Development of a 3D Printed Patient-Specific Orthosis for Wrist Immobilization in Long-Term Use

By

Jeeyong Chung

in partial fulfillment of the requirements for the degree of

Master of Science
in Mechanical Engineering

at the Delft University of Technology,

Supervisor:	Dr. ir. Gerwin Smit	TU Delft
Daily Supervisor:	Ir. Yff Verstraeten,	Manometric B.V.
	Ir. Vincent Laagland	Manometric B.V.
Committee Member:	Dr. Jie Zhou	TU Delft

Abstract

Background: Wrist immobilization orthosis is a commonly adopted treatment method for wrist regarding pathologies. In recent years, a group of 3D-printed immobilization orthosis for the upper extremity has been proposed. However, they were mainly developed as substitutes for traditional casts for the upper extremity for short-term usage. There has been no definite attempt to design 3D-printed orthosis to immobilize the upper extremity used as an assistive device for long-term usage.

Objective: Develop a patient-specific orthosis for wrist immobilization in long-term usage, which has suitable functionality, the comfort of wearing, and an efficient fabrication process by exploiting the benefits of Additive Manufacturing technology.

Methods: Structure concepts were generated by modes of donning and doffing and evaluated with criteria. The prototype was assessed together with an orthopedic technician. For the next, the prototype was validated with actual patients who were suffering from degenerative wrist pathologies. The subjects wore their wrist immobilization orthosis for two months and were asked about their experiences.

Results: In total, eleven wrist immobilization orthosis prototypes were validated with five subjects (two males and three females) suffering from degenerative wrist pathologies (Rheumatoid Arthritis: one subject, Osteoarthritis: three subjects, and Ehlers-Danlos syndrome: one subject). 45 % of prototypes provided excessive pressure on bony prominences. Around 55 % of prototypes caused unacceptable pain at distal palmar creases. Specifically, the movement of putting it on and off brought complications for 91 % of all prototypes. For three subjects who could use their orthoses for two months, the orthoses functioned well, decreasing pains in the wrist while having daily activities.

Conclusion: First, the structure of the wrist immobilization orthosis was well-designed, performing proper support during activities of daily living. Second, the comfort evaluation was conditionally positive; due to the rigid hardness of the material, two out of eleven orthoses were too painful to wear for the further test. Since the morphology of bony eminences and the amount of the cutaneous fats around those areas are dissimilar for all people, it was hard to design pain-zero orthosis for two subjects. Lastly, SLS printing with PA12 material offered apparent advantages over traditional fabrication methods. All works were conducted digitally from the scanning to fabrication, and there was no waste of materials. Despite six working days of delivery time from the outsourcing company, the orthosis did not require any labor-intensive procedures.

Acknowledgments

Throughout the writing of this thesis, I have received a great deal of support and assistance.

First, I would like to express my appreciation for Manometric. Thanks to them, I was able to enjoy this wonderful opportunity. This project let me have much multidisciplinary knowledge and meet the best people I know. It was my honor to work with them.
Second, I would like to thank Dr. ir. Gerwin Smit for agreeing to supervise my work and for all the discussions, guidance, and proofreading.
Moreover, I would like to thank Dr. Jie Zhou for agreeing to be one of the committee members and proofreading.
Lastly, I would like to thank my wife, Yeseul Kim, for having an incredible journey of a lifetime with me.

I hope this report succeeds in sharing my work and makes it an exciting read.

Jeeyong Chung
Delft, August 2021

List of Acronyms

ABS: Acrylonitrile Butadiene Styrene
ADL: Activities of Daily Living
AM: Additive Manufacturing
CTS: Carpal tunnel syndrome
EDS: Ehlers-Danlos syndrome
FDM: Fused Deposition Modeling
LTT: Low-temperature thermoplastic
MCS: Mold casting splinting
MJF: Multi Jet Fusion
OA: Osteoarthritis
PA: Polyamide
PLA: Poly-lactic Acid
RA: Rheumatoid Arthritis
SLA: Stereolithography
SLS: Selective Laser Sintering
UE: Upper Extremity

Table of Contents

1. Introduction

1.1. Anatomy and Mechanics of the Human Wrist Joint

The wrist joint is a stable link from the forearm to the parts of the hand that move sophisticatedly with small bones and ligaments. It is a complex of three joints; the radioulnar, the radiocarpal, and the mediocarpal joints with a group of nerves, blood vessels, flexors, extensors, and soft tissues (Figure 1) [1]. Since the median, ulnar, and radial nerves run superficially at the wrist, they are vulnerable to injuries that can potentially develop into traumatic neuropathy and neuromas [2].

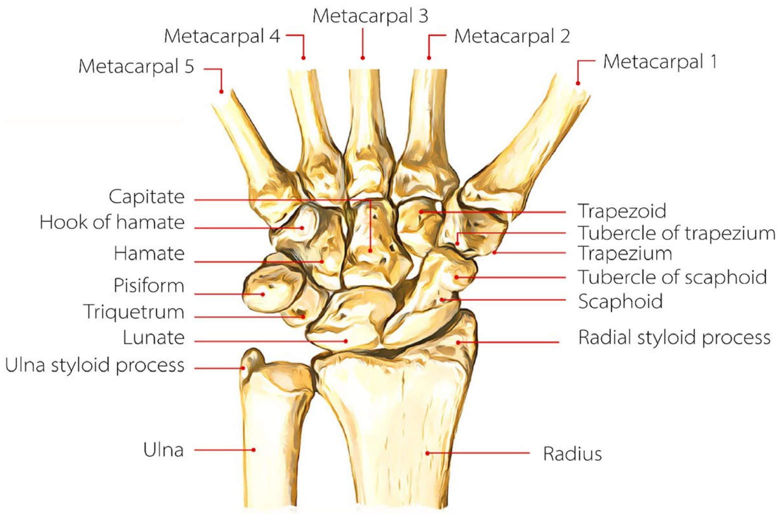


Figure 1 Structure of bones around the wrist [3]. The four carpal bones (the hamate, the capitate, the trapezoid, and the trapezium) in a row meet the metacarpal bones making up the palm. Metacarpal 1 is a part of the thumb. Another row of the carpal bones (the pisiform, the triquetrum, the lunate, and the scaphoid) meets the wrist's forearm side, which consists of the ulna and the radius.

Associated with the bones and ligaments, the wrist joint performs six significant movements. The first set of motions are flexion and extension; the flexion is called volar or palmar flexion, while the extension is called dorsal flexion. These two motions rotate the hand to the wrist joint in the sagittal plane consisting of the flexion and the extension. The next set of motions are deviation; the radial deviation and the ulnar deviation rotate the hand in the frontal plane to the wrist joint. The last set of motions are pronation and supination in the transverse plane [4]. Although there is no direct engagement of the wrist in transverse motions, the hand rotates to the forearm axis (Figure 2). In daily living, these motions combine and cooperate in carrying out ordinary activities, such as holding a cup of water, turning on a faucet, lifting a grocery bag from the floor, etc.

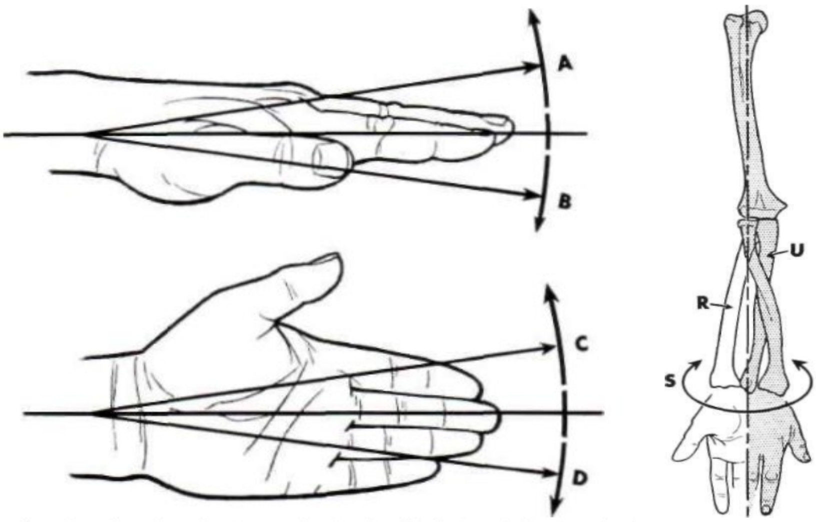


Figure 2 Motions of the wrist. A: Extension, B: Flexion, C: Radial Deviation, D: Ulnar Deviation, P: Pronation, S: Supination. R stands for the radius and U for the ulna[5]

1.2. Degenerative Pathologies on the Wrist

When the wrist's common mechanism gets injured, it causes weakness, stiffness, chronic discomfort, and often arthritis. Without proper treatment, it develops into notorious wrist pathologies regarding the wrist, such as Arthropathy, Rheumatic Arthritis (RA), Osteoarthritis (OA), Carpal Fractures, Distal Radius Fractures, Carpal Ligament Instability, De Quervain Tenosynovitis, Carpal tunnel syndrome (CTS), Dupuytren's disease, Intersection Syndrome, or else [2]. An orthotic device is required for rehabilitation or treatment depending on the severity of a patient's symptoms [6–8].

Osteoarthritis is one of the ten most disabling illnesses in developed countries and worldwide, 9.6% of men and 18.0% of women aged over 60 suffer from Osteoarthritis [9]. It is a degenerative joint disease that negatively affects the quality of a patient's life. Another chronic degenerative joint disease, Rheumatoid arthritis (RA), affects 0.3% - 1.0% of the world population with a higher presence in females [10]. Complications reported from arthritis patients were a high level of pain, stiffness of joint movements, Osteophytes, weakening of the muscle, restricted passive range of motion, and limitation on daily activities [11], [12]. The number of adults with doctor-diagnosed arthritis in the United States has been progressively increasing. The number is projected to be 72 million in 2030 and 78.4 million in 2040 [13], [14]. Thus, arthritis will be a burden to public health systems and it is demanding to prepare good solutions beforehand to accommodate these increases [14].

Management and treatment of the pathologies can be varied depending on the severity of a patient's condition. Non-surgical options, such as activity modification, immobilizing orthotic management, medications, exercise, or injection of steroids can be prescribed [15]. On the other hand, there are surgical options to offer pain release while keeping strength and dexterity if possible. Proximal row carpectomy, fusion, arthroplasty can be an option for surgical treatment; however, it could cause more loads on other joints and may end up with arthritis on nearby joints [16]. Since surgical treatments are recommended if non-surgical options failed to relieve pain, providing comfortable immobilization orthosis is important to let patients maintain their medical conditions [17], [18].

1.3. Traditional Wrist Immobilization Orthosis

Whether the trauma is acute, chronic, or degenerative, it is conventional to prescribe orthotic devices for patients, regarded as a "traditional benchmark treatment option" [19]. Its primary purpose is to assist weak muscles, block joint motion, mitigate pain or swelling of joints, and avoid joint positions that trigger undesirable pressure of the nerves, skin, and other soft tissues [20]. This traditional orthotic device has verified its clinical effectiveness in large longitudinal clinical trials [17], [21], [22].

There are principally four different types of immobilization orthosis for the wrist. The first one is called low-temperature thermoplastic (LTT) orthosis (Figure 3). As the name describes, LTT orthosis is made of LTT sheets. A practitioner puts LTT sheets on the patient's limb and forms the shape along the limb by heating the material. LTT orthosis has still been one of the best options for arthritis patients.

Figure 3 LTT wrist orthosis with Velcro straps (Left) and manufactured with LTT Sheet (Right)[23]

The second is Mold Casting Splinting (MCS). As also deduced from the name, MCS orthosis fabrication starts with casting a mold of the patient's limb. With the replicated cast model, pre-heated thermoplastic sheets are laid on the cast [24]. It is the same type of brace as LTT orthosis. These two devices have been prescribed for decades, but patients have criticized them both for their drawbacks.

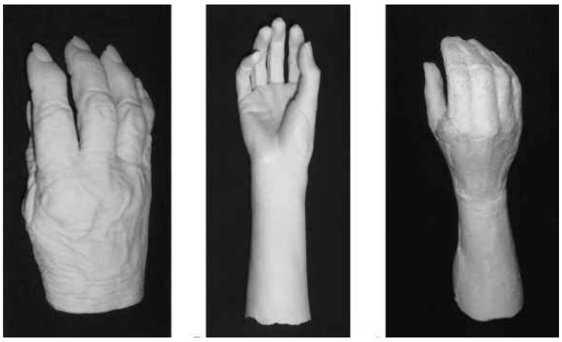


Figure 4 Positive molds of the hands and wrists to make MCS orthosis [25]. The outcome of this process is basically the same as LTT orthosis in Figure 3

Figure 5 Cast on the upper extremity (UE) to immobilize the wrist joint [26].

The third is plaster cast that has been frequently adopted by expertise (Figure 5). It is a great treatment method that provides well-distributed pressure and mild tissue contractures with enough immobilization [8]. However, a variety of inconveniences are already well-known. The cast is environmentally problematic, hardly washable, often allergic, unhygienic, impossible to observe the corresponding lesion visually, and bulky [27]. Due to its over-constrained structure, it is not appropriate to be adopted as a long-term treatment device. Therefore, casts have been indicated to recover temporal injuries, such as fractures or postoperative treatment for about ten weeks [8], [27].


Figure 6 Pre-fabricated wrist orthosis with enhanced FE-motion impedance [28].

The fourth and last method is pre-fabricated braces that are another commonly adopted treatment method (Figure 6). These 'off the shelf' orthoses are usually made in standardized sizes, such as small, medium, and large. Therefore, they hardly provide proper fitting and eventually resulted in being impractical [29].

Over the years, it has been reported that traditional wrist orthoses do not fit the needs of patients due to the following issues: sweat and odor, difficulties of cleaning them, deprived aesthetic value, difficult closures to use, bad fitting, and substantial physical disturbances, the cumbersome experience of donning and doffing weight complications, and damages on the functional abilities [30]. Pyatt et al. [30] conducted design research with RA patients who wore wrist braces to treat these issues. According to the article's conclusion, the prime undesirable feature of wearing splints was related to practical issues, including wrong fitting, pressure points, contamination, and too many restrictions. 'Negative social reactions' was the second most eminent aspect, affected by the splints' unpleasant appearance.

These orthoses not only frequently cause cutaneous issues; however, patients that wear these devices often express social discomfort and self-consciousness due to the unappealing device design. In conclusion, traditional orthotic devices are uncomfortable to the patients due to the problems discussed above [31]. For long-term users, this is not just a problematic social situation. From their review paper about the long-term wearing of immobilization splints, Andringa et al. [17] mentioned that a significant number of stroke patients complained about the discomfort of the wrist brace. They were unable to tolerate the orthosis for the prescribed hours per day, and that intolerance led the patients' medical condition to deteriorate. Therefore, the wrist orthosis's comfortableness and proper functioning are fundamental requirements for the long-term use of wrist orthosis.

1.4. Wrist Immobilization Orthosis with AM Technology

Even though the design requirements of the wrist orthosis have reached a certain degree of agreement, the traditional wrist orthotic products have fallen short of satisfying the patients in need of long-term treatment [17], [21], [32]. In the meantime, 3D printing technology advanced so rapidly that people believe the Additive Manufacturing (AM) technology could be a solution for fabricating orthopedic products. Thanks to its layer-by-layer stacking principle, AM almost does not have restrictions on geometrical complexity. Besides, the cost of manufacturing has been decreasing continuously over time. Accordingly, there have been many attempts to fabricate immobilization orthoses with AM technology. Kelly et al. [33] summarized AM wrist orthoses according to the 3D printing technology. The analysis concluded that more extensive adherence and better ventilation of the wrist orthosis are the improvements achieved by AM technology. Moreover, the examples pointed out that they needed fasteners for donning and doffing, better aesthetics, and clinician input. Although this review of wrist splint designs for AM has been referred from several succeeding papers, there was no improvement in the design requirements of wrist orthosis.

Blaya et al. [34] also addressed that 3D printed immobilization orthosis can have the following improvements; 1) water resistance, entailing better hygiene, 2) cost reduction, 3) capability of using sustainable and biocompatible materials, 4) lightness, and 5) superior aesthetics.

Figure 7 Representative examples of 3D printed wrist immobilization orthosis by Paterson, A. M. et al. [35] (Left), and Yan et al. [36] (Right). Although both orthoses were innovative in terms of fabrication and appearance, there was no consideration for usability for long-time series.

Through the literature study carried out in advance, 31 state-of-the-art orthoses were found from 35 articles (See Appendix A). A study done by Paterson, A.M. et al. in Figure 7 is a representative example [35]. They designed several wrist immobilization orthoses with different materials and patterns. They even made various concepts of closures. Although the study aimed at wrist orthosis for RA patients, who need immobilization devices for indefinite usage, the study never put their considerations on long-term comfortable wear. They mainly focused on developing automated modeling software to let medical practitioners generate custom orthoses on site.

Another example is a topology optimized 3D printed wrist immobilization orthosis by Yan et al. as shown in Figure 7 [36]. The study aimed at an orthotic solution for distal radius fracture treatment, requiring less than ten weeks recovery duration. The orthosis was designed to have the same level of mechanical strength as an ordinary cast but less material. Nevertheless, similar to other studies previously conducted, there were no further considerations regarding long-term usage.

1.5. Problem Definition

Recent design studies on UE immobilization orthosis with AM technology primarily focused on UE pathologies that entail a short-term treatment. Moreover, they did not take necessary design requirements into account but only showed AM technology's freshness by mimicking the old shape design of traditional orthotic devices. There has been no such thing as a 3D printed patient-specific wrist immobilization orthosis for chronic and degenerative wrist pathology that functions well with the comfortable wear. There is no clear point in time to distinguish between long-term and short-term usage. For clarification, in this project, short-term wear stands for about six weeks to recover from fracture injuries. On the other hand, long-term usage is defined as a longer period than short-term use, from multiple months to a couple of years.

1.6. Goal

In this thesis project, the research objective is:

*Develop a **patient-specific orthosis** for **wrist immobilization** in **long-term usage**, which has suitable **functionality, comfort of wearing, and an efficient fabrication process** by exploiting the benefits of **Additive Manufacturing technology**.*

A well-designed 3D printed patient-specific wrist immobilization orthosis for long-term use should embody the three following aspects: (1) functionality, (2) comfort of wearing, and (3) efficient production process. A long-term use of orthosis should function immobilizing flexions and deviations, preventing edema symptoms or pains or alleviating them. Furthermore, it should be comfortable to wear and not burdensome to put the orthosis on and off frequently throughout the day. Lastly, by taking advantage of AM technology, the fabrication process of the orthosis should be less labor-intensive and more cost-effective than the process of traditional orthotic devices, constructing minimalistic and aesthetically pleased structures.

2. Fundamentals of Wrist Immobilization Orthosis

2.1. Biomechanical Principles

Commonly used immobilization orthoses represent lever systems in order to impede joint movements. There are three types of lever systems; however, the most commonly used for Upper Extremity immobilization is the first-class lever system [20]. As depicted in Figure 8, In the first-class lever system, the fulcrum is located somewhere between where the effort force is applied and where the resistance force is applied. In the case of wrist immobilization orthosis, the fulcrum is positioned at the wrist joint. The effort force is on the forearm, and the resistance force is on the hand. The wrist immobilization orthosis can impede a wrist motion by holding these forces as a clinical device.

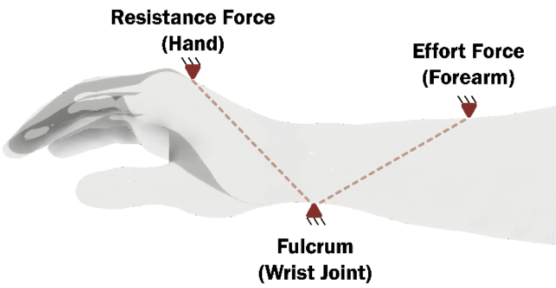


Figure 8 The first-class lever system of the wrist immobilization orthosis to impede dorsal flexion.

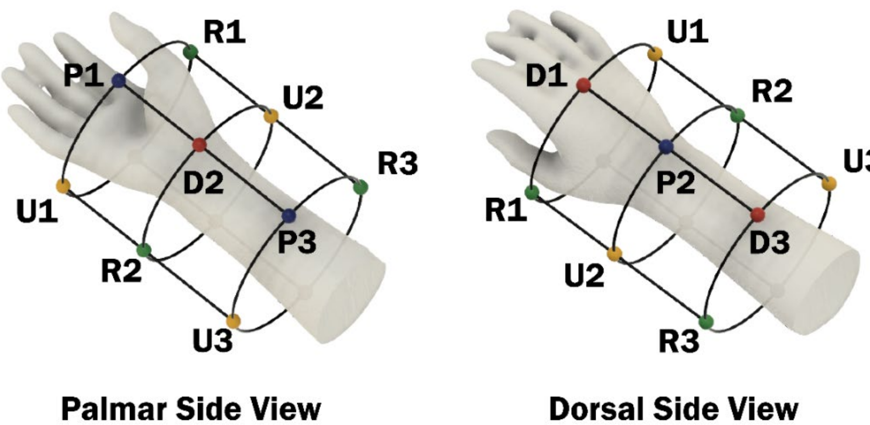


Figure 9 Visual expression of the structural scheme of the wrist immobilization orthosis. In order to block a wrist motion, physical masses are required at corresponding markers. For example, masses should be located at P1, P2, and P3 markers to impede palmar flexion.

As described in Chapter 1.1, there are four wrist motions that the wrist orthosis should block. Flexion, also known as palmar flexion or volar flexion, can be interrupted by placing structures that can take forces at <P1: palmar side of the hand>, <P2: dorsal side of the wrist joint>, and <P3: palmar side of the forearm>. Extension, also called dorsal flexion, can be interrupted by placing structures at <D1: dorsal side of the hand>, <D2: palmar side of the wrist joint>, and <D3: dorsal side of the forearm>. Radial deviation can be blocked by placing structures at <R1: radial side of the hand, between the thumb and index finger>, <R2: ulnar side of the wrist joint>, <R3: radial side of the forearm>. Lastly, the ulnar deviation can be blocked by placing structures at <U1: ulnar side of the hand>, <U2: radial side of the wrist joint>, <U3: ulnar side of the forearm>. In total, structures at 12 locations are to be placed to prevent any overuse of the wrist joint and possible symptoms, such as pain or swelling.

However, three crucial things should not be overlooked when designing wrist immobilization orthoses. One is forming rigid connections between force exerting points. Consequently, it will make the solid body parts of the orthosis. The second thing is allowing wearing on and off by adopting some openable mechanisms. Installing one or multiples of Velcro closure is an example of this. Lastly, the forces acting on the brace should be evenly distributed on the human body. It will optimize the comfort and effectiveness of the device [20]. Figure 9 visualizes how a wrist immobilization orthosis can be depicted structure-wise by combining all these geometric rules.

2.2. Structure of Traditional Wrist Immobilization Orthoses

The structural scheme in Figure 9 can show how traditional wrist immobilization orthoses are different from each other, as depicted in Figure 10. The traditional cast can be described as in Figure 10a. All structures are continuously connected and placed to obstruct all wrist motions.

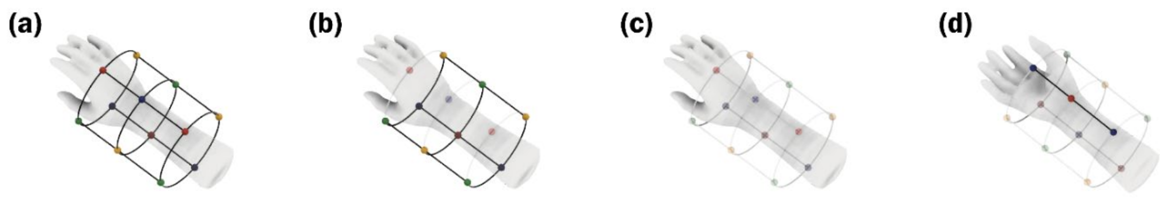


Figure 10 Structural scheme of traditional wrist immobilization orthoses: (a) traditional cast, (b) LTT orthosis, (c) pre-fabricated orthosis, and (d) pre-fabricated orthosis with an auxiliary stiffness enhancer.

On the other hand, LTT wrist immobilization orthosis can be described as in Figure 10b. Confined by its fabrication method, the LTT orthosis hardly has a complete circumferential structure. A blueprint or sketch of the LTT orthosis is drawn on an LTT sheet, and then it is intentionally deformed along the body part of a patient. This type of orthosis is supposed to care for long-term wearing. Therefore, a series of closures are applied on the empty column among the 12 points to let patients wear and remove the orthosis. However, the LTT orthosis is not enough to satisfy the patients due to its complications, such as ill-fitting, sweatiness, ugliness, and inconvenience [32].

To overcome the unpleasant feeling of the material, there are other options to choose from material-wise. One of these options is a wrist immobilization orthosis made of leather. Its material structure provides warmth and comfort but cannot be washed regularly, leading to severe odor and hygiene issues.

Pre-fabricated orthoses are the most approachable among immobilization devices (Figure 10c). Although this sort of orthosis does not provide a subtle motion impedance, anyone can get their orthosis from the nearby stores in standardized sizes, like S (small), M (medium), or L (large). Compression on the wrist from the elastic fabrics can alleviate pathological symptoms. An additional blocking material can slide in and out underneath the orthosis to enhance immobilization (Figure 10d).

2.3. Design Requirements

Despite the different material properties and disparities in the production process, the most recent approaches in Appendix A unquestioningly embrace the structure of the traditional orthoses. Thus, to start the design process with AM technology, it is more rational to examine the design requirements of the wrist immobilization orthosis for RA, OA, or other chronic or degenerative pathologies.

2.3.1. Functional Properties

According to Schofield et al. [20], the followings are the function of wrist immobilization orthosis: providing symptom release after overuse or injury, protecting joint alignment, maintaining tissue length to avoid contracture of soft tissue, and blocking power of movement to restrain overuse of the affected wrist joint. The functional requirements in Table i should be achieved by designing wrist orthosis to fulfill these demands. Therefore, as described in Chapter 2.1, a carefully designed wrist immobilization orthosis should impede dorsal and palmar flexion and radial and ulnar deviation, using the first-class lever principle. If it fails to block the motions, there is a hazard on the affected wrist joint, causing swelling or pain. Additionally, a wrist immobilization orthosis should allow pronation, supination, and grab motion [32].

Last but not least, the orthosis should release pains on the affected wrist joint during wearers' Activities of Daily Living (ADL) by carrying out the functions above. This requirement can be evaluated with actual long-term wearing, and the Pain Rating Scale (PRS) [37] can measure the magnitude of those irritations, which will be explained in Chapter 4.1.5.

Table i Design requirements of the wrist immobilization orthosis

Category	Description	Evaluation of Requirement
Function	Prohibit **Dorsal Flexion** movement	Pass
	Prohibit **Palmar Flexion** movement	Pass
	Prohibit **Radial Deviation** movement	Pass
	Prohibit **Ulnar Deviation** movement	Pass
	Allow **Pronation**	Pass
	Allow **Supination**	Pass
	Allow **Grab Motion**	Pass
	Ease pains on the affected wrist during Activities of Daily Living	Pain Rating Scale ≤ 1
Comfort	Minimize the mass of the wrist orthosis	≤ 300 g
	No pressure points at bony prominences	Pain Rating Scale ≤ 1
	No pressure points at distal palmar creases	Pain Rating Scale ≤ 1
	No pressure points at Radius or Ulna	Pain Rating Scale ≤ 1
	Minimize pains while wearing the orthosis on and off	Pain Rating Scale ≤ 1
Production	Minimize material cost	≤ € 200
	Minimize the number of materials used	≤ 1
Material Property	Biocompatible Material	Pass
	Maximized Surface Hardness	≥ Shore D 60
	Water/dirt-repellent	Pass
Morphology	The width of the forearm component	≥ half of the wrist and forearm
	The length of the forearm component	≥ two-thirds of the forearm
	No sharp edges and corners	Pass

2.3.2. Comfort

Comfort is the most vital and critical key factor of a wearable medical device for long-term usage. According to Veehof et al. [32], bad fitting and uncomfortableness were the main reasons to take off the orthosis. De Boer et al. [38] also pointed out that studies on wrist immobilization orthoses mainly focused on effectiveness, while scarce studies on comfort involved patients who had just received orthoses.

For a good experience wearing wrist immobilization orthosis, the device should be light enough for long-term wear at a maximum of 300 g for each orthosis. It is half of the weight of ordinary casts [27]. This guideline was set up by request from Manometric. An immoderately heavy device can strain the affected wrist joint. However, this requirement could diverge by the subjects' anatomy as a patient with a larger hand and forearm will need a bigger wrist orthosis.

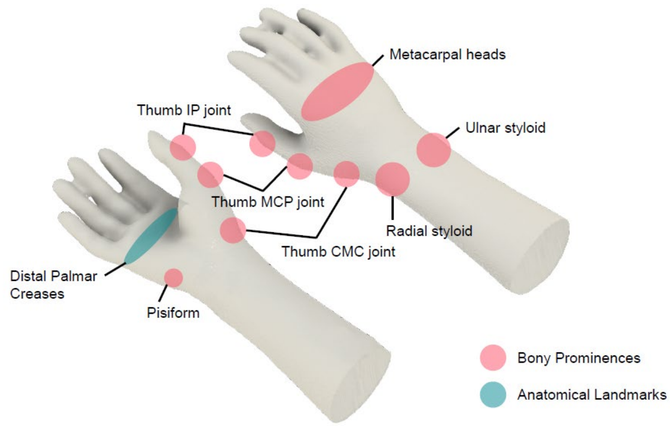


Figure 11 Bony prominences and anatomical landmarks on the hand and wrist [20].

For the wrist immobilization orthosis, it is noteworthy to care about bony prominences on the hand and wrist to provide moderate comfort. As shown in Figure 11, these prominences have less subcutaneous fat between bone and skin. They are susceptible to pain or injury when interference with a solid object happens. The areas that entail cautions are joints at the thumb (CMC, MCP, and IP), the dorsal side of the hand (Metacarpal heads), ulnar and radial styloid near the wrist joint, and pisiform [20]. Taking them into account, the wrist immobilization orthosis should not cause any pressure point on these areas with less than or equal to PRS of one point.

As mentioned in functional aspects, it can hardly grab when there is any pressure point at distal palmar creases. With more than PRS of one point, patients might feel uncomfortable and experience decreased functional ability. Reduced functionality is one of the most severe factors that cause patients to cease using their medical devices. Therefore, this criterion should be fulfilled for long-term treatment [32].

For the next, the wrist immobilization orthosis should not immobilize pronation and supination. Moreover, while letting so, pressure points should not be generated at the radius or ulna bones. Therefore, the PRS for this criterion is necessary to be less than or equal to a scale of one.

Another crucial aspect of usability of long-term wearing orthosis is the method of putting it on and taking off. In the case of long-term usage devices, it must be effortless to don and doff. Depending on their medical conditions, wrist orthosis can be removed and worn multiple times per day. Therefore, the PRS should be less than or equal to a scale of one during these executions.

2.3.3. Production

Considering the marginal aspects of the cost, the material cost should be less than 200 euros. This guideline was also set up by request from Manometric. Like the requirement regarding mass/weight, it could vary within a specific range according to the volume of the patients' UE.

Since this project's output is supposed to exploit the benefits of AM, it is vital to minimize the number of materials used. Adopting only one kind of material makes it possible to minimize the production cost, including printing and post-processing time.

2.3.4. Material Properties

In the selection of printing material, the characteristics of long-term usage must be taken into account. This project is not about suggesting a conceptual prototype but an actual prototype that will be utilized. Thus, while being used for an extended period, the orthosis should not adversely affect the skin. Defined by ISO 10993-1, biocompatibility is "the ability of a medical device or material to perform with an appropriate host response in a specific application [39]." 3D printing materials with biocompatibility certification guarantee the safety from cutaneous allergies.

Naturally, long-term usage of the orthotic device involves proper hygiene maintenance. RA patients have been dissatisfied, because traditional wrist immobilization orthoses are not water/dirt-repellent, requiring them to remove the device frequently [32]. Therefore, to cope with hygiene care, it is crucial to adopt water/dirt-repellent material.

Another material property to pay attention to is surface hardness. When it comes to commercial orthotic devices, it is common to give a multiple-year warranty. Therefore, it is essential to prevent physical damages on the orthosis, and the measurement called 'Shore D' can be referred to in this criterion. According to ASTM, materials with Shore D over 60 are considered extra-strong [40]. Thus, this type of material will bring an appropriate amount of durability for warrantied multiple years.

2.3.5. Morphological Properties

The width of the forearm component should be bigger than half of the wrist and forearm, and the length of it should be larger than two-thirds of the forearm. With these morphological criteria, the orthosis can provide proper support on patients' body parts. [20]. Moreover, in morphological decisions, the edges and corners should be unsharpened to avoid any physical harm or irritations.

2.4. Structural Constraints

Unlike ordinary wrist immobilization orthoses, the one with AM fabrication hardly has a limitation on constructing intricate body structures. Thanks to 'what you see, is what you have,' AM technology can make customized orthotic devices while saving wasted materials, reducing the weight, decreasing the production cost, and having an aesthetically better minimalistic design. Still, there are several constraints to follow for designing well-functioning immobilization orthosis.

2.4.1. Thumb Supporting Structure

A wrist immobilization may or may not have a structure with a thumb supporting part. However, it is noteworthy that most of the OA symptoms usually happen at the thumb first. Therefore, the orthosis' structure needs to provide a proper hindering over the movements on the thumb. To do so, the area between the markers, R1 and U2 (Figure 9) must have a solid body mass.

2.4.2. Connecting Isolated Skeletal Structures

AM technology can build a lean bar-shaped mass on the orthosis. However, this is not desirable in terms of distributing the pressure on the body and securing durability. It is similar to the wrist splint made of silver, which has a painful comfort due to concentrated forces on the bars. Therefore, a strip-like mass should be connected to neighboring masses after constructing a minimal structure if possible.

2.4.3. Full-Length Crossbeam

In a similar vein with the above constraint, a full-length crossbeam can deliver superior comfort and functionality. It is more efficient to hinder wrist movements with a non-amputated structure. Among four full-length crossbeams (R1-U2-R3, U1-R2-U3, D1-

P2-D3, and P1-D2-P3 in Figure 9), there has to be at least one full-length crossbeam in the structure.

2.4.4. Openable Mechanism

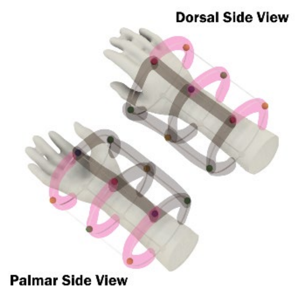
A wearable orthotic device requires an entry route to let the corresponding body part get in and out of the device. Otherwise, it cannot be reusable as traditional casts are. Thus, the accessibility of donning and doffing should be considered from the structural design phase by placing openable mechanisms at the markers that overlap with the entry route.

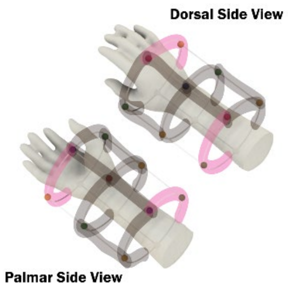
3. Concept Design

3.1. Structural Concepts by Modes of Donning and Doffing

Table ii categorizes possible structural concepts of wrist immobilization orthosis by modes of donning and doffing. No matter how the orthosis defines its structure, it must be worn on and taken off. Therefore, this is an appropriate criterium to generate independent skeletal structures.

Table ii Concepts of the wrist immobilization orthosis in of structural scheme according to how to wear and take off.

	Structural Scheme - Rigid body parts (Black lines) and openable parts (Pink lines)	Description of the way of donning and doffing
Concept 1		① Put a thumb into the thumb hole or thumb structure. ② Cover up the dorsal side of UE with the orthosis from above. ③ Fasten the openable parts.
Concept 2		① Put a thumb into the thumb hole or thumb structure. ② Cover up the palmar side of UE with the orthosis from below. ③ Fasten the openable parts.
Concept 3		① Put a thumb into the thumb hole or thumb structure. ② Cover up the radial side of UE with the orthosis from the side. ③ Fasten the openable parts.

Concept 4		① Put a hand into the orthosis, penetrating it from the proximal radial side to the distal ulnar side. ② Put a thumb into the thumb hole or thumb structure. ③ Rotate the orthosis and cover up the ulnar side of UE with the proximal side of the orthosis. ④ Fasten the openable parts.
Concept 5		① Put a hand into the orthosis, penetrating it from the proximal palmar side to the distal dorsal side. ② Put a thumb into the thumb hole or thumb structure. ③ Rotate the orthosis and cover up the dorsal side of UE with the proximal side of the orthosis. ④ Fasten the openable parts.
Concept 6		① Put a hand into the orthosis, penetrating it from the proximal dorsal side to the distal palmar side. ② Put a thumb into the thumb hole or thumb structure. ③ Rotate the orthosis and cover up the palmar side of UE with the proximal side of the orthosis. ④ Fasten the openable parts.

By taking the structural constraints into account, there are six ways of removing and wearing the orthosis as described in Table ii, and they are all possible cases of wearing it. Concepts 1, 2, and 3 are with the entry of linear translations. On the other hand, Concepts 4, 5, and 6 are designs with penetrating linear translations and rotational manipulations. The first three concepts have a more intuitive way of donning and doffing, and hence it is easier and more comfortable to put on and off. The latter three concepts have a more sophisticated way of wearing on, but they can provide more comprehensive support due to their circumferential shape. Assessment criteria were established based on the design requirements and orthopedic textbook theories to evaluate the concepts and determine the more promising concept.

Table iii Harris Profile evaluation table for structural concepts.

		Concept 1				Concept 2				Concept 3				**Concept 4**				Concept 5				Concept 6			
		-2	-1	+1	+2	-2	-1	+1	+2	-2	-1	+1	+2	-2	-1	+1	+2	-2	-1	+1	+2	-2	-1	+1	+2
Structural aspects	Circumferential structure	■				■				■						■				■				■	
	The number of full-length crossbeams				■				■				■			■				■				■	
	Support on palmar flexion	■					■						■				■		■				■		
Usability aspects	Location of openable mechanisms		■			■							■				■		■				■		
	The number of openable mechanisms	■				■				■					■				■				■		
	Intuitiveness and easiness of access				■				■			■			■				■				■		
Total Score		**-3**				**-3**				**+3**				**+4**				**-2**				**-2**			

3.1.1. Circumferential Structure

In the structural scheme, three planes are perpendicular to the forearm axis, and there are four markers in one plane, for instance, U2, D2, R2, and P2 markers in the plane at the wrist joint (Figure 9). By placing masses on these markers and connecting them, a circumferential structure can hold large forces stably. Since a fully circumferential structure can take a more significant force than a partially circumferential structure, the number of full loops on the structure would be a reference point. Concepts 1, 2, and 3 have no single loop on their body shape, bringing the lowest points. Besides, concepts 4, 5, and 6 have one loop at the wrist joint, and they got a fair assessment on this criterium. A complete set of three loops could be the best in terms of stiffness; however, it would be impossible to repeat wearing on and off, as the traditional casts are.

3.1.2. The Number of Full-Length Crossbeams

Likewise, the number of full-length crossbeams is a crucial evaluation criterium of structural aspects. A crossbeam with the length of three markers can impede a wrist motion effectively. Thus, concepts 1, 2, and 3 got a full score because of three full-length crossbeams, and the other concepts got one point.

3.1.3. Support on Palmar Flexion

With only one full-length crossbeam, it is not adequate to block a wrist motion. There should be a counter mass near the wrist joint, on the opposite side of the crossbeam, to set up a fulcrum. For example, Concepts 1 and 2 have all connected masses at U1, U2, U3, and R1, R2, R3, so that the structure can support ulnar and radial deviation capably. Based on one physiological research, palmar flexion is the wrist motion that brings the most prominent torque [41]. Accordingly, having rigid masses at all palmar flexion markers, P1, P2, and P3, would be the best scheme to support the most significant wrist motion. In consequence, Concepts 3 and 4 got full points on this.

3.1.4. Location of Openable Mechanisms

As palmar flexion is the motion with the largest torque, placing openable mechanisms at P1, P2, and P3 markers can cause ill-distribution of the pressure, leading to some pain and irritation to the wearers. Specifically, the location of the P1 marker is where distal palmar creases are, and it has a concaved surface, which makes it hard to provide a proper fastening. Based on this ground, Concepts 3 and 4 got full scores.

3.1.5. The Number of Openable Mechanisms

The less openable mechanisms are on the orthosis, the better support, and comfort in functionality. Although it also leads to more difficulties in wearing the orthosis repeatedly, there is no use of less functional immobilization orthosis. Therefore, concepts with three openable mechanisms got the worst assessment. Furthermore, the others with two openable mechanisms got the -1 point on their structures.

3.1.6. Intuitiveness And Easiness of Access

Depending on the number of openable mechanisms and their locations, the way of donning and doffing changes. Since one full-length crossbeam is empty, it is more intuitive for Concepts 1, 2, and 3 to make the hand and forearm in and out. On the other hand, it is less intuitive to wear the orthosis for the rest of the concepts. The wearer should penetrate the hand and wrist inside the structure, but the thumb first, and rotate the orthosis to fit entirely. Therefore, they got -1 points on this criterium.

3.1.7. Winning Concept

Overall, Concept 3 and Concept 4 were the most promising structure scheme for the wrist immobilization orthosis. Concept 3 got only one point less than Concept 4, but it got the worst scores on two criteria, where Concept 4 never had the worst scores from any criteria. Thus, Concept 4 was chosen as the winning concept.

3.2. Production Method

Additive Manufacturing (AM), also known as 3D printing and Rapid Prototyping, is a fabrication technology based on layer-by-layer stacking. Fused Deposition Modeling (FDM) is the most popular worldwide technology due to its reasonable cost and good accessibility. Likewise, Selective Laser Sintering (SLS), Stereolithography (SLA) are popular technologies in use. HP's Multi Jet Fusion (MJF) printing belongs to the powder bed fusion together with SLS printing. Depending on the technology, different types of materials can be used. Acrylonitrile Butadiene Styrene (ABS) and Poly-lactic Acid (PLA) are the most frequently printed material with FDM printers. Biocompatible liquid resins can be printed with SLA printers, and Polyamide (PA) powders are usually used with SLS or MJF printers. There are various combinations of printing methods and materials available. Therefore, an evaluation of approachable production methods was conducted, as shown in the Harris profile in

Table iv. The cost of MJF is slightly less than SLS, but in general, when it comes to the documentation of mechanical properties, SLS is more reliable than MJF [42]. Therefore, MJF was not included in the evaluation.

3.2.1. Production Cost

Thanks to the simplicity of its technological principle, there are many affordable FDM printers with a low budget. Moreover, it is way easier to have biocompatible options for FDM printers. On the other hand, SLA printer requires more complex post-processing and more expensive liquid resins. Inevitably, the production cost rises with this AM technique. The cost gets even higher in SLS printing because the SLS printer usually has colossal volume and expensive maintenance. Therefore, it is more reasonable to outsource SLS printing from 3D printing companies.

3.2.2. Geometric Freedom

Although AM technology has more geometrical freedom than any other manufacturing techniques, FDM printers do not have that much freedom than SLA or SLS printers. Despite aids from support structures in the printing process, FDM printers are not always suitable to generate complex shape forms.

3.2.3. Isometric Stiffness

Since the wrist immobilization orthosis takes forces in every direction, the orthosis must be capable of taking those forces isometrically. FDM printers have been well-known for their directional behaviors when it comes to stiffness. SLA and SLS printers can perform far better in this criterium.

3.2.4. Build Plate Dimension

It is always more desirable to fabricate the whole orthosis body structure at once. Any kind of auxiliary connector or gluing parts can significantly decrease the stiffness and increase the production cost. According to an orthopedic textbook, the wrist immobilization orthosis should span more than two-thirds of the forearm length, which is relatively formidable to SLA printers. There are SLA printers that can take care of this volume. However, it is not affordable and unnecessarily expensive, for now.

3.2.5. Other Criteria Regarding Material Property

No matter how perfect a printer of a particular type, there has to be available material that lives up to the design requirements in Chapter 2.3. The most crucial criterium is biocompatibility. The orthosis would be adhering to the wearer’s skin for hours, and the orthosis must not occur any adverse effects, such as allergic reactions. Filaments or resins with this certification can guarantee that there will be no such reactions.

Dirt-repellent and waterproof are both essential to manage hygiene for long-term treatment. High melting temperature and high surface hardness are both regarding durability. Other than that, several production-wise criteria were considered in the assessment.

3.2.6. Winning Production method

By comparing with the criteria, SLS printing with ‘EOS PA12' [43] was the best option to choose. Specifically, the only downsides of this combination are the high cost of production and longer lead time. However, it is still in the affordable range according to the design requirements.

The material properties of PA12 are shown in Table v. It is a polyamide powder material. It is biocompatible (according to EN ISO 10993-1) and has a well-balanced property profile. For the reason that a wrist immobilization orthosis should be reliable for at least two years, this material's superior mechanical property, chemical resistance, and long-term constant behavior are suitable for the end product. During the design iterations, different materials with similar mechanical properties as PA12 were used to save time and cost. Additionally, PA12 is watertight only when treated with the chemical vapor smoothing process after being printed [44]. Still, this extra step was omitted for time managing in the case of prototypes for user tests.

Table iv Harris Profile evaluation table for AM production methods.

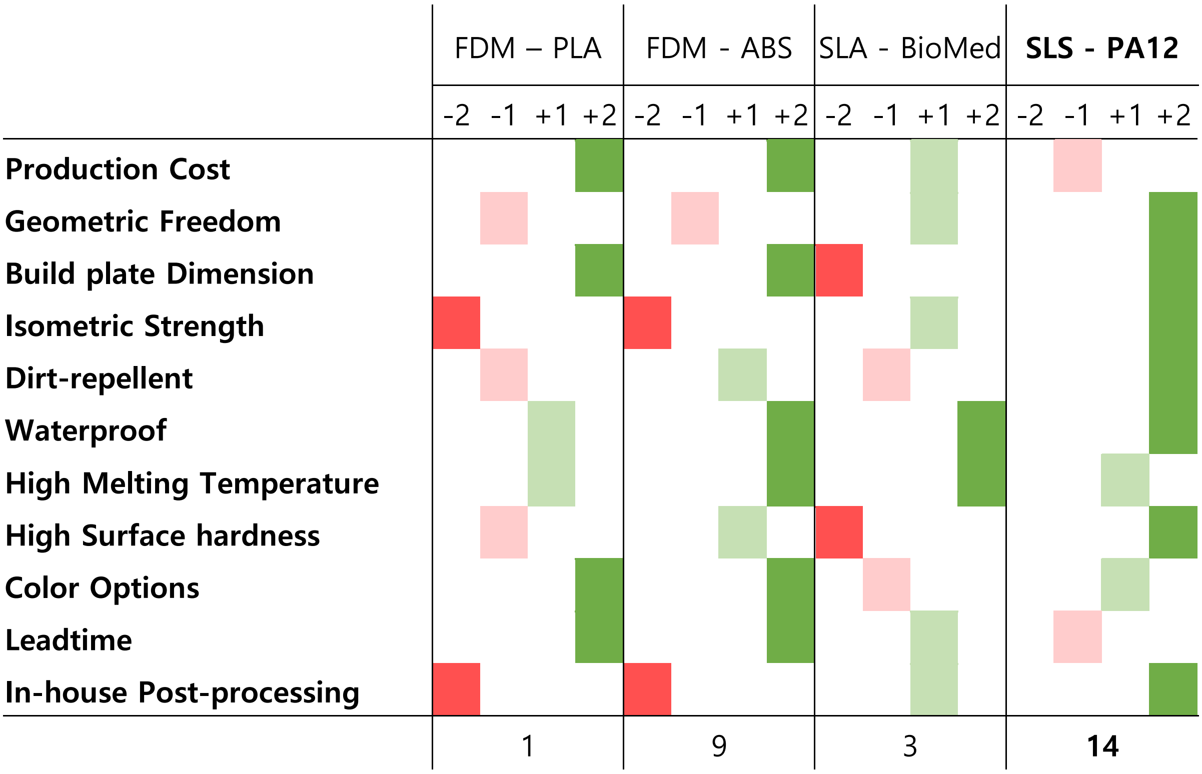


Table v Material properties of EOS PA12 [43]

MECHANICAL PROPERTIES	VALUE	UNIT
Tensile Strength	48 (XY) / 42 (Z)	[MPa]
Tensile Modulus	1650	[MPa]
Elongation	18 (XY) / 4 (Z)	[%]
Shore D Hardness	75	-
Charpy Impact Strength (+23 ℃)	53	[kJ/m^2]
Charpy Impact Notched Strength (+23 ℃)	4.8	[kJ/m^2]
Izod Notched Impact Strength (+23°C)	4.4	[MPa]
Flexural Modulus (+23 ℃)	1500	[kJ/m^2]

3.3. ePrototype Design

To comply with the design requirements in Chapter 2.3, several iterations were conducted based on concept 4 (Figure 12). The key idea of this winning concept is the combination of two full-length cross beams at the palmar and dorsal side and a fully circumferential loop at the wrist joint area. There are two openable mechanisms to provide firm fitting, one at the ulnar side of the hand and the other at the radial side of the proximal forearm area. The prototype modeling was done with surface 3D modeling software. The scans of the hand and forearm were taken by the 3D scanner from Manometric. Lastly, the fabrication of final prototypes for verification and user tests was outsourced from a 3D printing company. For the prototypes during design iterations, an SLA printer was used with the generic material.

Figure 12 The most promising concept of the wrist immobilization orthosis. Black lines stand for rigid parts, and pink lines stand for openable mechanisms.

3.3.1. First Design Iteration

For the first design cycle, semi-flexible structures were adopted for the openable mechanisms. Since PA12 is a durable material and has a non-brittle characteristic, the openable flap structure was applied. In this manner, the number of closures decreased, and it provided a less intimidating way of donning and doffing. Also, the structure at R2 and U2 markers moved to a more proximal location than where they were supposed to be. As radial and ulnar deviation take slightly more than a half force than palmar flexion does [41], these markers can be moved to the proximal side by allowing more spaces to enter the hand more manageable. Figure 13 shows the design of the first prototype, and as shown in Figure 14, the prototype was fit perfectly without making any plays. However, due to the lack of a more reliable fastener, the orthosis deviated a lot while having wrist motions (Figure 15). Especially when having palmar and dorsal flexion, the proximal part of orthosis even got away from the forearm. Therefore, from the next iteration, the proximal openable mechanism was connected with Velcro closure.

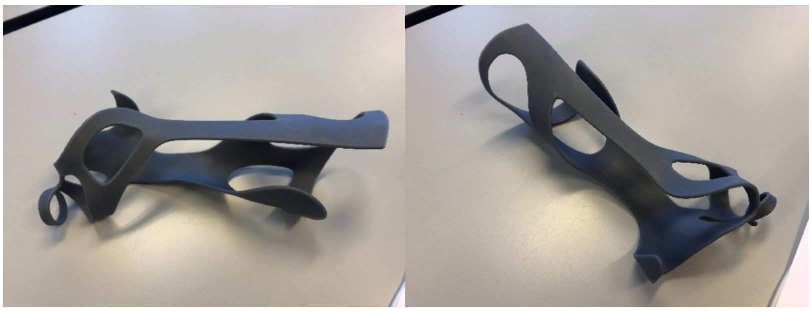


Figure 13 Prototype modeling of the first design iteration

Figure 14 Fitting of the first iteration prototype on the hand and wrist

Figure 15 Behavior of the first iteration prototype while wrist motions; from the left, dorsal flexion, ulnar deviation, and palmar flexion. There were quite significant deviations that occurred while flexions were made.

3.3.2. Second Design Iteration

Most of the details in the structure stayed as they were in the first prototype as shown in Figure 16. At the openable mechanisms on U1 and R3 markers, Velcro straps were adopted. They performed as proper fastening closures when wrist movements got engaged. In the case of the closure at the ulnar side of the hand, it was unnecessary to integrate this type of Velcro fastener, which brought unnecessarily cumbersome donning and doffing.

As shown in Figure 17, the orthosis fitted well on the UE. For every wrist motion, the orthosis impeded the motions and provided appropriate supports as well (Figure 18). Moreover, there was no problem with making a grabbing motion (Figure 19).

In all aspects, the prototype design seemed to meet functional and comfort requirements in Chapter 2.3. As a result, the second iteration prototype models were outsourced and printed in SLS type with PA12 material. They were prepared for in-house assessment with an orthopedic expert in Manometric.

Figure 16 Prototype modeling of the second design iteration

Figure 17 Fitting of the second iteration prototype on the hand and wrist

Figure 18 Behavior of the second iteration prototype while wrist motions; from the left, dorsal flexion, palmar flexion, ulnar deviation, and radial deviation. The orthosis supported all wrist motions well.


Figure 19 The orthosis was also satisfactory with allowing grab motion.

3.4. Verification of Prototype Design: In-house Test

The design of the second prototype looked promising; therefore, two wrist immobilization orthoses were manufactured with PA12. The orange-colored prototype in Figure 20 is for my own right UE, and the blue-colored prototype in Figure 20 is for an orthopedic expert in Manometric. Before having validation tests with actual patients, I had an in-house verification process with the orthopedic expert by wearing these orthoses to assess the functionality and comfort requirements in Chapter 2.3.

For both prototypes, the fitting of the orthoses was flawless (Figure 21 and Figure 22). They did not make any marginal plays and could hinder every wrist motion without generating any pressure point. Since both testers had no wrist-related disease, we could not judge whether the orthosis reduces pain on the affected wrist joint. Therefore, this requirement was put off to be verified with actual patients. About the requirements regarding comfort, they passed all requirements. However, the expert expressed a slight worry about the difficulty of wearing on and off. According to his judgment, it could be tough to educate the wearing method to patients or cause some irritations. Based on his recommendation, minor design changes were made; reduce the thickness of the flap structure at the proximal side of the radius, and make sure there are some flares at the edges where there are direct contacts with the wearer's skin.

In the rest of the design requirements, the orthosis prototype met all criteria, including the production cost, material property, and morphological requirements. As a result, it was determined that there would be no problem even if the next step were carried out with the final prototype design.

Figure 20 Final prototypes for in-house test printed in SLS-PA12. One was fitted for me (up), and the other was customized for the in-house orthopedic expert in Manometric (down).

Figure 21 Fitting of the final prototype on my own hand and wrist


Figure 22 Fitting of the final prototype on the orthopedic technician's hand and wrist

4. Evaluation of the Prototype Design

4.1. Evaluation Method

4.1.1. Test Procedure

Not only to identify the one-off possibilities of the prototype with the in-house test but to evaluate the design while wearing it for a long time, the user test evaluation process was accompanied by actual patients who need wrist immobilization orthoses for long-term treatment.

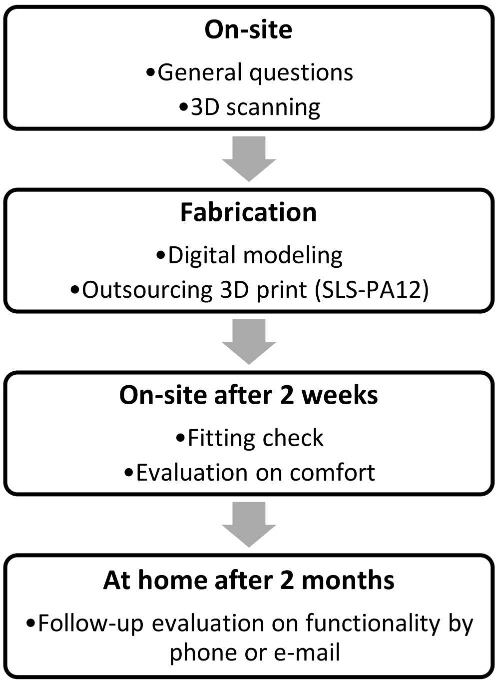


Figure 23 The procedure flow diagram of user tests.

The whole procedure of the user test is visualized in Figure 23. On the first visit, patients shared their lifestyle and discomfort and scanned the hand and wrist with Manometric's scanner. About two weeks later, the patients returned and wore the customized wrist immobilization orthosis prototype to evaluate its comfort and fit. If the orthosis did not fit well, the process went back to the fabrication step, and another orthosis was manufactured for better fitting. If everything was suitable, then they were asked to wear the orthosis for approximately two or three hours per day, depending on their medical conditions, for long-term duration. If they felt any displeasure from the device, they were recommended not to use the orthosis. After at least two months, subjects were contacted by phone or e-mail for follow-up questions and to evaluate functionality.

4.1.2. Study Population

A total of 5 patients who suffered chronic wrist pathologies were enrolled in this evaluation (2 males, 3 females). Three of the subjects were OA patients, one was an RA patient, and the other was an Ehlers-Danlos syndrome (EDS) patient (Table vi). EDS is another degenerative pathology of connective tissue disorders embracing joint hypermobility and hyperextensibility [37]. At the beginning of the project, this pathology was not included in the scope due to its rarity. However, chronic joint and limb pain are common symptoms for EDS patients, and they need wrist immobilization orthosis indefinitely [38]. Thus, the subject was assigned to the user test group. The youngest patient was 40-49 years of age, two patients were 50-59 years of age, and two patients were 60-69 years of age.

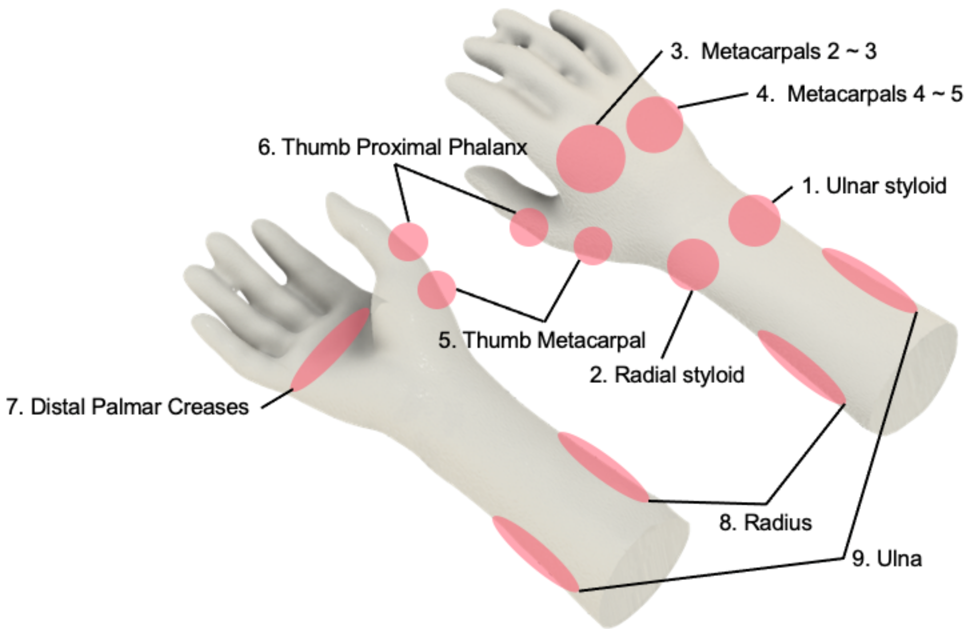


Figure 24 Assessment areas on comfort. According to in-house test results, these areas were selected and contents about bony prominences and anatomical landmarks from an orthopedic textbook [20].

4.1.3. On-Site Comfort Evaluation Method

Figure 24 visualizes the assessment areas to check if there was any pain or pressure when patients put on the wrist immobilization orthosis during the on-site evaluation. Based on in-house test results and contents regarding bony prominences in Chapter 2.3, the selection was determined. From area number one to six, I focused on determining any physical interference at the bony prominences. With the area of distal palmar creases, I can check whether the orthosis allows grabbing motion. Lastly, well executions of pronation and supination can be checked with radius and ulna areas.

Additionally, subjects were asked about whether any pain or disturbance was felt while donning and doffing the wrist immobilization orthosis. Since, as explained before, long-term treatment entails multiple times of wearing the orthosis on and off throughout the day, it is crucial to ensure no inconvenience during these executions.

4.1.4. Follow-up functionality Evaluation Method

After wearing the prototype for more than two months, the subjects were contacted by phone or e-mail. They received questions about how the orthosis affected their daily life. The questions consisted of how much pain they felt in daily activities with and without wearing the device. These activities were selected from the study by D. L. Nelson et al. in consultation with the in-house orthopedic technician, focusing on wrist engagement [45]. Selected tasks were Comb Hair, Perineal care, Writing, Drinking from a cup, Turning on a faucet, and Retrieving a bottle from the shelf.

4.1.5. Pain Rate Scale

Pain Rate Scale (PRS) is a scale that has long been used to compare the amount of pain that is difficult to quantify, and it is still well used in many domains [46]. The scale from zero to five maps the degree of pain from 'no hurt' to 'hurt worst,' helping subjects with poor health conditions to explain the size of the pain with ease. Since each subject has different medical conditions, I focused on the changes before and after wearing wrist immobilization orthosis rather than the absolute amount of pain.

4.2. User Tests Results

4.2.1. Validation with actual patients

A total of five subjects with eleven prototypes were assigned to the user test. All subjects had a degenerative disease; therefore, they needed to use wrist immobilization orthosis indefinitely. The pictures taken from the user tests are shown in Appendix B.

4.2.2. On-site Comfort Evaluation Results

On the day of delivering their customized wrist immobilization orthosis prototypes, the subjects were questioned if there was any pain on the assessment sites in Figure 24. A brief introduction was given about the design, and subjects had a chance to wear their prototypes. Unfortunately, due to the poor fitting, the prototypes of Subject 1 and Subject 3 were adjusted with a heat gun. Then, they received a second prototype with better fitting after two weeks from the first user test.

Table vi Demographic information of subjects and the PRS results of on-site comfort evaluation.

Subject No.	Orthosis No.	Affected Side	Pathology	Assessment Areas									Donning / doffing	Acceptance
				1 Ulnar Styloid	2 Radial Styloid	3 Metacarpals 2~3	4 Metacarpals 4~5	5 Thumb Metacarpal	6 Thumb Proximal Phalanx	7 Distal Palmar Creases	8 Radius	9 Ulna		
1	1	R	OA	0	0	0	1	1	2	0	0	0	1	Y
	2	R		0	0	0	0	0	0	0	1	0	3	Y
2	3	L	RA	2	2	1	0	0	0	3	0	0	2	Y
3	4	L	OA	1	2	0	0	0	0	0	0	0	2	Y
	5	R		0	0	0	0	0	0	4	0	0	2	Y
	6	L		3	5	0	0	0	0	3	0	0	4	N
	7	R		1	1	0	0	1	1	3	0	0	3	Y
4	8	L	EDS	0	2	0	0	0	0	0	0	0	2	Y
	9	R		0	1	0	0	0	0	0	0	0	2	Y
5	10	L	OA	0	2	0	0	0	0	4	0	0	4	N
	11	R		0	1	0	0	0	0	1	0	0	2	Y

The result of the comfort evaluation in Table vi shows quite clear tendencies. Four out of five subjects had the pain generated on ulnar and radial styloid and distal palmar creases. All subjects had pain or irritations when they were putting on and off the wrist orthosis.

- **(1) Ulnar and (2) Radial Styloid**

As palmar flexion is the motion driven by the most significant force, styloid areas were the most critical ones for comfort and functionality. Specifically for orthosis 6, the subject had relatively narrow space between radial and ulnar styloid. Therefore, the subject had severe pain generated in that area. As a result, the subject rejected to take the orthosis home.

- **(7) Distal Palmar Creases**

The distal palmar creases area plays a vital role when it comes to functionality. If any pain or interference occurred, patients would not have the full functional ability with the orthosis. However, in Orthoses 3, 5, 6, 7, and 10, the edges at this area were too high, resulting in pain.

- **Donning and Doffing**

All subjects had a certain amount of pain while wearing the orthosis on and off. Especially, subjects with relatively more severe irritations at the assessment areas had more pain upon removal and wear. As stressed earlier, the wrist immobilization orthosis for long-term treatment should not generate any disturbance while donning and doffing the orthosis, which could happen multiple times per day. However, the result is on the opposite side of what it was supposed to be. Therefore, further development should incorporate this and optimize wearability.

- **Medical Conditions**

Due to the medical condition of Subject 5, it was not possible for the subject to wear the orthosis. The subject received surgery on the left shoulder one day before the user test. Thus, he did not accept Orthosis 10 to take home and wear for a longer period.

4.2.3. Follow-up Functionality Evaluation Result with Long-term Usage

After two months, subjects were contacted by phone or e-mail to ask if there were any pains on the affected wrist joint. Figure 25 shows the results from Subjects 1, 2, and 5. Unfortunately, Subject 3 could not wear the orthosis due to the pain in her styloid area. Therefore, she rejected to wear the wrist immobilization orthosis. On the other hand, Subject 4 withdrew from the user test due to her severe medical conditions, causing communication difficulties with the subject. Finally, follow-up answers from Subjects 1, 2, and 5 were taken into account in total.

With the exception of the combing hair task from Subject 5, wearing the wrist immobilization orthosis decreased the pain with the scale of less than or equal to PRS of one point. Although this result had no statistical significance, the decreasing tendency was clear and consistent.

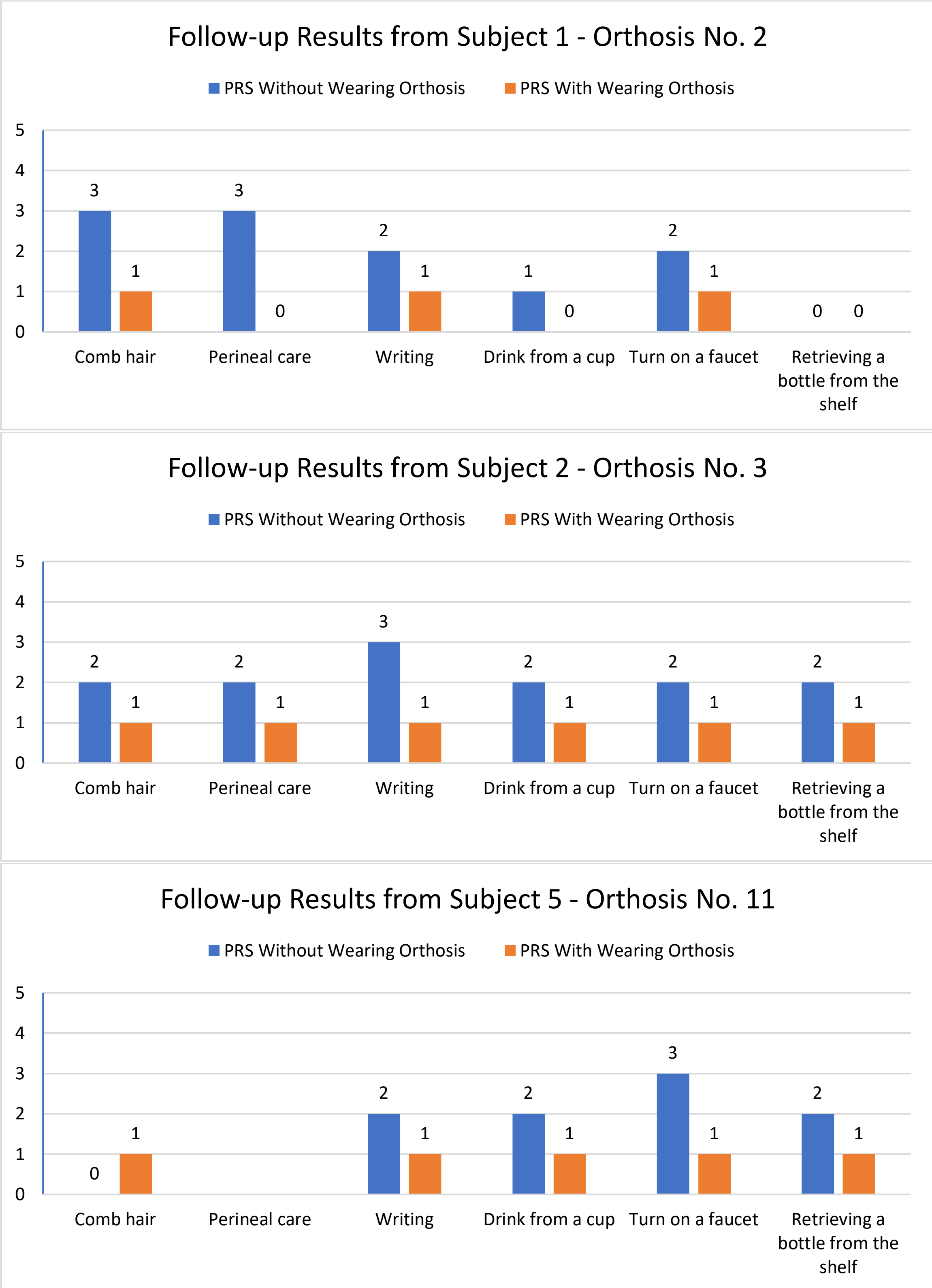


Figure 25 The PRS results of follow-up functionality evaluation after at least two months of using the wrist immobilization orthosis.

4.3. Back to Design Requirements

Referring back to the design requirement, the result of the evaluation is shown in Table vii. It was concluded that the orthosis is capable of functioning immobilization. What was notable is that the orthosis effectively alleviated pains during ADL, as long as the comfort of it was acceptable to wear for long-term usage.

When it comes to the requirements regarding comfort, it was not positive. Even though the weight-related requirement was met and there were no pressure points at radius and ulna bones, about 45 % of prototypes provided excessive pressure on bony prominences. Around 55 % of prototypes caused unacceptable pains at distal palmar creases. Specifically, the movement of putting it on and off brought complications for 91 % of all prototypes.

In other requirements, the material chosen allowed it to pass the evaluation related to production and material property. In addition, the morphological requirements were managed well during the 3D modeling process.

Table vii Design requirements of the wrist immobilization orthosis and the result of the evaluation

Category	Description	Evaluation of Requirement	Result of Evaluation
Function	Prohibit **Dorsal Flexion** movement	Pass	Passed
	Prohibit **Palmar Flexion** movement	Pass	Passed
	Prohibit **Radial Deviation** movement	Pass	Passed
	Prohibit **Ulnar Deviation** movement	Pass	Passed
	Allow **Pronation**	Pass	Passed
	Allow **Supination**	Pass	Passed
	Allow **Grab Motion**	Pass	Passed
	Ease pains on the affected wrist during Activities of Daily Living	Pain Rating Scale ≤ 1	Conditionally Passed
Comfort	Minimize the mass of the wrist orthosis	≤ 300 g	Passed
	No pressure points at bony prominences	Pain Rating Scale ≤ 1	Failed (five out of eleven orthoses)
	No pressure points at distal palmar creases	Pain Rating Scale ≤ 1	Failed (six out of eleven orthoses)
	No pressure points at Radius or Ulna	Pain Rating Scale ≤ 1	Passed
	Minimize pains while wearing the orthosis on and off	Pain Rating Scale ≤ 1	Failed (ten out of eleven orthoses)
Production	Minimize material cost	≤ € 200	Passed
	Minimize the number of materials used	≤ 1	Passed
Material Property	Biocompatible Material	Pass	Passed
	Maximized Surface Hardness	≥ Shore D 60	Passed
	Water/dirt-repellent	Pass	Passed
Morphology	The width of the forearm component	≥ half of the wrist and forearm	Passed
	The length of the forearm component	≥ two-thirds of the forearm	Passed
	No sharp edges and corners	Pass	Passed

5. Discussion

5.1. Comfort Of Wearing

According to the on-site comfort evaluation in Table vi, radial and ulnar styloid were the toughest bony prominences to fit the orthosis without generating pressure. It was expected to some degree in advance, because it usually has the smallest circumference among the forearms with the least subcutaneous fat. Moreover, the gap between radial and ulnar styloid differs for every single person. Thus, it was required to put extra care in the modeling process.

For Subject 3, the poor fitting made it difficult to wear Orthosis 6 for a more extended period. The subject even rejected to wear Orthosis 7 in the middle of the follow-up user test. The main reason was that even without movement, the pressure point resulting from device wear at the styloid area was too painful. The subject commented that wearing the orthosis was exhausting, difficult to work with, and could not cycle or do other sports.

Ideally, the pains during ADL with wearing the orthotic device should be a rating of zero. However, there were only three cases of zero PRS (Figure 25). Considering that Subject 3 stopped wearing the orthosis due to the pains on her styloid area, a better comfort with less painful contact would provide better results with lower PRS scores.

5.2. Functionality

By asking the follow-up functionality questions, it was noticed that the device had a functional effect during activities in real life (Figure 25). The structure of the prototype was rigid enough to impede wrist motions. Of course, this user test did not prove any clinical effectiveness, as this project was not intended to verify with a statistically significant subject group. However, it was meaningful enough to obtain practical information on the development phase process.

The peak pains from ADL were found from different activities for each subject (Figure 25). Since the severity and development of the pathology are all different, it would be impossible to generalize from which activity the orthosis was most effective.

5.3. Efficient Fabrication Process

By utilizing only one type of material to fabricate the orthosis, post-processing was barely necessary. Besides, digital modeling based on 3D scans took 4 hours per one orthosis. It took more than five business days to get one SLS 3D printing outcome from the outsourcing company. However, because traditional orthosis needs several days of labor-intensive work, it is a matter of lead time, not production cost. After ordering a printing, there is still room to multitask in the meantime. Therefore, it was a far less labor-intensive fabrication process. Moreover, there is still room to save production costs and reduce the lead time.

5.4. Strengths and Weaknesses

The final prototype of this project has strengths and weaknesses compared to existing solutions. The orthosis is lightweight and well ventilated due to its open structure, while immobilizing the excessive wrist motions. During the evaluation, two test subjects mentioned that after two months of usage, the orthosis was better than their traditional LTT orthosis in controlling perspiration and managing hygiene.

When it comes to the fabrication aspect, the material and production method brought simplicity. The orthosis did not require labor-intensive fabrication or time-consuming post-processing work due to consisting of only one body part. As traditional LTT and MCS orthoses are capable, the orthosis can be adjusted by applying heat for better comfort.

The organic design and open structure received positive feedback from the subjects. In addition, it is easy to conduct potential design changes in the future.

On the other hand, this open structure gave subject's the wrong interpretation of how to put it on and off. Even though the subjects received instructions, they pursued what they believed was the most intuitive action, which caused unnecessary pain on the wrist and less preference for the device.

The evaluation with long-term usage brought an 'all or none' result. For subjects who did not have problems with comfort, the orthosis functions well, but for subjects with poor fitting, they even gave up on wearing it. Therefore, a comfort improvement will be vital for further development.

Lastly, the coloring of the orthosis was not reliable. Subjects mentioned that it was difficult to get rid of stains on the orthosis. Thus, there must be additional surface treatment to provide reliability for long-term use.

5.5. Further Design Recommendations

In the next phase of development, comfort should be improved. Placing hard material directly on the styloid bones caused complications. This could be solved by optimizing the dimension of the crossbeam, improving scanner protocol, putting soft materials between the skin and the rigid material, or detouring the structure above the wrist.

Also, the stiffness of the entire body could be optimized in further research. Hence, every person's anatomy is different from each other; there is no constant value for the stiffness. Besides, according to the medical condition, a slight amount of motion may or may not be allowed. Therefore, this should be collaboratively resolved with orthopedic specialists.

The method of removing and wearing the orthosis should be improved. Other Concepts, for example, can be reviewed again for design change. Since Concept 3 also achieved good evaluation, it would be worth exploring the design with this concept, which has potential for a better method of donning and doffing.

Last but not least, the closure and fastening mechanism should be considered thoroughly. Patients suffering from degenerative wrist pathology may not be capable of manipulating those mechanisms as handy as people without complications. The way of manipulation can affect the general usability of wearing the wrist immobilization orthosis.

6. Conclusion

The goal of this project was to develop a 3D printed patient-specific orthosis for wrist immobilization for long-term usage, which has suitable functionality, comfort of wearing, and efficient fabrication process by exploiting the benefits of Additive Manufacturing technology.

First, the orthosis reduced pain at the affected wrist area in daily activities, observed from the follow-up user test. Therefore, we can conclude that the structure of the wrist immobilization orthosis was well-designed, performing proper support.

Second, the orthosis design was evaluated by five patients who were suffering from degenerative wrist pathologies. The result of the comfort evaluation was conditionally positive; due to the rigid hardness of the PA12 material, two out of eleven orthoses were too painful to wear for the further test. Since the morphology of bony eminences and the amount of the cutaneous fats around those areas are dissimilar for all people, it was hard to design pain-zero orthosis for two subjects. Therefore, more studies must achieve universal comfort with auxiliary soft materials to absorb and distribute pressures.

Lastly, SLS printing with PA12 offered apparent advantages over traditional fabrication methods. All works were conducted digitally from the scanning to fabrication, and there was no waste of materials. Despite six working days of delivery time from the outsourcing company, the orthosis did not require any labor-intensive procedures.

Bibliography

[1] D. C. M. Wong, G. K. L. Wansaicheong, and I. Y. Y. Tsou, "Ultrasonography of the hand and wrist," *Singapore Medical Journal*, vol. 50, no. 2, pp. 219–225, 2009.

[2] F. Draghi, *Ultrasonography of the upper extremity: Hand and Wrist*. Springer, 2018. doi: 10.1007/978-3-319-77341-4.

[3] E. Lab, "Capitate Bone," in *Definitions*, 2020. doi: 10.32388/3g0q6m.

[4] S. L. Werner and K. D. Plancher, "Biomechanics of wrist injuries in sports," *Clinics in Sports Medicine*, vol. 17, no. 3, pp. 407–420, 1998, doi: 10.1016/S0278-5919(05)70093-4.

[5] A. F. T. Mak, M. Zhang, and A. K. L. Leung, "The Anatomy and Mechanics of the Human Hand," *Comprehensive Structural Integrity*, vol. 9, pp. 329–363, 2007, doi: 10.1016/B0-08-043749-4/09065-0.

[6] J. Colditz, "Principles of splinting and splint prescription," in *Surgery of the hand and upper extremity*, Peimer, Ed. 1996, pp. 2389–2410. [Online]. Available: https://bracelab.com/wp/wp-content/uploads/Principles-of-Splinting-and-Splint-Prescription.pdf

[7] E. Taylor, J. Hanna, and H. J. C. R. Belcher, "Splinting of the hand and wrist," *Current Orthopaedics*, vol. 17, no. 6, pp. 465–474, 2003, doi: 10.1016/j.cuor.2003.09.001.

[8] MaryLynn A. Jacobs and N. M. Austin, *Orthotic Intervention for the Hand and Upper Extremity: Splinting Principles and Process*, 2nd ed. Wolters Kluwer Health, 2013.

[9] WHO, "Chronic rheumatic conditions," https://www.who.int/chp/topics/rheumatic/en/ (accessed Feb. 04, 2021).

[10] F. Draghi, *Ultrasonography of the upper extremity: Elbow*. Springer, 2018. doi: 10.1007/978-3-319-77341-4.

[11] N. C. A. Horsten, J. Ursum, L. D. Roorda *et al.,* "Prevalence of hand symptoms, impairments and activity limitations in rheumatoid arthritis in relation to disease duration," *Journal of Rehabilitation Medicine*, vol. 42, no. 10, pp. 916–921, 2010, doi: 10.2340/16501977-0619.

[12] J. C. Buckland-Wright, D. G. Macfarlane, J. A. Lynch *et al.,* "Osteophytes in the osteoarthritic hand: their incidence, size, distribution, and progression," *Annals ofthe Rheumatic Disases*, vol. 50, pp. 627–630, 1991, doi: 10.1136/ard.50.9.627.

[13] CDC, "Arthritis-Related Statistics," https://www.cdc.gov/arthritis/data_statistics/arthritis-related-stats.htm (accessed Aug. 11, 2021).

[14] J. M. Hootman, C. G. Helmick, K. E. Barbour et al., "Updated Projected Prevalence of Self-ReportedDoctor-Diagnosed Arthritis and Arthritis-AttributableActivity Limitation Among US Adults, 2015–2040," *ARTHRITIS & RHEUMATOLOGY*, vol. 68, no. 7, pp. 1582–1587, 2016, doi: 10.1002/art.39692.

[15] P. Lakshmanan, "Wrist Arthritis Treatment & Management: Approach Considerations, Splinting and Pain Relief, Early and Late-Stage Surgical Options." https://emedicine.medscape.com/article/1933090-treatment#d9 (accessed Aug. 10, 2021).

[16] D. le Nen *et al.*, "The arthritic wrist. I - The degenerative wrist: Surgical treatment approaches," *Orthopaedics and Traumatology: Surgery and Research*, vol. 97, no. 4, 2011, doi: 10.1016/j.otsr.2011.03.006.

[17] A. Andringa, I. van de Port, and J. W. Meijer, "Long-term use of a static hand-wrist orthosis in chronic stroke patients: A pilot study," *Stroke Research and Treatment*, no. December 2014, 2013, doi: 10.1155/2013/546093.

[18] American Academy of Orthopaedic Surgeons, "Arthritis of the Wrist," https://orthoinfo.aaos.org/en/diseases--conditions/arthritis-of-the-wrist/ (accessed Aug. 10, 2021).

[19] M. I. Mohammed and P. Fay, "Design and additive manufacturing of a patient specific polymer thumb splint concept," *Solid Freeform Fabrication 2018: Proceedings of the 29th Annual International Solid Freeform Fabrication Symposium - An Additive Manufacturing Conference, SFF 2018*, pp. 873–886, 2020.

[20] K. A. Schofield and D. A. Schwartz, "Orthotic Design and Fabrication for the Upper Extremity: A Practical Guide," Slack Incorporated, 2019.

[21] L. Ramsey, R. J. Winder, and J. G. McVeigh, "The effectiveness of working wrist splints in adults with rheumatoid arthritis: A mixed methods systematic review," *Journal of Rehabilitation Medicine*, vol. 46, no. 6, pp. 481–492, 2014, doi: 10.2340/16501977-1804.

[22] L. Woythal, P. Hølmer, and S. Brorson, "Splints, with or without wrist immobilization, following surgical repair of flexor tendon lesions of the hand: A systematic review," *Hand Surgery and Rehabilitation*, vol. 38, no. 4, pp. 217–222, 2019, doi: 10.1016/j.hansur.2019.05.004.

[23] Y. J. Cha, “Changes in the pressure distribution by wrist angle and hand position in a wrist splint,” *Hand Surgery and Rehabilitation*, vol. 37, no. 1, pp. 38–42, 2018, doi: 10.1016/j.hansur.2017.09.007.

[24] M. Fernandez-Vicente, A. E. Chust, and A. Conejero, “Low Cost Digital Fabrication Approach for Thumb Orthoses,” *Rapid Prototyping Journal*, vol. 23, no. 6, pp. 1020–1031, 2017, doi: 10.1108/RPJ-12-2015-0187.

[25] Extremity Splinting, “Replicasting Making Molds of the Hand.” https://www.mitchmedical.us/extremity-splinting/replicasting-making-molds-of-the-hand.html (accessed Jul. 14, 2021).

[26] Summit Orthopedics, “A Primer On Post-Surgical Casts.” https://www.summitortho.com/2014/05/09/primer-post-surgical-casts/ (accessed Jul. 14, 2021).

[27] F. Blaya, R. O. D’amato, P. S. Pedro *et al.,* “Study, design and prototyping of arm splint with additive manufacturing process,” *ACM International Conference Proceeding Series*, vol. Part F1322, pp. 1–7, 2017, doi: 10.1145/3144826.3145407.

[28] ETOS, “Neo G Stabiliserende Polsbrace.” https://www.etos.nl/producten/neo-g-stabiliserende-polsbrace---recht-universele-maat-120501838.html (accessed Jul. 14, 2021).

[29] M. A. de Souza, C. Schmitz, M. M. Pinhel *et al.*, “Proposal of custom made wrist orthoses based on 3D modelling and 3D printing,” *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS*, pp. 3789–3792, 2017, doi: 10.1109/EMBC.2017.8037682.

[30] C. Pyatt, S. Kelly, A. Paterson *et al.*, “Giving patients what they want: proposing additive manufacture as a method to design and fabricate wrist splints,” *Rapid Design Prototyping and Manufacture*, 2017, [Online]. Available: https://dspace.lboro.ac.uk/dspace-jspui/handle/2134/35154

[31] A. Fitzpatrick, M. Mohammed, P. Collins *et al.*, “Design optimisation of a thermoplastic splint,” *Solid Freeform Fabrication 2017: Proceedings of the 28th Annual International Solid Freeform Fabrication Symposium - An Additive Manufacturing Conference, SFF 2017*, no. December, pp. 2409–2418, 2020.

[32] M. M. Veehof, E. Taal, M. J. Willems *et al.*, “Determinants of the use of wrist working splints in rheumatoid arthritis,” *Arthritis Care and Research*, vol. 59, no. 4, pp. 531–536, 2008, doi: 10.1002/art.23531.

[33] S. Kelly, A. Paterson, and R. J. Bibb, "A review of wrist splint designs for additive manufacture," *Rapid Design Prototyping and Manufacture Conference*, 2015, [Online]. Available: https://dspace.lboro.ac.uk/dspace-jspui/handle/2134/21144

[34] F. Blaya, P. S. Pedro, J. L. Silva *et al.*, "Design of an Orthopedic Product by Using Additive Manufacturing Technology: The Arm Splint," *Journal of Medical Systems*, vol. 42, no. 3, Mar. 2018, doi: 10.1007/s10916-018-0909-6.

[35] A. M. Paterson, E. Donnison, R. J. Bibb *et al.*, "Computer-aided design to support fabrication of wrist splints using 3D printing: A feasibility study," *Hand Therapy*, vol. 19, no. 4, pp. 102–113, 2014, doi: 10.1177/1758998314544802.

[36] W. Yan, M. Ding, B. Kong *et al.*, "Lightweight Splint Design for Individualized Treatment of Distal Radius Fracture," *Journal of Medical Systems*, vol. 43, no. 8, 2019, doi: 10.1007/s10916-019-1404-4.

[37] C. L. Hicks, C. L. von Baeyer, P. A. Spafford *et al.*, "The Faces Pain Scale - Revised: Toward a common metric in pediatric pain measurement," *Pain*, vol. 93, no. 2, pp. 173–183, 2001, doi: 10.1016/S0304-3959(01)00314-1.

[38] I. G. de Boer *et al.*, "Disability and Rehabilitation The usage of functional wrist orthoses in patients with rheumatoid arthritis," 2009, doi: 10.1080/09638280701257031.

[39] Johner Institute, "ISO 10993 and Biocompatibility - Material Certificates Are Not Enough!," 2019. https://johner-institute.com/articles/product-development/and-more/biocompatibility-iso-10993/ (accessed Jun. 22, 2021).

[40] ASTM International, "ASTM D2240 - 15e1 Standard Test Method for Rubber Property—Durometer Hardness." https://www.astm.org/Standards/D2240.htm (accessed Jun. 22, 2021).

[41] J. M. Vanswearingen, "Measuring wrist muscle strength," *Journal of Orthopaedic and Sports Physical Therapy*, vol. 4, no. 4, pp. 217–228, 1983, doi: 10.2519/jospt.1983.4.4.217.

[42] A. B. Varotsis, "HP MJF vs. SLS: A 3D printing technology comparison | Hubs." https://www.hubs.com/knowledge-base/hp-mjf-vs-sls-3d-printing-technology-comparison/ (accessed Aug. 11, 2021).

[43] EOS, "Polyamide PA-12." [Online]. Available: https://www.eos.info/en/additive-manufacturing/3d-printing-plastic/sls-polymer-materials/polyamide-pa-12-alumide/ (accessed Aug. 11, 2021).

[44] Xometry, "Vapor Smoothing | 3D Print Finishing | HP MJF, SLS, and FDM Parts." https://www.xometry.com/capabilities/vapor-smoothing/ (accessed Aug. 11, 2021).

[45] D. L. Nelson, M. A. Mitchell, P. G. Groszewski *et al.*, "Wrist Range of Motion in Activities of Daily Living," in *Advances in the Biomechanics of the Hand and Wrist*, 1994. doi: 10.1007/978-1-4757-9107-5_29.

[46] M. v. de Angelis, F. Pierfelice, P. di Giovanni *et al.*, "Efficacy of a soft hand brace and a wrist splint for carpal tunnel syndrome: A randomized controlled study," *Acta Neurologica Scandinavica*, vol. 119, no. 1, pp. 68–74, 2009, doi: 10.1111/j.1600-0404.2008.01072.x.

[47] A. M. Paterson, E. Donnison, R. J. Bibb *et al.*, "Computer-aided design to support fabrication of wrist splints using 3D printing: A feasibility study," *Hand Therapy*, vol. 19, no. 4, pp. 102–113, 2014, doi: 10.1177/1758998314544802.

[48] D. Palousek, J. Rosicky, D. Koutny *et al.*, "Pilot study of the wrist orthosis design process," *Rapid Prototyping Journal*, vol. 20, no. 1, pp. 27–32, 2014, doi: 10.1108/RPJ-03-2012-0027.

[49] H. Kim and S. Jeong, "Case study: Hybrid model for the customized wrist orthosis using 3D printing," *Journal of Mechanical Science and Technology*, vol. 29, no. 12, pp. 5151–5156, 2015, doi: 10.1007/s12206-015-1115-9.

[50] G. Baronio, S. Harran, and A. Signoroni, "A Critical Analysis of a Hand Orthosis Reverse Engineering and 3D Printing Process," *Applied Bionics and Biomechanics*, vol. 2016, 2016, doi: 10.1155/2016/8347478.

[51] M. Houston-Hicks, D. J. Lura, and M. J. Highsmith, "Play Hands Protective Gloves: Technical Note on Design and Concept," *Technology & Innovation*, vol. 18, no. 2, pp. 207–210, Sep. 2016, doi: 10.21300/18.2-3.2016.207.

[52] H. Lin, L. Shi, and D. Wang, "A rapid and intelligent designing technique for patient-specific and 3D-printed orthopedic cast," *3D Printing in Medicine*, vol. 2, no. 1, 2016, doi: 10.1186/s41205-016-0007-7.

[53] A. Cazon, S. Kelly, A. M. Paterson *et al.*, "Analysis and comparison of wrist splint designs using the finite element method: Multi-material three-dimensional printing compared to typical existing practice with thermoplastics," *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, vol. 231, no. 9, pp. 881–897, 2017, doi: 10.1177/0954411917718221.

[54] A. M. Paterson, R. Bibb, R. I. Campbell *et al.*, "Comparing additive manufacturing technologies for customised wrist splints," *Rapid Prototyping Journal*, vol. 21, no. 3, pp. 230–243, 2015, doi: 10.1108/RPJ-10-2013-0099.

[55] Y.-J. Chen, H. Lin, X. Zhang *et al.*, "Application of 3D–printed and patient-specific cast for the treatment of distal radius fractures: initial experience," *3D Printing in Medicine*, vol. 3, no. 1, Mar. 2017, doi: 10.1186/s41205-017-0019-y.

[56] M. A. de Souza, C. Schmitz, M. M. Pinhel *et al.*, "Proposal of custom made wrist orthoses based on 3D modelling and 3D printing," in *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS*, Sep. 2017, pp. 3789–3792. doi: 10.1109/EMBC.2017.8037682.

[57] R. Kudelski, P. Dudek, M. Kulpa *et al.*, "Using reverse engineering and rapid prototyping for patient specific orthoses," *2017 13th International Conference Perspective Technologies and Methods in MEMS Design, MEMSTECH 2017 - Proceedings*, pp. 88–90, 2017, doi: 10.1109/MEMSTECH.2017.7937540.

[58] Y. E. Lim, N. H. Kim, H. J. Choi *et al.*, "Design for additive manufacturing of customized cast with porous shell structures," *Journal of Mechanical Science and Technology*, vol. 31, no. 11, pp. 5477–5483, 2017, doi: 10.1007/s12206-017-1042-z.

[59] A. P Fitzpatrick, "Design of a Patient Specific, 3D printed Arm Cast," *KnE Engineering*, vol. 2, no. 2, p. 135, 2017, doi: 10.18502/keg.v2i2.607.

[60] M. I. Saldaña-Martínez *et al.*, "3D splint prototype system for applications in muscular rehab by transcutaneous electrical nerve stimulation (TENS)," *Design and Quality for Biomedical Technologies X*, vol. 10056, no. March, p. 1005610, 2017, doi: 10.1117/12.2251649.

[61] F. Blaya, P. S. Pedro, J. L. Silva *et al.*, "Design of an Orthopedic Product by Using Additive Manufacturing Technology: The Arm Splint," *Journal of Medical Systems*, vol. 42, no. 3, 2018, doi: 10.1007/s10916-018-0909-6.

[62] J. Li and H. Tanaka, "Feasibility study applying a parametric model as the design generator for 3D–printed orthosis for fracture immobilization," *3D Printing in Medicine*, vol. 4, no. 1, 2018, doi: 10.1186/s41205-017-0024-1.

[63] G. C. Rosenmann *et al.*, "Development and evaluation of low-cost custom splint for spastic hand by additive manufacturing," *Advances in Intelligent Systems and Computing*, vol. 588, no. February 2019, pp. 701–711, 2018, doi: 10.1007/978-3-319-60582-1_70.

[64] K. Wang *et al.*, "The research on 3D printing fingerboard and the initial application on cerebral stroke patient's hand spasm," *BioMedical Engineering Online*, vol. 17, no. 1, Jun. 2018, doi: 10.1186/s12938-018-0522-4.

[65] F. Górski, W. Kuczko, W. Weiss *et al.*, "Prototyping of an Individualized Multi-Material Wrist Orthosis using Fused Deposition Modelling," *Advances in Science*

and Technology Research Journal, vol. 13, no. 4, pp. 39–47, Dec. 2019, doi: 10.12913/22998624/113543.

[66] P. Guida *et al.*, "An alternative to plaster cast treatment in a pediatric trauma center using the CAD/CAM technology to manufacture customized three-dimensional-printed orthoses in a totally hospital context: A feasibility study," *Journal of Pediatric Orthopaedics Part B*, vol. 28, no. 3, pp. 248–255, May 2019, doi: 10.1097/BPB.0000000000000589.

[67] K. H. Lee, D. K. Kim, Y. H. Cha *et al.*, "Personalized assistive device manufactured by 3D modelling and printing techniques," *Disability and Rehabilitation: Assistive Technology*, vol. 14, no. 5, pp. 526–531, Jul. 2019, doi: 10.1080/17483107.2018.1494217.

[68] C. Schmitz, Y. T. Mori, H. R. Gamba *et al.*, "Development and Evaluation of a Customized Wrist-Hand Orthosis using 3D Technology for a Child with Cerebral Palsy - A Case Study," in *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS*, Jul. 2019, pp. 1476–1479. doi: 10.1109/EMBC.2019.8857327.

[69] J. M. D. A. del Burgo, F. B. Haro, R. D'amato *et al.*, "Development of a smart splint to monitor different parameters during the treatment process," *Sensors (Switzerland)*, vol. 20, no. 15, pp. 1–14, Aug. 2020, doi: 10.3390/S20154207.

[70] Y. Chen *et al.*, "Application of 3D-Printed Orthopedic Cast for the Treatment of Forearm Fractures: Finite Element Analysis and Comparative Clinical Assessment," *BioMed Research International*, vol. 2020, 2020, doi: 10.1155/2020/9569530.

[71] C. H. Chu, I. J. Wang, J. R. Sun *et al.*, "Customized designs of short thumb orthoses using 3D hand parametric models," *Assistive Technology*, 2020, doi: 10.1080/10400435.2019.1709917.

[72] F. Górski, R. Wichniarek, W. Kuczko *et al.*, "Experimental studies on 3D printing of automatically designed customized wrist-hand orthoses," *Materials*, vol. 13, no. 18, 2020, doi: 10.3390/ma13184091.

[73] K. Łukaszewski, R. Wichniarek, and F. Górski, "Determination of the elasticity modulus of additively manufactured wrist hand orthoses," *Materials*, vol. 13, no. 19, pp. 1–18, 2020, doi: 10.3390/ma13194379.

[74] H. M. J. Janzing *et al.*, "Treatment of dorsally dislocated distal radius fractures with individualized 3D printed bracing: an exploratory study," *3D Printing in Medicine*, vol. 6, no. 1, Dec. 2020, doi: 10.1186/s41205-020-00075-4.

[75] S. Portnoy *et al.*, "Automated 3D-printed finger orthosis versus manual orthosis preparation by occupational therapy students: Preparation time, product weight, and user satisfaction," *Journal of Hand Therapy*, vol. 33, no. 2, pp. 174–179, Apr. 2020, doi: 10.1016/j.jht.2020.03.022.

Appendix A

- <Overview of the orthoses for upper extremity found in literature review>

A) Paterson et al. 2014 [47] / B) Palousek et al. 2014 [48] / C) Kim et al. 2015 [49] / D) Baronio et al. 2016 [50] / E) Houston-Hicks et al. 2016 [51] / F) Lin et al. 2016 [52] / G) Cazon et al. 2017 [53], [54], Paterson et al. 2015 [54] / H) Chen et al. 2017 [55] / I) Souza et al. 2017 [56] / J) Fernandez-Vicente et al. 2017 [24] / K) Kudelski et al. 2017 [57] / L) Lim et al. 2017 [58] / M) P Fitzpatrick 2017 [59] / N) Saldaña-Martínez et al. 2017 [60] / O) Blaya et al. 2018 [61], Blaya et al. 2017 [27] / P) Li et al. 2018 [62] / Q) Rosenmann et al. 2018 [63] / R) Wang et al. 2018 [64] / S) Górski et al. 2019 [65] / T) Guida et al. 2019 [66] / U) Lee et al. 2019 [67] / V) Schmitz et al. 2019 [68] / W) Yan et al. 2019 [36] / X) Burgo et al. 2020 [69] / Y) Chen et al. 2020 [70] / Z) Chu et al. 2020 [71] / AA) Fitzpatrick et al. 2020 [31] / AB) Górski et al. 2020 [72], Łukaszewski et al. 2020 [73] / AC) Janzing et al. 2020 [74] / AD) Mohammed et al. 2020 [19] / AE) Portnoy et al. 2020 [75].

Appendix B

- <Pictures from the user test with Subject 1 – Orthosis 1>

- <Pictures from the user test with Subject 1 – Orthosis 2>

- <Pictures from the user test with Subject 2 – Orthosis 3>

- <Pictures from the user test with Subject 3 – Orthosis 4 and 5>

- <Pictures from the user test with Subject 3 – Orthosis 6 and 7>

- <Pictures from the user test with Subject 4 – Orthosis 8 and 9>

- <Pictures from the user test with Subject 5 – Orthosis 10 and 11>

(Due to the subject’s severe health condition, it was not possible to take pictures of wearing the orthoses.