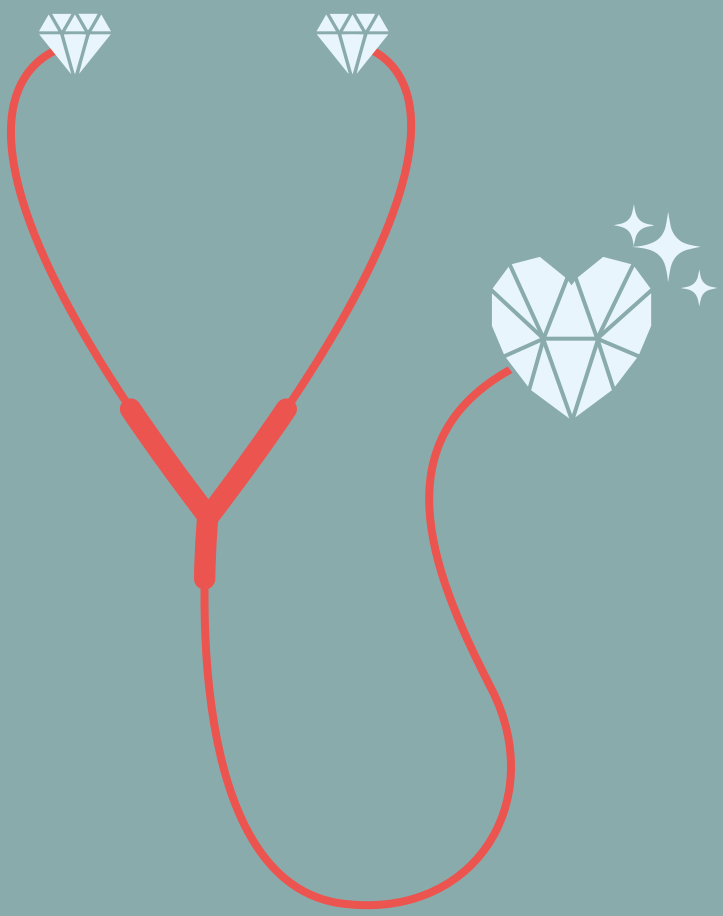
A MEDICAL JEWEL: THE HAND SPLINT

Automation of Ultra Personalized Products and Services



MASTER THESIS
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Master Integrated Product Design
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MASTER THESIS

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"Last but not least, I wanna thank me. I want to thank me for believing in me. I want to thank me for doing all this hard work" - Snoop Dogg

[Image 1] 3D scanning research with rheumatoid patients

Your hands are the most precious tools in daily life. Therefore, it is easy to imagine that people with diminished hand functionality experience a reduced quality of life. This implies for patients with joint problems. Consequently, the hand functionality should be increased through splinting. Splinting is a non-operative treatment for patients with commonly rheumatoid arthritis, osteoarthritis and ehlers danlos syndrome.

In this master thesis, an ultra personalized splint and service system has been designed. This product-service system includes the whole patient journey, from medical consult to gathering anthropometric data and producing the personalized splint. Throughout the design process, a computational design approach was leading. This started with defining the patient needs and the splint functionality. Thereafter, several options for data and parameter acquisition were explored. The options differed in the complexity of anthropometric data. The first concept was based on a 3D scan (3D), the second on a photograph (2D), and the third on hand measurements (1D). The latter involved the use of a statistical shape model (SSM).

With regard to the 3D scanning procedure, both mesh wrapping and digital posture correction were implemented and evaluated. Unfortunately, this did not result in an accurate design reference. Further research on posture correction for orthosis design is therefore recommended.

Additional research on 3D scanning of patients with rheumatoid arthritis gave great insight into the possibilities concerning the 3D scanning process (see image 1). 3D scanning involves great challenges with regard to patients with pathological hands. The process remains not viable until an instant 3D hand scanner becomes available. The SSM is proposed as a bridging solution towards the instant 3D scan or eventually incorporating the hand scan in artificial intelligence (AI) processing workflows.

Furthermore, a parametric computational design has been modelled. This design automatically adjusts to the anthropometric data of the patient. It allows for customization of the medical requirements and the aesthetic features. There has been emphasized on medical jewellery design. Different materials have been explored for this purpose.

Finally, the fit and functionality evaluation showed good results. The splint fits snugly and only a few aspect with regard to the functionality needs to change.

I am proud to present the first medial jewel, a hand splint worn by Adeline Eleveld.

EXECUTIVE SUMMARY

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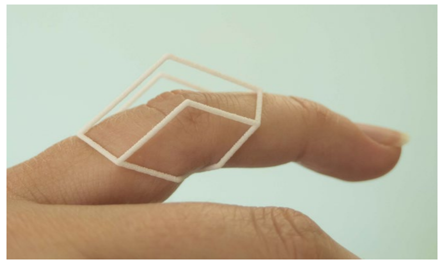


[Image 3] 3D printed splint Tjielp Design

Splinting is a non-operative treatment for people with joint problems. The three main conditions in which people experience joint problems are osteoarthritis, rheumatoid arthritis and the Ehlers Danlos Syndrome (EDS). The manifestation and origin of these problems are different per condition. There is wear and tear of the joint, inflammation and hypermobility where joints dislocate regularly. By stabilizing joints and therefore decreasing stress on the joints, splints reduce pain and increase function during daily activities (Jensen and Beasly). Patients with EDS experience pain due to hypermobility and dislocations, which contributes to functional impairment during daily life (Castori et al., 2010). Also, patients with rheumatoid arthritis experience physical disfunctioning, which results among other things in a significantly diminished quality of life (Matcham et al., 2014). Again, this underlines the importance of **increasing hand function in daily life by splinting**.[R1]★

There are different types and forms of splints: medical variants with velcro, plastic splints, and silver splints that are personalised by a silversmith. Depending on the joint involvement, there are various splinting solutions possible (see image 1). Patients with joint problems wear the splint every day, for the rest of their life until (or even after) surgery.[R2]★ Hence, the splint should be **comfortable to wear** and shouldn't obstruct daily tasks too much. Furthermore, patients prefer not to be continually reminded of their medical problems, hence an unobtrusive splint is preferred. Patients could refuse wearing something that they visually dislike even though it benefits their health. For these reasons, it is necessary to understand the **user's motives** and what prevents them from wearing this device.[W1]★

Numerous experts are involved in the patient journey which complicates the **cooperation between experts** and the **transfer of patient information**. The occupational therapist helps the patient with hand and wrist exercises and adapting their daily activities to the benefit of their medical condition. What's more, the patient is commonly treated by an rehabilitation doctor, a rheumatologist, or an orthopaedic surgeon. These experts are able to write a referral which is needed for the patients insurance to reimburse the costs for the splint. Moreover, they are in direct contact with the user and have a lot of knowledge about the medical condition and the treatment.

There is an interesting shift visible towards the **digitalization of personalized silver splints**. There used to be a clear distinction between craft production and personalized production, but nowadays digital modelling and fabrication techniques are closing this gap. Mass customization is emerging and this could not be more interesting for designing personalized splints.

Personalised finger splints offer more possibilities and have a more comfortable fit. Currently, this is manual labor carried out by a blacksmith. It is a time consuming process and requires an expert in the field of forging silver as well as medical problems. Moreover, it requires several consults and measuring appointments between the patient and blacksmith. All in all, it can take four to six weeks before the splint ring is finished.

When it comes to personalised design, **Fieldlab UPPS** has a wide range of knowledge and experience with collecting and analysing 3D data, parametric design, and digital fabrication techniques (see image 2). The Ultra Personalised Product and Service System (UPPSS) is a **multi-stakeholder** product service system (PSS), which consists of one or more of the following aspects: identity, the preferred look and feel (1), capabilities, the function and specific features (2), and fit (3). The fit concerns the interaction between product and customer/environment/other products, the characteristics and personalised interactions.

Anna Ruiter owns a design studio in Delft, named Tjielp Design. She specializes in customized products created using digital fabrication techniques (see image 4). This includes jewellery design, furniture and interior designs. As part of her work, Anna has developed a new personalised splint ring that looks less like a medical device and more like a jewel (see image 3). Currently, this is a design for a 3D printed ring that fits one person only. Ultimately Anna sees that this design process is partially automated so that many people can benefit from this personalised piece of medical jewellery.

[Image 4] Product made by Tjielp Design

Value

In a period of time where digital modeling and fabrication techniques are widely available, it is necessary to reconsider personalization in splint design. Ultra personalisation of product service systems enables a more efficient integration of stakeholder interests, resulting in better fitting and customized splints that can be manufactured at a higher speed. This will improve the patient's hand function in daily life and, as a result, his or her quality of life.

Problem definition

Currently, the manual production of personalised silver splints is time consuming and very costly. This is due to the fact that the process requires a blacksmith, who is an expert in forging silver for these medical problems. The manual process is carried out by the blackmith: he/she measures the patient manually (1), designs the ring according to the individual finger shape and it's problems (2), then produces the ring manually (3), and finally adjusts it a few times so that it fits the patient perfectly (4). Throughout this process, both the blacksmith and the patient have to make physical appointments to take the measurements and make the adjustments. This requires good planning and a lot of patient involvement.

In order to reduce time and costs, the design process should be automated. A computational design approach is recommended for this purpose since it has the ability to automatically transform anthropometric data (e.g. hand measurements or 3D scan) into a 3D design. Besides, this enables more design freedom. In terms of the entire product-service combination, the clinical picture and the patient demands are equally as significant as anthropometric data in order to inform the design. Furthermore, stakeholder collaboration and data sharing affect the smoothness of the splinting process. For example, the attending physician has information on the medical background, which is needed by the Tjielp Design to design a functional splint. When this information is not transferred properly, the process will falter. As a result, we arrive to the following problem definition:

> 'Creating a personalised finger splint design that automatically adjusts to the anthropometric data, resulting in a product-service combination that takes into account the whole patient journey. From the medical consult, to scanning/measuring the patient, and producing the personalised finger splint.'

Approach and structure announcement

A product-service combination is designed based on desktop research, scientific research, expert knowledge, and design thinking. The double diamond approach is leading in the design process and exists of four phases: discover, define, design, and validate (see image 5 on the next page). The activities that accompany the phases are analysis, synthesis, ideation, and implementation. Switching between ideation and implementation is an iterative process.

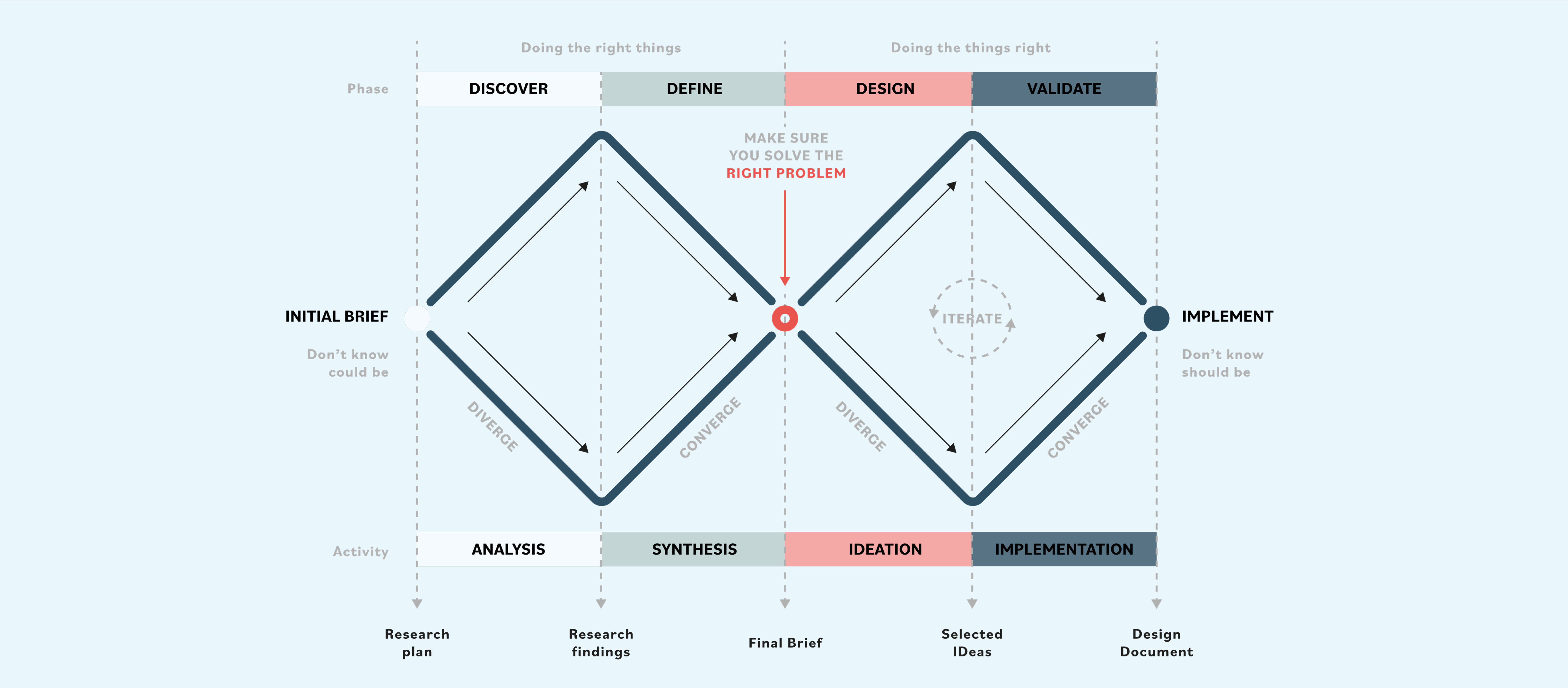
The first phase is about researching and defining the project scope. Therefore, in the discover phase: the clinical picture, current thumb splints, current splint procedure, the care path, competitor analysis, ultra personalized product service systems, digital modelling and fabrication, and 3D scanning in orthosis design is analysed. Throughout this phase multiple design requirements and whishes are pointed out with a red star. These requirements form the baseline for the design vision and design drivers in the following define phase.

R#★ and W#★

In the define phase the research is converged into a design vision and design drivers. The intended product-service combination is introduced and a starting point is provides for the functional and aesthetic design of the product. Thereafter, this can be used in the following design and validation phase where the solution space is discovered.

As mentioned before, the design and validation are intertwined. The design is validated and thereafter the validation is used to inform and improve the design. During the design phase, there will be diversion again to discover possible solutions. These solutions are implemented in the design and will be tested on whether or not they fulfil the design requirements. If not, the design has to be adjusted or will be taken off the table.

Finally, at the end of this graduation project the product-service combination most likely needs some additional iterations before implementation. Even after implementation the product-service combination has to be improved after the patient experience.



[Image 5] Double diamond approach by David Artoumian

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C H A P T E R O N E

DISCOVER PHASE

Contents

1.1 - Introduction

The first phase is about researching the user needs, clinical picture, current technologies, and the current market. As a result, this will lead to defining the scope of the project and setting up design requirements.

Designing a product-service combination for patients with joint problems requires knowledge about the anatomy of the hand and how particular joints are affected. Not only on product level, but also regarding the service it is crucial to understand who is involved in the process and how the patient experiences the journey towards the final splint. Moreover, to be able to redesign the splint process, an understanding of the current splint process is needed. The methods that are used for this purpose are, conducting interviews, constructing a patient journey and a care path.

There is a large variety of thumb splints on the market. Both established splint producers and new bees are active in the field. By analysing the current splint solutions and the competitors, insight is gained into the competitive position and inspiration can be taken for designing the new product-service combination.

The current trend towards mass customization enables the production of better fitting products, at a higher production speed and for a reasonable cost. What does this mean for splints: a product that desires personalisation? To answer this question, a deeper dive is taken into ultra personalised product service systems and how digital modelling and fabrication techniques enable design automation.

The workflow of a computational design approach in personalised product design is analysed. This workflow provides for the design phase and the validation phase in which the new product-service system is designed and implemented for evaluation.

Finally, the current landscape of 3D printing technologies for orthosis design is researched. Even though there are many 3D scanners available, the question remains whether they are suitable in a medical context for patients with pathological hands. Therefore, a more comprehensive research is conducted on 3D scanning in personalized orthosis design for patients with rheumatoid arthritis. This will be further elaborated in the design and validation phase.

1.2 - The clinical picture

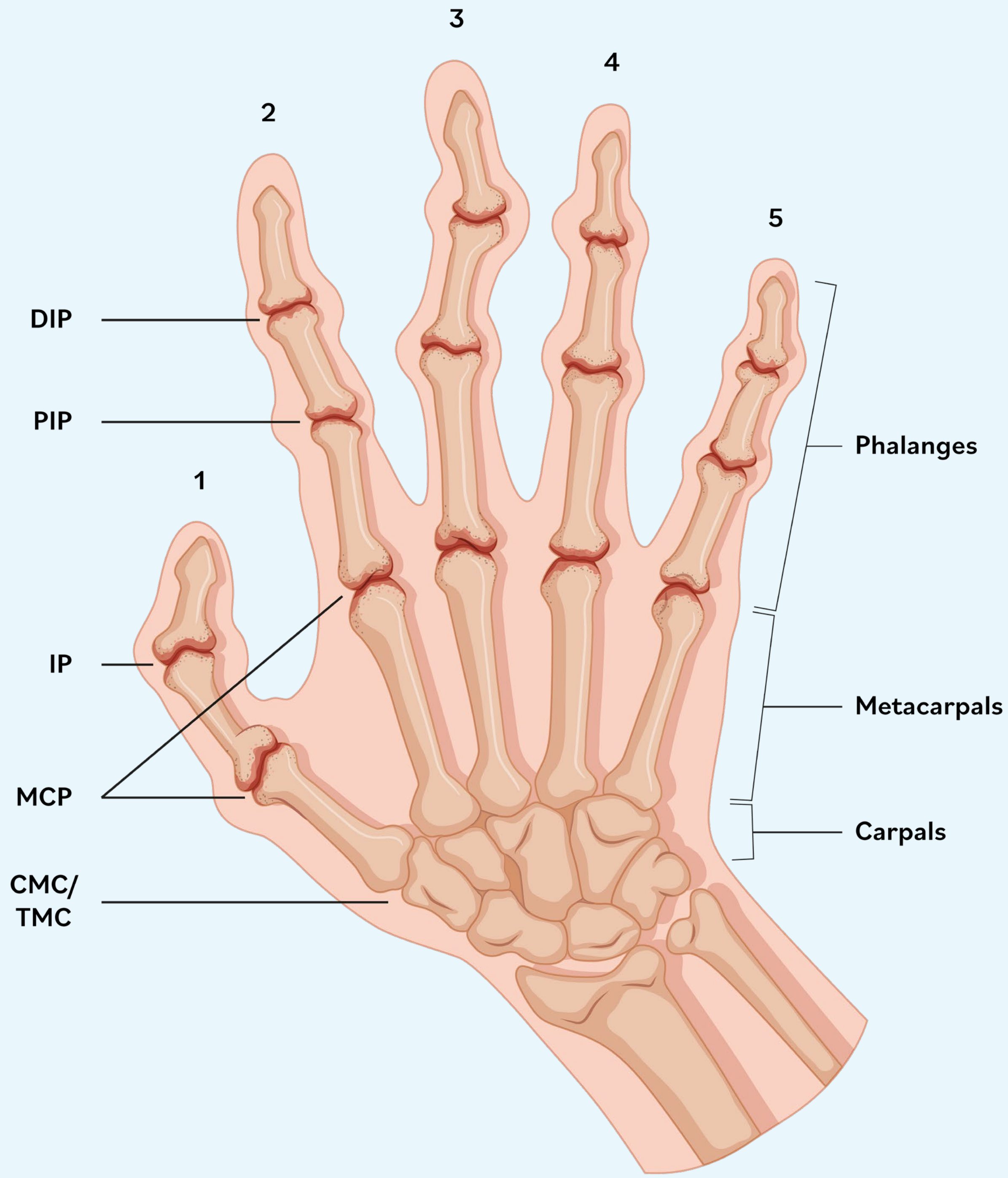
1.2.1 – Introduction

Splinting is a non operative treatment for people with joint problems. In order to design splints for the hand it is important to understand the anatomy of the hand and how particular joints are affected. Moreover, patients with the Ehlers-Danlos syndrome, osteoarthritis, and rheumatoid arthritis experience other symptoms that might affect the product-service system.

1.2.2 – Hand anatomy

Joints are the connectors between bones and movement enablers throughout the skeleton. In order to run smoothly, the end of the bones is covered with cartilage and is surrounded by stabilizing tissues like muscles, tendons, and ligaments. The human hand includes 27 joints that connect 27 bones (see image 6).

The bones that make up the wrist are called carpal bones. The metacarpal bones are located between the wrist and the phalanges. The phalanges are the finger bones. The proximal phalanges are the closest to the wrist, then the intermediate phalanges and the distal phalanges are the most distant finger bones. The joints in between the bones are named accordingly. The carpometacarpal (CMC) joint is the thumb base, the metacarpophalangeal (MCP) joints form the knuckles, the interphalangeal (IP) joint is the connection joint between the thumb bones, the proximal interphalangeal (PIP) joints are the finger joints that are closest to the wrist, and the distal interphalangeal (DIP) joints are the most distant ones. Finally the joints are numbered (1 till 5) from the thumb to the little finger, so the MCP1 is the metacarpophalangeal joint of the thumb and the DIP2-5 are the most distant finger joints of the four fingers. The MCP and the PIP joints are most commonly affected in rheumatoid arthritis (Khurana & Berney, 2005). Wear an tear of the CMC joint is a more common in osteoarthritis.



[Image 6] Hand anatomy by iimages via vectorstock.com

1.2.3 – The conditions

Finger disability occurs with a variety of conditions. People with osteoarthritis, rheumatoid arthritis and the Ehlers Danlos Syndrome commonly experience joint problems. The manifestation and origin of these problems are different per condition. There is wear and tear of the joint, inflammation and hypermobility where joints dislocate regularly. See image 11 for the overview of conditions.

Osteoarthritis (OA) is a joint disease in which the quality of the cartilage deteriorates and joint wear and tear occurs. This can result in **bone formation** directly under the cartilage which causes a decreased range of motion. Other symptoms are **pain**, **stiffness**, **swelling** of the joints, and **thickening of the phalangeal bone**. Splints are used in OA to reduce stress and stabilize the joints in order to prevent further wear and tear.[R1]★

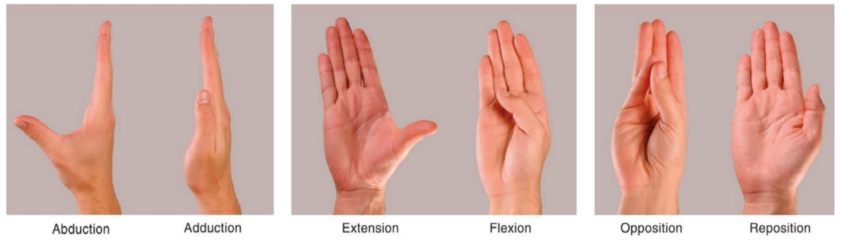
The disease can be divided into two forms, primary and secondary arthritis. In primary arthritis no clear cause can be distinguished and is mostly a consequence of old age in which joints wear and tear. Osteoarthritis (OA) is therefore the most common form of arthritis among older people. In some cases it is a combination of hard to define factors. In that case there is spoken of secondary arthritis, a form that can occur at a younger age and is attributed to factors as genes, injuries, obesity, and/or inactivity (Nuki, 1999). A different common factor of secondary arthritis is inflammation of other diseases. Such inflammation can be caused by the autoimmune disorder rheumatoid arthritis (RA) where the immune system attacks the joints. Another example is Psoriatic arthritis (PsA), an autoimmune disease that not only affects the joints, but also the skin (Belasco and Wei, 2019).

Ehlers-Danlos syndrome (EDS) is a connective tissue disorder. Approximately 3% of the population has the hypermobile type of EDS (Kumar & Lenert, 2017). The joints of these people are **hypermobile** and thus **joint dislocations and subluxations** occur often. Splints are commonly used to stabilize joints, decrease the joint range of motion so that the ligaments will not be overloaded (Jensen et al., 2020).[R1]★

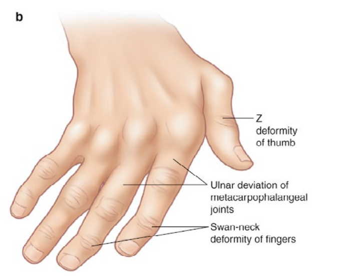
Rheumatoid arthritis (RA) is an inflammatory disease and affects approximately 1-3% of the population. Due to inflammation the cartilage, ligaments, tendons, and bones, the joint degrades over time (Grassi et al., 1998). With high disease activity the **joints are swollen and painful** and the hand functionality decreases (Harris & Stanley, 2003). **Rheumatoid nodules** are found in 20-30 % of the patients with rheumatoid arthritis (Grassi et al., 1998). In the hands these nodules occur on the extensor surfaces of the finger joints and other pressure areas. Splints for patients with RA are used to stabilize joints, decrease the joint range of motion, and to prevent bone erosion and finger deformities from becoming fixed.

When designing the product service combination, one must therefore be aware of possible high disease activity and it is important to reduce pressure points as much as possible to prevent nodules.[R2,3]★ Moreover, patients with rheumatoid arthritis experience other symptoms like **fatigue** and **pain in other joints** which will affect the splint process and possibly the splint design.

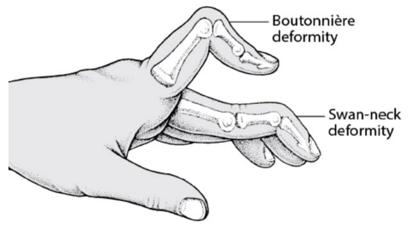
Weakening of the stabilizing tissue results in **finger deformations**. 90% of the people with RA develop hand deformities of which largely in the first 10 years of the disease course (Johnsson & Eberhardt, 2009), (Porter & Brittain, 2012). Splinting is an effective non-operative treatment to prevent deformities or existing deformities from becoming fixed. The most common deformities are ulnar deviation of the MCP joints, boutonnière deformity (BHD), swanneck deformity (SND), boutonnière deformity of the thumb, and swanneck deformation of the thumb (Johnsson & Eberhardt, 2009) (Giesen et al., 2010) (see image 8-10).



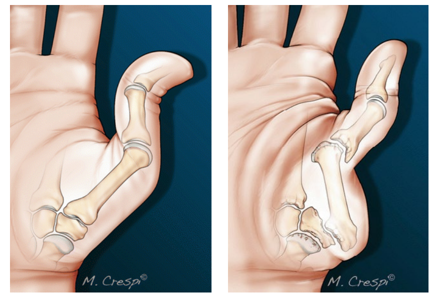
[Image 7] Abduction/adduction, extension/flexion, and opposition/reposition of the thumb (Note, 2020)



[Image 8] Ulnar drift (Inflammatory Arthritides | SpringerLink, n.d.)



[Image 9] SND and BHD (Steinberg, 2021)

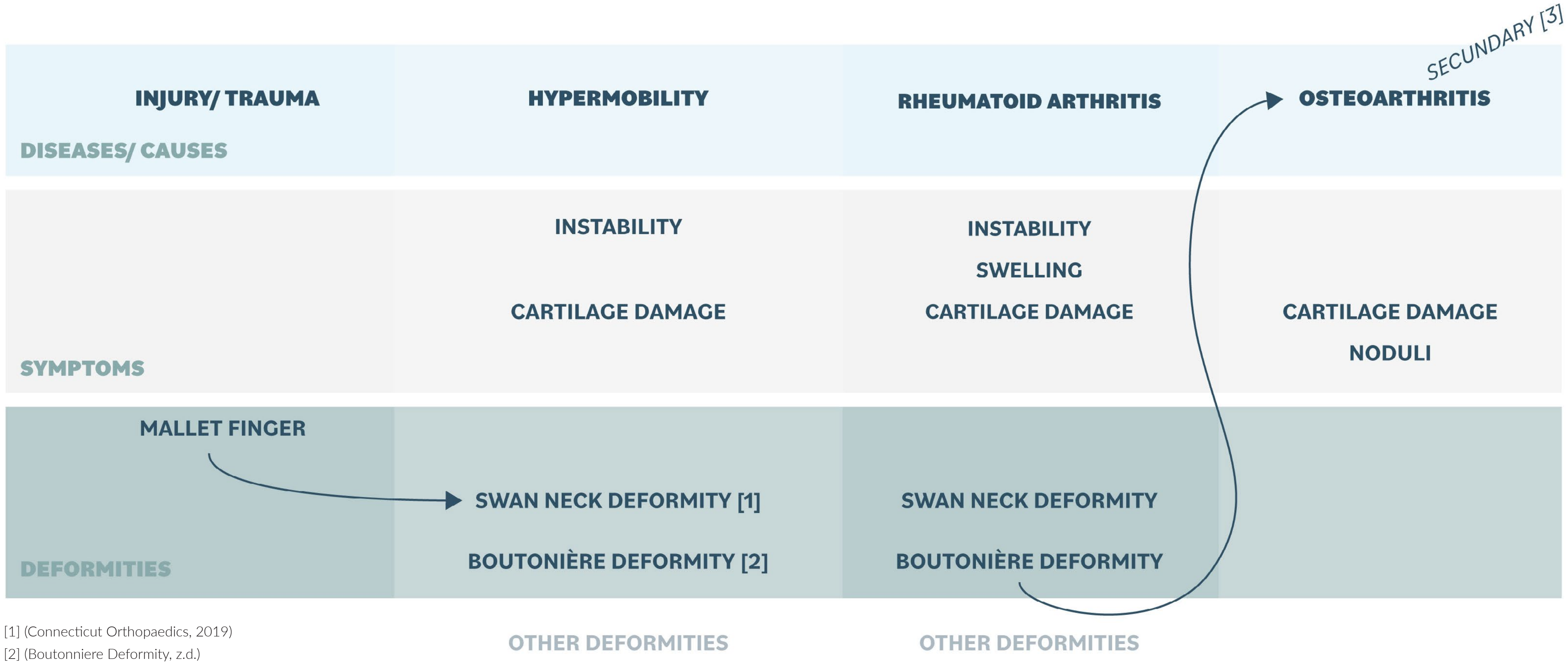


[Image 10] BHD and SND thumb (Boeckstyns, 2016)

Ulnar deviation is located in the MCP joints of the fingers and is characterized by the fingers drifting towards the ulna.

With a swan neck deformity, the PIP joint is in hyperextension and the DIP joint in flexion. The reverse is happening with a Boutonnière deformity, where the DIP joint is in hyperextension and the PIP joint in flexion.

In the boutonnière deformity of the thumb, the MCP joint is in flexion and the IP joint in hyperextension. With the swan neck deformity the CMC joint adducts, the MCP is in hyperextension and the IP joint in flexion.



[1] (Connecticut Orthopaedics, 2019)
[2] (Boutonniere Deformity, z.d.)
[3] (Stefan Vordenbäumen et al., 2012)

[Image 11] Symptoms and deformities per condition

1.2.4 – Thumb splint

Thumb splints are designed to stabilize joints irrespectively of the condition. Therefore, the same splint could be used for people with RA, OA and EDS. In the base, there are three possible joint involvements when it comes to thumb splint design, the CMC, MCP, and the IP joint. For RA and OA there could be also adduction of the thumb (see image 7). These four occurrences vary in composition and could occur independently as well. In order to cover the variation, multiple thumb splint designs are needed. For now, the most interesting case would be the CMC/ MCP stabilization splint with thumb abduction. This splint covers three of the four occurrences and is often used for people with RA who show a swanneck deformity. The splint has to stabilize the CMC joint, abduct the metacarpal, and place the MCP joint in slight flexion (Beasley, 2014).[R4]★

1.2.5 – Conclusion

To conclude, patients with EDS have instable joints, but not necessarily deformed fingers. Finger deformation does happen in OA, but this is less common and is often a result of RA, called secondary osteoarthritis (Stefan Vordenbäumen et al., 2012). Patients with rheumatoid arthritis show more complex cases with regard to hand deformity and additional symptoms like fatigue and pain in other joints which will affect the splint process and possibly the splint design. As a result, once the product-service combination has been validated in this patient group, it will also function for patients with OA and EDS.[R5]★ Furthermore, RA is a symmetric polyarthritis which means that it will affect multiple joints in both hands. In order to cover all resulting deformations, it is recommended to develop multiple splints for at least the previously described finger deformations.[W1]★ Moreover, arthritis in other joints that affect the product-service combination should be taken into account.[R6]★ Finally, the CMC/MCP splint shall be taken as starting point for the design of the product-service combination.

1.3 – Current thumb splints

1.3.1 – Introduction

There is a large variety of thumb splints on the market. Depending on the specific finger problems, the splint stabilizes, decreases the range of motion or immobilizes the joint completely. In this chapter, the current solutions will be discussed and the competitors in the field of computational silver splints are pointed out. Moreover, a distinction is made between craft production, mass production and personalized production.

1.3.2 – Current thumb splint solutions

Currently, there are many splints available on the market. It varies from simple finger stockings, prefabricated plastic splints, and splints with Velcro to high end personalized silver splints. In the table below, the three most common and innovative CMC/MCP thumb splints will be compared of which inspiration can be taken for the splint design. There are both handcrafted and computational designs available and the splints vary in shape, material, cost, time, durability, appearance, hygiene, complexity, and production method.

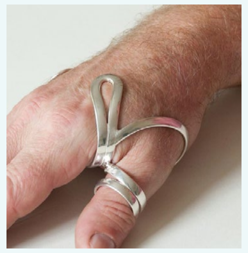
These five variations on the thumb splint give an indication of the current splinting solutions and their (dis)advantages (see image 12). First, the Orliman thumb splint is a prefabricated plastic splint. Orliman offers three sizes: small, medium, and large. The splint can be formed substantive with a fohn into the patients hand shape, which improves the fit.[W1]★ The disadvantage of this splint the the bulky and fleshy appearance.

The second, Novamed thumb brace is also a splint for the CMC and MCP joint of the thumb. The splint is fastened with Velcro and there are five available sizes. The advantage of this splint is that the splint is easy accessible and can be worn immediately. It is a robust splint which cannot break.[R1]★ However, the downside of this splint (and the Orliman splint) is that it covers a large area of the hand, which will obstruct the overall hand functionality.[R2]★

The third splint is a silver splint from WE design which is hand made and personalized. The downside of this splint is that it takes several weeks to produce and expert knowledge and tools are needed to adjust the shape. Moreover, the splint is about ten times more expensive than the splints on the left side of the table. This is due to the use of silver which is a precious material. On the other side, silver is a very aesthetic and durable material and because of the smooth surface also easy to clean and therefore hygienic.[R3,4]★

The fourth splint, from Artus3D, is also a personalized silver splint, but approached via digital modelling and fabrication. 3D scanning techniques are used to personalize the splint and it is produced with the lost wax method.

The last splint, is a splint from Manometric. This splint plays with other materials and even though it is not made of silver, it still has the jewel like appearance. Furthermore, they maintain the same digital modelling and fabrication approach as Artec3D. The drawback from these last two splints is that it requires a lot of time to setup the parametric design and the production time is around the same as the manually fabricated silver splints. However, there is more room for automation in the digital approach and thus the production can be speeded in the future.

FIT	Sizing system (e.g. xs, s, m, l)		Personalized splints		
THUMB SPLINT					
TYPE	Orliman thumb splint	Novamed thumb brace	WE design silver splint	Artus3D silver splint	Manometric splint
MATERIAL	Thermoplastic	Fabric and Velcro	925 sterling silver	925 sterling silver	Plastic
COST	€28,98	€34,95	€300 - €400	€300 - €400	€?? - €??
TIME	Instant	Instant	~3 weeks	~3 weeks	~3 weeks
DURABILITY	Plastic becomes dirty and dull over time	Velcro and fabric wears out over time	Highly durable	Highly durable	Highly durable
APPEARANCE	Clinical	Robust	Jewel like	Jewel like	Jewel like
HYGIENE	Retains moisture and dirt	Retains moisture and dirt	Smooth surface	Smooth surface	Smooth surface
COMPLEXITY	Buy and wear with small substantive adjustments	Buy and wear	Time consuming measure and fit procedure	Time consuming fabrication	Advanced measurement equipment
PRODUCTION	Mass fabrication Thermoforming	Mass fabrication	Handmade Silver bending	Computational design and silver casting	Computational design and plastic casting

[Image 12] Comparison table of current thumb splints

1.3.3 – Conclusion

The advantage of splints with a sizing system, on the left side of the table are that they are cheap, quickly accessible, and they have mechanisms and materials that allow shape adjustments. Unfortunately the splints cover a large area of the hand which results in a diminished hand functionality. On the other side, the personalized splints are personalized, aesthetically more pleasing, durable, and they are eligible for an automated design process which could speed up the splinting process in the future. The downside of these splints are the high costs.

1.4 – The current splint procedure

1.4.1 – Introduction

When introducing a new product-service combination it is important to understand how the current splinting procedure works. The typical procedure for a hand crafted silver splint is taken as example (see image 13).

The preliminary work for the splint is done by an occupational therapist, but the final silver splint is made by an orthopedic instrument maker. In this chapter, the steps of the current splint procedure are described. The whole procedure takes two to three weeks to complete but for complex splint shapes it takes more time.[R1★]

1.4.2 – Current splint procedure

Splint treatment and taking measures

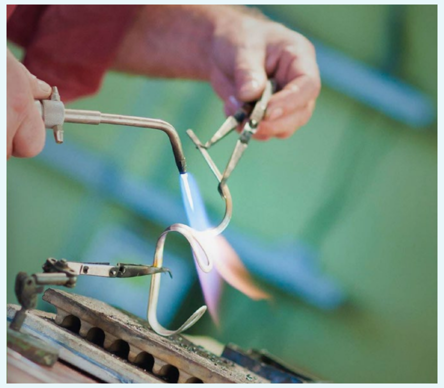
With the advice of the **occupational therapist**, a medical specialist (e.g. orthopedic surgeon) refers the patient to an orthopedic instrument maker. The **medical specialist** transfers all the necessary information regarding the patients condition and possible splint solution. Also, a referral is send to the **insurance company** since they cover most of the costs.

Together with the patient, the **orthopedic instrument maker** discusses the specific user requirements. For example, Being able to garden or play the piano might mean a lot to a patient and therefore the splint should not hinder those activities.[R2★] In that case one splint might be preferred over another.

After the patient and information transfer, the orthopedic instrument maker picks a splint from the producers' catalog and takes the measures of the patient. The measures of the hand are taken with a caliper and the fingers are measured with sizing rings. In more complex cases, a plaster cast is taken.

Splint producer

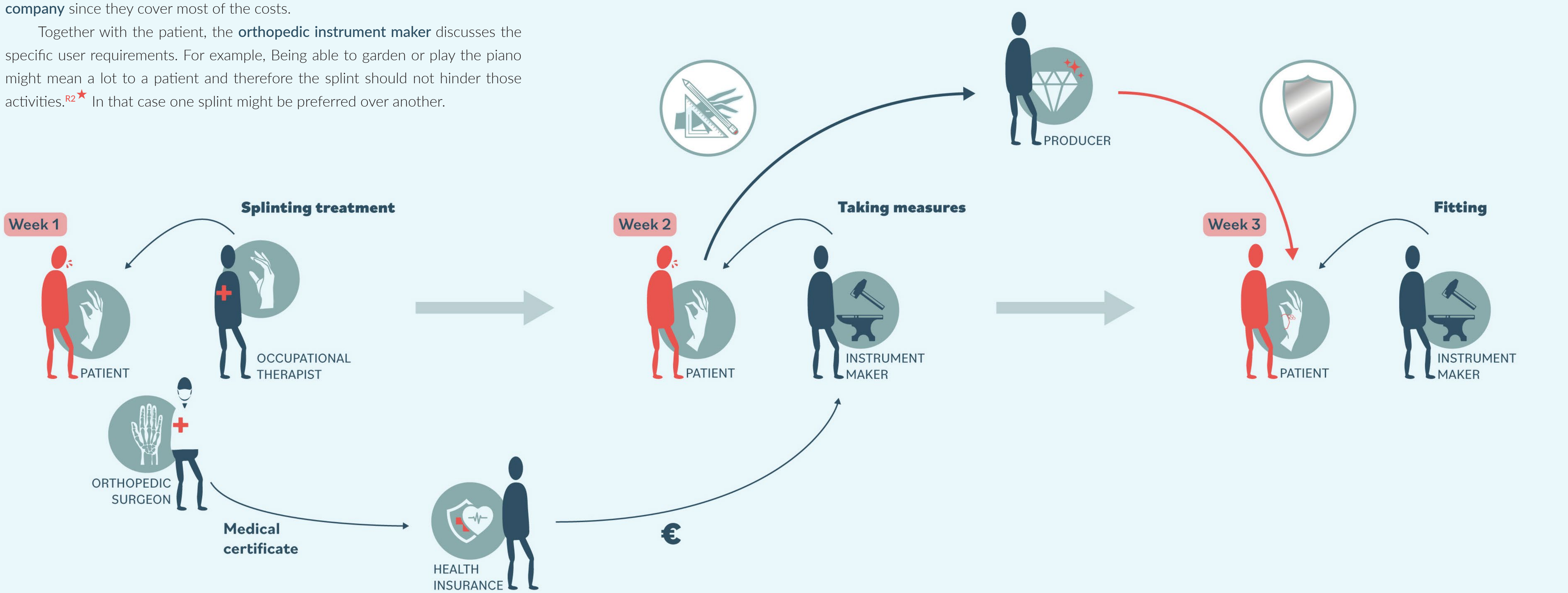
The splint producer is a party like WE Design who is specialized in the fabrication of medical aids made of silver. With the measures, the producer creates the personalized silver splint. The splint is made of 925 sterling silver wire and is heated and bend into the right shape (see image 14).



[Image 14] WE Design, splint production

Fitting and adjusting splint (several times)

After three weeks of production, the patient returns and the **instrument maker** fits the splint according to his/ her handshape. The patient should be able to make a fist, stretch the fingers, and make an 'okay' hand gesture. With these hand gestures, pressure points are located and can then be remedied. During daily life activities there will occur more pressure points and discomfort, therefore the patient should come back several times to have adjustments made. [W1,2★]



[Image 13] The current splint procedure

1.5 – The care path

1.5.1 – Introduction

Understanding solely the clinical picture and what is on the market will not be sufficient when designing a product-service combination. Human centred design starts with analysing the needs of the patient and understanding the system he or she is part of (Melles et al., 2021). It will give insight in who is involved in the decision making of the patient. To map the patient needs and the involved caregivers into a patient journey and care path (see image 15 on the next page), interviews with patients (n=2), an occupational therapist (n=1), and WE Design (n=1) were held. The interview questions and notes can be found in the appendices 2-4.

Awareness and ask for care

The patient journey starts with the patient who becomes aware of his or her physical dysfunction and decides to visit an ***general practitioner***. A general practitioner can do a physical examination, prescribe medication (e.g. painkillers, NSAIDS), and refer the patient to a physiotherapist, rheumatologist or directly to a surgeon.

Diagnosis and treatment

The process of seeing many specialists and making a diagnosis brings insecurity and worries for the patient. At this stage, communication between specialists and between the patient and specialists is key. The feeling of gratefulness and relief is predominant, since the patient is treated for his/ her condition.

> P2; 'I didn't have any rehabilitation following surgery 10 years ago whilst I should have, now I make sure that the rehabilitation doctor and neurologist keep in touch.

A ***physiotherapist*** helps the patient with performing exercises to reduce stiffness in the joints and to increase their range of motion (De fysiotherapeut, 2021).

A ***rehabilitation doctor*** aims to prevent disabilities or to minimize disabilities caused by traumas, diseases or conditions, so that the patient can function optimally in the society. The rehabilitation doctor coordinates the rehabilitation process and maintains contact with other medical specialists and the general practitioner.

With a more complex clinical picture, the ***rheumatologist*** in association with the ***rheumatism nurse*** could do a blood examination or take x-ray photos for a better diagnosis and treatment plan. In case of rheumatoid arthritis, the first step is to reduce inflammation with medication treatment (Behandelaars •, 2021). The rheumatologist could also decide to refer the patient to a surgeon or occupational therapist.

Depending on the diagnosis and the goal of the patient, an ***orthopedic or plastic surgeon*** decides to treat the rheumatoid arthritis with an anti-inflammatory injection or surgery . During a surgery it is possible to clean, completely secure, or replace the joint by a prosthesis. Also, the surgeon can refer the patient to a rehabilitation doctor, physiotherapist or occupational therapist after (or without any) treatment (Behandeling van reuma aan hand of pols, z.d.).

Therapy and splinting

The ***occupational therapist (OT)*** or ***hand therapist*** helps patients to perform and adjust their daily activities so that they can manage their disability caused by a certain condition. The OT could advise medical aids and facilities or supervises taking up work and hobbies. In some cases the occupational therapist fits a temporary (half a year maximum) splint to see if it reduces complaints and how it affects the patients' daily life (LUMC, 2014). When the OT together with the patient decides to go for a silver splint, a specialist like a rheumatologist, surgeon or rehabilitation doctor needs to write an official referral for the splint. This is necessary for insurance companies to (partially) reimburse the costs of the splint.

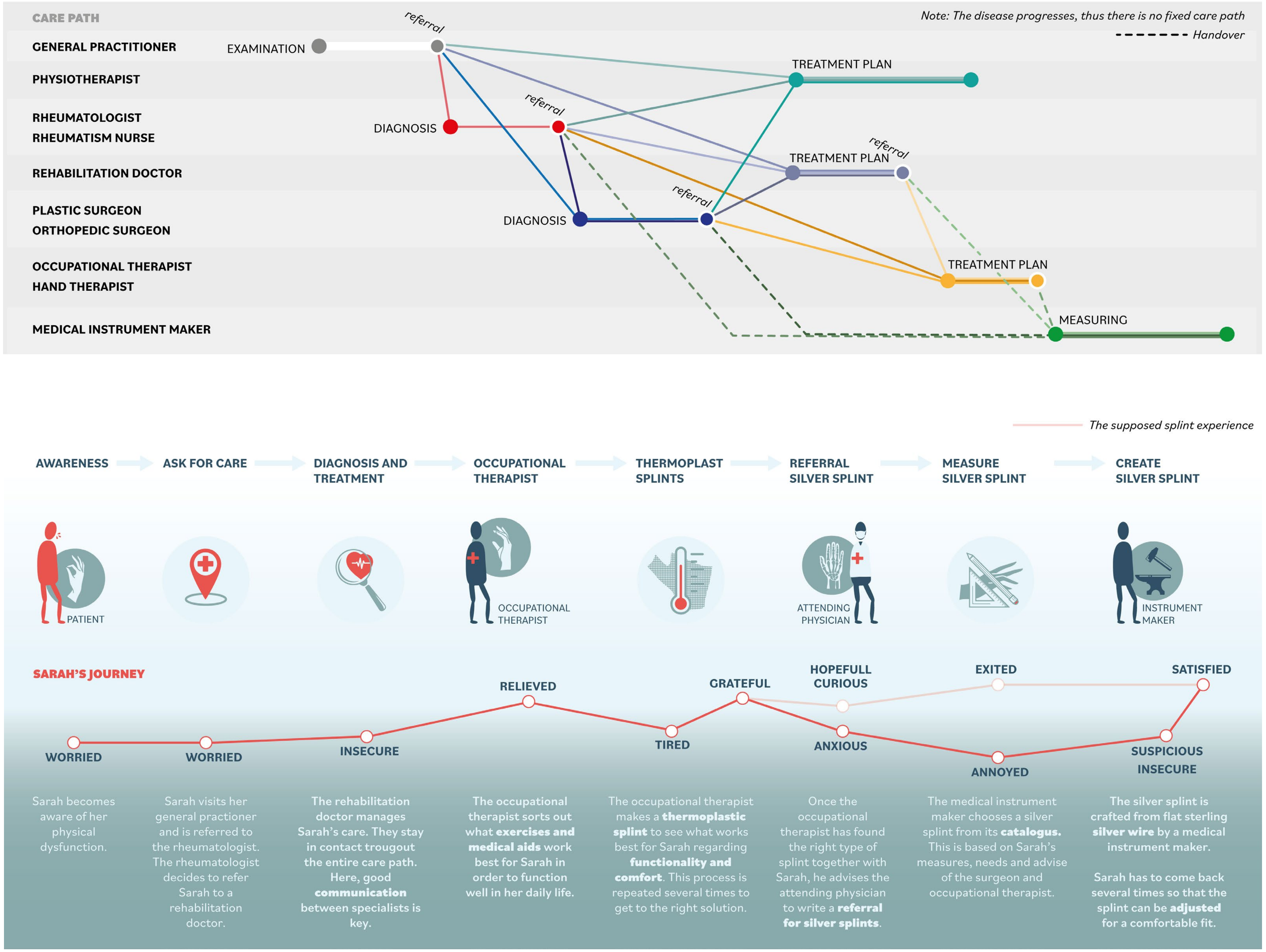
Silver spints are made by a producer like WE Design and fitted by ***orthopedic instrument makers*** who are closely associated with medical specialists (Het aanmeten van je pols-/handorthese, z.d.). The transfer of a patient from the OT to an orthopedic instrument maker is cumbersome, involves uncertainty, and sometimes even annoyance. This is in contrast with the curiosity and excitement that the patient experiences when he/ she qualifies for a silver splint. Throughout the patient journey, the occupational therapist is closely involved with the patient and his/her condition and needs regarding his/her daily life activities. This is a person that the patient usually trusts.

> P1; 'I find it annoying that the instrument maker does not know exactly what my medical background is.'

Therefore, in the new product-service combination for a splint ring, the process should be designed around the occupational therapist in order to reduce uncertainty, process steps, and to increase trust.[R1] ★

1.5.2 – Conclusion

The current patient journey and care path involves many parties. From medical specialists and therapists to splint producers and instrument makers. Seeing so many faces throughout the process results in insecurity from the patients side. When it comes to splinting, the occupational therapist understands the medical condition and knows what the patient needs with respect to their daily life activities. Currently, it happens too often that the patient does not have any contact after splinting with their OT, which makes them wonder if the function and fit of their new splint is right. Therefore, a closer bond between patient and OT is recommended and the future splint process should be designed around the OT.



[Image 15] The carepath and patient journey

1.6 – Competitor analysis

1.6.1 – Introduction

[Image 16] WE Design

For a proper competitor analysis, a distinction between craft production, mass production, and personalized production is made (Veza et al., 2013). When mass production meets personalization, we speak of mass customization and in this field digital modelling and fabrication techniques are increasingly important.

Furthermore, the competitive positioning is determined by the medical network and the lead time of a splint, which is also influenced by the level of automation (more towards mass production).[W1★] The three main parties that engage in this field are WE Design, Manometric, and Artus3D (see image 19).

The key aspects of personalization are further discussed in chapter 1.8 - Ultra Personalized Product and Service design and the workflow for personalized products is introduced in chapter 1.9 - Digital modeling and fabrication.

1.6.2 – Competitors in the field of personalized thumb splints

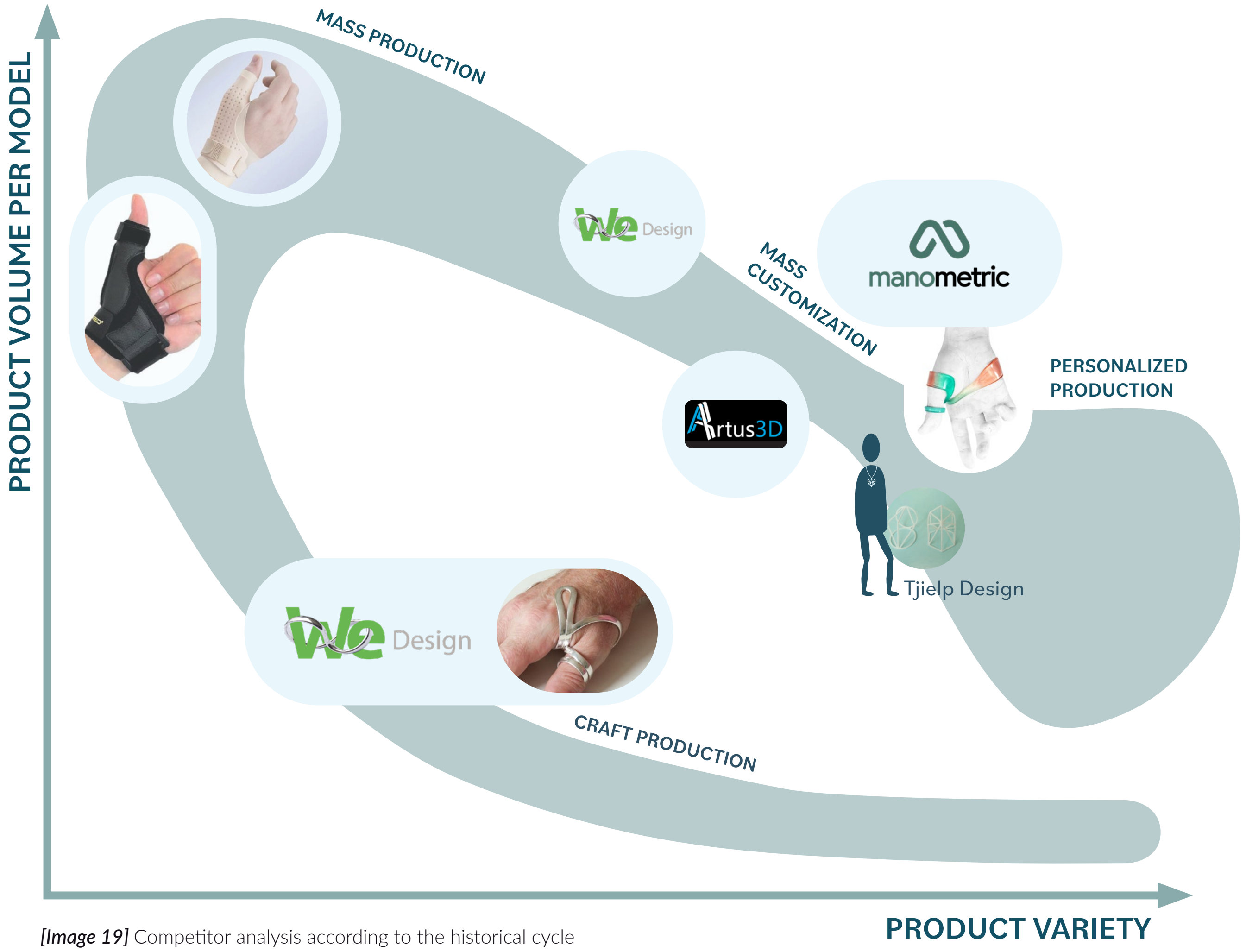
[Image 17] Manomatric

WE Design is an established silver splint supplier and is finding it's way from hand crafted splints to computational design (see image 16). For the less complex silver splints, like the rings, WE design makes use of computer aided design. The finger sizes are uploaded into the computational design and a well-fitting ring is fabricated afterwards. Regarding the more complex thumb and wrist splints, their procedure remains manual labor.

Manomatric is an odd one out, they are not part of an orthopedic center but they do have a fair amount of computational personalized splint ring designs (see image 17). The splints come both in silver and transparent plastic.[W2★] Next to the splint rings, they develop personalized CMC/MCP thumb splints made of a combination of colored plastics and one that is made of transparent plastic. The personalization of these splints is done using a hand 3D scanner. Manometric has developed the hand 3D scanner themselves and it is not available on the market, which benefits their position regarding personalization.

[Image 18] Artus3D

Thirdly, **Artus3D** is a spinoff of center orthopedics Rotterdam and they develop multiple computer aided and personalized finger and thumb splints (see image 18). They have a strong position since they are part of an orthopedic center and have knowledge on how to develop computational personalized silver splint designs (see appendix 5: Interview Wybren ten Cate).



[Image 19] Competitor analysis according to the historical cycle of manufacturing paradigms (Koren, 2010)

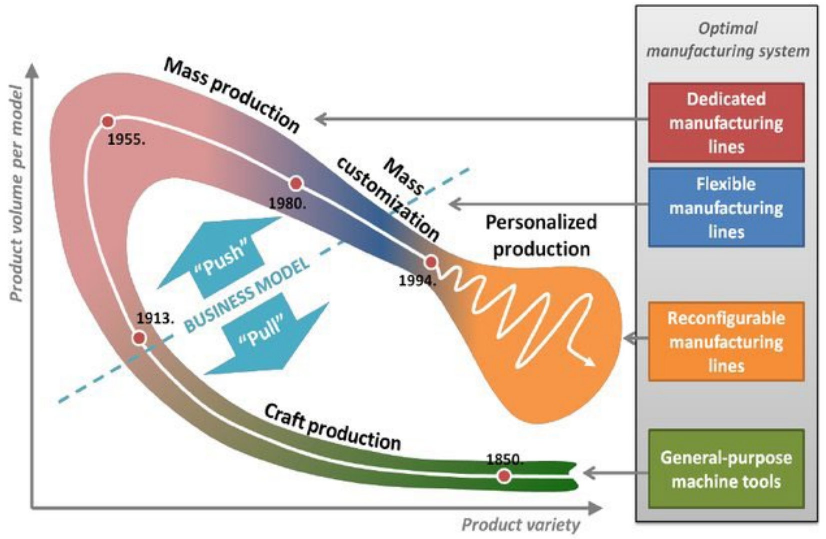
1.6.3 – Conclusion

The emerge of parties like Manometric and Artec3D indicates that there is a strong demand for computational personalized splints. What can be learned from these parties is that, on a product level, material choice is important to guarantee a certain level of quality with regards to durability and aesthetics. An automated splint process largely determines the viability and feasibility of the product-service combination. With regard to the context in which the service design exists, it is nearly impossible to compete in this field without arrangements with insurance companies. Moreover, a medical network is strongly recommended as this is where the sales market is to be found.[R1★] Lastly, non of the field's competitors emphasize on customization. Tjielp Design has therefore a great opportunity to enter the market with personalized splints which can be customized in collaboration with the user.[R2★]

1.7 – Ultra-Personalized Product Service Systems

1.7.1 – Introduction

Personalization in product design used to be very expensive and not for everyone. Nowadays, there is a trend toward mass customization, in which production capacity is raised so that ordinary people can obtain customised products at a reasonable cost (Koren, 2010), (Torn & Vaneker, 2019). Image 20 below, shows how the manufacturing paradigms changed over time.



[Image 20] Manufacturing paradigms (Koren, 2010)

But how do we define ultra-personalized product service systems (UPPSS)? Ultra personalization goes beyond 'the action of designing or producing something to meet someone's individual requirements' (Oxford Languages) by combining data and digital modeling and fabrication techniques. Fore example, Nachtigall et al., (2020) envisions a near future where shoes are personalised using algorithmic, parametric, and generative systems that are data-driven.

These 'individual requirements' of personalization can be divided into three different aspects: identity, capabilities, and fit. These aspects can be used as guidance throughout the design process and to describe the value of the personalized product design.[R1]★

1. Personalization in **identity** focuses on the perception of the product, where unique product properties (e.g. form, texture, colour, print, smell, taste, sound, feel) are the unique added values for the customers;
2. Personalization in **capabilities** focuses on the functions of the product, where the unique performance of the product is enabled by extra ingredients (e.g., electrical, mechanical, fluidic, and thermal components), demonstrating the added values of the product;
3. Personalization in **fit** addresses the presence of the personalized product regarding the interactions between the product and the consumer, the environments and/or other products that are used by the consumer. Characteristics of the product (e.g. the shape, size, mass, area, amount, quantity, colour palette) and the personalized interactions (e.g. comfort, tailored fit) represent the added values of the personalized products in this category. (addMANU booklet of the TU Delft)

1.7.2 – Accommodating variation

The mass produced thumb splints work with a sizing system that covers the central part of the population size distribution (e.g. xs, s, m, l). In some cases the splint can be altered in a way that it fits the individual better. This is done by fastening Velcro or by applying heat or force onto the material. The advantage of this approach is that the user can make the alterations themselves and don't have to wait for the help of an expert.

A more durable and better fitting solution is a personalized silver splint. With this option the patients measurements are taken at the beginning of the design process and thereafter a splint is made out of silver wire. The majority of these splints are handcrafted and require an expensive and time consuming process. Computational design could take over a part of the expensive and repetitive manual labor and lead towards a more viable solution.[W1]★

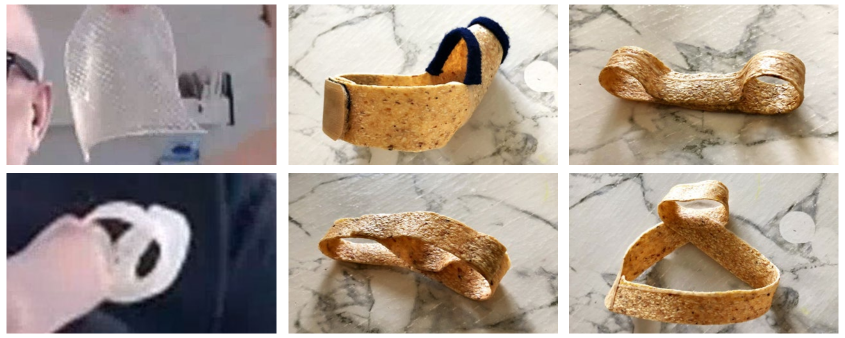
1.7.3 – Materials

The mass fabricated thumb splints are a quick solution for joint trauma, but when it comes to prolonged every day use of splints they are not sufficient. The splints are often made of soft materials to improve the fit and comfort, but these materials retain moisture and dirt. Therefore, it is recommended to look into other more durable materials, with for example a smooth surface that can be easily cleaned.

The current silver splint solutions are made from a 925 sterling silver wire. This is a durable material which contributes to a jewel like appearance and allows for good hygiene and wearing comfort. 925 sterling silver is an alloy of silver and copper, 92,5% and 7,5% respectively. Silver splints can be made with the FDM or lost wax casting fabrication technique. FDM will leave printing marks behind which could either be experienced as disruptive or it can become part of the aesthetic design. Because of that, the lost wax casting method might be preferred. The downside of this technique is that it requires and additional step in the fabrication process and the silver casting process is hard to control. Porosity can be caused by shrinkage and oxygen pickup during melting and casting (Improving Your Silver Casting – Technical Articles, n.d.). Irregularities that arise during casting also increase the risk of material failure. Especially shape adjustments or impact during daily life activities will make the silver splint prone to breaking in the case of porosity, irregularities and brittleness of the silver cast.[R2]★

Exploring combinations of different (breathing) materials, both flexible and rigid, will be interesting to improve comfort and possibly reduce costs. Such a type of splint can be made with the multi-material printing technique.

Finally, inspiration can be taken from the thermoplastic prefabs that the occupational therapist uses to explore the solution space (see image 21). By applying heat the material is easily formed after the exterior surface of the hand. The downside of this material is that the appearance is cheap looking and strongly depends on the artistic eye of the occupational therapist.[R3]★



[Image 21] Thermoplastic splints by Arno Groot

1.7.4 – Conclusion

To conclude, ultra personalized splints should meet the three different aspects of identity, capabilities, and fit. When it comes to identity and a jewel like appearance, silver or a similar precious metal is an obvious choice. But plastics can have a jewel like appearance as well, like we have seen earlier with the Manometric thumb splint. Regarding the capabilities, plastic splints offer an easier to control production process where casted silver splints are more brittle and therefore at risk of breaking as a result of shape adjustments or impact during daily life activities. Therefore, a certain amount of flexibility is required to withstand impact during daily life activities. The fit of the splint is mainly determined by the level of personalization. A sizing system covers a large part of the population and with soft or moldable materials it can be well fitted around the exterior surface of the hand. Even for personalized splints, small adjustments are often needed to reduce pressure points.

1.8 – Digital modeling and fabrication

1.8.1 – Introduction

A digital design approach of ultra personalized product design starts with composing a digital twin. The patient preferences are mapped and the human factors can be digitalized via a 3D scan or approached via a parametric model (SSM, DINED).[W1]★ Once there is a digital twin, various product designs can be made around it in computer aided design (CAD) software like SolidWorks or Rhino/Grasshopper. Design automation in this context means that a product design automatically adjusts to the digital twin of an individual. In this way, a personalized design doesn't have to be made separately for every individual.[R1, W2]★ Thereafter, digital fabrication techniques allow for quick production of the product design. A co-production of humans and robots automate the design process further (see image 23).

1.8.2 – Stakeholder collaboration

According to Nachtigall et al., (2020), UPPSS is a personalised, multi-stakeholder PSS that embraces four primary phases: Co-Analysis, Co-Design, Co-Manufacturing, and Co-Use. Since it is a multi-stakeholder process, there are additional challenges regarding the communication and data processing. Starting with co-analysis: how are the patient's particular preferences and expert advice converted into design parameters? Then, co-design and co-manufacture which are the processes where the gathered data is used to design and manufacture a personalized splint, most likely geographically near the patient or the attending physician. Finally, during co-use, information about the use of the product is gathered. The collected data must be saved and communicated to other stakeholders in the process across all four phases. As a result, the process remains clear and easy to trace for all parties involved.[R2]★

1.8.3 – Digital modeling

Nowadays, many manual tasks are taken over by computers. The same accounts for design where computational design is playing an increasingly important role. Computational design means designing with the use of computing power. Before, trying out different sizes, colors, or patterns used to be done manually. With the use of computational design and by encoding boundary conditions or design rules the computer does this for you. Therefore, this design approach makes it possible to easily explore design iterations.

A personalized design is in essence the same for every individual but differs in size and shape. Making these adjustments manually for every design is cumbersome and requires expensive manhours. With a computational design approach these repetitive tasks could be automated. The workflow for designing personalized products is as follows (see image 22).

The workflow starts with defining the design requirements. These requirements will be derived through analysing the product-service system and conducting additional research. Thereafter, a template for the computational design can be made. This template should match the design parameters that are derived during the data and parameter acquisition. The required data resembles the individual body dimensions. Further iterations on this template are informed by the data and parameter acquisition, the chosen manufacturing technique, and the product evaluation. The manufacturing technique determines the requirements for the computational design. It also affects the appearance and costs of the product service-system. Finally, the product-service system should be evaluated with the user. This information is used to iterate on the computational design and to finalize it.

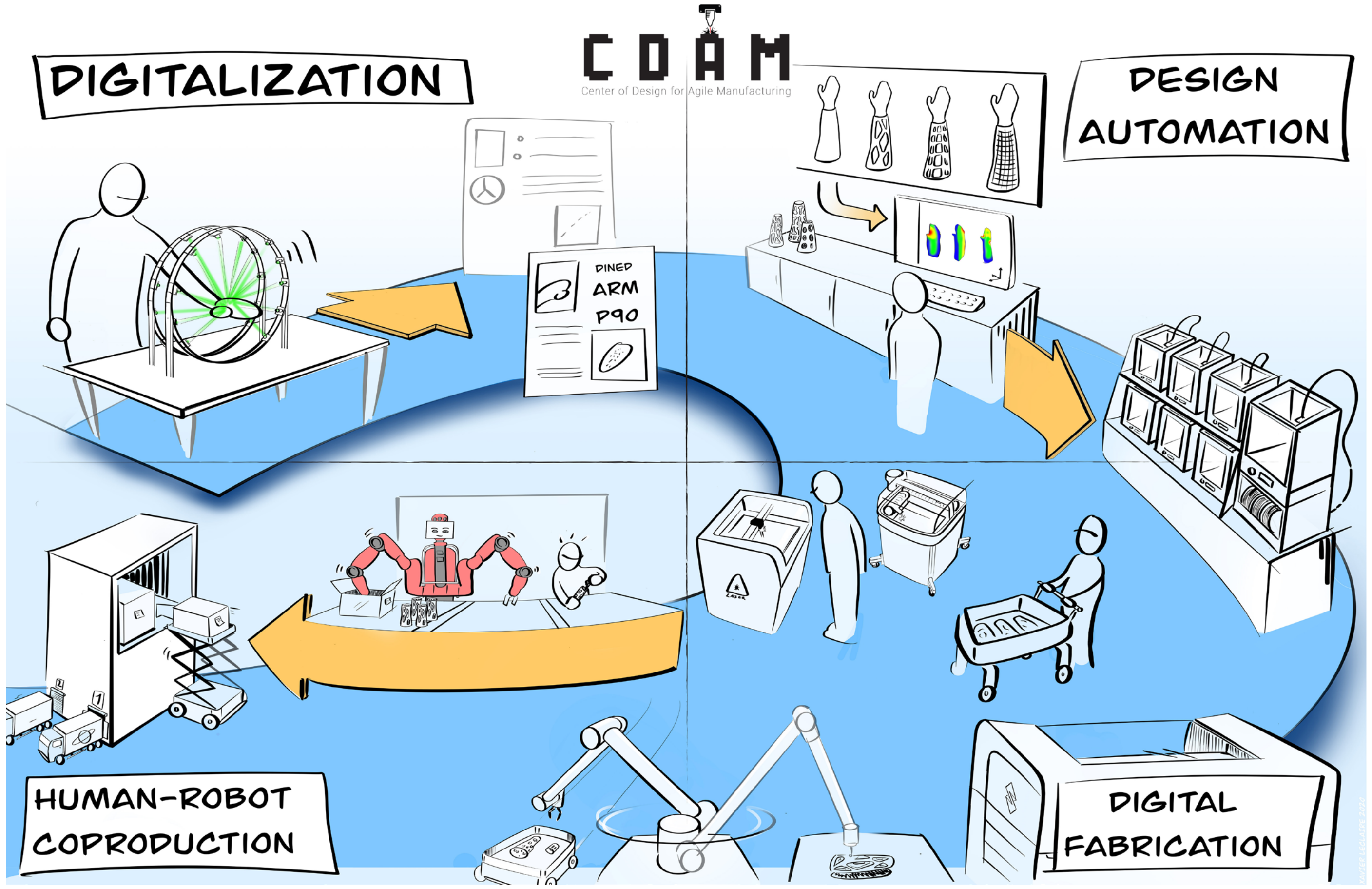
[Image 22] The workflow for designing personalized products

1.8.4 – Digital fabrication

Once the personalized design is finished, it is taken into production. Digital fabrication techniques are interesting in terms of automation because the machines are controlled by a computer. This simplifies the step from computational design to a tangible product design. Moreover, digital fabrication techniques like: subtractive manufacturing (e.g. milling, turning and drilling), additive manufacturing (e.g. Fused Deposition Modelling (FDM), Stereolithography (SLA) and Selective Laser Sintering (SLS)) and multi-material printing are interesting when it comes to small batch sizes. Especially in the case of personalized product design where every product will be fabricated only once.[R3]★

1.8.5 – Conclusion

Digital modelling and fabrication techniques are strong tools when it comes to automation of ultra personalized product design. It will reduce or even eliminate repetitive manual tasks and simplify the exploration of design iterations. However, the collaboration between the different stakeholders involves additional challenges with regard to the translation of stakeholder preferences into design parameters and the communication, processing, and storage of the gathered data. The workflow of personalized products offers guidance during the design process.



[Image 23] Design for advanced manufacturing made by the TU Delft

1.9 – 3D scanning in personalized orthosis design for patients with rheumatoid arthritis

[Image 24] 3D printed support for palmar scanning (Baronio et al., 2017)

1.9.1 – Introduction

Splinting is proven to be an effective treatment in early stage finger deformities. When the deformities are still passively correctable, finger orthoses are functional in stabilizing or fixating the affected joints. Currently, measurements for orthoses are mostly taken by hand. For more complex orthoses plaster casts are used to create the orthoses around. This method is useful for getting precise measurements, but it is inconvenient because of model storage and transit (e.g. a lab or makerspace) (Haleem & Javaid, 2019). A higher accuracy and efficiency can be obtained via 3D scanning technologies.

There is an emerge in 3D scanning technologies for personalization of orthoses. Where measurements for orthoses were mostly taken by hand, nowadays 3D scanning has shown to be a successful method of personalizing orthoses. In a review of 3D scanning applications in the medical industry, Haleem and Javaid (2019) write that 'It is vital for the medical field as it captures external measurements of the body in less time, cost and better manner'. Also in practice, the concept of 3D scanning is proven by companies and startups like Manometric, Artus3D, and Exo-l who develop both 3D scanners and orthoses based on 3D scans.

The current 3D scanning solutions, on the other hand, are limited to relatively simple body components, like the ankle, wrist, and a 'normal' thumb base. On the contrary, the disease of patients with rheumatoid arthritis (RA) involves additional challenges. RA is an inflammatory disease causing joints to degrade over time (Grassi et al., 1998). Because of the muscle weakness, swelling, pain, joint stiffness, and fatigue as a general symptom of RA (Grassi et al., 1998), it is sometimes impossible for the patient to hold the desired splinting position independently. 3D scanning aids to position the fingers and thumb could be helpful in this case. Regarding 3D scanning aids, inspiration can be taken from a research in 2017 where they designed a 3D printed support for palmar scanning (Baronio et al., 2017) (see image 24).

The position of the hand in which the 3D scan is obtained will affect the usability and the quality of the 3D scan. Ideally, the hands are fixed in the right splinting position without compromising on the scan result. For finger splints this implies that the affected finger(s) should be separated from the rest and a hand position with the fingers slightly bent (approx. 20 degrees) is ideal. Regarding the thumb, a MCP/CMC stabilization splint has to stabilize the CMC joint, abduct the metacarpal1, and place the MCP joint in slight flexion (Beasley, 2014). Therefore, the most functional position of the thumb is in pinch grip (see image 25).[R1]★

Personalization goes beyond taking accurate measurements of the patient's hand. It also involves the measuring procedure itself. This procedure should take

[Figure 25] Ideal splint posture with stretched fingers (left) and in pinch grip (right)

into account the patient's needs and challenges. They need a quick 3D scan procedure that requires little energy. The main challenge is to hold the preferred splinting position due to desease activity, pain and loss of handfunction. Requirements regarding these are subtracted from the 3D scanning research in chapter 3.2.3.[R3D.1-4, W3D.1-4]★

1.9.2 – 3D scanning techniques

Data and parameter acquisition is one of the first steps in the workflow of personalized products. How this is done will define the ultimate level of personalization and fit of the product design. Besides the impact on product level, the manner of data and parameter acquisition will greatly determine the measuring procedure and how the patient experiences the whole process. The important questions remain: What are the requirements for a 3D scanner for this application? Is it possible that the patient collects the anthropometric data at home by themselves with for example a smart phone? Or should it be outsourced to a 3D scanning company? This will be discussed in the following chapter.

Te current landscape of 3D scanning technologies is extensive and continues to grow. There are smart phone applications, hand held 3D scanners, full body scanners, and foot scanners available. Besides, there is a growing interest in hand scanners. To give some more insight, five different scanners will be compared in the following paragraphs.

Starting with the Artec Eva 3D scanner in the first column of the table in image 26. This device has a high resolution and is easy to use. The scanner is especially applicable for anthropometric analysis where an accurate 3D image is required. The downside of this 3D scanner is the high product price and long scanning time.[W1]★

An alternative for the Artec Eva is the considerably cheaper XBOX Kinect sensor. The downside of this 3D scanner is that it is not designed as 3D scanner which means that the software and the support could be inadequate.

The **Structure Scanner Pro** resembles the XBOX Kinect but is smaller, lighter and more user friendly. It has a lower resolution than the Artec Eva but most likely sufficiently accurate for obtaining 3D scans of the hand for orthotics design (Redaelli et al., 2021). The device itself is relatively cheap, but it requires a tablet.

Then there are **smart phone applications** that make use of LiDAR technologies. In theory, this would be ideal since the patient is be able to collect the anthropometric data at home. However, making a good 3D scan remains a challenge and also the accuracy seems too low for a good representation of the hand.

Finally, the **Curatio hand scanner** has a lot of potential since this would be the first hand scanner that makes a 3D scan in the blink of an eye. This particular 3D scanner is still being developed, therefore the exact specifications are not yet public.

The comparison of these 3D scanners gives an idea of what is (or will be) possible within the current landscape of 3D scanning technologies. The Structure Scanner Pro came up as the best option since it has a reasonable accuracy, especially considering its low costs. Moreover, it is a small hand held device which can be used by everyone owning a tablet. Instead of outsourcing the data and parameter acquisition, it is possible to hand over this step in the process to the attending physician like an occupational therapist. The Curatio is used by Manometric and the Structure Scanner Pro by Artus3D, which indicates that the accuracy of the 3D scan is sufficient.[R2] ★

1.9.3 – Conclusion

3D scanning in personalized orthosis design is challenging due to the absence of 3D scanning devices that are particularly designed for hands. furthermore, the research on '3D scanning in personalized orthosis design for patients with rheumatoid arthritis pointed out that there is need for an instant 3D scanning solution which captures the hand 360 degrees. The curatio hand scanner is the first existing 3D hand scanner that could do the job, but it is not on the market yet. For now, the most affordable 3D scanner with a reasonable accuracy is the Structure Scanner Pro.

3D SCANNERS					
TYPE	Artec Eva	XBOX Kinect	Structure Scanner Pro	LiDAR	Curatio
SIZE	262 x 158 x 63 mm	381 x 119.4 x 147.3mm	109 x 18 x 24mm	146.7 x 71.5 x 7.4 mm	N/A
WEIGHT	900 g	572 g	65 g	162 g	N/A
ACCURACY	0.1 mm	N/A	1.30 mm RMSE	LOW	1 mm
TIME TO SCAN	~20 - 40 sec	~20 - 40 sec	~20 - 40 sec	~20 - 40 sec	0.01 sec
TECHNOLOGY	Structured light	IR pattern triangulation	IR pattern triangulation	LiDAR	Photogrammetry
PRICE	€ 13.700,-	€ 100,-	€ 528,-	€ 799,- (Iphone 12)	N/A
REFERENCES	(3D Object Scanner Artec Eva | Best Structured-Light 3D Scanning Device, z.d.)	(Redaelli et al., 2021)	(Structure by Occipital - Give Your iPad 3D Vision, z.d.)	(APPLE iPhone 12 - 64 GB Zwart 5G, 2021)	(Curatio A Low-Cost amp; Dedicated 3D Hand Scanner, z.d.)

[Image 26] 3D scanner comparison table

1.10 – Conclusion

The three main conditions in which joint problems occur are, ehlers danlos syndrome, ostheoarthritis, and rheumatoid arthritis. Because of overly flexible ligaments and tendons, wear and tear, and degradation of the joints, the patients that have one of these conditions are in need of splints. These can reduce stress on joints, stabilize joints, decrease the range of motion, and/or prevent erosion and deformities. Patients' hands are often painful, stiff, and swollen. Additionally, the patients can experience hypermobility or arthritis in other joints, which will further affect the product-service combination. An extra level of difficulty for product-service design is that the symptoms do not only differ per condition, but also per patient. Within the scope of this master thesis, the MCP/CMC stabilisation splint is chosen as starting point since it involves multiple joints and the thumb is more complex to splint compared to the fingers. This will pave the way for future and less complex finger splints to expand the amount of splint types.

The current MCP/CMC stabilisation splints that are available on the market distinguish themselves in the extent of personalisation. There are splints with a sizing system, which are cheap, quickly accessible, and they have mechanisms and materials that allow shape adjustments. On the other hand, there are personalized splints, which are aesthetically more pleasing and durable. An example of a personalized splint is the silver splint from WE Design. Their process remains manual labor which takes three to four weeks to complete. This is a time consuming process, which demands a lot from the patient in means of energy and time. This in relation to a patient journey and care path that involves many parties and appointments already, indicates that there is need for an improved splinting process. The future splint process must be designed around the occupational therapist since he/she understands the medical condition and knows what the patient needs with respect to their daily life activities. This will enable a more centered splinting process and an improved patient experience.

The emerge of parties like Manometric and Artec3D indicates that there is a strong demand for computational personalized splints. The automation of these splint processes largely determines the viability and feasibility of the product-service combination. In addition, a medical network is indispensable and it is a must to have arrangements with insurance companies. Finally, non of the field's competitors emphasize on customization. Tjielp Design therefore has a great opportunity to enter the market with personalized splints which can be customized in collaboration with the user.

As mentioned before, the variation in conditions, manifestation, and symptoms per patient ask for tailor made care. Ultra personalisation lends itself perfectly for the design of this product-service combination so that merely all patients can be included. The three aspects of Ultra personalization are identity, capabilities, and fit. All three aspects are largely affected by the material choice. A material says a lot about the user: is he/she pragmatic, elegant, or likes to stand out? Also the mechanical properties are largely determined by the material choice. Finally, moldable materials enable shape adjustments. This will improve the fit. However, the fit of the splint is mainly determined by the level of personalization. Nonetheless, for personalized splints, small adjustments have to be made to reduce pressure points.

An ultra personalized design approach requires digital modelling and fabrication techniques. Computational power will speed up the exploration of design iterations and eliminates repetitive manual tasks through automation. Another aspect of ultra personalization is the collaboration between different stakeholders. This enables a richer design process and a more complete design in the end. However, data processing and sharing data between the different stakeholders will be challenging.

The iterative workflow of personalized products offers guidance during the design process. It starts with listing the design requirements, followed by data and parameter acquisition, the computational design, design for manufacturing, and finally the design evaluation. Regarding the data and parameter acquisition, this is commonly done with 3D scanning technologies. However, 3D scanning in personalised orthosis design comes with additional challenges for patients with pathological hands, like patients with rheumatoid arthritis. In general, but especially for this patient group, there is need for an instant 3D scanner that is designed for hands specifically.

The insights that were gained throughout this phase are converged into design drivers and a design vision in the next phase. Applying a focus in the design process will help in efficiently designing a new product-service combination.

CHAPTER TWO

DEFINE PHASE

Contents

2.1 – Introduction

The goal of the define phase is to converge all the information that was gathered during the discover phase into manageable chunks. This will make filtering the crucial features that will inform the design much easier.

A wide understanding of the clinical picture, patient demands, current technologies, and the current market was gathered throughout the discovery phase. A revised problem statement in the form of design drivers and a comprehensive design vision emerged from this. The design drivers are essentially statements about what the product must do or be. The design vision, on the other hand, is more of a broad statement that should inspire the design process.

Finally, the future splint procedure is mapped out as well as the final splint functionality. This will allow you to check the design choices. The aesthetic value of the splint design was also explored because there is an opportunity in jewel design.

2.2 – Design vision and drivers

2.2.1 – Introduction

The exploration of the context around the product-service system resulted in design requirements and a design vision. This will be leading in the design phase, where the product-service combination is further developed and validated. Please note that it is an iterative process, thus requirements could be added, deleted or changed throughout the design process. The final list of requirements can therefore be found in appendix 6.

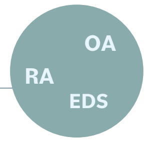
2.2.2 – Design drivers

The design requirements are categorised into seven design drivers which the product-service combination should meet (see the following page for the list of requirements). The drivers represent the patient, the other stakeholders (Tjielp Design, Fieldlab UPPS, and the occupational therapist), and the medical environment in which it will be implemented.

The product-service combination must . . .

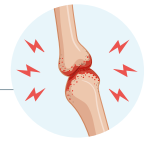
1. . . fit the user

R1.2.2; R1.2.3; R1.2.5; R1.2.6; R1.3.2; W1.3.3; W1.4.1; R1.7.1; R1.7.2; W1.7.1; W1.8.1



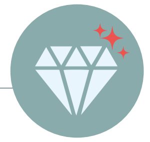
2. . . be functional

R1.2.1; R1.8.3; R1.9.1; R1.9.2; W1.2.1; W1.9.1



3. . . be consistent with the user's identity

R1.6.2; W1.6.2; R1.7.3



4. . . be executable within three weeks

R1.3.1; W1.3.2; W1.6.1; R1.8.1; W1.8.2

5. . . be suitable for long term daily life usage

R1.4.1; R1.4.3; R1.4.4

6. . . allow for good stakeholder collaboration

R1.5.1; R1.8.2

7. . . be medically certified

R1.6.1

2.2.3 – Design vision

The design vision is made up of three design pillars that developed from the discovery phase: Ultra Personalized Design, Inclusive Design, and Jewel Design.

Ultra personalized design means that the product, as well as the service, will fit the patient perfectly. A perfect fit is important for the splint to function well and to not aggravate the patients condition (R1.2.1; R1.2.3). The parameter acquisition in combination with the parametric design will largely determine the extent of personalization at a product level. An example of personalization in service design is that the service will be designed around the occupational therapist (R1.5.1). The OT has the required knowledge about the patients medical background and he is trusted by the patient. Here, digital modelling and fabrication techniques allow for an automated design and production process. As a result, the occupational therapist will be able to assist with the splint process without having any product design or jewellery experience.

Inclusive design refers to including all patients. Ultra personalization is ideally suited for inclusive design because it takes into account the individual user requirements. Patients with EDS, OA, and RA are the most common patient groups that qualify for splints (R1.2.5). Those patients have a significantly diminished quality of life because of a reduced hand functionality. Therefore, it is the more important to improve their hand functionality through splint design (R0.1). In the future, the product line will adopt multiple splints in order to cover the vast majority of the conditions (W1.2.1).

Jewel design plays a big part in the perception of the product-service combination. It is a great opportunity to appeal more to the user's identity by designing the product-service combination more as a jewel, but with the functionality of a medical aid (W1.6.2; R1.7.3; W0.1). Furthermore, this will strengthen Tjielp Design's market position, as no other rival approaches the splinting process like a one-of-a-kind jewellery experience (R1.6.2).

There will be given consideration to the user and their personal preferences, like the act of choosing wedding rings for example. The goal is for the patient to feel beautiful and confident in their jewellery. This should encourage the user to continue wearing the splints (W0.1).

The three pillars informed the following design vision:

'An **ultra personalized** product-service combination that **includes all patients** and emphasizes on **jewel design**.'

2.2.4 – List of requirements

Introduction 0

Requirements

- R0.1 – The splint must increase hand function in daily life
- R0.2 – The splint must be designed for long-term daily use

Wishes

- W0.1 – The user should feel motivated to wear the splint

Clinical Picture 1.2

Requirements

- R1.2.1 – The splint must reduce stress, stabilize joints, decrease the range of motion, and/or prevent deformities
- R1.2.2 – The product-service combination must take high disease activity into account
- R1.2.3 – The splint solution must not cause pressure points
- R1.2.4 – The splint must stabilize the CMC joint, abduct the metacarpal, and place the MCP joint in slight flexion
- R1.2.5 – The product-service system must fit patients with EDS, OA, and RA
- R1.2.6 – Arthritis in other joints (like finger, wrist, shoulder, elbow, etc.) that affect the product-service system must be taken into account

Wishes

- W1.2.1 – The product-service combination should offer a splint solution for the common deformities, ulnar deviation of the MCP joints, boutonnière deformity (BHD), swanneck deformity (SND), Z-deformation of the thumb, and swanneck deformation of the thumb

Current Splint Procedure 1.3

Requirements

- R1.3.1 – The splint process must not take longer than three weeks
- R1.3.2 – The splint must not hinder daily life activities

Wishes

- W1.3.1 – The amount of contact moments that involve the patient should be minimized
- W1.3.2 – The manual labor (measuring, designing, producing, fitting, adjusting) should be minimized

Current thumb splints 1.4

Requirements

- R1.4.1 – The splint must withstand impact from daily life activities
- R1.4.2 – The splint must be non obtrusive
- R1.4.3 – The splint must not pick up dirt
- R1.4.4 – The splint must be easy to clean

Wishes

- W1.4.1 – The splint should be adjustable to improve the fit

Care Path 1.5

Requirements

- R1.5.1 – The splint process must be designed around the occupational therapist

Competitor analysis 1.6

Requirements

- R1.6.1 – The splint must meet the medical requirements determined by insurance companies in order to qualify for compensation
- R1.6.2 – Tjielp Design must focus on personalized splints which can be customized in collaboration with the user

Wishes

- W1.6.1 – The production time should be as short as possible
- W1.6.2 – The splint should be offered in two to five different materials

Ultra-Personalized Product Service Systems 1.7

Requirements

- R1.7.1 – The product-service combination must at least contain one ore more of the personalization aspects of identity, capabilities, and fit
- R1.7.2 – The product must allow small shape adjustments
- R1.7.3 – The product aesthetics must be consistent for every piece

Wishes

- W1.7.1 – The product-service combination should be as personalized as possible while maintaining the price as low as possible

Digital modelling and fabrication 1.8

Requirements

- R1.8.1 – The product-service system must be suitable for digitalization and automation
- R1.8.2 – All stakeholders must be able to contribute to the design process by retrieving and adding data to the process
- R1.8.3 – The fabrication technique must be suitable for very small batch sizes (even n=1)

Wishes

- W1.8.1 – The digital twin must represent the patient as good as possible
- W1.8.2 – The design process should be automated as much as possible

3D scanning in personalized orthosis design 1.9

Requirements

- R1.9.1 – The 3D scan must be in a functional pinch grip splint posture
- R1.9.2 – The accuracy of the 3D scanner must be at least 1.3mm

Wishes

- W1.9.1 – The 3D scan should be made as quickly as possible

For the more extensive list of requirement, please have a look at appendix 6.

2.3 – Functionality of the thumb splint

2.3.1 – Introduction

Taking the swanneck deformity as starting point. The splint has to stabilize the CMC joint, abduct the metacarpal, and place the MCP joint in slight flexion (Beasley, 2014). Expanding the splint over the hand or wrist can add additional stability.

The splint must allow the user to **stretch their fingers**, **make a fist**, **pinch grip**, and possibly perform **other user dependent activities**. Pressure points on bony parts of the hand should be avoided at all times and joints must be bypassed in order to prevent disease activation. The illustration in image 27 shows an example of what a functional splint could look like. It conforms to the exact curvature of the hand, the interface is limited around bony hand parts, and it exceeds joints in order to prevent pressure spots and therefore disease activation. The splint is made up of three arches, each with its own set of functions, as mentioned below:

1. Fixating the CMC joint (2/3 MCP-CMC)
2. Limiting MCP extension and preventing adduction (1/2 IP-MCP)
3. Securing the hand splint

[Image 27] MCP/CMC stabilisation splint by WE Design

2.3.2 – Conclusion

Within this project, the CMC/MCP stabilization splint will be the main focus. This splint is commonly used in thumb base OA and with the swan neck deformity of the thumb, caused by RA or secundary OA. This splint type was chosen since it is suitable for a wide number of patients and allows for personalization. By developing this splint design and the service that goes with it, a lot of data for future and less complex finger splints will be acquired. Theretofore, the future steps toward more complex thumb and wrist splints will be simplified. This will eventually lead to a more comprehensive product line.

2.4 – Future splint process

2.4.1 – Introduction

The future splint process will be designed around the occupational therapist (see image 28). The whole splint process takes about three weeks to complete. In the future splint process Anna Ruiter provides a catalogue of splint designs and the parametric design in the form of an application with a self-evident user interface. In a timespan of 10-20 years, it is envisioned that every OT possess a 3D hand scanner and a 3D printer (both plastic and wax).

2.4.2 – Future splint process

Week 1

The beginning of the process is the end of the occupational therapy. At this stage, the OT has found the right splint treatment for his patient and takes his/her measurements. The patients measurements will be taken via a 3D scan of the hand in the preferred splint position. These, in combination with the OT's knowledge about the patient, his/her daily life activities and the requirements for the splint will be uploaded in the parametric design via an user interface. From there the design is automatically sent to the 3D printer for a plastic test splint.

The OT is in close contact with other specialists and once the design is uploaded, for example the orthopaedic surgeon can easily add a medical certificate to the patients splint application. Thereafter, depending on the patients health insurance, the costs of the silver splint will be (partially) covered.

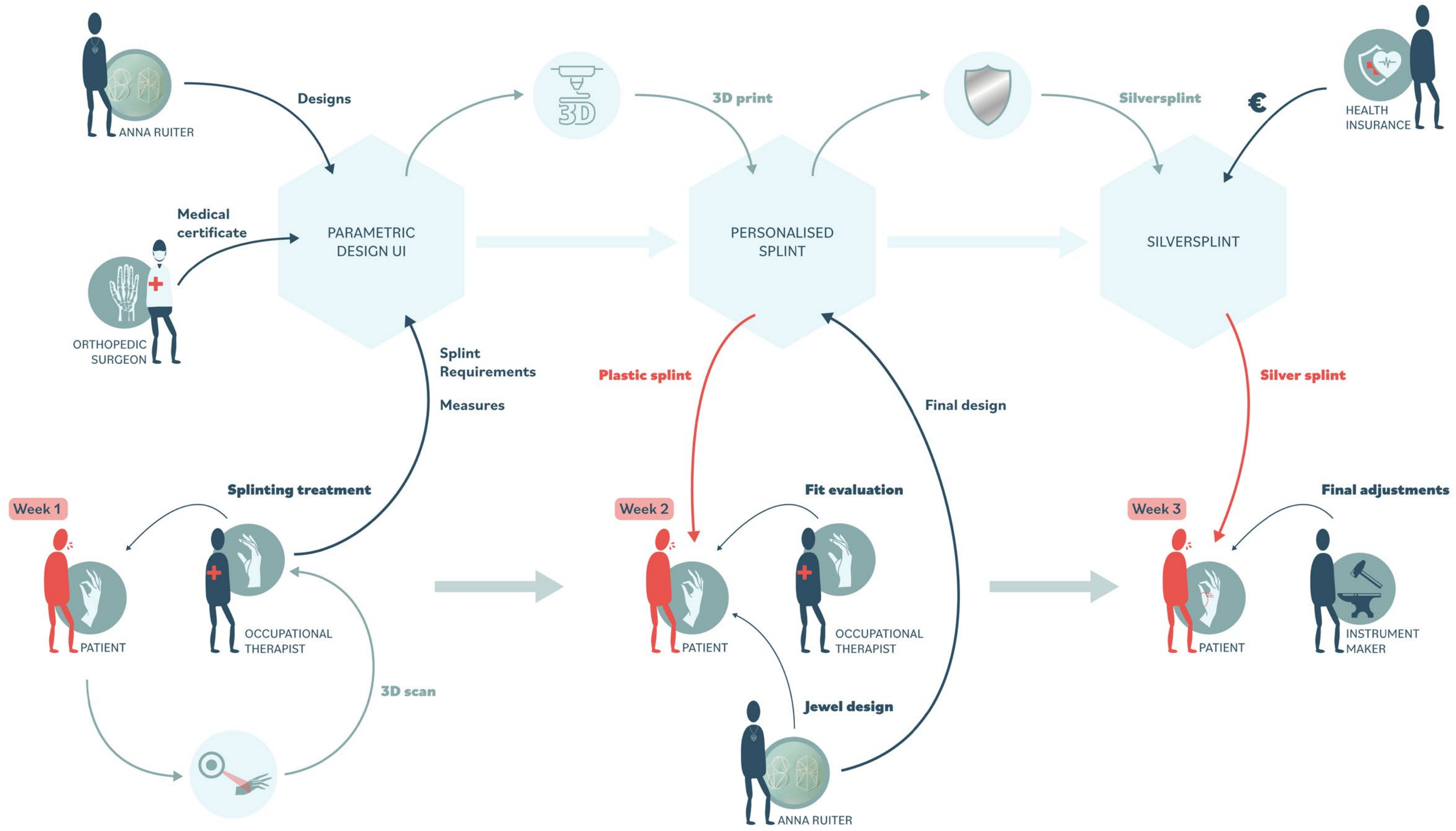
Week 2

After a week, the patient comes back to the OT and the splint fit is evaluated with a plastic test splint. At this stage, it could happen that the splint fits poorly and should be adjusted via the user interface. When the splint does fit properly, the patient visits Tjielp Design to discuss the wishes regarding the aesthetic design (shape, material, texture, color, diamonds, etc.) of the splint. Besides, a patient might want to order multiple splints with different designs or varying sizes. Once the patient, the OT, and Tjielp Design have agreed upon the final splint(s), the request for production will be submitted via a splint application.

Week 3

For silver splints, the third and final appointment will be at the orthopaedic instrument maker. He/she will make the final adjustments to reduce pressure points. The instrument maker has access to the splint application and will be able to read any notes that the OT made when evaluating the fit of the plastic test splint.

A follow up treatment is recommended to learn from the user experience and to prevent ill-fitting splints over time. Moreover, the material of old silver splints should be recycled into new splints.



[Image 28] The future splint process

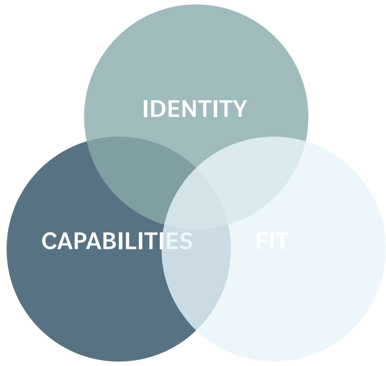
2.5 – Aesthetic design

2.5.1 – Introduction

The former splint generation's form language was heavily reliant on the bending of silver wire into the splint shape as a manufacturing technique. However, with the advent of computational design, we are no longer restricted to manual splint production and the adoption of digital fabrication processes has significantly enhanced the freedom of form. In addition, computational design can be used to explore various design iterations.

‘Seeking beauty through technology’

Is therefore the motto of Arturo Tedeschi, an expert in the field of architecture and computational design. The aesthetic design of the splint becomes increasingly important and the identity of the user can be reflected through it. Accommodating variation in the form by for example colour, texture, form, and material, as well as the opportunity to add diamonds, will allow the user to identify more with the product. Personalization of the fit and capabilities aspects will alter the identity of the splint design because they are interdependent as visualised below.



The right-hand collage depicts existing products that could be adapted into a splint design (see image 29). The style is comfortable, yet at the same time elegant, and empowering. The first and most critical consideration is that the splint should look comfortable and be inviting to wear. Because the splint requires a certain amount of robustness, it becomes bulky very quickly. As a result, elegancy is required to distinguish the splint as a jewel rather than a medical aid. Finally, because patients with rheumatoid arthritis have a significantly diminished quality of life, it is critical that the splint empowers them (Matcham et al., 2014).

Alexander McQueen at Paris Fashion Week Spring 2010
Perrin Paris x Zaha Hadid clutch

[Image 29] Aesthetic collage

2.6 - Conclusion

In this phase, based on the conducted research, a focus is applied on the design process in the form of a design vision.

The envisioned product-service combination is:

> 'An **ultra personalized** product-service combination that **includes all patients** and emphasizes on **jewel design**.'

The patient pathology is extremely specific and requires a tailor made approach on product level as well as the service design. The fit of the splint is crucial for a functional design and to avoid aggravating the condition. Secondly, the service must be designed around the occupational therapist to reduce the number of specialists involved and to gain the patient's trust. An ultra personalized design approach will therefore be kept in the design and validation phase. Consequently, digital modelling and fabrication techniques are useful in efficiently sustaining an ultra personalised approach in which all stakeholders are able to collaborate.

An ultra personalized design approach will enable inclusive design. For example, because it takes into account the individual user requirements regarding the splint fit and material choice. It is important to include patient groups with EDS, OA and RA because they experience significant loss of hand function and use splints most commonly. This affects their quality of life. However, this can be greatly improved through splinting. For the same reason, it is important to adopt multiple splint types in the product line in the future.

Splints are solely effective when they are worn all day and every day. Therefore, the identity of the splint becomes increasingly important in order to encourage patients to keep wearing the splint. Therefore, a great opportunity lays within jewel design. Moreover, with a one-of-a-kind jewellery experience, Tjielp Design will reinforce their market position, since no competitor emphasizes on a customized splint approach.

With regard to the functionality of the splint, it must stabilize the CMC joint, abduct the metacarpal, and place the MCP joint in slight flexion. In doing so, the general hand functionality should not be hindered. Next to the splint functionality, a future splint service is proposed. The service design is digitalised and designed around the occupational therapist. Within this service, Tjielp Design offers a jewellery experience, wherein the customer is able to compose their own splint design. Finally, there lies a great opportunity in 'seeking beauty through technology' as Arturo Tedeschi nicely puts it. His work can therefore be seen as inspiration source for future computational splint design.

3

C H A P T E R O N E

DESIGN & VALIDATION PHASE

Contents

3.1 - Introduction

In the following design and validation phase, the workflow for personalised products will be followed. The steps in the workflow concern the design requirements, data and parameter acquisition, computational design, design for manufacturing, and product evaluation. The design requirements have been drawn up during the discover and define phase previous to this phase. This list will be kept up to date with insights that will be gained in the following phase.

This phase starts with data and parameter acquisition. Three different concepts of data and parameter acquisition will be proposed. These concepts are based on 3D scanning (3D), a photograph (2D), and hand measurements (1D). The extent of personalisation will largely depend on the parameter input. For example, a 3D scan contains more anthropometric data and therefore will result in a more accurate digital representation.

To assess the feasibility of 3D scanning, a more in-depth research is conducted. This will reveal the implications regarding 3D scanning of patients with impaired hand, like patients with rheumatoid arthritis. Thereafter, the statistical shape model (SSM) is introduced as bridging solution. The advantage of using an SSM, is that it functions with minimal hand measurements, which will simplify the measuring procedure. However, when it comes to personalisation a 3D scan remains the most accurate representation of the exterior hand shape. Therefore, the workflow around 3D scanning will be evaluated. This will cover mesh wrapping and pose correction.

Mesh wrapping is done to retain the connectivity of a mesh, but to change the geometry as different hands have different exterior hand shapes. That every 3D scan and therefore every mesh has the same connectivity is crucial for the computational design to work parametrically. Otherwise, the computer aided design software does not recognise the same areas of the hand and does not 'know' where the splint curve must be located. Consequently, this step is implemented and evaluated in the following phase. The second step is the pose correction. It is often difficult to hold the preferred splint posture during the 3D scanning procedure without additional aids. Therefore, the hand model often needs post correction of the posture. This is done within the blender software with a digital skeleton (armature). Again, this step is carried out for a 'normal' hand to get an understanding of what problems you might encounter. Finally, based on the findings, a timeline will be proposed for the data and parameter acquisition.

The next step in the workflow is the computational design. This is made in Grasshopper, which is a visual programming language that runs within Rhinoceros. The most important aspect of the parametric design is that is automatically adjusts to the anthropometric data of the patient. Therefore, it has to be set up parametrically and parts in the script that could cause errors need to be minimized. Furthermore, the parametric design should allow for variation in the aesthetic features. How the script is build in Grasshopper, shall be explained in the following design and validation phase.

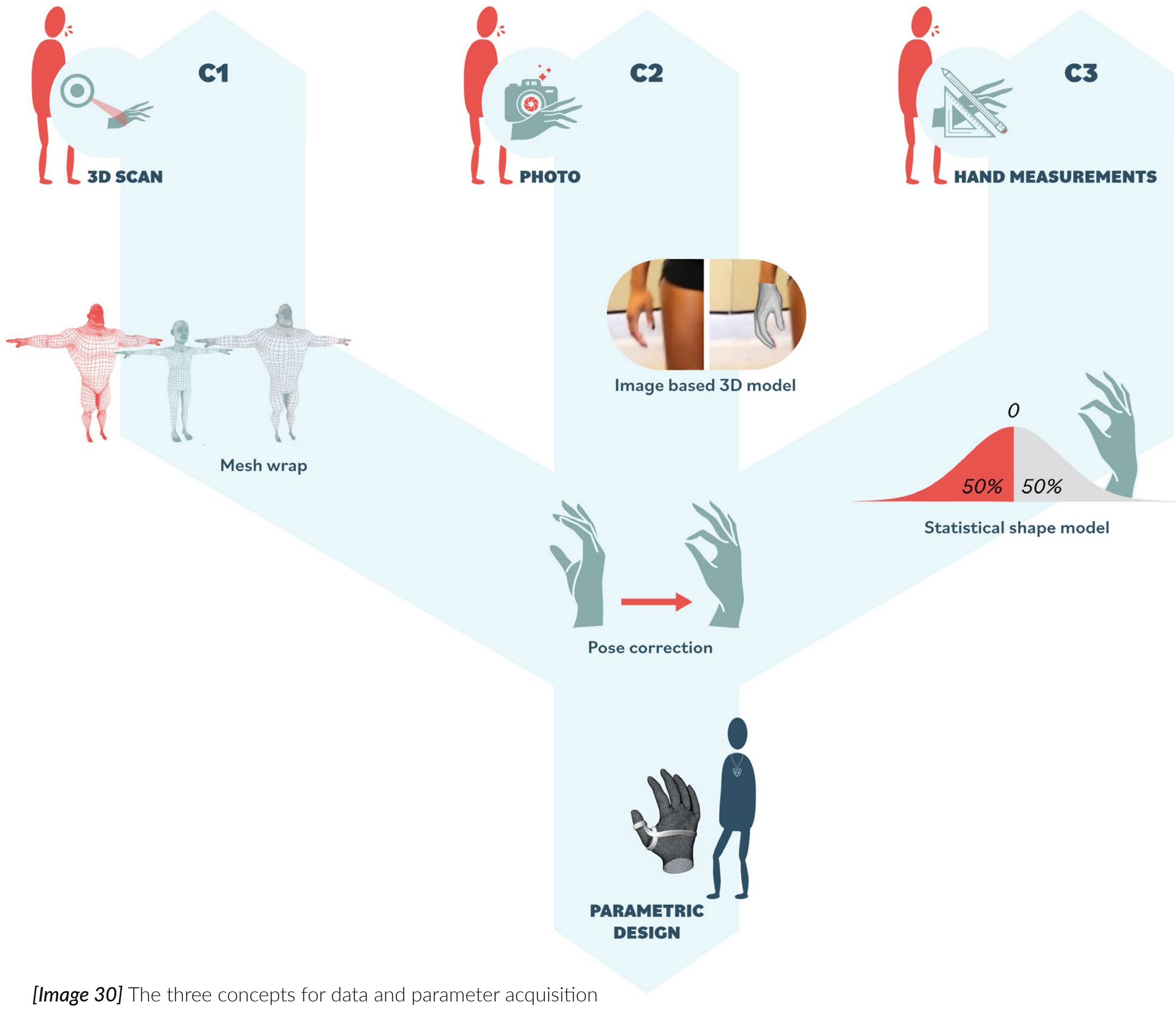
With regard to design for manufacturing, a few materials will be compared. The compared aspects are the material properties, mechanical properties, and the aesthetic properties. Theretofore, the splint will be produced in each of these materials for a complete and realistic evaluation. Since the material choice determines the product cost for the most part, the splint cost is also analysed in this chapter.

Finally, the same splints are thereafter used for the product evaluation. There are three possible test cases, namely the splint based on a 3D scan of a 'normal' hand, the splint based on a wrapped and post corrected 3D scan of a 'normal' hand, and a pathological hand. The latter was not evaluated due to the COVID-19 measures and lack of time. During the product evaluation, the fit of the splint will be assessed and recommendations are made for further research.

3.2 – Data and Parameter Acquisition

3.2.1 – Introduction

Data and Parameter Acquisition is an important step since it largely determines the workflow of the splint service and the personalization of the splint design. The most important design driver is that it fits people with EDS, OA, and RA. There will be three possible approaches discussed regarding the creation of a digital twin. Within the scope of this project, two of the three approaches to collect anthropometric data via 3D scanning technologies and the use of a SSM will be evaluated. This will cover, 3D scanning, the SSM, mesh wrapping, and pose correction. Finally, a time line for future data and parameter acquisition will be proposed, taking into account the differences between "normal" and "pathological" hand shapes.

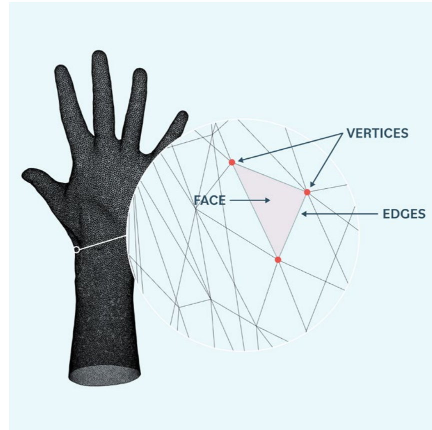


[Image 30] The three concepts for data and parameter acquisition

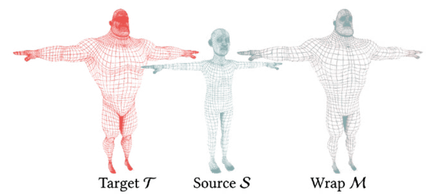
3.2.2 – Parameter acquisition / digital twin concepts

In the field of computer aided design, a digital twin is indispensable to achieve a high level of personalization. For this project specifically, a digital twin in the form of a 3D hand model will be used to design the splint around. There are several methods for acquiring the parameters for this 3D model, including: a 3D scan (3D) , a photo (2D), and hand measurements (1D) (see image 30). The difference between these three approaches lays in the level of complexity.

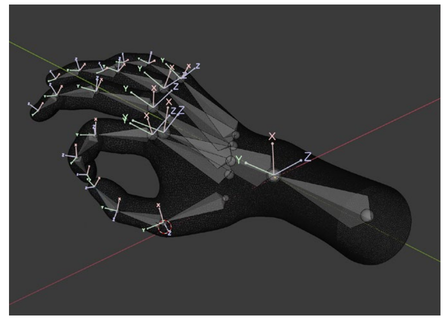
First, the parametric design process. Since the data must be translated into a 3D model, greater knowledge and ability is necessary for the less sophisticated measurements (1D and 2D). Second, when the complexity of the parameter acquisition increases, the necessity for advanced equipment increases. A 1D approach results in less anthropometric data, but allows for a quick and cheap measurement procedure, whereas a 3D scan is a one-to-one representation of the exterior hand shape, but requires advanced equipment. A photograph could be used to bridge these two approaches.



[Image 31] Mesh construction



[Image 32] Mesh wrap (de Goes & Martinez, 2019)



[Image 33] Pose correction (Blender Foundation, z.d.)

3D scan

The first approach, where a 3D scan of the patients' hand is made with a Structure Scanner Pro is the most straight forward since it is a direct digital copy of the exterior hand shape. For every 3D model, the parametric design has to 'know' over which parts of the mesh the silver splint should run. This information is based on the mesh connectivity and therefore should be the same for every 3D hand model (see image 31). This can be achieved with a wrap model. A wrap model is created by transferring a source mesh (3D hand template) to a target shape (3D scan) (de Goes & Martinez, 2019), (R3DS | Russian3DScanner, z.d.) (see image 32). By doing so, the mesh geometry will be changed into the individual hand shape, but the mesh connectivity remains the same. Thereafter, a pose correction is necessary to be sure of the right splinting position (Asanovic et al., 2019) (see image 33). Once these two steps are completed, the digital twin is ready to be loaded into a computer aided design program like Grasshopper. The parametric design will automatically adjust to the new input.

Photo (2D)

The second approach makes use of a photograph. Here the image data is translated into a 3D model, resulting in a digital twin. There is no available software to perform this process directly, but Boukhayma et al. (2019) presented a method to 'predict 3D hand pose and shape from a single RGB image'. They have used the MANO hand model with two sets of parameters as input: shape and pose (Romero et al., 2017). These parameter sets will then be derived from an RGB image which allows to predict a digital twin from a single image. Since the connectivity of the mesh remains the same, there is no need for the wrapping step in the process. Also the input pose parameters can be predefined. This will shorten the parametric design process eventually.

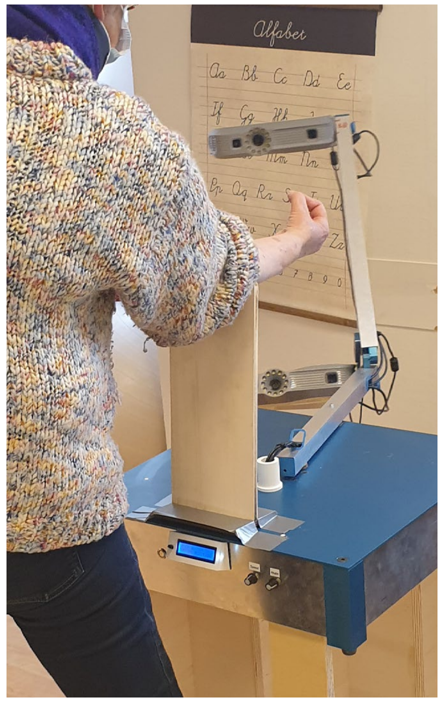
Hand measurements (1D)

The third approach is based on a statistical shape model (SSM) (Yang et al., 2021). The SSM is composed of a dataset of 3D hand models. With a predefined number of parameters as input, the SSM becomes a digital representation of the patients' hand (Allen et al., 2003), (Huysmans et al., 2020). Again, a constant mesh connectivity and hand pose allow for quick integration into the parametric design.

3.2.3 – 3D scanning of rheumatoid hands

Even though there are several 3D scanners available that create a good image, they might not be applicable for 3D scanning in orthosis design. With most hand held devices the scanning time is too long to create a clear image of the hand. In addition, other challenges will arise regarding patients with impaired hands. Particularly for patients with rheumatoid arthritis, in which 90 percent of patients have hand abnormalities, 3D scanning appears to be a difficult task. As a result, more research has been conducted on "3D scanning in personalized orthosis design for patients with rheumatoid arthritis" in appendix 7.

In this study, to evaluate whether 3D scanning is a viable option for personalizing finger and hand orthoses for patients with rheumatoid arthritis, an automated 3D scanning set-up with two rotating Artec Eva scanners was used (see image 34). This way, the 3D scan could be made faster and therefore the patient experience was improved and the in-scan movements where reduced.[R3D.5]★



[Image 34] Rotating Artec Eva setup

However, the results of the research where rather disappointing. Less than half of the hand postures produced a satisfactory 3D scan result. Furthermore, the 3D scans lacked roughly 30 – 60% of the information for an accurate design reference.

The simplicity in which the 3D scanning process was carried out was greatly determined by disease activity. Stiff joints, swollen, and painful hands also lead to a decreased scan quality. Furthermore, the quality of the 3D scan was affected by **muscle strain**, **tremors** and the **quality of the posture**. Not all patients were able to hold the posture without support, therefore a transparent strap was used to assist the patients. Adjusting the hand posture was solely possible if the joints where still flexible and not completely stiffened. The transparent strap could be functional in holding the position, but a more durable and less error prone replacement is desired for the future.[R3D.6]★

3D scanning hands of patients with rheumatoid arthritis revealed several complications. Positioning the patients' hand into the desired posture, as well as disease implications such as **pain in other joints**, **old age**, and **tiredness** caused **discomfort**. Ideally the patient goes through the 3D scanning procedure as comfortable as possible, which means that the 3D scan should be taken quickly.

Reducing the 3D scanning time will **decrease the in-scan movement**, **measure time**, and therefore **increase the patients comfort** and the **quality of the 3D scan** result. The technological advancements that enable quicker and more complete 3D scans of hands specifically, like the Curatio hand scanner, are unfortunately not yet available on the market. Therefore, it can be concluded that, until an instant 360 degrees 3D scanner becomes available (e.g. Curatio), 3D scanning will not a viable option for personalizing finger and hand orthoses for patients with rheumatoid arthritis.

3.2.4 – Statistical Shape Model (SSM)

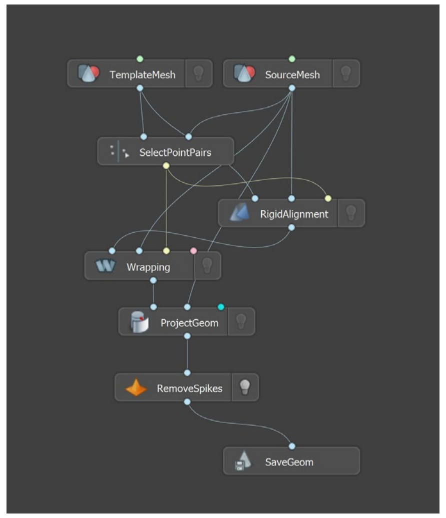
The Posture-invariant Human Hand Statistical Shape Model (SSM) represents the variation in shape and size of 3D hand models and is a very useful tool for human integrated digital twin applications, such as digital orthotics design. By adjusting predefined parameters of the SSM, the 3D model can be scaled into a digital twin of the patients' hand. Moreover, the posture could be predefined (desired hand posture in pinch grip) which saves extra work in post-processing the 3D hand models.

The SSM has the disadvantage of being a representation of the typical hand shape. Patients with osteoarthritis and rheumatoid arthritis have muscle atrophy, bony lumps, and joint enlargements, resulting in a hand shape that is anything but ordinary. The question remains whether the Posture-invariant Human Hand Statistical Shape Model captures the hand shape sufficiently for this particular patient group. Therefore it is recommended to build a large database of pathological hand scans. Of those scans an SSM can be build and used[RSSM.1]★.

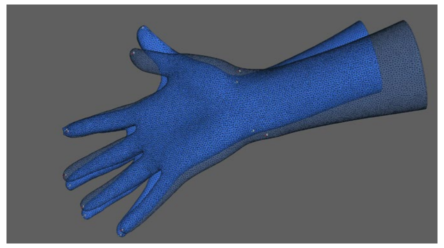
Regarding 'normal' hands the SSM remains to have the preference because of the simple measurement procedure. Taking measures by hand is preferable over 3D scanning since it does not require any advanced equipment. The procedure can take place at every location as well (R1.5.1). However, further research needs to be done on how the use of an SSM affects the physical fit of the splint.

3.2.5 – Mesh wrapping

As discussed before, the mesh connectivity is crucial for the design to work parametrically.[RAUT.1]★ For the SSM, the mesh connectivity is constant and the geometry is variable since the exterior hand shapes differ. But, for 3D scans, both the mesh connectivity and the geometry are variable. To make sure that the mesh connectivity is the same as the template which is used in the parametric design, the mesh needs to be wrapped with R3DS wrapping software. In order to get an understanding of whether this is feasible for implementation, the wrapping steps will be put into practice in the following chapter.



[Image 35] Node tree wrapping procedure



[Image 36] Mesh wrapping

The first step in wrapping a target mesh onto a source or template mesh is constructing the template mesh. Using Paraview software, an average template mesh of 15 3D scans of typical hands was produced.

Secondly, all 3D scans where wrapped onto this template mesh (see image 35). As can be seen in image 36, in both meshes seven landmarks (five on the tips of the fingers and two on the outer sides of the wrist) where pointed out as reference for the wrapping step. Once the wrap is completed, the mesh is once more projected onto the 3D scan to increase the geometry accuracy. Finally, the irregularities are removed from the mesh.

Afterwards, the previous two steps are repeated with the wrapped hand models to create a more accurate reference. This process results in a second template mesh and the final wrapped hand models with identical mesh connectivity, which can be used in the parametric design.

While performing the previously described steps, an issue arose. This was due to the quality of the 3D scans. Some scans where lacking data at the outer side of the thumb and that resulted in noise around those areas. However, the RemoveSpikes node succeeded to reduce the noise significantly.

3.2.6 – Posture Correction

Splints are solely functional if the hand is splinted in the right posture (R1.9.9). For people with full hand functionality it is already very hard to hold the exact posture. But especially for patient's who have impaired range of motion, it is not possible to hold a specific posture independently during the 3D scanning procedure. There are two options possible. The first is to use 3D scanning aids to force the hand into the preferred posture as discussed before in chapter 1.9.1. The second is to post correct the posture with blender software (Blender Foundation, z.d.). The latter will be discussed in this chapter.

Pose correction in Blender is done with a simplified digital skeleton. The skeleton is linked to the mesh. So when you move the skeleton, the mesh and therefore the exterior hand shape deforms with it. This allows you to put the hand in any posture you desire. It becomes more interesting when you are able to automatically apply the posture correction for every scan. Therefore, the armature (skeleton) has to be translated to other 3D hand models. This is done by a script written in Blender. The armature and script that are used for this implementation and evaluation are made by Toon Huysmans.

Axis orientation

After running the script for a few hands that were wrapped in the previous step, the first thing that came up is that the new pose is not accurately adopted. The axes of the thumb seem to have rotated while running the script. This is due to a part in the script that corrects the orientation of the axes of the finger and thumb bones. However, this particular correction does not apply for the thumb since it has a different orientation from the fingers. This part in the script must therefore be rewritten. To further evaluate the feasibility of the pose correction, the axes of the thumb are manually fixed after running the script.

OK-sign posture correction

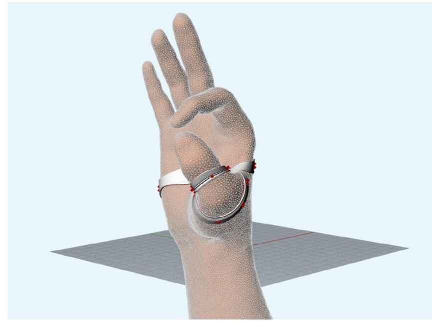
Subsequently, the pose correction itself. A posture with stretched fingers was put into a pinch grip posture. This resulted in a reasonable posture, but it did not look very natural as you can see in image 37. This can be allocated to the fact that the skeleton must be positioned better inside the mesh and that the bones must be linked more accurately to the mesh (exterior hand shape) in the weight paint mode (see image 38).RAUT.2★

Anatomical representation

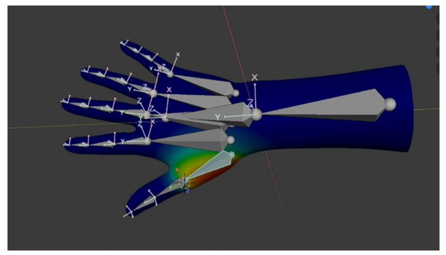
Another aspect is the representation of the bones and their range of freedom. The bones rotate in the joints around the x, y, z axis. This is relatively simple for hinge joints as the DIP and PIP of the fingers and the IP of the thumb, where there is only movement in one plane. But for ellipsoid MCP joints and the saddle CMC joint it is more complicated since there is movement in two planes (flexion/extension and abduction/adduction) and circumduction (circular movement in both planes). Also, the top part can glide inside the bottom part of these two joints which causes the axis of rotation to move. The saddle joint can also slightly rotate (see image 39) ('The Musculoskeletal System and Human Movement', 2016). The circumduction and displacement of the rotational point in particular, are not well represented in the model. In the case of the thumb, this means that the outer hand shape changes as the metacarpal moves out of its rotating position. As a result, the outer hand shape will be different from reality.RAUT.3★ Regarding pathological hands, this is even more challenging since there can be dislocated bones which causes the exterior hand shape to be unique.

Errors in armature translation

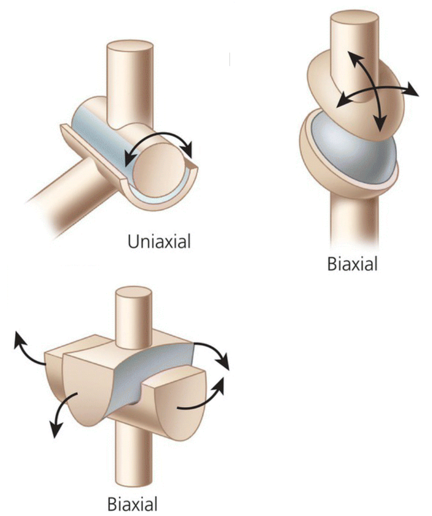
Finally, to minimize errors in translating the armature to other hand meshes, it is important to make the 3D scan of every patient consistently in the same posture.RAUT.4★ Patient's with pathological hands often have finger deformities which have to be corrected into the same posture as 'normal' hands. But, since the starting point is so much different from a hand in 'normal' rest pose, it will not be possible to copy the posture correction one-to-one. However, predefining the posture roughly will save time.



[Image 37] Corrected pose



[Image 38] Weight paint mode



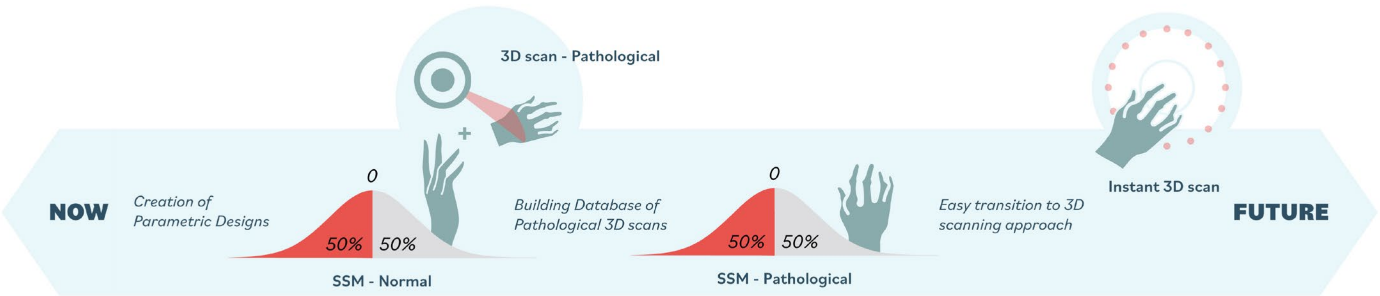
[Image 39] Hinge (top left), ellipsoid (top right), and saddle joint (bottom left) ('The Musculoskeletal System and Human Movement', 2016)

In conclusion, the skeleton and script created using the Blender software are functional in correcting the hand posture, but does not work perfectly yet. The script requires some improvements regarding the thumb to allow the armature to be mapped correctly to other hand meshes. A perfect positioning of the bones, an exact link between the bones and the exterior hand shape, and a proper representation of the numerous joint types are necessary for an accurate reference of the exterior hand shape and posture. Finally, for pathological hand shapes, it will be more challenging because of finger deformities and joint dislocations. Additional research is therefore needed to point out the bottlenecks for pathological hand pose correction.

3.2.7 – Future Data and Parameter Acquisition

Within the scope of this project, the first concept with a 3D scanning approach was evaluated. Even though the approach is not yet flawless and more iterations are needed, it can be concluded that it is feasible for 'normal' hands. Implementation of this approach and the development of new 3D scanners for hands particularly will pave the way for both 'normal' and pathological hands in the future.

Currently, 3D scanning is a cumbersome procedure which asks a lot of the patient in means of energy and time. Therefore, until quicker 3D scanners become available, a procedure like taking measurements by hand would have the preference. This can be achieved by using a statistical shape model (SSM) as a bridging solution. The proposed timeline will then be as follows (see image 40).



[Image 40] Timeline for data and parameter acquisition

The time line starts with an SSM of 'normal' hands. At this moment the focus is on setting up the parametric design and creating multiple splint designs. Those splints are designed around the SSM and can be personalized by adjusting the parameters.

Meanwhile, 3D scans of pathological hands are collected for research purposes and the construction of a pathological SSM. This will ensure a strong market position with regard to computational personalized splints for pathological hands.

The downside of using a SSM for personalization is that it is an approximation of the exterior hand shape, which could lead to an inadequate physical fit. As a result, 3D scanning will continue to be the preferred method in the future. This does not, however, imply that the SSM is obsolete. There is a substantial patient population that does not require a high level of personalization in terms of physical fit. For these patients the SSM method will be suitable.

3.2.8 – Conclusion

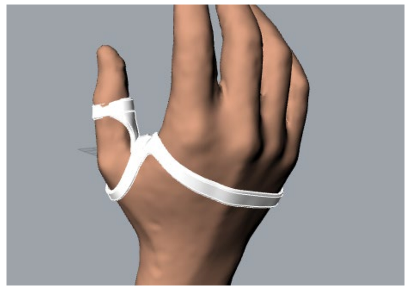
Collecting anthropometric data for an accurate digital twin can be done at three different levels: 3D scan, 2D image, and hand measurements. There are ways to translate simple measurements into a more complex 3D image. For hand measurements this could be done with a SSM and for a 2D image there exists a method to predict the 3D hand pose and shape from a single RGB image. Using a 3D scan is the most obvious approach since you can get started right away, however this is not without challenges.

From the research on 3D scanning of patients with rheumatoid arthritis can be concluded that patients find it difficult to hold the preferred splinting position due to joint degradation, muscle strain, and tremors. An instant 3D scanning device is needed to improve the patients experience as well as the quality of the scan. In some cases, an aid like a transparent strap is useful in holding the posture. But, more durable and error prone solutions should be explored.

Regarding the post processing steps for the mesh wrapping there were hardly any implications. However, for the pose correction of the thumb there is additional research required. This concerns an accurate representation of the joint range of motion since this influences the exterior hand shape and therefore the final physical fit of the splint. Within the scope of this project there was not enough time the evaluate the direct effect of this.

With respect to the currently available 3D scanners, the measurement procedure of 3D scanning is not assessed as feasible for patients with pathological hands. On the other hand, it is perhaps a little too much for patients with 'normal hands'. Therefore, the SSM is proposed as a bridging solution towards the instant 3D scan or eventually incorporation of the hand scan in artificial intelligence (AI) processing workflows.

1



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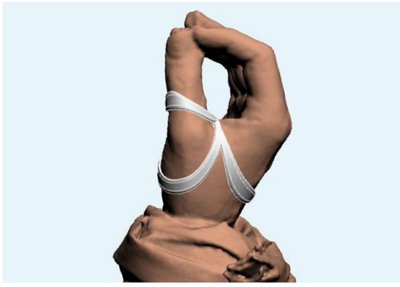

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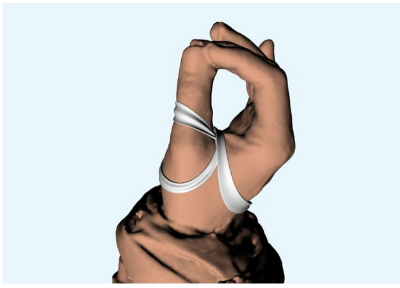

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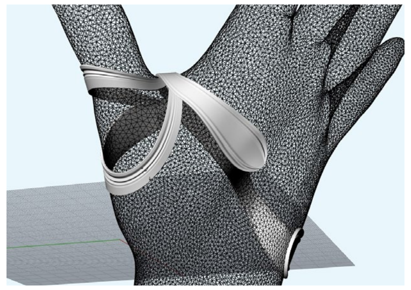

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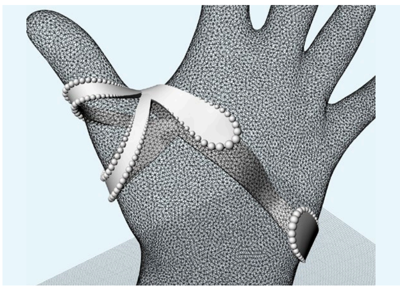


[Image 41] Design sprints

3.3 - Computational design

3.3.1 – Introduction

The computational design is made in Grasshopper, which is a visual programming language that runs within Rhinoceros. The advantage of this program is that it enables parametric design and works well with meshes. The parametric design process is based on algorithmic thinking. On the basis of the design rules and boundary conditions, the design automatically adjusts to the input parameters. The functionality of the personalized parametric design is largely determined by the input parameters. For the splint design, a mesh that represents the individual hand is used as input and the splint is designed around it. The design sprints and how the computational design is build parametrically will be discussed in the following chapters.

3.3.2 – Design sprints

From top to bottom, see image 41.

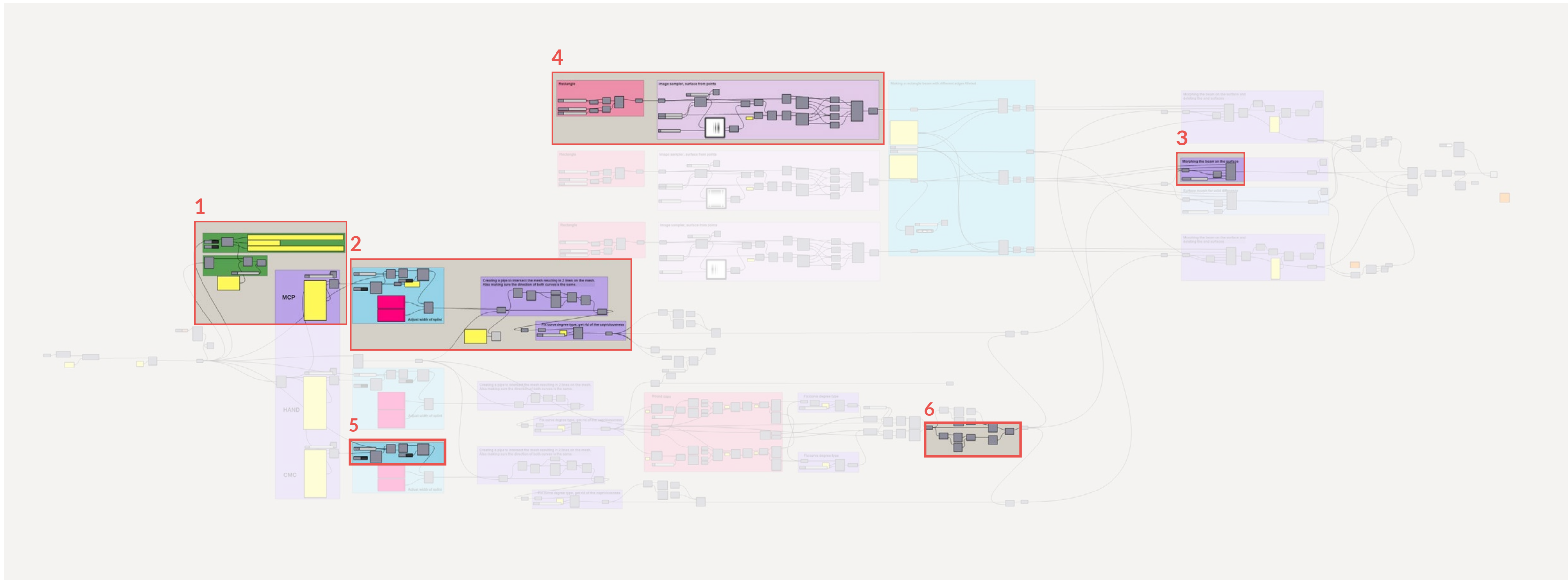
1. The first design is made by Mathijs de Heer. He created a parametric splint design which is largely functional. The arch between the CMC and the MCP joint had to be relocated since it was to close to the MCP joint. Also the appearance was still very medical.

2. Therefore, the second splint was adjusted to have a variable splint width. Besides, the splint path around the hand was changed.

3. In the third design sprint, a variable thickness which is based on a black and white image was added to the splint design.

4. The fourth iteration changed the aesthetics a little, but mainly translated the splint design to a template mesh of an average hand. The template was created by wrapping one template mesh to 14 3D scans and computing an average hand mesh from these scans.

5. The final splint is a variation on the aesthetic design.



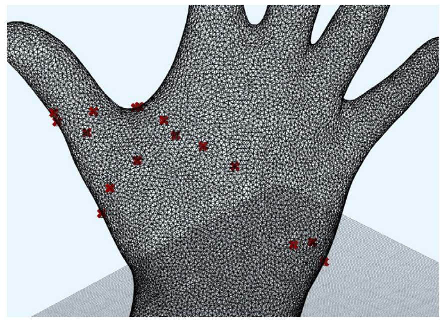
[Image 42] Computational design

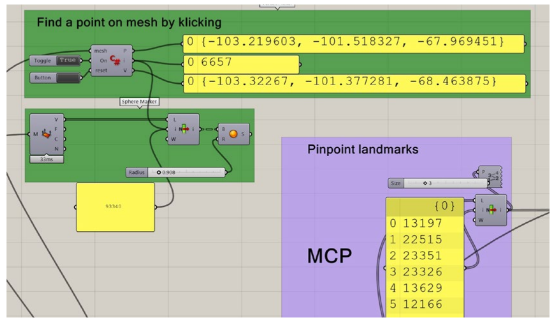
3.3.3 – Parametric design

There are four parametric design steps consisting of defining the landmarks, giving a variable width, morphing a design along the surface, and implementing the aesthetic design parameters (see image 42).

Landmarks #1

The first step in the parametric design process is defining landmarks on the mesh (see image 43). Please note that all meshes must have the same connectivity in order to find the landmarks at the expected location on the mesh. A spline is drawn through the landmarks and this defines the global geometry and the supporting function of the splint.

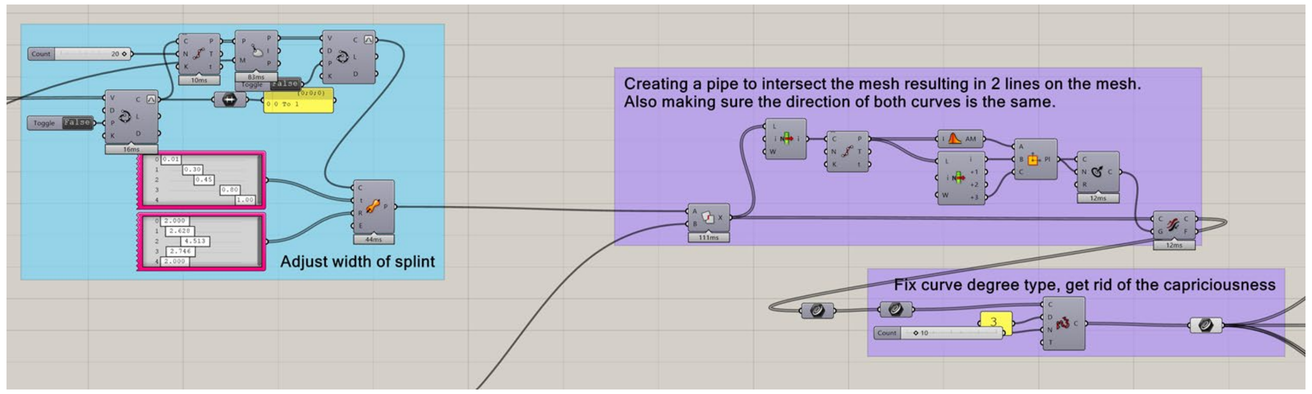




[Image 43] Placing landmarks within the grasshopper script

Variable width #2

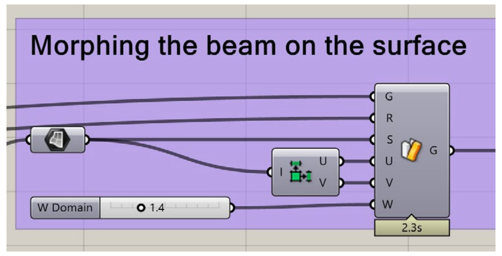
To give the splint a variable width, the command 'pipe variable' is used (see image 44). Where the pipe intersect with the mesh, there are two lines created. Then, the curve degree of these lines is adjusted to smoothen the curves. Afterwards, a clean 'network surface' can be created. When a patient needs more support at specific parts of the hand, the surface can be widened for more support.

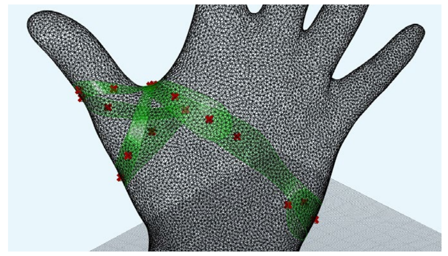


[Image 44] Creating a pipe variable within the grasshopper script

Surface morph #3

Once the surface is satisfactorily, any design (e.g. varying in geometry, pattern, texture, etc.) can be morphed along this surface (see image 45). The u and v domain must therefore match that of the surface. Multiple designs are created beforehand as a starting point to easily switch between different designs and to let the customer decide on which splint design appeals most to him or her.



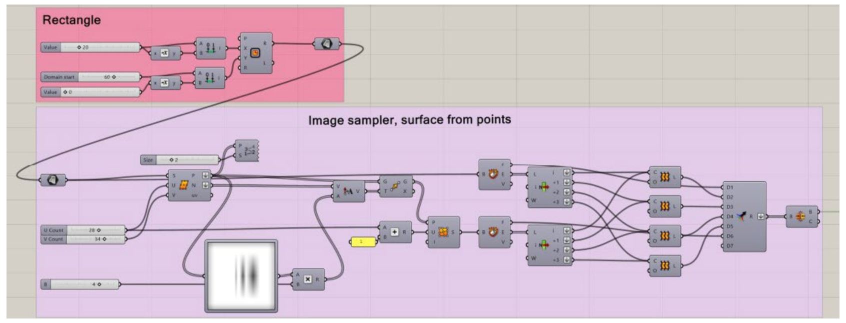


[Image 45] Creating a surface morph within the grasshopper script

3.3.4 – Aesthetic design

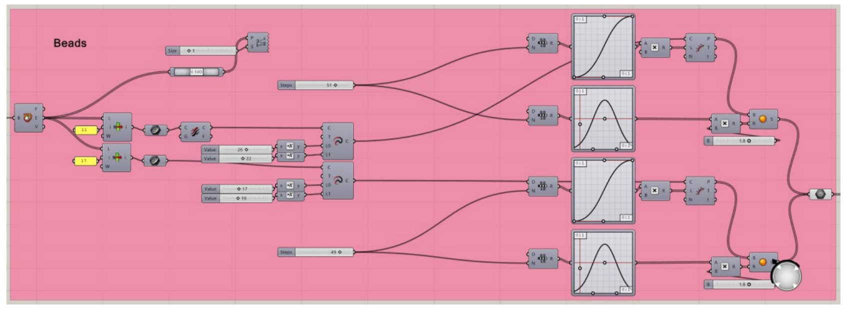
Aesthetic design #4

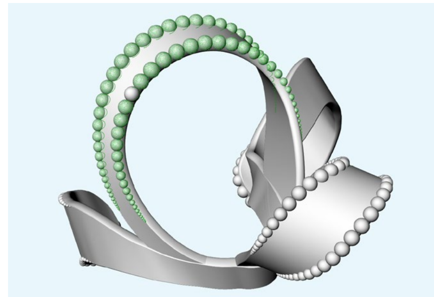
Furthermore, the parameters of the aesthetic design can be tweaked (see image 46). This allows Tjielp Design to customize the splint according to the customers wishes. In this example, with the use of an image sampler, points from a point grid are moved according to a black and white drawing. Afterwards, a surface is drawn through these points resulting in a geometry that resembles the imported black an white image.



[Image 46] Creating an engraved surface design within the grasshopper script

Another alternative is to add an aesthetic component like a diamond, or in this case beads around the edges of the splint (see image 47). The beads alter in size, number, and distance with sliders and graphs. With one piece of code, many visual appearances can be made.





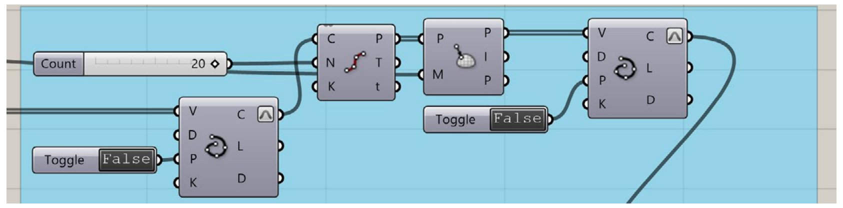
[Image 47] Creating beads within the grasshopper script

3.3.5 – Switching between meshes

In the ideal case, the parametric design adjusts flawlessly to a new hand mesh when it is uploaded into the computational design model.[WAUT.1]★ However, in reality there still remains some manual labor or there are aspects that require special attention for automation. These aspects are discussed below.

Number of landmarks #5

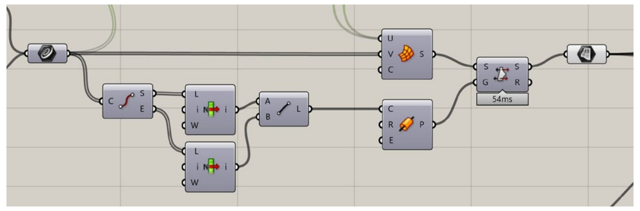
The first aspect is the number of landmarks (see image 48). This number should be minimized since it requires a lot of time.[WAUT.2]★ Even with a limited amount of landmarks, the spline still has to follow the mesh accurately. To do so, the spline is divided in, let's say 20 points, for which the closest points on the mesh are found. This results in a new spline that accurately follows the mesh, but retains a low number of landmarks.



[Image 48] Fixing the normal orientation within the Grasshopper script

Surface normals #6

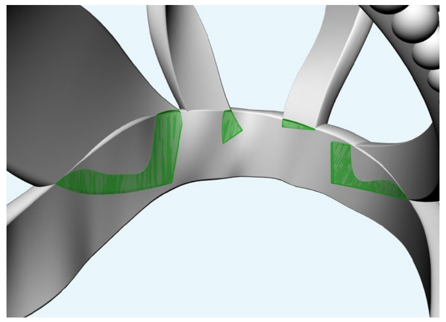
Secondly, the orientation of the surface normal, and the u and v domains are important for a smooth transition between hand meshes (see image 49). To make sure the surface normal always points outward, a geometry is created and the surface is flipped according to this geometry. Fixing the face normal direction solved the problem for 14 of the 16 hand meshes.



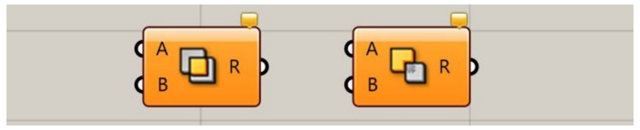
[Image 49] Fixing the normal orientation within the Grasshopper script

Arch connection

Finally, the path of the spline should be error prone despite of the thumb pose (see image 50). Within the current splint design, the MPC and CMC arches end up in the same point between the thumb and index finger. This part of the hand is irregular and causes errors in the connection of the arches.[RAUT.5]★ Overlapping parts are removed with the solid intersection and difference components.



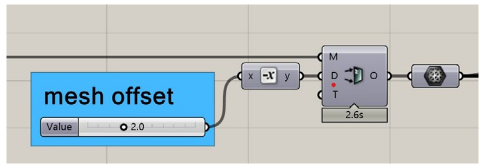
[Image 50] Removing protrusions from the arch connection within the Grasshopper script



In the next iteration it is recommended to look into ways to make the splint out of a single arch. This will solve the connection problems and reduce errors that could occur by switching between meshes.

3.3.6 – Design fit

If the design follows the exact exterior hand shape, the splint design is messy and therefore a more smooth curvature is suggested. As a result, the splint will be too wide and therefore must be shrunk in order to fit properly.[RAUT.6]★ In addition, the hand has soft tissue in which the splint is pushed into. Because of that it stays in place more properly. To achieve this, the WeaverBird plug-in for Grasshopper is used to offset the mesh (see image 51).



[Image 51] Shrinking the splint by applaying a mesh offset within the Grasshopper script

3.3.7 – Conclusion

The two most important aspects of the computational design are that it works parametrically so that it adjusts automatically to another hand geometry (1) and that the design can be altered according to the personal wishes of the patient (2). This includes the distribution of support, size, thickness, and aesthetic attributes.

When designing the computational design parametrically to make it suitable for an automatic workflow, the main issue that arose concerned the orientation of the surfaces. This caused several errors when switching between different mesh geometries. Fixing the face normal direction solved the problem for most models.

By changing the black and white image you are able to vary the surface shape of the splint. With the number sliders the proportions of the splint and the design attributes can be changed. This is still very limited with regard to the possibilities in the field of computational design. Therefore, it would be relevant to explore this further to be able to, as it were, knead the entire splint shape with a few number sliders.

3.4 - Design for manufacturing

3.4.1 – Introduction

Materials and digital fabrication techniques were briefly explored in relation to accommodating variance during the discover phase. The material properties, mechanical properties, manufacturing techniques, and the aesthetic properties with reference to splint use will be examined in greater depth in the following chapter.

The three materials that were chosen for this comparison are: 925 sterling silver, transparent resin, and Alumide (polyamide 12 filled with aluminium) (Technical Specifications | Transparent Resin | i.Materialise, z.d.), (Oceanz Alumide, 2021). These materials were chosen since: (1)silver is a stereotypical material for jewellery, (2)transparent resin is a less conspicuous material and on the other hand offers coloring possibilities for personalization, and (3)alumide is a cheap polyamide plastic which is filled with aluminium and therefore feels more like a metal instead of a plastic.

MATERIAL	**925 sterling silver** (CES EduPack2019)	**Transparent resin** (CES EduPack2019, *i.materialise)*	**Alumide** (CES EduPack2019, *Oceanz*)
DENSITY (kg/m³)	1.04e4 - 1.05e4	1.11e3 - 1.4e3	*1.4e3*
PRICE (EUR/m³)	4.38e6 - 5.09e6	2.15e3 - 3.49e3	1.2e4 - 1.27e4
YOUNG'S MODULUS (GPa)	70 - 80	2.35 - 2.47 *(2.65-2.88)*	*3.8*
TENSILE STRENGTH (MPa)	385 - 475	45 - 89.6 *(47.1 - 53.6)*	*40/32*
TOUGHNESS (kJ/m²)	48.8 - 61.6	0.135 - 0.165	8.01 - 10.7
HARDNESS	115 - 145 HV	11 - 22 HV *(82 shore D)*	*76 shore D*
DURABILITY (SALT WATER, SUNLIGHT, WEAK ACIDS AND ALKALIS)	Excellent	Excellent, fair, acceptable, limited use,	Excellent, fair, unacceptable, excellent
PRODUCTION TECHNIQUE	Lost wax casting	Stereolithography (SLA)	Selective laser sintering (SLS)
FINISH	Gloss	Transparent or colored	Grey
PRICE PER PIECE	207.32 €	143.50 €	15.02 €
PRODUCER	i.materialise, Shapeways	i.materialise, Shapeways, Oceanz	i.materialise, Oceanz
PRODUCTION TIME	3 weeks	3 weeks	3 weeks

[Image 52] Material comparison table

3.4.2 – Material and mechanical properties and evaluation

The first aspect of comparison are the material properties. The properties that are theretofore put in the table in image 52 are: density, price, stiffness, strength, toughness, hardness, and durability.

The density if the material is important regarding the user comfort since the product should be as light as possible so that it is non obtrusive (R1.3.2, R1.4.2).

Secondly the price and production technique determines largely the product costs. Therefore, researching cheaper material options is recommended. Moreover, especially for patients with a fast evolving disease course who switch faster to new splints, cheaper options are interesting.

Then, the stiffness, strength, and toughness of the material affects the functionality of the splint. It is important that the splint is strong enough to withstand impact during daily life activities (R1.4.1). It should therefore not be too brittle, but also not too elastic otherwise it loses its functionality.

The hardness will affect the aesthetics of the splint over time. When the material is too soft, the surface will become dull because of scratches.

Finally, the durability of a material is important since the splint must be designed for long-term daily use (R0.2). The four aspects that have the greatest impact on the materials sustainability are salt water (sweat), sunlight, weak acids (PH value of the skin), and weak alkalis (soap).

When the three materials are compared on the basis of the previously described aspects, 925 sterling silver is by far the strongest and most durable material. However, it is also 10 times more expensive than transparent resin or alumide. When the splint is made of 925 sterling silver, it is therefore crucial that it fits well for a considerable amount of time.

Transparent resin has bad material properties compared to 925 silver, but it is fairly durable and UV protection could be added. Also, the material is much cheaper than silver but the price per piece remains quite expensive, possibly due to the production technique.

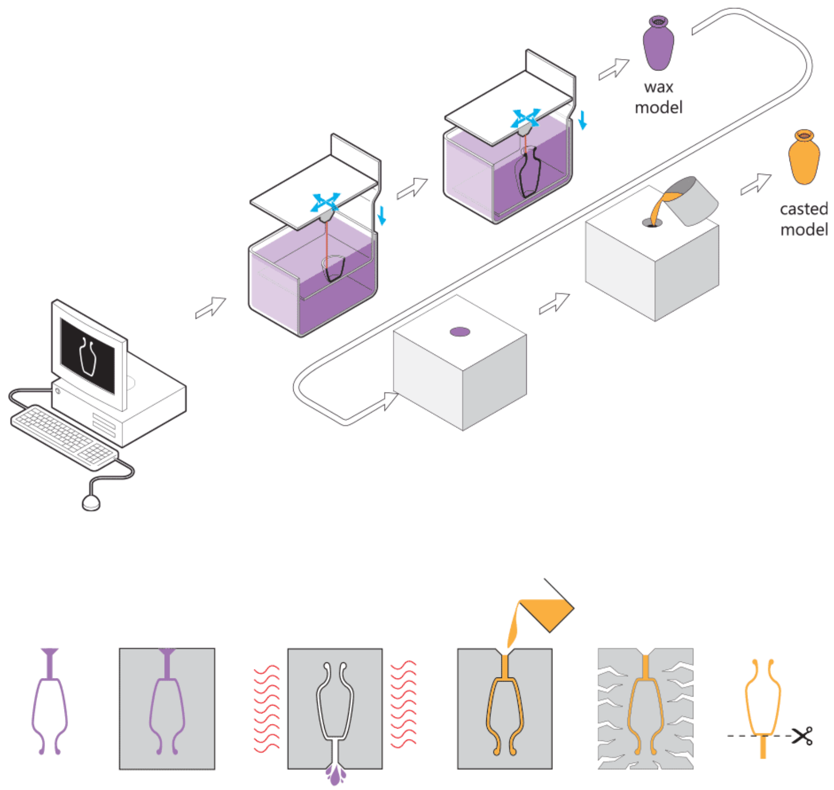
Finally, alumide is comparable to transparent resin, but the material is more expensive, slightly stiffer, tougher, and less strong. The price per piece is significantly cheaper than with the other two materials. However, the material is not resistant to weak acids which will be problematic for long-term use since the human skin is acidic (Vichy, z.d.).

3.4.3 – Manufacturing techniques

As discussed earlier in the discover phase in chapter 1.7.3 on materials. The manufacturing technique influences the quality and the aesthetic properties of the product. Therefore, it is important to not only look at the material properties but also at the way that it is made. The production techniques for the three selected materials will be explained and discussed in the following chapter.

Lost wax casting

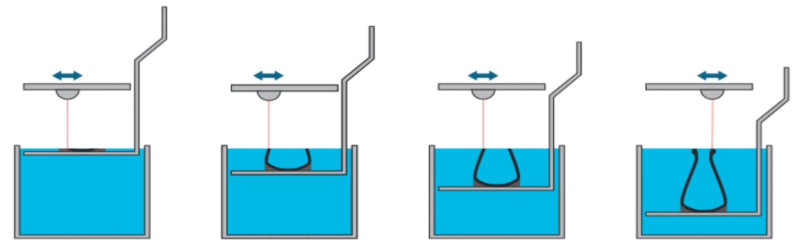
The typical manufacture technique for silver jewellery is lost wax casting (see image 53). This is an indirect 3D printing technique since the end product is manufactured with the use of a 3D printed model, but actually it is casted. This 3D model is printed in wax with the use of the stereolithograpy process. Secondly, a plaster mold is created around the wax model and put in an oven so that the wax is burned out. Then, the mold is ready to pour in the molten metal. Once the model is cooled down, the plaster mold can be broken to take out the pieces. Finally, the pieces will be sanded or polished according to the finish you desire.



[Image 53] The lost wax casting method (3D Printing Technologies | i.Materialise, z.d.)

Stereolithography (SLA) and resin casting

Stereolithography is used to 3D print resins (see image 54). The tank is filled with resin and every layer the platform goes a little bit further under in the resin. This small layer of resin is hardened with a laser. In this way the model is build up layer by layer. It does however need a support structure and therefore the design freedom is somewhat limited. The advantage of this technique is that you're able to print transparent materials.

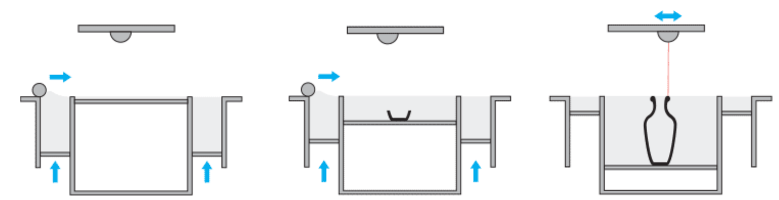


[Image 54] The stereolithography 3D printing method (3D Printing Technologies | i.Materialise, z.d.)

Manufacturing transparent resin products can be also done with the use of indirect 3D printing techniques. The product is printed with the selective laser sintering technique and casted afterwards. The mold can be made out of plaster, but if you want to reuse it later on it should be made of silicon. The advantage of resin casting is that it can be casted crystal clear and therefore has better aesthetic properties. Moreover the cast will most likely be stronger than the 3D printed part. The disadvantage is that the cast will instantly take over the details of the 3D printed part, necessitating additional finishing operations between the 3D print and the final cast. This adds up to the two extra steps the process already requires.

Selective laser sintering (SLS)

This 3D printing technique makes the object out of powder by melting specific areas of the layer onto the previous layer (see image 55). Every cycle, a new layer of powder is spread over the surface by a roller. Then, the laser melts selective areas that will form the object. The whole setup is preheated just below the melting temperature. Therefore, there is only a small amount of extra energy needed to melt the powder and this energy is applied by the laser. This method has the largest freedom of design since there is no support structure needed.



[Image 55] The selective laser sintering 3D printing method (3D Printing Technologies | i.Materialise, z.d.)

[Image 56] Silver splint

[Image 57] Resin splint

[Image 58] Alumide splint

3.4.4 – Aesthetic properties and evaluation

As the aesthetics of the splint is important for a jewel-like perception, the splints will be evaluated on their aesthetic properties. First, some general comments on the aesthetic design are made. The beads that cover the edges of the arches come forth really nicely. It adds some elegance to the splint design. However, this makes the splint also very feminine, which might not be preferred by everyone. The connection of the arches is, as expected, not that pretty. The connection lines are clearly visible and it makes the splint look cheap. Moreover, this makes you wonder whether the quality is good enough.

The silver splint looks like a high end medical jewel right away (see image 56). The shiny material, which has some weight, gives the feeling of a costly and durable splint. Also the texture is nice and smooth, which gives it a clean appearance.

Secondly, the resin splint is totally different from the silver variant (see image 57). It looks more modern and less classic. Nevertheless, this does not affect the jewel-like appearance. The resin is fully clear and hardly any 3D print marks can be found on the model.[RAUT.7]★ It has a blueish glow, which gives a cool and airy feeling. This splint would be the perfect splint for casual summer days.

Finally, the alumide splint (see image 58). This is a cold material with a glittering surface. It therefore feels more like a high end splint than it actually is. The surface has a sandy texture and might cause irritation of the skin. The look of the splint tends more towards a cheaper plastic, which is not meant for long term use.

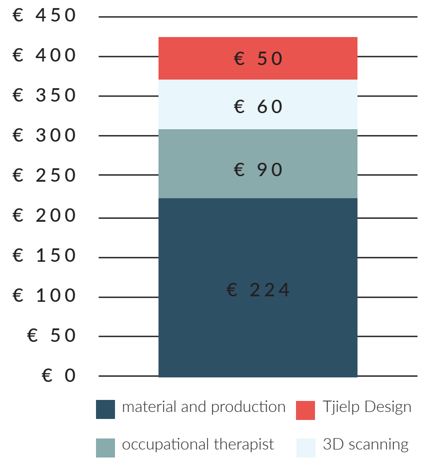
The material itself is quite brittle and possibly does not hold for long term purposes. However, in the second week of the proposed splint process where the patient wears the splint for a week, it would be the perfect solution. In this case, the splint is worn for a short test period to evaluate the design and fit.

To conclude, all three materials turned out nicely in this splint design. The design itself needs a few ore iterations with regard to the aesthetics of the arch connection. There is not an unambiguous conclusion on the aesthetic properties of the three materials. Every material suits a different purpose and a different person. This is precisely the advantage of ultra personalization, which enables for material variation.

3.4.5 – Cost analysis

To evaluate splint costs, a silver splint is used as an example. The costs are divided into four categories: material and production, occupational therapist labor hours, Tjielp Design design hours, and 3D scanning fees.How this is determined can be found in appendix 8.

As you can see in image 59, material and production costs account for more than half of the total. The hourly rate of the occupational therapist is relatively high. However, occupational therapy is covered by the insurance up to 10 hours a year. When the total amount of 10 hours is not used up, this could save money and put into more complex cases where taking the measures and adjusting the design asks for more time.



[Image 59] Estimated silver splint costs

3.4.6 – Conclusion

Design for manufacturing is validated by desktop research and the production of the splints in three materials with different production techniques. The three materials where, silver, resin, and alumide. It is important that the materials are strong enough and durable with regard to salt water, UV, weak acids and alkalis.

Silver is the strongest and most durable material and this is reflected by the price. The material properties of transparent resin are less good. Yet, it is also cheaper and can therefore be replaced more often. Alumide is the cheapest of all three materials. Unfortunately it is less strong and also the durability is not great. Therefore, this type of material is more suited for a temporary splint.

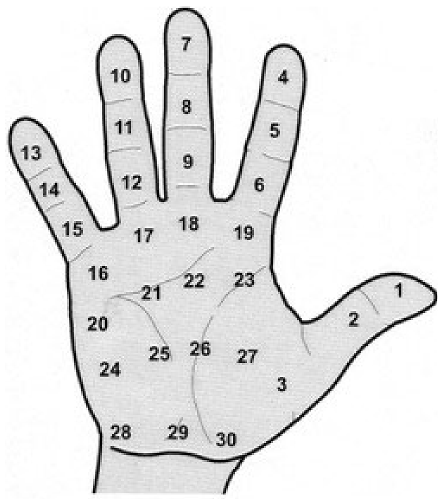
It is important to understand how the additive manufacturing techniques work in order to predict the mechanical and aesthetic properties. The lost cast waxing method, stereolithography (SLA), and selective laser sintering (SLS) have been discussed.

As previously thought, the additive manufacturing techniques did not interfere with the aesthetic perception too much. That's very positive since aesthetics are an important asset of the splint design. Furthermore, all three materials do well. The look and feel of the materials is completely different. However, all splints have a jewel-like appearance. The one is more casual, as the other is a classic piece of jewellery. This contributes to the personalisation aspect of identity, where every user would prefer a different material for a different occasion.

Finally, material selection and the associated manufacturing method can have a significant impact on splint prices. When a consumer wants multiple splints made of different materials, the expenditures of measurement and design hours only have to be spent once. Because of the digitization of the design process, this is possible.

3.5 - Product Evaluation

3.5.1 – Introduction



[Image 60] Schematic representation of the 30 points for pressure pain threshold assessment (Fernández-de-las-Peñas et al., 2010)

The two most important aspects of the user evaluation are the functionality and the fit of the splint. The functionality concerns whether the splint meets the requirements of: immobilizing the CMC joint, decreasing the range of motion of the MCP joint, and abducting the thumb (R1.2.4). On the other side it is important that the splint is comfortable and that other daily activities are hindered as little as possible (R1.3.2). Therefore, an user evaluation shall be conducted in the following chapter. This ended up becoming a self-evaluation due to unforeseen circumstances.

To evaluate the first aspect of splint functionality, the three hand gestures regarding the general hand mobility are made:

- Stretching fingers
- Making a fist
- Pinch grip

If the hand gesture could be made smoothly, it was rated as excellent. If it demanded a little effort, as acceptable. Otherwise it was rated as poorly or not possible. Thereafter, the range of motion in the MCP and CMC joint were determined. This concerned the amount of flexion and extension (mm), abduction and adduction (mm), and whether circumduction was possible (YES/NO). To measure the displacement regarding the CMC joint, a pencil was pressed against the MCP joint. Thereafter, the drawn line was measured with a calliper. For the MCP joint, the same procedure was followed, but then the pencil was pressed against the IP joint.

The second aspect concerned the fit evaluation. Inspiration was taken from a schematic representation of the 30 points for pressure pain threshold (PPT) assessment (see image 60). The comfort of the splint was assessed for every point that is in contact with the splint according to this representation. For this assessment, the splint was worn for 30 - 60 minutes while writing this thesis.

3.5.2 – User evaluation

There are three splints to be evaluated, the splint based on a wrapped and post corrected 'normal' hand scan (1), the splint based on a 3D scan of a normal hand (2), and a splint based on a wrapped and post corrected pathological hand scan (3). The latter was not evaluated in the course of this master thesis due to the COVID-19 pandemic.

Pose correction splint (reduced by 2mm)

The first splint is the splint with a digitally corrected posture (see image 61). As discussed before, in chapter 3.2.7, the posture correction resulted in a questionable hand shape. Especially around the metacarpal1, the splint shape does not follow the exterior hand shape as should be. This will increase functional discomfort because the splint can get stuck behind something.

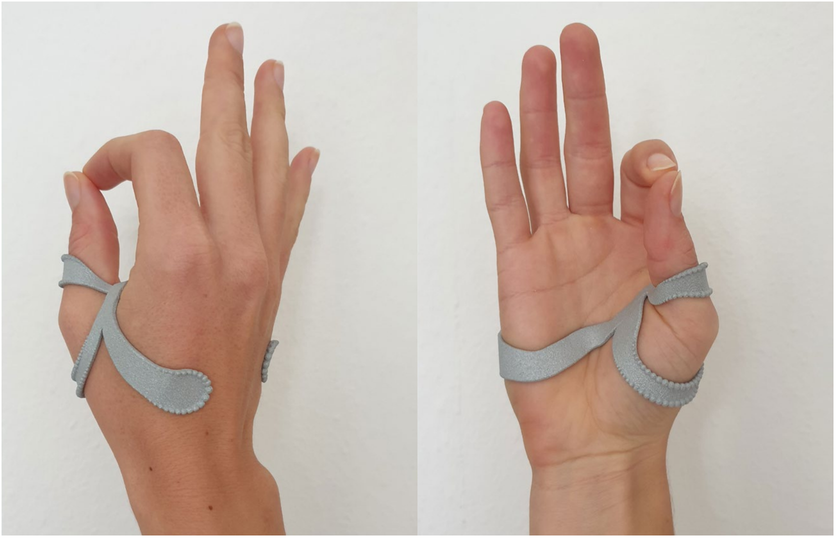
[Image 61] Pose correction splint

Furthermore, the fit and functionality of the brace was evaluated (see image 63). This evaluation pointed out that the range of motion for the CMC joint is too large. Both, the flexion and extension and the abduction and adduction ranges are too large. The CMC joint should be as much immobilized as possible, and it is not. The metacarpal1 must not be able to adduct, but with this splint it still can. Finally the MCP joint is too much immobilized. It only has 2mm of freedom, where it is allowed to fully flex. Finally, there were five pressure points located, which indicates an uncomfortable fit, or even a painful fit. When comparing multiple patient evaluations, the numbers allow for a more objective comparison.

It can be concluded that this splint fits poorly. From the three functionality aspects, only the requirement of decreasing the range of motion of the MCP joint was met. And even this was done too much, as a result of which the general hand functionality is reduced.

3D scan splint (reduced by 2mm)

The second splint that is to be evaluated is the splint based directly on a 3D scan. The evaluation is done with the alumide splint (see image 62). Unfortunately, the opening of the MCP arch is too small for the thumb to fit through smoothly. Besides that, the first thing you notice is the snuggle fit. It forms exactly



[Image 62] 3D scan splint

after the curvature of the hand. This indicates that resizing the splint by offsetting the mesh in the Grasshopper script is an accurate method. In rest pose, the metacarpal1 is adducted a little bit too much, which decreases the reach of the thumb.

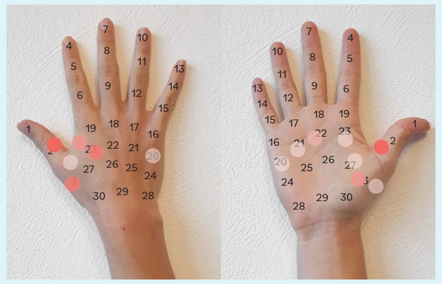
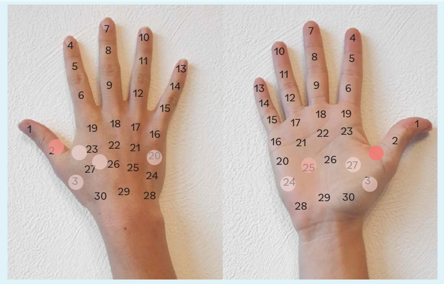
When we look at the table on the right, the MCP joint is again immobilized a little too much (see image 63). Furthermore, the CMC joint is fairly immobilized, and the metacarpal1 cannot adduct. There are only two pressure points located in-between the thumb and the index finger. These can be eliminated by moving the connection points of the MCP arch further apart.

3.5.3 – Conclusion

In conclusion, the '3D scan' splint has a better fit compared to the 'pose correction' splint. However, the fit is not yet optimal en needs adjustments. The MCP arch must be widened by moving the connection points of the arch further apart. This, given the fact that the thumb did not fit through the MCP arch, the MCP joint is immobilized too much, and there are pressure points located at the connection of the MCP arch.

For a better fit evaluation the splint should be worn during an entire day, from getting up in the morning until going to bed in the evening. Thereafter, the splint comfort should be evaluated every hour. This will give an indication for how the pressure points evaluate throughout the day. As a result, this will provide a more comprehensive picture of the splint comfort during daily life activities.

Finally, the same evaluation should be carried out with a patient with pathological hands. This will be different since they might experience more or less pain from pressure points at certain areas because of their condition. This probably results in an additional factors for ultra personalisation.

FUNCTIONALITY	**POSE CORRECTION SPLINT** Reduced by 2mm	**3D SCAN SPLINT** Reduced by 2mm
STRETCH FINGERS	YES	YES
MAKE FIST	YES	YES
PINCH GRIP	YES	YES
FLEXTION/EXTENSION	2mm **MCP** 12mm **CMC**	2mm **MCP** 6mm **CMC**
ABDUCTION/ADDUCTION	0mm **MCP** 10mm **CMC**	0mm **MCP** 0mm **CMC**
CIRCUMDUCTION	NO **MCP** YES **CMC**	NO
NOTES	*No snugly fit*	*Snugly fit, MCP joint is immobilized instead of decreased range of motion*
COMFORT		
30 POINT PPT Comfortable - Painful		
NOTES	*The thumb barely fit through the MCP arch. Putting the splint on was painful. Worn for 30 minutes.*	*The thumb barely fit through the MCP arch. MCP joint needs more freedom of motion. Worn for 60 minutes.*

[Image 63] Functionality and fit evaluation

3.6 - Conclusion

During the final design and validation phase, a product-service system was designed. The designed product is a personalized MCP/CMC stabilisation splint that can be customized according to the users' wishes. The accompanied service is designed around the occupational therapist. Once there is agreed upon the splint functionality, Tjielp Design offers a one-of-a-kind jewellery experience.

The viability and feasibility of the product-service combination heavily rely on the workflow's automation. In the ideal future, the design steps are controlled by a python script that addresses every design program automatically. In this way, the only manual step is gathering and uploading the anthropometric data. Thereafter, the manufacturer sends the personalised splint, which can be worn immediately. Until then, it is crucial to design the workflow so that it needs as little interference as possible. A start has been made with the automated design workflow.

The proposed data and parameter acquisition is made with a 3D scanner. After that, a template mesh is wrapped to this 3D scan. This results in a new mesh geometry (the patients' hand). With unchanged mesh connectivity, this mesh can be used for the next posture correction step. Post correction of the posture is needed for patients with both 'normal' and pathological hands. Holding the preferred splinting pose while making a 3D scan is difficult, if not impossible. Unfortunately, the posture correction did not result in a representative model of the hand in functional splint posture. The exterior hand shape, after posture correction, deviated too much from normal for a well fitting splint. A better understanding of the joints and their range of motion is needed for a more accurate digital representation of the hand posture.

Furthermore, 3D scanning of patients with rheumatoid arthritis, who have pathological hands, is challenging. For them, better instant 3D scanners designed for hands are a must. Until then, it is recommended to continue building an extensive database of splint designs for patients with 'normal' hands. For these patients, a statistical shape model (SSM) has the preference because of the simple measurement procedure. Moreover, this can be a bridging solution towards better 3D scanning technologies. Meanwhile, a large database of pathological hands should be made to build a pathological SSM from(comment: from weg halen?). Whether an SSM for these patients will be accurate enough, in terms of personalization, should be evaluated in a later stage.

The computational design works parametrically so that it adjusts automatically to another hand geometry. Another aspect of the design is that it can be altered according to the patient's personal wishes. The distribution of support and the aesthetic attributes are examples of this. With regard to design automation, the orientation of the splint surface(s) is crucial for a smooth transition between meshes. Another aspect that caused errors, is the connection between arches. These connections should be fixed or removed from the design. Also, because the bisectors are aesthetically unpleasant, they might decrease the mechanical properties of the splint.

The aesthetic features of the computational design can be altered with sliders. Black and white images are used to vary in the design of surface cut-outs. However, the design has not yet used its full potential with regard to algorithmic thinking. In the future, it is therefore recommended to further explore aesthetic design through computational design.

Another aspect of the workflow is designed for manufacturing. The splint is produced with the use of additive manufacturing techniques. In order to evaluate the material, mechanical, and aesthetic properties, three splints were manufactured and evaluated. The splints were made of 925 sterling silver, resin, and alumide. After comparing the three different materials, it can be concluded that silver is the strongest and most durable material. The other two materials have lesser mechanical properties. But even though they might fail sooner, splints in these materials can be replaced more often because of the low price. However, alumide did raise questions regarding long term use. The material appears to break easily, and the durability is not outstanding.

Furthermore, the splint will be exposed to sunlight, make contact with the acidic human skin, and encounter sweaty hands. Once in a while, the user washes their hands with soap. This soap will also affect the durability of the splint. It is therefore important that the material can withstand salty water, UV radiation, weak acids, and alkaline environments concerning daily life usage. All three materials are durable enough for the splint application.

The aesthetic properties of the three are far apart. The one thing they have in common is that it looks like a jewel. The difference in aesthetics resembles the difference between users. Some users like a more classical splint, whereas others prefer a modern variant. Also, different occasions ask for different splints. Material choice can therefore be very efficient in accommodating variance. Since the design process is digitalised, it is easy and relatively cheap to post order splints in different materials. The expenditures of measurement and design hours only have to be spent once.

Finally, the splint is evaluated on the functionality and fit. The current splint design, which is directly based on a 3D scan, fits snugly. As mentioned before, the splint, which is based on a post corrected 3D scan, did not fit well. This was due to a distorted exterior handshape resulting from the digital posture correction.

With regard to the overall functionality, the MCP arch must be widened so that the IP joint fits through smoothly. Additionally, this will reduce pressure points on the thumb and improve the MCP joint's range of motion.

3.7 - Recommendations

Splint process
- The splint process should be implemented and evaluated around the occupational therapist.
- Additional research should be conducted on the collaboration between the different stakeholders in the process and how this could be optimized.
- In the future there should be a design interface, which can be operated by everyone.
- A medical network should be obtained.
- Arrangements with insurance companies is recommended.

Data and parameter acquisition
- The Structure scanner pro appears to have potential for 3D scanning of 'normal' hands. Further research is needed to evaluate whether the resolution is sufficient.
- The representation of the joints in the armature should correspond more to reality with respect to joint types.
- The digital representation of the armature should have limits on the range of motion per joint. Otherwise it is not possible to post correct the posture without detailed knowledge about the hand movement.
- The mesh wrapping and pose correction should be implemented and evaluated for patients with pathological hands.

SSM
- The statistical shape model should be evaluated with regard to the accuracy of the digital hand representation.
- For pathological hands, it is recommended to build a large data base of 3D scans to build a pathological SSM.

Computational design
- The computational design must be further optimized for fast switching between meshes.
- The computational design should exist of one single spline, instead of three separate arches. This will decrease errors in the model and eliminate the bisectors.
- The aesthetic features should be further explored so that the splint can be 'kneaded' into the desired shape.
- The computational design should be rebuild in a way that it requires less computational power. This enables a faster workflow.

Design for manufacturing
- Further research should be conducted on the mechanical properties of the splint. And how different manufacturing techniques influence this.
- The splint shape should be redesigned for better mechanical properties.
- The splint design should be optimized with regard to costs, amount of material, and mechanical properties.
- Further research is needed on the durability of the materials.

Product evaluation
- The MCP arch should be minimally as wide as the IP joint. Preferably with a little slack for patient who have painful joints already.
- The connection points of the MCP arch should be moved more apart to increase the range of motion and to reduce pressure points.

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APPEN-
DIX

Contents

Appendix 1: Initial design brief

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 !

mily name: Keijser

initials: L.M.M. given name: Lies

nt number: 4445007

reet & no.:

ode & 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: Minnoye, A.L.M. dept. / section: SDE, MD

** mentor: Huysmans, T dept. / section: HCD, AED

2nd mentor:

organisation:

city: country:

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

APPROVAL PROJECT BRIEF
To be filled in by the chair of the supervisory team.

chair Minnoye, A.L.M. date 01 - 03 - 2021 signature

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

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

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

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

YES all 1st year master courses passed

NO missing 1st year master courses are:

name ______ date - - signature ______

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

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

Content: APPROVED NOT APPROVED

Procedure: APPROVED NOT APPROVED

comments

name ______ date - - signature ______

Design of a customisable splint ring 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 10 - 02 - 2021 31 - 07 - 2021 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, ...).

Osteoarthritis is a disease of the cartilage in the joints, also known as 'joint wear'. When someone suffers from hand arthritis he/she experiences pain and stiffness in the finger joints. To relieve the pain, a splint ring can offer a solution to reduce stress on the joints. Depending on the specific finger problems, the ring counteracts bending, overstretching, or immobilises the entire finger joint.

People with arthritis have to wear the splint ring every day and continue wearing them for the rest of their life until (or even continue wearing it after) he/she undergoes surgery. Therefore, the ring should fit well and shouldn't hinder daily activities too much. Besides, patients are preferably not confronted constantly with their medical issues and might prefer an unobtrusive splint ring. Sometimes people are vain and refuse to wear something that they visually dislike even though it benefits their health. For these reasons, it is necessary to understand the user's motives and what holds them back from using this device.

A physiotherapist or an occupational therapist helps the patient with hand and wrist exercises and adapting their daily activities to the benefit of their medical condition. When the arthritis becomes severe, people can go to an orthopedic surgeon to evaluate whether an injection or even surgery is needed. Also, these experts can write a referral which is needed for the patients insurance to reimburse the costs for the splint ring (most basic insurance packages do). In conclusion, these experts are in direct contact with the user, have a lot of knowledge about the medical condition and the treatment, and are able to write a referral.

There are many types and forms of splint rings (see image 2). There are medical variants with velcro, plastic splints, and silver splints that are personalised by a silversmith (10x more expensive). Specific rings address specific finger problems, here personalised finger splints offer more possibilities and have a more comfortable fit. Currently, this is manual labor carried out by a blacksmith. It is a time consuming process and requires an expert in the field of forging silver as well as medical problems. Moreover, it requires several consults and measure appointments between the patient and blacksmith. All in all, it can take four to six weeks before the splint ring is finished.

Anna Ruiter has developed a new personalised splint ring that looks less like a medical device and more like a jewel (see image 1). Currently, this is a design for a 3D printed ring that fits one person only. Ultimately Anna sees that this design process is partially automated so that many people can benefit from this personalised piece of medical jewellery.

When it comes to personalised design, Fieldlab UPPS has a wide range of knowledge and experience with collecting and analysing 3D data, parametric design, and digital fabrication techniques. Ultra Personalised Design and Services consist one ore more of the following aspects, (1) identity, the preferred look and feel, (2) capabilities, the function and specific features, and (3) fit, the interaction between product and customer/environment/other products, the characteristics and personalised interactions.

To conclude, the biggest opportunity lays in digitalisation, design automation and digital fabrication. This approach will reduce time and costs for personalised design. However, producing personalised designs is cumbersome and there are limited suitable production techniques available. This would therefore be the main limitation of the design project.

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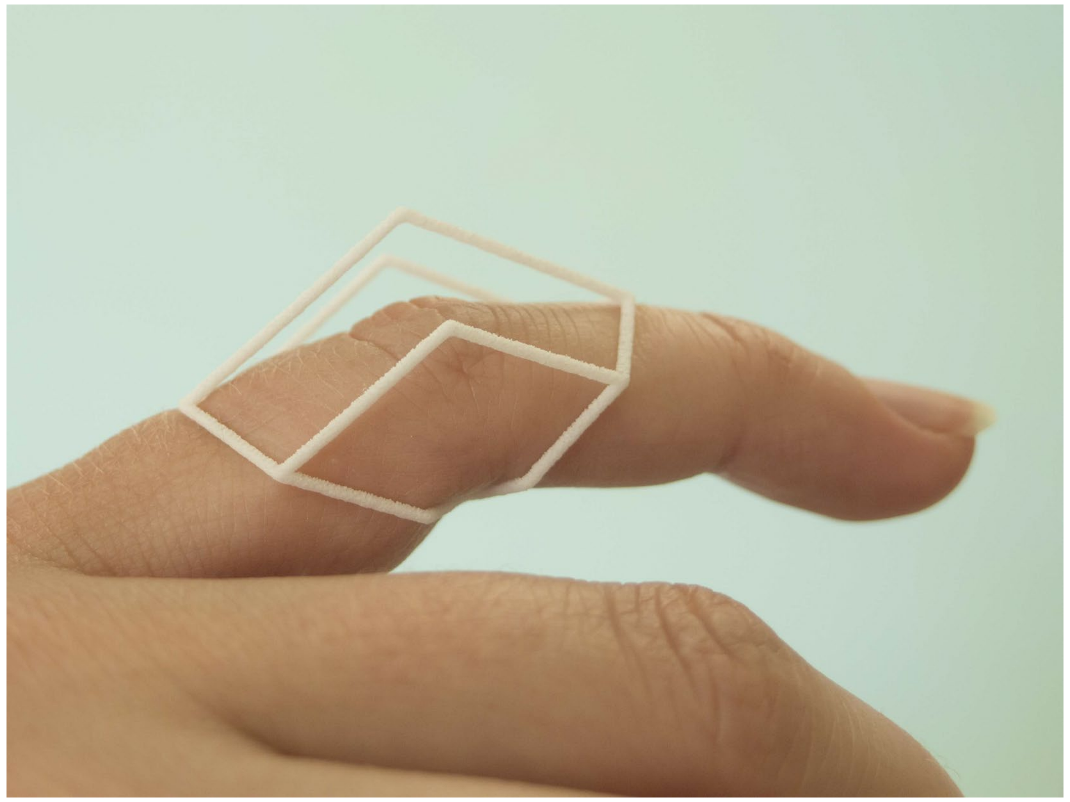


image / figure 1: Finger splint ring design by Anna Ruiter

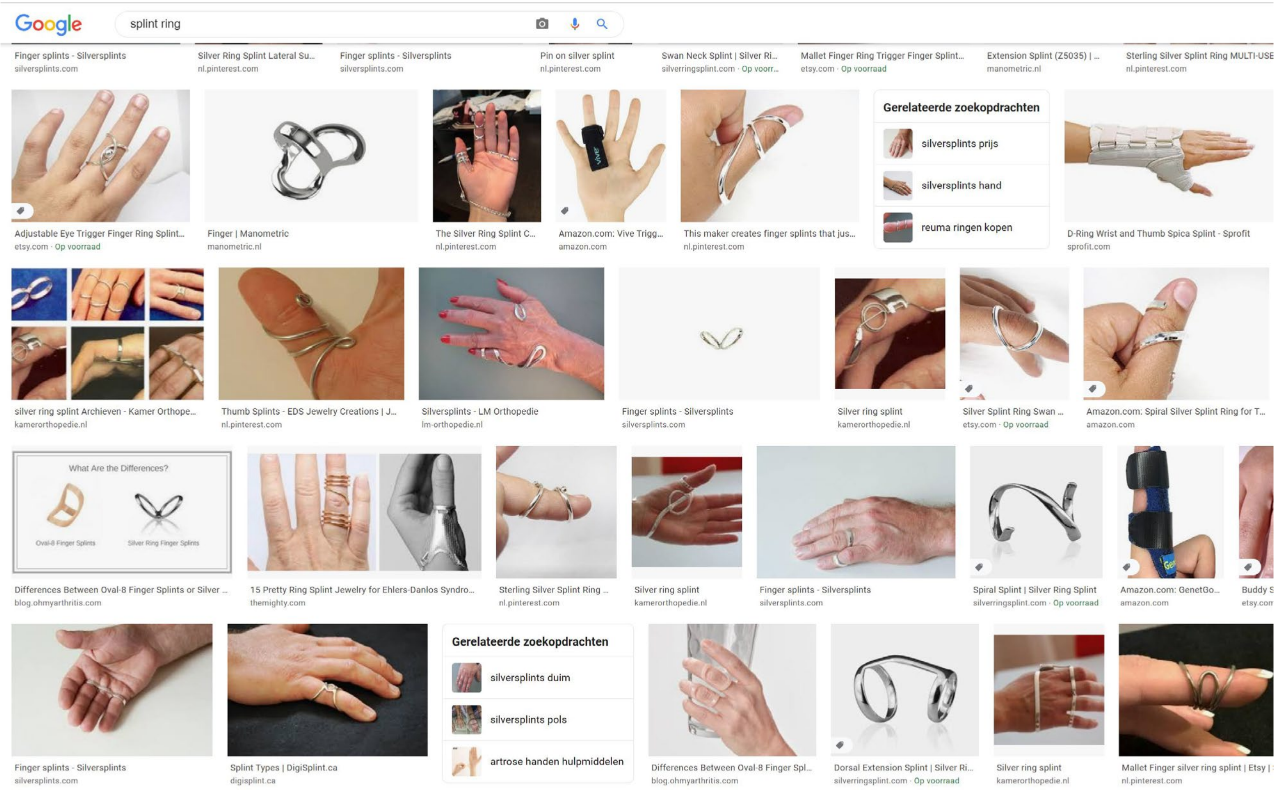


image / figure 2: Variety of finger splint rings

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.

Currently, the manual production of personalised silver splint rings are time consuming and very costly. This is due to the fact the process requires a blacksmith, who is an expert in forging silver and these medical problems. The manual process is as follows, the blacksmith measures the patient manually (1), designs the ring according to the individual finger shape and it's problems (2), then also produces the ring manually (3), and finally adjusts it a few times so that it fits the patient perfectly (4). Throughout this process, both the blacksmith and the patient have to be in the same room at the same time. This requires good planning and a lot of patient involvement.

In order to reduce time and costs, the design process should be automated. A computational design approach is recommended since it has the ability to automatically transform parameters into a 3D design. This approach (partially) takes away the manual labour and can be divided in the following steps.
First, generating a template using computational design. This splint ring template relies on the design requirements for a specific finger problem.
Secondly, data/parameter acquisition. 3D scanning techniques are used for acquiring personal body measures and shapes. This data is required for the personalisation of the finger splint ring.
Thirdly, design for additive manufacturing. The design is further prepared for manufacturing and the personalised design is produced. Other digital fabrication techniques can be considered here as well.
Finally, product evaluation. For the product evaluation an expert on design and the medical conditions is required. This means that there is need for someone who has experience with and expertise on the field of medical jewellery. Moreover, ethically it is not much appreciated when the craftsmen are sidelined.

In conclusion, by reducing the manual labour and automating the measuring, design, and production process, this will result in a more viable solution.

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.

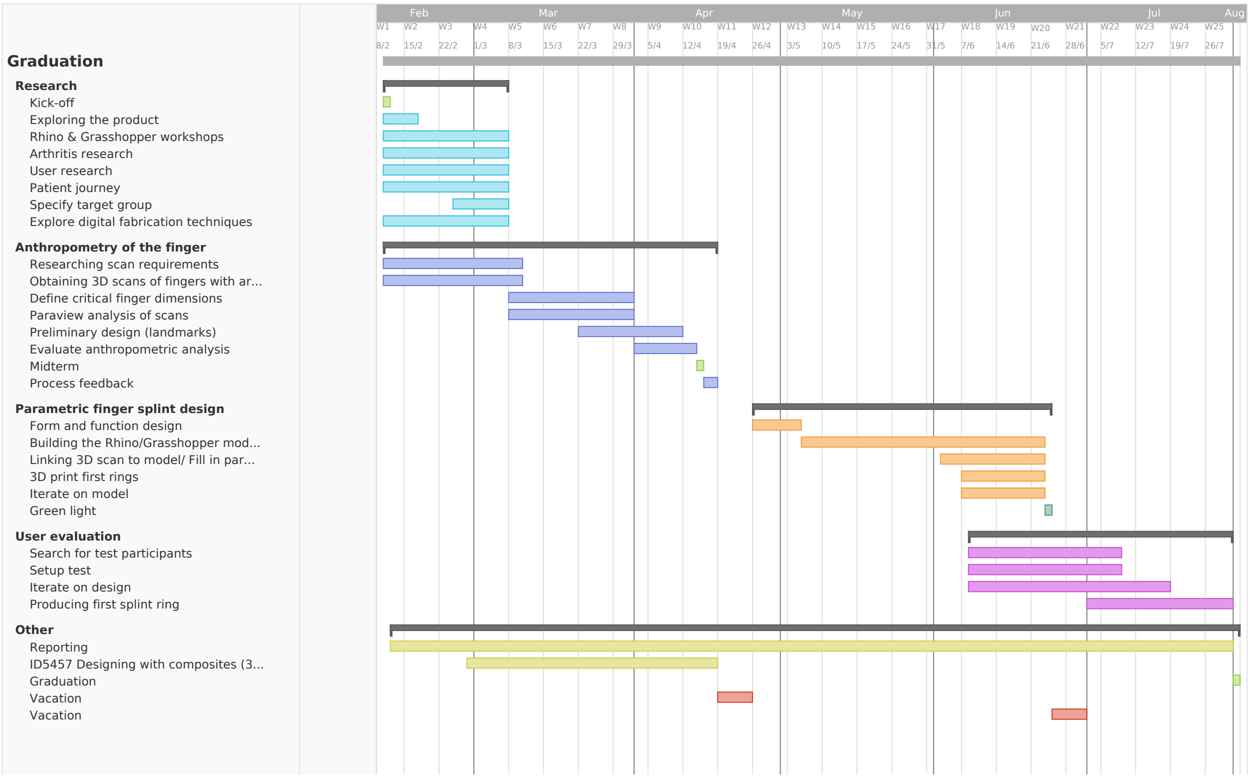
Creating a personalised finger splint design that automatically adjusts to the anthropometric data. Resulting in a product-service combination that takes into account the whole patient journey, from the medical consult, to scanning/measuring the patient, and producing the personalised finger splint.

Within this project there are three main personalisation aspects, fit, capabilities, and identity. Human centered design and computational design will have the main focus.
Fit: The splint ring should have a comfortable fit. Therefore I want to conduct research on hand arthritis and analyse the anthropometrics of fingers with arthritis. By determining the critical finger dimensions an indication can be made of where the ring design has to support the joint. Also, the product-service combination should fit the interaction between the patient and medics/other products/environments well. Therefore I will layout the current and new patient journey.
Capabilities: With the use of computational design software, an automated design can be made with statistical shape models. By importing 3D scans of fingers with arthritis or a few parameters (measured by hand), the ring design should adapt automatically. In this way there is little effort needed to create a personalised ring shape for every user. The most suitable type of scanning/measuring should be further determined. Since every splint ring is unique, it is not possible to produce in large quantities with the conventional production techniques. Digital fabrication techniques should be explored to see if it is possible to produce the rings somewhat automatically and at a lower cost than silversmiths make them (94-355 euro).
Identity: During the design process some changes in the aesthetic design might be needed. However, these should not detract from the jewel-like appearance. Also, people differ in their opinion when it comes to the material. Some people value a silver splint, where others prefer a discrete splint ring (e.g. high-quality nude plastic).

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 10 - 2 - 2021   31 - 7 - 2021 end date



Note: 25 weeks due to an elective course of 3ECTS (84h), national holidays, and holiday (two weeks).

I will start with researching the medical condition of hand arthritis and the corresponding target group. This should help with mapping out the current patient journey and the desired one. Since I haven't used Rhino and Grasshopper before I plan to follow the workshops of the Advanced Prototyping Minor (6 x 4 hours). This should provide me with enough knowledge and skills. During the research phase, I will explore the possibilities for anthropometric analysis and digital fabrication techniques since they might influence the design choices.
Secondly, I will explore different 3D scanning techniques and determine the requirements for the 3D scan. Then, I will dive into the anthropometry of the finger and determine the input parameters for the splint ring design and its ideal form.
When gathered sufficient information I'll continue with building the model. Before the green light I want to have (almost) finished the model so that I can start the user tests and the production of the splint ring. Probably, I will have to iterate on the design a few more times after that.

Deliverables:
- Thesis
- Product-service combination
- Prototype splint ring
- Presentation

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.

With two parents working in healthcare it's not strange that I developed an interest in the medical field. Also, during my MCs programme I found the medical projects the most interesting every time. That's why I decided to continue with the Medisign specialisation. More specific for this personalised splint ring project, I have a very vain grandma who is suffering from arthritis. And I can imagine that she won't wear a finger splint that is aesthetically unpleasant, and she won't grant herself an expensive silver splint made by a silversmith either. That's why I like this idea for the personalised silver finger splint and that I can contribute by simplifying and automating the design for it.

During my MCs programme the projects were mainly human centered. I especially enjoyed the expert consultations (medical and technical) during these projects. From the elective semester I acquired competencies in anthropometry (DINED, Paraview), and ZEN design (7 ZEN principles and model building). Also, I've learned about health psychology and forms of motivation.

In my spare time, I love to make stuff. Recently I learned epoxy casting and started making surfboard fins. Here I laminate the outer shell, in the middle I place a 3D printed core design and then I fill it up with epoxy. During this graduation project I like to learn more about these kind of production techniques (e.g. lost wax method) (LO1).

Around me I see that people are evolving a aversion towards mass consumption and the growing interest for second hand goods and personalized products of high quality. However, there is still a long way to go when it comes to efficiency and cost reduction, especially if you have to compete with mass production. Eventually I'd like to see personalised design for everyone. I would like to learn how we can simplify and (partially) automate personalised design. Therefore, I want to learn how to use computational design software (LO2).

FINAL COMMENTS

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

Appendix 2: Interview questions

I will briefly ask questions about your condition and clinical picture. Please don't feel obliged to answer every question if you don't want to. Afterwards, de questions will mainly relate to the hands in relation to finger and/or hand orthosis.

Becoming aware of complaints
When did the complaints start?
How does this affect your dayly life?
What made you decide to ask for care?
How did you experience this and what emotions did it arouse?

Ask for care
What did your care path look like until now?

Diagnosis and treatment
Who diagnosed you?
By whom have you been treateed?
What kind of treatment did you get?

Orthosis referral
Who has referred you for orthosis?
What made you decide to get orthosis?
What are your expectations of the orthosis?
What are your expectations of the exercises?

Measuring the orthosis
Where did you get the orthosis?
Why did you choose for this party?
Can you explain the steps of the process?
Step 1:
Step 2:
Step 3:
Etc.
How did you experience this process?

Fitting and adjusting
Did it fit well right away?
How does it fit compared to the temporary thermoplastic orthosis?

Daily use
Is this your first orthosis?
Could you explain how this orthosis works?
How do you feel while wearing this orthosis?
What do you think of the aesthetics of the orthosis?

Comfort
When do you wear the orthosis?
When are you not wearing the orthosis?
How is the fit around your exterior hand shape?
How important is a snuggle fit for you?

Appendix 3: Interview answers P1 (EDS)

BEWUSTWOREN VAN KLACHTEN

ANTWOORDEN:
Gewrichten uit de kom
Bij openen autodeur bijvoorbeeld
Links meer dan rechts, rechts is sterker
Veel spalken geprobeerd, maar onnatuurlijk en onwennig. Beperkend in beweegvrijheid.

STAP NAAR ZORG

ANTWOORDEN:

DIAGNOSE EN BEHANDELING

ANTWOORDEN:
Reumatoloog en revalidatie arts, sinds twee jaar, sinds vorig jaar de diagnose HED officieel gesteld.

DOORVERWIJZING ORTHESE

ANTWOORDEN:
Hand ergotherapeur heeft doorverwezen naar WEDESIGN, nog niks van gehoord, weet niet goed wat te verwachten hoopt wel op eleganter model.

AANMETEN ORTHESE

ANTWOORDEN:
Intensief proces, wel de moeite waard want het helpt. Maar lastig met drie kinderen.

PASSEN EN AANPASSEN

ANTWOORDEN:
Hand ergotherapeut heeft spalken gemaakt en nieuwe gemaakt als het wat ruimer moest oid.

DAGELIJKS GEBRUIK

ANTWOORDEN:
Overdag, niet snachts. De meest beweeglijke en als de klachten meer opspelen dan switch naar minder beweeglijke. Weet dat ze het eigenlijk wel eerder had moeten doen.
Blijft hangen achter spalk en glijdt dan af.
Kan breken dus moet wel beetje voorzichtig zijn.

ESTHETISCH

ANTWOORDEN:
Mensen vragen er altijd naar, maar hoort erbij. Vind het niet erg om mee over straat te gaan.

Bewegingsbeperking is onprettig
Handen wassen is onhandig
Blijven hangen is onhandig
Altijd contact met revalidatie arts
Vervelend dat ze geen revalidatie heeft gehad na operatie
Slechte communicatie tussen revalidatie-arts en neuroloog
Acceptatie van nieuwsgierigheid andere mensen

Lang proces
Niet vervelend, wel intensief
Fijn om te gaan omdat het helpt
Benieuwd, weet niet wat te verwachten
wil Niet bang hoeven zijn voor kapot of los gaan
Wat als de zilversplint straks niet lekker zit, is niet gratis
Nog niks gezien, denkt dat ze het met haar door gaan nemen
Teveel doen krijg ik pijn
Pijn
Kan altijd erger

Appendix 4: Interview answers P2

BEWUSTWOREN VAN KLACHTEN →

ANTWOORDEN:
Snowboard ongeluk. Pees afgescheurd. Skiduim

STAP NAAR ZORG →

ANTWOORDEN:
Tekst..

DIAGNOSE EN BEHANDELING →

ANTWOORDEN:
Skiduim, röntgen foto's. Slijtage in duim, begin artrose.
Injectie en thermoplast brace.
Niet duidelijk welk van de twee hielp.

Thermoplast zelf een beetje aangepast als het niet lekker zat.

DOORVERWIJZING ORTHESE →

ANTWOORDEN:
Doorverwijzing zilver orthese ivm verzekering. Orthopedisch chirurg heeft naar plastic brace gekeken en beslist over type.
Standaard type uit catalogus.

AANMETEN ORTHESE →

ANTWOORDEN:
Aantal maten van hand opgenomen en orthese 'besteld'.

PASSEN EN AANPASSEN →

ANTWOORDEN:
Na twee weken passen. Drie verschillende testen voor drukpunten (oke handgebaar, vingers strekken, vuist maken).

DAGELIJKS GEBRUIK →

ANTWOORDEN:
Eerste ziler splint was niet breed genoeg en kantelde tijdens gebruik. Gegoten zilver en is gebroken bij duim.

ESTHETISCH

ANTWOORDEN:
Tekst..

Onzeker over juiste afstelling
Gek dat er geen follow up is
Vervelend dat instrument maker niet precies weet wat medische achtergrond is
Alert op dat het wel goed afgested wordt
Wist niet dat het nog afgested mocht worden
Een keer of drie terug geweest
Weet niet wanneer het goed zit

Appendix 5: Interview notes W. ten Cate

Fingers are not as simple as cylinders, they are becoming more flat and small towards the tips.

The thumb is different from the other fingers. There are less thumb splints available on the market.

Manometric is not an orthopaedic company

There are endless possibilities:
Creating a splint design that is operable by people without grasshopper knowledge

Insurance companies do not pay enough to cover the costs for a swan neck splint. They categorise silver splints without paying attention to quality.

Improving the current design on comfort and effectiveness requires very accurate form variations. Anna Ruiter's splint ring design does not follow the finger anatomy precisely and is therefore not suitable for personalisation on a level that competes with others.

With all due respect, if Anna Ruiter wants to succeed she should sell her designs to orthopaedic companies. She has no medical network and she has no technical knowledge.

Anna's strong side is that she can provide aesthetically pleasant splint rings that are ergonomically sound.

Appendix 6: List of Requirements

Introduction 0

Requirements

- R0.1 – The splint must increase hand function in daily life
- R0.2 – The splint must be designed for long-term daily use

Wishes

- W0.1 – The user should feel motivated to wear the splint

Clinical Picture 1.2

Requirements

- R1.2.1 – The splint must reduce stress, stabilize joints, decrease the range of motion, and/or prevent deformities
- R1.2.2 – The product-service combination must take high disease activity into account
- R1.2.3 – The splint solution must not cause pressure points
- R1.2.4 – The splint must stabilize the CMC joint, abduct the metacarpal, and place the MCP joint in slight flexion
- R1.2.5 – The product-service system must fit patients with EDS, OA, and RA
- R1.2.6 – Arthritis in other joints (like finger, wrist, shoulder, elbow, etc.) that affect the product-service system must be taken into account

Wishes

- W1.2.1 – The product-service combination should offer a splint solution for the common deformities, ulnar deviation of the MCP joints, boutonnière deformity (BHD), swanneck deformity (SND), Z-deformation of the thumb, and swanneck deformation of the thumb

Current Splint Procedure 1.3

Requirements

- R1.3.1 – The splint process must not take longer than three weeks
- R1.3.2 – The splint must not hinder daily life activities

Wishes

- W1.3.1 – The amount of contact moments that involve the patient should be minimized
- W1.3.2 – The manual labor (measuring, designing, producing, fitting, adjusting) should be minimized

Current thumb splints 1.4

Requirements

- R1.4.1 – The splint must withstand impact from daily life activities
- R1.4.2 – The splint must be non obtrusive
- R1.4.3 – The splint must not pick up dirt
- R1.4.4 – The splint must be easy to clean

Wishes

- W1.4.1 – The splint should be adjustable to improve the fit

Care Path 1.5

Requirements

- R1.5.1 – The splint process must be designed around the occupational therapist

Competitor analysis 1.6

Requirements

- R1.6.1 – The splint must meet the medical requirements determined by insurance companies in order to qualify for compensation
- R1.6.2 – Tjielp Design must focus on personalized splints which can be customized in collaboration with the user

Wishes

- W1.6.1 – The production time should be as short as possible
- W1.6.2 – The splint should be offered in two to five different materials

Ultra-Personalized Product Service Systems 1.7

Requirements

- R1.7.1 – The product-service combination must at least contain one ore more of the personalization aspects of identity, capabilities, and fit
- R1.7.2 – The product must allow small shape adjustments
- R1.7.3 – The product aesthetics must be consistent for every piece

Wishes

- W1.7.1 – The product-service combination should be as personalized as possible while maintaining the price as low as possible

Digital modelling and fabrication 1.8

Requirements

- R1.8.1 – The product-service system must be suitable for digitalization and automation
- R1.8.2 – All stakeholders must be able to contribute to the design process by retrieving and adding data to the process
- R1.8.3 – The fabrication technique must be suitable for very small batch sizes (even n=1)

Wishes

- W1.8.1 – The digital twin must represent the patient as good as possible
- W1.8.2 – The design process should be automated as much as possible

3D scanning in personalized orthosis design 1.9

Requirements

- R1.9.1 – The 3D scan must be in a functional pinch grip splint posture
- R1.9.2 – The accuracy of the 3D scanner must be at least 1.3mm

Wishes

- W1.9.1 – The 3D scan should be made as quickly as possible

3D scanning

Requirements

- R3D.1 – The patient must not have swollen hands while making a 3D scan
- R3D.2 – The 3D scan must be accompanied by information on the specific joint problems
- R3D.3 – The 3D scanning procedure must not aggravate the condition, cause pain or discomfort to the patient
- R3D.4 – The splint solution must take place in the early or moderate stage of a swan neck deformity of the thumb
- R3D.5 – In-scan movements must be avoided
- R3D.6 – The 3D scanning aids must be durable and error prone

Wishes

- W3D.1 – The 3D scan is preferably taken seated
- W3D.2 – The RA patient has preferably multiple splints with different sizes for low and high disease activity
- W3D.3 – The patient should be actively called back for evaluation and follow-up treatment
- W3D.4 – The end of life of the splint should be taken into account

Statistical Shape Model

Requirements

- RSSM.1 – The SSM must be a representation of pathological hands

Design automation

Requirements

- RAUT.1 – Every mesh must have the same connectivity
- RAUT.2 – The armature in Blender must be precisely linked to, and located inside the mesh
- RAUT.3 – The armature must be an accurate representation of the bones and joint types
- RAUT.4 – The 3D scan must be made in a consistent posture for every patient
- RAUT.5 – Irregularities of the hand must be made smooth or avoided in the computational design
- RAUT.6 – The design must be shrunk to a snugly fit
- RAUT.7 – The manufacturing technique must not negatively affect the aesthetics of the splint design

Wishes

- WAUT.1 – The parametric design should automatically adjust to the anthropometric data
- WAUT.2 – The number of landmarks should be minimized

Appendix 7: 3D scanning paper

3D scanning in personalized orthosis design for patients with rheumatoid arthritis

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1. Introduction

Splinting is proven to be an effective treatment in early stage finger deformities. When the deformities are still passively correctable, finger orthoses are functional in stabilizing or fixating the affected joints. Currently, measures for orthoses are mostly taken by hand or for more complex orthoses plaster casts are used to create the orthoses around. This method is useful for getting precise measurements, but it is inconvenient for model storage and transit (e.g. a lab or makerspace) (Haleem & Javaid, 2019). A higher accuracy and efficiency can be obtained via 3D scanning technologies.

There is an emerge in 3D scanning technologies for personalization of orthoses. Where measures for orthoses were mostly taken by hand, nowadays 3D scanning has shown to be a successful method of personalizing orthoses. In a review of 3D scanning applications in the medical industry, Haleem and Javaid (2019) write that 'It is vital for medical field as it captures external measurement of the body in less time, cost and better manner'. Also in practice, the concept of 3D scanning is proven by companies and startups like Manometric, Artus3D, and Exo-l who develop both 3D scanners and orthoses based on 3D scans.

The current 3D scanning solutions, on the other hand, are limited to relatively simple body components like the ankle, wrist, and a 'normal' thumb base. Patients with rheumatoid arthritis will be the study's target group because their disease involves additional challenges. Rheumatoid arthritis (RA) is an inflammatory disease causing joints to degrade over time (Grassi et al., 1998). Because of muscle weakness, swelling, and fatigue as a general symptom of RA (Grassi et al., 1998), it is sometimes impossible for the patient to hold the desired splinting position independently. 3D scanning aids to position the fingers and thumb could be helpful in this case. Regarding 3D scanning aids, inspiration can be taken from a research in 2017 where they designed a 3D printed support for palmar scanning (Baronio et al., 2017).

Figure 1: 3D printed support for palmar scanning (Baronio et al., 2017)

The position of the hand in which the 3D scan is obtained will affect the usability and the quality of the 3D scan. Ideally the hands are fixed in the right splinting position without compromising on the scan result. For finger splints this implies that the affected finger(s) should be separated from the rest and slightly bent. A hand position with the fingers spread and slightly bent (approx. 20 degrees) is ideal (see figure 2). Regarding the thumb, the splint has to stabilize the CMC joint, abduct the metacarpal, and place the MCP joint in slight flexion (Beasley, 2014). Therefore, the most functional position of the thumb is in pinch grip.

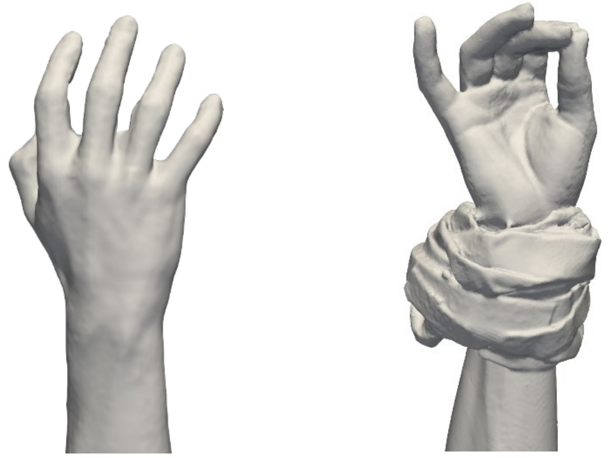

Figure 2: Ideal splint posture with stretched fingers (left) and in pinch grip (right)

2. Research question

Is 3D scanning a viable option for personalizing finger and hand orthoses for patients with rheumatoid arthritis?

Sub research questions:

1. Can a 3D scan of rheumatoid hands in a functional splinting position be obtained without worsening the condition or causing discomfort to the patient?
2. What types of 3D scanning aids are useful and non-obtrusive in achieving the correct splinting position?
3. How is the 3D scanning process affected by the patient's disease?
4. In terms of completeness and usability for thumb orthotic design, how is the 3D scanning result evaluated?

Personalization goes beyond taking accurate measures of the patient's hand. It also involves the measurement procedure itself. This procedure should take into account the patient's needs and challenges. Therefore, the main aim of this study is to determine whether 3D scanning is a desired tool for personalizing finger and hand orthoses for patients with rheumatoid arthritis.

3. Methodology

Participants (n=9)

The participants were consciously selected from the patient database of an orthopedic surgeon. The quotas for selection were at least one visible deformity in one of the hands and diagnosed with rheumatoid arthritis. Seven out of the nine participants were female, which is not strange since three-quarter of the rheumatoid arthritis prevalence is female (Nakajima et al., 2020).

Stimuli

There were no additional stimuli used during the 3D scanning procedure. The rotating Artec Eva setup, which will be introduced in the section titled "procedure – 3D scanning", could be seen as a stimulus.

Procedure – Survey

An invitation letter was sent to the participants prior to the day of the experiment. This letter was accompanied by an information sheet, informed consent form, and a short survey (see appendix FIXME). The participants were asked to read through the documents and to fill out the survey at their leisure and decide whether they voluntarily wanted to participate in the research. The survey was composed of general questions about the hand mobility and functionality and questions from the DUTCH-AIMS2 (questions 1-3 and 12-16) (TAAL et al., 1989). This survey was necessary to interpretate the 3D scans on hand function and mobility.

At the beginning of the 3D scanning procedure, the participants were asked to hand in the survey and informed consent form. And if there were still unclarities they were able to ask questions.

Procedure – 3D scanning

The 3D scanning day was organized at the Fysiotherpie Elisabeth practice www.fysiotherapieelisabeth.nl). Nine participants were scanned throughout the day. A timeslot of 40 minutes was allocated to each participant and the 3D scanning procedure, where a 1,5 meters distance could not be guaranteed, was limited to 15 minutes due to the COVID-19 measures. Both the participants and the researcher wore face masks and the equipment was disinfected after each participant.

After the participants handed in the informed consent form and the survey, the researcher commenced the 3D scanning procedure. The 3D scan data was obtained via an automated setup with two Artec Eva 3D scanners (www.artec3d.com/portable-3d-scanners/artec-eva) that rotated around the participants hand (see figure 3). The participants placed their hand in the right position with additional support under the lower arm. Once the hand was positioned, the researcher started the 3D scan and the two Artec Eva's rotated around the hand while making pictures. The quality of the scan was assessed after each scan and when the 3D scan was incomplete the steps were repeated.

Figure 3: Automated 3D scanning setup consisting of two rotating Artec Eva 3D scanners

Procedure – aids

Forcing rheumatoid hands in the desired splinting position could be painful or even worsen the patient's condition. Therefore, non-obtrusive aids to place the hand into the right splinting position where explored for this specific setup. Finger spreaders, tape, a glass plate and a transparent strap have been tested prior to the 3D scanning day. A finger spreader was tested in case the patient was unable to spread his/her fingers independently. Tape could assist the patient in holding the preferred splinting position. Support could be found on a glass plate to reduce a tremor and/or to hold the preferred splinting position. Finally, a transparent strap could be put around the MCP joint to slightly pull the thumb from adduction outward into the OK-sign. However, during the day itself, solely the transparent strap was used because it enabled for fast finger and/or thumb positioning. When the participant was wearing finger/hand orthoses, two 3D scans were obtained, one with the orthosis and one without.

Data collection

The collected data consisted of two 3D scans in two different positions, both left and right hand of the nine patients. This resulted in 36 3D scans, Stereolithography Mesh or object format, of around 30 MBs each and is stored locally on the researchers computer. These meshes are used in CAD software and data analysis and visualization applications such as Rhino and Paraview.

Visual data of the 3D scanning setup with the patient (1-3 pictures, see figure 4) and survey data regarding the patients clinical picture and hand functioning were collected. The participants were unrecognizable on the pictures or de-identified afterwards.

Figure 4: Patient photo's during the 3D scanning procedure

The data was meant for use during this graduation project to inform the design of a parametric finger splint design. The data will be stored on a server at the TU Delft for a timespan of 5 years and will be used for research and educational purposes only.

To protect the patients privacy, every patient received a number (LG-202101, LG-202102, etc.). The survey, image and 3D scan data was stored in a folder with the same patient number. The collected data was stored in a similar way with a reference to the left or right hand (e.g. The first patient, concerning the left hand was numbered as: LG-202101L, the 9th patient, concerning the right hand was numbered as: LG-202109R). Any personal information was kept separately from de data by the researcher and will be destroyed at the end of the graduation study.

Limitations

1. *Scanning setup*
   There are three main limitations of this study. The first limitation concerns the 3D scanning method. Despite the fact that the 3D scanning set-up with two rotating Artec Eva scanners rotated approximately 340 degrees, capturing every aspect of the hand was difficult. The 3D scanning setup was able to complete a 3D scan in a reasonable amount of time. Despite this, patients were required to keep their hands still in the same posture for much too long, potentially resulting in inaccurate 3D scans due to finger movements.

2. *Lacking medical expertise of an occupational therapist*
   The second limitation concerns the involvement of a medical expert like an occupational therapist. Normally an occupational therapist provides the patient with exercises which increases the range of motion of the hands before a splinting solution is found. Within this study, the patients were not necessarily treated by an occupational therapist which means that for some the range of motion could be improved by occupational therapy prior to making the 3D scan. Improving the range of motion allows for a better splinting position (with or without applying external force) and therefore a better fitting splint. Preferably the splinting process is started in an early phase where deformities are still flexible, however in practice many problems are reported in a later stage (Porter & Brittain, 2012), (Beasley, 2012).

3. *Lacking focus on rheumatoid thumb*
   During this study there was no specific focus on the rheumatoid thumb. Therefore the findings will reflect rheumatoid arthritis in the hands as a whole, rather than just the rheumatoid thumb. The disadvantage is that there where only a few rheumatoid thumbs, making it difficult to estimate the implications. On the other hand rheumatoid arthritis is Polyarthritis which means that you will never see solely a rheumatoid thumb, and therefore it is useful to have seen a variety of patient situations and its possible implications.

4. Results

Results – survey

The results of the survey give information about gender, disease and duration, and hand and finger functionality. In total there were 9 participants, two male and seven female, with all rheumatoid arthritis as the main type of arthritis. The disease duration variated from 18 years to 47 years.

All participants were able to straighten and spread the fingers of their left hand partially or completely. For the right hand this differed per person, some people were barely or not able to straighten and spread their fingers. Most participants were able to make a fist with both hands, three participants could partially or barely make a fist with the le hand. This accounted also for the right hand of three participants. All participants could (partially) perform a pinch grip with both the left and the right hand (see figure 5).

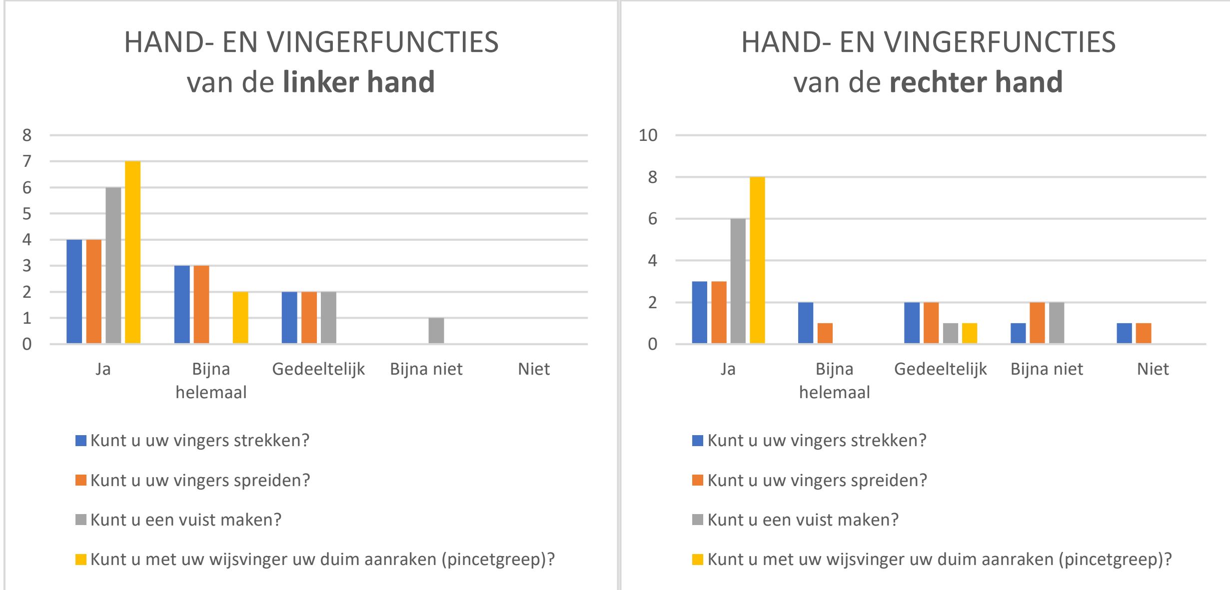

Figure 5: Hand and finger functionality of the left (left image) and right (right image) hand

All participants were (partially) able to write with a pen or pencil. There was no one who couldn't turn in a lock at all. It varied whether or not the participants could perform the other two activities (see figure 6).

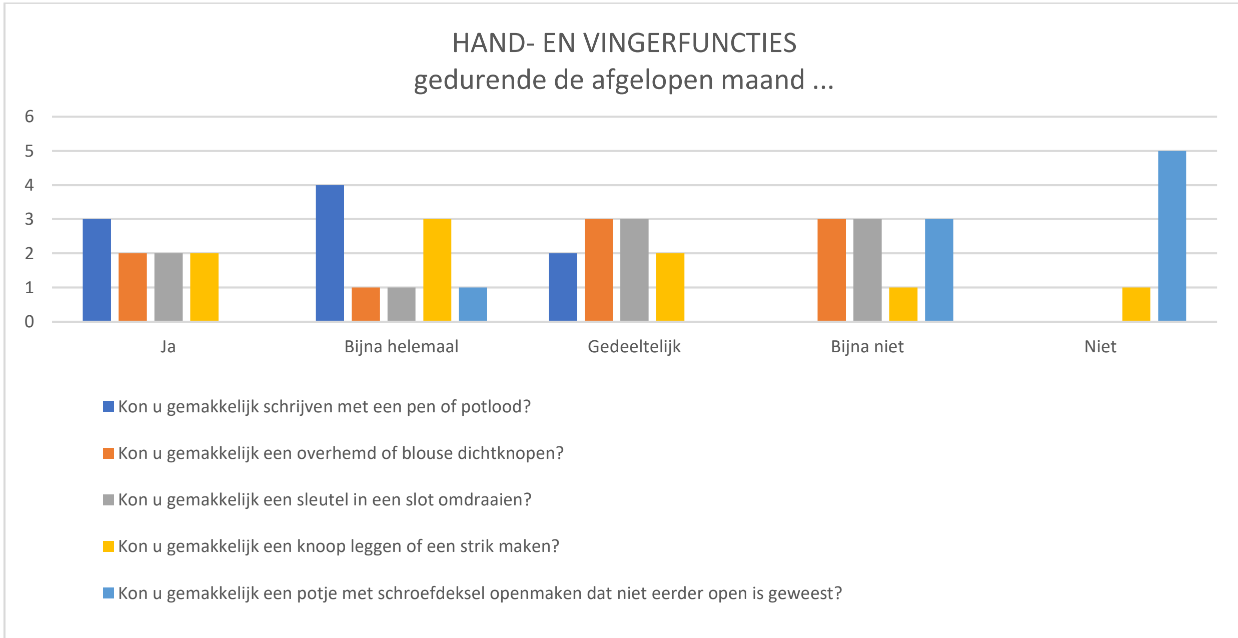

Figure 6: Hand and finger functionality during the past month

Results – 3D scanning procedure

The participants were able to finish the complete 3D scanning procedure. Depending on the participant's individual complaints, in some cases, holding the preferred splinting position was difficult and/ or uncomfortable for the participant.

All participants were able to straighten and spread their fingers far enough to capture each finger individually. They could perform a pinch grip which was necessary to make a 3D scan in the right splinting position. Only one participant could not make the gap between the index finger and the thumb large enough. Here the scanner was not able to capture the fingers separately.

P2 could not hold the left hand in the right splinting position without external support. A transparent strap was used to pull the MCP1 joint outward. The MCP1 joint of the right hand was rigid and could not be placed into position.

The MCP1 of the left hand of P6 was operationally secured and the MCP1 of the right hand was stiff. Holding the right splinting position required a lot of strength and the scan had to be taken quickly. P8 lacked strength in his fingers as well and experienced a lot of pain while holding the position. Afterwards he relieved tension by alternately straightening his fingers and making a fist.

Several participants experienced pain in other joints, like the shoulder and elbow, which made it uncomfortable to rotate their hand palm downward.

During the scanning procedure P1 took support from a walker and P4 had to sit down between the scans because of lower back pain.

P6 wore two swan neck golden splint rings on the ring finger and the little finger of the right hand. Two 3D scans were made, one with the splint rings and one without. The splint rings did not fit properly since the fingers could still fully extend while wearing them.

Finally, there were several attempts needed to capture the right 3D image and for nearly every patient the full half hour was needed to capture a 3D scan without movement.

Results – 3D scan data

During the 3D scanning day, 29 scans were obtained (figure 4). A red cross is drawn where the researchers did not succeed to make a good 3D scan due to finger movement or the like. More than half of the hand postures did not produce a satisfactory 3D scan result.

P#	Left hand (OK)	Right hand (OK)	Left hand	Right hand	Comments
P1	H1	X	X	X	
P2	H1	H2 H3	X	X	Difficulty with stretching fingers
P3	H3	X	H2	H1	
P4	X	H2	H1 H3 H1+3	X	Swollen hands
P5	X	H1 H3 H1+3	H2	X	
P6	X	X	H1 H1sm H2	X	Lacks strength for OK sign
P7	X	X	H1 H1sm H2	X	
P8	H2 H2sm	H3	H1 H1sm	X	
P9	X	H3	X	H1 H2	Relatively normal hands

N.B. H1=sharp fusion, H1sm=smooth fusion, H1+3=combination of two scans, X=no successful scan

Figure 7: Overview of the obtained 3D scans

The hands that were well captured, lacked roughly 30 – 60 percent of the information which appears as holes in the 3D model. Figure 8 shows an example of the right hand of patient two.

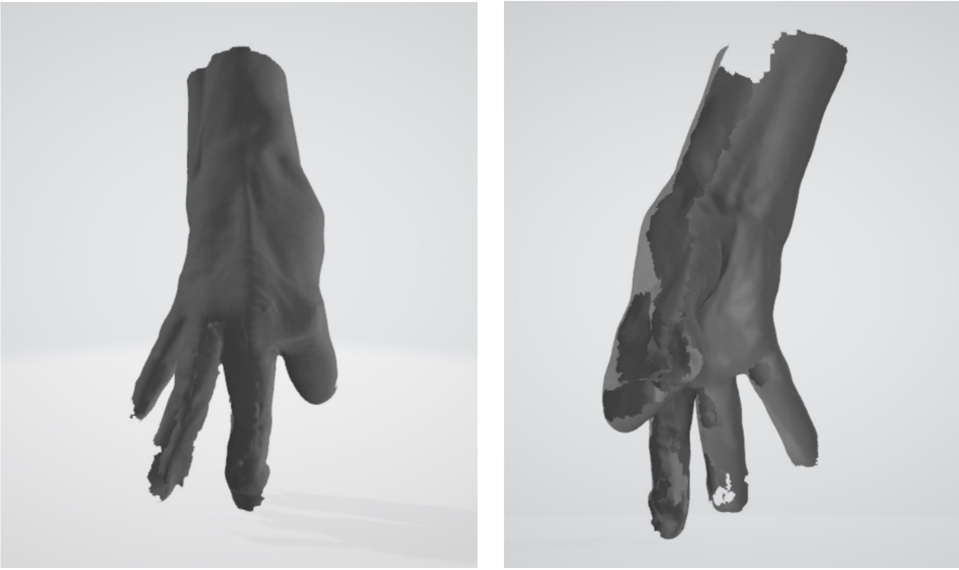

Figure 8: P2 H1, example of captured information

5. Discussion

Is 3D scanning a viable option for personalizing finger and hand orthoses for patients with rheumatoid arthritis?

To answer the research question, 3D scanning could be used to personalize finger and hand orthoses for rheumatoid arthritis patients. However, the process in its current form is not recommended as will be explained in the sub research questions, taking 3D scans of rheumatoid hands is not an easy task.

Sub research questions

1. *Can a 3D scan of rheumatoid hands in a functional splinting position be obtained without aggravating the condition or causing discomfort to the patient?*
   Obtaining a 3D scan in the functional splinting position is difficult. The survey's questions reveal the functionality of the participants' hands and showed to what extent the participants could maintain the proper splinting position during the 3D scan. As can be seen in the findings of the survey regarding how the participants perform various tasks with their hands. It took a lot of strength for numerous patients to hold the requested position due to their condition. Furthermore, they experienced pain while holding the position. As a result, it can be stated that while the 3D scanning method caused the patient discomfort, it did not prevent them from completing the procedure and did not aggravate their condition.

2. *What types of 3D scanning aids are useful and non-obtrusive in achieving the functional splinting position?*
   A transparent strap (figure FIXME) was the most useful 3D scanning assist, allowing the MCP joint to be moved outward in a slightly flexed position or to dissociate two fingers. The hand's shape was slightly distorted as a result of the aid, but this was not visible on the 3D scan afterwards. Moreover, it did not fix the joints in a certain position and could be released quickly after the 3D scan was made. As a result, any discomfort was reduced. Adjusting the position was solely possible if the joints where still flexible and not completely stiffened. However, in practice you will not find rigid joints since splinting is solely effective

in an early stage of joint degeneration. Finally, a more durable and less error prone replacement should be found for the transparent strap.

3. *How is the 3D scanning process affected by the patient's disease?*
Holding the functional splinting position required strength and was in some cases uncomfortable for the patient. It was difficult to obtain a 3D image without finger movement not only because of **muscle strain**, but also because of individuals who had developed a **tremor** as a result of their age. The 3D scans had to be retaken multiple times as a result of this and not every scan has led to a useful result.

There is no clear relation between disease duration and how the participants rated their hand functionality. This can be explained by the fact that deformity does not always imply a loss of hand function (Harris & Stanley, 2003). On the other side, P9 pointed out that two weeks prior to the 3D scanning day her hands were 'terrible'. So, rather than disease length, disease activity determines how functional the hands are at any particular time. Moreover, the simplicity with which the 3D scanning process is carried out is greatly determined by **disease activity**.

Other disease implications such as **pain in other joints**, **old age**, and **tiredness** did not necessarily effect the process, however it did result in experiencing discomfort. Ideally the patient goes through the 3D scanning procedure as comfortable as possible. This means that the 3D scan is taken quickly and that the 3D scanning setup is adjustable in height and angle so that the 3D scan could be taken seated and in a comfortable position.

4. *In terms of completeness and usability for thumb orthotic design, how is the 3D scanning result evaluated?*
From the 3D scan it is unclear if the hands and fingers contain rheumatoid deformities or if this might be the result of muscle tension. This information is crucial to interpretate the 3D scans during the splinting process and therefore questions about the affected joints, undergone surgery, and deformities should be included in the survey.

More than half of the hand postures did not produce a satisfactory 3D scan result. And, in the cases where a result was obtained, the 3D scans lacked information for an accurate design reference since the side of the thumb was frequently missed. When the scans are used for the design of an orthosis, it is likely that the orthosis will not fit properly around the side of the thumb. Therefore, it can be concluded that the 3D scanning result derived from the current 3D scanning method is not usable for proper thumb orthotic design.

Discussion topics/ Recommendations

For this study, the 3D scanning set-up with two rotating Artec Eva scanners had the most potential due to its accuracy and relatively quick scan. However, the method did not deliver results of good enough quality and in some cases no results at all. With the current method, 3D scanning is not a viable option for personalizing finger and hand orthoses for patients with rheumatoid arthritis.

There are technological advancements that enable quicker and more complete 3D scans of hands specifically like the Curatio hand scanner (figure 6). This hand scanner is developed at the TU Delft and is used by Manometric for orthotic design. Unfortunately, the Curatio is not yet available on the market.

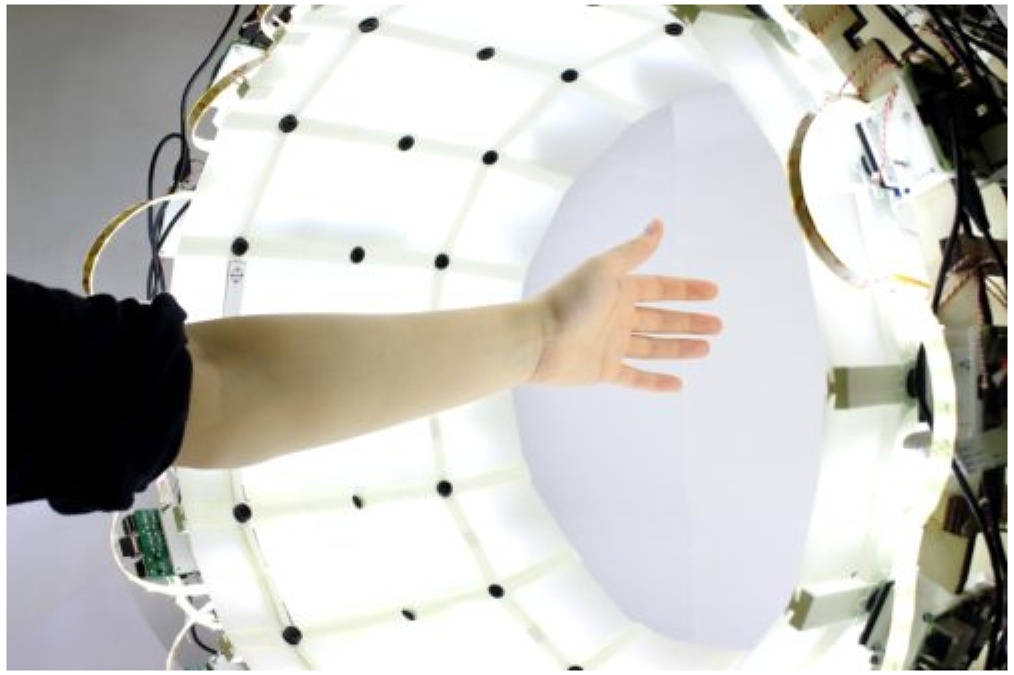

Figure 6: Curatio, the hand scanner

This causes a gap between what's currently possible and the future possibilities. Assuming that 3D scanning will become easier and cheaper over the years, it is wise to anticipate the future by designing orthotics based on 3D models.

As bridging solution the Posture-invariant Human Hand Statistical Shape Model (SSM) could be used (Yang et al., 2021). The SSM represents the variation in shape and size of 3D hand models and is a very useful tool for human integrated digital twin applications, such as digital orthotics design. By adjusting predefined parameters of the SSM, the 3D model can be scaled into a digital twin of the patients' hand. Moreover, the posture could be predefined (desired hand posture in OK-sign) which saves extra work in post-processing the 3D hand models. The SSM has the disadvantage of being a representation of the typical hand shape. Patients with osteoarthritis and rheumatoid arthritis have muscle atrophy, bony lumps, and joint enlargements, resulting in a hand form that is anything but ordinary. That's why the Posture-invariant Human Hand Statistical Shape Model could serve as a temporary solution, but individual 3D scans are required for good personalization of finger and hand orthoses for patients with rheumatoid arthritis.

6. Conclusion

With the current method, 3D scanning is not a viable option for personalizing finger and hand orthoses for patients with rheumatoid arthritis. Less than half of the hand postures did produce a satisfactory 3D scan result. Furthermore, the 3D scans lacked roughly 30 – 60% of the information for an accurate design reference.

The simplicity with which the 3D scanning process was carried out was greatly determined by disease activity. The quality of the 3D scan was affected by muscle strain, tremors and the quality of the posture. Not all patients were able to hold the posture without support, therefore a transparent strap was used to assist the patients. Adjusting the hand posture was solely possible if the joints where still flexible and not completely stiffened. The transparent strap could be functional in holding the position, but a more durable and less error prone replacement is desired for the future.

3D scanning hands of patients with rheumatoid arthritis involved several complications. Positioning the patients' hand into the desired posture, as well as disease implications such as pain in other joints, old age, and tiredness caused discomfort. Ideally the patient goes through the 3D scanning procedure as comfortable as possible, which means that the 3D scan should be taken quickly.

Reducing the 3D scanning time will decrease the in-scan movement, measure time, and therefore increase the patients comfort and quality of the 3D scan result. The technological advancements that enable quicker and more complete 3D scans of hands specifically like the Curatio hand scanner, are unfortunately not yet available on the market. Therefore, the Posture-invariant Human Hand Statistical Shape Model (SSM) is proposed as bridging solution. As a result, orthotics can be designed around a 3D model, making the transition to Ultra Personalised Product and Service design easier.

Appendix 8: Cost analysis

Desired splinting process	What	Who	Notes	Costs	Unit	Total
Step 1	Identify problem	Occupational therapist	10 free appointments within basic ensurance	€ -		€ -
Step 2	Splinting solution	Occupational therapist	The splint solution is found	€ -		€ -
Step 3	Design	Anna Ruiter	Parametric design			€ -
Step 4	Referral	Surgeon or other specialist	Advised by the occupational therapist	€ -		€ -
Week 1						
Step 5	Intake	Occupational therapist	Splint is picked from the catalogus	€ 60.0.00	0.25	€ 15.0.00
Step 6	Measurements	Occupational therapist	Measurements are taken bij hand and uploaded in the system	€ 60.0.00	0.50	€ 30.0.00
	Measurements +	External or occupational therapist	A 3D scan is made and uploaded in the system	€ 60.0.00	1.00	€ 60.0.00
Step 7	Production	imaterialise	Takes 2-3 weeks	€ 26.0.00	1.00	€ 26.0.00
	Production+			€ 210.0.00	1.00	€ 210.0.00
Step 8	3D print	External or occupational therapist	Takes one week	€ 13.0.00	1.00	€ 13.0.00
	3D print+			€ 14.0.00	1.00	€ 14.0.00
Week 2						
Step 9	Fit evaluation	Occupational therapist	Fit evaluation with 3D print	€ 60.0.00	0.25	€ 15.0.00
Week 3						
Step 10	Fitting and adjusting+	Occupational therapist or orthopedic instrument maker	Adjusting the splint until it has the right fit	€ 60.0.00	0.50	€ 30.0.00
Step 11	Final design	Anna Ruiter		€ 50.0.00	1.00	€ 50.0.00
Total - Low personalisation						**€ 179.0.00**
Total - High personalisation						**€ 394.0.00**