisation

This chapter presents the chosen concept, and then details the development a prototype. Prototype development is described in three phases of physical development, from proof-of concept towards a sewn, stretchable design. Then, interaction development is discussed. The chapter culminates by presenting the final prototype built for the purpose of a user test, detailed first physically and then in terms of use-case interaction.

CHOSEN CONCEPT

The results of the concept selection showed the potential for combining interaction elements from multiple concepts into the pressure-sensing casting concept. The resulting concept to be realized is named PressFit, for its use in fitting prostheses by registering CPOs' applied pressures. PressFit's characteristic feature is its integrated textile force-sensing matrix. This tool enables the tracking of pressure through all phases of the prosthetic process: from initial measurement intake, to modifications to the stump during plastering, to the tracking of socket fit in the long term. Because PressFit is made of a knit fabric, it retains elasticity, especially in the medial-lateral direction. This is of foremost importance because it enables the sleeve to adhere to every contour of the residual limb and be donned over any bulbous regions. Furthermore, this stretch also allows the same liner size to adhere to a range of stump sizes.

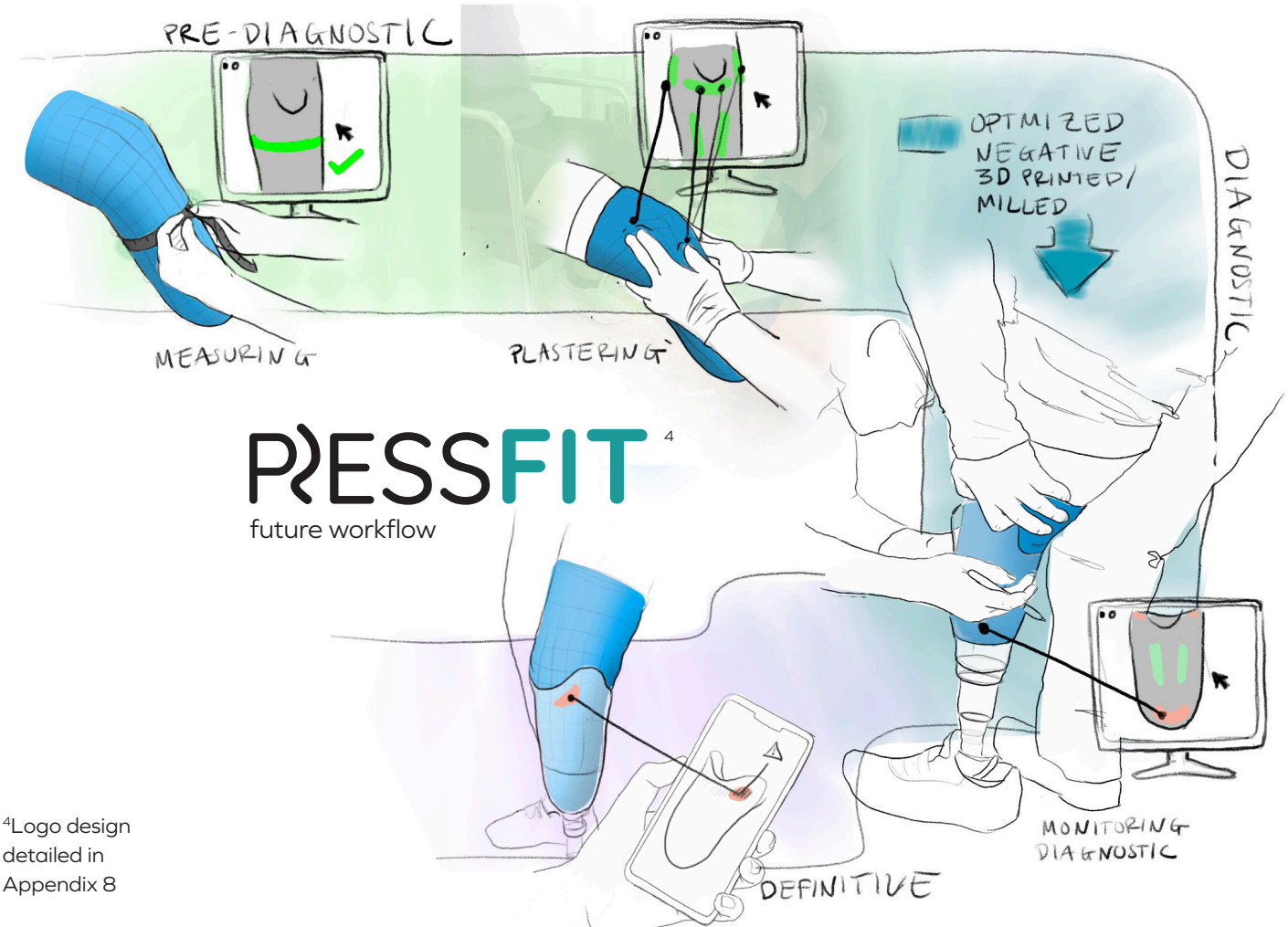


Figure 27. Envisioned future workflow

[4]Logo design detailed in Appendix 8

The envisioned future workflow is shown at the bottom of the previous page in Figure 27 This workflow utilises the tactile knowledge of the CPO in the pre-diagnostic phase, which maintains a quality face-to-face moment with the patient, while removing the time-consuming process of translating the plaster negative to a plaster positive. This is replaced with a digitalised manufacture via milling or 3D print. The digital model is constructed based on the applied pressures (either from overlaying on a scan, or eventually constructing a model directly from PressFit data)[5]. This period between plastering and delivery of diagnostic socket could take upwards of 3 days due to the need to wait for plaster to dry twice. In the envisioned process, this can be as quick as an overnight turnaround.

[5]This part of the process is out-of-scopeof this project and is discussed in Chapter 5 as a recpmmendaiton for further work.

DEVELOPMENT APPROACH

The goal of prototyping was not to arrive at a finalised, optimised product, but rather to explore the potential of a technology in new use cases and demonstrate its value on a small scale. Therefore it was decided to build PressFit for the first two use cases presented in the future workflow: measuring and plastering.

Measuring: During measuring, PressFit registers the tightness of the circumference measurement, providing feedback towards an appropriate tightness.

Plastering: During plastering, PressFit registers the location and intensity of the CPO's stump modifications, visualising this pressure and potentially giving feedback towards a specified pressure.

This phase of the project was approached with an iterative, research through design methodology, as well as co-design. In this, prototyping was a learning process in how to build force-sensing matricies, and effectively served as a probe to communicate with CPOs about the potential for this new technology. The physical prototype and user interaction (data visualiation) were in practice developed simulataneously, but for clarity will be presented here as two separate endeavors. This process is illustrated as Figure X below.

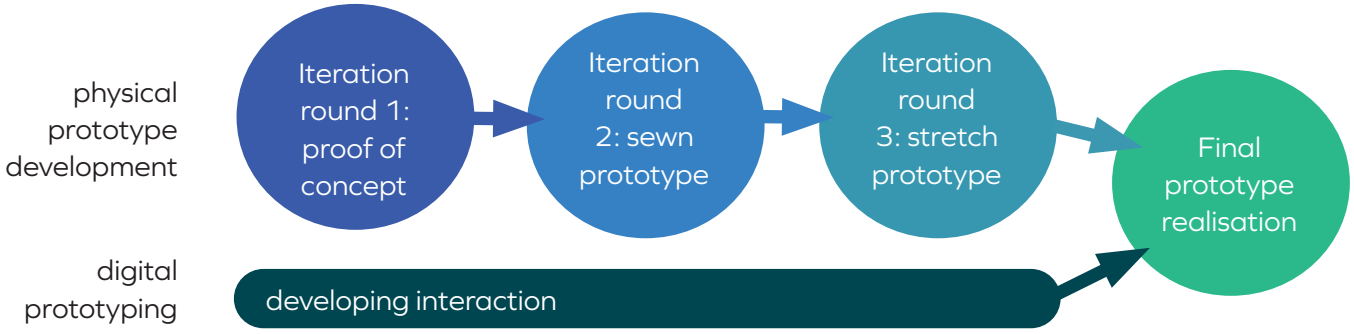


Figure 28. Prototyping approach

Technical Working Principle

The concept relies on the technical principle used in off-the-shelf force-sensitive resistance (FSR) pressure sensors. As force is applied over the sensor area, resistance through the sensor decreases. Thus, applied force is inversely proportional to resistance. It follows that when measuring voltage across the sensor, applied force corresponds to decreasing voltage. Unlike wiring individual FSRs, using a custom-made grid construction allows for quickly covering a large area with force sensitivity.

In more detail, the basic forse-sensing matrix is constructed from two layers of electrodes (conductive material) separated by a spacing layer (Satomi & Perner-Wilson, n.d.). To form a matrix, the two electrode layers should be perpendicular rows and columns. The chosen spacing layer must be piezoresistive, meaning that its resistance is high when unpressed, and reduces locally when pressed or stretched (Sundholm et al., 2014). A diagram of this principle is shown below in Figure 29.

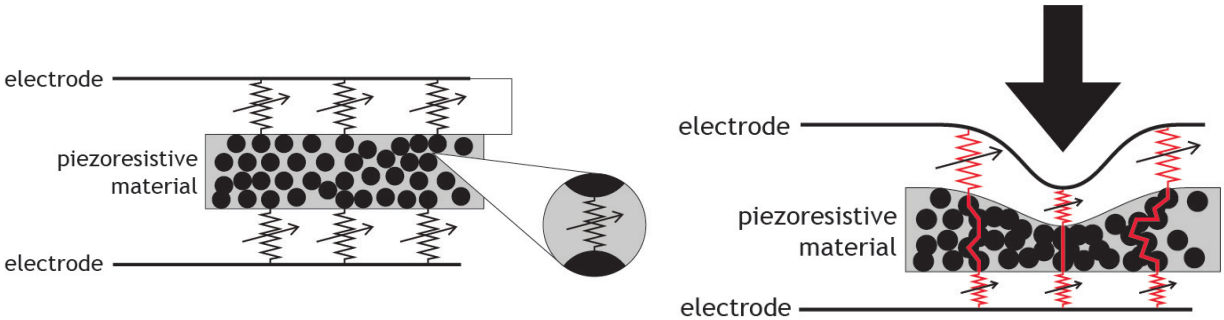


Figure 29. Visualisation of the sensor setup

Advantages of a textile sensor matrix

There are many advantages to constructing such a sensor matrix from textile materials over using off-the-shelf pressure sensors. Meters of conductive thread and a piezoresistive material are much cheaper than dozens of forse-sensitive resistors. Finally, the textile matrix is flexible and can integrated into an elastic fabric. A textile sensor also has advantages considering the users, patients and CPOs. A textile sensor matrix can be washable. This is extremely important if PressFit is to be worn by the patient daily during the use phase of the definitive socket, as many users wash their liner daily. Furthermore, a smart textile product appears less clinical than a sensor-embedded liner, which fits in with the attitude at Frank Jol that their prosthesis should not be viewed as a medical product but as a mobility tool, just as a specialised sports shoe.

DEVELOPMENT PART 1: PROOF-OF-CONCEPT

The goal of the first round of prototyping was to test whether such a simple force-sensing matrix could be built quickly and functionally. Furthermore, it was important to construct a sensor setup as quickly as possible in order to build and refine the software system to read, analyse and visualise the data. This data visualisation is described in the final section of the chapter, Interaction Design.

Material Selection

The material properties of the spacer and electrode materials would determine the behaviour of the constructed sensor, so it was important to choose materials which would be sensitive to the range of expected pressures. Materials were discovered through mention in literature studies in similar applicaitons, and discussed with smart textile experts at TU Delft Applied Labs and specialists in the conductive textile industry.

Electrode material. The chosen electrode material was SEFAR Sensing Skin conductive fabric. This woven fabric featured silver electrodes with dimensions shown in Figure 30. Additionally, Adafruit conductive thread was sourced for later-stage development. This conductive thread is 100% stainless steel. It can be used in a sewing machine to create stretchable electrodes and is rated as safe to wash (Stern, 2013).

Spacer material. The spacer material used was Velostat, also sourced at the Applied Labs. Velostat is a low-cost piezoresistive material used for packaging electronics. It has been tested as sensitive to the range of expected pressures an appropriate piezoresistive material for application in in-socket pressure monitoring by Hopkins et al. (2020).

For later-phase development, SEFAR Carbotex piezoresistive material was ordered. This material was recommended by a conductive textile engineer for use in the relatively low-pressure application of detecting pressing forces on the leg (P. Hofmann, personal communication, 14 June 2023).

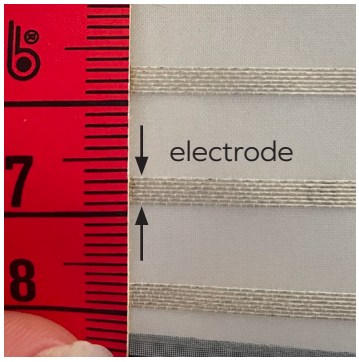


Figure 30. SEFAR sensing skin: 2mm electrodes with 8mm pitch

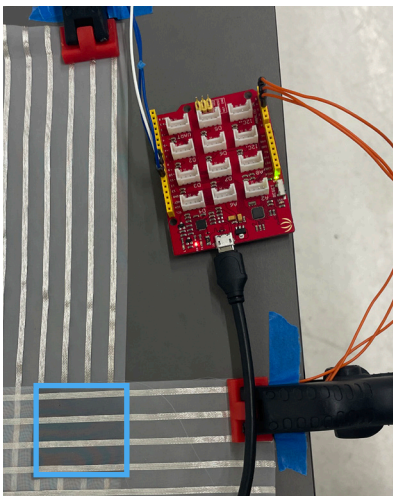


Figure 31. Proof-of-concept setup, with active sensor area in blue square

Proof-of-Concept Setup

Sheets of the Sensing Skin fabric were placed above and below a sheet of Velostat with a 90 degree rotation between them, and clamps used to secure jumper wires to the edges of the electrode strips on the Velostat (Figure 31, left).

Working with this setup enabled software development to begin while further materials were sourced. Arduino was chosen as the platform for software development for rapid prototyping. Arduino's internal pull-up resistors were enabled to pull the sensors to 'high' (off) when resting. The matrix is configured such that each column is read as an analogue input and each row is interpreted as a digital pin. The matrix is read by isolating one row at a time (setting the row of interest as an output and each other row as an input to effectively momentarily remove them from the circuit) and reading the signal across the columns. This is repeated for every row, assembling a matrix of sensor values. The program scans the matrix rapidly (1000 times per second) so that, to the user, it appears as if with no delay. The basic schematic for wiring is given in Figure 32 below.

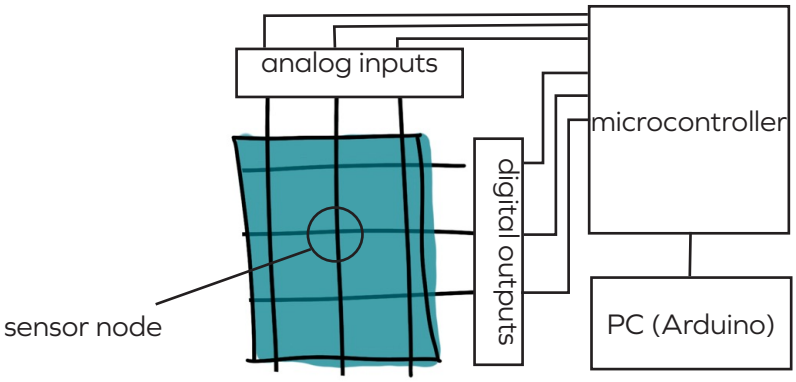


Figure 32. Basic schematic

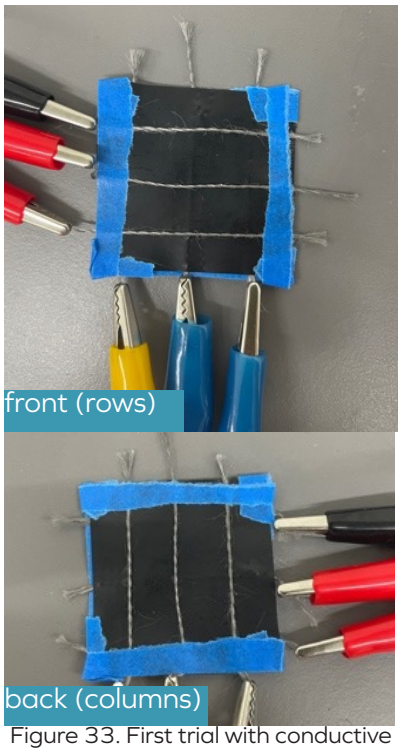


Figure 33. First trial with conductive thread

Flexible Design

The next step in the proof-of-concept phase was replicating the effect of the Sensing Skin using conductive thread, as this would eventually be used in the smart textile.

First, a small 3x3 matrix was constructed by simply attaching thread segments to a piece of Velostat and securing with electrical tape. This prototype can be seen on the left in Figure 33. This was tested to confirm that its performance was comparable to the Sensing Skin. Then a larger matrix was constructed for the purpose of testing its performance in discussion with a CPO and on a soft surface. This prototype featured a wider top section to cover the condyles of the knee, as this is an important location for applied pressure while creating 'the box' as discussed in Chapter 2:

Analysis. This prototype can be seen below in Figure 34a, and on a model knee in Figure 34b.

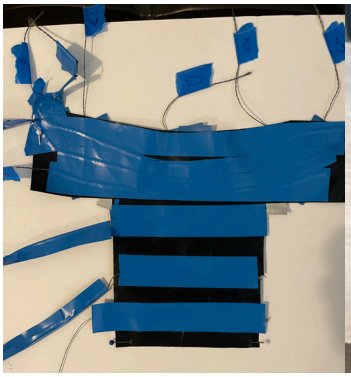


Figure 34a. Larger Velostat prototype, flat

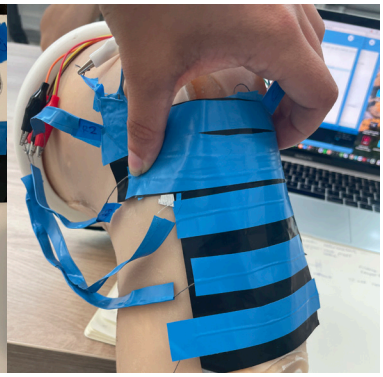


Figure 34b. Larger Velostat prototype, on model knee

CPO Involvement

In this first phase of prototyping, it was extremely important to investigate whether the range of the sensor sensitivty was appropriate for the designed use cases before continuing development. Therefore, a CPO was involved (Figure 35 at right). The CPO was asked to press on the sensor in two ways, first on a hard surface and then against a silicone model leg. This would give an impression of whether the sensitivity was appropriate. He was asked to press on a specified node as hard as he would while plastering. He was asked to repeat this three times to be able to check if the sensor responded similarly and no erroneous result was taken as significant. As seen in the graphs in Figure 36 below, pressing on the soft surface introduced noise into the readings, but the signal is still distinguishable. This would be the focus of later refinement in prototype phase 2. In the discussion following the trial of the prototype, the CPO mentioned that he saw potential for value in both a passive and active interaction with such a system. These recommendations informed the design of the use case interactions described in the final section of the chapter, Interaction Design.

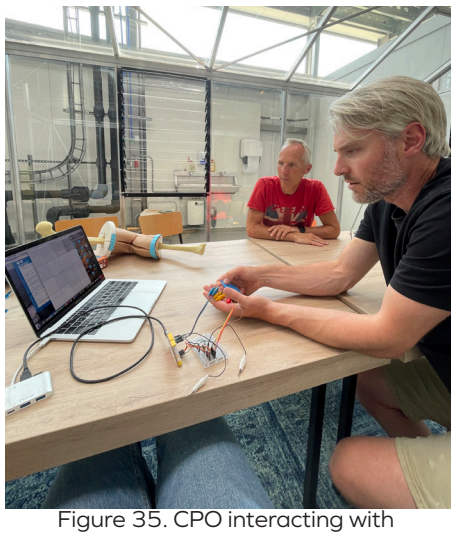


Figure 35. CPO interacting with sensor prototype

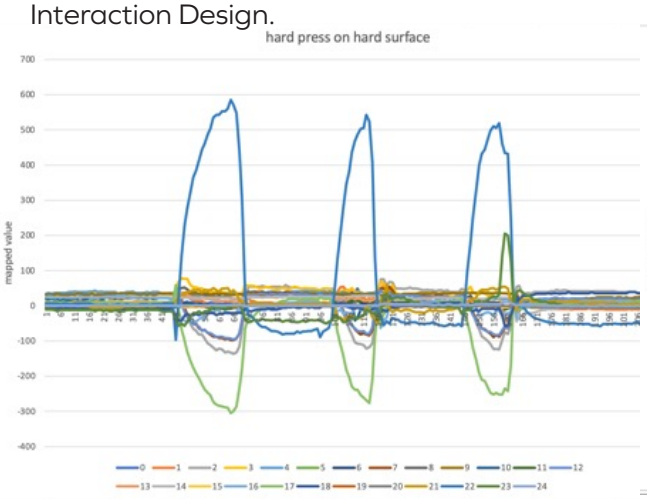


Figure 36a. Press on hard surface

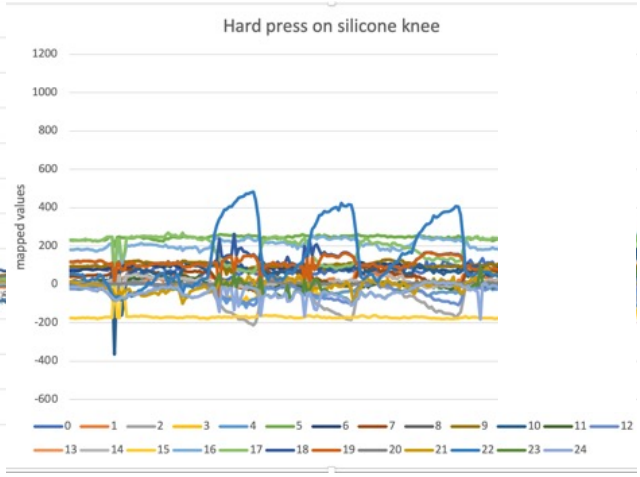


Figure 36b. Press on soft surface

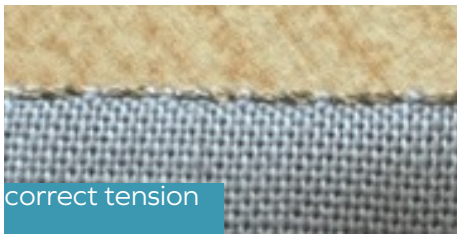
d this
fy?

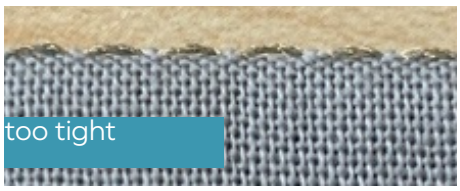
DEVELOPMENT PART 2: SEWING

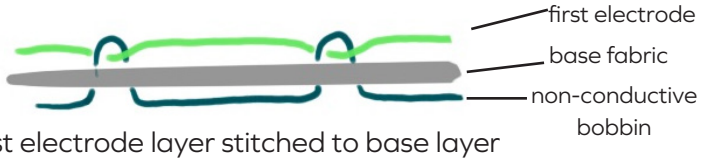
After the working principle was verified using conductive thread held with tape on Velostat, the step was taken to translate this design to a sewn version using a simple woven fabric as the base layer and Velostat or SEFAR Carbotex as the spacer layer. This intermediate step was necessary towards the goal of a sewn, stretchable version.

Construction Principle

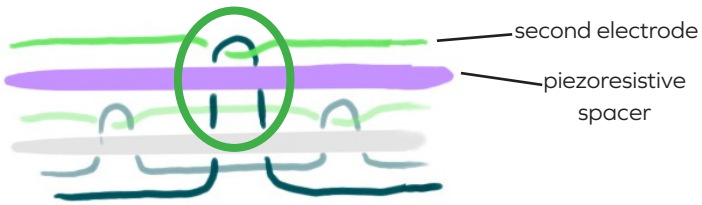
Constructing the sensor using a sewing machine requires two operations. First, one layer of electrodes (rows or columns) is stitched onto the base fabric using a non-conductive bobbin thread. Then, the spacing layer is attached and the second layer of electrodes is stitched, passing through both layers of fabric. This principle relies on tuning the tension of the conductive thread. When the non-conductive thread is loose enough, the second layer of conductive stiches should not ever pass thrugh the piezoresistive layer, which would render that sensor node invalid. This principle is illustrated in In Figure 37 below. Examples of a sewn electrode with correct tension and too tight is shown to the left in Figure 37.



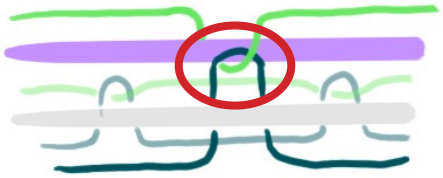




First electrode layer stitched to base layer



Second electrode layer added: good tension
(electrodes always separated by spacer)



Second electrode layer added: too tight
(electrodes touching always, node invalid)

Figure 37. Illustration of construction principle

Construction

In practice, it took many trials to achieve the correct thread tension as described in the previos section, and an orderly mapping of threads to wires. A few of the small prototypes as part of this learning process are shown below in Figure 38.

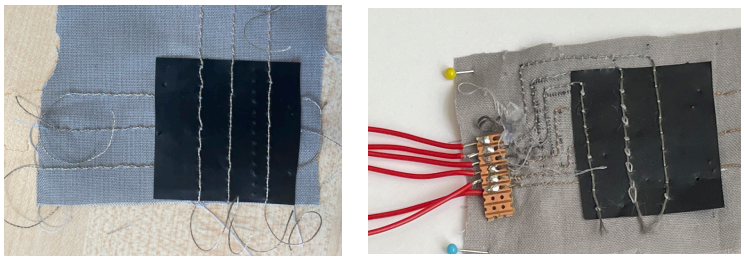


Figure 38. Sewn trial prototypes

Refinements

Thread-to-wire connections

When creating sensors with conductive thread, the challenge arises of needing to interface the conductive thread to wires to be able to integrate with the electronics. The first sewn prototypes were attached to wires using alligator clips as this was the quickest and easiest (Figure 39a, right). However, alligator clips are bulky, not secure, and introduce noise into the readings. Thus, a transition was made to soldering. Protoboard was cut and sewn onto the fabric. Thread was securely wound through a hole, and a wire soldered to the other side of the same conductive rail. This method was more compact, lightweight and sturdy (Figure 39b, right). However, a large matrix constructed with this method (Figure 40 below) gave completely unpredictable and false readings. Upon closer inspection, it was found by using a multimeter that current was passing through neighboring rows via microscopic threads of the conductive thread. So, subsequent iterations featured soldered connections further distanced from each other, to prevent this. Additionally, hot glue was added for extra stability on the soldered joints (Figure 39c, right).

Figure 40. Ambitious large matrix constructed with faulty wire connections

Figure 39a. Alligator clip connections

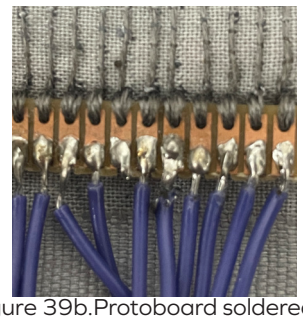


Figure 39b.Protoboard soldered connections (too close)

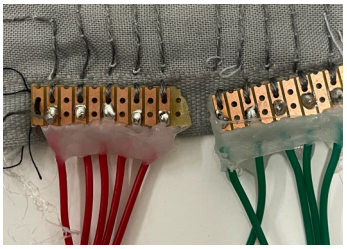


Figure 39c.Protoboard soldered connections (spaced)

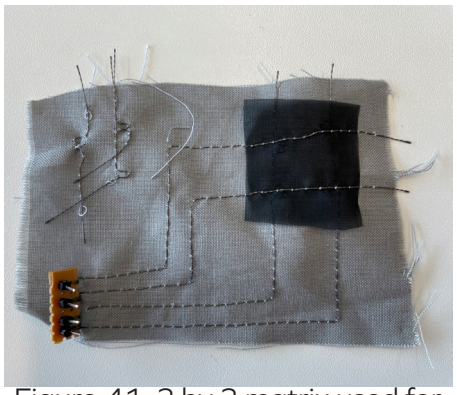


Figure 41. 2 by 2 matrix used for noise reduction

Reducing noise

Minimising noise in the signal is important to ensuring an accurate, interpretable result. Capacitors were added to the analogue signals as shown below in Figure 42. Capacitor value was chosen to remove noise in the form of alternating current of the environment. Additionally, a smoothing filter was added within the Arduino program. This form of noise reduction works by keeping a running total of a set amount of previous sensor values (in this case, 30) and outputting the running average. This removes distracting spikes in the data. These refinements were conducted using a small 2 by 2 matrix (shown in Figure 41 to the left) in order to isolate problems and clealy view node behaviour in the Arduino serial data (a larger matrix becomes crowded to read and interpret).

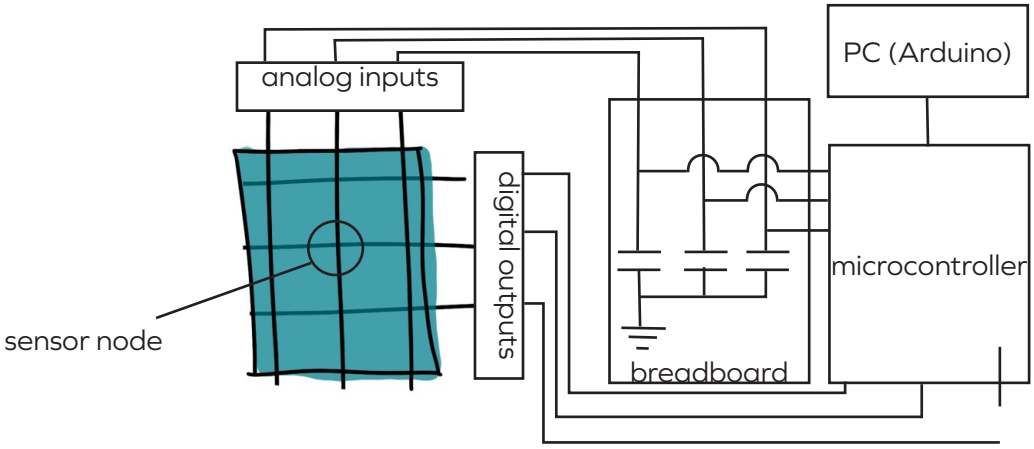


Figure 42. Schematic with capacitors on analog signals

To demonstrate the reduction in noise, the reading without noise-reduction filters are compared against the smoother readings in Figure 44 below. In these tests, the nodes are pressed with one finger, one at a time.

It is interesting to note the tendency of the neighboring node of the same column to react the second strongest next to the pressed node. Especially for column one, this is significant. A possibility for this is that the rows are closer in spacing in column one (see Figure 43 to the right), so a press at the blue node has a larger effect on the grey node). Moving forward into stretch development and interaction development, more care was taken for even spacing of rows and columns, and this issue was not significant.

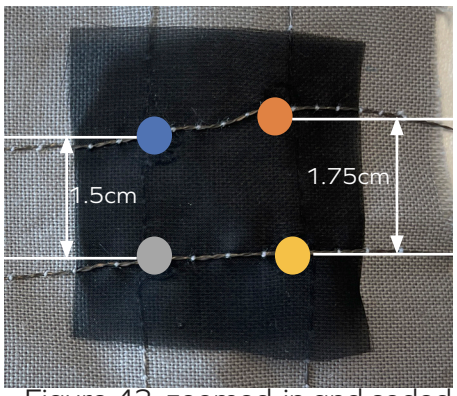


Figure 43. zoomed-in and coded 2 by 2 to match the graphs in Figure X(below)

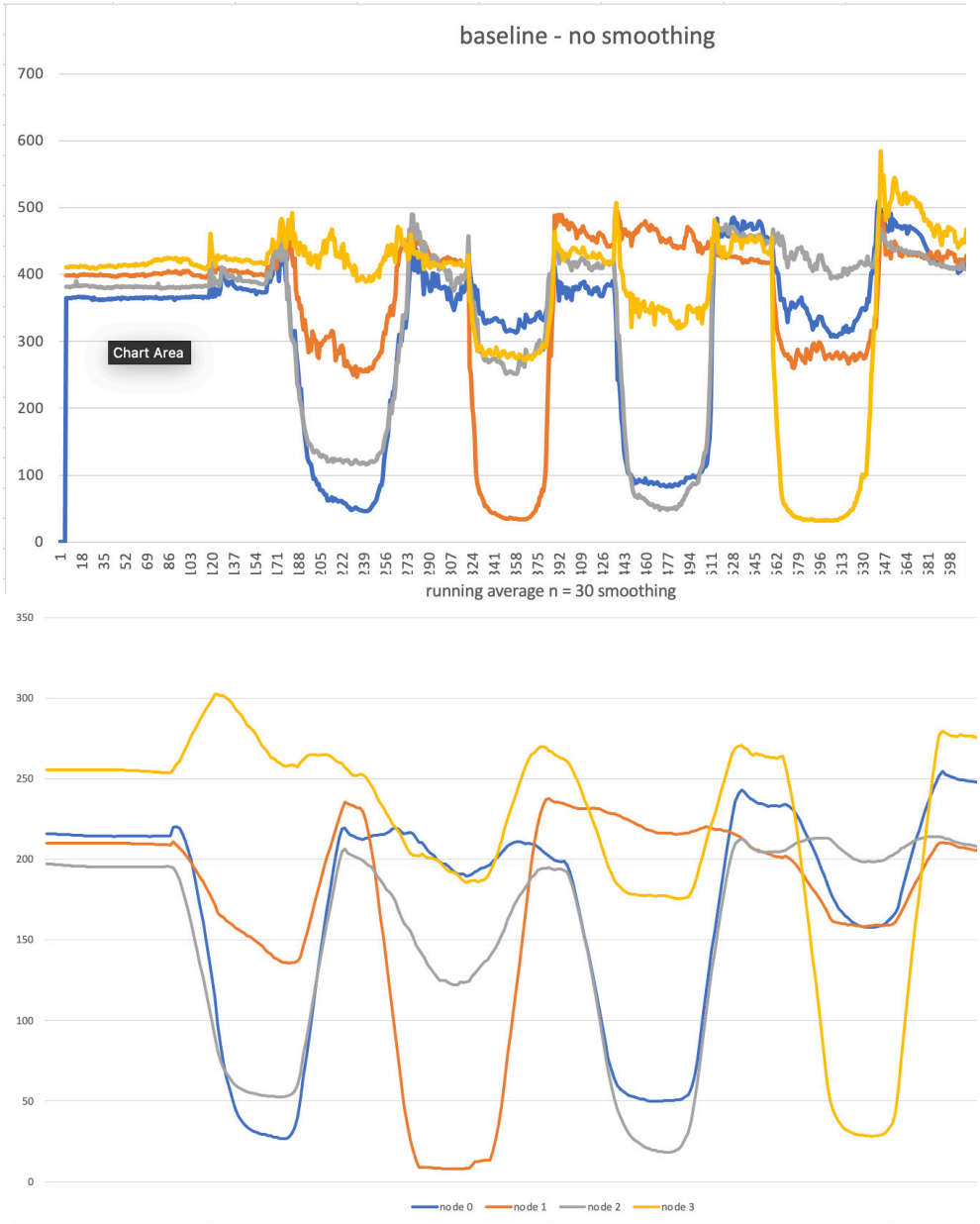


Figure 44. 2 by 2 matrix readings before smoothing (above) and after (below)

DEVELOPMENT PART 3: STRETCH

The final embodiment of the prototype was cretaed with the goal of being usable on a knee for testing with CPOs. A knit fabric was sourced with a dual-sided apperance. This material was chosen for its fine knit (allowing high precision) and appealing aesthetic quality. When cutting and mapping out the sensor, it was important to note that the sensor be constructed with the behaviour of weft knit fabrics in mind: knits exhibit greater stretch across their rows, rather than their columns (Uzzal, 2020). This is illustrated below in Figure 45. Therefore, the orientation of the sensor matrices was always constructed such that row-wise corresponded to the medial-lateral plane.

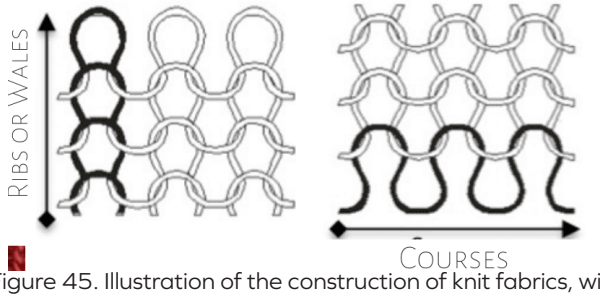


Figure 45. Illustration of the construction of knit fabrics, with the courses direction (right) providing more stretch

Stetch was enabled by using a zig-zag stitch. As the material is stretched, the zig-zag expands. A small sensor patch was constructed to tune the machine tension for zig-zag stitches. The dimensions of the zig-zag stitch are given below in Figure 46.

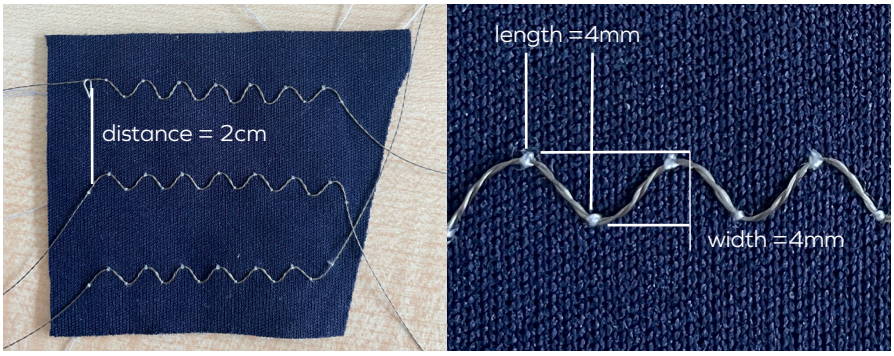


Figure 46. Characteristics of stretchy electrodes

It is important to note that the Carbotex fabric (the chosen spacer layer) is a woven non-elastic. To combat this, the Carbotex was cut between each column, re-enabling stretch in this crucial dimension. This did not effect the operation of the sensors. Demonstration of

a stretch matrix is shown below in Figure 47. In Figure 47a, the prototype is unstretched (neutral state). In 47b, it can be seen how the rows stithch zig-zags allow stretch by expanding in length and contracting in width. The unstretched prototype has a matrix spacing of 2cm by 2cm. With stretch, the x-direction expands to approximately 2.5cm. Contraction in the y-direction is minimal.

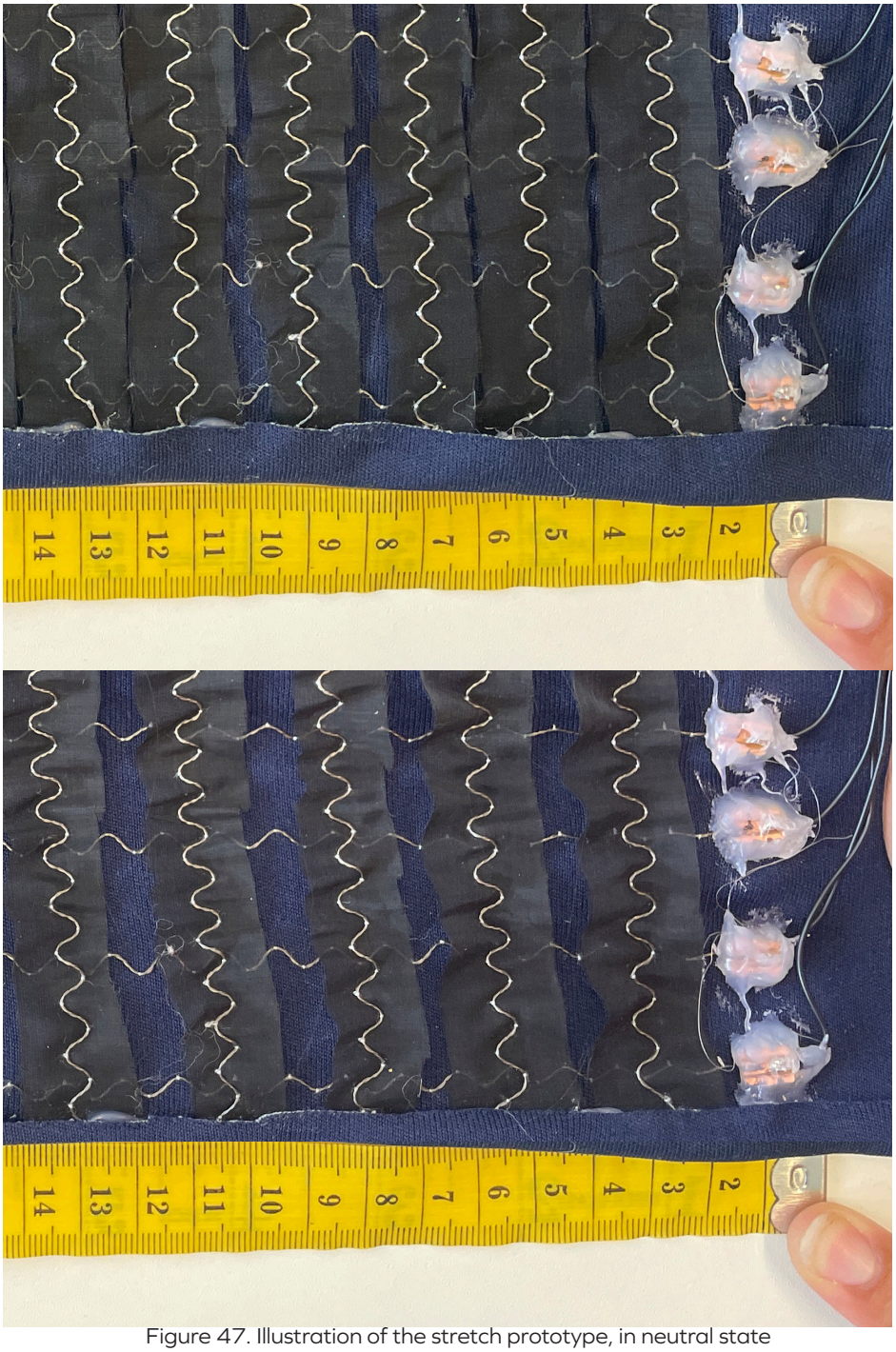


Figure 47. Illustration of the stretch prototype, in neutral state (above) and stretched (below)

DEVELOPMENT PART 4: INTERACTION DESIGN

Attention was given to the method by which force data is visualised. The open-source data visualisation software Processing was chosen as the application in which to develop this interface for its ease of integration with Arduino and widely availabe library. Processing code was developed to input the sensor values as comma-separated values from the serial data output of Arduino. How the interaction code fits into the total setup is given below in Figure 48.

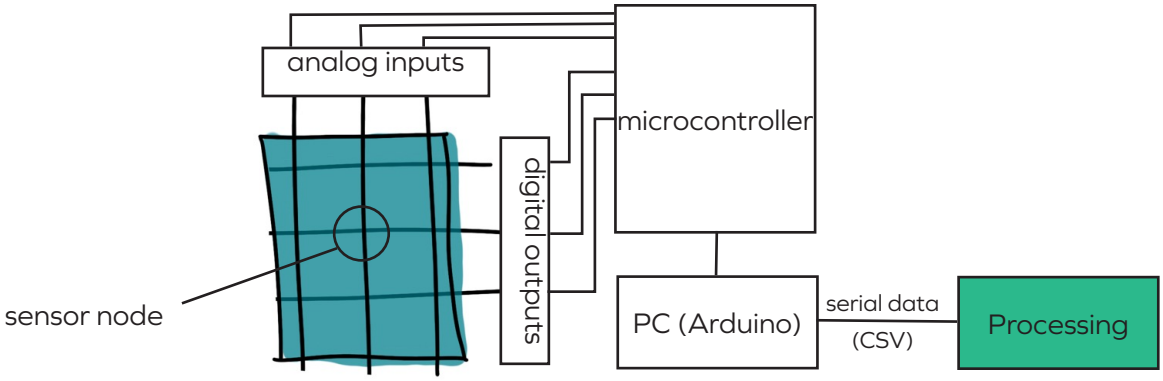


Figure 48. Schematic showing the addition of Processing

The chosen visualisation was to represent the sensor matrix as a grid of squares, and to shade each square from white (neutral, unpressed) to black (fully pressed). The below Figure 49 demonstrates an early prototype which exhibited noise in the neutral state (left) and when registering a node press (right).

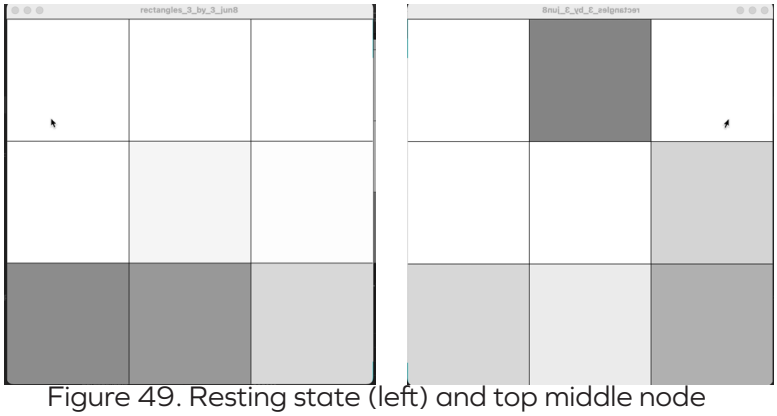


Figure 49. Resting state (left) and top middle node pressed (right) with noise present

Change in shade vs. change in shape

Discussions and demonstrations with co-workers at Gyromotics, as well as with a CPO from Frank Jol, brought up the cognitive misalignment between the sensor's physical functioning and how it was being mapped visually. Co-workers assumed the sensitive areas were the squares formed between pairs of perpendicular electrode rails, in accordance with the shaded square visualisation presented. To more accurately reflect the sensitive regions as the points at which perpendicular nodes intersect, an alternative visualisation of circles whose radii increased in direct relation to applied force was developed, as seen below in Figure 50.

Figure 50. Visually mapping sensor nodes to visualisation style

FINAL PROTOTYPE: PHYSICAL EMBODIMENT

Figure 51. Final prototype, front view

The realisation phase culminated in the construction of the final PressFit prototype for the purpose of evaluating with CPOs.

The final prototype was sized in order to fit on the model knee and on the designer's leg in preparation for user testing (seen in Figures 51 and 53 on the left). Sensor nodes were spaced 2cm apart for a total of 14 columns and 9 rows to balance density and complexity. Velcro strips were added to secure PressFit around the knee, and allow for small adaptations to larger or smaller legs. The dimensions of the sensor matrix are shown below in Figure 52. This is sufficient to cover many of the areas of applied pressure during plastering, namely the shin, the patellar region, and the femoral condyles.

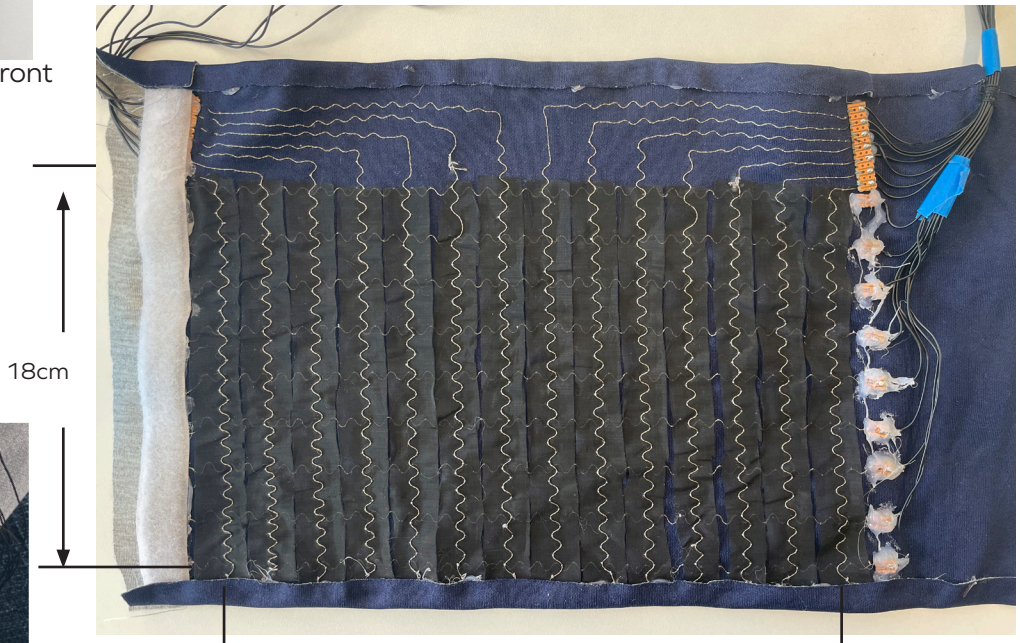


Figure 52. Dimensions of final prototype

Figure 53. Final prototype,on knee region

Calibration Function

The delivered prototype of PressFit features a calibration function. This function allows the user (a CPO) to make the system more or less sensitive in real-time by pressing the 'up' arrow key (more sensitive) or the 'down' arrow key (less sensitive). This is critical as the feedback provided by the tool is only useful if indeed the 'target' pressure aligns with the actual target pressure as defined by an experienced CPO. This feature is utilised in the Evaluation chapter to calibrate the sensitvity according the expertise of Frank Jol. Recommendations for the calibration function are provided in the final chapter.

Electronics Organisation

To prepare the prototype for user testing, the electronics were oragnized by desinging and 3D printing a case for the breadboard and microcontroller, seen in Figure 54 below. All wires were routed through one hole in the box. This greatly improved the aesthetic appearance which could positively influence perception of the tool, as well as increasing the robustness of the setup aganist movement and travel.

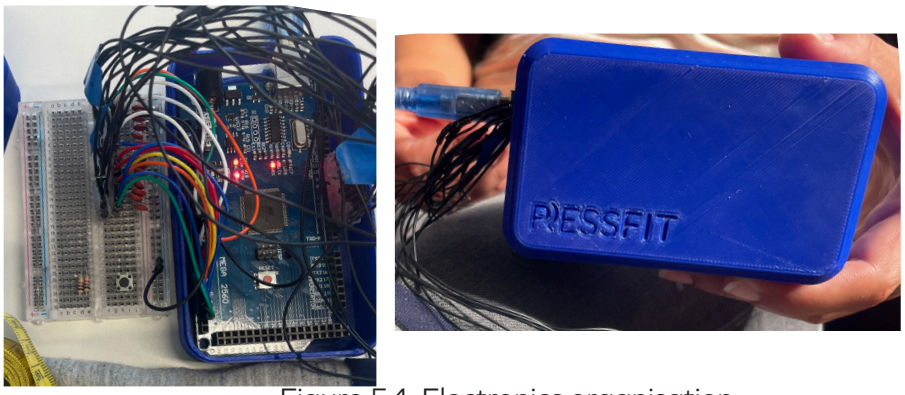


Figure 54. Electronics organisation

Limitations

Although care was taken that the sensor rows and columns be stitched as identically as possible (so that all nodes looked identical) inaccuracy as small as 2mm means that the row and column 'waves' line up out-of-phase. This does not have a dramatic effect on sensor performance but is important to consider in any further development of the design. Stitching with an embrodery machine could eliminate any error this introduces. A short investigation on embroidery machine usage was conducted and can be found in Appendix 10.

FINAL PROTOTYPE: USE CASE VISUALISATION

The basis for both use case visualisations is a flat 2D projection of the PressFit area, with an image or the right or left knee bones displayed in the center.

Measuring

The interaction for Measuring Mode is outlined below in Figure X, using screenshots from the Processing code mapped to actions on the residual limb. In this use case, if a majority of nodes in a given row are registered as being pressured, visualisation of circumference tightness at that row is triggered. The visualisation darkens in grey until a range specified as the 'target' tightness[6].

[6]The 'target' tightness as in the correct amount of applied pressure as determined and tuned by experienced CPOs using the calibration function mentioned in the previous section.

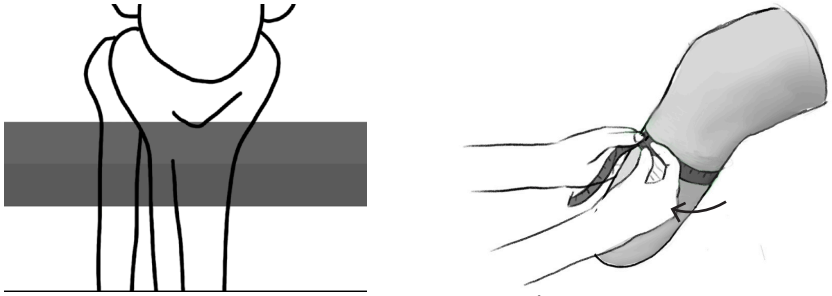


Figure 55a. Measuring - under target

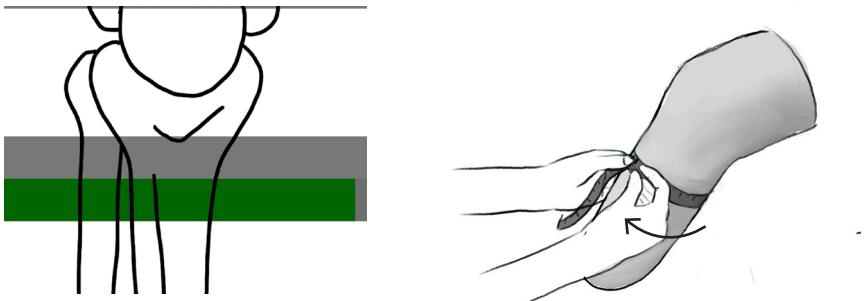


Figure 55b. Measuring - at target

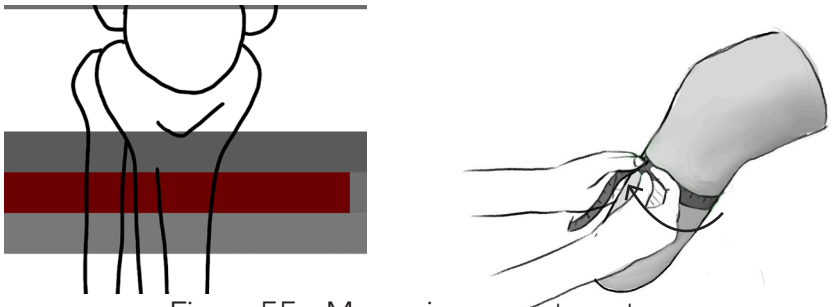


Figure 55c. Measuring - over target

Plastering

For the plastering scenario, the goal of the visualisation is to visualise to CPO and patient where pressure is being applied, and indicate progress towards the target pressure[IFX], and when the applied pressure becomes too much. Towards this goal, a combination in visualisation styles between the shade-varying squares and radii-varying circles was chosen. With this, the bounds of the square could represent the target applied pressure, thereby giving a visual indication of how much harder the CPO needed to press to achieve the correct force. This interaction concept for a singular node is shown below in Figure 56.

[1]Again, the target pressure as tuned using the calibration function with an experienced CPO.

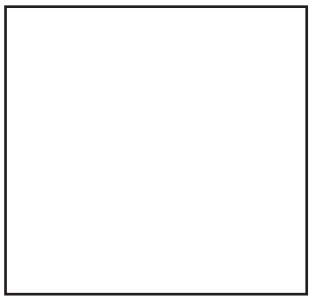


Figure 56a. blank node: no applied force

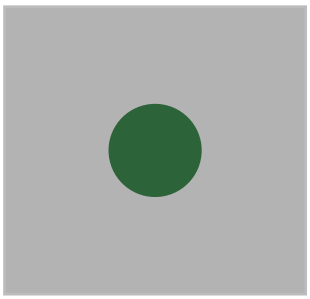


Figure 56b. grey node, small circle: pressure applied under target

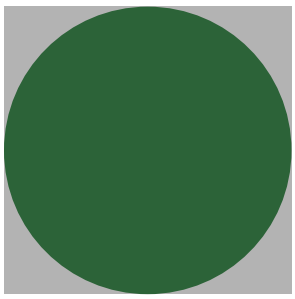


Figure 56c. grey node, circle circumscribed: target pressure reached

When applied globally to all nodes of PressFit, the interaction can be seen as below in Figure 57, a screenshots of the prototype. In this moment, pressure is applied at the distal end of the patella and on the sides of the leg (shaping the 'triangle').

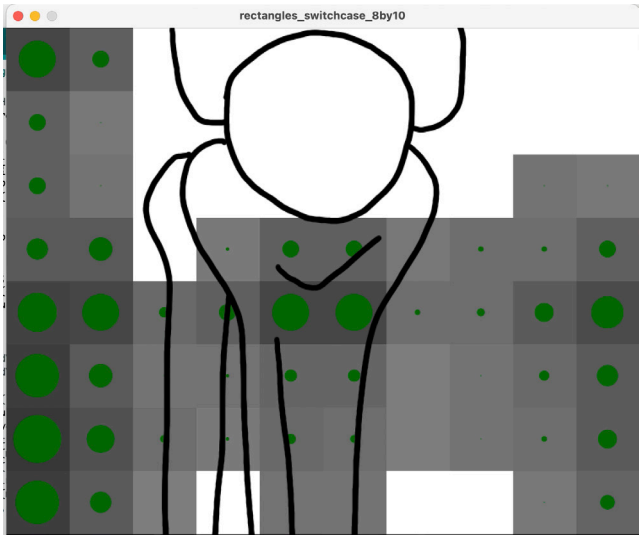


Figure 57. Applied pressure in plastering mode

5

Evaluation

This chapter details the evaluation test with CPOs at Frank Jol. First, the evaluation goal, setup and pilot test are discussed. Then, the method is detailed for both Measurement Mode and Plastering Mode. Results are then presented. Finally, the results are discussed and limitions of the study addressed, coupled with suggestions for mitigating them.

Evaluation Aim

The goal of the evaluation was to assess the performance of both designed use cases of PressFit against the design drivers, and receive feedback to inform further development after the conclusion of the graduation.

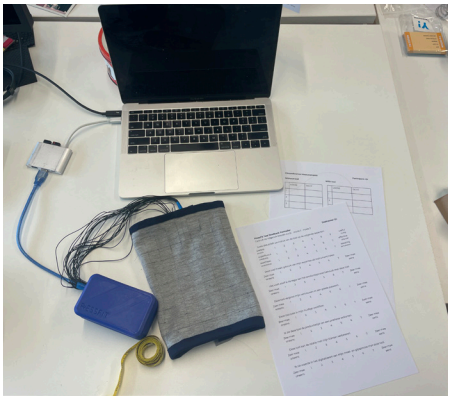


Figure 58. Evaluation materials

Setup & Materials

The evaluation was conducted using the version of PressFit described at the conclusion of Chapter 4. This consisted of the textile sleeve, the electronics contained in the 3D printed housing, and the laptop running the software applications. Additional materials were a measuring tape and printed evaluation forms. All materials are displayed to the left in Figure 58.

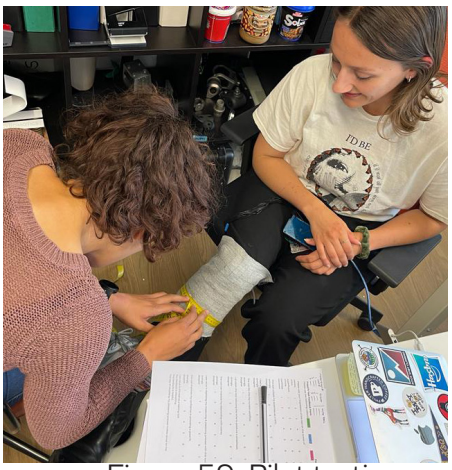


Figure 59. Pilot testing at Gyromotics

Pilot Testing

Calibrating at Frank Jol. Before the evaluation was designed, the protoytpe was brought to Frank Jol for calibration and adjusting. As the lead CPO at Frank Jol and having the most experience, Frank Jol was involved. For the measuring mode, he was asked to measure the stump circumference tightly and loosely according to his knowledge. The sensitivity of PressFit was adjusted in real-time using the in-built calibration function until the interface showed green for his applied tightnesses. One takeaway from this was that the evaluation should be conducted on an aßctual limb, not on the silicone leg, as the CPOs noted the lack of patella affected their ability to apply pressure correctly and accurately. Because the test involves manipulations around the patella and shin, it was decided the test could be executed on an intact limb.

Pilot testing at Gyromotics. A pilot test following the designed procedure was conducted with two coworkers at Gyromotics (seen in Figure 59 at left). The outcome of this test was small adjustments to be made to the prototype before the actual tests. These included lengthening the wires between PressFit and the electronics setup.

Method

Participants

5 employees of Frank Jol participated in the evaluation. As experience in the job was discovered in the analysis phase to have an effect on confidence and perspectives, this background information was obtained and can be seen in Table 5 on the left.

Table 5. CPO demographics

Participant ID	Experience as CPO
1	experienced (20+ yrs)
2	new (< 2 yrs)
3	new (< 2 yrs)
4	new (< 2 yrs)
5	experienced (10 + yrs)

Procedure

Measurement Mode

Performance of the tool in Measurement Mode consisted of a quantitative trial, followed by a qualitative assessment. The quantitative assessment consisted of a measuring exercise wherein the CPO was asked to perform two series of circumference measurements. First, the participant was instructed to measure the circumference the leg at a given location six times, alternating between "tight" and "loose" tensions as they perceived it. The particpant was provided with a sheet to record the measurements. Then, the participant was asked to repeat this, with the addition of the PressFit tool visualisation. This can be seen to the right in Figure 60. The participant was not instructed how the tool informed the participant of when the correct tightness was reached in order to assess whether this feedback was intuitive.

Qualitatively, the participant was asked to fill out a questionnaire following use of the tool which presented statements on a 7-point Likert scale assessing his or her perception of the tool and perceived usefulness. A short follow-up interview was also conducted regrading their experience. Usefulness was assessed using elements from the Acceptance Scale developed by Van der Laan et al. (1997) for assessing the acceptance of new technologies. The questionnaire was translated and provided in Dutch with the consult of Gyromotics colleagues.

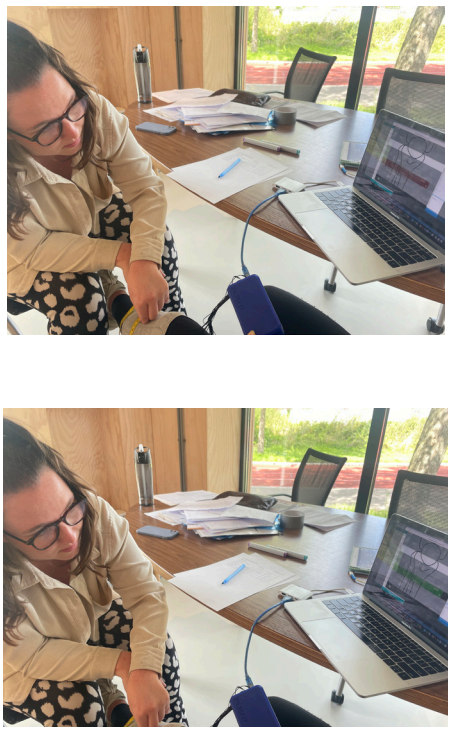


Figure 60. Participant using Measuring Mode. Too tight (above) and correct (below)

Plastering Mode

The evaluation of Plastering Mode consisted of a qualitative trial following a short verbal introduction of the purpose of this mode. The participant was asked to use the tool by applying pressure to the leg as they would when plastering until they determined they were pressing "hard enough" as the feedback from the tool informed them. This interaction is shown to the right in Figure 61. After this trial, the qualitative questionnaire and interview was repeated.

Figure 61. Participant using Plastering Mode

Data caputre

Due to the limitations of the prototype setup, serial data from Arduino could not be sent to Processing for visualisation and an additional application for data storage for later processing. So, participants' results were stored through screen recordings. Additionally, for measurement mode, quantitative data of circumference measurements was collected .

Results

Quantitative Results

The quantitative results from Measurement Mode were plotted in Figure 62 below to visualise the difference in precision and accuracy between CPOs with and without assistance from PressFit. The range of measurements for each participant is plotted for each of the four scenarios. Darker colored ranges on the left show the results without PressFit. Lighter toned results on the right show the reduction in range with the feedback from PressFit.

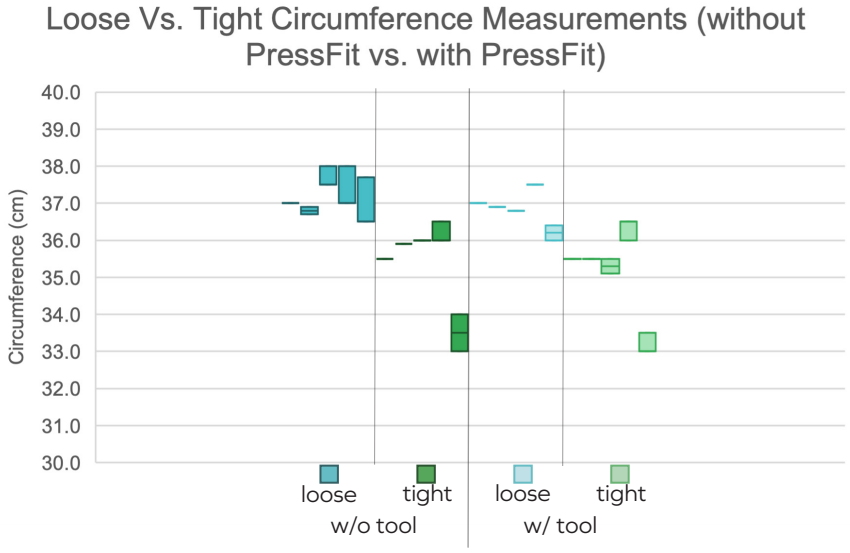


Figure 62. Measurement results plotted

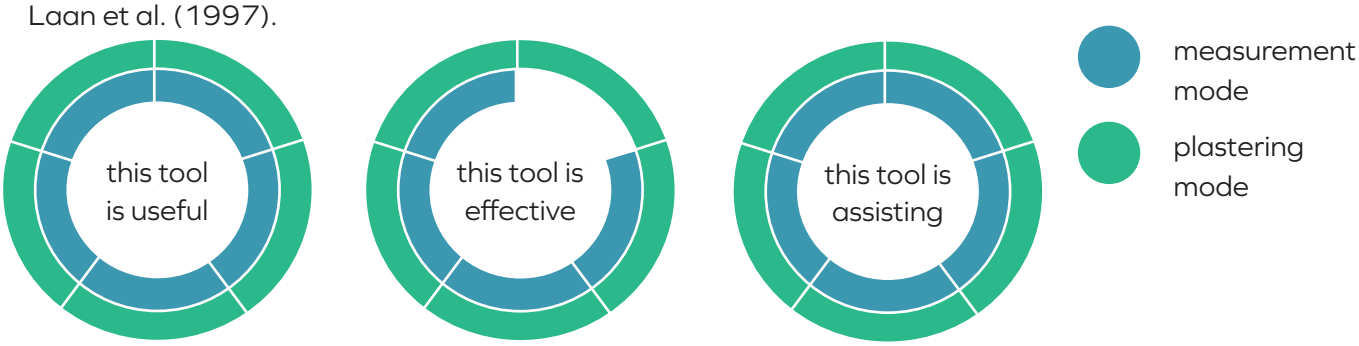
This graph also reveals the lack of accuracy between CPOs. SO, to isolate the precision, results were also normalised to account for lack of accuracy. To do this, the total range of measurements for each participant and the variance calculated for both cases, shown in Table 6 below.

Table 6. Variance of participant results

		1	2	3	4	5	mean	min precision
without tool	loose range (cm)	0.0	0.2	0.5	1.0	1.2	0.6	1.2
	tight range (cm)	0.0	0.0	0.0	0.5	1.0	0.3	1.0
with tool	loose range (cm)	0.0	0.0	0.0	0.0	0.4	**0.1**	**0.4**
	tight range (cm)	0.0	0.0	0.4	0.5	0.5	**0.3**	**0.5**

Qualitative Results

The results from the qualitative questionnaire for both modes are displayed below. Full results are available in Appendix 9. The first grouping correlate to the amount to which the participants accepted the tool according to the Acceptance Scale by Van der Laan et al. (1997).



Agreement on these three criteria indicate that the design has the potential to be accepted by CPOs in both modes.

Design Drivers

Capturing stump data. This design driver was assessed through the quantitative test of Measurement Mode.

Value and utilise CPO expertise. Experienced CPOs expressed that both tools made use of their expertise and handiwork. Newer CPOs disagreed with this statement because they believed they had not yet developed expertise in the practice. Similarly, newer CPOs agreed that the tool would increase their confidence in providing a good fit, but experienced CPOs voiced that they were already confident. All CPOs felt that the tool allowed them to feel in control of the measuring process, and 4 of 5 felt that it allowed them to feel in control of the plastering process.

Simplify production process. Participants did not foresee the tool decreasing the time to produce a prosthesis, but they also did not see it increasing. All participants agreed that both modes fit into their current workflow, thus being easy to adopt. One participant noted the potential for Measurement Mode to eliminate time-consuming rework due to errors.

Standardise production process. The quantitative results point to Measurement Mode beginning to standardise the process. One participant commented positively about Plastering Mode that it would allow for greater transparency and traceability through the process, which is closely tied to standardisation.

Improve patient-CPO communication. All five participants agreed that Plastering Mode would improve their relationship with clients, by providing evidence of why they make certain decisions and apply pressures. Four of five believed Measuring Mode would do the same.

"[this is useful becasue] recorrecting a socket due to measurement errors takes hours!"

-- measurement mode, P5

"You can always follow the path back through, to see where it's going wrong, if it's going wrong. You have more control."

-- plastering mode, P1

"Green is good. Red is also good, when you can explain it"

-- plastering mode, P2

"With this, you can show the customer what you have done and why you have done it"

-- plastering mode, P4

Discussion

Limitations and recommendations

Limitations of the evaluation are presented below, followed by recommended actions to be taken in following iterations to mitigate them.

Experimental setup and researcher involvement

In this study, the researcher was involved as the 'patient'. This limited the researcher's ability to fully observe all participant behaviour. in further studies, a second researcher (or patient) should be involved.

Inaccuracy in measurement location

The liner was doffed between participants in order to allow parrticipants to experience donning the liner. This meant that the placement of the liner on the leg differed as much as a few centimeters (along the proximal-distal axis). This error affected the accuracy of the measurements during Measurement Mode. However, this did not affect the precision of the measurements. Therefore the results in precision as presented above are still taken as valid.

In measurement mode, in addition to registering the tightness of the measurement, PressFit could also be coded to indicate if the CPO is measuring at specific height intervals (for examply, every 2 or 5cm). This could help to eliminate the error expeirenced in this trial of varying interpretations of the same height to be measured. Technical testing could also be conducted to verify repeatability by using PressFit on a rigid cylinder of known diameter.

Intuitiveness of donning

Because the prototype was an open-bottomed cylinder and not a closed-bottom liner as CPOs are used to, it was not obvious how far onto the limb to don the liner, or in what orientation. The orientation of the prototype radially was also not clear. Some participants found it easier to attach it to the leg with the Velcro closure at the anterior side, and assumed that this was then the correct orientation. This confusion does not affect the validity of the results because ease of donning the liner was not assessed on the questionnaire.

This false orientation cue could be eliminated in further prototypes which are built in-the-round as tube (do not need to be fastened onto the leg), and with visual use cues towards the front and back side.

Laboratory environment

It is important to consider these results given they are the outcomes of one trial conducted outside of the actual scenario with a client. Participants may have exhibited bias and respond differently to the tool in an actual apointment, without obvious researcher presence.

It is recommended to test PressFit with patients and CPOs. This would give valuable insights towards the tool's effectiveness in improving communication and trust between CPO and patient.

Sample size & data capture

While the results of this initial exploration are promising, it is important to acknowledge that the small sample sise (n=5) is too small to prove statistical significance. Testing with a larger sample size (n > 20) and standardising exactly where the measurements are being taken will make the results more valid and allow for more quantitative analysis of data. Additionally, to improve rigor, ensuring that all sensor data can be collected quantitatively (instead of just through a screen recording of visualisation which is difficult to parse and interpret), along with being synched to time, would be valuable.

6

Discussion

The final chapter begins by summarising the significant outcomes of the evaluation in a conclusion. Then, recommendations for future work along the avenues of hardware development, software development, and user interface development are presented. The chapter concludes with a personal reflection on the process and project.

CONCLUSIONS

The tested prototype scored high against four of the five design drivers. With implementation of the presented recommendations, there is potential for the design to be validated against all five design drivers. The evaluation also opened up new potential use cases, namely as a training tool for new CPOs.

One of the strongest benefits of PressFit is that it improves the standardisation and traceability of the prosthesis prescription process. This will have value for Frank Jol by allowing multiple CPOs to work on one prosthesis without concern for costly measurement errors, or the need for a physical plaster model. This will enable future expansion towards remote collaboration with CPOs in other countries as Frank Jol expands its customer base throughout Europe.

Another strength of PressFit is its potential to improve patient-CPO communication. This was embodied to an extent for the measuring and plastering use cases, but this potential goes beyond these. The use of PressFit to remotely monitor socket fit during the diagnostic and definitive phases (as described in the envisioned workflow in Chapter 4) could have significant benefits for the patient and Frank Jol. For the patient, it could prevent a bout of immobility brought on by healing a preventable infection, or worse, an expensive surgery. For Frank Jol, it would improve efficiency and save CPO time that previously would have been spent trying to diagnose fit issues in the office.

As this project was largely a proof-of-concept, the most significant conclusion is the elaboration of recommendations for further work, presented in the next section.

Limitations

This project opened up a wide array of technical avenues to pursue to refine and characterise the system. These technical issues were identified and at some points initial tests conducted, however, calibrating the sensitivity of the system to the CPO presses was more relevant and fruitful to the aim of validating the design drivers. It is recommended that first a more consistent, repeatable prototype be built using an embroidery machine, before beginning work to refine the system to specific technical requirements. Suggestions for further work into the technical behaviour of the system is detailed in the Recommendations section.

RECOMMENDATIONS

This project opens up many avenues for further development which will continue to rely on close collaboration between Frank Jol and Gyromotics. In addition to the importance of repeating the evaluation test following the listed improvements, and also testing with CPOs outside of Frank Jol, the following recommendations are posed.

Hardware development

Adding distal end and silicone (towards a liner)

PressFit as built for this project had an open distal end. It is a technical challenge to construct a sensor matrix including a closed distal end to also sense pressures there. Towards this same goal of makig PressFit function as an actual prosthetic liner, another investigation is adding a layer of molded silicone to the inner surface, to see if this is feasible and what effect it has on sensor performance.

Prototyping with embroidery machine

As documented, it took great care and patience to construct prototypes with the sewing machine, as an error of 2mm could be the difference between a valid sensor node and a puncture through the piezoresistive material at the point of intersection. Making use of an embroidery machine would standardise stitch size and tension, as well as allow for more complex stitch patterns. An exploration into using the Janome embroidery machine at the Applied Labs was conducted at the end of the project and a first draft of an embroidery pattern was designed and simulated, but within the time contraints and limited availability of staff at the Applied Labs it was not pursued further within this project. This investigation with more details can be found in Appendix 10.

Embroidery pattern to control stretch

With the precision and complexity enabled by the embroidery machine, it is recommended to explore a stitch pattern such as that shown in Figure 63. This pattern could minize stretch locally surrounding each node, thereby minimizing any decrease in sensitivity caused by stretching the matrix.

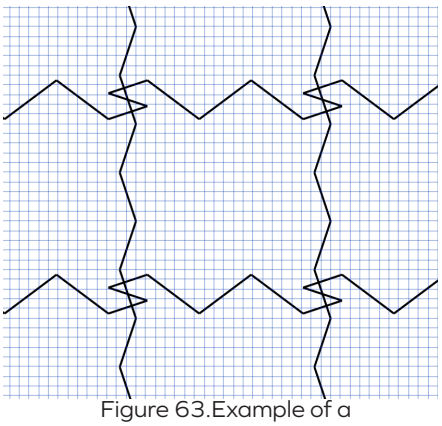


Figure 63.Example of a potential embroidery pattern

Controlled testing

Using (or building) a test rig for assessing sensor node performance would alllow for more controlled testing and optimisation of various sensor parameters.

Materials

SEFAR, the company approached at the beginning of the development phase, expressed interest in continuining to be involved in this project. It is recommended to explore what options they present for designing custom electrodes.

Electronics and software development

Programming and circuitry

Further work can be done to minimize noise in the system, for example by implenting algorithms which examine nearest neighbors to detect if a press is occuring or it is noise. Calibration is also of high importance, including being able to locally tune calibration based on stump region (higher sensitivity/lower target pressure on bony areas). Also, multiplexers can be integrated into the system to reduce wire bulk.

Transitioning the system from Arduino to a more robust programming environment could allow for creating a more stand-alone system that does not rely on a laptop, and can process visualisation and data storage simultaneously. This is also interesting for further development of remote use of PressFit during diagnostic and definitive phases.

Mapping to a digital stump model

As it fits into the envisioned workflow proposed in Chapter 4, it should be investigated how to translate the applied pressure data to an optimised diagnostic socket shape. The pressure data could be mapped over a 3D scan.Markers could be added to PressFit to align nodes with specific anatomical regions virtually. Another question raised through discussion with Gyromotics and Frank Jol is whether applied pressures alone can construct a digital stump model. To this end, it is of interest to see if pressure sensing can be combined with strain sensing, to not only detect force but also deformation.

Advanced visualisation

Within the scope of this project, the interface of PressFIt was limited to one 2D projection of the stump. An improvement is to build this into a 3D representation, or a 2D model with one frontal and two lateral views (shown in Figure 64 to the left).

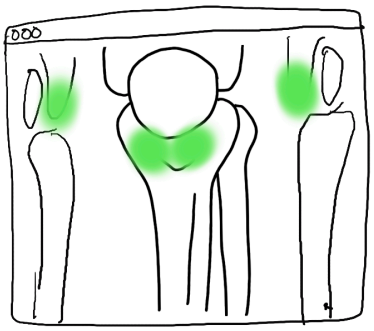


Figure 64.Potential visualisation with two lateral views

User interface development

Client-CPO interface

One avenue of user interface development is further imagining the interface the CPO and client will see during the appointment. As participants in the evaluation expressed, it can improve patient trust to see green icons on a screen during the plastering, to reassure them that what the CPO is doing is good. However, there is a balance between keeping the patient informed and overwhelming them with data.

Feedback types

It is also of interest to investigate adding non-visual feedback to the interactions, as it was noticed during the evaluation that sometimes participants missed when the interactin turned green because their attention was on the stump. Haptic feedback or audio feedback present interesting additions.

App Design

A final user interface area for further work is the app which is envisioned to facilitate communication between the patient and CPO throughout the diagnostic and definitive phases.

PERSONAL REFLECTION

It is amazing to look back at my project brief and realize how different where I finished is from what I anticipated I would be doing at the kickoff of the project. I believe this is a sign that I truly dove into the project context to uncover a challenge that I saw as interesting to approach, instead of taking what was given to me and not adding my own critical take. This project involved large amounts of ambiguity and openness. While stress-inducing, I also appreciated this freedom to take the project in the direction I wanted, and I ran with it. I did not start out knowing I would be building a smart textile. Therefore, I had to be resourceful and agile and learn quickly, and I am walking away with in-depth knowledge on a surprising, fascinating topic.

Throught the project, especially in the research phase and during the pivot from ideation to concept development and prototyping, I found it extremely helpful to seek guidance from experts outside my direct supervisory team. This was especially important as my chair and mentor's expertise did not lie in the field of smart materials. In one meeting with Kaspar Jansen, he questioned why I would even want to use pressure-sensing textiles as opposed to FSRs, for instance. Following interactions like this, I struggled to maintain confidence in my design choices and the validity of my project. But these conversations ultimately helped to shape me into a stronger designer, because having my choices challenged motivated me to better justify them for myself. It was also an important learning exercise in being my own project manager for the first time. I am the expert in my own project, and although I had sought the advice and input of an expert in the field in which I was working, it was up to me to process this insight given all of the context I had.

One of the goals for the graduation project is to gain in-depth knowledge on a specific subject. I jumped into this project with no prior knowledge about prostheses, but quickly found many aspects of the topic extremely fascinating and enjoyed learning from amputees, CPOs, and the employees at Gyromotics. I even sometimes found it difficult to halt research endeavours, such as discovering interesting experiments being conducted in academia. In these cases, it was deadlines which motivated me.

One competency that I listed as already posssessing, but hoping to further build in my graduation, was concept visualisation and sketching. This project definitely reinforced the value of concept visualisation. For one, during the research phase, I decided to visualise the research outcomes in the form of process diagrams and journey maps. Creating these diagrams was very challenging for me, as the processes seemed so complex and

nuanced that I wasn't sure how to "reduce" them to a readable chart. However, after numerous iterations and demonstrations to my supervisors and CPOs at Frank Jol, I came to appreciate that the goal of such visuals is not necessarily to conclude and present everything perfectly, but to elicit responses and spark discussions about certain aspects. Upon presenting my "final" journey maps to employees at Frank Jol, they were very enthusiastic about the value of such visuals to communicate their process to clients, and expressed wanting to even display the visuals in their office.

This project also reinforced the power of visualising concepts during the ideation and development phase, which strengthens my choice for a research through design method. It was my sketches that when shown to a CPO, sparked his creativity and helped the discussion flow.

One of the most challenging aspects of this project was completing it as an individual. Although I am largely an introvert and work well independently and autonomously, as many designers, I find myself getting caught in my own thoughts and stuck in loops if left unchecked. Therefore I involved others in various capacities, such as meeting frequently with a CPO from Frank Jol, attending Graduation Support Community meetings at the faculty, and asking for feedback from my Gyromotics supervisors in between meeting with my TU Delft supervisory team.

In the project brief presented at the kick-off (see Appendix 1), I stated what I hoped to gain in my graduation project in terms of personal ambitions. I wrote of my passion for interacting with users throughout the design process, learning through iterative prototyping, and working with experts in the orthopedic industry. I am proud to look back and see how I have continued along these pathways during this project, and hope to be involved with similar projects in the future.

X

Appendices

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: Dooley
initials: E.R. given name: Erin
student number:
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): IPD / Dfl / SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: Honours Programme Master
specialisation / annotation: Medisign / Tech. in Sustainable Design / Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Arjen Jansen dept. / section: SDE - MM
** mentor: Hilbrand Bodewes dept. / section: HCD
2nd mentor: Guido Hendriks
organisation: Gyromotics B.V.
city: Delft country: NL

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

Procedural Checks - IDE Master Graduation

TU Delft

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Arjen Jansen date 17 - 03 - 2023 signature _____

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: _____ EC

Of which, taking the conditional requirements into account, can be part of the exam programme _____ EC

List of electives obtained before the third semester without approval of the BoE

YES all 1st year master courses passed

NO missing 1st year master courses are:

name _____ date - - signature _____

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name _____ date - - signature _____

Initials & Name E.R. Dooley Student number _____

Title of Project Design of a Personalised Socket and Liner for Below-Knee Prostheses

Personal Project Brief - IDE Master Graduation

TU Delft

Design of a Personalised Socket and Liner for Below-Knee Prostheses — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 06 - 03 - 2023 — 21 - 08 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Gyromotics is a start-up which provides a tunable prosthetic foot to reinstate below-knee amputees with their freedom of movement, considering foremost active users. Their tunable ankle is novel because it allows users to switch easily between an angle comfortable for walking to running, a change which usually requires two separate prostheses.

Below-knee prostheses are typically attached to the stump (leg) by means of a rigid socket and flexible inner liner. Jolutions (Frank Jol) BV, an orthopedic and prosthetic specialist company, collaborate with Gyromotics to provide sockets and liners to patients in combination with Gyromotics' prosthetic foot. Liners are typically made from medical-grade silicone with a fabric coating, and are available in standard sizes. Sockets are currently produced following an analog process, where a plaster cast (negative) is made of the patient's stump, from which a positive model of the stump is created and modified, followed by the formation of the socket around this model.

Current liners are uniform in thickness, therefore not accommodating for irregularities/sensitivities in the stump, which can vary greatly from patient to patient, and for one patient also over time. Additionally, the volume of the stump fluctuates throughout a day. These details have an effect on the fit, comfort and performance of the socket. Patients are fitted for new sockets every few years, and replace liners as frequently as every few months. Current socket and liner methods can be uncomfortable and limiting for the user, and even lead to health problems.

The trend in the medical and broader product world towards ultra-personalised products presents a major opportunity for Gyromotics. Not only will digitising the process of fitting the stump and liner ensure that each patient receives a perfectly fitting, comfortable and enabling product the first time, but it also frees up the process to take place remotely, as the user is no longer required in-person for fitting. Valuable alignment and adjustment data that is currently all stored in physical models will be saved in each patient's digital file, greatly improving the speed of remaking a socket without having to do work twice. Furthermore, leveraging advanced additive manufacturing techniques can enable a more fine-tuned, dynamic socket that complies with the user's unique residual limb ____ (something about empowering the user?) ____ .

space available for images / figures on next page

introduction (continued): space for images

image / figure 1: Gryomotics' product offering, with the project focus (socket + liner) highlighted

image / figure 2: current innovations: Morph fully-3d printed prosthesis (left), Martin Bionics Socket-Less Socket (right)

Personal Project Brief - IDE Master Graduation

TU Delft

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The problem entails how to make the step from a digital model of a patient's stump to a personalised, comfortable, rapidly manufacturable liner and socket. Within this, a main issue to be addressed is finding a reliable, cost-effective production method and material. Personalised manufacturing opens up the world of rapid production techniques, namely 3D printing. However, this poses a large challenge for the liner, which should be flexible, as 3D printing silicones is currently difficult. An investigation into 3D printing and moulding, or combinations thereof, should be explored in the solution.

The scope of the project is not only to evaluate the solution in terms of mechanical performance and cost-effectiveness (feasibility and viability), but also with emphasis on physical ergonomics, user experience and aesthetics (desirability).

Within this problem definition, comfort is prioritised, because the use case of this design is an everyday/"leisure" socket. This will form the basis for later optimising the design for special use cases such as extreme sport.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Develop a method for producing a personalised liner and socket for below-knee prostheses. This method can be applied to a given set of stump data to prescribe a comfortable and secure liner and socket.

The end result will be this method, tested and validated by means of successful implementation for a patient (intake of scan data, generated 3D model of liner and socket, and production of liner and socket, concluding with evaluation on user).

The activities of the project will therefore be to research (user experience and needs, sockets and liners, stump anthropometry, technological possibilities), prototype and test various designs and production methods, and develop a generative approach for the chosen design. Testing with users will also be integral to this process.

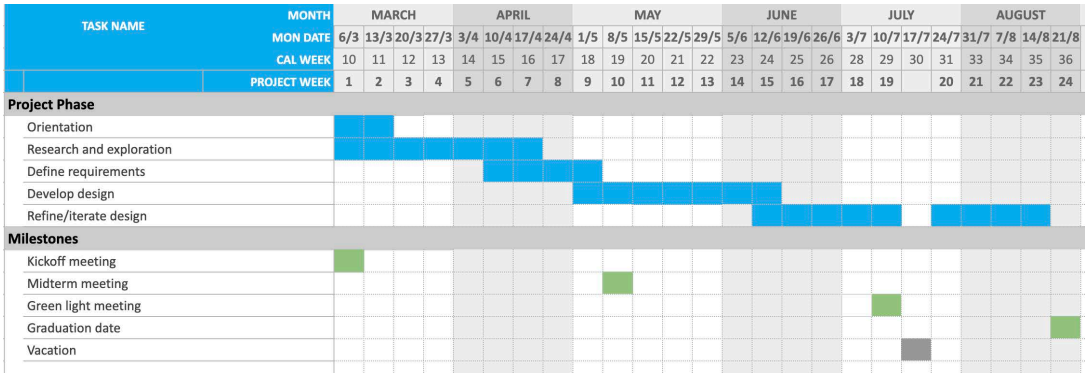
Initials & Name E.R. Dooley Student number

Title of Project Design of a Personalised Socket and Liner for Below-Knee Prostheses

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 6 - 3 - 2023 21 - 8 - 2023 end date



parallel activity during first 4 weeks: TA for Modelling course on Fridays, 13:45 to 15:45.

23 weeks are allotted to create a buffer for national holidays (1.5 weeks) and personal holiday (1.5 weeks).

Tentative graduation is within project week 24 (calendar week 36) to accommodate for scheduling with the supervisory team.

To be delivered at the completion of each phase:
Orientation: detailed planning and research questions
Research and exploration: research analysis report
Define requirements: program of requirements
Develop design: preliminary method and prototype
Refine design: improved method and prototype

Additionally, writing the report will be continuous throughout the project.

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

Although I took the Master Variant for Engineers (MVE) which replaced my elective semester, my experiences in internships throughout my mechanical engineering bachelors', and my AED and ACD projects, have led me to want a medical design graduation project. While interning at Manometric, I discovered my passion for interacting with users at all stages of the design process, learning through iterative prototyping, as well as learning from professionals in the orthopedic industry. I am very excited to explore these further in this project.

Acquired competencies from my MSc (and my bachelors):
- 3D modelling (Fusion 360) around 3D scanned body parts
- mechanical testing/procedure development
- designing for FDM and SLA 3D printing
- conducting user research and ergonomics testing
- concept visualisation and sketching

Additional competencies I hope to acquire and build in this project:
- generative 3D modelling (Rhino and Grasshopper)
- more complex mould design
- co-designing with users
- CAD rendering

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name E.R. Dooley Student number

Title of Project Design of a Personalised Socket and Liner for Below-Knee Prostheses

AMPUTATION PROCEDURE

The following section summarises the research conducted into the process towards a pre-planned amputation. This does not apply the emergency amputation scenario, where the amputation is made to prioritise the patient's life, without consideration for optimal placement or other factors.

When an amputation becomes necessary

The decision to amputate is reserved until all other treatment options have been exhausted, and is made by an interdisciplinary team consisting of a surgeon, rehabilitation doctor and physiotherapist, among others (Federatie Medisch Specialisten, 2020). An amputation becomes necessary when there is either a life-threatening serious infection, excessive tissue death renders a foot impotent (caused by lack of blood flow due to injury or chemical exposure), or the patient is experiencing untreatable pain due to vascular disease (Federatie Medisch Specialisten, 2020).

80% of those who undergo amputations in the Netherlands every year are over the age of 65, and 60% of amputees are male (Federatie Medisch Specialisten, 2020). 95% of amputations are performed due to vascular disease as a complication of diabetes. In younger patients, tumour (malignancy) and accidents are more likely to be reasons for amputation (van amputatie tot prothese, 2023). Of lower-limb amputations, the transtibial amputation is the most comman at 28% of all operations (Paterno et al., 2018).

The amputation procedure takes approximately one hour, and is performed by either an orthopedic surgeon, vascular surgeon or general surgeon (Feenstra, 2023).

Considerations for optimal prosthesis fit

If an amputation is decided, it must be determined what type of amputation will be performed. Towards this, factors such as the patient's age and mobility level before amputation are considered. In the case that a transtibial amputation is decided, the next decision to be made is at what height. This critical measurement results in a trade-off, as a longer stump gives more surface area for prosthesis adhesion (leading to a more secure fit), while also potentially limiting the build height left, that is, the area left between the distal end of the limb and the ground available for constructing the prosthetic system. Again, it is important to note that these considerations are only made if the amputation is pre-meditated. Often in the cases of Frank Jol patients, the amputation is made due to emergency measures following an accident, and therefore the leg is amputated at a height necessitated by saving

the patient's life. This adds to the challenge of fitting prostheses as residual limbs can be much shorter than "optimal" for a good fit.

Performing the amputation

The surgery can be performed by a general surgeon, orthopaedic surgeon, or vascular surgeon. The actual procedure lasts less than an hour (Feenstra, 2023). After the tibia and fibia are severed at the indicated height, remaining muscle is wrapped from the posterior side around the distal end of the severed bone, and sutured to muscle at the anterior side. Then, the tissue and skin flap is wrapped around the muscle flap, and sutured to the anterior side (Coughlan, 2023).

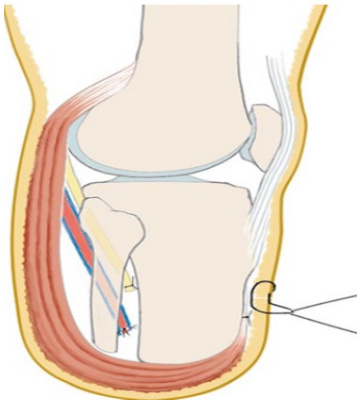


Figure FIXME. Cross-section of the transtibial amputation, illustrating the wrapping of muscle around the distal end of the residual limb, and the location of suturing (Coughlan, 2023).

Recovery (immediately post-operation)

The patient remains in the hospital to be monitored for about a week following the amputation. During this time, it is critical that the stump is washed daily, and that the patient stands and sits frequently to encourage blood flow (thuisarts.nl).

Recovery (rehabilitation)

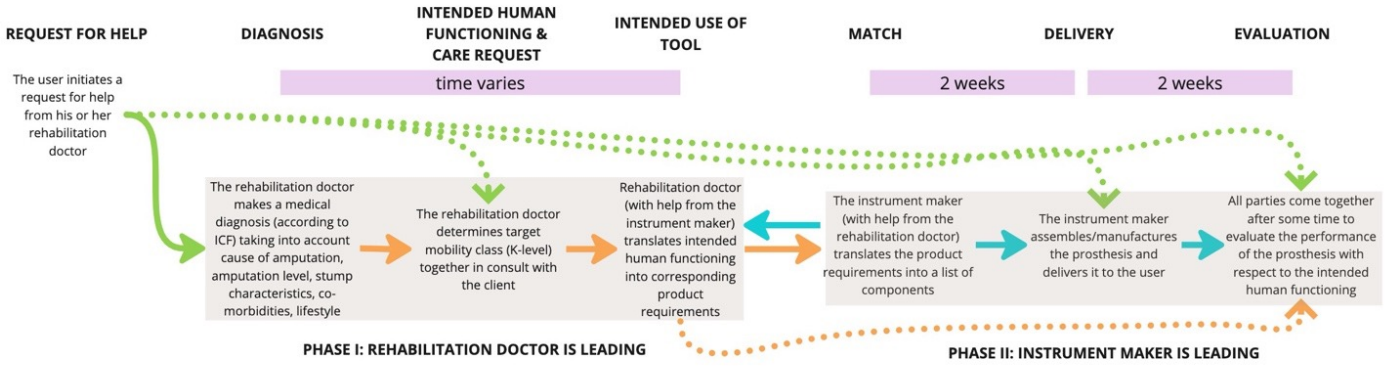
After the wound has healed to the point where the patient can begin to bear weight, he or she begins the journey of rehabilitation in collaboration with the rehabilitation doctor and physiotherapist in order to learn how to go about daily activities with their new residual limb, and how to exercise to maintain muscle.

Within the first few weeks following the amputation, the stump will experience shrinkage on the scale of centimetres circumferentially (I. Schouten, personal communication, 25 April 2023).

A3

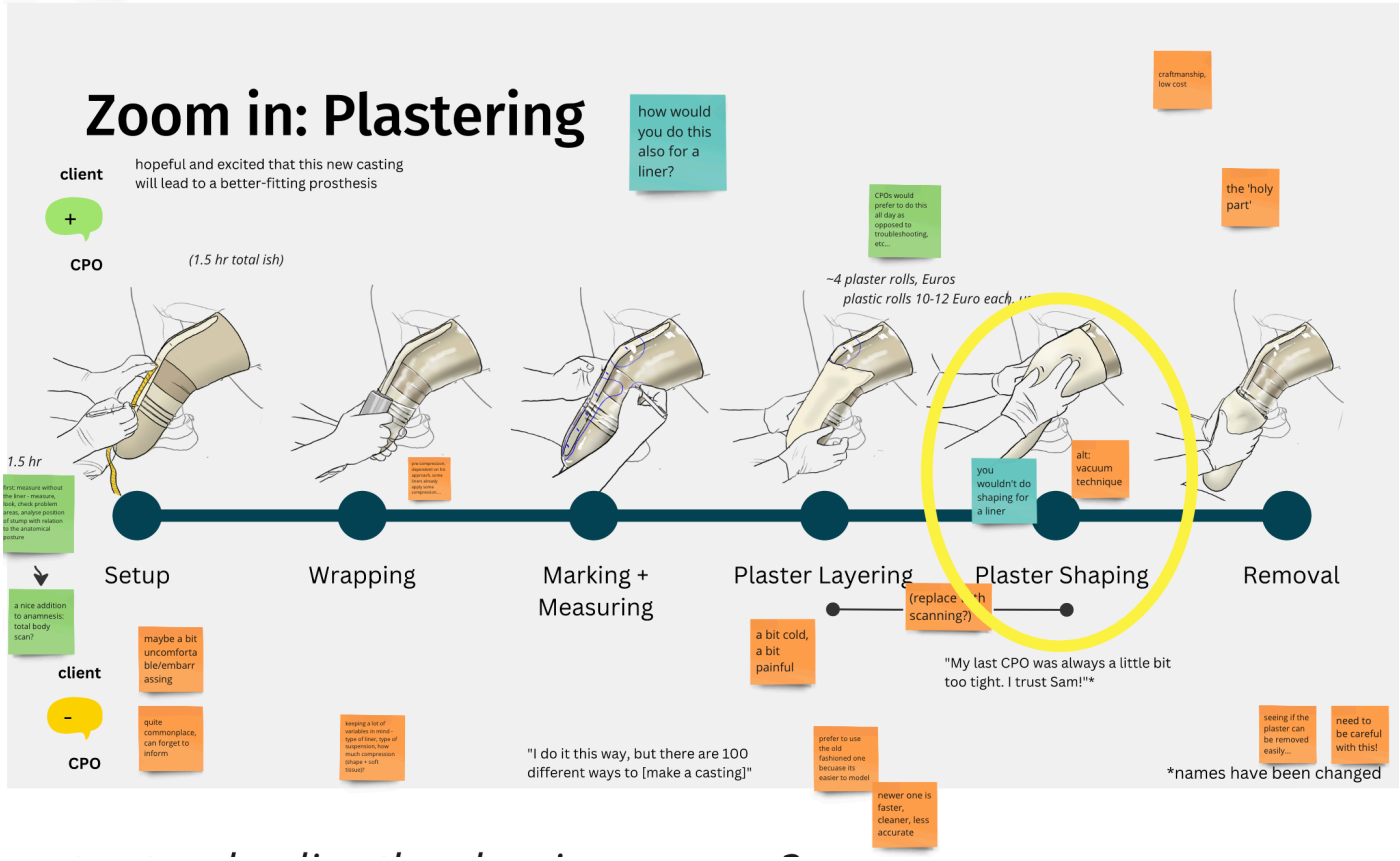
PROSTHESIS PRESCRIPTION

Below lays out the entire prosthesis prescription protocol as indicated by the Stuurgroep PPP (Stuurgroep PPP, 2022).

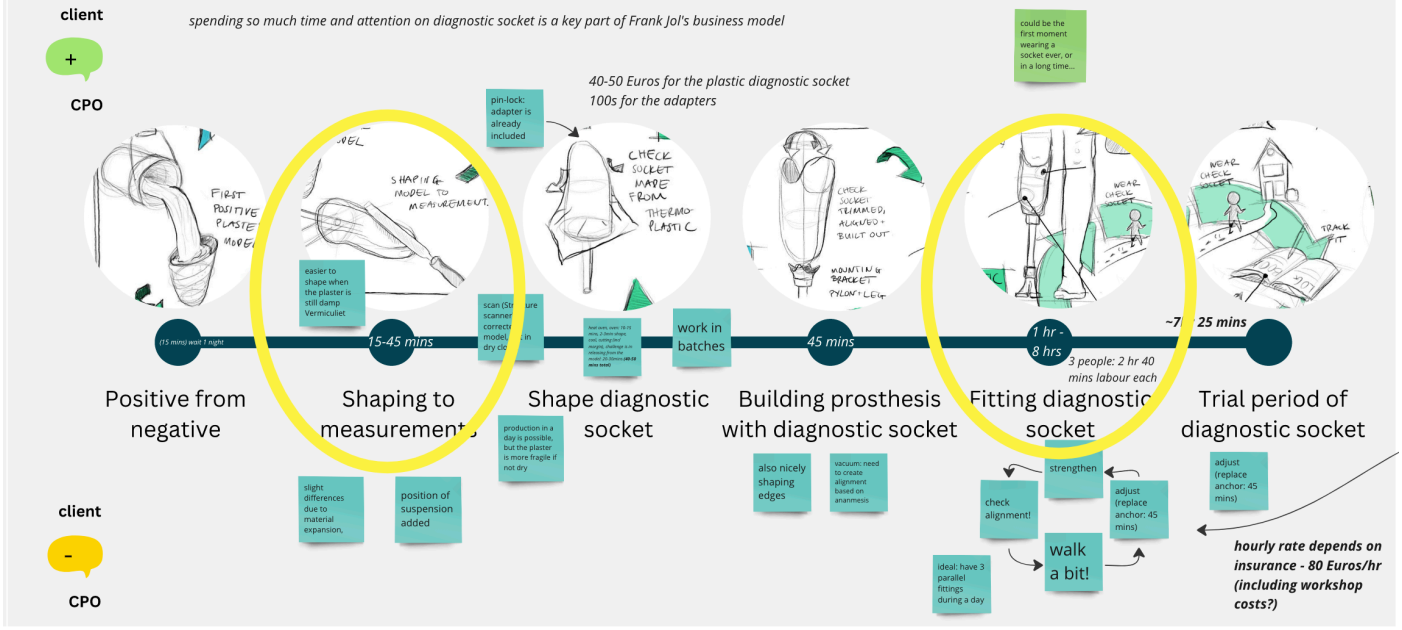


PROCESS MAPS

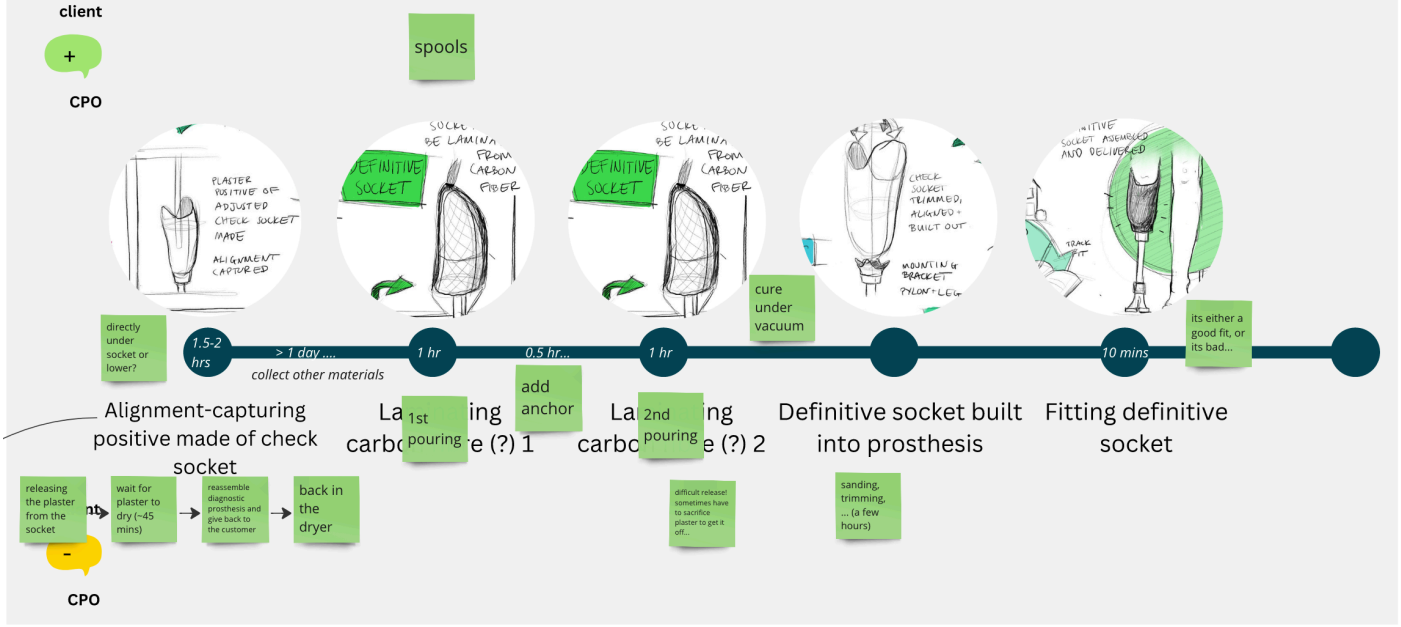
Discussing interim process maps with CPO



Zoom in: Diagnostic Socket

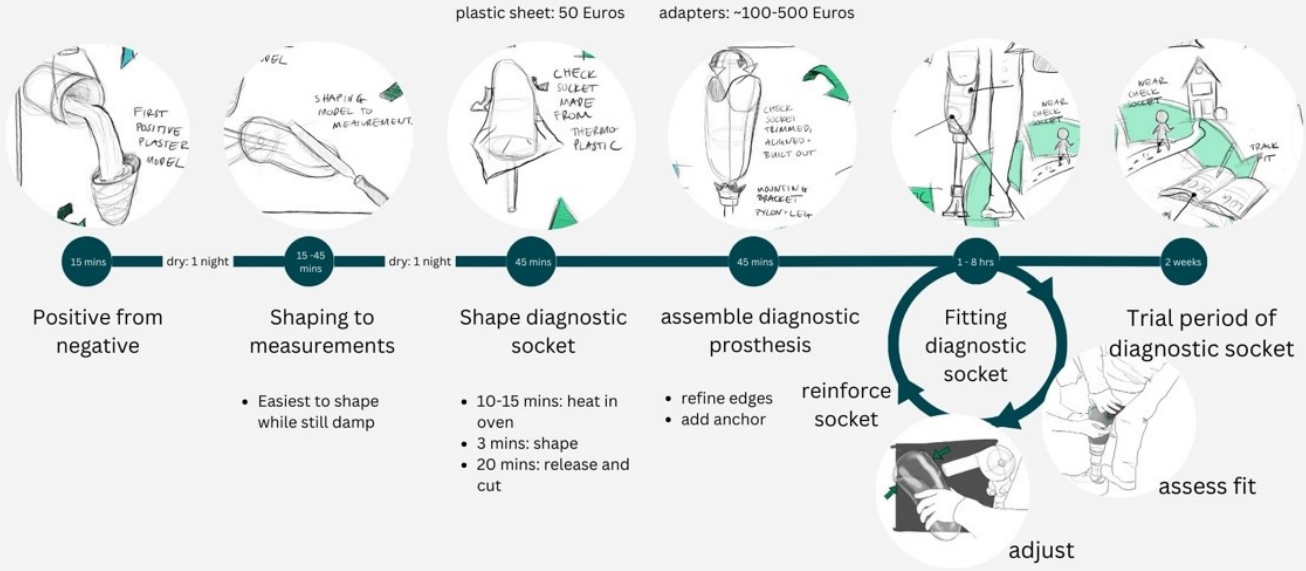


Zoom in: Diagnostic -> Definitive Socket

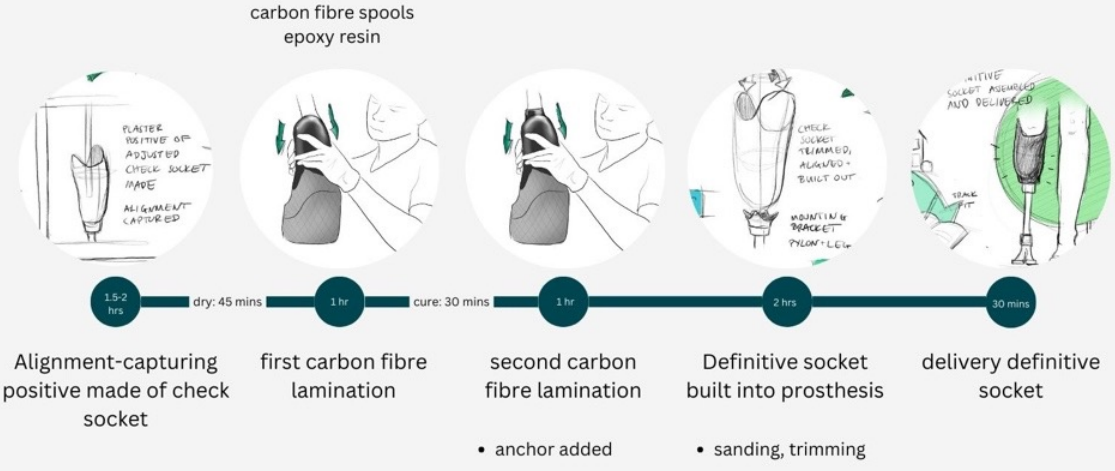


Final process maps

Diagnostic Socket



Definitive Socket



MARKET ANALYSIS

Company/ organisation	Product/project name	Category/s	Commercially available?	Year (most recent)	Material
Click Medical	RevoFit	adjustable socket (BOA)	yes	2023	Carbon fibre
Quorum Prosthetics	Quatro	Adjustable socket, custom socket	yes	2023	Jet fusion 3D printed
Augo (USA)	Augo Control	Adjustable socket, (proprietary), custom socket	yes	2023	3D printed plastics
Ottobock	MyFit TT	Custom socket, workflow intervention	yes	2023	Nylon polyamide 12 powder bed fusion print
Amparo (DE)	Confidence Socket	Workflow intervention	yes	2023	Low-temp thermoplastic
Össur (Worldwide)	Direct Socket TT	Workflow intervention	yes	2023	Laminated carbon fibre
University of Washington	ADAPT Prosthetic Platform	smart system	no	2018	Carbon fibre, spandex, and 3D print
Willowwood (USA)	Willowwood One, LimbLogic	connected system	yes	2023	BLE pump and attachment to socket
MotionTech (CH)	YourLiner	custom liner	yes	2023	3D printed silicone
Willowwood (USA)	Alpha Design	custom liner	yes	2023	Undisclosed production method, silicone, fabric
Blatchford	SilCare Breathe	sweat-management liner	yes	2023	Silicone, fabric

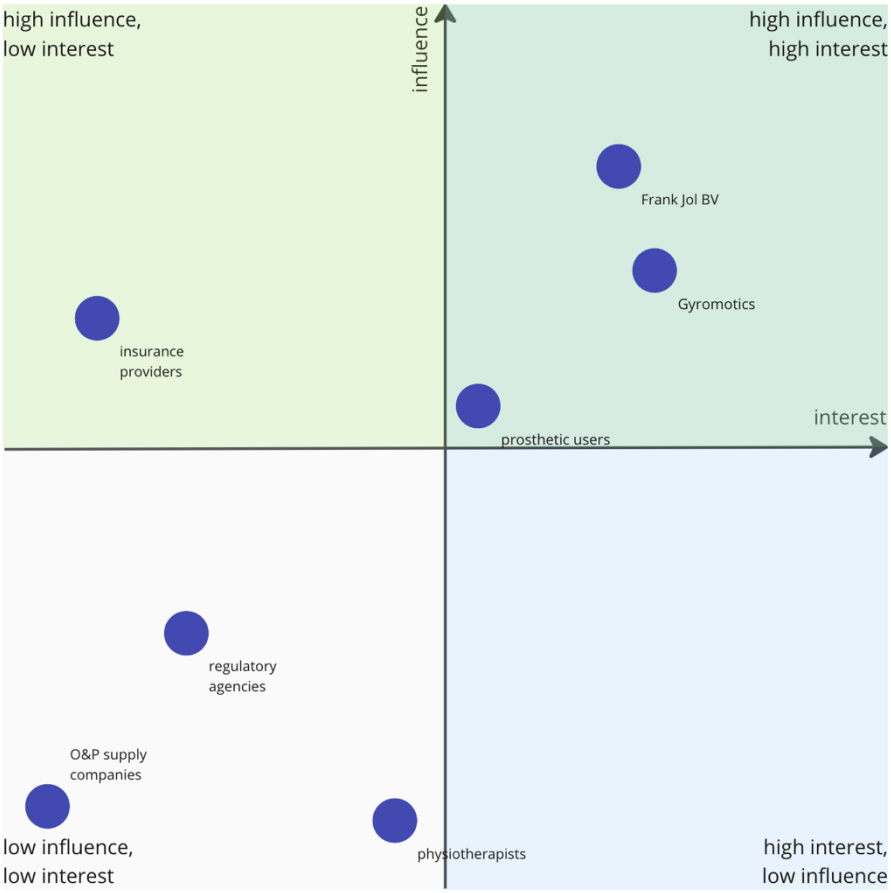
Adjustable sockets

Many new sockets on the market are adjustable-volume sockets, attempting to address the issue of short-term volume fluctuations in the residual limb (Barr et al., 2022). Three companies were found which have integrated BOA systems to achieve an adjustable socket. The BOA system was designed to make tightening snowboarding boots easier and quicker by means of an easy-turn knob added to control the lace tension. Companies either position their offering as a system which CPOs can integrate into their current socket lamination processes, or as a completely separate, stand-alone manufacturing process. In these cases, such as with Augo and Quorum, the adjustable socket is also achieved by involving 3D scanning and printing. Criticism of adjustable sockets is that users can have a tendency to over-tighten them, which can exacerbate existing problems with stump shrinkage (volume decrease)(Paternò et al., 2018).

Connected Sockets

The concept of a connected socket is being heavily explored in research, but is not yet common on the market. One exception is the LimbLogic system by WillowWood, a primary provider of liners in the USA and the Netherlands. LimbLogic allows the CPO to remotely monitor the patient's vacuum level, and allows the user to control the vacuum level with CPO-set limits using a mobile app.

STAKEHOLDER ANALYSIS



A6

INTERVIEWS

PATIENT INTERVIEWS

BACKGROUND

1. Tell me about your prosthesis:
2. Suspension type:
3. [vacuum] [pin-lock] [hybrid] [cushion]
4. Foot type:
5. Liner type:
6. Socket details:
7. How long have you had this socket?
8. How many (total) hours do you wear your leg on a typical day?
   <1 hr 1-3 hrs 3-6 hrs 6-9 hrs 9+ hrs
9. How many (total) hours did you wear your leg (socket) yesterday?
   <1 hr 1-3 hrs 3-6 hrs 6-9 hrs 9+ hrs
10. How many (total) hours did you wear your liner yesterday?
    <1 hr 1-3 hrs 3-6 hrs 6-9 hrs 9+ hrs
11. How long do you wear your leg at once without taking it off?
    <30 mins <1 hr 1-3 hrs 3-6 hrs 6-9 hrs

FIT AND COMFORT

1. How would you describe the fit of your socket?
2. Where do you experience discomfort?
3. Can you demonstrate doffing and donning your prosthesis?
4. **How many times do you estimate you don/doff your leg in a typical day?**
5. Your liner?
6. Can you describe what activities you do on a typical day, from morning to evening?
   Morning
   Afternoon
   Evening
7. **How do you know your leg is fitting well?**
8. Right now, what issues are you experiencing in your leg (liner, socket or foot), if any?
9. What have you done to try to fix this issue, if anything?
10. Has this worked? Why, why not?

11. Are there any issues you experience with your leg (liner, socket or foot) triggered by certain situations? (ex. weather, clothing, time of day, resting vs. activity?)
12. What have you done to try to fix this issue, if anything?
13. Has this worked? Why, why not?
14. Describe your perfect prosthesis?

STUMP

1. How do you take care of your stump?
2. Do you experience volume fluctuations in your stump? What do you do about it, if anything?

LINERS

1. **How often do you change your liner in a typical week? Why?**
2. What different liners do you have?
3. How often do you replace your liners (need to buy new ones)?
4. How do you know you need to replace your liner?

CONCLUSION

1. What else do you find important about wearing a prosthesis that I didn't ask you about?
2. Why do you come to Frank Jol? How is the experience here different?

CPO INTERVIEWS

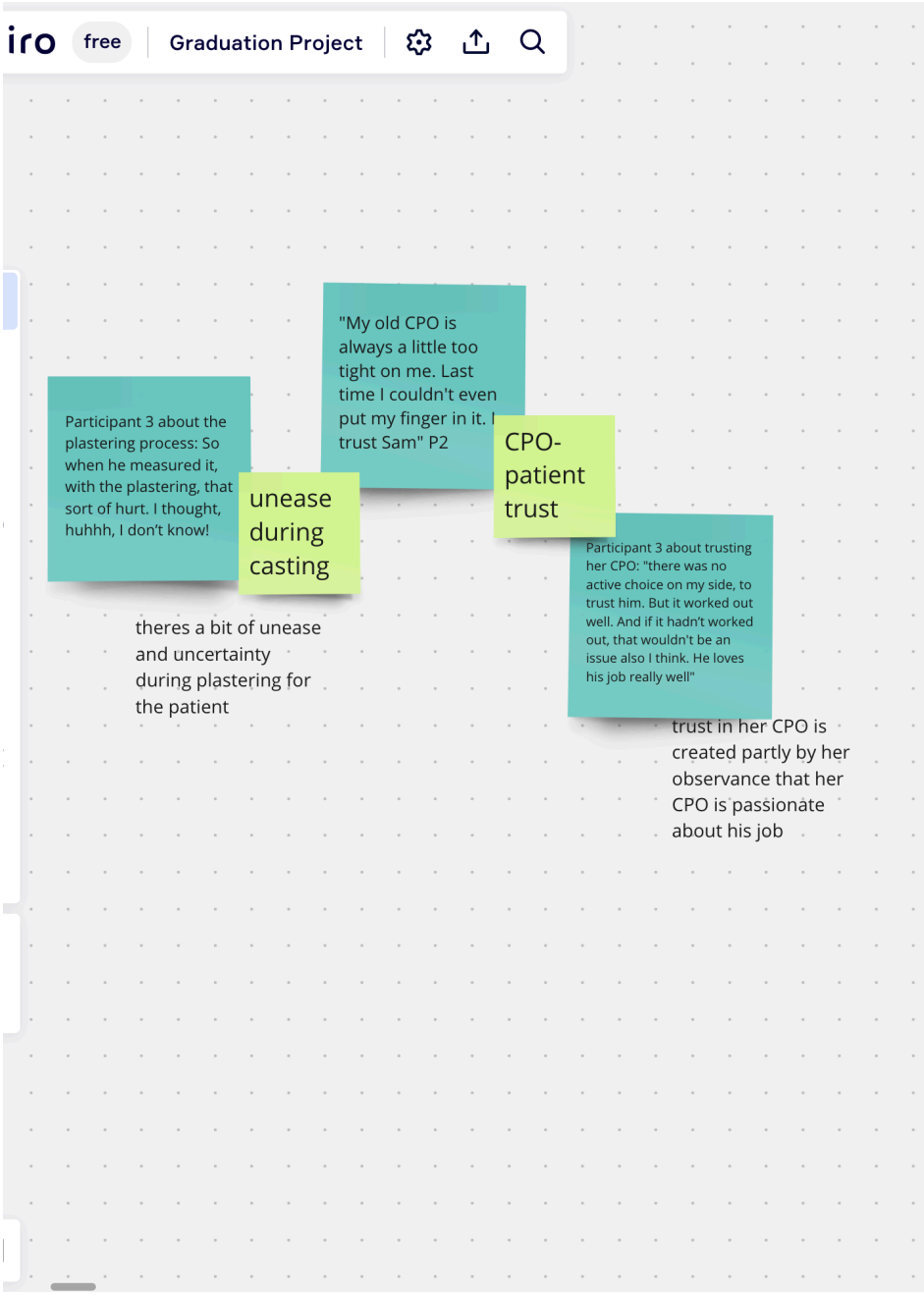
BACKGROUND

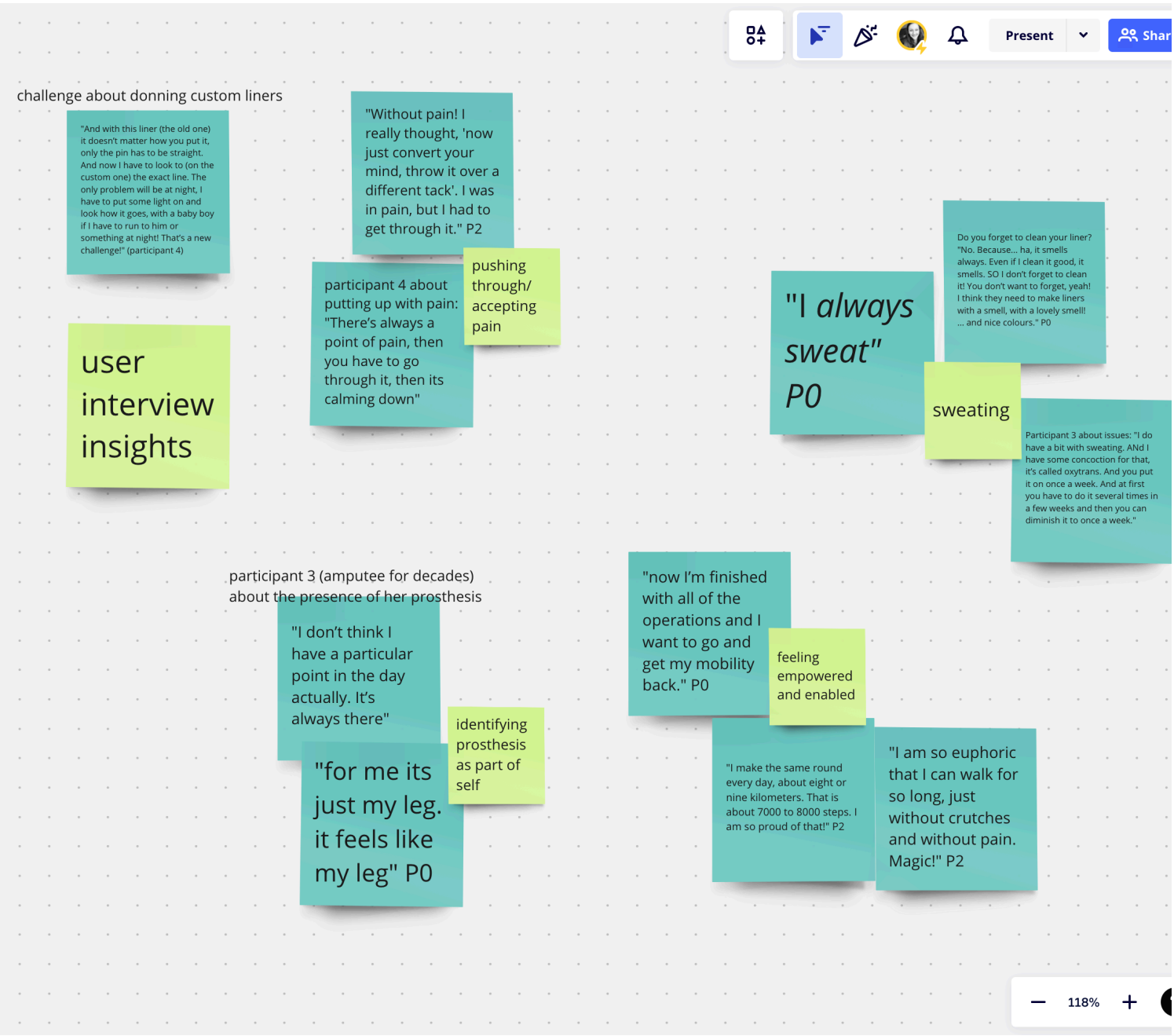
1. Name:
2. Years as CPO:
3. Companies worked for:
4. Can you briefly explain your background and experience?
   Client-facing side
   Production-facing side

PROCESS PERSPECTIVES

5. [I will show them a visual of the process of casting a stump, and ask them] What do you see as the most critical parts of this process? What do you do differently than this?
6. Can you demonstrate your measurement method (of the stump) to me?
7. What is your experience with alternate methods of stump volume capture (water displacement method, etc)?
8. With the direct socket technique?
9. Do you have experience using 3D scanning or other digital methods as a part of the prosthesis prescription process?
10. How do you see digital methods fitting into the prosthesis prescription process, if at all?
11. I have learned that clients can have a lower standard for a 'good fit' than the CPO. How do you see this, and what are some of the aspects that you might notice in socket fit that the client doesn't?
12. About trends in liners:
13. Do you have a preference in what liners you prescribe to clients? (brand, special feature, material?) Why?
14. What patterns do you notice in clients' experiences with liners? (what do they like, not like)
15. When do you choose to prescribe a custom-made liner, if at all? If so, what is your experience?
16. What issues do you encounter in the journey towards getting a client a fitting prosthesis? (socket/liner/foot?)
17. What issues do you encounter when manufacturing sockets?

INTERVIEW CLUSTERING




Present
challenge about donning custom liners
"And with this liner (the old one) it doesn't matter how you put it, only the pin has to be straight. And now I have to look to (on the custom one) the exact line. The only problem will be at night, I have to put some light on and look how it goes, with a baby boy if I have to run to him or something at night! That's a new challenge!" (participant 4)
"Without pain! I really thought, 'now just convert your mind, throw it over a different tack'. I was in pain, but I had to get through it." P2
participant 4 about putting up with pain: "There's always a point of pain, then you have to go through it, then its calming down"
pushing through/ accepting pain
user interview insights
"I always sweat" P0
Do you forget to clean your liner? "No. Because... ha, it smells always. Even if I clean it good, it smells. SO I don't forget to clean it! You don't want to forget, yeah! I think they need to make liners with a smell, with a lovely smell! ... and nice colours." P0
sweating
Participant 3 about issues: "I do have a bit with sweating. ANd I have some concoction for that, it's called oxytrans. And you put it on once a week. And at first you have to do it several times in a few weeks and then you can diminish it to once a week."
participant 3 (amputee for decades) about the presence of her prosthesis
"I don't think I have a particular point in the day actually. It's always there"
identifying prosthesis as part of self
"for me its just my leg. it feels like my leg" P0
"now I'm finished with all of the operations and I want to go and get my mobility back." P0
feeling empowered and enabled
"I make the same round every day, about eight or nine kilometers. That is about 7000 to 8000 steps. I am so proud of that!" P2
"I am so euphoric that I can walk for so long, just without crutches and without pain. Magic!" P2
118%

IDEATION

Template Morphological Charts

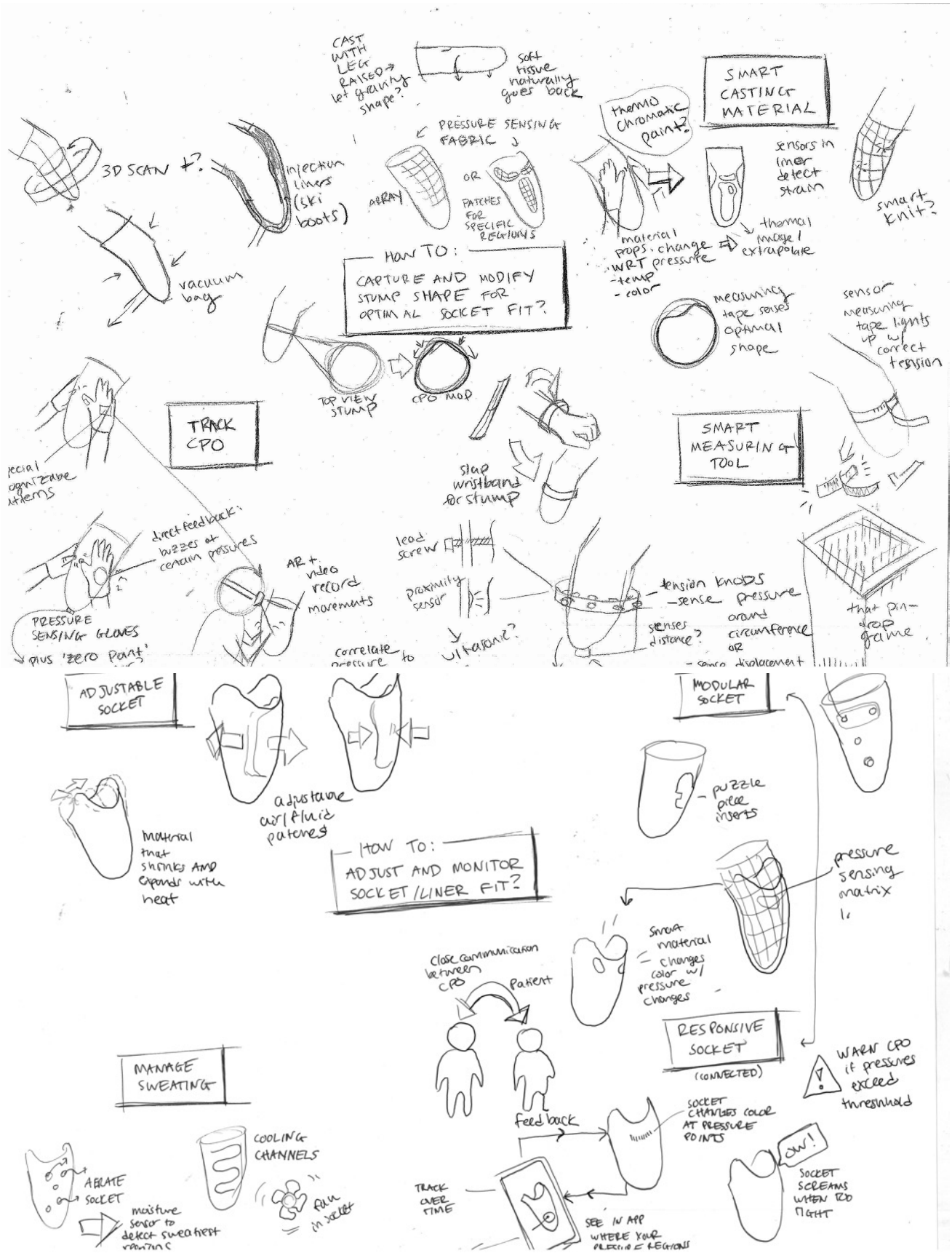
Pre-diagnostic phase

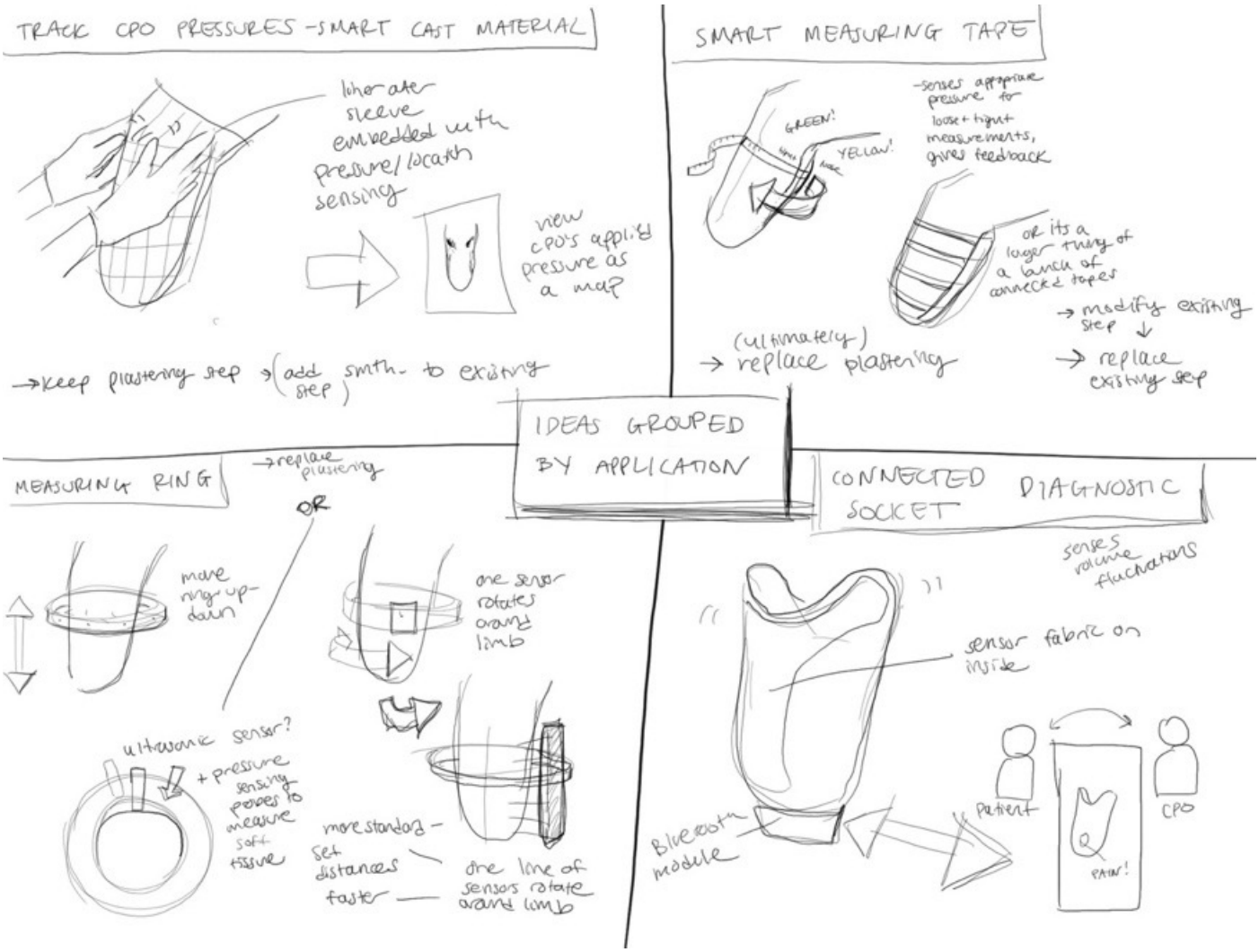
topic	step	possible solutions			
capture geometry	measure stump				
	capture stump volume				
	capture stump shape				
capture modifications to geometry	pre-compress stump for optimal fit				
	identify bony vs. soft tissue regions				
	apply pressure to specific regions only				
	track CPO modifications				

Diagnostic/definitive phase

topic	sub-function	possible solutions			
monitor and adjust socket fit	patient: mitigate painful points				
	adjust diagnostic socket size (tighen? loosen? all over? locally?) (by patient? by CPO?)				
	communicate/track socket fit to CPO				
	accommodate for stump volume fluctuations (by patient? by CPO?)				
	manage sweating				

IDEATION

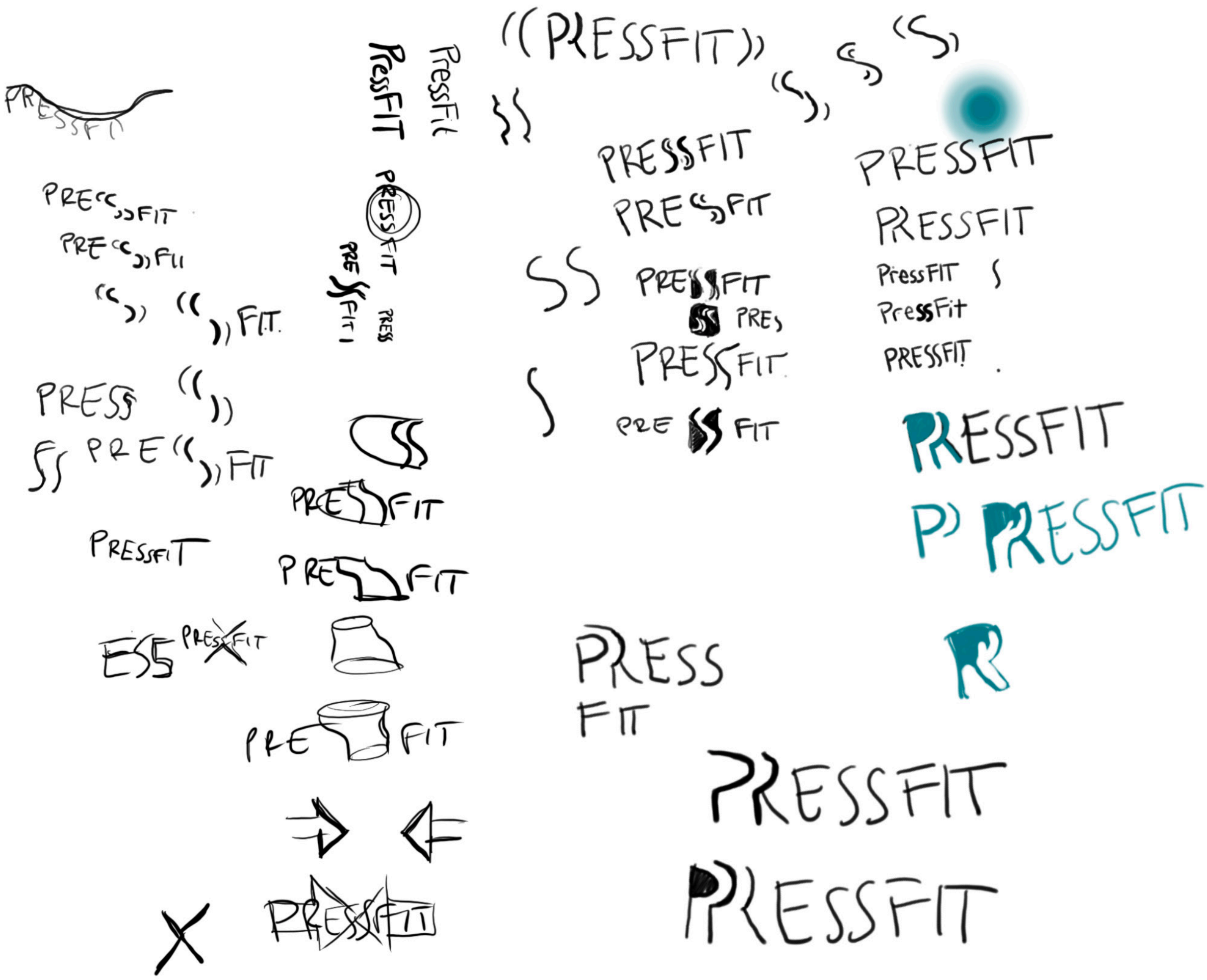

CAST WITH LEG RAISED → let gravity shape?
soft tissue naturally goes back
3D SCAN +?
injection liners (ski boots)
vacuum bag
PRESSURE SENSING FABRIC
ARRAY
OR
PATCHES FOR SPECIFIC REGIONS
thermo chromatic paint?
SMART CASTING MATERIAL
sensors in liner detect strain
smart knit?
material props. change WRT pressure → thermal image / extrapolate
- temp
- color
HOW TO: CAPTURE AND MODIFY STUMP SHAPE FOR OPTIMAL SOCKET FIT?
TOP VIEW STUMP
CPO MOD
measuring tape senses optimal shape
sensor measuring tape lights up w/ correct tension
TRACK CPO
special appointment attempts
slap wristband for stump
SMART MEASURING TOOL
direct feedback: buzzes at certain pressures
PRESSURE SENSING GLOVES
plus 'zero point'
AR + video record movements
lead screw
proximity sensor
ultrasonic?
correlate pressure to
tension knobs
- sense pressure around circumference
OR
- sense displacement
senses distance?
that pin-drop game
ADJUSTABLE SOCKET
material that shrinks and expands with heat
adjustable air/fluid patches
HOW TO: ADJUST AND MONITOR SOCKET/LINER FIT?
MODULAR SOCKET
puzzle piece inserts
pressure sensing matrix
sweat material - changes color w/ pressure changes
close communication between CPO
Patient
RESPONSIVE SOCKET
(CONNECTED)
WARN CPO if pressures exceed threshold
feedback
SOCKET CHANGES COLOR AT PRESSURE POINTS
TRACK OVER TIME
SEE IN APP WHERE YOUR PRESSURE REGIONS
OW!
SOCKET SCREAMS WHEN TOO TIGHT
MANAGE SWEATING
COOLING CHANNELS
ABLATE SOCKET
moisture sensor to detect sweatiest regions
fan in socket

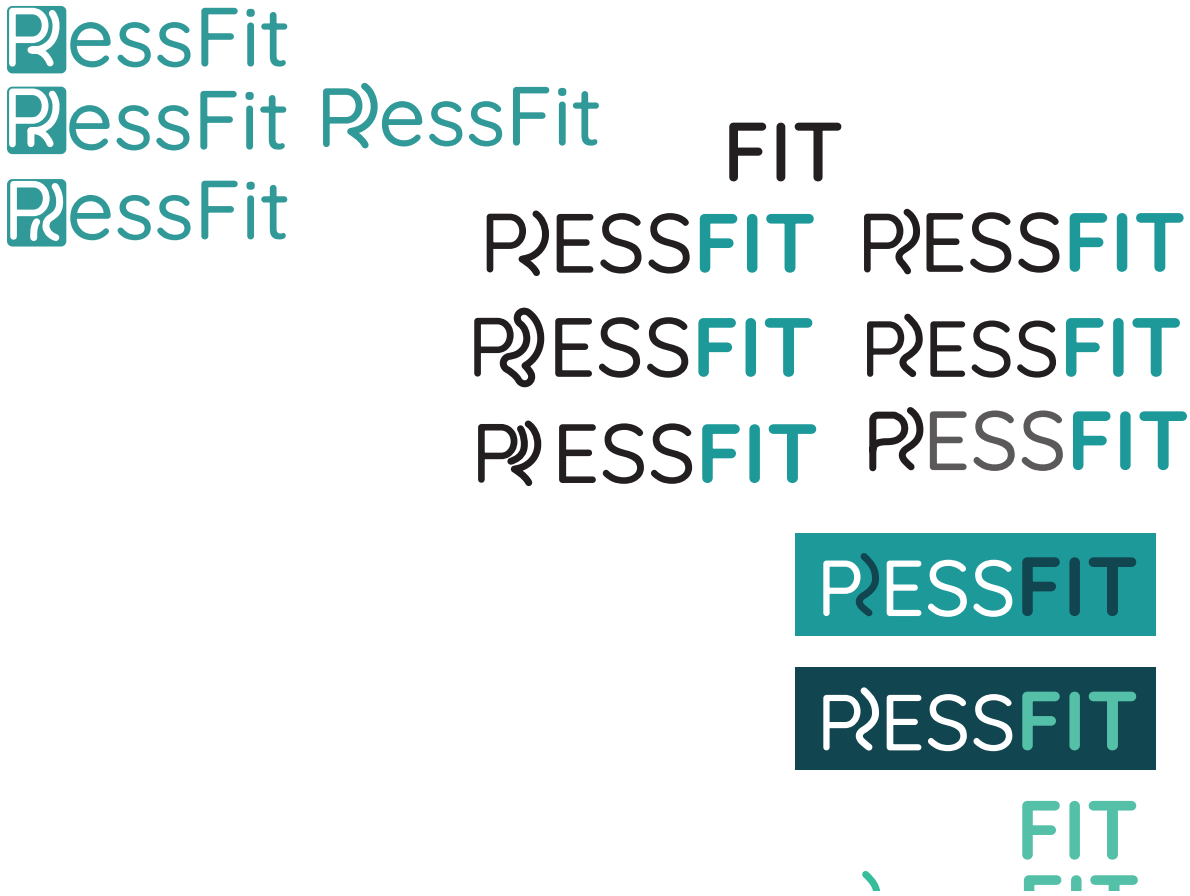

TRACK CPO PRESSURES - SMART CAST MATERIAL
liner ater sleeve embedded with pressure/ location sensing
new CPO's apply pressure as a map
→ keep plastering step → (add smth. to existing step)
SMART MEASURING TAPE
GREEN!
YELLOW!
- senses appropriate pressure for loose + tight measurements, gives feedback
or its a longer thing of a bunch of connected tapes
→ modify existing step
→ replace existing step
(ultimately) → replace plastering
IDEAS GROUPED BY APPLICATION
MEASURING RING
→ replace plastering
OR
more ring up-down
ultrasonic sensor?
+ pressure sensing pegs to measure soft tissue
one sensor rotates around limb
more standard - set distances
faster
one line of sensors rotate around limb
CONNECTED SOCKET
DIAGNOSTIC
senses volume fluctuations
sensor fabric on inside
Bluetooth module
patient
CPO
PAIN!

A8

LOGO DESIGN

The logo design was approached with the goal of communicating the applicaiton of pressure within the title PressFit. It was explored various ways in which the letters could be manipulated to appear as if one were pressing the other. Also, the font and colors were chosen so that the logo had a medical feel (blue tones), while still not feeling too serious or clinical (thus bright colors, rounded edgs).




RessFit
RessFit RessFit
RessFit
FIT
PRESSFIT PRESSFIT
PRESSFIT PRESSFIT
PRESSFIT PRESSFIT
PRESSFIT
PRESSFIT
FIT

A9

FINAL EVALUATION

PressFit Test Feedback Formulier **Deelnemer ID:**

Gebruik de volgende kleuren a.u.b.: mode 1 mode 2

Score alstublieft uw indruk van de tool op de volgende aspecten:

useless *zinloos*	1	2	3	4	5	6	7	useful *nuttig*
superfluous *overbodig*	1	2	3	4	5	6	7	effective *effectief*
worthless *waardeloos*	1	2	3	4	5	6	7	assisting *behulpzaam*

Deze tool maakt gebruik van mijn expertise als instrumentmaker.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

Het voelt alsof ik de regie van het productieproces behoudt met deze tool.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

Deze tool vergroot mijn vertrouwen in een goede pasvorm.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

Deze tool past in mijn huidige workflow.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

Ik zie deze tool de productietijd van een prothese verkorten.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

Deze tool kan de relatie met mijn klanten verbeteren.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

Ik zie waarde in het digitaliseren van mijn meet- en gipsproces met deze tool.

Zeer mee oneens	1	2	3	4	5	6	7	Zeer mee eens

	CIRCUMFERENCE MEASUREMENTS (CM)											
	WITHOUT TOOL						WITH TOOL					
	LOOSE			TIGHT			LOOSE			TIGHT		
1	37.0	37.0	37.0	35.5	35.5	35.5	37.0	37.0	37.0	35.5	35.5	35.5
2	36.8	36.9	36.7	35.9	35.9	35.9	36.9	36.9	36.9	35.5	35.5	35.5
3	38.0	37.5	37.5	36.0	36.0	36.0	36.8	36.8	36.8	35.5	35.3	35.1
4	38.0	37.0	37.0	36.5	36.0	36.0	37.5	37.5	37.5	36.0	36.5	36.5
5	37.7	36.5	36.5	33.0	33.5	34.0	36.0	36.2	36.4	33.5	33.0	33.0

Partipant ID	Please rate your impression of the tool on the scales of:	Please rate your impression of the tool on the scales of:	Please rate your impression of the tool on the scales of:	This tool utilises my expertise as a CPO.	I feel in charge of the production process with this tool.
PART A - measuring					
1	6	6	7	4	6
2	6	6	6	2	6
3	6	4	6	6	6
4	6	5	6	6	6
5	7	6	6	7	7
PART B - plastering					
1	7	6	7	4	7
2	7	7	7	2	6
3	6	6	6	4	4
4	7	6	7	5	6
5	7	6	6	7	7

Partipant ID	This tool improves my confidence in providing a good fit.	This tool fits into my current workflow.	I envision this tool reducing the time to produce a prosthesis.	This tool can improve my relationship with clients.	I see value in digitising my measuring & plastering process with this tool.
PART A - measuring					
1	2	6	1	6	7
2	7	6	3	4	6
3	6	6	2	5	6
4	6	5	6	5	4
5	7	6	6	7	7
PART B - plastering					
1	4	7	1	7	7
2	7	6	3	6	7
3	6	6	6	5	6
4	7	6	6	5	5
5	7	7	7	7	7

A10

EMBROIDERY MACHINE

This appendix describes the research and work conducted towards creating a version of PressFit using an embroidery machine.

Just as CAD designs must be prepared for machining in CAM software to program tool paths and order of operations, similarly must files for production on an embroidery machine be prepared.

Software

The software for designing the pattern used was Inkscape, a free, open-source vector design program, along with the Ink/Stitch plugin.

Pattern Design

Stitch Types

The Ink/Stitch plug-in provided various options for the type of stitch to fill a given vector with.

Stitch Order

Through trial and error it was learned the importance of the order and orientation of each vector path as it translated to how it would embroider. First, the embrodiery pattern was designed as a sketch in Fusion 360 for its ease of applying dimensions and creating rectangular patterns. However, when this was exported and imported into InkScape, each line segment was interpreted as a separate stitch, and some were read 'backwards'.

The pattern was then reconstructed from scratch in Inkscape, making sure that all paths to be sewn as a single thread without any cuts (meaning every row and column).

Simulation

To verify that the designed program would stitch as intend, the simulate option on Ink/Stitch was utilised. This gave a time-lapse simulation of how the machine would construct the prototype.

With 'needle points' checked, it becomes clear where the needle will puncture the material (the piezoresistive spacer layer).

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