Development of a Thumb Metacarpophalangeal Joint Splint

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Executive summary

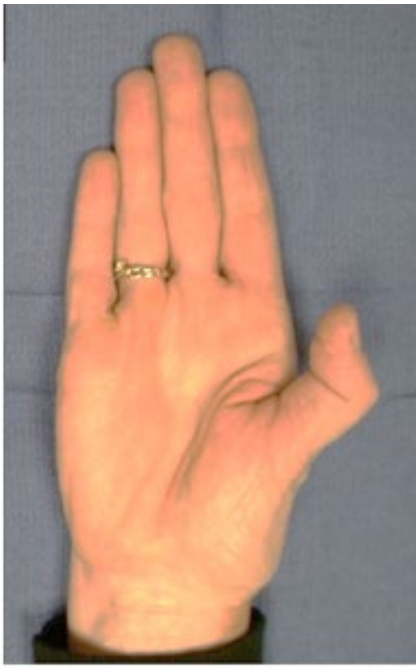


Figure 1: Hyperextended MCP1 joint destabilizing the thumb.

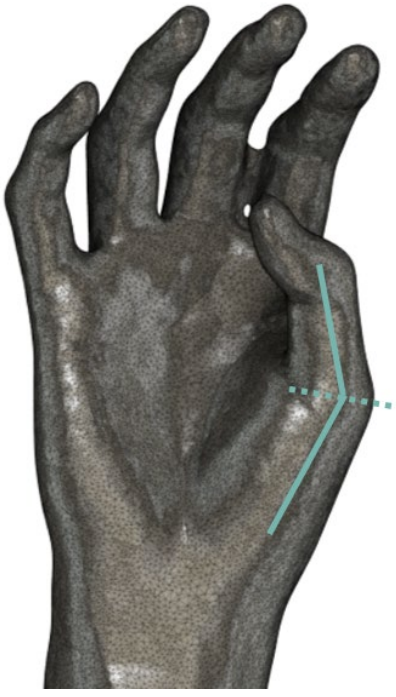


Figure 2: The new scanning pose with the thumb on opposition.

In daily life, we are constantly using our hands to do everything that is important to us. The thumbs play a critical role in this and losing stability of your thumb leads to a reduced Quality of Life. There are numerous conditions that can lead to joint problems in the thumb that negatively affect its stability, like rheumatoid arthritis, osteoarthritis, hypermobility, and dislocation injuries. Millions of people are affected by these conditions, even just within The Netherlands.

In this graduation project, a personalized thumb splint is developed which improves the stability of the metacarpophalangeal (MCP1) joint of thumb. Creating personalized products is not an easy business, so the design workflow for Ultra Personalized Products and Service Systems is used. In this project, that means making use of patient specific 3D scans to create a modifiable design template of a thumb splint. The template needs to be parametrically adjustable to facilitate the production through digital fabrication methods, like 3D printing.

The thumb splint is intended for patients who have mild joint laxity symptoms, meaning that the splint must prevent hyperextension of the MCP1 joint (Figure 1), but allow as much other movements of the hand as possible. This optimizes the patient's hand function. An elaborate exploration of the current thumb splinting market reveals deficiencies in existing solutions such as the splint slipping off too easily, causing painful pressure, being too bulky or too limiting. For this target group, Manometric currently designs unique thumb splints for each client from scratch. In this project, steps are taken to standardize the thumb splint design, allowing them to evaluate and improve the product performance and optimize their workflow more easily.

Different scanning positions and additive manufacturing methods were used to produce over 100 thumb splinting prototypes. Each one providing new insights to improve the fit, comfort, effectiveness, security, and appearance of the splint. This led to a final splint design where all the research and prototyping insights are combined.

The result is the splint shown in Figure 3, made of Multi Jet Fusion printed PA12 (nylon). It is modelled on a scan in a new position: a thumb in opposition (see Figure 2). It features a hinge which allows more flexion of the thumb, extension to a specified maximum and makes sure the splint stays snugly in place on the skin. It is well secured to the hand, does not cause painful pressure points, and facilitates almost all thumb movements except for (hyper-)extension of the MCP1 joint beyond 180°.

Parametric design rules were formulated to adjust the fit to any user, based on their 3D scan, wherein the thumb is in an opposed position.

Potential users were involved in the design process at four different moments to gain insights about criteria priorities and finally evaluate the ergonomics and performance of the splint. The final evaluation revealed that the splint functions as intended and has promising value. The viability of the new design was also evaluated with Manometric experts of different departments. While there is room for further detailing and optimization before implementation, the proposed thumb splinting architecture shows in promising step in the standardization of a solution for people who suffer joint laxity in the MCP1 joint.

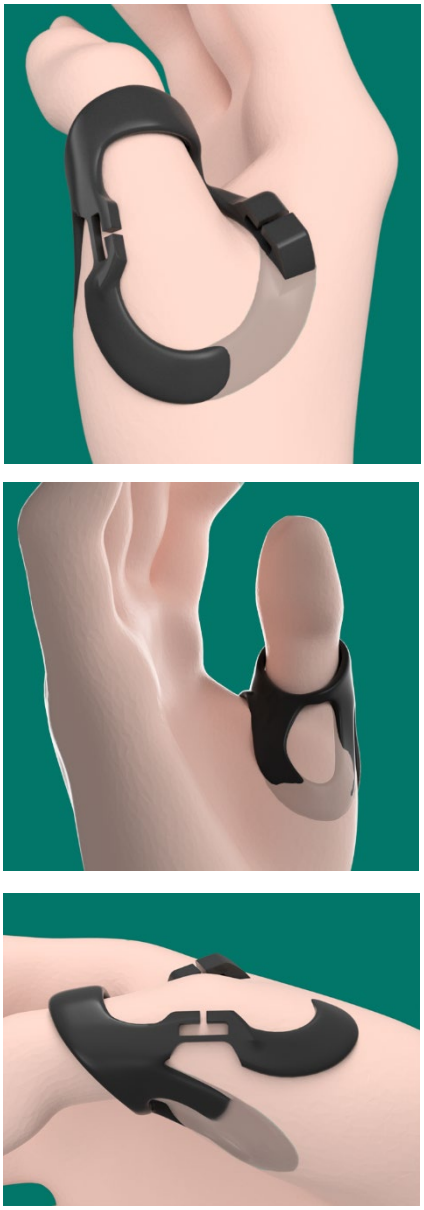


Figure 3: The new thumb splint design featuring a hinge at the MCP1 joint.

Contents

Glossary

LIST OF ACRONYMS

- OA – Osteoarthritis
- RA – Rheumatoid Arthritis
- QoL – Quality of Life
- O&P – Orthopaedic & Prosthetic
- ROM – Range of Motion
- LTTM – Low-temperature thermoplastic materials
- CAM – Computer Aided Manufacture
- CAD – Computer Aided Design
- AM – Additive Manufacturing

TERMINOLOGY

According to ISO standards an orthosis is defined as:

"An externally applied device used to compensate for impairments of the structure and function of the neuro-muscular and skeletal systems." (2020a).

The following ISO definitions are important to understand the context of this project:

- *Prefabricated orthoses* (Figure 4) are off-the-shelf orthoses, are designed to meet functional requirements and are normally available in a range, or confection sizes.
- C*ustom fabricated orthoses* (Figure 5) are designed and manufactured to meet the functional requirements of the individual user based on information such as moulds, models, measurements, and images (ISO, 2007).
- *Static orthoses* are rigid orthoses that do not include any moving or deforming parts and/or components, those can be used to position, hold and/or apply pressure to the joints.

Figure 4: prefabricated orthosis (Opelon, n.d.)

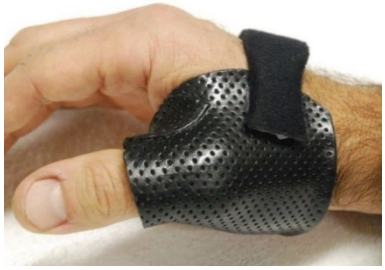


Figure 5: Custom fabricated orthosis (Young, 2019).

Figure 6: Dynamic orthosis (Middleton, 2019.)

Figure 7: adjustable orthosis (Push, 2016).

- *Dynamic orthoses* (Figure 6), on the other hand, are orthoses that include moving parts and/or components or allow intended deformation of non-articulating parts and can allow, lock, limit, assist or resist the motion of the joints.
- *Adjustable orthoses* (Figure 7) have physical properties that can be varied manually to support a desired clinical outcome (ISO, 2022).
- *Orthotics technicians* manufacture braces and splints under the direction of an orthotist.
- An *orthotist* is a person who, having completed an approved course of education and training, is authorized by an appropriate national authority to assess persons referred for orthotic treatment and to design, measure, and fit orthoses (ISO, 2020b).
- *Donning and doffing* are old English terms used in orthopaedics meaning ‘to take off’ (don) and ‘to put on’ (don).

Introduction

This chapter provides information about the assignment and background of the project. It introduces the client and provides initial project requirements and the problem statement. Finally, it introduces the approach and workflow of this project, along with a reading guide. Throughout this report, references are made to confidential appendices. Those contain sensitive background information regarding Manometric and are therefore not included in the publication. The important conclusions from the contents of the appendices are in the chapter of the body of the report.

BACKGROUND

Braces and splints, or *orthoses*, are medical devices that can be worn to support and/or (partially) immobilize certain joints of the user, like knees, ankles, wrists, or finger joints. They can be applied to treat many conditions, ranging from fractures due to trauma, to Arthritis, Hypermobility, or deformities. Joint problems usually manifest in pain and reduced function and are often the result of degenerative diseases like *Osteoarthritis (OA),* or of *Rheumatoid Arthritis (RA)*, an inflammatory joint disease, or of hereditary disorders that cause unstable joints, like in Hypermobility patients. Additionally, injuries can be a cause of long-lasting joint problems. An orthosis can be used to stabilize such problematic joints, to reduce the pain, and improve the function.

Figure 8: Selection of the wide variety of thumb braces currently available.

Orthoses are designed to improve biomechanical function, encourage proper joint alignment, or protect limbs. They increase users' ability to function and improve their *quality of life* (*QoL*) (Jin et al. 2015).

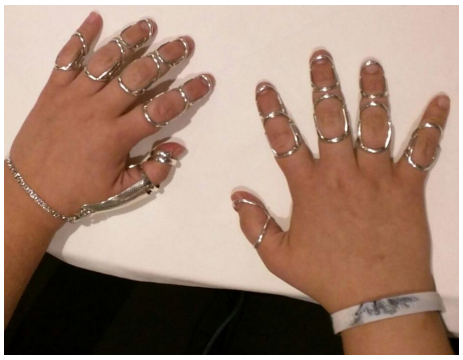


Figure 9: Silver ring splints.

There are many different types of orthoses for different body parts. The focus of this project is on hand- and thumb orthoses. Even within that category, a lot of variety in design, materials, appearance, and function can be found. Figure 8 displays that variety. Some braces only block one specific joint movement to better support it. Other larger braces can stabilize two or three different joints by immobilizing them completely or partially. Usually, the larger braces have a more medical appearance. Some suppliers try to improve the desirability of orthoses by minimizing the size of the solution and making it appear almost jewel-like. An example of such solutions are silver splint rings (Figure 9). What type of splint a patient requires depends on their disorder, the severity of it, and their personal preferences regarding freedom of movement, aesthetic values, and desired activities. These motives, and the reasons that patients might dislike certain orthoses, need to be understood to design a new splinting solution that patients want to wear.

Orthoses are available off-the-shelf, or patients can see medical specialists to acquire a custom-made splint to fit them as comfortably and effectively as possible. A patient's path to acquiring a custom-made orthosis is not an easy one. Initially, a patient requires a diagnosis from a medical expert (like a rheumatologist or hand surgeon). Physical therapists can also help them with hand exercises to improve daily activities and hand function. With a referral from such a medical expert, the patient is sent to an orthopaedic expert who can work with an orthotist and/or orthotic technician to design and fabricate the personalized orthosis. This requires an in-take consult, to communicate the patient's needs and get measurements, and one or more fitting moments when the product is finished. In The Netherlands, the orthotist needs the medical referral to receive reimbursement from the patient's health insurance.

MANOMETRIC

Manometric is a company that was started by TU Delft alumni in 2016 to create custom fabricated *orthopaedic and prosthetic* (*O&P*) products, including orthoses. Their mission is to change orthoses and prosthetics from necessities to products people love to wear. Their primary focus at this moment (in 2023) is on creating O&P products for the upper limbs. Manometric uses proprietary 3D scanners (see Figure 10) to rapidly capture the 3D anatomy of patients. They work with in-house orthotists to see patients, understand their needs, create a 3D scan, and order the correct product. The resulting 3D scan is then used to digitally design the product. Once the digital design is finalized, the orthoses are produced using additive manufacturing methods, among others.

Figure 10: Manometric ManoX 3D scanner (Manometric)

Traditionally, orthotic technicians are dependent on years of experience to create and adjust O&P products that meet the individual patient's needs. Manometric aims to replace this experience-based process and create a data-driven process, where the fit and function of their products is quantified based on objective inputs like the 3D scans and client information. This enables more detailed product evaluation and (partial) automation of the design process, which can increase the

quality of their products and the efficiency of their workflow over time. This way, they create products that consistently perform well, on many different patients. Manometric works with patients, orthotists, orthotic technicians, 3D modellers, designers, and production experts to aim for fast, high quality and personal patient service. Chapter 1.5.1 provides more background on traditional fabrication methods and the Manometric workflow.

THUMB ORTHOSES

The hand is a fundamental part of a person's day-to-day activities, and the thumb plays a unique role in this. The joints of the thumb offer a wide range of motions and the muscles allow powerful grips as well as very precise movements. Losing even a small part of the thumb's functionality can have a large negative impact on the life of a patient, as seemingly simple movements like grasping or pinching objects become painful or impossible.

Figure 11: Manometric MCP Air Thumb Brace.

While many varieties of thumb orthoses exist and Manometric provides its standard silicone and nylon thumb braces (Figure 11 and 12) to many patients, they seek a more minimal solution for patients that do not require the firm support of these existing products. They have found that patients with mild symptoms, for example, in early stages of disorders like RA and OA, or with lower complexity joint problems desire solutions that are more discreet and offer the thumb more freedom of movement. Manometric currently delivers numerous *standardized* products, like the products in Figure 11 and 12, where the digital design process is partly automated based on a *design 'template'* and an individual's hand measurements or 3D scans. This process is (almost) entirely data driven, which helps to further develop and improve the products. Their current portfolio does not offer a small thumb splint as a standard. Instead, for patients that require a different (non-standard) product, it requires Manometric significant additional work and time to especially design it from scratch, relying more on the orthotist's experience, than objective data. Chapters 1.2.3 and 1.3.1 will go into more detail about the current product portfolio and workflow of Manometric.

Figure 12: Manometric Silicone Thumb Brace.

PROBLEM DEFINITION

Once a medical expert has referred a patient to an orthotist, the orthotist creates a patient-specific brace for them. The conventional fabrication of prescribed, custom orthoses is an expensive, labour-intensive, and specialized process. Chapter 1.5 explains those processes in detail. Meanwhile, the demand for orthoses is rising due to a growing and aging population with increasing health problems like diabetes, heart disease and obesity, increasing the pressure on instrument makers (American Academy of Orthotists and Prosthetists, 2016). Therefore, the use of *additive manufacturing* (*AM*) technologies to fabricate orthoses and prosthetics is becoming more popular, as, according to Jin et al. "it has the potential for rapid and cost-effective fabrication and transformative service of custom O&P products." (2015). Figure 13 shows examples of custom-made O&P products fabricated with additive manufacturing.

Figure 13: examples of O&P products using additive manufacturing.
(Right - Invent Medical, middle – Forward AM, left – Scientifeet.)

Besides the growing pressure on orthotists, there are functional and compliance problems with existing thumb orthosis. "*Medication compliance* refers to the degree or extent of conformity to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage, and frequency." (Cramer et al., 2008). The concept of compliance is important in the O&P industry, because, according to Basford and Johnson, "even if beneficial, an orthosis may be discarded by patients if it is not essential to performing daily activities, is uncomfortable or if the patient feels it highlights their disability." (2002). This means that the effectiveness of a splint or brace depends heavily on the patient's individual needs that are not always optimally met, due to an unavailability of fitting products or lack of attention to personal detail throughout the care path (Terry et al., 2015).

The thumb is not an easy limb for O&P products, due to its many degrees of freedom in mobility and variable shape and volume. Off-the-shelf thumb braces are often bulky, offer a poor fit and poor mobility, as shown in Figure 14. Manometric found in conversation with clients that even personalized products from orthotists are sometimes still too bulky and sweaty. This can lead to low compliance due to unnecessary immobilization, an uncomfortable fit, or an unappealing appearance. On the other hand, the compact silver splints are most often chosen for their hygienic advantages or jewel-like appearance. However, it was found that those can cause uncomfortable pressure points, impede movements unnecessarily, snag behind object during daily activities or be insufficiently secured to the hand, as demonstrated with the splint in Figure XX. Confidential appendix J contains a Figure showing these deficiencies of an existing thumb silver splint.

Figure 14: example of a bulky prefabricated orthosis.

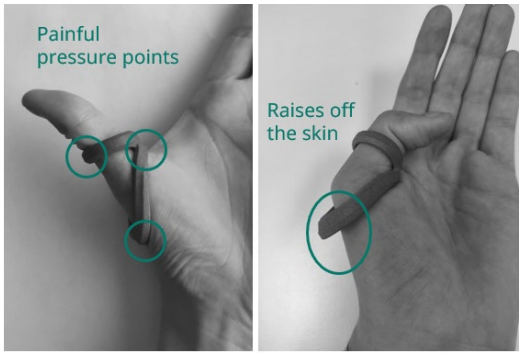


Figure 15: example of a thumb splint's shortcomings.

The problems surrounding the fabrication and usability of orthoses are among the reasons why Manometric develops braces and splints using 3D-scanning and -printing. However, there is no efficient and effective solution for a standard small thumb splint yet. This means that when a client requires such a product, the splint is designed by hand. Appendix J (confidential) shows a representation of a few of the many unique thumb splint designs that have been made by Manometric in the past. Manometric wants to improve their thumb splints and make the thumb splinting process more data driven. They currently do not have a sufficient understanding of the users of these products, their collective conditions, needs and wants, to come to a standard design template. In this project, the context will be explored to gain this understanding to come to one orthosis design template that can help most of these patients that have mild symptoms and want a less bulky, freer thumb splint.

All these aspects regarding the design, fabrication and usability of orthoses and specifically thumb splints, lead to the following problem definition for this project:

"Develop a design template for a patient-specific thumb orthosis that enables a personalized fit based on objective patient data and allows Manometric to provide products in a way that is beneficial for all involved stakeholders."

UPPSS DESIGN WORKFLOW

The structure of this project is based on a design workflow for Ultra Personalized Product and Service Systems (UPPSS). The goal is to create a thumb orthosis design that can be personalized to fit and function for one specific individual. The result of such a workflow is a "modifiable" template design that processes the patient data and outputs the final splint design. To this end, the computational design approach, digital modelling, and digital fabrication methods are used. Figure 16 shows a generalized design workflow for personalized products, proposed by Minnoye et al. (2022). It is an iterative process wherein first the design criteria need to be defined, based on an analysis of the problem and context of the project. Then, the correct data and parameters of the individual's hand and thumb shape need to be collected. Based on that, a design template is created which can be used to create a personalized design. With the personalized design, the materials and manufacturing limitations need to be used to tune the product geometry. Finally, the function and fit of the product need to be assessed to improve the next iteration of the design.

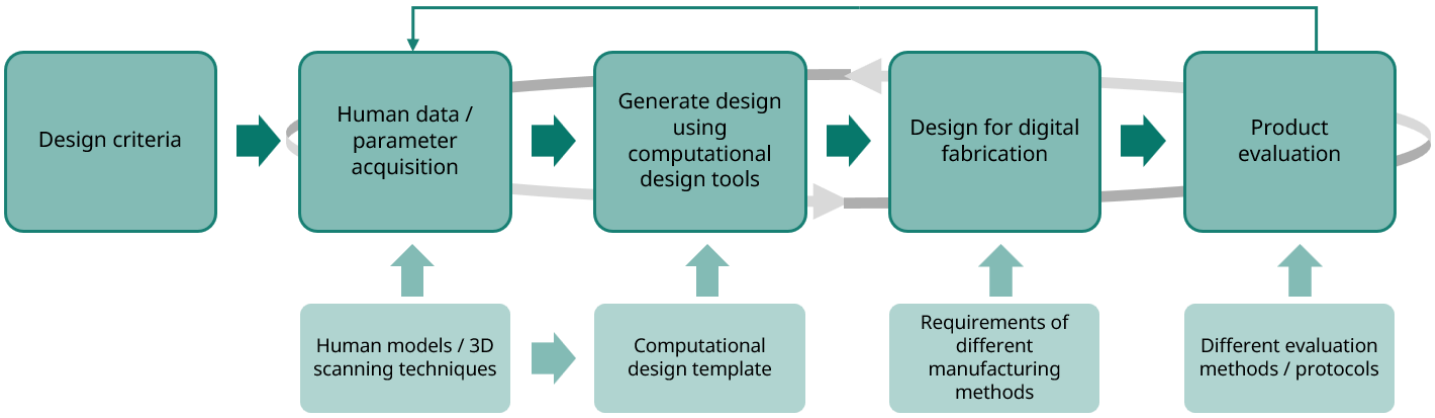


Figure 16: Design workflow for personalized product (edited from: Minnoye et al. 2022).

Within the scope of this project, the workflow is not completely executed. The focus is on exploring the problem and designing and validating a new type of thumb orthosis. Therefore, the computational design template is not created as that requires significant time and expertise and is not a priority in this project Manometric has the in-house expertise to perform these steps. However, the implementation of the proposed concept in a UPPSS must be viable so the proposed design workflow remains the leading guide of the design process. The computational implementation step still needs to be considered in this project to facilitate smooth implementation. Instead of a computational model, the parametric design rules are formulated on paper and manually assessed.

PROJECT APPROACH

While the personalized product workflow facilitates the consideration of the UPPSS implementation, the traditional double diamond approach is used to shape the project. It consists of four stages: discover, define, develop, and deliver as proposed by the British Design Council (2022). Figure 17 on the next page shows how this approach was used to shape the project. It also contains a reading guide with the contents per chapter.

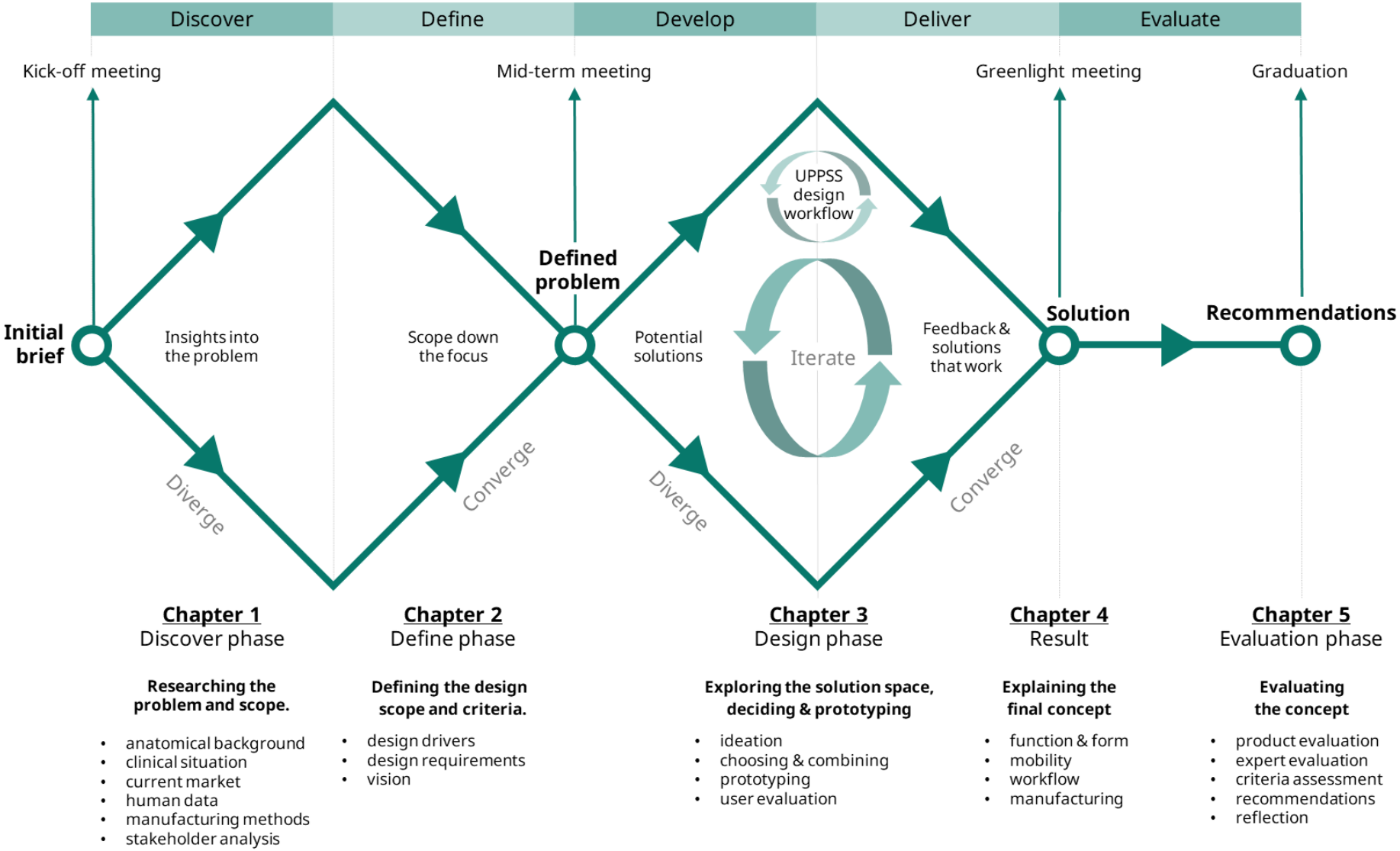


Figure 17: Project approach based on the double diamond model and reading guide.

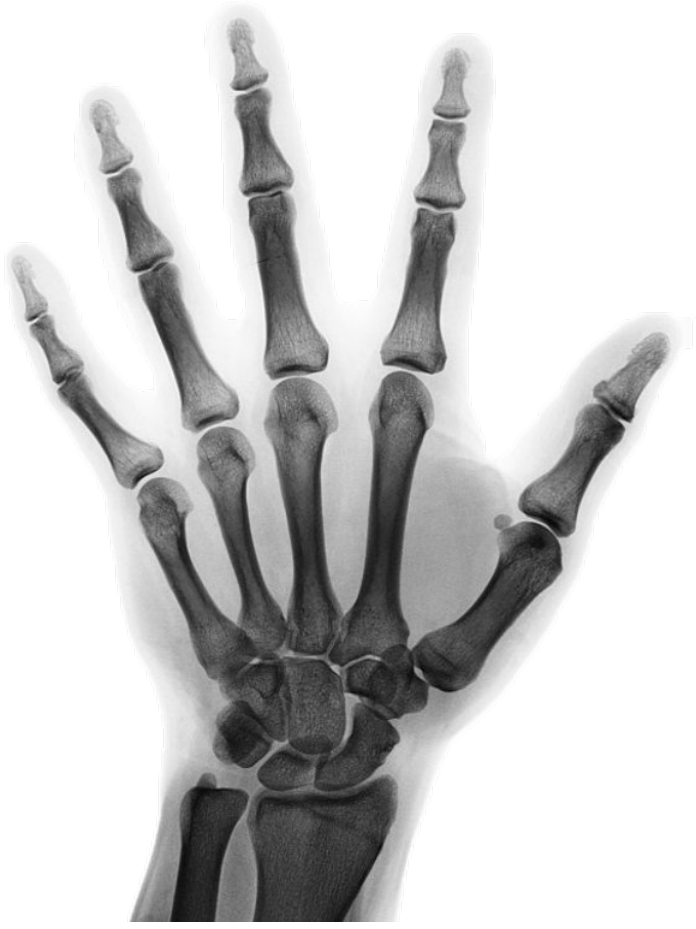
1. Discover phase

CONTENTS

INTRODUCTION

To further define the scope of this design project and design a thumb orthosis that successfully fulfils its functions and supports the right patients, a wide foundation of knowledge is required about the clinical situation and existing thumb splinting solutions. This part of the report contains the knowledge acquired from a literature study of the relevant medical information, an analysis of existing thumb orthoses and details of the relevant fabrication processes. A literature study of patient data types provides a background for the requirements related to this part of personalized product workflow. Finally, in Chapter 1.3 the stakeholders are analysed to understand their interests in the development of this new splint, including a study of the target users based on interviews with users and medical experts. Besides literature, different experts in the fields of orthopaedics, digital fabrication, additive manufacturing, and users of orthoses were consulted. The combined conclusions from this foundation of knowledge come together in the design drivers, criteria and vision defined in Chapter 2.

Throughout this part of the report, the notation: $^{(R\text{-}x.x)}$ refers to design requirements or wishes that were concluded from that section, listed in Chapter 2.2. The notation $^{(R\text{-}app.x.x)}$ refers to additional requirements in Appendix A.



1.1 CLINICAL SITUATION

This chapter introduces the anatomical and pathological knowledge required to understand this report, the design requirements and future design decisions from a medical perspective. Relevant anatomical and kinesiological (i.e., movement) details of the hand and thumb are provided and conclusions are drawn related to the function and ergonomics of the splint. After a literature study of possible pathologies, the relevant user target group can be pin pointed. Important findings are highlighted and related to the previously explained design problem.

1.1.1 ANATOMY

Firstly, Figures 1.1, 1.2 and 1.3 show the relevant orientation and directional terms used by anatomists to efficiently communicate about body parts and function. The reference point in anatomy is the *anatomical position*, shown in Figure 1.3, where the thumbs point away from the body (Marieb & Hoehn, 2019). Unless otherwise indicated, this position and these anatomical terms will be used throughout this report.

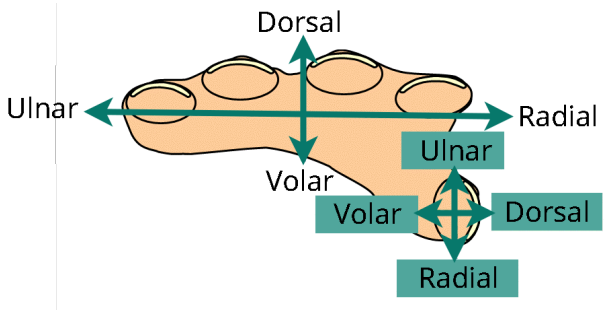


Figure 1.1: Orientation terms of the hand from distal top-view (edited from Colditz, 2016).

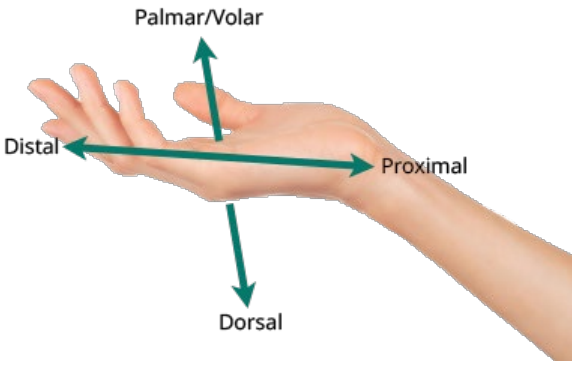


Figure 1.2: hand with directional terms.

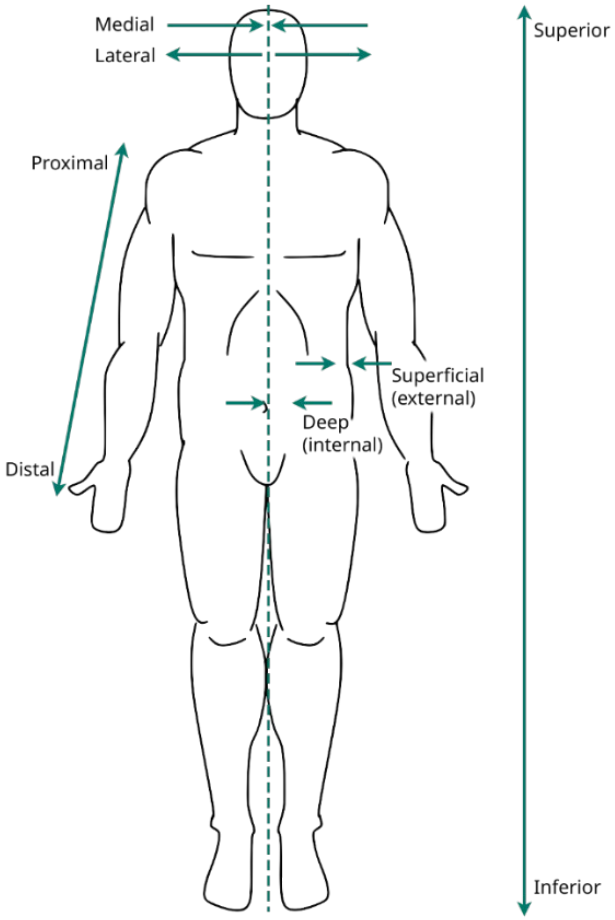


Figure 1.3: anatomical position with orientation and directional terms.

THE HAND

Figure 1.4 shows a palmar view of the bones in the right hand with the anatomical terms for the bones and joints. These terms will also be used throughout this report. The important ones to remember are highlighted in bold. The bones of the fingers are the *phalanges* and are attached to the *metacarpus* (palm). The joints connecting the palm and fingers are therefore called *metacarpophalangeal (MCP)* joints and the joints in the fingers are called *interphalangeal* (*IP*) joints. Of the *carpal* (wrist) bones, the *Trapezium* is at the base of the thumb and articulates with the metacarpal bone of the thumb in the *carpometacarpal* (*CMC1*) joint. (Marieb & Hoehn, 2019).

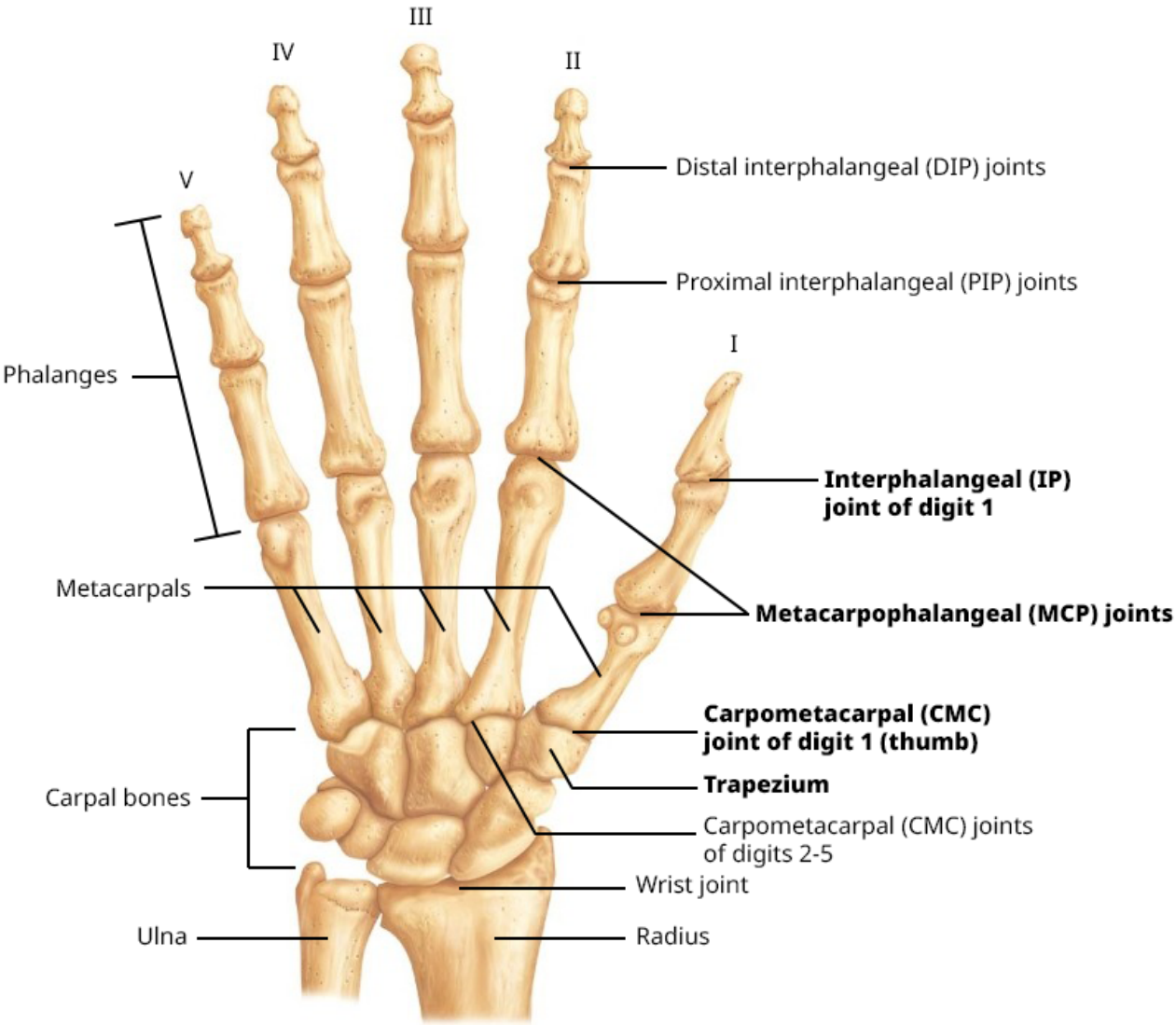


Figure 1.4: Bones and joints of the hand (edited from Marieb & Hoehn, 2019).

THE THUMB

The thumb is a unique finger. The trapezium is not in line with the other distal carpal bones, which causes the thumb to lie at about a 45° angle with the index finger out of the plane of the hand in the palmar direction. The *volar surface* of the thumb is turned towards the other digits so humans can arc their thumb across to all the other digits (Oatis, 2008). This allows a person to pick up objects with the tips of our fingers rather than just the sides, as chimpanzees would. This, along with the high sensitivity in the fingertips enables a human's fine motor coordination (Gazzaniga, 2008). This dexterity is considered critical for tool use and production, which is one of humanity's defining characteristics (Karakostis et al., 2012). Napier (1956) classified hand function in 2 groups: The *power grasp* and *precision grasp*, shown in Figure 1.5. "In the power grasp, the object is held between palm and the finger surfaces with primary need for force. In precision grasp, the object is held with the tips of the fingers and the thumb with less force and high precision."

The stability of the thumb is crucial to perform these grasps and to manipulate objects (Nanayakkara et al., 2017). If this stability is reduced because of injury or disease, this can have a large impact on a person's ability to accomplish tasks that require grasping in daily life (Ladd et al., 2014). Seemingly simple tasks like holding a glass of water or using a computer mouse can become difficult or painful. The thumb provides roughly 50% of hand function (Wei & Colony, 1989). This means that the stability of the thumb joints needs to be maintained for a high quality of life [(R-1.2)], which is why thumb orthoses can be of great importance to such patients. *The stability* of a joint refers to "the ability of a segment or joint to maintain its alignment when subjected to muscle forces and or external loading." (ISO, 2020c). The effectiveness of a new splint design needs to be evaluated using these different grasping movements.

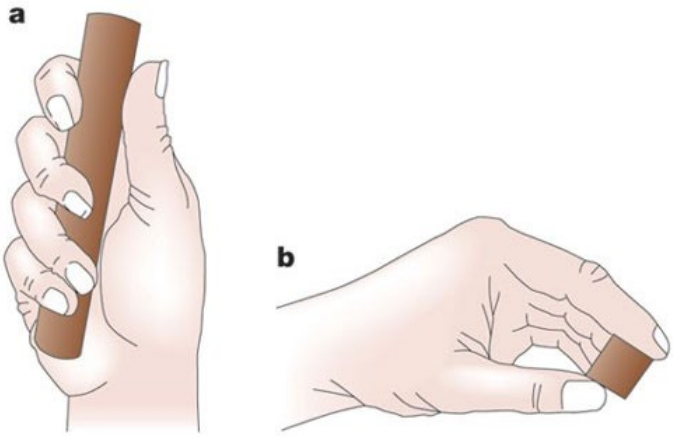


Figure 1.5: a - the power grasp (left) and b - the precision grasp (right) (Castiello, 2005).

Joints

All movements of the complete thumb are made up of the motions shown in Figure 1.6. Figure 1.7 shows an overview of movements of each individual thumb joint, a mechanical representation of its type and their *range of motion* (*ROM*).

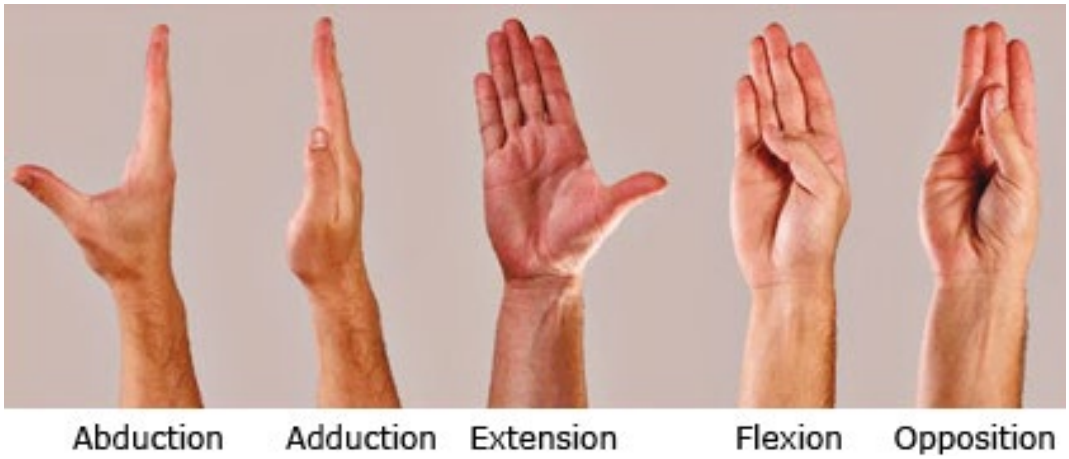
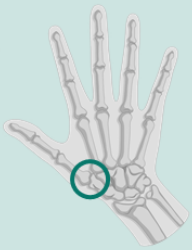
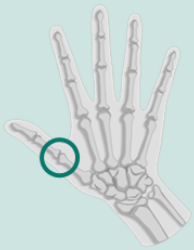
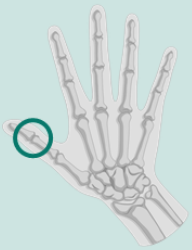
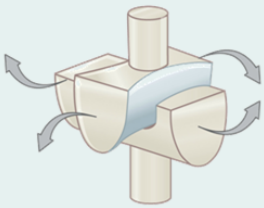
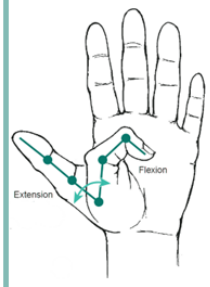
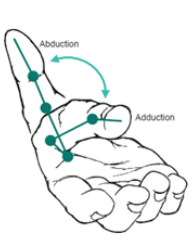
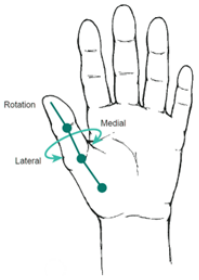
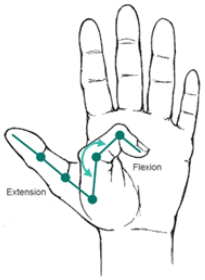
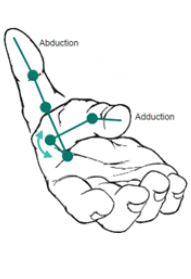
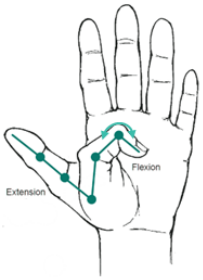


Figure 1.6: Movements of the thumb.

(below) Figure 1.7: Overview of the thumb joints, their types, movements, and ROM. (Sources: [1] = Freepik (n.d.). [2] = Faisal, 2020. [3] = Marieb & Hoehn, 2019. [4] = Drake et al., 2005. [5] = Oatis, 2008.)

joint [1]	 **CMC1** Biaxial		 **MCP1** Biaxial		 **IP** Uniaxial
joint type [2]	 Saddle joint		 Condyloid joint		 Hinge joint
movements [3,4]	 extension/flexion	 abduction/adduction	 rotation minimal	 extension/flexion	 abduction/adduction minimal	 extension/flexion
ROM [5]	Flexion: ~15° Extension: ~20-80°	Abduction: ~25-70°	Medial: ~30° Lateral: ~15°	Flexion: ~0-80° Hyperextension: ~10°	Unknown, but very limited	Flexion: ~75-90° Extension: ~0-5°

Thumb mobility

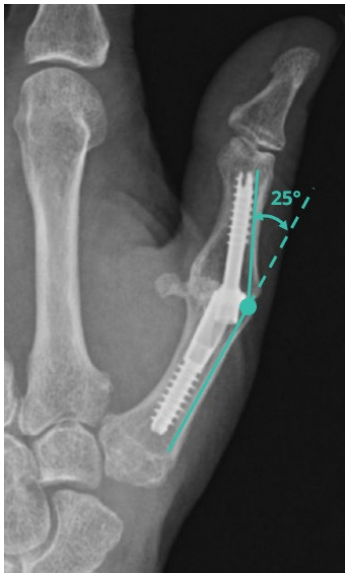


Figure 1.8: Arthrodesis of the MCP1 joint at 25° (edited from: Oteo-Maldonado, 2020).

The CMC1 is the largest contributor to the thumb's unique range of motion. ROMs of the CMC1 and MCP1 joints are not clearly reported. Different studies report varying ranges and large differences between individuals, which makes it hard for clinicians to determine abnormal joint movements of the thumb (Oatis, 2008). This also creates complexities for the design of thumb orthoses, as different individual patients display different ROMs and require different degrees of immobilization. Literature mentions varying MCP1 immobilization angles from 15 to 30° of flexion, for example, in surgical *arthrodesis* (or: fixation) of the joint (see Figure 1.8) (Oteo-Maldonado & Merino-Carretero, 2020) (Teunis et al., 2022).

Within the current Manometric workflow, the orthotists determine the position of the hand during the 3D scan, such that it is optimized for immobilization of that individual. This aspect is further discussed in Chapter 1.4.2.

In addition to the power grasp and precision grasp, *opposition* of the thumb (see Figure 1.6) is a crucial movement in daily life activities and must be facilitated by a thumb orthosis [(R-1.2)] (Oatis, 2008). Besides that, according to Manometric orthotists, mobility of the hand and thumb should always be maximized to offer the user as much function and freedom as possible [(R-1.6)]. Figure 1.7 shows the complexity of the thumb's movement. Consulting it provides insights into the movements that could be blocked by a thumb splint, depending on the patient's pathology. This also highlights what movements should not be blocked by the splint, such that the patient has the highest thumb functionality possible, while still providing the required support. These insights are discussed in Chapter 1.2 and related to the current thumb splinting market.

Synovial joints

The three thumb joints are *synovial joints.* Figure 1.9 shows the general structure of a synovial joint. This structure keeps the bone ends together and facilitates smooth movements, compression absorption and structural reinforcement (Marieb & Hoehn, 2019). The MCP1 joint is supported by the joint capsule, *collateral ligaments*, and a *volar plate* (Figure 1.10) (Oatis, 2008). The complexity of synovial joints can cause a wide variety of medical problems. If the structures are not functioning properly, the stability of the thumb can be negatively affected. Chapter 1.1.2 will dive further into those clinical problems.

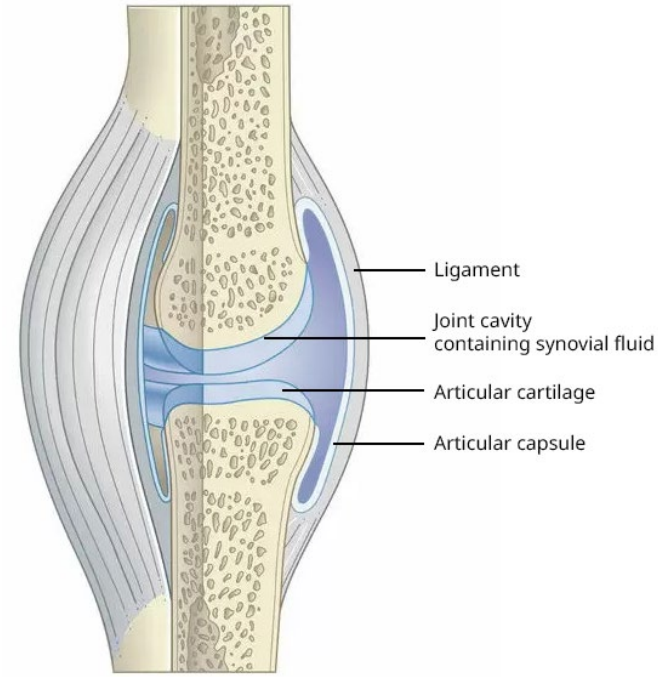


Figure 1.9: General structure of a synovial join (Marieb & Hoehn, 2019)

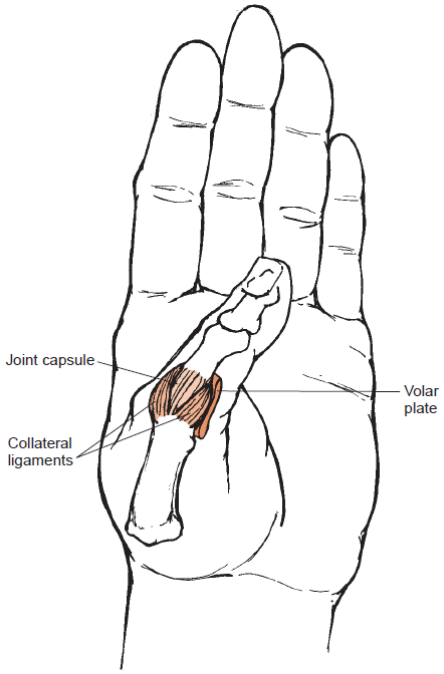


Figure 1.10: Stabilizing bodies of the MCP joint (Oatis, 2008).

Muscles

For the hand, most muscles are in the forearm and move the fingers via long tendons. Other movements of the fingers are enabled by *intrinsic muscles of the hand* in the palm. Figure 1.11 shows muscles of the hand that bring about the thumb's movements. It also lists what movements the mentioned muscles bring about. For the design of the splint, especially the muscles highlighted in bold are important. The *Adductor pollicis* and the *Thenar muscles* make up most of the soft tissue around the thumb (Marieb & Hoehn, 2019). The figure also shows that the muscles and tendons at the thumb cause its shape to become somewhat conical as the muscly base of the thumb narrows into an area of thin tendons. This shape makes it difficult to keep wearables for the thumb in place and avoid them sliding off.

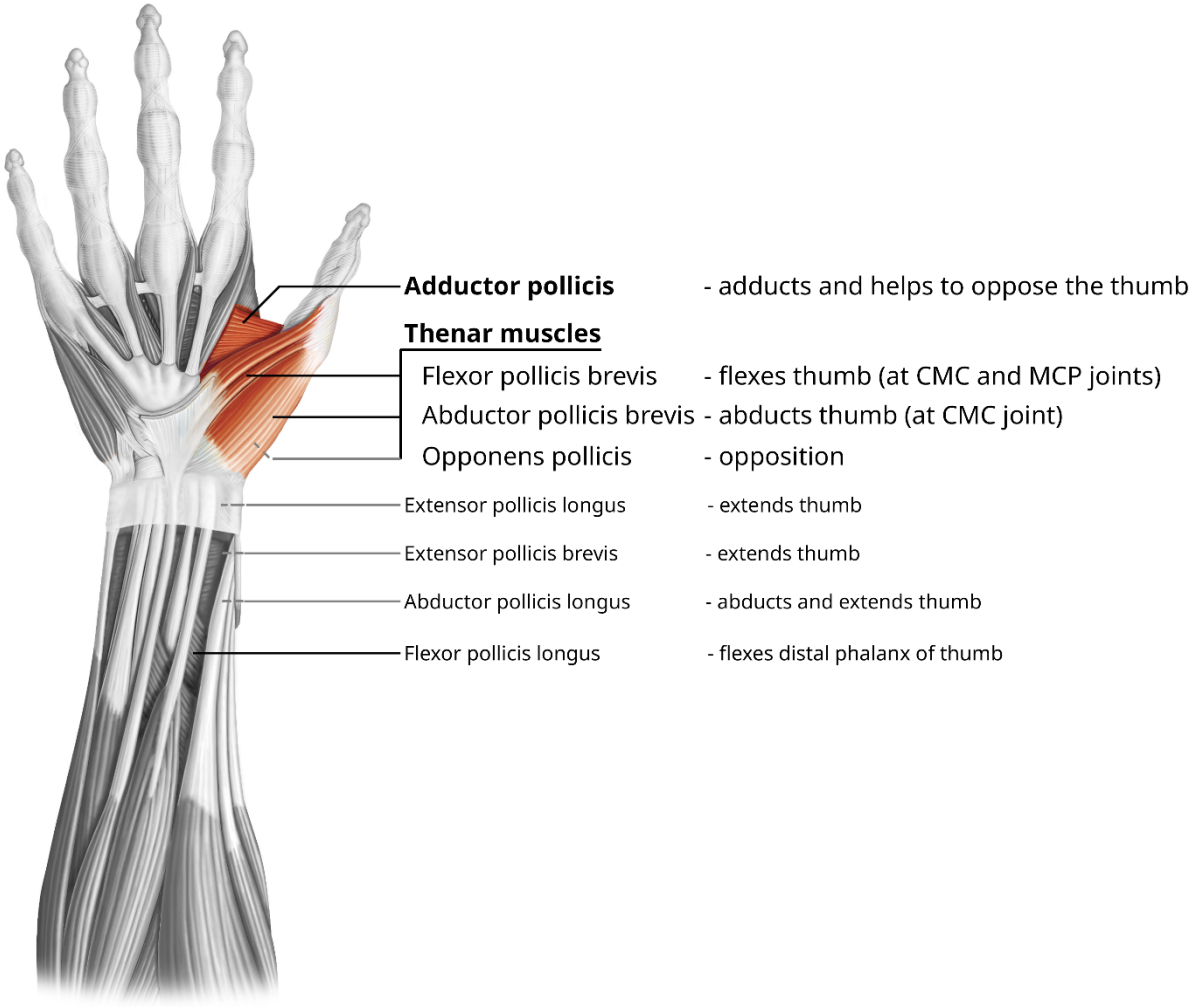


Figure 1.11: Palmar view of the muscles of the thumb (edited from Falcetti, 2015) (Marieb & Hoehn, 2019).

SPLINTING THE THUMB

A literature review of works related to splinting the thumb and interviews with orthotists (see Appendix B for the questions) were used to gain the following insights for the splint design.

The lack of muscles and fat in the wrist, fingers and on the dorsal side of the hand cause bones and tendons (in certain hand positions) to lay superficially below the skin. According to orthotists, those areas, marked blue in Figure 1.12, are sensitive to pressure and in designing a thumb splint should therefore be avoided (R-2.1). Besides that, the *creases* in the palm (marked in green) correspond to joint movement and should therefore remain clear if those joints are not included in the orthosis (R-2.4) (Schofield & Schwartz, 2019). Conversely, the large Adductor pollicis and Thenar muscles on the palmar side, associated with opposition of the thumb, offer some cushioning. However, to move the thumb, those muscles require space to contract and alter the shape of the palm (Drake et al., 2005). Limiting this space will limit the thumb's mobility, which should be avoided (R-2.4). Similarly, an adequate *first webspace* between the thumb and index finger is required for most of the thumb's mobility and should therefore not be obstructed either (R-2.4) (Jensen et al., 1993). Finally, the lateral arches of the hand that create the concave shape of the palm must be followed, to maintain mobility of the hand and other fingers (Duderstadt-Galloway et al., 2018). The shape of the thumb, sensitive areas, changing shape of the palm and webspace make it difficult to design wearables for the thumb. Figure 1.12 highlights the mentioned areas and their limitations.

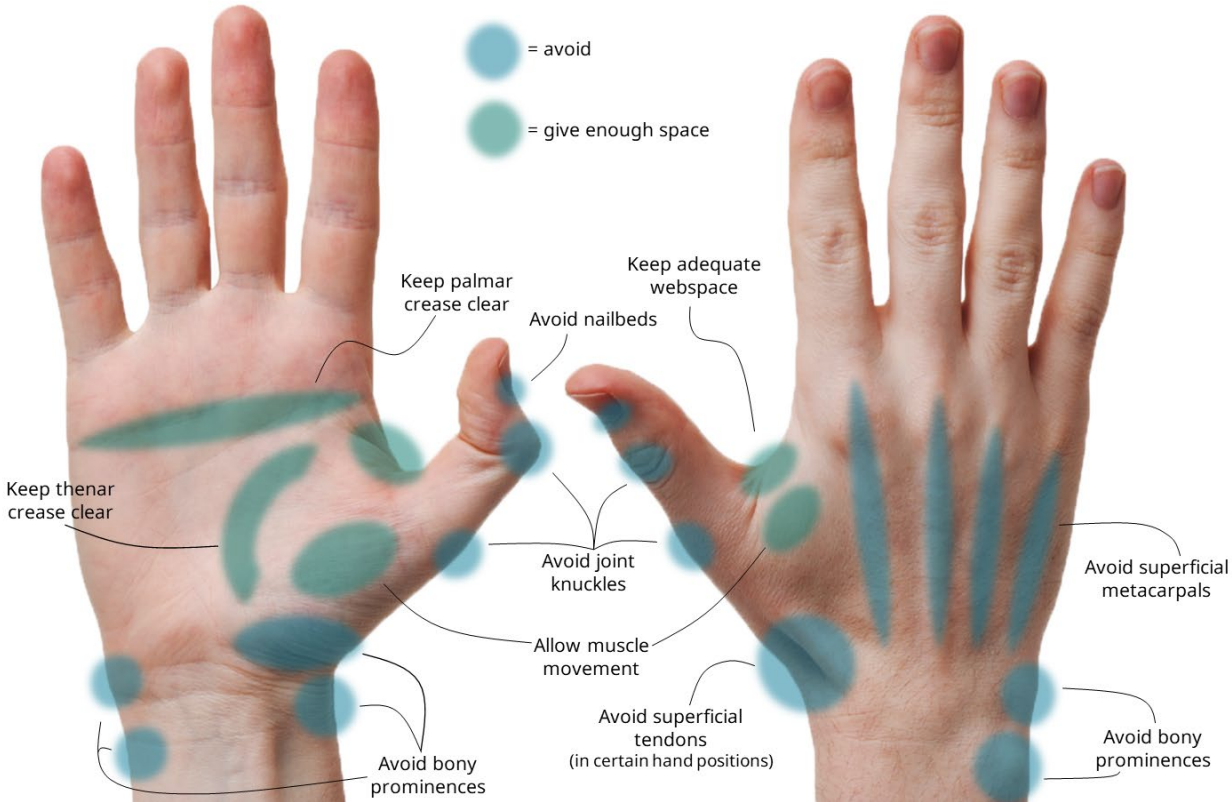
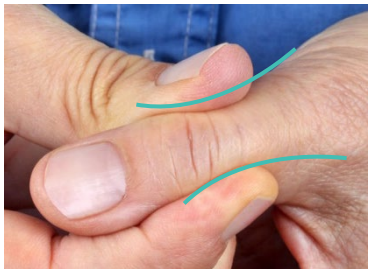
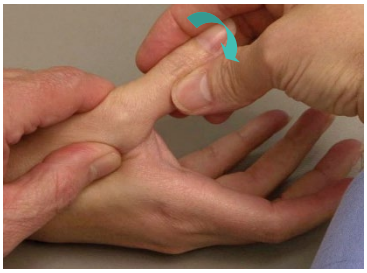
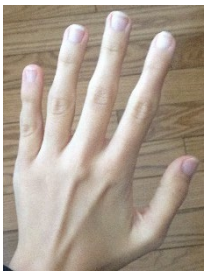


Figure 1.12: Critical areas of the hand anatomy for a thumb splint design (Edited from Evan-Amos, 2002).

THUMB ANATOMY VARIATION

To design a thumb splint that can be parametrically adjusted to accommodate individual users, an understanding of anatomical variations in the thumb is required. An analysis of 10 3D scans of past Manometric patients with MCP1 splints was performed and Manometric experts were consulted to determine the most notable anatomical variations listed in Table 1.1. In this analysis, the target users found in the problem statement, with mild joint complaints, are considered. This means that severe deformities as found in later stages of RA and OA are not considered, as such patients would require a more supportive orthosis. Chapter 1.1.2 covers the pathologies in more detail.

Condition	Relevance
"Mushroom" thumb The IP joint is thicker than the metacarpal and phalanx of the thumb. This is the case for almost everyone but is much more pronounced in some individuals. 	The splint must accommodate the size of the IP joint to enabling easy donning and doffing. This aspect of the anatomy might also be an opportunity to keep the splint in place, which is a common strategy for finger splints.
Thumb rotation While the thumb is usually oriented such that the volar side faces the 5th digit (pinkie), in some individuals it is rotated more towards the 2nd digit (pointer) or the opposite way, more radially. 	The orientation of the thumb determines the direction of movement. If the thumb is slightly turned, the splint should be oriented such that it still blocks MCP1 extension and allows opposition.
Narrow webspace In some individuals, the thumb is closer to the palm causer the webspace to be narrow. 	Due to variations and movement in the webspace, it is generally advised the avoid the webspace in thumb splinting. A narrow webspace makes it more challenging to digitally model the splint on the scan.
Bony prominences In some people, the bony prominences are more pronounced than average. Those areas are more sensitive to pressure. 	Bony prominences should be avoided in the splint design. It might be useful for the orthotist to mark bony prominences on the 3D scan so they can be used in the parametric design.

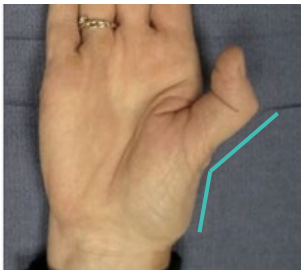
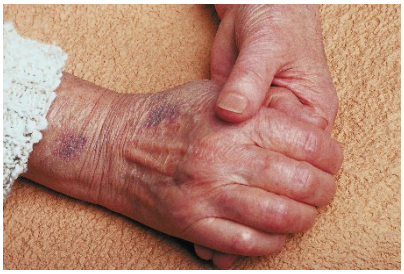
Hyperextended MCP1 A swan-nek deformation (see Chapter 1.1.2 for more info) leads to a hyperextended MCP1 joint.		The splint is used to minimize the swan-neck deformation. It is especially important to correctly position the hand for the scan (Chapter 1.4.2) for a proper splint design.
Sensitive skin Especially patients of EDS can have a more sensitive skin than most. This means that it can be more painful and bruise more easily.		A basic requirement of the splint is that it causes minimal discomfort. However, the heightened sensitivity is a crucial aspect for user testing as it cannot be simulated.

Table 1.1: Notable anatomical variations to consider in the parametric design of a thumb splint.

1.1.2 PATHOLOGY

As mentioned, synovial joints are complex biomechanical structures, and a wide variety of conditions can lead to problems with the joints of the hand. Bracing or splinting is a non-invasive way to remedy symptoms or slow the development of a disorder. Eventually, surgical treatment cannot always be avoided when the damage is too severe, but orthoses can delay such an intervention (Biz et al., 2019).

Orthoses for the thumb can be applied to different joints for a wide variety of reasons. Manometric found a group of people that need a new kind of thumb splinting solution. To create a product that people love to wear, it first needs to become clear who this group is and what conditions they suffer.

In this section, the possible afflictions of patients are explored and the group for whom a new compact thumb splint should be designed, is defined. This provides an understanding of their collective needs and limitations, which is important to design the correct medical aid. Figure 1.13 summarizes this pathology study. The terms highlighted in bold are the ones in the defined user group, which is further explained in the conclusion of this chapter.

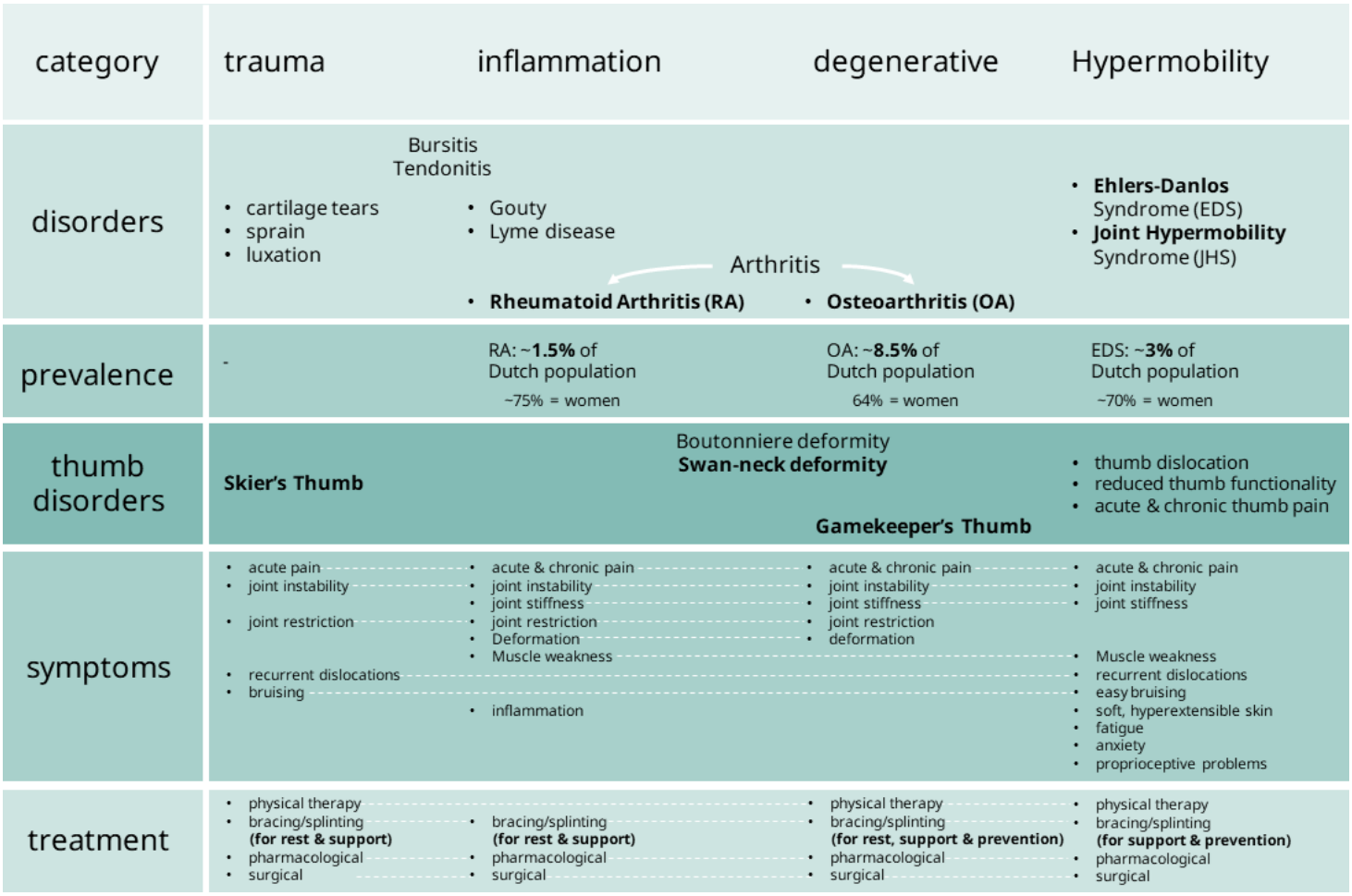


Figure 1.13: Overview of disorders related to hand joints, their prevalence, and symptoms.

TRAUMA

Most common trauma-induced joint injuries can be the result of cartilage tears, sprains, or dislocations. In this category, orthoses are mostly used after a *dislocation* (or: *luxation*), which is the result of two bones that are forced out of alignment and usually leads to spraining and inflammation of the joint as well as difficulty moving it. Repeat dislocations are a common problem because the stability of the joint is reduced due to stretching of the joint capsule and ligaments (Marieb & Hoehn, 2019). Orthoses can be applied to maintain stability of a dislocated joint throughout recovery and afterwards.

Skier's Thumb

Especially the thumb is a common sight of dislocation trauma. In the MCP1 joint, that injury is called *Skier's Thumb*. Forced abduction of the thumb leads to stretching or tearing of the *ulnar collateral ligament* (*UCL*), as shown in Figure 1.14, which heals uncommonly slowly. Patients present with pain at the MCP1 joint, bruising, inflammation and added joint laxity. *Joint laxity* refers to the 'looseness' of ligaments which leads to synovial joints having a range of motion beyond normal limits (Sacks et al., 2019). To avoid chronic instability of the MCP1 joint, an immobilization brace or hyperextension blocking splint can be applied throughout the recovery process and can continue to offer support during high-risk situations afterwards [R-app.1.5] (Anderson, 2010).

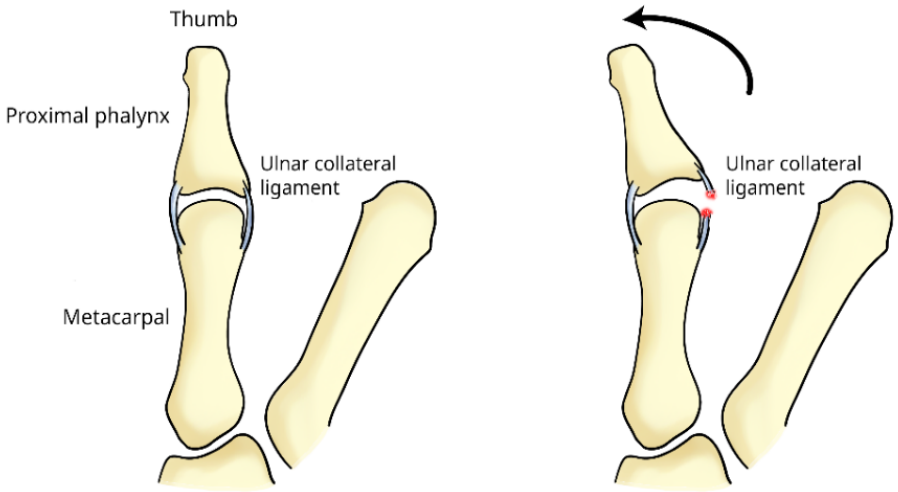
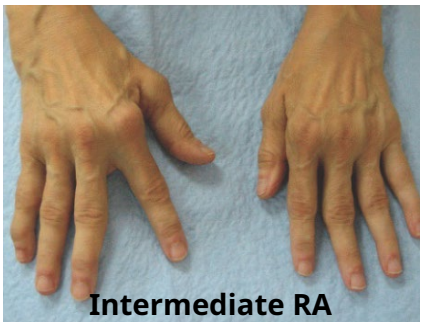


Figure 1.14: Injury to the ulnar collateral ligament due to forced abduction (Weerakkody, 2022).

INFLAMMATION



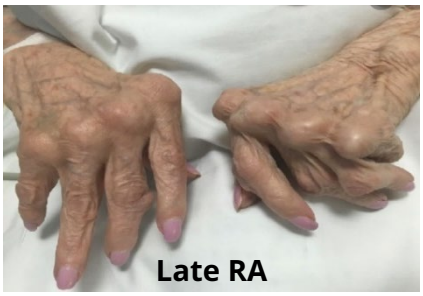


Figure 1.15: Stages of RA. top - Early (Lillicrap, n.d.). middle – Intermediate (Von Feldt, 2016). bottom – Late (Moore, 2022)

Inflammation is the immune system's response to injury and infection. It leads to clinical symptoms of pain, swelling, heat and redness. Inflammation can be acute, for example, when caused by injury, or chronic (Drake & Gombart, 2010). *Rheumatoid Arthritis* (*RA*) is a chronic inflammatory joint disorder, with a worldwide prevalence of about 5 per 1000 adults and 15 per 1000 in The Netherlands (Volksgezondheid en Zorg Info, 2022). It can affect people of any age but is most prevalent around the age of 60. It affects women 2 to 3 times more often than men. In the early stages, swelling, tenderness, stiffness, and muscle weakness are common. As it develops it leads to pain, worsening deformation, and restriction of joint movement, as show in Figure 1.15.

The management of RA is currently focused on slowing down the development of the disease and easing pain, primarily through pharmacological treatment (Aletaha & Smolenn, 2018). Orthoses can be used in all stages of RA to decrease pain, reduce swelling, and prevent deformities [(R-app.1.6)]. The effectiveness of these orthoses varies heavily among patients and depends on compliance and the ergonomic demands of the user's daily life, such as the activities they want to perform and the mobility they require for that. Some patients have lower compliance (less wearing time than recommended by the orthotists), leading to a less effective treatment (Egan et al., 2001), which needs to be avoided [(R-1.7)].

Thumb deformities

Hand or finger *deformities* can occur when ligaments lose their ability to stabilize joints and leads to abnormal alignment of a skeletal segment (ISO, 2020c). Although they especially affect patients of RA, deformities can be the result of any trauma or disease that weaken the joint's surrounding capsule or ligaments. Such deformities in the hands can negatively affect a patient's QoL due to pain, decreased hand function and anxiety. Deformities get progressively worse (Johnsson & Eberhardt, 2009). A *boutonniere deformity* of the thumb (Figure 1.16) can often be stabilized by a splint around the IP joint. A *swan-neck deformity* begins at the collapse of the CMC1 joint which causes the MCP1 joint to compensate by hyperextending (Neumann & Bielefeld, 2003). A splinting solution for this is more complicated, as it involves the base of the thumb, to stop the MCP1 joint from hyperextending [R-1.1]. A study by van der Giesen et al. (2010) showed that silver ring splints and prefabricated thermoplastic splints can both improve the quality of life for patients, but negative side effects, like sweatiness or the splint slipping off, are considerable. Once these deformities reach severe stages, surgical reconstruction is often required (Boeckstyns, 2016).

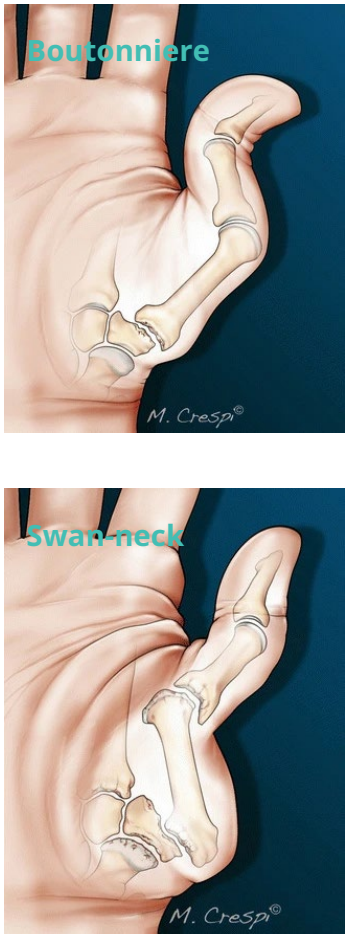


Figure 1.16: Boutonniere deformity (top) and a swan-neck deformity (bottom) (Boeckstyns, 2016).

DEGENERATIVE DISORDERS

Osteoarthritis (*OA*) is the most common chronic type of arthritis also known as "wear-and-tear arthritis". In 2020, over 1,5 million people in The Netherlands had the OA diagnosis of which 64% were women (Volksgezondheid en Zorg Info, 2022b). It is most prevalent in the aged because it is a result of use over time. OA can cause joint pain, worsened by activity, joint stiffness, joint locking, or joint instability (see Figure 1.17), but symptoms are usually not as severe or crippling as those of RA. Conservative treatments include physical therapy, pharmacological treatment and bracing and splinting to support the joints. Eventually, surgeries to replace the joints might be necessary (Sinasus, 2012).

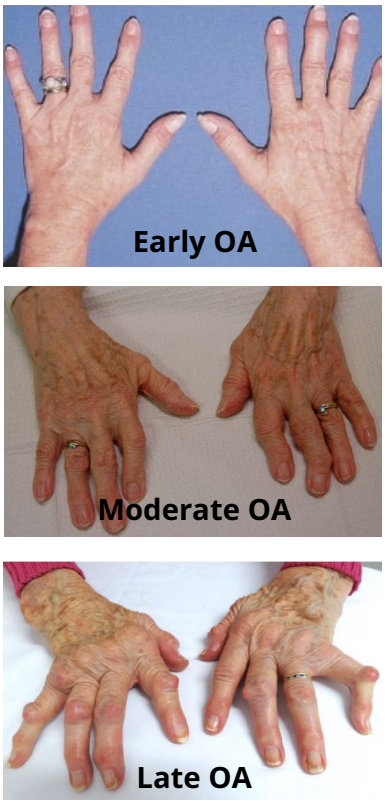


Figure 1.17: Stages of OA. top – Early (what-when-how, n.d.). middle – Moderate (Hegeman, 2015). bottom – Advanced (Lexmedicus, n.d.)

Gamekeeper's Thumb

Gamekeeper's Thumb is a thumb joint disorder like Skier's Thumb. The difference is that Gamekeeper's thumb is a degenerative disorder and is caused by gradual injury of the UCL because of overuse, instead of injury. The result of both disorders is very similar; patients suffer pain at the MCP1 joint, inflammation and added joint laxity. An orthosis can be used to support the MCP1 joint throughout recovery and afterwards (Weerakkody, 2022).

HYPERMOBILITY DISORDERS

The last relevant category of disorders that can affect joints and lead to patients requiring orthoses, is *joint hypermobility*. According to Jensen et al. (2020 joint hypermobility is synonymous with joint laxity and is defined as movement of joints beyond their normal range of motion, as shown in Figure 1.18. It is usually caused by weakened joint ligaments. *Joint Hypermobility Syndrome* (*JHS*) is a hereditary disorder of connective tissue that presents with joint hypermobility. It is estimated that 2 to 3 in 100 persons suffer JHS (Jensen et al. 2020). Similarly, *Ehlers-Danlos syndrome* (*EDS*) consists of a group of inherited connective tissue disorders, of which *classical*- and *hypermobile EDS* (*cEDS* and *hEDS*) present joint hypermobility as well (Parapia & Jackson, 2008) (Mir, 2003). Approximately 3% of the population has symptomatic hypermobility EDS, of which roughly 70% is female. Symptoms of JHS, cEDS and hEDS are almost indistinguishable and the acronym EDS will refer to all three disorders in the rest of this report.

Figure 1.18: Demonstration of joint laxity in the thumb.

EDS symptoms

Patients with EDS present a considerable spectrum of symptoms, including chronic and acute pain, chronic fatigue, muscle weakness, anxiety, impaired sleep, recurrent dislocations, joint stiffness, joint instability, reduced joint functionality and proprioceptive problems (*proprioception* = the sensation of body position and movement, allowing coordination of the body (Tuthill & Azim, 2018)). (Tinkle et al., 2017). EDS often goes undiagnosed, but it can have significant negative effects on the QoL. In an experiment to investigate living with EDS, Terry et al. found that patients experience pain, fatigue, and repeated 'cycles' of injury after dislocations leading to heightened anxiety and catastrophizing about the future, requiring them to modify or restrict their daily activities. Patients feel that EDS is poorly understood by physicians and society and feel stigmatized, whereas they express that feeling understood is instrumental for their pain acceptance. Some impactful quotes from participants of their research that explain the impact on the QoL are below (2015).

…day in day out you're managing your pain and it's a lot of pain, it's a dull ache and it makes you sleepy and it makes you tired and you're exhausted (Female, age 30).

…it's just difficult to know how much to push yourself because then you are worried about injuring and then you're setting yourself back, it's a vicious cycle really (Female, age 27).

I teach like rock-climbing, surfing, body boarding and all of that stuff, like, and I'm not going to stop doing it because I'm in pain like you can't live your whole life with pain dictating what you can and can't do (Female, age 45).

EDS management

Treatment of EDS can be done conservatively as well as through surgery. A study by Song et. Al (2020) described and compared the effectiveness of available EDS treatments. They found that physical therapy with exercises to improve joint stability is a common and effective approach. Different types of medication can be used to reduce the pain. However, the most effective option for managing pain was found to be splinting, with 38 of 54 patients reporting improved symptoms. The most important benefit of using orthoses was their role in improving proprioception and joint stability. Additionally, they can help to reduce fatigue and anxiety (Reina-Bueno et al., 2020). The downside was issues with inconvenience, aesthetic, and discomfort. Chapter 1.2 covers a more detailed analysis of the advantages and disadvantages of different splinting techniques.

1.1.3 CONCLUSION: SPLINTING AS TREATMENT

It was found that the stability of the thumb is of crucial importance to maintain QoL, which can be improved by applying a splint. In designing thumb orthoses, the user should still be able to make a power grip, precision grip and perform opposition of the thumb. Further mobility should be maximized. It is not useful to determine the exact desired ROMs, because this differs significantly per individual. The important muscles to consider for a thumb splint are the thenar muscles and the Adductor pollicis. An overview on page 30 shows how different anatomical sights must be accommodated in a new splint design. Finally, a list of anatomical variances was compiled, that should be considered while design a modifiable thumb splint template, to accommodate most users.

The disorders that are relevant specifically for splinting the thumb are: Skier's- and Gamekeeper's thumb, Arthritis thumb deformities and EDS. In cases with severe joint complexities, like in moderate or severe RA and OA, the complete thumb needs to be stabilized from the CMC1 joint. This requires a larger hand orthosis that immobilizes most of the thumb, usually including the MCP1 joint. However, in early RA and OA, EDS and injuries, patients do not require such a high level of immobilization to remedy their symptoms. Specifically joint laxity problems (resulting in pain, dislocation, fatigue, etc.) can be solved by blocking only specific movements, and the further mobility of the thumb should be prioritized. For them, the CMC1 joint should remain (mostly) free. This mobility should improve hand function and increase the compliance. Therefore, while CMC1 braces are bulkier, an MCP1 splint provides an early solution to support patients who suffer from joint laxity in the MCP1 joint. This brings us to the following goal for the defined user group:

*The splint must **block the MCP1 joint from hyperextending** (R-1.1), thereby minimizing joint pain, anxiety, fatigue, proprioceptive problems, and repeated dislocations while allowing other movements and improving the thumb's functionality **for patients who suffer joint laxity because of EDS, Skier's- and Gamekeeper's Thumb, and Swan-neck deformations from early RA or OA** (R-app.11.2).*

Chapter 1.2 further elaborates on the functions of existing braces and splints and how they fulfil or fall short of patient's needs and why the focus for the new splint should be on MCP1 hyperextension from a market perspective.

The word cloud in Figure 1.19 shows the problems and symptoms that the defined user group experiences. These are aspect to consider while designing and evaluating for patients who suffer these issues. For example, by designing for sensitive skin, testing the effect of a splint on proprioceptive capabilities, compensating for muscle weakness in donning and doffing [R-2.2], and discussing the cognitive load with users.

Figure 1.19: Word cloud summarizing problems and symptoms of target users.

1.2 EXISTING THUMB ORTHOSES

There are many different types of hand orthoses currently available that fulfil a variety of functions. From the previous chapter on pathology, it became clear that orthoses can be applied in various ways to remedy the effects of disorders such as joint injuries, rheumatoid arthritis, osteoarthritis, and EDS. This chapter will list and discuss existing hand orthoses, with a focus on the thumb, and the portfolios of Manometric and competitors are highlighted.

Appendix K (confidential) contains an elaborate list of 32 unique designs of currently available thumb splints at different providers, including Manometric's portfolio. These were discovered through internet searches and advise from Manometric. Figure 1.20 gives a visual overview of the variety in the current market of thumb orthoses. This list is not exhaustive, but covers most existing variations, materials and features in thumb orthoses and can be used as inspiration and to study advantages and disadvantages. The table on page 45 summarizes Appendix K and gives an overview of the most important characteristics of 7 common thumb orthoses.

Figure 1.20: Existing thumb orthoses (see also: Appendix K).

1.2.1 ORTHOSES ARCHITECTURES

The function primarily dictates the shape of an orthosis (or: *product architecture),* which can vary from bulky to compact. Chapter 1.1.1 covered the ROM of the thumb and each joint. The list in Appendix K includes thumb orthoses that affect the entire thumb for severe symptoms and smaller ones with less limitation for lighter symptoms.

Generally, the more immobilization the splint offers, the more robust the design. As the study on pathology showed, more developed disorders like severe RA or OA, require those bulkier braces, that limit the ROM more and offer better pressure distribution. Such orthoses have large surface areas of contact with the skin and surround the thenar muscles to limit their contraction. These usually feature a cushioning material like neoprene or silicone to enable a more comfortable fit and pressure distribution. Immobilization at the CMC1 joint is not direction specific because it requires complete enclosure around the thenar muscles and usually the wrist or hand. Some offer high rigidity whereas others still facilitate a larger ROM. Additionally, some large braces also enclose the MCP1 joint, limiting its ROM variably. Such robust orthoses can be applied for multiple thumb disorders. Larger orthosis architectures are often more difficult to don and doff, which can be considered a downside in terms of patient ergonomics.

Figure 1.20 shows that almost all orthoses immobilize the thumb in a slightly *opposed position*, with flexed and adducted CMC1 and MCP1 joints. This is done to facilitate opposition with the rest of the fingers, even for a completely immobilized thumb. While the exact angles for a functional position vary per person, it is generally understood that splinting the thumb in this position is preferable (Supan, 2017). It is notable that almost all existing thumb orthoses are static and contain no moving parts. This is likely due to the wide ROM of the thumb and added complexity of fabricating relatively small orthoses with mechanical degrees of freedom.

Other orthoses are specifically intended to affect only the IP or MCP1 joint while keeping the others free or to only block a joint in one direction, still allowing other movements. Those are intended for patients with joint laxity problems due to injuries, EDS or in earlier stages of arthritis because they require less immobilization. It was found that the CMC1 joint is the most important thumb joint in terms of hand function and that unnecessarily limiting this joint negatively influences patients' compliance of the orthosis. This is where the more minimal and jewel-like MCP1 splints come in. Their architectures are compact and aesthetically appealing materials like silver are chosen to minimalize or improve the visual impact of the splint.

The MCP1 joint can be more easily supported than the CMC1 joint by using a *first-class lever*, as shown in Figure 1.21. The orthosis provides a stable post for opposition of the other fingers to the thumb, increasing function (Duderstadt-Galloway et al., 2018). Such a system is commonly used in orthoses and can immobilize or block a joint. For an MCP1 block, the *Fulcrum*, which is the axis where the immobilization happens, is on the volar side of the thumb, near the crease of the joint. The *effort force* is proximal on the dorsal side of the thumb. The *resistance force* works distally on the dorsal side. All the forces must be balanced for a comfortable and effective brace. When the thumb is extended, either by the force of thumb muscles or of external forces, the resistance force provided by the orthosis blocks the movement. This force is counteracted at the Fulcrum which is supported by the effort force. For finger orthoses, this usually means that the *arms* should be as long as possible to optimize the mechanical advantage of leverage and reduce the magnitude of forces working on the thumb. However, the effort arm should not be so long that it impedes the CMC1 joint, nor should the resistance arm impede the IP joint. Additionally, where possible, the orthosis should be wider, to distribute the pressure over a larger area, which lessens the compressive and shear forces on the skin (Schofield & Schwartz, 2019). Besides that, the MCP1 joint is usually blocked from hyperextending in a slightly flexed position, to ensure that a point of pain cannot be reached and that the MCP1 joint is in a comfortable and functional position while preventing a swan-nek deformation. The exactly ideal angle of blocking extension varies among individuals, depending on their ROM, but is generally in a range between 15 and 30°. The first-class lever system needs to be implemented such that the forces of the thumb cannot deform the splint beyond the maximum extension angle. The choice of material and shapes and thicknesses of the splint are deciding factors in this.

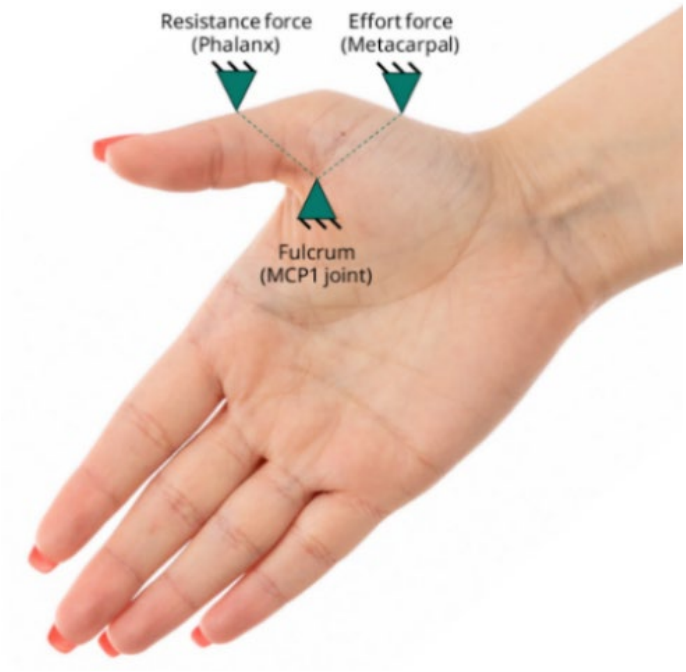


Figure 1.21: First class lever in MCP1 splint.

1.2.2 CURRENT MARKET

Table 1.2 summarizes Appendix K by highlighting the biggest variations in the current thumb orthoses market. The overview is ordered from lightest symptoms to most severe. This clearly shows the differences between products intended for different types of users. It was determined that the target user group for the new thumb splint suffers light symptoms and only needs support to block MCP1 extension, while the mobility of the thumb is otherwise maximized. This allows the scope to be focused on the first 3 types of example products: splints in varying materials and flexible braces. It can be concluded that, while a few solutions for this patient group exist, all of them have downsides that decrease the medical compliance. These aspects are further detailed in Chapter 1.2.4.

Besides the varying architectures, the overview shows that different rigid materials like silver and thermoplastics are used, as well as flexible textiles or silicones. It is also important to note that orthoses can be produced based on different types of patient data. Most prefabricated designs are likely based on large data sets of hand dimensions, to create a sizing system which accommodates most users. Suppliers of custom orthoses make use of ring and hand measurements (Figure 1.22) or 3D shapes or scans (Figure 1.23). The hygiene is another relevant aspect. Some types of plastic or metal splints are significantly more convenient to make and keep clean, than perforated or textile orthoses. Finally, the variety in costs of thumb orthoses is notable, ranging from around 20€ store-bought prefabricated braces to 500€ custom fabricated products. The most important *competitors* to Manometric are OIM and Livit Orthopedie, who also create custom hand- and wrist-orthoses for a target market in The Netherlands.

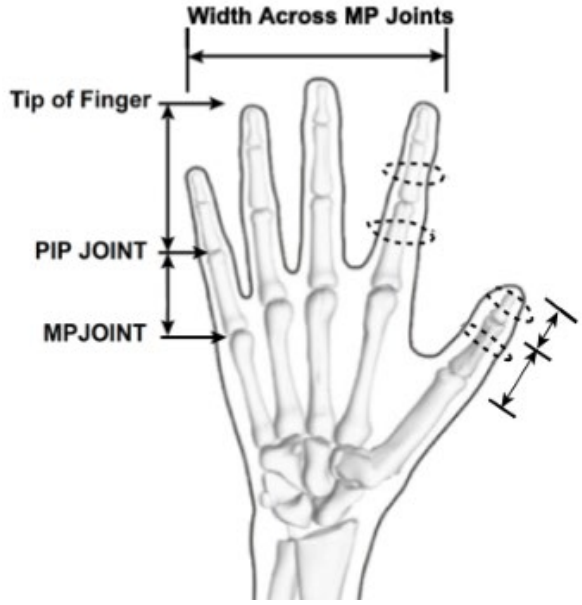


Figure 1.22: example of hand measurements for orthosis fabrication (JAS, 2014).

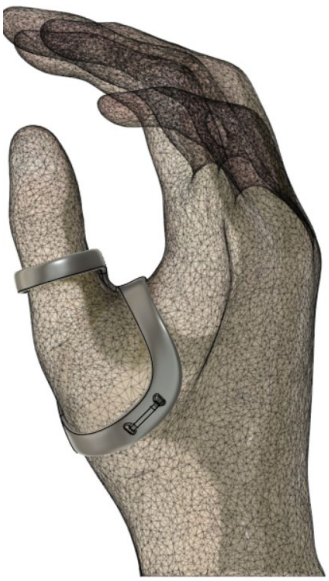
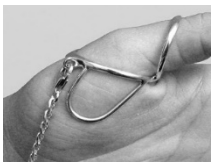
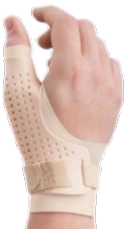


Figure 1.23: 3D scan for orthosis fabrication.

Product	Artus 3D IP block	Silverringsplint MP1 & IP Stabilization brace	Orliman breathable thumb splint	Manometric Silicone Thumb Brace	Push Thumb CMC Brace	Dunimed Thumb support	Livit Silicone wrist/hand brace
							
Type	Custom	Custom	Prefabricated Adjustable, with strap & shape	Custom Adjustable, with strap	Prefabricated Adjustable, with strap & shape	Prefabricated Adjustable, with strap	Custom Adjustable, with strap
Functions CMC1			(partially) immobilize CMC1	immobilize CMC1	(partially) immobilize CMC1	immobilize CMC1	immobilize CMC1
MCP1		block MCP1 extension support MCP1	(partially) immobilize MCP1	support MCP1		immobilize MCP1	Immobilize MCP1
IP	block IP extension & lateral support	block IP extension					
Pathology	Light symptoms Joint instability	light symptoms OA, RA, EDS.	light symptoms OA, RA, EDS, rehabilitation.	severe symptoms OA, RA, rehabilitation.	 OA, joint instability, postoperative.	severe symptoms OA, RA, EDS, rehabilitation, postoperative.	severe symptoms OA, RA, wrist problems
Price	~€100-200*	~€100-300*	€20	~€300-500*	€45	€35	~€400-600*
Materials	nylon plastic	silver	perforated thermoplastic, Velcro, nylon textile liner.	silicone, nylon plastic	thermoplastic, “bendable” aluminium insert, Velcro	nylon textile, neoprene, PP, Velcro.	silicone, Velcro
Data type	3D Scan	Ring & distance measurements	Sizing system	3D Scan	Sizing system	Sizing system	Plaster casting
Production	computational design, additive manufacturing.	silver shaping & smithing	mass fabrication & thermoforming	computational design, additive manufacturing, silicone shaping	mass fabrication & metal bending	mass fabrication	silicone shaping
Appearance	minimal	jewel-like	medical	medical	medical	robust	medical
(dis)-advantages	+ minimalistic appearance + cheap material + much ROM - slips off	+ elegant appearance + hygienic + much ROM - exp. material - slips off - pressure points	+ accessible + thermally improve fit +breathable + some ROM - bulky - suboptimal fit - appearance	+ distributed pressure + adjustable - bulky - sweaty	+ bend to improve fit + Free MCP & IP - bulky - suboptimal fit	+ accessible + supportive - bulky - suboptimal fit - not water resistant - appearance	+ pressure distribution + robust - (very) bulky - sweaty - appearance

(*) Estimated insurance reimbursement amounts based on Dutch healthcare insurance rate indices.

Table 1.2: Summarized overview of thumb splinting market (See also: Appendix B).

1.2.3 MANOMETRIC PORTFOLIO

As explained in the Introduction, Manometric is a young company that specializes in modernizing, objectifying, and improving the process of designing and fabricating custom orthoses, using 3D scanning and additive manufacturing. Their focus is currently on solutions for the hand and wrist. Due to the wide variety of thumb orthoses and their applications, it is important to know what exactly is missing from Manometric's current portfolio and what 'gap' in the market is currently not sufficiently covered by it. It was already found that in the current market, patients with light symptoms have limited options that offer mobility. To further understand this gap, the product order history at Manometric was analysed and interviews were conducted with different Manometric experts.

LEVELS OF STANDARDIZATION

Firstly, the history of product orders at Manometric was analysed to find the types of products that Manometric currently makes for the target patient group. For this analysis, it is important to understand the structure of Manometric's portfolio. The R&D department products that can be parametrically adjusted to personalize the fit. However, they do not have a solution for everything yet, which means some products are made in a more traditional way, based on orthopaedic experience. Manometric's portfolio therefore made up of a 'spectrum of *standardization*'. It is shown in Figure 1.24 (Confidential Appendix J contains a version with Manometric product examples). A goal of this project is to move the thumb splint design further towards standardization. Standardizing products and basing them on objective data can lead to a more predictable and consistent product performance, and efficient workflow, which is important to improve their products and patient experience.

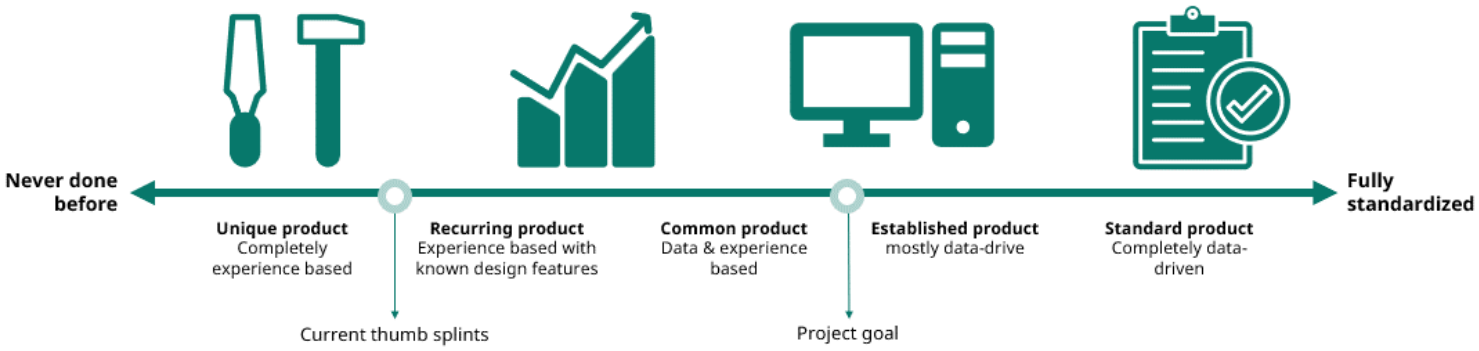


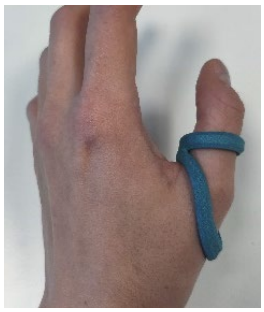
Figure 1.24: Standardization spectrum of Manometric products.

Appendix J (confidential) contains an analysis of the thumb splinting solutions of Manometric, including unique and standard products and a comparison with similar competitors. From this it becomes clear that the standardized solutions are robust braces for the CMC1 joint that cover most of the palmar and dorsal side of the metacarpus (palm). These solutions are fitting for patients with moderate or severe symptoms of RA, OA or deformations. However, from talking to Manometric's orthotists and analysing the order history, it becomes clear that many clients with light symptoms prefer compact and minimal solutions, for practical and aesthetic reason. Manometric currently solves this by manually designing new products based on the experience of their orthotists. Those have a more minimal impact on the hand, while still performing the function of blocking specific movements. Reviewing the designs of those Manometric thumb splints delivered in the past provides insights into what such a splint needs and how they can be improved. Those architectures can have functional deficiencies that lead to problems like the splint being too limiting, sliding off, getting displaced, causing pain, being too large, or breaking.

1.2.4 FEATURE EVALUATION

From the analysis in Appendix J and the list of existing orthoses in Appendix K, a lot can be learned about what features are desirable for the new thumb splint, and what should be avoided. Those conclusions were found through literature research, conversations with orthotists, designers at Manometric and experienced users as well assumptions based on the available information about the orthoses' design and functions. Table 1.3 gives an overview of the most important learnings and how they relate to the design requirements. The features marked in green are generally desirable and need to be considered for the new splint, blue could be valuable to take inspiration from or integrate partially and grey should be avoided if possible.

Feature		Conclusions	R-#
Chain/strap around the hand Many hand orthoses come with a strap around the wrist or hand. This helps to keep the orthosis in its proper place and can strengthen the support that the orthosis provides by facilitating a resistance force on the ulnar side of the hand/wrist.		Avoid. Patients prefer a product without something around the wrist as it adds bulkiness. They also have durability and production complexity issues. Only implement if necessary to avoid losing the splint.	**1.3** **2.8**

Adjustable shape In some orthoses smart use is made of materials that enable the orthotist (or user) to adjust the shape of (confection) products to the individual user's anatomy. For example, through plastic deformation of metal parts, metal inserts and (low temperature) thermoplastic materials. It is important to consider the material's fatigue failure.		Desirable. Allows orthotist to make last-moment adjustments thereby reduces the need for re-fittings.	**3.9**
Swan-neck splint This is the most basic way to block the MCP1 joint's hyperextension. Many features can be added to this architecture to improve its performance. Thumb swan-neck splints are minimal and can be manufactured from varying materials to meet a client's personal preferences. Generally, these architectures slip off too easily due to the conical shape of the thumb and its variable shape.		Insufficient architecture as-is. Slips off too easily. (According to patients and orthotists). However, it presents a valuable minimalistic way of approaching the thumb splinting challenge.	**1.3** **2.1** **2.3** **2.7** **2.8**
Push on thenar muscles Pushing on the thenar muscles at the base of the thumb not only encloses the limb but also limits their space to contract and therefore adds to the immobilization of the CMC1 joint. Squeezing on the thenar muscles causes minimal discomfort and might help to secure a thumb splint more properly at the base of the limb.		Feature requires adaptation. As-is, it immobilizes the thumb too much, but the squeeze around the thenar muscles can improve splint security.	**1.3** **1.2** **1.6** **2.4**
IP joint addition In some splinting architectures, a loop around the IP joint is added to the simple swan-neck splint. This architecture also blocks extension of the IP joint which can be requested for patients who suffer joint laxity on both joints. For these architectures, the nailbed and cuticles become a critical point.		Can be implement. but as add-on feature only, since blocking the IP joint is not necessary for all patients in the user target group.	**-**

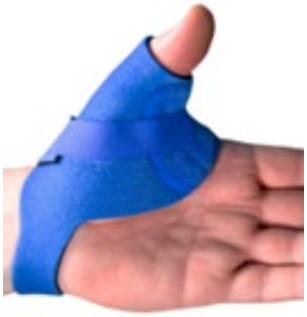
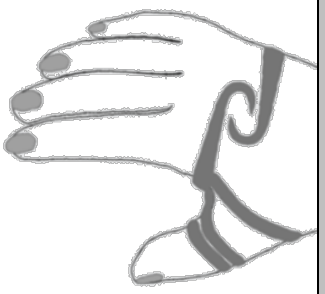
Wrap around radial side Some architectures wrap around the radial side of the hand, at the base of the thumb (CMC1 joint). This architecture allows for straps to be attached or a squeeze to be used around the hand. However, by wrapping it around, the ROM at the CMC1 is limited by the architecture. Additionally, sensitive areas on the dorsal side of the hand can cause discomfort.		Avoid. Experience with such architectures shows that it Limits CMC1.	**1.3** **2.1**
Wrap around dorsal side Some architectures wrap around the dorsal side of the hand following the lateral arch, towards the ulnar side. This allows the splint to 'hook' around the hand and stay more securely in place as well as provide a resistance force on the ulnar side of the hand. However, the dorsal side of the hand has many superficial sensitive structures and prominences to avoid.		Avoid. Too many sensitive areas on dorsal side.	**2.1**
Wrap around palmar side Some architectures wrap around the palmar side of the hand following the lateral arch, towards the ulnar side. This allows the splint to 'hook' around the hand and stay more securely in place as well as provide a resistance force on the ulnar side of the hand. However, the wrapping across the hand laterally makes the design bulky and somewhat limits the mobility of the hand.		Avoid. Patients have expressed that a free palm is important in performing many daily tasks. Besides that, the bulky size of such a splint does not fit the wishes of the users for a compact solution. Only implement if necessary to increase the security of the splint.	**2.1** **2.4** **2.8**

Table 1.3: Overview of existing thumb splint design features and their influence on the design requirements for the new splint.

1.2.5 CONCLUSION: THE NEW THUMB SPLINT

To meet the demand of clients with milder symptoms, who want to better support their thumb, without immobilizing the CMC1 joint, Manometric requires an MCP1-block that can be standardized and parametrically adjusted into a personalized fit for individual clients (R-3.3). The splint should block hyperextension of the MCP1 joint and thereby minimize the negative effects of the patient's joint laxity (R-1.1) while facilitating other movements (R-1.2). Existing MCP1 blocks often present deficiencies such as poor splint security (it slides off easily) and painful pressure points.

The following can be concluded:

*Manometric requires a new solution to replace the unsatisfactory unique solutions with a new design for a thumb splint that can be **standardized** (R-3.1), has a **compact architecture** (R-2.8), **comfortable fit** (R-2.1) and **facilitates most movements** (R-1.6) while blocking MCP1 hyperextension (R-1.1).*

A wide variety of thumb splinting features was considered, and conclusions were drawn about their effect on the desirability and feasibility of the product. For the design of the new splint, the following design challenges were found:

1. To find the correct locations to balance the necessary forces to create a first-class lever, without causing discomfort over time.
2. To create a balance between adequately securing the splint to the hand without unnecessarily impeding on the hand functionality.
3. To create comfortable points of contact to fulfil its function (pt. 1) and properly secure it (pt. 2), without the architecture becoming painful overtime, too bulky or sweaty.

1.3 STAKEHOLDER ANALYSIS

This project is primarily patient centred. The previous chapters have mostly offered insights into the design requirements from the patient's perspective. This chapter will further highlight the patient journey and Manometric workflow, which shows that other stakeholders like the orthotists and manufacturers cannot be overlooked, for the thumb splint to become a viable part of the workflow. In this chapter, relevant stakeholders and their interests and concerns for this project are identified.

1.3.1 MANOMETRIC PROCESS

As mentioned previously, Manometric steps away from traditional orthosis fabrication methods by objectifying the process and making it data-driven instead of experience driven. This chapter contains an analysis of that workflow and the patient's role in it, to come to conclusions about how the new thumb splint must fit into this modernized workflow,

The journey mapping method is used to summarize the patient journey (see Figure 1.25). This helps to gain insights into the stages that a patient goes through to acquire a Manometric brace or splint (Zijlstra, 2020). The method was adapted so it also includes processes that the patient does not experience directly, but that affect the fabrication of the splint.

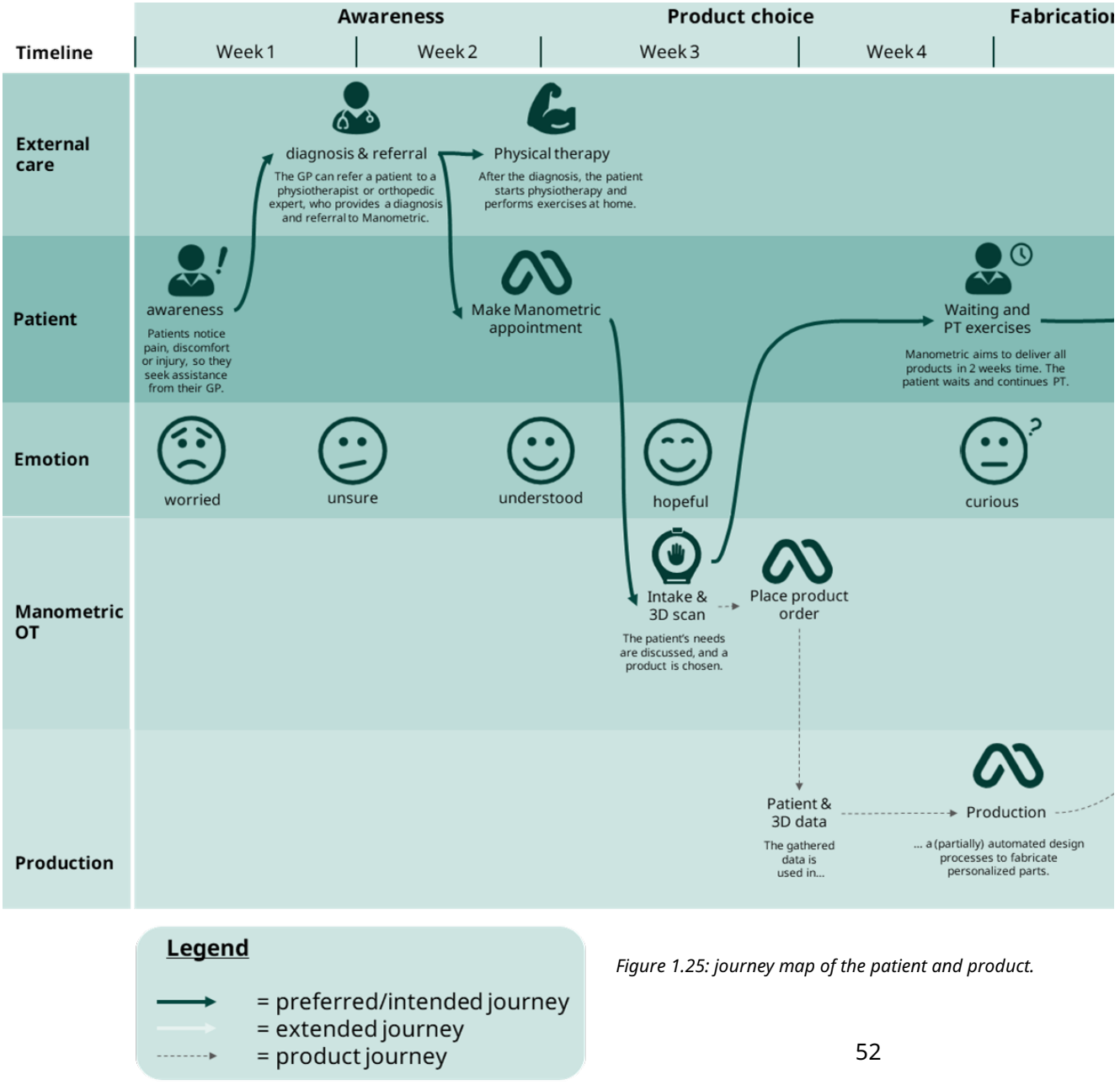
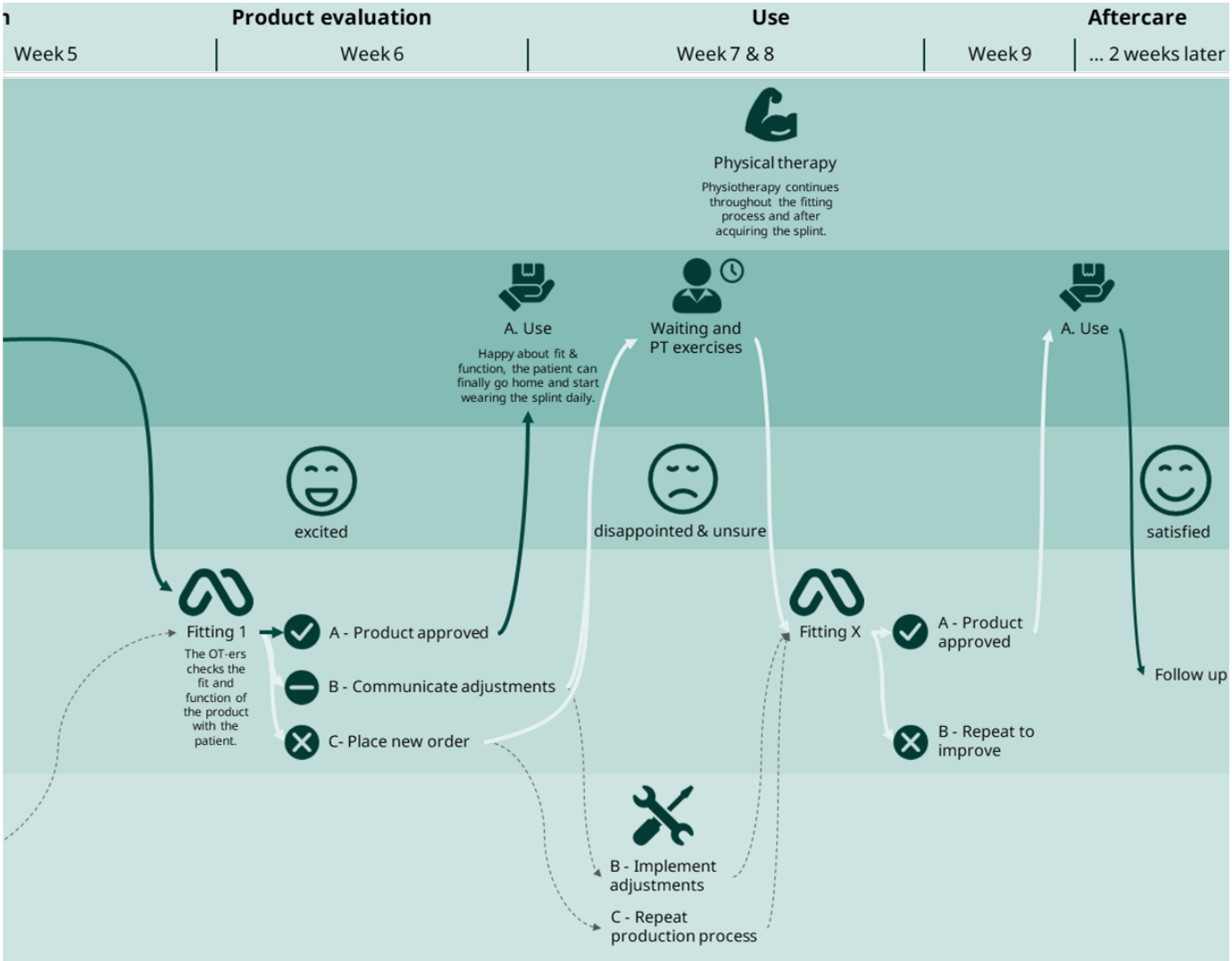


Figure 1.25: journey map of the patient and product.

Figure 1.26 contains a simplified overview of the process, which enables a quick surface-level understanding of the important problems and design requirements. The map was created based on knowledge shared by different Manometric experts (orthotists, Senior Designer, Digital Production Specialist) and semi-structured interviews with patients (n=3). The interview questions can be found in Appendices C and D. The patient journey map has been updated and improved throughout the project to increase its completeness.



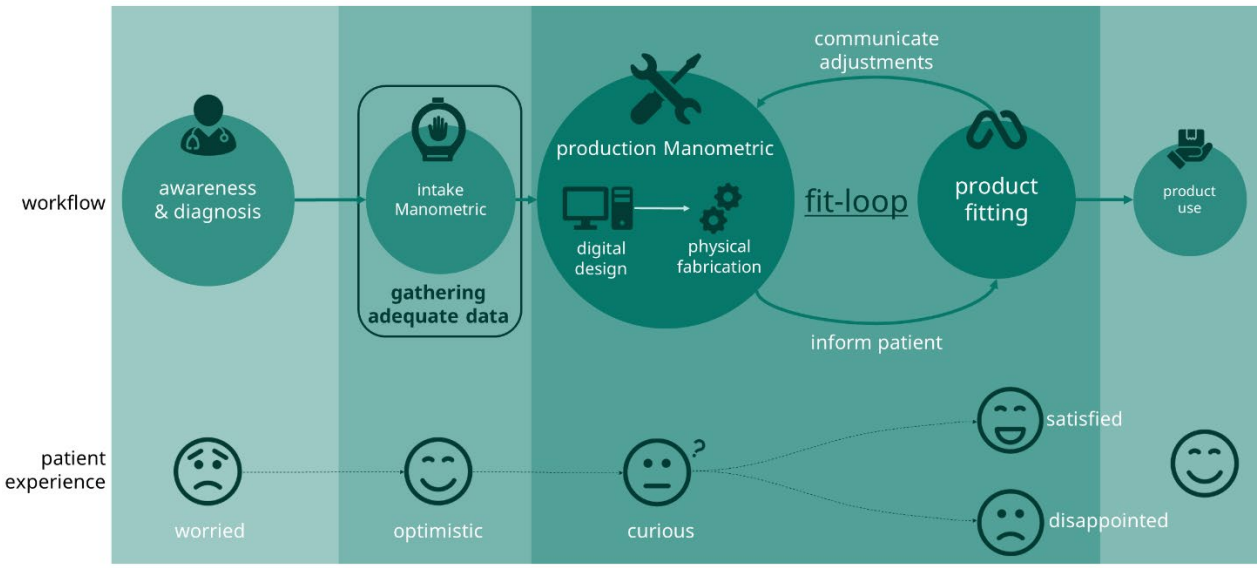


Figure 1.26: Simplified overview of the workflow and patient journey (see also: Figure 1.25).

In short, the current process of Manometric is as follows: as in the traditional workflow, a patient first comes in after a referral from a medical expert. During the first in-take at Manometric, the product choice is discussed, and a 3D scan or measurements are taken, which starts the production process. The patient comes back for a product fitting and can either leave satisfied with their product, or the product is not adequate and needs to be adjusted. In that case, the patient needs to return for a follow-up fitting. This is the most important limitation of the orthopaedic workflow: the *fit loop*. More repeated fittings have a negative effect on the emotional and physical well-being of the patient. Besides that, it leads to higher costs in terms of money and time for Manometric. It is therefore crucial that adequate data is gathered during the in-take to base the production process on (R-3.2). It is part of the design challenge to define exactly what data is required from the in-take. Chapter 1.4 will elaborate on this further. Besides that, this analysis highlights the importance of managing the patient's expectations. The innovativeness of Manometric's workflow can set high expectations with patients who might think anything is possible. Warning a patient about possible fit loops and limitations of the products can help to avoid serious disappointment. For the new thumb splint, any real-world limitations should be communicated at the first fitting (R-app.11.11). Finally, the journey map shows that the complete process for the thumb splint, from in-take to product fitting must be achieved within Manometric's intended delivery time (R-app.12.2).

1.3.2 STAKEHOLDER FIELD

Figure 1.27 displays an overview of the stakeholders in an onion diagram adapted from the methods by Cramer (2019) and by Sami (2018) wherein direct stakeholders are those within Manometric that can directly influence the workflow and who can be concerned with ownership, investment, performance, etc. and external stakeholders are those with diverse objectives and varying ability to influence the project. Connected stakeholders are those who are in immediate contact with the patient and therefore have large stakes in and influence on the patient experience. The most important concerns of different stakeholders are briefly mentioned in the diagram. Conflicting stakes are highlighted with a white dotted line.

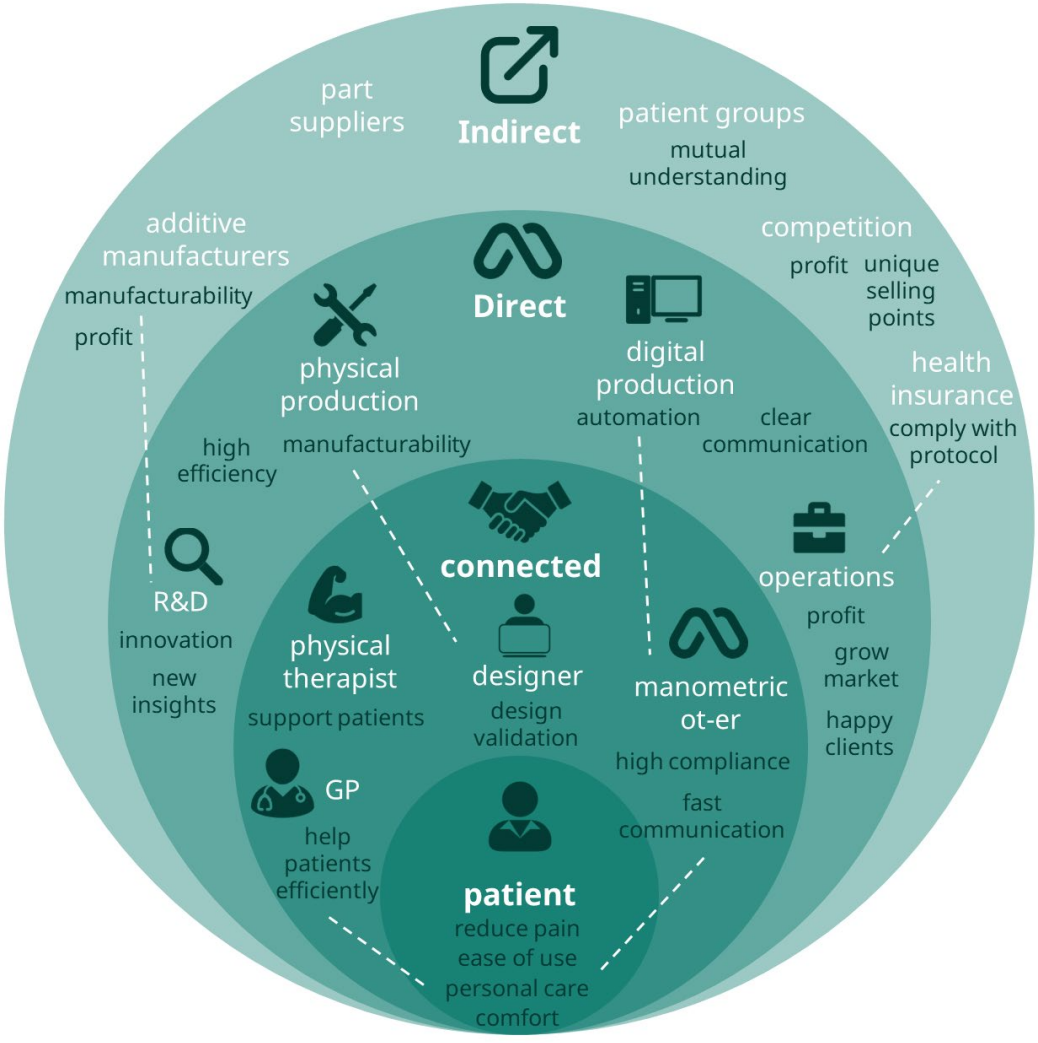


Figure 1.27: Stakeholder overview.

The overview reveals conflict between a patient's need for comfort and personal attention, and the connected stakeholders' need for efficiency. Whereas the patient requires specific individual help, an orthotist sees many more patients in the same day, the production teams need to fabricate all those products and management wants to grow in the market to reach even more patients. This is where the automation through parametric design comes in. However, automating the design process can initially lead to lower compliance, and therefore needs be carefully integrated and well-tested. Additionally, a conflict arises between manufacturability and ultra-personalization, leading to limited options for scalable production. The UPPSS design workflow solves this through digitalizing the design and manufacturing process. Manufacturability also limits the designers' space for innovation. A balance must be found between the scalable producibility of the thumb splint and the level of innovation required to create a new splint that people love to wear. Finally, the influence of health insurers cannot be overlooked as all products must meet their protocol standards (R-app.10.1) for Manometric to receive reimbursement.

1.3.3 PERSONAS

From this stakeholder analysis, it was concluded that a more in-depth understanding of the patients, orthotists and 3D designer was required. This is done through 3 personas, based on the method from the Delft Design Guide (Zijlstra, 2020). They are based on semi-structured interviews (See Appendix B and C) with 4 patients, 2 digital production experts, 1 physical production expert, and 3 Manometric orthotists.

The user interviews revealed how patients in the targe group view their condition. It is largely described as a problem that causes pain in unexpected moments, which causes anxiety. The level of symptoms varies per day and per individual. For some, a splint or brace is crucial in daily life activities as it provides support that they could not live comfortably without. For others, an orthosis is rather a failsafe that enables them to do anything without worrying about hyperextending their thumb. Most importantly, the patients are bothered when an orthosis limits them more than necessarily. On the other hand, they find a small thumb splint annoying due to it slipping off, getting caught or causing pain. In terms of aesthetic, users emphasize the importance of a discreet design, so they are not viewed as 'handicapped' by acquaintances or colleagues. Some patients value an elegant jewel-like appearance, such as that of silver rings. However, the functional and comfort criteria they expressed far outweigh the need for aesthetic details. Additionally, some express the importance of hygiene; the product should be easy to clean with water, and preferably not feature materials that absorb stains (R-3.8).

The Manometric interviews revealed that a major bottleneck in the workflow is communication. Different departments have many responsibilities and full agendas, leaving little time for elaborate conversations or documentation for every individual patient. This emphasizes the importance of correct data communication and usage. For the designer to create the new splint, the design protocol needs to be clear and complete. For the design protocol to be good, the orthotist needs to know exactly what details to communicate.

Figure 1.28: 3 personas of: user, OTer, producer.

1.3.4 CONCLUSION: STAKEHOLDERS

The journey mapping method revealed the importance of the fitting loop limitation. The data that needs to be gathered at the in-take must be clearly defined and related to the splint design features to minimize the amount of fitting loops required. This was emphasized further in interviews with Manometric production experts, who express the importance of clear, selective data communication. Besides that, the expectations of the patient need to be managed carefully, to prevent possible disappointment.

The stakeholder analysis revealed several conflicts, especially highlighting the difficulties of balancing ultra-personalization with a viable and efficient workflow. The UPPSS design workflow, introduced in the Introduction, must be intelligently applied to achieve this.

Finally, the personas on the previous page reveal the most important stakes of three key stakeholders in this project: the patient, the orthotist, and the production expert. The patient interviews offered more insights into the needs of the target user group and confirmed the conclusions from Chapter 1.2 regarding the downsides of existing thumb splinting products.

1.4 PATIENT MEASUREMENTS

Custom fabricated orthoses are created to meet the functional requirements of the individual user based on information such as moulds, models, measurements, and images. One of the first steps of creating such an orthosis is to acquire the correct amount and types of data to base the splint design on. Some products are created based on hand measurements, others on 3D shapes. In this chapter, the types of data that are used in orthopaedics are explored and the important aspects of Manometric's 3D scans for the new splint design are highlighted.

1.4.1 TRADITIONAL METHODS

SIZE MEASURING

At the in-take with the patient, depending on the type of product needed, the orthotist can take measurements of the patient's anatomy. For silver ring splints, it is common practice to use ring sizes (Figure 1.29) and distances between joints to determine the critical dimensions of the splint. However, this is more difficult for the thumb, due to its more complex shape and movements.

Figure 1.29: Ring size measuring tools.

PLASTER MOULDING

In some cases, when body measurements do not provide enough data to shape the orthosis, traditional orthotist can use plaster to create a three-dimensional negative mould of the limb (See Figure 1.30). The mould is used to pour a positive cast with liquid plaster. Although such a cast is inherently accurate, the orthotist's skill is then required to make modifications to optimize the function and fit of the orthosis. For example, by providing additional space at bony prominences or firmer pressure on comfortable areas. The plaster moulding method is usually used for larger products like foot and wrist orthoses. (Farhan et al., 2021) (Supan, 2017, p.42).

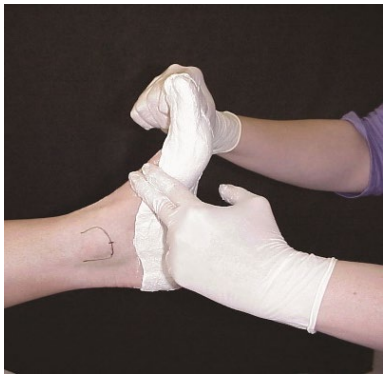


Figure 1.30: Plaster casting (Podiatry Today, 2018).

1.4.2 MODERN METHODS

3D SCANNING

A personalized splint is essentially the same for every user, but it can differ in shape and size to better accommodate the anatomy of the specific user. Using ring sizes to define the splint design is perhaps a more scalable method, as it does not require every orthotist to have access to a 3D scanner. However, for Manometric, the efficiency and accuracy benefits of 3D scanning weigh up against this argument. For the complex shape and anatomical variances of the thumb, using hand measurements is likely not enough data to come to a good splint design. Therefore, the ManoX 3D scanner will also lay the foundation for the workflow of the new thumb splint.

Figure 1.31: Laser triangulation tool in an IPad add-on (Structure.io, 2022)

Figure 1.32: LiDAR scanner on an Iphone (Apple, 2022).

Figure 1.33: The Artec Eva handheld scanner in use (McMillion, 2022)

Scanning technologies

The introduction of 3D scanning made an important change in the world of orthopaedics, allowing orthotist to more easily obtain detailed and accurate data and enabling technicians to use digital modelling and digital fabrication to create custom fabricated products. Different 3D scanning technologies are used in O&P products today, such as laser triangulation, LiDAR scanning, structured light scanning, and photogrammetry (Twikit, 2022). Laser triangulation is an older method, used in add-on scanners like shown in Figure 1.31. It uses the angle of a returning laser to calculate distances, which returns accurate results, but requires significant time to scan an entire object. LiDAR scanners are found in most new models of iPhones. It accurately measures distances to map out three-dimensional spaces but offers poor relatively resolution.

Structured light scanning is used in more professional and costly handheld scanning devices such as the Artec Eva (Figure 1.33). It makes use of a light pattern that is reflected into its camera and shows the distortion in the light as it comes across curves. This results in high precision data of the object's geometry (McMillion, 2022).

However, for structured light scanning, as well as IR pattern triangulation and LiDAR scanning, to collect data from all angles of the object (a hand, in this case), either the scanner or the object must turn 360°, which takes time. In O&P, this is a serious limitation, as it is difficult for patients to remain completely still for long enough. That is why the ManoX 3D scanner makes use of photogrammetry.

The ManoX uses multi-image photogrammetry-based scanning technology to capture data on the shape and appearance of the human hand and lower arm. This is done by simultaneously taking images from multiple angles, as shown in Figure 1.34, and determining the relative positions in space of many points, creating a point cloud to represent the shape. From that, a digital 3D model of the hand is created as a polygon mesh that can be used to determine dimensions of the hand or to immediately model products on.

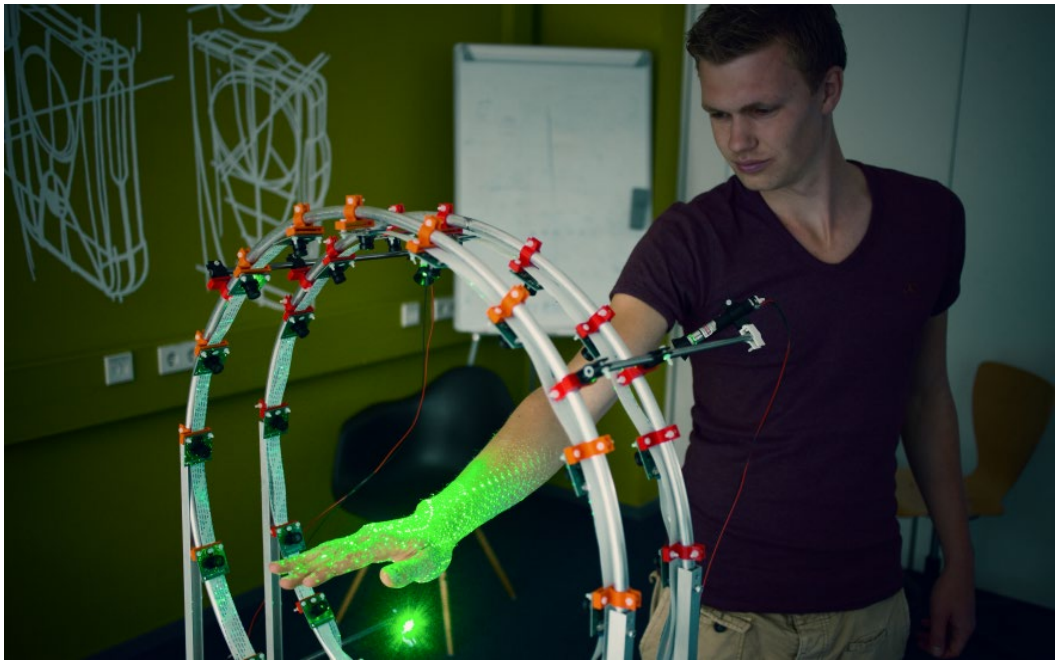


Figure 1.34: Manometric co-founder with an early photogrammetry 3D scanner prototype (TU Delft, 2015).

smoothing

To improve the usability of the 3D scan, it can be smoothened (See Figure 1.35) before being used to design a product. This makes it easier to create formfitting shapes without unexpected, jagged edges. However, the degree of smoothing needs to be carefully considered, because too much smoothing can negatively influence the accuracy of the scan and lead to poorly fitting products.

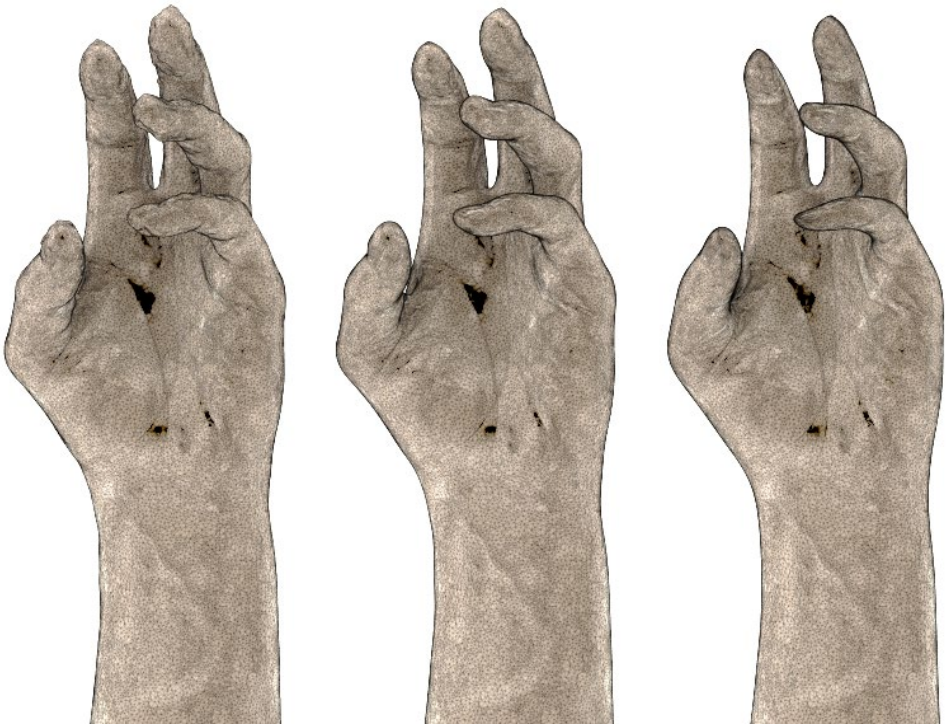


Figure 1.35: Different degrees of smoothing. Left – unsmoothed, middle – moderate smoothing, right – highly smoothed.

SCANNING POSE

Besides the anatomical variations in shape and size of the thumb, the position of the hand during the scan is a crucial aspect of the fabrication process. Currently, Manometric uses different optimized hand poses for different products, to design the splint around it. In Chapter 1. it was found that the ROMs of the thumb joints are variable among individuals and that not one perfect angle exists to create a functional pose for all. Similarly, the angle at which the MCP1 joint needs to be blocked can vary per individual.

In the current workflow, Manometric has determined the optimal scanning poses, depending on the product. The orthotist determines what the correct position is for an individual patient to make the scan in. This allows them to facilitate the individual ergonomic needs of the user. For the new thumb splint, the ideal scanning pose needs to be determined. A crucial difference with the current workflow is that the new thumb splint will be designed for movement rather than for limitation. This means that a new scanning pose is likely required. It is important that the patient can maintain the scanning position, despite the effects of their condition or lack of dexterity (R-app.7.4).

PARAMETRIC ORTHOSIS DESIGN

Manometric aims to create data-driven parametrically adjustable designs, because this enables them to create products with consistent performance and because creating custom digital models, even based on a 3D scan, is a labour-intensive process. The computation design approach uses a combination of algorithms and parameters to solve the design problem using computer processing. In this case, the parametric design approach is used, which is interactive and allows a set of rules and inputted parameters to determine the design. The rules define the relationships between different elements of the design and are based on research of the product and design requirements. The parameters are values like angles and distances that can be derived from the 3D scan or come as manual input from the orthotist (Ramage, 2022). There are various software packages that can be used, such as CATIA, SolidWorks and Rhino Grasshopper. For the new thumb splint, this automation process must be considered to facilitate a smooth introduction into the Manometric workflow (R-3.3). In the initial phases of implementation, it is likely that manual work is still required to control the quality of the resulting orthoses.

Landmarks

Anatomical landmarks are objectively determined locations on the hand such as palmar creases, joints, or bony prominences that might influence the shape of the orthosis. Those marks can be an important foundation of the parametric design approach as design rules can be dependent on them. The relevant landmarks for the thumb splint need to be determined, to lay a foundation for the future computational design of the splint.

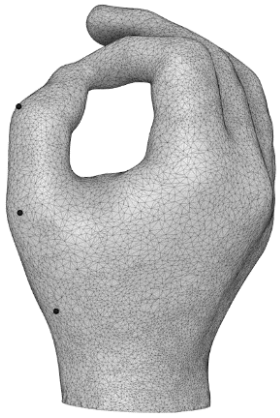


Figure 1.36: Landmarks on the hand.

1.4.3 CONCLUSION: GATHERING THE DATA

To design a new thumb splint that can be standardized, the utility of a 3D scan must be considered. The analysis in Chapter 1.1.1 showed a wide variety in anatomical shapes among individuals. The 3D data regarding the shape and dimensions of a patient's hands and the landmarks will be used to shape the design of the splint and be parameters for the computational design rules. When using 3D scans to design orthoses, it is important that some of the steps from traditional fabrication are not overlooked. In a traditional workflow, orthotist could remove or add materials in their moulds before using it to produce the final product. This facilitates a tighter fit around soft tissue or a more space around sensitive prominences. Such alterations might be relevant to improve the products in a modern workflow as well. They need to be carefully measured and documented to be objectively integrated into the parametric design.

Secondly, the position in which the 3D scan is made is critical for the success of the orthosis design. Testing with different scanning poses is required to determine what would be optimal position for the new thumb splint. This is especially relevant because this splint will be designed to facilitate movements. This means that modelling the orthosis around the most functional static position of the thumb is likely not the best approach for a splint intended for motion.

1.5 MATERIALS & FABRICATION

The production process of custom fabricated orthoses quite unique. Each product is slightly different to create an optimal fit and function for individual users. In this chapter, the traditional fabrication process will be discussed and compared to Manometric's modern workflow to learn the crucial aspects required for orthoses design from a traditional perspective and how the design should fit in the Manometric workflow and production processes. Additionally, the possible material choices for orthoses are explored and their advantages and disadvantages are listed to draw conclusions about the materials and production of the new splint.

1.5.1 TRADITIONAL FABRICATION

Figure 1.37 shows the current possible splinting procedures. A patient is usually referred to an orthotist by their general practitioner, physical therapist, or orthopaedic surgeon. They include a medical referral, necessary client data and recommendations about the splinting solution to the orthotist. The orthotist then talks to the patient about requirements and wishes for the brace or splint, to come to a design. After the referral, orthotists can produce their own products or work with an orthotic technician and external producers to fabricate their products. Alternatively, for custom upper extremity orthoses, it is common for physical therapists to provide their own products by making use of *Low-temperature thermoplastic materials* (*LTTM*), which are applied directly on the limb and require no further anatomical data.

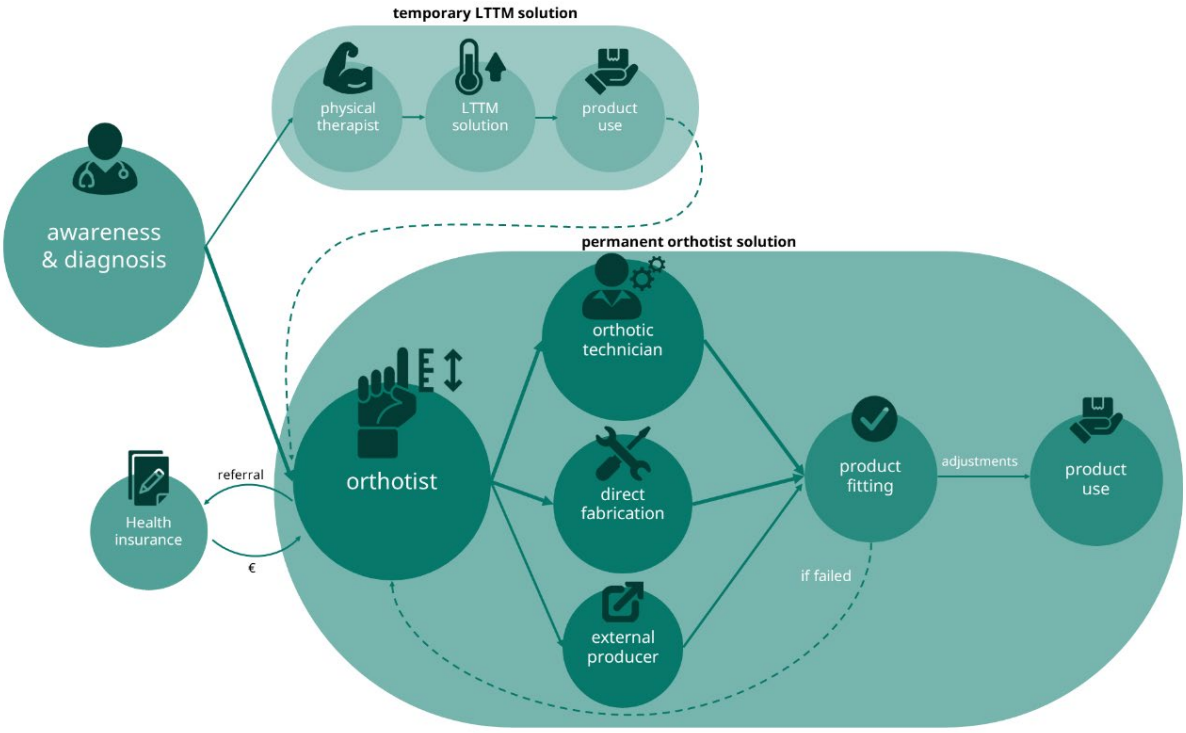


Figure 1.37: Current orthoses procedures.

LTTM ORTHOSES

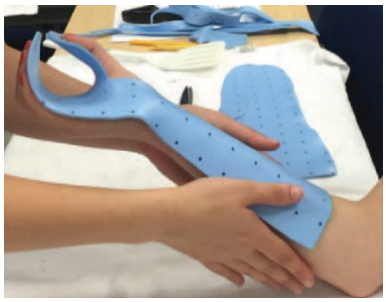


Figure 1.38: molding an LTTM orthosis. (Schofield & Schwartz, 2019)

Figure 1.39: LTTM thumb brace. (Schofield & Schwartz, 2019)

LTTM orthoses are sculpted out of sheet material immediately on the limb, after being heated to about 60°C and cutting out the appropriate shape, as shown in Figure 1.38. When it cools down, it hardens in the correct shape. This allows the patient to walk away with a working product, like the thumb brace in Figure 1.39, after just one visit. Such orthoses are custom fabricated quickly and relatively cheaply, but the process is entirely based on the therapist's experience and difficult to repeat. Usually, this intervention by the therapist is a temporary solution and the patients are referred to an orthotist if the problem persists. Other downsides to this method are that the solutions are often not durable and have an unappealing medical appearance. Different LTTMs with different characteristics are available. The rigidity, resistance to stretch, conformability, impressionability, thickness, perforation, and activation time are all variables in working with LTTM.

THERMOPLASTIC ORTHOSES

Orthotists generally do not use LTTMs. They make use of higher temperature thermoplastics, that cannot be applied to the skin and requires different fabrication methods. These types of thermoplastics are not only more durable but can offer more rigidity once cooled. For many hand- or finger sizes, orthotic technicians have an array of standard castings, moulds, and sheet patterns which they can use in production. Sometimes a custom plaster mould is made. A sheet of thermoplastic material is heated in the oven, cut into the correct shape, and usually vacuum formed over the cast. Once it has cooled and hardened, the part is removed, the trimlines are finalized and smoothed, and the product is finished to optimize the comfort based on the patient's ergonomic requirements or wishes regarding use and activities (Supan, 2017). At an appointment with the patient, the orthosis can be partially reheated and adjusted to optimize the fit and sometimes several appointments are required before the fit is sufficiently comfortable and functional (ASHT, n.d.).

SILICONE ORTHOSES

Silicone is a type of elastomer that is commonly used in manufacturing of orthoses when less rigidity is required (Figure 1.40). A wide variety of silicone types is available that offer different degrees of hardness, categorized by their *shore values*. Besides that, the flexibility of a product depends on the thickness and shape. Processing methods for silicone are usually similar to those of thermoplastic orthoses; by being shaped from solid sheets onto a mould. Silicone products need to be vulcanized on their mould at elevated temperature to obtain the required shape stability. Orthoses can also be produced of *liquid silicone*, through injection moulding. Both types of silicone can facilitate a wide range of product flexibilities (Mourik et al., 2017). Generally, silicone orthoses are less rigid than thermoplastics and can offer more comfortable contact with the skin due to its compressibility. These products are usually on the bulkier and sweatier side due to the required thickness. They are especially applicable for patients with sensitive skin. Silicone inserts can be used to pad specific areas of a thermoplastic brace with a more flexible material to improve the comfort of the product (Figure 1.41) (Schofield & Schwartz, 2019).

Figure 1.40: Custom fabricated silicone thumb brace. (Livit, 2018)

Figure 1.41: Soft silicone padding used in insoles (Advanced Orthopaedics, 2019)

SILVER ORTHOSES

Silver is a (generally) skin-safe metal which offers a much higher rigidity than most plastics, and therefore allows thinner shapes to be used. It can be unforgiving and cause painful pressure points. Silver is a precious metal, which makes it significantly more expensive than alternative materials. However, it is hygienic and offers good aesthetic characteristics. Silver ring splints (see Figure 1.42) are a type of simple swan-neck splinting solution that is commonly used around digits 2 to 5 for patients with EDS, to block hyperextension. The splints are made of 925 sterling silver. In the case of silver orthoses, an orthotist often orders their products at an external party. Those silver specialists use the measurements from the orthotist to shape the products over standard moulds and create a personalized fit.

Figure 1.42: Silver ring swan-neck splint.

Silver splints can be made through a variety of metal shaping methods, including metal casting, wire shaping and other silver smithing methods. Silver casting can be done with standard moulds or custom moulds using the *lost wax casting* method (or: 'investment casting') (Srinivasan, 2012), which is inherently suitable for personalized products (Mourik et al., 2017). In wire shaping (Figure 1.43, left), silver wire is heated and then shaped or soldered to create the desired design, sometimes over steel moulds to obtain the correct shape and dimensions. This process, and other silver smithing production processes like detailing and cold shaping (Figure 1.43, right) are still costly manual labour (Chad's Silversmithing, n.d.).

Figure 1.43: Silver smithing methods. Left – wire shaping, middle – detailing, right – cold shaping.

Silver products are always polished (Figure 1.43, middle) and often tumbled to obtain the right surface finish. At the fitting with the patient, the orthotist can make minor adjustments to the silver product by plastically deforming the metal. Some adjustments by reheating the silver can also be made by smithing experts outside of the fitting room.

OTHER CUSTOM ORTHOSES

For hand orthoses, the rigidity of the plastic is not as important as, for example, in knee braces, because the forces are significantly smaller. Metal inserts are sometimes used in thermoplastic or silicone solutions to provide additional rigidity. This is a common practice in dorsally applied finger splints against hyperextension (Duderstadt-Galloway et al., 2018). Softer materials like neoprene or other foams are useful for clients with sensitive skin and enlarged prominences. These materials can allow a more comfortable contact with the skin in otherwise rigid thermoplastic braces. Some patients still require leather orthoses, usually due to personal preference or habituation. Those are made by sewing sheet patterns based, but this is not used often in the developed world (Supan, 2017).

TRADITIONAL FABRICATION: CONCLUSION

Exploring the traditional fabrication methods has further shed light on the current thumb splinting market. While Manometric applies modern fabrication methods, which are discussed in the next section, they also make use of most of these traditional methods and combine them. Understanding these methods is important to make decisions regarding the materials and manufacture of the new splint. From the traditional fabrication methods, the following conclusions can be drawn for the new thumb splint:

- Sheets of thermoplastic material (including LTTM) are not a viable material option due to the lack of dimensional freedom and the amount of manual labour for Manometric.
- Silicone and silver are suitable traditional material options as they can be applied using computational fabrication methods.
- The rigidity of the splinting material and shape must be based on the magnitude of forces the splint should support. Smaller body parts with relatively weak muscles, like the thumb, require less thickness and less rigidity than, for example, a knee orthosis (Schofield & Schwartz, 2019).
    - Silver requires less thickness than plastic solutions but is significantly more expensive and thinner parts create poorer pressure distribution.
- Through perforation or airy architecture, a splint should be made as breathable as possible, especially for warmer climates and sensitive skin, without causing localized areas of weakness[(R-2.9)].
- The splinting material and solution must have adequate conformability to properly fit the patient's anatomy, avoiding bony prominences[(R-2.1)] (Schofield & Schwartz, 2019).
- Flaring the material outward around bony prominences helps to prevent painful pressure points (Schofield & Schwartz, 2019).
- Orthoses of any material must be adequately finished to avoid sharp edges and corners.
- Combinations of materials can be used to combine their beneficial characteristics. High temperature thermoplastics and metal can offer rigidity, while silicone or neoprene components can improve comfort.

1.5.2 DIGITAL FABRICATION

Manometric and competitors are working on innovative ways to use *Computer aided manufacture* (*CAM*) methods for direct fabrication of the final orthosis, which can reduce the cost of fabrication, enable (partial) automation, permit the orthotist to create novel structures and help to make the splinting process more data driven. After obtaining a 3D scan of the patient's hand, it becomes especially interesting to apply *computer aided design* (*CAD*) tools to design directly on the 3D scan. The digital design (or *digital model*) can then be turned into a tangible product through various CAM methods.

ADDITIVE MANUFACTURING

Additive manufacturing can be used to directly fabricate orthoses, or to create models and moulds for other processing methods. For example, wax models can be 3D printed to fabricate silver products in lost-wax casting. Moulds for liquid silicone products can be 3D printed as well. A wide variety of material and processing options are available but not all of them are suitable for O&P fabrication. Medical products must conform with regulatory standards, most notably, the materials must be certified for long-term skin contact. A literature review reveals several additive manufacturing methods used in the production of O&P products. The most common ones are *fused deposition modelling* (*FDM*), *stereolithography* (*SLA*) and *selective laser sintering* (*SLS*) (Chen et al., 2016) (Wojiechowski et al., 2019).

FDM

FDM printing (Figure 1.44) is low cost and offers biocompatible material options PLA, ABS and TPU (Choo et al.,2020). However, the geometrical limitations and low resolution (All3DP, 2021) (3D Insider, 2018) make it an unsuitable method for this project.

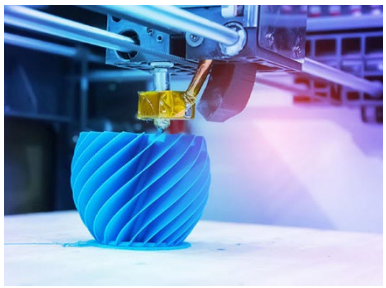


Figure 1.44: FDM printing.

SLA

For SLA printing (Figure 1.45) many medical resin materials have been developed and tested. The precision of this method can be extremely high, as it depends on the size of the laser (All3DP, 2021) (3D Insider, 2018). However, the materials are generally more rigid and brittle than other AM methods, which is not desirable for orthoses as they would offer less compliance and sooner break. They are also sensitive to UV light (Wojiechowski et al., 2019).

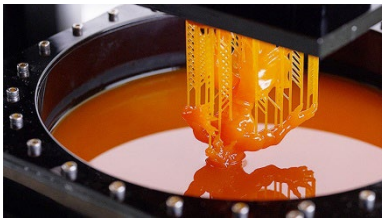


Figure 1.45: The result of SLA (resin) printing.

SLS

Figure 1.46: The result of SLS (powder bed) printing before cleanina.

SLS printing (Figure 1.46) is a developing method that is becoming lower cost wherein layers of polymer powder are deposited in a bed and selectively fused together by a CO^2 laser. This makes it as precise as an SLA printer. A large benefit of this method is that no supports are required (All3DP, 2021) (3D Insider, 2018). However, the surface finish is rough, so the products usually require post-processing to be comfortable on the skin. Not many materials can be used in SLS printing but among them are PA11, PA12 (also known as Nylon) and thermoplastic elastomers, which are often used in medical applications including orthoses (Eos GmbH, 2021). This makes SLS printing the most popular choice for 3D printing of orthoses (WeMatter, 2022).

MJF

Figure 1.47: The cleaned result of MJF (powder bed & fusion) printing.

A newer player in the AM of orthoses is Multi Jet Fusion printing, invented by HP (Figure 1.48). Like SLS, in MJF the printer lays down a layer of material powder on the printing bed. Then, an inkjet head deposits both a fusing and detailing agent onto it. Finally, infrared heating of the layer causes the areas with the fusing agent to melt together with the underlying layers and the detailing agent remains a powder. This means that MJF printing does not require support material either. Unique to MJF printing is the fact that layers become completely fused, which improves the detailing, durability, and mechanical strength of the part (Figure 1.47). Not many different materials are available in MJF yet but PA12 is a popular choice in the medical world as a skin-safe material. (Kauppila, 2022)

Figure 1.48: Result of MJF (powder bed & fusion) printing being cleaned (HP, 2022).

1.5.3 CONCLUSION: SPLINT FABRICATION

On page 69, learnings were listed regarding the splint design based on conclusion from the analysis of traditional fabrication methods. For the new splint, Manometric's modern approach will be used. The primary requirements related to fabrication are precision, dimensional freedom, biocompatibility, and a fit with the computational design workflow of Manometric. The amount of manual labour needs to be reduced by making use of digital 3D scans, partially automated digital design, and additive manufacturing methods. SLA, SLS and MJF printing are viable options to produce the new thumb splint and prototypes. All come with their own advantages and limitations.

Silver products are often ordered because of the aesthetic, hygienic and mechanical properties of the material. Using AM in a technique like the lost-wax casting process can make this a viable option. An important downside to using silver is the high cost of the raw material, complex manufacturing process and the stiff mechanical characteristics on the material, causing painful pressure in some cases.

2. Definition phase

CONTENTS

INTRODUCTION

The problem statement introduced at the start of this project was:

"Develop a design template for a patient-specific thumb orthosis that enables a personalized fit based on objective patient data and allows Manometric to provide products in a way that is beneficial for all involved stakeholders."

The analysis phase has offered rich insights and takeaways regarding the joint problems, thumb anatomy and functionality, existing thumb splinting solutions, Manometric's workflow and possible production processes. This information was used to better understand the problem statement, define the scope of the project, and find design criteria for the new thumb splint. In this chapter, those insights are gathered and synthetized into design drivers, a design vision and a list of requirements and wishes. The design drivers encompass the new problem statement and explain what the new design must be, whereas the design vision is meant to inspire the design process. Finally, the envisioned function, workflow and aesthetic value are further elaborated.

2.1 DRIVERS

The design drivers describe the most important design challenges that came forward during the analysis phase, as opportunities. The 4 design drivers that were concluded from the analysis phase are:

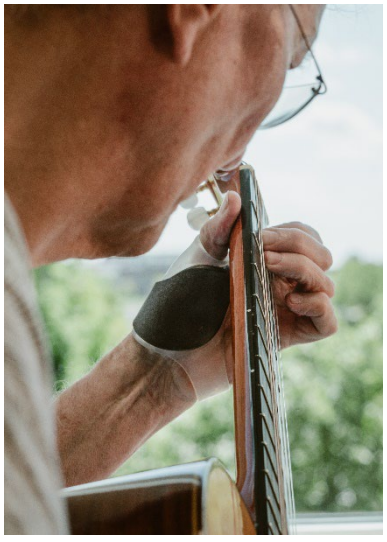


Figure 2.1: Example of a happy Manometric client where desirability and function were balanced.

A SPLINT THAT PEOPLE LOVE TO WEAR

- Challenge: Desirability vs. Function

An appreciated orthosis has a high medication compliance (Figure 2.1). To create a thumb orthosis that people love to wear, the different aspects of what makes an orthosis desirable need to be discovered. A thorough understanding was gained of the thumb's anatomy, function, and movements, which led to conclusions about the anatomical and kinetic challenges that need to be solved to come to a comfortable product. Then the study of the clinical situation was used to define who exactly needed a new type of orthosis and why:

*The splint must **block the MCP1 joint from hyperextending**, thereby minimizing joint pain, anxiety, fatigue, proprioceptive problems, and repeated dislocations while allowing other movements and improving the thumb's functionality **for patients who suffer joint laxity because of EDS, Skier's- and Gamekeeper's Thumb, and Swan-neck deformations from early RA or OA**.*

Plenty of existing braces can fulfil the function of blocking hyperextension of the MCP1 joint. However, upon further exploring the desirability, it was found that the new splint should not only be functional and comfortable but also have a compact architecture and facilitate other movements. The key here is to involve the users in the design process. This is the only way to reveal the aesthetic preferences, practical hiccups and daily life struggles that can make or break the compliance of an orthosis.

PROVIDE SUPPORT, FACILITATE MORE

- Challenge: Limiting vs. Enabling

During the market analysis, it was found that though many varieties of thumb splints exist, very few designs focus on facilitating movement, instead of immobilizing. The anatomical study showed the wide ROM of the thumb and its importance in daily life activities. This forms an important part of the desirability challenge as an immobilizing brace unnecessarily limits the target group and decreases their hand function. For those patients that only require minimal limitation in blocking MCP1 hyperextension, a design needs to be created that balances adequate blocking with the facilitation of most (if not all) other thumb movements (Figure 2.2).

Figure 2.2: Providing support while enabling activities.

EFFICIENT PERSONAL CARE

- Challenge: Personalization vs. Efficiency

For an orthosis to optimally fulfil its functions, it needs to be slightly different for each individual user. Personalized products are generally ideal from a user's perspective, but complex from a business perspective, due to the required logistics and manufacturing. The market analysis pointed out that:

Manometric requires a new solution to replace the unsatisfactory unique solutions with a new design for a thumb splint that can be ***standardize****, has a* ***compact architecture****,* ***comfortable fit*** *and* ***facilitates most movements*** *while blocking MCP1 hyperextension.*

The study on patient measurements showed that the use and pose of the 3D scan would be critical in creating an effective splint template that can be parametrically adjusted (Figure 2.3). To make the workflow for personalized products efficient, a clear definition of the required data needs to be formulated. The correct data (i.e., 3D scan pose, landmarks, etc.) need to be used to create a balance between personalization and an efficient workflow to create a sufficiently personalized yet viable product.

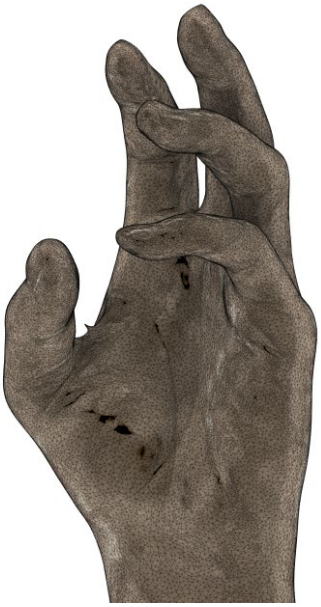


Figure 2.3: The pose and landmarks on the scan need to be defined.

ADDITIVE MANUFACTURING

- Challenge: Limitations of AM

Manometric relies heavily on additive manufacturing to provide personalized products (Figure 2.4). However, as chapter 1.5 highlighted, most AM processes come with limitations in terms of cost, tolerances, durability, and mechanical properties. Hyper personalization and additive manufacturing go hand in hand, because AM enables a viable production batch size of n=1. Additionally, CAM methods enable computational design approaches. The design needs to be planned and tested such that it can be parametrically adjusted and fabricated within the limitations of explored options in AM, to create high quality splints for each individual user.

Figure 2.4: Additive manufacturing used to create new geometries for personalized thumb orthoses.

2.2 DESIGN REQUIREMENTS

The design requirements and wishes that resulted from the analysis phase can be placed in the following categories that encompass the goals of this design project. The key requirements are listed here, the complete list of criteria can be found in Appendix A. The checklist for a list of design criteria by Roozenburg & Eekels (1998) was used to ensure the completeness of the list. Topics that are outside the scope of this project were removed.

1. PERFORMANCE

Firstly, the new splint should adequately remedy the negative effects of injury, EDS, and deformities in the MCP1 joint by blocking hyperextension. Besides that, the thumb and hand should remain functional, which means the splint should facilitate mobility while staying in its proper position.

Requirements

1.1 The splint must prevent **hyperextension** (= continuing extension beyond the anatomical/straight position) of the **metacarpophalangeal joint** of the thumb (= MCP1 joint). It must block extension of the MCP1 joint at **15-30°** of flexion, depending on the user's personal needs.
1.2 The splint must improve the **thumb stability** such that it forms a stable post for the other fingers, facilitating grips for daily live activities, so at least **opposition**, a **pinch grip** and a **power grip** are possible.
1.3 The splint must be **sufficiently secured** in place so it cannot move into a **suboptimal position** or be **accidentally lost** during normal daily use.
1.4 The splint must function as intended for **8 hours of daily usage** for at least **2 years**.
1.5 The performance of each individual splint must be **consistent**.

Wishes

1.6 The splint should **maximize the thumb's mobility**, while fulfilling all requirements.
1.7 The **medication compliance** of the splint should be as high as possible.

2. ERGONOMICS

To make a product that people love to wear, it is crucial that the user’s preferences are met. The new thumb splint should not only comfortably fit each individual client, but also meet their practical and aesthetic demands.

Requirements

2.1 The splint must not cause any **pressure points** that lead to discomfort or pain during (continuous) daily usage.
2.2 The splint must enable easy **donning and doffing** within 5 seconds (each), considering users with low dexterity.
2.3 The splint must not obstruct the user's daily activities by **snagging or catching** behind objects.
2.4 The splint must leave **enough space** to facilitate **thumb mobility** (see requirement A) in the areas of the hand (palmar creases, first webspace, thenar muscles) indicated in green in Figure 1.12, Chapter 1.1.1.
2.5 The splint design template must **accommodate anatomical variances** such that it fits 95% of the target user group.
2.6 The splint must fit the **aesthetic values** of the target group.

Wishes

2.7 The fit of the splint should be as **snug** as possible, while fulfilling all requirements.
2.8 The splint should be as **compact and discreet** as possible.
2.9 The splint should cause as little **perspiration** as possible.

3. PRODUCTION

In manufacturing the splint, the feasibility and viability of the design are tested. Since each splint is unique, most conventional production processes are not viable. The splint should be parametrically adjustable to fit most users and the design and production process should fit Manometric's workflow. Additionally, several material requirements were found.

Requirements

3.1 The design template must enable **personalization** for individual users to facilitate **consistent** performance. (See also R1.5).
3.2 The splint design template must use **accurate measurements** of an individual's **3D anatomy** to facilitate a **parametric design approach**.
3.3 The design template must be **documented in parametric design rules** that lay groundwork digital parametric automation of the design process.
3.4 The **mechanical strength** of the splint must be sufficient to block extension such that reaction forces can be applied without it **breaking or deforming.**
3.5 The production process must be **technically feasible** for individually personalized products with a **batch size n = 1**.

3.6 The production process must be **economically viable** for individually personalized products with a **batch size n = 1**.
3.7 The splint material must be (certified) **safe to use on the skin.**
3.8 The splint must be **cleanable** with tab **water and soap.**

Wishes

3.9 The design template should minimize the amount of **fitting loops** (see Chapter 1.3.1) necessary to provide clients with a good splint.

2.3 VISION: THE NEW SPLINT

These design drivers and criteria result in the following *design vision*:

*Create a compact thumb splint design that people **love to wear**, by providing support in the right places to avoid MCP1 **hyperextension**, while maximizing the **thumb's mobility** and hand function, and ensure the viability of **hyper personalization** of the splint by gathering the **correct data** and intelligently applying **additive manufacturing** processes.*

In this section, the requirements are translated into a description of the envisioned result. This helps to place the requirements in their context and clearly defines the boundaries of the design space.

The starting point of this project was the suboptimal workflow for thumb splints, due to a lack of standardization. The analysis phase was intended to uncover the collective conditions, needs, and wants of people who require a thumb splint, what functions it should fulfil and how it could be made. The gathered knowledge can now be used to design one splint architecture that will work for most people who suffer MCP1 joint laxity.

SPLINT IN MOTION

A user must still be able to make a power grip and a pinch grip, along with other user specific activities such as using a computer mouse and grabbing a glass of water. For each thumb joint, the following conclusions can be drawn regarding the function of the splint:

- **CMC joint**

  It was found that to maintain the functionality of the thumb, the CMC1 joint needs to remain free. However, the CMC1 joint is easily limited, especially around the thenar muscles and webspace. It was also found that the thenar muscles and webspace might be a good place to apply pressure to secure the splint, due to the soft tissue there. This means that while the CMC1 joint should

remain as free as possible, in practice it might be limited somewhat. It is crucial that this is minimized, but the extremes of the ROM of the CMC1 are not required for most tasks in daily life.

- **MCP joint**

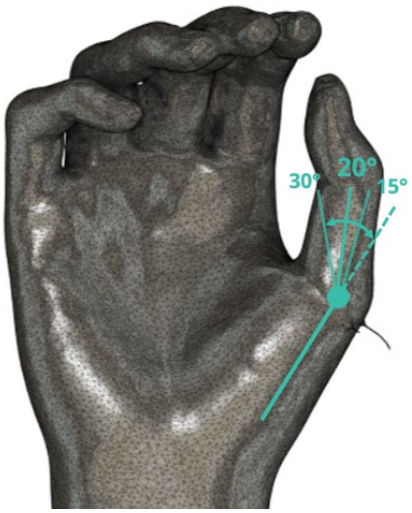


Figure 2.5: Extension must be blocked at is ~20° of flexion.

The MCP1 joint is usually immobilized to facilitate a functional position. It is blocked against hyperextension in slight flexion to avoid reaching the point of pain and further deformation. The maximum allowed extension can vary per person but should be roughly 20° of flexion (see Figure 2.5), which is the average of the 15 to 30° range that is commonly found in literature. The position used during the 3D scan, decided by the orthotist, can be used to determine the direction and precise angle. For flexion of the MCP1 joint the same applies as for the CMC1 joint; it should be facilitated as much as possible, but in practice might need to be limited somewhat to properly secure the splint. It might be valuable to implement a dynamic or compliant mechanism into the splint to enable motion more comfortably. However, this adds manufacturability and durability complexities.

- **IP joint**

Figure 2.6: Silver splint example that includes a block for the IP joint.

For some patients, especially those with deformities and EDS, it might be valuable to limit the extension of the IP joint as well (see Figure 2.6). However, that is not the focus of this design project. Primarily, the IP joint should remain free, and flexion should be facilitated.

SPLINT SECURITY

A critical problem found in the function of current thumb splinting solutions is that they easily slip off (Figure 2.7). That is why the security of the new splint design is a priority. The splint should stay in its functional position on the thumb throughout daily life activities and during gripping motions. A balance needs to be found between bulky mechanisms, like chains and straps to secure the splint, and the desired compact architecture of the splint.

Figure 2.7: Existing splint design slips off easily.

THE SPLINTING WORKFLOW

The thumb splinting process needs to be more standardized. However, for this project, it is more realistic to aim for creating an established product (see Chapter 1.2.3), that can be manually designed consistently by following a protocol of design rules. This means that one orthosis architecture template needs to be created and the design protocol needs to be written. To facilitate this, the orthotist must know precisely what data they need to provide in and around the 3D scan. Once the digital model of the design is finished, the conversion to the correct AM method needs to be made. The limitations of these methods must be considered in the architecture design.

Finally, the evaluation of the new thumb splint needs to result in clear limitations of the orthosis. As described throughout this chapter, designing orthoses is about finding balances among a wide range of variables. Not all problems might be optimally solved as this would cause other problems to become too significant. The resulting limitations of the product need to be clearly communicated to the patient throughout the care path. This will enable them to manage their expectations and will result in a higher compliance.

ERGONOMICS

Ergonomics are an important factor that will influence the compliance of the new thumb. Patients have practical and aesthetic reasons to want a smaller splint. Generally, patients who do not require firm support, dislike the bulky thumb braces because they get in the way of every-day activities; they limit their mobility and get snagged behind objects. The medical appearance of an orthosis can be a nuisance because users do not want to feel or be seen as “handicapped”. From patient interviews, it was concluded that, while aesthetic details could become important in a later phase, they first want a solution that is compact, yet sufficiently supportive and comfortable. That is why in this project, the aesthetic detailing, such as the smoothness of the curves, symmetry, finishing of edges, etc., will not be considered, to focus on general form and function first. The envisioned compactness of the new splint is already a start to finding an aesthetic balance between robustness and minimalism. The opportunity will be created to add a level of elegance to the design, which can make the splint more appealing and less medical.

3. Design Phase

CONTENTS

INTRODUCTION

In this phase, the systematic design process is documented that lead to the proposed concept in Chapter 4. The design space is explored to discover opportunities to solve the problems and evaluate solutions. The process is a combination of a traditional iterative design cycle, with diverging and converging phases in increasing levels of detail, and the UPPSS workflow for personalized products, consisting of design requirements, data acquisition, iterative concept development, parametric rules, and design for manufacturing. After the initial diverging phase, prototyping was the primary method of evaluating and iterating on the concepts, Figure 3.1 shows the vast number of developed prototypes that are detailed throughout this chapter.

Figure 3.1: All the prototypes created for the development of the concept.

3.1 IDEATION

After weeks of researching the problem and analysing all the existing solutions, the first step of the design process was to diverge and freely explore to problem space, including the input from others to increase the richness of the ideas. First, initial ideas were documented and the How-To method from the Delft Design Guide (Zijlstra, 2020) was used get a feeling for the problem space.

3.1.1 DIVERGING: BRAINSTORMING

Two separate brainstorming sessions were held, each of roughly 120 minutes. The goal was to explore the problem scope, define the important subproblems and ideate solutions for them. One brainstorm was held with peers; 3 industrial design students and 1 mechanical engineering student and the other brainstorm was held with the team of Manometric: 3 senior designers from the R&D department, 1 orthotist and 1 industrial design intern. The sessions are shown in Figure 3.2 and 3.3.

Figure 3.2 and 3.3: Brainstorm sessions with peers (left) and design experts (right).

The brainstorm method was an altered combination of the Brainstorming & Brainwriting and Braindrawing methods described in the Delft Design Guide (Zijlstra, 2020). The sessions consisted of the following steps:

1) a brief problem introduction,
2) individually brainwriting about the problem scope and context,
3) aligning the problem vision into 1 mind map,
4) formulating How-to's,
5) choosing the post relevant or interesting How-to's,
6) brainstorming, brainwriting and brain drawing to solve the How-to's,
7) personal votes for most promising ideas,
8) discussing the opportunities and limitations of the results with the group.

The mind map in Figure 3.4 contains the combined result of the 2 brainstorm sessions exploring the problem and the context. It shows the complexity of the scope and what the participants find most important within the context of thumb splinting. The larger words and thicker lines represent items that were mentioned more often. The new insights from these sessions were also retroactively used to further define the scope of this project as was outlined in Chapter 2.

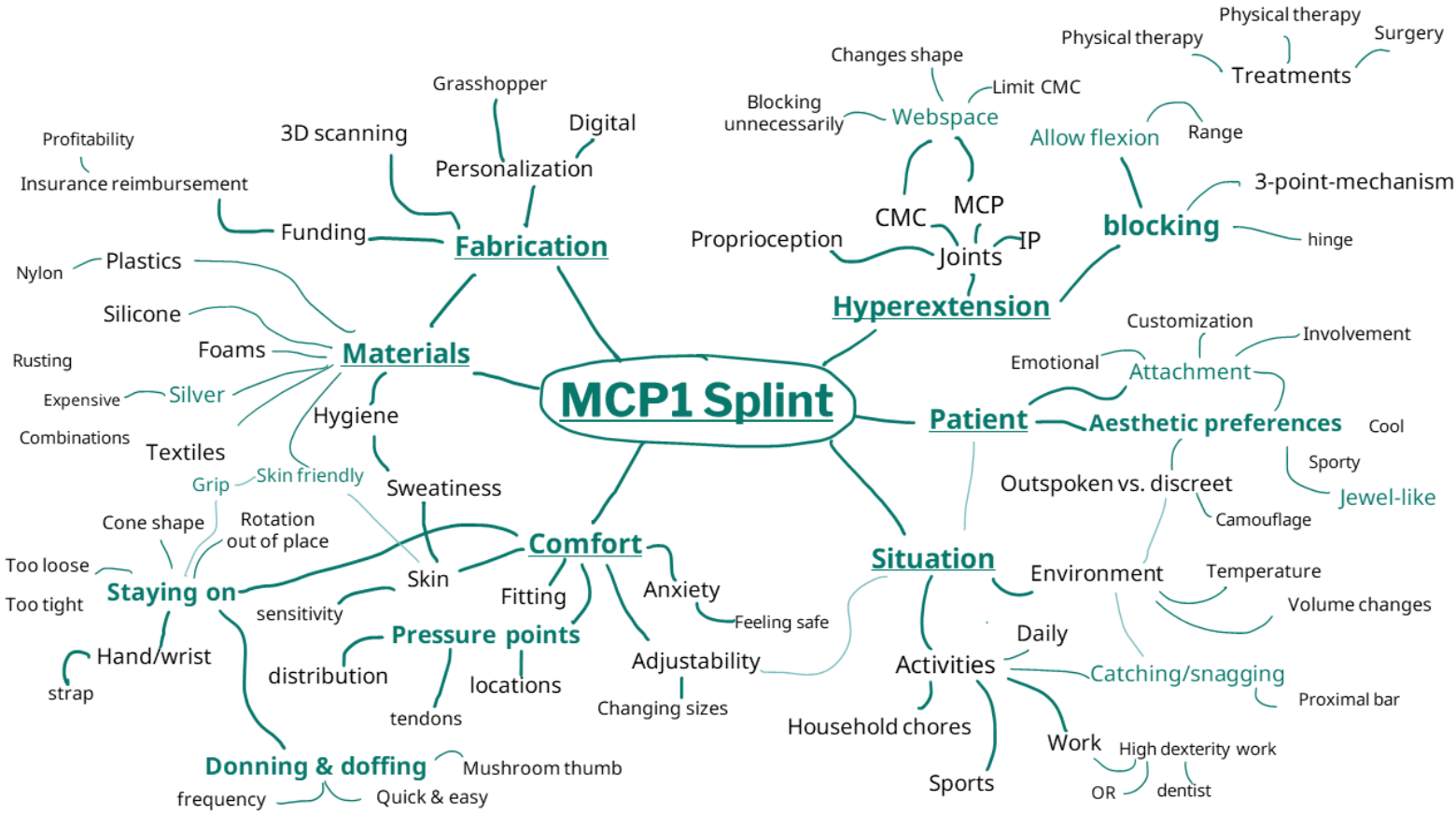


Figure 3.4: How-to's formulated during the brainstorm sessions.

Based on the mind map, the How-to method from the Delft Design Guide was used again to support the idea generation process (Zijlstra, 2020). The formulated how-to's are mapped in Figure 3.5 and the ones that were chosen to solve are highlighted. The choices were made based on a consensus within the group about How-to questions that best covered the most important problems to solve, reached through voting and discussion. Again, this offered new insights about the priorities of (possible) stakeholders and helped to further shape the scope, requirements, and evaluation criteria for the to be designed splint.

Participants were provided with tools to sketch or write and rotated the sub-problem sheets to be exposed to each other's ideas. The participants were also explained the SCAMPER method from the Delft Design Guide to help them if they were stuck. This resulted in a large number of ideas which inspired the following designing activities.

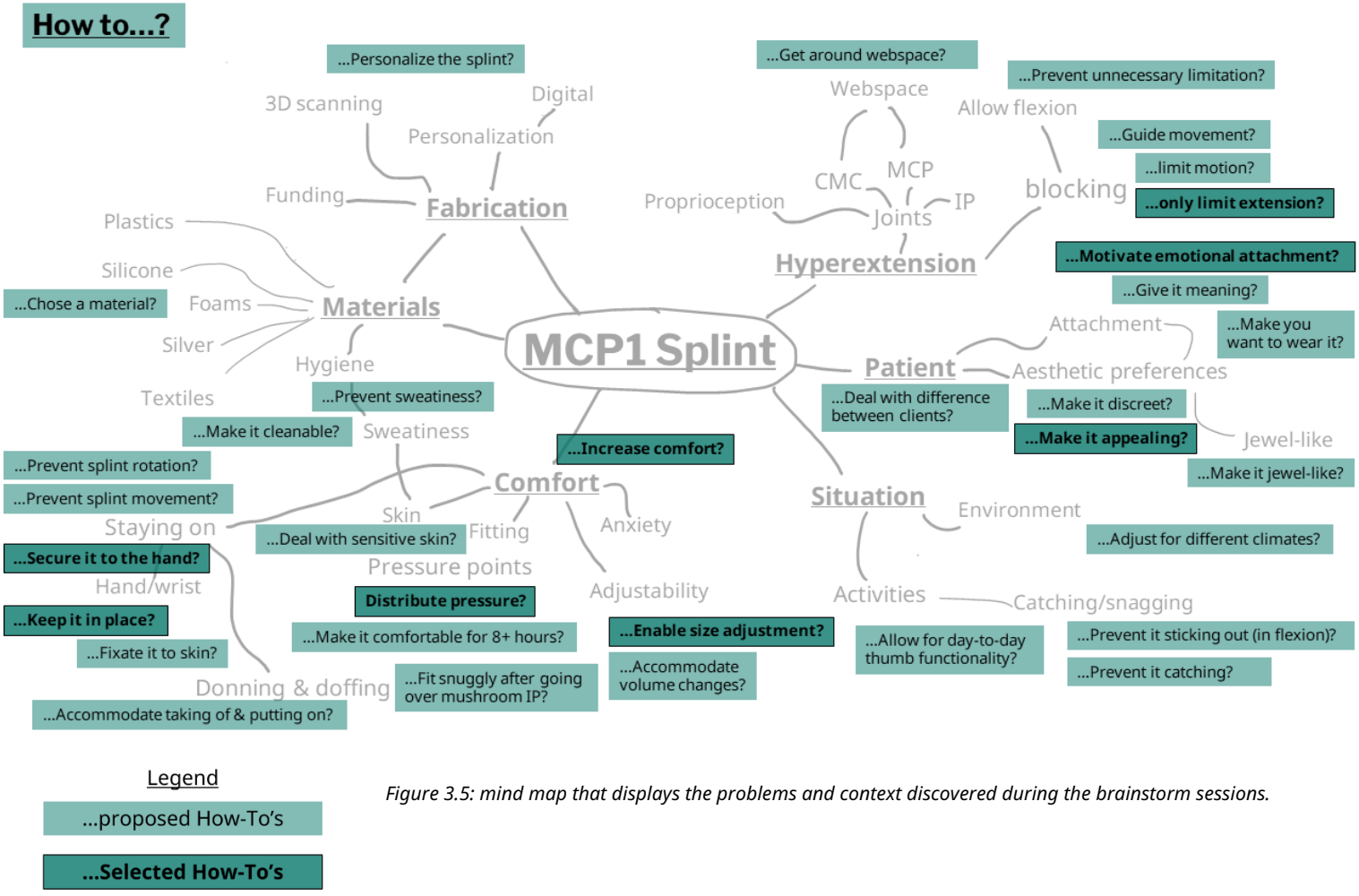


Figure 3.5: mind map that displays the problems and context discovered during the brainstorm sessions.

3.1.2 ORGANISING: C-BOXES

The results of the braindrawing and brainwriting activities performed by both brainstorming groups were summarized and organized in a C-box. Since creating novelty is not a goal for this project, the C-box method from the Delft Design Guide (Zijlstra, 2020) was adapted. Throughout the analysis phase, it became clear that an important aspect of the to be designed solution is that it is not as bulky as other existing thumb braces and instead is more compact. The innovativeness axis (horizontal) was therefore replaced by one to map the potential size of all ideas. The feasibility axis (vertical) was left unchanged from the original method. The goal of the C-box is to categorize and evaluate the large number of ideas to decide which ones to continue the ideation and conceptualization phase with. Figure 3.6 contains the C-box with a selection of the ideas, for legibility. The complete C-boxes are in Appendix D. It shows the wide variety of developed ideas and the peak of the diverging phase before converging.

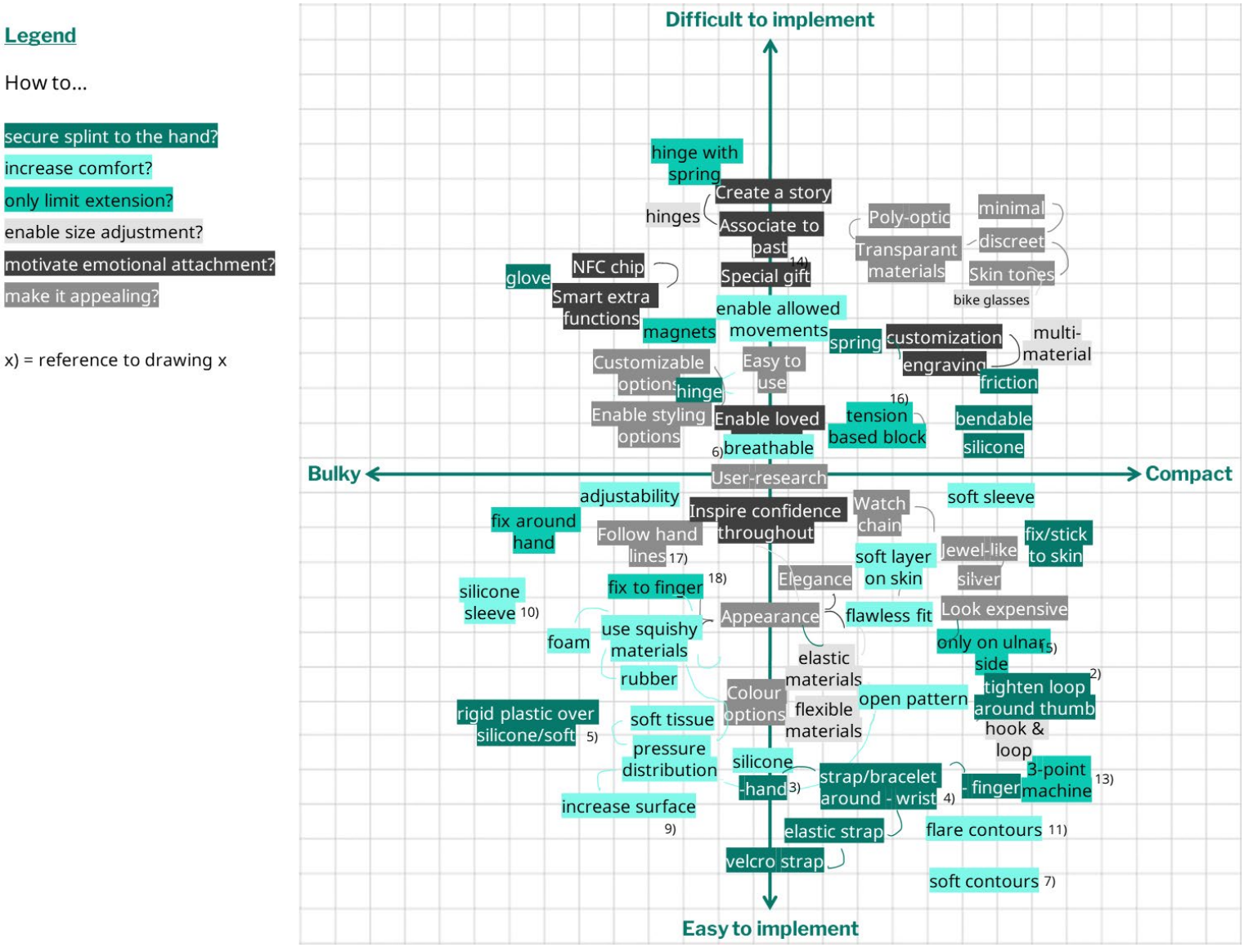


Figure 3.6: The result of the diverging phase and brainstorming sessions in an altered C-box (see also: Appendix G).

During the brainstorm sessions, the participants each had the opportunity to evaluate the generated ideas and express preferences and thoughts through a voting system. Generally, the ideas in the bottom-right quadrant are most fitting within the project scope and those ideas, along with the votes of the participants were the focus of the next phase of ideation. However, the ideas in the other quadrants were not immediately discarded either. Many ideas could be combined that were used to generate solutions from the large pile of ideas. The votes of the participants and the criteria described in the next section were leading in selection of the 6 ideas that were continued.

3.1.3 CONVERGING: EVALUATION

With a large number of ideas organized, evaluation criteria become a vital part of the converging process. Chapter 2 outlined the design criteria in detail, but not all requirements can be used to evaluate ideas in the absence of prototypes. Besides that, some requirements are easily evaluated because they are either met, or not. However, as Chapter 2 highlighted, other requirements create a design challenge (driver) where a balance must be found. To facilitate efficient and accurate evaluation of ideas, concepts and prototypes throughout the design process, a simplified list of challenging key considerations is formulated:

- ***Hygiene**: The splint should stay as clean as possible and be easy to clean when necessary.*
- ***Comfort**: The fit of the splint and pressure points should be as comfortable as possible.*
- ***Appearance**: The splint should have an appealing and discreet appearance that matches the users' wishes.*
- ***Security**: The splint should fit snuggly and reasonably stay in place during usage.*
- ***Easy donning & doffing:** It should be as easy as possible for the users to don and doff the splint.*
- ***Freedom of mobility**: The splint should block MCP1 hyperextension but offer as much freedom of movement of the thumb as possible as well.*
- ***Scalability**: The splint should be designed and manufactured such that it can be a scalable part of Manometric's workflow.*

Then, inspiration was taken from the Weighted Objectives method from the Delft Design Guide (Zijstra, 2020) to assign priority to the criteria. The method was altered to include the interests of most stakeholders. Each stakeholder was first asked whether any criteria were missing and then asked to divide 100 points to determine the weight of them. Figure 3.7 contains the averaged results from left to right in order of highest weights. Appendix E contains the complete data set.

It can be concluded that overall, the freedom of mobility and comfort receive the highest weights, whereas easy donning and doffing and hygiene score significantly lower. Scalability is especially important to Manometric's production experts and designers. The opinions on the aesthetic appearance vary among stakeholders, but users expressed the importance of the compactness of the splint. Both users emphasized the importance of security of the splint. While all criteria remain important for the success of the splint, this poll has confirmed the importance and completeness of the 7 key consideration that will be used throughout the design process. Additionally, this overview helps to prioritize the freedom of mobility, comfort, and security of the splint in the decision-making steps.

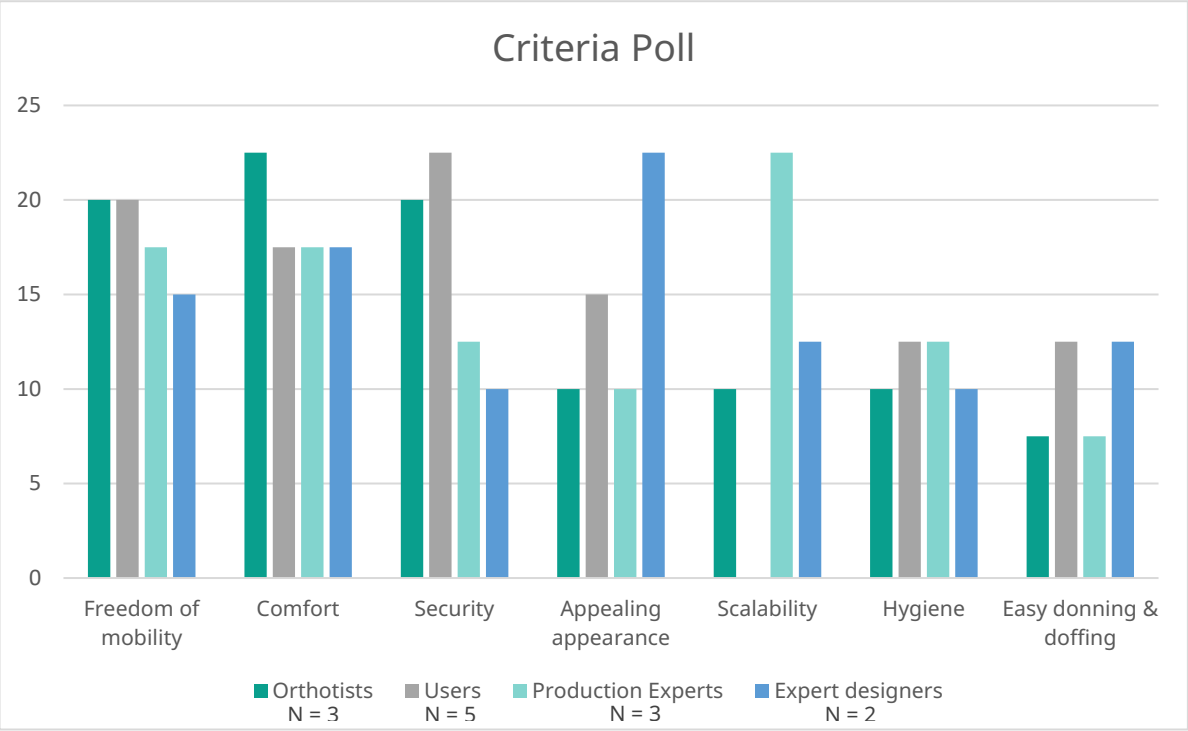
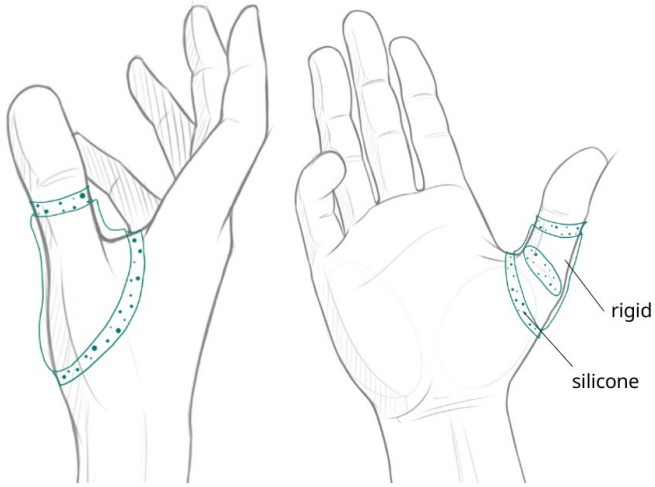
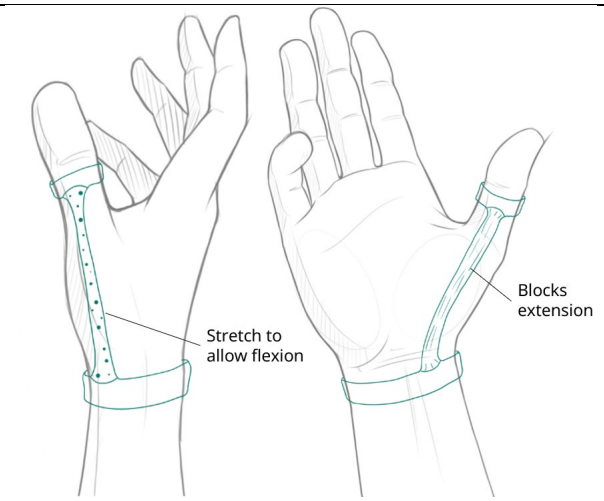
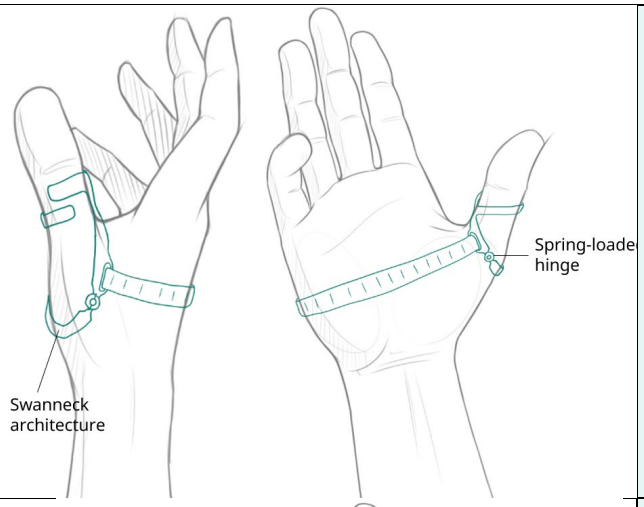
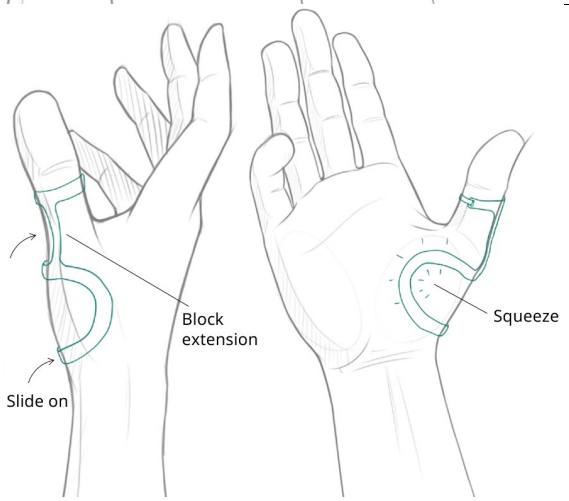
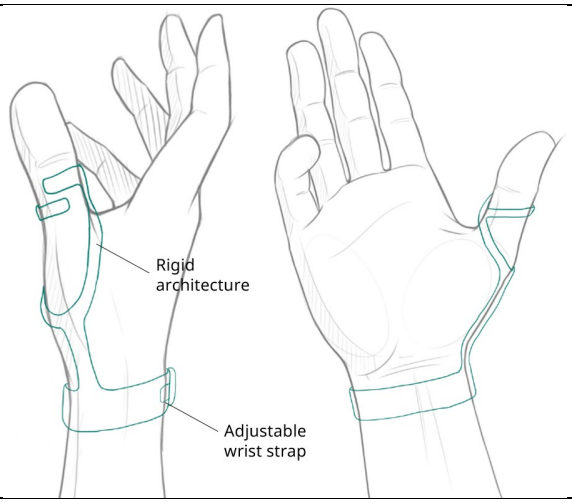


Figure 3.7: averaged assigned weights from different stakeholders (see also: Appendix E).

3.1.4 CONVERGING: DEVELOPING IDEAS

With the key design considerations in mind, the ideas and sketches that resulted from the brainstorm sessions and combined ideas were reviewed and assessed. The ideas that had the potential to meet most requirements and score well in at least 4 of the 7 key considerations, were chosen to continue with. Table 3.1 shows the resulting 6 ideas. The 7th entry shows feature ideas that could be separately implemented in most concepts. Appendix F contains a more elaborate overview of them. These 6 ideas were then evaluated using the Plus, Minus, and Interesting (PMI) method from the Delft Design Guide. This method was applied in collaboration with 2 Manometric orthotists, 2 Manometric senior designers and 3 potential users to increase the richness of the insights.

Solution (see also: Appendix F)	**PMI results**
Silicone mini A concept inspired by the existing silicone brace, where the lower layer touching the skin is compressible silicone and the outer shell offers rigidity. Architecture of the outer shell can be optimized for the right mobility.  	*(eliminated)* + large area of distributed pressure. + comfort: allows flexion. + control over architecture optimization. - limited adjustability. - complex production. - not so discreet. - could get sweaty. - likely poor security. - might limit CMC. I: innovative. I: "adhesive" material exploration.
Tension based A concept where extension is blocked by pulling on the phalanx instead of pushing, enabling all other movements. A strap around the wrist anchors the brace.  	+ comfort: limiting pressure points. + comfort: allows much freedom of movement, including flexion. - not minimal. - palm not free. - possible discomfort @ wrist. - complex production. - difficult donning/doffing. - limited adjustability. I: innovative. I: many material options.

Hinge Swanneck Regular swannecks for the thumb are not properly secured and/or too limiting. Integrating a spring-loaded hinge could solve these issues by pressing on the skin while in flexion. A strap around the hand can be used secure it.		+ helps to avoid catching/snagging. + minimal design. + without strap: palm free. - complex production: hinge. - with strap: bulky. I: many material options. I: hinge could be replaced with a flexible/moving material.
Squeeze-on A concept that makes use of the soft tissue around the thenar muscles to be slid on from the side and squeeze the rigid architecture in place, securing it with minimal volume. The architecture around the phalanx can be optimized to provide support.		+ easy donning/doffing. + squeezing allows for adjustability. - might be too loose. - bulkier (than swanneck) - squeezing can cause material deformation. - limited material options. - palm occupied. - might limit CMC1. I: includes thenar push.
Wrist strap A concept that facilitates improved security by connecting the splint to a strap around the wrist.		*(eliminated)* + well secured. + enables adjustability. - not minimal: too large. - possible discomfort @ wrist. - also limits CMC1.

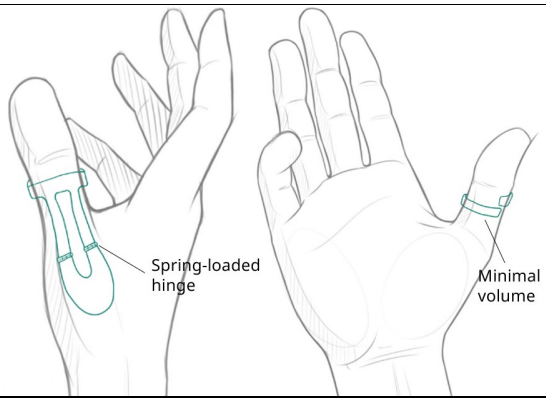
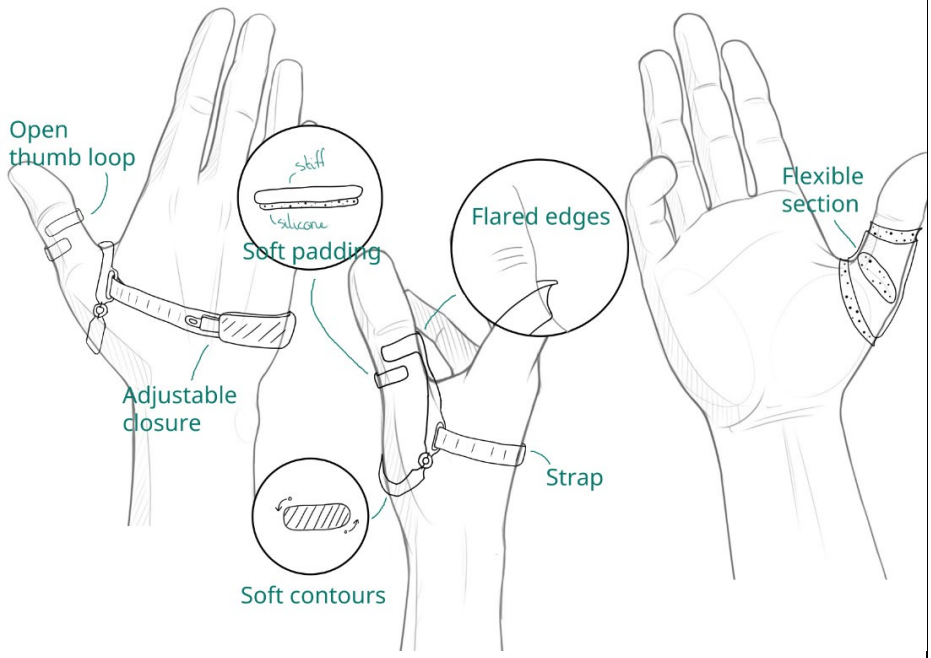
One sided A concept that focusses on minimalizing the volume of the splint by using the simplest possible first-class lever. A spring-loaded hinge can improve the security. 	+ quite minimal design. + easy donning/doffing. + palm completely free. - complex production: hinge. - could cause pressure discomfort. - likely too loose. - could add: cushion I: hinge could be replaced with a flexible/moving material.
Feature list Features that came from the ideation phase that can be considered for implementation to improve most concepts. 	**Open thumb loop:** + provides adjustability (for mushroom thumb). - might reduce mechanical leverage. **Adjustable closure:** + provides adjustability. - more complex production. **Soft padding:** + comfortable pressure distribution. + more grip on skin. - more complex production. **Soft contours & flared edges:** + more comfortable pressure. I: aesthetic impact. **Strap:** + improved security. - bulkier. - more possible points of discomfort. I: around wrist or hand. **Flexible sections:** + facilitate more movement. - More complex production.

Table 3.1: Overview of the 6 chosen ideas and insights from the PMI method.

From discussing the 6 concepts and features with stakeholders, paying attention to the 7 key considerations, several conclusions were drawn. The PMI evaluation led to the elimination of the 'Silicone Mini', 'Wrist strap' ideas, due to the number of downsides compared to the others. Especially the bulky size of those concepts makes them unappealing along with the predicted lack of freedom of movement. Stakeholders were interested to see the further development of the other proposed concepts. The next step was to start prototyping the ideas and developing them into concepts.

3.2 PROTOTYPING

With the remaining ideas, an extensive prototyping journey was initiated. The prototypes are initially based on only my own (healthy) hand, so N =1. There were several rounds of prototyping that lead to the concepts that were finally tested with potential users. This final evaluation will be described in Chapter 5.

3.2.1 RAPID PROTOTYPING

The first round of prototyping was done using Polymorph mouldable plastic, a type of LTTM. This enables a quick evaluation of the working principles of the concepts, focussing on comfort and blocking extension. Figure 3.9 shows the prototypes and important findings. The tension-based concept only sufficiently blocked extension at a specific angle, as shown in Figure 3.8. The concept would also cause issues with users snagging behind objects like doorhandles. It was therefore discontinued. The other concepts worked but revealed issues, such as deformation around weak connections, like the open thumb loop, and painful pressure points.

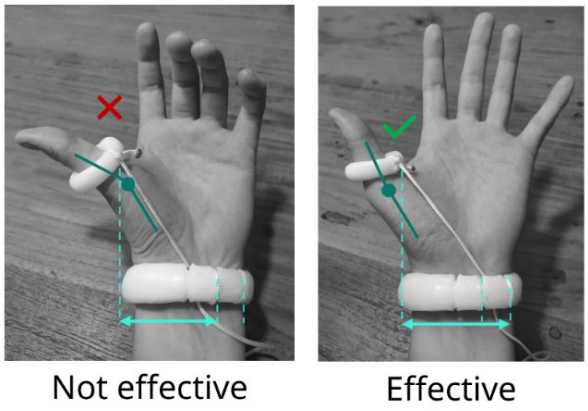


Figure 3.8: LTTM prototype demonstrating the inconsistent effectiveness of a tension-based concept.

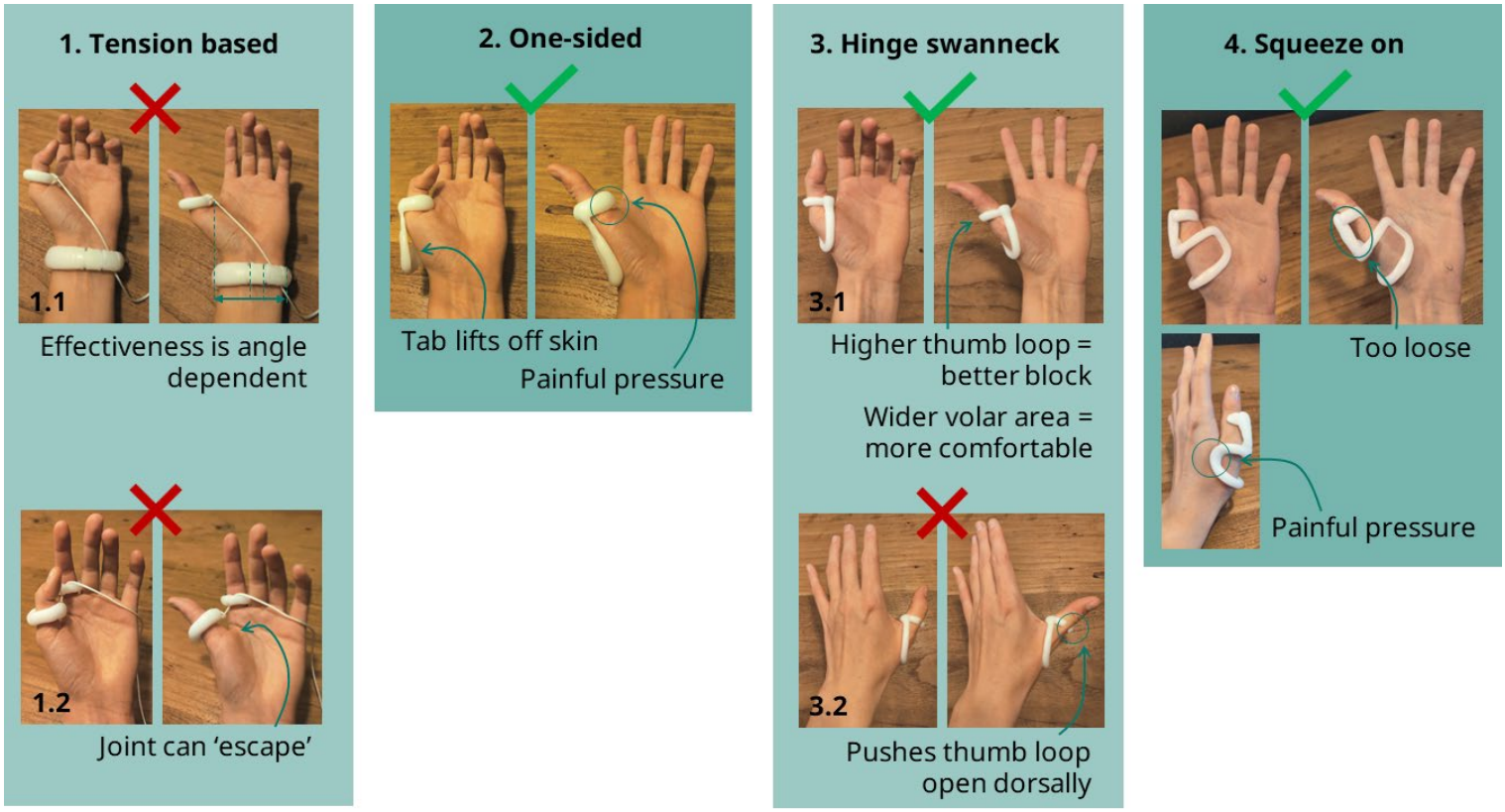


Figure 3.9: summary of the first prototyping round with Polymorph plastic.

3.2.2 PROTOTYPE DEVELOPMENT

With an understanding of the concepts' working principles, more refined prototypes were developed to further evaluate and improve the concepts to meet the key criteria. Figure 3.10 summarizes this prototyping process. Each concept's development and the important learnings are discussed in the next sections. These prototypes were modelled in Autodesk Fusion360 on a smoothed 3D scan of my right hand in one of Manometric's predetermined poses (see confidential Appendix L). The prototypes were printed in PA11 using the SLS method because it allows the required dimensional freedom, has similar mechanical properties to PA12 (which is a material commonly used for final products by Manometric) and was readily available. However, this material and finishing is not skin-safe and is therefore not suitable for the final product.

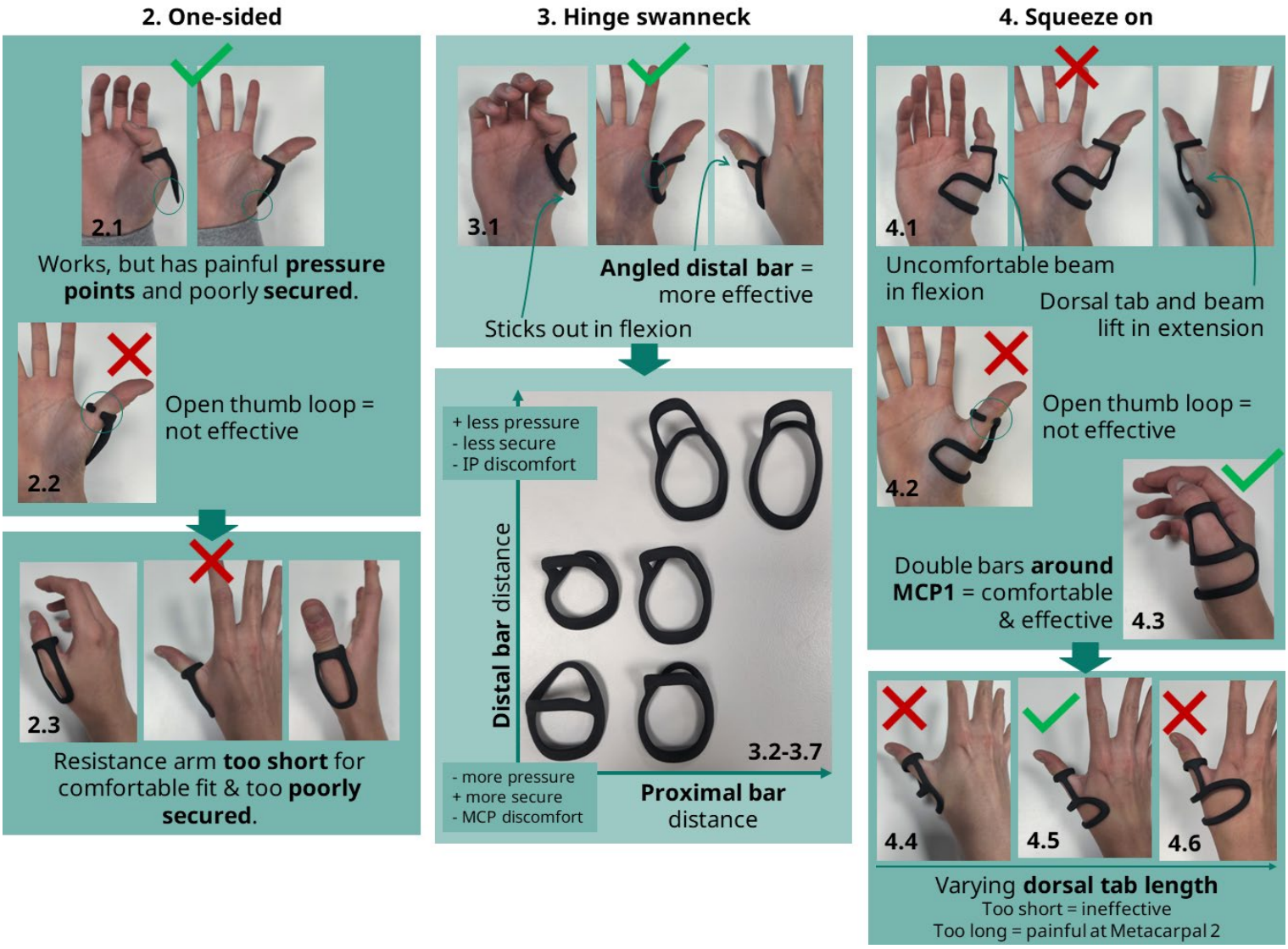


Figure 3.10: summary of 2nd and 3rd prototyping round with SLS printed PA11.

ONE-SIDED ARCHITECTURE

The one-sided concept worked in blocking hyperextension and is the most minimalistic solution. However, after several rounds of prototyping, it was found that it could not be properly secured and the pressure was painful due to the short resistance arm, seen on the left in Figure 3.11. An additional tab must be added on the radial (see Figure 3.11, right) or palmar side of the thumb. The radial addition caused discomfort at the MCP1 joint and unnecessarily impeded the thumb's flexion. A palmar addition creates an architecture that is similar to the swanneck architecture. The one-sided concept was discontinued and the swanneck architecture, which features more prominent elements to secure it and distribute force on the palmar side, was chosen for further development.

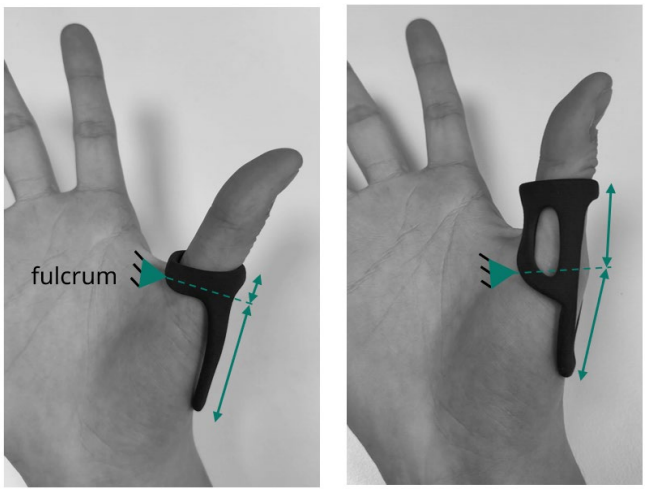


Figure 3.11: Comparison of the one-sided concept without (left) and with a radial 'tab' (right) to lengthen the resistance arm.

SWANNECK ARCHITECTURE

While the swanneck architecture is an existing solution, it was explored and variations were created to discover what causes the problems in this architecture, found during the market analysis in Chapter 1.2. A thumb swanneck can effectively block hyperextension but it slips off too easily, creates painful pressure points, and does not stay in place on the skin, as indicated in Figure 3.12.

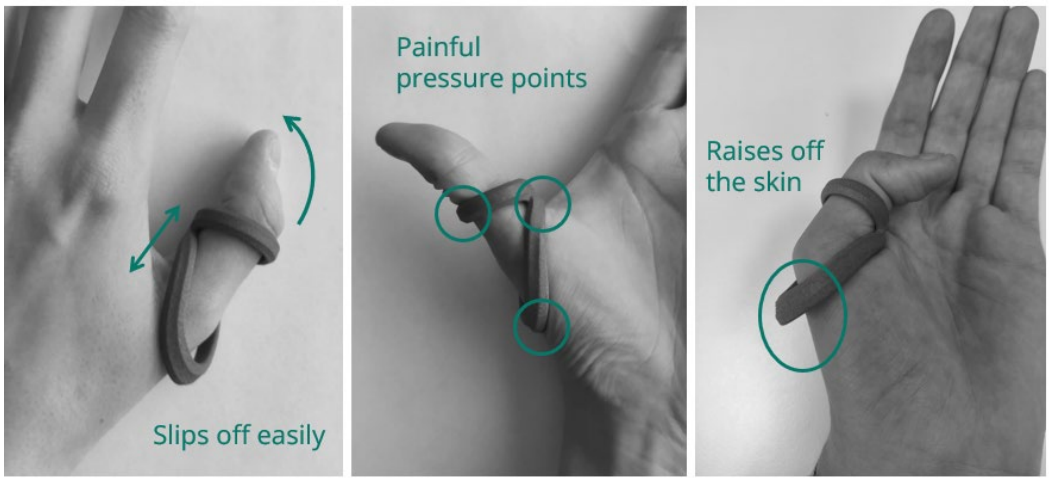


Figure 3.12: Problems to solve in existing swanneck splint architecture.

The architecture was changed to have an angled distal bar (thumb ring) and varying distances between the Fulcrum and the distal and proximal bar, as shown in Figure 3.13. This improved the design. The angled thumb ring improved security and comfort. It was found that the longer distances lead to less painful pressure, which is consistent with the workings of the first-class lever. However, longer distances between the bars lead to more space for the splint to slip off and decreased security. The swanneck architecture by itself was not found to be sufficiently secured and comfortable to continue with. The next step to improving the swanneck architecture was to introduce the hinge, to improve the security of the splint and improve mobility, as proposed in the original idea. This is discussed on page 101, after the static solutions have been highlighted.

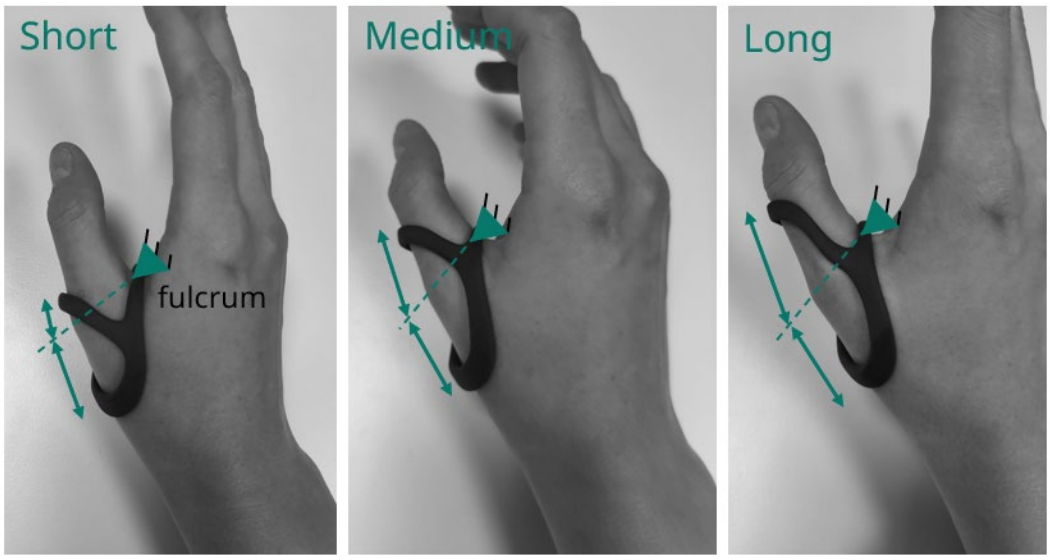


Figure 3.13: Variations of the swanneck architecture with angled thumb loop and varying force arm lengths from the Fulcrum.

SQUEEZE-ON ARCHITECTURE

While the swanneck architecture showed promising development in the prototyping phase, especially with the possibility of a hinge integration, the squeeze-on concept (see Figure 3.14) is a promising solution to further improving the security and comfort of the splint.

The squeeze-on concept is based on the idea that the splint can be held in place by squeezing it around the thenar muscles using a 'tab' (or: loop of material) on the palmar side and one on the dorsal side of the hand. Development of this concept was focussed on testing varying sizes, shapes, and positions of both tabs in terms of comfort, security, freedom of mobility and appearance. Figure 3.14 shows the further progression in a selection of the created prototypes for this concept.

With such a larger splint architecture, it is more difficult to follow the conclusions drawn in Chapter 1.1.1 regarding areas of the hand that should be avoided with the splint. Many of the prototypes led to discomfort in sensitive areas, especially on the dorsal side of the hand. Conversely, the larger areas do facilitate a better pressure distribution leading to lower forces and less pain. A balance must be found in the tightness of the squeeze between security, comfort, and mobility. This architecture could lead to an impeded CMC1 joint if the tabs are too large and/or tight, which should be avoided. Additionally, some deflection occurred in early prototypes, especially in far extension and flexion. The shape was adjusted to minimize movement of the static splint, because of the changing thumb position. Finally, the thumb ring should not be positioned too distal (close to the IP joint) that it obstructs the IP joint movement and unnecessarily impedes flexion of the thumb.

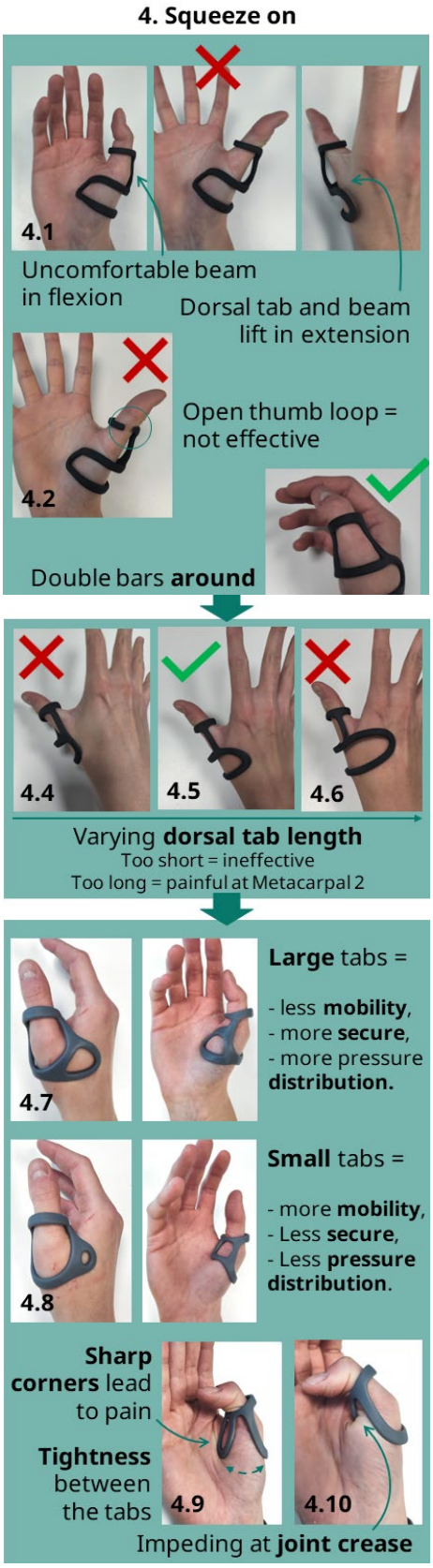


Figure 3.14: development prototypes for the squeeze-on concept.

Final squeeze-on concept

The architecture in Figure 3.15 is the most optimized result of the development of this concept without adding dynamic aspects to the orthosis. The first-class lever is constructed by the elements at a (Fulcrum), b (resistance force), and c (effort force). At a and c, the palmar and dorsal tabs respectively create a better pressure distribution. Due to the position of the dorsal tab (g), the tabs are squeezed around the thenar muscles and avoid sensitive areas. The squeeze is created by placing the tabs (at point a and g) 2-3 mm inside the scan during digital modelling. At d, the material is thin, so the joint crease is minimally obstructed during flexion. The 2 dorsal bars around e are carefully modelled to closely fit the skin but allow enough space for the joint to articulate. Finally at f, the webspace is left as unobstructed as possible.

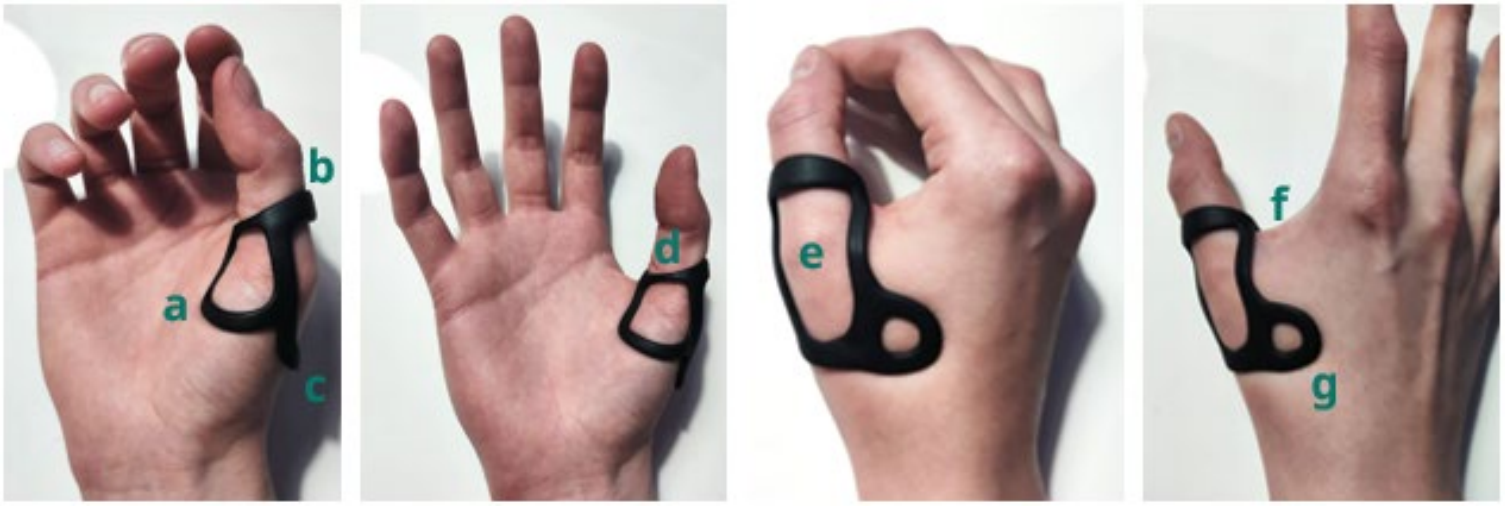


Figure 3.15: optimized architecture of the squeeze-on concept.

While this architecture is an improvement over the swanneck architecture and initial prototypes, there are limitations. The most evident ones are the inability of implementing a living hinge, like in the swanneck concept. Besides that, elements c and g can still lift off the skin when the thumb is far in flexion. This leads to displacement of the splint. Finally, while this architecture worked on my hand, it is likely that the shape, angle, size and position of the dorsal tab at g add significant complexity to making this architecture work for anyone. In the next section, these conclusions have been utilized in a new architecture concept.

WEB-SQUEEZE ARCHITECTURE

During the development of the swanneck and squeeze-on prototypes described in the previous section, a new, combined architecture was created. The aim is to combine the concept of squeezing between the palmar and dorsal side of the hand, and the minimalistic approach of the swanneck architecture, this is shown in Figure 3.16. The concept is presented in Figure 3.17.

Figure 3.16: How features are combined to lead to the new web-squeeze architecture.

Elements a through f are the same as in the squeeze-on architecture described above. The palmar tab (a) is an addition to the swanneck architecture that facilitates the tightness (or squeeze) between the two sides of the hand, it also distributes the pressure on the palmar side (at the Fulcrum) over a larger area. The crucial difference is the simplification at g. Instead of squeezing around the base of the thumb, it more closely follows the swanneck architecture. The pressure is applied more distally, just below the webspace. This enables a lower complexity architecture with a similar working principle, tightening in an area of soft tissue that facilitates this feature without causing discomfort. While this architecture feels less secure than the squeeze-on architecture, it is less complex, more discreet, more comfortable and displays less deflection during flexion. In the next section, these conclusions are used in the final prototyping step which lead to the final concept proposed in Chapter 4.

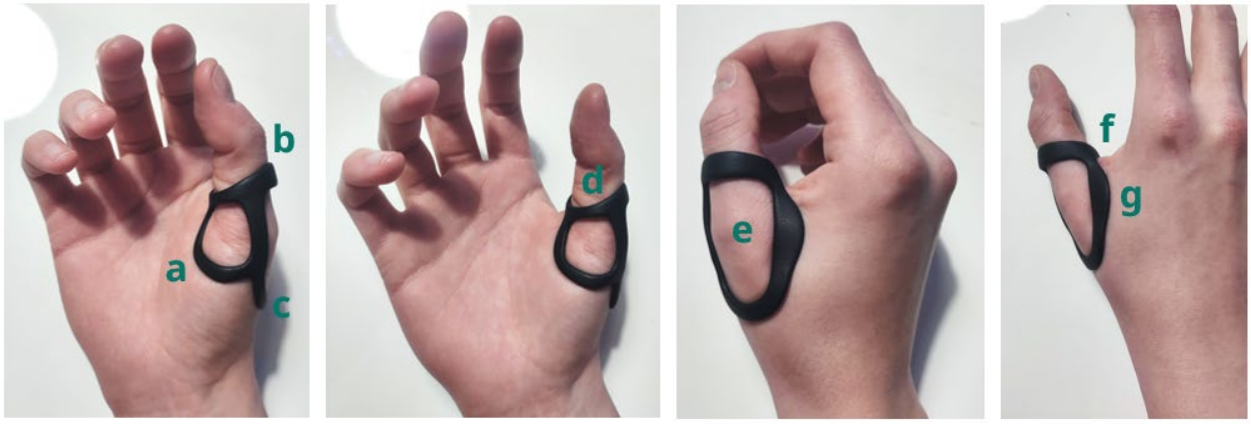


Figure 3.17: Web-squeeze concept, a combination of the swanneck and squeeze-on architectures.

STATIC ARCHITECTURES EVALUATION

In Table 3.2, the 4 static prototypes presented in the previous section are assessed against the 7 key considerations formulated in Chapter 3.1.3. The Harris Profile method is used in accordance with the criteria prioritization that resulted from the criteria poll. The concepts are not detailed enough to warrant a detailed Weighted Objectives evaluation. The table shows the perceived advantages and disadvantages of the concepts and explains why the squeeze-on and web-squeeze concepts are continued.

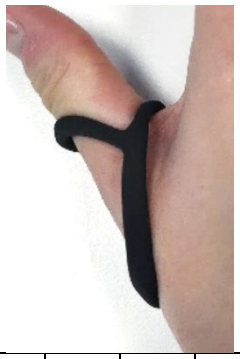
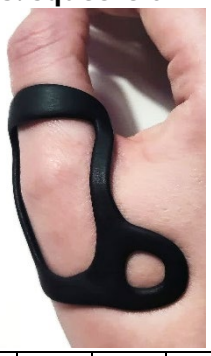
	1. One-sided 				2. Swan-neck 				3. Squeeze-on 				4. Web-squeeze 			
	--	-	+	++	--	-	+	++	--	-	+	++	--	-	+	++
Freedom of mobility			■				■			■					■	
Comfort	■	■				■					■				■	■
Security	■	■				■					■	■			■	
Appealing appearance			■				■			■					■	■
Scalability			■				■			■					■	
Hygiene			■				■				■				■	
Donning & doffing			■	■			■			■					■	
Result	✗				~				✓				✓			
Notes	Too poor scores on two important criteria.				Not too poor, but not promising either. The hinge might help.				Good scores at the top but there is space for improvement.				Improvement over nr. 3, except in security. Most promising architecture.			

Table 3.2: Harris Profile of the 4 static concepts.

HINGE

The goal of implementing a spring-loaded hinge in the splint is to improve the security of the splint by pressing it against the skin and improving the thumb's mobility by allowing more flexion. This would create a dynamic orthosis with a pivot axis through the MCP1 joint. Figure 3.18 shows two ways to approach this; through a hinge mechanism that requires assembly, or an adjustment in the material to create a flexible section. The hinge should be *pretensioned* to be pressed onto the skin in flexion, while allowing extension to a specified maximum.

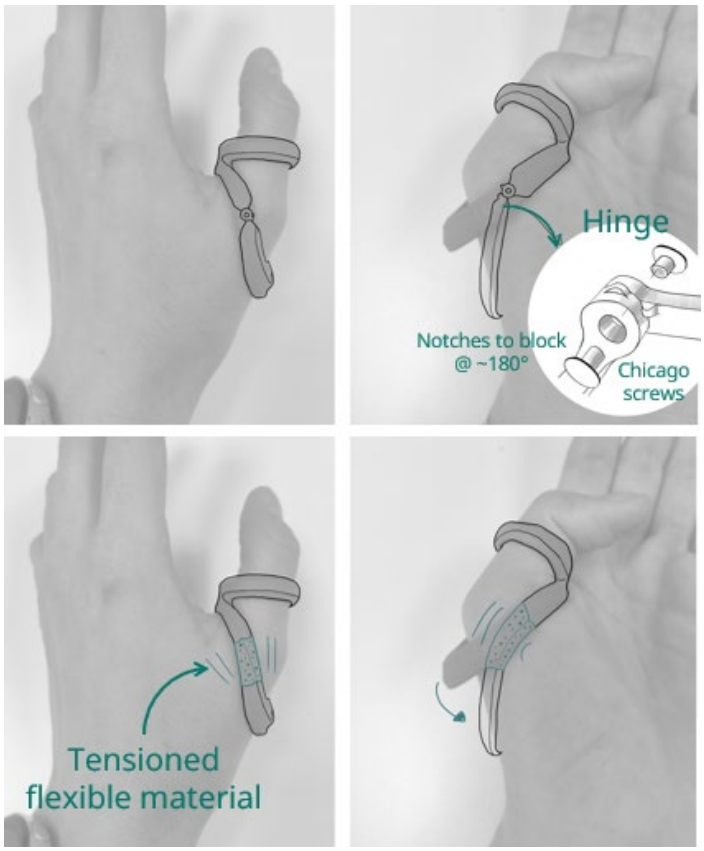


Figure 3.18: Ideas to create a dynamic orthosis by integrating pivot points at the MCP1 joint.

Hinge type A: Multi-material printing

In a conversation with advanced additive manufacturing expert Joris van Dam (TU Delft, Industrial Design Engineering) it was found that Material Jetting is an AM method that could be used to create a multi-material solution with a pretensioned, anisotropic, or limitedly flexible section in a single part. However, this method does not result in durable products yet and is expensive and therefore not scalable for Manometric. This led to the exclusion of multi-material single print solutions. The hinge should either require assembly or be printed in a single material.

Figure 3.19: Creating a hinge with Chicago screws.

Figure 3.20: Integrating spring steel parts.

Figure 3.21: IKEA sealing clip features a compliant mechanism hinge (IKEA, 2021).

Hinge type B: Assembly hinge

Testing a mechanism with Chicago screws (Figure 3.19) showed that the placement of the hinge is crucial; if it is not in exactly the correct position and direction, the thumb will not be able to articulate comfortably with it. Integrating a simple spring steel spring (Figure 3.20) proved the effectiveness of tensioning the hinge to press against the skin and stay in place, especially in flexion. However, after talking to production experts at Manometric about this solution, it was concluded that such a small mechanism would lead to a complex and time-consuming assembly process. Additionally, in their experience, such small mechanisms with relatively high forces are not durable and the patient would likely return within 2 years for repairs. This led to the exclusion of small, tensioned assembly mechanisms for the new thumb splint. The same effect as the spring steel prototype should be created in a single material print.

Hinge type C: Single print hinge

A *compliant mechanism* "achieves force and motion transmission through elastic body deformation." (Howell et al., 2013). Figure 3.21 shows a well-known IKEA sealing clip that successfully utilizes such a compliant mechanism. This principle can be used to integrate a hinge in a single print splint as well.

A *living hinge* (Figure 3.22) would facilitate flexibility around the MCP1 joint. By modelling the splint with an angle at the MCP1 joint, as opposed to straight, the splint becomes 'pretensioned' to stay on the skin in flexion, instead of sticking out. To still ensure the proper blocking of hyperextension, the standard design for a living hinge is adjusted (see Figure 3.23) such that bending the hinge in one direction is obstructed by 2 blocks that will be pushed together when extending the hinge.

For this application, silicone and silver are not viable as they are too compressible and too strong respectively to realize a hinge as envisioned in Figure 3.23. The next step is to test different AM materials for the living hinge application.

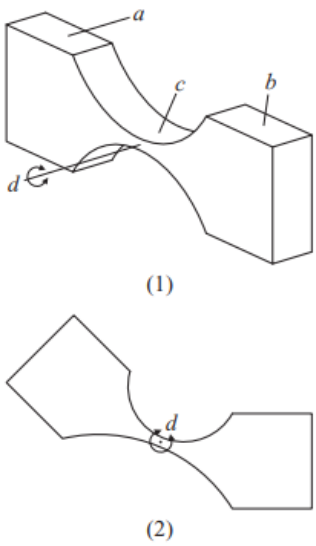


Figure 3.22: Living hinge, where a & b are rigid sections connected by a thin living hinge segment c which rotates around the d-axis (Howell et al., 2013).

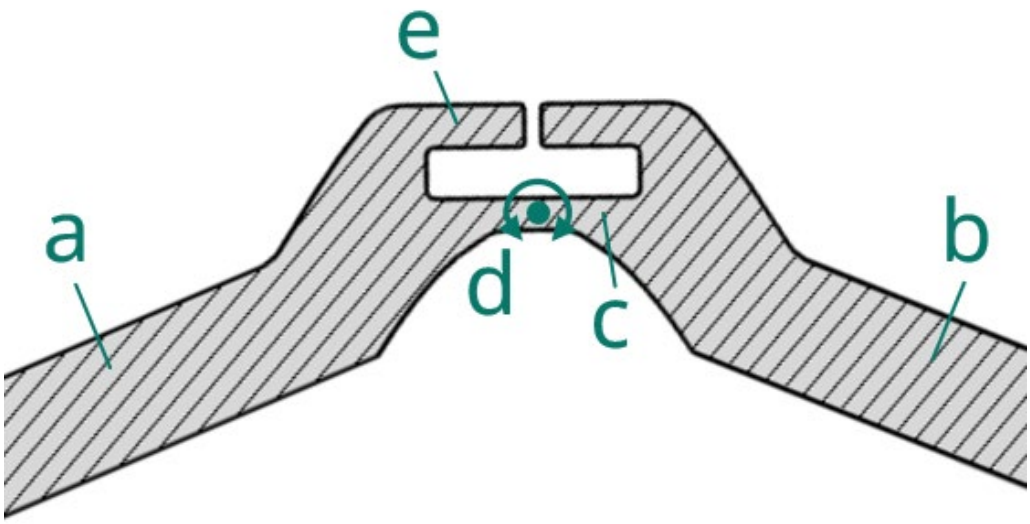


Figure 3.23: Adapted living hinge where addition e inhibits hyperextension.

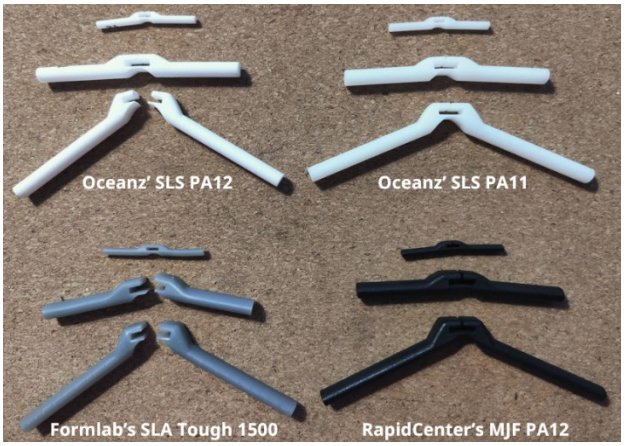


Figure 3.24: A selection of the prototyped hinge samples.

Nr. of cycles	Straight hinge	
	c = 1.5mm	**c = 1mm**
SLS PA12	34	100 (max)
SLS PA11	100 (max.)	77
SLA	1	15
MJF PA12	100 (max.)	100 (max.)
	bent hinge	
	c = 1.5mm	**c = 1mm**
SLS PA12	100 (max)	53
SLS PA11	100 (max)	100 (max.)
SLA	29	40
MJF PA12	100 (max.)	100 (max.)

Table 3.3: Results of the cycle to failure test.

Hinge material study

For such applications, the most important concepts to consider are fatigue, tolerances, and material strength (crucially different from stiffness because strength relates to resistance to failure, while stiffness relates to resistance to deflection.) (Howell et al., 2013). For this reason, most products with living hinges are injection moulded, but this is not an option for the thumb splint. Chapter 1.5.2 introduced several AM methods and materials that might be used for the new thumb splint. Due to the anisotropic, brittle layer-by-layer construction of 3D printing, it is not generally suitable for living hinges, as it leads to a low number of cycles before failure. However, using MJF printing and post-processing steps can increase this number. It is generally found that within the AM world, nylon-based plastics offer the best strength to facilitate living hinges. (HUBS, n.d.).

The living hinge was prototyped in PA11 and PA12 using SLS and MJF printing and Formlab's Tough 1500 resin for SLA printing. Figure 3.24 shows a selection of samples. Table 3.3 shows the number of cycles the samples were exposed to, to test their durability. It was experimentally determined that the thickness for section c should be 1mm. This is thick enough to exceed the minimum wall thickness of the printing methods (due to tolerances) and thin enough to create the desired flexibility. The thicker samples (1.5mm) presented much reduced flexibility and in some cases even broke earlier. While PA11 is known to have a higher tensile strength, both PA11 and PA12 performed sufficiently. The SLS prints had the desired flexibility but had a smaller number of cycles before failure. Especially the PA12 MJF printed parts performed well, as predicted. The SLA prints did not perform sufficiently, the prints were too brittle, and the tolerances of the prints were worse than of the other printing methods. All in all, the best material choice for the integration of a living hinge is MJF printed PA12, since MJF printed PA11 is not available. Besides that, the bent hinges generally presented a higher durability than the straight ones.

HINGE INTEGRATION

The next step in the prototyping journey was integrating the hinge into the newly found architectures. The hinge was tested in the swan-neck architecture, but the security was still not sufficient. The tension caused by the hinge was not enough to keep it in place. The added value of the palmar tab in terms of comfort and security of the splint is therefore considered critical.

The adapted living hinge, as presented previously, was placed inside the squeeze-on and web-squeeze architectures. The critical step to accomplishing this is shown in Figure 3.25: the radial bar was split to create two separate tabs (the palmar and dorsal tabs). This facilitates an angle and a hinge at the MCP1 joint in the dorsal tab, while the palmar tab maintains its supportive function.

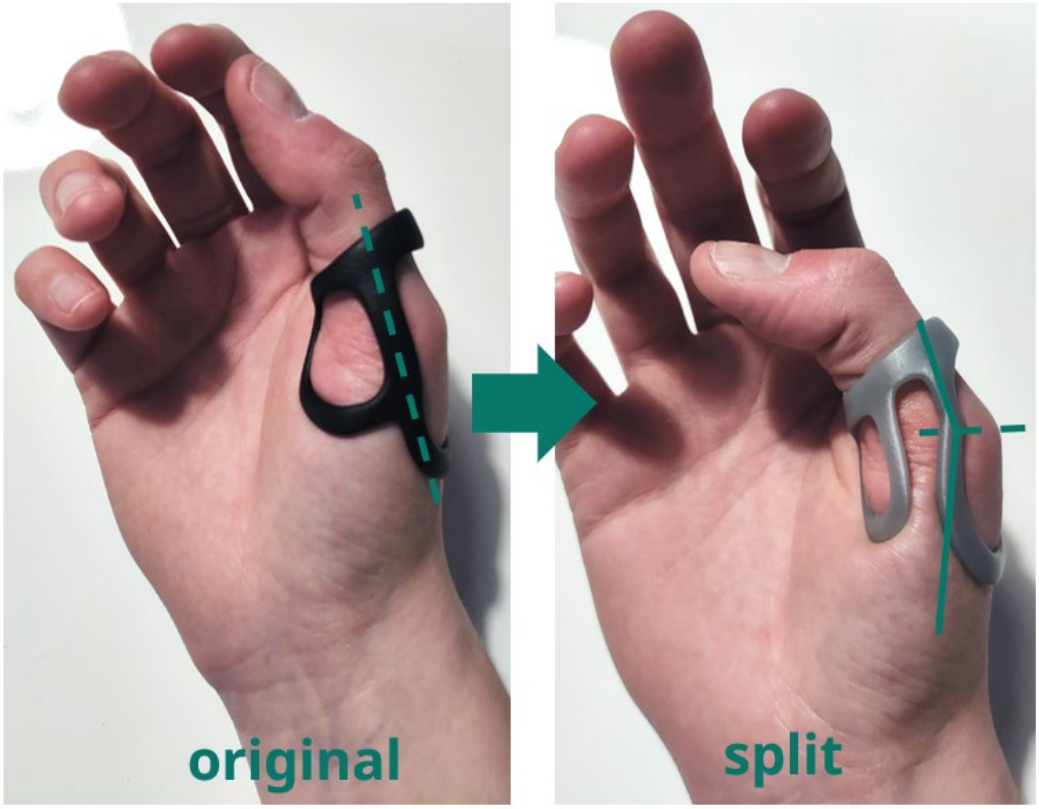


Figure 3.25: Splint architecture split into two separate tabs for hinge integration.

Figure 3.26 shows how the hinge is integrated into a prototype. The splint is modelled with an angle in the dorsal tab at the MCP1 joint, such that the splint stays in place and on the skin in flexion. The hinge at the MCP1 joint allows further flexion. Extension is possible up to the limit provided by the blocks at the top of the hinge. This prototype shows that the working principles of the splint with a hinge are functioning as predicted. However, it highlighted some further issues with the palmar tab, which inhibits flexion, and the material thickness of the splint in areas where deflection should not occur. Those issues are solved in further iterations.

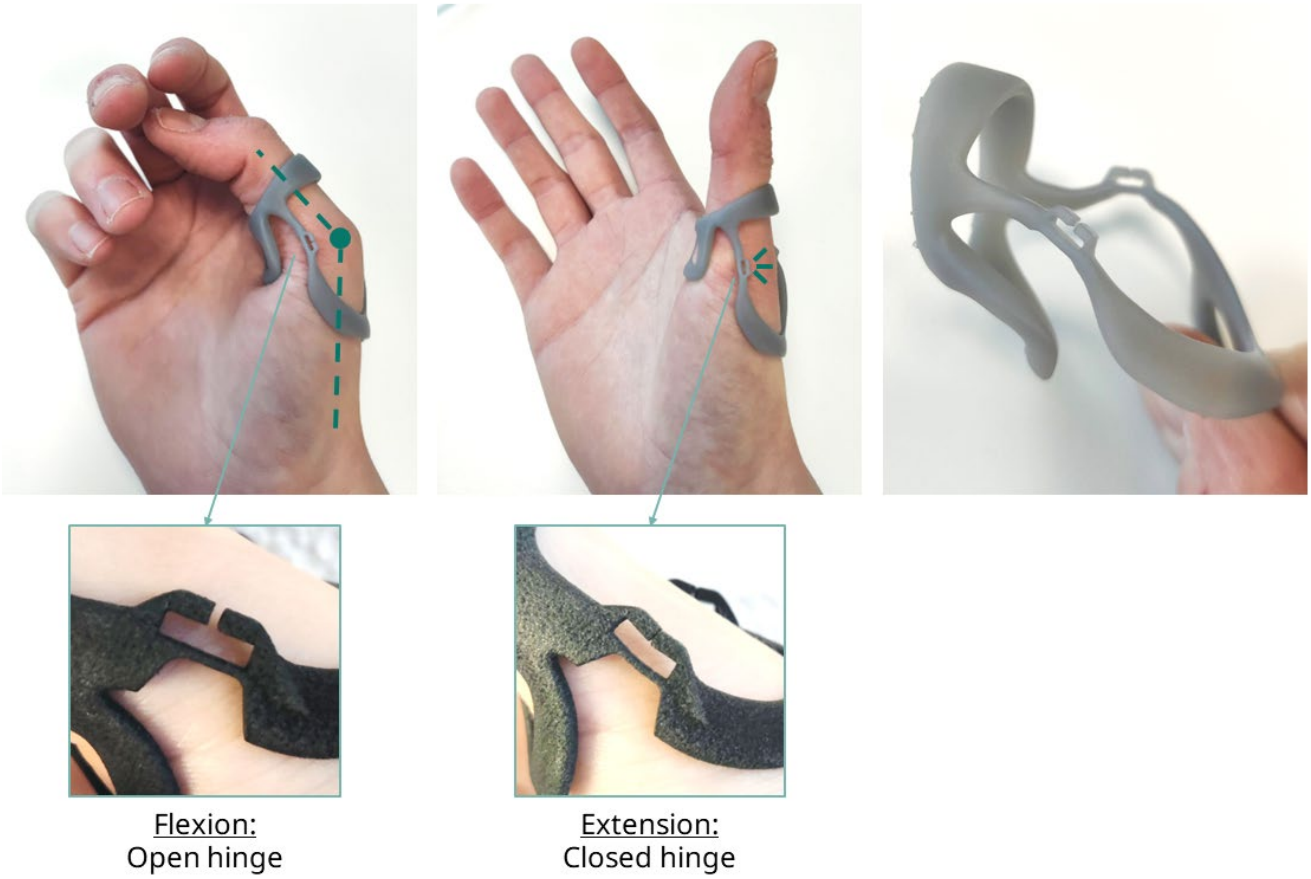


Figure 3.26: Adapted living hinge integrated in a thumb splint prototype.

3.2.3 FIRST USER EVALUATION

The prototype development phase allowed numerous concepts and variations to be tested on one person. That phase resulted in two static splinting architectures that pass the evaluation based on the 7 key considerations. It also introduced the desirability and feasibility of implementing a living hinge to create a dynamic orthosis. To gain more insight into the value of these results, and better assess the concepts against the requirements, a first evaluation with different users was performed. After that, a final concept can be proposed in which all the learnings from the prototypes are integrated.

METHOD

The static and dynamic orthosis concepts of the web-squeeze and the squeeze-on architectures were each tested with three potential users. Of all 4 concepts personalized fit designs were modelled on the three patients' respective 3D scans. The participants were selected from a group of Manometric clients who received an MCP1 thumb splint and fit the intended user group. Because they are Manometric clients, it was not allowed to give the participants prototypes for long-term at-home testing. Instead, with each participant, the regular Manometric fitting appointment procedure was followed to test the fit, comfort, and functionality of the splint in 15 to 20 minutes. The procedure (see also: Appendix G) consists of discussing the patient's symptoms and their current Manometric splinting solution. Then, for each architecture, the splint is fitted and the 'snugness' of the fit is observed. Then, the comfort and mobility of the thumb is questioned by testing some movements. Finally, the security of the splint and the ease of donning and doffing is checked.

The concepts were also compared to the user's current Manometric product. Qualitative answers to questions and observations were used to draw conclusions, with the support of a Manometric orthotist present. Appendix G contains the complete step-by-step procedure. Chapter 5 contains a more elaborate evaluation of the final concept. Two of three participants expressed in advance that they were not satisfied with their current orthoses. They mentioned causes such as their splints providing insufficient support, shifting out of position too easily (even slipping off completely) and causing uncomfortable pressure points.

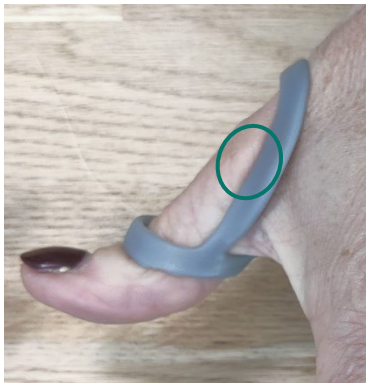
RESULTS

Table 3.4 shows the results of testing. Because it was a completely qualitative experiment, the most important positive and negative comments per user per architecture are included. Where possible, pictures are added below in Figure 2.27 to portray the issue.

	Participant #1		Participant #2		Participant #3	
	Positive	**negative**	**Positive**	**negative**	**Positive**	**negative**
1. Squeeze-on static	-	**Fig 2.27-a.** Dorsal tab did not fit properly over the muscle, causing improper fit.	The palmar tab adds extra support that feels comfortable and secure.	**Fig. 2.27-e.** Dorsal tab did not fall correctly on the skin. Too much space radially.	The extra dorsal loop makes extension more comfortable (due to pressure distribution.)	The dorsal loop lifts off the skin when thumb extended.
2. Web-squeeze static	**Fig 2.27-b & c.** Extension blocking is effective & comfortable.	On the ulnar side, the splint cuts into the wider MCP1 joint. Dorsally, the splint lifts off the skin.	The squeeze works to keep it in place.	There is too much space radially.	-	The palmar tab does not fit will over the thenar muscle. The webspace also blocks donning.
3. Squeeze-on hinged (split)	The support provided by the palmar tab is helpful.	Thumb ring was too tight to fit over the IP joint.	-	**Figure 2.27-f.** The palmar tab did not fit over the thenar muscles.	-	The ulnar hinge does not close at the same time as the radial hinge: ineffective.
4. Web-squeeze hinged (split)	The split architecture makes it easier to fit the palmar tab correctly.	-	**Figure 2.27-d.** The angle at the MCP1 works to keep the splint on the skin.	On the radial side, there is a gap, especially in extension.	The hinge works well to block extension and the angle keeps it in place.	The MCP1 does not fit comfortably inside the dorsal loop (Fig. **2.27-b**).

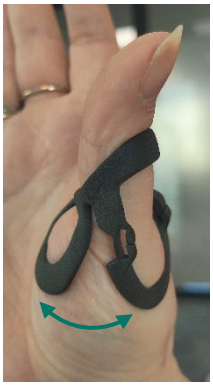
Table 3.4: Results of the first user testing of the static and dynamic concepts of 2 remaining architectures.

A – improper dorsal tab fit.



B – extension block is good but the dorsal tab too narrow for MCP1.

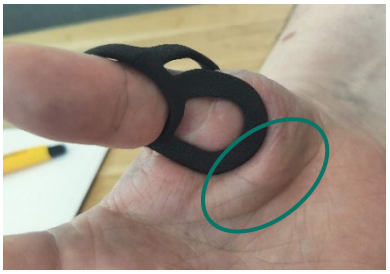
C – splint lifts off the skin dorsally.



D – palmar tab improved fit over thicker thenar muscle.

Figure 2.27: pictures from first user evaluations.

E – Improper fit of dorsal tab & too much space radially.



F – Palmar too tight to fit over the thenar muscles, causes skin folding.

Static splints

The response to both new static architectures was overall positive from each participant. The web-squeeze architecture was favoured by 2 of the 3 participants. In these cases, the added complexity of the dorsal loop in the squeeze-on concept created an imperfect fit (see Figure 2.27-E). Although the splints were modelled on the correct scans, several anatomical variations, over time changes, movement and the scanning pose caused fitting issues: A wide IP joint created difficulties in donning and doffing the splint, due to the thumb loop circumference. A wider MCP1 joint causes discomfort with the dorsal loop. Figure 3.28 shows the effect of that problem. Participant 3 has a higher webspace, which blocks proper donning of the splint. Finally, the varying thicknesses of the thenar muscles make it difficult to properly optimize the distance between the palmar and ulnar tabs in a static splint (Figure 2.27-d).

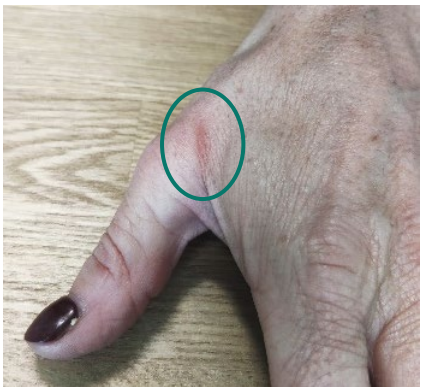


Figure 3.28: Discomfort caused by a tight MCP1 fit.

On the other hand, the squeeze-on concept was generally considered more 'supportive' and more secure. This was largely due to the firmer pressure at the base of the thumb. The palmar tab, which was identical in both concepts, was considered a welcome improvement over the participants' current splints. It provides more support at the base of the joint and the slight squeeze improves the overall security of the splint.

Dynamic splints

All 3 participants expressed a preference for the 'split' architectures. The separate tabs (Figure 2.27-d) allow more room for variation in the thickness of the thenar muscles as the material can deflect somewhat. The hinged concepts worked as predicted (see Figure 2.27-d) and were positively received by participants. 2 of the 3 participants expressed preference for the hinged concepts, because they feature the split tabs and felt less likely to slip off. One participant expressed concern about something getting stuck inside the hinge.

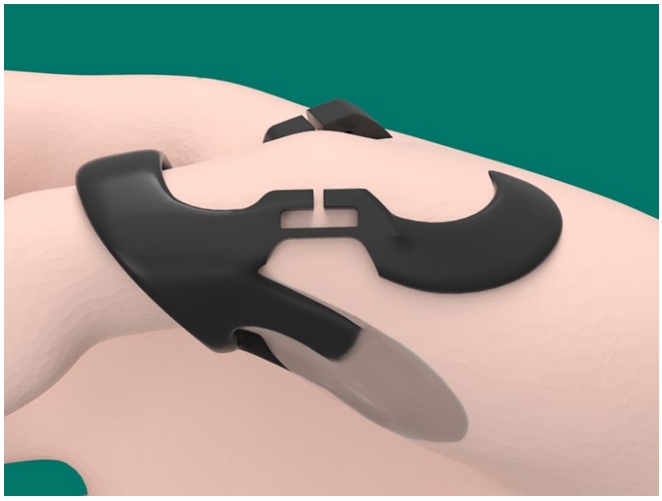
Within the 10 to 15 minutes that each splint was worn, only 1 case of discomfort was expressed because the web-squeeze concept was fitted too tightly around the MCP1 joint (Figure 3.28). The insights from this user evaluation were used to come to one new concept that became the final concept, which is described in Chapter 4.

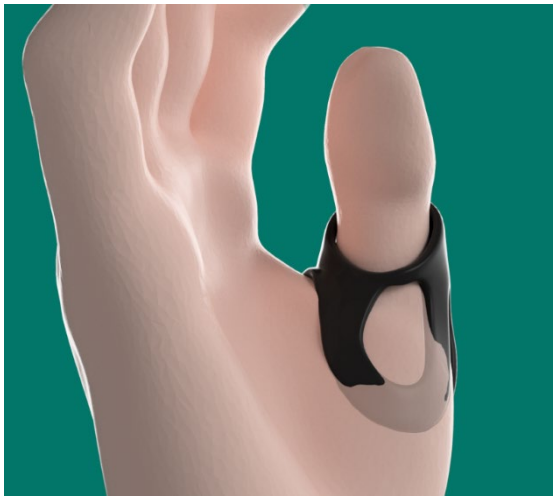
4. Final Concept: A New Thumb splint

CONTENTS

INTRODUCTION

The process outlined in Chapter 3 resulted in the concept explained in this chapter. It aims to satisfy the design requirements, overcome the challenges, and meet the vision explained in Chapter 2. This chapter highlights how the new MCP1 thumb splint tackled the described challenges, the function and appeal of the splint, the freedom of mobility, the workflow and manufacturability. The evaluation of this concept is performed in Chapter 5.





4.1 FUNCTION AND FORM

The findings described in Chapter 3 were used to come to one improved architecture. The new splint is shown in Figure 4.1 and the important features are annotated. The 3D scan has a decreased capacity, to make the parts below the scan visible.

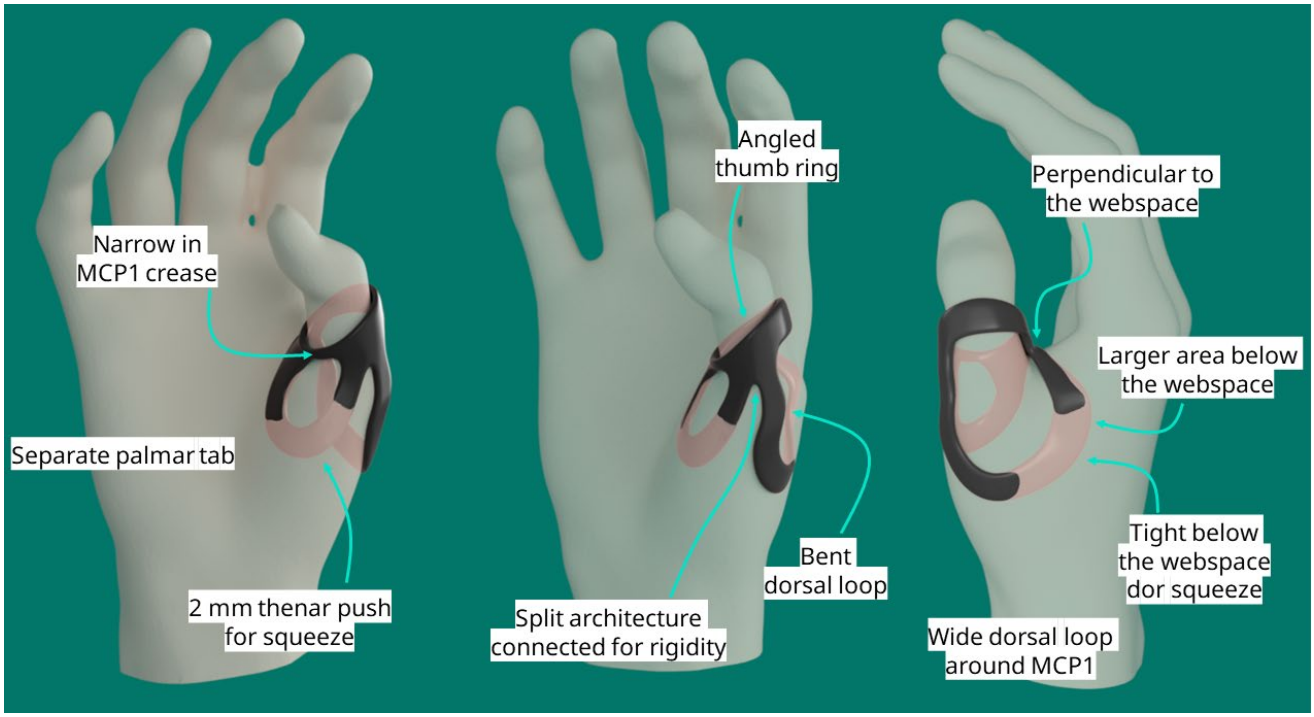


Figure 4.1: Annotated renders of the new thumb splting architecture.

The concept makes use of a split architecture, with a separate palmar tab and dorsal loop. This facilitates the integration of a living hinge and was found to improve the fit and comfort, due to the added form flexibility. As such, the architecture can be considered in 3 parts: a palmar tab, a dorsal loop, and a thumb ring. Each part is briefly highlighted below. A light 'squeeze' just below the webspace improves the security of the splint. To avoid undesired deflection and assure the rigidity of the first-class lever mechanism, the two halves are merged over a length of 15 mm on the radial side of the thumb loop, as shown in Figure 4.1. The splint blocks extension at 15 to 30° of flexion and thereby prevents hyperextension. Besides that, the mobility of the thumb is mostly unobstructed, and the splint is compact and sleek, easily fitting under a glove and not snagging in a jacket sleeve. The thumb ring is large enough to accommodate easy donning and doffing. The concept is a single material solution that is 3D printed out of PA12 using the Multi Jet Fusion method, which enables efficient integration in Manometric's current workflow. The material is easy to clean with water and soap.

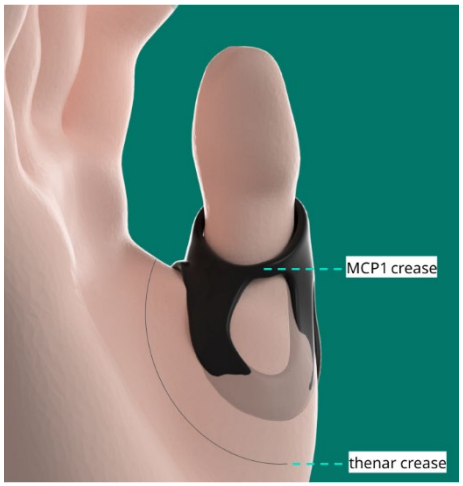


Figure 4.2: The palmar tab.

Figure 4.3: 2 mm push into the scan at the palmar tab.

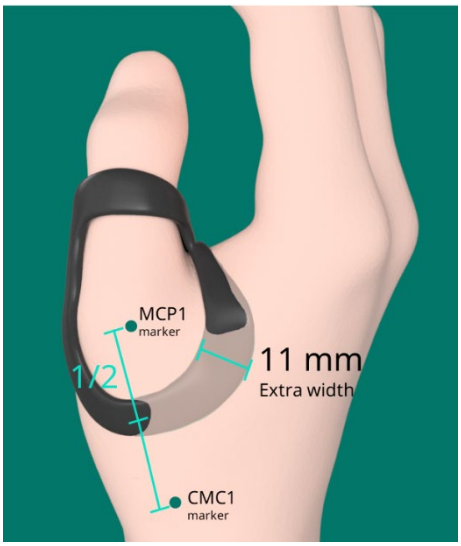


Figure 4.4: The dorsal loop is ½ between the MCP1 and CMC1 landmarks & has extra width at the push on the ulnar side.

PALMAR TAB

The palmar tab is adapted from the previous version by extending towards the thenar crease. This allows it to fall comfortably over the thenar muscles when the thumb is in flexion, while not impeding on the crease (Figure 4.2). The rounded and flat shape ensures that it sits comfortably on the skin without sharp edges and corners. The palmar tab facilitates an improved pressure distribution at the Fulcrum, leading to a more comfortable user experience.

Besides that, the palmar tab plays a role in creating a pressure on the thumb between the palmar and dorsal sides of the splint. This so called, 'squeeze' effect, which affects the soft tissue area just below the webspace, at the Adductor pollicis, improves the security of the splint. The strength of the squeeze effect is balanced such that it does not cause uncomfortable pressure or the CMC1 joint and thenar muscles to be restricted. This is determined by the amount of '*push*' that is given on both tabs, which is done by modelling it ~2 mm below the scan (see Figure 4.3). Finally, users expressed that the pressure applied by the palmar tab at the top of the thenar muscles provides a desirable support that keeps the MCP1 joint in comfortable flexion, reminding the wearer not to (over-) extend the thumb.

DORSAL LOOP

The new architecture is most like the web-squeeze concept described in Chapter 3.2.2, which was more favoured by users and led to less complications with the fit. However, additional surface area and space around the MCP1 joint on the dorsal side were added to imitate the advantages of the squeeze-on concept. This means that the dorsal tab is now a loop around the MCP1 joint from the radial to the ulnar side of the thumb ring, reaching ½ of the distance towards the CMC1 joint (see Figure 4.4). On the ulnar side, below the webspace, is an area of increased width which is also 'pushed' into the skin ~2mm. This comprises the other side of the squeeze effect explained previously.

As shown in Figure 4.5, the dorsal loop is not a smooth shape but features a bend at the MCP1 joint. Chapter 4.3 details the placement and angle of this bend. The integration of living hinges on the dorsal tab, further explained in Chapter 4.2, improves the splint's performance by facilitating a better freedom of mobility.

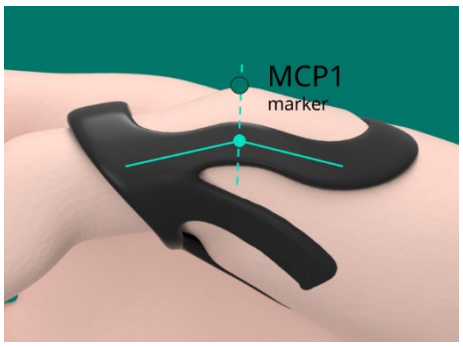


Figure 4.5: The bend in the dorsal loop is based on the angle in the MCP1 joint on the scan.

THUMB RING

The thumb ring is placed 2/3rds of the distance towards the IP joint, from the MCP1 joint. This ensures a long enough resistance force arm, without impeding on the freedom of the IP joint. The thumb ring is angled, as shown in Figure 4.6. The angle improves the effectiveness, security, and comfort of the splint. It allows the resistance arm to be sufficiently long on the dorsal side, while the thumb ring falls in the crease of the MCP1 joint on the volar side. In the crease, the thumb ring is narrowed to 3 mm, which improves flexion of the thumb. On the dorsal side, the thumb ring is 9 mm wide, which facilitates a better pressure distribution. The thumb ring is not perfectly round but follows the shape of the 3D scan instead. The width of the thumb ring is increased based on a ring measurement of the IP joint, to ensure comfortable donning and doffing. This is further specified in Chapter 4.3.

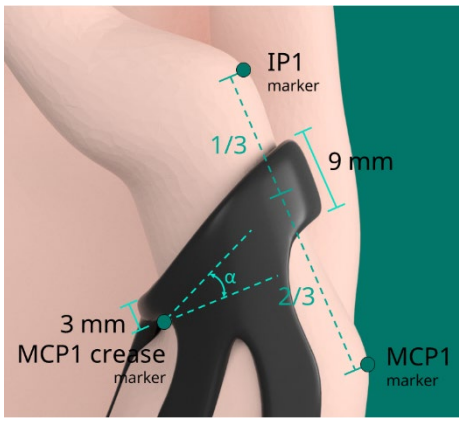


Figure 4.6: The thumb ring dimensions.

4.2 THUMB MOBILITY

This orthosis was designed for movement instead of immobilization. Chapter 2 defined how each joint of the thumb should be affected by the new design. This section covers how this vision was accomplished in the new concept, including the implementation of a hinge.

THUMB MOVEMENTS

The previous section explained how the 3 main parts of the splint are designed such that each joint and the thenar muscles are minimally impeded by the new architecture. Especially opposition, flexion of the CMC1 joint and flexion of the MCP1 joint were found to be critical movements that are often inhibited or poorly facilitated in existing splinting solutions. Throughout the prototyping phase, a balance was sought between securing the splint to the hand and still allowing

those movements of the thumb. The splint features a bend in the dorsal loop at the MCP1 joint. The bend creates an angle in the splint that pushes the splint on the skin dorsally, especially in flexion (Figure 4.7). The security of the splint is improved because it stays on the skin and squeezes around the thenar muscles. The precise required angle of the bend differs per individual, as it is determined by the individual's natural ROM. To facilitate this personalization, the 3D scan is made in different position than usual: the thumb should be in opposition.

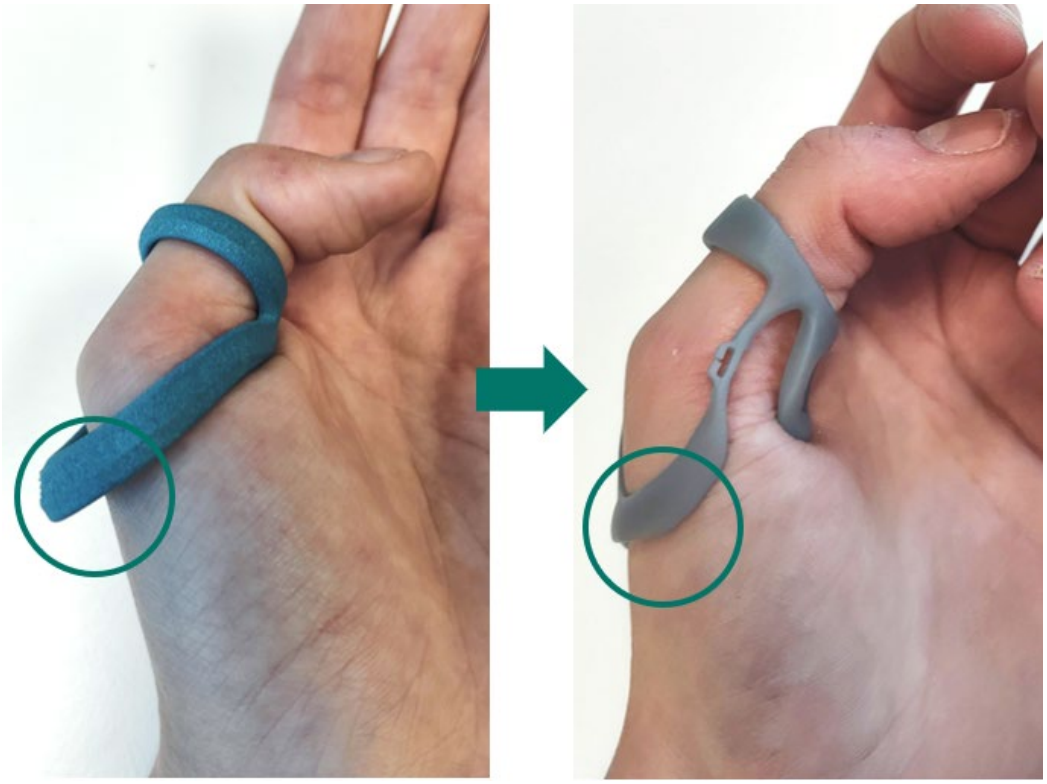


Figure 4.7: Prototype showing the improved splint performance when the thumb is in flexion.

3D SCAN POSE

The 3D scans from the ManoX form the foundation of the design process. In the initial prototyping rounds a functional position determined by an orthotist was used. Throughout the prototyping process, it was found that the splint should be modelled with a considerably smaller angle at the MCP1 joint compared to other scans used by Manometric. As shown in Figure 4.8, a new scan was created for further prototyping. In the new scan, the thumb is placed quite far in opposition, touching the 5th digit (pinkie). The pinkie and IP joint are then straightened to open the hand, which minimizes the negative impact on the quality of the scan, as the lighting is less blocked, and the overall hand shape is less complex that way. The angle at the MCP1 joint is not defined because this allows the splint to be designed

at the correct comfortable angle for each patient. This scan allows the splint to be modelled in flexion, which creates a smaller angle at the MCP1 joint and thereby improves the fit, security, and mobility performance of the splint. Chapter 5 contains a reflection on how the changed scanning position might influence the Manometric workflow.

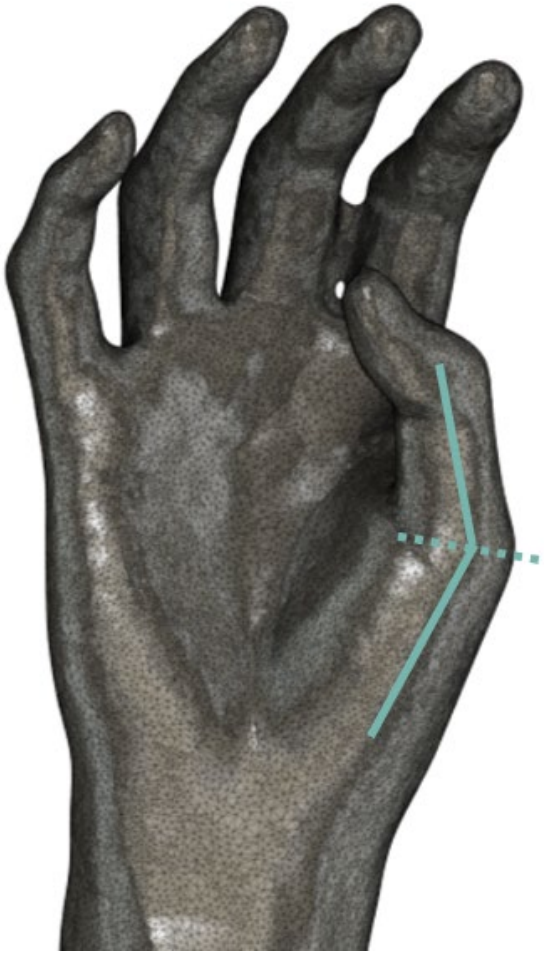


Figure 4.8: The new 3D scan pose for improved thumb mobility and splint security.

HINGE IMPLEMENTATION

The downside to using a 3D scan in opposition is that the splint pushes the thumb into opposition by default. In Chapter 3, it was concluded that that is not the most useful immobilization position. Therefore, this splint does not immobilize the thumb in this position, instead it allows further flexion and some extension through integration of a living hinge.

The bends in the dorsal loop on both sides of the MCP1 joint determine the position of the hinges. Chapter 3.2.2 described how the hinge design shown in Figure 4.9 was created and prototyped. The design consists of a living hinge with a minimum thickness of 1mm, this allows flexibility to further flex the MCP1 joint as well as extend it. However, the blocks on top of the hinge are separated by a 0.6 mm gap that closes and blocks extension at 15 to 30 degrees of flexion. To ensure the rigidity of the extension blocks, the material thickness is no less than 3 mm in those areas. This hinge design is a proof of concept and can be further optimized to improve its performance and durability. More about this is documented in Chapter 4.3. The final evaluation with users in Chapter 5 also considers the mobility of the thumb with and without a splint to draw conclusions about how the new architecture, modelled on a new scan, with an integrated hinge influences the mobility of the thumb.

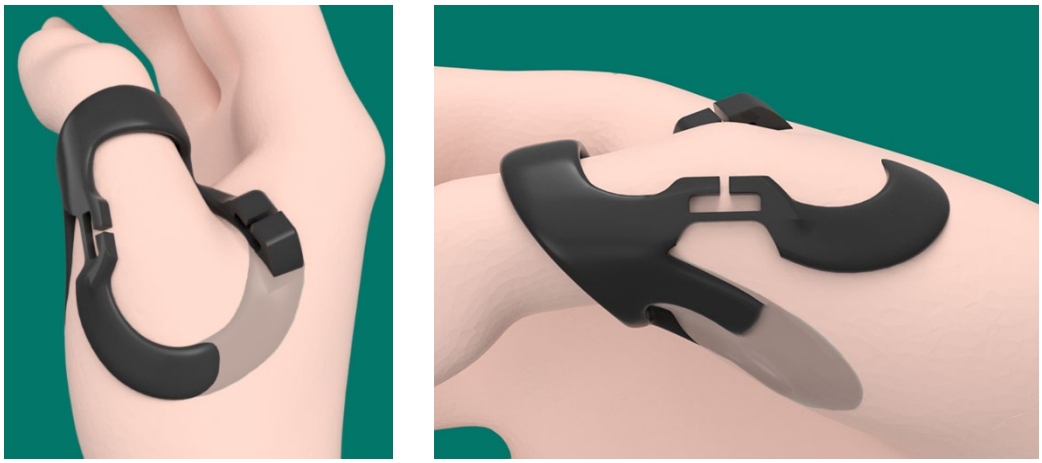


Figure 4.9: Hinge integration in the new thumb splint.

4.3 WORKFLOW

The new splint design does not constitute a large deviation from the current Manometric workflow. The new architecture is designed to accommodate any patient within the defined target group. This means that Manometric does not need to design new products for each user but can instead use the proposed architecture. The automation of the new design has not yet been performed, but the design rules formulated in the following section can form a foundation for this process. If these objectified design rules are followed manually, like a protocol, the new concept will move up on the standardization spectrum. This enables a more efficient workflow and facilitates the gathering of more data to better understand the performance of the product and opportunities for improvements over time.

LANDMARKS

Figure 4.10 displays the landmarks and scanning position that are required to create the new design on any 3D scan. The required landmarks are at the three joints of the thumb. On the volar side, the joint creases and the middle of the thenar muscles are marked. These landmarks are not new and do not add complexity to the orthotists job. Finally, the ring size of the IP joint is required input data. The new scanning position might require some practice. Chapter 5 contains a reflection on the impact of the new scanning procedure.

PARAMETRIC DESIGN RULES

Using the smoothed scan and the landmarks, the complete design rules in Appendix H can be used to shape the splint architecture. Table 4.1 contains a selection of important parametric rules to be indicative of the formulation. Figure 4.11 makes the design rules visual, which enables a designer to follow the rules manually. While the eventual automation of the design process requires computational implementation, these design rules form a foundation for that step. They can be seen as a protocol for designers to follow to ensure the creation of consistent products for different patients. The rules were evaluated and improved with insights from 2 Manometric 3D designers to assess completeness and clarity. Before manual implementation.

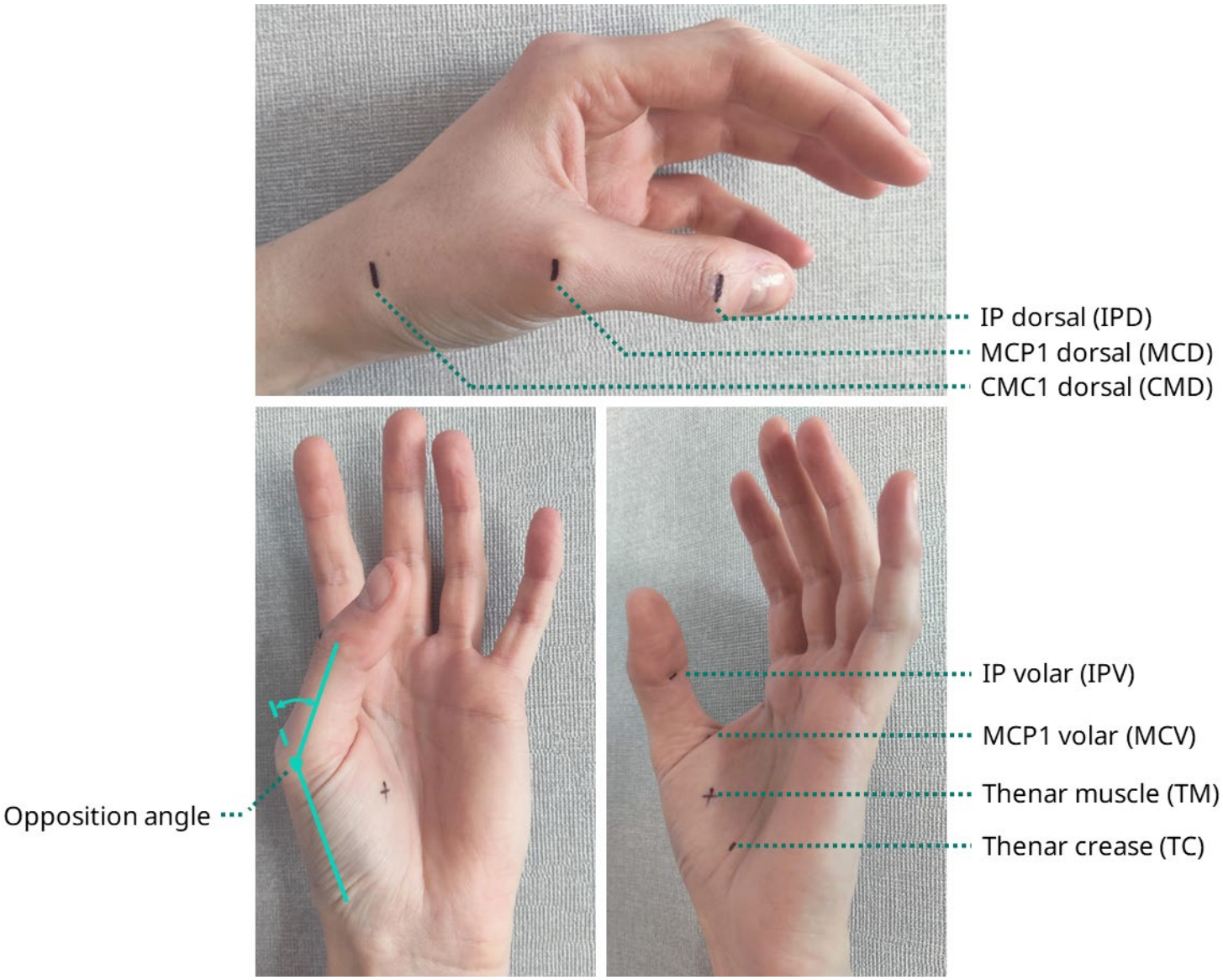


Figure 4.10: Anatomical landmark locations and scanning pose required for the new splint design.

Design rule description
All: The flat shape of the complete splint is given a 2.5 mm thickness with rounded edges. Fillet radius = 1.75 mm.
Thumb ring: On the dorsal side, the middle of the thumb ring is at 2/3rds the distance between MCD and IPD, towards IPD.
Thumb ring: On the volar side, the middle of the thumb ring lines up with the MCV (MCP1 volar crease).
Palmar tab: At the connections with the thumb ring, the palmar tab is 7 mm wide. At the proximal end of the palmar tab, it is 9 mm wide.
Palmar tab: The proximal end of the palmar tab is at 1/2 of the distance between TM and TC.
Palmar tab: The palmar tab follows the shape of the scan and is pushed ~2 mm below the outline.
Dorsal loop: The radial side of dorsal loop runs parallel to the dorsal side of the thumb, following the bend caused by the MCP1 joint, until the proximal end of the loop.
Dorsal loop: The bottom of the palmar tab is at 1/2 of the distance between MCD and CMD.
Hinge: The radial hinge is placed such that the central axis splits the MCP1 bend through its middle.
Hinge: The ulnar hinge is placed such that the central axis splits the MCP1 bend through its middle.
Hinge: The cross-section of both hinges is identical and constant through the complete thickness, described in Figure 4.11.

Table 4.1: Selection of the parametric design rules (see also: Appendix H).

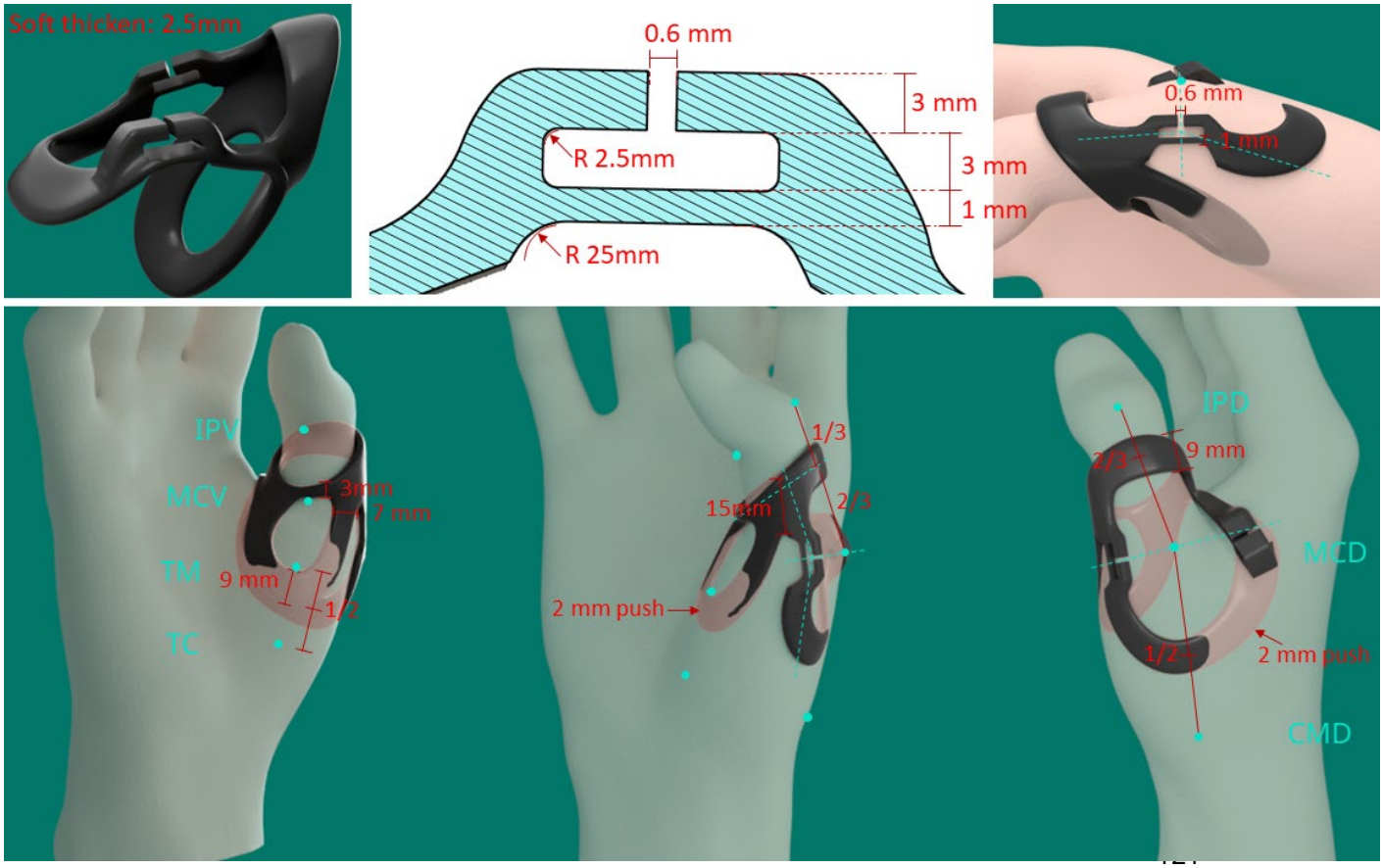


Figure 4.11: Indicative visual to accompany the parametric design rules.

4.4 DESIGN FOR MANUFACTURING

Chapter 1.5 described a variety of suitable material and manufacturing options for a thumb orthosis based on traditional methods as well as the modern implementation of additive manufacturing in the personalized products industry. Throughout the prototyping process, several AM methods were used, with different materials, to test their suitability. The chosen material for the new thumb splint is Multi Jet Fusion printed PA12. This section covers the considerations that led to this choice, the limitations and the design features that are influenced by this material and production choice.

MATERIALS

Chapter 1.5 introduced several ways in which AM could be used to directly produce orthoses and to print moulds for silver, silicone, or resin products. It became clear during the ideation and prototyping phases that silicone was not a suitable solution for the new thumb splint, due to the bulkiness, sweatiness, and manual labour complications of processing it. The critical feature of the splint that was decisive in the material selection was the living hinge. For this application, silver and liquid resin casting materials were found not applicable as they are too strong, and too brittle respectively. Multi-material prints and assembled hinge mechanisms were found unfeasible and unviable at this time, due to durability and costs. 3D printed living hinges also come with durability limitations, but nylon plastics and MJF printing were found most suitable.

PA12

After testing different materials and printing techniques, MJF printed PA12 was found most suitable (Figure 4.13). Not only did the living hinge perform sufficiently in initial testing, but this material also meets the other design requirements. It is a commonly used in the industry of O&P and there are certified skin-safe options available. It can easily be cleaned with water and soap and with the 2.5 mm thickness and 7 to 9 mm widths, the material offers plenty of mechanical rigidity to fulfil its function. Manometric is already familiar with this material, as they have been using it in their product portfolio. It has proven sufficiently durable to them over the years. Since it is a thermoplastic, the orthotists can locally reheat the material and make minor adjustments on the spot, which helps to decrease the number of fitting loops.

Finally, there are plenty of suppliers of skin-safe MJF printed PA12 available in The Netherlands as well internationally so integrating it into the Manometric workflow, and further upscaling it, should not be problematic.

MJF PRINTING

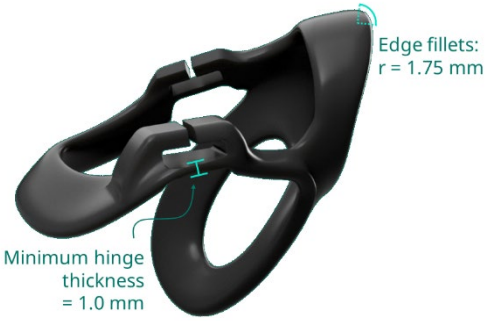


Figure 4.12: Tolerances for MJF printing.

Multi Jet Fusion printing creates a more isotropic and resilient result than with any other AM method, which makes it especially suitable for printing a living hinge. The method also offers almost complete dimensional freedom where no supports are required. Manufacturers advise tolerances of ±0,3% and an accuracy of ±0.3 mm, but a minimum wall thickness of 1.0 mm. According to a Serviceteam engineer at Materialize, a smaller thickness, in accordance with the tolerances, might be printable but the chances of failure become significantly higher, making it unviable business practice to accept orders with such dimensions. This design rule only poses a significant limitation for the living hinge of the new splint (Figure 4.12). Living hinges with a minimum thickness of 1.0 mm were tested and found sufficiently effective. For future implementation, it might be valuable to collaborate with manufacturers to explore the possibilities of thinner walls and how that impacts the durability and performance of the living hinge.

Figure 4.13: MJF PA12 part with PolyShot finishing (Materialize, 2022)

Other design rules for this printing method include a maximum solid wall thickness of 10 mm, to avoid warping caused by temperature differences and a minimum fillet size 0.5 mm on all edges, as sharper edges are susceptible to damage (Figure 4.12). The specifications in the previous sections showed that these limitations are not significant for the design. PA12 MJF printed parts are most commonly grey but can be given almost any colour at a heightened cost. A colour or pattern can make up the outer layers of a printed part. This allows the user to make a choice that fits their aesthetic preference. The parts can also be finished in different ways, such as polishing and tumbling. A PolyShot Surfacing, developed by Dye Mansion, can be used on any PA12 part, including coloured ones and creates a smooth semi-gloss finish. This finishing is especially desirable for this orthosis as it leads to a smooth surface to which dirt and fluids are less likely to stick, making it easier to clean as well. The smooth surface is also comfortable on the skin.

4.5 COST ESTIMATION

A detailed estimation of the costs of the product and operations for Manometric is made in Appendix M (confidential). This estimation gives an idea of the viability of the design for Manometric.

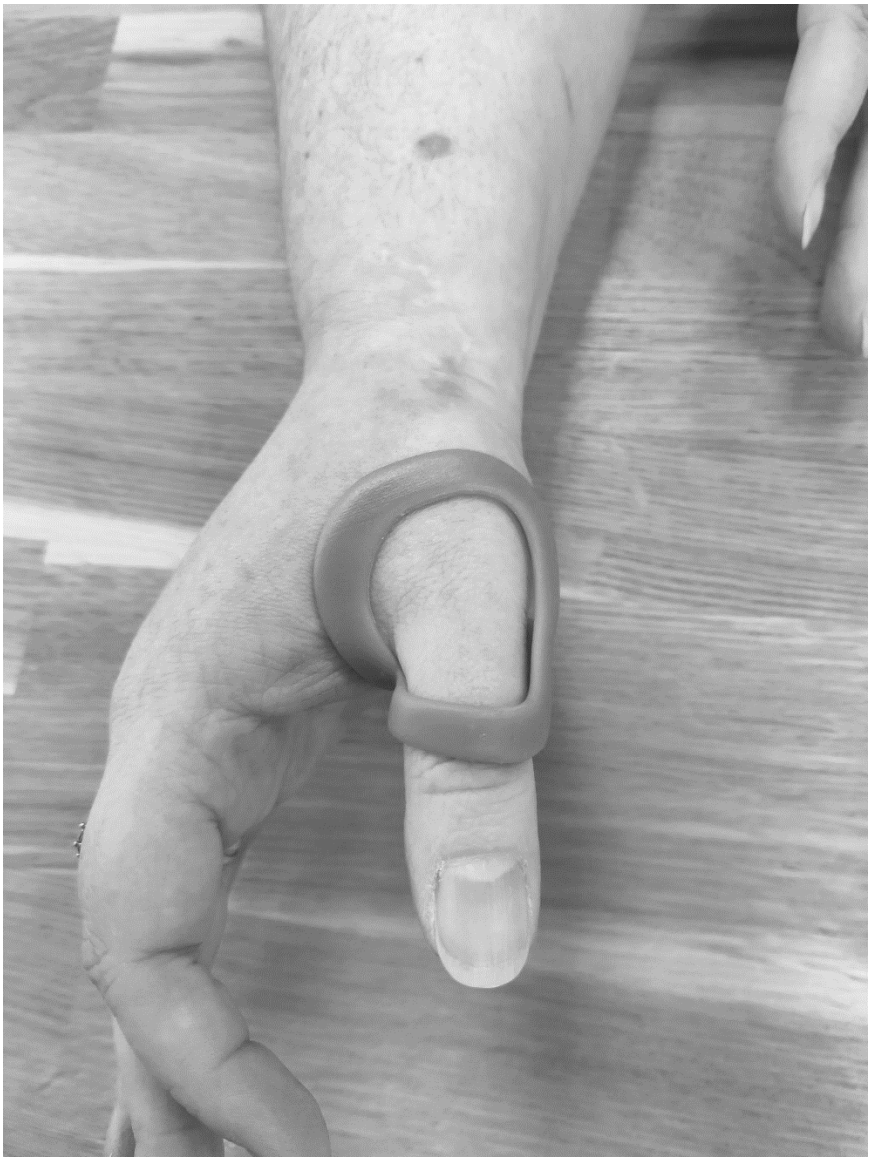
While this estimation does not provide a definitive final price, it shows that Manometric is likely able to produce the thumb splint within the cost limit of the health insurance reimbursement for a personalized thumb splint (estimated €100-300 in Chapter 1.2.2). It also shows that the material and production choice is not the deciding factor in the cost of the splint, but rather the internal workflow. Further standardizing the design and learning the design protocol can greatly reduce the amount of time spent by the 3D designer. It is also important that the number of fittings with the orthotist is minimized. While the design facilitates this, by considering the results of the anatomical variances analysis and by allowing last-minute adjustments, the design can be further optimized and standardized to further reduce orthotist costs.

5. Evaluation phase

CONTENTS

INTRODUCTION

In this final chapter, the proposed concept is evaluated against the requirements and goals set in Chapter 2. The concept is evaluated with 3 different users and several Manometric expert to draw conclusions about the desirability, feasibility, and viability of the concept. Recommendations are formulated to address the shortcomings of the proposal and method and advise about the continuation of the concept's development.



5.1 FINAL PRODUCT EVALUATION

The concept proposed in Chapter 4 was produced for 3 participants on their respective 3D scans in opposition, following the parametric design rules. The participants are the same as those who took part in the testing described in the prototyping phase. They were selected from a group of Manometric clients who received an MCP1 thumb splint and fit the intended user group. The goals of the experiment are to assess the effectiveness of the parametric design rules and evaluate whether the proposed concept meets the criteria regarding performance and ergonomics from a user's perspective. Additionally, the added value of the hinge is evaluated by comparing the same architecture with and without it. The new concept is also compared to each individual's current splint to assess how it meets Manometric's standard. Besides the usual procedure followed in the Manometric fitting room, a literature review was performed to gain insights into ways to test the effectiveness of orthoses and the function of the hand in a short time span.

5.1.1 METHOD

For each participant 4 splints were created:

- A normal splint, following the parametric design rules,
- a normal splint, following the parametric design rules, but without the hinge,
- a tighter one, with a larger push on the palmar tab (+1 mm) and dorsal loop (+1 mm),
- a bigger one, with a reduced push on the palmar tab (-1 mm) and dorsal loop (-1 mm).

These variations were created to ensure that at least one product would fit, so the experiment had a higher chance of success. The splints were made of SLS printed PA11. This material was readily available and performs similarly to PA12, with enough durability to endure the testing procedure. Because the participants are Manometric clients, it was not allowed to give the participants prototypes for long-term at-home testing. Instead, a 15-to-30-minute procedure was followed. Appendix I contains a complete step-by-step overview of the experiment procedure and the results.

PROCEDURE

In short, the experiment went as follows. Each splint size was fitted on the participant and the best fit was chosen to continue with. The mobility of the thumb with and without the splint was assessed using angle measurements in pictures. The splint's initial comfort score in a relaxed hand position was provided using the adapted pain sensitivity map (Fernández-de-las-Peñas et al., 2010) in Figure 5.1. This method enables the quantification of the product's comfort and was adapted to be specific to relevant areas of the hand and thumb. The participants evaluate the painfulness of pressure applied by the splint in different areas on a scale from 0 to 5.

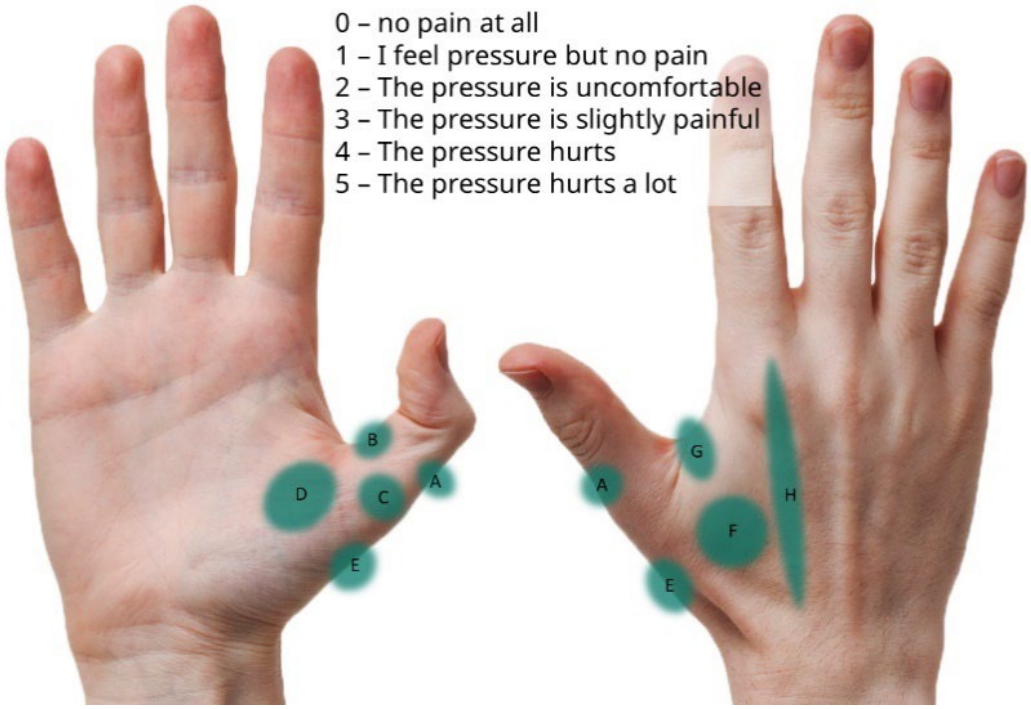


Figure 5.1: Pain sensitivity map.

An adapted Sollerman Hand Function Test (see Appendix I) was used to have the participant perform a series of activities intended to test hand grips, shown in Figure 5.2, that are a representation of daily life activities (Sollerman & Ejeskär, 1995). The researcher takes note of the time taken to carry out tasks, the level of difficulty and the quality of hand performance. For each activity, points are scored between 0 and 4, where 0 means that the activity could not be performed, and 4 means that it was performed completely healthily, in accordance with the expected hand grips shown in Figure 5.2. The more points awarded, the healthier the hand function. This method enables quantification of the hand function and has been proven reliable in other literature (Physiopedia, n.d.).

This test was performed twice, once with and once without the splint, to observe the difference. After 15 to 30 minutes of wearing the splint and performing the exercises, a second set of comfort scores was supplied, once in a relaxed hand position again, and once with the thumb maximally extended. The session was ended with a comparison of the splint with and without the hinge and of the participant's current splint. A semi-structured interview was used to gather qualitative insights from the users. To see the complete procedure and results of the experiment, refer to Appendix I.

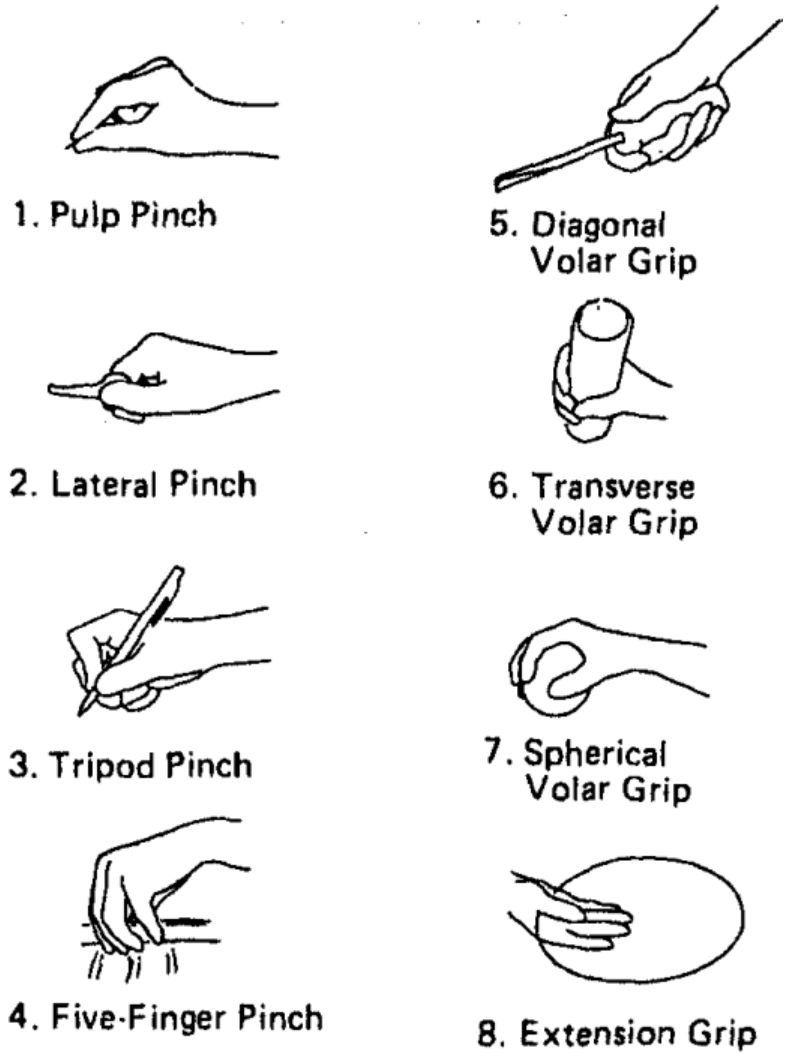


Figure 5.2: Sollerman's 8 main handgrips to test hand function.

5.1.2 RESULTS & CONCLUSIONS

The evaluation with 3 participants is first used to draw conclusions about the performance and ergonomics of the splint. These conclusions are also used in Chapter 5.3 to assess the final concept against the list of design criteria.

PERFORMANCE

For each of the three participants, the splint blocked extension before a point of discomfort was reached. For 2 participants, it was at 15 to 20° of flexion, which is ideal as it keeps the thumb, including the CMC1 joint, in a stable and healthy position. However, for 1 participant, the extension was blocked at ~180° (or 0°). While this was sufficient in the experience of the user, it is not ideal. Upon testing the splint without hinge, it did not present this problem. This likely means that, in opposition, the angle of the MCP1 joint for this individual was small enough (~20°) that the gap in the hinge was too wide, allowing too much extension, as shown in Figure 5.3. Overall, the results regarding the main function of the splint are sufficient to show that the concept is promising and can perform well. However, there are details that need further investigation to ensure consistent performance for all patients.

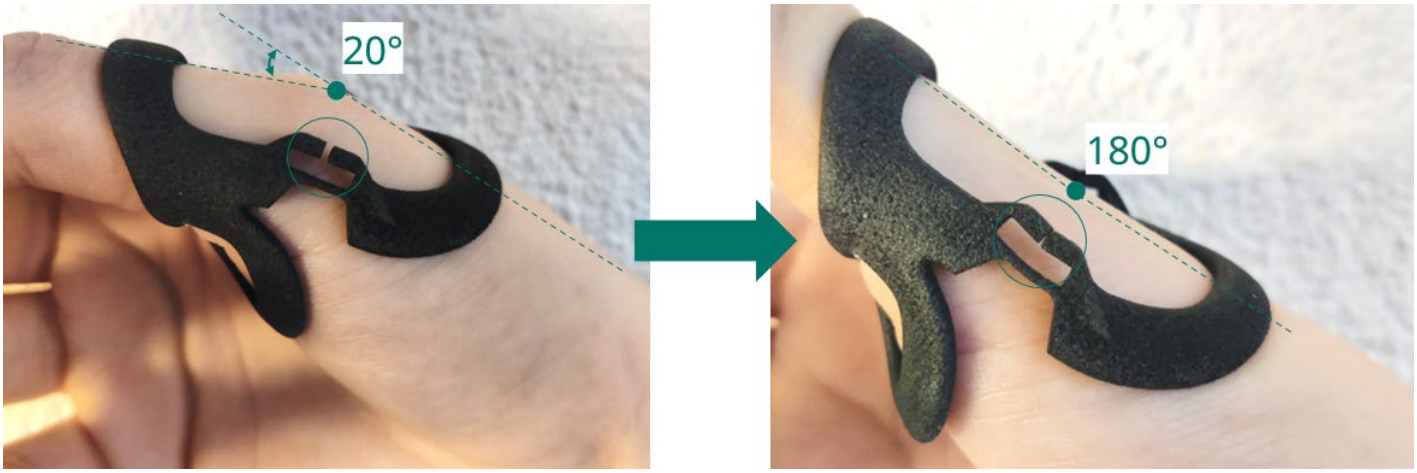


Figure 5.3: The angle in the initial scan determines the maximum extension angle if the hinge gap size is not scaled accordingly.

Mobility

The further mobility of the thumb and function of the hand in daily life activities are important aspects of the splint's function. Firstly, looking at the range of motion of each participant with and without the splint showed that, besides blocking extension, the splint slightly impedes flexion and adduction of the CMC1 joint and flexion of the MCP1 joint. This is caused by the palmar tab, which pushes into the thenar muscles when the thumb is exaggeratedly flexed. Although the ROM is reduced, the splint performance is a success in terms of thumb mobility, considering that the very limits of the ROM are not considered relevant for a user's QoL. The required motions: opposition, a pinch grip and a power grip could be performed by all participants with no difficulty. This was further proven in the hand function test.

Hand function

Regarding the results of the hand function test, it is important to note that 2 of the participants wear the splint on their non-dominant hand, which leads to a reduced hand function score for any individual in any context. Table 5.1 shows the participants' average performance of the tasks with and without the splint.

Activity Nr.	**grips** (Sollerman & Ejeskär, 1995)	**avg.**	
		without	**with**
1. Pick up coins from flat surface, put into purse.	Pulp pinch	3	3,67
2. Lift wooden cubes over edge (5 cm in height).	Five-finger pinch	4	4
3. Lift weight (3kg) over edge (5 cm in height).	Transverse volar grip	1,67	3,33
4. Turn screw into wood with screwdriver.	Diagonal volar grip	1,67	2,67
5. Pick up nuts and put on bolts.	Pulp pinch, lateral pinch, tripod pinch	3,67	3,33
6. Write with a pen.	tripod pinch	2,67	2,67
7. Fold paper, put into envelope.	Five-finger pinch, lateral pinch	4	4
8. Put paper clip on envelope.	Pulp pinch, lateral pinch	3,67	4
9. Pour water from the jug (1L).	Transverse volar grip	0,33	2,67
Total (of 36)		**25**	**30,33**

Table 5.1: Average results of the adapted Sollerman's hand function test.

Although it is not a perfect score, the hand function notably improves when wearing the splint. The low scores are partly due to the non-dominant hands, but the 'without' scores highlight the true struggle that this target group has with seemingly simple tasks at which a healthy individual could easily score 32 to 36 points. In all activities, wearing the splint improved the hand function, except in activity 5: placing a nut on a bolt. This activity revealed that the participants have difficulty repeatedly performing the lateral pinch grip. This requires them to adduct the thumb and close the webspace, which is impeded by the splint. This caused the splint to shift from its position (see Figure 5.4). While completely closing the webspace is not often necessary in daily life, this aspect of the thumb's mobility was not sufficiently considered in this design.

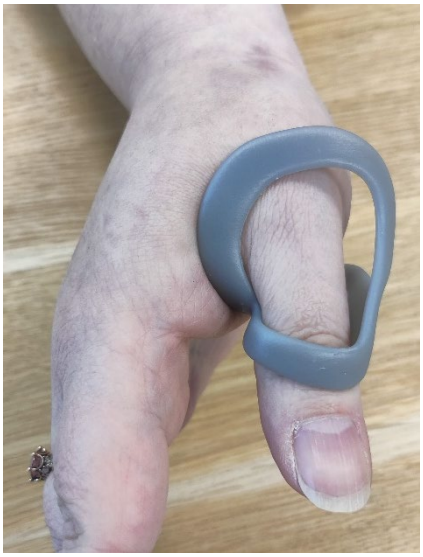


Figure 5.4: Exaggerated demonstration of what happens after repeated lateral pinch grips.

Finally, the results showed that particularly the power grips (diagonal and transverse volar grip) are difficult for patients in this group. The splint notably improves the performance. This indicates that the splint provides the required support for users to better perform activities that involve large forces, such as grasping heavy objects. Participants also expressed that they feel more confident performing these exercises with the splint on:

"I haven't picked up a heavy jug with just my right hand in 3 years, usually I need to support it with both, but I think with this on I will give it a try."

Security

Throughout the experiment, the participants wore the splint for 15 to 30 minutes, including Sollerman's hand function activities. Like during the first user evaluation sessions, the security of the splint was a noteworthy improvement over their current Manometric products. The squeeze effect created below the webspace works as intended. The same is true for the bend in the dorsal loop. Following the shape of a flexed thumb instead of a relaxed thumb enables it to squeeze around the thenar muscles and stay on the skin, solving a major problem found in the existing splinting architectures. Naturally, the splint is not completely stuck in its position, as that would make donning and doffing too difficult. Occasionally, it is necessary to push the splint back in position, especially after adducting the thumb, which can cause the splint to rotate radially (see Figure 5.4).

The splint can still move somewhat distally along the thumb up to the IP joint, which is necessary for donning and doffing. This is generally not experienced as an issue because flexing the IP joint pushes it back in place. Overall, the security of the splint is a significant improvement over the existing splint design, considering the amount of mobility that is simultaneously provided.

ERGONOMICS

Figure 5.5 shows the average comfort scores of the splint with the hand relaxed (top) and when the thumb is maximally extended (bottom). In general, it shows positive results, as 12 of the 16 scores are below 2, meaning no discomfort is experienced. However, the pressure caused by the splint can be uncomfortable in the webspace and at the bottom of dorsal tab, and slightly painful at the dorsal side of the thumb loop, when the thumb is extended. This is not acceptable result, as the splint is intended to stop the user from hyperextending, and 2 participants expressed that the firm pressure serves as a reminder about their limitations. However, further steps could be taken to improve comfort in these areas.

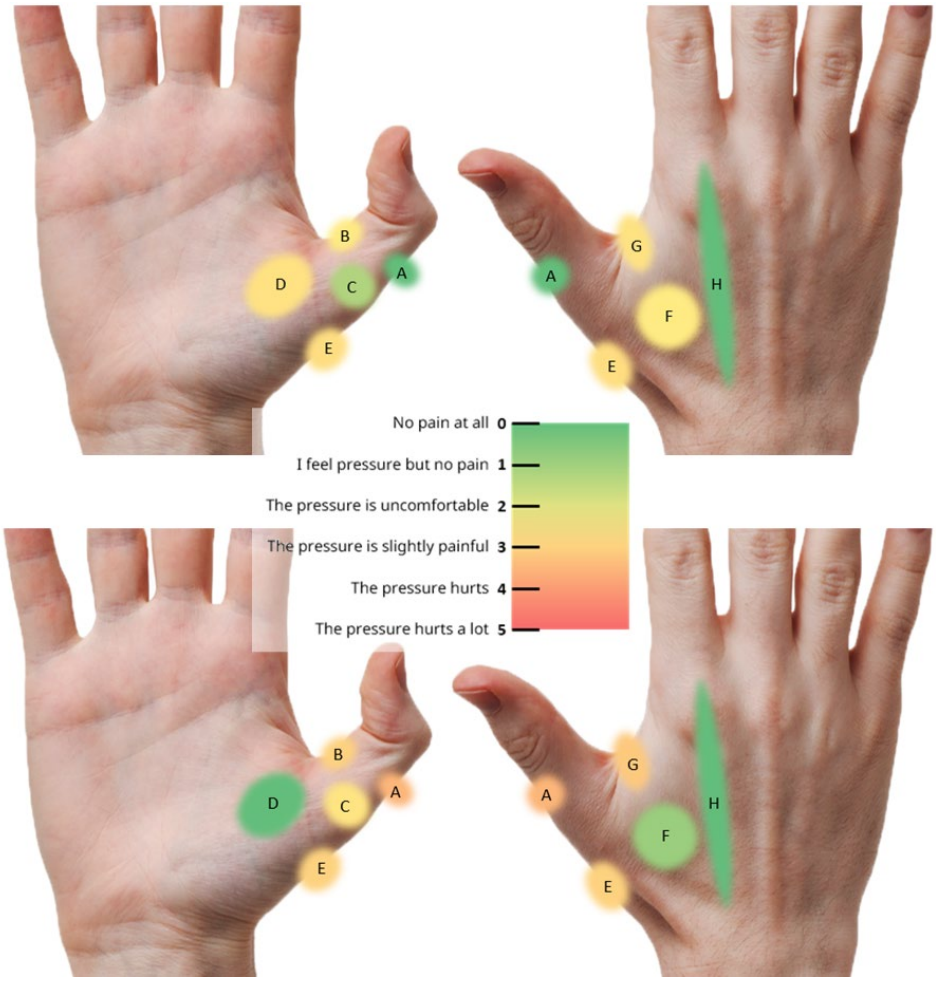


Figure 5.5: average comfort scores with a relaxed hand position (top) and the thumb maximally extended (bottom).

Overall, the splint is considered comfortable, and does not cause pain while performing daily live activities. The fit is snug around the thumb but not too tight that it causes discomfort or visible marks on the skin within the testing period. However, the long-term effects have only been experienced by me, and were not tested with the participants. Besides comfort, the ergonomic assessment included donning and doffing, which was not a problem for any participant due to the widened thumb loop. Snagging or catching behind objects did not pose a problem throughout user testing, due to the compact design and improvements described under 'security'. Enough space was left in the required areas to facilitate sufficient thumb mobility, except for adduction, as the hand function test proved. Within the testing time, participants did not express concerns about perspiration and due to the thin architecture of the splint, this is not assumed to be a problem.

Anatomical variance

Chapter 3 highlighted the design decisions made to accommodate anatomical variances. With the 3 experiment participants, 2 rounds of prototyping were performed. This helped to gain real world insights about improving the fit before the final product evaluation. This means that the final experiment does not offer rich insights into the true validity of the of the design in terms of accommodating anatomical variances. For the 3 participants, the fit of the splints created by following the parametric design rules was good. There were no areas too tight and no visible gaps between the skin and the splint. The performed experiment did not allow an assessment with a high number of participants, so this aspect is further evaluated with insights from experts in Chapter 5.

Aesthetic values

The aesthetic of the design was discussed with each participant. The most important aesthetic preferences expressed in early interviews with users were compactness and discreetness. The appearance should not be too medical and for some, a jewel-like elegance would be preferred. In the new design, compactness was prioritized, as that was generally the largest problem with the appearance of current braces. Besides that, no further steps have been taken to assess and improve the appearance of the product. The participants expressed that the size and shape of the concept was in accordance with their wishes.

"People would really have to look closely, to see that I have a medical thing on my thumb. The silicone one screamed it."

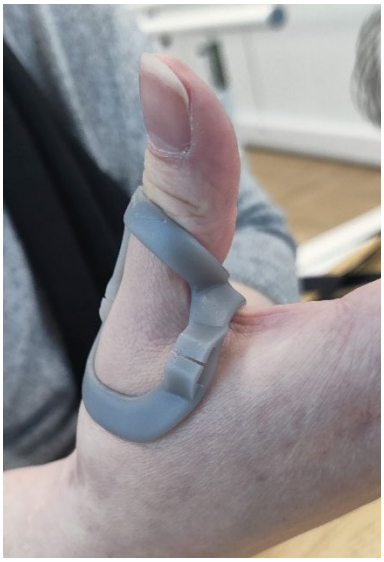


Figure 5.6: Appearance of the tested prototypes.

Despite the appearance not having been a large consideration in this project, 2 of the 3 participants said that they would already wear the splint with its current appearance (Figure 5.6). This means that its functional advantages outweigh the aesthetic downsides. The third participant would prefer a skin-coloured option, to make it more discreet, which is an option in the final material choice.

5.2 EXPERT EVALUATION

To further evaluate the concept, insights from an orthotist, 3D production expert and senior designers were used. Their experience with high numbers of patients and O&P products helps to assess the real-world potential of the design, outside the limitations of an experiment set-up.

ORTHOTIST

One orthotist was present at the experiments to observe and ensure proper client care. The experiments were followed by a discussion. The outcome of this evaluation of the product was largely positive. He believed that the concept could add value for the specified group of clients, who have milder symptoms. Currently, those clients would either receive the standard silicone thumb brace or a unique design. With this thumb splint architecture available, he believes a small group of people can be provided more freedom before their condition worsens, instead of immobilizing them unnecessarily. The architecture is shaped such that it likely accommodates many anatomical variations, and he does not foresee a high complexity in this regard. The hinges are completely new, and the orthotist understands the potential but is concerned about the durability. He would immediately be interested in trying the new architecture but needs more proof regarding the durability and consistency of the hinge, before prescribing it to patients. One concern about the architecture is how the squeeze effect would work for people with more sensitive skin than the experiment participants. It could cause them more discomfort or even bruising. Finally, the orthotist sees the value of the new scanning position and how it adds to the mobility of the thumb and security of the splint. However, a clear protocol needs to be developed in order for him to consistently find the correct pose with any patient.

3D PRODUCTION EXPERT

The 3D production expert is responsible for designing the splint based on the parametric design rules. The rules and the final design were discussed for assessment. He did not foresee any significant issues throughout the production process of the proposed concept. All dimensions and shapes are within the limitations and fit within the current workflow. While the design rules were

complete and factualm some improvement in the visual aids and clarified wording would be required for him to independently model the new thumb splint. He had questions regarding the placement and positioning of the hinge, it is currently dependent on one landmark and that is likely not enough to always find the correct orientation of the hinge's axis. In previous products with hinges, the placement of such an axis has proven a delicate issue. The current design rules are likely not sufficient to consistently create a good hinging system for any patient. Further experimentation and analysis are required to ensure the correct correlation between the gap, to original scan position angle and the maximum extension angle. Besides that, the amount of push given at the palmar tab and dorsal loop is now defined as ~2mm. The 3D modellers are likely able to estimate the correct push based on the shape of the 3D scan. He did not foresee this being a large issue for the performance of the splint.

SENIOR DESIGNERS

From colleague designers, feedback has been provided regarding the proposed concept. While the effectiveness of the architecture is plausible to them, the hinge is a source of concern, especially the durability of it. The durability is not only dependent on the normal usage of the hinge, but also other unpredictable user behaviour, such dropping the splint from a height or improperly storing it. Besides that, the design of the hinge as well as the complete splint can be further refined to increase the aesthetic appeal. For Manometric, it is important that their products fit their aesthetic language, and the current design does not fit that description yet. A second source of concern for the designers is the effect of the new scanning pose on the quality of the scan. Although the 3 new scans of the participants turned out well, the chances of scans failing is significantly higher in the new position, due to the added complexity around the webspace and thenar muscles, which are visible in the unsmoothed scan shown in Figure 5.7.

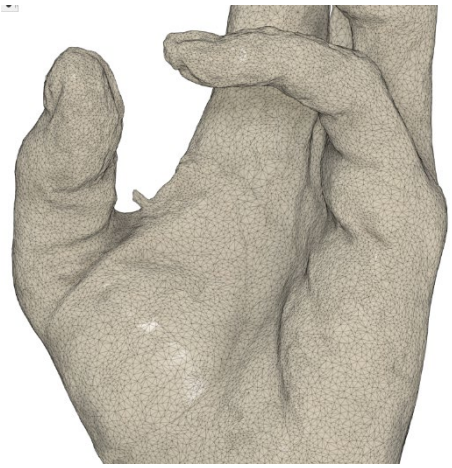


Figure 5.7: Complexities added to the 3D scan geometry around the webspace and thenar muscles.

5.3 CRITERIA EVALUATION

With the insights from the product and expert evaluations, the concept can be critically assessed against the list of requirements formulated in Chapter 2. Table 5.2 contains this assessment. The requirements that have not been fully met are highlighted and advice for further development is proposed.

Nr.	Status	Description
PERFORMANCE		
r1.1	~	The splint must prevent **hyperextension** (= continuing extension beyond the anatomical/straight position) of the **metacarpophalangeal joint** of the thumb (= MCP1 joint). It must block extension of the MCP1 joint at **15-30°** of flexion, depending on the user's personal needs.
r1.2	✓	The splint must improve the **thumb stability** such that it forms a stable post for the other fingers, facilitating grips for daily live activities, so at least **opposition**, a **pinch grip** and a **power grip** are possible.
r1.3	✓	The splint must be **sufficiently secured** in place so it cannot move into a **suboptimal position** or be **accidentally lost** during normal daily use.
r1.4	✗	The splint must function as intended for **8 hours of daily usage** for at least **2 years**.
w1.5	~	The performance of each individual splint must be **consistent**.
w1.6	✓	The splint should **maximize the thumb's mobility**, while fulfilling all requirements.
w1.7	✓	The **medication compliance** of the splint should be as high as possible.
ERGONOMICS		
r2.1	✓	The splint must not cause any **pressure points** that lead to discomfort or pain during (continuous) daily usage.
r2.2	✓	The splint must enable easy **donning and doffing** within 5 seconds (each), considering users with low dexterity.
r2.3	✓	The splint must not obstruct the user's daily activities by **snagging or catching** behind objects.
r2.4	✓	The splint must leave **enough space** to facilitate **thumb mobility** (see requirement 1.2) in the areas of the hand (palmar creases, first webspace, thenar muscles) indicated in green in Figure 1.12, Chapter 1.1.1.

r2.5	~	The splint design template must **accommodate anatomical variances** such that it fits 95% of the target user group.
r2.6	~	The splint must fit the **aesthetic values** of the target group.
w2.7	✓	The fit of the splint should be as **snug** as possible, while fulfilling all requirements.
w2.8	✓	The splint should be as **compact** as possible.
w2.9	✓	The splint should cause as little **perspiration** as possible.
PRODUCTION		
r3.1	✓	The design template must enable **personalization** for individual users to facilitate **consistent** performance. (See also R1.5).
r3.2	✓	The splint design template must use **accurate measurements** of an individual's **3D anatomy** to facilitate a **parametric design approach**.
r3.3	✓	The design template must be **documented in parametric design rules** that lay groundwork digital parametric automation of the design process.
r3.4	✓	The **mechanical strength** of the splint must be sufficient to block extension such that reaction forces can be applied without it **breaking or deforming.**
r3.5	✓	The production process must be **technically feasible** for individually personalized products with a **batch size n = 1**.
r3.6	✓	The production process must be **economically viable** for individually personalized products with a **batch size n = 1**.
r3.7	✓	The splint material must be (certified) **safe to use on the skin.**
R3.8	✓	The splint must be **cleanable** with tab **water and soap.**
w3.9	~	The design template should minimize the amount of **fitting loops** (see Chapter 1.3.1) necessary to provide clients with a good splint.

Table 5.2: Criteria evaluation.

To further develop the concept and achieve the (partially) failed criteria, the following is advised:

- R1.1: The preferred position of 15-30° flexion was not consistently achieved. To do this, firstly, the gap distance in the hinge likely needs to be numerically related to the angle of the bend at the MCP1 joint in the scan. If, in the 3D scan, the MCP1 joint is at all smaller angle, the same gap size will lead to insufficient blocking, as was seen in the 3rd product evaluation

participant. This correlation needs to be tested on a higher number of participants.

- R1.4: While Manometric has had positive experience with the durability of PA12 products, the new concept has not been exposed to any long-term testing. Despite positive initial tests, especially the hinge could pose a limitation in achieving this requirement. More rigorous and long-term real-world testing is required to determine the true durability limitations of the proposed concept.
- R1.5: The consistency of the design template's performance was not sufficiently proven by the performed product evaluation. Testing with a higher number of participants is required to test and further improve the formulated design rules.
- R2.5: See advice for R1.5.
- R2.6: Because the potential users interviewed in this project expressed that the function of the splint was priority, the aesthetic of the result was not elaborately considered. Large steps can be taken to improve the aesthetic value of the design, and thereby further improve its desirability. Potential users should be involved in the process to unearth their aesthetic preferences in more detail.
- R3.7: The final product evaluation was not elaborate enough to test the number of required fitting loops. The design template needs to be tested on a larger number of participants to establish whether the design rules are clear and accommodating enough to result in a good thumb splint for anyone.

5.4 RECOMMENDATIONS

The following recommendations have been prepared to address the shortcomings of the proposed design and method, that were found in the different evaluation and assessment activities.

Durability

Several aspects of the design need to be evaluated in a long-term testing set-up. Most pressingly, the durability of the hinge design needs to be assessed using more rigorous cycle testing. The number of cycles and force before failure needs to be found and used to determine the technical feasibility of such a single-material hinge print. Additionally, the detailed design and dimensions of the hinge can likely be further optimized to improve its performance and durability. Through force simulations (such as a Finite Element Analysis) different configurations could be tested and optimized before prototyping them and testing them in the real world. The PA11 and PA12 prototypes survived testing within the scope of this

project but that does not prove the feasibility of the concept for 2 years of continuous daily usage.

Aesthetic

Despite the importance of aesthetic on the medication compliance of an orthoses, it was not prioritized in this project. Although the proposed concept was accepted by the participants, this acceptance can be increased if the appearance of the splint is more carefully investigated and tested. The material choice of PA12 limits the possibilities for the appearance of the product, as a jewel-like silver appearance or a discreet clear material or not possible. However, the finishing, colour, and shape of a PA12 splint can be adjusted in a wide variety of ways to improve the appearance. More elaborate interviews with potential users can be held to discover their aesthetic values for a compact thumb splint. Manometric has shown in their other products that when the details are carefully considered, the overall appearance of the product can be made to look more professional, finished, and elegant than the current proposal.

Scanning pose

In the final evaluation with experts, concerns regarding the quality of the 3D scans in the new scanning position surfaced. This problem did not present itself throughout testing, but more elaborate testing is required to discover the significance of this problem. It is possible that in a higher number of scans in the proposed pose, a larger number of scans fails, or shows artifacts that impede the workflow of the 3D production experts. In that case, experimentation with the position and orientation of the hand is required to determine whether an opposed scanning position is viable.

Automation

When the shortcomings mentioned previously have been faced, automation can become a consideration for this product. Partially automating the generation of the splint shape can optimize the workflow for 3D production. The parametric design rules were formulated with the goal of automation in mind and the shape of the architecture is generalized such that (partial) automation is likely possible. However, before taking steps to automating the splint design, it should first be implemented in the Manometric workflow as an established product. This way, the experience of everyone at Manometric can first be used to manually assess the viability and feasibility of the new splint.

IP joint

For some patients, especially those with deformities and EDS, it might be valuable to limit the extension of the IP joint as well. This was not the focus of this design project but according to Manometric experts it could help about 30% of the user group and could therefore add significant value. For the primary orthosis architecture, the IP joint should remain free, and all motion should be enabled, but an additional feature might be implemented to block IP extension, while still enabling flexion as much as possible.

5.5 PERSONAL REFLECTION

When I started my bachelor's degree at IDE, I thought: “I am going to come up with the greatest ideas here!” As it turns out, maybe that’s not my strongest side. Instead, I have found myself most enjoying the analytical problem definition stage, skipping the creative bit, and then diving into an analysis of the details again. I firmly believe that most of the work in solving a problem, is understanding the problem: understanding it *really well*. I used that approach in this project, and I think it paid off. The result seems to work well and makes a lot of sense. However, I do think that my analytical mind limits me at times, which is also notable in the results of this project. In the end, I am happy with my result. I am proud of what I delivered. But I do not think I got the most value out of the time that I put in it. There were probably more out-of-the-box ideas and approaches that could have enriched the project. This highlighted to me that I need to question my comfort zone more and try to open my mind to more creative approaches. That is not easy, though, on your own.

This leads me to another thing that I firmly believe in: that a good solution can only be the result of *collaboration*. Most of all, this project taught me that I am a team-player at my core; I always find out what others love to do best and discovering how we can complement each other to do even better, and I get energy from discussing design challenges with others. I consider myself quite capable at planning and managing responsibilities, and this project had to prove it. Keeping myself motivated, on track, on schedule and inspired could be a challenge. Luckily, I quickly learned that, even when the project is my own, your team is still all around. Whether it was in an inspiring conversation with Toon or Willemijn about new angles to approach a problem, helpful questions from my colleagues, or a brainstorm with friends.

Throughout this project, I have done my best to make use of all the expertise that surrounded me at Manometric. Being able to walk to any department and ask them difficult questions that they actually knew the answer to, was a small paradigm shift for me. Once I got the hang of it, I think I learned a lot from all the different experts at Manometric, from the orthotists to the fabrication experts, that improved my results.

If you give others your time and attention, they will be inclined to give you some of theirs, as well. I concluded that I have no interest in continuing in this industry alone; I need to continue finding my complementing teammates, to come to valuable results together.

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Appendices

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: Gerritse 5913
initials: P.R. given name: Puck
student number:
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): ★ IPD ( ) DfI ( ) 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: Toon Huysmans dept. / section: Applied Ergo & Design
** mentor: Willemijn Elkhuizen dept. / section: Mechatronics Design
2nd mentor: Vincent Laagland
organisation: Manometric
city: Den Haag country: Nederland

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 Toon Huysmans date 13 - 09 - 2022 signature Toon Huysmans Digitally signed by Toon Huysmans Date: 2022.09.13 15:08:10 +02'00'

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: 34 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 31 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 C. van der Bunt date 19 - 09 - 2022 signature C. van der Bunt Digitally signed by C. van der Bunt Date: 2022.09.19 09:56:32 +02'00'

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

- also approved for Medisign

comments

name Monique von Morgen date 20 - 09 - 2022 signature

Initials & Name P.R. Gerritse 5913 Student number 4666712

Title of Project Development of a Thumb Metacarpophalangeal Joint splint.

Personal Project Brief - IDE Master Graduation

TU Delft

Development of a Thumb Metacarpophalangeal joint splint.

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 02 - 09 - 2022 08 - 02 - 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, ...).

Braces and splints (orthoses) are medical devices that can be worn to support and/or (partially) immobilize certain joints of the user, like knees, ankles, wrists or hands. Especially patients with arthritis might be prescribed a brace or splint, to relieve joint pain and support a weak or inflamed joint. Arthritis occurs when there is a loss of cartilage and leads to pain, swelling and/or loss of motion. The joints can be affected by arthritis due to many different reasons, such as osteoarthritis, injury, infections or certain medical conditions (such as rheumatoid arthritis). Generic models of splints and braces are easily accessible in drugstores and are usually bought with the purpose of reducing joint pain or reducing risk of injury. However, for patients with arthritis braces and splints might also be prescribed by a doctor or specialist and are then often personalized in fabrication to fit. Besides braces and splints, treatments for arthritis include pain relief medication and skin creams. Physiotherapy can help to maintain mobility and strength. Eventually, surgery and even joint replacement or joint fusion might be considered. Patients of arthritis often work with physiotherapists and/or other orthopedic experts throughout the treatment. In 2013, 10% of people 75+ in The Netherlands said to be making use of orthoses, such as orthopedic shoes or wrist braces (CBS, 2015). In 2020, an estimated 260.000 patients in The Netherlands were diagnosed with rheumatoid arthritis (CBS, 2021) and due to the aging population, the number of people needing care to treat arthritis is estimated to grow (Volksgezondheid en Zorg info.nl).

The fabrication of prescribed, personalized orthoses is an expensive, labor-intensive and specialized process. The traditional method (among other labor-intensive methods) requires plaster molding to create a model of the limb with handmade corrections and then molding a heated thermoplastic around the model. This requires a lot of time and expertise, and as the pressure rises due to the aging population, it is becoming more difficult to find enough of these professionals. Besides that, according to Manometric, the resulting products often offer low compliance and a low satisfaction rate with patients. That is why Manometric aims to develop braces using 3D-scanning and -printing to create a more comfortable and fast patient experience with more attention to the personal needs of the patients.

Manometric is a company that was started by TU Delft alumni in 2016. They use a 3D scanner to measure patients and to provide personalized orthopedic and prosthetic (O&P) (3D printed) products. Figure 2 shows an overview of braces that make up Manometric's current product portfolio from their website. Currently, they use the 3D scanner as well as hand measurements to create their products. Their mission is to change orthoses and prosthetics from necessities to products people love to wear. The team members include Mechanical Engineers, Software Engineers, Industrial Product Designers, Production Specialists and Orthopedic Technologists. Manometric works with patients and wants to provide fast, high quality and personal services.

There are traditional braces that support/immobilize the carpometacarpal (CMC, see Figure 1-left) and metacarpophalangeal (MCP, see Figure 1-left) joints of the thumb. These thumb splints are currently usually large, clunky braces that immobilize the thumb completely, which makes for a less than ideal patient experience, according to Manometric. They saw an opportunity here to improve these braces by using their 3D technology to design and create a thumb splint that is more comfortable, more form fitting, stylish and quicker to produce. Manometric has already developed a new brace that supports/immobilizes the CMC and MCP joints using their 3D-scanning and -printing method (Figure 2-middle). In this project, the goal is to use Manometric's methods to create a new solution for a splint that immobilizes only the MCP joint, instead of both.

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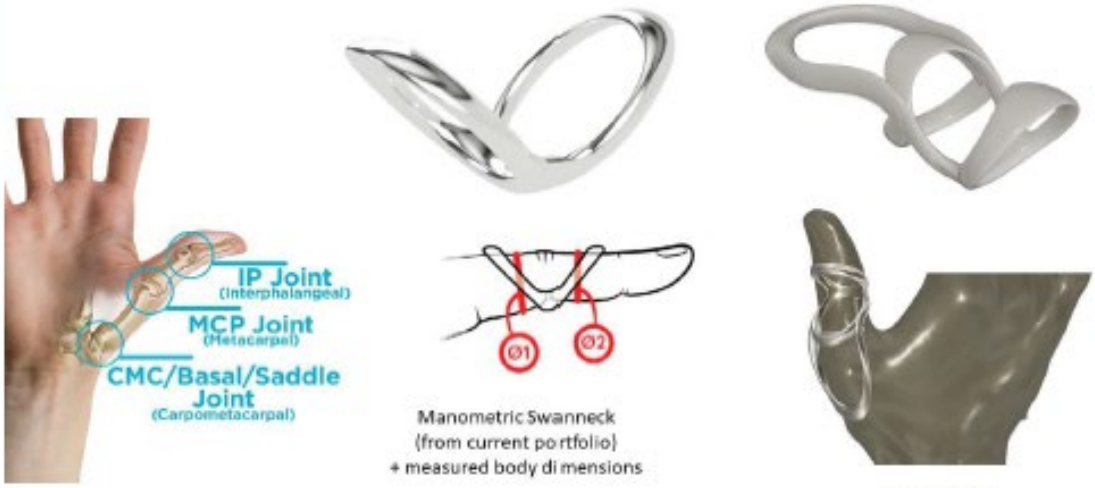


Thumb joints

Manometric Swanneck
(from current portfolio)
+ measured body dimensions

Impression:
Manometric Swanneck for Thumb

image / figure 1: left - Thumb joints. middle - Manometric Swanneck splints. Right - Impression of thumb Swanneck.

image / figure 2: Current product line of Manometric braces. (Manometric.nl, n.d.)

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.

For this project, patients that suffer from MCP joint arthritis in the thumb are the target user. A thumb splint will be developed to support and immobilize the MCP thumb joint that, while making use of the strengths of Manometric's 3D technology, methods and mission, should improve the complete patient-journey (from prescription to evaluation and adjustments) and -satisfaction, and reduce the required time and labour for production. By using Manometric's approach to designing and fabricating O&P products, the new design for a thumb MCP joint splint should become a product that patients want to wear.

The silver Swanneck splint (Figure 1, middle & Figure 2, bottom-left) immobilizes the extension of a finger and is one of Manometric's most frequently prescribed products. They are currently manufactured based on hand measurements (and not 3D scans). Such a Swanneck splint is also frequently demanded for the thumb, but Manometric's current Swanneck designs are not suitable for the thumb, due to the web-space between the thumb and index finger. Most existing thumb orthoses immobilize the complete thumb (all 3 joints shown in Figure 1) and are therefore extremely limiting and bulky. A Swanneck splint of the thumb would immobilize only the MCP (and/or IP, see Figure 1) joint of the thumb and could be more comfortable and stylish than the bulky existing thumb orthoses, while still being effective. Manometric is looking to use their modern approach to designing and fabricating O&P products for a design of a splint that immobilizes the thumb MCP joint in extension. Figure 1-right shows a tentative idea from Manometric of the concept. However, this is not firmed up and requires much research, testing and development. The fabrication process of the new splint should be more time and cost effective than traditional methods. Manometric wants to offer a comfortable fit and stylish product, making patients want to wear their splint. Finally, it is important for patients that insurance companies reimburse the cost of the new splint as it might otherwise not be a cost-effective alternative to standard braces.

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.

This project will consist of an analysis of the medical (and biomechanical) situation and the patients' wishes for the product, and an analysis of the production methods and Manometric's workflow (measuring to final product) and product portfolio. This is followed by the generation of a detailed parametric design template for a splint that can be used by Manometric to create personalized thumb splints. Prototypes will be used to validate and iterate the design.

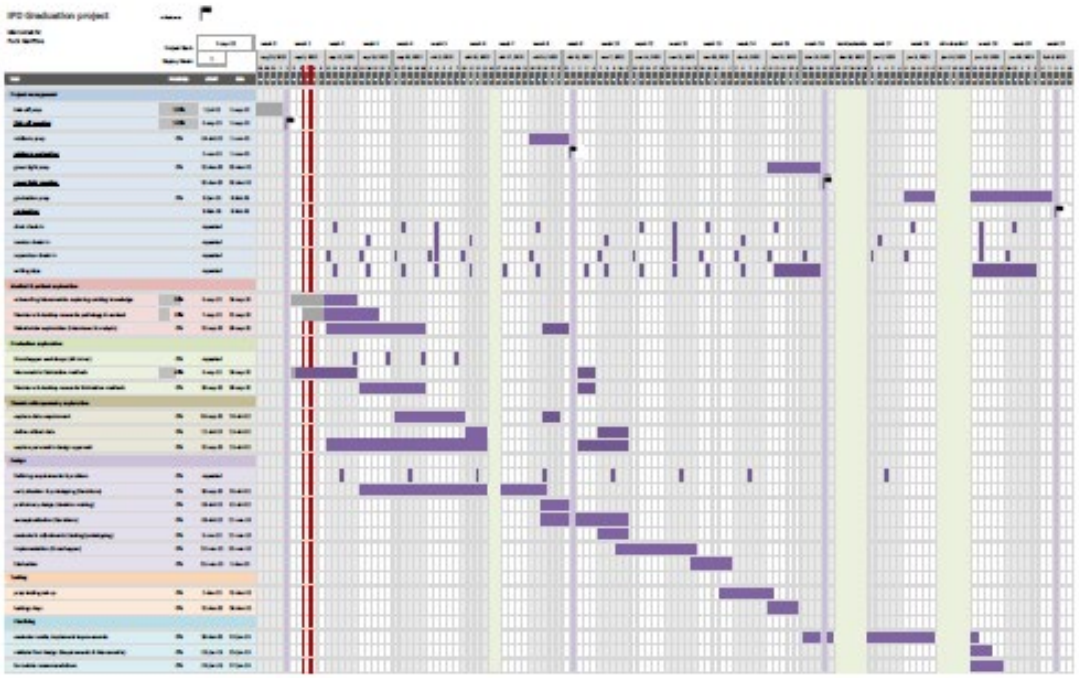
In order to solve the defined problem, first an elaborate analysis of the problem and context needs to be performed. This will include:
1) Gaining a thorough understanding of the MCP thumb joint and the medical condition (arthritis), along with other necessary knowledge of the complete hand, patient journey (mapping) and a stakeholder analysis. 2) Understanding existing treatments, limited to conservative (non-surgical) therapy, specifically braces and splints, and their limitations and advantages. 3) Finding the critical body dimensions for a personalized design and understanding the methods for measuring patients and how to implement those in a design in Grasshopper. 4) Investigating manufacturing methods of the existing products and understanding Manometric's production portfolio and 3D technology workflow.
Besides performing literature reviews and desktop research on these topics, through Manometric I can be connected to patients, orthopedic experts and brace designers to interview them about their experiences and expertise. Manometric can also provide (confidentially treated) body dimensions data from patient measurements and scans. With that foundation of knowledge, designs can be generated, using drawings, CAD models and/or digital & physical prototypes. A parametric design approach, based on previously researched anthropometric data will be used to come to a concept direction. This can be iteratively developed and detailed to fit the envisioned patient journey and production process. The design will be implemented in Grasshopper to automate certain body dimension dependent personalization steps of the thumb splint (the 'design template' in Grasshopper). The concept will be evaluated with end users using physical looks-and-works-like-real prototype(s).

Personal Project Brief - IDE Master Graduation

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 2 - 9 - 2022 8 - 2 - 2023 end date



Above is an updated version of my planning for the project, including the main milestones. I have also included the full size PDF in an extra file for legibility. I will be using this chart throughout my project in Excel, to keep it updated and make sure I stay on track. I will also document any deviations from this planning and add tasks if/when they come up. The planning is divided into the categories of project management, research and designing activities: project management, medical, production and anthropometry exploration, framing, design performing and finally validation. I will dedicate each Tuesday of a working week as a "writing day" to update my thesis, sources and ensure I'm not forgetting to document my progress. Currently, I have planned weekly check-ins with my chair or mentor and supervisor and a meeting with the whole team roughly every 3 weeks (including the milestone meetings).
As expected, the starting weeks of the project will be all about researching the relevant topics through literature, desktop research and interviews. A new aspect of the project for me, will be gathering and analyzing anthropometric data an using that in a parametric design approach. I have planned significant time for me to explore these concepts and will be following Grasshopper workshops from the AP minor. I have added steps (and time) for multiple design iterations after evaluating prototypes, fits and manufacturability, starting early in the research phase. I will conclude this project with elaborate testing and have left a week of breathing room before my graduation, in case testing runs longer. The planning is such that I will have my design requirements and first preliminary design ready at the mid-term meeting. This way, I can check the completeness of the exploration/research and my envisioned design direction with my supervisory team. After that I want to have the design and test results ready before the green light meeting, to discuss the final iteration steps. The Greenlight meeting is quite early, before the Christmas holiday, to accommodate the supervisory team's availability. Finally, at graduation, the complete validation results can be presented along the final iteration and well-founded recommendations.
(I have included a short break for a trip in mid-October, a week at Christmas and a week for skiing.)

Personal Project Brief - IDE Master Graduation

TU Delft

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.

I am especially interested in design projects that are related to improving the quality of healthcare. My strengths as a designer are not so much in designing strategies or interactions or coming up with numerous original ideas, but rather in thoroughly investigating the situation to reveal a solution. I enjoy the detailing phase; to get the details right (for all stakeholders, from end user to manufacturer) and testing them, to ensure the quality and suitability of a design. In the past, I have had opportunities to develop my professional soft skills (Delft Hyperloop) and recently I have shifted my focus back to design hard skills, specifically related to medical design.

When I found Manometric, I felt connected to their mission to use 3D scanning technology and making it accessible to improve the quality of healthcare. Besides that, their team consists, among others, of IDE alumni and orthopedic experts that sounded like I could learn a lot from them. It seemed my interests in designing for healthcare, ergonomics, biomechanics, and detailed embodiment design would match with their expertise and mission.

In this project I want to prove that I am ready to start my professional career as a sufficiently independent designer who can properly manage a large project on her own and go from a thorough context analysis to a validated concept proposal with well-founded recommendations. I still want to further develop/improve (in order of priority):

- ... my ability to involve patients and medical experts in the design process, by performing interviews and testing prototypes with them, as I have not had the opportunity to gain much experience with (real) healthcare stakeholders in the past. This means that I want to learn and practice more specific and professional interviewing and testing techniques specifically for patients on one hand and skilled professionals on the other.
- ... my knowledge of and skills with information sources regarding medical situations. I want to quickly become an expert on the current medical situation, and I need to practice my literature reviews (and desktop research methods) and want to learn about other information sources that could help me. Often at IDE, literature reviews, data gathering and simulations are rushed and therefore I do not feel that I have sufficiently learned how to prove that my design work is (completely) valid. I want to be more in control of my theoretical knowledge of the project and combine this with better interviewing and testing techniques, so I can perform a validation that makes me and the project stakeholders feel confident about the results. (Which is not to say that everything about the design needs to be 100% perfect already, but that the results and recommendations should be well-founded.)
- ... my skills with implementing the design in Grasshopper, as I have very little experience with this.
- ... my digital modeling skills, specifically how to combine this with the process of 3D scanning human anatomy.
- ... my visual communication skills.
- (... my understanding of my role as a designer in the complex, high stakes, bureaucratic medical world. I am not sure how to make this goal more concrete, as it is a world that I discover project-by-project, but I want to make the most of this project with Manometric to further open my eyes to the possibilities and limitations that I have as a medical industrial designer.)

FINAL COMMENTS

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

APPENDIX A: LIST OF REQUIREMENTS & WISHES

Design criteria				
nr.	**type**	**category (Roozenburg & Eekels)**	**description**	**evaluation**
1	Performance			
1	R		The splint must prevent **hyperextension** (= continuing extension beyond the anatomical/straight position) of the **metacarpophalangeal joint** of the thumb (= MCP1 joint).	*testing*
2	R		The splint must block extension of the MCP1 joint at **15-30°** of flexion, depending on the user's personal needs.	*testing*
3	R		The splint must improve the **thumb stability** such that it forms a stable post for the other fingers, facilitating grips for daily live activities, where at least **opposition**, a **pinch grip** and a **power grip** are possible.	*testing*
4	R		The splint must not negatively affect the stability of the thumb **carpometacarpal** (CMC1) joint.	*expert evaluation*
5	R		For patients suffering Skier's thumb, the splint must provide support throughout the recovery process and afterwards to **prevent repeated luxation**.	*testing*
6	R		For patients suffering RA, the splint must provide support to **slow deformation**.	*expert evaluation*
7	R		The splint should be **sufficiently secured** in place so it cannot move into a **suboptimal position** or be **accidentally lost** during normal daily use.	*testing*
8	R		The performance of each individual product/splint must be **consistent**.	*testing*
9	R		The **mechanical strength** of the splint must be sufficient to block extension such that reaction forces can be applied without it **breaking or deforming.**	
10	W		The splint should maximize **the thumb's mobility,** while fulfilling all requirements.	
11	W		The **medication compliance** of the splint should be as high as possible.	
2		Environment		
1	R		The splint must withstand splash water (from hand washing) daily for 2 years.	*testing + estimation*
2	R		The splint must **function as intended** (= meeting all requirements) in environmental temperatures from -10 to 40 degrees Celsius.	*material data*
3		Life in service		
1	R		The splint must function as intended for 8 hours of **daily usage.**	*estimation*
2	R		The splint must function as intended (not break, tear or deform plastically) for at least **2 years** of daily usage.	*estimation*
4		Maintenance		
1	R		The splint must be cleanable with **tab water and soap**.	*material data*
5		Target product cost		
1	R		The **product costs** of the splint must not exceed the **reimbursement**	*cost price*

			amount that Manometric can receive from health insurers for this product (= ~200-400 eu).	*estimation*
6		Quantity		
1	R		The production process must be **technically feasible** for individually personalized products with a **batch size n = 1.**	*y/n*
2	R		The production process must be **economically viable** for individually personalized products with a **batch size n = 1.**	*y/n*
7		Production facilities		
1	R		The splint design template must be based on **defined objective human data** collected during the first **in-take** at Manometric.	*y/n*
2	R		The splint design template must use **accurate measurements** of an **individual's 3D anatomy** to facilitate a **parametric design approach.**	*y/n*
3	R		The design template must enable **personalization** for individual users to facilitate **consistent** performance. (See also R1.8)	*y/n*
4	R		The **3D-scan pose** required for the design of the splint must not cause **pain** for the patients in the target group.	*testing + expert evaluation*
5	R		The design template must be **documented in parametric design rules** that lay groundwork for the digital parametric automation of the design proces.	*y/n*
8		Aesthetic, appearance, and finish		
1	R		The splint must fit the **aesthetic values** of the target group.	*user questionnaire*
2	W		The splint should be as **compact** and discreet as possible.	
9		Materials		
1	R		The splint material must be (certified) **safe to use on the skin.**	*material data*
2	R		The splint design must facilitate **minor adjustments** by the orthotist during the fitting.	*testing*
3	R		At least 1 of the material options must be suitable for users with common **skin allergies**: nylon, silver, nickel, latex.	*meet regulations*
10		Standards, rules, and regulations		
1	R		The splint must meet the requirements determined by **insurance companies** to qualify for compensation.	*meet regulations*
11		Ergonomics		
1	R		The splint must not cause pressure in the **to be avoided areas** of the hand (bony prominences, superficial tendons) indicated in blue in Figure 1.12, Chapter 1.1.1.	*testing*
2	R		The splint and patient journey must be suitable for users that suffer from: **Joint Hypermobility Syndrome (JHS), Ehlers-Danlos Syndrome (EDS), Skier's- and Gamekeeper's Thumb, and Swan-neck deformations from**	*testing + expert evaluation*

			early RA or OA by considering their pathological symptoms described in Figure 1.19, Chapter 1.1.3.	
3	R		The splint must leave **enough space** to facilitate **thumb mobility** (see requirement 1.2) in the areas of the hand (palmar creases, first webspace, thenar muscles) indicated in green in Figure 1.12, Chapter 1.1.1.	*testing*
4	R		The splint must not cause any other **pressure points** that lead to discomfort or pain during (continuous) daily usage.	*testing*
5	R		The splint must not cause **pinching or folding of the skin** that leads to discomfort or pain during (continuous) daily use.	*testing*
6	R		The splint must enable easy **donning and doffing** within 5 seconds (each), considering users with low dexterity.	*testing*
7	R		The splint must not obstruct the user's daily activities by **snagging or catching** behind objects.	*testing*
8	R		The splint design template must **accommodate anatomical variances** such that it fits 95% of the target user group.	*testing*
9	W		The splint should cause as little **perspiration** as possible.	
10	W		The fit of the splint should be **as snug as possible**, while fulfilling all requirements.	
11	W		Throughout the patient journey, the **patient expectations** should be managed to reflect the real-world limitations of the splint design.	
12		Product policy		
1	R		The design template should minimize the amount of **fitting loops** necessary to provide clients with a good splint.	*testing + expert estimation*
2	R		The **delivery time** of the splint must be no more than 2 weeks (= 10 working days).	*production time estimation*

APPENDIX B: MANOMETRIC OT-ERS INTERVIEWS (R=3)

SESSION 1

Pathologie (30 min)

1. Welke van bovenstaande splints wordt naar jouw ervaring het meeste toegepast?
2. Waarom wordt die toegepast? Om welke aandoeningen gaat het dan? (Bv. veel trauma (Gamekeeper's en Skier's thumb) of juist chronische problemen (Artritis, Joint Hypermobile Syndrome en EDS?)).
3. Met welk doel wordt zo'n splint gebruikt?
    a. Wordt zo'n MCP1 splint vooral toegepast voor dagelijks gebruik of juist in specifieke situaties zoals tijdens het sporten?
    b. Gaat het dan vooral om het verminderen van alledaagse pijnen? Of juist het voorkomen van pijn en trauma als gevolg van overstrekking of andere ongelukken?
    c. Of gaat het vaker over het ondersteunen van het gewricht zodat er bv. meer kracht gezet kan worden?
        i. Zijn er naast ondersteuning of pijn andere redenen dat patiënten een MCP1 splint nodig kunnen hebben?
4. Zou een MCP1 splint regelmatig toepasbaar zijn voor mensen met artritis (reumatoïde of artrose)? Vaak beginnen die problemen bij de basis van de duim en zullen zij dus eerder een brace zoals #5&6 nodig hebben? Of is dat niet het geval en kan artritis ook leiden tot problemen specifiek bij MCP1 en niet CMC1?
5. Welke bewegingsvrijheden kunnen het MCP1 gewricht en de duim van een patiënt hebben? En wat is belangrijk om juist te beperken? Waarom? Als mogelijk: Hoeveel graden (flexie/abductie) gaat het om?
6. Onder welke hoek wordt het MCP1 gewricht vaak geïmmobiliseerd? Waarom? (15-20 graden flexie).
7. Zilver splints laten over het algemeen weinig bewegingsvrijheid toe in vergelijking met bv. siliconen of plastic braces. Denk je dat het voor het MCP1 gewicht (en de aandoeningen die je noemde) beter is om wel wat meer vrijheid toe te laten?
8. Heeft het dragen van zo'n MCP1 splint invloed op de ontwikkeling van een aandoening? Bv. Positief: het gewricht tijd geven voor herstel. Negatief: het gewricht kan stram worden door gebrek aan beweging (vooral bij Artrose).
9. Denk je dat het regelmatig nodig is om samen met het MCP1 gewricht ook het IP-gewricht te ondersteunen met een splint? In welke gevallen wel of niet?

Bestaande splints (20 min)

10. Over #1: Welke kenmerken van deze splint verschillen veel tussen patiënten? Bv. de hoek tussen de ringen.
11. Over #2: Wat is de functie van dat extra push vlak?
    a. Op welk gewricht heeft dat effect en wat is dat effect?
12. Wanneer zou een band of ketting (#3&4 om de hand wel nodig zijn, en wanneer niet? Waarom?
13. Waarom zit er een extra push in #3?
14. Wat zijn nadelen of problemen die je tegen bent gekomen van splint #1? En #2?
    a. Welke problemen worden door patiënten aangekaart?
15. Deze splint blokkeert ook het IP-gewricht, is dat nodig?

Automatisering (10 min)

16. Waarom is een MCP1 splint nog niet eerder geautomatiseerd? Is er niet genoeg vraag naar, of komt het door grote variatie in eisen vanuit de hulpvraag?
17. Als het design geautomatiseerd zou zijn, zou je die dan vaker voorschrijven dan je nu een special voorschrijft?
    a. Schrijf je nu regelmatig bv. een siliconen brace (#5/6) voor bij patiënten die ook genoeg zouden kunnen hebben aan een MCP1 splint? Of schrijf je dan altijd een special voor? Waarom?
18. Hoeveel patiënten schat jij in dat we met een MCP1 (en evt. IP) splint zouden kunnen helpen? (aantal per maand, percentage van totale clientèle?).

SESSION 2

Over de klanten

1. Ik ben nu aan het focussen op het voorkomen van hyperextensie van het MCP1 gewricht. Voor zover ik nu begrijp zijn kunnen dit daarvoor relevante aandoeningen zijn: (Miro)
    - EDS en JHS
    - Trauma (skiers en gamekeeper's duim)
    - Swanneck deformatie (als gevolg van artrose, reuma, ongeluk, etc.)

    Klopt dat, denk jij? Mis ik nog niet? Ik heb bv. reuma en artrose grotendeels overgeslagen nu.

2. En heb daarbij dit persona gemaakt. Herken je dit? Is er een groep die ik hiermee niet goed vertegenwoordig?

- Het lijkt vooral om iets oudere werkende vrouwen te gaan maar kan het zijn dat ik de volgende mensen over het hoofd zie?
    i. Jong mensen
        - Ik heb er 2 gesproken, die wel hypermobiele duim hebben maar nog geen pijn. Zie je veel jongere mensen (30-)?
    ii. Mannen
        - Die kom ik zeer zelden tegen in mijn research, maar kan ik die zomaar “overslaan”? Voor hun zijn esthetische waarden namelijk misschien wel heel anders.
    iii. Ouderen
        - Die geen baan meer hebben en minder fysiek actief leven leiden, maak kan ik die zomaar “overslaan”?

<u>Over de eisen</u>

Aan eisen moet het product sowieso voldoen, b.v.:

- Moet MCP1 extensie blokkeren bij 15-25 graden.
- Moet oppositie toestaan.
- Moet stevig op de plek blijven zitten.

3. Maar er zijn ook criteria die ik kan gebruiken om te kiezen welke concepten beter zijn. Ik heb in Excel een lijstje met criteria.
    a. Mis ik nog iets, denk jij? Evt. toevoegen.
    b. En als jij die criteria een gewicht zou moeten geven, waarbij het totaal 100 is, hoe zou je die dan verdelen?

<u>Over de concepten</u>

4. Ik heb inmiddels een aantal denkrichtingen, zie Miro board. Ik ben benieuw wat jouw gedachtes zijn over die ideeën en of je al grote na- of voordelen ziet.

<u>Overig</u>

5. Welke mate van flexie (oppositie) is nodig om een functionele duim te hebben?
    a. Hoe zou ik dat kunnen bepalen?
    b. Verschilt dat veel per patiënt?
6. Is het handig om verstelbaarheid na te streven?
7. Is het handig wanneer een splint ter plekke aangepast kan worden? Of doe je dit juist liever niet?

Afsluiting

8. Ik heb volgende week gesprekken met klanten over hun ervaringen met huidige producten en mijn ideeën.
    a. Zijn er dingen die jij denkt dat ik moet vragen om me verder te helpen?
    b. Of dingen die jij graag zou willen weten over die klanten?

APPENDIX C: USER INTERVIEWS (N=5)

SESSION 1

About you

1. Can you tell me what you know about your double jointed-ness?
    a. How bad is it and in what joints is it most noticeable for you?
    b. When was it diagnosed & how?
    c. Do you know what caused it? (Trauma or hereditary)
2. What are issues that you encounter in daily life as a result of your double jointed-ness?
    a. What are the benefits, if any?
3. How do you think it impacts your life? Physically and mentally?
    a. Are there activities you don't participate in because of your double jointed-ness? (Sports or games or other things you miss out on?)
4. Do you often experience pain or dislocation? What other discomforts do you experience?
5. Do you ever feel misunderstood, excluded, marginalized?
6. How does your double jointed-ness develop over time? Are there bad days and good days? How? Has it gotten worse since you were little, or less bad?

Braces & splints

7. Do you currently have any braces or splints that you can use to improve your joint stability? For what joints, what type?
    a. Have you ever had any in the past?
8. If no, do you think you could benefit from having one and what are those benefits?
    a. For what joints would you most want a brace or splint and why?
9. If I were to develop a thumb splint specifically for you, do you think you would wear it a lot? Why? When and when not?
    a. What requirements would it need to fulfill? (Aesthetic, comfort, function, cost, material, etc.)
10. Lets take a look at some of the existing products.
    a. Which one do you think looks most effective for you?
    b. Which one do you think looks most attractive to you?
    c. Which one do you think you'd be more likely to wear on a daily basis, why?
11. How important would the aesthetic of such a brace be for you?
    a. And can you indicate what kind of aesthetic you would like? (sporty, elegant, cool, minimal, flashy, homey, camouflaged, jewel-like etc.)

How important would the sleekness of such a brace be for you?

SESSION 2

Intro

1. Hoe gaat het inmiddels? Hoe gaat het met uw duim en huidige brace?

Huidige brace

1. U heeft nu 1 van de Manometric siliconen braces. Hoe ervaart u die op dit moment?
    a. Wanneer draagt u die?
    b. Wanneer juist niet? Waarom?
    c. Wanneer doet u die kort af?
2. Wat zijn de grootste voordelen die u uit deze brace haalt?
3. En wat zijn de grootste nadelen? (Is de **functie van de duim** te veel gelimiteerd, is de brace **te groot** en is het **uiterlijk** een probleem?)
4. Zijn er al langere duur effecten die u merkt? Minder pijn, meer functie, etc.?
5. Maakt u veel gebruik van de verstelbaarheid van de brace? Of zet u hem eigenlijk altijd hetzelfde?

Criteria

Aan eisen moet het product sowieso voldoen, b.v.:

- Moet MCP1 extensie blokkeren bij 15-25 graden.
- Moet oppositie toestaan.
- Moet stevig op de plek blijven zitten.

9. Maar er zijn ook criteria die ik kan gebruiken om te kiezen welke concepten beter zijn. Ik heb in *Excel* een lijstje met criteria.
    a. Mis ik nog iets, denk jij? Evt. toevoegen.
    b. En als jij die criteria een gewicht zou moeten geven, waarbij het totaal 100 is, hoe zou je die dan verdelen?

Esthetiek

1 van de criteria is de visuele aantrekkelijkheid van het product, omdat bv. die siliconen brace wel werkt, maar mensen dragen die soms liever niet vanwege de bulky look.

1. Hoe zou u uw eigen stijl omschrijven in een paar woorden? (bv. kleurrijk, elegant, praktisch, sportief, professioneel, duur, chaotisch, simpel, etc.)

Als we bv. naar uw huidige brace kijken:

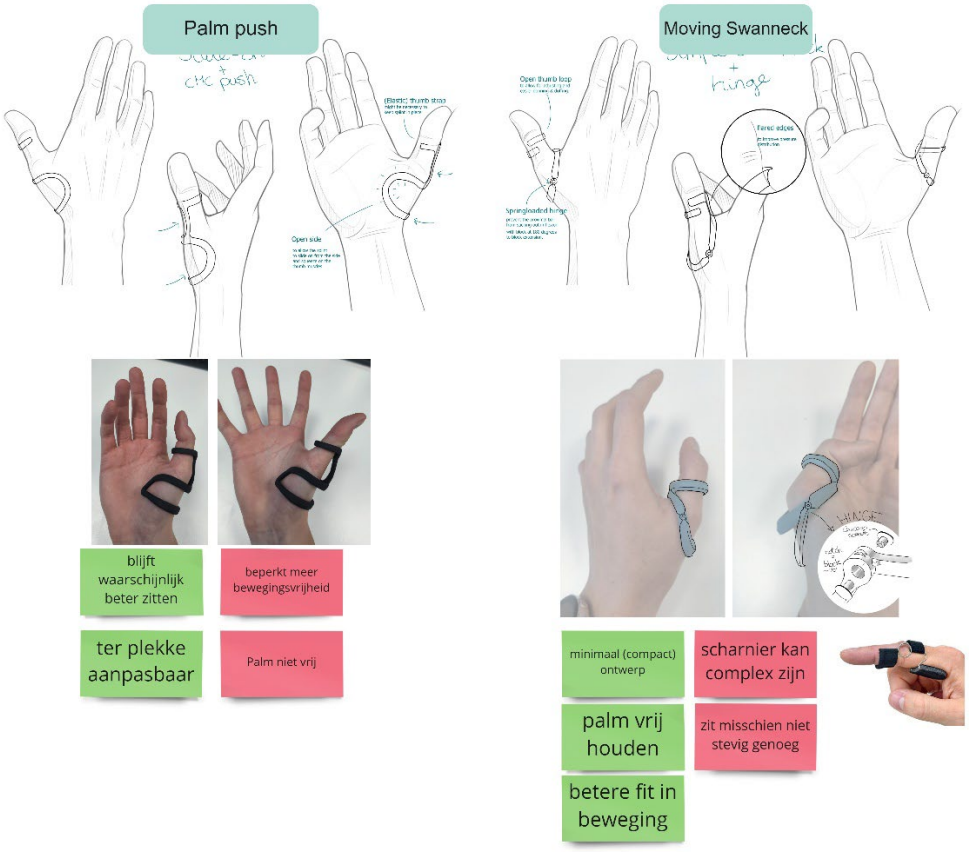
1. Wat zijn de belangrijkste aspecten die voor u de aantrekkelijkheid kunnen vergroten:
    a. Zichtbaarheid, grootte, materiaal, vormgeving, versiering, kleur,

2. Draagt u zelf sieraden? Ringen (naast evt. trouwring), horloge, ketting, etc.
3. 4 keer exact hetzelfde product, welke zou u liever kiezen en waarom?

(Original images shown to interviewee contained confidential scan pose)

<u>Nieuwe splint</u>

4. Ik ben met een paar concepten nog bezig die ik graag (deels) even zou toelichten, en dan ben ik vooral benieuwd naar hoe jij erover denkt.



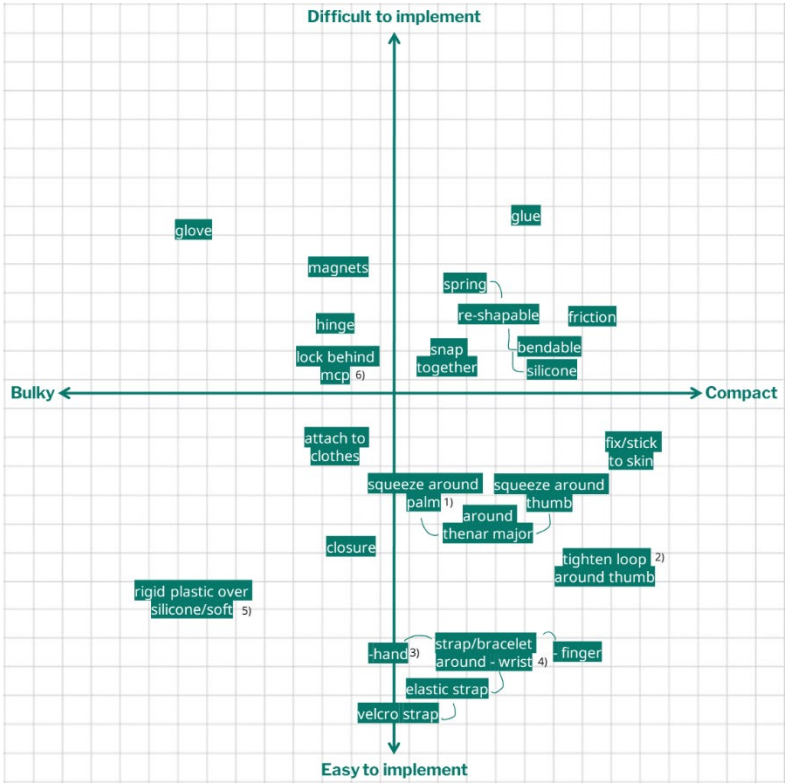
APPENDIX D: C-BOXES

Legend

How to...

secure splint to the hand?
increase comfort?
only limit extension?
enable size adjustment?
motivate emotional attachment?
make it appealing?

x) = reference to drawing x

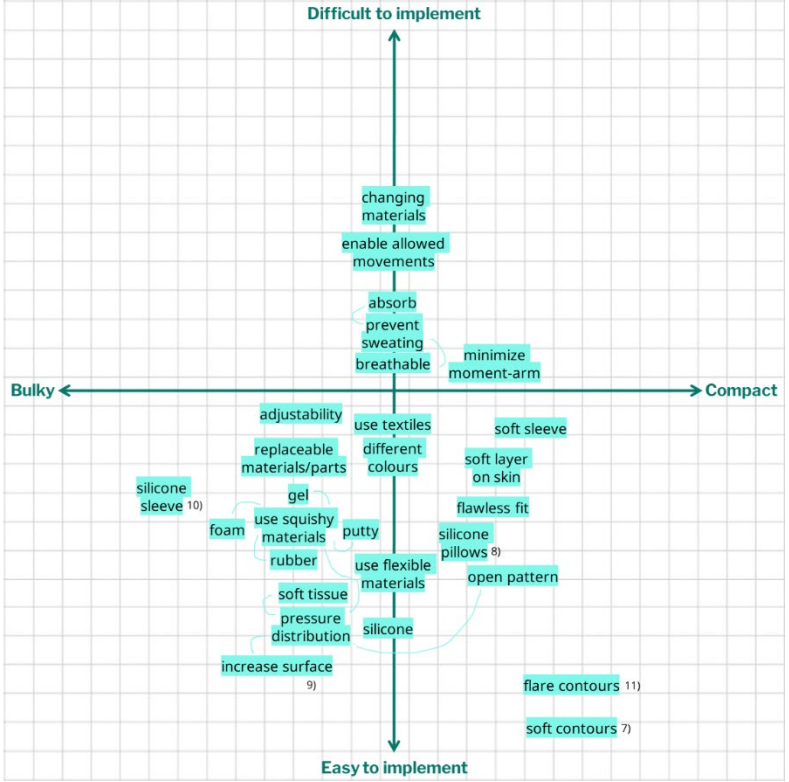


Legend

How to...

secure splint to the hand?
increase comfort?
only limit extension?
enable size adjustment?
motivate emotional attachment?
make it appealing?

x) = reference to drawing x

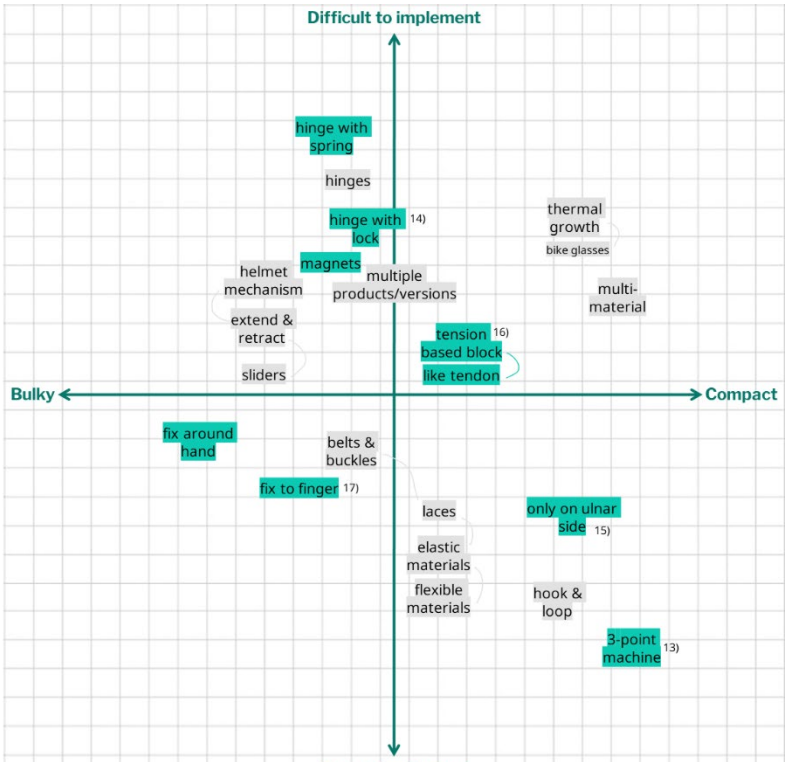


Legend

How to...

secure splint to the hand?
increase comfort?
only limit extension?
enable size adjustment?
motivate emotional attachment?
make it appealing?

x) = reference to drawing x

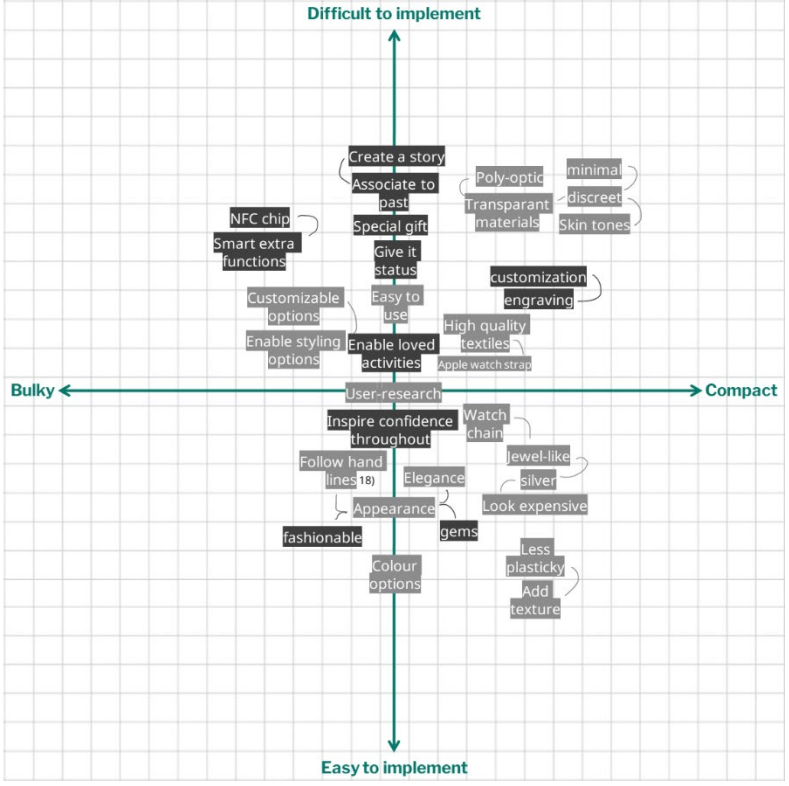


Legend

How to...

secure splint to the hand?
increase comfort?
only limit extension?
enable size adjustment?
motivate emotional attachment?
make it appealing?

x) = reference to drawing x



Legend

How to...

secure splint to the hand?

increase comfort?

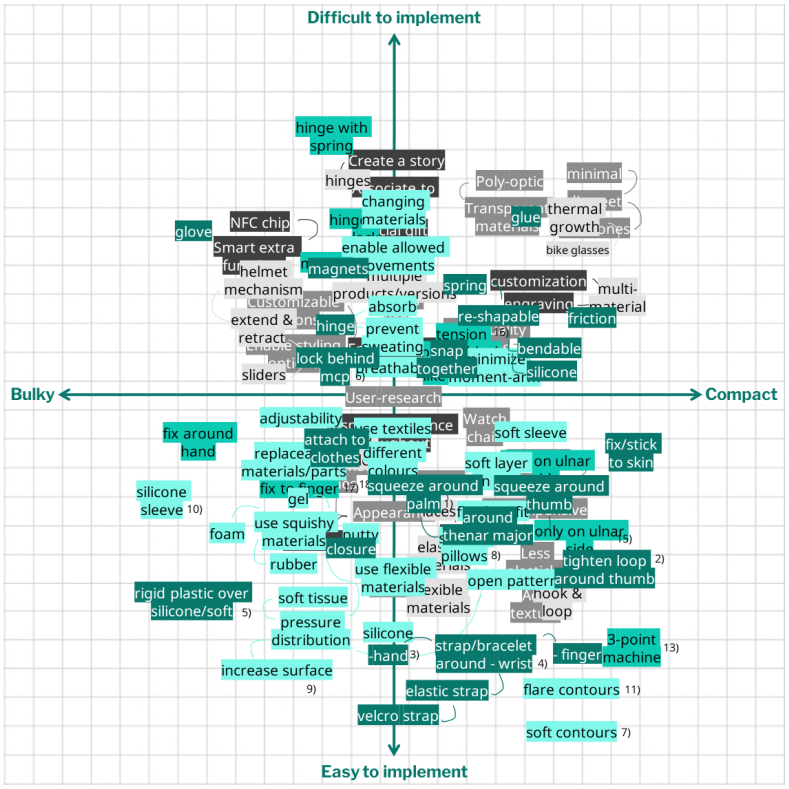
only limit extension?

enable size adjustment?

motivate emotional attachment?

make it appealing?

x) = reference to drawing x

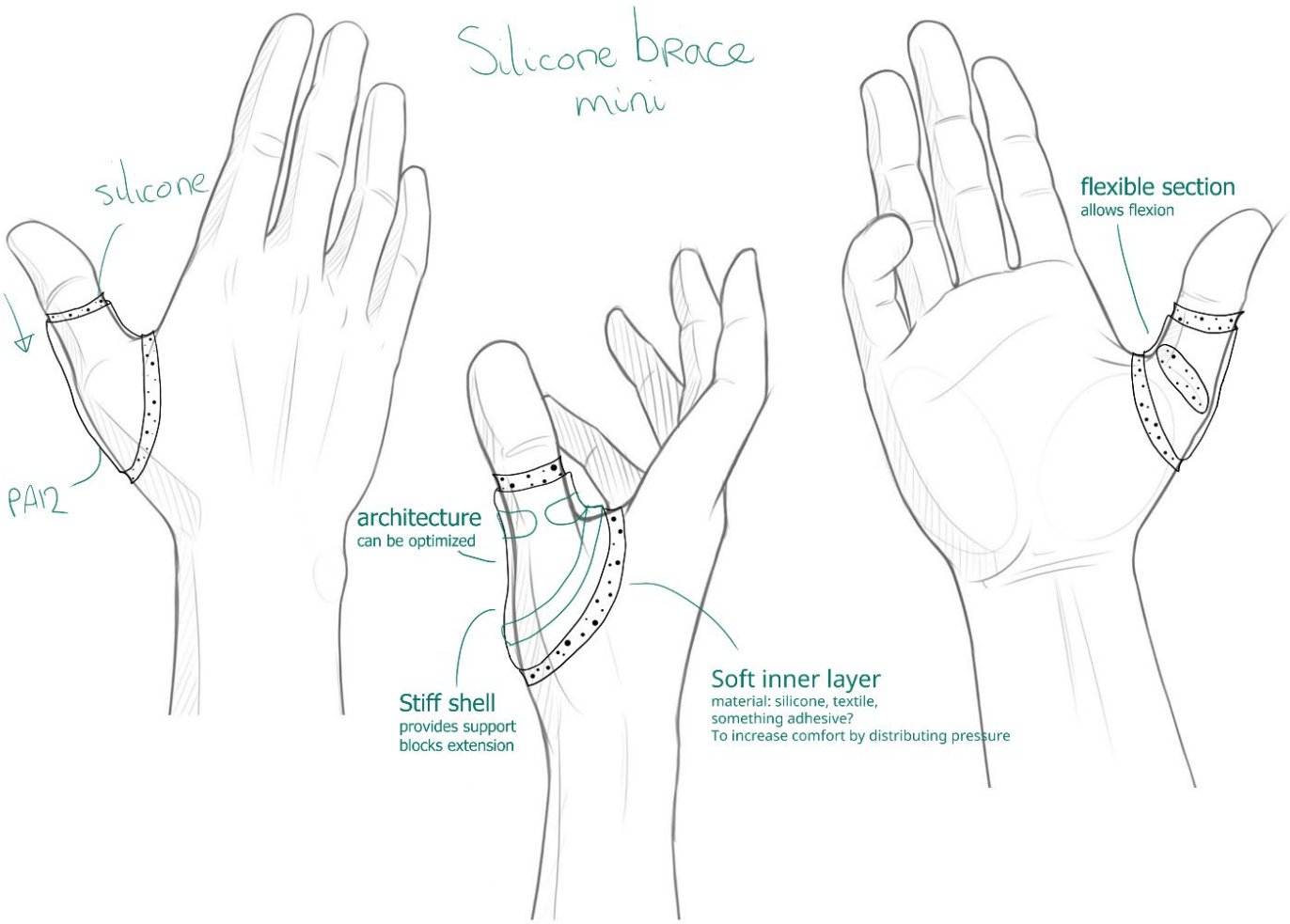


APPENDIX E: WEIGHTED CRITERIA

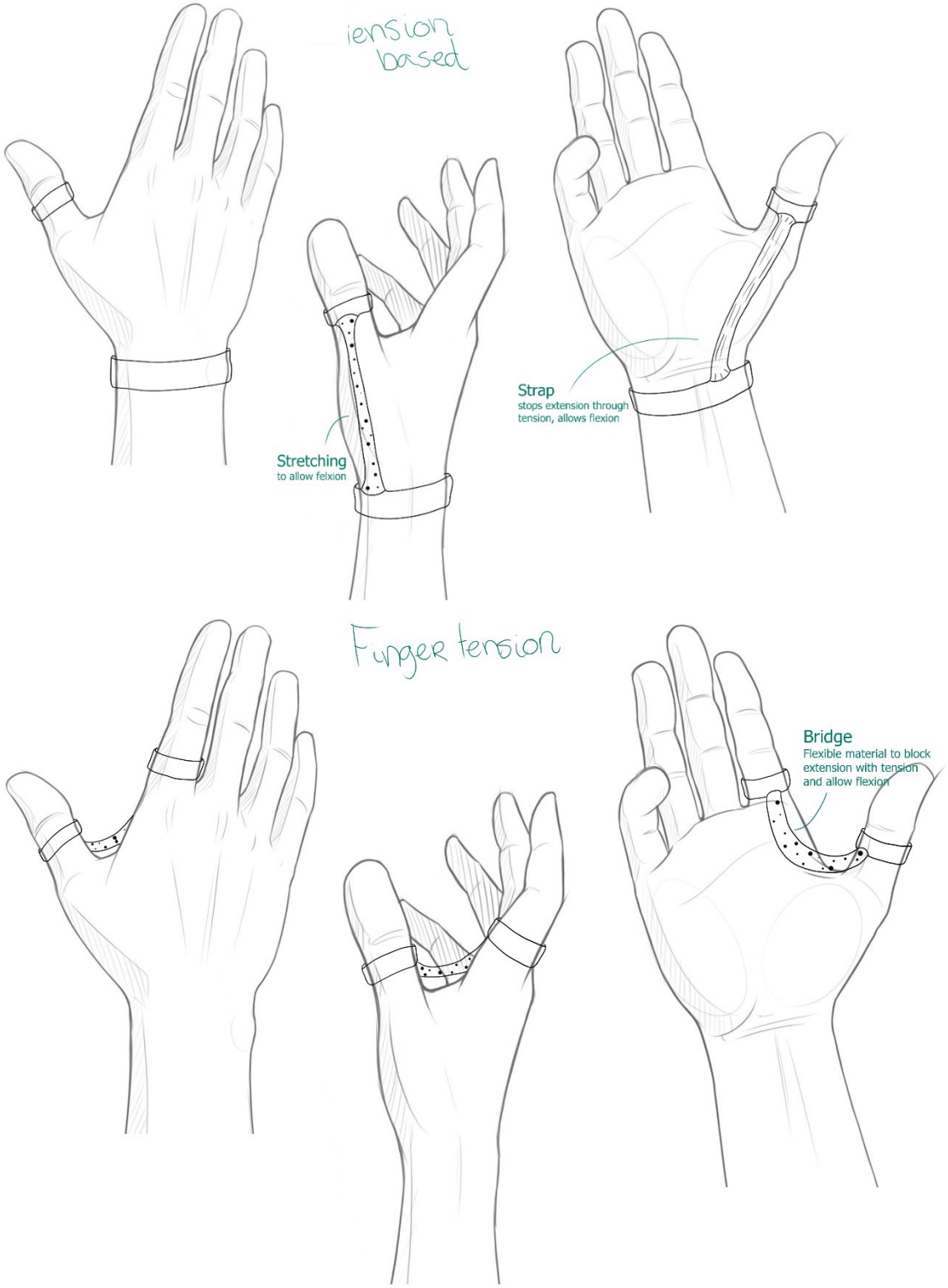
Criteria	Designer (me)	Orthotists	Users	Production Experts	Expert designers	Avg.
Hygiene Cleaning and staying clean	5	10	12,5	12,5	10	10
Comfort Avoiding pressure points	15	22,5	17,5	17,5	17,5	18,5
Appealing appearance Discreet, elegant	20	10	15	10	22,5	15,5
Security Stays tightly and securely in place (in movement)	15	20	22,5	12,5	10	16
Easy donning & doffing	10	7,5	12,5	7,5	12,5	10
Freedom of mobility Allowing opposition	20	20	20	17,5	15	18,5
Scalability (Labour and costs)	15	10		22,5	12,5	15

criteria	Designer (me)	Orthotist #1	Orthotist #2	Designer #1	Designer #2	User #1	User #2	Production Expert #1	Production Expert #2
hygiene (schoon blijven & maken)	5	10	10	10	10	5	20	15	10
comfort (drukpunten voorkomen)	15	20	25	20	15	15	20	15	20
aantrekkelijk uiterlijk (onopvallend, stijlvol)	20	10	10	20	25	25	5	10	10
blijft strak & stevig zitten (in beweging)	15	20	20	10	10	25	20	15	10
makkelijk aan & af doen	10	10	5	10	15	10	15	5	10
bewegingsvrijheid (oppositie toestaan)	20	20	20	15	15	20	20	20	15
scalability (labour & costs)	15	10	10	15	10			20	25
total:	100	100	100	100	100	100	100	100	100

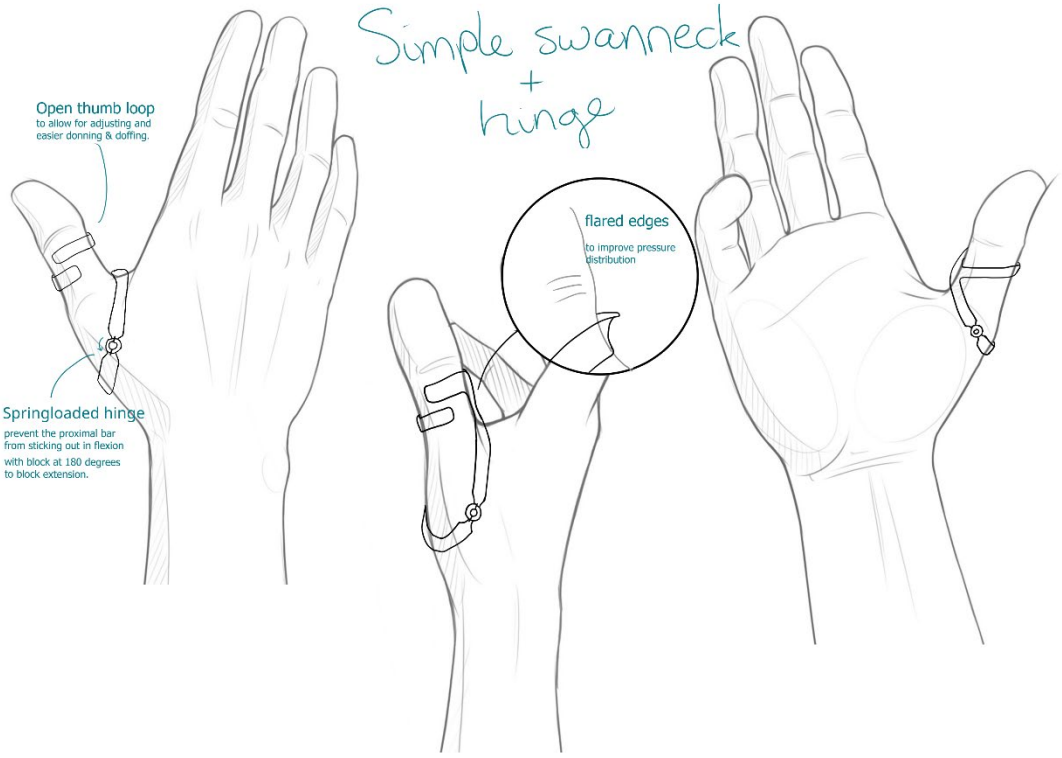
SILICONE MINI

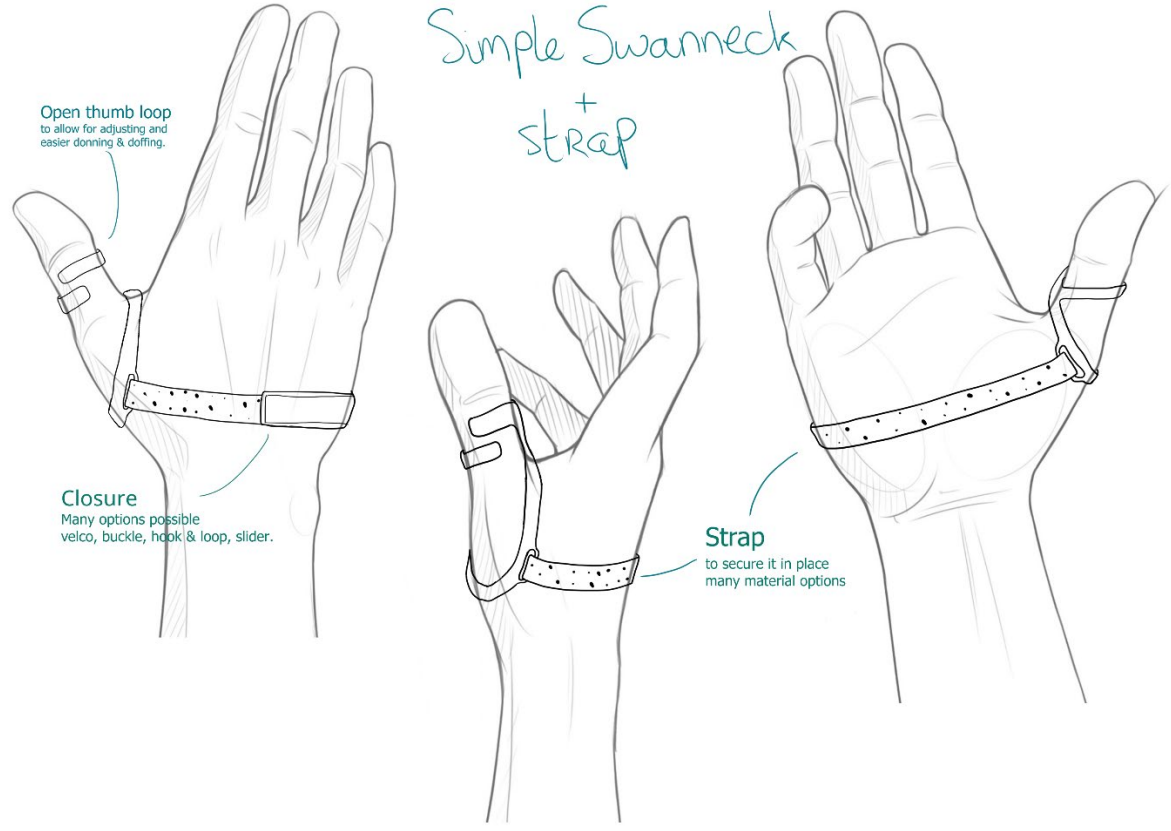


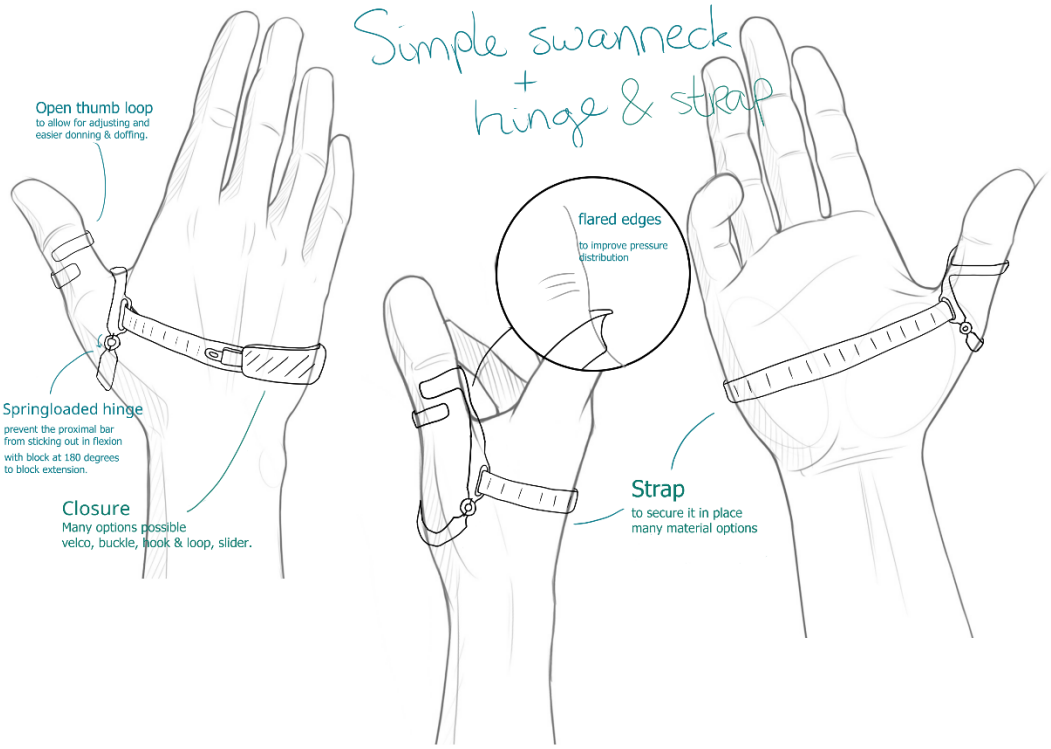
TENSION BASED



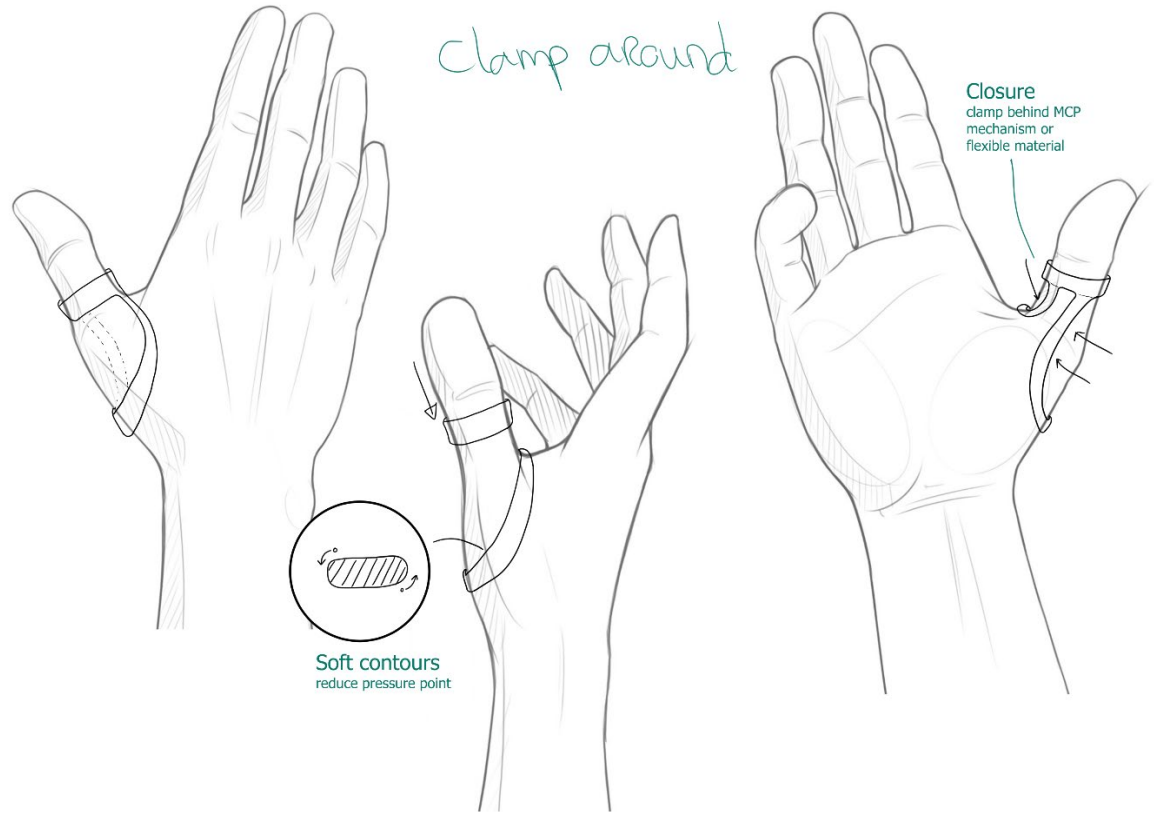
HINGE SWANNECK

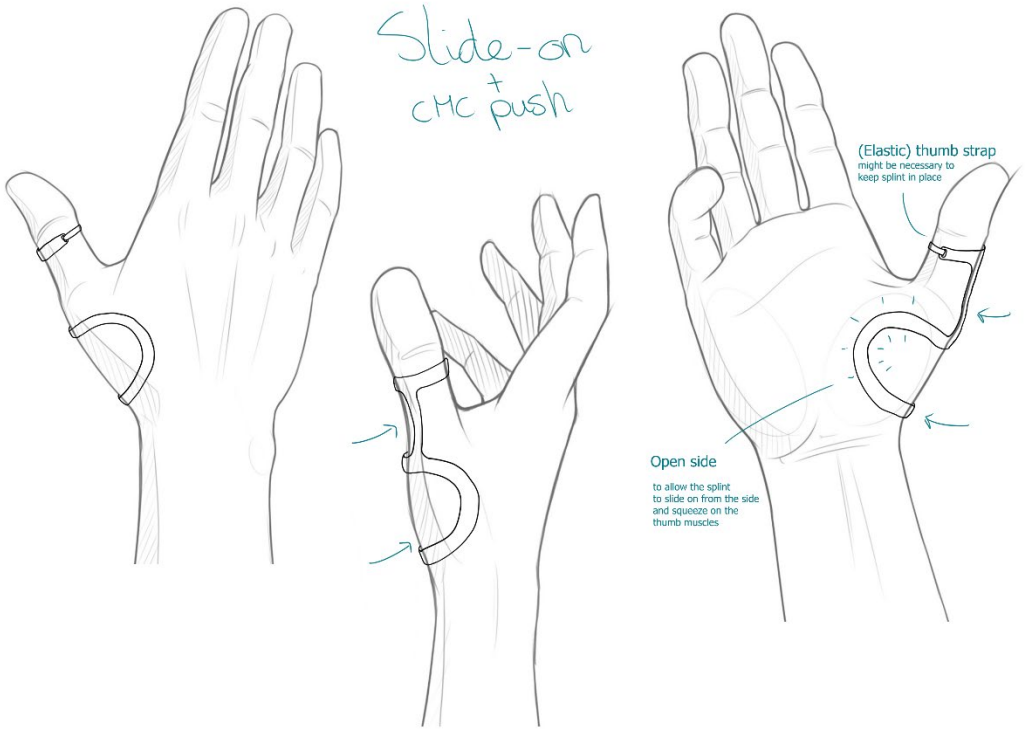





Simple swanneck
+
hinge & strap
Open thumb loop
to allow for adjusting and
easier donning & doffing.
Springloaded hinge
prevent the proximal bar
from sticking out in flexion
with block at 180 degrees
to block extension.
Closure
Many options possible
velco, buckle, hook & loop, slider.
flared edges
to improve pressure
distribution
Strap
to secure it in place
many material options

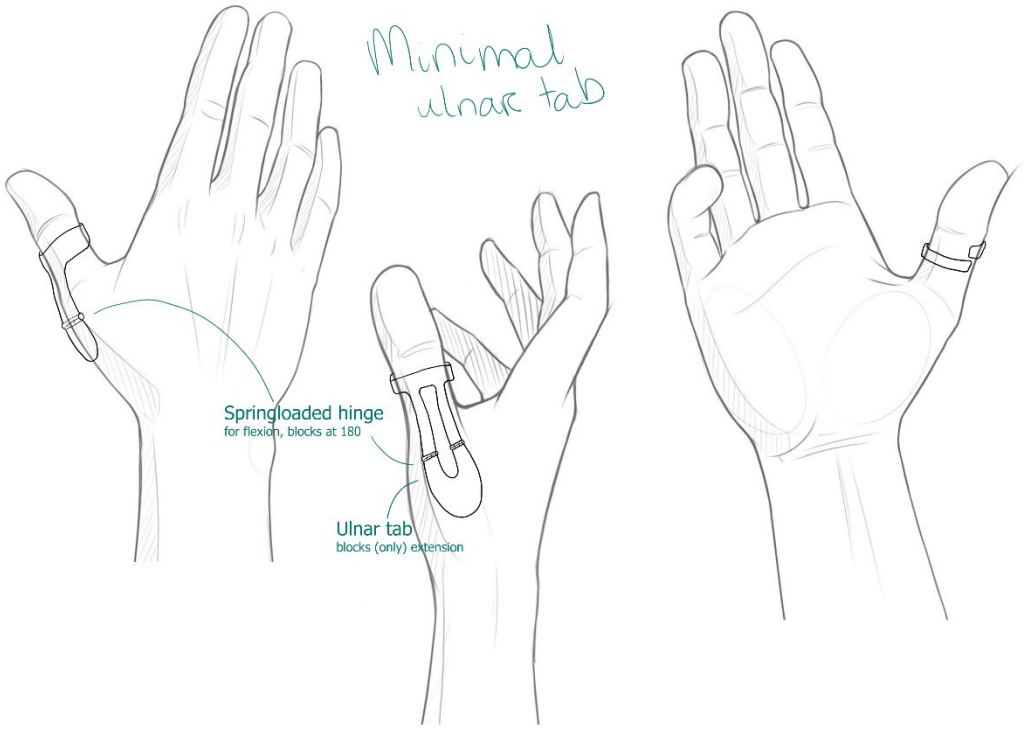
SQUEEZE-ON


Clamp around
Closure
clamp behind MCP
mechanism or
flexible material
Soft contours
reduce pressure point

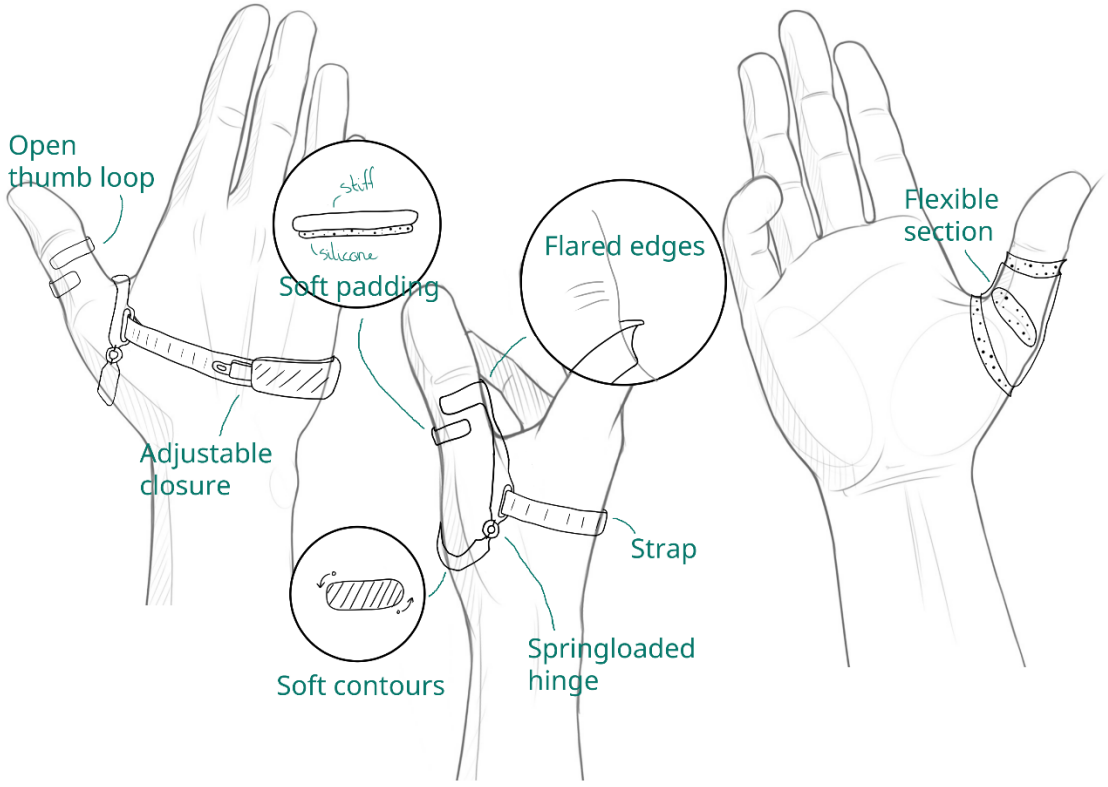


WRIST STRAP

ONE SIDED



LIST OF FEATURES



APPENDIX G: FIRST USER EVALUATION

INTRODUCTION

Briefly describe the project, the goals of this experiment and the variants of the static and dynamic splints. Read & fill in the informed consent form. Ensure orthotist is present for Manometric client treatment regulation and expert input. Tell the participant that if they feel any pain or discomfort, we can immediately stop the experiment and take breaks.

- How are you experiencing your current thumb splint?

1ST FITTING

Of each splint architecture, 3 versions are made: a normal one, a tighter one and a looser one. First fit the normal one of each architecture, then determine whether the tighter or looser one might be better. Do this for all 4 architectures: dorsal-tab, dorsal tab with hinge, squeeze-on, squeeze-on with hinge. Check the following:

- Does it fit snuggly on the skin? Are there gaps?
- Are there places where the pressure on the skin is too much, causing discomfort?
- Does the splint effectively block extension at ~20°?
- Can you comfortably oppose your thumb? And a pinch grip? And a power grip?
- How is the further mobility of the hand and thumb?
- When moving repeatedly, does it slide/turn/move?
- When the thumb is extended: are there any gaps/discomfort?
- When the thumb is flexed: are there any gaps/discomfort?
- After wearing it for a while, any further comments, or changes?

Document the reason for the preference. Take pictures of the final fit.

DESIGN DISCUSSION

A short co-design session with the user:

- Is this splint an improvement over your current product? Why? What aspects are better and what is worse?
- If they had a magical pen in hand, how would they change the shape of the splint?
- How likely do you think it is that you'd wear this splint?
- Would the appearance of the splint, as I'm currently showing it, be reason for you not to wear it?

APPENDIX H: PARAMETRIC DESIGN RULES

Nr.	Notes
	Thumb ring
	The thumb ring is shaped after the outline of the thumb provided by the scan, across its complete height and cross-section. (It is not a perfect circle or ellipse).
	On the dorsal side, the middle of the thumb ring is at 2/3rds the distance between MCD and IPD, towards IPD.
	On the volar side, the middle of the thumb ring lines up with the MCV (MCP1 volar crease).
	The height of the thumb ring is 9 mm on the dorsal side.
	The height of the thumb ring is 3 mm on the volar side.
	The 2 sides are connected around the thumb in straight lines around the circumference.
	The thumb ring is biaxially scaled in the transverse plane such that its inner dimensions are no smaller than the IP ring size measurements.
	The thickness of the thumb ring is 2.5 mm across the complete cross-section.
	Palmar tab
	The middle of the ulnar side of the palmar tab is connected to the thumb ring 5 mm along its circumference from the MCV.
	The middle of the radial side of the palmar tab is connected to the thumb ring 5 mm along its circumference from the MCV.
	At the connections with the thumb ring, the palmar tab is 7 mm wide.
	At the proximal end of the palmar tab, it is 9 mm wide.
	The proximal end of the palmar tab is at 1/2 of the distance between TM and TC.
	The radius of the curve at the proximal end of the palmar tab is ~10 mm at its middle.
	The palmar tab follows the shape of the scan and is pushed ~2 mm below the outline.
	The thickness of the dorsal loop is 2.5 mm across the complete cross-section.
	Dorsal loop
	The middle of the radial side of the dorsal loop coincides with the middle of the radial side of the palmar tab, merging the shapes.
	The middle of the ulnar side of the dorsal loop is connected to the thumb ring at the top of the webspace.
	At the connections with the thumb ring, the dorsal loop is 7 mm wide.

	The radial side of the dorsal loop follows the shape of the scan until the proximal end of the loop.
	The radial side of dorsal loop runs parallel to the dorsal side of the thumb, following the bend caused by the MCP1 joint, until the proximal end of the loop.
	The radial hinge is placed at the radial bend, which is on the transverse axis of the MCD, on the outside of the scan.
	At the bottom of the dorsal loop, it is 9 mm wide.
	The bottom of the palmar tab is at 1/2 of the distance between MCD and CMD.
	The radius of the curve at the proximal end of the dorsal loop is ~20 mm at its middle.
	The ulnar side of the dorsal loop follows the shape of the scan, including the bend caused by the MCP1 joint, until the thumb loop.
	The ulnar hinge is placed at the ulnar bend, which is on the transverse axis of the MCD, below the middle of the webspace.
	At and proximal to the hinge, the dorsal loop is 12 mm wide.
	At and proximal to the hinge, the dorsal loop is pushed ~2 mm inside the scan.
	The thickness of the dorsal loop is 2.5 mm across the complete cross-section.
	<u>Hinge</u>
	The angle and placement of the hinges is determined by shape of the dorsal loop as described above.
	The radial hinge is placed such that the central axis splits the MCP1 bend through its middle.
	The thickness of the radial hinge is the same as the material thickness: 2.5mm.
	The ulnar hinge is placed such that the central axis splits the MCP1 bend through its middle.
	The thickness of the ulnar hinge is the same as the material width: between 12 and 7mm.
	The cross-section of both hinges is identical and constant through the complete thickness, described in the figure to the right.
	<u>Other</u>
	The ulnar area connecting the palmar tab, dorsal loop, and thumb ring features a fold perpendicular to the webspace, such that thumb ring is parallel to the thumb, and the connecting area is parallel to the webspace.

APPENDIX I: FINAL CONCEPT EVALUATION

This appendix contains the full procedure of the final concept evaluation along with the reasoning for certain method choices and the quantitative results. Chapter 5 contains the conclusions drawn based on this experiment. The goals of the experiment are to assess the effectiveness of the parametric design rules and evaluate whether the proposed concept fulfils the criteria regarding comfort, function, and appeal from a user's perspective. Additionally, the added value of the hinge is evaluated by comparing the same architecture with and without it. The new concept is also compared to each individual's current splint to assess how it meets Manometric's standard.

METHOD

Briefly describe the project process, the goals of this experiment and the variants of the splints. Read & fill in the informed consent form. Ensure orthotist is present for Manometric client treatment regulation and expert input. Tell the participant that if they feel any pain or discomfort, we can immediately stop the experiment and take breaks.

BASELINE

First discover the mobility of the thumb without a splint. Document this using picture for later evaluation of the angles.

- Try to use the tip of your thumb to touch the palm of your hand in as much flexion as you can.
- Extend your thumb normally.
- Oppose your thumb.
- Are you experiencing any pain or discomfort performing these movements?

FIRST FITTING

Of the new splint with and without the hinge, 3 versions each were made: a normal one, a tighter one and a looser one. First fit the normal one, then determine whether the tighter or looser one might be better. Repeat the questions from the first fitting and see whether it has improved.

- Does it fit snuggly on the skin? Are there gaps?
- Are there places where the pressure on the skin is too much, causing discomfort?
- Does the splint effectively block extension at ~20°?

- Can you comfortably oppose your thumb? And a pinch grip? And a power grip?
- How is the further mobility of the hand and thumb?
- When moving repeatedly, does it slide/turn/move?
- When the thumb is extended: are there any gaps/discomfort?
- When the thumb is flexed: are there any gaps/discomfort?
- Does this splint feel like an improvement on the one previously tested, why?
- After wearing it for a while, any further comments?

Document the reason for the preference. Take pictures of the final fit.

MOBILITY

Check the the mobility of the thumb with the splint on. Document this using picture for later evaluation of the angles.

- Try to use the tip of your thumb to touch the palm of your hand in as much flexion as you can.
- Extend your thumb normally.
- Oppose your thumb.
- Are you experiencing any pain or discomfort performing these movements?

PAIN SENSITIVITY MAP

The pain sensitivity map of Fernández-de-las-Peñas et al. (2010) was adapted for this experiment. Figure 1 shows the pain sensitivity map that was used for participants to quantify their comfort. While wearing the splint, each zone (A-H) is addressed to assess the total comfort level. Comfort ratings were given in a relaxed, slightly flexed position, as well as a maximally extended position.

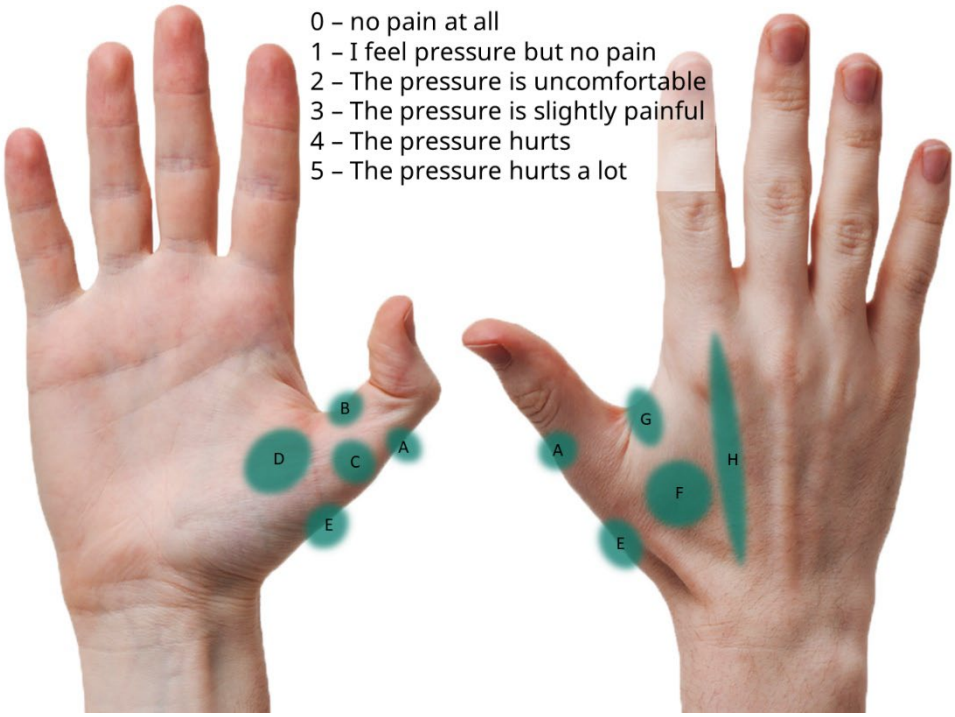


Figure 1: Pain sensitivity map used for participants to quantify their comfort.

HAND FUNCTION TEST

The Sollerman Hand Fuction Test (Sollerman & Ejeskär, 1995) was adapted for this experiment. It is performed twice: once with and once without the splint. Table 1 shows an overview of all grips in which a normal grip pattern can be divided and what percentage of use in activities of daily living (ADL) that handgrip has. Table 2 shows the exercises that were performed by each participant and what grip type they test. Not all of Sollerman's activities could be performed within the limits of the Manometric office, as certain spaces or materials were not present. However, all the grips with a percentage use in ADL of 10% and higher were tested.

Hand Grips		**Position**	**Percentage use in ADL(%)**
Pulp pinch	 1. Pulp Pinch	The object is held between the thumb and the index or the middle finger, or both	20

Lateral pinch	 2. Lateral Pinch	The object is held between the thumb and the radial side of the index finger	20
Tripod pinch	 3. Tripod Pinch	The object is surrounded by the thumb, index and middle finger. It may have contact with the web of the thumb	10
Five-finger pinch	 4. Five-Finger Pinch	The object is held between the thumb and the four fingers together. It has no contact with the palm	15
Diagonal volar grip	 5. Diagonal Volar Grip	The object is held with the thumb against the four fingers. It has contact with the palm and its axis is diagonal to that of the hand	15
Transverse volar grip	 6. Transverse Volar Grip	The object is held with the thumb against the four fingers. It has contact with the palm and its axis is transverse to that of the hand	14
Spherical volar grip	 7. Spherical Volar Grip	The object is surrounded by the thumb and the four fingers and has contact with the palm	4
Extension grip	 8. Extension Grip	The object is held between the thumb and the four fingers, which are extended in the interphalangeal joints. It has no contact with the palm	2

Table 1: Overview of all handgrips categorized by Sollerman & Ejeskär (1995).

Nr.	**Activity**	**Grip**	**Percentage use in ADL (%)**
1	Pick up coins from flat surface, put into purse.	Pulp pinch	20
2	Lift wooden cubes over edge (5 cm in height)	Five-finger pinch	15

3	Lift weight over edge (5 cm in height)	Transverse volar grip	14
4	Turn screw with screwdriver	Diagonal volar grip	15
5	Pick up nuts and put on bolts	Pulp pinch, lateral pinch, tripod pinch	20,20,10
6	Write with a pen	Tripod pinch	10
7	Fold paper, put into envelope	lateral pinch	20
8	Put paper clip on envelope	Pulp pinch, lateral pinch	20, 20
9	Pour water from the jug	Transverse volar grip	14

Table 2: activities performed during the adapted Sollerman Hand Function Test.

Each activity was scored according to the following overview:

Score	Performance
0	The patient could not carry out the task
1	The task was partially performed within 60 seconds
2	The task was completed, but with great difficulty, or the task was not carried out with the prescribed hand-grip, or the task was not completed within 40 seconds but within 60 seconds
3	The task was completed, but with slight difficulty, or the task was carried out with the prescribed hand-grip but with slight divergence from normal, or the task was not completed within 20 seconds but within 40 seconds
4	The task was carried out without any difficulty within 20 seconds and with the prescribed hand-grip of normal quality

The scoring system takes notes of the time taken to carry out tasks, the level of difficulty and the quality of hand performance. The maximum achievable score is 9 times 4, 36. Patients with normal hand function would achieve 36 points with the dominant hand, and 33-35 with the non-dominant hand. The lower the total score, the poorer the hand function.

DESIGN DISCUSSION

A short co-design session with the user:

- Repeat the pain sensitive map step, now that the user has worn the splint and performed the movements that simulate daily life activity.
- Also fit the architecture without the integrated hinge and check the comfort and mobility of the thumb. Does the hinge have a significant impact on the user's experience?

- Is this splint an improvement over your current product? Why? What aspects are better and what is worse?
- If they had a magical pen in hand, how would they change the shape of the splint?
- How likely do you think it is that you'd wear this splint?
- Would the appearance of the splint, as I'm currently showing it, be reason for you not to wear it?

RESULTS

The results included qualitative insights from the fittings, interviews and observations throughout the experiment that were not transcribed. The conclusions in Chapter 5 mention the important qualitative findings. The section below shows the qualitative results of this experiment that were also used to draw conclusions in Chapter 5.

PAIN SENSITIVITY MAP

Zone	participant 1			participant 2			participant 3			Avg.
	1 min	15-30 min		1 min	15-30 min		1 min	15-30 min		
	Relaxed	Relaxed	Extended	Relaxed	Relaxed	Extended	Relaxed	Relaxed	Extended	
A.	0	0	2	0	0	3	0	0	2	**0,78**
B.	0	0	1	0	0	2	1	1	1	**0,67**
C.	0	1	0	0	0	1	0	0	1	**0,33**
D.	1	1	0	1	1	0	0	0	0	**0,44**
E.	0	0	2	1	2	1	1	1	1	**1**
F.	0	1	1	0	1	0	0	0	0	**0,33**
G.	0	1	1	1	1	2	0	1	2	**1**
H.	0	0	0	0	0	0	0	0	0	**0**
avg.	**0,125**	**0,5**	**0,875**	**0,375**	**0,625**	**1,125**	**0,25**	**0,375**	**0,875**	

Zone	Average			avg.
	1 min	15-30 min		
	Relaxed	Relaxed	Extended	
A.	0	0	2,33333333	**0,78**
B.	0,333333	0,333333	1,33333333	**0,67**
C.	0	0,333333	0,66666667	**0,33**
D.	0,666667	0,666667	0	**0,44**
E.	0,666667	1	1,33333333	**1**
F.	0	0,666667	0,33333333	**0,33**
G.	0,333333	1	1,66666667	**1**
H.	0	0	0	**0**
avg.	**0,25**	**0,5**	**0,9583333**	

HAND FUNCTION TEST

Activity Nr.	**participant 1** (Splint on non-dominant hand)		**participant 2** (Splint on non-dominant hand)		**participant 3** (Splint on dominant hand)	
	without	**with**	**without**	**with**	**without**	**with**
1. (coins)	3	4	3	3	2	3
2. (cubes)	4	4	3	4	4	4
3. (weight)	3	3	0	3	2	3
4. (screw)	2	3	0	2	2	3
5. (nut & bolt)	4	3	3	3	4	3
6. (write)	3	3	3	4	3	4
7. (fold)	4	4	4	4	4	4
8. (paperclip)	3	3	3	3	3	3
9. (jug)	2	3	0	2	0	2
Total (of 36)	**28**	**30**	**19**	**28**	**24**	**29**

The following highlights can be found in the data:

- Overall, the hand function improved for each participant. However, the hand function is not yet as it would be in a healthy patient.
- The transverse and diagonal volar grips (screw, weight and jug) were especially challenging for the participants, but the execution improved with the splint. Those activities also required the most force of all activities 9the power grips).
- The pinch grips improved less than the power grips.
- All handgrips improved for each participant, except:
- for 2 participants, the lateral pinch (paperclip, nut & bolt) performance worsened because of the splint.