3D scanning assist

Design of a
3D scanning assist
for spasticity patients
in support of
orthosis design

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In Collaboration with

Artus3D
Centrum Orthopedie

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Preface

This report marks the end of my studies at Industrial Design Engineering at the Technical University of Delft. It has been a privilege to work amongst some of the brightest minds I have met.

The project allowed me to gain insight into the orthopaedic industry, perform an authentic full product design cycle, work and test the product with patients and explore all possibilities for the design of this product.

I would like to express my gratitude to my supervisors Lars Broxterman (Artus3D), Toon Huysmans (TU Delft) and Gianni Orsini (TU Delft) for their guidance and support throughout this project. Without them this project would not have been possible.

I also would like to thank the many people whom I had contact with in the company of Artus3D and Centrum Orthopedie Rotterdam. Their expertise helped me in understanding the orthopaedic context better.

Finally, I would like to thank my parents, brother and friends who supported me throughout the project.

Floris Alderliesten

Executive summary

This project focuses on the exploration and development of an assistive device that allows the use of 3D scanning in the creation of personalized orthoses for spasticity patients.

Spasticity is the symptom of various neurological diseases and is characterized by a prolonged contraction of the muscles. For upper limb spasticity, this leads to patients' hands being in a cramped position and are unable to move it into a desired position without external force. To prevent the spasticity to worsen over time, orthoses are used to stabilize the hand and stretch the muscles. Currently, the hand orthoses for spasticity are still being formed the traditional way: a long process of gypsum molding, casting and the forming of thermoplastic material.

Artus3D is a company that provides automated software to design and manufacture personalized hand orthoses from a single digital 3D scan of a hand. Due to the nature of spasticity, the hands need to be stretched into an open position before the 3D scanning is applicable. Together with Centrum Orthopedie, Artus3D is looking for a solution to stretch the hand and encorporate their 3D scanning & software technology into the design of spasticity orthoses. The problem consists of two parts: the orthosis design and the 3D scanning support. This project focuses on the 3D scanning support and the enabling of scanning spastic hands.

The 3D scanning support keeps the spastic hand in a stable position and is designed for patient visits in the orthopaedic context. It uses a ball joint and a sliding joint in order to constrain the hand in the desired position. It is usable up to MAS 3 and has been designed to fit the 5th to 95th percentile of the population. The design follows the shape of the hand, keeps clear of important areas near the thumb, base of the hand and limits the amount of material at the lower arm; with the intent of capturing as much information in the 3D scan, while keeping high usability for the orthopaedic technologist and comfort for the patient.

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Glossary

Distal phalange	Bone at the tip of the fingers
Intermediate phalange	Bone at the middle of the fingers
Proximal phalange	Bone of the finger, closest to the hand
Metacarpal bones	Palm bones
MCP (Metacarpophalangeal)	Knuckle joints (Including thumb joint)
PIP (Proximal Interphalangeal)	Finger joint, closest to the hand
DIP (Distal Interphalangeal)	Finger joint, furthest from the hand
IP (Thumb Interphalangeal)	Thumb joint, furtest from the hand
CMC (Carpometacarpal)	Thumb base joint
Carpals	Wrist bones
Digit	Term that describes both the fingers and thumb
Flexion	Term for bending a joint
Extension	Term for extending a joint
Ulnar side	Pinky-side of hand, side of the Ulna bone
Radial side	Thumb-side of hand, side of the Radial bone
Palmar side	Lower side of the hand
Dorsal side	Topside of the hand
Orthosis	Device that supports/immobilizes a limb
Solvable spasticity	Spasticity where the hand is able to return to a neutral position
Spasms	Short and intense temporary contractions of a muscle
convection orthosis	Solvable spasticity
hyperextension	Overextending of a joint

Chapter 1: Project introduction

Towards the design of a 3D scanning assist for spasticity

1.0 Introduction

Spasticity is the symptom of various neurological diseases and is characterized by a prolonged contraction of the muscles. For upper limb spasticity, this leads to patients' hands being in a cramped position and are unable to move it into a desired position. To prevent the spasticity to worsen over time, orthoses are used to stabilize the hand and stretch the muscles.

This project is in collaboration with Artus3D and Centrum Orthopedie. Artus3D is a company that provides automated software to design and manufacture these personalized hand orthoses from a single digital 3D scan of a hand. Centrum Orthopedie is an orthopaedic company that specializes in muskoskeletal health and rehabilitation of patients, striving for personalized and high quality care.

Currently, the hand orthoses for spasticity are still being formed in the traditional way: a long process of gypsum molding, casting and the forming of thermoplastic material.

The goal of this project is to design a solution to make the 3D scanning of spastic hands possible. The challenge lies in the nature of the spastic hand: In order to get a usable 3D scan of the hand, the hand should be kept in an open and stable position.

This project aims to design an assistive device that keeps the hand in an open position using minimal material that could impact the accuracy of the 3D scanning, while focusing on the comfort and usability in the orthopaedic context.

1.1 Background

Currently, there is only one commercialized example known by Centrum Orthopedie of a 3D scanning assist for spasticity, as seen in Figure 1. This device makes use of several hinges and ball joints to place the hand in a scannable position.

For a physiotherapist who performs regular patient visits, this might not be the ideal solution due to its volume and weight. For this reason a research project has been setup within Centrum Orthopedie to develop their own 3D scanning assist of spastic hands. The result of this project is found in Figure 2.

This product is connected to the arm from the topside to allow for scanning the lower side of the arm. It uses a finger holder and separate thumb holder that are changeable in height. A second person holds the metal beam while the hand is scanned. Challenges remain in the non-adjustability of setting up the device while in use, the covered thumb connection and a way to be used by a single person.

In research, few studies have been performed to the passive holding of spastic hands. One paper suggested manually stretching the hand and developed a non-adjustable finger holder (Baronio et al, 2017). Hand measurements are taken, after which the device is 3D printed. Then the device is applied and the hand is scanned in the right position. This method is elaborate and time intensive, resulting in the need of a custom made device and most likely leads to two separate appointments due to the printing time.

Another research used a beam for the hand to hold the in a vertical position (Perry et al., 2021). It leads to the shape of the hand being non-adjustable.

The final research is actually a stretching device for spasticity, but when adjusted shows opportunity for 3D scanning (E. H. Kim et al., 2013) (Figure 3). The contraption is large, but stretches the fingers and holds them in a neutral position. Not all patient can place their hand completely horizontally on a table, therefore using it might become difficult.

Figure 1: Mechanical hand stretcher (Antonius Köster GmbH, n.d.)

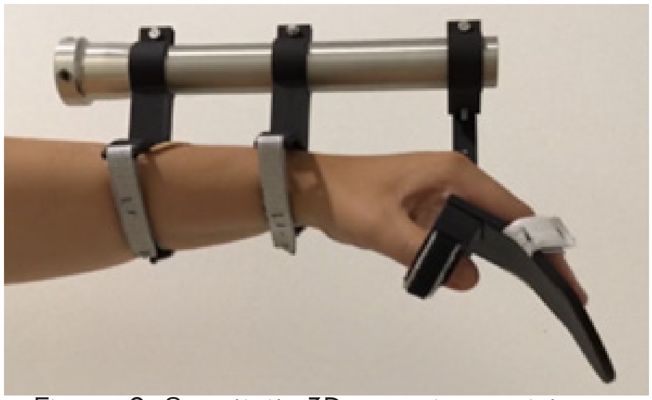
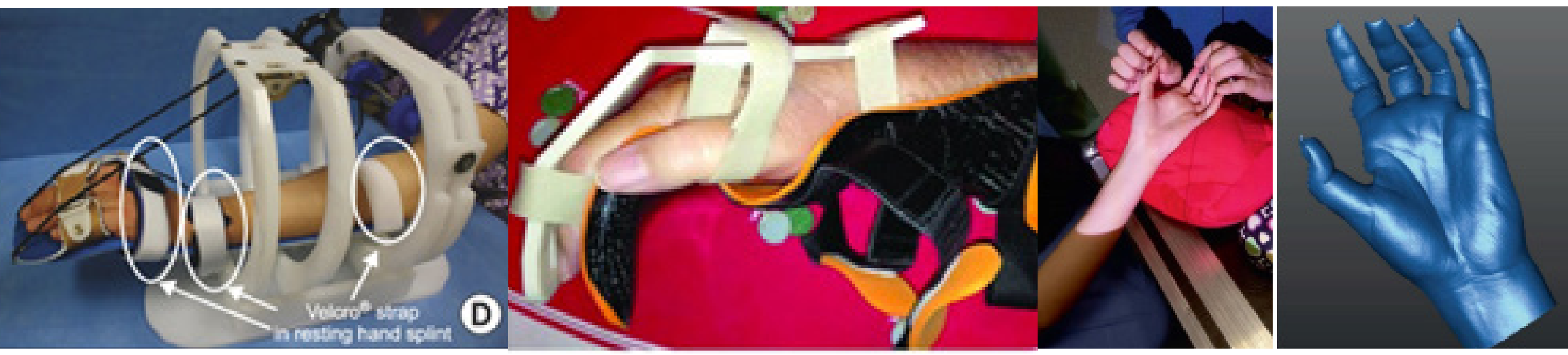


Figure 2: Spasticity 3D scanning assist (Van Den Hoven, 2020)

Figure 3: Existing spasticity scanning assists (Adapted from E. H. Kim et al., 2013; Baronio et al., 2017)



1.2 Artus3D

Artus3D is a company focusing on the 3D scanning technology and manufacturing of personalized orthotic products. The company started with a focus on parametric hand orthosis design and soon began a collaboration with Centrum Orthopedie. In 2021 they officially launched their software and enable the companies to create their all-in-one perfect fit solution for the customer (Artus3D, 2021). As well as various types of personalized orthoses, Artus3D produces orthotic silver rings and silver braces based on predelivered measurements of the customer.

Their interest in this project is in line with their goal of enabling automated digital production in the orthopaedic sector by integrating 3D scanning using the Structure Sensor Pro iPad scanner and additive manufacturing for the creation of spasticity orthoses (Figure 4).


Figure 4: Digital scanning of hand (Artus3D, 2021)

1.3 Centrum Orthopedie

Centrum Orthopedie is a family business specializing in the supplying and measuring of orthopaedic aids. The company started in 1986 with four people and soon expanded into new branches of shoemaking, inlay soles and leg prosthetics (Centrum Orthopedie, 2023).

Currently with twelve locations, they cover most of the conurbation in The Netherlands. The business strives for high quality care with a focus on user experience, delivering custom solutions and re-enabling patients' movement freedom (Figure 5).

In recent years, the company moved towards the usage of 3D printing techniques together with Artus3D. Their interest is in expanding and modernizing their portfolio of spasticity orthoses for higher quality patient care.


Figure 5: Personalized orthosis (Centrum Orthopedie, nd)

1.4 Approach

This graduation project follows an iterative approach with a similar structure to the triple diamond method. It consists of multiple diverging and converging phases, moving from discovery to definition, ideation, conceptualizing, materializing and finalizing. This is shown in the design process overview in Figure 6 below.

The project starts with research into the different elements that make up the context of this project. It starts with an introduction to spaticity, orthoses, and moves towards interviews and patient visits.

Now the context of the project is set and the reframing chapter provides a direction is for the upcoming design of the project. Through iterative and prototype driven testing ideas are evaluated in the ideation and conceptualization phases. The design chapter ends with a final Hifi concept that is used as a basis for materializing in the detailing chapter. Here the concept is worked out into a working product that is tested in the evaluation chapter. This report ends with the finalizing chapter, where final improvements are implemented and recommendations are made for a possible follow-up for the project.

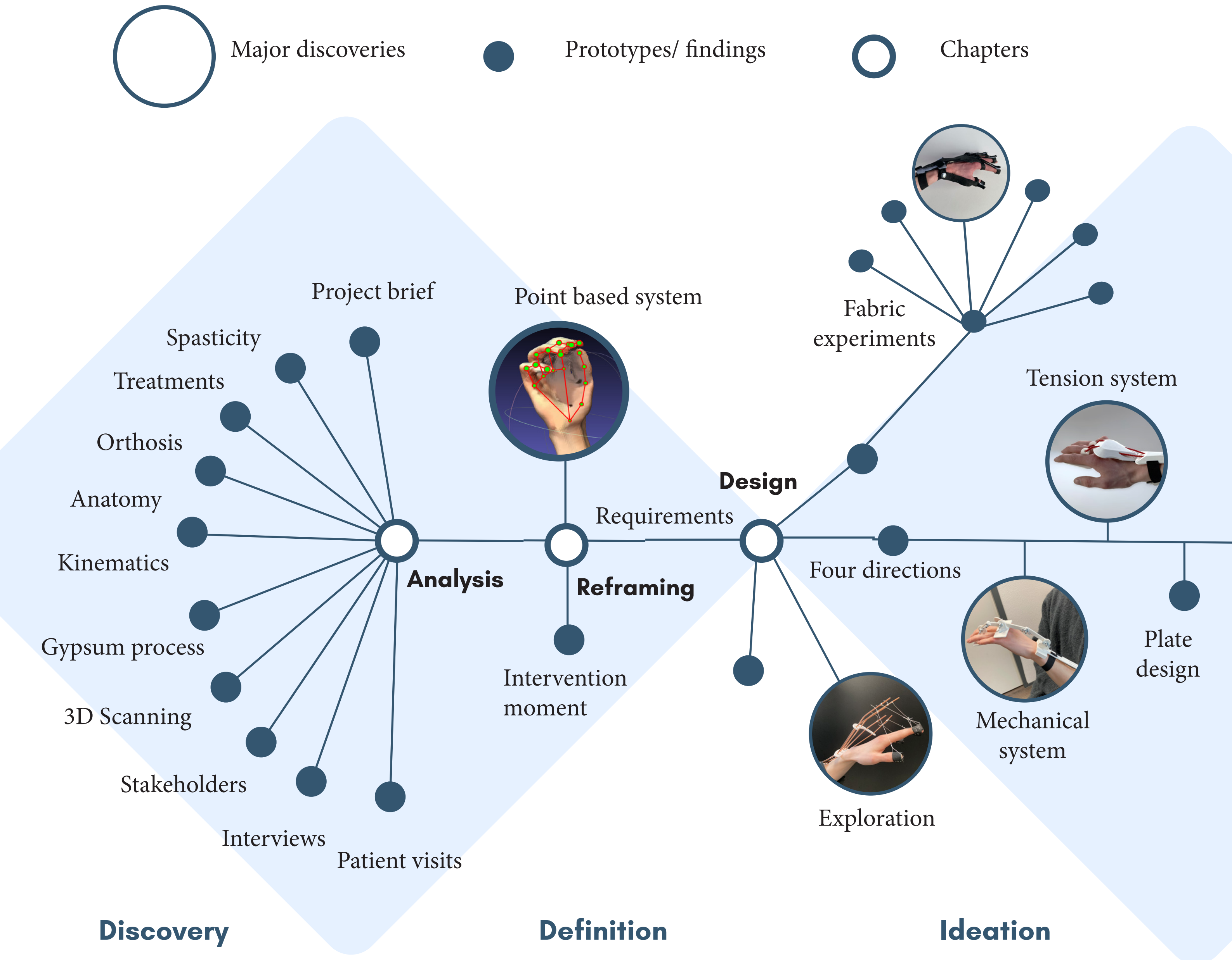


Figure 6: Design process overview

1.5 Design methodology

The initial phases of the project use interviews, patient visits and literature research for creating the context in which the problem takes place. The second phase uses an iterative process of prototyping and creating low fidelity prototypes with the intent to quickly test, use and/or discard ideas. The amount of detail in the prototypes is slowly increased until a high fidelity protype that marks the end of the conceptualizing phase. Design drawing forms the basis of most iterations.

The final phase uses a working prototype for patient testing and evaluation. In the finalizing chapter the product is discussed based on its feasibility, desirability and viability in the context of the design (Figure 7).

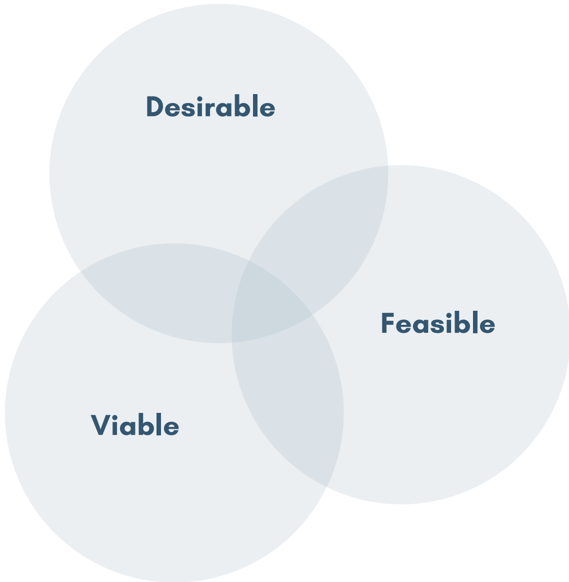
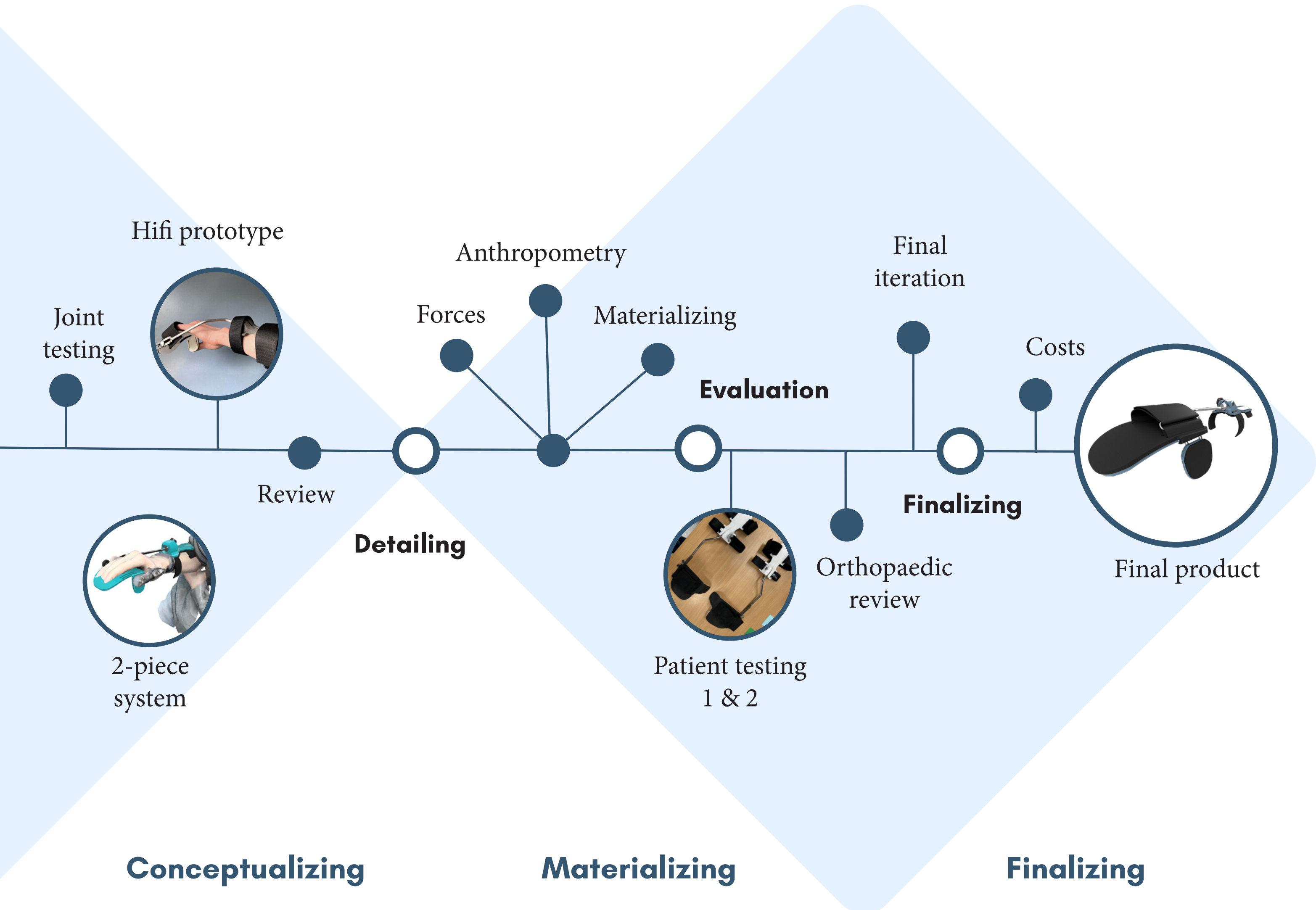


Figure 7: Desirability, feasibility & viability



Chapter 2: Analysis

Towards the design of a 3D scanning assist for spasticity

2.0 Introduction

This chapter will provide an overview of the information needed for the upcoming design process. It covers spasticity, why orthoses are used, what other treatments are available and creates boundaries in movements of the hand through a kinematic diagram.

A patient care path is displayed, as well as the orthosis manufacturing and 3D scanning. Patients have been visited to gain familiarity with spasticity in practice, while interviews have been used to gain perspectives on the subject.

Key takeaways have been gathered throughout the analysis and are viewed in blue blocks on the right pages. They form the basis for requirements and create boundaries and guidelines for the project.

2.1 Spasticity

Spasticity is a condition where the muscles are continuously contracted because of problems in the signaling of the brain and nerves (National Institute of Neurological Disorders and Stroke, 2023). Different causes of spasticity include stroke, spinal cord injury, brain injury or diseases like cerebral palsy (CP) and multiple sclerosis (MS) (Dysport, 2021). It appears in both the upper and lower limbs with varying degrees of severity, ranging from mild stiffness to severe limitation of movements (Figure 8).

The condition is found either bilateral (on both sides) or unilateral (on one side), with bilateral often having varying degrees of severity on either side (also called asymmetrical spasticity) (Chen et al., 2020). As spasticity is a symptom of other conditions that affect the central nervous system it is often found as a result of diagnosis and treatment of other conditions (Physiopedia, 2022).

Spasticity vs spasms
Spasticity and spasms are comparable, but the difference is that spasticity is continual, while spasms are perceived as temporary spasticity with sudden contractions (MS Australia, 2023). Spasticity can affect any muscle, but for spasms there are generally four different conditions identified: extensor spasms, flexor spasms, clonus and stiffness (Stachowiak, 2022).

Extensor muscles are used to extend the limb. When a knee has extensor spasm, then the leg will be involuntarily extended. For the flexor spasms this is the opposite, where the leg moves into a bent position. Clonus is the medical term for muscle twitch: quick repeating movements like tapping a finger. Stiffness limits the movement of a limb and ranges from a minor discomfort to a complete inability of movement and could worsen over time. This is applicable to both the upper and lower limbs.

Flexor or extensor
It is often the case that spasticity has a combination of muscles affected. If these are both extensor and flexor muscles (extending and bending), then the bending muscles will in most cases win over the weaker extensor muscles, according to Klerks. This leads to a shape that is similar to a clenched fist. Nearly 80% of the cases have this clenched fist, or are similar to this variant within Centrum Orthopedie. This same situation goes for the elbow and shoulder joint, making the patient sit more hunched and inward, sometimes sitting skewed towards one side

Spasticity scales
Several scales of spasticity have been developed, with the Modified Ashworth Scale being most commonly used. No equipment is needed, other than the movement of the joint. It ranges from no muscle tone to complete rigidity. Other less common scales are the Ashworth and Tardieu scale (Damiano et al., 2002; Shirley Ryan AbilityLab, 2016).

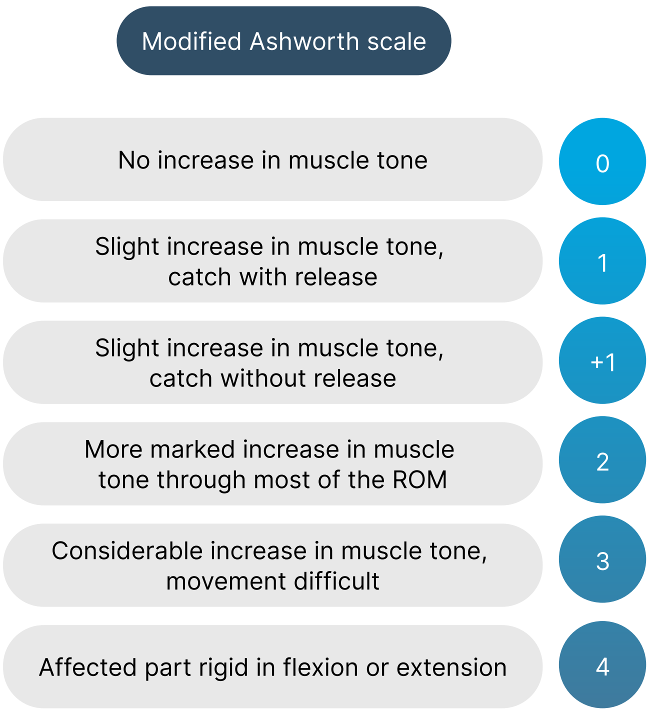


Figure 8: Modified Ashworth Scale (MAS)

Spasticity and Centrum Orthopedie
Centrum Orthopedie delivers both convection orthoses and personalized orthoses that are fitted or measured while visiting their patients (Figure 10). Most of their clients are found within care homes, either through appointment or during walk in consultation hours. From research, connections are found between age and a higher chance of stroke, doubling every 10 years after age 55 (Centers for Disease Control and Prevention, 2023). Around 38% of the patients with stroke develop spasticity, while 50% of the persons with traumatic brain injury will develop some type of spasticity (Hersenletsel-uitleg, 2024). During interviews with orthopaedic advisors of Centrum Orthopedie, a large portion of their patients have gotten spasticity through cerebral infarction, stroke or spinal cord injury. Most of the patients they visit are elderly, although as mentioned before, this result could be biased due to the frequent visiting at care homes. To keep in line with the client base of Centrum Orthopedie, the context of elderly care and patient visits is chosen for the design of the project.


Figure 9: Spasticity in fingers, most notably index finger, combined RA & spasticity in ring and little finger. Rarer MCP thumb hyperextension is seen


Figure 10: MAS 1+ spastic hand

Spasticity and elderly
The context in which the spasticity takes place varies between the elderly patients, as the location differs per patient. On the other hand, there are also many similarities that serve as reference for the project:

One of these points is the reduced mobility and strength of the patients. Some patients could have paralysis on one side of their body, rendering them unable to move their arm. Others might have reduced cognition, forgetfulness or could find treatments scary, making complex interventions undesirable. They could become tired more easily and intensive interventions might take a toll on them. Also the condition of Rheumatoid arthritis could sometimes be found, reducing the range of motion for one or multiple fingers (Figure 9).

On a wider level, the patients are often bound to a wheelchair, with most visits taking place in their own rooms. With little space available to move around the patient, scanning becomes a challenge.

Key takeaways

- Elderly as target group
- Spasticity causes the hand to be in a closed position
- Occurs both unilaterally and bilaterally

2.2 Orthosis

Different solutions are available for spasticity, but in this project the focus is on the static splint-type orthosis for spasticity. This section will go deeper into the differences, types and advantages.

Brace or splint

An orthosis is an external device that is worn around a limb, in this case around the hand to provide support or immobilization. It is the name for a group of orthopaedic devices which also includes braces and splints. The difference is that a brace aims to provide support to the hand, while splints are used to immobilize the hand. For spasticity a splint is used. There are also subgroups of splints: ranging from static, static-progressive to dynamic splints.

Centrum Orthopedie prefers to use the static splints, as those are easy to use and provide enough stretch to the fingers. For spasms, dynamic resting splints are sometimes recommended, as they have a finger plate that allows movement and catches the spasm using its spring back plate.

Spasticity and orthoses

For spasticity the orthoses are used as a way to stretch the muscles of the spastic hand, preventing it to contract. Over time it protects against permanent muscle shortening and bone growth within the fingers that limit the movement. It is also a solution with low intensity and low cost that could be used in early intervention.

Furthermore, it keeps the hand clean. When the hand is continually in a closed position, dirt will start forming inside the hand, making it unclean and stink. In more severe spasticity, the orthosis prevents the fingernails from forcing themselves into the palm of the hand, as this could lead to wounds and infections. For the caregivers it helps in their daily tasks, from putting on clothes without the fingers catching in the fabric, to better clean the hand of the patient. Orthoses are worn usually 8-10 hours per day.

Convection versus personalized

Convection orthoses are orthoses with predetermined sizes S, M and L. They have a metal strip on the inside to slightly bend the orthosis in the right shape. Personalized orthoses are individually made orthoses that take more time, but have better fit and customizability to the patient. Nearly all of the personalized orthoses are currently treated using a process of creating a gypsum cast from the hand and thermoforming the orthosis by hand at the manufacturing site.

Material

Orthoses vary in materials, ranging from the original thermoplastic material that is moulded to shape; and the newer, more rigid 3D printed Nylon. Sometimes orthoses are inlayed with foam for extra comfort, but reduce cleanability. The newer Nylon orthoses have the advantage of high strength, shorter production time, easier cleanability and better fit. The final product has bands added to the sides of the orthoses to attach it to the hand.

Figure 11: Overview of an orthosis directly from the 3D printer from various perspectives

The personalized orthosis

The orthosis of Artus3D is seen in Figure 11. It consists of four main features: the wrist, hand base, fingers and thumb. The fingers are rested on a fingerplate that is created from a flat surface or curves lightly with the fingers. The thumb connection is located outside of the main orthosis, but sometimes is placed more parallel. It is created slightly broader to allow for enough room for the thumb. The hand base follows the main shape of the hand, moving from a flat horizontal cylinder-shape to the wrist. Two features include the curves of the thumb base and pink base. The orthosis gradually follows the shape of the wrist towards the hand base and splits into the thumb.

The orthosis follows the shape of the lower side of the hand, so that the hand is placed in a resting position. At the fingers there is an extension to prevent the fingers and thumb from getting out of the orthosis. As it is a resting orthosis, it does not need a perfect fit, therefore a maximum of 3 millimeters of tolerance on each side is allowed at the hand.

Thumb and fingers

Because the thumb has out of plane movements (e.g. opposition, radial abduction; relative to the fingers), the current design chose to assist the fingers and thumb separately. Short walls are needed to keep the fingers and thumb in place, while no sharp edges should be present or could push into the skin, leading to discomfort.

Variations

A less common variation makes use of a hand roll attached to an orthosis (Figure 12). In care homes these hand rolls are used to keep the hand open in more severe spasticity. Other times they make use of a foam stretch ball that is placed inside the hand.

Figure 12: Hand roll keeping the fingers open

Lower arm

The length of the arm support is chosen by the orthopaedic technologist, as well as the hand position. Its main function is creating a comfort fit, as well as a connection of the orthosis to the arm. It needs to be following the shape of the lower arm smoothly and the top side has a tolerance of approximately 3-5 millimeterss.

Key takeaways

- Focus is on a resting orthosis
- 3 millimeters of tolerance at the hand, 5 millimeters at the lower arm
- Orthosis follows the outline of the hand and lower arm

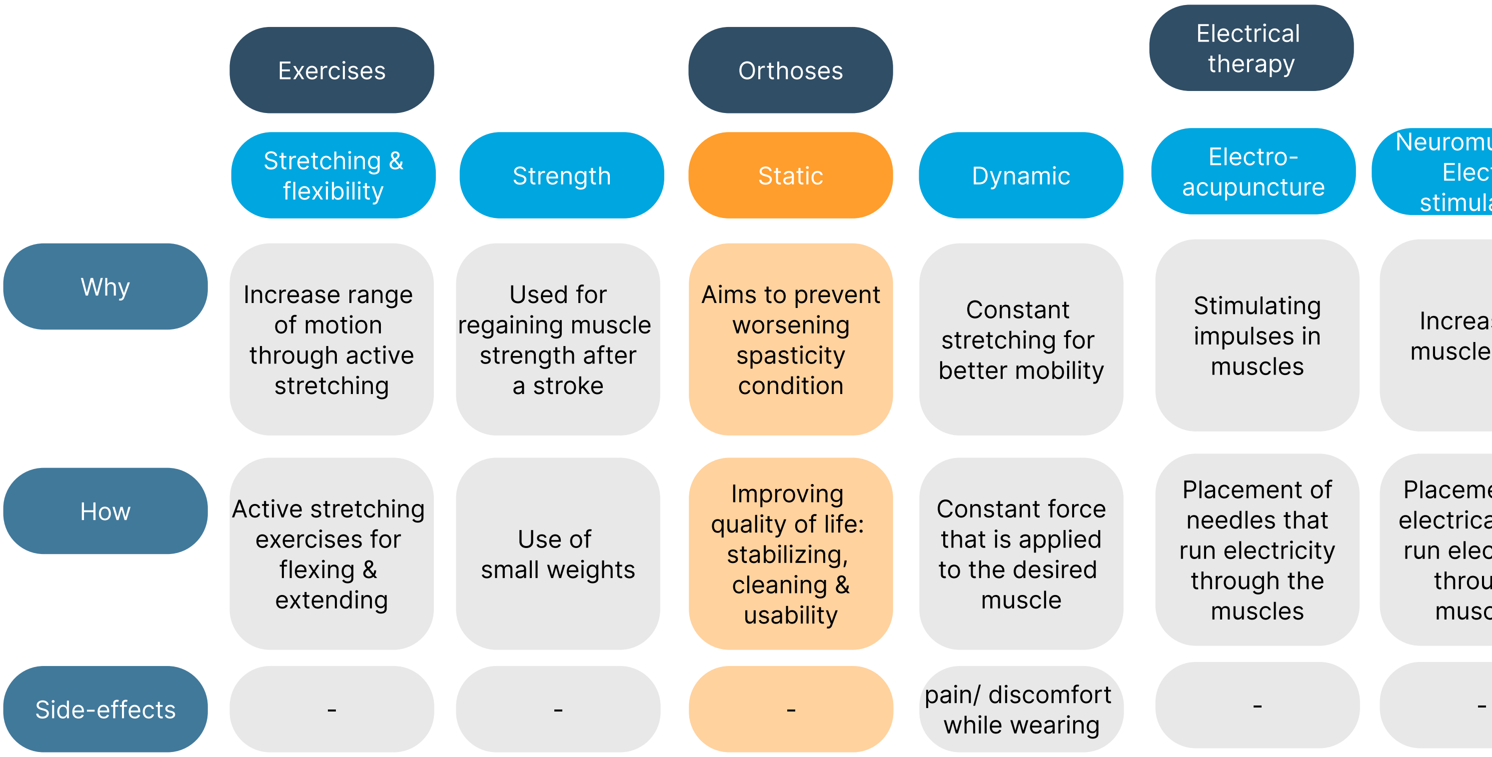


Figure 13: Treatment overview as explained below. Highlighted orange is the project focus

2.3 Treatments

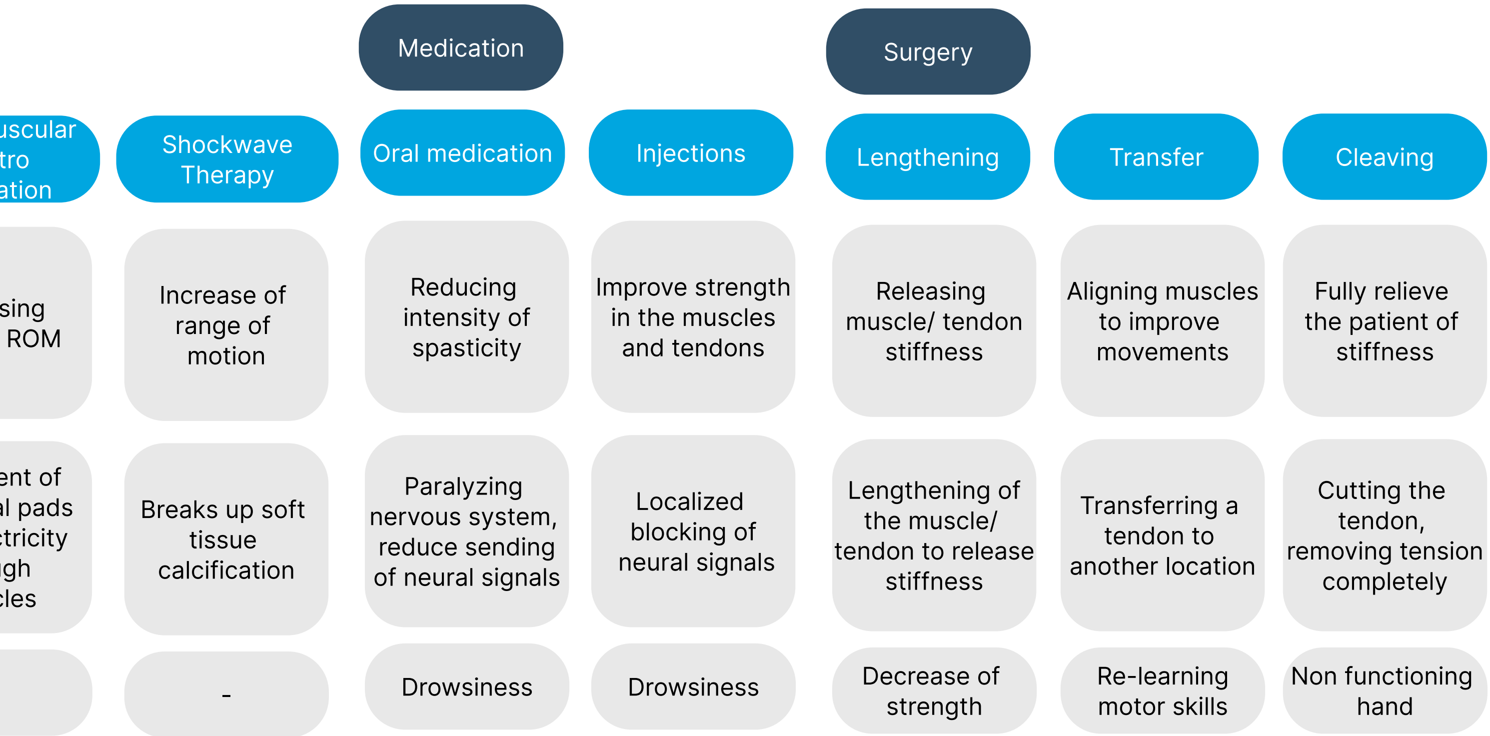
Before treatments are discussed, a medical examination is given and ranges from neurological testing to examining the medical history & the use of MRI scanning. The prescribed treatments differ in intensity and range from physical therapy to orthoses, paralyzing injections and surgery if the previous options did not resolve the problem (Pilitsis & Khazen, n.d.). An overview of most common treatments is found in Figure 13.

Physical therapy
Physical therapy uses exercises to stretch the muscles for increased range of motion or focus on exercises using weights to remain strength for performing daily tasks. These are generally prescribed in addition to other treatments, as they are easily accessible and have virtually no side effects.

Orthoses
Orthoses are used to increase the range of motion through constant stretching and help with hand functioning (Orfit Industries, 2022).

In this overview the orthoses are subdivided into static and dynamic orthoses. Static orthoses keep the hand in a stable position that is easily cleanable. It holds the fingers together in a stretched position and makes tasks like putting on clothes easier to perform. Dynamic orthoses provide a constant force to the finger to improve its range of motion, but causes discomfort while wearing. These are also more complex to fabricate and use. Therefore, for long term wearing, static orthoses are preferred over dynamic orthoses by Centrum Orthopedie.

Medication
Medication is used to relax the muscles: Baclofen, Diazepam, Dantrolene sodium and Tizanidine are most often used (Cleveland Clinic, 2022); as well as Botuline Toxine (Botox). are injected and decrease the amount of impulses sent from the nerve cells or slow down the neurological functions of the nervous system. Although this calms the spasticity, the effects are paired with tiredness and/or of drowsiness (UPMC, 2023). Over time habituation occurs, leading to increase of doses.



Electrical therapy
Variations of electrical therapy are used to stimulate the muscles for lowering their electrical activity during rest. A systematic review showed 45-60% decrease in spasticity and recommended it as an effective rehabilitation strategy (Bekhet et al., 2019)

Shockwave therapy
Shockwave therapy is a relatively new method that uses pressure waves to break up the tissue of the spastic muscles, in order to reduce the amout of signals sent and promote the natural healing process. This way the muscle fibres will heal in their new realigned state. Studies show a positive result, however optimum protocols were not determined (Martínez et al., 2020).

Surgical intervention
The final intervention is surgery. These range from tendon lengthenening so the joint is positioned into a neutral position (Austin Health, n.d.) to transferring the tendon to a different location in order to create a counter movement and balancing the spasticity. Another option is removing the tightened material surrounding the joint. The final option is cleaving: cutting the tendon and removing all tension.

Centrum Orthopedie
Centrum Orthopedie works via the rule of only intervening when there is discomfort and to keep the amount of intervention as low as possible. If the person experiences slightly bent fingers, but does not hamper the person in their daily life, there is no immediate reason to intervene.

In addition to the above treatments, Centrum Orthopedie sometimes uses a gypsum roll or a pluche ball inside the hand to keep the fingers from the hand base and prevent dirt buildup with severe spasticity. There are also combinations of treatments possible where exercise, shockwave therapy and orthoses are used parallel. This is determined on individual basis.

Key takeaways

- The use of an orthosis is a low intensity intervention out of a range of treatments
- Centrum Orthopedie uses the minimal intervention principle

2.4 Anatomy of the hand

This section gives insight into the basics of the human hand and provides a link to common conditions related to aging.

Bones

The basic frame of the human body is created by the bones. They consist of a hard, mineralized tissue called osseous tissue, or bone tissue (Florêncio-Silva et al., 2015). The bones create a skeletal system that protects and provides support to the surrounding muscles, ligaments and organs (Anderson, 2021). They help storing and releasing minerals, while some bones produce blood cells and regulate fat. The skeletal system forms the basis on which the muscles function and help facilitate the movements created by the muscles. With age, the bones become more fragile. Minerals within the bone slowly start to decrease and makes them brittle, also known as osteoporosis. This project is aimed at upper limb spasticity and takes place at the forearm and the hand. To better understand their relationships, the different bones are explained below:

The forearm consists of two bones: the ulna and the radius. These are connected to the upper arm (humerus) and the hand. The hand bones are divided into three groups: The Carpal bones, the Metacarpal bones and the Phalanges (TeachMeAnatomy, 2020).

The Carpal bones are a group of 8 bones that make up the wrist and connect the hand to the forearm. They are further subdivided into the proximal row and the distal row (Tang, 2022). (Scaphoid, Lunate, Triquetrum and Pisiform) (Trapezium, Trapezoid, Capitate and Hamate) (Figure 14).

The Metacarpal bones form the structure of the hand palm and consist of five bones, while the Phalanges are the bones for the fingers and the thumb (Figure 1). These can be subdivided into the proximal (close), Intermediate (middle) and distal (far) bones. Each of the fingers has three Phalanges, except for the thumb. It misses the Intermediate phalanx and therefore only has two phalanges (Dawson-Amoah, 2023).

Figure 14: Skeletal frame of the hand (TheSkeletalSystem, 2022)

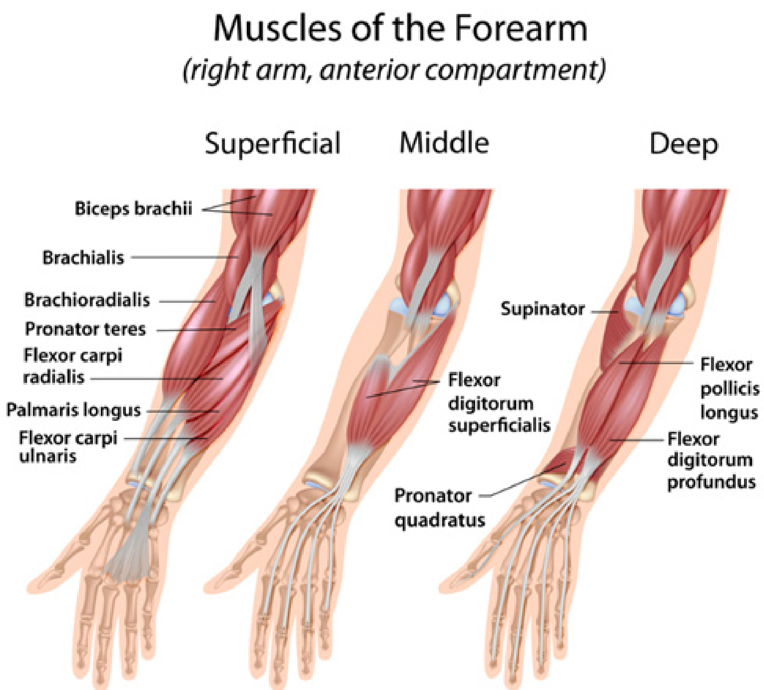


Figure 15: Muscles of the forearm: anterior side (The Orthopedic & Sports Medicine Institute, 2024a)

Joints
The joints are the connection points where the bones come together. These points are covered in articular cartilage: a firm, smooth and rubbery surface that damps incoming shocks and helps with articulation (Physiopedia, n.d.).

When people get older, these cartilages will slowly get thinner and wear down through repeated movements or mechanical stresses. This is also known as Osteoarthritis (Mayoclinic, 2021). In the hand the joints are divided into the wrist joint, CMC, MCP1-5, IP, PIP2-5 and DIP2-5, also shown in the kinematic diagram on the following pages.

Ligaments
Ligaments are placed around the joints: tough bands of tissue that prevents movements in unwanted directions (Martin, 2017). A sprain is the stretching or tearing of a ligament. With age, the ligments become less elastic and reduce range of motion, leading to a higher chance of injury (AdminOrthoCare, 2019).

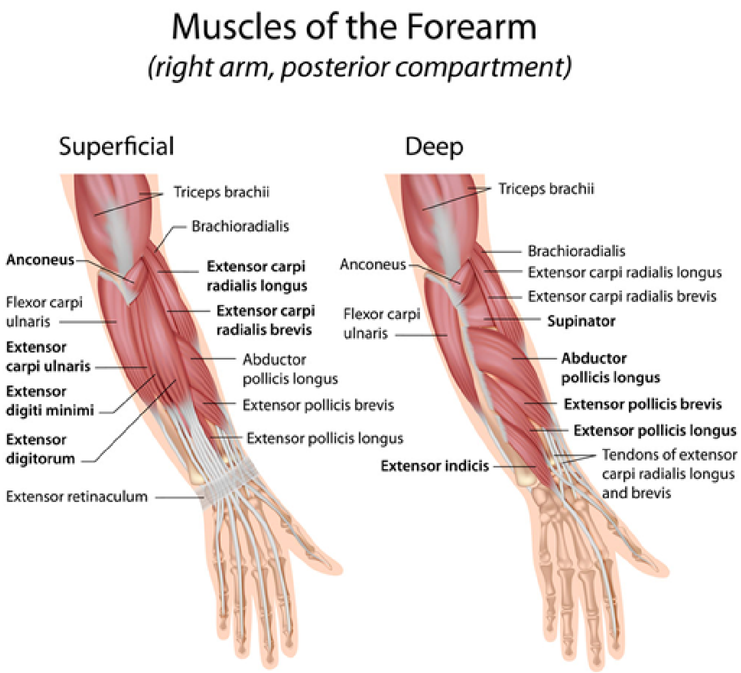


Figure 16: Muscles of the forearm: Posterior side (The Orthopedic & Sports Medicine Institute, 2024b)

Muscles
The muscles are the enablers of the musculoskeletal system. They create the movements that make us function. The muscles are subdivided into three main groups: skeletal muscle, smooth muscle and cardiac muscle (Healthdirect Australia, 2021).

Skeletal muscles are muscles that are controlled consciously. They often are connected on two separate bones that together create a joint. When the brain signals the muscle to contract through the nervous system, the joint will turn in the direction of the muscle and a movement is made. The skeletal muscles in the lower arm are therefore the focus for this project.

There are around 34 muscles related to the functions of the hand, but there is still a slight debate within literature whether some muscles in the upper body are extensions of certain muscles (like the Anconeus) or fall in different categories (like the adductor Pollicis) (Okwumabua, 2023; Sendić, 2023).

Some people might even miss certain muscles: a case study found that in 13.2% of their subjects (n=562) the palmaris longus was absent (Nasiri et al., 2016). Before diving into the details, it is best to know that although the categories might vary slightly, the muscles are still the same.

Generally, the forearm is divided into the anterior (frontside) and posterior (backside) forearm. Within the anterior forearm, there is a division between the superficial, intermediate and deep muscles. For the posterior forearm, there is a division between the superficial and deep muscles. For the anterior forearm the muscles are divided into the superficial, middle and deep layered muscles.

The hand is divided into extrinsic muscles and intrinsic muscles. These are viewed in Figure 15, 16 and 17 on the following page.

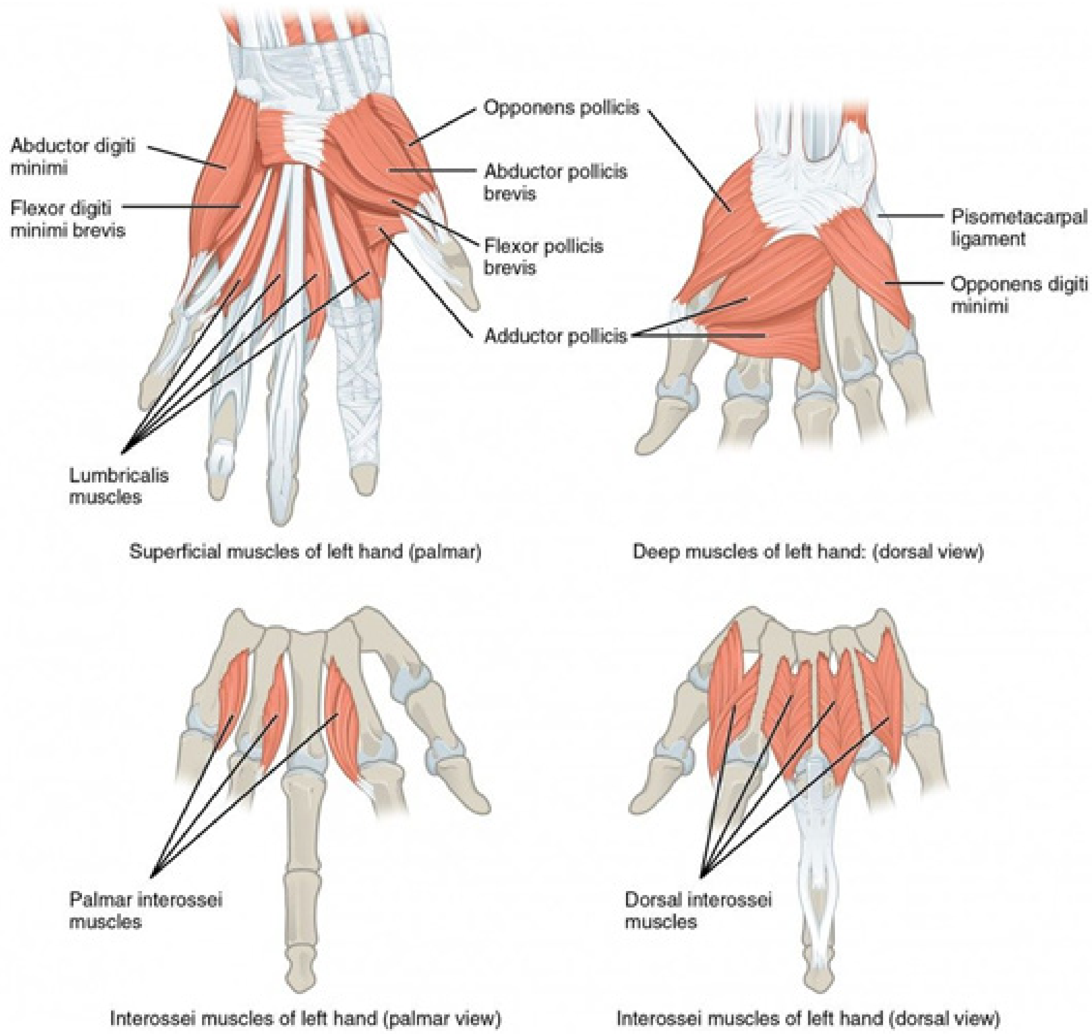


Figure 17: Muscles of the forearm: Posterior side (StoryMD, n.d.)

Extrinsic means that the muscle belly is located outside the hand; as they are located in the forearm. It is also the reason that the fingers have such a high strength, in contrast to when the muscles would be completely located in the fingers (McGavin, 2014). The intrinsic hand is then subdivided into four more groups: Thenar (thumb), hypothenar (little finger), interossei (sideways motion of fingers) and lumbricals (flexing and extending of the knuckle joints).

Often when speaking of muscles, antagonist muscle pairs are mentioned. These are muscles that oppose (counteract) each other (Lumen Learning & OpenStax, n.d.).

For spasticity, when a pair is affected, often the flexor muscle is stronger than the extensor muscle. Therefore, most of the hands found are in a closed position.

Key takeaways

- Muscle bellies located in lower arm
- In antagonist pairs, flexor muscles win over extensor muscles
- All muscles can be affected

2.5 Kinematic diagram

A kinematic diagram is found in Figure 18. It shows the different joints and movement directions. All DIP, PIP and the IP joint are normal hinges. All MCP joints are saddle joints: having movement in both the horizontal and vertical directions, without rotation. The CMC joint is a ball joint with slight rotation among the vertical direction. Finally, the wrist is also displayed as a bi-directional joint, as the actual rotation of the wrist is created in the lower arm.

In literature there are two types of range of motion: total range of motion and functional range of motion (Bain et al., 2014). For the project, the functional range of motion is used, as it defines the range that is used in daily activities.

Using the data from Ryu et al. for wrist joint movement (1991) and the data of Bakarat et al. for thumb movement (2013), an overview has been created that displays the required range of motion that the assist should provide.

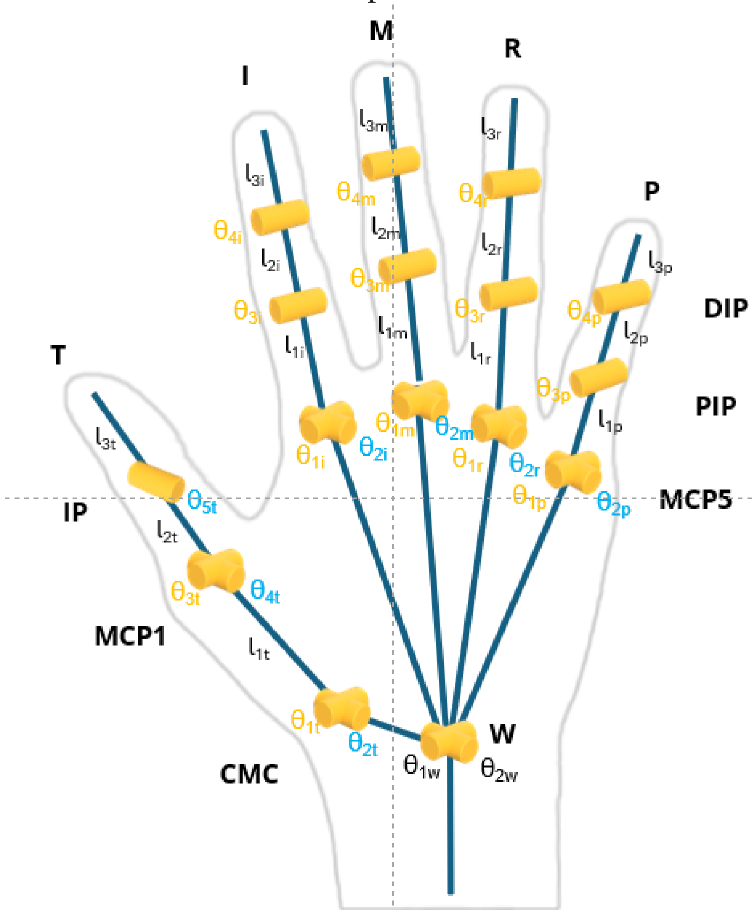


Figure 18: Kinematic diagram

Wrist functional

40 deg extension
40 deg flexion
40 deg ulnar-radial deviation

Finger functional

MCP	**19 deg**	**extension**
	71 deg	**flexion**
PIP	**23 deg**	**extension**
	87 deg	**flexion**
DIP	**10 deg**	**extension**
	64 deg	**flexion**

Thumb functional

IP	**12 deg**	**extension**
	88 deg	**flexion**
MCP	**8 deg**	**extension**
	60 deg	**flexion**
CMC	**61 deg**	**anteposition**
	31 deg	**retroposition**
	63 deg	**radial abduction**
	10 deg	**adduction**
	grade 9	**opposition**

Key takeaways

- Functional range of motion is used
- Degrees of freedom for each of the joints is displayed above

2.6 Stakeholders

A stakeholder map has been created showing the connections between the stakeholder groups (Figure 19). They are separated on their proximity to the patient: close contact, direct contact and indirect contact. Artus3D is positioned at the instrument maker, while Centrum Orthopedie is located at the medical specialist.

Patient
The patient is the person with spasticity that needs treatment and is the driver in the process. Their goal is to have the spasticity treated and to reduce the effect it has on their daily lives. The spasticity could vary in intensity and is found more often with elderly as an age-related symptom.

Medical specialist (Orthopaedic technologist)
The medical specialist consists of a group of specialized occupations that are involved with the treatment of the spasticity: the geriatrician, the surgeon, the plastic surgeon, the neurologist and the orthopaedic technologist.

The orthopaedic technologist performs the fitting of convection orthoses and determines if there is a need for creating personalized orthoses. If decided necessary, they will create a cast of the hand of the patient. The geriatrician specializes in elderly care and is trained on working with people with chronic disease and age-related cognitive and physical impairments (CareerExplorer, 2024). The orthopaedic surgeon and plastic surgeon are specialized in performing surgical interventions; such as muscle relocation, muscle elongation and bone removal. The neurologist specializes in treating conditions related to the nervous system (Eske, 2023).

Instrument maker
While some roles have overlap, the instrument maker generally does not have direct involvement with the patient and creates the orthoses based on the therapist's description. A digital scan or plaster model is delivered by the therapist, after which the orthosis is generated and manufactured. The company of Artus3D is located here.

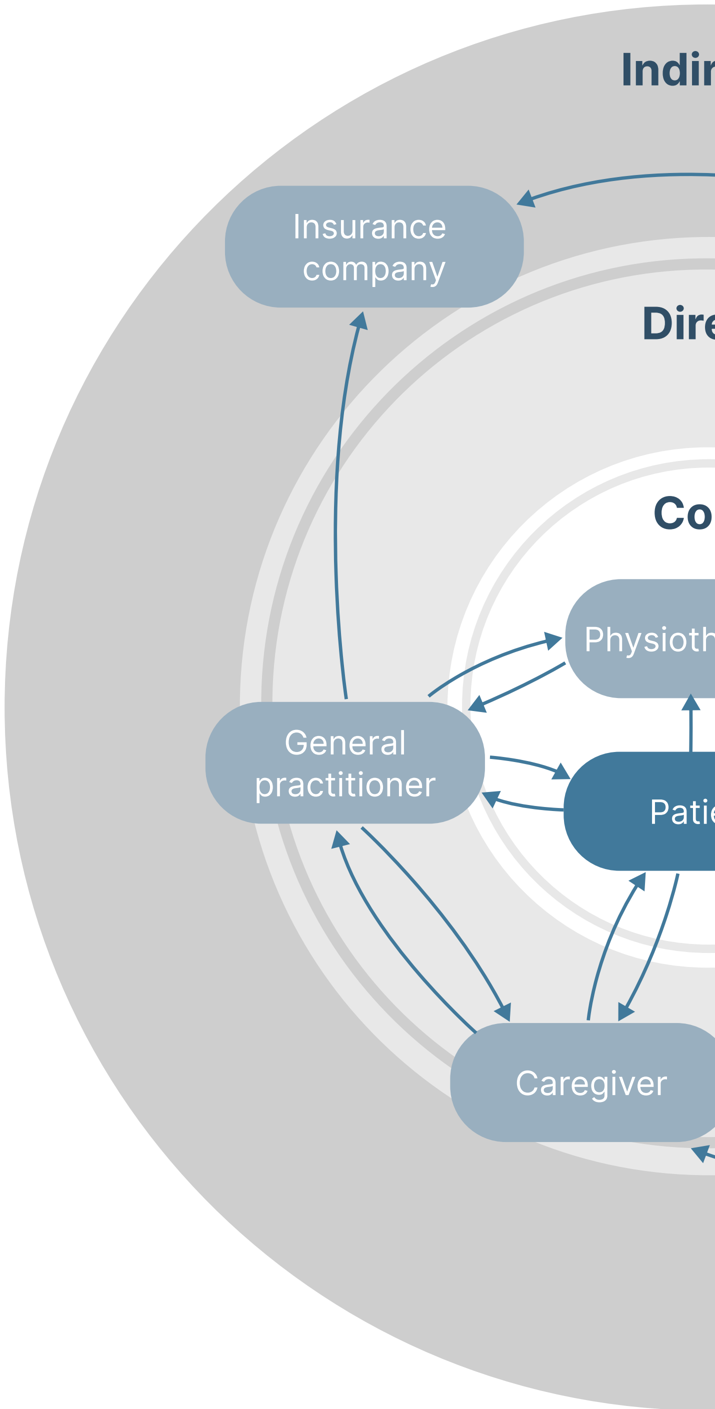
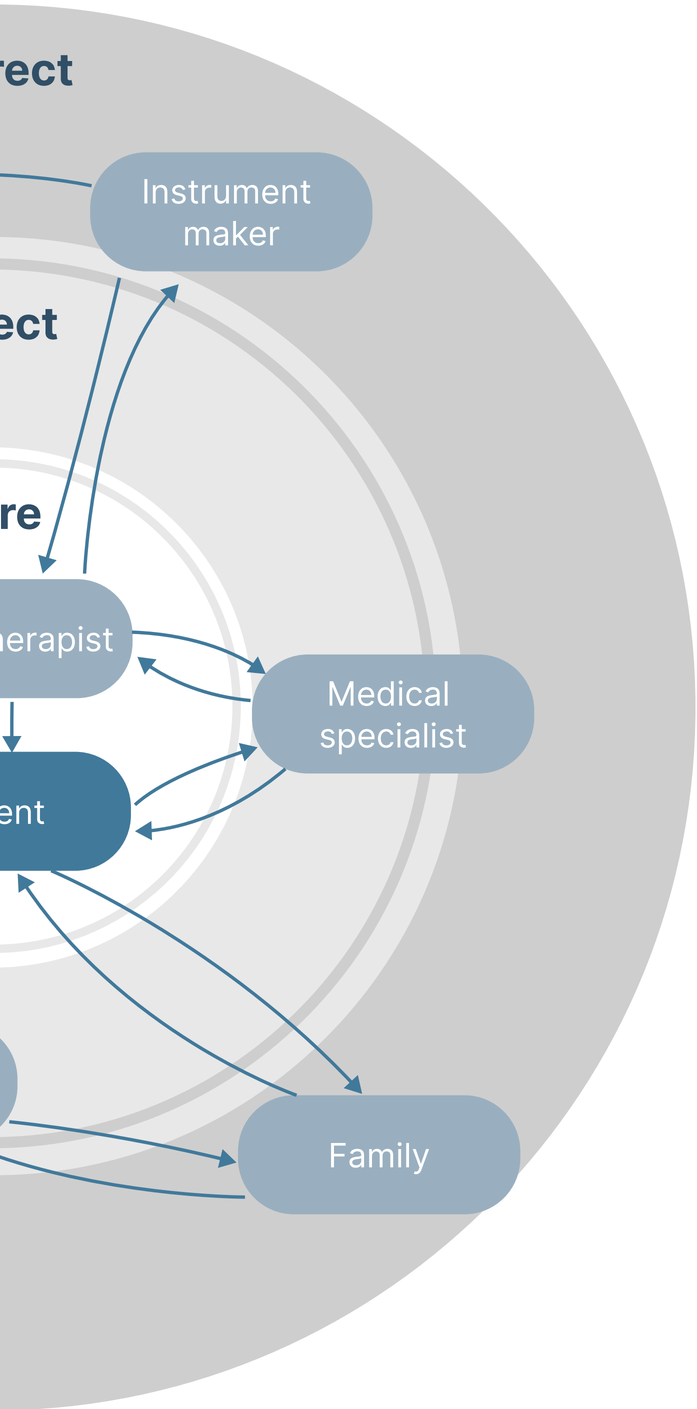


Figure 19: Stakeholder overview

General practitioner
The spasticity is usually discovered at the general practitioner or with the therapist during consultation hours, a regular check-up, the caretaker noticing symptoms or through the consequence of other diseases. The general practitioner will refer the patient to the therapist and together they create a treatment plan for the patient. The referral is mandatory for reimbursement by the insurance company. Gezondheidsnet, 2020).



Therapists (physiotherapist)
The therapists are one of the main actors in the process. The therapist refers to a group of therapists, ranging from physiotherapists, occupational therapists and hand therapists. Their goal is to guide the patient through varying exercises & treatments to reduce the impact of spasticity and to regain functionality in the spastic hand to assist in daily life. Each of the therapists have a specific expertise that will affect the interaction with the patient.

The physiotherapist has an expertise on the musculoskeletal system; focusing on improving strength, movement and range of motion (Seladi-Schulman, 2020). The occupational therapist is related to the physiotherapist, but the main difference is that the occupational therapist will look at regaining the motions, skills and actions used for tasks in daily life (Barrell, 2020). The hand therapist has similar education as both the physiotherapist and the hand therapist, but are more specialized on hands, wrists and shoulders (Bailey, 2022).

Family
The family plays an important social support role for the patient. Although most are not directly involved in the caring process, one or two members will take on the role of the caregiver to assist and help explain the patient the process. They could also be the ones who discover the spasticity and ask the caregivers, who in turn create an appointment with the medical specialist and physiotherapist.

Caregiver
The caregiver is the person or persons who provide support to the patient. This could be an employee in the care home or a family relative visiting regularly at the home of the patient. They assist in the daily tasks and challenges that the patient has to deal with, like putting on clothes or using the bathroom. They update the doctor and physician through direct conversation or by keeping a patient diary.

Insurance company
At last there is the insurance company, who is focused mainly on selling insurance policies that protect people from unforeseen expenses or risks. Before reimbursement of the orthosis is given, a valid referral from the general practitioner is required. A separate section of the instrument makers have the task to acquire said reimbursements from the insurance companies.

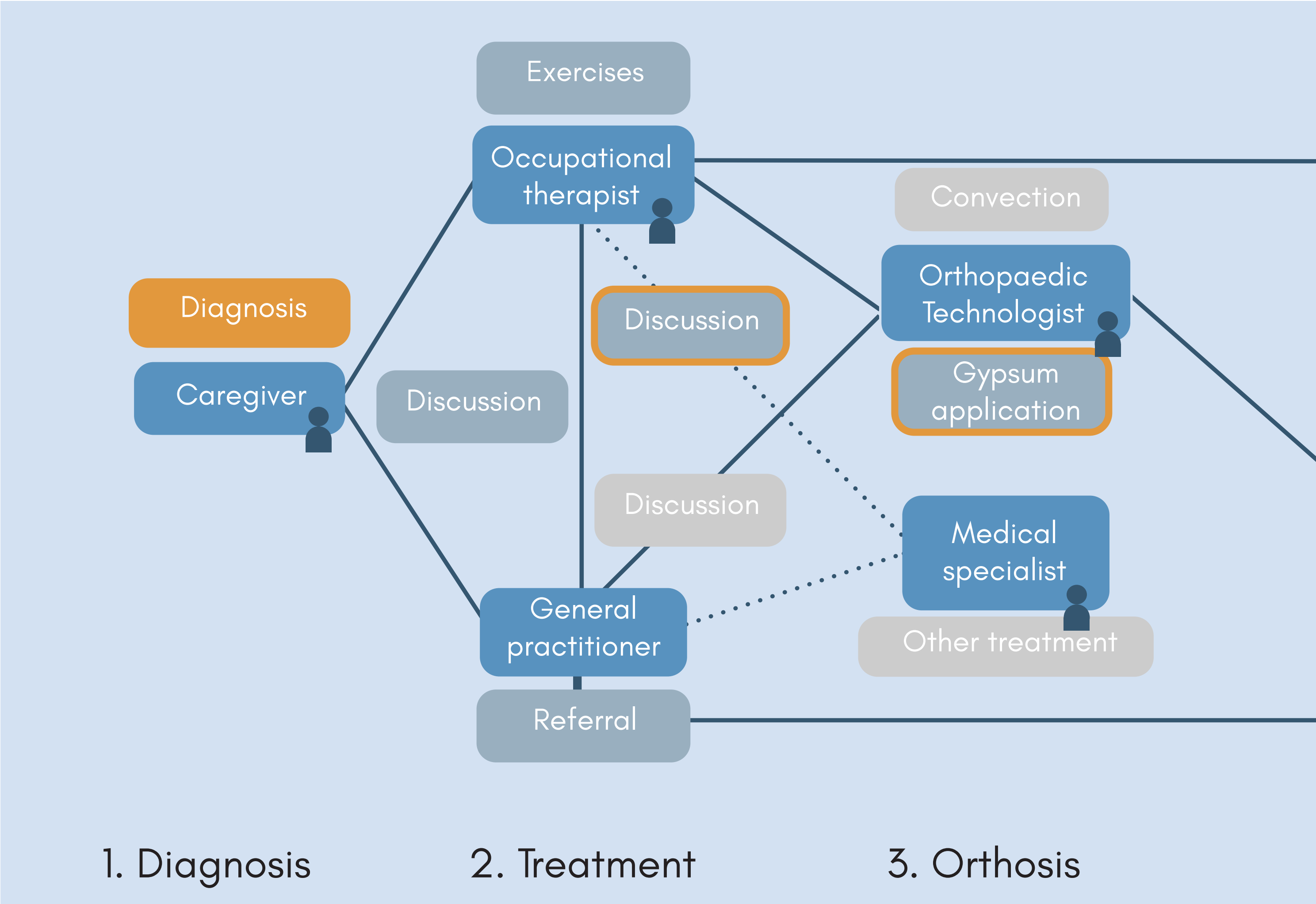


Figure 20: Traditional patient care path & project influences

Starting point Stakeholder

2.7 Patient care path

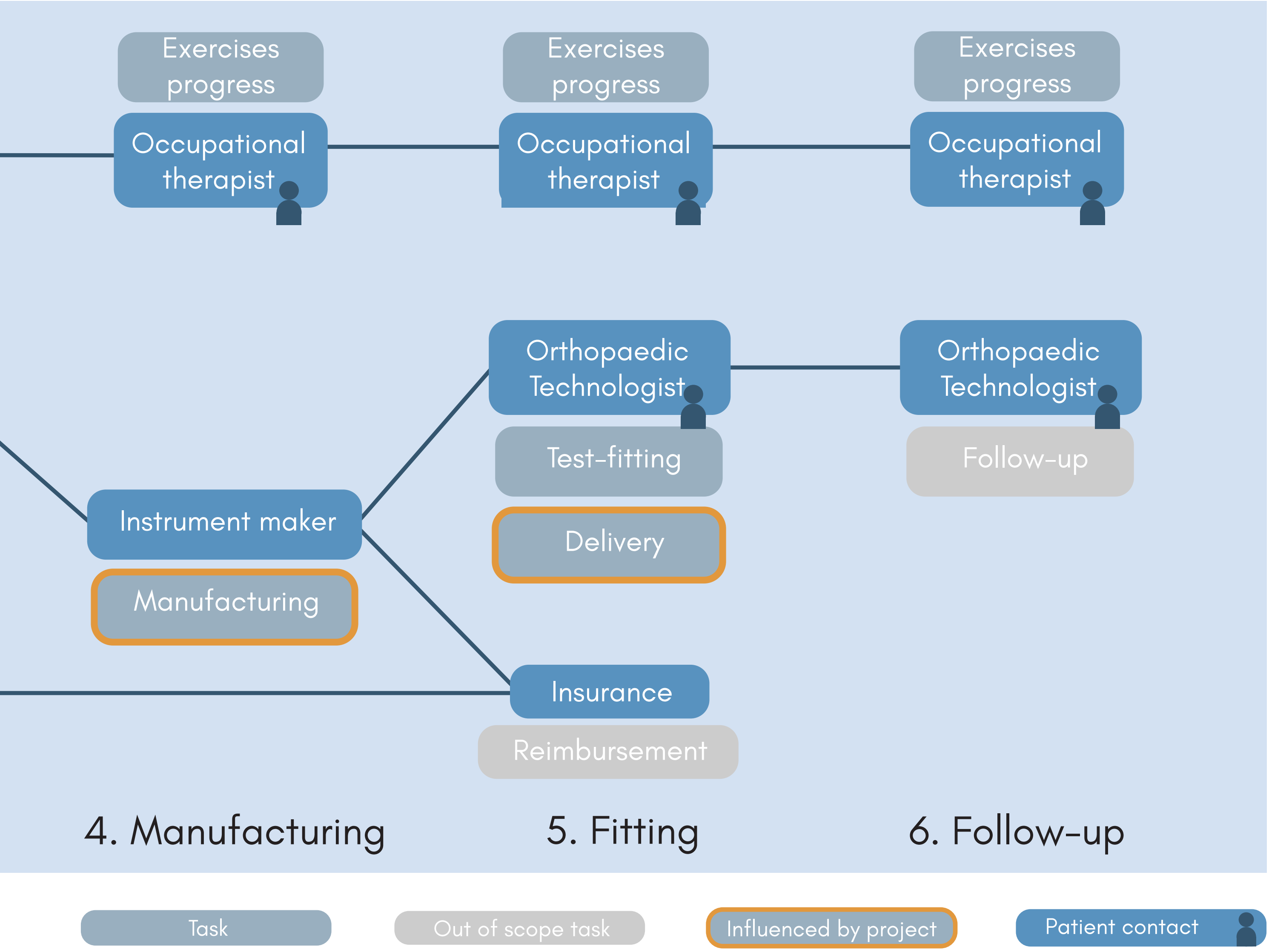
The patient care path shows the steps that a patient goes through from initial diagnosis of spasticity to the fitting of the orthosis. This is seen in Figure 20.

1. Diagnosis
The first step in the process is the diagnosis. Spasticity could be found by the caregiver, family, via an appointment with the occupational therapist, general practitioner or orthopaedic technologist in another appointment. For clarity, it is assumed that the caretaker discovered the spasticity.

2. Treatment
The next step is determining what treatment will suit best for the patient. First is decided between the GP and the occupational therapist whether treatment is really needed. Does the patient have difficulties with it? Is exercise alone enough as remedy? The least invasive treatmens have preference.

3. Orthosis
When it is decided that intervention is needed, options are discussed with the orthopaedic technologist first. A convection orthosis is fitted to see if it provides enough stretch or resting in the situation of the patient. If it is not enough, it is decided to go for a personalized orthosis and a gypsum cast is made in the same appointment, or in the following appointment (depending on conversation with the occupational therapist).

If it is found that the hand is too severely affected for an orthosis, or the patient has negative experiences (sensitive skin), a medical specialist is called in. From here, the options for treatments are discussed. Sometimes shockwave therapy is recommended in addition to splinting. Other times Botox injections are used to calm the muscles. These options open up many different trajectories for the patient and are out of scope for the project.



4. Manufacturing

The gypsum mould is used to create a cast by the instrument maker, followed by the process of orthosis manufacturing and thermoplastic material forming. Documents are processed for insurance and the orthosis is ready for delivery.

5. Fitting

The orthosis is delivered and test fitted with the patient. Minor adjustments can be made on location. Otherwise, changes are written down and the orthosis is brought back to the instrument maker. Around the same time insurance is arranged for the reimbursement of the orthosis.

6. Follow-up

The final step includes a follow-up of the orthopaedic technologist to see if the orthosis functions well or changes need to be made.

Ideal care path

The ideal care path focuses on reducing the time needed for patient measuring, manufacturing and removes the need of gypsum. The process becomes less invasive, more clean and results in an orthosis with better fit. Manufacturing will have less manual involvement, reducing the time it takes from 2-3 hours of manual forming to ten minutes of 3D model cleaning & adjusting. Delivery speed becomes quicker, reducing delivery from three to two weeks. The orthosis lasts longer & improves cleaning more than the convection and thermoplastic orthoses. Earlier discovery could lead to faster intervention and higher chance of reducing the severity of spasticity

Key takeaways

- Reduction of patient invasiveness
- Cleaner & quicker process
- Less manual involvement manufacturing

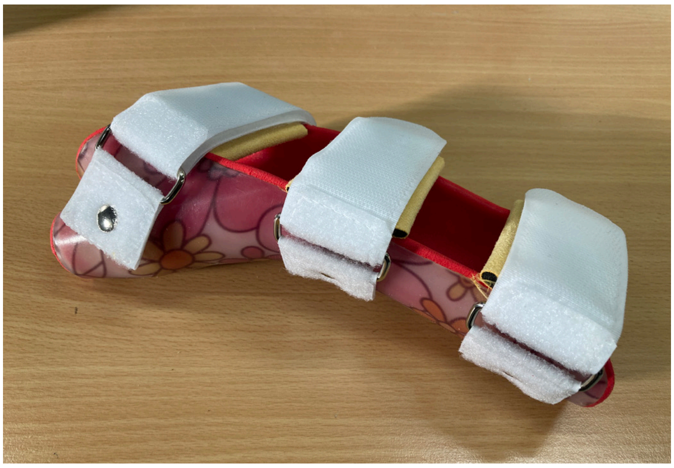
2.8 Gypsum orthosis process

Preparation and measurements
The process starts with measuring the main dimensions of the MCP length, wrist width, diameter, finger length and measurements of the lower arm diameter at two places for reference. To prevent uncleanliness, bubble wrap is placed below the hand and the hand is covered with a glove and wrapped in plastic. A bowl of water is prepared, along with the materials for the gypsum process.

The dimensions are noted in a document. It also allows for extra requests of customizations by the orthopaedic technician, for example: adding an extra band or placing the hand in 10 degrees extra dorsiflexion.

Gypsum application
The first step is applying a cutting plate in order to open up the gypsum cast in the final step when the material has set. In following steps, gypsum cloth gauze is applied around the hand, moisturized and smoothed. Additional reinforcements are made for the thumb by first dipping the gypsum cloth in water and adding it to the hand.

After some time, the gypsum has set and is opened up with the knife, following the cutting board. Slowly the mould is removed, giving extra attention to the thumb and bent back into position. The process takes 20-30 minutes (Haynes, 2024). Now the mould is ready and brought back to the manufacturing site.



Orthosis manufacturing
The topside of the gypsum mould is closed up again at the manufacturing site. The holes near the fingers and thumb are closed as well.

The inside of the mould is coated with wax and gypsum is poured in. When the gypsum has set, the mould is removed and a positive cast remains. Because of the wax, the gypsum does not stick to the mould and makes removing easier.

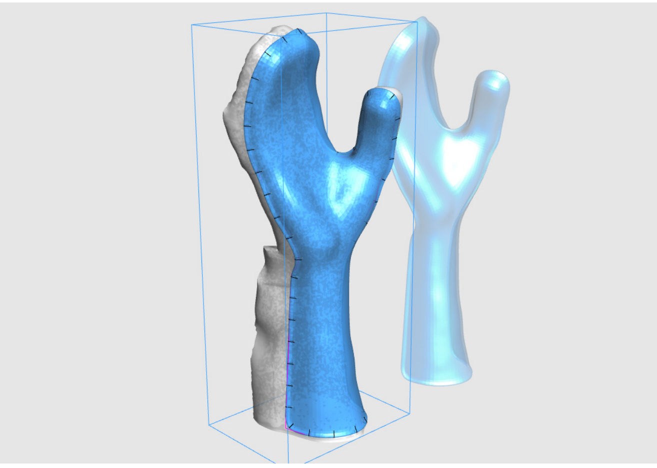
By using the positive cast as a basis, thermoplastic material is formed around it to create the orthosis. Sharp edges are removed and cut to shape. The inside is padded with foam material and on the outside velcro bands are added.

Delivery
The delivery takes place within three weeks of the gypsum application the orthosist by the logistics department. Sometimes products finishes earlier and the time of arrival is reduced to two weeks. Insurance documents are arranged and patient specific documents are archived.

Key takeaways

- 20-30 minutes for gypsum application
- 2-3 contact moments with patient
- 2,5-3 hours of manufacturing the orthosis
- 3 weeks before delivery

2.9 3D scanning orthosis process



3D scanning

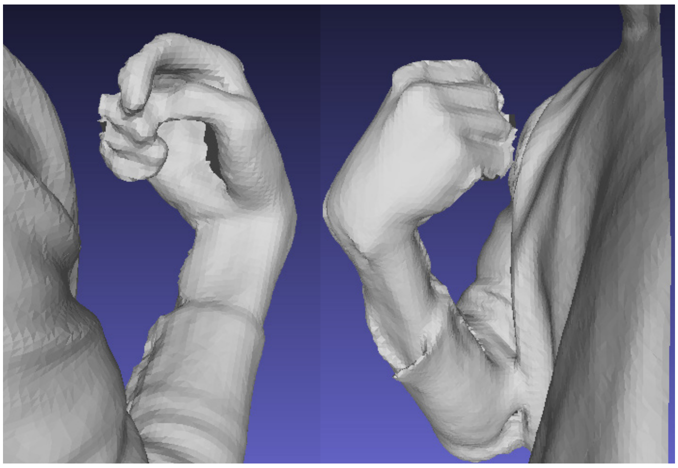
The process of scanning starts with the patient positioning their arm away from their body. While they keep the hand still, the orthopaedic technologist uses the Structure 3D Scanner to digitally capture the hand.

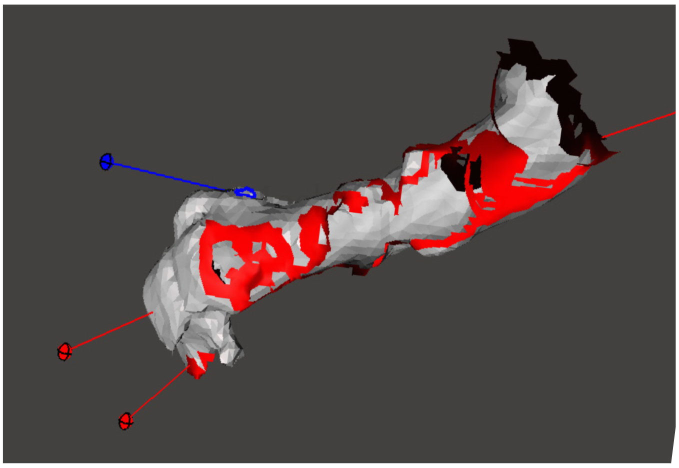
The scanning software will indicate whether the distance from the camera to the hand is correct and shows the parts that are already scanned. After the scan is complete, it provides an overview of the scan for reviewing and is sent to the cloud based manufacturing platform

From mesh to digital orthosis

For most orthoses the software automatically recognizes the hand and designs the product around it. For spasticity it is still rarely used, but for the times it does occur, the scan is sent to the instrument maker. The instrument maker will manually clean the mesh from obtrusions and create the outline of where the orthosis should be formed. Finally the orthosis is generated sent to the 3D printer.

The software allows options to customize material, color, thickness and the type of orthoses.





Manufacturing
After the digital model is formed, it is ready for printing starts. Most TPU orthoses are printed using the Formlabs 3D SLS printer and processed within the company. Using air pressure, the small particles from of the SLS are removed. Now the orthosis is ready for delivery. There is also the option to smoothen the TPU material using vapor smoothing, but comes with additional costs.

For spasticity, the orthoses are made from Nylon (PA12); a rigid material that is easy to clean. Due to the complexity of printing Nylon, these orthoses are currently outsourced. Upon arrival, the product is finished by adding bands and minor modifications like smoothing.

Delivery
The orthoses are now ready for delivery in 2-3 weeks and are fitted with the orthopaedic technologist. Sometimes small modifications are needed, like removing small edges and the product is brought back to the manufacturing area. Larger problems, for example bending the finger holder more is not possible. Then a new orthosis is needed; although this almost never occurs.

Key takeaways
- Scanning 4-5 minutes
- Manual labour from scan to finished product less than one hour
- 2-3 weeks before delivery

2.10 3D scanning in detail

3D scanning is the process of digitally capturing a physical object using non-contact methods and accurately translating its physical dimensions, such as height, width and length to the digital environment (Artec 3D, 2023). This is achieved by creating numerous data points and placing them in a digital coordinate system, after which the points are connected and a polygon surface is formed. Its applications range from recreating complex objects to various surfaces and places that are otherwise difficult to measure (Jaco, 2022).

There are various types of scanners, ranging from full body scanners to rotating table scanners and handheld scanners. The types that are most commonly used are laser triangulation scanning, structured light scanning, photogrammetry and computerized tomography (Waraksa, 2023). From these types of scanners, Artus3D uses the structure sensor scanner that uses the structured light scanning technique: a method where a pattern of near infrared light is shone onto the object. Using multiple beams per second, images are captured and variations in the reflections are analyzed on patterns and turned into a mesh (McMillion, 2022).

The advantage of structured light scanning is that it is suited for small object scanning; the scanning process is quicker and is less affected by environmental light like laser based scanning (Shining 3D, 2022). Compared to photogrammetry, it has a smaller focal area to better capture details and flat surfaces (Sekula, 2023). Another advantage is the possibility to move the scanner around the object, instead of the object itself rotating. This way more detail is captured in places that could otherwise be covered by the object itself (Figure 21).

Specialized scanners have also been developed for the orthopedic industry, such as the Curatio: a dedicated hand scanner that could create a 3D model in a single image (Fieldlab UPPS, n.d.).With technologies improving, dedicated software and Ipad scanners are already becoming more accepted in the orthopedic industry and with the high quality cameras found in smartphones, scanning with a phone could become the next trend.

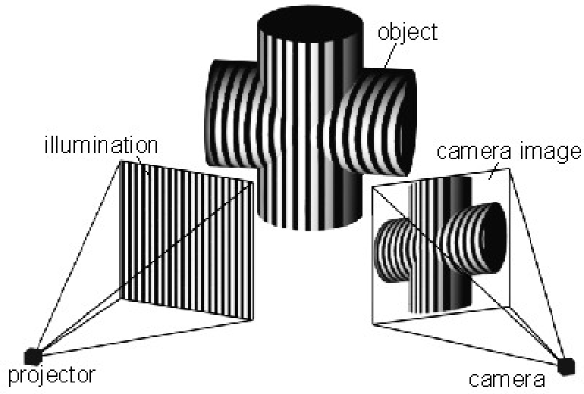


Figure 21: Structured light 3D scanning

For achieving the highest quality scans it is important to keep a consistent distance from the object so that the focal range is optimally used and to keep the object centered. This is around one meter for the structure sensor (Structure.io, n.d.). It should also be possible to walk around the object for full scan coverage. The scanner works best when no direct sunlight reflects on the object.

For scanning hands and lower arms it is best to capture part of the shoulder as well. It helps providing reference for the scanner, as the hand is a relatively small object. Because the scanner moves at a set distance around the outside of the hand, it is difficult to capture areas that are hidden from the scanner, like the inside of a closed hand.

For getting the scan on the inside of the hand, an imprint could be made and is scanned instead. The scans are then digitally combined into one. Generally this is not used with spasticity orthoses, as the hand would be in such a state that other treatments like the gypsum roll or botox injections are preferred.

Key takeaways

- Scanning around the object
- Keeping a consistent distance from the object
- Also capture part of the shoulder for scanning hands

2.11 3D model cleaning

After the 3D scan is created it is not directly ready to be used in the orthosis generation process. Most likely there are unwanted artifacts and surfaces that are accidentally scanned. For the scanning it could even be intentionally done for better scan referencing, like scanning part of the shoulder.

Artus3D uses the program Meshmixer to use in the cleaning. It is a program that allows for easily changing parts of a mesh. There are options on selecting and removing triangles from the mesh and to fill holes and add surfaces. The program works organically, meaning that one could use brushes that gradually alter the mesh. Different options are available like plane cuts, cutting off parts of the scan or smoothing; making the texture of the scan smoother.

When cleaning the hands, the first step is to remove the large artifacts that are not part of the arm. Then the artifacts and inaccuracies that are part of the the hand are removed. When the basic shape of the hand is visible, the scan is further smoothed. Sometimes there are changes of the scan made to improve the shape of the orthosis, like changing the angle of the thumb or centering the wrist. This is done by cutting the component and slightly rotating it. Then the object is combined again.

When the shape of the hand is ready, the outline of the wrist and hand is selected and extended upwards. The thumb is extended outwards. Finally, for better fitting of the orthosis, the fingers and thumb are slightly elongated to prevent them from moving over the edge.

From a quality perspective it is important that the main dimensions of the scan are definable. This means that it is clear where a location is and that the dimension could be measured. These measurements are found in the finger length, MCP width, thumb length, thumb width, wrist width, and lower arm width. For extra certainty, the wrist, lower arm, MCP and thumb circumferences are also taken. For the orthosis to be accurate, the area near the base of the hand and the thumb commissure are should be visible.

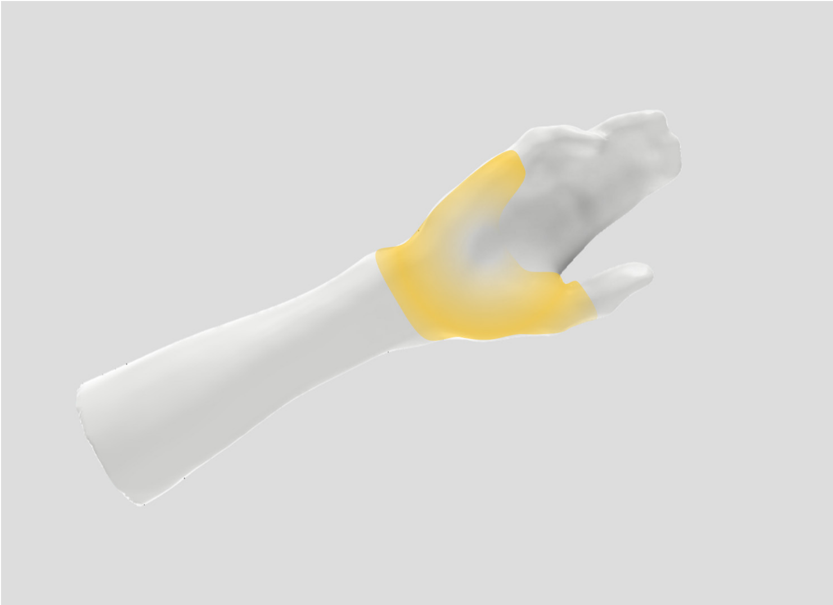


Figure 22: Key area for orthosis generation

Figure 22 shows the location where highest detail is required. Most of the previously mentioned measurements are found in this area. This area consists of relatively hard tissue that does not have much flexibility to adapt to the orthosis shape. For example the wrist and knuckles need high accuracy, while the lower arm consists mostly of soft tissue and will adapt to the shape more easily.

For the cleaning itself it is important that the initial scan is complete and has enough resolution. With lower resolution the scan loses its accuracy and loses the details of the hand. The hand and lower arm should approach 10k triangles to provide enough detail for the orthosis generation. After the model is roughly cleaned, the triangles are subdivided and approach 35k triangles. It increases the resolution and creates the smoothness that the orthosis needs.

Key takeaways

- Small positional changes are possible in Meshmixer
- The scan is cleaned manually
- The scan approaches 10k triangles in order to create a personalized orthosis

Figure 23: One of multiple care homes Centrum Orthopedie attends

2.12 Patient visits

During a patient visit to multiple care homes (Figure 23), together with an orthopaedic advisor of Centrum Orthopedie, several cases of spastic hands were observed. Beforehand rules were explained on privacy, capturing images and to step out of the room if the situation would become delicate.

The first patient visit needed renewal of the orthosis (Figure 24, 25). The patient had a light spasticity in the fingers and a thumb that would automatically push inwards. The old orthosis used five straps to secure the hand and had rubber ridges to keep the fingers in place. Upon arrival, some of the straps were placed incorrectly by the patient. It was explained that the orthosis did not fit comfortably and that area near the thumb did not touch the skin. The ridges at the fingers hurt, so the patient did rarely wear the orthosis. The new orthosis uses four straps and was slightly bent to shape.

The new orthosis was welcomed and felt more comfortable then the old orthosis. The patient seemed calm and accepted the help from the orthopaedic advisor.

Another patient experienced spinal cord injury and had spasticity in a single hand. It was allowed to touch the hand and feel how the spasticity behaved. The MCP joint had slight resistance, while the PIP and DIP joints were incapable of moving. It was explained that bone growth had taken place and the fingers had permanent reduced range of motion. The new orthosis did fit, however some adjustments were needed near the thumb and along the index finger. These were marked on the orthosis and were taken back.

Figure 24: Old orthosis for spasms

Figure 25: Example of mild spastic hand MAS 1 with convection orthosis. Notice the half tray of the chair on which the orthosis rests

In addition to patients who needed orthoses for hands, also orthoses for the foot were fitted. During the day, all patients were approachable and friendly to the staff. Some were accompanied by a family member or caregiver, so there would be always three to four people in the room.

In conversation with some of the staff at the care home it was found that this specific care home actively made effort in recognizing early signs of spasticity. Constant stretching, frequent rubbing of the fingers and having slightly bent fingers were early signs. This type of effort was explained to be uncommon among care homes.

It was explained that because of the high working pressure and many patients in the health care, these signs are often overlooked by the caregivers; and that they are usually not directly instructed to pay attention to it. Most patients see a wide range of healthcare professionals, each with their own specialization and focus.

Most of the patients do not mind the help, while some even enjoyed the attention. For some it became mentally tiring with the people standing around and activities happening. Suddenly there is much to process in an otherwise calm day.

The patients in the carehomes were mostly elderly and female. The staff approximated the female to male ratio to be 70:30 and explained that this was because women get older then men on average.

The main importance of the orthosis is that the hand is in an open position and therefore keeps the hand clean. It also makes sure that the patient does not get stuck on something, like their clothes. The final patient was in a wheelchair and had lowered mobility in the shoulder and lower arm, hunching inwards.

Key takeaways

- Most patients have limited mobility
- Few care homes pay attention to early signs of spasticity
- The majority of the elderly are female

2.13 Interviews

Interviews were conducted to gain a deeper understanding into the process. In later stages of the project regular conversations were made and written down. These interviews were used as point of entry into the context. The answers are translated as well as possible, trying to keep their original intention.

Orthopaedic advisor 1:

[Could you describe an average patient visit?]

“Often I travel to a care home or hospital and meet with the physiotherapist and patient on location. There the limits of the hand movements are found and kept in that position, while I apply the gypsum. An average appointment takes between 15 and 30 minutes. After the gypsum has set, it is removed and a negative mould of the hand is created for making the positive version.”

[Are there differences in spasticity?]

“Not all spasticity is equal, sometimes fingers have more spasticity then others. The most difficult part of the orthosis is the thumb, as all of the fingers are easier and are in a single line. The goal of an orthosis is to keep the life of the patient as easy as possible and to reduce the decline: prevent small wounds, infections & dirt.”

[Who are your patients with spasticity?]

“The majority of spasticity cases comes from Cerebral hemorrhages. I treat at least dozens of patients per year. However I see relatively few young people with spasticity, but that is because I often visits care homes. Most patients are limited in their movement and often are in a wheelchair, sometimes with a hemi table.”

[What makes a good orthosis?]

“There is a balance between the wrist and the fingers: when the wrist is extended, the fingers will extend less. A good orthosis takes an approximate angle that seems proper for all the joints and is worn around 8-10 hours per day.“

[What should I keep in mind when designing?]

“Nearly 90 percent of the cases is spasticity in a closed position. Sometimes the thumb is inside the hand. When you design, preferably do not pull on the fingers, you could overextend the other joints; nor put high pressure on a single part. Take note that not all patients can move their hand vertically or place them on a table. The product should be able for travel in a car. Orthoses are used for 1-2 years.”

Orthopaedic advisor 2 :

[What is the reason for this project to exist?]

“One of the reasons for this project to exist is that it takes a long time before the orthosis is ready, as it takes approximately 30 minutes. As of now, the scanning is complicated because the hand needs to be kept in a neutral position. Some hands have reduced range of motion and it is not easily possible to place them on a table.”

[What are important qualities of an orthosis?]

“One key aspect of the thumb is the ‘duimkom’ [webspace]. Another point is that as much material on the skin is preferred for comfort. On the other hand, the 3D modelling needs as few material as possible to improve the scanning quality. The height of the orthosis not as important while the orthosis is open from the topside.”

[Your research showed data of hand sizes with age 20 to 60 years old, is that a specific target group?]

“At the time hand sizes were needed for the continuing of the research, but the target group could as well be 60+, as most of our orthoses are brought to those clients.”

[Do you have tips for me on the project?]

“It is important to keep the comfort of the patient in mind. Preferably do not use sharp materials or edges that press into the skin. Some way of holding the device while scanning could be useful”

Instrument maker :

[What are important points for creating an orthosis? Do you need a certain scanning quality?]

“For the orthosis, mainly the detail is important; the wrist, lower side of the hand, the thumb and the fingers need to be clear. The scan should show the shape of the hand. From there, improvements of the scan can be made. If you would make a device that holds the hand, then from the scan it should be clear where material needs to be removed.”

[Do all scans need post processing?]

“For normal orthoses like MCP stabilisation, the software will automatically filter the hand from the mesh and shows the orthosis options. With spasticity, currently the scanning is not used. Sometimes a scan is made from a gypsum cast, or from a hand that is similar in size, but those are exeptions. Those scans need to be manually cleaned and the outline of the orthosis needs to be drawn.”

[Are there sometimes more difficult scans that you need to address?]

“Some of the orthopaedic technologists will scan the whole room instead of the hand. Then the software does not recognize it and I need to clean the mesh. It also leads to the scan having fewer data points and thus a lower quality scan. Generally that does not happen.”

[Are there different ways that orthoses for spasticity are created?]

“There are technologists who will hold the hand in a stretched position or ask me to make digital modifications to it. Other times they make a scan of the gypsum cast from the hand. Some technologists have their own intricate ways of scanning, but so far it has worked out in the end.”

[How do they treat the more severe hands?]

Closed hands are not scannable, therefore you should focus on scannable hands. The more severe hands are treated with gypsum rolls.

[Do you have tips for me for the design?]

“It should be comfortable to the patients and for the scan it should be clear what is the hand and what is the product. It is nice if the area near the thumb is clear.”

Nurse

[When do you discover that a patient has spastic hands?]

“Quite often we find them during their daily care or during sessions with the ergo/physiotherapist.”

[Are those hands lighter or more severe?]

“Most of those hands are severe, as nurses are not trained to directly pay attention to it. Therefore they happen to be found during other sessions. By that time the spasticity has worsened”

[Can you recognize spasticity in advance?]

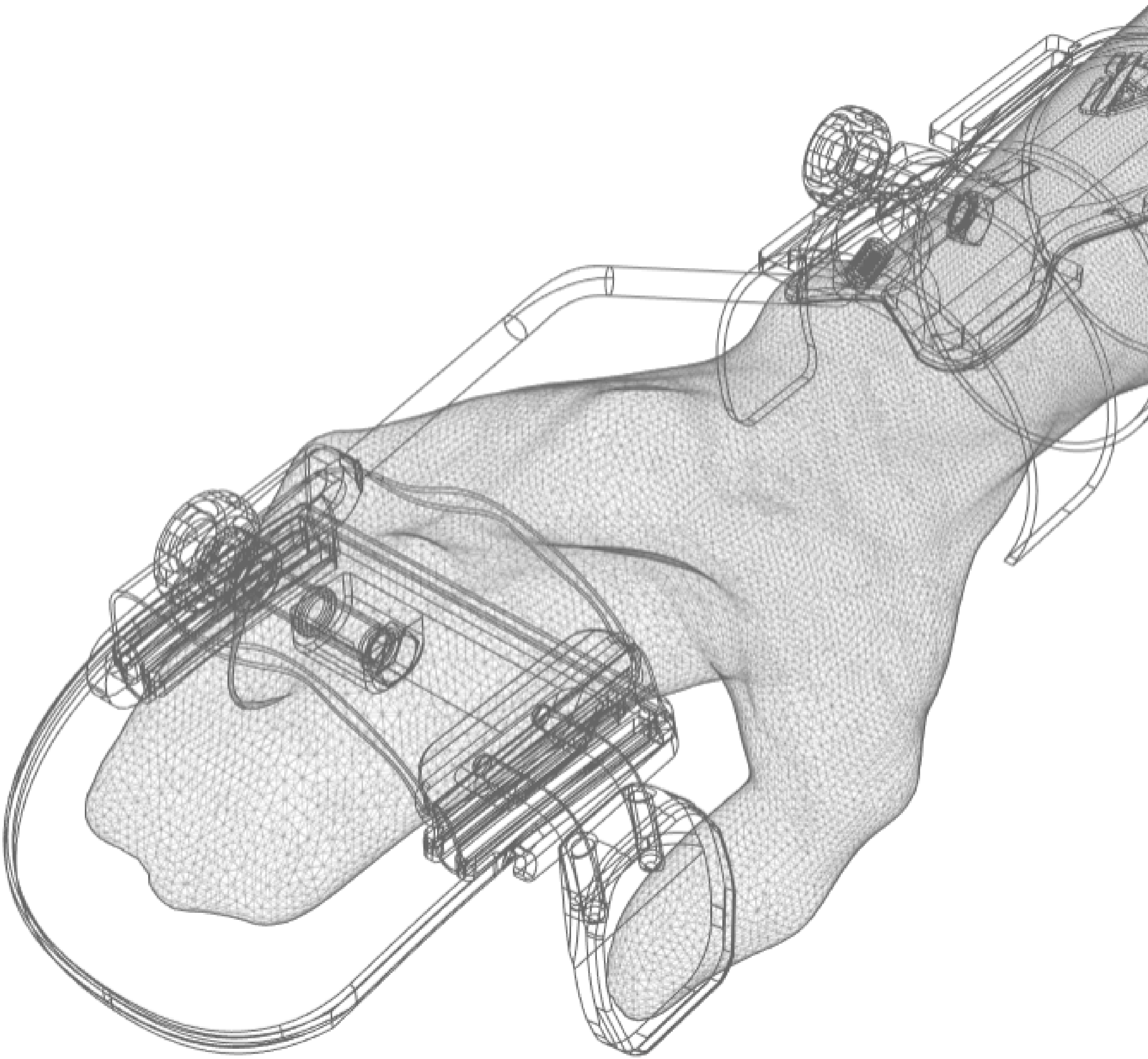
“Early signs of spasticity include patients rubbing their hands frequently, stretching them and having the hand often in a closed position. Sometimes the muscles contract at the shoulder as well, making them sit in an uneven position.

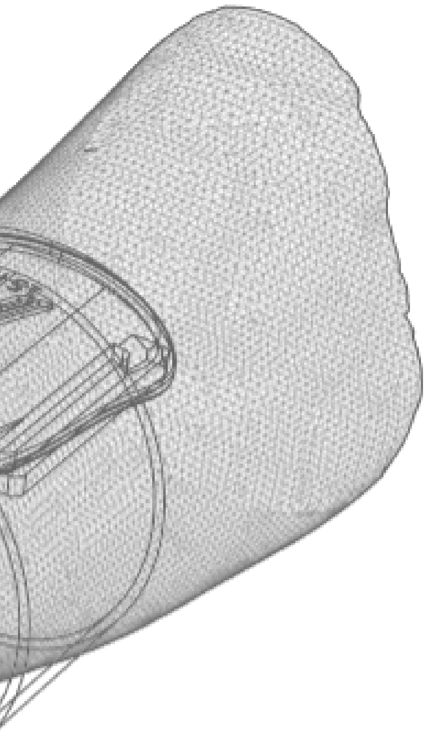
[Why hasn’t anything been done to this before?]

“Most care homes are too busy with their daily tasks, it just slips by. The pressure on the system is very high. One of our nurses happens to be specialized in spasticity and setup a program for early recognition in our care home. There are posters that instruct the nurses and family members of the signals.”

Key takeaways

- Travelable solution
- Keep comfort to the patient
- Clear division device and hand
- Scannable up to 90 degrees MCP
- Early recognition of spasticity



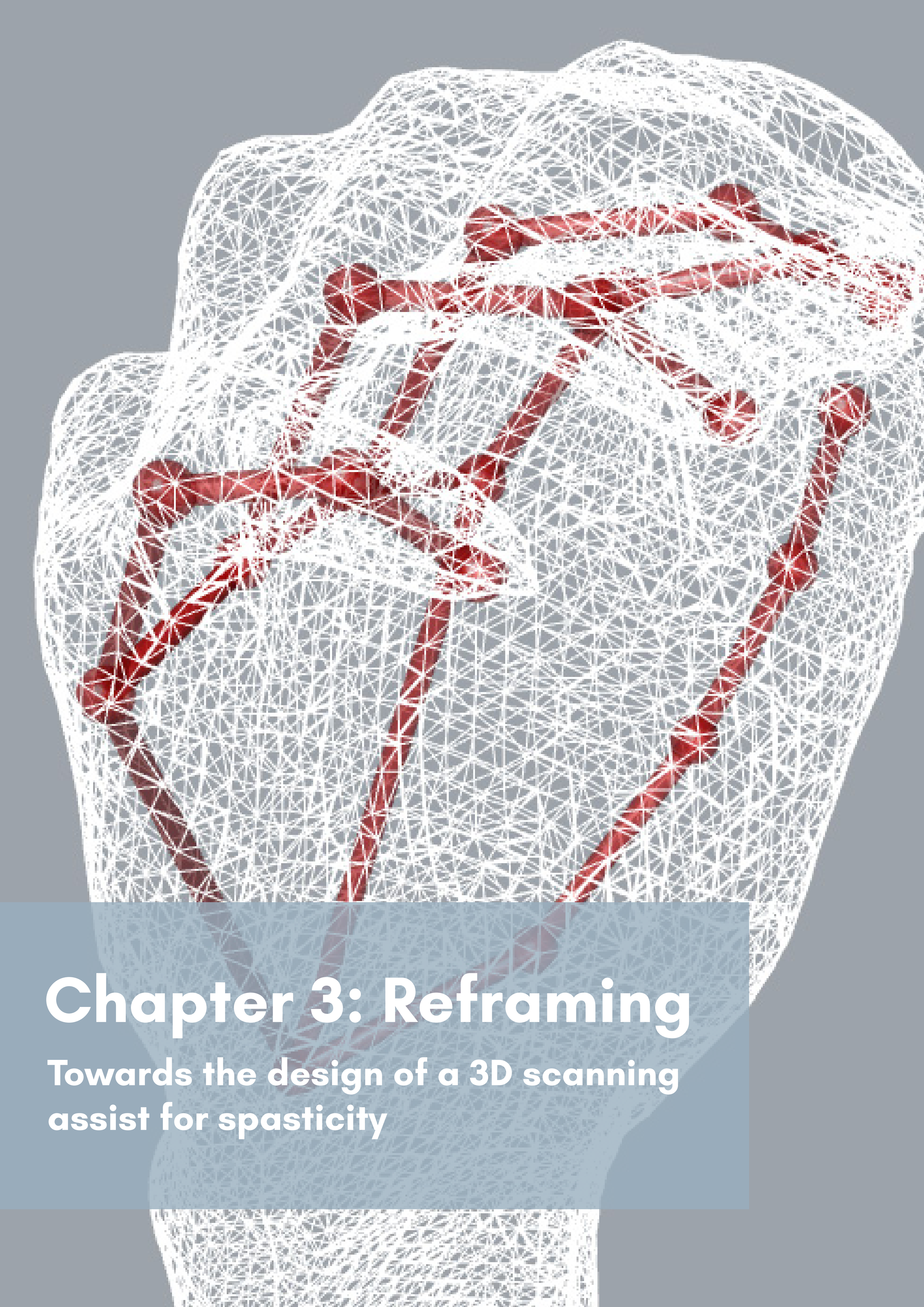


2.14 Conclusion

This chapter provided a basis for the upcoming design process of the product. An overview has been created on spasticity, what types of treatments there are available, what an orthosis is and where it is used in the orthopaedic context. An introduction to the hand has been made, leading to a kinematic diagram that displays the natural movements and range of motion of the hand and provides boundaries for the design process.

A patient care path has been created, as well as an overview of the stakeholders. Their roles and interests in the project have been discussed. The section on the 3D scanning method leads to insights into the context of the product. The current gypsum process is explained along with its influence is on the project.

Interviews with the instrument maker, orthopaedic technologists, and nurse provided insights on how the product will be used, what is expected from it and what role it is playing in the orthopaedic context.



Chapter 3: Reframing

Towards the design of a 3D scanning assist for spasticity

3.0 Introduction

This chapter presents and discusses three design directions for the further development for the project. It uses the outcomes from the previous chapter to identify design opportunities for the reframing of the project. Three moments of intervention into the context have been discussed to further define the point of entry for the project.

And an exploration has been made to the use of recognition software to create a skeletal point system inside the 3D model of the hand, with the intention of creating a point system that dynamically changes the angle of the hand.

The chapter ends with a reframing of the assignment, as well as a requirement list that has been created using the information from the previous chapters.

3.1 Reframing the problem

With the overview of the analysis complete, it is now possible to take one step back from the original assignment and see how the problem fits within the created context. From there, the assignment is reframed based on the opportunities found within this context and a design direction is created.

Original assignment
The original assignment was divided into two segments: Design of a physical prototype that keeps the hand in a stable position and to design a software that makes the scan usable for orthosis generation. After inquiry at the company on the process, it was found that currently none of the spastic hands were directly 3D scanned (some orthoses are indirectly recreated via gypsum model scanning).

This means that instead of increasing the segment of the 3D scanning of spasticity patients (as initially assumed), the focus shifts more towards the earlier stages of introducing the 3D scanning technology into this segment. With few research available in devices for the 3D scanning of spastic hands, an extra step of exploration is needed before starting the designing phase.

For the digital representation it was found that the digital model cleaning is currently being performed manually for spasticity orthoses, and that creating a usable scan in the first place is the main challenge and the primary desired outcome for the company.

"Design of a new approach in the orthopaedic setting, consisting of a prototype product that assists in the 3D scanning of the lower arm and hands of patients with spasticity to improve the scanning quality and adjustability when in use, in addition to software that creates a usable digital representation of the hand and lower arm for manufacturing personalized orthoses"

Following this logic, the aim of this project is to use the 3D scanning technology within the context of orthosis design for spasticity with the outcome of creating a digital twin for orthosis manufacturing.

In essence
Bringing it to the essence of the project, the outcome should be to find a way to get enough information from of the hand of the patient to be able to create a personalized orthosis that has enough detail for it to be effective:

"Find a way to extract enough patient information for the design of a personalized spasticity orthosis"

Intervention moment
Instead of directly starting with designing, an exploration is made into the intervention moment in the project. Where in the process does this project take place? This moment could be divided into three distinct phases:

1. Before the 3D scanning
This direction aims at preparing the patient hand before the 3D scanning will start. It focuses at the designing of a physical assist that improves the posture of the hand; in turn improving the quality of the scan. This one is closest to the original brief.

2. During the 3D scanning
This is at the moment of intervention. Instead of 3D scanning the hand, are there other ways of gathering enough information from the patient hand?

3. After the 3D scanning
This direction aims at post-processing the 3D scanning result so that given enough information, any scan of a hand could be easily and accurately processed.

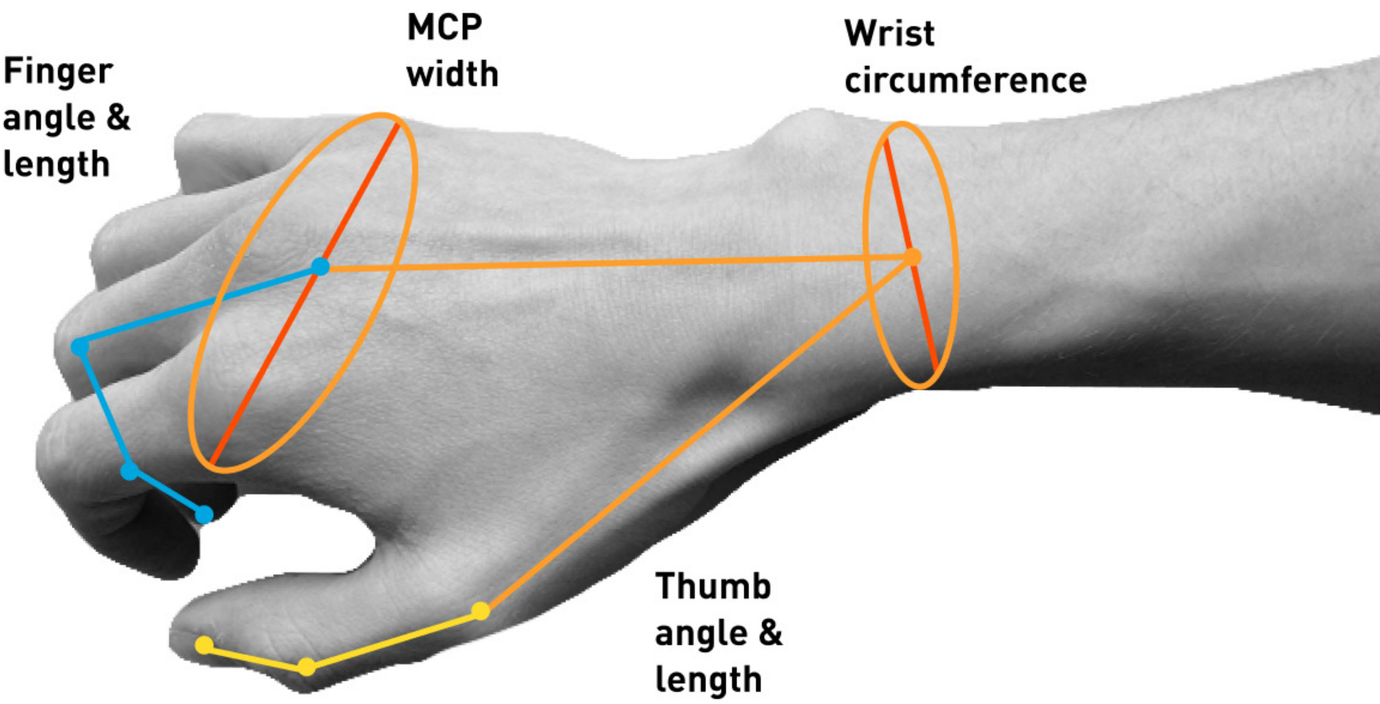


Figure 26: Measurement system

All three moments created possibilities of replacing the gypsum process for a more novel and clean approach. Ideas ranged from physical devices that kept the hand stable to using a new measurement system based on a measurements of the MCP, wrist, fingers and thumb. A template could be used in the digital environment that adapts to the hand, working together with the already existing software. A point system could be used to create a digital skeleton of the hand, in turn making it able to modify the hand shape and generate an orthosis around it (Figure 26).

In discussion with the client and coaches it was decided to continue with the direction of a physical device. Although all three directions were promising, there were time constraints in the breadth and feasiblity of tackling all these problems in the project. To keep focus and to find a direct solution to the problem of implementing 3D scanning in the system, it was decided to continue with the physical device (Figure 27).

Nevertheless, the point system is further explored in the next section for a long term solution.

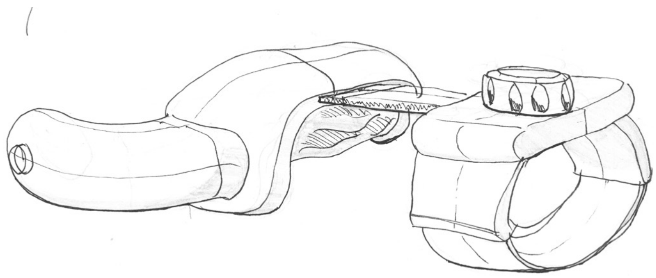


Figure 27: Example physical device

Reframed assignment

This project aims to design an assistive device that keeps the hand in an open position using minimal material that could impact the accuracy of the 3D scanning, while focusing on the comfort and usability in the orthopaedic context.

3.2 Point-based system

This system uses a hand-recognition software called Mediapipe. It creates a skeleton point system of the hand (Figure 28). Normally it is used in recognizing gestures, but with some alterations of the python code, also the coordinates of the image are given. These coordinates are then filtered using a grasshopper script and displayed in the 3D environment (Figure 29 & 30).

The idea behind the system is to create a way of capturing the hand or a 3D scan in multiple images and using the coordinates to create an accurate skeleton model of the hand. This skeleton could then be used to shape the hand into the desired position, meaning that the scanned hand is not required to be stretched.

An option was to use Grasshopper to make a photo studio with multiple perspectives to capture the 3D model. However a custom python script was needed to capture multiple images as Grasshopper & Rhino did not provide that on its own.

Also the use of Blender was considered for the imaging and import the renders into Mediapipe, followed by an output of coordinates that were filtered in Grasshopper. Then having an orthosis directly created from those points and ready to be modified with the angle.

At last, a reference model could be used that adapts itself to the dimensions of the scan. This way the mesh is ensured to be manifold (complete) and eases the post-processing. Using the same skeleton points it is placed into position and an orthosis is created.

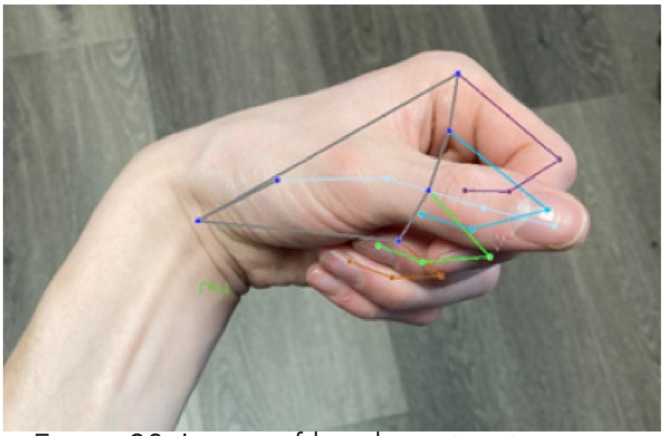


Figure 28: Image of hand point system

The main reason for not continuing this direction was that the Mediapipe software is based on 1D imaging, not on complete 3D models. The points were slightly flattened and did not follow the shape of the hand, only from a single point of view.

Without proper knowledge on creating custom python scripts in Grasshopper and a chance that the Mediapipe coordinates might not be accurate enough, the idea could lead to having to create a complete new 3D model hand recognition software. Within the given timeframe there might be a high risk that the outcome of this idea would not lead to the desired result. Therefore the idea was put to a halt.

Nonetheless, it still seems like a great opportunity that could change the orthopaedic industry and is therefore included in this report. It might become a starting point for other projects with a high focus on hand recognition software, or implementing a variable point system in the process of a new generation orthoses. The design software could customize the individual joint angles with a single swipe or drawing of the physiotherapist, creating a more fluent workflow and personalized approach. In turn making the intervention even less invasive.

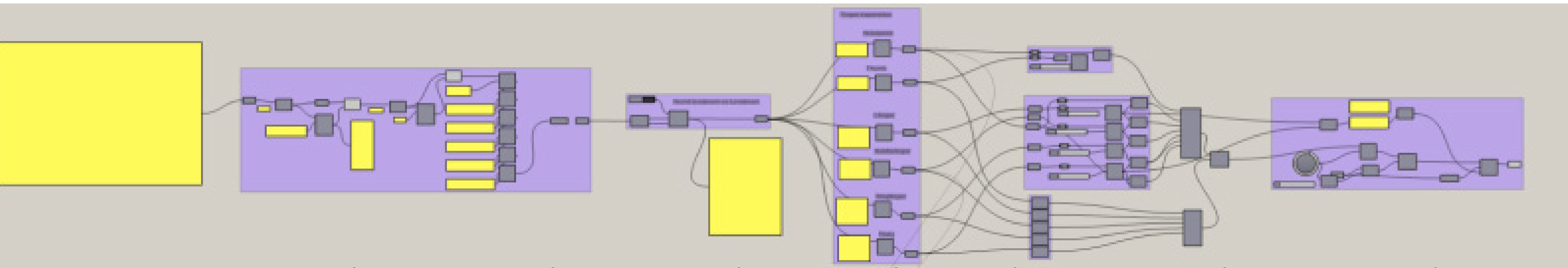


Figure 29: Grasshopper script that converts data points from Mediapipe to coordinates into mesh

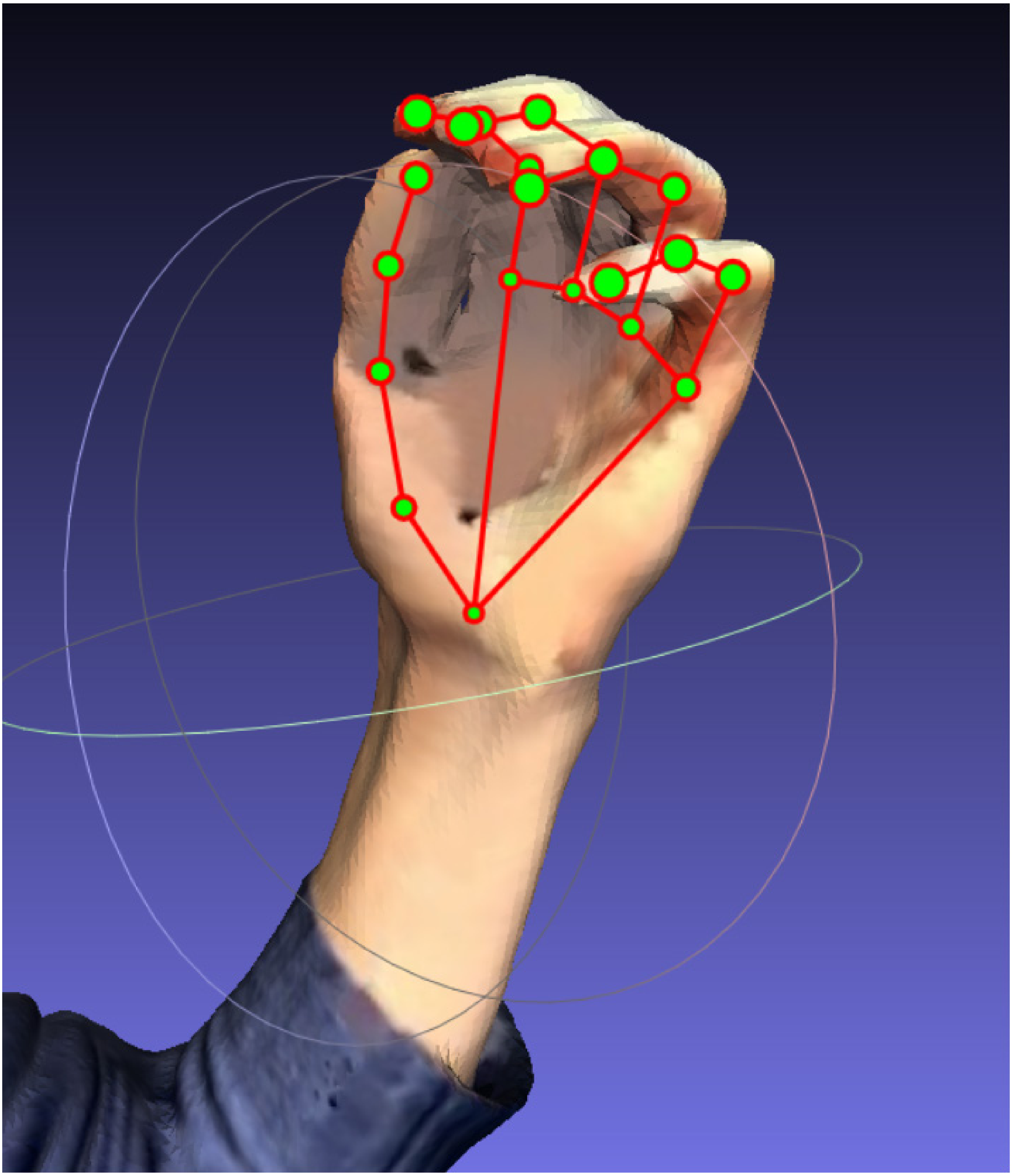


Figure 30: Digital model with hand point systems

3.3 Requirements

Using the outcome of the redefining phase, the analysis is used to form requirements that are used as basis through the process, these are found below. The requirements refer to the chapter paragraph from which they follow. They are subdivided into main requirements and subrequirements that are part of a main requirement. Non functional requirements (NFRQ) are added to describe the general properties of the product.

Ch.	**Requirement**	**Definition**
3.1	RQ1	The solution consists of a physical product that assist the 3D scanning
3.1	RQ2	The outcome of the approach is a digital model for orthosis generation
1.2	RQ3	The solution makes use of Artus3D's 3D scanning technology
2.2	RQ4	The digital twin provides enough information to create a personalized orthosis:
2.8		RQ4.1 80% of the lower side and sides of the wrist definition visible
2.8		RQ4.2 95% of the detail in the outline of the thumb is visible
2.8		RQ4.3 95% of visibility in the thumb-index commissure
2.8		RQ4.4 MCP knuckle width is determinable
2.8		RQ4.5 Total finger length (wrist to fingertip) is determinable
2.8		RQ4.6 90% visibility in the Thenar eminence (thumb base)
2.8		RQ4.7 90% visibility in the Hypothenar eminence (pinky base)
2.2		RQ4.8 At least 80% of the lower arm is visible
2.1	RQ5	The product is usable for spasticity on the Ashworth scale of 0-2
2.1		RQ5.1 The product keeps a hand with moderate muscle tone in a steady position
2.5		RQ5.2 The product allows total finger angle ROM from 0-90 degrees
2.5		RQ5.3 The product allows wrist flexion/extension ROM from 54-60 degrees
2.5		RQ5.4 The product allows wrist ulnar/radial deviation ROM from 40-17 degrees
2.12		RQ5.5 The product allows total thumb flexion parallel to the fingers
2.5		RQ5.6 The product allows total thumb abduction/adduction at 30/10 degrees
2.5	RQ6	The product has adjustability at the the DIP, PIP, MCP, IP and wrist joints
2.12	RQ7	The total setup and scanning time takes less than 30 minutes
2.11	RQ8	The product is applicable in the orthopaedic context
2.12		RQ8.1 The product fits in a volume of 40x40x40 (travel bag)
2.12		RQ8.2 The product does not weight more than 6 kg
2.12		RQ8.3 The product is operable by 1-2 persons
2.12		RQ8.4 The product is able to be attached within 5 minutes
2.11		RQ8.5 The product is operable when a patient sits in a wheelchair
2.11		RQ8.6 The product is operable when a patient cannot fully extend their arm outwards
2.11		RQ8.7 The product is operable when a patient cannot place their arm vertically
2.11	RQ9	The product fits for the 5th to 95th percentile of the elderly population
2.7	NFRQ1	The product is designed for multiple patients, not for single use
2.1	NFRQ2	The product is usable for both left and right handed spasticity
2.1	NFRQ3	The product is designed for continual spaticity, not spasms

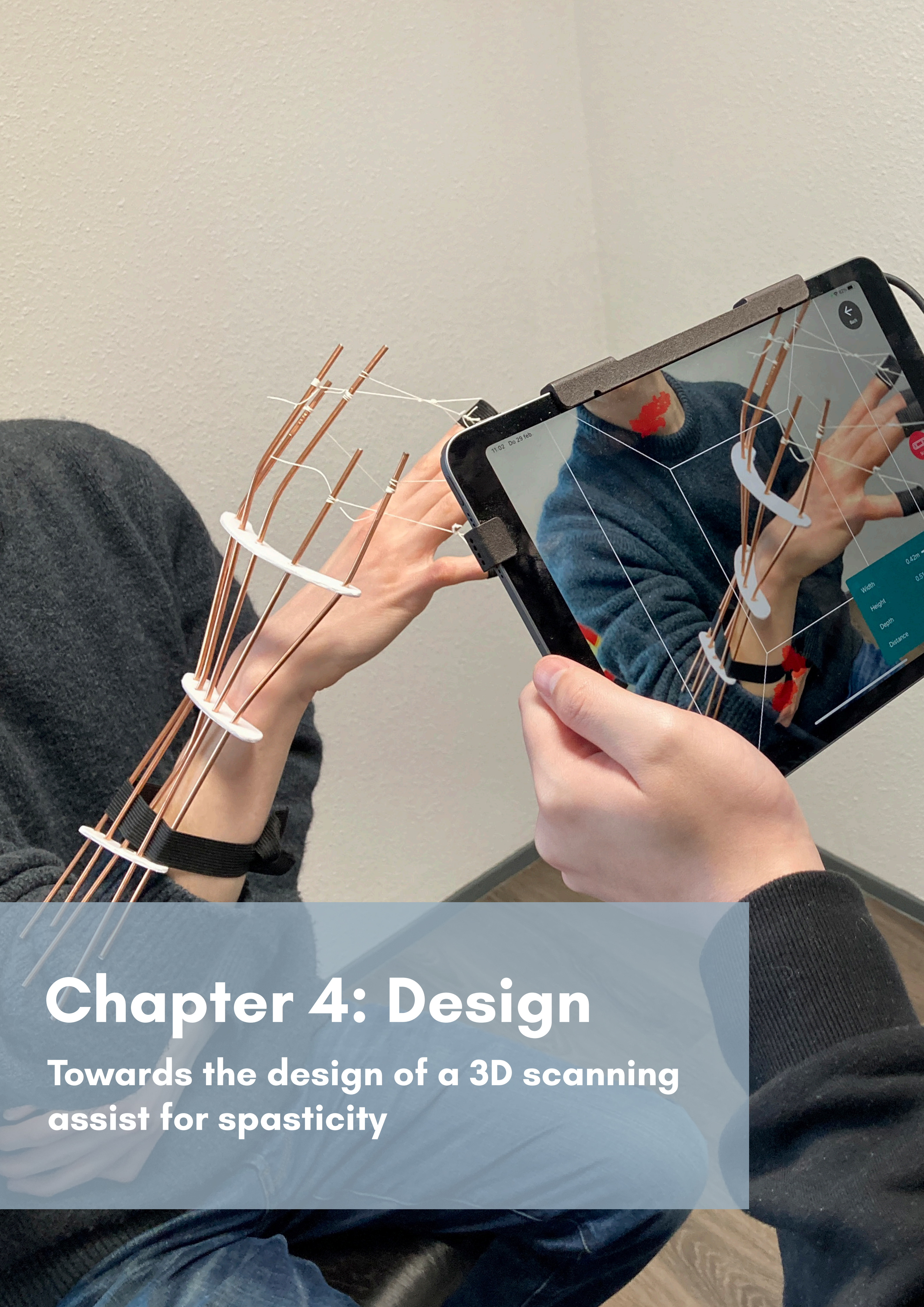
3.4 Conclusion

Using the three directions that were discussed in this chapter, the direction of intervening before the actual 3D scanning has been chosen. From this starting point, requirements have been generated for the upcoming design project.

The moment of intervention during the post processing of the scans did reveal an opportunity for a point based skeletal system. This however has not been chosen, due to high foreseen risks that could impact the feasibility for the remaining of the project. Nonetheless, the system is still considered for a long-term solution.

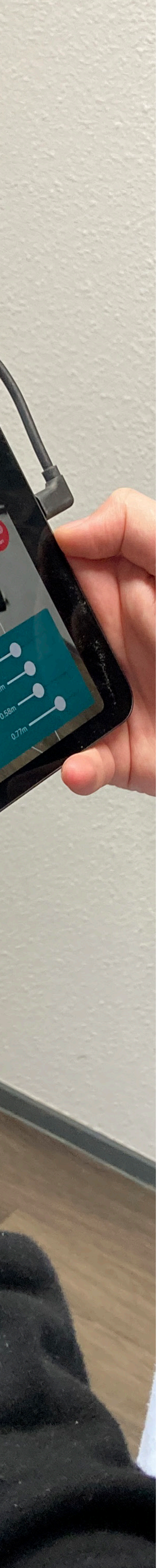
This chapter lead to a reframed assignment for the upcoming project:

"This project aims to design an assistive device that keeps the hand in an open position using minimal material that could impact the accuracy of the 3D scanning, while being used in the orthopaedic context"



Chapter 4: Design

Towards the design of a 3D scanning assist for spasticity



4.0 Introduction

This chapter will go deeper into the process of creating the product, while using the analysis and the chosen direction as a basis for the design.

With the novelty of this problem, finding the right solution for this project was mainly focused on iteratively creating designs that were performing better than its predecessor.

A selection of the milestones will be shown that proved to be relevant to the project, along with the ideas that created the path towards the product.

As with most design processes, ideas sometimes happened sporadically, in quick succession or were vunerable to change over time. Therefore, the intent of this chapter is to create an overall image of the process, rather than a step-by-step approach: its ups & downs, key insights and major changes are presented.

4.1 Exploration

The first step towards the product design is to explore the possibilities: What is desired? What is not desired? Does the 3D scanning have limitations? A wide variety of ideas were sketched and consecutively worked out.

Figure 31: Prototype build area

Build area

One of the findings was that for a 3D scan result to be usable, some of the critical areas needed to be kept clear (Figure 31). Most importantly are the thumb-index commissure in red, keeping the MCP width of the hand visible, the wrist and lower side of the handpalm (Bijman, 2024). The area in yellow does allow for some material to be used, as it is a shape that is relatively simple to reconstruct. Green is the preferred area for the product, as the generation of the orthosis does not interact directly with the prototype.

Iterative process and sketching

Nearly two full A4 sketchbooks have been used in the process, along with many small written notes and ideas along the way. An example using sketching in the process is shown in Figures 32 to 35. Most prototypes viewed in this chapter were created following this process.

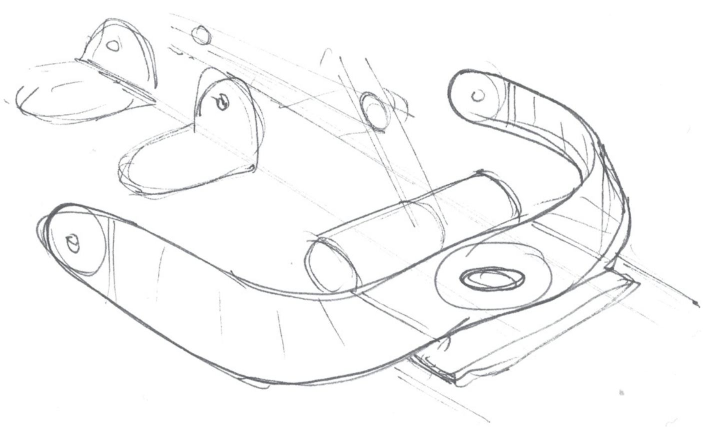


Figure 32: Sketch

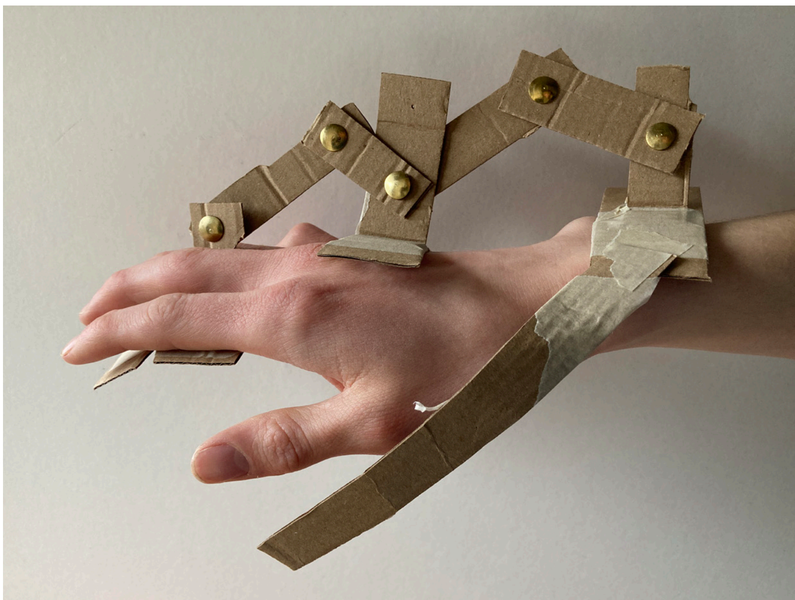


Figure 33: Cardboard model

Anthropometry
One of the major aspects in this project is the fit of the product onto the hand of the patient. As the product should adapt to many hand sizes and degrees of freedom with both left and right handedness, it is kept in mind during the exploration.

This includes varying finger length, hand breadth, thumb length, hand length, wrist circumference and underarm length. As previously mentioned in the analysis, for now the target group is female elderly, as they are more represented in the care homes that Centrum Orthopedie serves.

The wrist
One of the main questions for the design is whether it should lean towards a wearable that keeps the hand in place, versus an external device placed on a table or uses a stand. Due to the frequent travelling of the physiotherapist from patient to patient, small devices slightly larger than the orthoses themselves are preferred over larger installations.

Which leads to the question where the holding forces should come from. A wearable device will most likely use the wrist and lower arm for support. The wrist joint therefore needs to account for several rotations and size differences. One possible solution is seen in Figure 36.

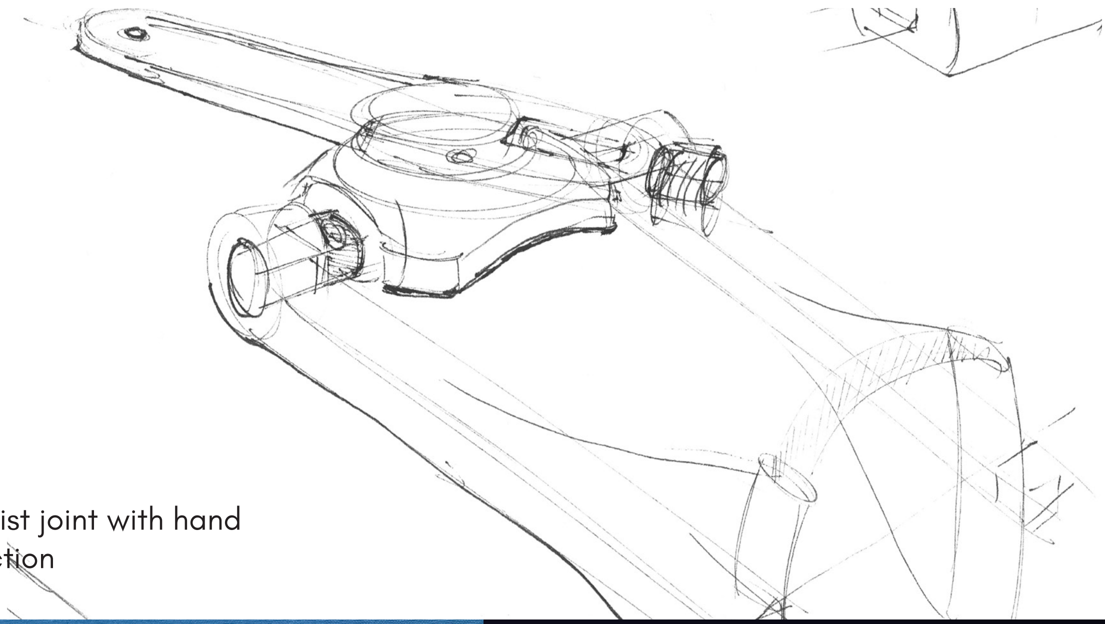


Figure 36: Wrist joint with hand length correction

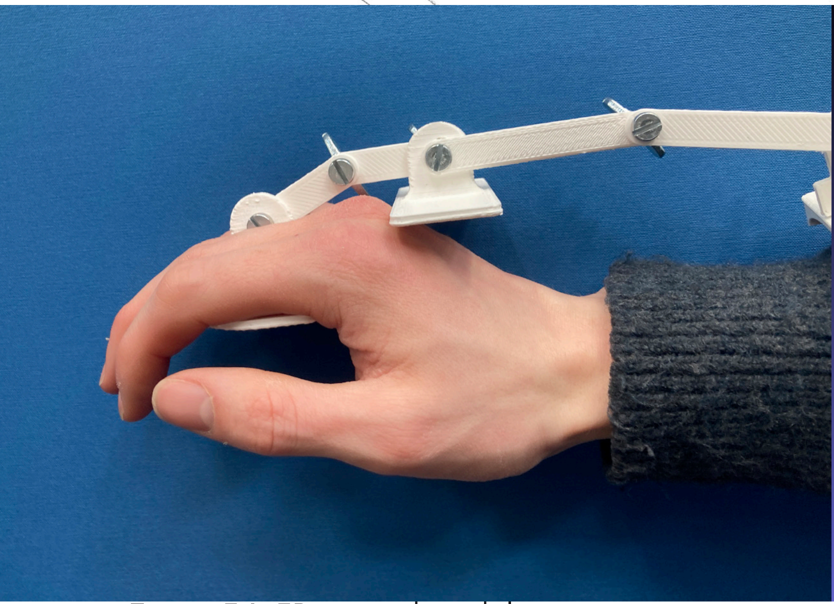


Figure 34: 3D printed model

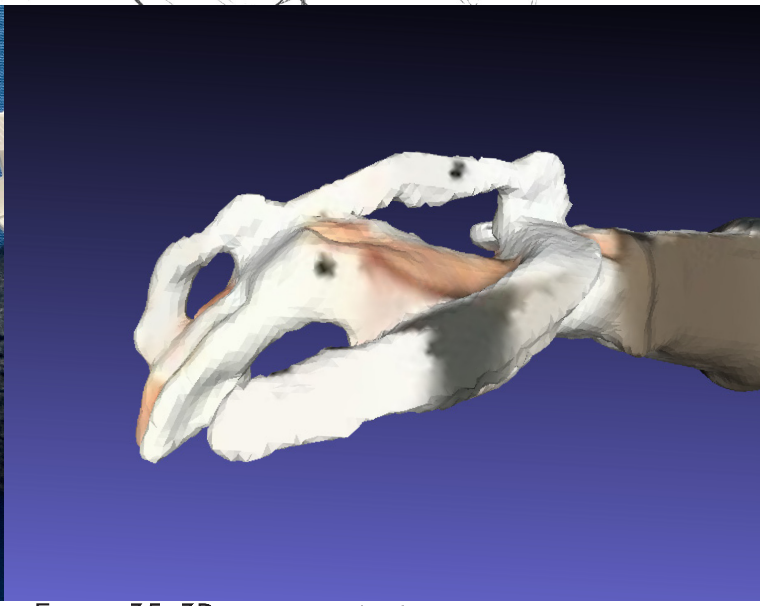


Figure 35: 3D scanning test

Exoskeleton pulling system
One idea that initially seemed nice to use was a pulling system that extended the fingers and thumb through a rope that moved inside a movable plastic frame. Upon testing it was found that those forces on the rope needed to be surprisingly high, creating a resulting force near the MCP to counteract the movement. With the added complexity of varying finger length and circumference to hold it into position, the idea was put to the side (Figure 37).

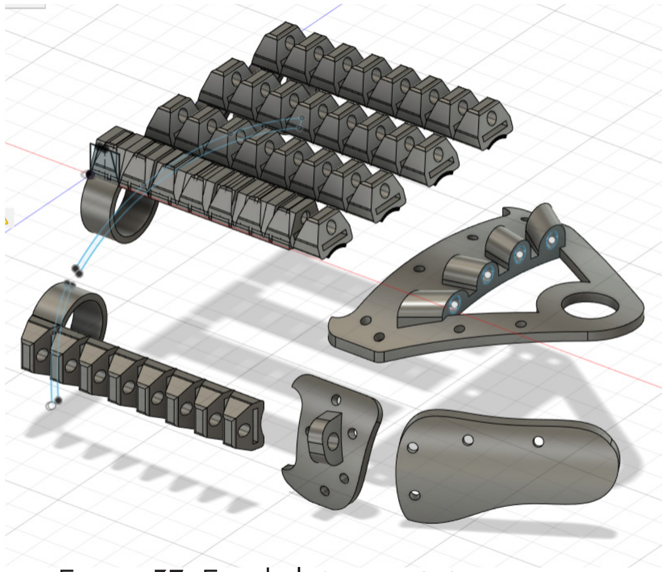


Figure 37: Exoskeleton prototype

Press button hinge interaction
One of the ideas was to create a push button hinge: a button that allows the joint to easily change position when pushing. On an interaction level, the prototype seemed desirable, with the idea of having multiple joints through a prototype (Figure 38). The mechanism itself worked well, although for now was left to the side because it needed to be either parallel to the joint (blocking the scan) or by placing the joint above it (needing to create a larger structure to keep it following the movements).

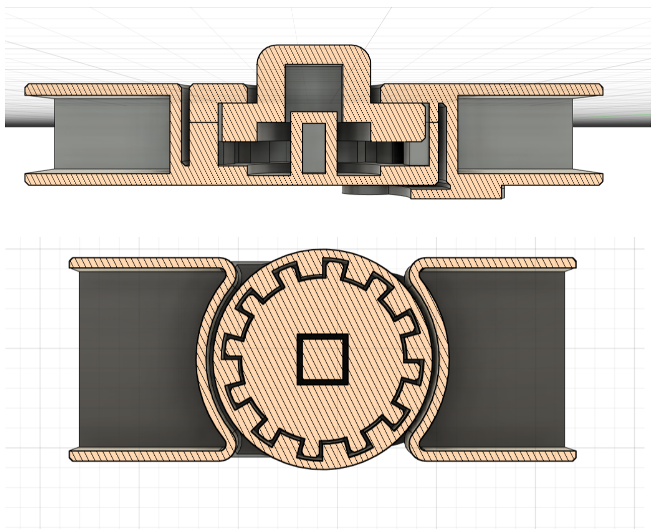


Figure 38: Button hinge prototype

Complexity and joint distances
So far, taking the mechanical approach to simulate the finger seems to create challenges in keeping the anthropometry workable. With different hand sizes comes a varying joint distance, which in turn creates a need for adaptable beams. This creates complexity and rules out ideas like Figure 39, where the finger bending could be simulated through double mechanical couplings.

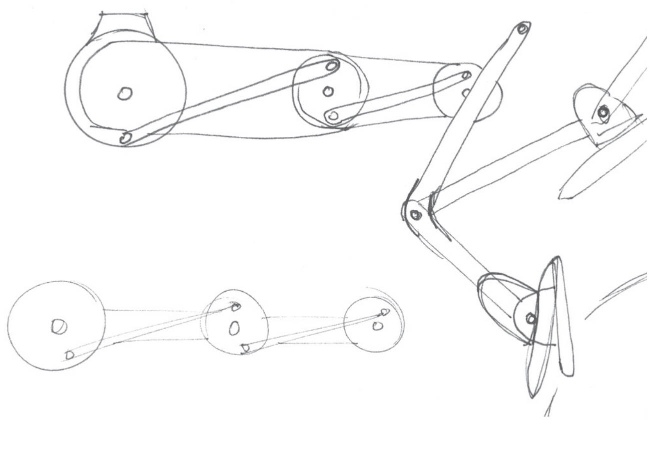


Figure 39: Sketches of mechanical hinges

Baseline prototype
In order to find out what the scan result is of a theoretical prototype, allowing the locking of the movements of each joint separately, a baseline prototype has been made (Figure 40-42). This serves as a starting point in finding out what is desired and what is not.

The prototype uses hinges and sliders to set the hand lengths and widths that need to be variable. Although it is more of a visual model, using it is difficult, the mechanisms are complex and already it seems to block a large part of the scan.

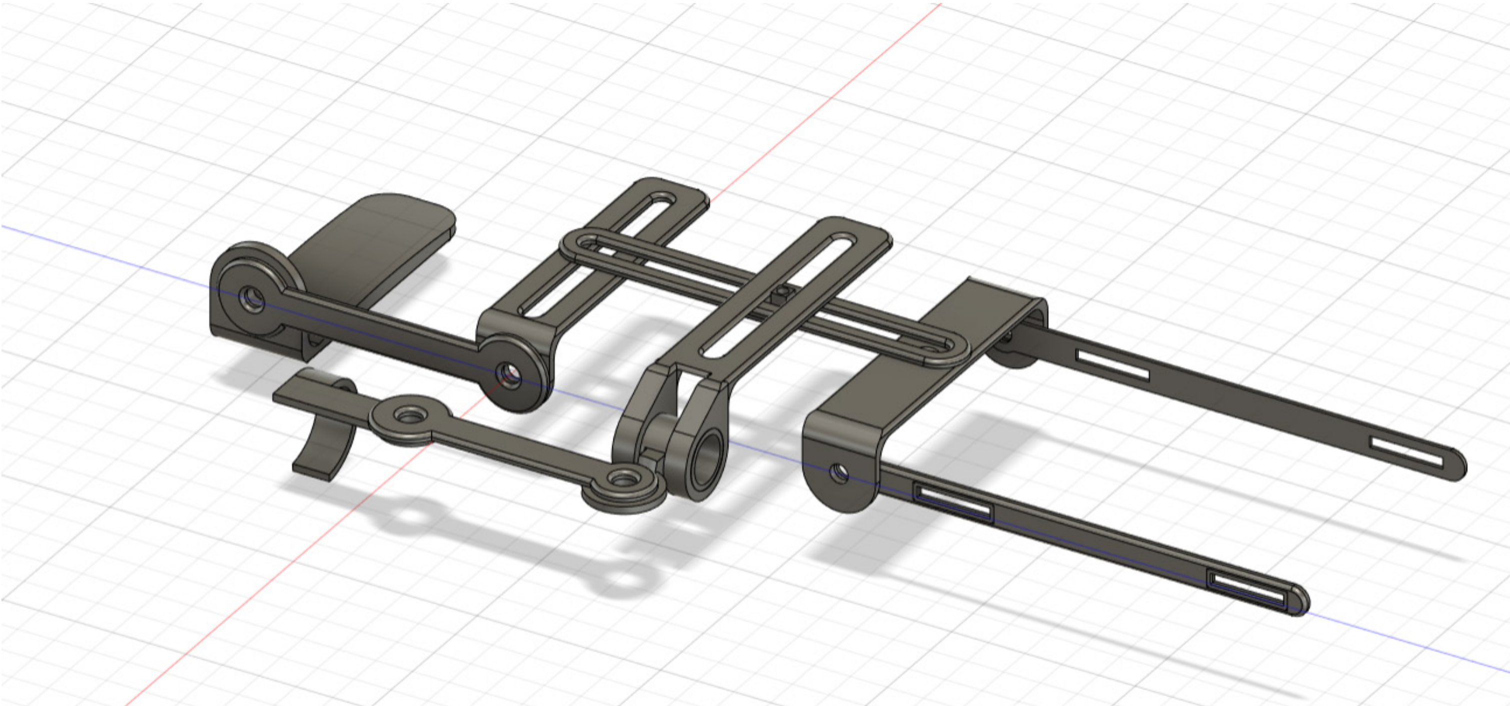


Figure 40: Baseline prototype

After scanning it was found that the prototype indeed blocked a large part of the scan and in turn reduced the accuracy of the hand. Due to its volumous shape, the scan now merges both the hand and the prototype together. This is undesirable, as it will lose its accuracy and reference points that are needed for the orthosis generation. The scan is merged at the side of the finger and bottom/outer side of the thumb. Also the connection bars on either side of the wrist create extra material. All with all, this prototype provides insight into how to not solve the problem, therefore helping in readjusting the solution space of the project.

Key takeaways

- The inside of the hand should be kept open
- High individual joint setup complexity might clash with anthropometry later on

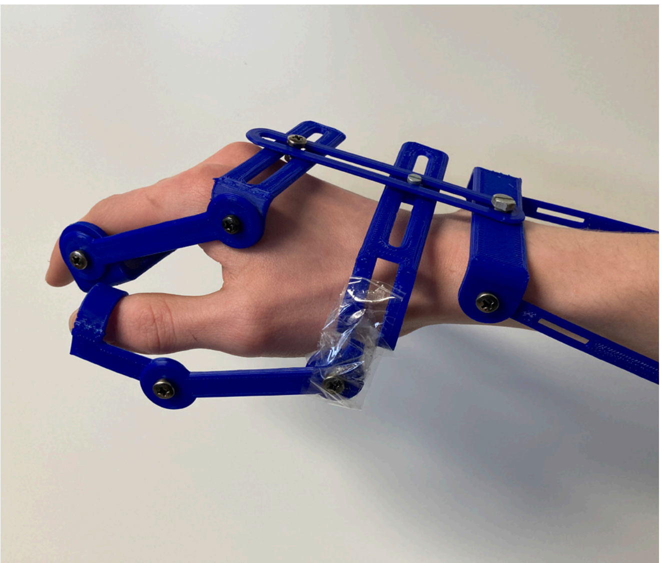


Figure 41: Baseline prototype on hand

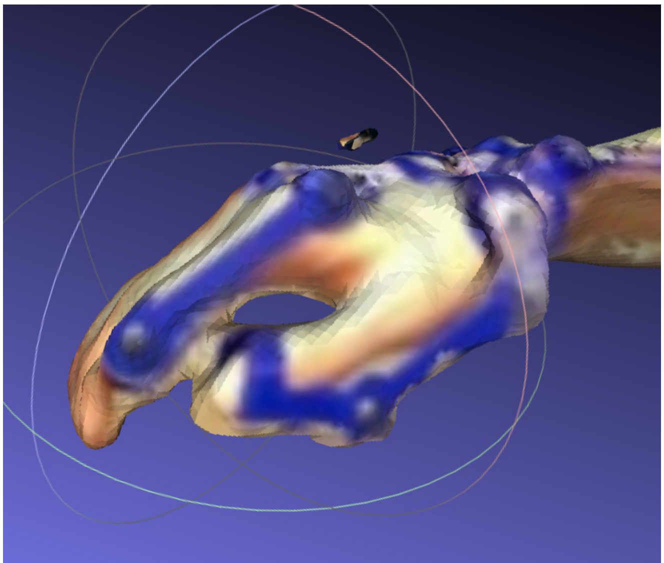


Figure 42: 3D scan of baseline prototype

4.2 Directions

After the initial experimentation from the previous section, it was found that more testing was needed with the 3D scanner in order to create a better understanding of what works in the design and what does not. Four ideas were selected on diversity and were prototyped with the intention of creating visual models to simulate using the product with the 3D scanner. The scanning results are viewed in the upcoming pages.

Mechanical upper side prototype (Left top)
The idea behind this prototype is to use five mechanical connection points to enable a wide range of positions for the fingers. By applying the structure on the topside, it does not interfere with the critical scanner area. The thumb is kept in place using a band, attached from the wrist. To keep the fingers straight, a leverage is created at the MCP, before securing the mechanism at the wrist.

Fabric tensioning prototype (Right top)
This idea uses pieces of fabric to stretch the fingers to the topside of the hand. Having the fingers attached individually and from the outside might make application easier than putting on a glove-type system. Due to the shape following the outside of the fingers, most of the inner hand is kept free.

Finger plate holder prototype (Left bottom)
By keeping the idea simple and using a plate to hold the fingers, the finger shape and width is still visible and could be found from the scan. The connection point to the wrist is made on the ulnar side to keep the scanning area for the thumb free. The thumb rests on a small plate.

Exoskeleton prototype (Right bottom)
The exoskeleton uses very thin strings to keep the fingers and thumb in place, with the intention of them not showing up in the resulting scan. The strings are connected to a frame that is attached to the wrist.

Outcomes
The resulting scans are viewed in Figures 43 to 46 and were reviewed by Bijman, digital corrector for Centrum Orthopedie and Artus3D.

The mechanical prototype showed good detail on the ulnar side of the hand, along with a high detail on the wrist and inside of the handbase. Some of the area near the fingerplate was not captured, but shows enough information for the MCP width to be deducted. Adjusting and placing the hand in position proved relatively difficult.

The fabric prototype showed proper clearance for the handbase, fingers and thumb commissure. The fingers could be individually adjusted through velcro. The material did not hold force because its elasticity. The fabric provided more comfort over the sharp plastic parts.

The finger plate holder created an easy reference for the orthosis fingers, although the plate was not changeable in shape during the setting. The thumb was held through a small beam panel, but made the commissure unclear.

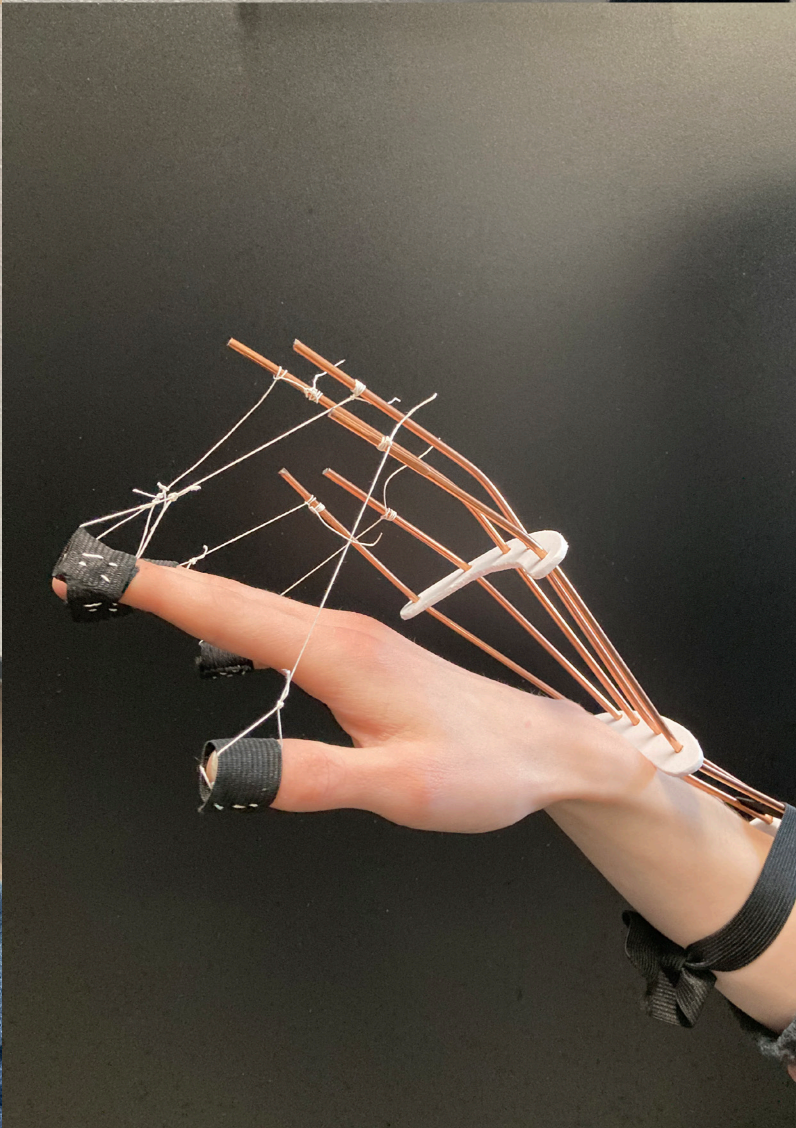
Finally, the exoskeleton prototype created an interesting effect of the wires not showing up in the scan. However, creating a prototype based on tension from a wire (singular direction) might prove difficult in the upcoming process.

When asked for comparison, Bijman favored the fabric and exoskeleton over the mechanical and plate holder designs because of model quality and reduced mesh cleaning needed for orthosis fabrication

Key takeaways

- Individual finger adjustment is favoured over a single plate
- The area near the thumb commissure needs clearance



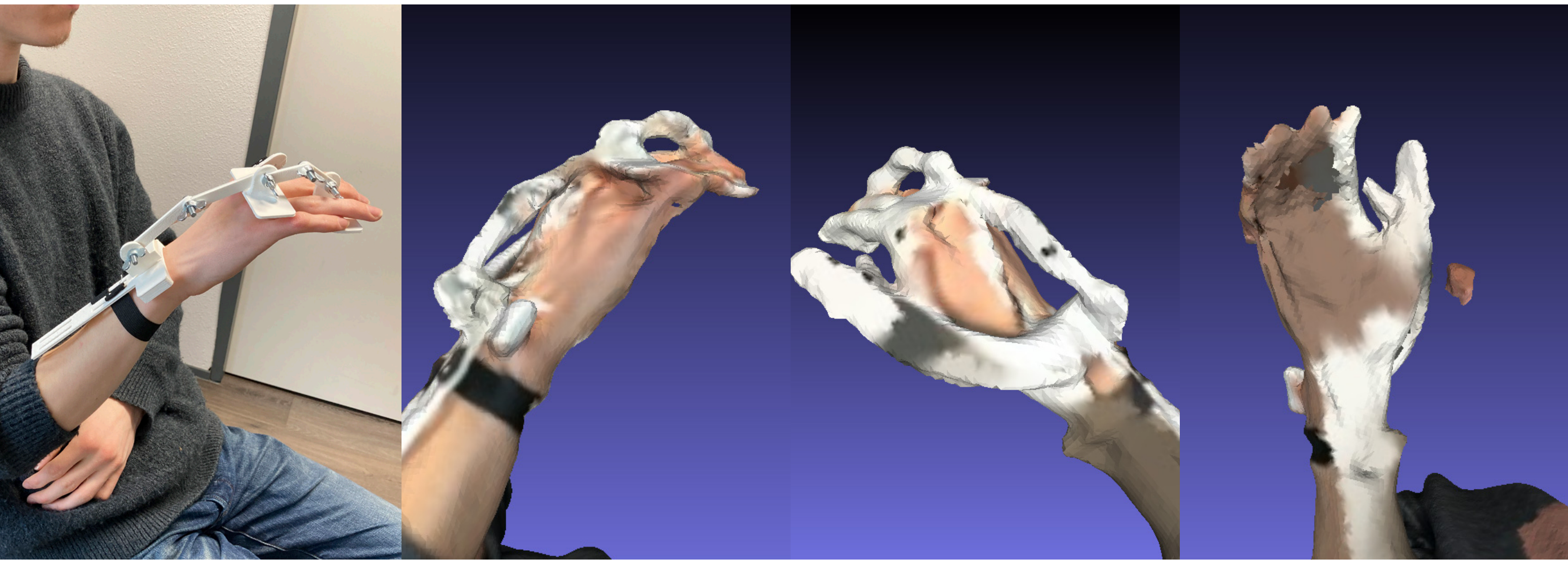


Figure 43: Topside mechanism prototype

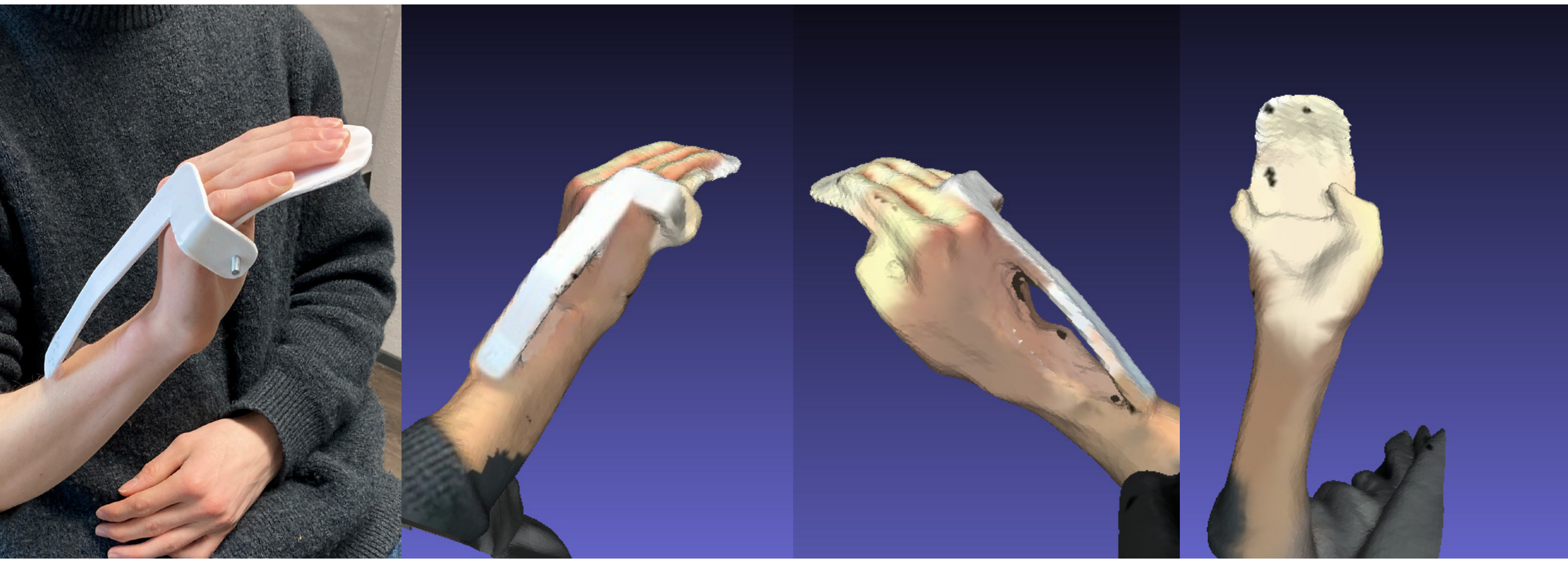


Figure 45: Hand plate prototype

	Topside	Fabric	Hand plate	Exoskeleton
Lower arm circumference	9	9	8.5	8.5
Lower arm width	10	10	9.5	9.5
Wrist circumference	6	9.5	10	9.5
Wrist width	8.5	9.5	10	10
MCP circumference	6.5	9	7.5	10
MCP width	8.5	10	9	10
Fingerlength from MCP	10	10	8	10

Figure 46a: Instrument maker review 1/2

Figure 44: Fabric material prototype

Figure 46: Exoskeleton prototype

	Topside	Fabric	Hand plate	Exoskeleton
Thumb webspace	7	10	3	10
Thumb length	5	10	4	9.5
Thumb width	4	9.5	4	10
Wrist position angle	9	10	9.5	9.5
Fingers position angle	9	9.5	9	9.5

Average score	7.71	9.67	7.67	9.67
Perceived scan quality	9	10	9.5	9.5
Perceived usability	9.5	7.5	8	7

Figure 46b: Instrument maker review 2/2

4.3 Prototyping fabric

Along with the feedback of Bijman in the previous section, the decision was made to continue prototyping using fabric. With having fabric as a base material, there were opportunities for comfort, ways to individually adjust the fingers and to keep the design moving closely around the hand.

It was found that if spasticity is only found in the fingers, stretching it would overextend the MCP, as the force would go to the MCP instead; leaving the fingers still bent. Therefore, a separate connection near the proximal phalange was needed to stretch the fingers.

A wrist connection was made through a band attached near the lower arm (Figure 47). Prototypes have been made to individually adjust the fingers, ways to counteract the ulnar deviation through a band (Figure 48), and test if another connection via the lower side of the thumb was possible (Figure 49). The results lead to a final prototype viewed in Figure 50.

Figure 47: Wrist extension band

Figure 48: Thumb extension & wrist deviation

Figure 49: Palmar thumb support

Figure 50: Fabric hand stretching prototype

Scanning result
The scan result was well usable to create an orthosis out of it. The commissure, lower side and sides of the fingers were detailed, as well as the wrist. There are some artifacts from the prototype on the fingertips, but those do not affect the orthosis generation/ could easily be brought down to size when needed (Figure 51).

Figure 51: Fabric digital scan

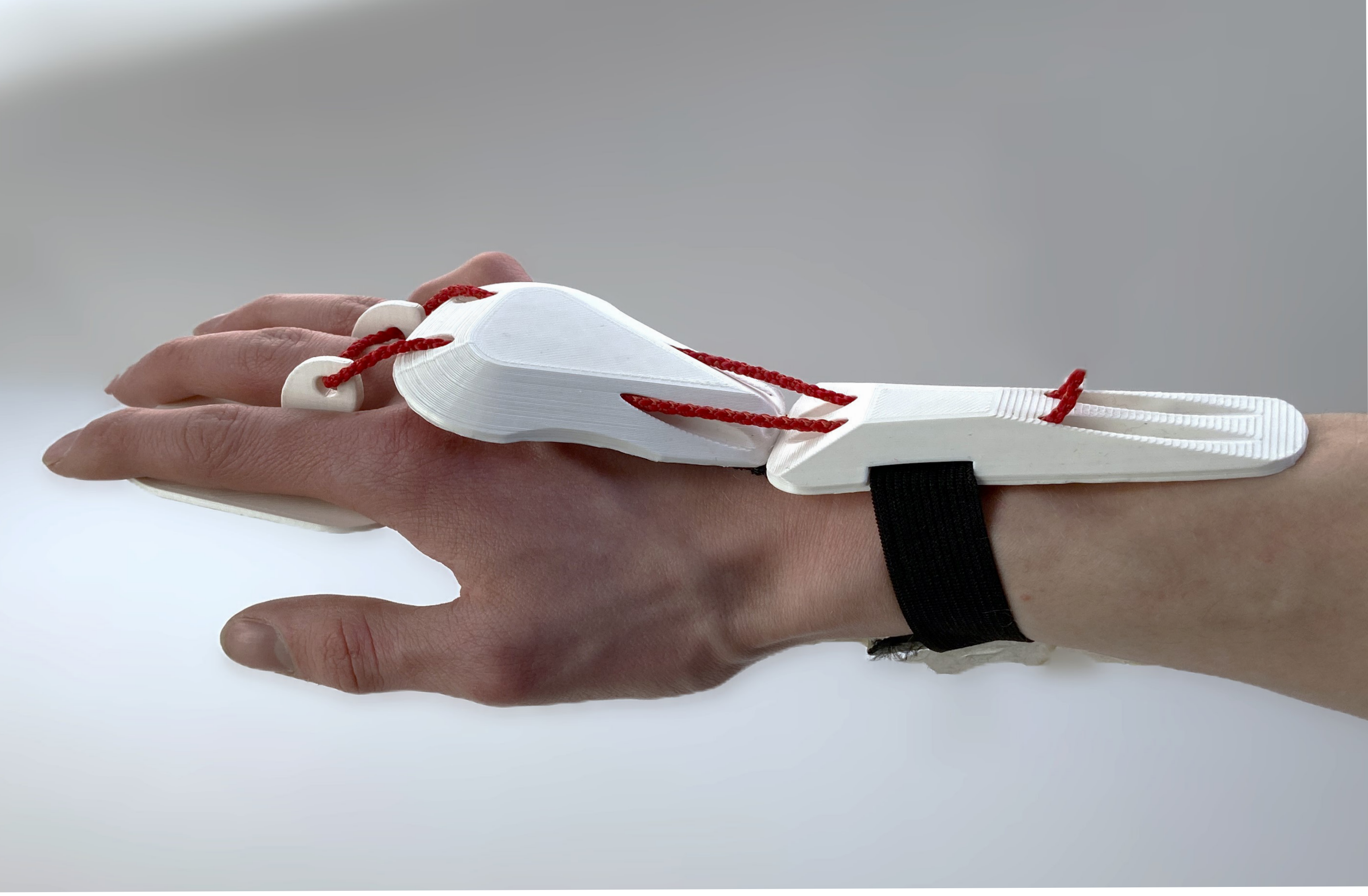
Usability
Putting on the prototype was found difficult, as the connection near the proximal phalange needed to go over each finger individually, all while trying to keep the fingers in an open position; similar to placing a glove over a closed fist.

The individual adjustments and connections made using it difficult, as stretching the wrist changed the maximum extension of the fingers and thumb, meaning that the fingers needed constant readjustment.

To use anthropometry in this type of design, there are relatively many measurements to take into account: Even if hand measurements were assumed scaling linearly, multiple sizes for both left and right are needed. The upcoming iterations need reduced complexity and make it easier to put it on.

Key takeaways

- Individual phalange stretching was needed to prevent MCP overextension
- Reduce complexity



4.4 Prototyping tension system

With the outcome of the previous section, a change in material could lead to a new way of thinking and reduce the complexity. One of the major changes is to divide the product into three components: the fingers, hand and wrist. The thumb is included into the hand component.

Tensioning system
The tensioning system is still used as the stretching of the fingers, MCP and wrist angles are related. By using a wire moving through all these points, they could be adjusted in a single movement.

Most of the complexity is then found near the lower arm; and by creating a new interaction of using a rotating knob or a rope lock (Figure 52) to slowly tension the device, it becomes more friendly and stable to use.

Finger plate
One of the changes is moving towards a single hand plate. It reduces the ten individual adjustments needed to just one adjustment. From there the fingers are relatively easy to place into position.

Hand connection
The hand connection is used to guide the wire from the finger plate to the wrist attachment and provides rigidity to the system (Figure 53-54). The thumb is included with the hand connection and the focus now is on placing the fingers in a proper connection first.

New boundaries
While initially working with the idea of making a prototype that solves all shapes of spasticity, the question that comes up is: at what angle does the orthosis become obsolete? After further inquiry with the company, the total finger angle is set at 90 degrees from the MCP, with the thumb needing to be able to go outside of the hand.

This is because if the fingers are flexed more than 90 degrees, the scanner will inevitably have difficulties creating a high quality scan; similar to a thumb that keeps inside of the hand. With these cases, gypsum rolls or stretch balls become a more effective solution than orthoses.

Figure 52: Prototype variations: rope lock & thumb extension

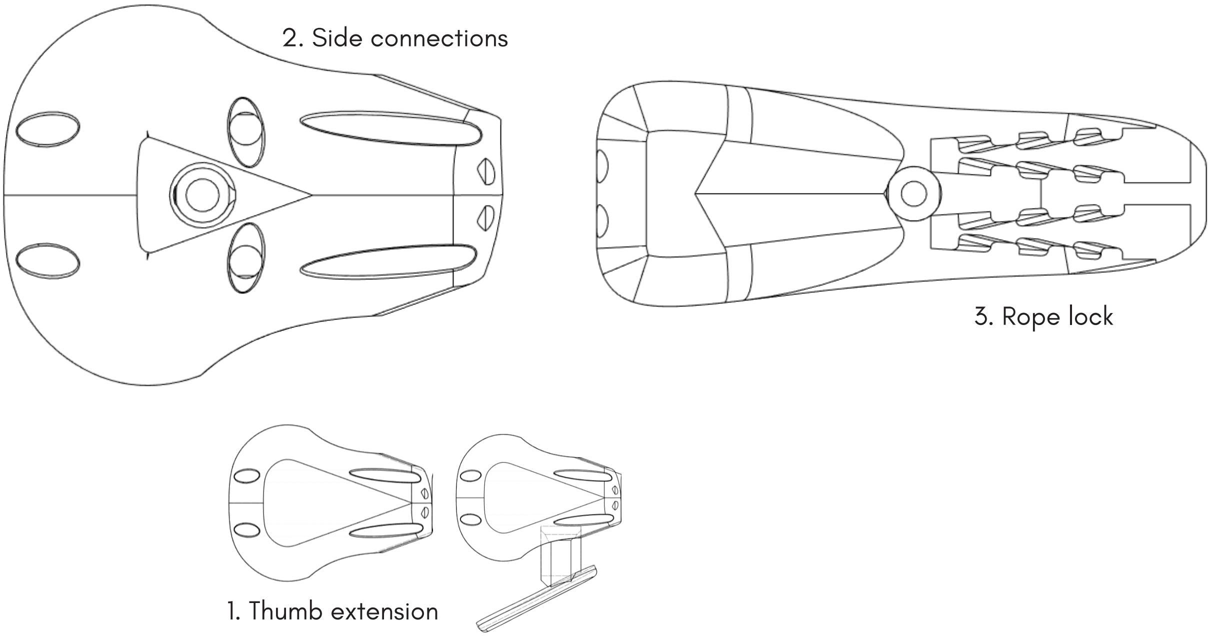
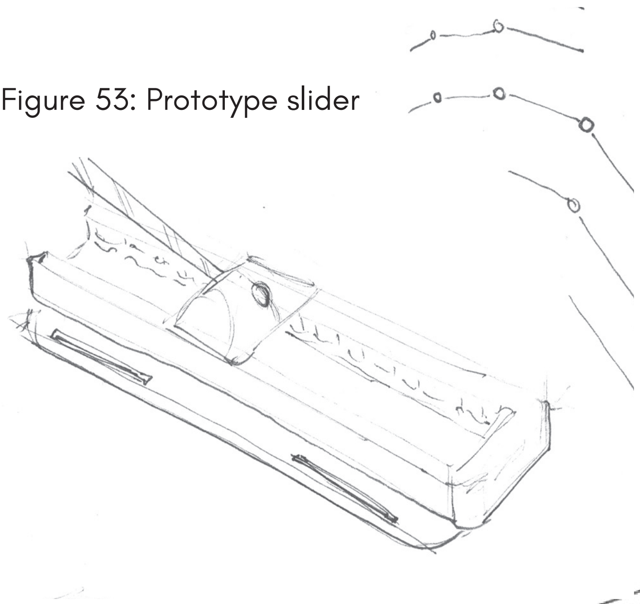


Figure 53: Prototype slider



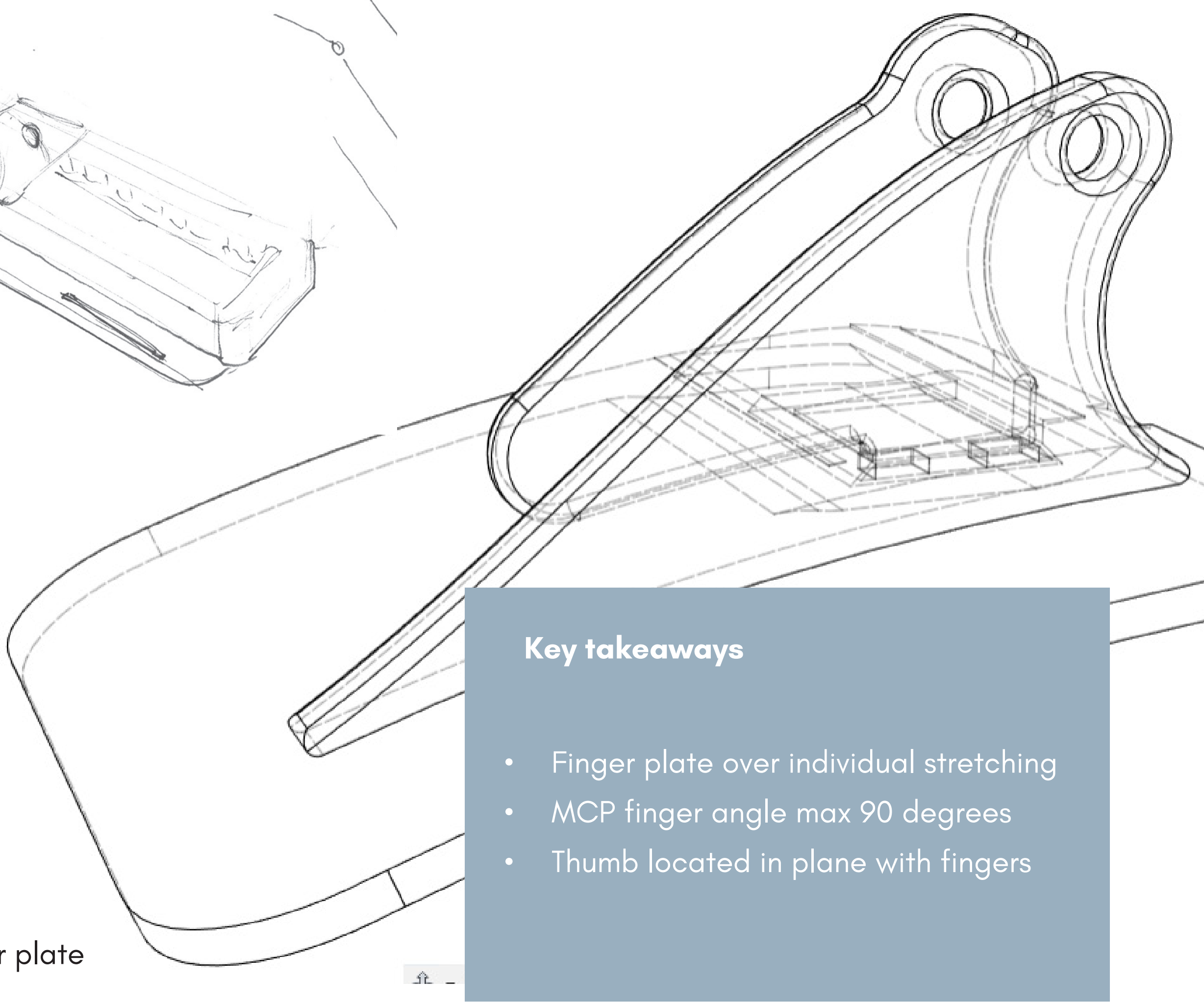


Figure 54:
Adjustable finger plate

Key takeaways

- Finger plate over individual stretching
- MCP finger angle max 90 degrees
- Thumb located in plane with fingers

Prototyping of plates
Several iterations have been made towards the design of the plate: testing how the angle, width and thickness affected its usage. The top connection points were used to prevent the plate from sliding too far downward and attach the plate to the rest of the prototype. One version had a movable connector for in-between the fingers, while another used bent versions to help the hand into position (Figure 56).

A different type of suspension of the plate was also considered (Figure 55), which lead to the prototype on Figure 57. Having the connection moving from the lower side of the fingers along the ulnar side of the hand keeps the thumb free, while creating opportunities for the thumb to become adjustable.

Thumb holder
In the following versions it was found that the thumb holder might be able to attach to the finger plate. This frees up area near the top of the thumb, working its way to the central part of the hand. Because the thumb rests on the plate with spasticity pushing towards it, all sides around the thumb are now cleared for scanning. The bottom of the thumb is found via the surface of the plate.

Different versions were constructed to find the desired shape. Some were under an angle, while others were curved. One idea consisted of a sliding plate that could change the holding width of the thumb. The upcoming iterations could make use of a rubber like material to prevent the slipping of the thumb.


Figure 55: Topside attachment prototype


Figure 56: Prototypes for plates

Interaction
While testing the finger plates, it was found that if the complete prototype had to be attached to the arm, there still was some difficulty with getting the fingers in between the connectors. What if the hand were to be secured on the plate first, and in a second step the rest of the prototype was attached? This would make the whole process easier and will be tested in the next iteration.

Results
One problem that kept coming back was that when stretching the fingers with the prototype, a lot of force was applied in between the knuckles of the MCP. Although the skin is less sensitive there, there still was discomfort. Upcoming iterations should make sure that the hand is rested in position more than actively being stretched via wire.

Altering the interaction to a two step process might make using the device easier, along with a new thumb holder and by removing the original connection points, it could easier be attached.

"Creating a two-step process where the hand is rested more than actively being stretched via a tension system"

Figure 57: Ulnar side attachment prototype

Key takeaways

- Thumb plate combined at fingers
- Two step attachment
- Fingers should be resting instead of actively being stretched

4.5 Change in perspective

In this iteration the product is approached from a new perspective. The previous iteration consisted of three main components located at the wrist, the hand and the finger. These are tensioned via a wire to bring the hand into position. This prototype changes the operation: Instead of tensioning the components to stretch the fingers, could the fingers be held in place? By making a finger plate attached directly to the wrist, it removes the need of the hand component and is replaced by a metal beam. Now there are only two main components in the product that keep full movement control of the hand. These are the finger holder and the wrist attachment (Figure 60).

Finger holder
The finger holder keeps the fingers in place using a velcro band (Figure 58); and holds the thumb via an attached thumb plate. This version was mainly created to get an idea of the concept. It is seen that the finger plate is too small and the fingers are cramped inside. Also the plastic beam is flexible. The idea behind the concept is that by moving the finger holder to a higher or lower position, it automatically changes the wrist angle. By rotating the hand plate itself, the finger angle is adjusted at the MCP. This way only two main components are needed to get full control of the hand.

Foam padding
This iteration makes use of 3mm EVA foam padding at the wrist for added comfort. Also the joint sphere needed to be inserted in some way, which has been done through a filled in hole in the bottom. The foam covered this up invisibly.

Wrist attachment
The wrist needs to be simulated and lockable in both horizontal and vertical directions while allowing for twist because of the fingers (rotation of the wrist happens through the lower arm, keeping the top of the wrist relative to the hand: the twist is only needed for the finger positions specifically). A ball joint would be perfect for this. Several variations are possible to lock the ball in place. For this iteration a screw insert with bolt is used to clamp the joint. In later iterations this could be similar to a turning knob on the topside or left or right side (Figure 59).

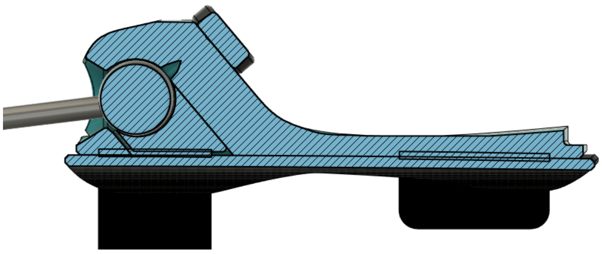


Figure 59: Section view of ball joint

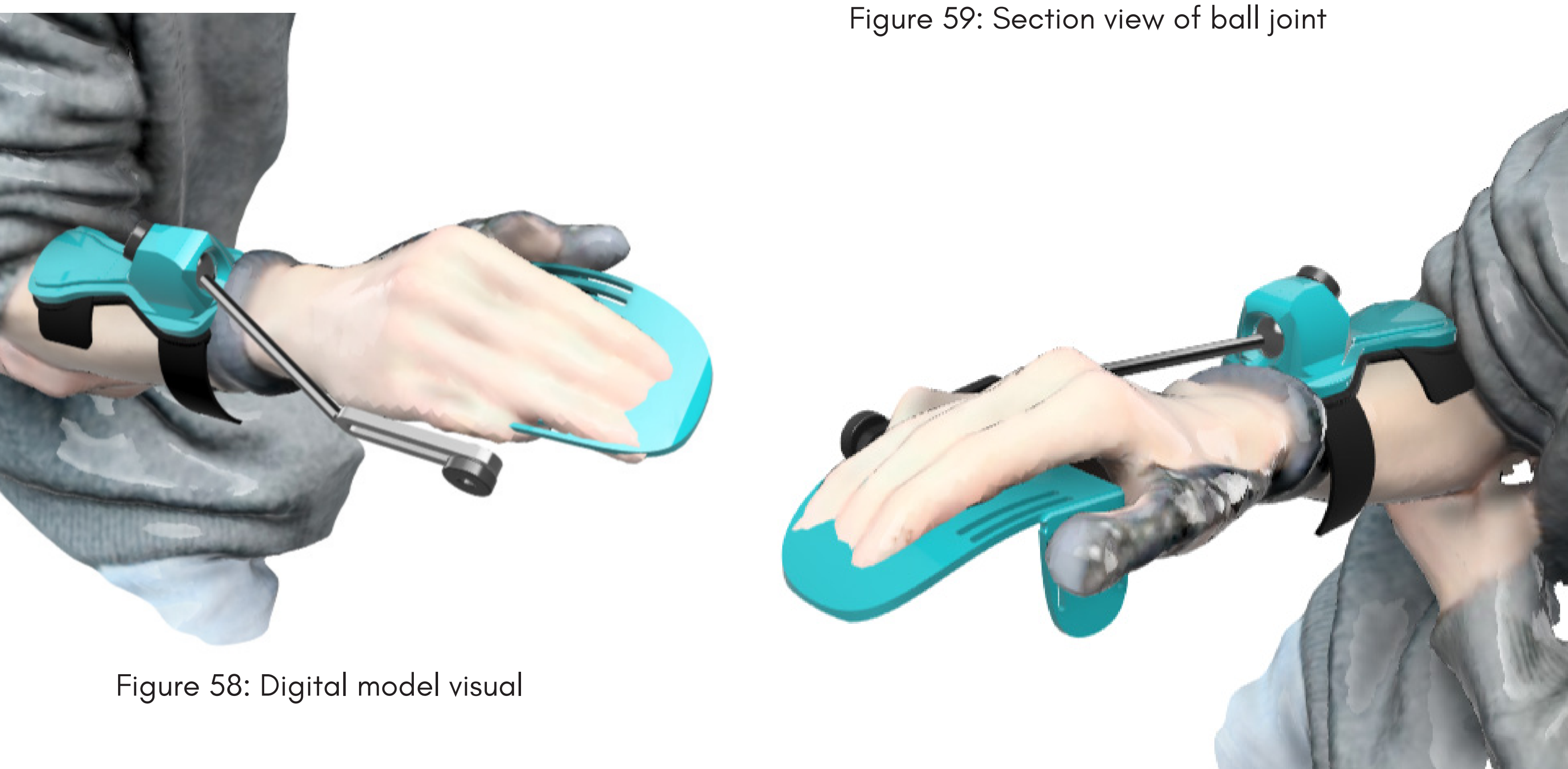


Figure 58: Digital model visual

Feedback session
During a feedback session with students several points for improvement have been identified. As of now, the plate is too narrow and the band squeezes the fingers together. The plate was originally designed to fit on a personal scan. Larger hands therefore have difficulty in fitting. The extra material of the band on the lower side presses in the way of the connector rod to easily adjust. Also, the band is placed too far forward and should be placed at the proximal phalange instead of near the PIP.

The connector rod now presses into the skin when moving downward and therefore did not reach the desired angular range of which the product should move. A new shape of the rod is needed. Using the rotating knob on the right side to clamp, while bringing the plate in place was found difficult. This interaction should be performed more easily, as the physiotherapist has to also keep the hand stretched in parallel while in use.

The wrist attachment felt too thin and flimsy. More material, either through rubber material near the bottom or a wider base that extends outward was suggested (Figure 61).

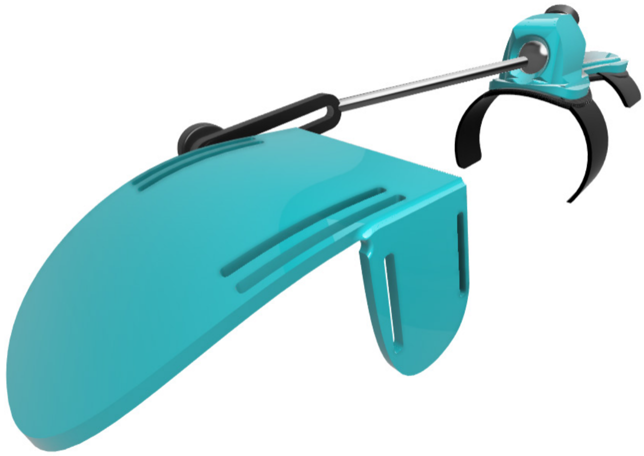


Figure 60: Hand plate

Key takeaways

- Ball joint for wrist attachment
- Component at dorsal side of hand replaced for rod
- Insights for next iteration

Figure 61: Concept testing & Finger plate narrow

4.6 High fidelity prototype

Now that the general concept has been defined, it is time to create a higher fidelity prototype to use as a step-up to the final design. Using higher quality materials, milling, SLS printing and steel threading, the new prototype was created. The sizing is based on a previous scan that has been increased in size to p50 hands. The focus now is on the conceptual testing, its mechanisms and materials. Definite sizes are still to be determined.

Wrist attachment

While the previous iteration missed bands to connect to the arm and were supposed to fit in with the foam, this iteration has four band holders located on either side of the wrist. The midsection has been widened and the screw locking mechanism is changed to a clamping mechanism.

With the new design SLS printed out of TPU, a flexible material, the steel sphere is inserted more easily. The skin contact with TPU is comfortable, therefore no EVA foam used. It might be considered for next iterations (weighing the benefit of a softer material versus the need for extra manufacturing).

RVS steel joint

From online material sourcing, two tapped RVS spheres for the joint presented itself: one 15mm diameter ball with M5 tread and one of 20mm diameter with M6 internal thread (Figure 64).

Depending on the needed strength of the connector rod (M5 needing a 5mm rod and M6 a 6mm rod) and locking capacity (added surface area versus friction), both were bought and tested. Two versions of the prototype were printed with SLS and TPU. Other steel spheres of 30 and 40mm M6 were bought as a backup if these do not work.

Hand plate

The hand plate made a slight improvement by replacing the holding bands to a thicker material and redesigning the attachment point of the metal rod. It is printed from PLA using FDM and bent to shape by heating it to approximately 60 degrees Celcius over a stove. A spring presses the plate against the connection point, locking it in place.

Figure 62: Milling the slots for the rod plate

Connector rod

The previous iteration connector rod could be used bilateraly because of its two dimensional shape, but due to it colliding with the hand, a new, more complex shape was needed. Although multiple iterations were tested, the more complex shape seemed necessary. It did create the opportunity to more quickly change from device instead of rescrewing the hand plate to the connector rod.

Depending on the strength needed for the threaded connection with the joint (the place with highest force localization), both 5mm and 6mm rods were threaded and tested. Initially instrumental steel was used, but was replaced with non-hardened steel, as it could not be threaded due to its hardness (breaking a thread cutter in the process).

A metal plate was milled from 3mm steel and MIG welded to the rod. Now hand sizes are adjustable. Having the opportunity to both mill and weld in a single project is a perfect learning experience and is greatly appreciated by the designer (Figure 62).

Figure 63: Finished prototype

Results

This prototype is a high fidelity version of the previous model. The wrist attachment has been changed, as well as the connection points and the hand plate. The product gives insight into the final shape of the model and how it will be used. It follows the shape of the hand and the interaction feels logical to users. As of now, the prototype is mostly for visual purposes, as the thumb plate is too flexible and the hand plate is currently too small and needs an iteration (Figure 63).

New improvements

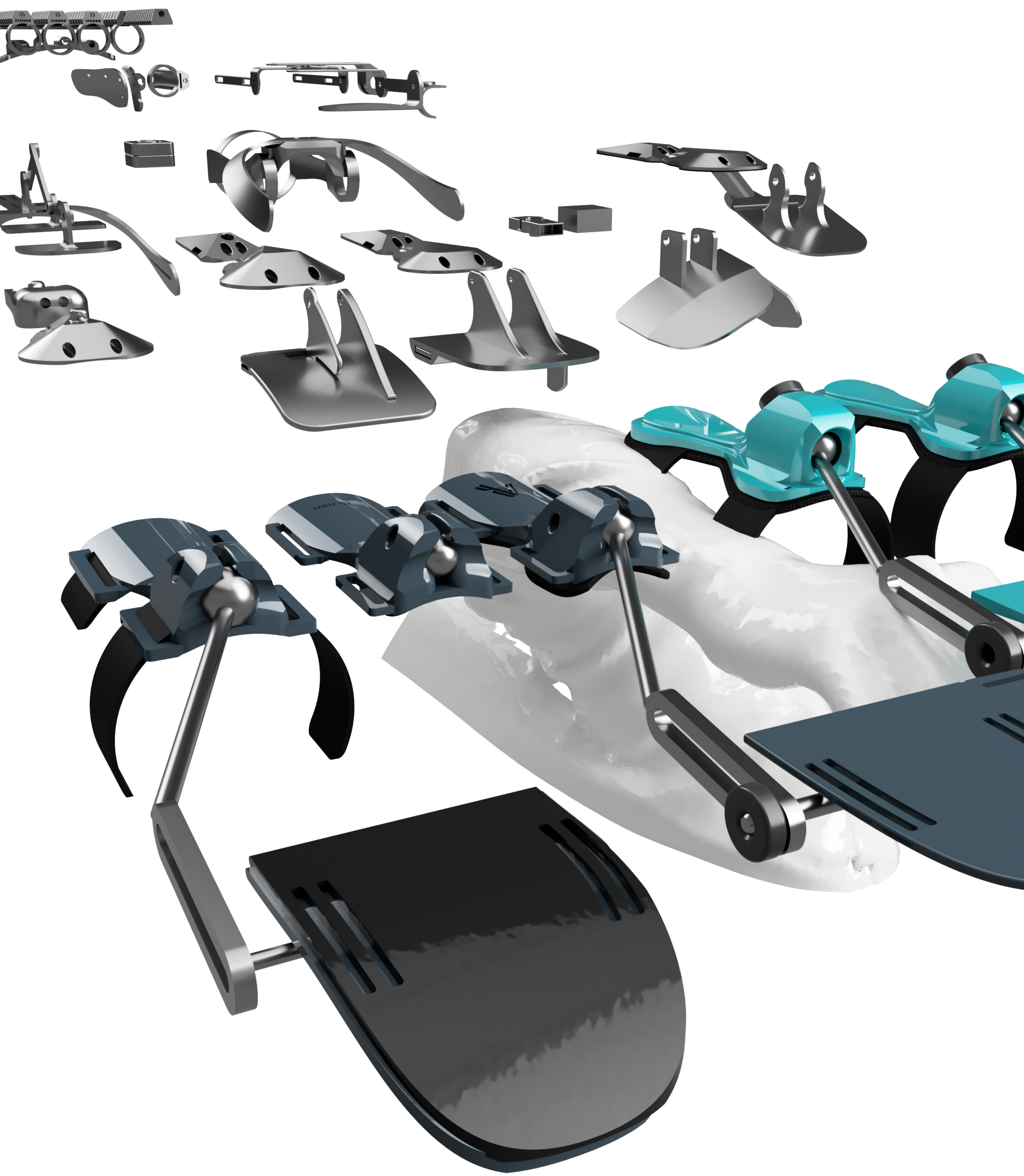
The concept is now ready for the next phase where it is further materialized with definitive forces, sizes and materials in mind. Opportunities are found in the ball joint holding force, thickness of the wrist plate, hand plate and thumb holder.

The next phase will go further into detail for the improvements in the design and shows an overview of those points.

Figure 64: 15 and 20 mm joint connection

Key takeaways

- Metal ball joint
- Visual model with clear interaction
- 15 and 20mm joint connection tested



4.7 Conclusion

This chapter showed the milestones of a prototype-driven process in the designing of the product, moving from the initial sketching, discovery and idea phases to a high fidelity prototype; ready for the final detailing iteration & product evaluation.

The process moved from mechanical and technical prototypes in the exploration stage towards more adaptable individual-finger-stretching systems in the fabric prototype stage. After reconsideration of the level of individual finger detail needed, the tension system reduced user complexity to a single plate. The next iterations removed materials and adding functionality via a ball joint, while the high fidelity prototype improved the feasibility on a manufacturing level.

As of now, varying parameters in the design have been considered and were tested to improve functionality, reduce complexity and make the product easier to use. The next chapter will implement the anthropometry that was kept in mind during this chapter and a final prototype is created for evaluation.

Chapter 5: Detailing

Towards the design of a 3D scanning assist for spasticity

5.0 Introduction

With the concept now defined, this chapter makes a critical review of the prototype to find improvement points before the patient testing. Different types of printing are experimented with and reviewed to find what fits the product best. Anthropometry is calculated and final dimensions are added to the product.

For the final prototype there is experimented with the wrist joint Torque with different amount of tensioning and is compared to spasticity wrist Torque as found in literature.

Finally, a left handed and a right handed prototype are constructed including the reviewed improvements points. A new hand plate is created for the patient testing in the following chapter.

5.1 Product review

With the final concept defined, it is time to make one more iteration before the evaluation. Below, an overview of improvement points is displayed (Figure 65). These points are further discussed in this section. Anthropometry, forces and costs are discussed in the next sections.

Handplate
The current handplate is not wide enough for larger hands and needs to be widened according to the anthropometric data. The slots where the bands are inserted need to be narrowed down, as the bands themselves now slide and makes applying the device difficult.

Connection handplate and rod
The connection needs a new iteration, as currently it has too much slack and makes use more difficult. Instead of a bolt head, a turning knob should be designed.

Rod
The rod is adjustable in length, while following the general hand shape. The anthropometry needs to be included, possibly changing the bent angle of the rod.

Connection rod and wrist attachment
A side effect of connecting the joint via threading is that the thread loosens when turned counterclockwise. when pressure is applied. Solutions to either locktite the thread or to create a small spotweld are considered.

Wrist attachment
Finally, the wrist attachment needs to be slightly widened to better divide the pressure. The TPU material makes the joint slip when enough pressure is applied so that needs to be looked into. The tightening connection needs added horizontal extensions for better area coverage of the screw.

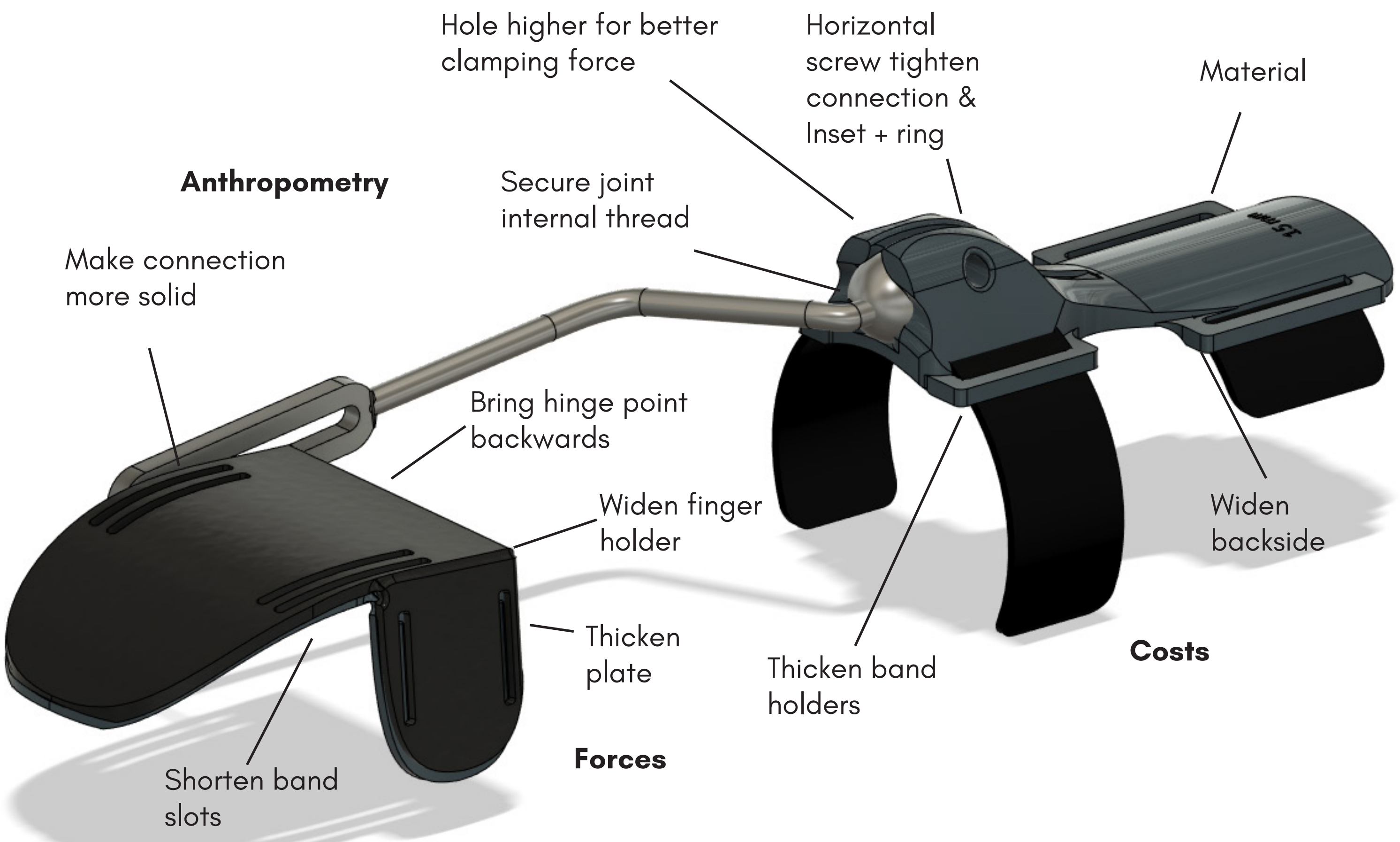


Figure 65: Overview of improvement points

5.2 Materials testing

The wrist attachment still has some problems with the joint slipping in the TPU prototype. Therefore different materials have been explored, as well as choosing the materials for the other components.

SLA printing

The first option was to use SLA printing for the part. The manufacturing itself was relatively easy, but with some additional steps over other processes. When the object was ready, remaining resin material was removed in an ultrasonic cleaner with isopropyl alcohol. The next step has the supports removed. Finally the part was placed in an UV curing chamber for hardening of the material. The material was found very brittle and seemed unsuitable for the product, other than a visual model (Figure 66).

FDM printing

The FDM version was printed easily from PLA, but had some difficulty removing supports on the lower side. Tree supports were used that only touched the buildplate. EVA foam padding is needed, as the material is rough to the touch on the lower side. An advantage of the material is that it is thermoplastic, therefore preheating the material and inserting the ball joint into the socket was relatively easy. The joint seems to hold better than the TPU material (Figure 67).

Finger band

The finger band has been changed to elastic material and velcro on the topside. This better holds the fingers to the plate, without cutting into the fingers.

Figure 66: SLA printing prototype

Figure 67: FM version

Band holders

The backside has been widened slightly and the band holders have been increased in thickness.

Wing nut

The connection bolt for the wing nut now makes use of M6, resulting in all threads of the prototype being M6 and gives consistency to the design. A larger type of wing nut is added for better comfort while turning. A ring has been placed near it to improve locking. The bolt seems to be squeezed into the PLA, but prevents the head from turning.

Mechanism

The joint and rod have been made from regular steel and are post processed with steel wool for a more smooth appearance. Sharp edges have been removed and connections are solidified.

Locktite

The ball joint and rod have been connected with Locktite, making it the only glued connection in the prototype. It seems to hold well. Plan B is to weld the components together.

Key takeaways

- FDM printed prototype
- All threads are now M6
- Connection glued with Locktite

5.3 Anthropometry

This section covers the anthropometry of the product. Two databases of DINED have been used: Dutch adults of 60+ and a private database with age 50-79 (DINED, 2022).

The main dimensions of the product are based on the finger length, total hand length, hand width, thumb width and wrist circumference (Figure 68). Data on thumb position in the adduction/abduction plane was not directly available but is assumed based on thumb width, length and angle. From the Dined database the p5 of females and p95 of males were used for the product to ensure coverage of the population. Figure 71 shows the smallest size and variation in brackets. The wrist circumference shows a 'c' after the number, as it is a circumference instead of a direct measurement.

The shape of the wrist was recreated using a p5 female and p95 hand in the Dined Mannequin tool based on hand length and width. These were converted to a 3D model and placed over each other in Fusion360. Figure 70 shows the difference in size. The topside matches approximately 40 mm, while after this, the material needs flexibility to match (for the product approximately 10mm). Different wrist shapes were explored (Figure 69).

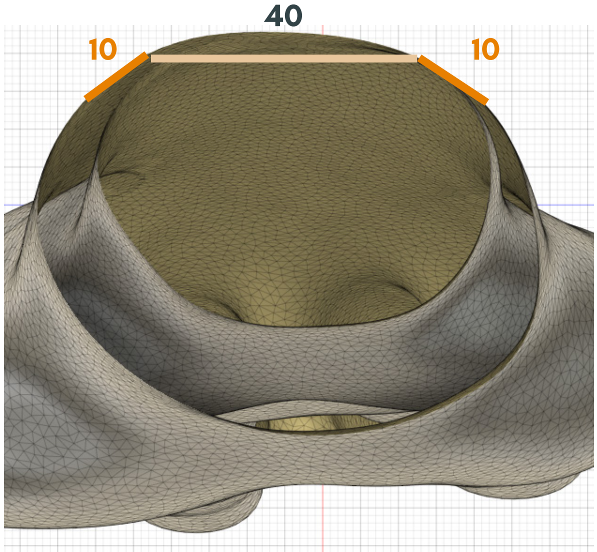


Figure 68: Wrist shape overlay hand length & hand width p5-p95

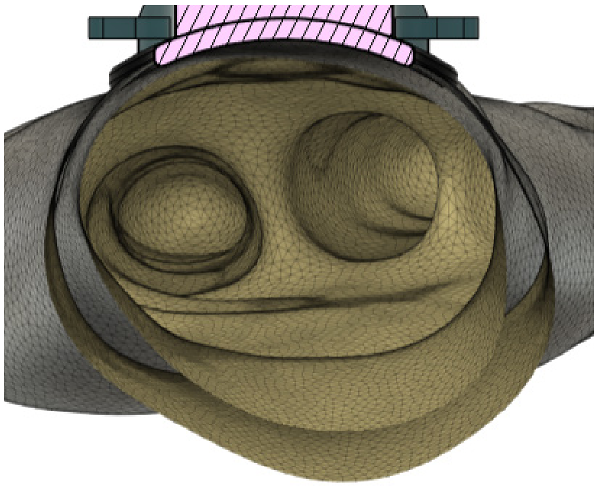


Figure 69: Wrist shape overlay wrist circumference p5-p95

Product dimension	Database	p5 female	p95 male	Difference
Finger length	Middle length (private)	68	90	22
Hand length	Hand length (Dutch Adults)	163	207	44
Hand width	Hand width (without thumb) (Dutch Adults)	74	98	24
Wrist circumference	Wrist (private)	142	200	58
Thumb width	Thumb breadth (Dutch adults)	18	27	9
Thumb length	Thumb length (private)	41	63	22
Lower arm width	Estimation	-	-	-

Figure 70: Measurements from Dined databases converted to prototype

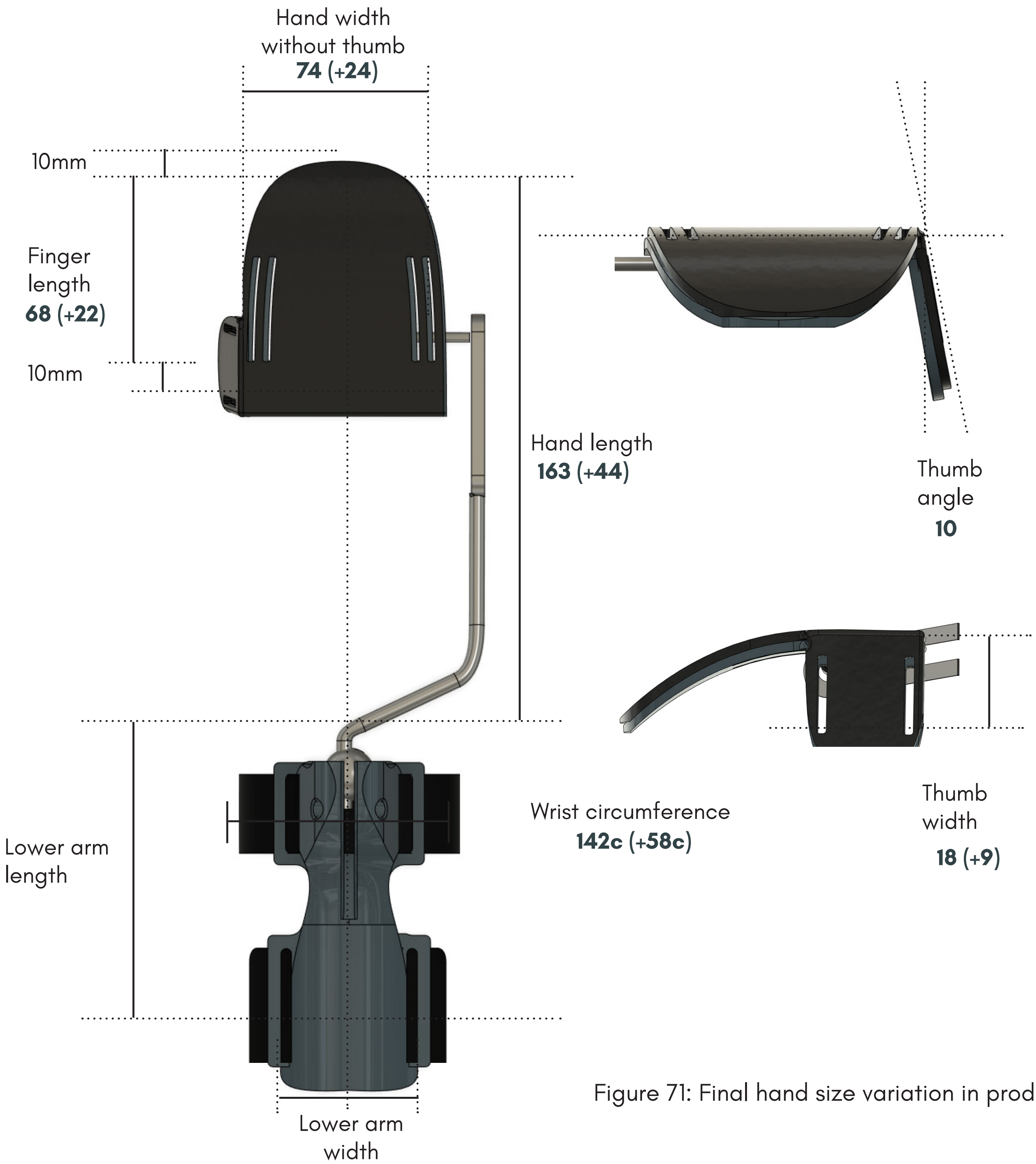


Figure 71: Final hand size variation in product

The hand length seems feasible using the slider, as well as the arm width and thumb. What needs testing is the hand width: whether a one-size-fits-all solution would work. Most likely it needs to be subdivided into two size ranges (eg. 74-85 and 86-98). Finger length is then assumed linearly with the breadth. At last, the excess material of the wristband needs consideration as it is 58mm for the smallest hand.

Key takeaways

- 44mm variation for connection rod
- Hand width variation is 24mm: needs testing on width
- The smallest wrist has 58mm of excess wristband material

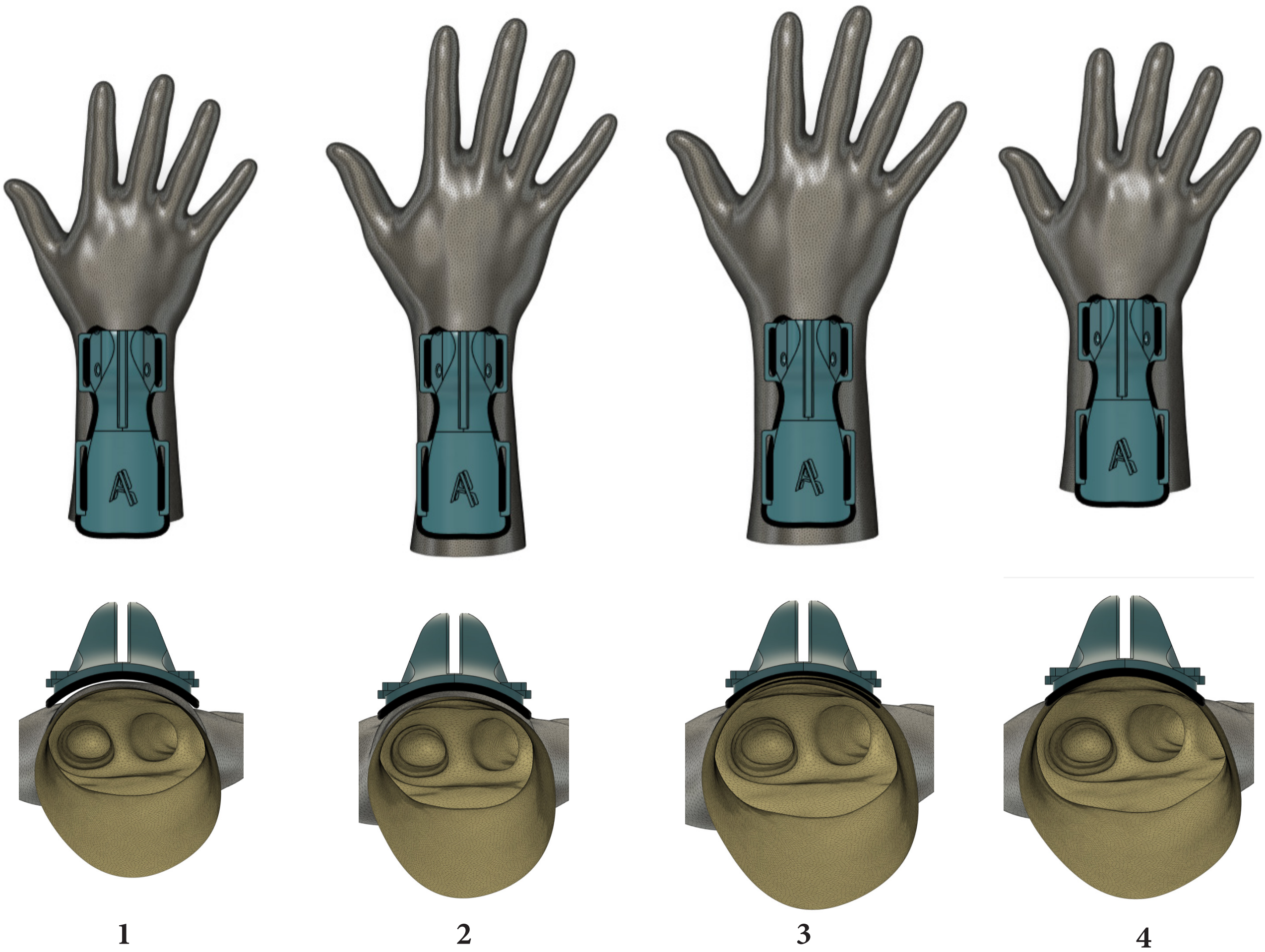


Figure 72: Fitting of product on hand sizes based on hand length & wrist circumference p5-p95

Wrist fitting

Four hands were generated for the product to test the fit. These hands are based on the hand length of the p5-p95 and the wrist circumference of p5-p95 (Figure 74). Each of the extremes of the bounding box has been chosen and the fit is viewed in Figure 75. It is seen that all prototypes fit on the wrist, but that there are large variations in how it fits. Between test 2 and 4, there is a large variance seen in distance from the side of the prototype to the side of the wrist, while between test 1 and 3, there is a large variation between the size of the hand and the prototype. The foam padding ensures that the bands near the top will not press into the skin of the smaller hand.

Figure 73 shows the variance in hand size of p5 and p95, adapted from Figure 75. A hand was scanned in the correct position and scaled digitally to fit the hand sizes. For the smaller hand it is seen that there is more room on the width of the plate. It is assumed that there is still some room for adjustments of the hand on the plate due to the elastic material that holds the fingers.

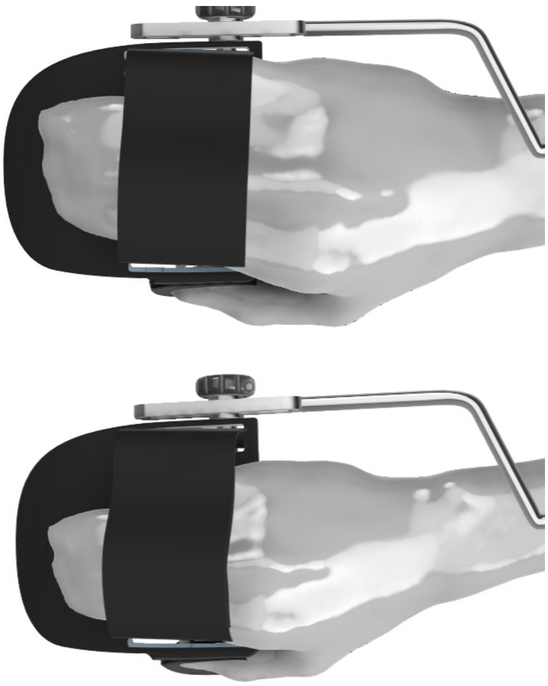


Figure 73: Hand sizes p5-p95

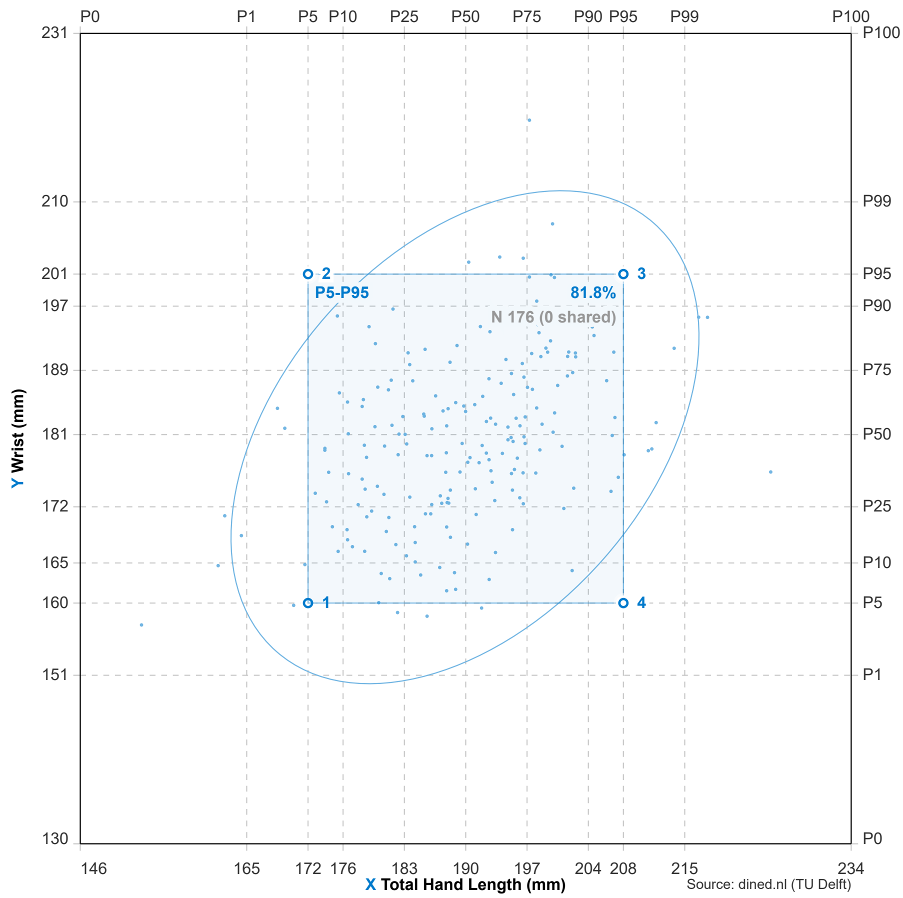


Figure 74: Hand length and wrist circumference p5-p95

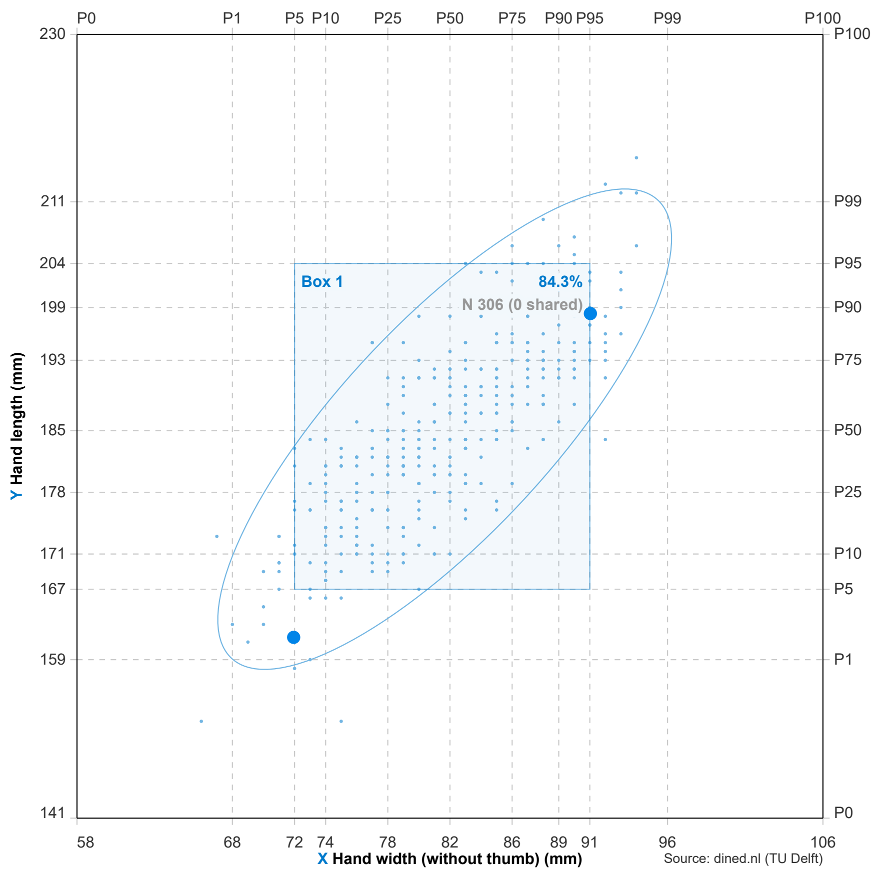


Figure 75: Hand length to hand width p5 and p95

5.4 Forces experiment

Before testing the device on patients, the holding force of the ball joint needs to be determined. The setup is viewed in Figure 76. The prototype is clamped to a table and a hanging scale is placed at 150mm while slowly weight is added. This was repeated three times and the average is taken for the final Torque force. The clamping force of the screw was estimated into low, medium and high hand tightening due to no equipment for measuring torque at the wing nut.


Figure 76: Setup with hanging scale at 150mm

During testing it was found that the TPU material kept slipping, either because of the flexibility of the material, its texture or the small particles that come of the material. With the patient testing being prescheduled, the decision has been made to continue testing forces with an FDM printed model of PLA, as the clamping forces were significantly higher. This way, at least for the patient testing a conceptually working prototype could be used.

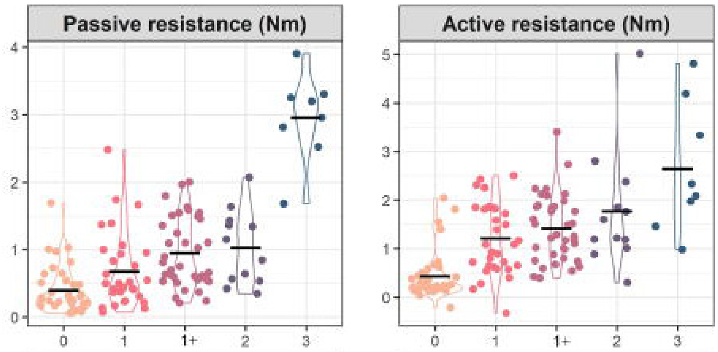


Figure 77: Passive & active resistance per Modified Ashworth Scale (Mahmoud et al., 2023)

Resistance force spasticity

From research it was found that the maximum resistant force when bringing a spastic hand into position is 9 Newton per 30mm/s, with angular movement not significantly different from 60 and 90mm/s (Kawamura et al., 2022). After estimation of their setup, the point from the wrist to the fingers is assumed 150mm. This approximates 1.35 Nm of resistance Torque in angular movement. Research also showed passive and active resistance of the wrist on 1 and 2 Nm on a MAS scale of 2 (Mahmoud et al, 2023), as seen in Figure 77. Passive resistance equals muscle and tissue stiffness, while active resistance equals the spasticity. Please note that slow stretch was used to prevent stretch reflex.

Results

The results from the experiment are seen in Figure 78. By comparing the resulting Torque to the Torques found in research, it was found that the prototype on average would hold spasticity on a MAS scale of 2 with average resistances approaching the 3 Nm with a medium to high clamping force. This does not include the added Torque from the stretch reflex if the hand is stretched too fast, as the slow method is preferred to keep the hand as relaxed as possible. This means that the prototype should hold its position.

Clamping force (Estimate)	Test 1 (kg)	Test 2 (kg)	Test 3 (kg)	Average (kg)	Force (N)	Torque (Nm)
Low	0.8	0.74	0.76	0.76	7.46	1.12
Medium	1.92	1.91	1.93	1.92	18.8	2.82
High	2.25	2.15	2.22	2.21	21.6	3.24

Figure 78: FDM prototype Force & Torque testing, 0.15 meter

5.5 Left and right handed prototypes

A new design has been made for the prototype. Compared to the previous version in chapter 4.6, this design has anthropometry included. It has a new design hand plate with integrated bolt, metal pipe and rings for easier wing nut locking. The wing nuts are increased in size to improve leveraging (Figure 79-81).

The connection point has been brought backwards in line with the thumb holder. It consists of a M6 threaded bolt that is inserted into the plastic to prevent rotation, three rings and a metal tube to remove sharp edges and serve as spacer to the slider. A wing nut has been used to both rotate and secure the hand plate.

Two designs have been made for both a left and right hand for testing, as for now it is not sure what the condition of the patients is. Between the designs there have been minimal changes made, only smoothing the connection of the wrist joint bolt. For the testing this will not make a difference, as the workings are the same.

From the previous sections it was found that FDM performed best and is continued in the design. Because the material is harder, now EVA foam is added for comfort on the skin contact points. Thicker band holders are included and the newly discovered problem of the loosening wrist joint tread (the metal rod to the steel joint) is secured using Locktite thread locker (stronger variant).


Figure 79: Newly created connection point


Figure 80: Integrated hex bolt

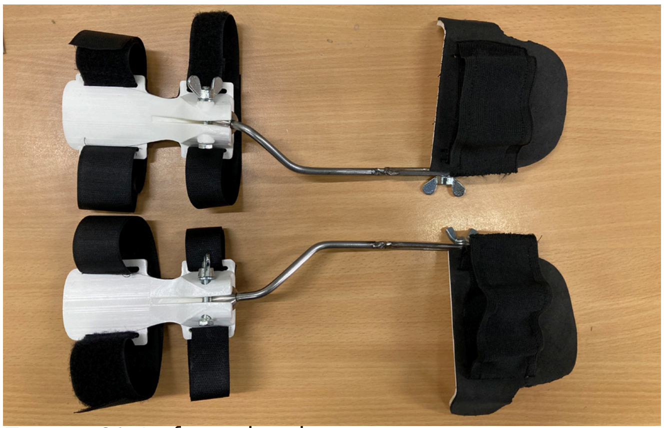
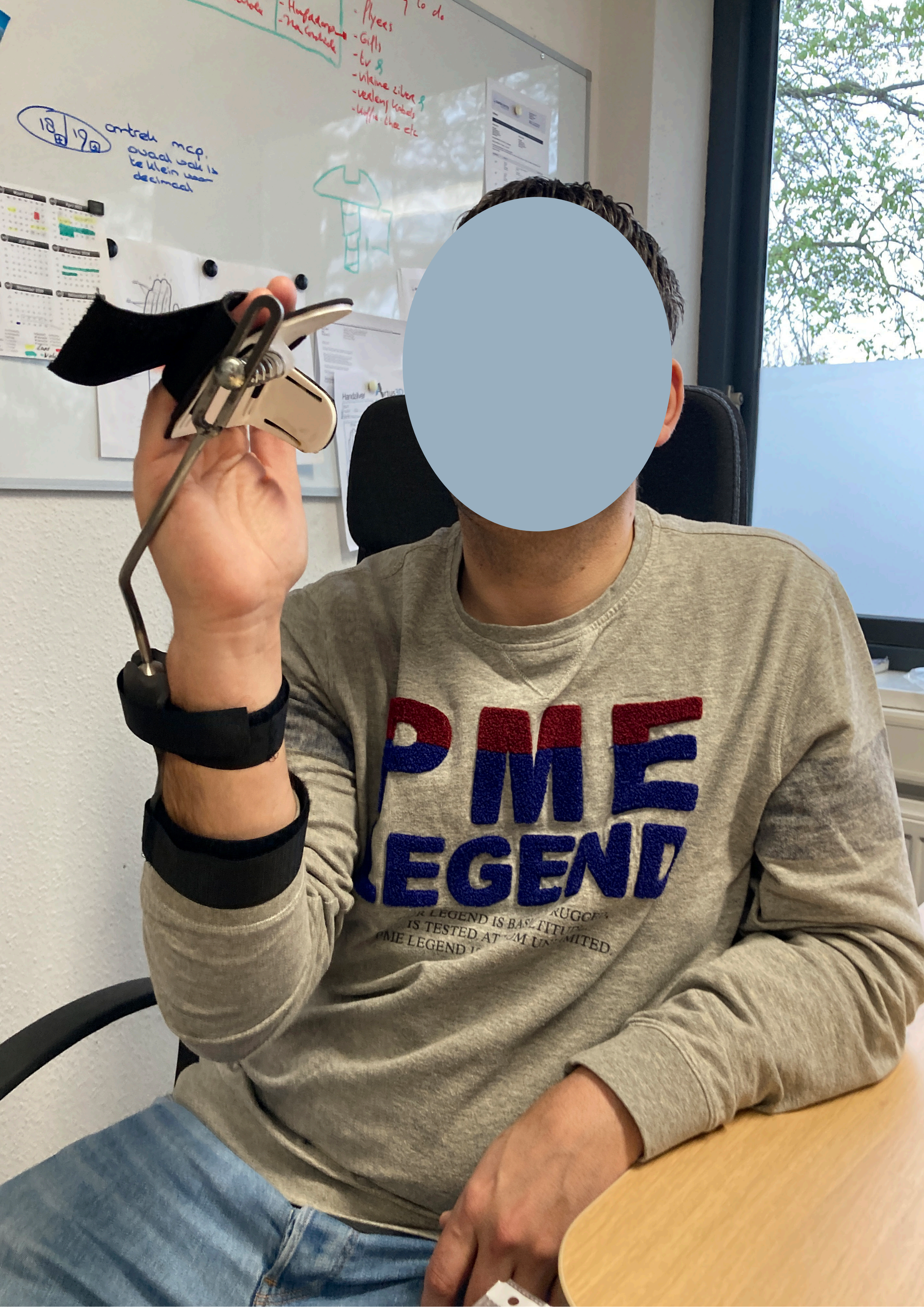


Figure 81: Left and right prototype

Key takeaways

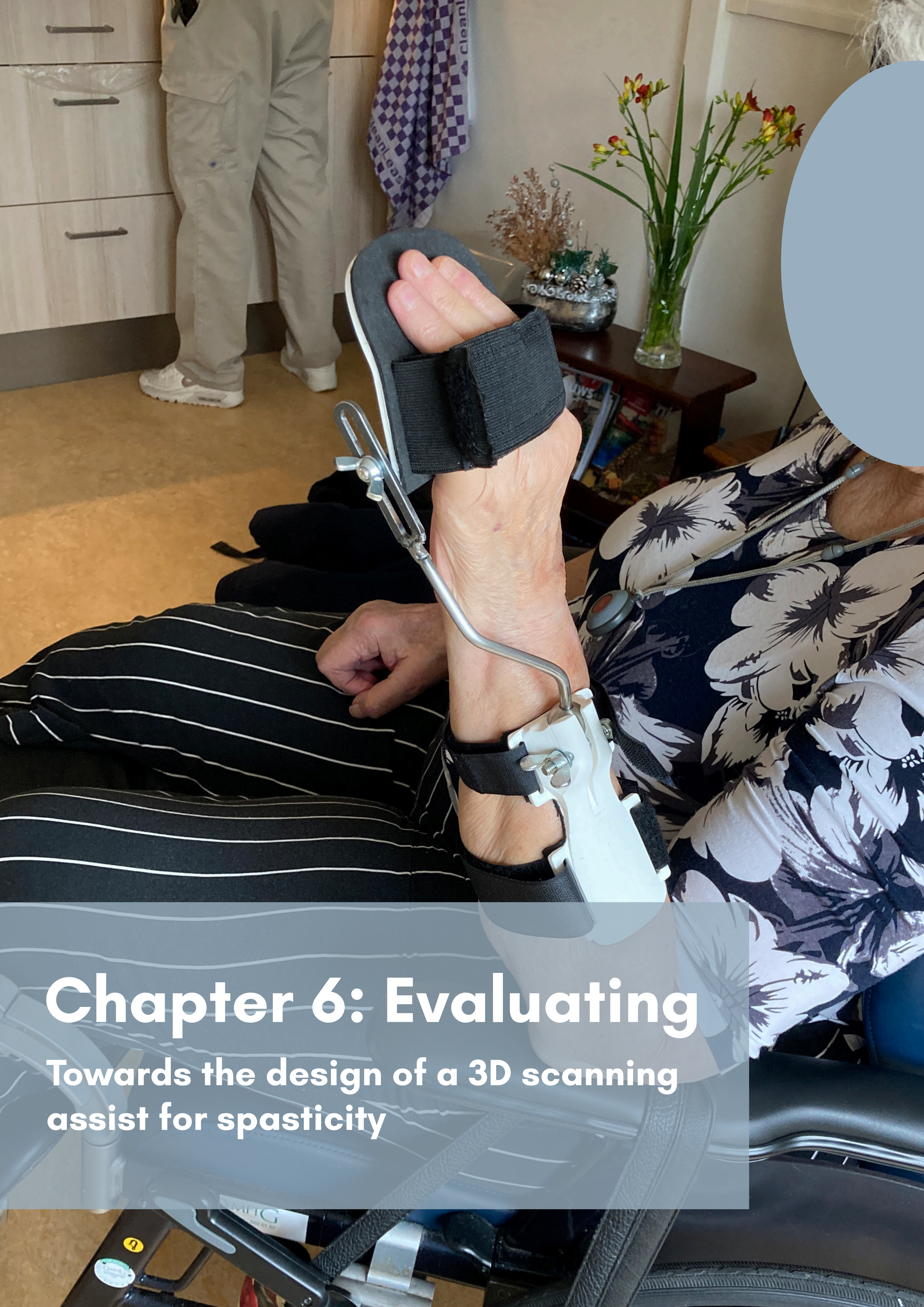
- New plate design following MCP
- Left and right prototype
- Anthropometry added to design


PME

5.6 Conclusion

Two prototypes have been created that are now ready for testing. Mechanical improvements have been made to the attachment point of the finger holder, the wrist joint and thumb holder. Anthropometry is added as well as materials have been selected for the patient testing.

With the increased hand size, the prototype is now usable for the p5 to p95 population, based on hand width and finger length. An experiment with holding Torque calculations found that the prototype could widthstand MAS 2 spastic hands.



Chapter 6: Evaluating

Towards the design of a 3D scanning assist for spasticity

6.0 Introduction

This chapter will evaluate the prototype in two sessions with patients. Before the research starts, possible improvement points are discussed with orthopaedic technologists for the prototype and provides valuable insight in the way how they would use the device. Directly after the meeting the patients of the first session were visited. The second session happened on a different day.

In the first session, two patients with MAS 1 and 1+ are tested. Their original appointment was for the delivery of convection orthoses. Scans are created and digital models of orthoses are made by the instrument maker from those scans.

The second session has two patients of MAS 1 and 3, of which one patient needed both hands scanned. This patient also had Rheumatoid arthritis, which affected the use of the product. The scans are also turned into digital models of the orthoses.

Finally an evaluation is given on the experiment with both the orthopaedic technologist and the instrument maker. Further improvements are given for a final iteration.

6.1 Orthopaedic pre-test

During the product review with the orthopaedic technicians the product was tested and its workings were explained. The main results are viewed below:

- The device in itself seems to work and the handling by the technicians was observed differently than initially expected. Instead of securing the fingers first and then attaching the wrist attachment, the arm was put inside the wristbands first, so that the velcro did not need to be fully adjusted.
- The fingerplate was locked before moving the wrist joint, while the wrist joint itself was beforehand slightly locked to better hold the movement.
- With the intention of the device being easy to use, only slight explanation was needed: the locking mechanism of the wrist joint and how to place the holder at the fingers correctly.
- The bands at the fingers are found too complicated, while attempting to place the fingers inside. It should open up more easily.
- The thumb plate could be adjustable, or have a conical shape to better hold the thumb. Perhaps a way to keep the thumb steadily in the vertical direction, like a plate could be useful.
- Keeping the arm up by itself is difficult by the patient, therefore a more clear way to hold the prototype is needed.
- One could easily attach a hand roll to it instead of the plate, this way also more severe spasticity could be treated.
- There was somehow a mechanical problem where the bolt securing the wrist joint was slipping at the base instead of tightening. It is nice to find this out now instead of during the patient testing. It was glued in place, ready for testing: more attention is needed.
- The lower side material could be thicker for more comfort when working with elderly.

All with all, the reviews were positive. With enough confidence in the product it is now ready for the patient testing (Figure 82).

Other interesting points that came up during the review were that patients find the gypsum process scary, therefore the hand will be more tense. It is important to keep the patient comfortable and relaxed, as it will directly relate to the tension of the hand. Also the scanner that is used is a Turtle scanner, this scanner is slightly less suitable and different than the ones prefered by Artus3D.

Figure 82: Orthopaedic technologists testing the device

6.2 Patient testing session 1

An overview of the patient testing is viewed below. Beforehand the orthopaedic technologist was instructed on the procedure of the device. It consists of two sessions on two days travelling between care homes.

Goal
The goal of the first session is to find out if the device works with lighter spastic hands & if creation of an orthosis is possible. The second session focuses on more severe spastic hands, how it compares to the gypsum process and where design opportunities are found.

Evaluation criteria
Both sessions will evaluate the product on smoothness of operation, the time it takes of using the device, how the prototype behaves in the context and how it is experienced by the orthopaedic technologist and instrument maker.

Materials
- 2 Prototypes (left and right)
- Turtle 3D scanner & Ipad
- Declaration of participation
- Calliper
- (as a backup) extra bolts and nuts
- (as a backup) Superglue
- (as a backup) Titebond thread securer

Procedure
- Research introduction

Explain the patient it is a student research together with Centrum Orthopedie and that it makes the process of splinting easier using 3D scanning. State clearly that this is not a medical intervention but a research. Explain the upcoming process and that if the patient is unsure, he/she could easily stop the process. Finally ask if they could sign the declaration of participation.

- Basic details interview

Write down the basic information on: gender, severity of spasticity, physical condition, left or right handedness in spasticity and cause.

- Prototype application

The orthopaedic technologist will now explain the device to the patient and start slowly applying it. The researcher makes observations on the different stages on the of application. Images are made and the process is timed.

- 3D scanning

The hand of the patient is now held in a scannable position (determined per specific patient case) and kept still. The orthopaedic technologist starts with the scanning process. Afterwards, the scan is shown to the patient.

- Prototype removal

The prototype is removed and observations are made. When the prototype removed from the patient, the timer stops.

- Research questions

After the research, questions are asked on their experience: What do they like and not like of the process? Was it easy to keep their hand into the air? Depending on the patient, a comparison is asked between the gypsum and the scanning.

Patient well-being
At all times the well-being of the patient has priority above the research. The researcher will follow the instructions of the orthopaedic technologist and physiotherapist. They will deem what is reasonable within the given time frame and patient endurance & intensity tolerance.

Results
The desired results of this experiment are to find out if the product works, creates a usable 3D scan and gain some insight into the situation of new patients, other than the patients visited during the initial stages of the project. If possible, a comparison with the gypsum process is made.

The condition of the patient is discovered on the spot, as well as finding out whether gypsum is required. Details on left and right handedness of the patients and intensity are to be discovered.

6.3 Results session 1

Patient 1

Male, elderly, wheelchair, Left MAS 1

The client had paralysis in the left side of his body, unable to move the hand and leg. There was some tension but controlled near-full range of motion by the orthopaedic technologist was possible. The original appointment was for a convection orthosis.

At first the process was explained and the client reacted positively, curious about the 3D scanning and what the assist does. When the experiment actually started and the process began, seemingly a nervous atmosphere emerged from the patient, not quite sure what exactly was going to happen and three persons standing around him.

Jokingly explaining that the 3D scanning was mostly a 'cool' way of creating a new orthosis, the mood was relieved into a more relaxed and laughing atmosphere process. This helped with the hand, as the tension reduced and the process of handling became easier. Further telling that the new orthosis would fit more precise than the convection one reassured the client.

The assist was slided around the arm and tensioned using the velcro and went relatively smoothly. Then the hand was placed near the finger holder and the fingers were put in place. There was difficulty in getting the fingers inside the strap, making slightly troublesome. Then the hand was set to position and the wrist joint was secured. Finally the hand plate was tensioned and the hand is scanned.

The client was showed the final 3D scan and was impressed by it. In total it took 6-7 minutes. He also asked if he could keep the prototype on, as it nicely stretches his fingers. He hoped that perhaps it could make his situation better.

At this point the patient became tired and was guided to bed. Although not all of the questions were asked, the product underwent the whole process and a 3D scan is made. Sufficient information was gathered (Figure 83-84).

Patient 2:

Female, elderly, wheelchair, Right MAS 1+

The client did have trouble responding, mostly nodding and speaking in soft breaths. She had a double cerebral infarction and could move her right arm limitedly. With a first positive experiment performed, continuing with this experiment was deemed safe by the ergotherapist and orthopaedic technologist.

The device was applied more handily then at the previous client. The assist was slided onto the arm, after which the fingers were secured. They were placed relatively easy. Then the bands were attached and the thumb put in place. The wrist bands were secured and the wrist joint was slightly tightened. Now the hand is put in place and then completely secured (Figure 85).

With the hand ready for scanning, there was some difficulty in keeping the hand upright. The first attempt failed to capture the bottom of the hand. Due to the limited space, scanning was difficult and multiple objects were captured as well. The ergotherapist had to stand behind the wheelchair and keep the hand stable in a 45 degree angle, while holding the metal beam. This worked, but slightly moved the scan. The total time took approximately 6 minutes from putting on to taking it off.

"Can I keep the device on? It stretches my fingers nicely"

Figure 85: Held at the metal beam

Figure 83: (top) Collage of using the device

Figure 84 (bottom): Orthopaedic technologist 3D scanning

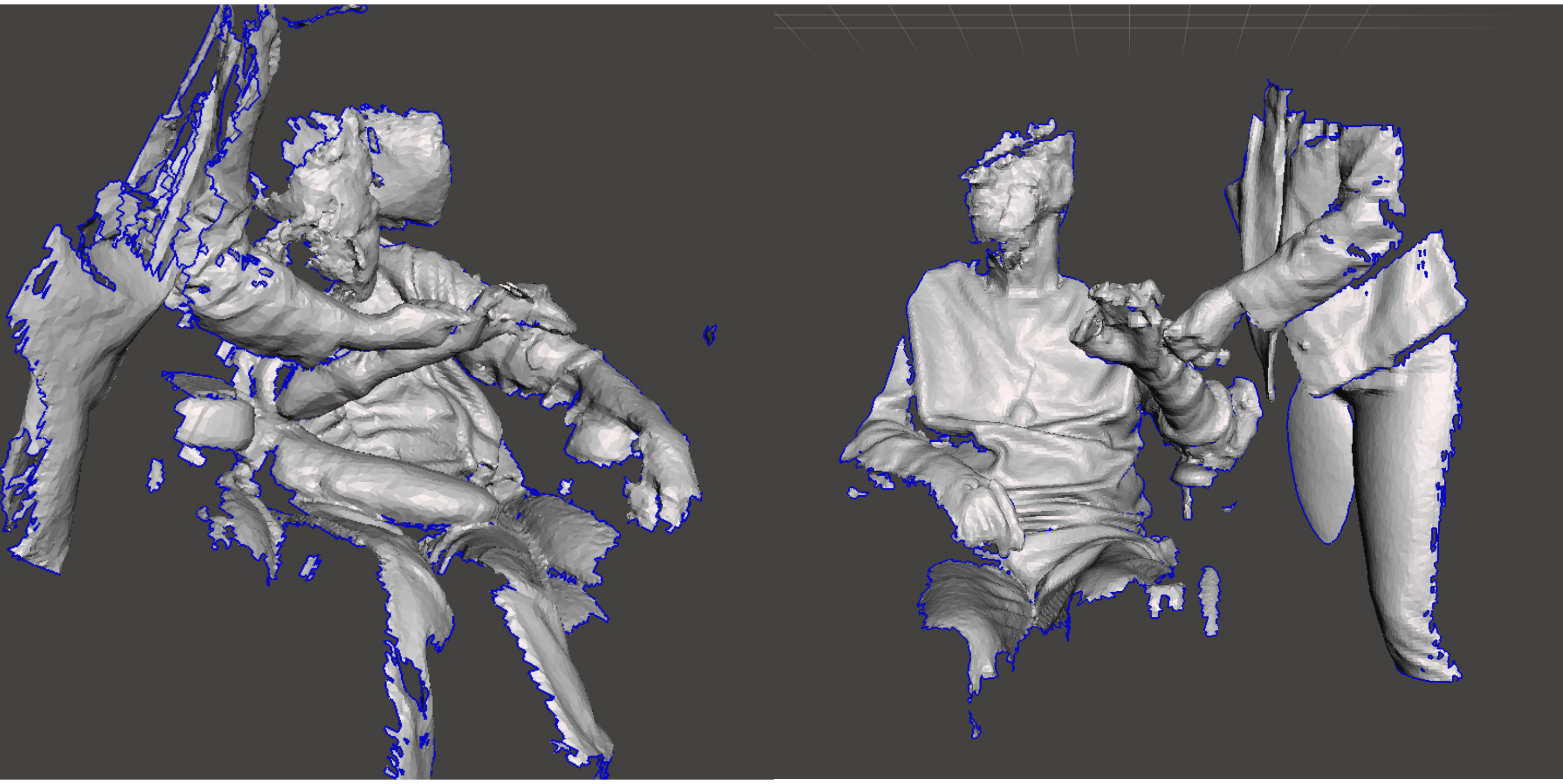


Figure 86: Full size 3D scan meshes of both patients

6.4 Scan to orthosis

The scans that were made of both patients are now processed for the digital generation of the orthosis. The process for one orthosis is viewed in Figure 87.

As seen in Figure 86, a large amount of the surrounding area near the hand is scanned as well. This should be cleaned to be able to create an orthosis from it. It also reduces the amount of triangles that make up the mesh of the scan, in turn reducing file size and improves processing speed when the file contains only the hand and arm.

The second step is cleaning the hand itself. The first image of Figure 87 shows the outline of the assisting device clearly. The two bands are viewed, as well as the thumb holder and the hand of the person holding the device. The second image highlights and removes these components; the thumb holder, wing nut and top bands.

The mesh is further cleaned of lost artifacts and rough areas are smoothed. Holes in the mesh are filled and some of the hand details are further defined, removing slight movements from the scan.

Sometimes when cleaning, the triangles in an area become few and detail is lost. Therefore a subdivision command is used keep the detail when changing the mesh. The hand shape is extruded at the outer sides of the mesh, following the contours of the orthosis. Finally the material is smoothed and ready for generation. Total time for patient one: 23 minutes, patient two: 18 minutes.

The hand is imported into the software and an outline of the orthosis is drawn in image 7. The product goes through final materializing and the results are seen in images 8 and 9. The total time for patient one: 8 minutes, patient two: 6 minutes

The orthoses are ready to be printed. Both orthoses were processed and reviewed by Bijman.Visibility on the lower side of the hand was clear and keeping the webspace open near the thumb was appreciated. Thumb had slight movement, leading to a wider thumb scan and need adjustment. MCP width was clear and the fingerplate eased the cleaning; giving enough information to define the shape. One orthosis has a slight ulnar bend due to having the assist not held completely straight.

Figure 87: Processing of 3D scan to final digital orthoses

6.5 Patient testing session 2

Patient 3

Female, elderly, wheelchair, left and right MAS 1+ and Rheumatoid Arthritis

The original appointment was for an adjustment to a leg prosthesis, but the hands had to be looked at because they had a slight contraction. Both hands needed a resting orthosis, creating an opportunity for testing the prototype twice, in addition to comparing it directly to the gypsum process. The patient was very calm and seemed to enjoy the attention.

The patient had Rheumatoid arthritis which lead to her having some fingers that have permanent contraction. It created some difficulty in placing the fingers correctly on the finger board with her fifth finger moving inwards. The gypsum process also experienced some difficulties (Figure 88-89).

Another point of attention is the spasticity in the flexion of the thumb MCP. This lead to the MCP moving inward, while the desired position is outward. It is a rarer type of spasticity, but interesting to see how it interacts with the plate.

The scanning itself took 6:31 minutes for the first hand with having to take a second scan because some detail was missing on the little finger side. The second hand was scanned right the first time with 3:12 minutes. For the gypsum it was 8:03 for the first hand and approximately 8:42 minutes with cleaning for the second hand (Figure 90).

Patient 4

Female, elderly, wheelchair, left, MAS 3

The patient needed attention to a spastic left hand which appeared to be MAS 3. The woman had relatively small hands and had little strength in her arm (Figure 91).

Applying the prototype went relatively easy as the hand was placed on the armrest of the wheelchair. However, during scanning it was found that the elastic bands for the fingers were not tensioned enough and that the fingers got loose. This might be due to the smaller size fingers.

The patient had less mobility and the protoype was held by the researcher. The hand was held at approximately 20-30 degrees from the horizontal, due to the lack of mobility in the arm. The second scan worked better with more detail of the lower side. The scanning took 5:16 minutes.

Then the gypsum was applied. Fewer images were taken of the process, as the patient became nervous and thought it would be over by now. The gypsum process this time only took 5:24 minutes without cleaning up.

Due to the situation of the patient it was decided that is was now time for rest. Enough data has been collected for the scan and interaction with the prototype. The patient was reassured and the research was ended.

Figure 90: 1. Thumb MCP spasticity, rarer version where the MCP moves inward. 2. Desired MCP position 3. The fifth moves inwards, which leads to difficulty adjusting the band


Figure 88: Gypsum process - Rheumatoid arthritis made putting on the glove more difficult.


Figure 89: Bringing the MCP of the thumb downward and outward while the gypsum dries

Figure 91: The process of putting on went slightly slower due to the condition of the patient

Figure 92: Photoseries of putting on the prototype, scanning and removing it

6.6 Gypsum comparison

It is ideal that in the second session the hands were more varied than at the first session for the testing. Normally it is to be seen what interventions are needed on the spot, whether the hand is left or right handed and if a convection orthosis would suffice. Being able to directly compare the gypsum process with the prototype on the same patient is an opportunity not to be missed (Figure 92-93).

For comparison, there is looked at speed, usability, discomfort to the patient, how the both methods fit in the context and the cleanliness of each method.

Speed

For the averages of the three hands that underwent both processes, the times are: 7:23 minutes for the gypsum process and 4:59 minutes for the scanning. That is 2:24 minutes quicker on average, or 32% quicker. These times do not include the explanation to the patient, as well as the relaxing of the hand as those are similar to both processes.

Usability

In terms of usability, both methods created usable models for an orthosis. The gypsum process does have the advantage of being more flexible in position, mostly for the thumb.

Figure 93: Photoseries of the gypsum process with the same patient

It allows the hand to be positioned exactly as desired, while for the prototype the thumb needs a digital correction, as will be seen in the next session. The gypsum process did have the disadvantage of needing to bring more small materials. As said by the technologist: “Where are the gloves? I need to refill my bag again soon”. The scanning process does not use consumable items.

Discomfort & cleanliness

One advantage of the prototype is that the hand is visible at all times. Having the whole hand covered in gypsum could make the patient feel less comfortable. Also cutting the gypsum open with a scalpel near their arm was slightly suspenseful. On cleanliness, some gypsum dust was left on the patients and in the sink that needed cleaning. the scanning did not need any cleaning and might be seen as an advantage.

Context

Both techniques fit the context, however one conflicting perspective emerged: on the one hand people say they want more personalized care, while at the same time aim to reduce the time of patient visits. The patients that were visited seemed to enjoy the attention. Personalization versus efficiency is an opportunity to be further explored.

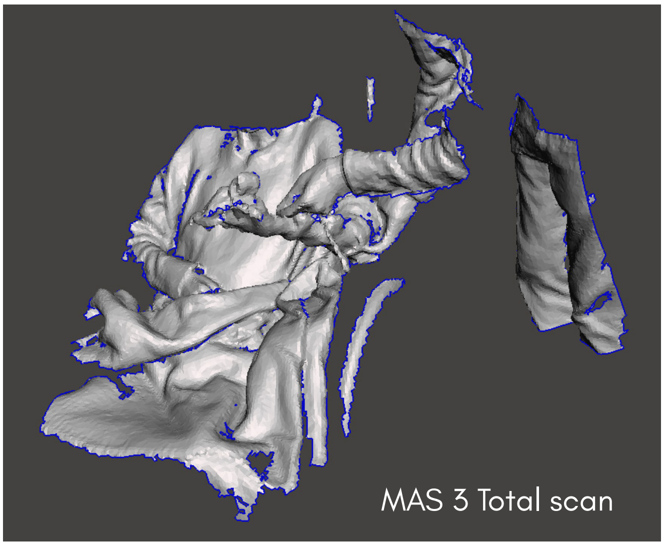
6.7 Scan to orthosis 2

This cleaning session folows similar steps to the previous session. Where the first session focused more on the process of cleaning and whether it is possible at all, here the speed of the instrument maker and accuracy of the scan are determined. The following page shows the resulting scans with parts of the product that impact the scan are highlighted in orange.

It was possible for each of the scans to create an orthosis out of it. The MAS 1+ spasticity scans were relatively quickly made in 17:30 and 18:02 minutes in cleaning. The MAS 3 spasticity scan proved more difficult with 26:48 and needs measurement validation with the patient. The times for the actual orthosis generation were similar, approximately 4 minutes.

One of the reasons for the longer time was that the scan had captured a large amount of the environment around the hand, in turn reducing the local quality of the hand. It is also seen in the amount of triangles in the scan: The whole mesh had 54 k trangles, while the hand portion of it only had 4.7 k triangles (Table 3). This led to a lower accuracy, also missing some portion of the fingers. The instrument maker now had to first repair the mesh, before being able to clean it.

The other scans had a higher amount of triangles, leading to higher accuracy with 9.1 k and 7.9 k triangles respectively. This gives enough detail to capture the hand for the orthosis. In order for the MAS 3 orthosis to be viable, the instrument maker has to compare the sizes of the scan to the patient data and rescale the hand. Although the general shapes are clear, after remeshing the model from 4.7 k to 33 k (7x increase), detail is lost.



MAS 3 Total scan

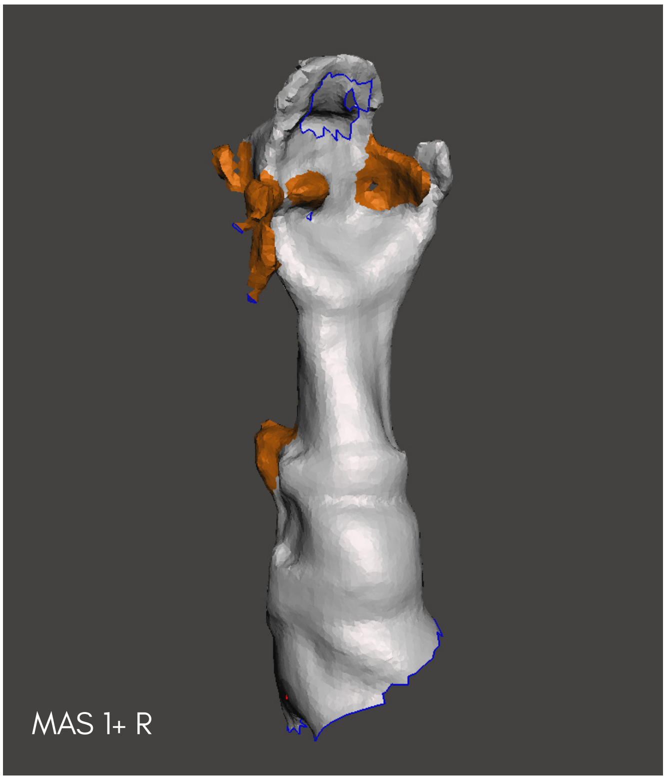
During the review with the instrument maker, it was explained that the lower amount of triangles in the model was due to the 3D scanning of the orthopaedic technologist and not because of the product. When scanning, capturing a part of the body is desired for reference of the scanner. but this should be a part of the shoulder instead of the whole person.

The areas of the wrist, base of the hand, fingers and thumb are well definable for orthosis generation. It is desired that the wristbands are visible for removal. The fingers are slightly unclear, but are extended from the MCP length; which is definable.

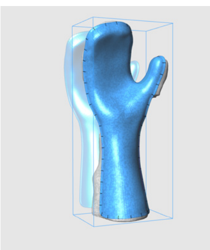
It would help if there was a reference photo available, as from the scan of the MAS 3 it is difficult to find the webspace near the thumb. There is a small hole visible, but it seems slightly higher than the normal. The bands seem to be pressed into the skin in the weaker parts. Although it is not a direct problem, sometimes people have increased sensitivity. The thumb plate should have a small piece removed to better see the thumb, other than that the instrument maker does not experience hinder of the device.

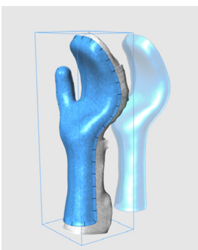
	Scan cleaning [minutes]	Orthosis modelling [minutes]	Total scan [amount of triangles]	Hand selection [amount of triangles]	After remesh [amount of triangles]
MAS 1+ (L)	17:30	3:58	41 k	9.1k	42 k
MAS 1+ (R)	18:02	3:43	50 k	7.9 k	36 k
MAS 3 (R)	26:48	4:16	54 k	4.7 k	33 k

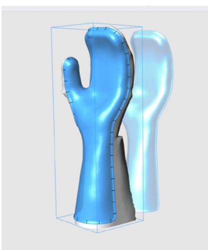
Table 3: Information on scan cleaning time & amount of triangles

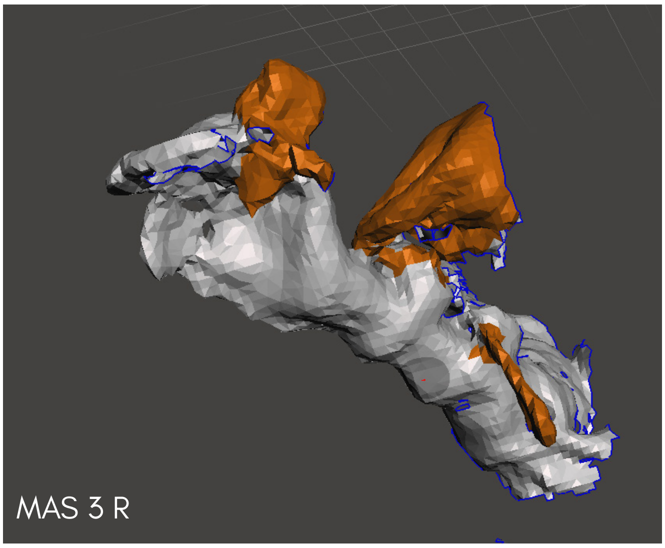

MAS 1+ R

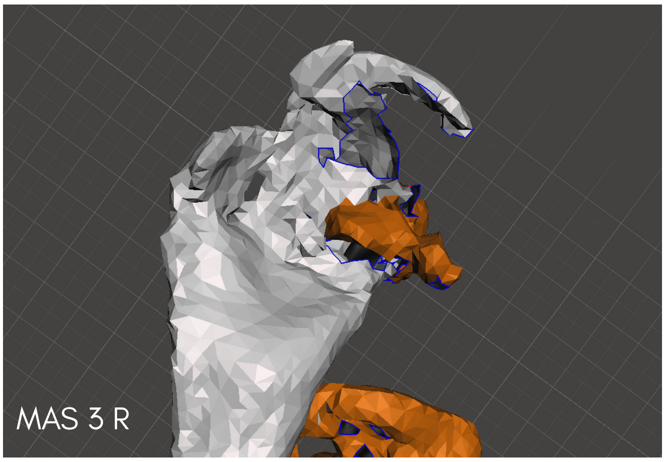

MAS 1+ L

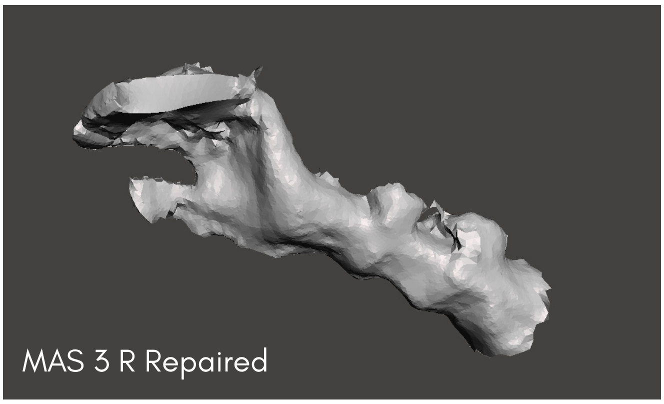


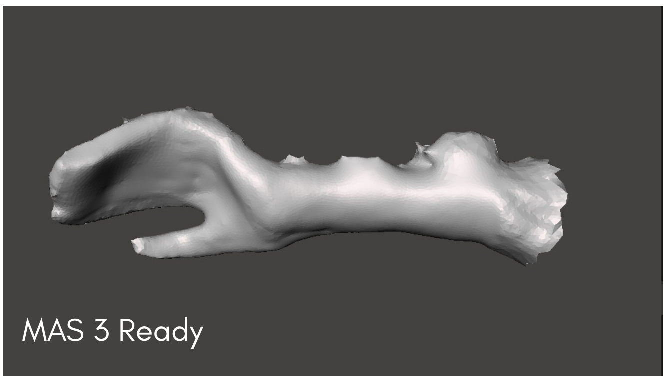





MAS 3 R


MAS 3 R


MAS 3 R Repaired


MAS 3 Ready

6.8 Evaluation

The research provided insight into the usage of the prototype. The patients ranged from MAS 1 to MAS 3 and showed characteristics that were expected in using the device in the context. 3D scans were made, modified into digital models and finally orthoses. The product is directly compared to the gypsum process and evaluated. This section will provide a final evaluation of the device on observations, a review with the orthopaedic technologist and the instrument maker.

Physical device
The physical device was able to keep the hands of the patients in an open position and allowed for the 3D scanning of five hands in total. The average time it took for all hands was 5:29 minutes. Taking into account it is the first time the device has been used over the standard method of applying gypsum, the time is competitive. More important is the scanning quality: the scans for both patients of the first session were usable to create a digital orthosis, as well as the three scans from the second session. The MAS 3 hand did need to be verified on size because of the lower amount of triangles.

The prototype withheld the forces of a MAS 3 hand, while also being usable with patients with smaller hands. The wrist joint bolt did slip in the pre-testing, but was quickly resolved.

The application of the device was also different between sessions: where at first the hand was placed through the bands and the wrist was connected first, now the handplate was connected first and the bands of the wrist were placed around afterwards. The securing of the joints of the device was similar: Firstly the wrist joint was slightly locked to limit movement, then the hand plate was set, with finally the wirst joint being completely secured. This was ideal, as the slight resistance created a more controlled movement of bringing the hand into position and holding it while further adjusting the device.

Orthopaedic technologist
From discussion with the orthopaedic technologist it was found that the velcro on the wrist was new, therefore difficult to peel apart. The main improvement points were for the handplate. The fingers should be more easily placable in the plate. The finger band could be attached differently.

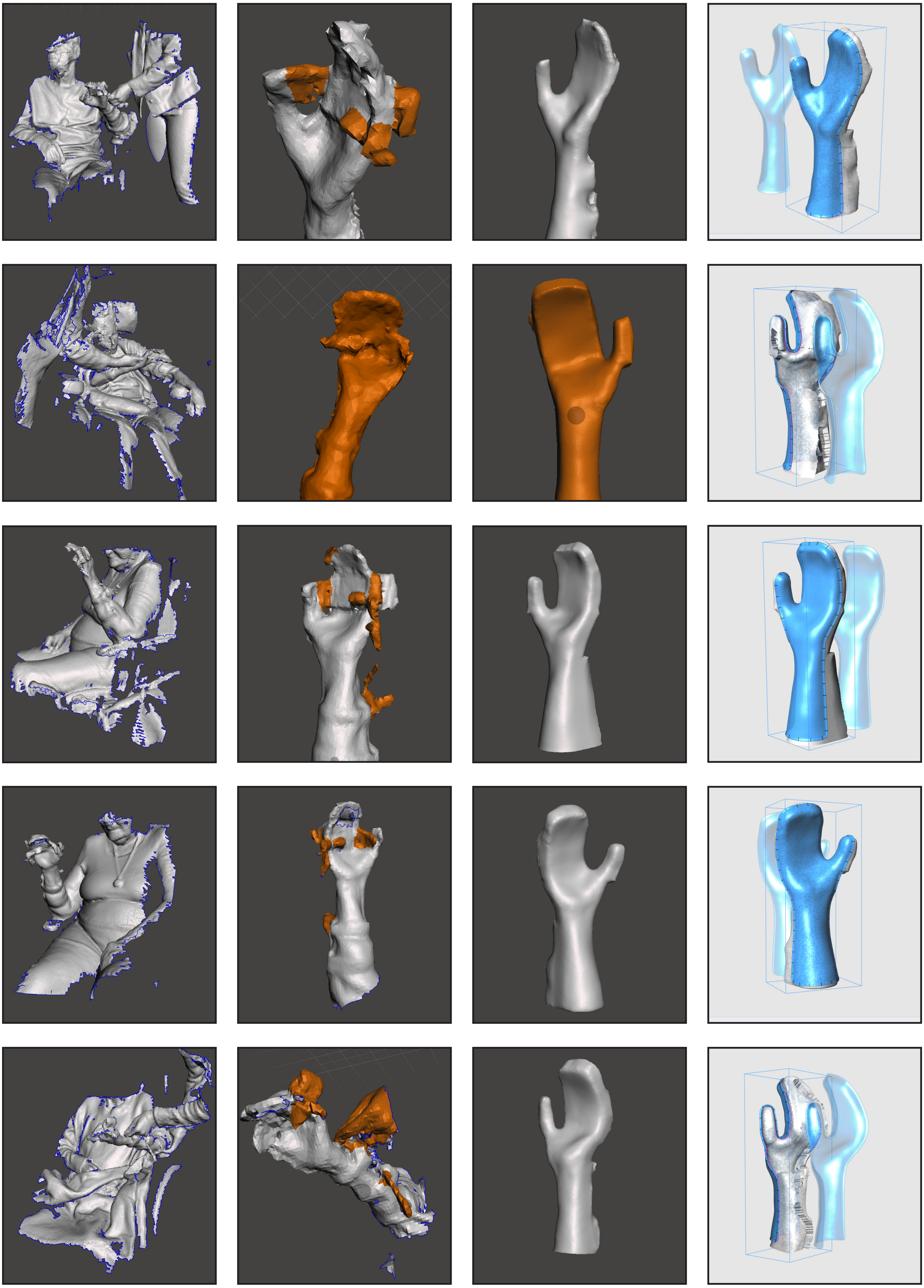
Also for the thumb there could be a way to guide it into place, or to use a slideable plate for different hands. One important point to look at is seen with patient 3: the thumb MCP was not in a correct position. Although it is a rarer variant of spasticity, having the thumb in a non optimal position could prove challenging to other patients.

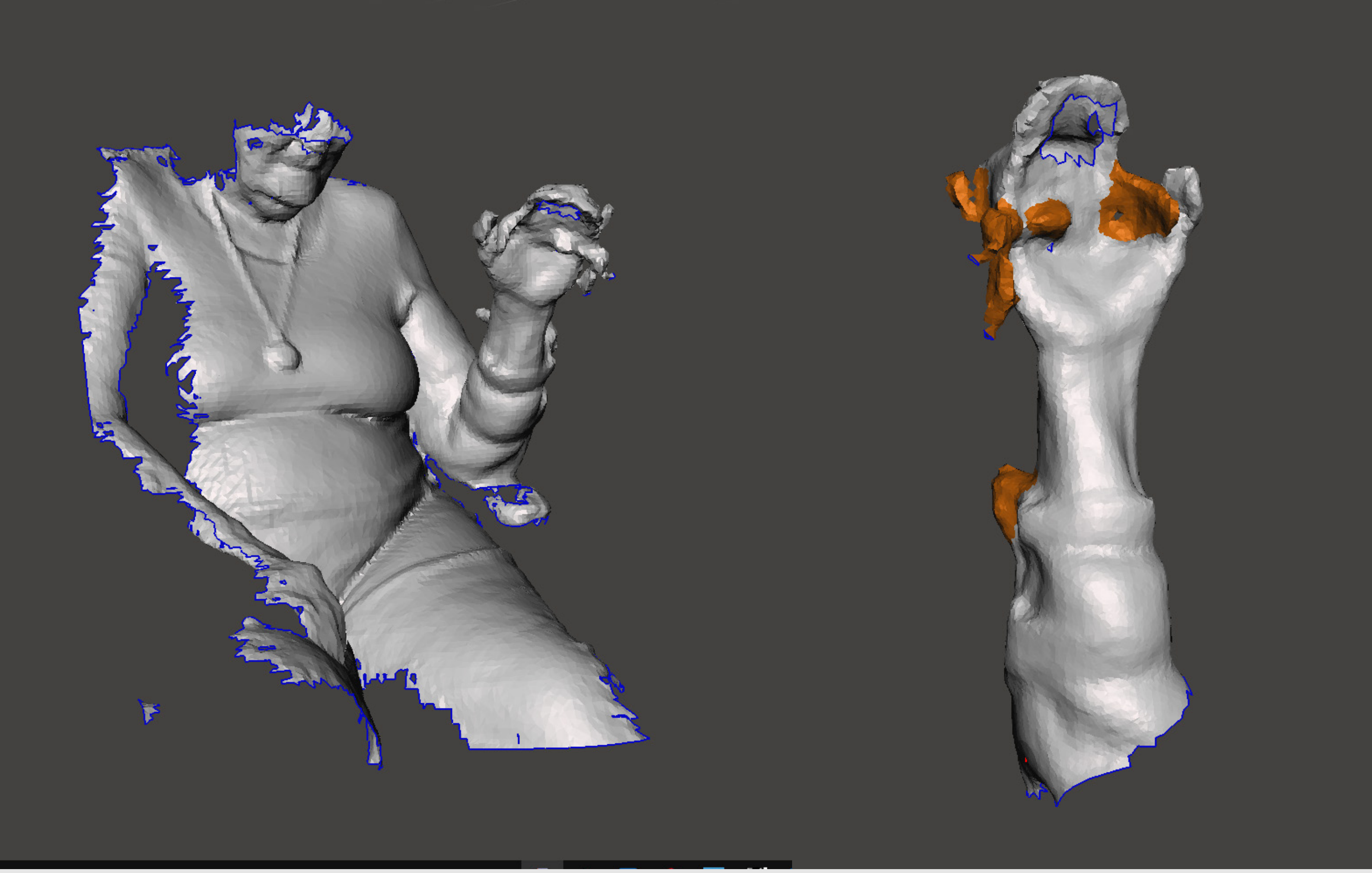
It should be further explored whether an orthosis (or in this case purely a night orthosis) is the right aid for a patient with Rheumatoid arthritis, or if silver splints could be used as well.

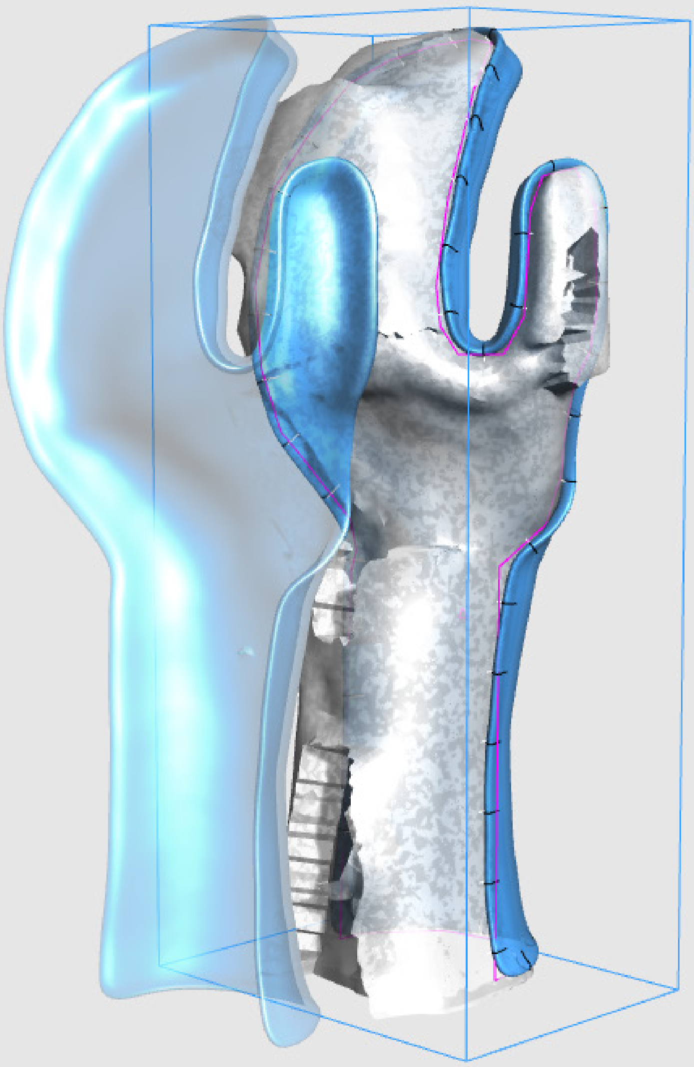
Instrument maker
The instrument maker did not experience direct hinder of the device, other than some extra cleaning. The wrist bands were well identifiable. The thumb plate could have more material removed to increase the webspace visibility.

The first session scans showed a large scanned area around the hand and needs cleaning. From the scans the prototype is clearly viewed and is removed. Due to the large scanning area, the detail in the hands was lower then when only scanning the hand itself. This could also be because of the type of scanner used. The visibility of the hand base, wrist circumference, fingers and thumb proved enough for the creation of an orthosis.

The second session had two out of three hands easily cleanable, with the third hand having difficulties because of the low amout of triangles in the scan. Similarly to the first session, this is more due to the 3D scanning than due to the prototype. At this stage, the cleaning takes most time in manual involvement in the process and could be a new point of interest. In the total time, the scanning process has less manual involvement than the gypsum process.







6.9 Conclusion

Two sessions of patient testing have been performed on spastic hands from MAS 1 to MAS 3 on both left and right handed spasticity. Varying patient conditions gave insight into the situation that the product is used.

In the first session, two patients with lighter spasticity were researched. The device created two scans that were used to create a digital orthosis. The second session consisted of three spastic hands, of which two hands had Rheumatoid arthritis. Placing the fingers onto the finger holder proved more difficult with this patient. Recommendations are made for another iteration.

The product and scans have been reviewed by the orthopaedic technologist and the instrument maker.
The product was found to be usable by the orthopaedic technologist and improvements for the finger holder and the velcro bands were suggested. The instrument maker did not experience hinder of the prototype when preparing the scan, other than extra time was needed for removing it. The thumb plate could have extra material removed to better show the thumb webspace in the scan. This would make identifying the thumb easier.

Chapter 7: Finalizing

Towards the design of a 3D scanning assist for spasticity

7.0 Introduction

This is the last chapter of the design where final improvements are made of the product. A showcase of the product is viewed, as well as a review of the previously made requirements is given. Furthermore, the product costs and a bill of materials are given and recommendations made for possible continuation of the project.

The chapter ends with a vision on the healthcare sector and orthopaedic industry, as well as a personal reflection on the project and learning goals.

7.1 Final product iteration

This is the final iteration of the product in this project. Using the feedback from the evaluation phase from both the 3D scanning and scan preparation several points have been improved and are discussed below Figures 94 and 95.

The main improvement is a new hand plate design. Where the old design consisted of a single piece, the new version has a separate thumb component. This is because some of the previous scans had the thumb commissure being merged with the top of the thumb plate. With the new design there is a separation, so in the scanner the partition is more clear, while some material has been removed on the top of the plate to allow for more room and a clearer image of the thumb commissure.

Another change is the use of a buckle for easier securing the band at the fingers. The band is now put through and secured more straightforward. To prevent discomfort from the metal, an extra layer of fabric is sown on the inside of the band with an overhang, completely covering the buckle on the side of the hand.

The ball joint was placed forward slightly to improve its range of motion, and in turn making it more comfortable to put on or off with the patient.

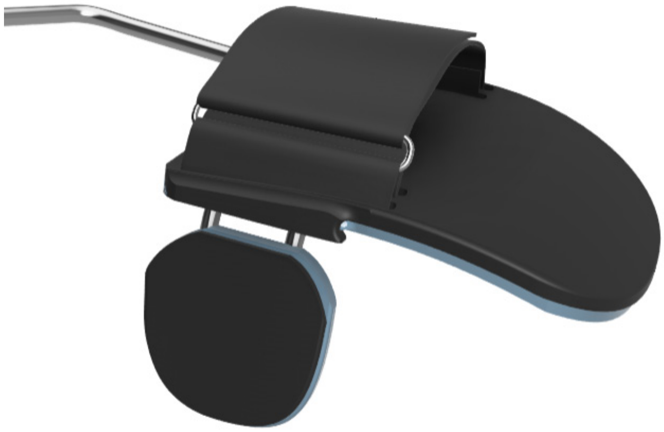
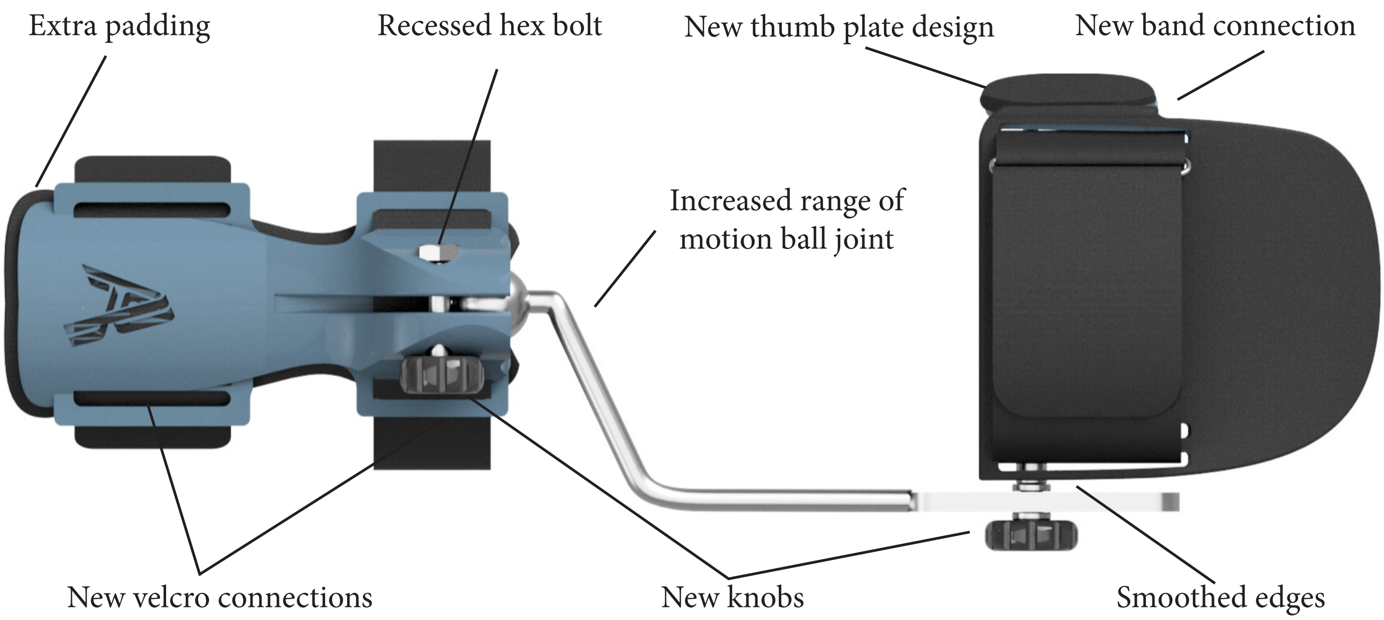


Figure 94: New hand plate design

Other changes include extra padding on the wrist to improve comfort, a recessed hex bolt so it prevents slipping, new turning knobs for better turning and more grip and general smoothing of remaining sharp edges.

The velcro connections have been remade to reduce the amount of pulling that is needed, now consisting of mainly soft velcro with a slight strip of the hooked velcro. The bands buckle on the opposite side of the knob to solve the problem of guiding band along the knob itself.

Figure 95: Design improvements



7.2 Costs

The product is going to be used by 14 orthopaedic technologists. Therefore 28 devices need to be made. A material cost breakdown is viewed below. The individual product material cost approximates 80 euros, with the custom SLS printed components comprising of 73% of the total cost. Due to the low product volume, 3D printing is better suited for these parts.If decided to print these components internally, these could reduce the final cost greatly. Another option is to contact the external printing company and to request a quote for printing multiple parts in a single batch and reduce handling costs.

A final option could be to digitally combine the parts, so when the quote is given, only the single handling costs are calculated. Also considered is the manufacturing time. This approximates 90 minutes for a single prototype including setup time. Successive manufacturing of multiple prototypes is estimated at half of the first prototype time due to the possibility of batch manufacturing and in turn reducing the need for equipment switching. With a minimum wage of €13.27 per hour in the Netherlands, this costs €19.90 for the first prototype and €9,96 for following prototypes. This creates a total cost price range between €90.37

Pcs	Name	Details	Price ex. VAT [€]	Price total	Source
1	Wrist component PA	SLS printed PA black	21.03 / pcs	21.03	
1	Hand plate PA	SLS printed PA black	19.33 / pcs	19.33	
1	Thumb plate PA	SLS printed PA black	18.03 / pcs	18.03	
2	Turning knob	M6 star brass tapped	2.32 / pcs	4.64	
1	Wristband 1 Velcro	25 x 350 mm	3.90 / mtr	1.37	
1	Wristband 2 Velcro	38 x 350 mm	1.60 / mtr	0.56	
1	Finger holder 1 Elastic	50 x 200 mm	6.50 / mtr	1.30	
1	Finger holder 2 Elastic	50 x 60 mm	6.50 / mtr	0.39	
1	Steel plate	16 x 70 x 3 mm	3.78 / pcs	3.78	
1	Steel rod	200 x d6 mm	2.07 / pcs	2.07	
1	Wrist padding foam	EVA Foam 3mm	7.85 / mtr	0.06	
1	Finger padding foam	EVA Foam 3mm 80cm2	7.85 / mtr	0.09	
1	Thumb padding foam	EVA Foam 3mm	7.85 / mtr	0.02	
1	Hex bolt	M6 x 60 mm Stainless steel	4.07 / 20 pcs	0.41	
1	Hex bolt	M6 x 40 mm Stainless steel	1.60 / 10 pcs	0.16	
3	Spacer	M6 Steel	1.32 / 100 pcs	0.04	
1	Steel hollow tube	40 x d8 steel	4.91 / mtr	0.20	
2	Steel thumb rod	40x d4 steel	2.07 / pcs	4.14	
1	Steel ball joint	20mm M6	2.00 / pcs	2.00	
1	Buckle	10x50 Stainless steel	3.14 / 4 pcs	0.79	
		Total material cost		**80.41**	
	Glueing & cutting		20 min		
	Band attachment		10 min		
	Slot milling		20 min		
	Welding		15 min		
	Threading		15 min		
	Final assembly		10 min		
		Total processing cost	**90 min**	**19.90**	

7.3 Requirements review

With the product ready, a final review of the requirements is given below. Alterations are highlighted in blue.

The product is a physical device that has been tested and found assisting in the creation of spasticity orthoses during the product evaluation and makes use of Artus3D's scanning technology. Therefore requirements 1-3 are fulfilled.

The product was able to create a usable mesh for the orthosis with the wrist, outline of the thumb, thumb base and pinky base having enough visibility and detail in the scan. According to the instrument maker, for all five scans the MCP and finger length were determinable, as well as the shape and detail of the lower arm.

Apart from RQ 4.3, the other sub-requirements of 4 have been fulfilled. As the meshing of the thumb to the plate is a recurring problem with the scanning technique itself (not enough accuracy), the aimed 95% visibility could have been too optimistic. Using a higher accuracy scanner would improve this. The instrument maker was however able to determine the thumb webspace and from there determine the commissure, so it was visible. Furthermore, the new handplate design shows opportunity to solve the situation, but still needs further testing before this requirement is fulfilled.

The product was found usable up to a MAS 3 of spastic hands and keep them in a steady position. It has proper finger ROM in the flexion and extension, wrist ROM in the flexion, extension and both ulnar and radial deviation. The thumb is able to move into a flexed position until being parallel to the fingers and has 30/10 degrees abduction/adduction of the finger height by placing the thumb higher or lower; in turn fulfilling requirement 5.

During testing one of the patients showed hyper-extension in the thumb MCP and altered the normal shape of the hand. Although it is something that occurs less frequently than the closed hand spasticity, it is a point of interest and is added in the recommendations.

Requirement 6 shows that adjustability was needed in all of the joints for optimal orthosis design. By taking a deeper look into the specific requirements for an orthosis, it was found that it does not use the DIP and PIP joints in the orthosis design and the shape of the fingers is assumed. Therefore those are removed from the requirement.

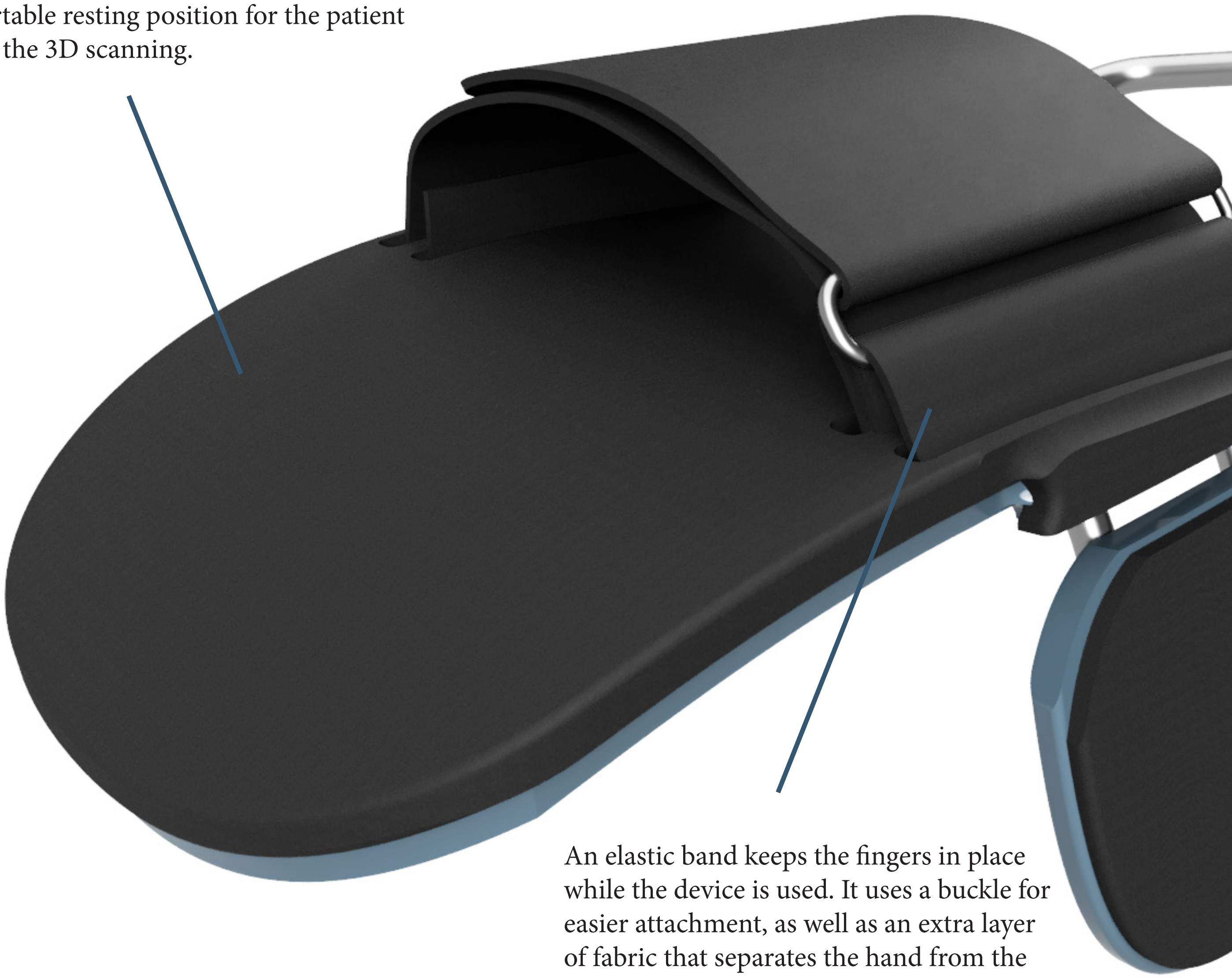
The scanning time of the orthosis averages around 5 minutes and is operable by two persons. It fits the orthopaedic context, is travelable, weighs only 230 grams per piece and has a volume of 34x16x10. It is usable by patients who cannot extend their arms fully (both horizontally and vertically) and is designed for the p5-p95 population. Therefore requirements 7 and 8 are fulfilled.

For the non-functional requirements, the product is designed for multiple uses and with spasticity in mind. By creating both a left and right handed prototype, the concept is usable for left and right hands, while still being usable in the context (RQ8).

Ch.	Requirement		Definition
3.1	RQ1		The solution consists of a physical product that assist the 3D scanning
3.1	RQ2		The outcome of the approach is a digital model for orthosis generation
1.2	RQ3		The solution makes use of Artus3D's 3D scanning technology
2.2	RQ4		The digital twin provides enough information to create a personalized orthosis:
2.8		RQ4.1	80% of the lower side and sides of the wrist definition visible
2.8		RQ4.2	95% of the detail in the outline of the thumb is visible
2.8		RQ4.3	80% of visibility in the thumb-index commissure (From: 95%)
2.8		RQ4.4	MCP knuckle width is determinable
2.8		RQ4.5	Total finger length (wrist to fingertip) is determinable
2.8		RQ4.6	90% visibility in the Thenar eminence (thumb base)
2.8		RQ4.7	90% visibility in the Hypothenar eminence (pinky base)
2.2		RQ4.8	At least 80% of the lower arm is visible
2.1	RQ5		The product is usable for spasticity on the Ashworth scale of 0-2
2.1		RQ5.1	The product keeps a hand with moderate muscle tone in a steady position
2.5		RQ5.2	The product allows total finger angle ROM from 0-90 degrees
2.5		RQ5.3	The product allows wrist flexion/extension ROM from 54-60 degrees
2.5		RQ5.4	The product allows wrist ulnar/radial deviation ROM from 40-17 degrees
2.12		RQ5.5	The product allows total thumb flexion parallel to the fingers
2.5		RQ5.6	The product allows total thumb abduction/adduction at 30/10 degrees
2.5	RQ6		The product has adjustability at the MCP, IP and wrist joints (PIP, DIP not required)
2.12	RQ7		The total setup and scanning time takes less than 30 minutes
2.11	RQ8		The product is applicable in the orthopaedic context
2.12		RQ8.1	The product fits in a volume of 40x40x40 (travel bag)
2.12		RQ8.2	The product does not weight more than 6 kg
2.12		RQ8.3	The product is operable by 1-2 persons
2.12		RQ8.4	The product is able to be attached within 5 minutes
2.11		RQ8.5	The product is operable when a patient sits in a wheelchair
2.11		RQ8.6	The product is operable when a patient cannot fully extend their arm outwards
2.11		RQ8.7	The product is operable when a patient cannot place their arm vertically
2.11	RQ9		The product fits for the 5th to 95th percentile of the elderly population
2.7	NFRQ1		The product is designed for multiple patients, not for single use
2.1	NFRQ2		The product is usable for both left and right handed spasticity
2.1	NFRQ3		The product is designed for continual spaticity, not spasms
2.13	NFRQ4		The product is comfortable to use to the patient
2.13	NFRQ5		The product uses foam or fabric on places where the product touches the patient’s skin
2.13	NFRQ6		The product should not heavily stretch the muscles to prevent discomfort for the patient

7.4 Showcase

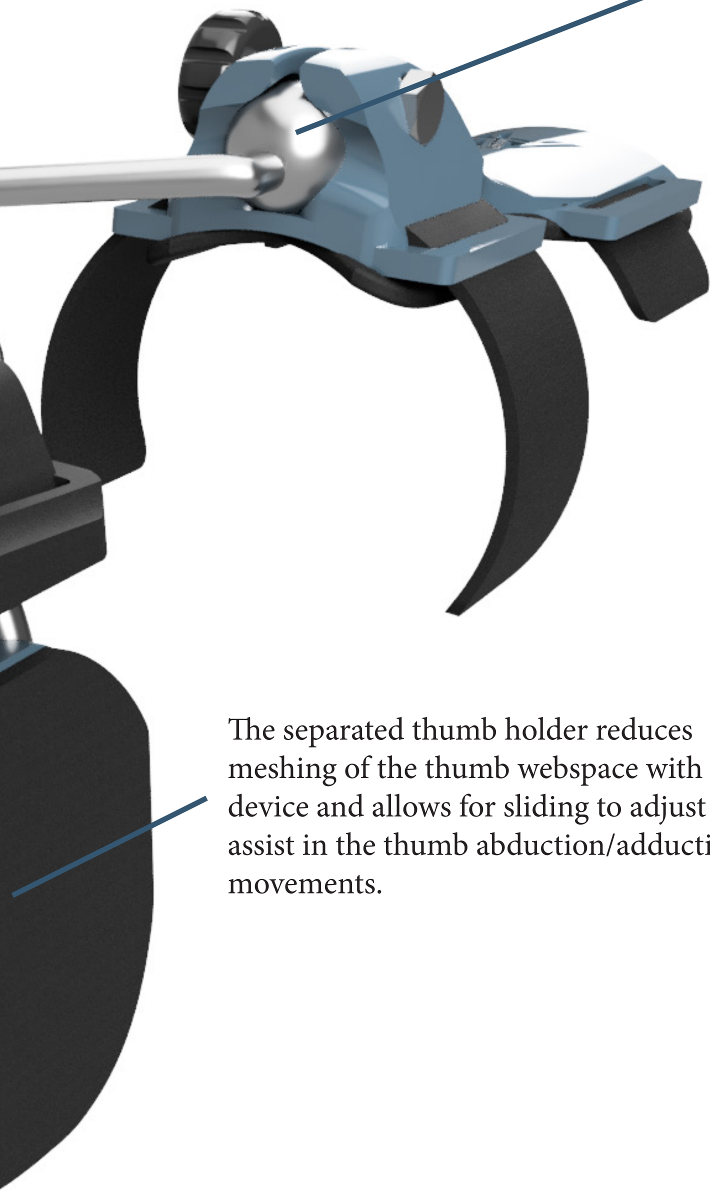
The finger plate is covered in foam and has a light curvature to place the fingers in a more comfortable resting position for the patient during the 3D scanning.



An elastic band keeps the fingers in place while the device is used. It uses a buckle for easier attachment, as well as an extra layer of fabric that separates the hand from the metal of the buckle.

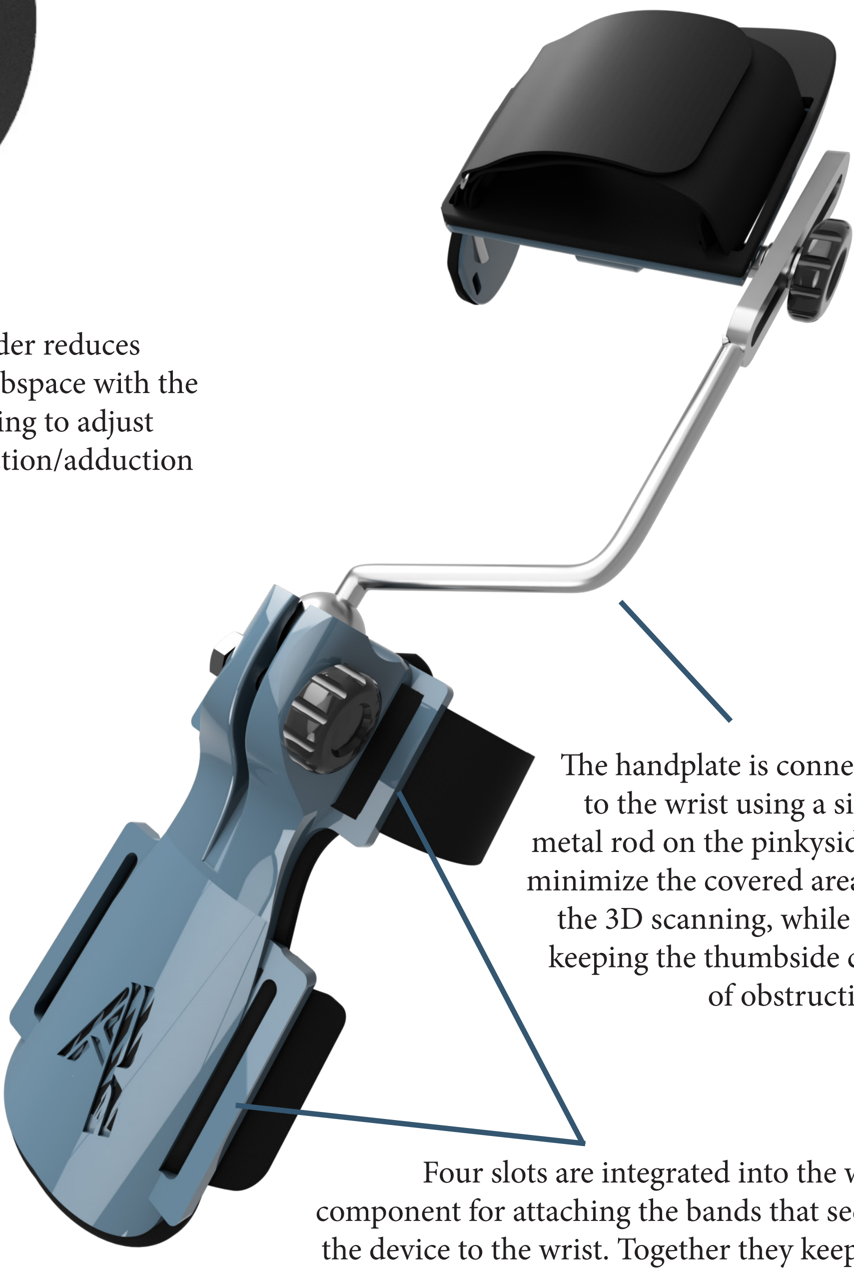
The product works by the use of a wrist attachment and a hand plate that together constrain the hand movements via two friction turning knobs. The product has been designed to minimize the amount of area that is covered for improving the scanning quality, while remaining comfortable to the patient and usable by the orthopaedic technologist. The separate thumb attachment prevents meshing in the scan so that for the instrument maker the components of the hand are well identifable.

The product weighs less than 250 grams and fits in a travel bag. It is usable up to MAS 3 spasticity and the scanning time & application takes five minutes in total. The three main components have been manufactured using SLS and are printed in Nylon, while the metal components are created from stainless steel. Together they create a product, with high strength and durability that is ready to be used in the orthopaedic context.



A ball joint is used to simulate the wrist movements, enabling full range of motion for keeping the wrist in the desired position. The joint is secured using a turning knob that tightens the housing, in turn locking the joint.

A turning knob and a slotted plate are used to adjust the handplate for variable hand length and finger angle.



The separated thumb holder reduces meshing of the thumb webspace with the device and allows for sliding to adjust assist in the thumb abduction/adduction movements.

The handplate is connected to the wrist using a single metal rod on the pinkyside to minimize the covered area for the 3D scanning, while also keeping the thumbside clear of obstructions.

Four slots are integrated into the wrist component for attaching the bands that secure the device to the wrist. Together they keep the wrist component in place, preventing rotation and improve hand stability.

7.5 Discussion

Currently being one of the few products specifically designed for scanning spastic hands in the orthopaedic context, it fills the need of Artus3D for keeping the hand in a scannable position and helps Centrum Orthopedie in creating the personalized care they want to deliver to their patients.

Desirability
This product opens up a new market segment for Artus3D on the design of personalized orthoses for spastic hands. It enables the use of 3D scanning & 3D printing in this segment and creates a higher level of automation in the orthosis manufacturing process of Centrum Orthopedie. The product is usable up to MAS 3 and covers the 5th to 95th percentile of the population.

For Centrum Orthopedie the product allows for better personalized care of the patients. The orthosis is customly designed to the patient's hand, creating a better fit, uses a more durable material, has easier cleaning of the orthosis and removes the invasiveness aspect from the gypsum application & moulding process with the patient. No gypsum is neccesary in the process anymore and there is no need to use a scalpel near the hand that could make the patient nervous. There is no need for consumable items like gypsum, gloves or foil and reduces the preparation time.

Currently, most manual involvement is found in the processing phase of the scan and is outside the scope of this project. Automating this process will further reduce the costs and is added as a recommendation. Furthermore, the project is an improvement on the orthosis generation process on efficiency, however it does not increase the amount revenue by selling more orthoses.

Feasibility
The product is used in the dynamic orthopaedic environment where the condition of the hands are often discovered on location. When travelling to the patients' care homes, the orthopaedic technologist needs a travelable solution. The assists for left and right handedness together weigh less than 500 grams and fit in a travel bag. It is operable by two persons and allows hand movements from 90 to -10 degrees flexion/ extension and both ulnar and radial deviation of 40 and 20 degrees respectively. The shape of the device has been designed to minimize its influence on the resulting scan and keeps clear of important scanning areas like the hand base, wrist, MCP, and thumb commissure. The two turning knobs allow it to move in various positions to hold the desired position for the hand.

One limiting factor for the project is that MCP hyper extension of the thumb is not accounted for. When comparing the assist to the commercially available product (as discussed in Chapter 1), it is seen that the product does include extra thumb support to counteract this. A whole separate exoskeleton mechanism with ball joints has been made for specifically keeping the thumb MCP into position. For a travelable solution, this is not ideal for implementation. A separate, external plate could be made that counteracts the movement, or it could be digitally modified into the right shape.

One recurring problem was the meshing in the resulting scan. When scanning the hand on itself there is enough detail, but when the environment around it is also scanned, the details of the hand become lower due to the bounding box in which the scan should fit and meshing occurs. The scanner that was used during testing was outdated and there are similar and newer versions already available. It is expected that these higher quality scanners will prevent the meshing.

Viability
The product fits in the workflow of Artus3D: moving from 3D scanning and scan preparation to orthosis generation and 3D printing. The cost of the product ranges between 100 and 180 euros per piece. With 2-5 spastic hands per week per location, its main advantage is the reduction of time in the manufacturing process, by removing most of the manual labour from the personalized orthoses from 2-3 hours to only 20 minutes of 3D model preparation. This is the new limiting factor due to its high cost in manual involvement, but is out of scope for this project. Recommendations on automating this process are made.

7.6 Recommendations

The product
On a product level, one final improvement could be made to the thumb plate in relation to hyper extension of the MCP. Although the symptom is less occuring, a specialized plate that is swappable with the current thumb plate could be used to keep the MCP in a more neutral position. In the design, the accuracy of the scanning and meshing should be taken into account in relation to the amount of extra material that is used for support. This way the scan quality is optimized. The use of a single three millimeter, round shaped rod could be used to minimize this material (Figure 96).

Another idea is to make the thumb plate slidable in the horizontal position for better positioning of the thumb in the adduction and abduction directions. A rotating lock with a cam could keep the metal pieces in place by rotating. The metal pieces should only be needed to extended to increase the range.

The system
On a system level improvements could be made by using a reference image for the instrument maker for easier identification of the key components in the scan. The processs of taking reference sizes that are currently used in the gypsum method are also recommended to be continued in the 3D scanning process for easier size validation.

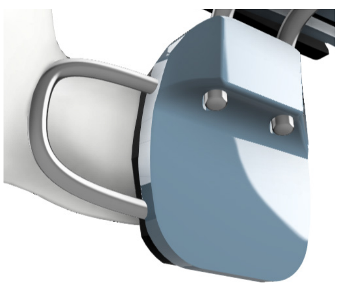
Model preparation
As of now, the 3D model preparation has the highest manual involvement in the process, taking around 20 minutes per orthosis. For Artus3D to improve efficiency, a way to reduce this time should become the next step. This could be achieved by a way of explaining the software what is the hand model and what is the product. Options include the use of color coding to identify and remove the product or for example the use of hand recognition software. As seen in chapter 3, Mediapipe was already able to recognize the hand and create skeleton points of the model. Bringing the idea one step further, a reference mesh could be merged to the current mesh and use the size of the hand.

Earlier detection
When the model preparation is automated, one would suggest to improve the device for more severe spastic hands of MAS 4 and 5. There will inevitably be challenges on the scanning of closed hands (due to the nature of the 3D scanning being performed on the outside of the hand) and the use of a gypsum imprint could be more effective. Then a combination of scanning and this imprint could be used to create a two-step orthosis. The imprint is scanned separately and placed into the hand model. It could have reference locations for correct placing and finally combining those meshes.

For now, it is recommended to invest in the earlier detection of spasticity in all care homes. This way the hands that are treated are still in a mild condition (MAS 1-3) and fits the use of the product better. As orthoses are regarded one of the less invasive methods, these could be preferred over other treatments like injecting botox or surgery. In turn this could increase the need for personalized orthoses and result in a higher amount of clients.

Starter pack
With the vision of Artus3D to further scale their software internationally, it might be wise to create a starter pack with their software including the 3D scanner and the scanning assists. This way it helps their customers and give them a starting point for measuring and treating their patients, while making the scanning quality more consistent. Although this is out of scope, it could be a point of interest that could be considered.

Figure 96: Hyper extension corrector plate



7.7 Vision on the orthopaedic sector

Health is of great importance to everyone and is not only the absence of illness, but the state of complete physical, mental and social well-being (World Health Organization: WHO, 2023).The World Health Organization states that every human has 'the right to attain the highest attainable standard of physical and mental health' (2023). And although the Netherlands is regarded to have one of best health care systems in the world (Ministerie van Volksgezondheid, Welzijn en Sport, 2023), improvements are still possible.

The healthcare sector today in 2024 is under high pressure due to the increasing elderly population, staff shortages and cutbacks from the government (Zorgdesq, 2021). There are long waiting lists (Ministerie van Volksgezondheid, Welzijn en Sport, 2023) and people worry if they could get the care they need or if it is still affordable (Ministerie van Algemene Zaken, 2022). After the privatization of the sector led to more competition between insurance companies to provide the best care for the lowest cost, it also created more administrative tasks for the healthcare personnel (Radboudumc, 2021).

Also in the orthopaedic sector, the consequences are visible. During conversations at the company, people explained that due to the insurance companies' best care for lowest cost practices, the craftsmanship for orthotic and prosthetic devices had to be reworked and more decisions were made on a financial level. Whereas first products were 'highest quality for highest care', now choices had to be financially justifiable based on its functionality or the insurance company would not reimburse the costs.

Currently there seems to be a dissonance between the WHO's statement of 'highest attainable care' and the 'best care for the lowest price'. With the all-or-nothing policy of the insurance companies for reimbursement there is now a gap where if people do want to have the highest care, they have to pay themselves. Treatments are chosen by the insurance companies and focus on what is minimally required.

If a patient already has the need for a prosthetic device, then that could have a large mental impact in itself. Why not go the extra mile and make the device look aesthetically pleasing to care for their mental health and their self-image? Mental health care should weigh more into the decision-making process. Instead it seems like the patient needs to get the care themselves and has to fight against policies and people whose aim it is to not spend money on non-functional attributes.

On a more positive side, the use of 3D printing technologies and 3D scanning is becoming more popular among the orthopaedic sector and allows for a way of creating personalized orthoses more easily and at a lower cost. With the options on hyper customization it creates a shift where the focus is on the patient again. Because the costs are expected to be similar between the competitors because of using a similar technology, there could be a surge where competitiveness will move towards a need for higher product quality and functionality in order for a company to stand out.

Health should not be about making money or getting financial gain from ill people, but to bring out the best in society and aid the people in need. There should be a way of having insurance that allows you to choose the treatment you need, instead of insurance companies choosing it for you. The basic costs could be covered and there should be the option of paying the extra costs yourself.

People should be reminded to also value the mental and social well-being aspects of health, other than focusing solely on the physical aspect. Instead of financially opposing the patients who are in a vulnerable position, help and guide them through the system. More attention should go to the well-being of the patient. If the orthopaedic sector has the knowledge and craftsmanship to make the highest quality of products that they and their patients desire, then why not support them?

7.8 Conclusion

This project entailed the design of an assistive device that keeps the hands of patients with spasticity in an open position using minimal material that could impact the accuracy of the 3D scanning, while focusing on usability and comfort in the orthopaedic context. The project was performed in a prototype-driven approach using various iterations that together created the path to a final product.

The final product design is able to be used with hands up to MAS 3 and is usable within the orthopaedic context. It consists of a wrist component that connects to a hand component via an articulating joint that holds itself in position. The hand component keeps the fingers and thumb stable while keeping the scanning quality on the hand base, MCP length, finger length, thumb outline and commisure.

With the use of this product, Artus3D is now able to expand the use of their scanning technology into the creation of personalized orthoses for hands with spasticity. It removes the need for using the traditional gypsum process and improves cleanliness, accuracy and faster creation time of the orthosis. In the evaluation phase it was found that for automation of the whole process, the preparing of the mesh is still performed manually and is an opportunity to further explore.

7.9 Personal reflection

Reflecting on the project

While looking back on the project, I realised there were multiple moments where I was searching and suddenly the solution became clear; leading to new ways of exploration and prototyping.

After the analysis it was found that none of the spastic hands were currently directly 3D scanned, while I initially assumed they already did some of them. They were actually made via a complex way of re-enacting the hand shape by finding a similar sized hand and scan that one. It changed the scope from improving an existing system more towards introducing a system to the segment of spastic hands.

Another moment was that of a point based system: 'Why design a physical product if you can alter the software around it using hand recognition and point based adaptability?' I still feel that on the long term it could work and reduce the manual labour in the cleaning process, as of now that takes up most time. For the short term, however, the idea of having a working product being used and opening up a new segment in the market is also a highly desirable solution.

I was surprised by the large effect of setting boundaries in the project, even when it seemed clear already: What is the core of the problem? Where do we focus on? By continually refocusing, it helped me make difficult decisions that have had great impact on the project. Some decisions were even altered when new information became clear.

One of those choices was the use of a hand plate over individual finger adjustment. This was linked to the desire on helping all severities of spastic hands (even up to MAS 5) and differences between fingers on some types of spasticity. When I made the decision to keep it on the hands that are able to be brought back to their original state, the need for individual finger control became less than the added complexity of using it. This made me rethink the idea to use a hand plate instead.

With the goal of making many prototypes & iterations during the project, I started exploring all possibilities. I intended to explore a variety of materials, shapes and interactions. It is often said that one should 'trust the process'; and that is exactly what I have done.

Starting the designing phase with a baseline prototype and multiple mechanical solutions, I quickly found out that complexity will not solve the problem. However, in following iterations I did want to add customizability for the different hand sizes, meaning those two were bound together. A way was needed to reduce complexity of the prototype and keep enough detail in the 3D scan.

This back and forth between complexity, functionality, interaction & scanning quality led to many iterations towards the final product. 'What works? What does not work?' Sometimes ideas were tested on paper, while others needed physical validation. It is nice to see that with every iteration the project pieced together.

Interestingly, I am beginning to understand the design decisions made for the earlier shown commercial hand scanner assist as seen in the beginning of the project. There the thumb is secured using two sliders, a ball joint and a whole external holding support. Most likely, they also had difficulty with the movements of the thumb. During the project I found out that the thumb is actually quite a specialized limb and that I have never really thought about that.

As of now, I am happy with the result, as from all five of the tested hands an orthosis was able to be made. The instrument maker did not find the assist hindering with the scan cleaning and had enough information for the creating. Broxterman explained that the product is going to be used for the 3D scanning and that the focus now is on the cleaning of the scan, something I see as quite an achievement in itself.

Reflection on my learning process

My initial learning goals for this project were to introduce myself to the orthopaedic field, apply the knowledge I acquired during my studies at Industrial Design Engineering at the TU Delft and to learn to design with a positive impact on patients.

During the project I came into contact with many people with experience in the field, as well as during the patient visits with the orthopaedic technologists, ergotherapists, physiotherapists and caregivers. They introduced me to the ways of how patients are treated, what elements are important to look at and how the spasticity behaves. For me it also was a way to see behind the scenes and view how the system operates.

In the weekly visits at the company I learned from the instrument maker and my company coach, where I conversed on many topics, from manufacturing and processing to logistics and collaboration visits. I got acquinted with SLS and SLA printing and used more FDM printing. There I used a range of materials from PLA to Nylon and from TPU to UV resin.

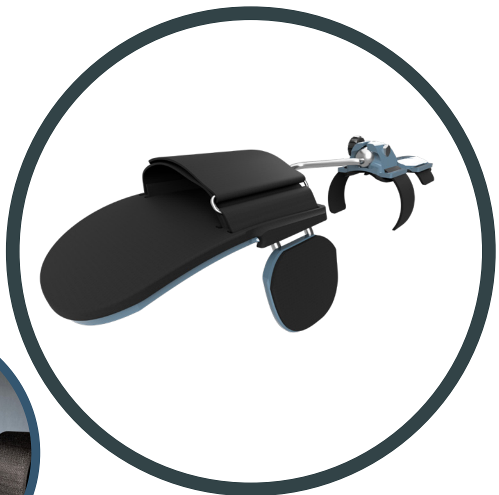
During the project I wanted to design iteratively using many prototypes. I gained experience in CAD design, Rhino & Grasshopper, Mediapipe, Python and InDesign. I never thought I would use a needle and thread for sewing prototypes, let alone learning to use an industrial sewing machine at the company. At Delft I also used a milling machine for creating the slots in the metal strips, as well as gaining some experience in MIG welding.

What surprised me most during the patient visits was that there was a relatively short time to give the patients the care they need. Even while there was a high drive to help the patients, the personal connection was only given within that timeframe, before having to move on to the next patient. I assume that it is due to the high working pressure in the healthcare.

With the privatisation of the healthcare sector, the insurance companies only pay for the lowest amount of care that a patient really is required in order to create competitiveness in the field and lower the prices. From stories with the employees I learned that it caused a change in the craftsmanship and quality that they could deliver. To me it felt like a disconnect between economical efficiency and the care one would ideally like to give or be given. Why would people want to make a profit on the ill? And why have most people just accepted it the way it is?

On the brighter side, at the company I also got the opportunity to create my own silver ring. There I carved my design in wax, which is used to create a negative version in gypsum to create a casting tree. The mould was preheated in a large oven, as well as melting the silver in another oven. Finally the silver was cast and a blowtorch was used to burn off the oxygen and prevent oxidation.

In the end I feel like I learned many things, of which some I would have never guessed beforehand. I experienced many manufacturing processes, materials and even got the opportunity to cast my own silver ring. Moving through a design process is almost like opening a present, surprising you each and every time with the outcome. It is what makes it so interesting to me and is what I want to continue to do in the future.



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Appendix A: Project brief

Personal Project Brief – IDE Master Graduation Project

[redacted]

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT
Complete all fields, keep information clear, specific and concise

Project title Design of a product-system for patients with upper limb spasticity

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

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

Worldwide, there are over 12 million patients affected by spasticity, including 80% of Multiple Sclerosis patients (MS) and 80% of patients with Cerebral Palsy (CP) [1]. Spasticity is a symptom caused by a range of conditions that affect the neural pathways and brain (e.g. spinal cord injury or brain injury). For the patients it leads to constant stiff or contracted muscles in the affected limbs. While it could happen with any muscle, it is often found in the flexor muscles of the upper limb (arm) or extensor muscles of the leg [2]. This project will focus on the upper limb: the forearm, hand, fingers and thumb.

Although there is currently no cure for spasticity, there is a variety of treatments aimed at preventing it from getting worse: using therapy, excercise, splinting and surgery to cut the tendons and release tension [3]. This project is aimed at the orthosis intervention stage, where bringing the hand in a (semi-) neutral position using an orthosis stretches the muscles and prevents side-effects of a spastic clenched fist. These include preventing the nails pressing into the hand leading to pain and infections, accumulation of dirt within the hand and to help with daily tasks like putting on clothes.

Currently these orthoses are made using a long process of creating a model of the patient's hand: using gypsum to make a negative mould, remanufacturing it to create a positive mould, creating an orthosis around it. This is where Artus3D comes in. Artus3D is a company that is collaborating with Centrum Orthopedie and uses 3D scanning technology & automated parametric design software to instantly create a perfect-fit orthoses from a 3D scan of the hand with accurate dimensions. This improves quality while reducing cost and complexity in the process. The challenge lies in that hands with spasticity are difficult to scan due to their closed position, and there are limited (generic) devices available that could assist with scanning. Therefore the goal is to design a product-system that assists in the scanning of the spasticity patient's forearm and hand, in addition to a software that creates a usable digital 3D representative model to design the final parametric orthosis on.

[1] https://www.hopkinsmedicine.org/health/conditions-and-diseases/spasticity
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4229996/
[3] https://my.clevelandclinic.org/health/symptoms/14346-spasticity

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introduction (continued): space for images

image / figure 1 Hand scanning / parametric software design / Lower arm spasticity (clenched fist)

image / figure 2 Hand positioning device / scanning support devices developed in research setting (non adjustable in use)

DESIGN FOR our future TUDelft

Personal Project Brief – IDE Master Graduation Project

Problem Definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.
(max 200 words)

Currently, most 3D scanning assists do not take into account the patient situation, whether they are bedbound, in a hospital or the severity of spasticity. Because of this, some devices put the patient in an impossible position: expecting a full arm stretch for scanning of the hand, leading to discomfort, while there could be spasticity in the shoulder as well (figure 2.1).
For the physiotherapist, the current method for gypsum moulding is time & resource intensive. Therefore 3D scanning could provide a solution. In the current market however, the scanning assists are still being researched (figure 2.2, 2.3) or are for general purpose stability (figure 2.1). These are either difficult to use or too heavy to bring along in patient visists (figure 2.1); or non-adjustable while in use (figure 2.2).
For the orthosis designer, it is preferred to have as much scanning area as possible to improve the scanning quality and to reduce the amount of cleaning for the digital model. On the other hand, the patient has a benefit with more supporting surfaces, as it means less localized pressure and thus higher comfort. A tradeoff is needed.
Therefore, the scope of this project aims to iteratively develop towards a product-system and prototype that improves the scanning quality, adjustability and experiences for the patient, physiotherapist and orthosis designer. On the larger scale, it should increase efficiency in the complete process: Reduced waiting times, fewer appointments, costs and perhaps enable to intervene sooner; preventing the spasticity to worsen during the production weeks. It will be tested against the current methods & system, before a final evaluation and recommendations are given for further development within the company.

Assignment

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

Design of a new approach in the orthopaedic setting, consisting of a prototype product that assists in the 3D scanning of the forearm and hands of patients with spasticity to improve the scanning quality and adjustability when in use, in addition to software that creates a usable digital representation out of the scan for manufacturing personalized orthoses.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

This project uses a practical and iterative approach with the use of sketching, patient journeymapping, prototyping, product evaluations, interviews and testing. The setup will make use of a combination of the expanding and converging means of the Double Diamond method and components of the scrum methodology for task division are used.

The initial weeks will have literature research being performed and design guidelines & requirements set, creating an overview of the context. Stakeholder interviews are performed and boundaries are set. Then the iterative approach will take place, while the product and software will be periodically evaluated by experts and patients. Also, when the project allows it, the product will be tested in a physiotherapist setting with real patients.

The final prototype will be evaluated and recommendations for future product development by the company are advised.

Project planning and key moments

*To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a **kick-off meeting**, **mid-term evaluation meeting**, **green light meeting** and **graduation ceremony**. 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 course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	6 Nov 2023
Mid-term evaluation	16 jan 2024
Green light meeting	14 Mar 2024
Graduation ceremony	19 Apr 2024

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	
For how many project weeks	
Number of project days per week	

Comments:

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).

Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.
(200 words max)

Since I was a child, I have been interested in movements and building things. From self-winding grandfather clocks at 14 years old to mechanical moon calendars and sustainable hurdy gurdies. During my minor in Advanced Prototyping I learned about 3D printing, scanning, CAD & CAM; it opened up near infinite new possibilities. To better direct my focus to what I want to do in the world, I started Integrated Product Design with a specialisation in Medisign. I enjoy the idea of helping people, and what better way to do it in the medical field. I got acquainted with orthopedics and now I am learning about the intricacies and movements of the human hand.

In this project I want to prove my design & prototyping skills I learned during my time at the TU Delft. I want to introduce myself to the orthopedic field; and to develop my knowledge on physiotherapy. I want to learn how to design for a positive impact on the patient; especially in a condition like spasticity, which it is non-curable. The product to be designed will be relatively new and specific to patients with spasticity. It would be great if it could have a positive influence towards them and that it will help guide towards future product development in this type of products.