The V3D Socket

Designing a Volume-adjustable, Affordable, 3D printable, Transradial, Prosthetic socket

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By

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ABSTRACT

The conventional fabrication process of prosthetic sockets is known for being labor-intensive and time-consuming. It takes the user to wait 2-5 weeks to receive the prosthetic socket. In addition, most of the conventional sockets have fixed volumes that do not consider the volume fluctuations that the user experience daily because of muscle activities and comorbid medical conditions. 3D printing has shown promising results in producing lower limb sockets; however, upper limb sockets are overlooked. The goal of this master thesis is to design and fabricate a volume-adjustable, affordable, 3D printable transradial, prosthetic socket.

In this research, the V3D (Volume-adjustable, 3D printable) socket has been developed with a material cost of only €30. The socket provides a volume-adjustable closure system around the residual limb, easiness of donning and doffing without skin shearing, full elbow extension, high range of flexion, low weight, and breathability. The socket was designed to be able to withstand a load of 50N that can be applied axially or transversely at the tip of the socket without breakage. The designed socket was 3D printed using the Fused Deposition Modeling (FDM) printing technique, from tough Polylactic Acid (tough PLA). Mechanical and human assessments have been conducted to evaluate the strength, function, and comfort of the developed socket.

Results have shown that the socket managed to withstand a load up to 100N that was applied axially and transversely, respectively, without showing any signs of damage. During testing the socket with 5 participants for evaluating its comfort and function, the socket has succeeded to achieve full contact with the residual limbs, while offering volume-adjustability that accommodated the differences in size and properties of the residual limbs among participants. Not only that, but also, the socket succeeded to allow full elbow extension, a range of flexion up to 95°, and donning and doffing in less than 10 seconds without applying any shear forces on the skin.

The developed V3D socket has proven the possibility to 3D print reliable sockets using the FDM printing technique with a total labor time of 4 hours per socket, and a total fabrication time of 5 days with a material cost of only €30. In addition, the socket has proved that it can be fitted using a caliper in case 3D scanners are not available. That advantage makes producing the V3D socket feasible in communities that do not have access to 3D scanners. Furthermore, the socket can be parameterized such that users with similar geometry and comparable sizes of residual limbs can fit the same socket, which would make the fabrication process less labor-intensive and less time-consuming as it was aimed for.

PREFACE

As a 15-year-old girl in Egypt who was fascinated by the majors of the STEM (Science, Technology Engineering, and Mathematics) fields, nine years ago I have joined a project-based learning high school, aiming to find my own passion. At that stage of my life, I was first exposed to the basics of scientific research and to the idea of building things from scratch. That is when my passion for majoring in mechanical engineering started. Graduating from high school, I was grateful to be one of the 25 girls from Egypt who was granted a full scholarship to pursue my bachelor's study in the United States. Leaving home, at the age of 18, and chasing my goal of learning more in-depth about mechanical designing to turn ideas into reality was always my motive to overcome the challenges I found in that journey. Towards finishing my bachelor's degree in mechanical engineering, I used to feel that something was missing. Only, when I got the opportunity to work on developing a pressure-redistribution bed for preventing the formation of pressure ulcers for children with brain injuries, I found what I was missing. I was missing to feel that what I have been learning can impact and change someone's life for the better. That is when I decided to pursue a master's degree in biomechanical engineering. Particularly, in the second year of my master's study, when I got the opportunity to develop hand splints for people suffering from joint pain, was when my mindset has changed. At that stage, I was confident that I want to make my thesis project on a topic that makes a difference in someone's daily life. When I was asked to choose from some topics for my thesis work, developing a 3D-printable prosthetic socket was my first choice without any doubts.

Helping people with upper-limb amputation to have a comfortable prosthetic socket, that no longer shears their skin, no longer cost them hundreds of euros, and no longer makes them wait up to 5 weeks to receive their socket and keep replacing it to fit the changes of their residual limbs, was my new goal. To be honest, it was never easy. It was not only challenging to put myself in the shoes of a person with upper limb amputation to understand their needs and develop a socket from scratch but also to keep myself energetic to keep all the work on track. During my master's study, I was away from my home country, and my beloved ones for more than a year after the pandemic of COVID-19 hit the world. It required a lot of self-discipline, and adaptability to accept those facts and willingly clear my mind to innovate, design, build and graduate on time.

Now after achieving that goal and developing the V3D socket with a material cost of only €30 for people with transradial amputation, I must say that all of what has been accomplished was not only because of my effort. I am so grateful to God who was so generous to bless me with the Justus and Louise van Effen Excellence scholarship to pursue my master's study at TU Delft, who guided me in that journey to find my passion and reach my goals. I am very grateful for Dr. Gerwin Smit, my first supervisor, who was very generous and supportive in guiding me to tackle the challenges of my thesis project. I am also very grateful to Mrs. Femke de Backer-Bes, the certified prosthetist whose critiques and feedback on my design helped me to improve it further. Moreover, I am thankful for Mr. Jan Van Frankenhuyzen and Mr. Reinier van Antwerpen who helped me in the prototyping phase of the socket. Also, I am thankful to Prof. Paul Breedveld for his helpful feedbacks that helped me organize my thesis report. Not to mention, I am extremely thankful to my parents, and my brothers; Osama and Amr, for their great support during all my educational journey, and for always believing in me. I am also very thankful for all my teachers, and friends who supported and encouraged me to reach my goals. Finally, I am very grateful to God for blessing me with my fiancé, Ibrahim. That man who was always by my side in that hard time, and willingly was supporting and guiding me not only personally, but also with his critiques that helped me enhance my design. I love you from the bottom of my heart, Ibrahim…

Israa Abdelaziz
Delft, May 2021

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INTRODUCTION

1.1 BACKGROUND INFORMATION

1.1.1 Upper limb prosthetic sockets

It is estimated that about 15 out of 100,000 newborns in the United States are affected with congenital upper limb anomalies, and 6000–10,000 people undergo upper limb amputations each year [1]. To perform daily life activities, people with upper limb absence use prostheses. An upper extremity prosthesis is an artificial replacement of the lost part of the body, aiming to restore some of the lost functions of that part. It consists of a socket, a suspension tool to the arm, a power source, and joints depending on the amputation level. The socket is the most important part of a high-performance prosthesis [2], [3]. A socket is a cavity that fits the unique geometry of the residual limb, the remaining part of the body after an amputation, for a secure connection between the limb and the prosthesis [4]. The goal of a socket is to smoothly transfer loads while distributing the load evenly to limit pressure concentrations. To achieve that, the socket has to be well-fitted and comfortable for a functional prosthesis [5]. If the socket does not fit well, that can cause pain, blisters, ulceration, and damage to the skin and the tissues underneath [4], [5]. Therefore, to avoid those problems, the socket needs to be replaced regularly as long as the residual limb changes over time, causing the socket to wear out [4], [6]. The socket design varies based on the amputation level, which can be: shoulder disarticulation, transhumeral, elbow disarticulation, transradial (below elbow), wrist disarticulation, and transcarpal [7], see Figure 1.1. Among those levels, transradial amputation is the most common [8].

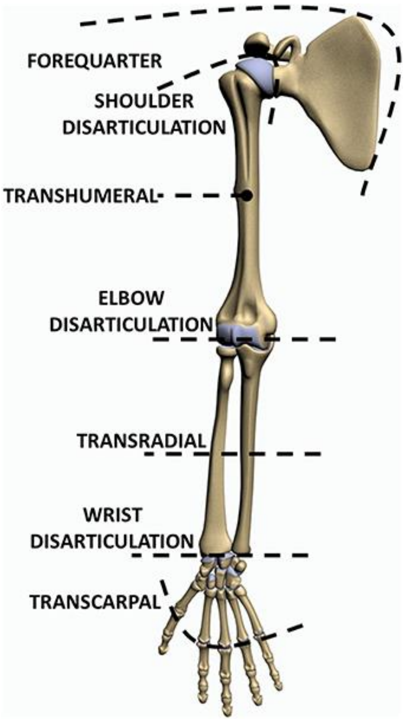

Figure 1.1 . Upper limb amputation levels [9]*. Transradial amputation is the most common.*

1.1.2 Conventional fabrication process of sockets

The conventional fabrication process of sockets is known to be time-consuming and labor-intensive [10]–[12]. It involves applying some pressure on the residual limb where the socket trimline will be pushing (called the rectification process), wrapping the limb in plaster-soaked bandages to make a negative mold, filling the negative mold with plaster to make a positive mold, vacuum forming a heated thermoformed sheet around the positive mold to create a diagnostic socket, and fabricating the final socket after making sure that the desired fit is achieved, see Figure 1.2 [13], [14]. To receive a conventional socket, the patient has to wait 2-5 weeks and sometimes even more [14]. In addition, the fabrication process is irreversible when errors happen [14]. In other words, if the diagnostic socket does not happen to fit the residual limb accurately, the prosthetist may have to repeat the entire process. Moreover, if the patient experiences rapid anatomical changes to the limb or gains some weight, a new socket has to be made.

Figure 1.2. Conventional fabrication process of sockets. (a) Rectification process (b)-(d) Creating a negative mold of the residual limb (e) Filling mold with plaster (f) Positive mold of the residual limb [15].

Most of the conventionally fabricated sockets have fixed volumes, although the residual limb experiences volume fluctuations due to swelling or comorbid medical conditions, especially in the first two years after an amputation. In addition, it experiences volume fluctuations due to muscle activities with performing different daily tasks [16]–[18]. Therefore, fixed volume sockets lead to discomfort which is one of the reasons leading the user to abandon the entire prosthesis [18], [19]. The price of a conventional socket ranges from hundred dollars to thousands of dollars for a new fitting [20]. Thus, having to regularly replace the socket to fit the volume changes of the residual limb adds up to the total cost of a prosthesis. In addition, A prosthesis use rate of 93% was reported for patients who get fitted with a prosthesis within the first month after the amputation. On the other hand, without the early fitting of a prosthesis, a prosthesis use rate of 43% was reported [21]. Moreover, rejection rates of prostheses are up to 52% for people with upper limb amputation and vary for children from 30% to 50% [19], [22]. Reasons for the high rejection rates were mostly uncomfortable fitting of the socket, heavy weight of the prosthesis, limited functionality, non-attractive appearance (especially for children), and high cost [19]. Therefore, making comfortable, volume-adjustable sockets could reduce the rate of abandoning upper limb prostheses as they would:

- Make donning and doffing the socket easy so that no shear forces would be exerted on the skin as fixed volume sockets do.
- Allow early fitting of the prosthesis since it will adapt to the changes of the residual limb happening in that stage.
- Reduce the total cost spent in replacing the prosthesis because of volume change of the residual limb.
- Allow the user to fine-tune the socket fitting based on the task the user is doing.

In addition, making the fabrication process less time-consuming and less labor-intensive would accelerate the receiving and fitting time of the prosthesis.

1.1.3 3D printing approach

Computer-aided Design (CAD) and Computer-aided Manufacturing (CAM) have entered the orthopedic and prosthetic field with the aim of reducing labor work and achieving high personalization to the user. In this approach, the entire labor-intensive process for making a positive mold of the residual limb is replaced by 3D scanning where a digital image of the stump is taken. Then the scan of the residual limb gets modified via CAD software. After that, the prosthetic socket is designed based on the modified scan, and finally, the socket is 3D printed, see Figure 1.3, [10], [23].

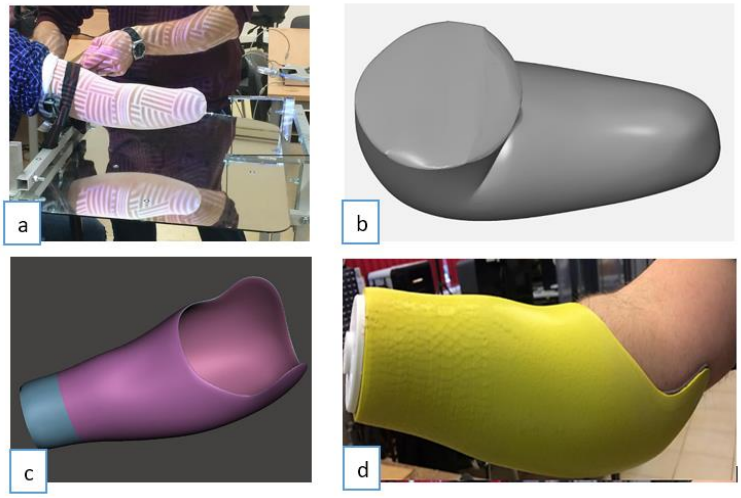

Figure 1.3. 3D scanning and printing of a transradial socket (a) scanning process (b) scan model into CAD software (c) CAD modeling of the socket (D) 3D printed socket [2].

Three-dimensional (3D) printing, which is also commonly known as additive manufacturing, is defined as “The fabrication of objects through the deposition of thin layers of material using a print head, nozzle, or other printer technology” [24]. There are different techniques of additive manufacturing; Fused Deposition Modeling (FDM), Selecting Laser Sintering (SLS), and Stereolithography (SLA). FDM is the most common where a thermoplastic material fed into the printer head is heated and extruded, creating layers of the cross-sections of the component [23]. SLS technique uses a laser to fuse a layer of powdered polymer material, such as Nylons and polycarbonates, to bind the material together, building a solid structure. SLA technique uses a liquid photosensitive resin that hardens when exposed to ultraviolet (UV) light [4]. This new manufacturing approach is known for its ability to fabricate high complex geometries, print high personalized and customized devices, save material, allow rapid design improvements, and perform the fabrication process with less cost, time, and manual work compared to the traditional fabrication method [7], [19], [23], [25]–[28]. 3D printing showed promising results for fabricating lower limb sockets, and terminal devices of the prosthesis [14]. Since upper limb prostheses do not need to be bear high weight compared to lower limb sockets, 3D printing comfortable and reliable upper limb sockets is a high potential. After conducting a literature review on the recent research done on 3D printed upper limb sockets during the past 10 years, see Appendix A: Literature review, it was found that compared to lower limb sockets, fewer attempts were focused on 3D printed upper limb sockets. The main results and gaps found are summarized and listed below:

- Most of the 3D printed sockets are with fixed-volume and are transradial sockets.
- Most of the 3D printed sockets are made from (Polylactic Acid) PLA or (Acrylonitrile Butadiene Styrene) ABS.
- Durability is a common concern of 3D printed upper limb sockets.
- There is almost no mechanical assessment of the 3D printed sockets to check their reliability.
- There is no guideline as to which 3D printing settings to use for producing a reliable socket; different printing settings among studies were found for sockets printed from the same material, and no reasoning was mentioned for choosing those settings.
- Involving a certified prosthetist in the socket designing process is recommended before it is 3D printed for the safety of the user.
- Involving the patient's feedback in the designing process is valuable and may help to reduce the rejection rate of prostheses.

1.2 PROBLEM DEFINITION

This thesis work addresses the conventional fabrication process of upper limb sockets from two aspects. First, the labor-intensive and time-consuming nature of the process. Second, the fixed-volume sockets resulting from this process, which need regular replacement for accommodating the volume fluctuations of the user's residual limb, which adds up to the total cost of the prosthesis.

1.3 GOAL & OBJECTIVES

Based on the problem statement, and the fact that transradial amputation is the most common for upper limb amputations, the goal of this master thesis is to tackle that problem through designing a volume-adjustable, affordable, 3D printable, transradial, prosthetic socket. To achieve that goal, the following objectives were set:

- Define the needs of people with transradial amputation to deliver the design requirements of the socket.
- Design the transradial socket in collaboration with a certified prosthetist.
- Develop a prototype of the socket.
- Perform mechanical assessments to the socket.
- Perform human evaluation to the socket.
- Evaluate the overall performance of the socket, and what needs further improvement.

2

METHODS

2.1 ENGINEERING DESIGN PROCESS

2.1.1 Introduction of methodology

Generally, a design methodology is used as a systematic approach towards turning some requirements into a product that meets those requirements, following some guidelines. Since this thesis work involves designing, building, testing more than making observations and doing analytical experiments, a design methodology to solve the mentioned problem was chosen [29]. In this research, the Engineering Design Process, known as EDP, which is commonly used in creating functional products and processes was followed. This methodology is known to be a highly iterative process where part of the process can be repeated many times for improving the design and meeting its requirements. The steps of this methodology are shown in Figure 2.1. If we divide the phases of this methodology, we will find that it has main three phases: pre-design phase, designing and development phase, and evaluation phase.

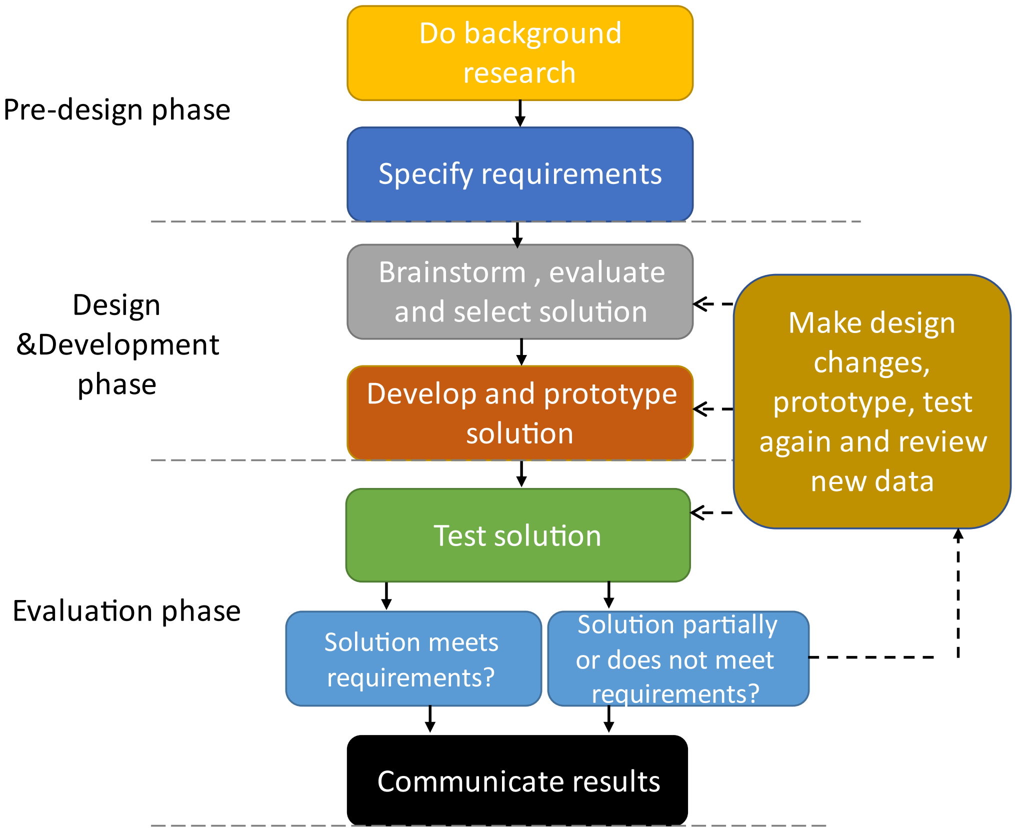

Figure 2.1. The Engineering Design Process (EDP) used to achieve the objectives of this research [29].

2.1.2 Pre-design phase

After making a clear definition of the problem that the research aims to solve, the first step in the pre-design phase is to conduct a background study about the problem to be able to derive the user's needs and to be aware of the current solutions. This study was conducted in Chapter

3, and it focuses on the types of prostheses, the history of common transradial sockets with their advantages and disadvantages, suspension methods of sockets, design consideration of transradial sockets, and the common adjustable closures used with prostheses.

The second step of this phase is to specify the design requirements of the socket. Those requirements would be derived from the study, conducted in Chapter 3. Starting from this step, a collaboration with the certified prosthetist*, Femke de Backer-Bes* from *De Hoogstraat rehabilitation center*, was made to have regular feedback and critiques on the developed design for further improvement. With deriving the design requirements of the desired solution, this phase ends, and the second phase starts.

2.1.3 Design & development phase

The first step in the design and development phase is to generate concepts. In Chapter 4, the morphological chart was used for generating different concepts in an analytical and systematic manner through combining different solutions that can fulfill each of the (sub)functions of the desired solution. To evaluate the generated concepts from the morphological chart, a method for concept selection was then applied. That method is the Pugh method, which is also known as the Decision-matrix method. Its main goal is not to select the best concept to apply but the best concept or combination of concepts to further develop, which opens the mind of the researcher for more ideas. Combined with this methodology, critiques from my supervisor, some MSc colleagues, and the certified prosthetist, Femke, were always requested to further improve the design.

The second step in this phase is to develop the selected concept. Therefore, the selected concept was optimized in Chapter 5 in which a preliminary design of the selected concept was developed via Fusion 360. To make a quick evaluation of the design, some parts of the socket were 3D printed for testing their function using the FDM printing technique, and the Ultimaker S5 3D printer. It was meant not to 3D print the entire design in this step, but samples, to save time and material. Based on the evaluation of the samples, design iterations or further improvements were decided and implemented. After that, material selection and printing settings of the socket were decided, mentioned in Chapter 6. Based on those decisions, the prototype of the design was created. With producing the socket prototype, this phase ends, and the entire product evaluation phase starts.

2.1.4 Evaluation phase

The last phase of the EDP process is to evaluate the developed solution. In this step, explained in Chapter 7, mechanical assessment of the socket structure, and human evaluation of the socket comfort and function was performed to validate the design requirements of the socket. Based on the results of those tests, conclusions of what needs to be improved in the design were reached. As an outcome of this thesis work, a collaboration with Radboud University Medical Center (RUMC) was established. In this collaboration, the socket design was handed to RUMC to be part of the 3D Sierra Leone project. The aim of that project is to develop 3D printable arm prostheses for people with transradial amputation in Sierra Leone. In that collaboration, the socket is expected to be adapted to fit their requirements. Then the socket will be tested on Dutch users and users from Sierra Leone.

3

BACKGROUND STUDY

3.1 TYPES OF PROSTHESES

Generally, there are two main types of prostheses: passive and active [30]. A passive prosthesis cannot move to actively grasp objects, and it mainly serves an aesthetic purpose. Therefore, a cosmetic prosthesis is a passive prosthesis, see Figure 3.1. On the other hand, an active prosthesis has a functional purpose as it allows the user to grasp objects. There are two types of active prostheses: a myoelectric prosthesis and a body-powered prosthesis [30], [31].

Figure 3.1. Cosmetic prosthesis, which serves mostly for an aesthetic purpose [32].

A myoelectric prosthesis contains electrodes that are placed over the skin to measure the electrical signals generated by the muscles of the residual limb. Those signals are then sent to command the terminal device of the prosthesis, which is the electric hand, to perform the desired motion, see Figure 3.2 [33]. For this type of prosthesis, the prosthetic socket needs to secure a space for the electrodes, control unit, and battery that are responsible for operating the prosthesis motors. On the other hand, a body-powered prosthesis is not powered by an external source, but by the user's body. It is usually suspended to the user's body with a shoulder harness. It commonly ends with a hand or a hook that opens and closes through body movement such as stretching out the arm or moving the shoulder in such a way that pulls cables connected from the harness to the terminal end of the prosthesis [34].

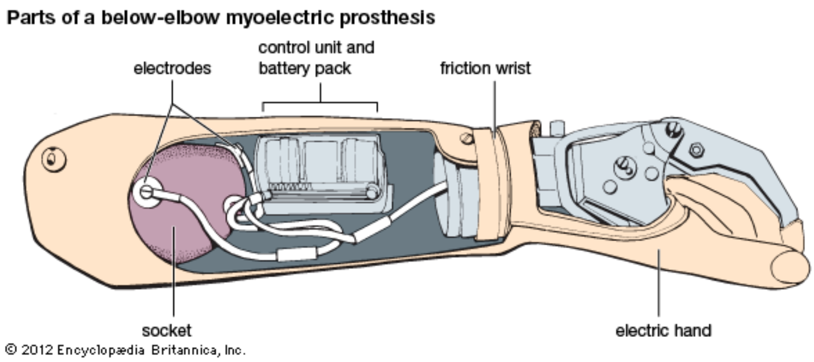

Figure 3.2.A myoelectric prosthesis where electrodes are taking part in the socket to measure electrical signals before generating the desired motion of the electric hand [35].

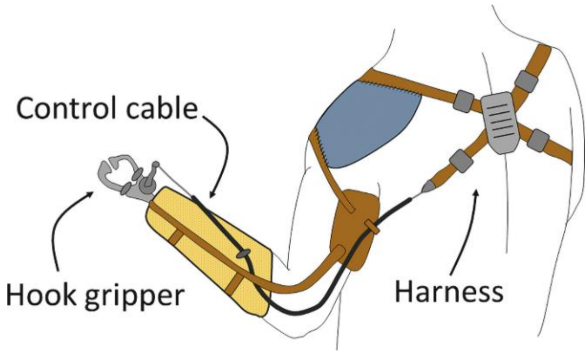

Figure 3.3. Body-powered prosthesis which involves a shoulder harness whose movement opens and closes the terminal device of the prosthesis through the connected control cable [36].

3.2 HISTROY OF TRANSRADIAL SOCKETS

3.2.1 Transradial amputation

Transradial amputation is one of the most frequent amputation levels [37]. It is the transverse loss of a part of the forearm where the remaining length of the forearm can vary. The length of the transradial residual limb is classified as very short, short, medium, and long based on the limb length from the elbow [7]. That length impacts the possible functions of the forearm; mainly the range of flexion, extension, pronation, and supination, see Figure 3.4. According to Peter et al., "it is crucial to preserve the length of the residual limb for improved pronation, supination, and prosthetic fit" [38].

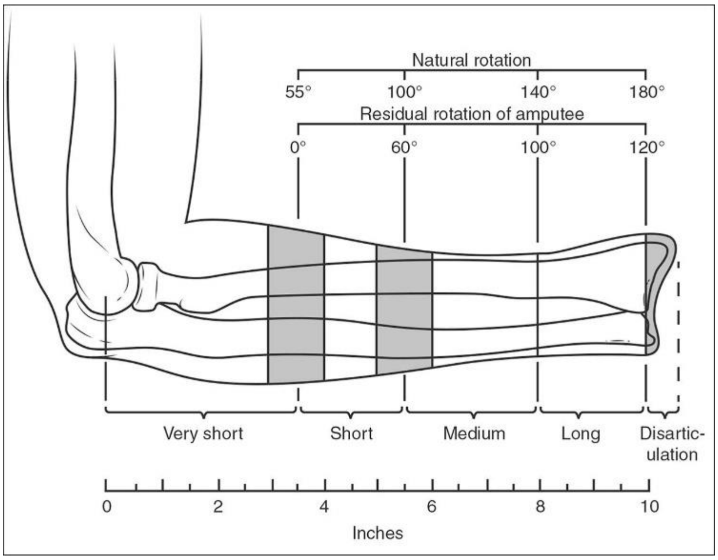

Figure 3.4. Degree of rotation at different levels of forearm amputations [38]. *A Very short residual limb has the least range of arm rotation (pronation and supination).*

3.2.2 Suspension methods of transradial sockets

To guarantee a high performance of a prosthesis, a prosthetic socket needs to be securely suspended to the residual limb. There are different ways of socket suspension; suspension with straps where a harness is used, silicon suspension where a silicon liner is used, vacuum suspension where the residual limb is connected to the socket by applying vacuum, Osseointegration where screws are implanted into the arm bones for direct attachment with the prosthesis, and self-suspension [3], [39]. Self-suspension is the most common for transradial sockets. It works by enveloping over bone prominences of the elbow joint; mainly the olecranon and epicondyles, as shown in Figure 3.5, and compressing or constricting some soft tissues of the residual limb, [33].

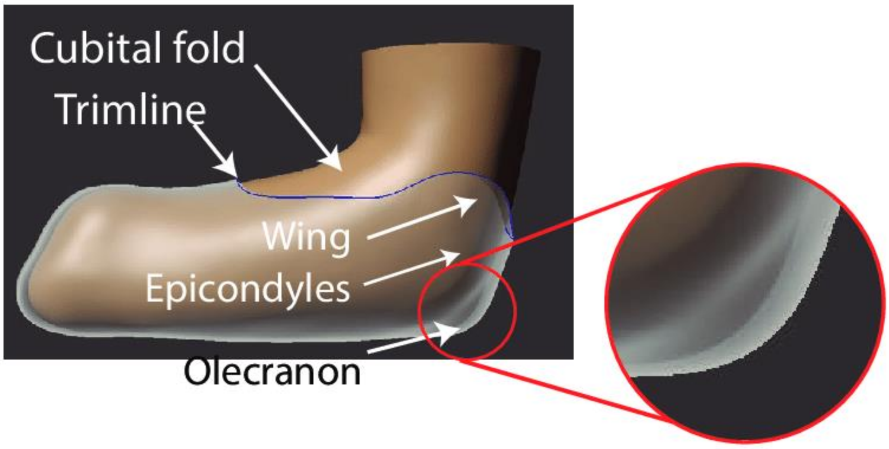

Figure 3.5. Covered elbow prominences in self-suspension sockets [14].

3.2.3 Transradial socket designs

Since 1968, some self-suspension sockets started to be developed and used worldwide, see Table 3.I. The most common ones are summarized in Table 3.I with their features and drawbacks [3], [40].

Table 3.I. Conventional transradial sockets with their features and drawbacks.

Socket name	Features	Drawbacks
Muenster-type socket [3], see Figure 3.6A	Used for short residual limbs, achieves Secure-connection as it is a full-contact socket	Both limit range of motion, have a difficult fitting procedure, may cause skin irritation due to shearing the skin, cause perspiration problems, and soft tissues often bulge distal to the cubital fold during flexion
Northwestern university socket [41], see Figure 3.6B	Used for long residual limbs, takes great care of the biomechanics of socket design	
¾ transradial socket [42], see Figure 3.6C	Both overcome ventilation problems, improve suspension, and increase Range of Motion (ROM), and increase ease of donning	Both increase the probability of debris.
Ergonomic socket design [43], see Figure 3.6D		
High-Performance Variable Suspension Prosthesis (HPVSP) [44], see Figure 3.6E	Used for short to mid-length residual limbs, suitable for different activities including sporting activities as it offers increased prosthesis versatility	Requires a silicon liner that causes some ventilation problems; heat dissipation, and moist conditions
WILMER open socket [45], see Figure 3.6F	Good ventilation, easy to don and doff, offers adjustability, and strong enough to transfer forces	Difficult to manufacture

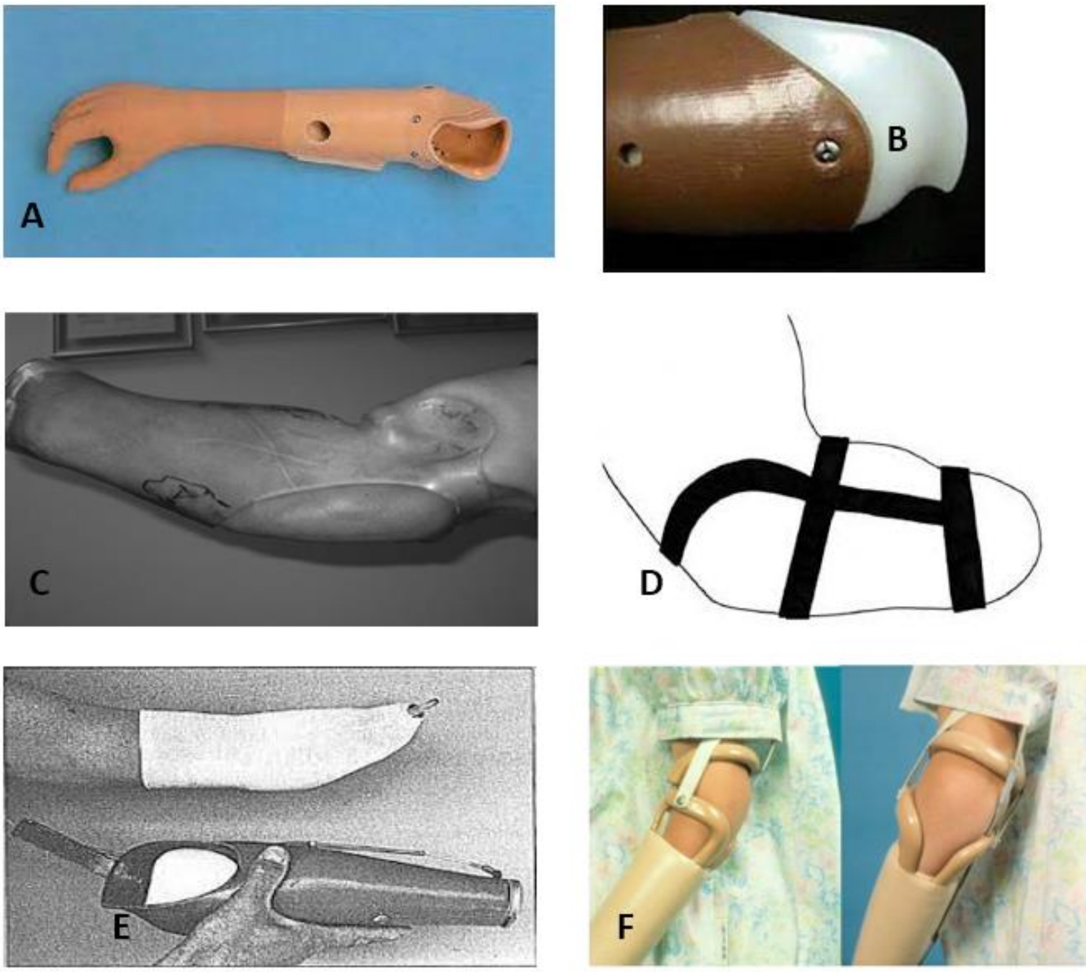

Figure 3.6. Common conventional transradial sockets (A) The Muenster-type socket [3] *(B) The Northwestern University sockets* [41] *(C) The 3/4 transradial socket* [42] *(D)The Ergonomic socket design* [43] *(E) The HPVSP prosthesis* [44] *(F) The WILMER open socket* [46].

After developing those common transradial socket designs, some self-suspension interfaces started to address the problem of bulging the residual limb soft tissues by accommodating some openings for their release. The ACCI (Anatomically Contoured and Controlled Interface) was introduced for users with very short residual limbs. It is a supracondylar interface where elongated wings are covering the epicondyles, the olecranon region, cubital region while relieving the antecubital region [3], [41], see Figure 3.7A. Then, the TRAC (Trans-Radial Anatomically Contoured) interface was introduced for more aggressive contouring. It is a supraolecranon interface that extends over the olecranon and covers the antecubital region, epicondyles, distal radial region, wrist extensor, and flexion musculature, see Figure 3.7B. Therefore, this interface is more secured when the socket is loaded [3], [47]. After that, the CRS (Compression–Release Stabilization) interface, which is also known as High fidelity interface, is the latest introduced one. It works by covering the underlying bones of the residual limb along their entire length with three or more longitudinal depressions. In addition, it has openings between longitudinal depressions for releasing displaced soft tissues, aiming to add further stabilization between the socket and the residual limb, see Figure 3.7C [3], [48].

Figure 3.7. (A) The (Anatomically Contoured and Controlled Interface) ACCI socket [41] *(B) The (Trans-Radial Anatomically Contoured)TRAC socket* [47] *(C) The (Compression–Release Stabilization) CRS socket* [48].

3.2.4 Liners

Concerning having soft contact with the skin, liners, see Figure 3.8, are the most common inner shells that users of conventional sockets wear between the residual limb and the socket shell. The main tasks of a liner are to increase the comfort and enhance the suspension of the prosthesis. A liner is also used to make donning and doffing easier since conventional sockets are made to the exact size of the residual limb, which requires applying shear forces on the residual limb for fitting. The standard liners in the market are made from silicone or polyurethane (PU) or copolymers (TPE) [49]. The common disadvantage of the three types of liners is that they inhibit the cooling process of the skin. Therefore, many users give up wearing the liners because of complaints about perspiration or having pains or unpleasant odor [50]. After contacting Femke, a certified prosthetist, to know more about liners, she mentioned that some users still wear liners because they do not have many options to choose from.

Figure 3.8. Example of a liner [51]. *It is used below the socket to add comfort while donning and doffing the socket and to enhance the suspension of the prosthesis.*

3.3 DESIGN CRITERIA OF TRANSRADIAL SOCKETS

When designing a socket, two main design criteria need to be considered. The first criterion is the comfort and safety of the residual limb, and the second one is the smooth load transfer from the residual limb to the terminal device of the prosthesis. Usually, there is a tradeoff between both criteria as achieving smooth load transfer without force losses requires very secured attachment to the limb which in some cases could be uncomfortable [3].

The comfort and safety criterion can be divided into three main aspects: residual limb Range of Motion (ROM), ventilation, and contact with the skin. First, Range of Motion (ROM) is mainly referring to the elbow flexion and extension movements for short residual limbs [47]. For long residual limbs, it can refer to elbow flexion and extension movements, and to pronation and supination. When designing a socket, it is important not to restrict that range of motion so that the users can comfortably perform different activities. Second, ventilation refers to avoiding all the skin problems that can happen from accumulating waste products of the residual limb and sweating which is a rich medium for raising bacteria in the socket interface. Therefore, having openings in the socket frame is important for achieving this aspect to avoid skin infections, odors, blisters, and so on. The third aspect of this criterion refers to the normal pressure and the shear (friction) forces that are applied on the skin of the residual limb during socket usage. High pressure and high friction can lead to pressure ulcers, pain, and skin irritations [3].

The smooth load transfer criterion has two aspects; having stable and secured suspension and achieving balanced load distribution that fits the biomechanics of the residual limb. First, having stable suspension is needed during static and dynamic loading of the socket. With short residual limbs, the suspension is mostly achieved by enveloping the olecranon, and epicondyles, see Figure 3.5, while with long residual limbs, the suspension is mostly achieved through compressing the (anterior and posterior) or (lateral and medial) sides of the residual limb. Second, achieving balanced load distribution refers to loading the load-tolerant areas of the residual limb, while relieving sensitive and bony areas. Due to the low elastic modulus of the soft tissues, some motion is lost because the force of the residual limb is wasted in the deformation of the soft tissues. Therefore, for smooth load transfer, compressing the soft tissues between the underlying bones and the socket interface is needed to avoid energy loss [3]. Other general design criteria that are worth mentioning are the ease of donning and doffing, ease of performing maintenance, cost, appearance, and weight. A summary of the two main design criteria and their aspects is shown in Figure 3.9.

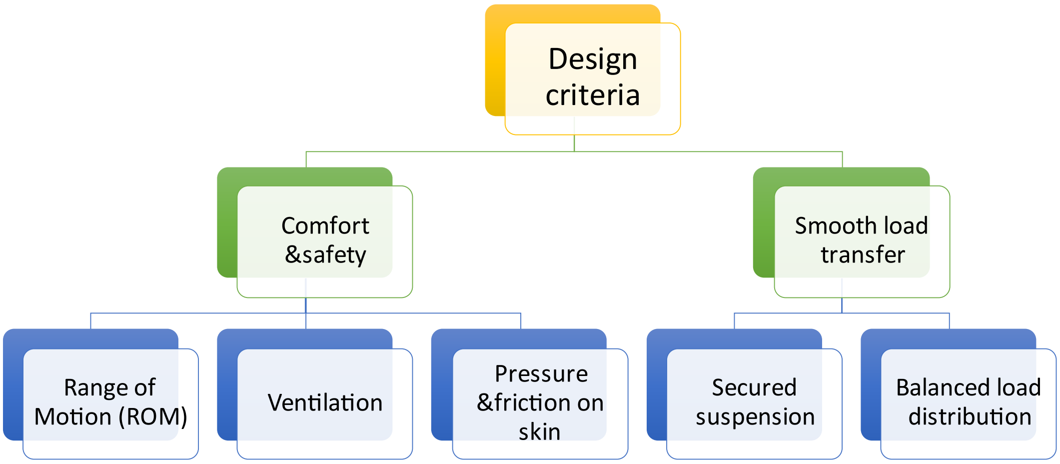

Figure 3.9. Design criteria of a transradial socket. Designing a user-friendly transradial socket means achieving comfort and smooth transfer of loads through considering each aspect of both criteria.

3.4 ADJUSTABLE CLOSURE SYSTEMS

Different types of adjustable closures have been used for lower limb prostheses to offer adaptability to the volume fluctuations of the lower residual limb. Some of those closures can be adapted to upper limb prostheses. Listed below are the adjustable mechanical closures that are commonly used [52]:

- **Hook & loop:** A Hook & loop closure is a fastener closure system. A good-quality hook and loop system can support high loads and have a long lifetime. Nevertheless, it makes some noise during opening and closing, and it may stick to clothes, see Figure 3.10A.
- **Adjustable hose clamps:** This closure allows precise adjustment, but with moderate pressures, the hose can slide off the nipple. Since this closure is made from metal, it could be uncomfortable for the user if it were part of the socket that is in contact with the skin for a long time, see Figure 3.10B.
- **Ratchet lock:** This closure type allows precise adjustment, but it can apply excessive tightening if not tightened accurately, see Figure 3.10C.

- **Ladder lock:** A ladder lock is used for macro volume adjustments. Using this closure for people with upper limb absence could be inconvenient since the user would need to hold the ladder in place with one hand and tighten the lock with another hand, see Figure 3.10D.
- **Lace-Tension mechanism:** This closure mechanism uses lace for manual adjustability around the residual limb through a small mechanical tensioner which the lace is wrapped around. This mechanism is very common in snow boots and sportive shoes. It is easy to adjust and has strong lace. Examples of some commercial lace-tension mechanisms are the BOA tensioner, and SIDI Tensioner, see Figure 3.10 E&F.

Figure 3.10. Adjustable closure systems in literature (A) Hook & loop [53] *(B) Adjustable hose clamp* [54] *(C) Ratchet lock (D) Ladder lock* [55]*. Lace-Tension mechanisms (E) The BOA lace-tensioner* [56] *(F)The SIDI lace-tensioner* [57]*.*

Knowing the socket suspension methods, design considerations for developing a user-friendly transradial socket, and the adjustable closure systems available in the market, the design requirements of the socket can then be derived. Also, knowing the common designs of the conventional transradial sockets, it can be decided if some features of those designs can be adapted in the 3D printing approach or not.

4

CONCEPT GENERATION

4.1 DESIGN REQUIREMENS AND WISHES

4.1.1 Assumptions

Starting from this step, a certified prosthetist, *Femke de Backer-Bes,* from *De Hoogstraat Revalidatie* was invited to be involved in the design phase. Her main input was reviewing the design requirements and giving critiques on the developed designs to end with a user-friendly transradial socket. Before deriving the design requirements of the desired transradial socket, the following assumptions were made. The socket is:

- For users with the most common geometries of residual limbs; cylindrical and conical, mentioned by *Femke de Backer-Bes.*
- For patients, whose residual limb is considered very short, short, and medium based on the definition given in Figure 3.4.

4.1.2 Design requirements

The design requirements of the desired transradial socket are derived based on the background study, conducted in Chapter 3, with the aim of producing a user-friendly transradial socket. Therefore, the socket needs to:

1. **Allow full extension (0°) and flexion up to (110°) of the elbow:** Flexion and extension range are usually affected by the prosthetic socket. Without a prosthesis, people with transradial amputation can achieve full extension, which is reached at 0°, and flexion up to 146° [47]. With prosthetic sockets, the full range of extension and flexion is never achieved, see Figure 4.1. Flexion is up to 98° for the Muenster and Northwestern sockets, while it is up to 110 degrees for the TRAC socket. Extension is up to 20° with the Muenster socket, up to 12° with the Northwestern socket, and up to 10° with the TRAC socket [47]**.** A full extension (0°) and flexion up to (110°) is aimed for the designed socket to add comfort to the user while performing different daily life activities. The chosen range of flexion is based on thee TRAC socket range which is one of the recent socket interfaces that is accepted by people with transradial amputation.

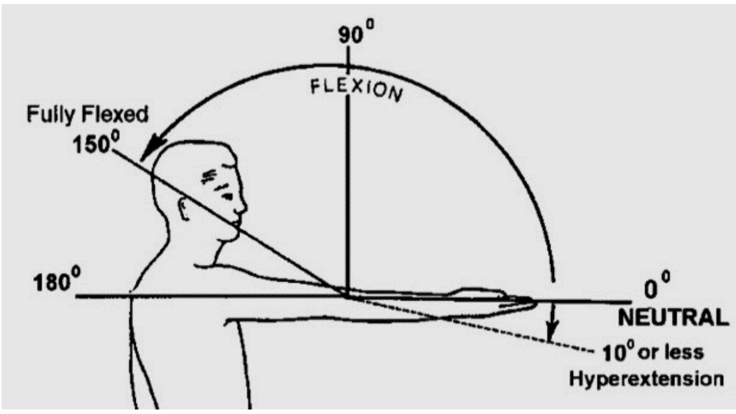

Figure 4.1. Range of motion of the elbow without an arm amputation, mainly flexion and extension. Full extension is achieved at 0° and full flexion is achieved at 150° [58]*.*

2. **Have a tightening and loosening system:** This requirement is needed to enable the user to tighten and loosen the socket around their residual limb in case of volume fluctuations. Since the stiffness of the residual limb varies from a user to another, the degree of adjustability needed for each case would be different. To quantify this requirement, the range of adjustability of the socket will be measured in how much the socket can be pushed inwards or outwards the residual limb for tightening, and loosening, respectively. Since it is critical not to overtight the socket, the socket was designed to push into the residual limb up to 15mm distance inwards. In addition, a higher range of adjustability was decided for loosening the socket to make the cleaning the socket easy besides adapting to the volume increase of the residual limb. That range was decided to be 30mm distance outwards the residual limb.
3. **Easy to don and doff**: A max. of 1min. is the limit for donning or doffing the socket. Since the desired socket is volume-adjustable, wearing the socket is expected to be an easy task as the user would only need to loosen the socket, don the residual limb into it, then tightening the socket.
4. **Can withstand being loaded axially and transversely up to 50N:** The socket is meant for performing basic daily life activities such as eating, performing hygiene activities, and shopping. Based on that definition, a maximum load of 50N was set as the limit load on the socket. For example, if the user wants to go to buy groceries, a bag with a maximum mass of 5kg (~ 50N) is allowed. That load can either be applied axially or transversely, which are the common ways for carrying a bag, see Figure 4.2.

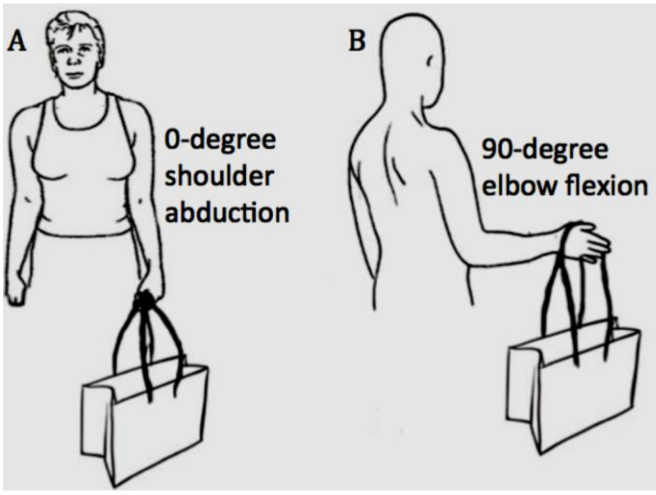

Figure 4.2. Illustration of the axial and transverse loading of the socket [59]*. Also, those are the common ways for carrying a bag.*

5. **Provide a secured self-suspension method to the residual limb:** This requirement means that the main suspending method to the residual limb will not include extra straps e.g., harness, but it will depend on enveloping some of the elbow prominences and constricting load-tolerant areas of the soft tissues of the residual limb. This method was chosen over a non-self-suspension method because every extra piece that gets added to the prosthesis requires extra effort from the user. For example, a harness was not decided to be a method of suspension as it gives a feeling of constructing the trunk of the user. It is hard to don and doff, hard to clean, forces the users to wear clothes underneath, may cause irritation especially in the armpits, and have poor cosmetic to the overall shape of the prosthesis [46].
6. **Can be customized to fit different types of wrist units**: Wrist units mostly can be circular or oval, see Figure 4.3, depending on the desired function of the wrist unit and the type of attachment to the terminal device (the artificial hand). Therefore, having a

design that can be customized to fit oval or circular wrist units will give the user the freedom of choice to the terminal device based on their needs.

Figure 4.3. Wrist units. (A) Circular wrist units [60]*. (B) Oval wrist units* [61]*. The socket model needs to be customized for the user to fit oval or circular wrist units based on the user's preference before producing the socket.*

7. **Can be adapted to a cosmetic and a body-powered prosthesis:** Basically, for adapting the socket to a cosmetic prosthesis, there is not a special feature to add to the socket, but to design a socket with an overall anthropomorphic geometry so the overall shape of the prosthesis follows the contours of the unaffected arm. For adapting the socket to a body-powered prosthesis, the socket should easily provide a space where a hook can be added to the design to allow the attachment of the harness.
8. **Be breathable:** Most of the existing standard sockets cover the entire residual limb such as the Muenster socket and the Northwestern university socket. Also, although some existing sockets do not cover the entire skin such as the ¾ transradial socket, ergonomic socket, and the WILMER socket, there is still a high probability of perspiration between the socket frame and the skin [3], [39]. To ensure that the designed socket will not result in skin irritation, blisters, and ulceration, the socket needs to be breathable with openings that are big enough for ventilation, and small enough for preventing the formation of marks on the skin.
9. **Be safe to the skin:** Since the user is expected to be in contact with the socket most of the day, the socket needs to be safe to the skin from wearing it until taking it off. First, during donning, the socket needs to be designed such that it does not shear the skin of the user but apply normal forces for suspension. The surface pressure may not exceed 4kPa to avoid blood occlusion [62]. Then, after wearing it, the material in contact with the skin needs to be FDA approved, soft and, does not provoke allergic reactions.
10. **Easy to clean**.
11. **Be weather-proof:** The socket does not oxidize and does not dissolve with water.

4.1.3 Wishes

1. **Maximal material cost of €100:** This cost includes the filament and all the non-3D paintable parts for assembly. It excludes the manufacturing cost.
2. **Maximal thickness of 4mm:** A maximal socket thickness of 4mm was decided such that the socket does not interfere with the users' clothes or restrict their styles.

Table 4.I. Summary of the design requirements and wishes of the socket.

#	Design requirements and wishes
1	Full extension of the elbow (0°) and flexion up to (110°)
2	Volume adjustability (15mm for tightening and 30mm for loosening)
3	Easiness of donning and doffing (within 1min.)
4	Load-resistance (50N axially & transversely)
5	Secured self-suspension
6	Adaptability to different types of wrist units
7	Adaptability to cosmetic and body powered prostheses
8	Breathable socket
9	Safe contact with the skin
10	Easy to clean socket
11	Weather-proof socket: does not oxidize, does not dissolve with water
W1	Maximal material cost of €100
W2	Maximal thickness of 4mm

By looking at Table 3.I, none of the common conventional transradial sockets can fulfill all the design requirements to be adapted to a 3D printable socket. Therefore, a new design was needed.

4.2 CONCEPTUAL DESIGNS

4.2.1 Brainstorm and concepts generation

To brainstorm ideas and generate different concepts, the morphological chart methodology was used. The morphological chart is an advanced design methodology in which (sub)functions of the desired design are listed corresponding to all the possible options or solutions that can fulfill those (sub)functions. Most of the options shown in the morphological chart, see Table 4.II, are derived from the background study conducted in Chapter 3. Based on this chart, 5 concepts were generated through combining solutions of each (sub)function together, see Figure 4.4. The generated concepts are explained in detail in APPENDIX B: Concept designs.

Table 4.II. The morphological chart for generating different concepts. From this chart, concepts are generated by combining options of each sub(function) together. All the options in the table were derived from the background study in Chapter 3.

(Sub)functions	Option 1	Option 2	Option 3	Option 4
Self-Suspension, recall Figure 3.7	ACCI (Anatomically Contoured and Controlled Interface) methodology	TRAC (Trans-Radial Anatomically Contoured) methodology	CRS (Compression –Release Stabilization) methodology	–
Volume adjustability, recall Figure 3.10	Hose clamp	Velcro (Hook & loop)	Lace-tension mechanism	Ladder lock

Soft contact with skin	Liner	3D printed flexible inner shell	Stump sock	–
Full elbow extension& flexion up to 110°	Elbow hinge	Make socket that attaches only below elbow	–	–
Ventilation	Breathable material	Make some openings in the socket	–	–

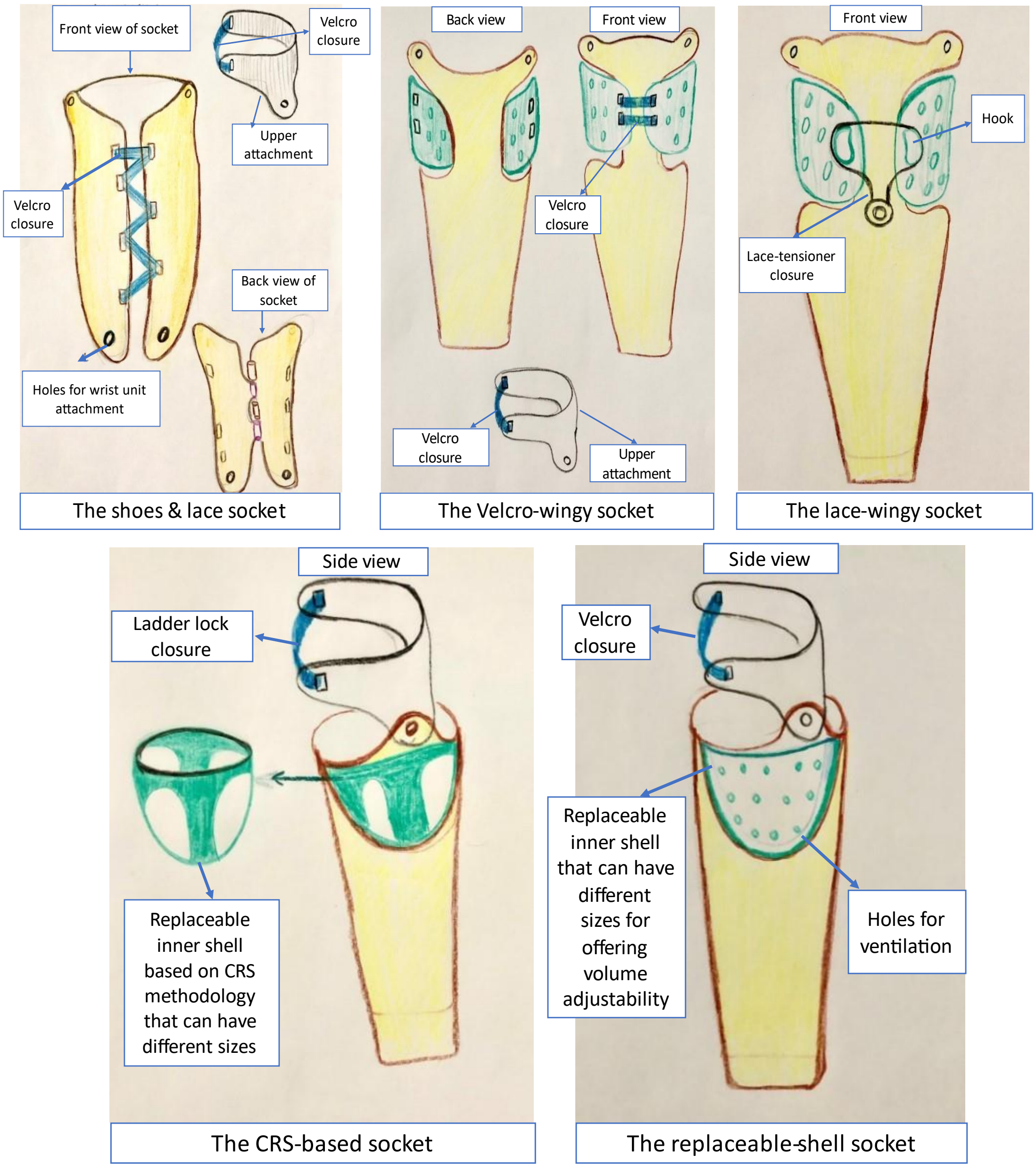

Figure 4.4. Generated concepts of the morphological chart. All concepts are sketched and explained in detail in I APPENDIX B: Concept designs.

4.2.2 Concept selection

To evaluate the generated concepts, a concept selection methodology was chosen. This methodology is the Pugh matrix whose goal is to select the best concepts that can be combined for further improvement of the design. In this methodology, one of the concepts is chosen to be a reference concept, where the rest of the concepts are compared to it based on a selection criterion that is derived from the design requirements. A reference concept is the one that fulfills the basic requirements of the socket. If a concept fulfills a criterion more or less efficiently than the reference concept, that concept gets a + or a -, respectively, for that criterion. If the concept is in the same level as the reference concept, it gets a 0. The summation of all pluses, minuses, and zeros for each concept is then calculated, and the concepts are ranked. Designs with the highest rankings can be combined if possible, see Table 4.III. This methodology was chosen as it reduces bias by providing a systematic approach during concept selection, more details about the Pugh matrix are in APPENDIX B: Concept designs. After applying this methodology, two concepts got the highest scores: The Velcro-wingy socket and the lace-wingy socket, see Figure 4.4. Since both concepts are similar except their closure systems, they were fused into one concept, see Figure 4.5 & Figure 4.6.

Table 4.III. The Pugh matrix for evaluating the generated concepts and selecting the concepts to combine and further improve. The Velcro-wingy socket and the lace-wingy socket received the highest scores. Although the shoes and lace socket has the same score as The Velcro-wingy socket, the shoes-and lace concept failed to fulfill some of the selection criteria compared to the Velcro-wingy concept. More explanation of the concepts and the Pugh matrix are in APPENDIX B: Concept designs.

Selection criteria	**Concepts**				
	The shoes & lace socket	The Velcro-wingy socket (Reference concept)	The lace-wingy socket	The CRS-based socket	The replaceable inner shell socket
Volume-adjustability	**+**	**0**	**+**	**-**	**-**
Elbow Range of Motion (ROM)	**+**	**0**	**+**	**0**	**0**
Design reliability	**-**	**0**	**0**	**-**	**0**
Ventilation	**-**	**0**	**0**	**0**	**0**
Easiness of cleaning	**+**	**0**	**0**	**-**	**-**
Adaptability to different wrist units	**-**	**0**	**+**	**0**	**0**
Self-suspension	**0**	**0**	**0**	**+**	**0**
Sum +'s	**3**	**0**	**3**	**1**	**0**
Sum -'s	**3**	**0**	**0**	**3**	**2**
Sum 0's	**1**	**0**	**4**	**3**	**5**
Net score	**0**	**0**	**3**	**-2**	**-2**
Rank	**2**	**2**	**1**	**3**	**3**
Continue with concept?	**No**	**Yes**	**Yes**	**No**	**No**

The selected socket concept, shown in Figure 4.5 & Figure 4.6, consists of three main parts: the main shell, the adjustable wings, and the upper attachment. The upper attachment will be connected to the main shell using revolute joints at the elbow, labeled as elbow hinges. The adjustable wings and the main shell are one connected piece at the back strip only, see Figure 4.6. The aim of the adjustable wings is to provide rotation around the longitudinal axis of the residual limb. Tightening the adjustable wings would push on the soft tissues of the medial and lateral sides of the residual limb for secure suspension, and efficient transfer of forces with the main shell. Evaluating this concept, it gives the user volume adjustability where it is needed. In other words, the design offers the user to freely adjust the socket around the residual limb without interfering with the wrist unit. In addition, the end of the socket can be customized to be elliptical to fit oval wrist units, and it can be circular to fit circular wrist units. Thus, this design gives the users freedom to choose the terminal device of their prostheses based on their needs. Therefore, this concept was selected.

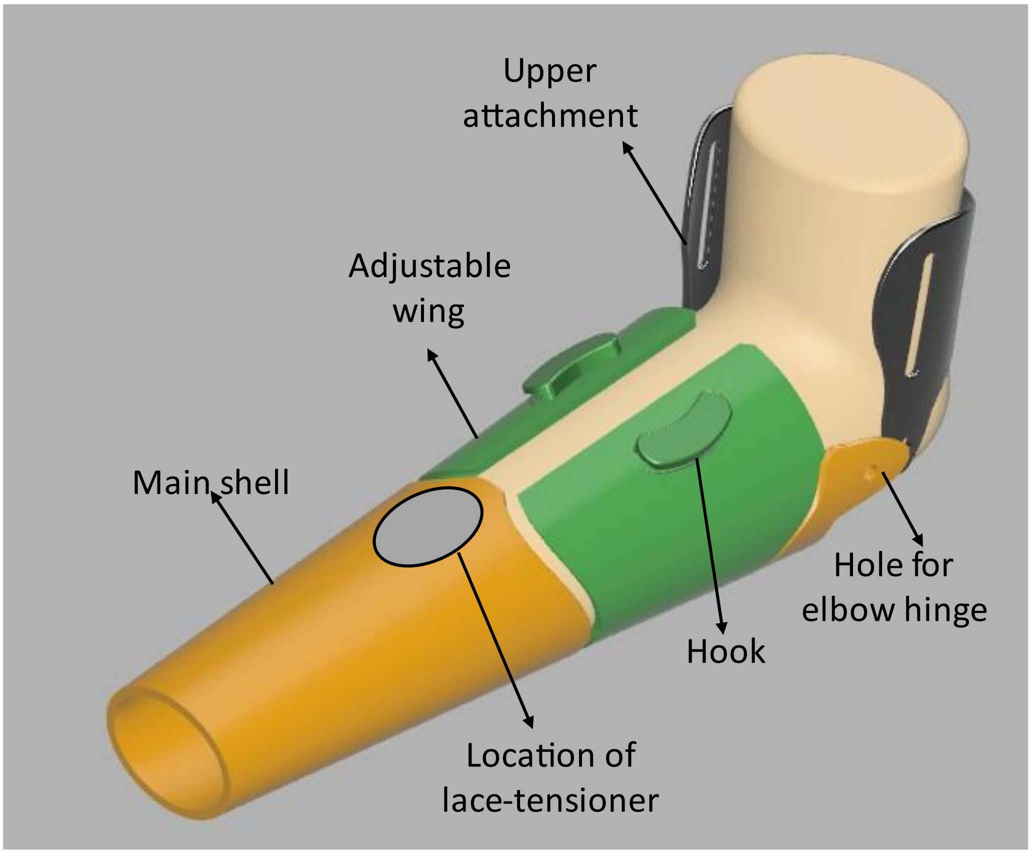

Figure 4.5. The selected socket concept. In this concept, volume adjustability is offered by the adjustable wings. A lace-tension mechanism would be used in this design to tighten and loosen the adjustable wings around the residual limb via a lace that would be fixed in the hooks. The end of the socket can be oval or circular to fit different types of the wrist unit. Choosing an oval or circular end would be left to the user's choice depending on the goal of the prostheses.

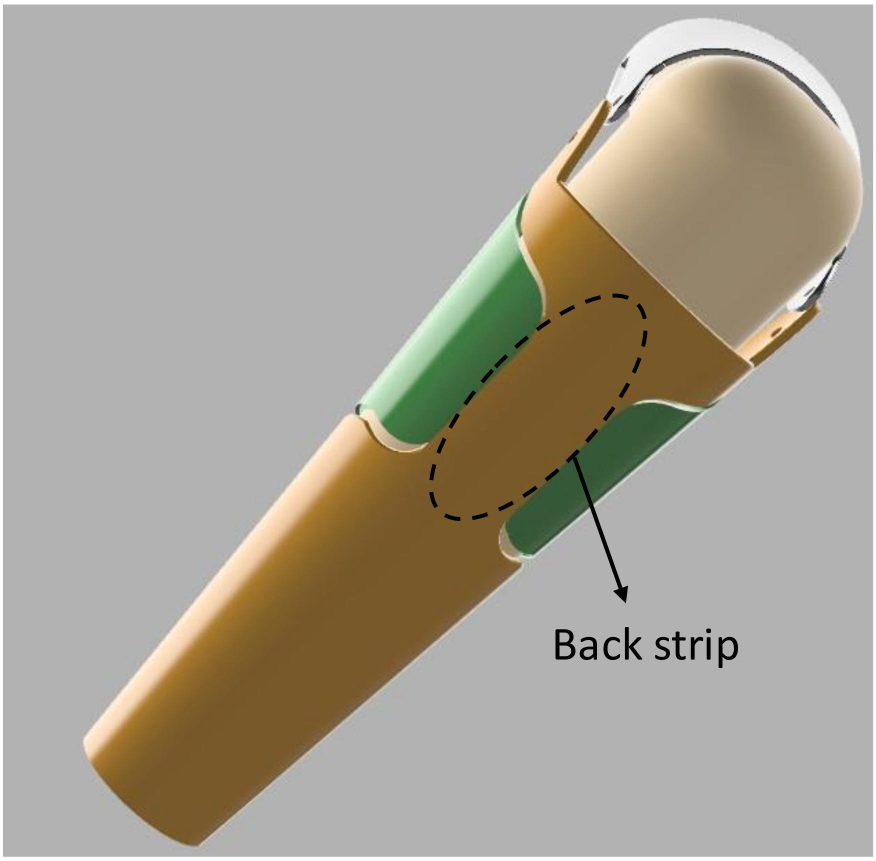

Figure 4.6. The selected socket concept, back view. The adjustable wings and the main shell are all one connected piece at the back strip of the socket.

Although the shoes & lace concept and the Velcro-wingy concept, shown in Figure 4.4, have the same rank, see Table 4.III, The shoes & lace concept failed to fulfill some of the selection criteria, indicated by – signs in the matrix. To visualize the 3D model of the shoes & lace socket concept, see Figure 4.7. The socket has two parts; an upper part which is called the upper attachment, and a lower part, making the rest of the socket, see Figure 4.7. The lower part of the socket consists of two identical halves that get connected using hinge joints, see Figure 4.8. The lower part has openings where a Hook and Loop (commercially known as a Velcro) closure can be attached, which mimic the laces of the shoes. Although this design can allow a wide range of adjustability due to the hinge joints connecting both halves, the design requires a certain type of wrist unit for attaching the terminal device (hand). Therefore, this design would constrain the user when choosing the terminal device of their transradial prosthesis, which may result in abandoning the entire prosthesis. In addition, since the adjustability feature is given to the socket along its entire length, that means that adjusting the socket may interfere with the wrist unit which would have a fixed size. Because of those disadvantages and the many parts of the socket that needs to be assembled and thus maintained, the concept was not considered reliable, and was not selected.

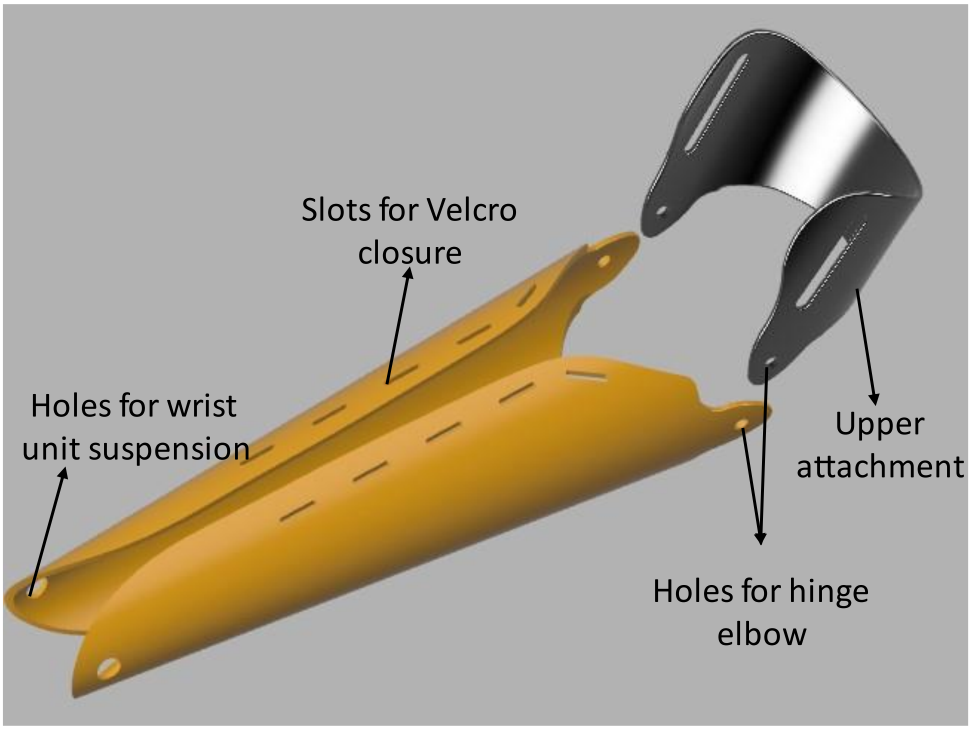

Figure 4.7. 3D model of the shoes & lace socket concept. It has two identical halves that get connected through hinge joints in the back. It offers volume-adjustability along the entire length of the prosthesis through the rotations of the two identical halves. This concept was not selected because it can adapt to only one type of wrist units, and when adjusting the identical halves, the socket will interfere with the wrist unit, making it less reliable.

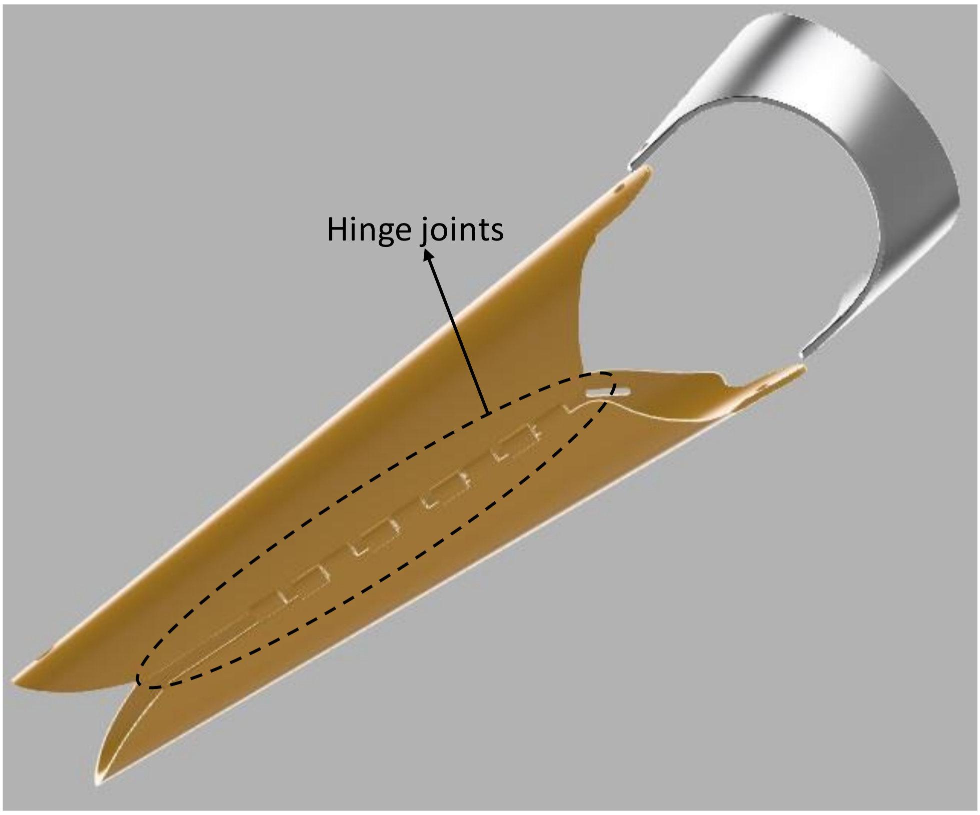

Figure 4.8. 3D model of the shoes & lace concept: Back view where the two identical halves are connected with hinge joints to allow rotation about the longitudinal axis of the residual limb to offer volume-adjustability.

4.2.3 Limitations of selected concept

Looking at the selected concept, see Figure 4.5 & Figure 4.6, from a mechanical perspective, when loading the socket with a transverse load such that the socket is in bending, the load would only be carried by the rigid structure of the socket, which is the main shell only. The adjustable wings would not be carrying the load since they are not rigid, but loose. Since the cross-section of the socket suddenly shrinks at the back strip, see Figure 4.6, that decreases the area moment of inertia of the socket cross section tremendously. Thus, stresses at the back strip, especially its end, could create a critical area where the socket can break when loaded in bending. To overcome this concern, optimization of this concept was needed for a balanced distribution of loads along the socket.

5

CONCEPT OPTIMIZATION

5.1 SOCKET OPTIMIZATION

5.1.1 Loading scenarios of the socket

In this section, the selected concept of the socket was optimized such that it does not break when loaded in bending to verify the 5^{th} design requirement of making a socket that can withstand axial and bending loads up to 50N without breakage. The most common scenarios for loading the socket are when an axial or transverse force is applied at the tip of the socket, mimicking the common ways for carrying a bag, see Figure 5.1. With the current design, loading the socket in bending, with a transverse force, raises a concern that a critical area would develop near the end of the socket. As mentioned in Chapter 3, part of developing a transradial socket depends on achieving a wise distribution of loads where the bony regions of the residual limb are avoided, some soft tissues are released, and load-tolerant soft tissues are compressed. Another aspect of achieving wise distribution of loads is balancing the load distribution along the socket parts to guarantee a long-life span for the socket. To make sure that this aspect is achieved in this concept, the current socket design was optimized to end with a balanced weight-bearing socket.

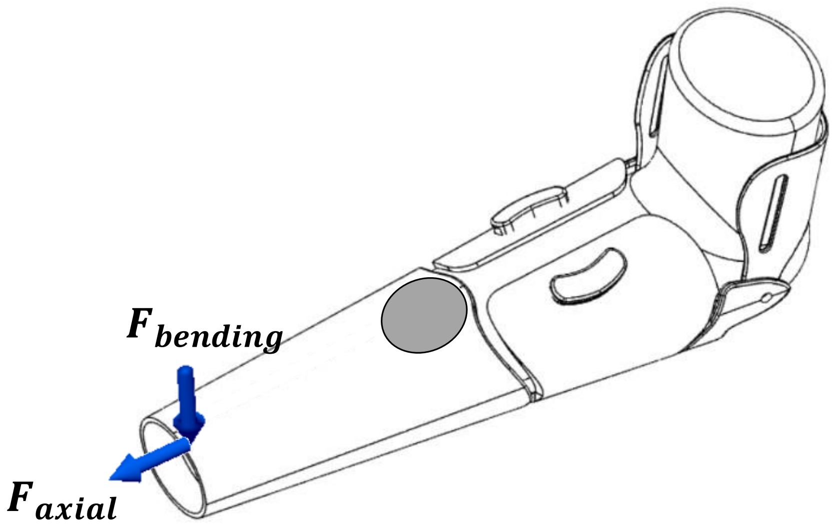

Figure 5.1. The common loading scenarios of the socket. Those scenarios mimic the common ways of carrying a bag, recall Figure 4.2.

5.1.2 Optimization options of the concept

The scenario when the user is wearing the socket and flexing the elbow with 90 degrees is approximated to be the same as if the socket is a cantilever beam since the socket proximal end cannot translate or rotate in any direction when it is fitted, see Figure 5.2. To strengthen the structure of the current socket design, there are three critical parameters of the cross-section of the critical area: the thickness *(h),* the width *(b),* and the centroidal distance *(y)* from the centroid *(C)* of the cross-section to its outer surface, see Figure 5.2. Those three parameters are affecting the area moment of inertia *(I)* and the bending stresses ($\sigma_{bending}$) carried by that cross-section at the back strip, see Eq. (5.1). In Eq. (5.1), *M* is the applied moment at the cross-section, and the cross-section is approximated as a rectangle since the back strip has only a little curvature compared to the rest of the socket.

$$\sigma_{\text{bending}} = \frac{\text{My}}{\text{I}} = \frac{\text{M}(0.5\text{h})}{\frac{1}{12}\text{bh}^3} \tag{5.1}$$

To optimize the socket structure, there were three options to consider. The first option was to increase the cross-sectional area at the back strip, see Figure 5.2. If this option were chosen, increasing the cross-sectional area would have been done by increasing the thickness (*h*), rather than increasing the width (*b*). That conclusion was based on Eq. (5.1) where the thickness (*h*) has a greater effect on reducing the bending stress than the width *(b)* since the thickness is cubic. To implement this approach, the thickness of the entire socket would need to be increased, not just the thickness at the back strip, to keep a uniform socket structure without discontinuities. Therefore, following this approach was expected to increase the socket weight, and make it bulky.

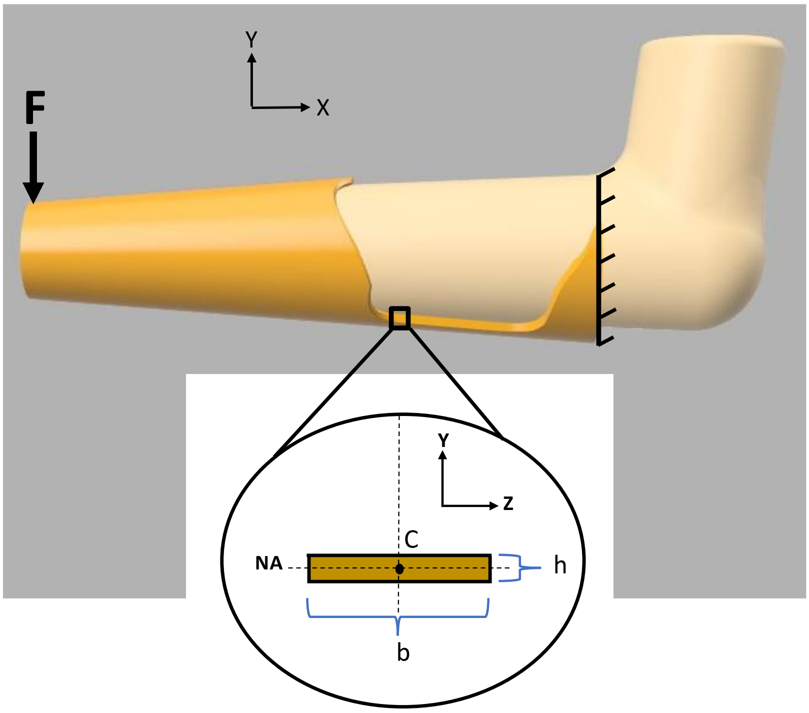

Figure 5.2. Main shell of the selected concept with the critical area highlighted. The socket is approximated to act as a cantilever beam since the socket proximal end cannot translate or rotate in any direction when it is well fitted to a residual limb. A closer look into the cross section at the back strip shows the main parameters that would affect the capability of the cross section to withstand stresses.

The second option was to optimize the design by adding a top strip to the concept, see Figure 5.3, so that the stresses tolerated by the back strip in the original design becomes divided on the top and back strips in the optimized design. Similarly, in this design, only the main shell is carrying the load as the adjustable wings are loose. With this option, the cross-sectional area at the locations of the strips is now doubled, see the cross-section in Figure 5.3. With this option, the bending stress equation would have a different area moment of inertia *(I),* see Eq. (5.2), and a different centroidal distance value *(y)* than the case in the first option. In Eq. (5.2), *A* is the cross-sectional area of the strips, and (*d*) is the perpendicular distance from the Neutral Axis (NA) to the centroid of each individual cross-section.

$$\sigma_{\text{bending}} = \frac{\text{My}}{\text{I}} = \frac{\text{M}(\text{d} + 0.5\text{h})}{2(\frac{1}{12}\text{bh}^3 + \text{Ad}^2)} \tag{5.2}$$

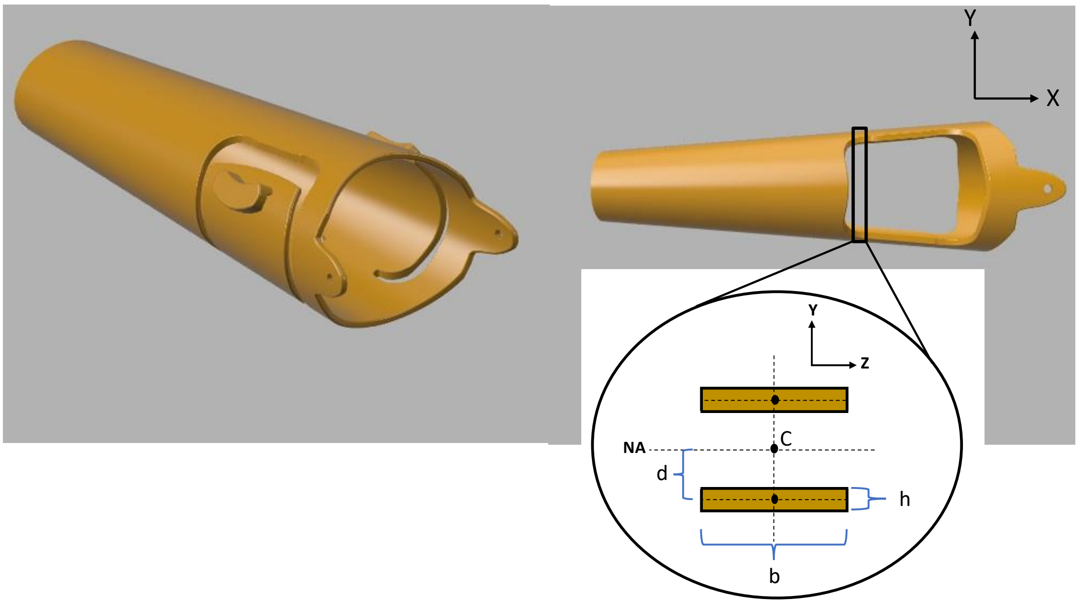

Figure 5.3.The second optimization option where top strip is added to the design. The top strip was added so that the stresses applied on the socket becomes divided on both strips to achieve a balanced weight-bearing socket.

The third option was to adjust the main shell design by having two strips that are in the lateral and medial directions of the residual limb; not the posterior and anterior direction as in the second option, see Figure 5.4. With that option, the cross-section of the strips in option 2 would be flipped, see the cross-section in Figure 5.4. This change will tremendously increase the thickness (*h*) of the cross-section and reduce the width of the socket *(b).* As a result, the area moment of inertia *(I)* and the distance *(y)* would increase compared to the original design, see Eq. (5.3). In Eq. (5.3), the cross-section of the strips is approximated to be rectangular for the sake of comparison. This option would offer the highest strength to the socket compared to the other two options without having to change the socket thickness or make it bulky as in option 1. Besides, with two strips instead of one as in the first option, the stresses at the critical cross-section will be divided on both strips, not only one.

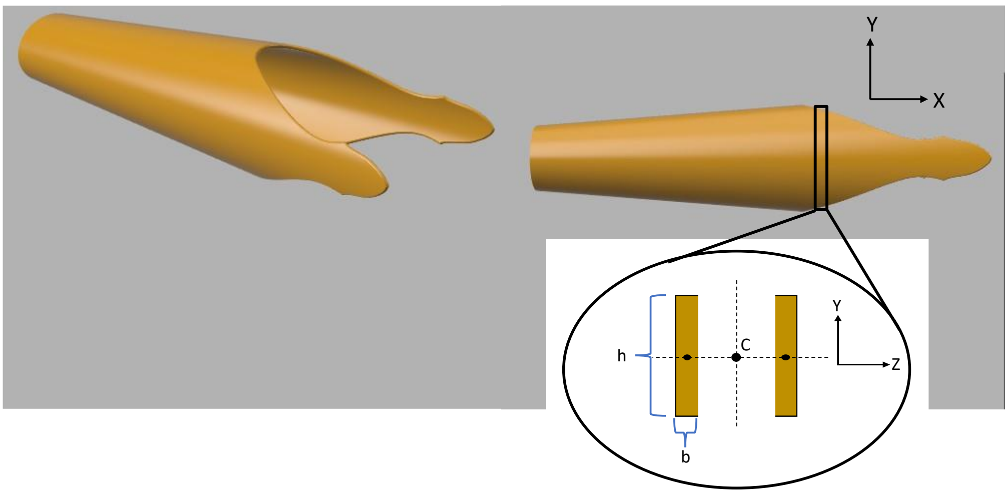

Figure 5.4. The third optimization option. The design has lateral and medial strips to increase the thickness (h) of the cross-section and increase the area moment of inertia to decrease the bending stresses at those strips. The cross-sections were approximated to have rectangular profiles for the sake of comparison with the other options.

$$\sigma_{\text{bending}} = \frac{\text{My}}{\text{I}} = \frac{\text{M}(0.5\text{h})}{2(\frac{1}{12}\text{bh}^3)} \quad (5.3)$$

5.1.3 Selected concept

The three options for optimizing the socket concept can strengthen its structure. Choosing the best option was based on the resulting effect of each option on the socket weight and the adjustability range. If the first option were chosen, a noticeable increase in the socket thickness to strengthen the socket would be needed compared to the case if the second or third option were chosen. That increase in thickness would increase the socket weight but would not affect the adjustability range more or less than the other options. If the second option were chosen, a minimal (if not) increase in the socket thickness would be needed since the load would be divided upon both strips. Thus, this option would not increase the socket weight compared to the first option. Besides, the second option would not affect the adjustability range more or less than the other options too.

If the third option were chosen for socket optimization, the socket strength would be the greatest, even more than needed for the application of this socket, without having to increase the thickness. Thus, with this option, the socket weight would not be affected compared to the first option. Nevertheless, the third option would affect the adjustability range as the adjustable wings would be covering the posterior and anterior sides of the residual limb. Those sides do not have as many soft tissues as the lateral and medial sides of the residual limb. Thus, the adjustable wings would not be accommodating as many changes of the residual limb as if they were in the lateral and medial direction. Also, in this scenario, the suspension below the elbow would not be as secured since there are not many soft tissues to compress. Furthermore, pushing on the posterior and anterior sides of the residual limb where the radius and ulna bones are located could be uncomfortable to the user, especially when the socket is loaded. Based on the discussion above, and the design requirements of the socket, it was decided to choose the second option, the design with top and back strip shown in Figure 5.3, to optimize the socket structure.

5.1.4 Proof of selected concept

In this subsection, proof that the optimized concept, shown in Figure 5.3, would strengthen the structure of the original socket concept, shown in Figure 4.5 & Figure 5.2, and reduce the bending stresses at the critical area of the socket design with a factor of 101 is shown. The critical area refers to the end of the strips where the cross-sections of the socket tremendously decrease causing the area moment of inertia to decrease, and the bending stresses increase, see Figure 5.5. The analysis in this proof was performed under the assumption that the sockets act as cantilever beams since all translations and rotations for the socket part below the elbow are restricted when it is fitted to the residual limb. In addition, the cross sections were approximated to have rectangular profiles, see Figure 5.6, since the strips are barely curved.

In this analysis, a thickness *(h)* of 3mm, width *(b)* of 36mm, and a distance *(d)* value of 26.5mm were used based on the designed model of the socket. The thickness and width of the socket strips are fixed parameters that would not change from a user's size to another, but the *(d)* value would change according to the size of the residual limb. A force *(F)* of 50N was considered in the analysis based on the maximal force set in the design requirements. A moment arm *(r)* of 150mm was used based on the location of the critical area in the current design with respect to the distal end of the socket. The area moment of inertial (*I*) and bending stress *(σ)* at the critical area of both concepts are presented and calculated in Table 5.I.

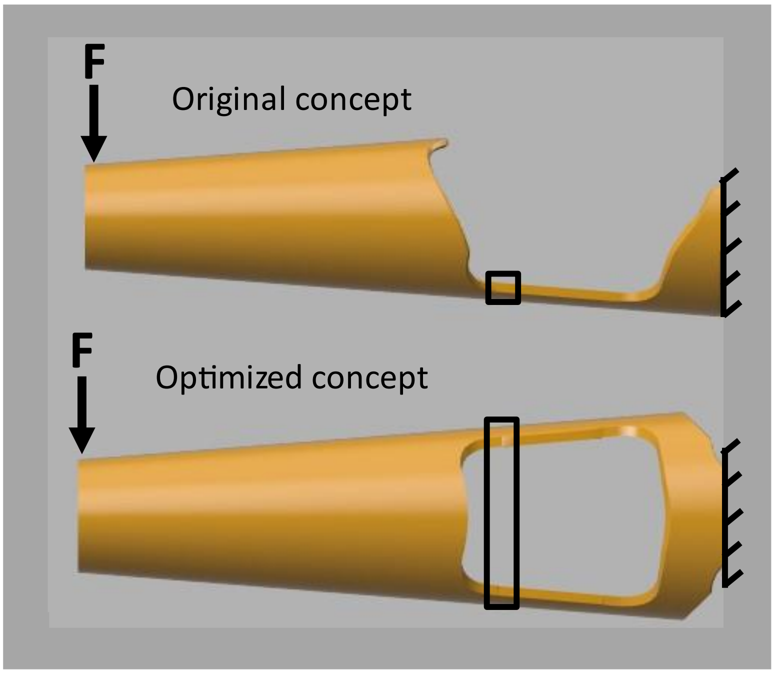

Figure 5.5. The original and optimized sockets in bending. Only the main shell of the socket are considered in this proof since the adjustable wings are loose parts that are not carrying the loads with the main shell. Both sockets are assumed to be acting as cantilever beams. (A) The original concept. (B) The optimized concept.

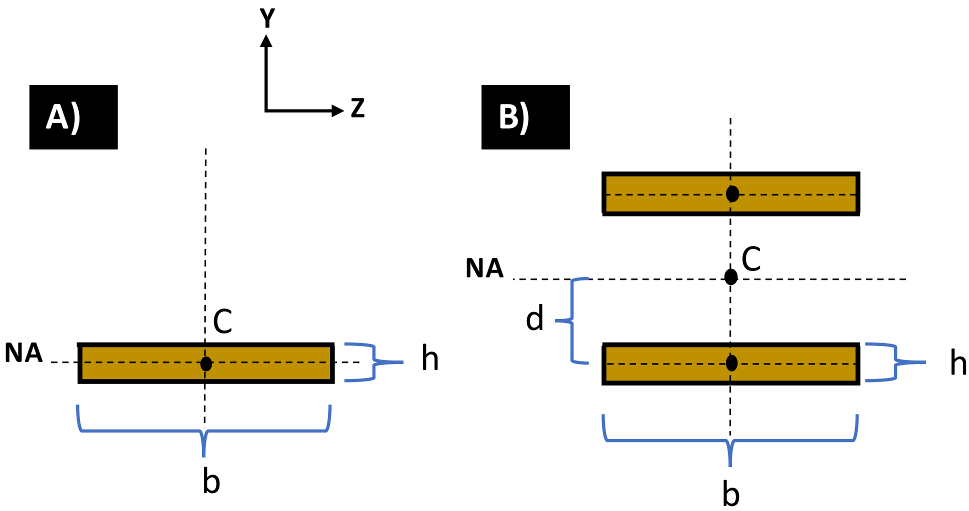

Figure 5.6. Cross-sections of the sockets at the socket strips. (A) Cross-section of the original design (B) Cross-section of the optimized design (option 2). The optimized design has double the cross-section of the original design and has a different location of the centroid and the neutral axis (NA), which would increase the area moment of inertia and decrease the bending stresses at the strips.

In both designs, the cross-sections at the critical area have the same thickness *(h)* and width *(b).* Adding a top strip has shifted the neutral axis of the cross-section to be in the middle of both strips. That shift has tremendously increased the area moment of inertia as shown in Table 5.I. With that shift, the parallel axis theorem was applied to the calculations of the area moment of inertia of the optimized design where another factor was added to the equation, Ad^2. In addition, with that shift, the centroidal distance *(y)* value of the optimized design has increased as well. As a result, the bending stress at the critical area of the socket was reduced by a factor of 101 compared to that of the original design. Therefore, adding a top strip to the socket design has strengthened its structure as desired.

Table 5.I. Comparison of the area moment of inertia and bending stress at the critical area of both designs; the original and the optimized design. The bending stress at the critical area of the optimized design is 101 times less than that of the original design.

Parameter	Equation (original design)	Value	Equation (optimized design)	Value
I	$\frac{1}{12}bh^3$	$8.1 \times 10^{-11}m^4$	$2(\frac{bh^3}{12} + Ad^2)$	$1.52 \times 10^{-7}m^4$
y	$0.5h$	$1.5 \times 10^{-3}m$	$0.5h + d$	$0.028m$
M	$F * r$	$7.5Nm$	$F * r$	$7.5Nm$
σ	$\frac{My}{I}$	$139.8Mpa$	$\frac{My}{I}$	$1.38Mpa$

5.2 VOLUME-ADJUSTABILITY

5.2.1 Adjustable wings

After adding a top strip to the socket design for achieving balanced distribution of loads, the other features the socket needs to provide were optimized. One of those features was the volume-adjustability that the socket needs to offer to accommodate the volume fluctuations of the residual limb. Recalling the original concept, see Figure 4.5, the adjustable wings were the part of the socket offering the desired volume-adjustability feature. Those wings were designed to allow rotation around the longitudinal axis of the residual limb such that the user can tighten and loosen them for changing the socket volume. The adjustable wings were designed to be connected to the socket at the back strip only to allow that rotation, see Figure 5.7B. To test whether the adjustable wings can provide the needed range of adjustability, 15mm of pushing distance inwards the residual limb, and 30mm outward, a sample of the socket was 3D printed with a thickness of 2mm, see Figure 5.7.

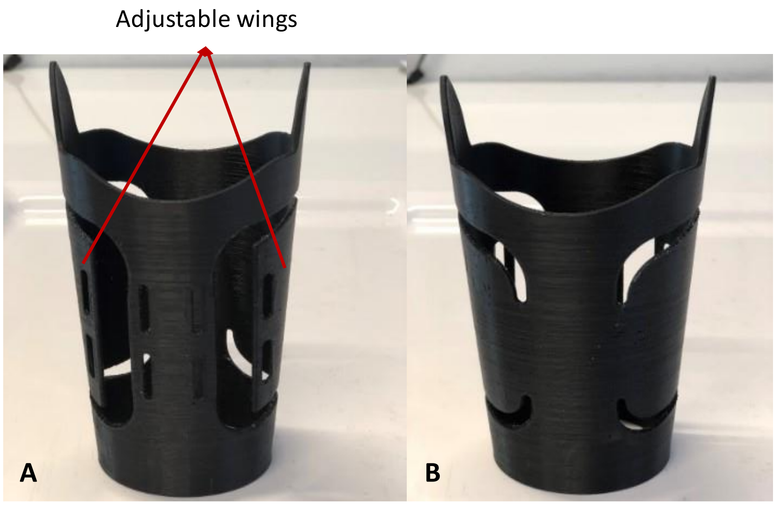

Figure 5.7. A 2mm 3D printed sample (from tough PLA) of the optimized design (A) front view (B) back view. The adjustable wings are connected to the socket through the back strip. The cut slots in the adjustable wings were temporally added for a quick test of tightening the wings. They are not part of the socket design. The sample showed that the attachment of the adjustable wings to the socket needs to be optimized to increase the range of volume adjustability around the residual limb. Also, it showed that the socket thickness needs to increase.

The printed sample showed that the adjustable wings allowed some rotation when tightening them, see Figure 5.8. However, since the wings are connected to the back strip of the socket, they would only provide partial enclosure of the lateral and medial sides of the user's residual limb. That can be visualized from Figure 5.8 where the red arrow shows the partial curvature of the wings as if it is tightened, and the green one shows the ideal needed curvature to surround the sides of the residual limb for a secured connection. Besides, it was noticed that when pushing by hand on the top and back strips, it was easy to bend the surface. That was an indication to increase the socket thickness. Therefore, it was decided to increase the socket thickness to 3mm to strengthen the socket, and check if the adjustable wings still can offer convenient flexibility to allow the desired rotation. As an extra test, a notch was added to one of the wings to compare the resulting range of adjustability to that of the wing without the notch, See Figure 5.9.

Figure 5.8. Partial (red) vs. complete (green) enclosure of the adjustable wings during tightening. Achieving secured suspension of the adjustable wings to the residual limb when it is tightened requires a complete enclosure of the wings to each of the sides of the residual limb as the green arow shows. The printed sample does not offer that as the adjustable wings are connected to the back strip of the socket. Therefore, each wing in the current design cannot achieve a complete enclosure.

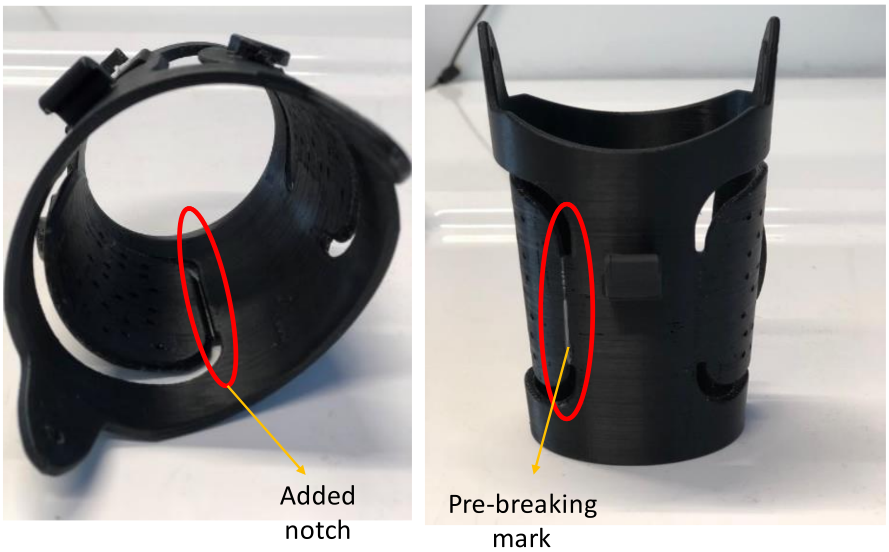

Figure 5.9. The second sample with 3mm including a notch. The sample did not achieve the desired range of volume adjustability, and adding the notch weakened the connection of the residual limbs to the socket main shell. A white mark, labeled as the pre-breaking mark, appeared on the surface of the socket. Based on this sample, it was decided to connect the adjustable wings to the socket main shell using hinge joints to increase the volume-adjustability range and achieve secured connection.

The printed second sample was stiffer than the first sample, due to increasing the socket thickness from 2mm to 3mm, and both wings did not give the desired range of adjustability. In addition, rotating the wing with the notch resulted in a clear white mark along the length of the notch, which was an indication of breakage, see Figure 5.9. Based on the second sample, it was concluded that having the adjustable wings connected to the socket structure through the back strip would result in breaking the wings with few repeated rotations and would not achieve the desired range of adjustability and a secured connection to the socket. Furthermore, with the current design, the user would have to buy a new socket every time the wings break. As a result, to overcome those challenges, it was decided to optimize the current design by connecting the adjustable wings to the socket structure through hinge joints that can increase the range of adjustability and make it feasible to replace the adjustable wings if it happened that the user broke them.

5.2.2 Hinge designs

Hinge joints are known for their ability to provide a high range of rotation. To adapt hinge joints into the socket design, three hinge designs were modeled; the sliding hinge, the hook-like hinge, and the 3-pieces hinge, see Figure 5.10. The sliding hinge was designed such that the adjustable wing can be connected to the socket through sliding, indicated by a black arrow in Figure 5.10. It was designed to allow only two degrees of motion of the adjustable wings; rotation around the longitudinal axis of the socket and sliding motion along the length of the shell, shown in Figure 5.10A, when assembling the socket. The shell was designed to have a closed end such that the adjustable wings cannot fall from the shell. The Hook-like hinge was simply designed such that the adjustable wings connect to the main shell of the socket through a hook that is modeled along the back strip, see Figure 5.10B. The 3-pieces hook was designed to be connecting the adjustable wings to the main shell by passing a metal rod through the three hinge joints shown in Figure 5.10C.

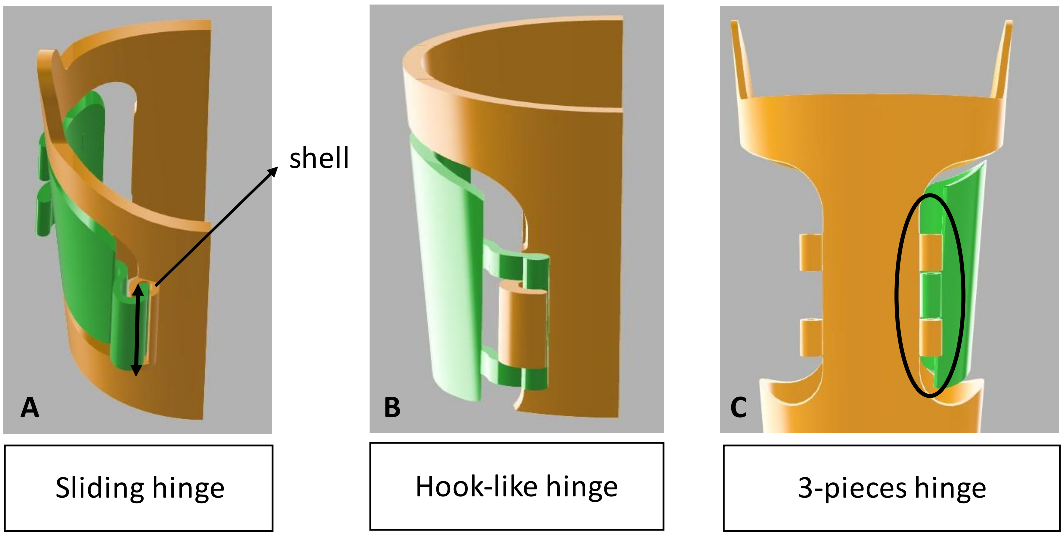

Figure 5.10. The models of the hinge joints when adapted to the socket design. (A)The Sliding hinge connects the adjustable wing (shown in green) to the hinge shell through sliding till a closed end of the shell. (B)The adjustable wings are hooked to the main shell. (C)The 3-pieces hinge requires a metal rod to connect the adjustable wing joint to the main shell joints.

To choose the best hinge design, each model was 3D printed and evaluated based on the range of adjustability it offers, and the security of the connection between the main shell and the wings, see Figure 5.11. After 3D printing the hinge models, the sliding hinge succeeded to provide a secured connection without having to use a non-3D printable material, but it could not provide the desired range of adjustability. The Hook-like hinge was not providing a secured connection and was not providing the needed adjustability range. In addition, it had the weakest structure compared to the other designs. The 3-pieces hinge exceeded the needed adjustability range and provided a secured connection. Based on these results, it was decided to use the 3-pieces hinge.

Figure 5.11. 3D printed samples of the three hinge joints. The 3-pieces hinge was the most secured design, and it was providing the widest range of volume adjustability of the wings compared to the other two designs.

The chosen 3-pieces hinge design provided more range of adjustability than needed, see Figure 5.12. That wide range can make the fitting of the socket inconvenient for the user during donning and doffing. Also, it can result in overtightening the residual limb than needed. To limit this range of adjustability to the desired range, a small shield, see Figure 5.13, was added to the main shell design. In addition, the hinge of the adjustable wing was optimized where sharp corners were replaced by curved corners, see Figure 5.13 C. With those changes, the connection between the adjustable wings and the socket main shell was optimized to achieve the desired range of volume-adjustability and provide secured connection with the socket.

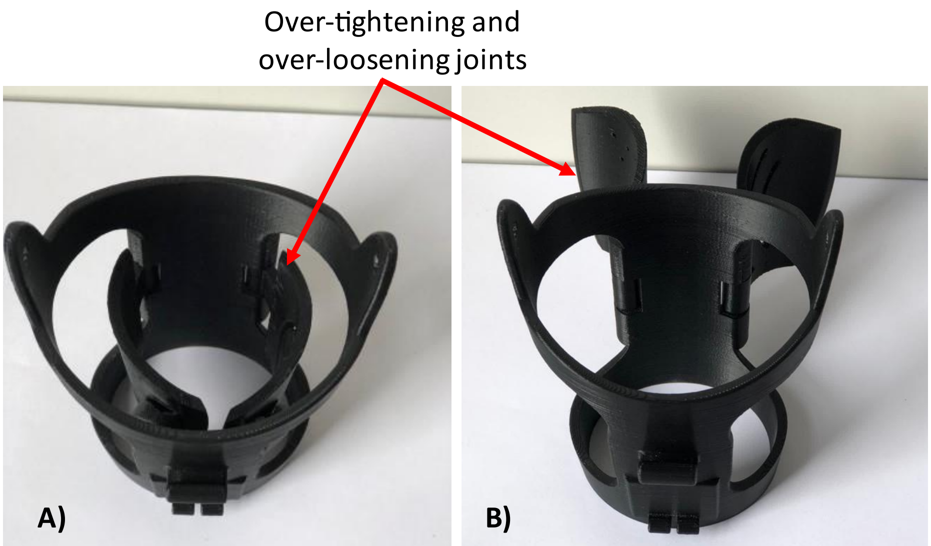

Figure 5.12. 3D printed sample of socket with the 3-pieces hinge. The current 3-pieces design does not limit the adjustability range of the wings. With it, the adjustable wings can over-tighten (A) and over-loosen (B). Therefore, a shield was needed to be added in the design to limit that range.

Figure 5.13. The improved version of the 3-pieces hinge. (A) Model of the hinge with the added shield that can limit the range of volume adjustability of the wings. (B) 3D printed sample of the optimized hinge with the adjustable wings assembled. (C) Optimized corner of the wings where the hinge joint is connected to the adjustable wing through a curved corner instead of a flat one that can easily break.

5.2.3 Closure of wings

An essential aspect of achieving volume adjustability is having a reliable closure mechanism that can tighten and loosen the adjustable wings. A reliable closure, in this case, needs to be easily used with only one hand, strong such that it does not suddenly break, and it can be fixed well to the main shell of the socket without falling. In the selected concept, a lace-tension mechanism was chosen to be the closure of the wings since it was the easiest to adjust with one hand, does fit the desired budget, and can easily be replaced. Therefore, lace-tension mechanisms in the market were looked up. The mechanisms found in the market were mostly part of sportive shoes or snow boots. There were three main common brands; the BOA lacing system, the SIDI tensioner, and the MAVIC tensioner. Choosing the tensioner was mainly based on the tensioner geometry to decide whether adapting it to the geometry of the socket would be feasible or not. Since the SIDI tensioner, shown in Figure 5.14, have a simple geometry, making it feasible to adapt housing for it in the socket design, it was chosen. Two samples of the housing tensioner were modeled, and 3D printed, see Figure 5.15.

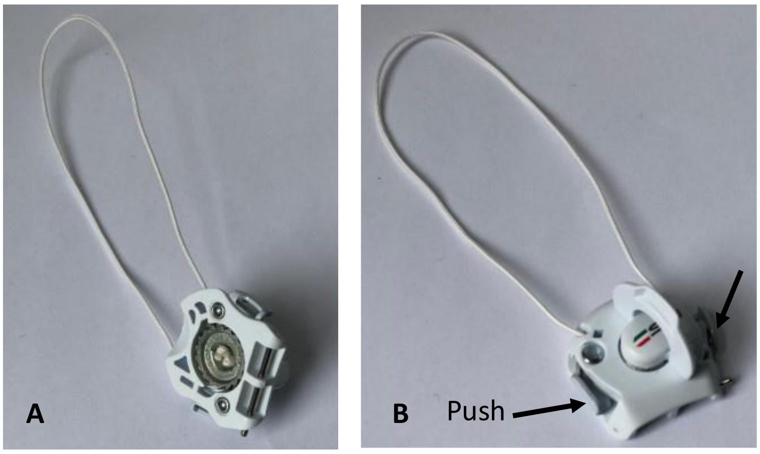

Figure 5.14. The SIDI tensioner. (A) Back view. (B) Front view. Its geometry makes it easy to model a housing for it in the socket main shell. It was found that it requires two hands to loosen the socket though; one to push on the side bottoms, and another to pull the tightened lace. That makes the tensioner hard to operate with one hand only. Therefore, another lace-tension mechanism had to be selected.

Although the secured connection that the housing achieved with the tensioner, it was found that the tensioner is not user-friendly for this application of the socket. The tensioner allows the user to easily tighten the adjustable wings by rotating the tensioner knop clockwise, but if the user needs to loosen it, the user must use two hands; one hand to push on the side buttons of the tensioner, shown in Figure 5.14B, and another hand to pull the lace. The tensioner does not allow loosening by rotating the knop counterclockwise. That mechanism could be dangerous in case the user overtightened the lace but could not manage to loosen it, so another lace-tensioner mechanism was tried.

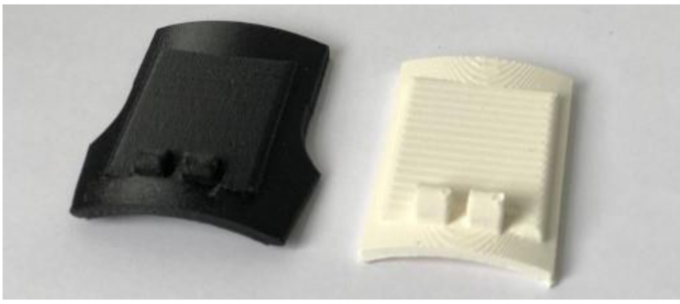

Figure 5.15. Housings of the SIDI tensioner. Two housings with few dimensional changes for exactly fitting the SIDI tensioner.

The BOA tensioner and the Mavic dial tensioner were the left options to choose from. The BOA tensioner is very known and used in many medical applications besides some sportive shoes and boots. It is known for its simple mechanism and strong lace, which is made from Stainless steel. Nevertheless, it was not the selected alternative because it was hard to find a BOA tensioner that can easily be fitted in the design. Most of the found BOA dials in the market were replacement parts to fit the housing in the BOA snow boots which were not clear to duplicate. Also, the BOA specialized snap dials whose housing could have been developed for the socket were out of stock. On the other hand, the MAVIC tensioner was found to be providing the same easy mechanism of tightening and loosening with only one hand, as the BOA tensioner. Developing a secured tensioner for the Mavic tensioner was challenging as it has more curvature compared to the SIDI tensioner, and a little end for snapping it into the housing, see Figure 5.16B. Therefore, some designs with few parametric changes were designed and 3D printed for testing its fitting to the tensioner, see Figure 5.17. After finding which sample fits the tensioner the most, achieves secured connection, and can be replaced without getting stuck, its design was adapted to the main shell design to host the Mavic tensioner.

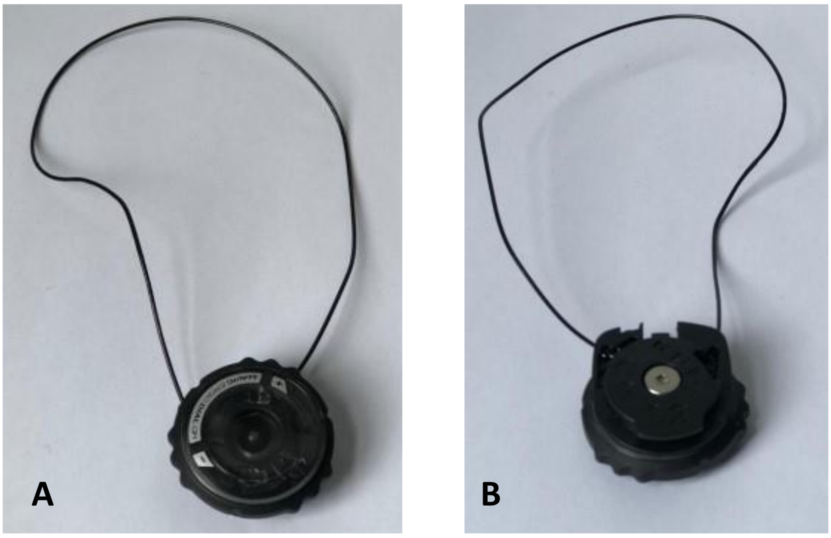

Figure 5.16. The MAVIC Tensioner. (A) Front view (B) Back view. Designing a housing for this tensioner was challenging because of the geometry of the base of the tensioner, as there is a little part to snap into the tensioner housing to achieve secured connection.

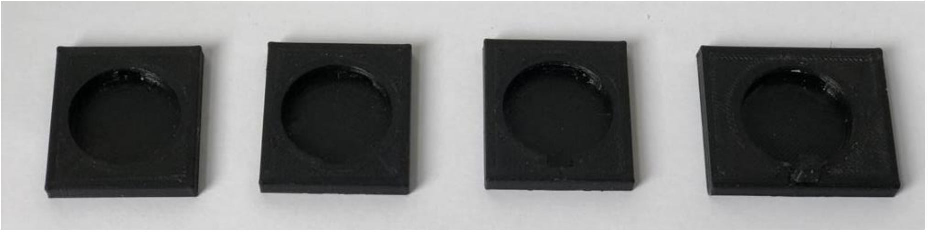

Figure 5.17. 3D printed samples of the housings of the MAVIC tensioner with few dimensional variations. The one that achieved the most secured connection to the tensioner was selected and adapted in the socket design.

5.2.4 Hooks of wings

Having a reliable hook as a part of each adjustable wing is another critical aspect of having a reliable closure around the residual limb. A reliable hook was defined to be the one that can securely hold the lace of the tensioner in place within the hook area, and the one that does not have sharp ends such that it does not result in cutting the lace. In addition, a reliable socket was defined to be curved so that the forces (F) of the lace get distributed over the hook area, see Figure 5.18. Otherwise, if the hook geometry were flat, the lace would be pushing on the corners of the hook which would deform the hook over time till it breaks, see Figure 5.18. As a result, different hook designs were evolved from simple two-piece hook to one big, curved hook, see Figure 5.19. The curved hook in Figure 5.19 was chosen to be adapted in the socket design as it fulfills the defined criteria of a good hook, and it provides a bigger contact surface with the adjustable wings so that it would not easily break.

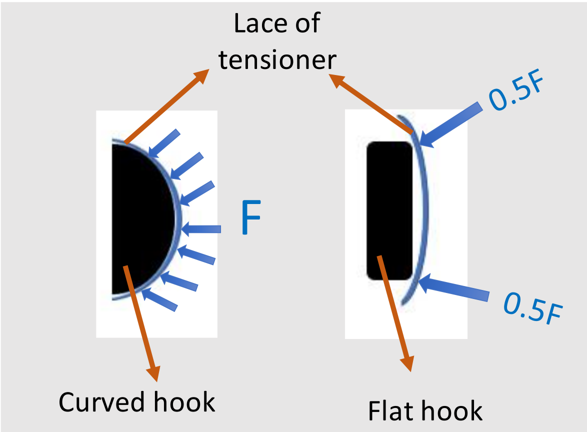

Figure 5.18. Hooks with curved vs. flat profiles. (A) Curved hook (B) Flat hook. The lace force (F) gets distributed over the curved hook surface area. With the flat hook, the lace force would be pushing on the corners of the hook which would deform the hook over time due to continuous compression till it breaks.

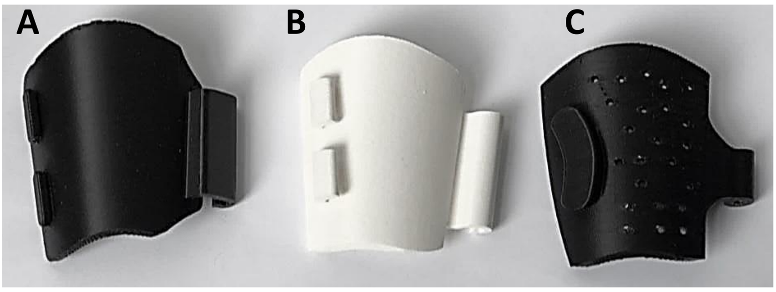

Figure 5.19. 3D printed samples of the adjustable wings with different hook designs. (A & B) flat two-piece hooks. (C) A curved one-piece hook. The curved hook was preferred and selected as the forces of the lace would be distributed over its area. Thus, the hook would not deform or breaks easily as it is the case in (A & B).

5.3 VENTILATION

Skin infections, pressure ulcers, odors, and sweat are common symptoms with sockets that lack ventilation. Unfortunately, most of the filaments in the market are hygroscopic, meaning that they absorb moisture from the environment, so the material of the designed socket will most probably be absorbing sweat if the socket is not breathable. Therefore, accommodating some openings in the socket is needed as a source of ventilation. Different geometries of openings can fulfill this purpose. However, it is critical to choose the geometry that would not leave marks, on the user's skin. Two designs of openings were modeled, see Figure 5.20, To test which design would leave marks on the skin, adjustable wings with both geometries and the top half of the socket were 3D printed to build a quick version of the prototype, see Figure 5.21. The prototype was tried directly on the skin for 15 minutes to check which geometry can quickly cause marks. The curved openings whose width was 2mm did cause marks, but the circular holes, whose diameter is 2mm as well, did not even after keeping wearing the socket for 30 minutes. In a previous study conducted by Hilde Jansen on a similar topic, the researcher performed a similar test where holes with different diameters were tested for leaving marks. The researcher found that the 2mm holes were small enough not to leave marks and big enough to provide ventilation, which agrees with the findings of this research [52]. Therefore, circular holes were adapted in the socket design as a source of ventilation.

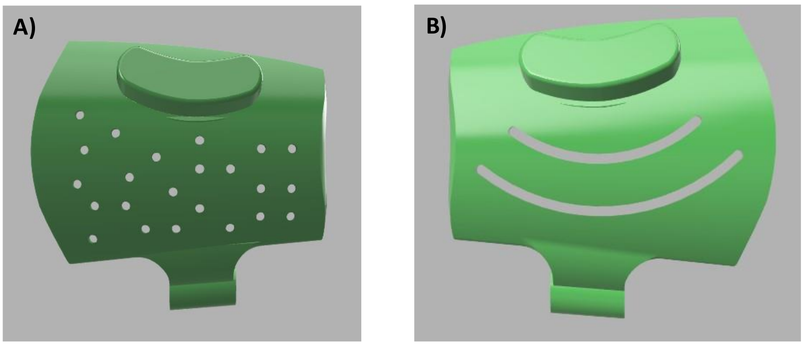

Figure 5.20. Different models for ventilation openings. (A) Wing with circular holes for ventilation (B) Wing with curved openings for ventilation. The wing with circular holes did not leave marks on the skin unlike the wing with curved openings.

Figure 5.21. Quick built prototype of the top half of the socket for testing whether the ventilation openings would cause marks on the skin or not. The curved openings caused marks on the skin, but the 2mm holes did not. Therefore, the curved holes were adapted in the socket design as a source of ventilation.

5.4 SELF-SUSPENSION

5.4.1 Upper attachment design

Suspension is the most critical feature in the socket. If the suspension is loose, the socket fails to transfer forces from the residual limb to the terminal device. Also, it can be dangerous if the suspension becomes loose while the user is carrying an object. The selected concept involved a self-suspension method through the upper attachment, recall Figure 4.5, that was modeled to contour the elbow prominences. A reliable self-suspension method would be a method that is secured such that the socket does not slip when it is loaded, have a soft contact with the skin such that it does not cause skin irritations and leave marks on the skin, and can be adjusted with one hand by the user. Also, it should not be pushing or interfering with the bony region of the elbow prominences; the olecranon, and epicondyles.

Three models of the upper attachment were designed, 3D printed, and tested, see Figure 5.22. Design A of the upper attachment, see Figure 5.22A, was meant to end with curved sides to compress some of the soft tissues of the upper arm (above the elbow), mincing the attachment method of the conventional sockets, see Figure 1.2d. Curved slots were added for ventilation, and for reducing the part weight. After 3D printing, the design, and trying it, the socket was found to be uncomfortable in the sense that it bulges the soft tissues. Design B is similar to design A except that its sides do not push but envelope the upper arm, see Figure 5.22C. After testing this design, it was found that when flexing and extending the elbow, the upper attachment was pushing on the medial epicondyle and the olecranon. This discomfort was increasing when loading the socket. In addition, both designs A and B were causing marks on the skin because of the curved slots. Those problems were considered when modeling design C of the upper attachment, see Figure 5.22. In this design, a more curved base was modeled such that the upper attachment would not interfere with the elbow prominences, causing discomfort. Also, it was decided not to include any open slots in it to avoid leaving marks on the skin and to avoid weakening the part since its height is now less than that of Design A and B. Consequently, design C was adapted to the optimized version of the socket design.

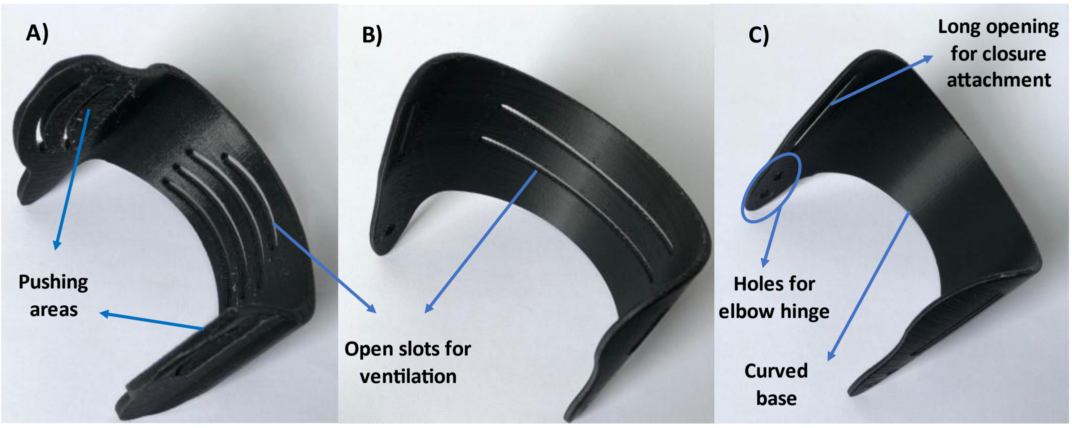

Figure 5.22. Different designs of the upper attachment. (A) Design A with curved sides for pushing on the skin soft tissues. (B) Design B with enveloping sides to enclose the soft tissues of the arm. (C) Design C with more curved base for comfortable fit to the arm. Design C was the chosen design for its comfortable fit to the arm without pushing on the elbow olecranon.

5.4.2 Upper attachment closure

Besides designing the 3D printed upper attachment, choosing a reliable closure is critical for having a reliable self-suspension. In the selected concept, a hook and loop closure, commercially known as a Velcro, was selected for three reasons. This closure is easy to find

and adapt to the socket design, used in heavy-duty and many medical arm splints, and it allows adjustability with one hand.
With this approach, there were two concerns to think about. First, a normal Velcro texture is not smooth to the skin. Second, donning the upper attachment, which is a rigid structure, for a long time may cause skin irritation. As a result, it was decided to think about a soft layer that can cover the inner rigid surface of the upper attachment and make the loop of the Velcro soft to the skin.

Inspired by sportive arm straps that are used by people lifting weights, it was decided to fabricate a washable comfy arm strap that the user can fit in the upper attachment. It was aimed that the designed strap be reusable such that the user can take it off, wash it, and reuse it to help to prevent odors and skin infections. To implement this idea, two different approaches were followed. First, an arm strap was ordered, and then cut and customized to fit the design of the upper attachment, see Figure 5.23. The second approach was to fabricate a brand-new arm strap from thick and soft fabric. The resulted strap, shown in Figure 5.24, did not have foam inside but had a back Velcro closure for securing the connection to the upper attachment. Both straps met the aimed goal, but the first arm strap was more elegant and comfortable because of the foam inside. Therefore, it was selected for the final version of the socket.

Figure 5.23. Customized arm strap. This arm strap was ordered and then customized to fit the size and design of the upper attachment. This strap has foam inside which can give comfortable fitting of the socket to the skin. It has a Velcro closure for suspending the socket to the user's arm. This design was chosen for the final version of the socket for its comfortable fitting.

Figure 5.24. Second design of an arm strap. This strap was designed and fabricated from thick and soft fabric. It provides the same function as the customized strap in Figure 5.23 but it had back Velcro closure.

5.5 ELBOW EXTENSION & FLEXION

Before generating a concept of the socket, it was aimed to achieve full extension (0°) and flexion range up to 110°. To fulfill this requirement, the selected socket concept involved a hinge, which is basically a flat head screw, that connects the upper attachment of the socket to the main shell, recall Figure 4.5. Fulfilling this requirement does not only require a hinge joint near the elbow but also a wise selection of where to have that hinge in the design, considering the lateral and medial epicondyles, see Figure 5.25. From a first glance, it sounds ideal to have the elbow hinges aligned with the axis of rotation (flexion/extension) of the elbow. Nevertheless, that can result in having the hinges interfering with the elbow epicondyles during flexion and extension which would cause discomfort, especially when loading the socket. To provide flexion and extension while avoid interfering with the elbow epicondyles, the hinges were decided to be located 20 mm below the elbow epicondyles such that the residual limb would force the main shell to provide the needed rotation.

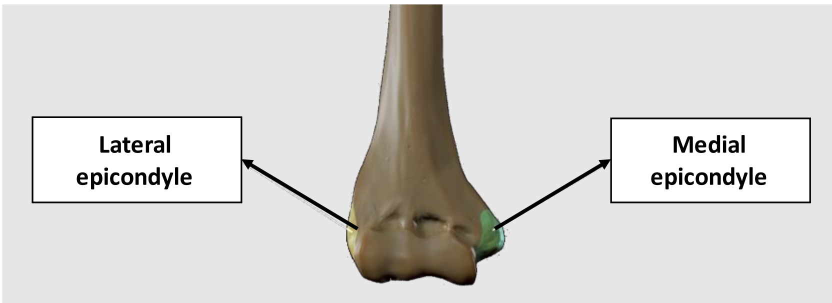

Figure 5.25. Epicondyles of the elbow. The medial epicondyle is larger than the lateral epicondyle. To allow flexion and extension without discomfort, the elbow hinges were modeled to be 20mm below the epicondyles.

5.6 FINAL DESIGN

Through this chapter, the basic design requirements and wishes of the socket were verified through the optimization process of the design. The optimized design was named the V3D socket referring to the volume-adjustability and 3D printability features of the socket. After optimizing the socket structure and improving the design of each part of the socket concept, the updated version of the socket model is shown in Figure 5.26 & Figure 5.27. Drawings for the final design are in APPENDIX D: CAD drawings. With the end of this chapter, the design requirements and wishes, shown in Table 5.II, were verified, and a prototype of the socket was to be developed.

Table 5.II. Summary of the design requirements and wishes that were verified in this design phase of the socket in this chapter, with the verification method.

#	Design requirements & wishes (W)	Verification method
1	Full extension of the elbow (0°) and flexion up to (110°)	Verified within the elbow hinge in the socket design
2	Volume adjustability (15mm for tightening and 30mm for loosening)	Verified through optimizing the 3-pieces hinges in the design that allows rotation around the residual limb for volume-adjustability
3	Easiness of donning and doffing (within 1min.)	Verified though providing a user-friendly lace-tensioner closure in the socket design and designing an arm strap that is easy to adjust.
4	Load-resistance (50N axially & transversely)	Verified through optimizing the socket design through adding a top strip to balance the load distribution along the socket
5	Secured self-suspension	Verified through designing the upper attachment and making the arm straps made from soft comfy fabric and Velcro closure for suspension
6	Adaptability to different types of wrist units	Verified as the selected design can have oval or circular end to fit oval and circular wrist units
7	Adaptability to cosmetic and body powered prostheses	Verified as the designed socket has an overall elliptical shape to mimic the overall geometry of the non-affected arm for serving as a cosmetic prosthesis. Also, a hook can be adapted into its design to suspend a harness and cables to turn it into body-powered prosthesis.

8	Breathable socket	Verified as holes were incorporated in the socket design as a source of ventilation
9	Safe contact with the skin	Verified as soft arm straps were designed and fabricated for a soft contact with the skin
10	Easy to clean socket	Verified as the socket was designed such that the adjustable wings can be loosened 30mm distance outwards to allow the user to clean the inner parts of the socket
W2	Maximal thickness of 4mm	Verified as the optimized socket has a maximal thickness of 3mm

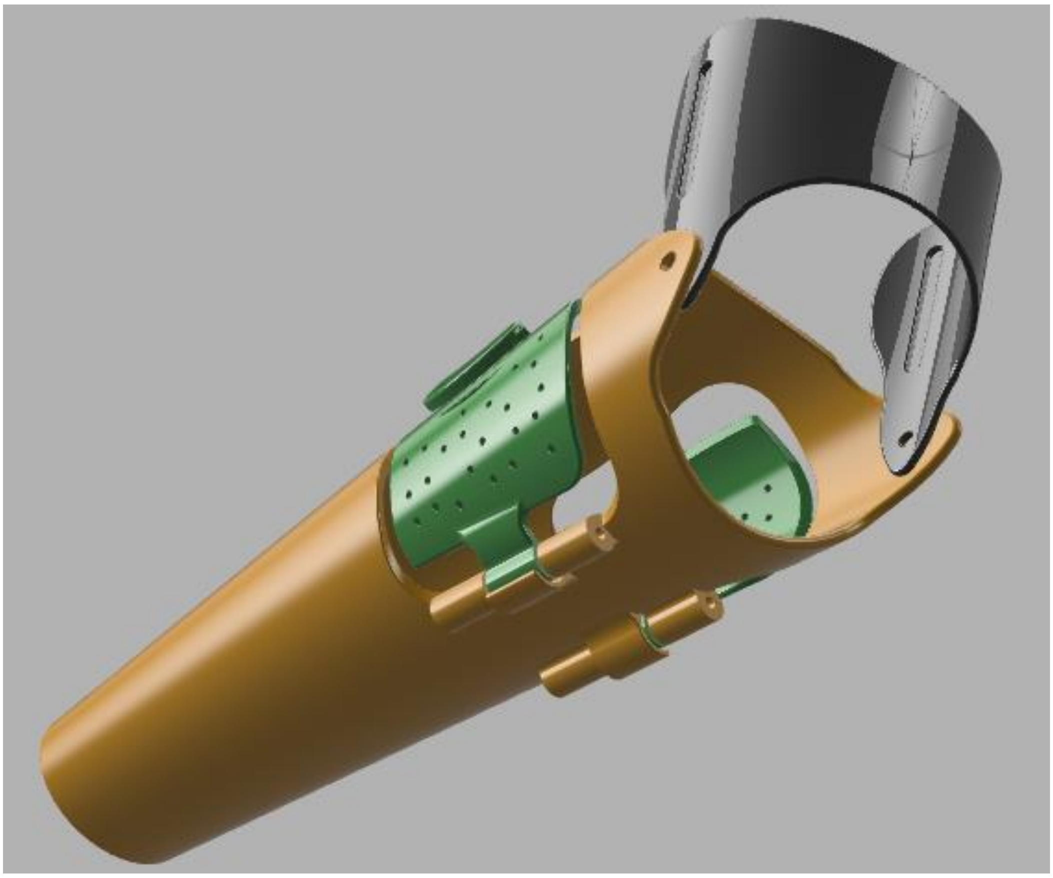

Figure 5.26. The V3D socket, back view. The back hinges were optimized to have a shield that restricts the range of rotation of the adjustable wings. The adjustable wings have holes for providing ventilation.

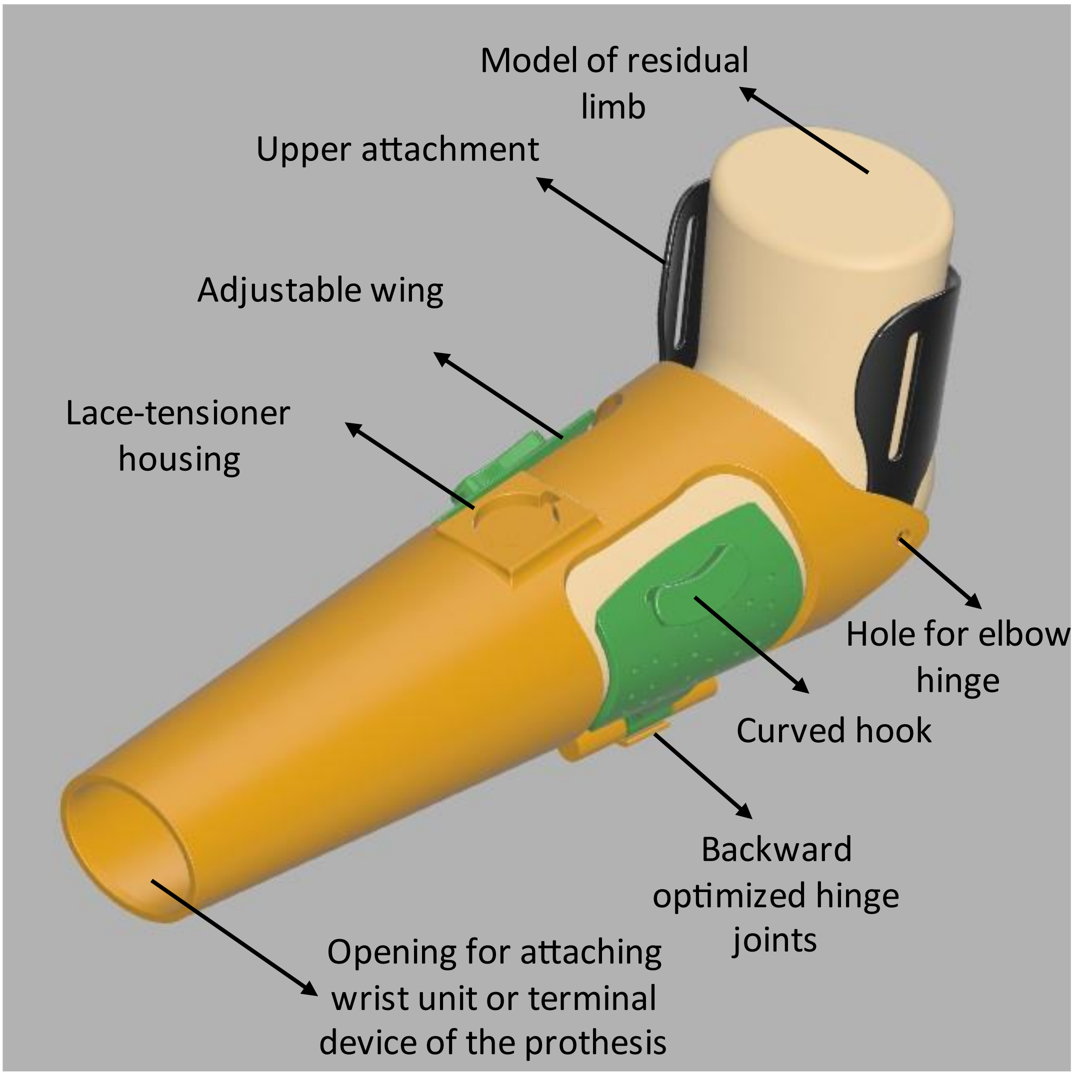

Figure 5.27. The V3D socket after optimization. The socket offers volume adjustability through the adjustable wings, and a lace-tension mechanism that would be inserted in the tensioner housing. The socket ends with an opening for attaching a wrist unit or a terminal device (artificial hand). That end can be customized to be oval or circular depending on the preference of the user and the type of wrist unit that will be attached. The upper attachment (above the elbow) has two long slots at the sides for attaching a Velcro closure. The upper attachment connects to the lower socket using a screw with flat end that acts as an elbow hinge to allow flexion and extension.

6

PROTOTYPING

6.1 MATERIAL SELECTION

Prototyping the V3D socket requires selecting the right material and printing parameters that suit the application of the socket. As mentioned in Chapter 1, there are three techniques for 3D printing: Fused Deposition Modeling (FDM), Selecting Laser Sintering (SLS), and Stereolithography (SLA). FDM is the most common printing technique in the prosthetic and orthopedic technique because its 3D printers are widely available in the markets with cheaper prices compared to the other techniques. Therefore, this printing technique was selected for producing the V3D socket to make its fabrication process feasible in a wide range of communities. Based on the literature review conducted on the status of 3D printed upper limb sockets in the last 10 years, see Appendix A: Literature review, the durability of the 3D printed parts is the main concern among studies. Durability refers to the ability of the material of the part to resist cyclic loading without breaking. In this thesis work, producing a durable 3D-printable socket would depend on three factors: the socket design, the material making the part, and the printing process of the part. In this subsection, the focus is on selecting a material that fits the application of the socket and meets its design requirements.

With 3D printing using the FDM technique, there is not a wide variety of materials to choose from. In this research, the Ultimaker S5(330 x 240 x 300 mm) was used for printing the socket. Therefore, it was a requirement that the selected material needs to be printable with an Ultimaker printer. As a result, a list of 3D printing filaments with their mechanical properties was made and summarized, see Table 6.I. Materials that had missing important mechanical properties in their technical data sheets were excluded from the list. To translate the raw data, given in Table 6.I, into meaningful parameters that the researcher can compare and evaluate the materials based on, the researcher used the raw data, shown in Table 6.I, to calculate the specific stiffness, specific tensile strength, and specific flexure strength. That was performed by dividing each of the tensile modulus, tensile strength, and flexure strength over density, respectively, see Table 6.II.

Table 6.I Properties of 3D printing filaments that can be used with an Ultimaker 3D printer.

Material	Tensile modulus (Gpa)	Tensile strength (Mpa)	Flexure strength (Mpa)	Density (g/cm^3)	Hardness (shore D)	Impact strength (kJ/m^2)	Cost (€/750g)
Nylon	0.579	27.8	24	1.14	74	34.4	65
PLA	2.35	49.5	103	1.24	83	5.1	40
Tough PLA	1.82	37	78	1.22	79	9	48
ABS	1.62	39	70.5	1.10	76	10.5	46

Table 6.II. Information used for comparing the 3D printing filaments for printing the socket parts. In this table, Nylon has the least specific stiffness, and PLA has the least impact strength. Both materials were excluded for making the socket. Tough PLA and ABS have comparable properties, but ABS is more demanding when 3D printing. Therefore, the selected material was tough PLA. Specific stiffness is in units of (Gpa/(g/cm^3)), while specific tensile and flexure strength are in units of (Mpa/(g/cm^3)).

Material	Specific stiffness	Specific tensile strength	Specific flexure strength	Hardness (shore D)	Impact strength (kJ/m^2)	Cost (€/750 g)
Nylon	0.507	24.38	21.05	74	34.4	65
PLA	1.895	39.92	83.06	83	5.1	40
Tough PLA	1.491	30.33	63.93	79	9	48
ABS	1.472	35.45	64.09	76	10.5	46

6.1.1 Specific stiffness and strength

Before comparing the material properties, it is important to know what each property means, considering the application of the socket. First, specific stiffness is also known as stiffness to weight ratio. High specific stiffness is needed in applications where minimum weight is targeted with achieving the least possible deflection such as aerospace applications. Similarly, specific strength is known as the strength to weight ratio. High specific strength is needed in applications where the design limitation is the load at breakage [63]. For isotropic materials, the flexure strength is ideally the same as tensile strength. Since it is intended to use the FDM technique whose prints are anisotropic [64], specific tensile strength and specific flexure strength of the printing materials have different values. Reflecting those properties on the socket application, specific strength is the most critical property since it is more dangerous if the socket breaks while the user is carrying an object relative to if the socket deflects. In general, both properties are critical, but the priority in this application was given to the specific strength whether it is specific tensile strength or specific flexure strength. From Table 6.II, Nylon has the least specific strength and stiffness, making it semi-flexible. Therefore, Nylon was excluded from the comparison, and the rest of the materials were compared based on the rest of the properties.

6.1.2 Hardness and impact strength

Hardness refers to the resistance of a material to penetration such as indentation and scratch, in response to an applied load [65]. Impact strength refers to the capability of the material in withstanding a suddenly applied load without fracturing [66]. Looking at Table 6.II, the higher the value of hardness, the lower the value of impact strength. That can easily be thought off when thinking about glass. Glass is a very hard material, but with applying a sudden load on it, it shatters. For the application of the socket, it is propriety to have a socket that does not break with sudden loading for the safety of the user, especially while carrying an object. From the remaining materials in Table 6.II, PLA has the least impact strength, while tough PLA and ABS have comparable values.

While the durability of printed prostheses from PLA is a repeated concern in literature, PLA was excluded from the material list.

6.1.3 Selected material

After excluding Nylon and PLA, the remaining materials were Tough PLA and ABS. Tough PLA was developed after PLA with the main difference of having double the impact strength of PLA for producing more durable prints. Since the cost and mechanical properties of the remaining two materials is comparable. A wish of having a less demanding printing process was added to consideration to make the fabrication process less time-consuming and labor-intensive as it was aimed for. ABS is known for being a demanding material when 3D printing as it requires a closed chamber compared to tough PLA. Therefore, tough PLA was the selected material for fabricating the socket.

6.2 PROTOTYPING PROCESS

6.2.1 Printing parameters

Another important factor in developing a durable socket is the printing parameters for building the socket structure. Some of those parameters were mentioned in the literature to be affecting the strength of the printed part such as printing orientation, % infill, and layer thickness [67]–[70]. Printing orientation refers to the orientation of the part in which the printer nozzle will be building layers. It can vary from 0^0 to 90^0 degrees, see Figure 6.1. In fact, printing orientation was found to be affecting the printing time, strength, surface finish, part accuracy, and amount of support [71]. Reflecting that on the socket, different printing orientations were assigned to the socket parts. Since the FDM technique depends in building a part on adhering layers that form the cross- sections of the part upon each other, it was critical to choose a printing orientation where layers would not be separated when the socket is loaded, axially and transversely. For example, if the socket were loaded axially, it would be easier to separate the layers if the main shell is printed with a 90^0 printing orientation since the load would be perpendicular to the layers and pulling them apart. Therefore, 90^0 printing orientation and closer degrees (e.g., 75^0) of printing orientation were excluded for printing the main shell. The 0^0 printing orientation was decided for printing the main shell of the socket since the loads and stresses would be along the layers' direction not perpendicular to them. In addition, this printing orientation would cost less support material (~70g) and time (~7hrs.) than printing with 45^0 orientation.

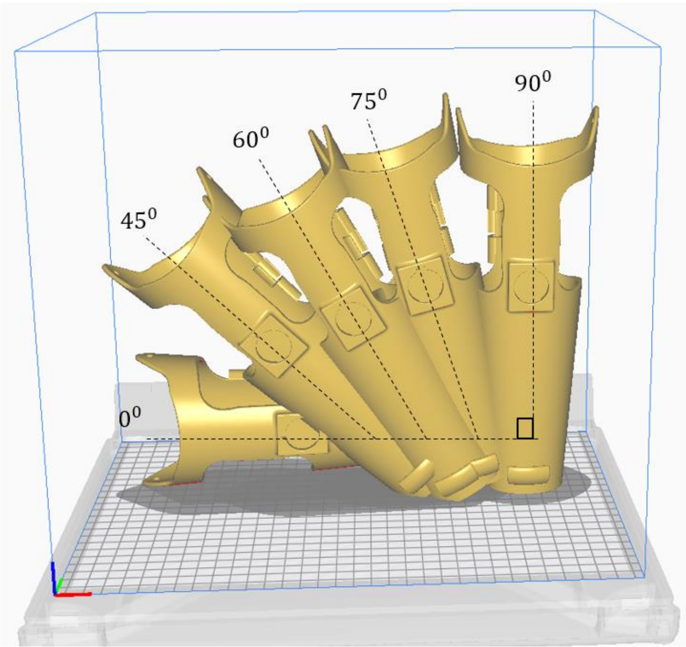

Figure 6.1. Different printing orientations of the socket from 0° to 90°. The socket was decided to be printed along the 0^0orientation so that the layers would not be perpendicular to the applied loading, causing them to be separated.

Since the main shell has the tensioner housing that needs to be securely snapping the lace-tensioner, and printing orientation was mentioned in literature to be affecting the accuracy of the pint, a quick test was made to investigate that. Two samples of the tensioner housing were 3D printed: one with 0^0 orientation, and another one with 90^0 orientation, see Figure 6.2. The printed sample with 90^0 was providing more secured connection to the tensioner compared to the 0^0 one. Since the main shell including the tensioner housing was decided to be printed with 0^0printing orientation, it was decided to glue the tensioner in the housing just for providing a more secure connection to it.

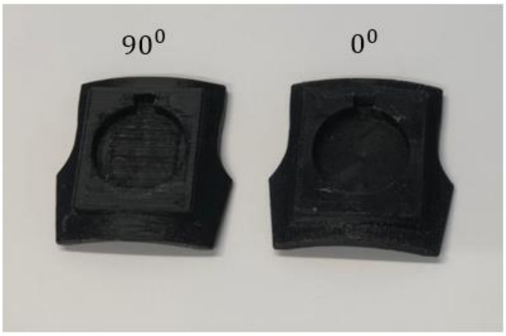

Figure 6.2. 3D printed samples of the tensioner housing with different printing orientations. The goal of printing those samples was to test the effect of the printing orientation on the accuracy of the print. The same housing designs were printed with two different printing orientations. The housing sample printed along a printing orientation of 90^0 was more securely fitting the tensioner than the other sample, and thus more accurate.

The Printing orientation of the adjustable wings and the upper attachment were decided to be at 90^0 printing orientation with respect to the printing bed, see Figure 6.3. That means that the layers would be built perpendicular to the printing bed. For the adjustable wings, that decision was made such that when applying tension on the hooks of the wings, the layers making the wings including the hooks, would be parallel to the applied force. If it happened to be perpendicular to the force, that would easily separate the layers. For the upper attachment, it was critical to have the layers at the open slots, where the Velcro straps get attached, parallel to the force of the Velcro straps when tightening them, see Figure 6.3. Therefore, that orientation was decided. Finally, after selecting the tough PLA as the printing material and choosing the printing orientation, and other printing settings mention in APPENDIX E: Prototyping, the socket parts were 3D printed.

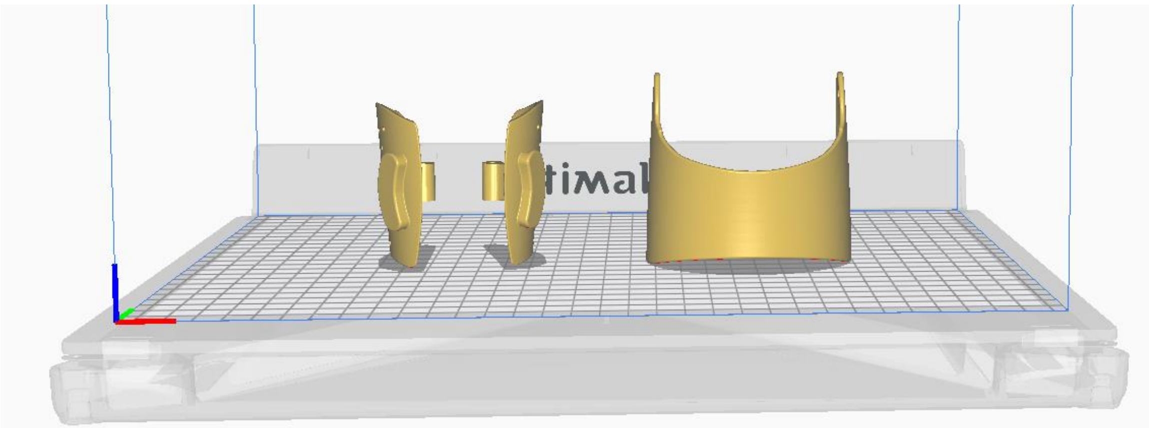

Figure 6.3. Printing orientation of the adjustable wings and the upper attachment. The parts will be printed perpendicular to the printing bed to avoid having their layers separated due to the applied forces of the tensioner lace and the Velcro closure, respectively.

6.2.2 3D printed socket

After 3D printing the main shell, adjustable wings, and the upper attachment, and removing the support material, the socket was assembled, see Figure 6.4. The steps for assembling the socket were summarized in APPENDIX E. The maximum material cost set for the socket in the design requirements was €100. After assembling the socket, and calculating the total cost of its components, see Table 6.III , the material cost per socket was only €30. With producing hundreds of them, the cost of the non-3D printable parts is expected to be lower. Thus, with mass production, the total cost of the socket will decrease. The weight of the 3D printed socket was 170g. A conventional socket weights around 240g [14], so the V3D socket has less weight. Since the weight of the socket is subjective to the size of the user's residual limb, a definite answer of the estimated weight of the socket cannot be given. Overall, the socket cost and weight has proven to be less than those of conventional transradial sockets.

Figure 6.4. The V3D socket prototype. The socket was 3D printed from tough PLA. Then the adjustable wings were assembled to the main shell via metal threaded rod, and the lace-tensioner mechanism was snapped in the tensioner housing. After that the upper attachment was connected to the socket main shell at the elbow through flat head screws. Note that at the distal end of the socket, curved hooks were 3D printed as part of the main shell. Those hooks were modeled to only be able to perform the mechanism assessment on the prototype, and they are not part of the socket design.

Table 6.III. The cost of the socket components. The total cost of the socket did not exceed €100 as required. Only €30 was the material cost of the socket, which is expected to decrease with mass production.

Part	Materia cost/socket
Mavic tensioner	€6
Screws and connecting rods	€1
Arm strap with Velcro closure	€8
Printed material	€15
Total	€30

After prototyping and assembling the socket from tough PLA, the socket has fulfilled the design requirement of having a material cost below €100, as the socket material cost was only €30, and the socket passed the design requirement of having a socket that is safe to be in contact with the skin as the PLA material is FDA approved. With ending this chapter, the design & development phase of the socket had ended to start the evaluation phase.

7

EVALUATION

7.1 VERIFICATION AND VALIDATION OF DESIGN REQUIREMENTS

Before designing the V3D socket, a set of design requirements and wishes were derived to design the socket based on, recall Table 4.I. In Chapter 5, verification of most of the design requirements and wishes was performed through optimizing the socket design in terms of enhancing its structure and optimizing the designs of each part of the socket. After prototyping the socket, see Chapter 6, verification of the rest of the requirements and wishes was completed through selecting the suitable material for this application and having a material cost of the socket of only €30. After verifying the design requirements and wishes, and prototyping the socket, it was time to validate the design requirements that needed so. Those are the 1st to the 5th design requirement which are summarized in Table 7.I. Therefore, to validate those requirements, mechanical and human evaluation of the socket were performed, explained in section 7.2.

Table 7.I. Summary of the design requirements that need validation to prove whether the socket fulfills them or not.

#	**Design requirements to be validated**
1	Full extension of the elbow (0°) and flexion up to (110°)
2	Volume adjustability (15mm for tightening and 30mm for loosening)
3	Easiness of donning and doffing (within 1min.)
4	Load-resistance (50N axially & transversely)
5	secured self-suspension

7.2 MECHANICAL EVALUATION

7.2.1 Axial load test

Since there is a high potential that the socket be loaded axially or transversely when the user is carrying an object, or accidentally fall or hit an object, it was decided to assess the performance of the socket in similar scenarios. The aim of the those tests was to validate the 4th design requirement in Table 4.I, which was making a socket that can withstand a load of 50N(~5kg) that is applied axially & transversely without experiencing any layer breakage or socket damage. Therefore, an axial load test, a bending test, an impact strength tests were performed. This subsection addresses the axial load testing. Before conducting this test, the socket design was adapted so that a bag with loads can be suspended to its end. Therefore, two hooks were added to the socket design near the wrist where the user will mostly be carrying a bag or an object, see Figure 7.1. To perform the testing experiment, a model of a cylindrical residual limb was designed, and 3D printed to be fitting the socket while it was clamped and loaded. The printed model was then drilled to pass a 10mm diameter metal rod that can be fixed to a bench clamp, during loading, see the testing setup in Figure 7.2. Then the test started with attaching a bag at the hooks where loads were added gradually from 2.5 kg to 10 kg, see Figure 7.2. The socket was loaded till 10kg, although 5kg would have been enough for passing the test, to assure the safety of the user when loading the socket. After loading the socket up to 10 kg (~100N), no signs of damage or changes were observed on the socket. Therefore, the socket has passed this test.

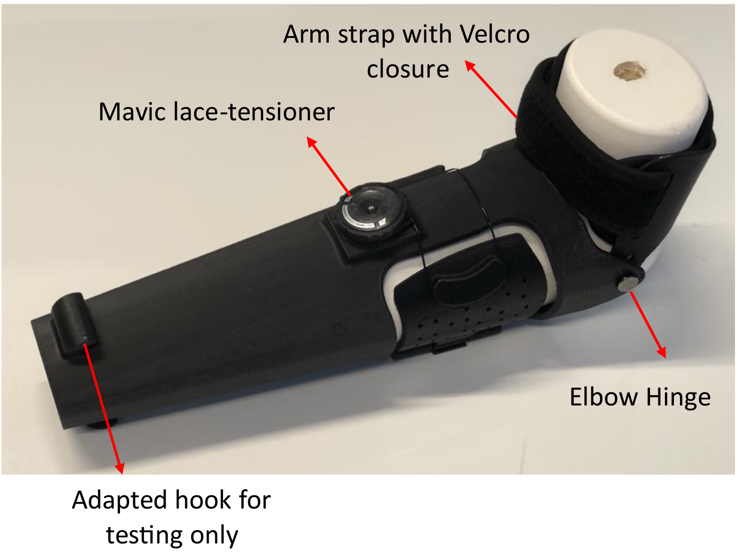

Figure 7.1. 3D printed socket after assembly. The adapted hook near the wrist end of the socket is not part of the main design of the socket. It was added only for hanging a bag there as part of the mechanical assessment of the socket.

Figure 7.2. Setup for axial load testing of the socket. A bag, with weights in, was suspended to the hooks of the socket to test if loading the socket axially would result in any damage or separation of layers. A pass of the socket was given if the socket could withstand 50N without any damage. The socket succeeded to withstand axial load up to 100N without any signs of damage, so it passed that test.

7.2.2 Bending test

The aim of this test was to ensure that the socket can withstand the induced bending stresses when a transverse load up to 50N(~5kg) is applied at the tip of the socket without breaking, mimicking one of the common scenarios for carrying a bag. Therefore, a test setup was prepared to mimic this scenario as if the user is flexing the elbow at 90° while wearing the socket and loading the socket, see the setup in Figure 7.3 & Figure 7.4. The experiment started by loading the socket gradually from 2.5 kg to 10 kg. It was meant to exceed the desired limit of 5kg to check if the socket will break or experience noticeable damage if the load was doubled. After loading the socket with 5kg transversely, no signs of damage were noticed. With doubling the applied load (10 kg), only deflection at the tip of the socket was noticed, see Figure 7.4. Nevertheless, after removing the load, no signs of deformation were observed, and the socket returned to its initial state. Therefore, the socket has passed the bending test as well.

Figure 7.3. The setup of the bending test. The setup was meant to mimic the real scenario where the user would be loading the socket transversely as if the user is carrying a bag.

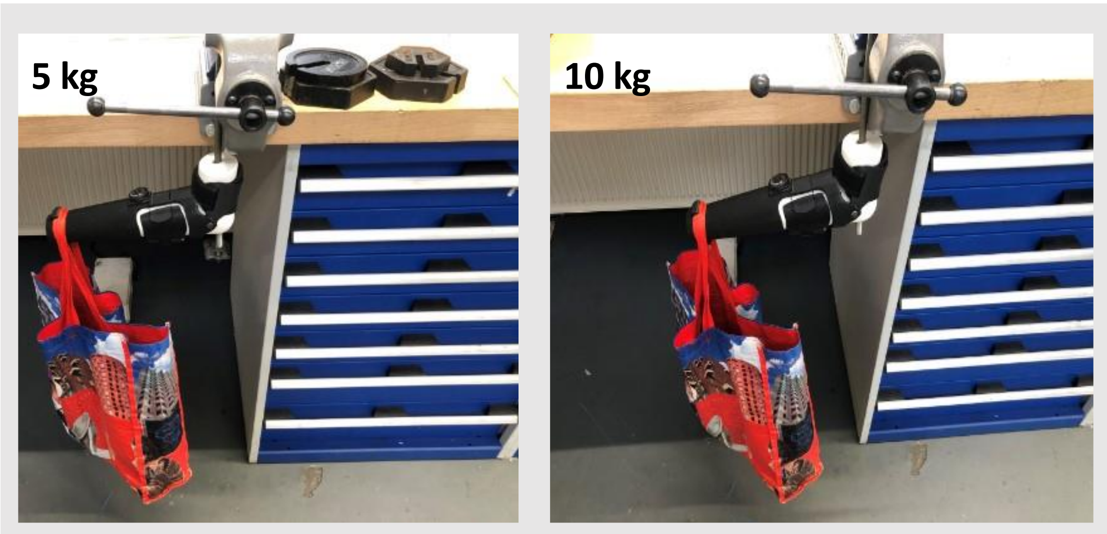

Figure 7.4. Bending test of the socket. The socket needed to withstand a 50N that is applied transversely at the tip of the socket without any signs of damage or breakage to pass this test. The socket succeeded to withstand transverse loads up to 100N without showing any signs of damage.

7.2.3 Impact strength

Impact strength refers to the capability of the material to withstand sudden loading without fracture. After mimicking the common loading scenarios of the socket, another scenario where the user could occasionally drop the socket or when the socket suddenly hit an object were tested as well. Therefore, in this experiment, the socket was dropped from a height of (~240mm) to mimic this scenario. The chosen threshold is higher than the average height where a used could drop the socket from to ensure the reliability of the socket in a similar scenario. A pass of this test was considered if the socket did not experience any damage after the free fall. After dropping the socket from that height, no signs of damage were observed, and all the assembled components remained in place. To reach the limits of the socket and test in which direction it would break, the socket was dropped from 5m twice, see the video of all the impact strength tests. After the first drop, no signs of damage were observed. Nevertheless, when the experiment was repeated, the socket cracked from the front and the back along the direction where layers were adhered together as shown in Figure 7.5. Overall, the socket has passed the impact strength test since it did not show any signs of damage when it was dropped from the 2.4m height.

Figure 7.5. Cracks of the socket after dropping it twice from a 5m height. The socket cracked along the direction that it was printed in (printing orientation of 0° angle with respect to the printing bed) as expected. That cracking direction is the same direction where layers of filaments were adhered together. The red arrows show the locations of cranks, see the video of all the impact strength tests. The test passed the impact strength test after it was dropped from 2.4m without showing any cracks or any signs of breakage. The 5m height test was only performed to see where the cracks would develop in the socket it was hit by an object suddenly.

7.3 HUMAN EVALUATION

7.3.1 Aim & Evaluation method

After conducting the mechanical evaluation of the socket in different scenarios to validate the 4th design requirement in Table 7.I, it was time to validate the rest of those design requirements. In addition, through this evaluation, it was to find out which fitting parameters of the residual limb are critical for producing a comfortable, good-fitted socket, and to answer this question "Does the socket need to be customized for each user or can it be modular such that one socket can fit different users? If yes, what range of diameters can fit one socket?". Therefore, an evaluation method and a testing protocol were prepared. Since testing with participants with transradial amputation was not feasible due to the COVID-19 pandemic happening in parallel with this research, the socket was tested by participants without arm amputation. Therefore, the top half of the socket only was used in the evaluation such that participants can pass their hands from the socket to don it. Also, two hooks were adapted to the socket design so that participants can hang a bag to the socket while wearing it as part of the evaluation, see Figure 7.6. Two sizes of the socket were produced for the evaluation: a small and a medium size socket, see Figure 7.6.

Figure 7.6. Testing sockets for the human evaluation. Two different sizes were produced to fit different participants from both genders; small and medium size sockets.

Before conducting the human evaluation, an approval of the Human Research Ethics Committee (HREC) was obtained, and an informed consent was prepared to be handed to each participant to give permission for publishing the results of the experiment, see the approval in APPENDIX H: Human testing. In addition, a testing protocol was prepared, and it involved the following steps:

- Hand a new stump sock to each participant if they are not wearing a shirt with long sleeves for a comfortable fitting of the socket.
- Take measurements of the participants' forearm with 90° flexion of elbow, using a caliper.
- Let the participants don the socket and note down the donning time.
- Ask the participant to flex and extend their elbow, record the maximum range of flexion and extension, and the locations of discomfort based on the participant's feedback.
- Ask the participant to twist their forearm to see if the socket would constraint supination and pronation movement and note down locations of discomfort.
- Hang a bag with 0.5kg weight, axially, on the hooks of the socket and record any slipping of the socket, and locations of discomfort.
- While loading the socket with the 0.5kg, ask the participant to flex and extend their elbow, and record the locations of discomfort.
- Finally ask the participant to doff the socket and note down any marks left on their skin.

7.3.2 Results & Iteration of design

In this evaluation, five participants have volunteered: four females and one male. Their ages ranged from 24 to 30 years old. The average wearing time of the socket was 20 minutes. Three participants were fitted to the small socket size, and two participants were fitted to the medium socket size, taking advantage of the lace-tension mechanism, offering the volume-adjustability. All the participants managed to fully extend their elbow, see Figure 7.7, and flexion range varied among participants based on how comfortable the socket fitting was to their forearm. For participants where the socket was comfortably fitted to their forearm, flexion was around 95°. On the other hand, for participants where the socket was tightly fitted such that some of the soft tissues at the anterior side of the forearm were compressed, flexion range was around 85°. All participants managed to don and doff the socket in less than10 seconds after giving them instructions on how to do that. For the upper attachment (above the elbow), the arm strap was securely attached to the participants' arms, and no slipping was recorded while performing the basic movements of the forearm. On the other hand, loading the socket with 0.5kg resulted in slipping of the upper attachment up to 5mm, while the participant is fully extending the elbow. Overall, the socket has passed the targeted design requirements, shown in Table 7.I, except that flexion range was up to 95° and was dependent on the fitting of the socket.

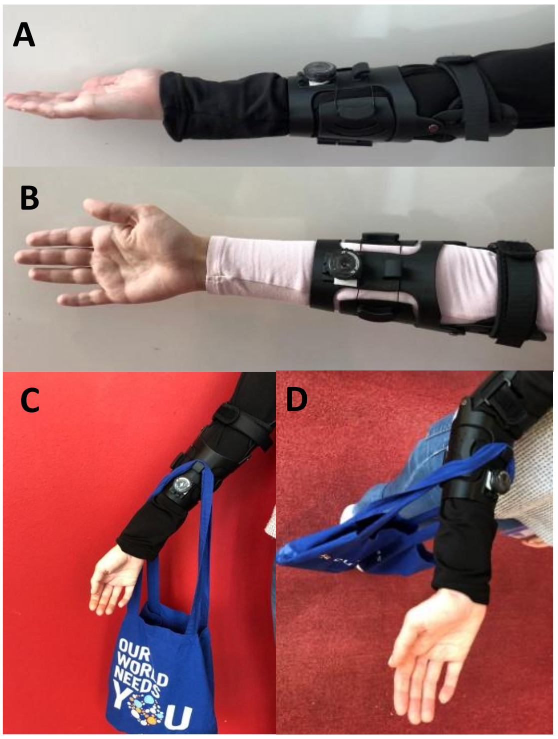

Figure 7.7 Human testing of the socket. (A) Full extension of elbow (B) forearm pronation (C & D) Action of carrying a bag while extending and flexing the elbow.

From the human evaluation, it was found out that tight fitting of the socket would result in discomfort at the following locations, see Figure 7.8:

- The distal end of the socket during pronation and supination.
- The medial epicondyle during flexion and extension, especially with loading the socket.
- The proximal end of the socket near the elbow joint where soft tissues gets bulged when the participants flex their forearm.

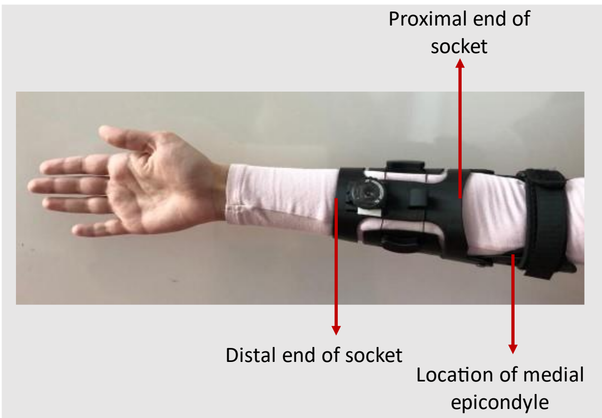

Figure 7.8. Areas of discomfort for the participants. The discomfort at the distal end was during pronation and supination. The discomfort at the medial epicondyle was during flexion and extension. The discomfort at the proximal end was only during flexion when the soft tissues at the cubital fold of the elbow was bulging.

After fitting the same socket size to multiple participants and recording the diameters along the transverse and sagittal plane, see Figure 7.9, of the participants' forearms, the acceptable ranges of differences in the diameters were concluded. For a comfortable fitting of the socket, an acceptable range up to 7mm was recorded for the diameters along the transverse plane. That is where the adjustable wings are offering volume adjustability and taking care of those differences. On the other hand, a range up to 3mm in the sagittal plane was recorded.

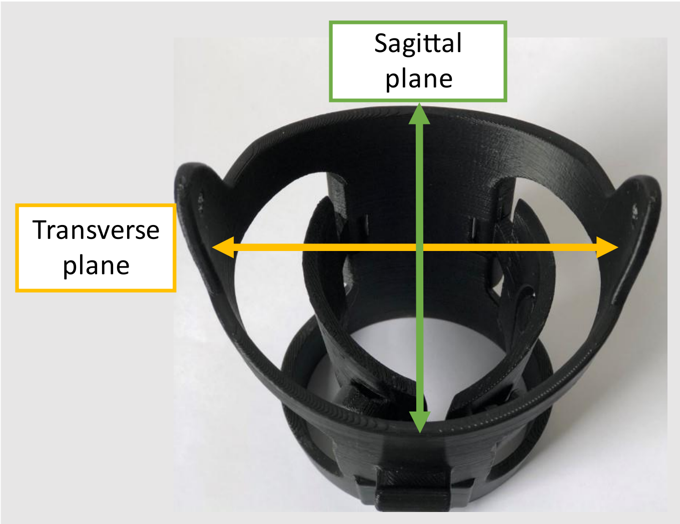

Figure 7.9. Planes of the socket where measurements are taken for socket fitting. Dimensions along the sagittal plane are very critical for customizing a comfortable socket.

Based on the human evaluation, it was concluded that producing comfortable fitting and functional socket depends on the dimensions of the residual limb in two positions; one positions where the elbow is flexed at 90° and another position where the residual limb is flexed and pronated, twisted, up to 90° depending on the residual limb length. Consequently, a systematic guideline with the important parameters for fitting the socket was constructed, see APPENDIX G: Fitting guideline. Besides, it was concluded that one socket size can fit different residual limbs because of the volume-adjustability feature of the socket. The limiting factor for the differences in the residual limb sizes would be the diameters of the residual limb along the sagittal plane where volume-adjustability of the socket is not offered. Furthermore, the measurements taken of the forearm diameters using a caliper haven proven that 3D scanners are not necessarily needed to be able to customize the socket size. In addition, based on the human evaluation, a simple iteration in the V3D design was concluded to increase the flexion range. That iteration would include increasing the curvature of the proximal of the socket such that it would not interfere with the cubital fold of the residual limb and prevent flexion range, see Figure 7.10. By the end of this evaluation, the socket has succeeded to validate all of the design requirements, shown in Table 7.I, except achieving a flexion range of 110°.

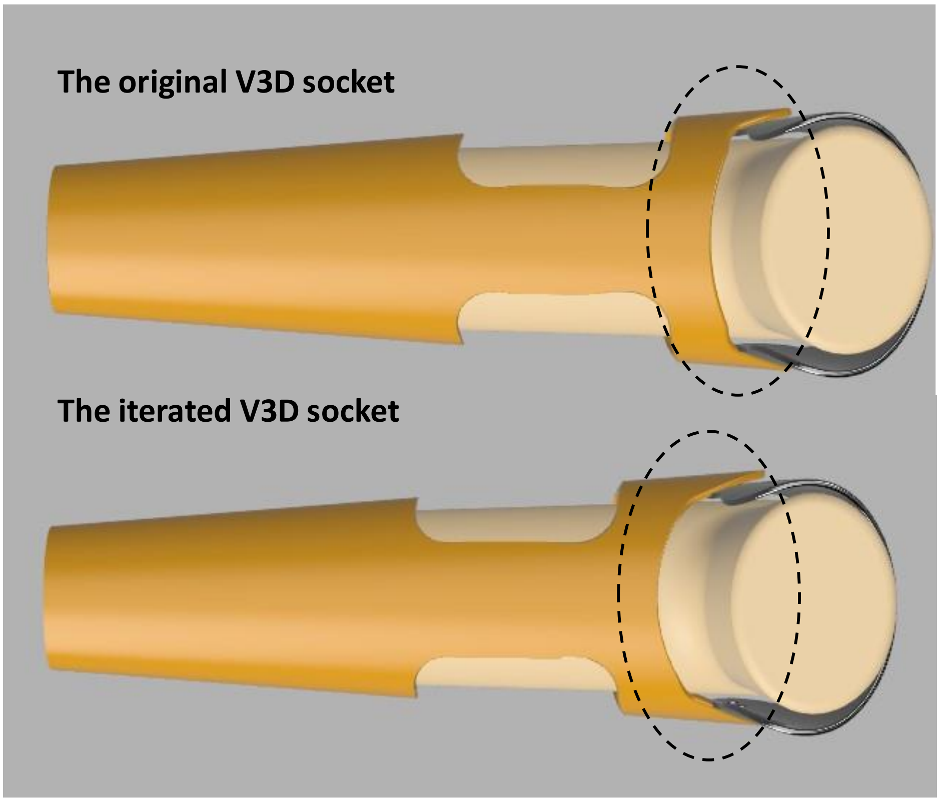

Figure 7.10. Iterated V3D design to allow higher range of elbow flexion. In the iterated design, the proximal end of the socket was optimized by increasing its curvature and increasing the length of the strips connecting the socket to the upper attachment at the elbow hinge locations. The optimized parts of the socket are circled to see the difference between the original V3D socket and the iterated one.

7.4 VERIFICATION & VALIDATION

After performing the mechanical and human evaluation of the socket, the design requirements of the socket are recalled corresponding to their verification and validation methods and whether the socket succeeded to meet each one of those requirements or not. Some of those requirements were validated through the mechanical and human evaluation, and others were verified through the designing and prototyping phase, see Table 7.**II**. From Table 7.**II**, the socket has passed all the design requirements except that it achieved a flexion range of 95° instead of 110°. To increase that range, a simple iteration in the V3D socket was performed where the curvature of the proximal end of the socket was increased as shown in Figure 7.10.

Table 7.II. Summary of design requirements, their validation methods, whether each design requirement was met or not, and the section where it was validated. The socket has met all the design requirements except that the maximum flexion range is 95°, while the targeted range was 110°.

#	**Design requirement & Wishes (W)**	**Verification & Validation method**	**Met or not?**
1	Full extension of elbow (0°) and flexion up to (110°)	Verified in the design phase & validated through human evaluation	Full extension is met, flexion is up to 95°
2	Volume adjustability	Verified in the design phase & validated through human evaluation	Met

3	Easiness to don and doff (max. of 1 min. for each)	Verified in the design phase & validated through human evaluation	Met
4	Load-resistance (up to 50N axial and transverse load)	Verified in the design phase & validated through conducting the mechanical evaluation	Met
5	Secured self-suspension	Validated through human evaluation	Met without loading the socket
6	Adaptability to different types of wrist units	Verified within the design & was considered during concept selection	Met
7	Adaptability to cosmetic and body-powered prostheses	Verified within the design	Met
8	Breathable socket	Verified within the design through providing holes for ventilation	Met
9	Safe contact to the skin	Verified during material selection as PLA is FDA approved and a biodegradable material used in medical objects [72] & verified through designing comfortable arm straps for safe contact with the skin	Met
10	Weather- proof socket	PLA is not soluble in water, but it absorbs it if left in a tank of water for multiple days [73].	Met
11	Easiness of cleaning	Verified within the design through considering a wide range of loosening the adjustable wings to allow cleaning the socket from the inside.	Met
W1	Maximal material cost of €100	Verified in the prototyping phase	Met (material cost per socket is €30)
W2	Maximal thickness of 4mm	Verified within the design	Met (socket thickness is 3mm)

8

DISCUSSION

8.1 EVALUATION

8.1.1 Mechanical evaluation

Performing mechanical assessment of the socket was very critical for validating the reliability of the socket when loaded in different scenarios. The socket has passed all the mechanical assessment tests and did not show any signs of damage even with axial and transverse load up to 100N. Nevertheless, there were few limitations to those tests. For the axial loading test, when the socket would be axially loaded in reality, the user would be fully extending the elbow, not flexing it with a 90° angle as the case in the test. However, mimicking that scenario would ruin the experiment, since the socket would not be securely suspended to the rigid model of the residual limb which cannot be compressed or indented similar to a real arm. Thus, if this approach were applied, the socket with the load would have easily slipped. For the bending test, since the 3D printed residual limb is a rigid structure, again that cannot be compressed or indented, it had to be designed small than the size of the socket to pass through it. As a result, it could not achieve full contact with the top and back strips of the socket. That means that the strips were not fully supported by the residual limb as they would be in real application. This limitation could have affected the amount of deflection noticed at the end of the socket. Part of that deflection could have been just tilting of the socket since it can rotate at the elbow hinge connection. Overall, the socket has succeeded to pass the mechanical evaluation, and validate the 4th design requirement of withstanding axial and transverse loads of 50N.

8.1.2 Human evaluation

Conducting a human evaluation of the socket was critical for evaluating the comfort and function of the socket and validating the design requirements. One of the aims of that evaluation was to answer this question: “Does the socket need to be customized for each user or can it be modular such that one socket can fit different users? If yes, what range of diameters can fit one socket?” During the evaluation, the small-sized socket fitted three participants, and the medium-sized socket fitted two participants (a male and a female). Differences in the diameters along the transverse plane of the forearm were taken care off by the adjustable wings. However, along the directions of the socket where volume-adjustability is limited, the posterior and anterior strips, limited range of differences can be accommodated by the socket. A tight fit of the socket affects the flexion range and causes discomfort which can lead to abandoning the entire prosthesis. Therefore, one socket size can fit different residual limbs as long as the difference in their sizes are along the transverse plane, up to 7mm, and not along the sagittal plane. In addition, the option of customizing the socket must be always available in case some subjective differences need to be considered in the socket model.

8.2 STRENGTHS & LIMITATIONS FOR FUTURE WORK

8.2.1 Strengths

There are many advantages in terms of the fabrication process, and the design of the V3D socket. The fabrication process of a customized V3D socket for a client includes taking the fitting parameters, customizing the socket model to the size of the user, printing the socket model, removing the support material, and assembling the socket. The estimated total time from the first visit of the user for taking the fitting parameters to picking up the socker is 5 days including 4 hours of labor work. Those 4 hours include taking the right parameters of the residual limb for fitting the socket (~30 min.), customizing the socket size in a CAD software (~2 hrs.), preparing the model for 3D printing (~30min.), and assembling the socket parts (~1hr.). The mentioned hours are overestimated as customizing the socket model can easily be automated in generic CAD software program such as Fusion 360 and SOLIDWORKS, which would cut the total number of hours. Comparing 5 days of fabricating the V3D socket to 2-5 weeks for fabricating conventional sockets, the V3D socket has saved much time, and cost as its material cost does not exceed €30 while conventional sockets cost hundreds of euros.

In addition, the short fabrication time of the V3D socket promotes it to be used for early fitting for people who have just gone through a transradial amputation. As mentioned before, early fitting of a prosthesis has proved to increase the acceptance rate of the prosthesis, and the acceptance rate of the user to the changes accompanying their amputation. In addition, the volume-adjustability feature of the socket would help those users to smoothly fit the socket and adapt to the volume fluctuations which are very common in the first two years after an amputation. Not only people with recent amputation would benefit from that feature, the V3D socket gives the user the freedom to fine-tune the socket fitting while performing different daily tasks. With the V3D socket, the user would not need to take off the whole prosthesis to relax their residual limbs as the adjustable wings can easily be loosened. Therefore, the Volume adjustability and short fabrication time of the socket makes it a high potential for early fitting.

Furthermore, taking the needed parameters of the residual limb for customizing the socket, see APPENDIX G: Fitting guideline, can easily be obtained using basic measuring tools such as a caliper if 3D scanning is not accessible. That feature promotes the V3D socket to be fabricated in communities that do not have access to 3D scanners. Moreover, the V3D socket does not require buying a liner, which can cost hundreds of euros and is usually used with fixed-volume socket to ease the donning and doffing. The V3D socket simple donning and doffing system does not require them because of its volume-adjustable closure system that does not apply shear forces on the skin.

Finally, as an outcome of this thesis work, a collaboration with Radboud University Medical Center (RUMC) was established to develop 3D printable arm prostheses for people with transradial amputation in Sierra Leone. In that collaboration, the socket design and the thesis work was handed to contribute to developing those prostheses and test them on Dutch users and users from Sierra Leone.

8.2.2 Limitations and future work

There are some limitations to the V3D socket that need to be considered for future work. First, in this research, only mechanical and human evaluations with participants without arm amputation were conducted. However, clinical evaluation with participants with varying lengths and geometry of the transradial residual limb is needed. To be specific, the socket function and comfort, need to be evaluated for residual limbs that are categorized in length (very short, short, and medium), and categorized in shape (conical and cylindrical). Second, the fitting guideline, shown in APPENDIX G: Fitting guideline, needs to be tested to establish a standardized method for customizing the socket size based on direct measurements of the residual limb. Third, the elbow hinge acts as a revolute joint, which allows only 1 Degree of Freedom (DOF) for flexion and extension. Replacing this joint with a ball and socket joint would allow 2DOF; 1DOF for flexion and extension and another DOF for pronation and supination. That change can result in making the movement of the affected arm more natural as the unaffected arm. Forth, 3D printing the adjustable wings of the socket from Polypropylene (PP) instead of tough PLA could be a better option since PP does not absorb moisture as tough PLA. Finally, to make sure that the iterated version of the V3D socket can provide higher range of flexion, it is recommended to 3D print its model and test the resulting flexion range.

9

CONCLUSION

The aim of this work was to address the labor-intensive and time-consuming conventional fabrication process of transradial sockets, and to address the fixed-volume problem of conventional sockets that require the user to keep replacing the socket to fit the volume fluctuations of the residual limb. As a result, the goal of this study was to develop a volume-adjustable, affordable, 3D printable, transradial, prosthetic socket. In this thesis work, the V3D (Volume-adjustable 3D printable) socket was designed, in collaboration with a certified prosthetist, and developed using the FDM 3D printing technique with a material cost of only €30. The socket has passed all the mechanical assessment tests and the function and comfort evaluation tests except that the socket allows maximum flexion range of 95° while it was aimed for 110°. The estimated time for developing the socket is 5 days which includes taking the fitting parameters, customizing the socket size using a CAD software, preparing the socket for printing, 3D printing the socket (~2days), leaving the socket in water for dissolving the support (~ 1day), and assembling the socket. The total labor work in this process does not exceed four hours. In addition, the socket has proved that it can be fitted using a caliper in case 3D scanners are not available. That advantage makes producing the V3D socket feasible in communities that do not have access to 3D scanners. Finally, the human evaluation has proven that the socket can be parameterized such that users with residual limbs that are within the same range of diameters can be handed the same socket size, which would reduce the labor-work even more as it was aimed for.

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APPENDIX A: LITERATURE REVIEW

3D printed upper limb sockets: A literature review.

Israa Abdelaziz December 2020 Supervisor: Dr.ir. Gerwin Smit

Abstract

Background: A socket is a bridge between the amputee's residual limb and the prosthesis. Its conventional fabrication process is known to be time-consuming, and labor intense. 3D printing showed promising results in fabricating prostheses and lower limb sockets. However, 3D printed upper limb sockets are overlooked, and no recent reviews covered a detailed overview of their state of the art.

Objective: Review the literature of recent research done on 3D printed upper limb sockets in the past 10 years to provide an overview of the involved steps in the fabrication process, customer satisfaction, and gaps to be worked on

Study design: A literature review

Methods: A literature search was mainly performed via 4 databases: Scopus, PubMed, ScienceDirect, and Web of science using a Boolean combination of keywords. Relevant studies from citations and other resources were included too.

Results: A number of 40 articles were included in the review. Publications on 3D printed sockets were mostly for transradial amputees and were describing the fitting method, printing procedure, and assessments. The majority of the sockets were 3D printed from ABS and PLA. Other promising materials were reported for more satisfying user experience.

Conclusion: Literature indicated inconsistency in the 3D printing settings for the same printing material among studies. It was not clear if 3D scanning can result in better fitting than traditional fitting. Almost no assessment of the mechanical properties of the printed sockets was performed. The less labor work, freedom of design, high customization level, and cost-effectiveness of 3D printed sockets indicate promising results for upper limb amputees.

Introduction

Background

It is estimated in the united states that about 15 out of 100,00 newborns are affected with congenital upper limb anomalies, and 6000–10,000 people undergo upper limb amputations each year [1]. In order to perform daily life activities, upper limb amputees use prostheses. An upper extremity prosthesis consists of a socket, a suspension tool, a power source, and joints depending on the amputation level. The socket is the most important part of any upper limb prosthesis for high performance [2], [3] . A socket is a cavity that fits the unique geometry of the residual limb of an amputee for a secure connection between the limb and the prosthesis [4]. The goal of a socket is to smoothly transfer loads while distributing the load evenly to limit pressure. To achieve that, the socket has to be well-fitted and comfortable for a functional prosthesis [5]. If the socket does not fit well, that can result in pain, blisters, ulceration, and damage of skin and tissues underneath [4], [5]. Therefore, to guarantee a good alignment, the socket needs to be replaced regularly as the residual limb will change over time, causing the socket to worn out [4], [6]. The socket design changes based on the amputation level, which can be: shoulder disarticulation, transhumeral (above elbow), elbow disarticulation, transradial (below elbow), wrist disarticulation, and partial hand [7].

Fabricating a conventional socket is known to be time-consuming and labored intense [10]–[12]. The fabrication process, shown in Figure 1, briefly involves wrapping the limb in plaster soaked bandages to make a negative mold, making a positive mold, then vacuuming a thermoformed sheet around the mold to create a diagnostic socket and then fabricating the final socket after making sure that the desired fit is achieved [13]. To receive a conventional socket, the patient has to wait 2-5 weeks and sometimes even more [14]. A conventional socket can cost from a few hundred dollars for a duplicate socket to thousands of dollars for a new fitting [6]. Thus, having to regularly replace the socket to fit the volume changes of the limb adds up to the total cost of a prosthesis. Rejection rates of prostheses are up 52% for people with upper limb amputation and vary for children from 30% to 50% and even higher for those with below wrist reductions [19], [22]. Reasons for the high rejection rates were mostly uncomfortable fitting, heavy weight, limited functionality, non-attractive appearance (especially for children), and high cost. The dissatisfaction with the socket fitting is another reason for prosthesis rejection [19].

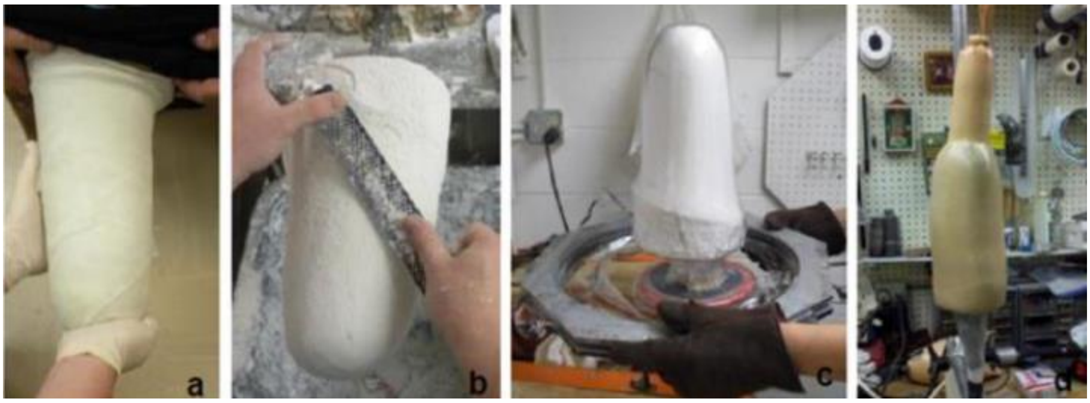

Figure 0.1. *The traditional fabrication process of a transfemoral prosthesis (a) negative mold (B) positive mold (C) testing the mold with a diagnostic socket (D) final product* [74].

Three-dimensional printing, also called Additive Manufacturing (AM), is defined as "The fabrication of objects through the deposition of thin layers of material using a print head, nozzle, or other printer technology" [24] . There are different techniques of additive manufacturing; Fused Deposition Modeling (FDM), Selecting Laser Sintering (SLS), and Stereolithography (SLA). FDM is the most common where a thermoplastic material fed into the printer head is heated and extruded in semi-molten form through a nozzle creating layers of the cross-sections of the component [23]. SLS techniques use a laser to fuse a layer of powdered polymer material, such as Nylons and polycarbonates, to bind the material together building a solid structure. SLA technique uses a liquid photosensitive resin that hardens when exposed to ultraviolet (UV) light [4]. 3D printing showed promising results for fabricating lower limb sockets, and terminal devices of the prosthesis [14]. 3D printing has a high potential for fabricating upper limb sockets [7], [19], [23], [25]–[28] for its ability to:

- Fabricate high complex geometries.
- Print high personalized and customized devices.
- Save material compared to traditional fabrication methods.
- Allow rapid design improvements.
- Perform the fabrication process with less cost, time, and manual work compared to traditional methods.

Problem statement

An updated overview of the state of the art of the current 3D printed upper limb sockets is needed. An overview of their advantages, limitations, and included steps for fabrication is required to define the gaps and research points to be worked on. Defining such gaps and the needs of upper limb amputees would accelerate the progress of fabricating reliable 3D printed upper limb sockets similar to lower limb sockets.

Objective

The objective of this paper is to search the literature to assess the current 3D printed upper limb sockets during the last 10 years. The search is performed in terms of the fabrication steps, needed facilities and materials, current methods of assessment, and whether a satisfying and reliable socket is achieved or not. That search later defines the gap points and recommendations for future work.

Methods

Search query

The literature search for this review was performed through 4 databases*; Scopus, PubMed, ScienceDirect, and Web of Science* using the following Boolean Combination: ((3D printing OR Additive Manufacturing OR rapid prototyping) AND (upper limb OR upper extremity OR prosthetic) AND sockets. The search was focused on publications from 2010 to 2020, and the search was limited to English. The literature search resulted in 381 references that were then screened and filtered according to a selection criterion that will shortly be explained.

Selection criteria

A screening of the 381 articles was done based on their title and abstract. That resulted in 49 articles from whom articles focusing on rapid prototyping, 3D printing, 3D scanning, fitting methods of upper limb prosthesis including the socket, or statistics of upper limb amputation were included. Also, articles focusing on materials used in this field while mentioning sockets were included. Articles focusing on lower limb sockets, or not mentioning sockets at all were excluded. The literature search was filtered using PRISMA flow chart shown in Figure 2.

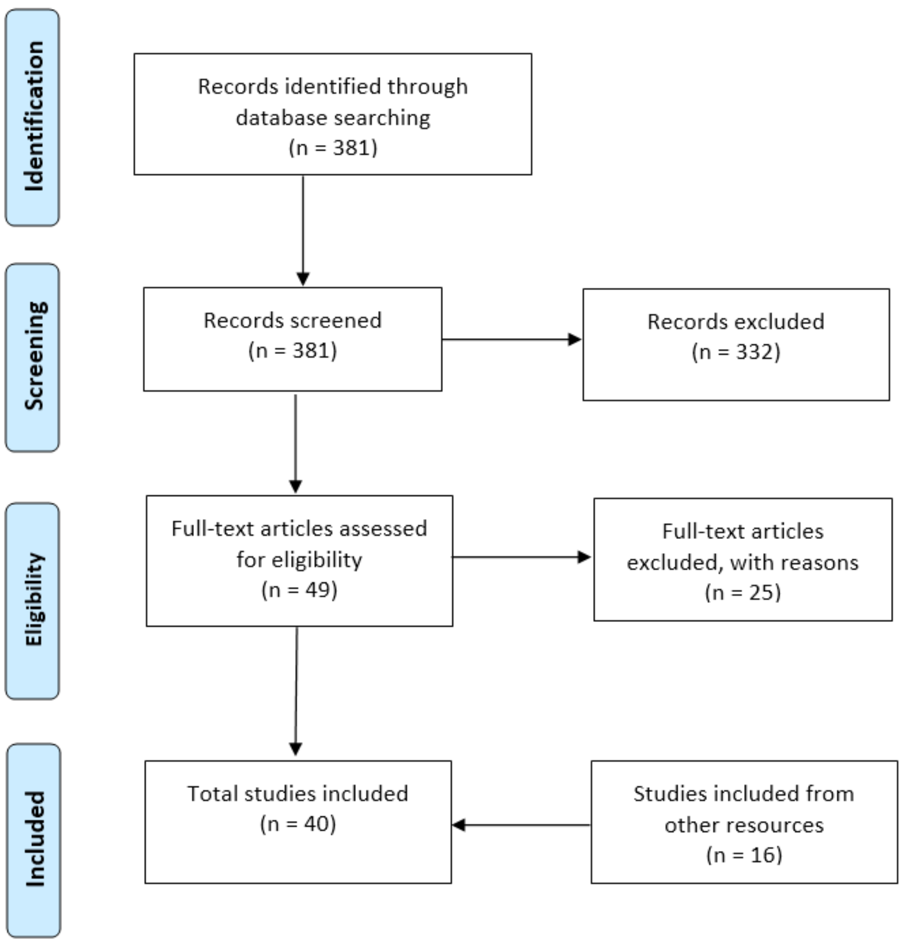

***Figure 2**. PRISMA Flow Chart for the literature search.*

Results:

Search results

The search resulted in 381 articles that were filtered using PRISMA Flow Chart, Figure 2, where 332 articles were excluded after screening the title or the title and the abstract. That left the following 49 articles: Scopus (n=13), Web of Science (n=8), ScienceDirect (n=21), and PubMed (n=7). Then 25 articles were again excluded after having a deeper look into the content of the articles. The excluded articles were mostly focusing on lower limb sockets, very general, or were focusing on the terminal device and not mentioning sockets at all. A big gap was noticed between the number of studies in the literature that are focusing on Lower limb sockets compared to upper limb sockets.

The remaining 24 articles were assessed with their references such that 16 more studies were considered. That resulted in 40 studies that were mostly case studies (n= 18), reviews (n = 10), research articles (n = 5), book chapters (n=2), and reports (n=3), and two theses. Any article that involved experimenting on a human subject and performing assessment was classified as a case study. Otherwise, if a human subject was not involved in testing, it was classified as a research article.

Reviews were mostly general and addressing the role of rapid prototyping or 3D printing, and 3D scanning or Computed Tomography (CT) in the field of Prosthesis and orthosis. Book chapters were mostly about materials used in this field, and two theses were focused on 3D printing sockets. Some of the case studies were not focused on only fabricating upper limb sockets, but the whole prosthesis where the socket was integrated into the prosthesis design, Figure 3. The majority of the case studies were making sockets for transradial amputees.

Figure 3*. Transradial prosthesis with the socket integrated* [28].

3D printing approach

In order to use the 3D printing approach for fabricating sockets, different steps from the traditional fabrication method are applied. The process was reported in different studies to involve the following steps [10], [23]:

- Fitting the patient's stump by obtaining a digital image of the individual or a cast of their stump using a scanning tool.
- Modifying the obtained scan using generic programs e.x Autodesk Fusion 360.
- Designing the socket using CAD software and the modified scan (Figure 4).
- 3D printing the design or a mold for it.

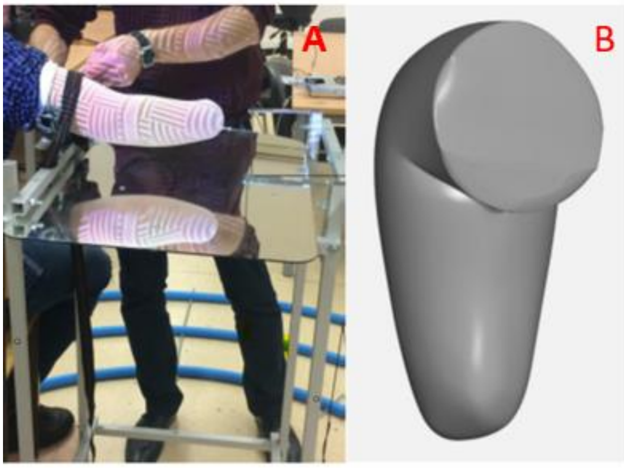

Figure 4*. (a) Scanning and (b) modeling process of a transradial socket* [2].

Fitting upper limb sockets

Fitting a patient with a prosthesis within the first 4 weeks after an amputation increases the likelihood of acceptance of the device [21]. Different methods for fitting sockets or prostheses generally were mentioned in literature [74]–[77]. For fitting a socket that is fabricated using the traditional casting method, a negative mold is made over the residual limb, Figure 1. This method is applied after applying some pressure on some key areas to change the shape of the limb to produce a better fitting socket [78], which is called the rectification process. To fabricate a 3D printing socket, the process requires a scanning tool for fitting [10]. That scan can be obtained via X-ray, magnetic resonance imaging (MRI), computed tomography (CT), or by a hand-held scanner [11]. Hand-held scanner tools were the most common in the literature compared to the other mentioned options. Different scanner types are mentioned in Table I. A 3D scanner price can start from $300 for a generic scanner to thousands of dollars for high-accuracy scanners [23]. Computed tomography (CT) is another scanning tool that was used in some studies [79]–[81] . In addition, remote fitting is a third fitting tool that was addressed and adopted in many studies [19], [22], [75]–[77]. This method is developed for unsophisticated designs that require simple measurements, Figure 5. It was mainly tested for fitting open source prosthesis such as Cyborg Beast [75]–[77].

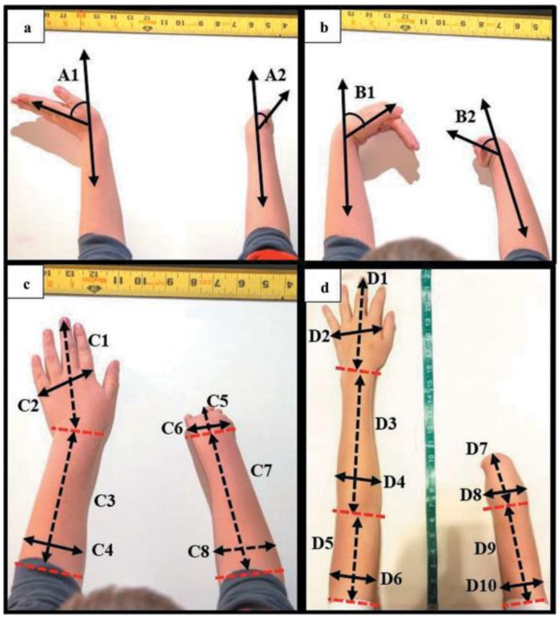

Figure 5*. Remote fitting process for a transradial prosthesis* [26].

3D printing techniques and critical parameters

Different 3D printing techniques were mentioned in the literature including FDM, SLS, and SLA. FDM is the most common, widely available, and cheap technique that results in quick prints [23]. SLS comes in the second place, which is used for printing accurate and flexible geometries [23]. SLS technology was recommended as the ideal technology for fabricating sockets and any parts where constant stability in all directions is needed [82]. That statement was mentioned to be true too for 3D printing with the FDM™ULTEM™material [82]. Infill density was reported in some studies to be significantly affecting the durability, rigidity and strength of the printed parts. Other parameters were mentioned that affect the finish of the printed parts such as the temperature for heating the filament and the layer height. The smaller the layer height, the smoother the end product, but the longer the time taken [19]. Printing time and cost were barely mentioned in literature. The average printing time was mentioned to be 15 to 20 hours [74]. Mostly the fabrication cost of a whole prosthesis is mentioned but not sockets alone. 3D printing of a socket was reported to be printed as one piece or divided horizontally or vertically and then assembled Figure 6 [2].

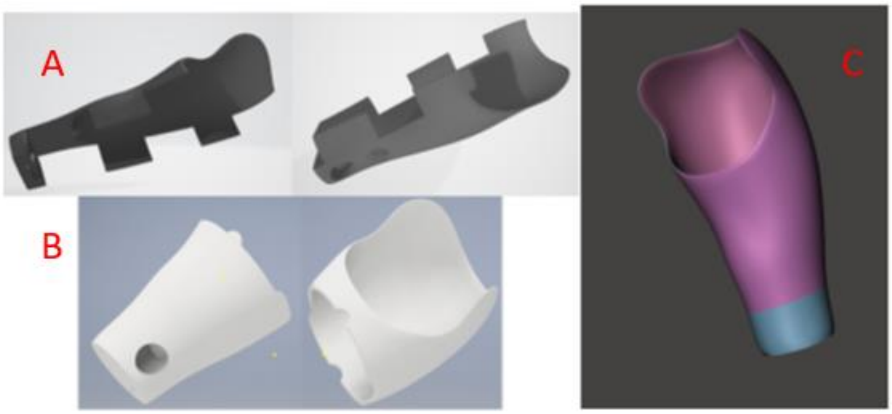

***Figure 6**. Different modeling methods before printing a transradial socket. (a) socket divided vertically (B) socket divided horizontally (C) One-piece socket (no division)* [2].

3D printing materials

The most common materials for fabricating upper limb sockets are Polylactic Acid (PLA) filament and Acrylonitrile Butadiene Styrene (ABS) filament [28], which can also be seen in Table I. Several studies [23], [28], [75], [83] mentioned the properties of PLA filament with its advantages and drawbacks in the prosthesis field. It was mentioned that PLA:

- Has similar properties to a thermoplastic.
- Can withstand the sanitizing heat of dishwasher without deforming.
- Has shown to have a shape-memory effect, which makes it required for adaptive sockets.
- Is mostly used for low-cost applications.
- Lacks structural stability in the presence of moisture and high temperature.
- Is biocompatible but lacks durability.

After PLA, and ABS, other materials are used for printing sockets, and prostheses generally such as Nylon, PLACTIVE™ (PLA with 1% copper nanoparticles), NinjaFlex™, FilaFlexTM as shown in Table I. However, Nylon, in particular, was highlighted to be used for parts requiring durability, and was favored in literature for fabricating sockets [2], [23], [28]. Moreover, urethane or TPE filaments were mentioned to be useful within the socket for areas where flexibility is required [23].

Table I. 3D printed sockets using FDM printers since 2013

Ref.	Amputation level	Fitting method	Printing material	Printing time	Socket cost
[84]	Transradial	–	ABS	–	–
[85]	Transradial	–	ABS	–	–
[1]	Transradial	–	ABS	–	–
[75]	Transradial	Sense 3D scanner	PLA	–	–
[86]	Transradial	Artec, Eva 3D scanner, Z Brush	Polypropylene	–	–
[74]	Index finger	Remote Fitting	PLACTIVE™	–	–
[22]	Transradial	Z scanner + CT scanner	NinjaFlex™, FilaFlex™	–	–
[77]	Transradial	Remote Fitting	PLACTIVE™	–	–
[2]	Forearm (3 sockets)	3D scanning with Davis SLS-3 Scanner	ABS, Nylon, Polycarbonate	Ave. of 15 hrs.	–
[6]	Transhumeral	–	PLA, NinjaFlex™ thermoplastic polyurethane	–	–
[14]	Transradial	Optical scanner (circa)	PLA, PLACTIVE™, (PETG)	Ave. of 15 hrs.	£3 (PLA), £9(PLACTIVE), £10(PETG)
[87]	Transradial	Canon Powershot SX420IS	PLA	14 hrs.	–

Table II. Comparison of 3D printing parameters among studies

Ref.	Material	% Infill	Print speed(mm/s)	Extrusion Temp. (C)	Layer thickness	Other parameters
[85]	ABS	–	–	–	0.254mm	–
[2]	ABS	40	60	230	0.3mm	–
[75]	PLA	40	60-100	–	0.15-0.25mm	Travel speed of 150-200mm/s, & heated bed with 50 C
[85]	PLA	10	90	230	–	–
[14]	PLA	15	–	–	0.18	0.4mm Nozzle printing at 45 degrees angle relative to the bed
[87]	PLA	100	60	210	0.2	0.4mm Nozzle

Discussion

Integrating digital tooling into clinics

In this literature, 40 articles were examined to have a clear idea of the status for fabricating upper limb sockets. Throughout this review, it was observed that upper limb sockets are overlooked although they were found to be the most difficult part to manufacture in a prosthesis [2], [88]. Although the high reported rejection rates of the conventionally fabricated prostheses including conventional sockets, and their labor-intense fabrication method, 3D printing of prosthesis is not taking place in clinics. That is mostly because most clinicians do not have enough expertise that is needed to include rapid prototyping techniques and have a lack of training and access to the 3D printing technology [88]. Besides, some prosthetists may not be willing to incorporate this technology because the time they would spend designing, modeling, and printing may not be covered by insurance reimbursement [88]. Moreover, with the fact that digital methods are not taught at P&O centers under ISPO guidance, introducing new technologies into clinical practice is challenging [88]. In an attempt to narrow the gap between the DIY communities and clinicians, clinicians showed their concern regarding 3D printed sockets that are not fitted under the supervision of a professional or certified prosthetist, which is the case in DIY communities [88]. That concern was raised too in another article explaining that handing a prosthetic device by a person who has not been educated with the biomechanics requirements of the residual limb could result in over tightening the limb which may cause skin and tissue damage [23] . Therefore, if the 3D printing approach of sockets will take place, the designing and fitting process has to be done under the supervision of a certified prosthetist as recommended in many studies [1], [11], [75]–[77], [89].

Fitting upper limb sockets

A well-fitting socket means taking care of the properties of the residual limb such as the anatomy, bony structure, underlying soft tissues, and nerves [16], [52], [90]. Based on the included case studies, achieving a perfect fit of a 3D printed sockets is difficult to reach from a first fitting, especially if the socket is not adjustable. In traditional fabrication, the prosthetist performs the rectification process to make sure that the socket will not be applying pressure on bony structures, but on soft tissues with a good grip [78]. Not only that but also, they fabricate a transparent diagnostic socket to check the goodness of their fitting before handing the final socket. On the other hand, in the 3D printing approach, it was observed in many studies that fitting is purely done by scanning the affected arm, and applying some pressure later on when modeling [14]. Then if the printed socket does not have the needed fitting, estimations of corrections are made before re-printing it. That trial and error methodology cannot always guarantee a good fit and could be a waste of time and material later for mass production. There is not a systematic, quantitative, and accurate assessment that can reflect a good fitting of a socket before or after testing the socket with the patient. Only one attempt was mentioned where CAD software was used to assess the overlap between the model of the stump and the designed socket using the “Boolean intersection” feature.

Adopting a systematic process, similar to the rectification process in 3D printing, could achieve better fitting from the first iteration of 3D printing. Adopting this step with digital tooling was considered in only one study [14] among the 18 included case studies. That study suggested that to result in a well-fitted socket, the 3D printed diagnostic socket could be heated and re-contoured to the desired fit if the 3D printing material has thermoplastic characteristics like PLA [14]. Besides, the study suggested that to incorporate these adjustments into CAD modeling, either the same modifications made to the socket would be approximated or the inside of the modified diagnostic socket would be scanned [14] before re-printing the socket. In general, adopting a well-structured process for fitting 3D printing with the help of scanning tools is needed besides a quantitative method of assessment for the socket fitting.

3D Scanning

It is not clear in literature if scanning can result in better fitting than traditional techniques. Most of the studies were using hand-held scanners as shown in Table I. However, the used scanners are different among studies, which makes it hard to perform any comparison or conclude if 3D scanning achieves a better fitting. That inconsistency in results could be because there is no data in literature on the minimum requirements of resolution for a 3D scanner, or the fact that multiple types of 3D scanners are in the market, Table I, and not all of them can capture the complex anatomy of the residual limb. It could be also that a good scan is taken, but corrections to the scan, including the applied pressure on the stump model, are randomly done, or a scan is just taken for the limb without applying any pressure. That problem could be solved if a certified prosthetist is involved in the digital scanning process such that they fabricate a positive mold of the stump with manual corrections done (rectification process). Then the stump mold gets scanned for digital modeling with the corrections. This way the socket, especially a self-suspension socket, can be designed with the real corrections that fits each unique residual limb for resulting in good fitting without having to estimate some corrections when modeling.

Multiple conditions were found to result in a low-accurate scan and bad fitting. lighting condition of the location where a scan is taken can significantly affect the accuracy of a scan [91]. In addition, taking a direct scan of a patient could be difficult for the scanned individual because of breathing or any sort of unconscious shaking of their body [23] if the scanning process is not quick. In addition, it is not clear in literature if a stationary scanning tool would result in more accurate scan than a hand-held scanner or if scanning an individual directly is better than scanning a cast of the residual limb. Apart from the scanning tool, the pause or angle of the elbow for transradial sockets was found to be affecting the final fitting in some studies.

Less common scanning tools were found in literature, which are Computed tomography(CT) [79]–[81] and Remote fitting. A CT scan can show the bony structure of the residual limb and it allows 3D reconstruction of the soft tissues and organic shapes that are not easily modeled in CAD software [79]. That type of scan is rich with helpful information for designing a well-fitted socket, since the underlying characteristics of the stump would be taken care of [16], [52], [90]. However, Computed Tomography technology is mostly only accessible in hospitals and purchasing them could be much expensive compared to hand-held scanners.

Scanning tools could not be an option for cases living in some developing countries or isolated areas. Remote fitting though, which was addressed by Zuniga et al. in multiple studies [19], [22], [75], [76] could be. In this method, simple measurements are taken from pictures that have the affected and non-affected hand of the patient, Figure 5. However, using this method for fitting a self-suspension socket where each residual limb has its own details and unique geometry, it is not clear if that method could be good enough at least for adjustable sockets. In fact, none of the studies performed a comparison between the accuracy of sockets fitted using 3D scanning, plaster casting, and distance fitting procedures. Therefore, more testing to the effectiveness of scanning is needed for resulting in satisfying fitting.

3D Printing techniques and parameters

Throughout all the articles that reported 3D printing sockets, the most common materials used were PLA and ABS. However, no agreement was found between the printing settings of the same material. In Table II, it can be seen that for sockets printed from ABS, different layer thickness was used, and for sockets printed from PLA, different % infill, printing speed, extrusion temperature, and layer thickness were used. In addition, none of the articles reasoned their choices of settings. % infill is the density of the interior structure of the printed part [19], which was mentioned to be affecting the durability and rigidity of the printed parts; however, it is randomly chosen among studies. Additionally, studies showed that printing orientation does affect the mechanical properties of printed objects. It was found that printing along the Z orientation, normal to the printer bed, has the lowest resistance against mechanical forces compared to printing along other orientations [82]. Besides, the study showed that there is a strong correlation between the stiffness and the printing geometry, such as the layer-height and printing orientation of the printed objects. There is a lack of information to which of the printing parameters are significantly affecting the effectiveness of 3D printed upper limb sockets. Conducting more studies on those parameters is need for releasing a guideline for 3D printing more durable and reliable sockets.

3D Printing materials

There are not many variations of 3D printing materials for upper limb sockets. Throughout the literature search, it was found that one of the requirements for making a good 3D printed socket is making it from a user-friendly material in terms of smoothness, sanitary, and safety to the skin. Throughout the included literature, PLA and ABS were the most common materials. However, PLA was favored more than ABS because it shows homogenous thermoplastic properties unlike ABS [28]. In addition, Nylon was mentioned to be the most appealed material [2], [23], [28] because of the smoothness and strength of the printed socket. It was mentioned that sockets made from nylon-resin are reliable and predictable regarding stiffness and other properties [14]. Moreover, it was mentioned that using Nylon 618 and Nylon 680 with an infill of 40% can result in printed parts with the same strength as injection-molded parts [28]. Górski *et al.* fabricated a socket from Nylon and compared it to other sockets fabricated from ABS and polycarbonate [2]. The Nylon socket was believed to have the smoothest surface, less tendency towards fracture and deformation than the other used materials; however, this result was only observational. On the other hand, it was mentioned that nylon has a tendency to unstick to the printer bed, so it is a bit demanding in the manufacturing process [2].

Some studies introduced new materials, called "smart materials" that can change shape, size, or properties over time and based on environmental changes such as temperature, humidity, and pressure. Such materials were mentioned to have folding and de-folding capabilities based on the desired requirements. shape memory polymers are some of them, which have the potential to deform and uniform based on temperature [17], [83]. Adopting this technology to sockets can have promising results by changing the socket volume in some conditions to achieve better fitting.

Beside smart materials, PLACTIVE^{TM}, which is PLA with the addition of 1% copper nanoparticles, was introduced and tested by Zuniga et al. as an antibacterial material since copper has antimicrobial properties [22], [28], [75]. That material was tested against bacteria that are causing the most common home and hospital-acquired infections. The test results of these studies showed that the antibacterial material maintained the thermoforming properties of PLA. However, more tests are needed for the longevity of the antibacterial properties, and testing with a high number of subjects is needed for validation. Since there is not a single material that can gather all the needed requirements for a good socket [52], [90], more testing is needed to select the material that can fulfill the least requirements of a reliable socket.

Assessment

Deciding whether a socket would be reliable and satisfying to the user or not depends on testing its comfort, strength, safety to the skin, and ability to transform load smoothly [52]. Assessment is mostly common to the function of the prosthesis where *box & block* test was the most repeated test beside user satisfaction surveys and questionnaires [22], [75], [86]. However, the literature shows a lack for different types of assessments for the upper limb socket. Lack of assessing the mechanical properties of the socket, and lack of data needed to predict the life cycle of the socket are the most common concerns in literature [22], [27], [28], [84], [85]. It was reported that more tensile testing is needed for assessing the printed parts durability and strength which was also recommended by the FDA [27], [92], [93]. One of the few studies that performed an assessment to the mechanical properties and the comfort of a 3D printed socket is the study of Williams et al [6]. The study measured the range of motion provided by the socket, the maximum force and torque that the socket can withstand before slipping, and the pressure across the socket at different orientations.

Not to mention, there is a lack of assessment to the user experience, and the long term performance of the 3D printed prosthetics. That was easily concluded as most of the studies did not report any follow up assessments with patients. In contrast, catastrophic failures, standardized safety and durability tests of lower limb sockets are documented [14], which have resulted in promising results for 3D printed transtibial sockets. Therefore, structured and standardized tests for the mechanical properties, comfort, and user experience of upper limb sockets are needed similar to lower limb sockets.

Recommendations & future work

Based on the results of the literature search, 3D printed sockets show promising results in terms of achieving less manual work, high customization, rapid adjustments. For future work, it is recommended to always involve a certified prosthesis in the design process of a socket to avoid skin and tissue damage. In addition, it is recommended to involve the patient feedback in the design process to result in a personalized comfortable socket and reduce the chance of socket and prosthesis abandonment. Moreover, the following list summarizes the gap points found in the literature regarding 3D printing upper limb socket:

- Adopting a structured scanning process for fitting 3D printed sockets using digital tooling is needed to avoid random fitting errors, and to systematically manage to know the source of those errors.
- Performing quantitative testing of the comfort and fitting of sockets is needed.
- Performing an assessment of the strength, durability, and life cycle of the printed sockets by testing their mechanical properties quantitatively is needed.
- Comparing socket fitting of standard casting approach, 3D scanning, and remote fitting is needed.
- Comparing the accuracy of socket fitting using stationary 3D scanners vs. hand-held scanners was not studied yet.
- Investigating the effect of printing parameters on the strength, reliability, and effectiveness of the printed socket is highly needed.
- Testing the function and comfort of sockets 3D printed from smart materials like shape memory polymers could be promising.
- Standardizing safety and durability tests for upper limb socket is needed similar to lower limb sockets.
- Documentation of the most promising materials for 3D printing sockets is needed.

Conclusion

Three-dimensional printing has shown its promising results for the fabrication of lower limb sockets, and terminal devices. However, 3D printed upper limb sockets are overlooked. In this literature review, an overview of the status of 3D printed upper limb sockets was provided since 2010 with the gap points. In total, 40 articles were included and examined for the fitting methods, printing techniques and settings, printing materials, and types of assessment of the 3D printed socket. It was found that most of the printed sockets are for transradial amputees, and are made from PLA or ABS. The printed sockets show promising results in terms of achieving less manual work, rapid adjustments, and high customization. On the other hand, durability issues, lack of assessment of mechanical properties, lack of information to the printing settings that can result in a reliable socket, and lack of systematic fabrication process for achieving a well-fitted socket are all points of concern for future work. In addition, it was not clear in literature if 3D scanning would result in better fitting than the conventional fitting method. Finally, a certified prosthesis, and patient's feedback are recommended to be involved in the design process for any future work.

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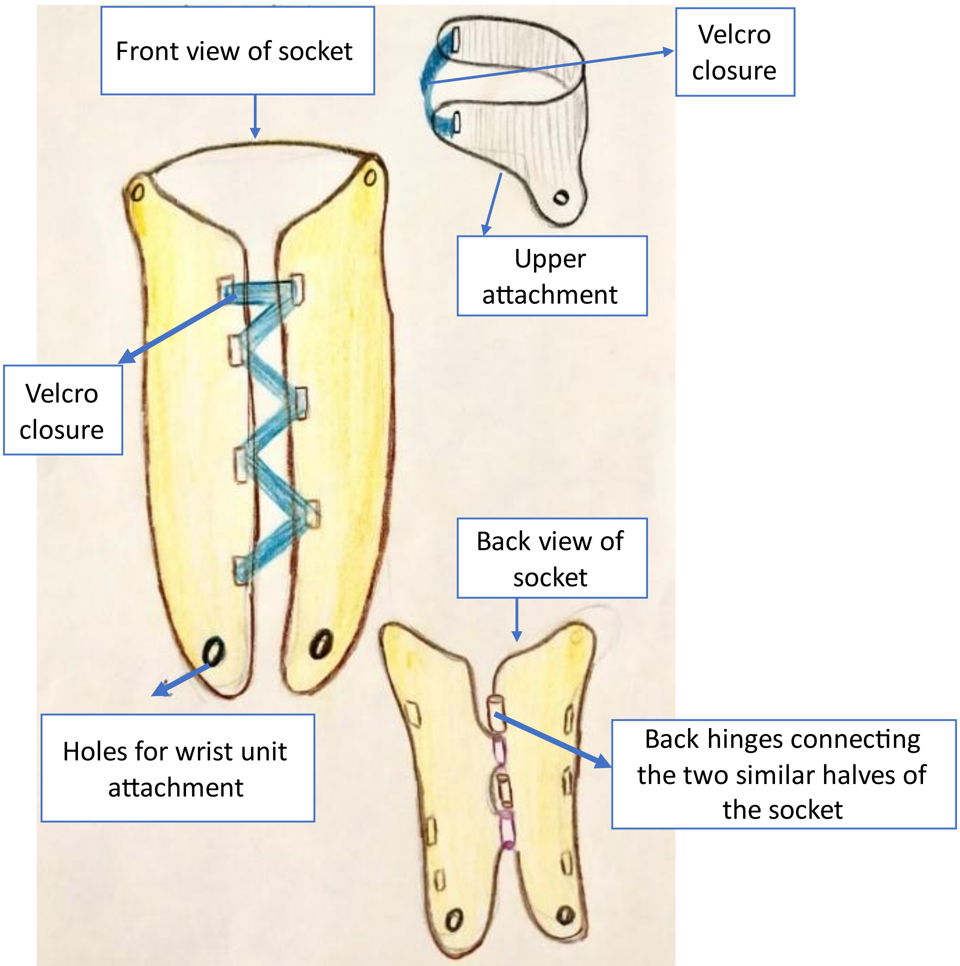
APPENDIX B: CONCEPT DESIGNS

The shoes & lace socket concept:

This concept has two main parts; an upper attachment to be used above the elbow, and a lower socket to be used below the elbow. Both parts would be connected used a hinge joint at the elbow. The lower socket consists of two identical halves that get connected using hinge joints in the back. The lower socket offers volume adjustability because of the rotation given by the hinge joints around the longitudinal axis of the socket. The closure of the lower socket and the upper attachment are Velcro straps that get connected to the lower socket through open slots. The upper attachment offers self-suspension through enveloping some of the elbow prominences, mainly the olecranon, enveloping the soft tissues above the elbow.

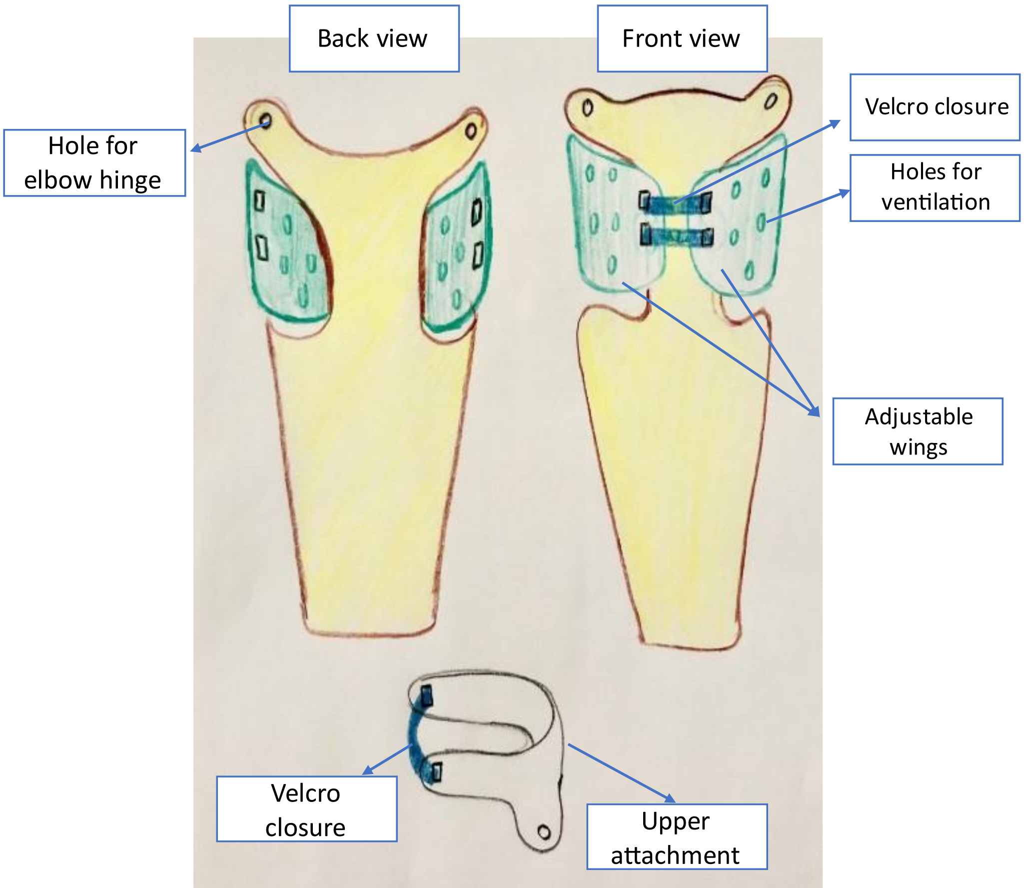


Concept features

- ✓ Volume adjustability is always offered and easily performed with one hand.
- ✓ Offers full elbow extension.
- ✓ Offers self-suspension through the upper attachment based on the ACCI methodology.
- X Design is suitable for only one type of wrist units.
- X Tightening and loosening the socket would interfere with the wrist unit.
- X Design has many components to attach, which reduces reliability.

The Velcro-wingy socket concept:

This concept consists of two main parts; the main shell colored in yellow, and the adjustable wings which offers the volume adjustability around the residual limb. The rotation of the adjustable wings about the residual limb is expected to be offered by the design itself as the adjustable wings are only connected to the main shell from the back, but they are loose from the front and the sides. Their length depends on the length of the residual limb. The adjustable wings have holes for ventilation. They have Velcro closure to allow tightening and loosening around the residual limb. The other part of the socket is the upper attachment which has a Velcro closure as well, and it connects to the main shell through a hinge joint at the elbow similar to the previous concept, aiming to allow full flexion and extension. In this concept, the end where the wrist unit or the artificial hand is attached can be customized to be oval or circular based on the desired type of wrist units of the user. Since this concept provides the basic design requirements of the socket, it was chosen to be a reference design in the Pugh matrix for evaluating the other concepts.

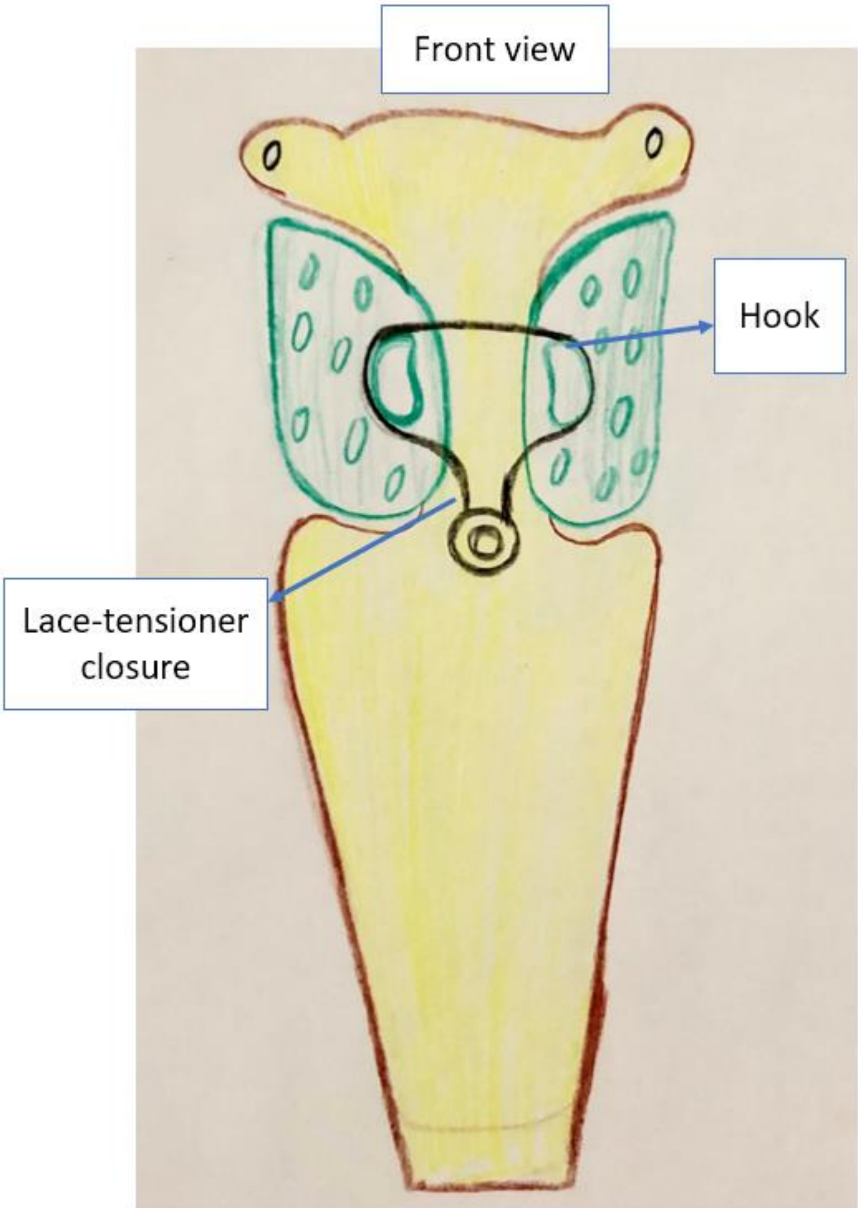


Concept features:

- ✓ Volume-adjustability is always offered through the adjustable wings.
- ✓ Has openings for ventilation.
- ✓ Concept offers full elbow extension.
- ✓ Offers self-suspension through the upper attachment based on the ACCI methodology.
- ✓ Socket end can be circular or oval for connecting different types of wrist units.

The lace-wingy socket concept:

This concept is an extension of Concept B. It has the same components except that the closure of the adjustable wings is a lace-tension closure instead of a Velcro closure. The lace-tensioner closure offers volume adjustability by allowing the adjustable wings to be tightened and loosened. The upper attachment still have the same Velcro closure as the Velcro-wingy socket.

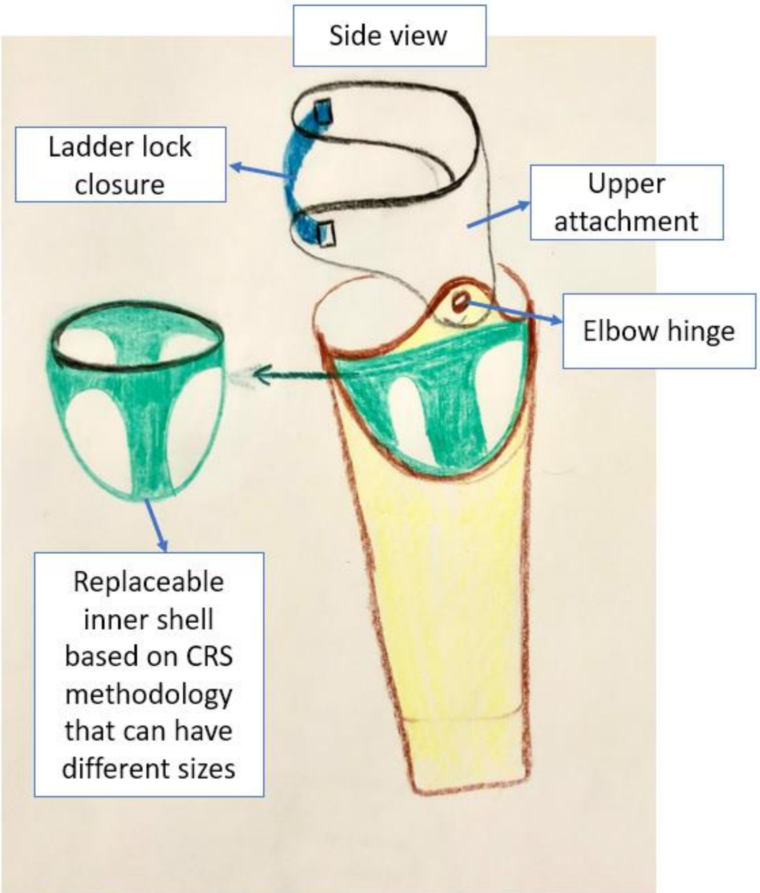


Concept features:

- ✓ Volume-adjustability is always offered and easily performed with one hand.
- ✓ Has openings for ventilation.
- ✓ Provides full elbow extension.
- ✓ Has reliable closure.
- ✓ Offers self-suspension through the upper attachment.
- ✓ Socket end can be circular or oval for connecting different types of wrist units.

The CRS (Compression Release-stabilization) based socket:

This concept consists of three parts; the upper attachment, the replaceable inner shell, and the main shell of the socket (colored in yellow). The upper attachment offers self-suspension similar to all the previous concepts except that it does not have Velcro closure but ladder lock closure. The replaceable inner shell offers suspension based on the CRS suspension methodology where some soft tissues of the residual limb are compressed, and some are released through the openings of the shell. Those openings offer the volume adjustability. The surface of the main shell is all closed except at the openings of the inner shell. The upper attachment and main shell are connected through elbow hinge to offer the needed range of flexion and extension.

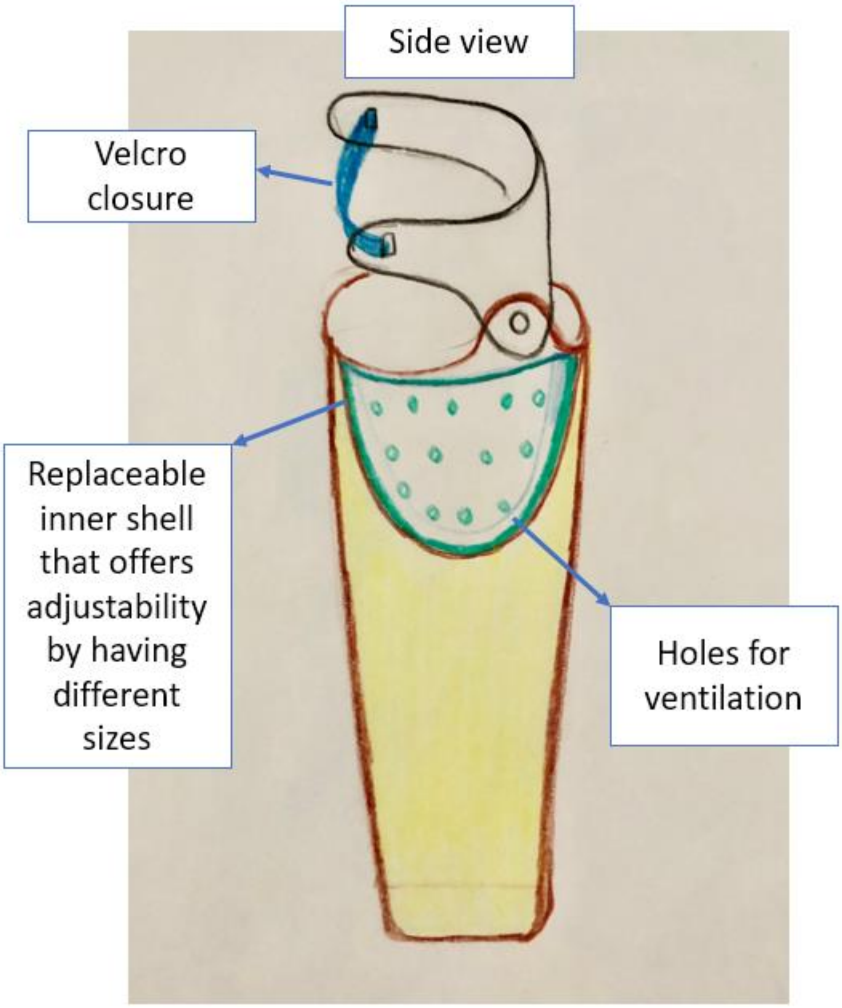


Concept features:

- ✓ There is no need for socket closure below the elbow.
- ✓ Offers full elbow extension.
- ✓ Secured suspension with the residual limb (CRS).
- ✓ Socket end can be circular or oval for connecting different types of wrist units.
- X Volume-adjustability not offered unless the inner shell is replaced.
- X Ladder lock closure could be hard to adjust with one hand.

The replaceable-shell socket concept:

This concept is similar to the previous concept except that the upper attachment does not have a ladder lock closure but a Velcro closure. Also, the replaceable inner shell does not offer suspension to the socket through the CRS methodology. The adjustability in this socket is offered through replacing the inner shell with modular shells that have dimensional changes based on the change in the volume of the residual limb. The inner shell has holes for ventilation.



Concept features:

- ✓ There is no need for socket closure below the elbow.
- ✓ Offers full elbow extension.
- ✓ Offers openings for ventilation.
- ✓ Socket end can be circular or oval for connecting different types of wrist units.
- X Volume-adjustability is not offered unless the inner shell is replaced.

Concept selection:

For concept selection, the Pugh method was used where the Velcro-wingy concept was chosen as the reference concept since it provides the basic design requirements of the socket. Each of the other concepts is evaluated in comparison to the reference concept based on the selection criteria shown in the table below. In the selection criteria, the basic functions of the morphological chart were included in the selection criteria. Easiness of cleaning and design reliability were included since they are part of the design requirements. Design reliability in this evaluation is defined as the number of parts needed for assembling the socket. The more the parts in the socket, the more maintenance would be needed from the user to keep it in a good state. Therefore, more parts were not desired.

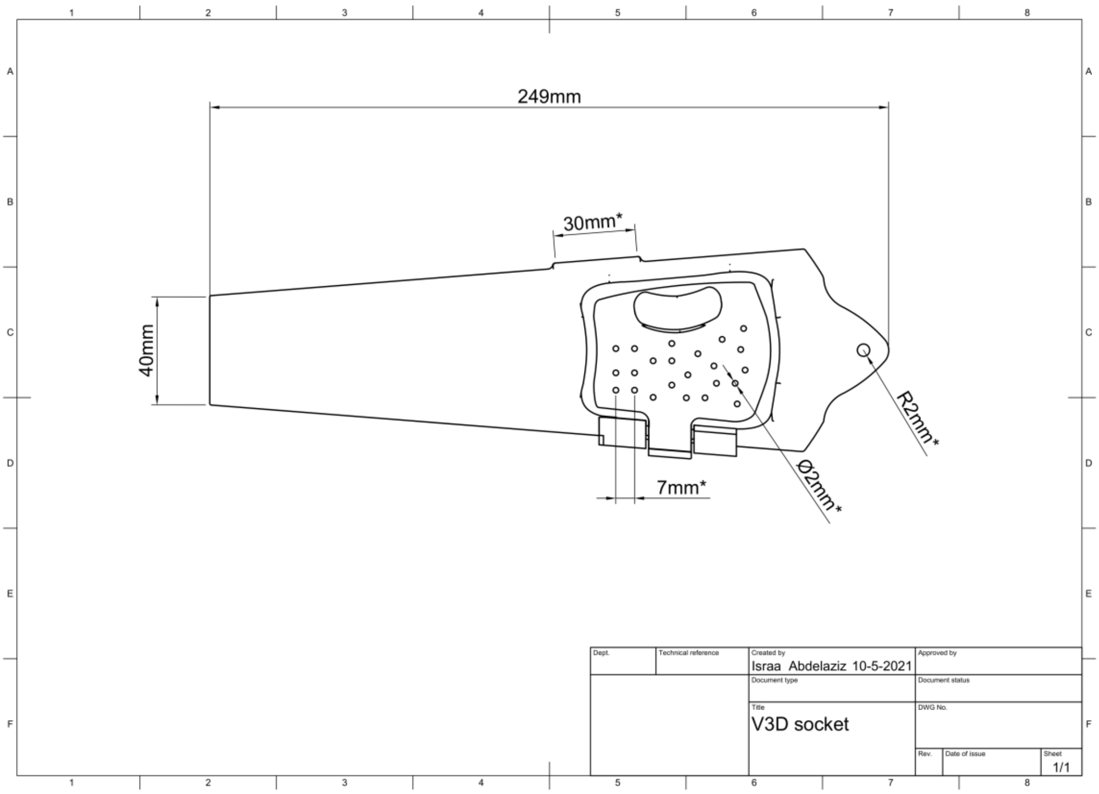
Since the Velcro-wingy concept was the reference concept, it was given zeros for all the criteria since it fulfills the basic requirements. The other concepts are judged based on the selection criteria and evaluated in comparison to the reference concept. From the 5 concepts, concept the lace-wingy socket concept had the highest rank, and concepts the shoes & lace socket concept and the Velcro-wingy socket concept had the same rank. However, the shoes & lace socket concept failed to fulfill the selection criteria, adaptability to wrist units, design reliability, and ventilation. Therefore, it was excluded. The Velcro-wingy socket concept and the lace-wingy socket concept were decided to be combined and further developed.

Selection criteria	**Concepts**				
	The shoes & lace socket	The Velcro-wingy socket (Reference concept)	The lace-wingy socket	The CRS-based socket	The replaceable inner shell socket
Volume-adjustability	**+**	**0**	**+**	**-**	**-**
Elbow Range of Motion (ROM)	**+**	**0**	**+**	**0**	**0**
Design reliability	**-**	**0**	**0**	**-**	**0**
Ventilation	**-**	**0**	**0**	**0**	**0**
Easiness of cleaning	**+**	**0**	**0**	**-**	**-**
Adaptability to different wrist units	**-**	**0**	**+**	**0**	**0**
Self-suspension	**0**	**0**	**0**	**+**	**0**
Sum +'s	**3**	**0**	**3**	**1**	**0**
Sum -'s	**3**	**0**	**0**	**3**	**2**
Sum 0's	**1**	**0**	**4**	**3**	**5**
Net score	**0**	**0**	**3**	**-2**	**-2**
Rank	**2**	**2**	**1**	**3**	**3**
Continue with concept?	**No**	**Yes**	**Yes**	**No**	**No**

APPENDIX D: CAD DRAWINGS

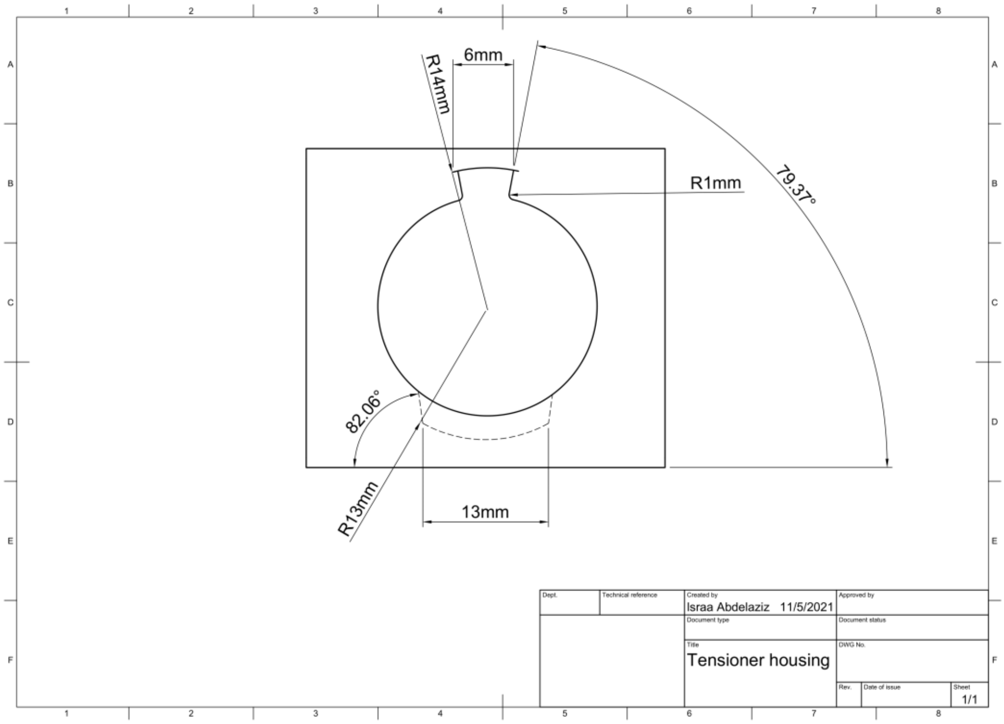
Socket assembly:

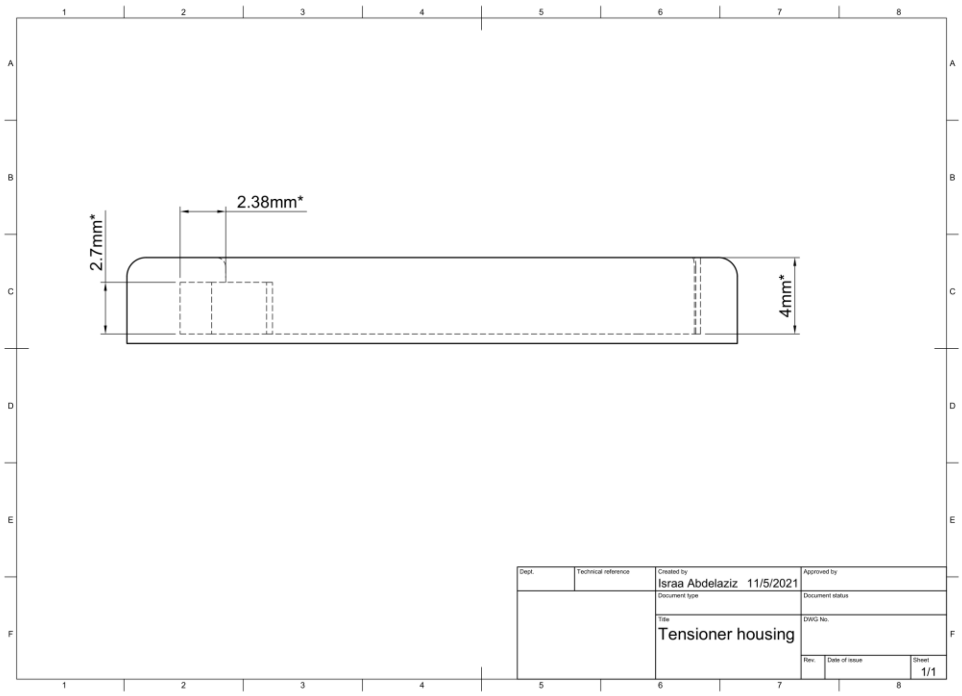
The drawings in this appendix are shown for the sake of having a general sense of the size of the printed socket. Since the size of the socket is subjective to the user, some of the dimensions of the socket change from user to another. All the dimensions that are stared in the following drawing do not change with changing the socket size such as the socket thickness (Always 3mm), the ventilation holes diameter (Always 20mm). Other dimensions change such as the opening for the wrist unit as it changes from a unit to another, and the length of the socket.



<u>Sample of the MAVIC lace-tensioner housing:</u>

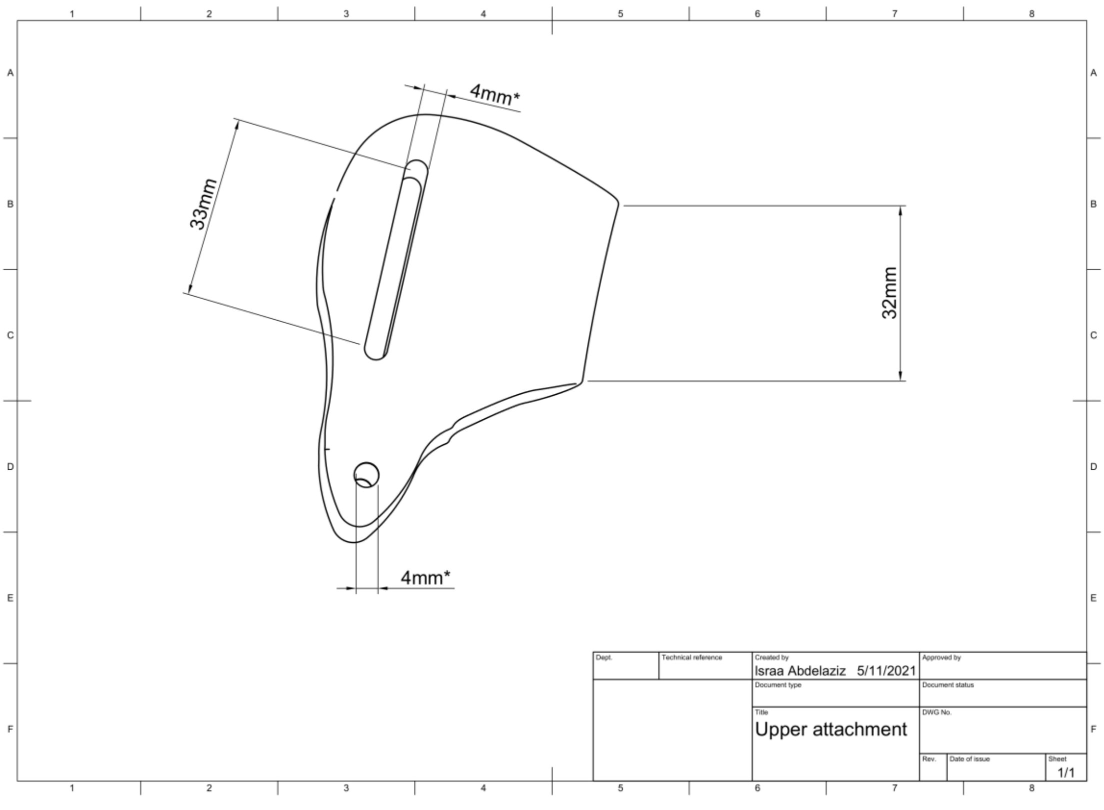
The dimensions of the housing of the lace-tensioner mechanism do not change from a socket to another as it purely depends on the used lace-tensioner. The following two drawings are for a sample of the tensioner housing (front and right views, respectively).





Upper attachment:

The dimensions of the upper attachment change from a user to another except the holes for the elbow hinge, and the width of the slots where the Velcro closure is added to avoid weaking the part.



APPENDIX E: PROTOTYPING

Printing settings used for all the socket parts: Extruder 1 (Tough PLA)

According to Yao et. Al., "tensile strength of materials decreases as layer thickness increases from 0.1mm to 0.3mm" [67]. Therefore, to have a moderate layer thickness that balances printing time and strength, a layer thickness of 0.15mm was chosen. Besides layer thickness, infill density is another critical printing parameter that refers to the density of material inside the print [94]. Infill density was mentioned in the literature to be affecting the strength of the printed part as well. When 3D printing a part, it can be printed with 100% infill density; however, this is only needed for high weight-bearing structures. Since the designed socket has a 3mm thickness and is designed for a maximum weight of 5kg (~50N), it was not needed to use 100%. Infill density of 60% was decided in the middle of the socket with a top and bottom thickness of 1mm. Since the Ultimaker S5 used for printing the socket has dual extruders, PVA (Polyvinyl Alcohol) which is a dissolvable filament was used as the support material of the socket structure during printing. Based on the mentioned printing settings, the socket was 3D printed. See the printing settings below:

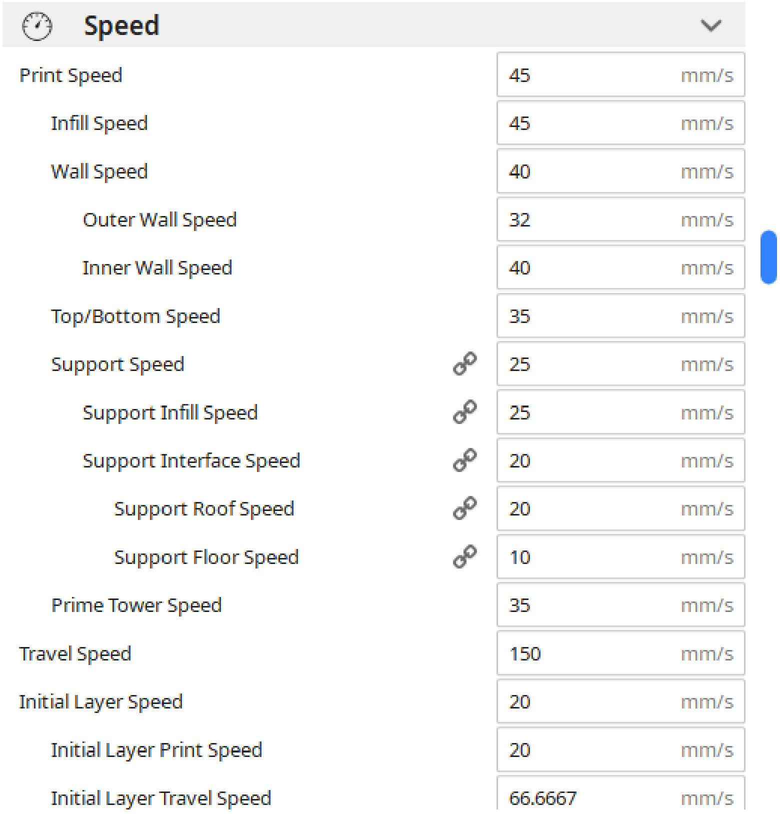
Quality		
Layer Height	0.15	mm
Initial Layer Height	0.2	mm
Line Width	0.35	mm
Wall Line Width	0.35	mm
Outer Wall Line Width	0.35	mm
Inner Wall(s) Line Width	0.35	mm
Top/Bottom Line Width	0.35	mm
Infill Line Width	0.45	mm
Skirt/Brim Line Width	0.35	mm
Support Line Width	0.4	mm
Support Interface Line Width	0.35	mm
Support Roof Line Width	0.35	mm
Support Floor Line Width	0.35	mm
Prime Tower Line Width	0.35	mm
Initial Layer Line Width	120	%

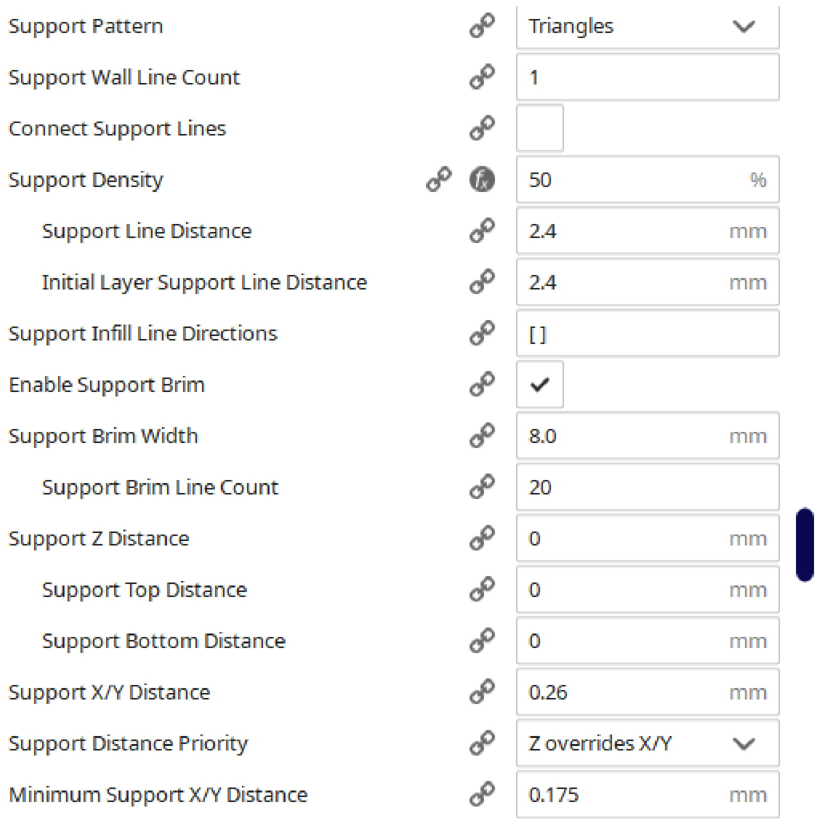
Infill

Infill Extruder	Not overridden
Infill Density	60 %
Infill Line Distance	2.25 mm
Infill Pattern	Triangles
Connect Infill Lines	✓
Infill Line Directions	[]
Infill X Offset	0 mm
Infill Y Offset	0 mm
Randomize Infill Start	
Infill Line Multiplier	1
Extra Infill Wall Count	0
Infill Overlap Percentage	0 %
Infill Overlap	0.0 mm
Infill Wipe Distance	0 mm
Infill Layer Thickness	0.15 mm

Material

Build Volume Temperature	24 °C
Printing Temperature	215 °C
Printing Temperature Initial Layer	215 °C
Initial Printing Temperature	205 °C
Final Printing Temperature	200 °C
Extrusion Cool Down Speed Modifier	0.7 °C/s
Build Plate Temperature	60 °C
Build Plate Temperature Initial Layer	60 °C
Flow	100 %
Wall Flow	100 %
Outer Wall Flow	100 %
Inner Wall(s) Flow	100 %
Top/Bottom Flow	100 %
Infill Flow	100 %
Skirt/Brim Flow	100 %


Speed
Print Speed 45 mm/s
Infill Speed 45 mm/s
Wall Speed 40 mm/s
Outer Wall Speed 32 mm/s
Inner Wall Speed 40 mm/s
Top/Bottom Speed 35 mm/s
Support Speed 25 mm/s
Support Infill Speed 25 mm/s
Support Interface Speed 20 mm/s
Support Roof Speed 20 mm/s
Support Floor Speed 10 mm/s
Prime Tower Speed 35 mm/s
Travel Speed 150 mm/s
Initial Layer Speed 20 mm/s
Initial Layer Print Speed 20 mm/s
Initial Layer Travel Speed 66.6667 mm/s


Support Pattern Triangles
Support Wall Line Count 1
Connect Support Lines
Support Density 50 %
Support Line Distance 2.4 mm
Initial Layer Support Line Distance 2.4 mm
Support Infill Line Directions [ ]
Enable Support Brim
Support Brim Width 8.0 mm
Support Brim Line Count 20
Support Z Distance 0 mm
Support Top Distance 0 mm
Support Bottom Distance 0 mm
Support X/Y Distance 0.26 mm
Support Distance Priority Z overrides X/Y
Minimum Support X/Y Distance 0.175 mm

Dual Extrusion

Enable Prime Tower	✓
Prime Tower Size	20 mm
Prime Tower Minimum Volume	6 mm^3
Prime Tower X Position	299.56 mm
Prime Tower Y Position	211.56 mm
Wipe Inactive Nozzle on Prime Tower	✓
Prime Tower Brim	
Enable Ooze Shield	
Nozzle Switch Retraction Distance	16 mm
Nozzle Switch Retraction Speed	20 mm/s
Nozzle Switch Retract Speed	20 mm/s
Nozzle Switch Prime Speed	20 mm/s
Nozzle Switch Extra Prime Amount	0 mm^3

Printing settings used for the support material: Extruder 2 (PVA)

Infill

Infill Extruder	Extruder 2
Infill Density	20 %
Infill Line Distance	7.5 mm
Infill Pattern	Triangles
Connect Infill Lines	✓
Infill Line Directions	[ ]
Infill X Offset	0 mm
Infill Y Offset	0 mm
Randomize Infill Start	
Infill Line Multiplier	1
Extra Infill Wall Count	0
Infill Overlap Percentage	0 %
Infill Overlap	0.0 mm
Infill Wipe Distance	0 mm
Infill Layer Thickness	0.15 mm

Material

Build Volume Temperature	24	°C
Printing Temperature	220	°C
Printing Temperature Initial Layer	220	°C
Initial Printing Temperature	210	°C
Final Printing Temperature	205	°C
Extrusion Cool Down Speed Modifier	0.7	°C/s
Build Plate Temperature	60	°C
Build Plate Temperature Initial Layer	60	°C
Flow	100	%
Wall Flow	100	%
Outer Wall Flow	100	%
Inner Wall(s) Flow	100	%
Top/Bottom Flow	100	%
Infill Flow	100	%
Skirt/Brim Flow	100	%

Speed

Print Speed	35	mm/s
Infill Speed	35	mm/s
Wall Speed	30	mm/s
Outer Wall Speed	25	mm/s
Inner Wall Speed	30	mm/s
Top/Bottom Speed	20	mm/s
Support Speed	25	mm/s
Support Infill Speed	25	mm/s
Support Interface Speed	20	mm/s
Support Roof Speed	20	mm/s
Support Floor Speed	10	mm/s
Prime Tower Speed	10	mm/s
Travel Speed	150	mm/s
Initial Layer Speed	20	mm/s

Build Plate Adhesion

Enable Prime Blob	☐
Build Plate Adhesion Type	Brim
Build Plate Adhesion Extruder	Extruder 2
Skirt/Brim Minimum Length	250 mm
Brim Width	3 mm
Brim Line Count	8
Brim Distance	0 mm
Brim Replaces Support	☐
Brim Only on Outside	✓

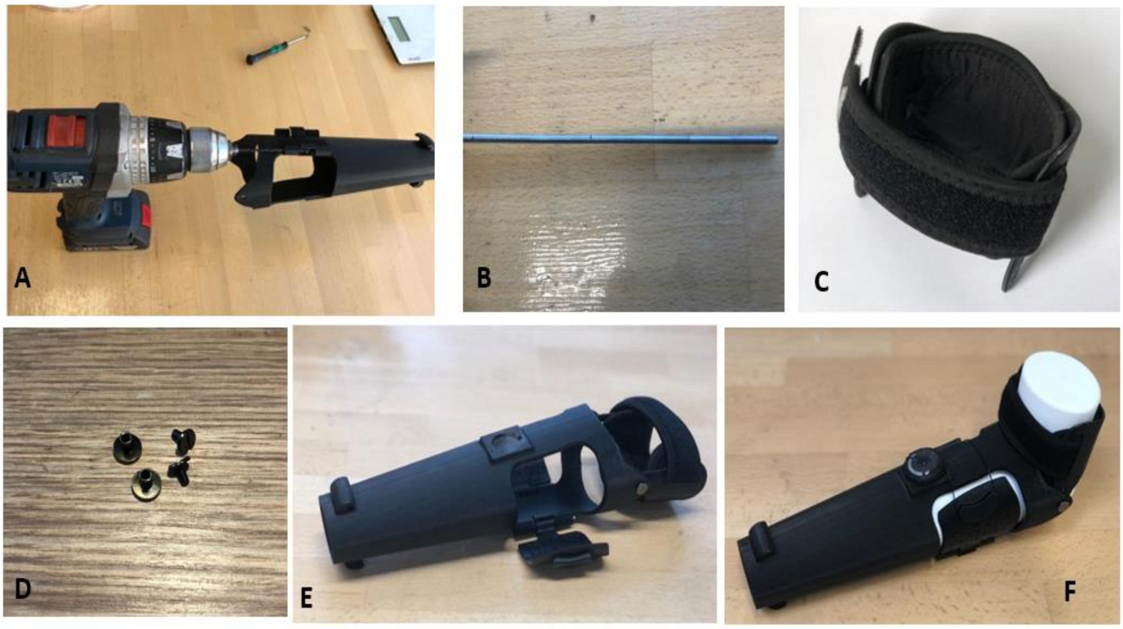
Dual Extrusion

Enable Prime Tower	✓
Prime Tower Size	20 mm
Prime Tower Minimum Volume	6 mm^3
Prime Tower X Position	299.56 mm
Prime Tower Y Position	211.56 mm
Wipe Inactive Nozzle on Prime Tower	✓

Socket Assembly

After 3D printing the main shell, adjustable wings, and the upper attachment, the parts were left for a day in a tank full of water where the support material, PVA, had dissolved. To assemble the socket, the parts shown in the figure below were used, and the following steps were implemented:

1- The holes of the hinge joints of the main shell were drilled with a 3mm drill to remove extra materials to pass a 3mm rod. In this step, a threaded rod was preferred more than a flat surface rod as a threaded one achieved secured connection to the hinge joints.
2- The elbow joints were used to connect the upper attachment to the main shell.
3- Finally, the MAVIC tensioner was snapped into the tensioner housing after a little bit of sanding.

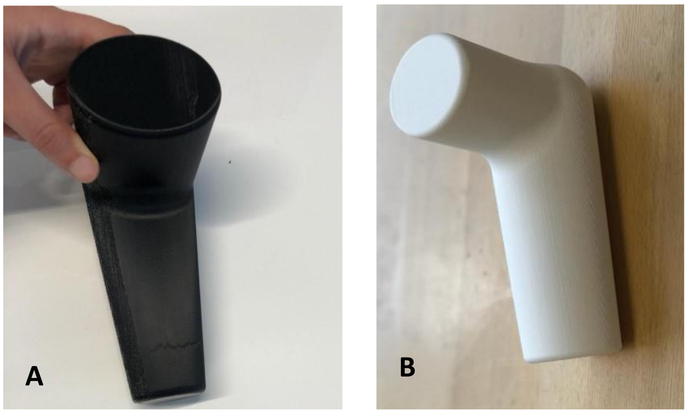


Assembly of the socket. (A) Drilling the hinge joints of the socket main shell. (B) the threaded metal rod used for connecting the adjustable wings to the main shell through the hinge joints. (C) the upper attachment with the foam arm strap that has a Velcro closure. (D) flat-head screws for connecting the upper attachment to the main shell at the elbow location. €. Assembled socket before adding the tensioner. (F) Prototype of the socket after finishing assembly where a residual limb is fitted to the socket (shown in white).

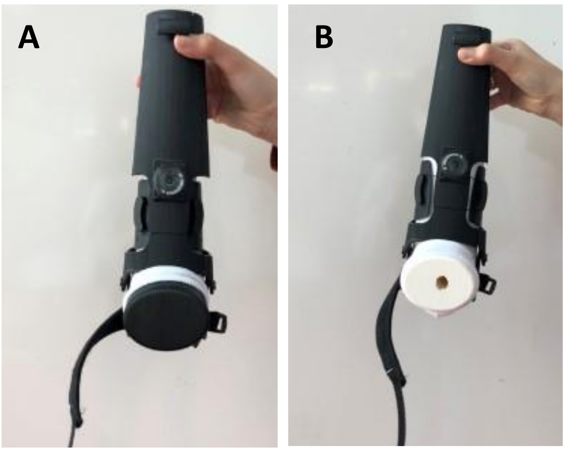
APPENDIX F: EXTRA TEST

Evaluating the security of connection of the socket:

One of the assumptions that the socket was designed based on, was that it targets people with conical or cylindrical residual limbs, which are the most common. To evaluate the ability of the volume-adjustable closure system of the socket to securely fit the cylindrical and conical residual limb as it was aimed, a short experiment was performed. First, two models of stump's were designed, and 3D printed: a cylindrical stump and a conical stump. Then, each stump was fit in a cotton sock to avoid slipping since the socket and the stumps have slippery plastic surfaces. After that, each stump was fit to the socket such that the adjustable wings are the only part suspending the stumps to the socket, without the upper attachments. Then, the socket was tightened around the stump and held upside down. After that, a shaking force was applied at the tip of the socket to see if the stumps will stay in place or not, see the recorded video, and the figures below.



3D printed stumps (residual limbs). (A) Conical stump (B) Cylindrical stump. The socket should be able to achieve the purposes of volume-adjustability to both types of stumps and achieve secured connection to them.

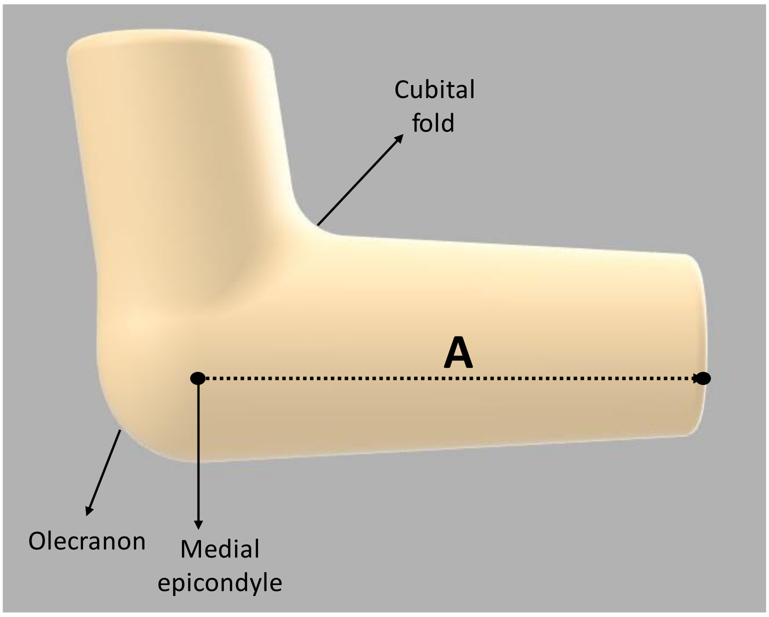


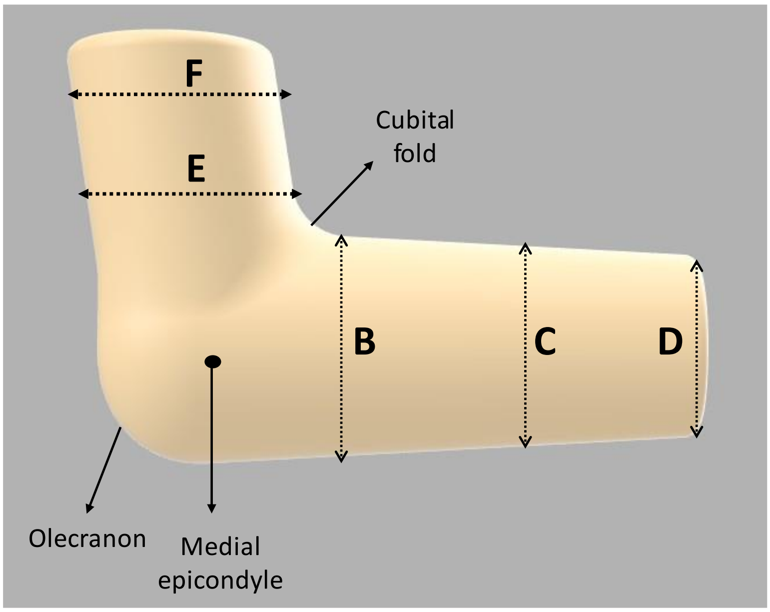
3D printed stumps fitted with the socket for testing. (A) Conical stump fitted (B) Cylindrical stump fitted. To evaluate the capability of the volume-adjustable closure of the socket to hold both stumps in place, a test where each stump type was fitted to the socket while holding it upside down and applying a shaking force at the socket tip was performed. Both sockets stayed in place, and the socket succeeded to achieve full contact with their surfaces.

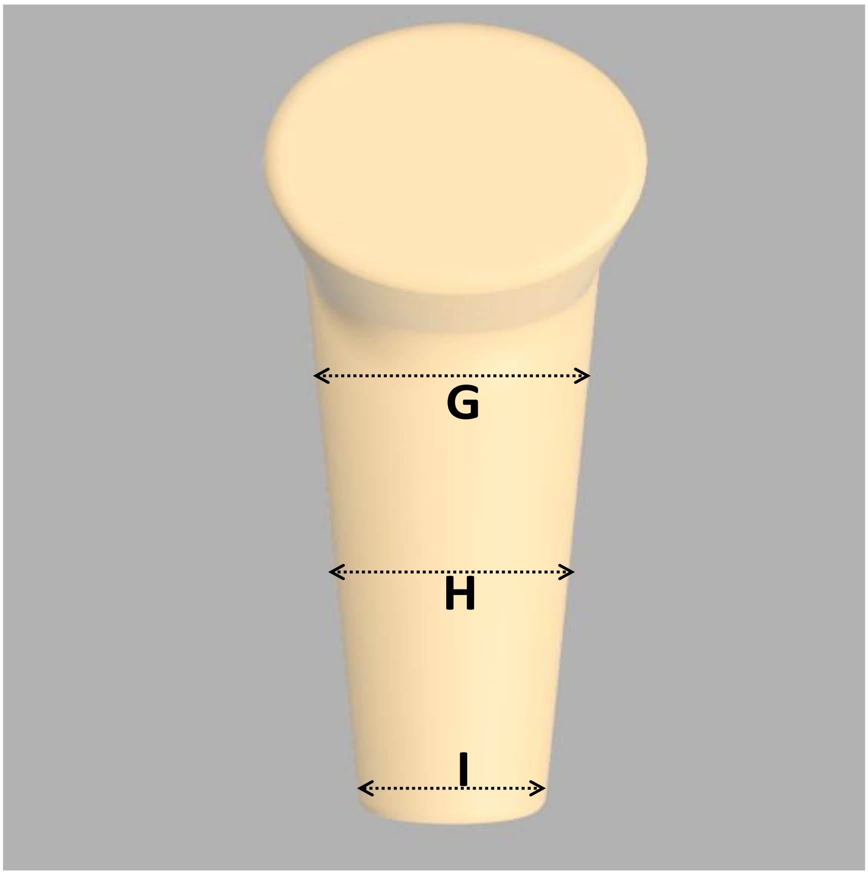
Based on this short experiment, the socket has succeeded to achieve full contact with the most common geometries of residual limbs, the conical and the cylindrical ones, without falling. That means that the socket can achieve a secured connection with the residual limb which is needed for achieving smooth load transfer and for adapting to volume fluctuations of the residual limb.

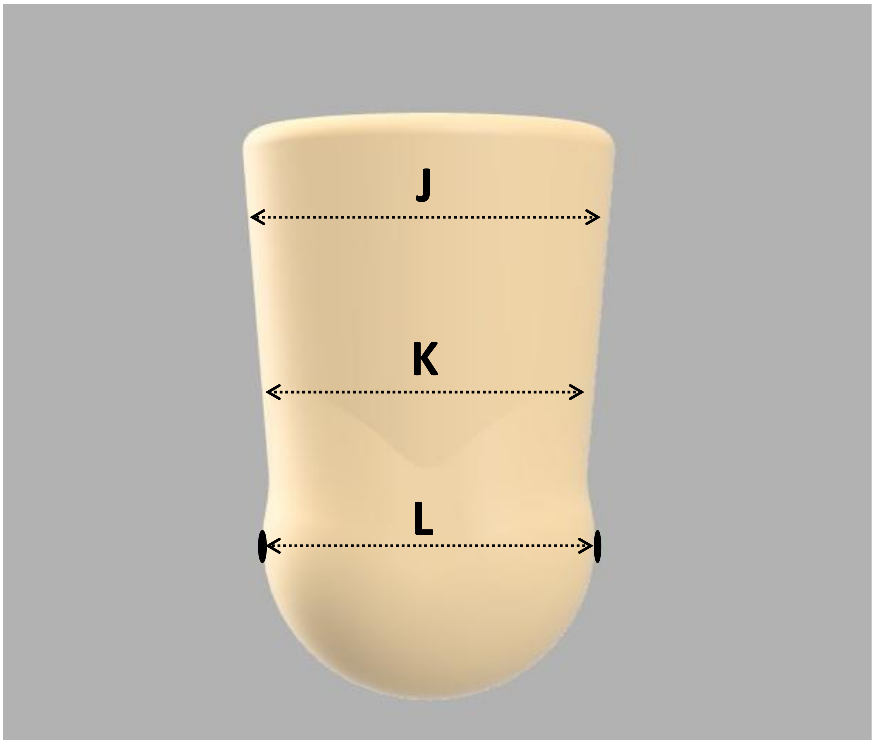
APPENDIX G: FITTING GUIDELINE

Taking the fitting parameters of the user's residual limb is the first step to do before customizing the socket model. The fitting parameters are needed in two positions of the affected arm: one with 90 degrees flexion of the arm, and another one with 90 degrees flexion plus pronation of the residual limb. Since the degree of pronation and supination are affected by the length of the residual limb, the targeted pronation degree for short residual limb is 60 degrees which is the maximum possible pronation range, and 90 degrees for medium residual limbs. Since pronation is almost zero for very short residual limbs, measurements would not be taken in that position, but only 90-degree flexion. The parameters to be taken in both positions are labeled from A to L in the following table and figures:






G
H
I


J
K
L

A	The length of the residual limb from the medial epicondyle till the tip of the residual limb
B	The first diameter of the proximal ellipse of the residual limb
C	The first diameter of the middle ellipse of the residual limb
D	The first diameter of the distal ellipse of the residual limb
E	The first diameter of arm above the olecranon
F	The first diameter of the arm below the biceps.
G	The second diameter of the proximal ellipse of the residual limb
H	The second diameter of the middle ellipse of the residual limb
I	The second diameter of the distal ellipse of the residual limb
J	The second diameter of the arm below the biceps
K	The second diameter of the arm above the biceps
L	The distance between the lateral and medial epicondyles

APPENDIX H: HUMAN TESTING

Ethics approval to the human evaluation:

Date 12-04-2021
Contact person Ir. J.B.J. Groot Kormelink, secretary HREC
Telephone +31 152783260
E-mail j.b.j.grootkormelink@tudelft.nl

Human Research Ethics Committee
TU Delft
(http://hrec.tudelft.nl/)

Visiting address
Jaffalaan 5 (building 31)
2628 BX Delft

Postal address
P.O. Box 5015 2600 GA Delft
The Netherlands

Ethics Approval Application: 3D printed transradial prosthetic socket
Applicant: Israa Mohamed Kamal Abdelaziz, Israa

Dear Israa Israa Mohamed Kamal Abdelaziz,

It is a pleasure to inform you that your application mentioned above has been approved.

Thanks very much for your submission to the HREC which has been approved.

We do additionally note/advise the following:

1) Please ensure that any covid risks are clear in the Informed Consent - and we would advise checking the overall IC form for clarity

Best wishes,

Good luck with your research!

Sincerely,

Dr. Ir. U. Pesch
Chair HREC
Faculty of Technology, Policy and Management

The informed consent handed for each participant:

Informed consent

Purpose of the research: The purpose of this research is to test the comfort of the designed prosthetic socket while performing some pre-determined daily life activities.

Benefits and risks of participating: There are no materialistic benefits of participation. However, participation will help to improve the socket design to achieve better comfort for people with upper limb absence who wear prostheses. The participant may experience mild discomfort from the socket. Once the user feels so, the participant is free to take off the socket. Because of COVID, the participants shall not take part of the experiment if they experience some health complains, and they are asked to wash their hand before wearing the socket. Instructions on how to wear the socket will be given to the participant, so that no physical assistance will be needed from the researcher to keep distance.

Procedures for withdrawal from the study: You can withdraw from the study any time without having to give a reason. However, when you decide so, please inform the researcher to pick up the experiment device (prosthetic socket).

Collected data:

- No information about the identity of the participant is needed except the age, and forearm parameters.
- Pictures of the user arm while wearing the socket will be collected (if agreed by the participant).
- The user feedback about the socket and possible recommendations for socket optimization will be collected through an interview and (maybe) a questionnaire.
- The collected data will be analysed by the researcher and be presented as part of the research thesis report, which will be published later via TU Delft. It is possible that the collected data will be published later as part of a research paper. The participant can access the collected data via e-mailing the researcher (iabdelaziz @tudelft.nl).

Consent Form for [3D printed transradial prosthetic socket]

Please tick the appropriate boxes	**Yes**	**No**
Taking part in the study		
I have read and understood the study information dated [----/---/---], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	○	○
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	○	○
I understand that taking part in the study involves [an interview (if possible) and a questioner with the participant, and that the collected information will be recorded as written notes.]	○	○
I consent to give permission to the researcher to have a picture of my arm after and before wearing the socket, and that this picture could be published later.	○	○
Risks associated with participating in the study		
I understand that taking part in the study may involve: a temporary physical discomfort to the participant forearm such as having some marks from wearing the socket.	○	○
Use of the information in the study		
I understand that the information I provide will be used for [assessing the design of the provided prosthetic socket for further improvement, and that the collected data will be part of the researcher thesis report. Also, the collected data can be part of research paper that will be published later.]	○	○
I understand that personal information collected about me that can identify me, such as [e.g. my name and my age], will not be shared beyond the study team.	○	○
Future use and reuse of the information by others		
I give permission for the information that I provide to be archived in [*TU Delft repository as part of a thesis report*] so it can be used for future research and learning.	○	○

Signatures

____________________   ____________________   ________

Name of participant [printed]   Signature   Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

______________________   __________________   ________

Researcher name [printed]   Signature   Date

Study contact details for further information: [*Israa Abdelaziz, iabdelaziz@tudelft.nl*]