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Diploma Thesis

Design of an adjustable temporary socket for a transradial prosthesis

in partial fulfilment of the requirements for the degree of Diplom-Ingenieur, submitted to the Vienna University of Technology under supervision from

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Abstract

The loss of a hand can affect the autonomy of a person and impair their daily life, as well as impact the social and mental status. A prosthesis restores a degree of functionality of the lost limb and can help to decrease phantom pain. Not only the prosthetic socket is one of the crucial factors, whether a prosthesis as a whole is rejected or accepted, but also how fast it can be provided. There is a “Golden Period”, the first month after the amputation, where a prosthesis should be supplied. Current long waiting times are highly influenced by the unique fitting procedure which has to be adjusted for each individual amputee.

With a temporary socket, that can be adjusted in its length and diameter, it should be possible to fit different patients with a few quick adaptations and thereby provide them with the opportunity to make their first contact with a prosthesis and so better use the invaluable time of the “Golden Period” before the individual socket can be supplied. In this thesis a design for such a prosthetic socket, called the *BeneFit* socket, is presented. Different parts were constructed, using Autodesk Fusion 360 and a 3D printer, and assembled into a prototype. This prototype is evaluated in a monocentric, non-interventional explorative study with experts and users, which included a questionnaire. The *BeneFit* socket fulfils the requirements, that were set for it, such as being easy to don and doff and lightweight. The socket is able to change its diameter as well as its length and perceived to be quite satisfactory according to the survey. The design of the *BeneFit* socket should still undergo some changes, the most important one being the scaling down of the dimensions.

Zusammenfassung

Der Verlust einer Hand kann die Autonomie einer Person beeinflussen, ihr tägliches Leben stark beeinträchtigen und sich auf den sozialen und mentalen Status auswirken. Eine Prothese stellt einen Teil der Funktionalität der verlorenen Extremität wieder her und kann helfen Phantomschmerzen zu reduzieren. Ob eine Prothese abgelehnt oder angenommen wird hängt nicht nur vom Prothesenschaft ab, sondern auch davon wie schnell sie zur Verfügung gestellt werden kann, idealerweise wäre das innerhalb der „Goldenen Periode“, dem ersten Monat nach einer Amputation. Derzeit verursacht die Anpassung des für jeden Amputierten individuell gefertigten Prothesenschaftes lange Wartezeiten.

Mit einem temporären Prothesenschaft, dessen Länge und Durchmesser verändert werden kann, sollte es möglich sein, verschiedene Patienten durch ein paar schnelle Veränderungen am Prothesenschaft zu versorgen und ihnen somit die Chance zu bieten erste Kontakte mit einer Prothese herzustellen und so besser die außerordentlich wertvolle Zeit der „Goldenen Periode“ zu nützen, bis ein individueller Prothesenschaft bereitgestellt werden kann. In dieser Diplomarbeit wird ein Design für einen solchen Prothesenschaft, der *BeneFit* Schaft genannt wurde, vorgestellt. Verschiedene Teile wurden mit Autodesk Fusion 360 und einem 3D Drucker konstruiert und zu einem Prototypen zusammengesetzt. Dieser wurde in einer monozentrischen, nicht interventionellen, explorativen Studie, die einen Fragebogen inkludierte, mit Experten und Anwendern beurteilt. Der *BeneFit* Schaft erfüllt die Anforderungen, die an ihn gestellt wurden, ist einfach zum An- und Ablegen, leicht und der Schaft kann seinen Durchmesser, wie auch seine Länge verändern. In der Befragung wurde er als ziemlich zufriedenstellend beurteilt. Das Design sollte aber noch verändert werden, zum Beispiel gehören die Dimensionen verkleinert.

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1 Introduction and Background

The human hand is a very complex system, able to perform varyingly dexterous movements, grips and gestures, all of which allow us to use tools, carry out daily routines, and to communicate with others. The loss of it is a traumatic experience that can decrease the autonomy of a person and impair their daily life (1). Thereby, it can also affect the social and mental status of the person (2). The number of people affected by the loss of a limb is high and constantly rising: in 2005 1,6 million people were living with an absent limb in the United States alone, and this is projected to more than double in the year 2050 (3). Approximately one third of the aforementioned total number amputees of indicates those with amputations of the upper limb (4). 92% of these amputations can be categorized as “minor amputations” (amputations of fingers) and the remaining 8% as “major amputation” (amputations below or above the elbow) (4). Apart from functional impairments, amputees often (95%) suffer from amputation-related pain, with the most common pain being phantom pain (79,9%) (5). Phantom pain can subside to a certain degree through the use of a prosthesis (6). Other interesting aspects are the costs. According to a study by Currie and colleagues (7) amputees pay more than half a million dollars in their lifetime for healthcare.

After an amputation, a prosthesis can help to cope with the loss of an upper limb and to regain upper limb function while eliminating pain (6).

Depending on their functionality, upper limb prostheses can be categorized into two classes: passive prostheses (which include cosmetic and task-specific functional prostheses) and active prostheses (which can be body-powered and externally-powered) (1).

While cosmetic prostheses mainly act as aesthetic replacements, functional prostheses are designed for a specific purpose, such as work or sports (1). Body-powered and cable-driven systems are widely in use (8). They profit from being uncomplicated and inexpensive (8). This prosthesis is controlled by the body´s own force. A harness and cable system make it possible to use the movement of joints near the amputation in order to control the mechanical terminal devices (9). One important advantage of body-powered systems is the greater proprioceptive feedback, by giving the body a greater sense of the motion, position and action of the prosthesis, compared to externally powered prostheses (9). This is possible because of the harness, which on the other hand can cause discomfort or be cumbersome to don and doff (9). Of course, it is crucial that the user can produce sufficient force with the controlling body motion and has the required range of motion to operate the prosthesis. The user needs to be able to create forces between two and five times that of the grip force of the terminal device (9). The cable of the harness needs to be pulled around 50 mm in order to operate a hook through its full range of motion (9).

In the beginning of the 20th century, the development of externally powered prostheses began and were ready to be brought to market by the late 1950's (8). As the name suggests, these prostheses use an external power source, such as a battery, to supply the necessary energy for movement (1). A subcategory of externally-powered prostheses is the myoelectric prosthesis, which uses electromyographic (EMG) signals, which are obtained from the muscles of the residual limb, to control the movement of the prosthesis (1). Electrodes, that are placed on the skin, can sense the electromyographic

signals/electric potentials, that are generated by the contraction of the underlying skeletal muscles (10). In the two-channel approach, a classical control approach for a myoelectric prosthesis, the signals of two antagonistic muscle groups available from the stump are used to control the myoelectric hand. The used muscle groups for transradial amputees are normally the wrist flexors and extensors (10). The electrodes, which detect these signals, are typically integrated in the prosthetic socket and need to maintain skin contact (10).

One crucial, yet often overlooked, part of every prosthesis is the socket (11). The socket of a prosthesis plays a vital role whether a prosthesis is accepted or not (12). A poor socket fit can lead to rejection of the whole prosthesis (12). As the socket represents the interface of the prosthesis with the user, it is an important factor as to how well the user is able to control the terminal device for myoelectric prostheses (11). The loss of contact between the electrodes in the socket and the skin, decreases the quality of control. The socket should thereby not limit the remaining range of motion but provide stability while fitting comfortably (12).

Apart from the socket itself being a crucial aspect, whether a prosthesis is rejected or not, it is also important how fast it can be supplied (13). Research from Malone and colleagues (13) suggests that there is a “Golden Period”, which is within the first month after the amputation for fitting upper-limb prostheses. The initial type of the prosthetic device did not play a significant role (13). All of the patients, who were injured at work and were fitted with a prosthesis in this “Golden Period”, returned to work, while only 15 percent of patients that were fitted later than one month accomplished this (13).

Furthermore, patients fitted with a prosthesis outside this period became more reliant on their remaining upper limb and often suffered from painful phantom symptoms (13). 93% of patients, who were fitted with a prosthetic device within the first 30 days after their amputation, used their prosthesis in their pre-amputation job or other activities, while this was only the case for 42 percent of patients, who were fitted with a prosthesis after one month (13). Patients fitted with prosthetic devices outside the “Golden Period” took from six months up to two years to return to work, while the mean time between injury and return to work, for patients fitted with a prosthesis within the first month, was four months (13).

Currently, it can take more than a month for a patient to be fitted with an individually constructed prosthesis (14). This is also due to the fact that the design of each prosthetic socket has to be adjusted and thereby fit an individual amputee.

The goal of this thesis is to improve and accelerate prosthetic fitting experience for below elbow amputees in hope of reaching an ultimate satisfaction on their road to recovery. To do so, a temporary socket, which can change its shape to fit different patients with a few quick adjustments, has been designed and created, which is called the *BeneFit* socket. The socket should be easy to don and doff, easy to adjust, be comfortable and provide a stable base to mount the prosthetic limb.

In the next subchapter a short history of prosthetics, focusing primarily on the prosthetic socket, is presented. In the next different suspension methods for prostheses are briefly discussed and finally the requirements for the *BeneFit* socket are set. In the following chapter different parts of the whole prosthesis

and the *BeneFit* socket are explained, as well as the construction with the available tools. Next the socket is assembled and supplied with a myoelectric terminal device and the means to control it. Then the *BeneFit* socket is also tested in a survey by users and experts. The results of the survey as well as the limitations of the design are presented. Afterwards these results as well as possible improvements are discussed.

1.1 History of prosthetics

Before the 20th century most remarks in literature on upper limb prostheses are found in reference to warfare (8). One famous example of an early prosthetic limb is the prosthesis of the mercenary Götz von Berlichingen (see figure 1) in the 16th century (15).This prosthesis enabled him to continue wielding a sword after the loss of his hand and wrist (15).

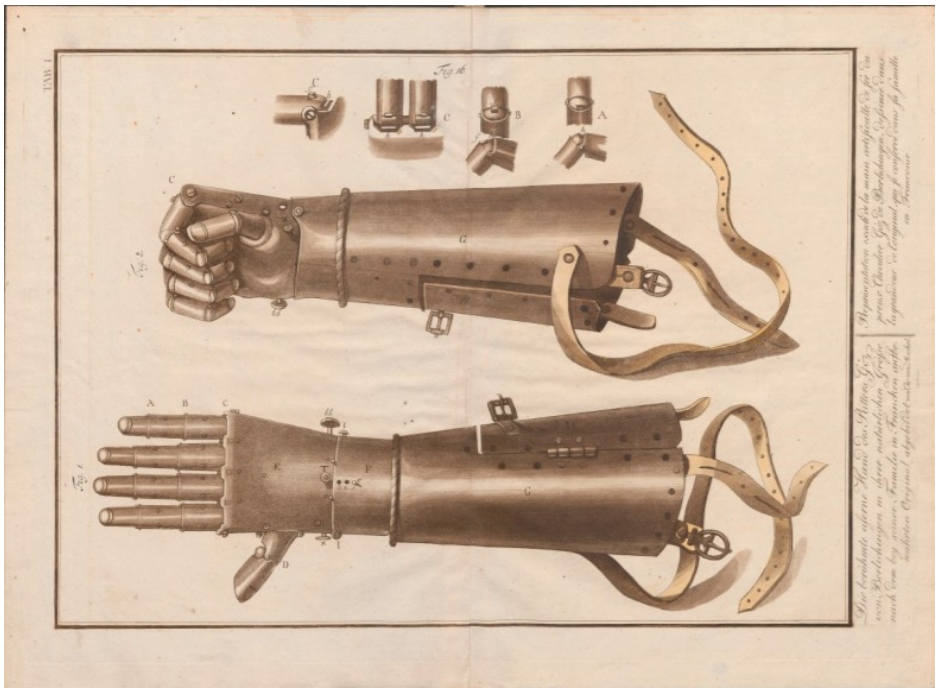

Figure 1: The iron hand of the knight Götz von Berlichingen (adopted (16))

In the beginning of the 20th century with the emergence of industry and during the wartime the demand for upper-limb prostheses increased (12). During this time also the development of the externally powered prostheses began (8). In order to use the electrically actuated hand prostheses the sockets needed to be able to host electrodes, which have continuous contact with the skin.

In the second half of the 20th century the Muenster type socket (see figure 2 left), as well as the Northwestern University Supracondylar Suspension Technique (see figure 2 right) and the Otto Bock style Muenster were developed for transradial amputees (8).

The amputee´s elbow as well as the stump is encompassed by the socket (17). The Muenster type socket´s ability to self suspend is mainly due to anterior/posterior compression and some medial/lateral stabilization (18). It clasps the stump in the sagittal plane between the antecubital fold and the olecranon fossa (17). The Northwestern type socket achieves suspension through a medio-lateral grip just superior to the epicondyles of the elbow and is preferable for longer stumps (17).

Since then there were no significant changes in the common design of transradial sockets for prosthetics (19).

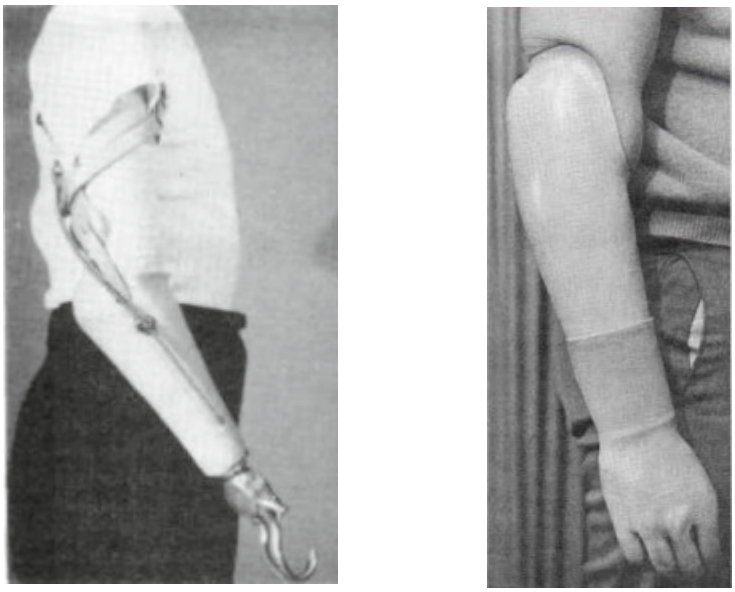

Figure 2: left: Muenster type socket (adopted (20)) right: Northwestern University Supracondylar Suspension Technique (adopted (21))

A more novel idea for a socket design has been proposed by Sang and colleagues (22), which includes pressure-adjustable chambers, which can alternate between a tight/working and relaxed status depending on the need. With this possible alteration between the two states, the socket should be more comfortable to wear.

1.2 Different suspension methods for prostheses

A prosthesis can be attached to a patient through straps, silicone suspension, vacuum suspension, osseointegration or mechanical suspension.

1.2.1 Silicone suspension

With the help of a roll-on silicone liner (see figure 3) it is easy to create true suction suspension (19). The silicone liner is rolled onto the remnant of the amputated limb, where it can adhere to the skin. Silicone liners are especially

beneficial if a long transradial stump is available, since forearm rotation can be preserved (19).

Figure 3: Silicone liner (adopted (23))

For myoelectric prostheses the silicone liner can ensure contact between the skin and the electrodes with the help of snap electrodes (19). These electrodes have to be attached separately when donning the prosthesis, which can be bothersome (19).

Additionally, silicone liners have poor thermal conductivity, which hinder the human body's natural mechanism that regulates temperature. The localized increase in temperature leads to perspiration, which accumulates inside of the liner (24). A temperature increase of a few degrees significantly decreases the comfort of the socket (24). Due to the increased moisture as well as shear and stress forces skin problems, such as acroangiodermatitis, allergic contact dermatitis, bullous diseases, epidermal hyperplasia, hyperhidrosis, infections, malignancies or ulcerations, can arise (25).

1.2.2 Vacuum suspension

In order to ensure a continuous contact between the residual limb and the prosthesis, a vacuum can be imposed inside the socket. This results in the fact that no air accesses the stump, not unlike the silicone suspension. Sweat will again accumulate and similar problems to the silicone suspension can arise. A liner is not necessary in case of a vacuum suspension.

1.2.3 Osseointegration

Some of the drawbacks of a conventional socket mentioned before, that arise from enclosing the stump with a socket can be eliminated with Osseointegration. According to Brånemark Osseointegration refers to the stable fixation of titanium into bone (26). This is accomplished in two separate surgeries: During the first surgery, a titanium implant (fixture) is embedded in the residual bone and no loads are applied on this implant for six months (27). In the second surgery a titanium rod (abutment) is placed inside the titanium implant, which also penetrates the skin (see figure 3) (27).

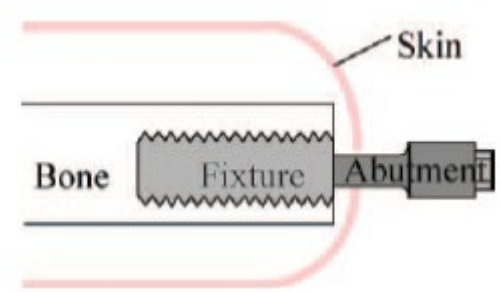

Figure 4: Schematic view of the implant system for osseointegration (adopted (27))

A prosthetic device can be mounted on the abutment, which eliminates the need of a socket (28). The remaining limb is less constricted, however the skin-penetration by the abutment can cause infections (26).

1.2.4 Mechanical suspension

With a mechanical suspension it should not be necessary that the prosthesis socket perfectly mirrors the stump. This makes it easier that one prosthetic socket can be fitted to different stumps.

A mechanical suspension can use laces (or something akin to them) in order to fasten a prosthetic socket, similar to boots. No vacuum is needed for this suspension, which makes it possible to design more breathable sockets. This should cause less hindrance of the body´s heat regulation and therefore reduce sweat as well as problems caused or exacerbated by it.

1.3 Requirements of the adaptable, temporary *BeneFit* socket

Since the socket is an integral part of a prosthesis, which through an uncomfortable fit can lead to abandonment of the whole prosthesis, it should not be neglected as a low-level technology (8). The different suspension techniques have their individual advantages and disadvantages.

The creation of an individual socket takes time. Seeing as the early fitting of a prosthesis in an important factor in its overall acceptance, and because the socket is the part of the prosthesis that needs to be adjusted for each patient in order to fit tightly yet as comfortable and save as possible, it should mirror some parts the patients stump, it seems worthwhile to create a more versatile, shape-changing prosthetic socket in order to fit different stumps, so the patients can be aided sooner.

After the literature research and consultations with the experts, the following properties were deemed to be of importance for an adaptable, temporary

prosthetic socket: It should fit the majority of people, be easy to adjust in diameter and length, be lightweight and easy to don and doff. Furthermore it should provide a stable base for mounting a prosthetic hand and a smooth transition, be comfortable and breathable.

Since it is necessary to fit different patients, it should have a mechanical suspension with a fastening mechanism. This fastening mechanism should be able to switch between a relaxed state and a tightened state. The socket should not have a fixed centre of rotation in order to adjust to the individual anatomical rotational axis of the patients elbow.

The *BeneFit* socket should be biocompatible, provide space for electrodes and restrict the movement as little as possible or rather have a large range of motion.

2 Materials and Methods

In the first chapter the different parts used to build the prosthesis are explained. First the supplied parts from Ottobock, which need to be incorporated to the design, are shortly introduced, followed by the various components of the prosthetic socket.

The chapter on manufacturing explains the processes needed to construct the socket. First the used tools are shortly introduced. Afterwards the different steps, like 3D printing, adaptation of screws and cushioning material, are explained. In the following the *BeneFit* socket is assembled. Finally the survey which helps to evaluate the design is explained and presented.

The prosthesis should provide new amputees with the opportunity to make their first contact with a prosthesis and so better use the invaluable time of the “Golden Period” before the individual socket can be supplied. The prosthesis should be able to change its length and diameter and thereby its shape, so it can be adjusted to the patients needs. Compromises between adaptability and stability have to be made. For example the used material needs to be rigid to provide the stability to support the terminal prosthesis, yet elastic so it can adapt to the diameter of the patients stump. The prototype can be seen in figure 5. The hard shell is designed using Autodesk Fusion 360 (Autodesk Inc., California, U.S.).

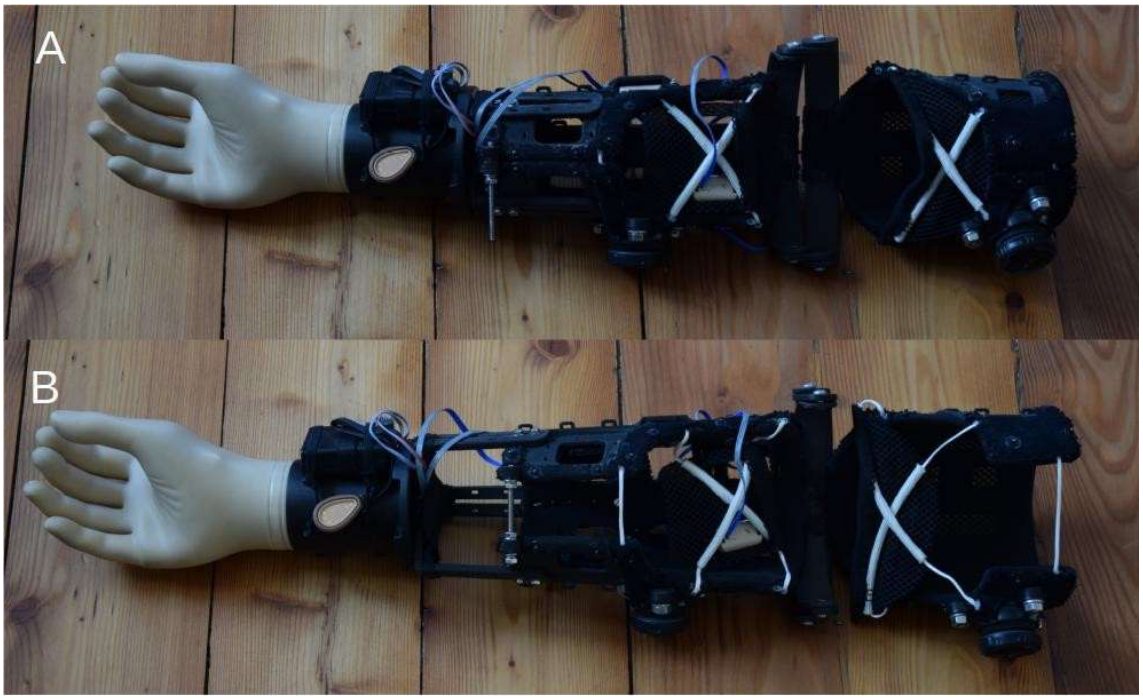

Figure 5: A: assembled prosthesis with minimal diameter and length; B: assembled prosthesis with maximal diameter and length

2.1 Concept

The *BeneFit* socket has a hard outer shell and a soft inner cushioning layer. The hard shell provides the mechanical stability and determines the general shape of the socket.

In order for the patient to be able to operate a myoelectric prosthesis the hard shell should supply an option to mount and fixate electrodes. These electrodes must maintain skin contact with the patients forearm, thereby they are able to use EMG signals to control the movement of the prosthesis.

2.1.1 Electrodes

The MyoBock-electrodes (29) (Ottobock Healthcare GmbH, Germany) used are provided by Ottobock (see figure 6). The contacts are suitable for people with allergies, since they are made from titanium (29). They are less sensitive to low

and high frequency interferences, due to shielding and filtering technologies (29). They remain quite sensitive in the range of low muscle signals (29). The logarithmical amplification of the signal can be changed by turning a dial on the back of the electrode.

Each electrode has two removable arms, which can be used to fixate the electrode.

figure 6: Electrodes (adopted (30))

2.1.2 Electric wrist rotator, MyoRotronic and lamination ring

The electric wrist rotator, MyoRotronic (31) and lamination ring (32), as well as the MyoEnergy Integral (32), MyoCharge Integral (32) and the SensorHand Speed (33) are supplied by Ottobock.

The electric wrist rotator 10S17 (31) (see figure 7: left) can rotate more than 360°. On the distal end the SensorHand Speed (see chapter 3.1.4) can be mounted, while on the distal end the MyoRotronic (see figure 7: middle) can be connected. With the help of the lock ring it can be fixated to the lamination ring (see figure 7: right).

The electric wrist rotator 10S17 has an operating voltage of 6/7,2 V, an approximate no-load current of 150 mA, an approximate stall current of

1000 mA and an idle speed of 13,5 RPM (31). It weights 96 g and corresponds to a rotation angle of 81 °/sec (31).

If the electric wrist rotator 10S17 is combined with the MyoRotronic the electromotive pronation and supination as well as the opening and closing of the hand are enabled and can all be controlled by two electrodes.

The MyoRotronic has a static current of 1 mA, an operating temperature from 0 to +70 °C and a load dependent power off between 30 ms and 10 s (31).

The lamination ring has an outer diameter of 50 mm. It is used to form the connection between the electric wrist rotator 10S17 and the prosthetic socket.

Figure 7: left: Electric wrist rotator 10S17 with lock ring at distal end; middle: MyoRotronic; right: Lamination ring (adopted (34))

2.1.3 MyoEnergy Integral and MyoCharge Integral

The MyoEnergy Integral 757B35=3 (see figure 8) serves as the power supply of the prosthesis. It has several components which are inseparably connected. The battery has two cells (see figure 8:1), one of which also houses the electronics (see figure 8:2), which protect against short circuits, overvoltage, undervoltage and charging outside the allowable temperature. Two cables connect the MyoEnergy Integral with the MyoRotronic, the supply cable (see

figure 8:3) and the communication cable (see figure 8:4). The supply cable establishes the connection between the two components, while the communication cable serves to exchange data as well. The charging receptacle (see figure 8:5) serves as contact to the MyoCharge Integral, has an LED to indicate the current charging level, as well as an LED and a beeper which give feedback on the operating status and serves as the on-off-switch.

The MyoEnergy Integral has a capacity of 600 mAh, an approximate output voltage of 7,4 V, an approximate charging time of 2,5 h and is based on lithium polymer technology (32). Its approximated dimensions are two times 52x25x10 mm (32).

Figure 8: MyoEnergy Integral: 1: two battery cells; 2: electronics; 3: supply cable; 4: communication cable; 5: charging receptacle

The MyoCharge Integral (see figure 9) can be connected to the charging receptacle of the MyoEnergy Integral in order to charge it. It stays in place thanks to an integrated magnet.

The MyoCharge Integral has an operating temperature form 0 to +60 °C, a storage temperature from -20 to +60 °C, a supply voltage from 100 to 240 V and a main frequency from 50 to 60 Hz (32).

Figure 9: MyoCharge Integral

2.1.4 Ottobock SensorHand Speed

The Ottobock SensorHand Speed (see figure 10) is a myo-electrically controlled prosthetic hand. It has a quick-disconnect wrist unit, which can be mounted on the electric wrist rotator. The Ottobock SensorHand Speed has been developed for everyday use, not for extreme activities. The SUVA-sensor technology, which is integrated in the thumb, can sense when an object starts to slip and automatically increase the grip force to regain stability. The FlexiGrip function provides grip flexibility. One can choose between six different programs for optimal adjustment.

The Ottobock SensorHand Speed has a static current of 2 mA, an operating temperature range from 0 to +70 °C, an opening width of 100 mm, a proportional speed from 15 to 300 mm/s, a proportional grip force from 0 to approximate 100 N and a service life of 5 years (33).

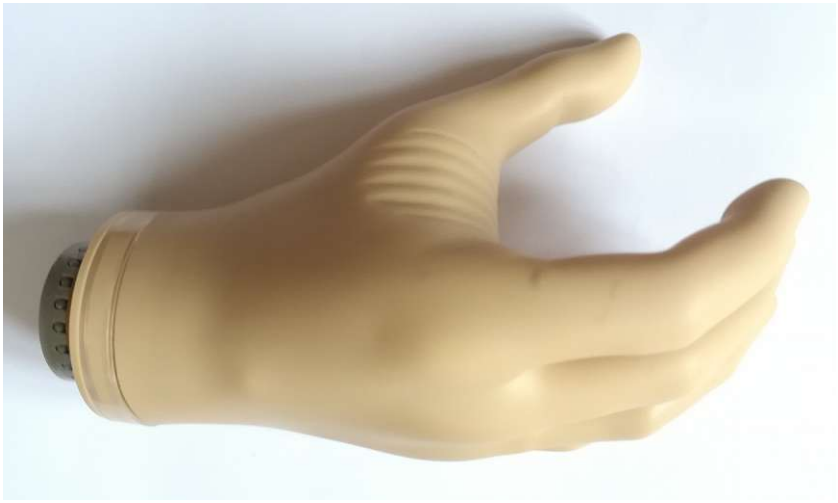

Figure 10: Ottobock SensorHand Speed

2.2 *BeneFit* socket design

In order to add the main function of being adjustable in size to fit different patients solutions and compromises between changeability and stability had to be found. The socket has a modular design.

The hard shell (see figure 11) consists of many different parts. The radial and humeral parts, the two largest, are connected using a double-hinge joint. Both parts have the cross-sectional shape of an open circle, in order to have an adjustable diameter. They can be closed via a fastening mechanism, a RevoFit2™ (35). Thereby the adaptation of the *BeneFit* socket in transverse direction is provided.

Three rails connect the radial part and quick disconnect adapter. Through this rail system the length of the prosthetic socket can be adjusted.

To increase the comfort and minimize the injury risk there are no sharp edges on the hard shell and the inner edges of the socket were bevelled in order to provide a smoother transition (see figure 12).

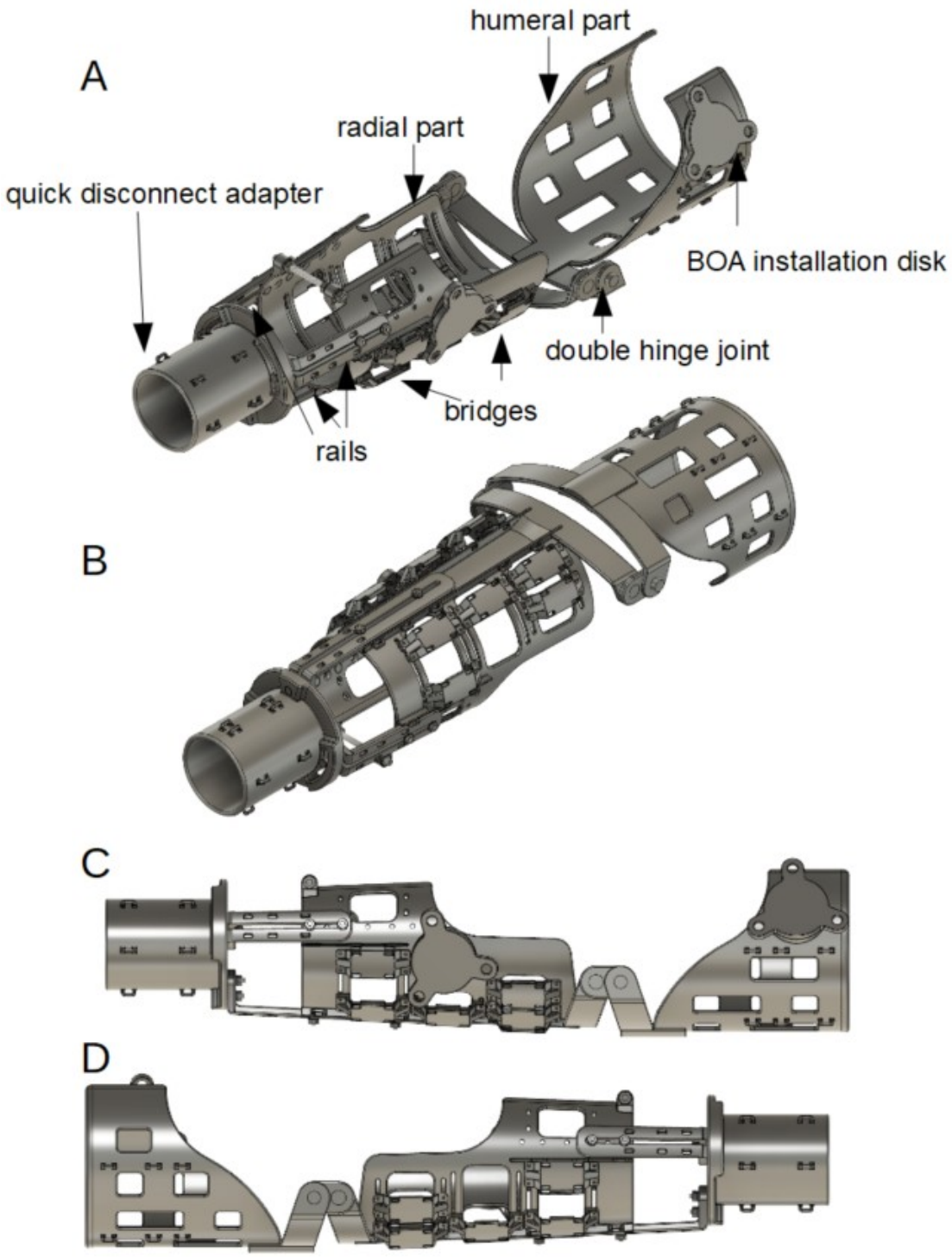

Figure 11:

A: isometric view form above of assembled hard shell; B: isometric view form below; C: left side view; D: right side view; the humeral part and the radial part are connected by a double hinge joint, BOA installation disk mounted on both humeral and radial part, multiple bridges mounted on radial part, three rails connect the distal end of the radial part and the quick disconnect adapter

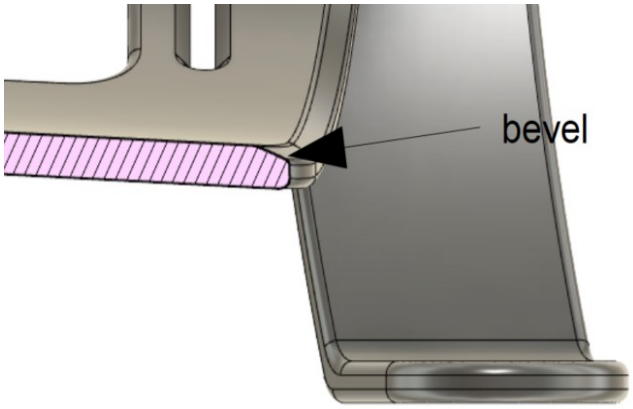

Figure 12: cut through radial part: bevel visible

2.2.1 Radial part and attachments

Radial part

The radial part (see figure 13) is generally cone-shaped, since this resembles closely the human forearm. To estimate the approximate dimensions of the stump and thereby the inner dimensions of the *BeneFit* socket, the forearms of different people of different genders as well as different ages were measured. The inner diameter at the proximal end is 190 mm. At the distal end there is an inner diameter of 74 mm. It has a length of 190 mm and a wall thickness of 3 mm.

At the proximal end, the socket encloses less of the circumference of the forearm. This is done to be more comfortable and less restrictive to the movement of the elbow.

An arc is attached at the proximal end, whose form is independent from the adaptations of the diameter of the rest of the radial part. The ends of the arc connect to the double hinge joint.

An adjusting M4 screw can be placed at the distal end connecting the two flanges. The screw makes an adaptable yet rigid connection at the distal end possible. This should add stability, while not decreasing the adaptability.

On the left side a circular plate is visible, where the BOA installation disk (see later) can be attached, on which the RevoFit2™ Diagnostic Reel Base is mounted.

Four fins (see figure 13 B and E), two long ones and two short ones, add rigidity in longitudinal direction, while conserving more elasticity in transverse direction. Therefore, the diameter of the socket stays more easily adjustable. The fins also have the advantage of adding stability to the rail system (see rails beneath).

Loops can be found on these fins. They provide an attachment for an elastic band, which can be used to fixate the battery needed for a myoelectric prosthesis, as well as a variety of other things/components.

On both the right- and left-hand sides, electrodes can be placed into the larger openings and individually adjusted to the optimal position. These electrodes can be fixed into place with the help of bridges (see bridges beneath). Without this system it would not be possible to control the terminal device. The slits on both sides of the openings are necessary in order to place screws, which fixate the bridges.

The rails (see rails beneath) can be attached by screws to the radial part. Multiple screw holes are placed along the sliding path of the rails. Therefore, it is possible to use the optimal ones depending on the overlap of rail and radial part.

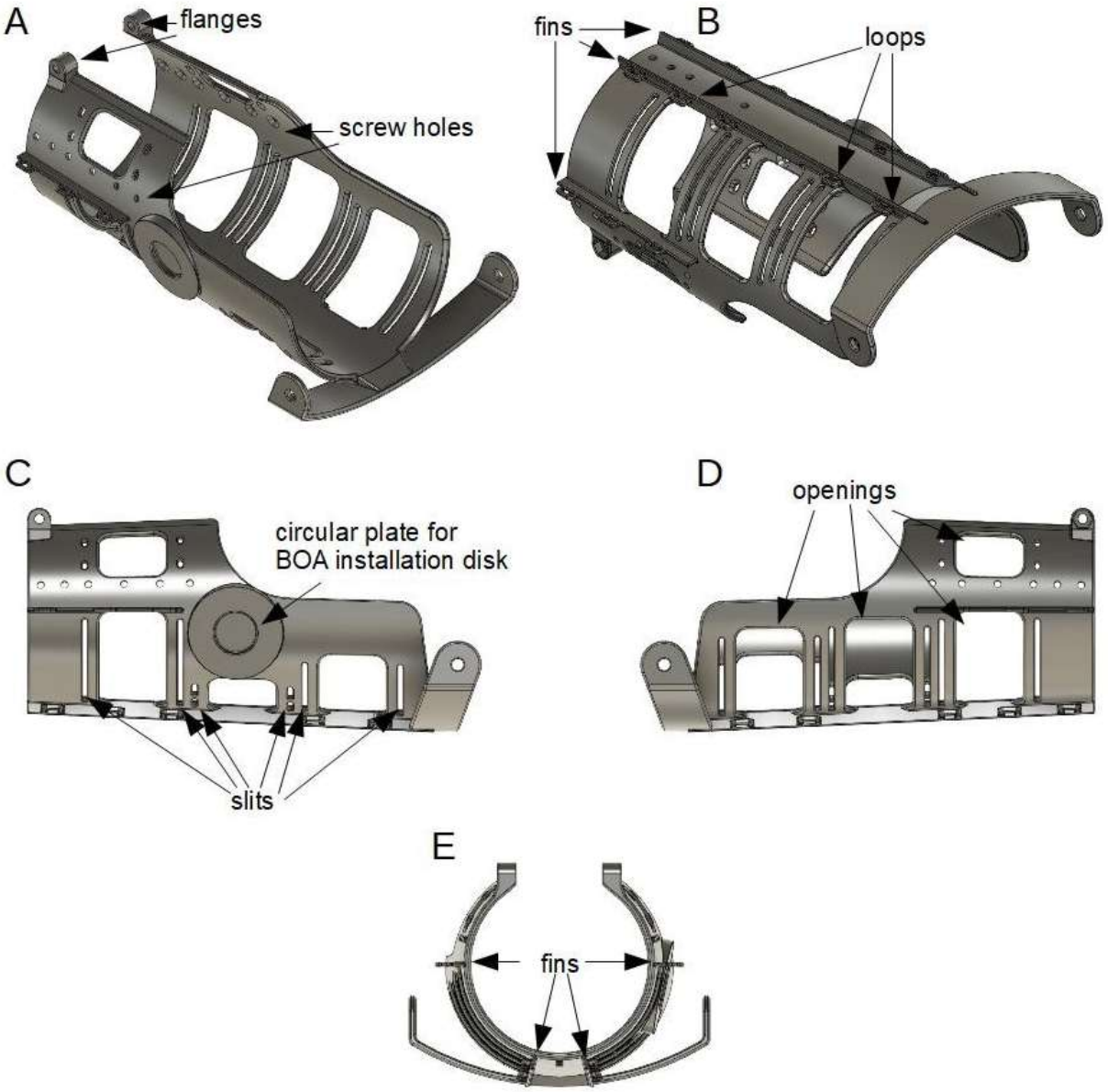

Figure 13: A: isometric view from above of the radial part; B: isometric view form below; C: left side view; D: right side view; E: view from distal end; arc/attachment to double hinge joint at proximal end; four fins; two flanges at distal end; multiple screw holes for M3 flat head screws to attach rails; multiple openings for electrode placement on each side; on each side of an opening a slit for M2 flat head screws; multiple loops for elastic band attachment; on the left side circular plate for BOA installation disk

BOA installation disk

Different fastening mechanisms were considered. The RevoFit2™ system (see chapter 2.2.3) was chosen, due to the fact that it is easy to use and has less protruding parts than some of the other considered fastening mechanisms. The BOA installation disk (see figure 14) is used as a transition piece between the RevoFit2™ Diagnostic Reel Base and the radial part. Three M6 flat head screws can be placed inside the three holes. With the help of M6 screw nuts, the reel base can be fastened to the BOA installation disk, which can, in turn, be mounted on the circular plate on the left side of the radial part.

Figure 14: BOA installation disk: transition piece between the RevoFit2™ Diagnostic Reel Base and the radial part

Bridges

The Bridges (see figure 15) need to be able to lock the electrodes into a fixed position. M2 screws are placed through the four holes and the slits on the radial part. By tightening the corresponding M2 nuts, the bridges are no longer moveable. In turn they fixate the electrode, the arms of which have been placed inside the gaps on each side.

Trough the two slits on each side, elastic bands can be threaded in order to attach a battery or other components.

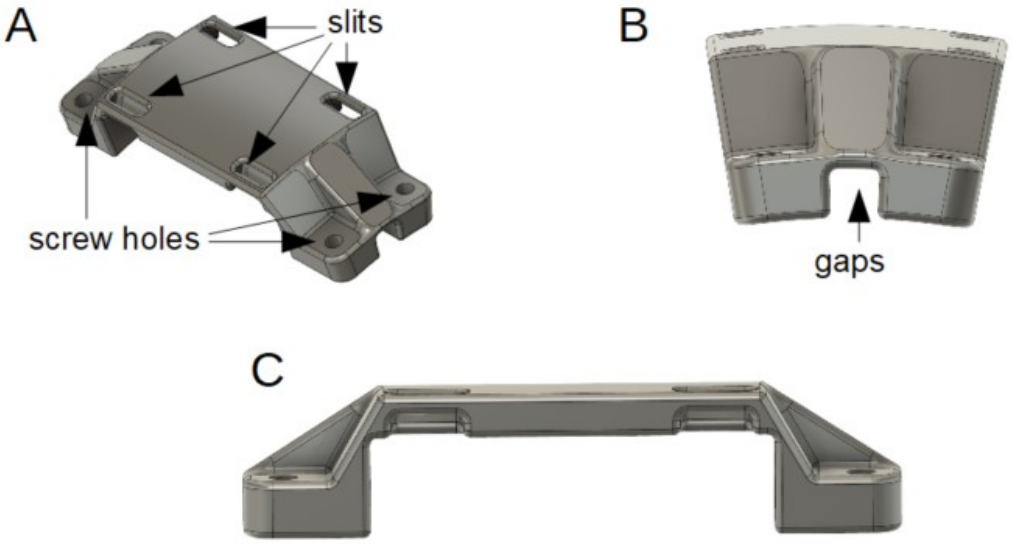

Figure 15: A: isometric view of bridge; B: frontal view; C: side view; four screw holes for M2 screws; four slits for elastic band attachment, two gaps to fixate the electrode

Rails

The three L-shaped rails (see figure 16) are each 5mm thick and enable the prosthetic socket to change length. Through the big slit in the middle of each rail, M3 screws can be threaded. The rails form the transition from the adaptable radial part to the rigid quick disconnect adapter. The position of the rails relative to the quick disconnect adapter can be adjusted in radial direction as well as along the circular arc. When the rail is in the desired position it can be fixated by two M3 flat head screws. Each rail has three slits on each side through which an elastic band can be threaded in order to attach a battery or other components.

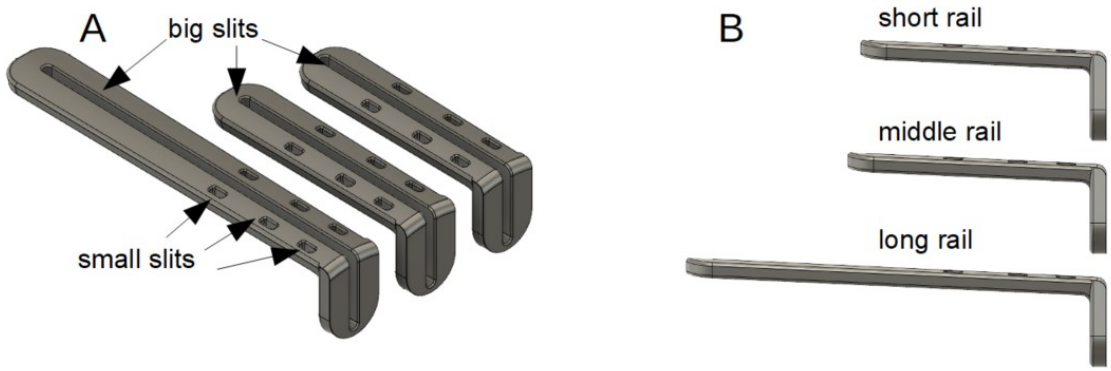

Figure 16: A: isometric view of rails; B: side view of rails; big slits in the middle for M3 screws; small slits for elastic band attachment

By sliding the rails, the length of the radial complex can be extended from 265 mm to 310 mm (see figure 17). Each rail is connected to the radial part by two M3 flat head screws and their corresponding nuts.

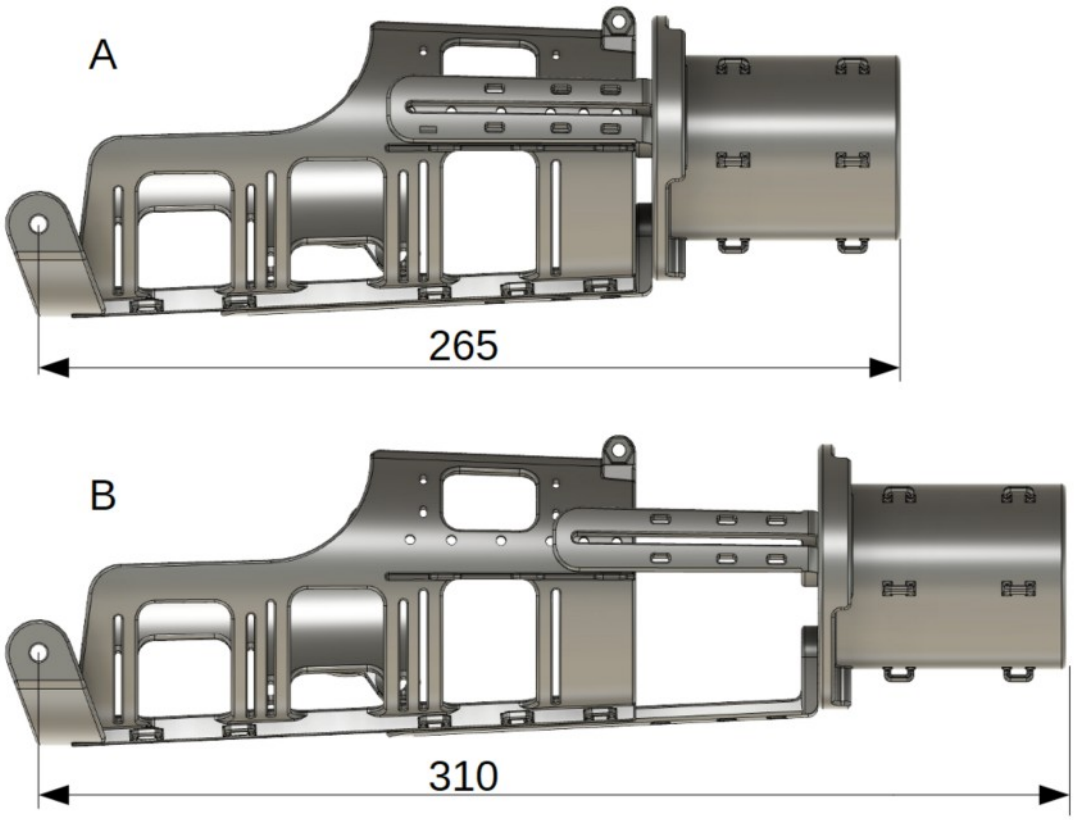

Figure 17: side view of radial part + rails + quick disconnect adapter;

A: in short arrangement 260 mm; B in long arrangement 310 mm

Quick disconnect adapter

The quick disconnect adapter (see figure 18) is a cylinder with an inner diameter of 50 mm and an inside length of 70 mm and has a wall thickness of 3 mm. Inside this cylinder, an electric rotator (for example Art. no. 10S17) plus a lamination ring (for example Art. Nr.:10S1) can be mounted. It is on this electric rotator that different prosthetic hands can be donned.

At the proximal end there is a flange, which can be connected to the rails. The two slits on each the right and left side enable the positional adaptations of the rails along the circular arc.

On the outside of the cylinder multiple loops can be used to attach elastic bands. These bands in turn can be used to attach a battery or other components.

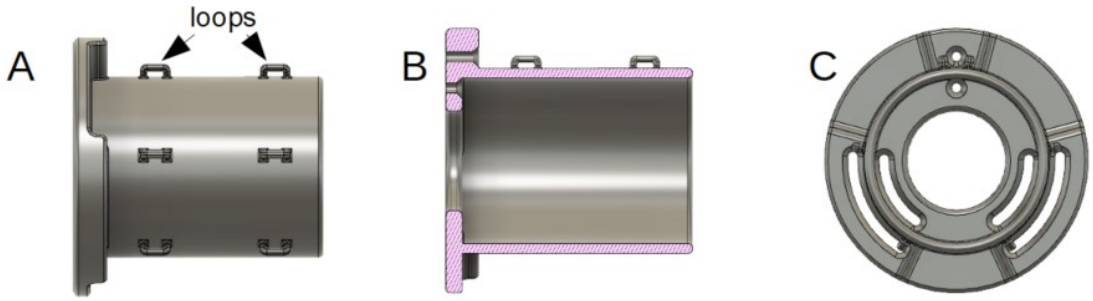

Figure 18: quick disconnect adapter: A: side view; B: cut through the middle; C: view form distal end

Double hinge joint

Since the position of the rotational axis of the elbow differs from person to person, the prosthetic socket itself should not have a fixed centre of rotation around the elbow joint. This can be accomplished by using a double hinge joint (see figure 19). This plate is the intermediate piece between the humeral and radial part. Each part can be attached to the plate by the combination of a M4

sleeve nut and a M4 head screw. This combination serves as the hinge bolt. The plate itself has a length of 35 mm, a width of 20 mm and a thickness of 4 mm.

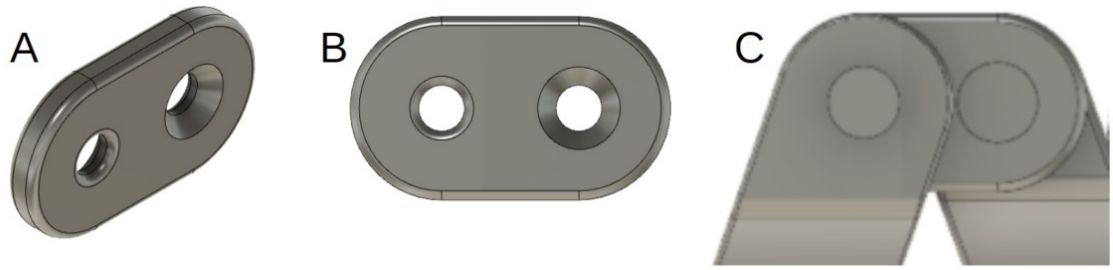

Figure 19: intermediate piece between the humeral and radial part;
A: isometric view of intermediate plate; B: side view of intermediate plate; C: side view of assembled double hinge joint

2.2.2 Humeral part

The humeral part (see figure 20) is an open cylinder with an inner diameter of 101 mm. It has a length of 145 mm and a wall thickness of 3 mm.

Similar to the radial part, the socket encloses less of the circumference of the upper arm at the distal end. This is again done to be more comfortable and provide a larger range of motion.

An arc is attached at the distal end, whose form is independent from the adaptations of the diameter of the rest of the humeral part. The ends of the arc connect to the double hinge joint.

Elastic bands can be threaded through loops on the outside, which in turn can attach a battery or other components.

On the left side, a circular plate can be found, upon which the BOA installation disk can be attached, on which the RevoFit2™ Lamination Dummy is mounted.

The multiple holes reduce the weight as well as increase the breathability of the prosthetic socket.

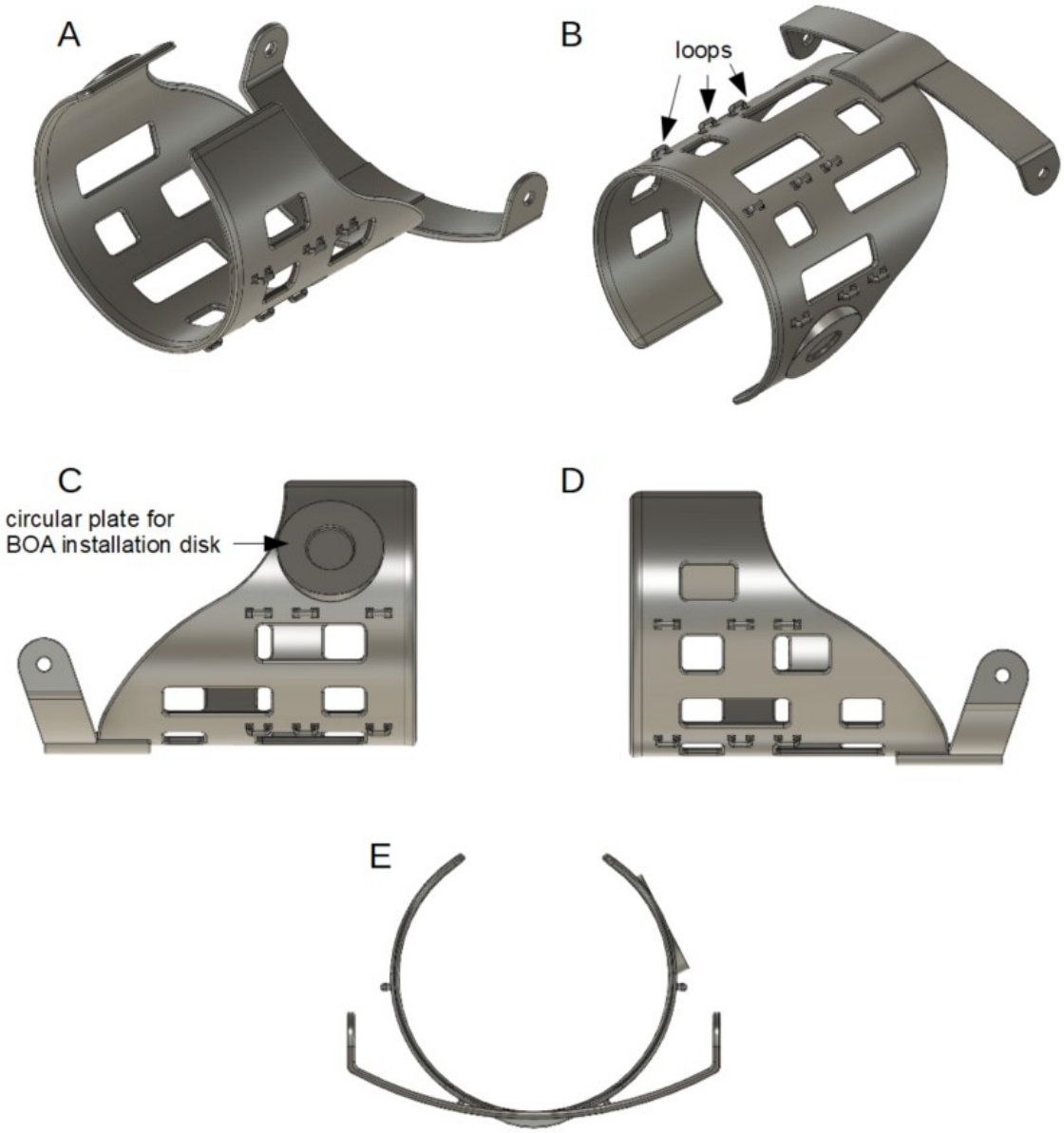

Figure 20: humeral part: A: isometric view form above; B: isometric view form below; C: left side view; D: right side view; E: view from distal end; arc/attachment to double hinge joint at distal end; multiple loops for elastic band attachment; on the left side circular plate for BOA installation disk

2.2.3 Fastening mechanism/RevoFit2™

Two different RevoFit2™ kits are used as fastening mechanisms: the RevoFit2™ Diagnostic Kit and the RevoFit2™ Lamination Kit (see figure 21), both were provided by Ottobock Vienna. The RevoFit2™ Diagnostic Kit consists of a Boa® tool, a six-foot RevoFit™ Tubing, a seven-foot Lace, a Lace Feeder, a RevoFit2™ Diagnostic Reel Base and a High Power Boa® Reel. An additional Replacement Lace Pack is provided in the RevoFit2™ Lamination Kit as well as a RevoFit2™ Lamination Dummy instead of a RevoFit2™ Diagnostic Reel Base.

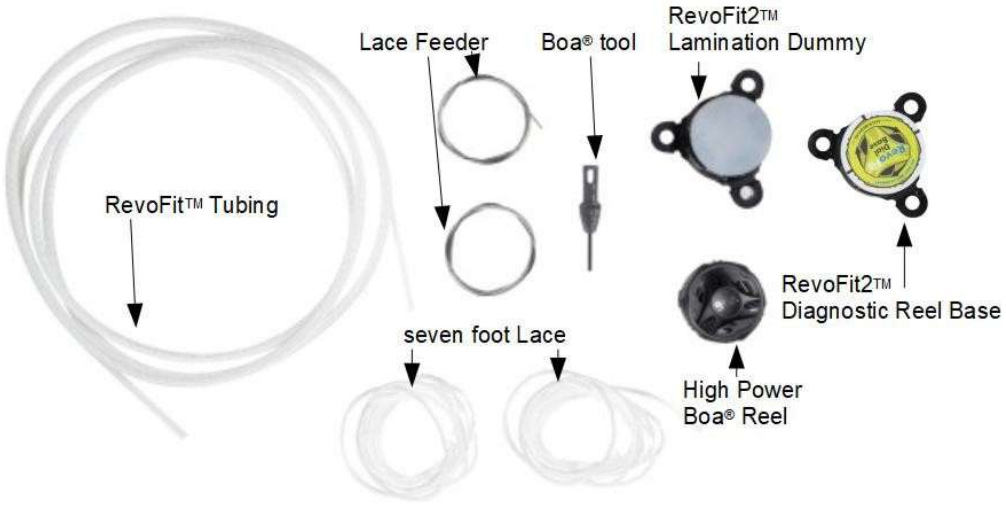

Figure 21: RevoFit2™ Lamination Kit + RevoFit2™ Diagnostic Reel Base (adapted (35))

2.2.4 Cushioning material form 3MESH

A cushioning material is placed on the inside of the hard shell in order to provide more comfort, since the direct contact of the hard shell with the stump could be rather painful. The cushioning material on the other hand should not be too thick or too soft, because this could decrease stability. 3MESH spacer fabric by Müller Textile Group is used for this purpose. It has high permeability, comfortable padding characteristics, good coating and lamination properties, long service life, high-quality soft touch, optimal pressure distribution, good

stabilization, low weight and temperature and climate control (36). 3MESH meets the standard 100 by Oeko Tex (class 1) and is therefore biocompatible (36).

For the *BeneFit* socket, various different 3MESHs were examined. The 6020 material in black was selected, which has a thickness of 3 mm (see figure 22). This was chosen because of its relatively small thickness, while still possessing good cushioning properties as well as feeling pleasant to the touch.

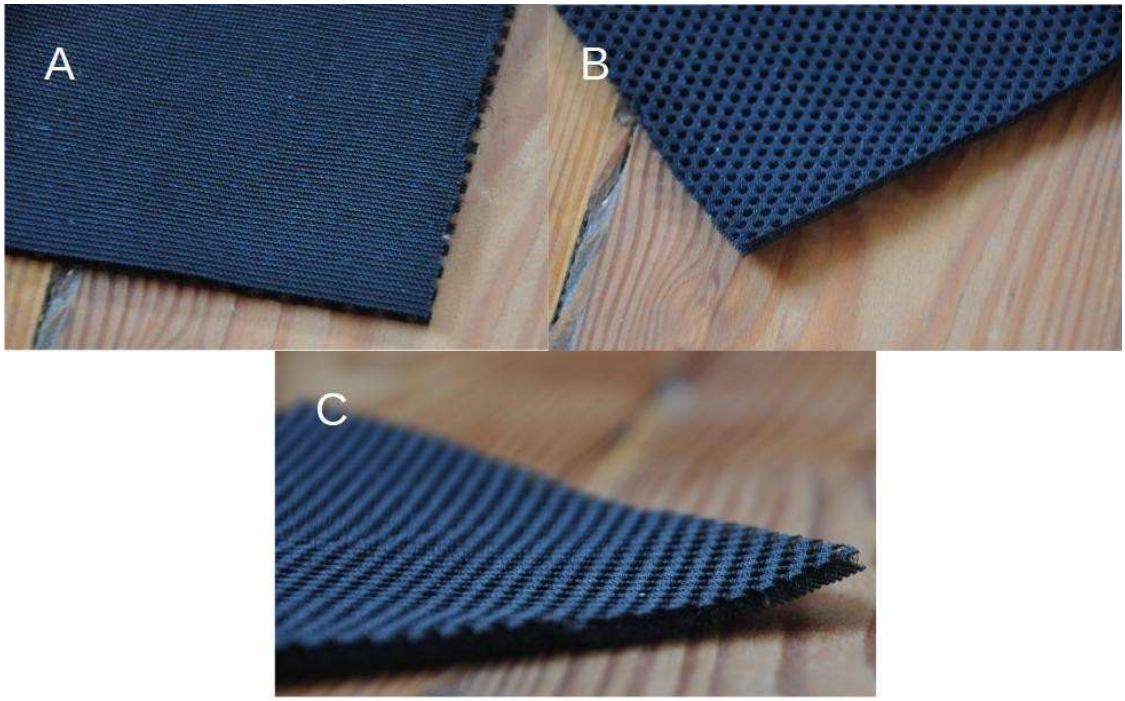

Figure 22: Cushioning material: 3MESH spacer fabric 6020 black: A: side that touches the skin; B: side which attaches to the hard shell; C: thickness of 3MESH spacer fabric visible

This cushioning material was also used to fashion two cushioning pads. A cushioning pad for both the humeral and radial parts, the latter having small opening into which electrodes can be placed.

2.2.5 Adhesive /Turbocoll Power Mix

Turbocoll Power Mix is a 2-component super-power adhesive (see figure 23), that has a high tensile strength. It is used to attach various parts of the prosthetic socket (see chapter 3.2.5 and 3.2.6).

The Turbocoll Power Mix has a gelation time of under 5 minutes, a curing time smaller than 45 minutes, is temperature-resistant from -60 to 120 °C, is gap filling up to 4 mm, has a maximal elongation of 25 %, a maximal shore hardness of 75 ShoreA and a maximal tensile strength of 400 kg/cm^3.

Figure 23: Adhesive /Turbocoll Power Mix (37)

2.3 Manufacturing

2.3.1 Tools

The 3D printed parts were printed at the Institute of Engineering Design and Product Development of the Vienna University of Technology by Dipl. Ing. Markus Puchinger.

Most of the post-processing work and assembly was done at home, this was also due to the Corona pandemic and therefore the tools there available had to be used.

Markforged Mark Two 3D-Printer

3D-printing was chosen to manufacture the hard shell. It had the big advantage that the in Autodesk Fusion 360 designed parts could be constructed directly, no extra steps, except a short post-processing was necessary. Also the process of 3D-printing profits from being easy and fast.

The Markforged Mark Two (Markforged, Massachusetts, U.S.) (see figure 24) was a professional carbon fiber 3D-printer (data sheet: see appendix). It used the Continuous Fiber Reinforcement (CFR) process to print strong parts (38). Composite materials could be produced using the Mark Two 3d printer, making a better strength-to-weight ratio possible (39).

Onyx, the material of choice for the prototype, was a micro carbon fiber-filled nylon known for its strength, toughness and chemical resistance (datasheet: see appendix) (40).

Figure 24: Markforged Mark Two 3D-Printer (adopted (41))

Grinders

Three different grinders were used one angle grinder and two electrolytical grinding machines.

The Bosch Professional GWS 750-125 (see figure 25) was an angle grinder. It could be used to cut different screws. It has a rated input power of 750 W, a no-load speed of 11000 rpm, a disc diameter of 125 mm and a power output of 380 W (42).

Figure 25: Angle Grinder: Bosch Professional GWS 750-125 (adopted (42))

The two different electrolytical grinding machines were used: Toledo Combimachine TCT-15 (see figure 26) and the Parkside double bench grinder with flexible drive shaft PDFW 120 A2 (see figure 27).

The Toledos Combimachine TCT-15 has a supply voltage of 230 V, a frequency of 50 Hz and a power input of 125 W.

Figure 26: Toledo Combimachine TCT-15

The Parkside double bench grinder with flexible drive shaft PDFW 120 A2 has a rated voltage of 230 V, a frequency of 50 Hz and a rated idle speed from 0 to 11500 rpm (44).

Figure 27: Parkside double bench grinder with flexible drive shaft PDFW 120 A2 (adopted (43))

2.3.2 3D printing and post processing of printed parts

All parts of the hard shell designed in Autodesk Fusion 360 were printed by the Markforged Mark Two 3D-Printer. A layer height of 0.02 mm, a density of 33%, two full edge layers, ten top and bottom layers as well as triangle fill were set for all parts.

After printing, the material had to be post-processed. The supporting material was removed from the individual parts by simply ripping it away or with the help of a Stanley knife. The surface where the supporting material was attached was sanded with the help of PDFW 120 A2, sandpaper of grade 240 and a nail file. The result can be seen in figure 28. The assembled hard shell can be seen in figure 29.

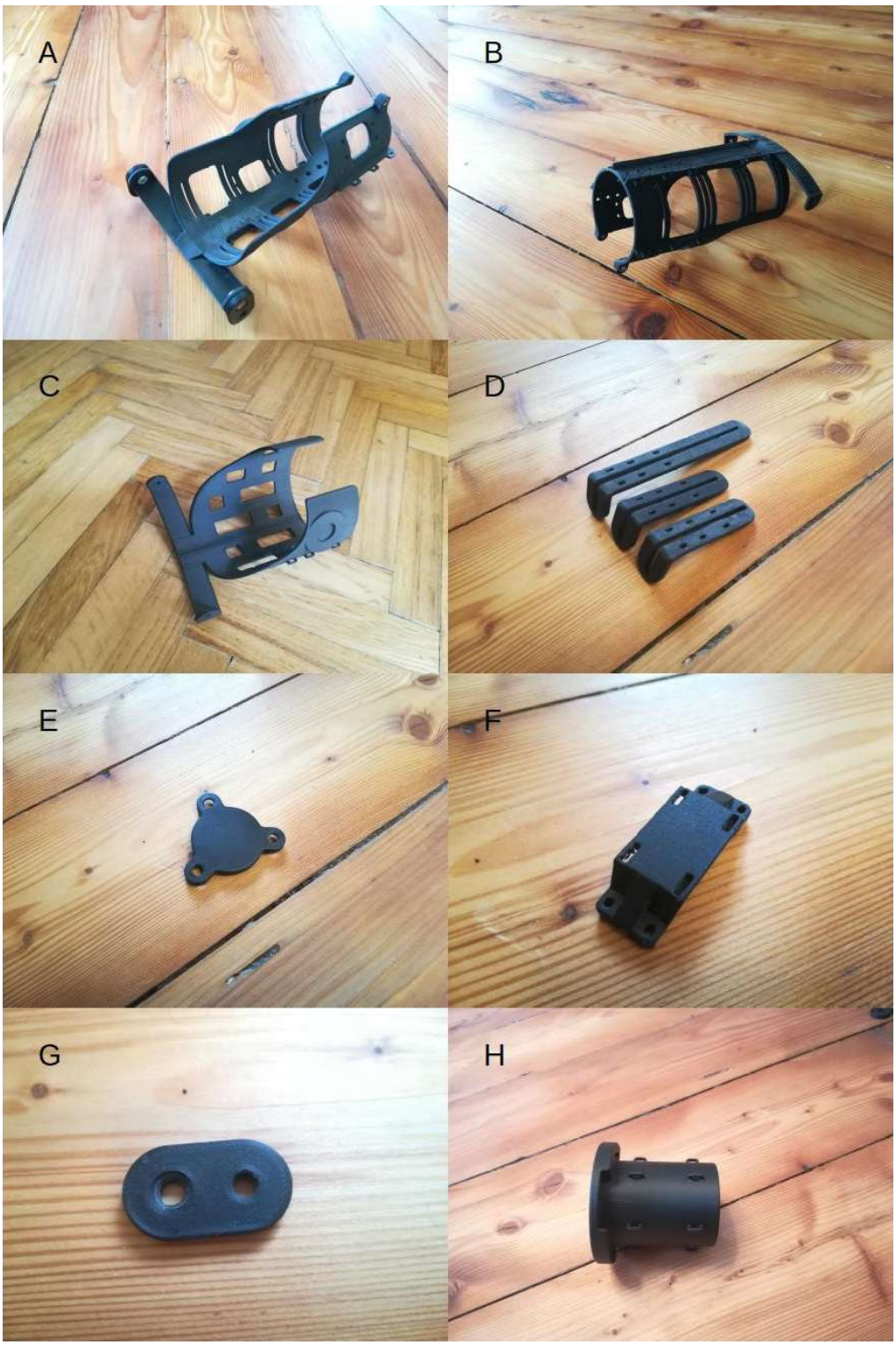

Figure 28: printed and post-processed parts: A: radial part from above (plates of double hinge joint attached); B: radial part from below; C: humeral part; D: rails; E: BOA installation disk; F: bridge; G: plate of double hinge joint; H: quick disconnect adapter

Figure 29: assembled hard shell

2.3.3 Adaptations

Since the optimal length of the screws used for this prototype often did not correspond to the standard length of screws, the screws needed to be shortened. All screws and sleeve nuts were cut with the angle grinder and subsequently polished using both electrical grinding machines and various hard grinding tools. The new length of the different screws can be extracted from table 1.

Table 1: new length of screws

screw	purpose	original length	new length
6 x M3 flat head screws	attach rails to radial part	16 mm	11 mm
3 x M3 flat head screws	attach rails to quick disconnect adapter on the smaller arc	16 mm	13 mm
3 x M3 flat head screws	attach rails to quick disconnect adapter on the larger arc	20 mm	18 mm
4 x M4 Phillips head screws	bolt of the double hinge joint	10 mm	3 mm
4 x M4 sleeve nuts	bolt of the double hinge joint	15 mm	7 mm
1 x M4 headless screw	adjusting screw at distal end of radial part	1000 mm	60 mm
6 x M6 flat head screws	attach BOA installation disk to RevoFit2™ Lamination Dummy/RevoFit2™ Diagnostic Reel Base	16 mm	13 mm

The cushioning material also needed to be fashioned into the correct form. First, two cutting templates were made of linen. One covered the inside of the radial part, while the other one covered the inside of the humeral part. For the radial part every opening had to be cut free and slits had to be cut into the cushioning of the radial part in the corresponding place of screw holes in the hard shell. This was done in order to be able to access the screws later.

With the help of these cutting templates, the 3MESH spacer material was fashioned into the appropriate form.

Two pads were made from the cushioning material to improve the comfort by placing them in the recesses for the elbow (see figure 34).

A third cushioning pad was fashioned (see figure 30). The cushioning pad had a circular shape and could be mounted on the rails by three elastic bands which were sewn to it. This pad cushioned the proximal end of the quick disconnect adapter. (see figure 30)

Figure 30: left: cushioning pad with 3 elastic bands attached; right: mounted cushioning pad to cushion the distal end of rail and quick-disconnect adapter.

2.3.4 Bonding hard shell and cushioning material

First, the inside of the radial part was abraded. Then the area and the corresponding precut 3MESH spacer material were degreased and cleaned with acetone.

The corresponding pre-cut 3MESH spacer material was placed inside the radial part. Once all of the openings were aligned, the correct position was secured by clamps only on one side, leaving the other side movable.

The bonding was done step by step. First, the two components of Turbocoll Power Mix were mixed, then the adhesive was applied as even as possible on one side of the inside of the radial part. Afterwards, the cushioning material was

placed upon it. After 5 minutes the clamps were removed. Subsequently, the second half of the inside of the radial part was covered with newly mixed adhesive, as before, the cushioning material was placed upon it.

The bonding of the humeral part with the 3MESH spacer material occurred in the same fashion. Afterwards the adhesive dried for 24 hours. The results can be seen in figure 31.

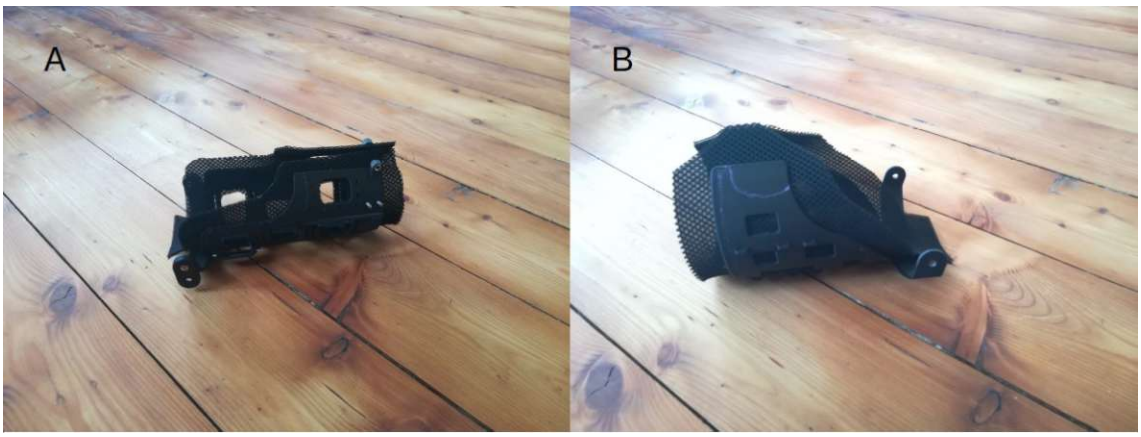

Figure 31: A: radial part with 3MESH spacer material; B: humeral part with 3MESH spacer material

2.3.5 Mounting of RevoFit2™

The RevoFit2™ Tubing consisted of two parts: An outer textile shell and an inner plastic tubing (see figure 32). Different test bonding techniques were tried between Onyx material and the outer textile shell plus the inner plastic tubing, as well as between the Onyx material and only the inner plastic tubing. The best bond could be achieved by first abrading the hard shell as well as the inner plastic tubing, then cleaning and degreasing the area with acetone and finally completely surrounding the inner plastic tubing with adhesive. Therefore, for the most parts only the inner plastic tubing was used.

Figure 32: RevoFit2™ Tubing: outer textile shell + inner plastic tubing

The RevoFit2™ Lamination Dummy and the RevoFit2™ Diagnostic Reel Base each were fastened to a BOA installation disk with three M6 screws and nuts. The remote route, which created an angle of 90 degrees, was chosen as the lace routes through the lamination dummy and the diagnostic reel base. The orientation of the diagnostic reel base on the radial part and of the lamination dummy on the humeral part was determined. The tubing path was chosen by trial and error. Special attention was paid that no kinks would arise. The path was marked with chalk on the hard shell. Multiple possible paths were marked and tried after the installation before the best one was chosen.

The BOA installation disks as well as the plates on the humeral and radial part were roughened on the surface and cleaned with acetone. They were connected by the Turbocoll Power Mix.

Each sector of the tubing was glued individually. First, both tubing and hard shell, were abraded, cleaned and degreased. Then, the tubing was placed in the correct position and secured with the help of clamps. The plastic tubing was

completely surrounded with the Turbocoll Power Mix. After letting the adhesive cure for 45 minutes, the clamps were removed and the next section of the tubing was mounted. The results can be seen in figure 33.

Figure 33: hard shell with cushioning material on the inside and tubing/ RevoFit2™ Lamination Dummy/RevoFit2™ Diagnostic Reel Base attached to the outside; A: right side humeral part; B: left side humeral part with RevoFit2™ Lamination Dummy; C: left side radial part with RevoFit2™ Diagnostic Reel Base

After letting the adhesive cure for 24 hours, the dry edges of the Turbocoll Power Mix were smoothed by abrasion with the help of the electrolytical grinding machines.

The projecting 3MESH spacer material was glued to the outside of the hard shell.

In order for the *BeneFit* socket to be more aesthetically pleasing, a piece of black fabric was placed over the tubing. The textile was sewn to the 3MESH spacer fabric and partially glued to the hard shell.

The textile shell of the tubing material was sewn onto the cushioning pads. The edge closest to the elbow joint for each pad was hemmed in order to be more comfortable (see figure 34).

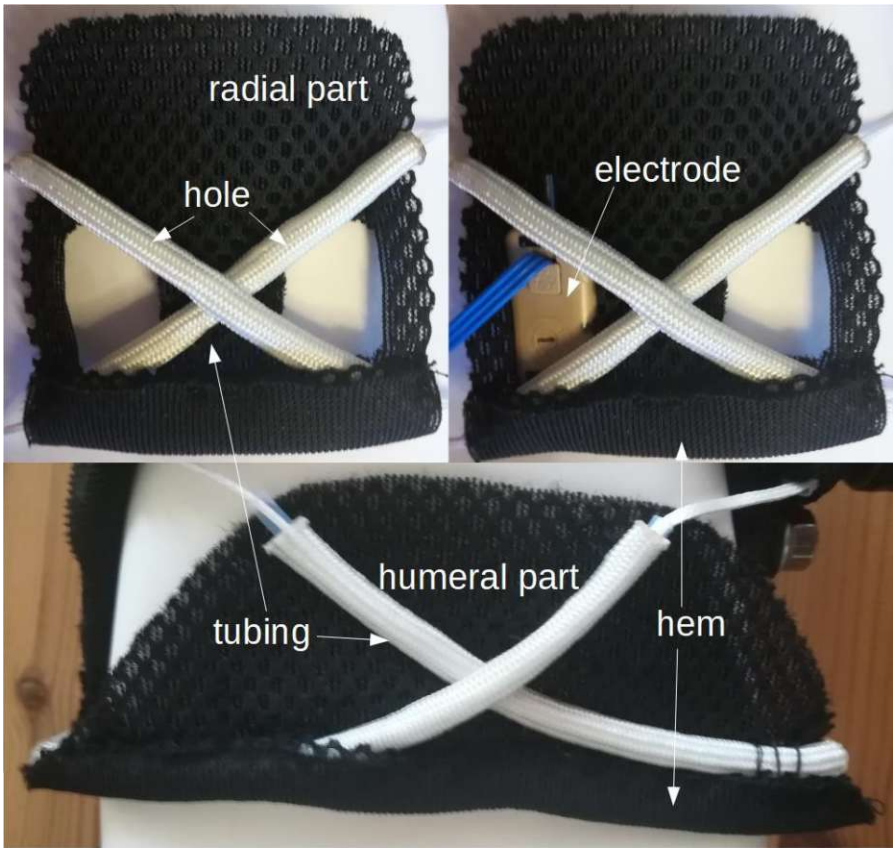

Figure 34: above: radial pad with tubing and hem; below: humeral pad with tubing and hem

The lace was fed through the tubing using the lace feeder. Multiple lace fastening paths were tried. The best path did not use all the tubing. On the radial part, only the tubing going to the reel base, the one mirroring this on the right side and the most proximal tubing were used. On the humeral part, the

tubing going to the reel base, the one mirroring this on the right side and the most distal tubing were used.

The lace was fed through the spool of the High Power Boa® Reel and attached with knots. The reel was inserted into the base and locked there by turning it counter clockwise. Afterwards. the fastening mechanism was ready for use. By turning the High Power Boa® Reel clockwise, the mechanism tightened and could be loosened by pulling the High Power Boa® Reel.

2.3.6 Assembly of the *BeneFit* socket

The quick disconnect adapter was connected to each rail by two M3 flat head screws (see figure 35). One screw had a length of 18 mm while the other one had a length of 13 mm. By loosening these screws, the rails could be moved in the radial direction as well as along the circle arc.

The long slit along the middle of the rail tended to cause the entire rail to become deformed, especially when a screw passing through the middle of it was tightened. To prevent this, an elastic band could be placed around the outside.

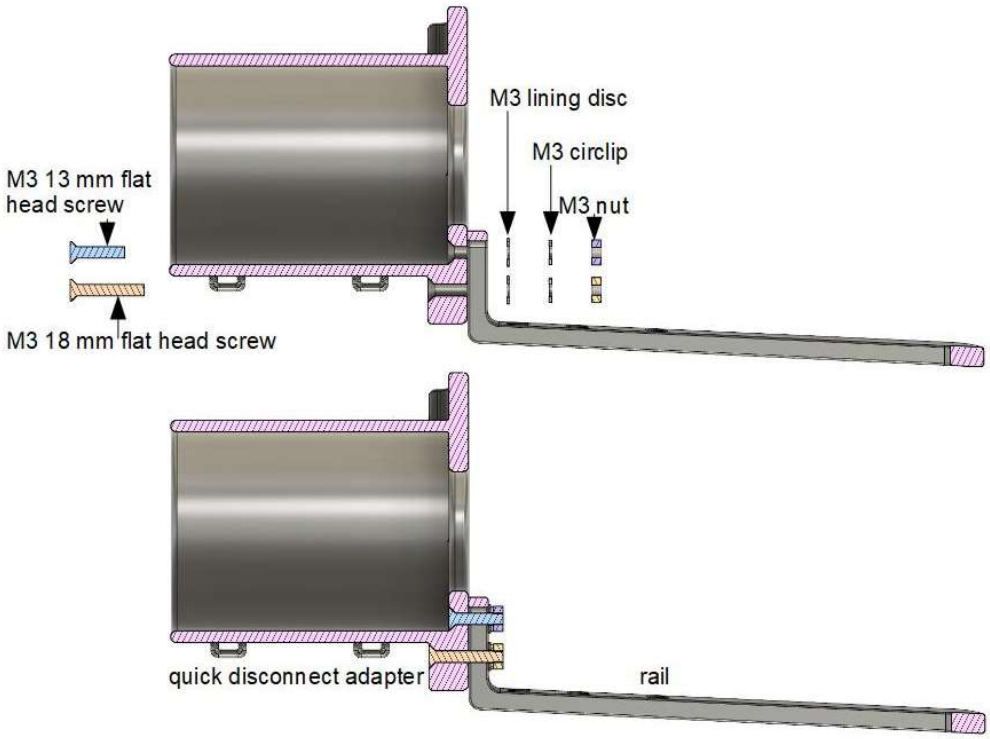

Figure 35: Assembly of quick disconnect adapter with rail by two M3 flat head screws + two M3 lining discs + two M3 circlips + two M3 nuts

Each rail was connected to the radial part by two M3 screws with a length of 11 mm (see figure 36). The rails could slide along the radial part before the screws were tightened and fastened.

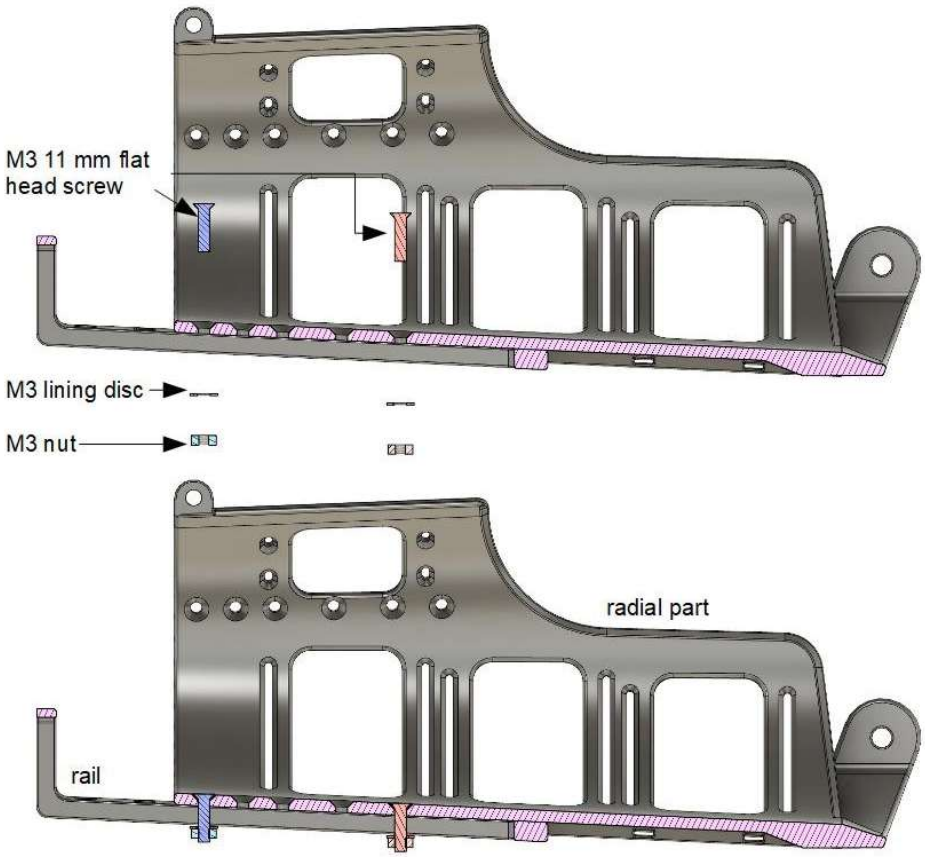

Figure 36: Assembly of radial part with rail by two M3 flat head screws + two M3 lining discs + two M3 nuts

The two flanges at the distal end of the radial part were connected by a 60 mm long M4 headless screw (see figure 37). With the help of four M4 nuts the distal diameter of the radial part could be adjusted and fixated.

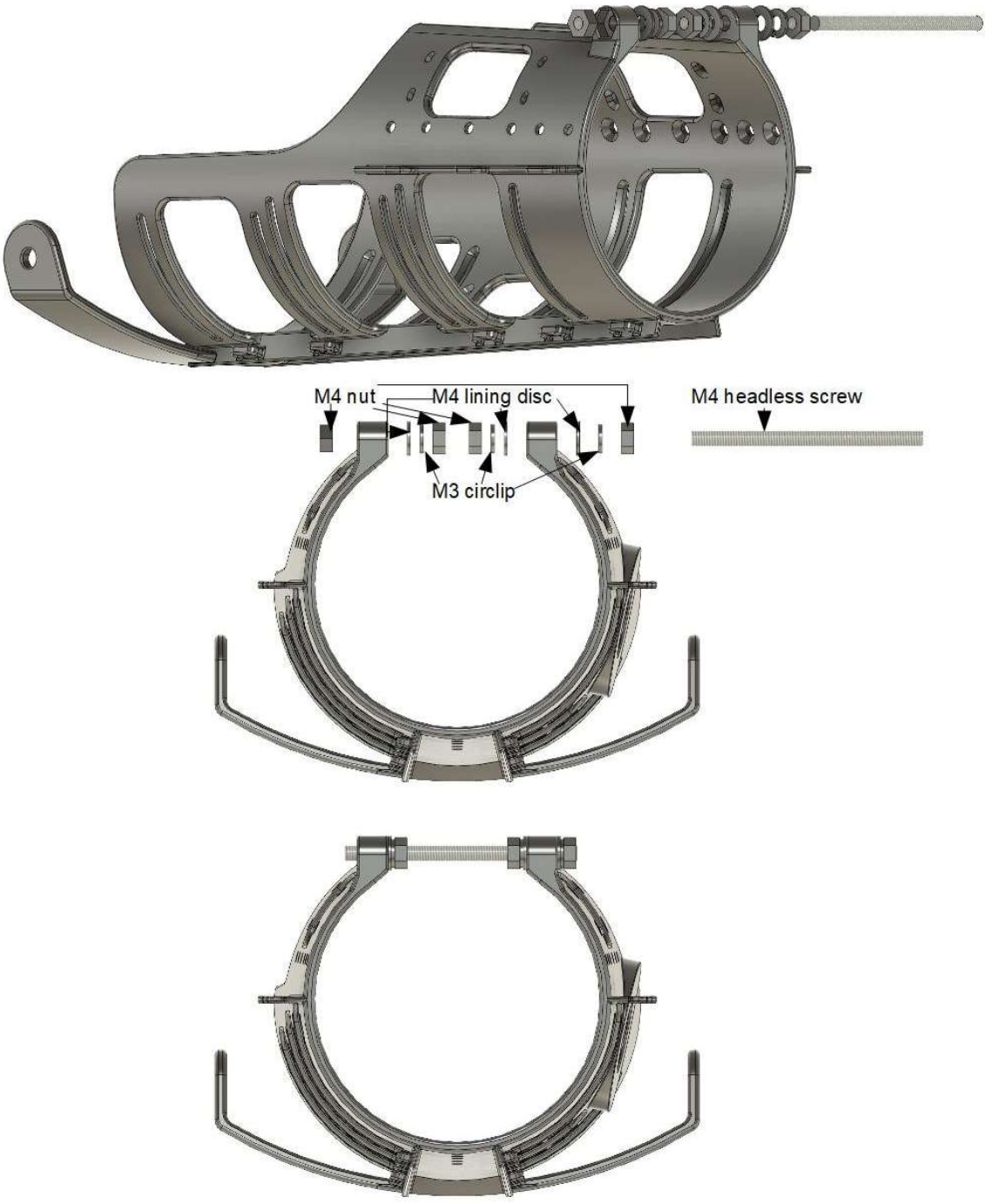

Figure 37: connection of flanges by one M4 headless screw + three M4 lining discs + three M4 circlips + four M4 nuts

The bolts of the double hinge joint consisted of M4 sleeve nuts with a length of 7 mm and 3 mm M4 head screws (see figure 38).

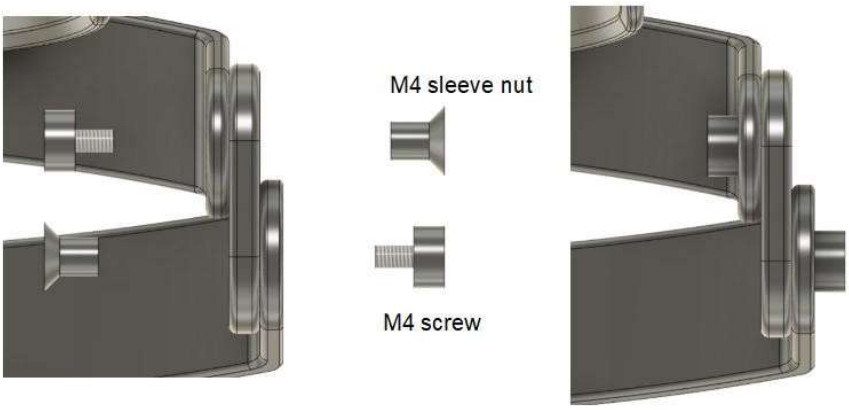

Figure 38: Assembly of double hinge joint by two M4 sleeve nuts + two M4 screws

The completely assembled *BeneFit* socket can be seen in figure 39.

Figure 39: Assembled prosthetic sleeve

After the *BeneFit* socket was assembled, the prosthetic hand with all the other necessary components was mounted.

The lamination ring was connected to the quick disconnect adapter by a simple press fit. From the electric wrist rotator, the protective cover, the lock ring as well as the red protective plug were removed and the motor cable unplugged. The protective cover from MyoRotronic was removed and the motor cable was threaded through the middle. MyoRotronic was slid onto the electric wrist rotator according the right arm arrangement, then the motor cable was plugged into the MyoRotronic. The battery and electrode cables were threaded through the proximal hole of the quick disconnect adapter and the lamination ring.

Afterwards they were connected to the MyoRotronic in the corresponding placement.

The electric wrist rotator was placed into the lamination ring and secured by the lock ring. The SensorHand Speed was mounted onto the distal end of the electric wrist rotator. The two battery cells were bound together using velcro and, together with the charging receptacle, fixated to the outside of the socket with the help of elastic bands. The electrodes were placed into their corresponding openings. The completely assembled prosthesis can be seen in figure 40.

Figure 40: completely assembled prosthesis

2.4 Evaluation of the *BeneFit* socket

A survey was conducted in order to evaluate and improve the construction of the *BeneFit* socket. Occupational and physical therapists, medical doctors, orthopaedic technicians and engineers often work together in order to help amputees. Therefore to get an appropriate feedback not only transradial amputees, but experts from the field of prosthetics took part in the survey. With feedback from users and experts from all the different areas a better understanding of the prosthetic socket could be gained, as well as ideas for improvement.

The corresponding study was designed as a monocentric, non-interventional explorative study. The following lists the talking points covered:

- how comfortable it is to wear
- how stable the prosthetic socket is
- if it provides a stable base for mounting a prosthetic hand
- how much the prosthetic socket restricts movement
- if the prosthetic socket is able to fix electrodes in a certain position, in order that constant contact between the patients skin and the electrode is established

Since in this study no medical treatment was included, the risk for the participants were relatively little, but also the benefits. In line with new insights discovered in the surveys, the design of the prosthetic was re-examined.

Before taking part in the study the participants had to sign an Informed Consent Form. The survey was approved by the ethics committee of the Medical University of Vienna (approval number 1724/2021).

2.4.1 Procedure of the survey

Before taking the survey, the prosthetic socket was shown to the participants, the functions were explained and then they were provided the opportunity to examine and wear the prosthetic socket on a voluntary basis. If the participant was an amputee and consented, the length from the elbow crock as well as the circumference of the remains of the forearm were measured. Afterwards a questionnaire was given to the participants, where feedback and comments were recorded and an additional short interview was conducted.

The questionnaire included in the survey is based on to the Quebec User Evaluation of Satisfaction with assistive Technology (45) and can be seen in the appendix. Two versions of this questionnaire were available depending on the participant's group affiliation. The questionnaire aimed to gauge participant's estimated satisfaction with ten different properties of the *Benefit* socket. This estimate was measured using a scale of 1 to 5, where 1 corresponds to not satisfied at all, 2 to not very satisfied, 3 to more or less satisfied, 4 to quite satisfied and finally 5 to very satisfied.

The properties being assessed are:

- dimensions
- weight
- ease in donning and doffing
- safety, stability and security
- durability
- breathability
- comfort

- effectiveness (the degree to which the device meets the needs)
- range of motion
- fit

The questions from the interview to the participant in this interview included:

- Can you imagine using this prosthetic socket? (For clinicians: Can you imagine your patients using this prosthetic socket?)
- Is there a specific function you would like your (your patients') prosthetic socket to have?
- Are there any comments, remarks or proposals for the next prototype you would like to make?

3 Results

In this chapter, the technical data of the constructed prototype of the *BeneFit* socket is given. Afterwards the results of the survey are presented. First some general results are given and later they are further elaborated on in the subchapters which focus on the questionnaire and the interview respectively.

3.1 The *BeneFit* socket

By using a cushioning material, which meets the standard 100 by Oeko Tex (class 1) and is the only element to touch the skin, the socket is biocompatible.

Through the rail system, the *BeneFit* socket is adjustable in length. The radial part can change its length from 265 mm to 315 mm. If the attached hand prosthesis is included (which has a length of 155 mm), the length has a range from 420 mm to 470 mm.

The diameter of the *BeneFit* socket can also be adjusted using the *RevoFit2*^{TM} system or the adjusting screw. The different diameter can be seen in table 2.

table 2: normal(not adjusted), maximal and minimal diameter and circumference of the radial part of the *BeneFit* socket, at 5 cm and 10 cm distance from the olecranon

	5 cm from the olecranon		10 cm from the olecranon	
	Diameter	Circumference	Diameter	Circumference
Normal	85 mm	267 mm	76 mm	239 mm
Maximal	88 mm	276 mm	81 mm	255 mm
Minimal	66 mm	207 mm	62 mm	195 mm

The *RevoFit2*^{TM} system enables easy donning and doffing of the prosthetic socket or switching between a tight and relaxed state.

It has no fixed centre of rotation between the humeral and radial parts. Sublimation and pronation of the forearm are no longer possible. The maximal angle between radial and humeral part of the socket, without an arm or stump in it, is 195° and the minimal is 60°. If someone is wearing the *BeneFit* socket the maximal angle is of course 180°, the minimal angle varies. For thinner forearms the minimum stays at 60° but for thicker ones it can change. For example in a few cases it increased to 80°.

The socket itself weighs 500 g. If the MyoBock electrodes, electric wrist rotator, MyoRotronic, lamination ring and MyoEnergy Integral and Ottobock SensorHand Speed are included the whole system weighs 1120 g.

With the help of bridges or the pads MyoBock electrodes can be fixed on the *BeneFit* socket. A prosthetic hand can be mounted securely to the socket, after installing a lamination ring as well as an electric wrist rotator and some other parts in the cylinder of the quick disconnect adapter.

3.2 Results of the survey

Of the thirteen participants in the survey, four are amputees, of which three actively work in the field of prosthetics. All amputated individuals are male and only one has an amputation on the right side of the body. Within this group of participants, the time since the loss of the hand ranged from 17 weeks to 11 years. In one case the absence of the limb was due to Dysmelia, therefore, the individual had an absent limb since birth.

The length from the olecranon to the tip of the stump ranges from 7 cm to 16 cm. The circumference of the forearm 5 cm from the olecranon has a scope from 24 cm to 20,5 cm and a mean value of 22,125 cm. At a distance of 10 cm the maximal value of the circumference is 26 cm, while the minimum is 17,5 cm. Of the nine experts three are female and six male. Two medical doctors, three orthopaedic technicians, one textile engineer, two occupational and one physical therapists took part in the survey. Their experience in their field ranged from 6 months to 40 years.

All participants without an amputation, who attempted to don and doff the *BeneFit* Socket were successful in achieving a relatively good fit (see figure 41). All of them were able to control the prosthetic hand (open/close and rotate to left or right). No adaptation of the electrode position was necessary.

Of the four amputees participating, one was not able to don the socket, due to the unconventional shape of his stump. The other three were able to don the socket and move the prosthesis as a whole, but none of them achieved a good fit on their stump (see figure 42). This is due to the big minimal circumference of the socket compared to the circumference of the stumps. Only one tried to control the hand, which was possible for him, but only by forcing contact between the stump and the electrodes.

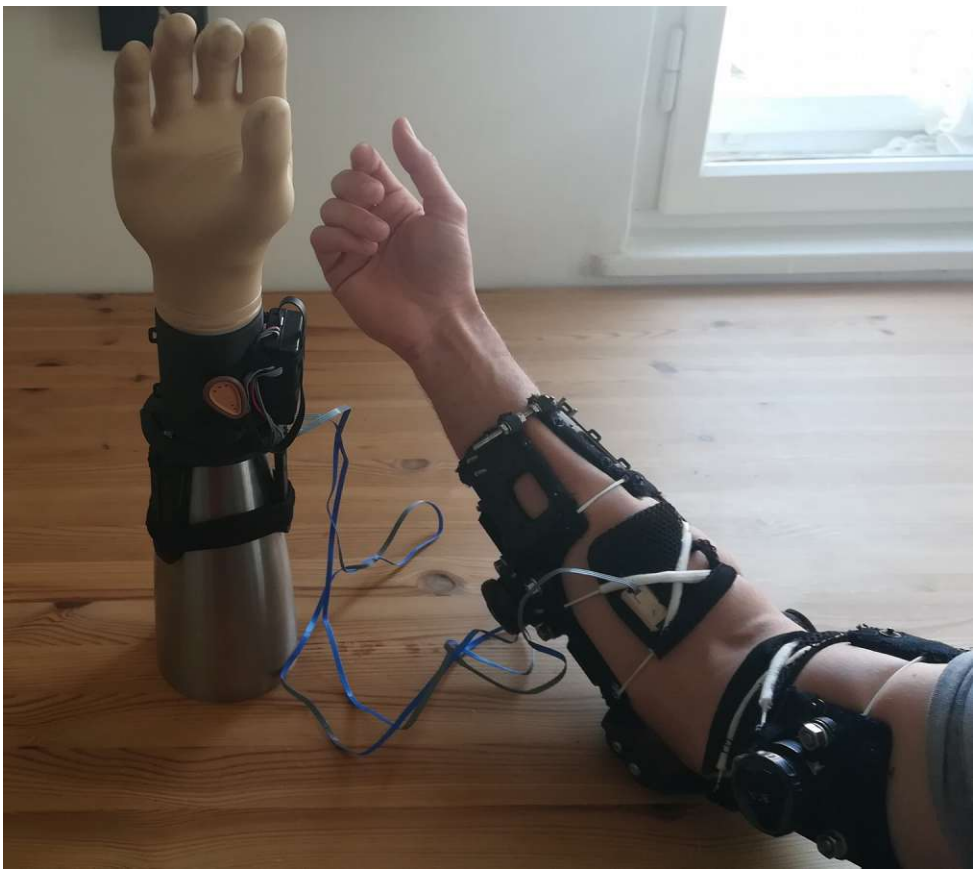

Figure 41: Test setup for people without an amputation. The rails are disconnected from the radial part, the quick disconnect adapter and the prosthetic hand are removed. The participant is able to don and doff the prosthesis and control the prosthetic hand with the help of the electrodes

Figure 42: Volunteer/amputee wearing the *BeneFit* socket on the left side

3.2.1 Results of the questionnaire

The estimated satisfaction of all participants with the ten different properties of the *BeneFit* socket can be seen in figure 43 in form of a box plot and their corresponding values can be found in table 3. Figure 44 and table 4 present information for only amputees, whereas information reflecting expert's satisfaction can be seen in figure 45 and table 5.

The overall average estimated satisfaction is: 3,918 (very close to 4 which corresponds to the statement quite satisfied). For the amputees this number is 3,475 and for the experts 4,128.

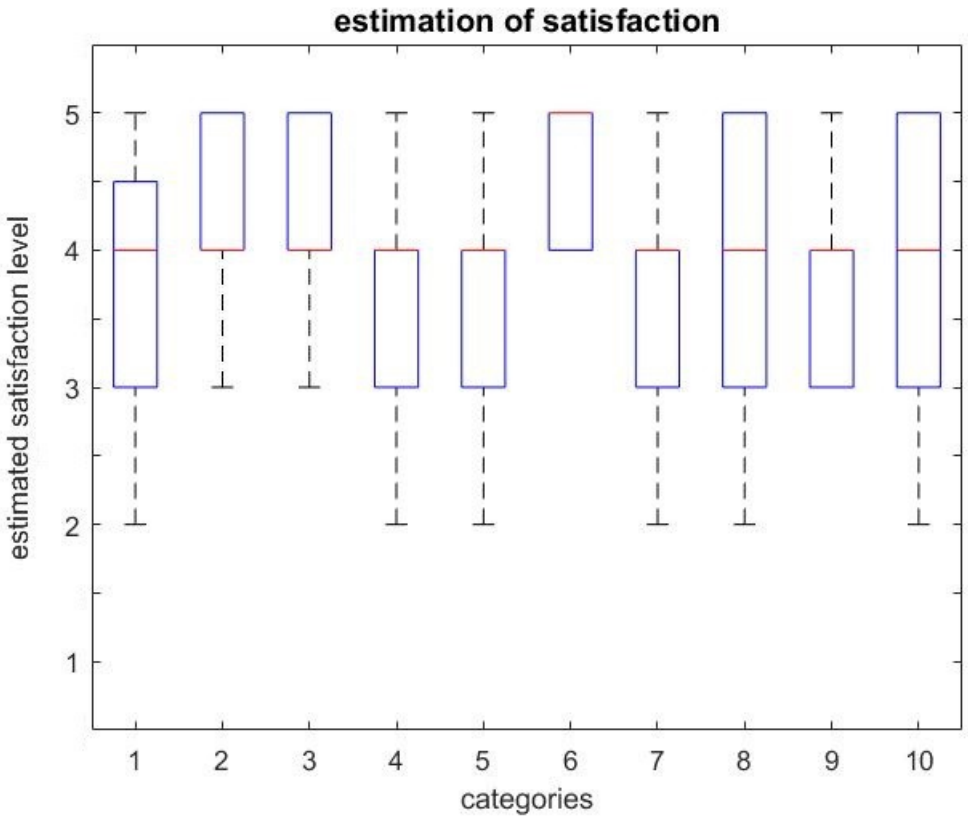

Figure 43: boxplot of estimated satisfaction of all participants:

satisfaction level: 1=not satisfied at all; 2=not very satisfied; 3=more or less satisfied; 4=quite satisfied; 5=very satisfied;

categories: 1=dimensions; 2=weight; 3=ease in donning and doffing; 4=safety, stability and security; 5=durability; 6=breathability; 7=comfort; 8=effectiveness; 9=range of motion; 10=fit

table 3: results questionnaire all participants

	mean	median/ most frequent value	maximum/ minimum	standard deviation/ variance
dimensions	3,71	4 / 4	5 / 2	1,05 / 1,11
weight	4,31	4 / 5	5 / 3	0,75 / 0,56
ease in donning and doffing	4,39	4 / 4	5 / 3	0,65 / 0,42
safety, stability and security	3,62	4 / 4	5 / 2	0,96 / 0,92
durability	3.58	4 / 4	5 / 2	0,79 / 0,63
breathability	4.69	5 / 5	5 / 4	0,48 / 0,23
comfort	3,54	4 / 4	5 / 2	0,97 / 0,94
effectiveness	3,8	4 / 5	5 / 2	1,11 / 1,23
range of motion	3,77	4 / 4	5 / 3	0,7 / 0,48
fit	3,77	4 / 5	5 / 2	1,07 / 1,15

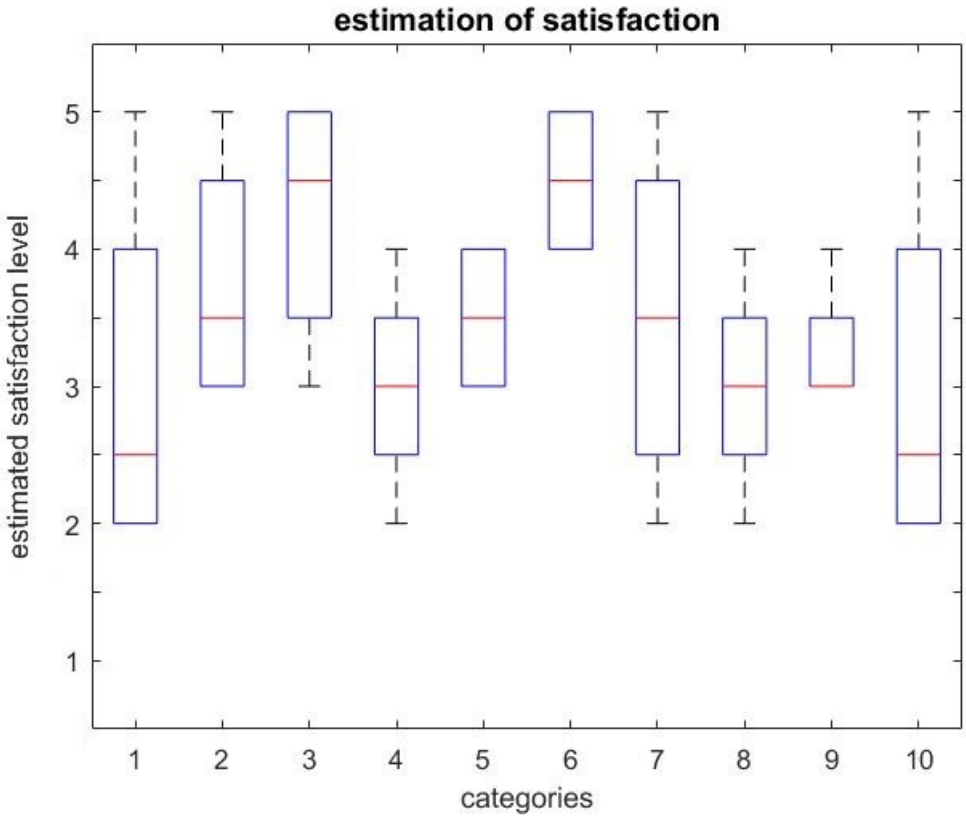

Figure 44: boxplot of estimated satisfaction of the amputees: categories: 1=dimensions; 2=weight; 3=.ease in donning and doffing; 4=safety, stability and security; 5=durability; 6=breathability; 7=comfort; 8=effectiveness; 9=range of motion; 10=fit

table 4: results questionnaire amputees

	mean	median/ most frequent value	maximum/ minimum	standard deviation/ variance
dimensions	3	2,5 / 2	5 / 2	1,41 / 2
weight	3,75	3,5 / 3	5 / 3	0,96 / 0,92
ease in donning and doffing	4,25	4,5 / 5	5 / 3	0,96 / 0,92
safety, stability and security	3	3 / 3	4 / 2	0,82 / 0,67
durability	3,5	3,5 / 3	4 / 3	0,58 / 0,33
breathability	4,5	4,5 / 4	5 / 4	0,58 / 0,33
comfort	3,5	3,5 / 2	5 / 2	1,29 / 1,67
effectiveness	3	3 / 3	4 / 2	0,82 / 0,67
range of motion	3,25	3 / 3	4 / 3	0,5 / 0,25
fit	3	2,5 / 2	5 / 2	1,41 / 2

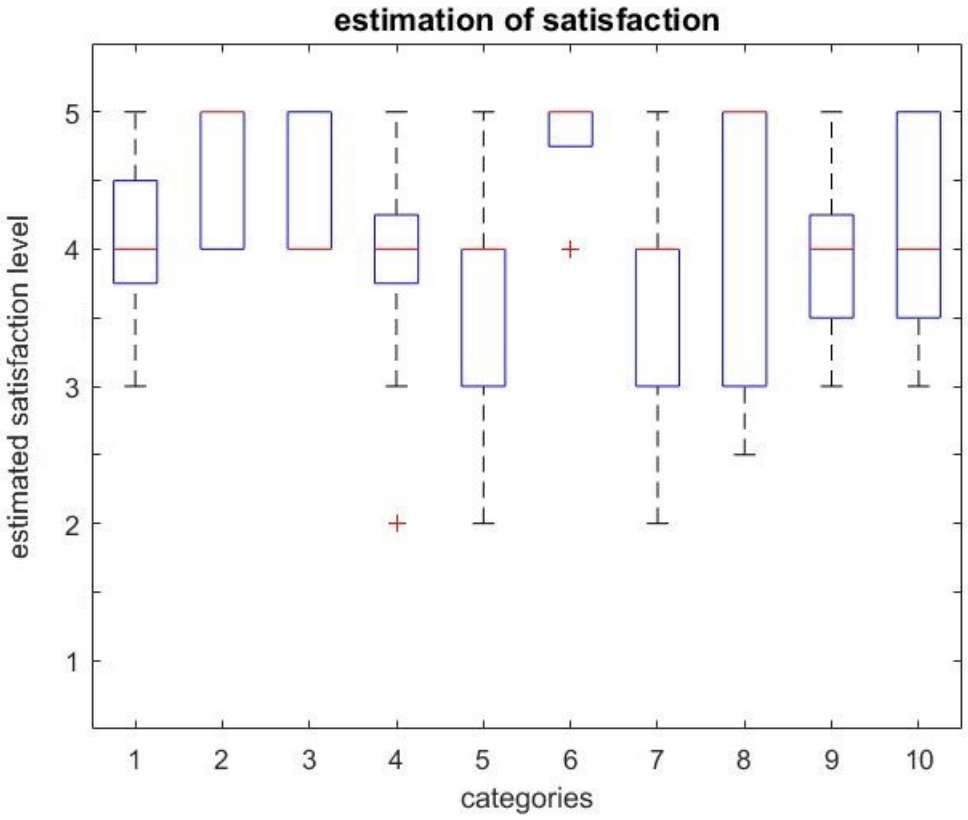

Figure 45: boxplot of estimated satisfaction of the experts:

satisfaction level: 1=not satisfied at all; 2=not very satisfied; 3=more or less satisfied; 4=quite satisfied; 5=very satisfied;

categories: 1=dimensions; 2=weight; 3=ease in donning and doffing; 4=safety, stability and security; 5=durability; 6=breathability; 7=comfort; 8=effectiveness; 9=range of motion; 10=fit

table 5: results questionnaire experts

	mean	median/ most frequent value	maximum/ minimum	standard deviation/ variance
dimensions	4,06	4 / 4	5 / 3	0,68 / 0,46
weight	4,56	5 / 5	5 / 4	0,53 / 0,278
ease in donning and doffing	4,44	4 / 4	5 / 4	0,53 / 0,278
safety, stability and security	3,89	4 / 4	5 / 2	0,93 / 0,86
durability	3,71	4 / 4	5 / 2	0,95 / 0,9
breathability	4,78	5 / 5	5 / 4	0,44 / 0,19
comfort	3,56	4 / 4	5 / 2	0,88 / 0,78
effectiveness	4,17	5 / 5	5 / 2,5	1,06 / 1,13
range of motion	4	4 / 4	5 / 3	0,66 / 0,44
fit	4,11	4 / 4	5 / 3	0,74 / 0,55

In the questionnaire, the participants were also asked to mark three of the ten items they consider to be the most important. The results can be seen in figure 46 or table 6.

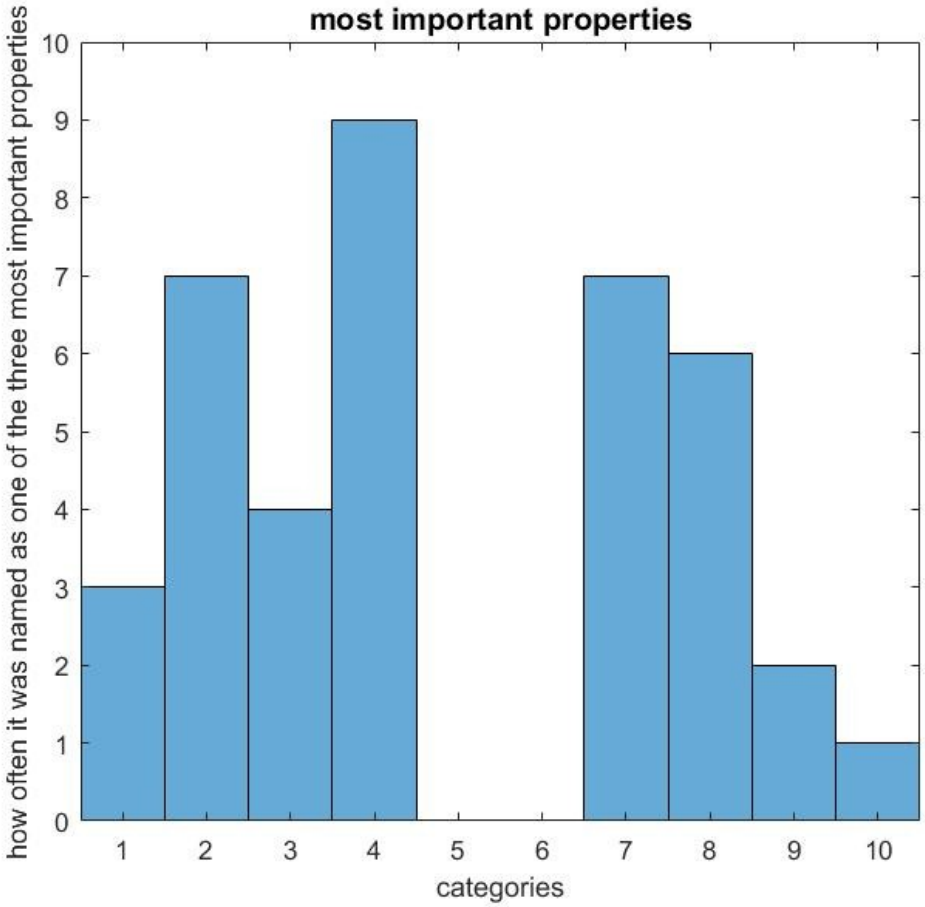

Figure 46: Histogram of how often properties were named as one of the three most important items (1=dimensions; 2=weight; 3=.ease in donning and doffing; 4=safety, stability and security; 5=durability; 6=breathability; 7=comfort; 8=effectiveness; 9=range of motion; 10=fit

table 6: properties ranked after importance

Rank	Votes	Properties	Rank	Votes	Properties
1.	9	safety, stability and security	6.	3	dimensions
2.	7	weight	7.	2	range of motion
2.	7	comfort	8.	1	fit
4.	6	effectiveness	9.	0	breathability
5.	4	ease in donning and doffing	9.	0	durability

3.2.2 Results of the interviews

Everyone involved in the study could envision themselves or patients/clients using a prosthesis of this type, but often only in a limited setting, such as in a rehabilitation centre or as an intermediate solution (as it is intended). It was repeatedly mentioned, that such a prosthesis is useful and that there momentarily is a gap which this prosthesis could fill.

Other specifics discussed most often include the overall dimensions, - which are currently too big – the electrode positions – which should be as individually adaptable as possible – the placement of the BOA reel – which could be positioned symmetrically – and the possible cushioning of the yet unfastened laces.

4 Discussion

In this chapter a few points of the study are discussed. Then the satisfaction of the requirements is analysed, followed by some new ideas for improvements for a second generation.

4.1 General feedback

The adaptability of the *BeneFit* socket is the main advantage. Through its changeable length and diameter it is possible to fit different patients with this socket and provide them with the opportunity to make their first contact with a prosthesis and so use the invaluable time of the “Golden Period” before the individual socket is supplied.

Most of the participants seemed to like the idea and concept of the socket rather well. They could imagine using this or a similar prosthesis as a first test, a first contact or also for testing, whether a prosthesis is controllable with electrodes. There might be a bias in this study, since the participants are not part of a random sample, but rather, are individuals selected based on their interest in the research topic. Since the survey was done face to face with the creator of the *Benefit* socket, the participant might also be inclined to give more positive feedback, then negative.

Often, they only saw limited use in daily life. For example, one expert, an orthopaedic technician with many years of experience, said, he could imagine such a socket being successful in rehabilitation centres or a similar context, but could not see this being a marketable success. Additionally, he could see potential for a similar concept for a body-powered prosthesis (though similar concepts are already available on the market). Furthermore, he stated, that he

could imagine a similar product being useful for the lower extremities, for transtibial amputees.

Another area of application was suggested in the interviews: the changeability of the socket would be very useful when supplying children with a prosthesis. With this added advantage children would not need to change socket that often. Of course the design would need to be scalded down significantly.

4.2 Satisfaction of requirements

From the results in chapter 4.2.1 it can be seen that overall satisfaction is close to 4 (corresponding to "*quite satisfied*"), which for a first prototype is a relatively good result. Still, it should be noted, that the participating amputees were less satisfied. This is especially noticeable in the categories of dimensions, weight, safety, stability and security, effectiveness, range of motion and fit.

The dimensions of the current *BeneFit* model were too big for all the amputees, which of course also affects the perceived safety, stability and security since there is no secure fit possible. This is due to the fact that the *BeneFit* socket was modelled using the measurements of forearms of persons without amputations. Because of this all experts were able to don and doff the socket, which probably will not be the case for a new design with smaller dimensions. The amputees often have a smaller circumference of the arm with the amputation, which could be also due to the muscular atrophy because of the missing hand (46). Changing the dimension will hopefully also raise the satisfaction level of the safety, stability and security, comfort and thereby also effectiveness. If these properties of the *BeneFit* socket could be improved, it

would be an important step, since they are also three of the four most important satisfaction items (see chapter 4.2.1).

The weight of the socket itself is small (500 g), but the electric wrist rotator, the MyoRotronic, the MyoEnergy Integral and SensorHand Speed add some considerable weight (620 g). This can also explain why the experts, where the quick disconnect adapter (756 g) was removed in order for them to be able to don the socket (see figure 41), scored the weight better than the amputees. Since all of the previously mentioned items, except the battery, have to be placed at the distal end of the prosthesis, the moment arm is rather large and therefore the moment, that needs to be exerted by the elbow, increases significantly. By shortening the socket and therefore the moment arm, the moment can be decreased and thereby the perceived weight of the prosthesis should be decreasing as well. Since the terminal device and the other necessary electronics tend to be heavy, compared to the socket, this is a rather common problem in prosthetics.

During the survey the battery was mounted on the quick disconnect adapter (which was criticised by some participants) in order to provide a faster adaptation of the socket, so it did not need to be moved, when the quick disconnect adapter was removed. Surely, the battery can be moved to a more proximal location on the prosthesis, which was the original intention. The various loops and slits found on the socket allow the battery to be placed on the patient's prefered location.

According to the questionnaire (see chapter 4.2.1) the socket is easy to don and doff, thanks to the RevoFit2™ systems. But it was mentioned that this system is only usable by unilateral amputees. If the patient were to be missing both their

arms, they would not be able to use it. Also, to open the RevoFit2™ system a sufficient force is necessary, which requires a relatively healthy other arm of the patient. However, it should be mentioned that all amputees were able to open and close the system.

The participants involved in the survey had some difficulties judging durability, since they could only see, handle and test the prosthesis for a short period of time. This was often mentioned, while filling out the questionnaire. In general, the durability of the *BeneFit* socket seemed to be judged as the least important factor in the survey, as it received no votes (see chapter 4.2.1). This may be due to the fact that its intended purpose is acting as an intermediate solution. According to one participant 3D printed materials often are not sufficiently robust.

The other satisfaction item which received zero votes, is the breathability of the socket, even though in literature this is one of the more common problems among other suspension methods, like the Vacuum suspension (see chapter 2.2.1 and 2.2.2). The *BeneFit* socket is rather satisfactory regarding this property. At one point, a participant mentioned concerns that too much breathability may not provide enough protection against cold weather.

For the amputees, where the prosthesis did not achieve a good fit, the range of motion was also not easy to evaluate. Like many other sockets the *BeneFit* socket inhibits the pronation or supination of the forearm. The range of motion could be increased for example by widening the proximal recess on the radial part for the elbow, but it would also decrease the stability of the socket. Since the stability is deemed to be of more importance than the range of motion and the satisfaction level of the range of motion is higher than the one of safety,

stability and security, rather the opposite should increase the general satisfaction level of the whole prosthetic socket. It is difficult to find the right compromise between the two opposing properties.

In the questionnaire the aesthetics of the *BeneFit* socket are neglected, but they were discussed a few times in the interviews. The relatively technical, once also referred to as high-tech, look, was appreciated by some, while others would have preferred a more natural look. This will of course differ from person to person and can not be generalised. The look might not be the most important quality of a prototype but should nevertheless be considered.

table 7: satisfaction of requirements

Requirements	Satisfaction
fit the majority of people	~
easy to adjust in diameter and length	+
easy to don and doff	+ (4,39)
Switch between relaxed state and a tightened state	+
provide a stable base for mounting a prosthetic hand	~ (3,62)
provide space for electrodes	+
Comfortable	~ (3,54)
breathable	+ (4,69)
biocompatible	+
lightweight	+ (4,31)
restrict the movement as little as possible	+ (3,77)
not have a fixed centre of rotation	+

4.3 Towards the revised design – a second generation of the *BeneFit* socket

Removable cushioning:

Already in the first two interviews it was empathized, that a prosthesis of this kind needs to be cleanable. This is very important for hygienic reasons. The cushioning layer should be removable so that it can be switched for different patients. Since this is an important property and has no real disadvantages, a

solution was found and tried immediately. This solution was presented in the rest of the survey.

Similar to chapter 3.2.4 two cushioning layers were fashioned out of the 3MESH spacer material, but no slits had to be cut for the screws and the holes for the electrodes were often not completely cut out. Then the male parts of twenty snap fasteners (six on the distal end, four on the upper side and ten around the hole for the elbow) were sewn to the old cushioning layer of the radial part which already is glued to the hard shell. The same was done with thirteen male parts of snap fasteners (five on the proximal end, two on the distal end and six around the hole near the elbow) on the humeral part. The male part of snap fasteners are placed on the outside of the prosthesis, so no pressure marks are created (see figure 47). In a new prosthesis the snap fasteners could be sewn directly to the hard shell, by adding small holes in the corresponding places to the model of the hard shell.

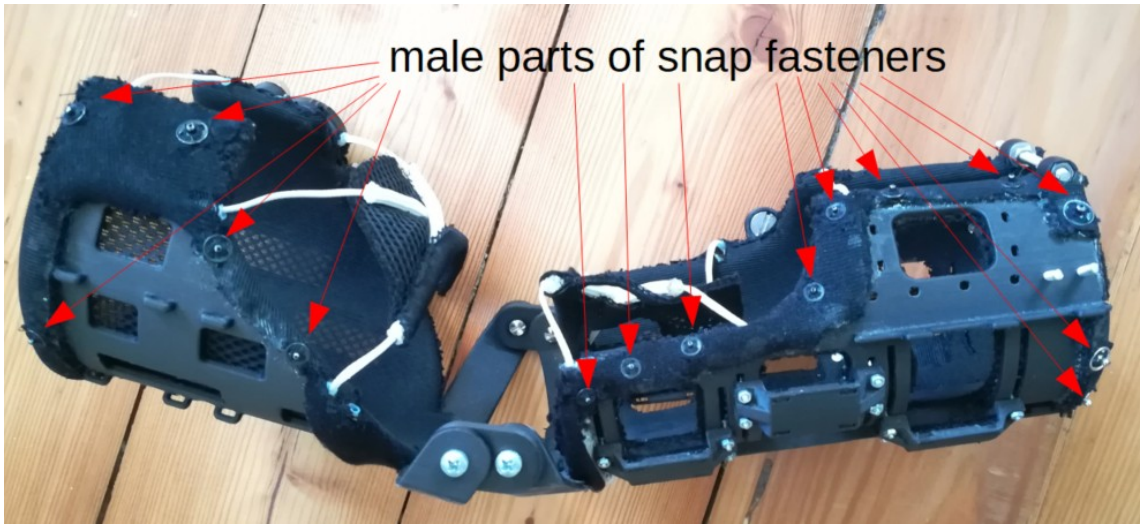

Figure 47: humeral and radial parts with male parts of snap fasteners sewn on

The twenty or respectively thirteen female parts of the snap fasteners were sewn to the new cushioning layer for the radial or humeral part in the corresponding places. Additionally four sets of snap fasteners were sewn to the cushioning layer of the radial part as well as two elastic bands in order to create four loops. The same was done with two elastic bands and two sets of snap fasteners for the humeral part. The cushioning layer of the humeral part was also partially sewn together to fit nicely around the proximal edges (see figure 48 and 49).

Figure 48: cushioning layer of radial part with snap fasteners and elastic bands

Figure 49: cushioning layer of humeral part with snap fasteners, elastic bands and partially sewn together

By fastening the snap fasteners the cushioning layer can be attached to the hard shell and also due to the inherent stability of the 3MESH spacer material it stays in place (see figure 50). The cushioning layer now is also smoother due to the absence of slits, which are no longer necessary since the layer can be removed in order to access the screws.

Figure 50: radial and humeral part of the *BeneFit* socket with second cushioning layer attached: above: seen from the side; below: seen from the back

Hole in bridges:

Another idea suggested in an interview was to add a hole to the bridges in order to be able to access the dial, which can be used to change the amplification of the electrodes. This would have the advantage that the bridge would not need to be removed, when the amplification setting is changed and does not seem to have any disadvantages.

Also an additional hole on the distal end to thread the electrode cable through should be useful.

Rails:

A new rail model, which has connections across the big slit in the middle, could prevent the rails from deforming and enlarging their slit, if a screw which passes through the middle is tightened. Then the elastic band would no longer be necessary. A model of this rail can be seen in figure 51.

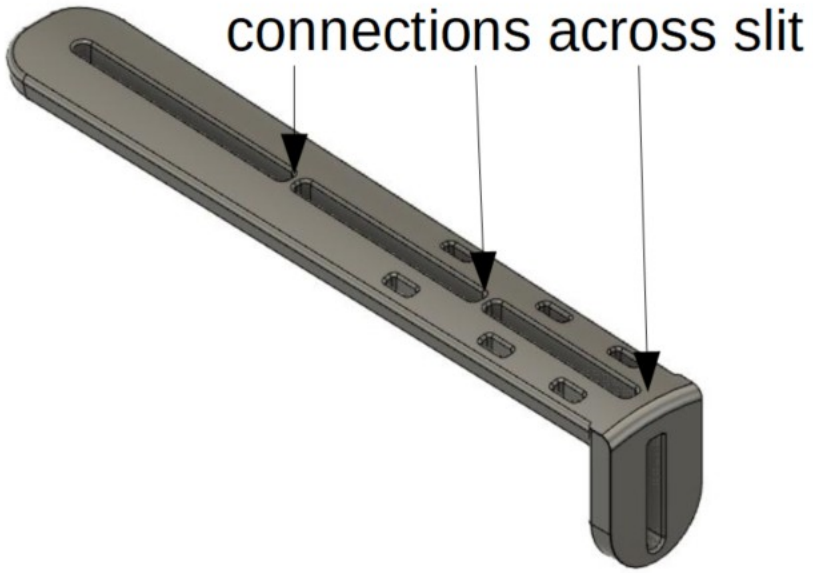

Figure 51: second version of a rail with additional connections across the slit

Dimensions:

As already mentioned in chapter 5.1 the dimensions of the socket need to be adjusted. From the new measurement from the survey a diameter of 83 mm at 5 cm distance from the olecranon and a diameter of 74 mm at 10 cm distance would seem a good idea. The length as well should be shortened, not only to provide shorter options but to reduce the perceived weight (see chapter 5.1).

The most distal electrode holes were never used and are probably unnecessary. The recess for the elbow also seems to be rather large and stability could be gained by scaling it down. Then the High Power Boa® Reel could be moved to a more proximal location.

Another option to shorten the prosthetic socket would be to use a prosthetic device without rotation. By eliminating the rotation the cylinder of the quick disconnect adapter could be shortened, because the electronics necessary for this take up less space. This is an additional option which could be provided and chosen after the patients preference.

Cushioning pads:

The laces of the RevoFit2™ system create pressure marks and are not really comfortable where they directly touch the skin (see figure 52). The cushioning pads in the recesses of the elbow are rather small. They were chosen so that if the socket is closed to its minimal size, there are no free laces. This was done so that there would not be any overlap or blockage before the minimal diameter was reached.

A solution for the pressure marks might be to offer multiple cushioning pads in different sizes, which can be attached to the already existing pad with snap fasteners or something similar. This would also make the *BeneFit* socket more hygienic since the cushioning which touches the skin can then be easily exchanged.

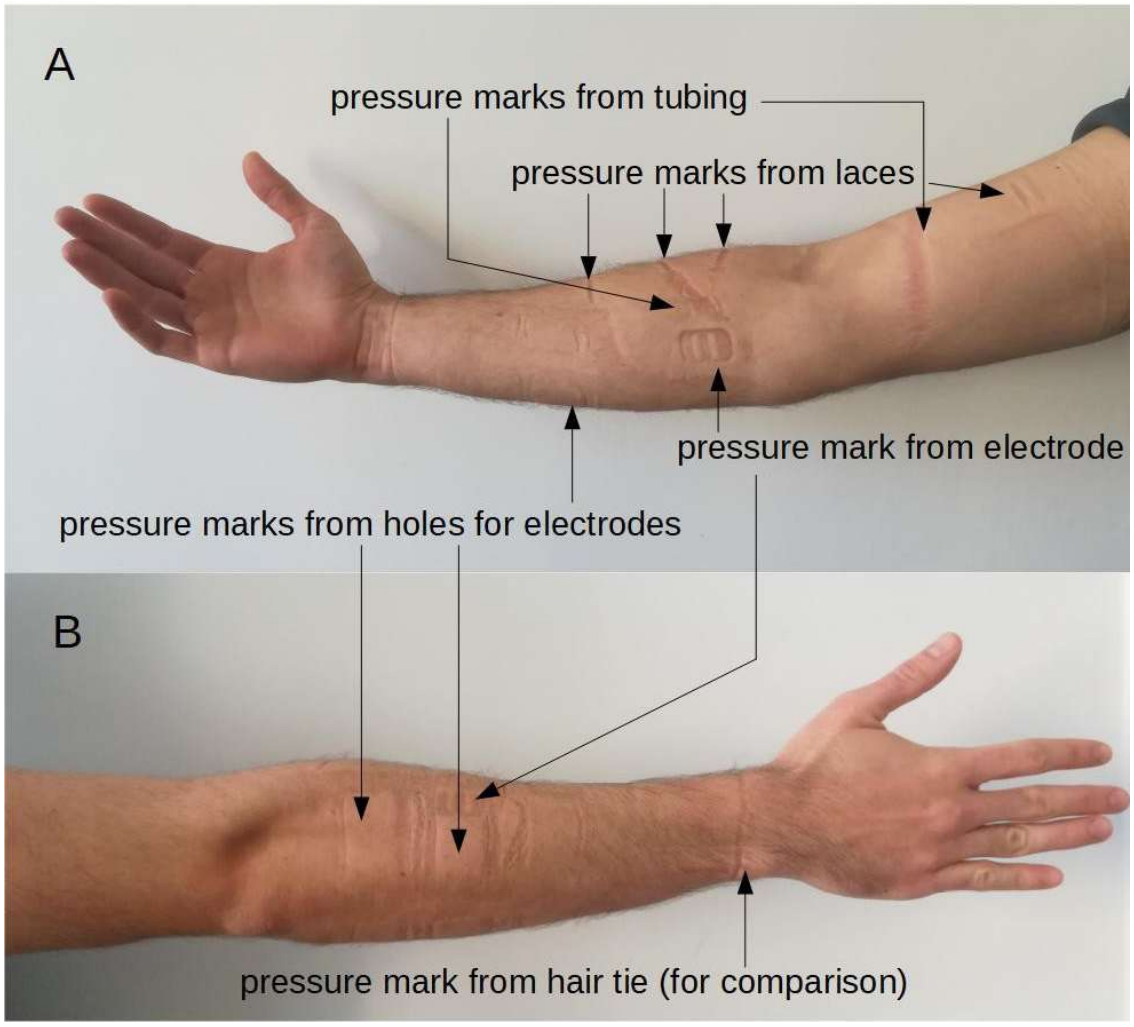

Figure 52: pressure marks from tubing, laces and electrodes on arm after wearing the socket for one hour, A: anterior side arm, B: posterior side arm

Another proposed idea is to exchange the cushioning pads with plastic caps. These caps should be made from a not too rigid material. They should distribute the pressure more evenly and the electrodes could also be mounted more securely. Such a pad should eliminate the pressure marks of the tubing (see figure 52). This pad would need to be cushioned, but this should not be a problem. It could be done similar to the cushioning of the hard shell. The solution mentioned in the passage before should be feasible with such a cap as

well. A disadvantage of such a pad could be that it could decrease the range of motion, or the comfort when the elbow is flexed.

As can be seen in figure 52 the holes in the hard shell and the cushioning material leave marks as well on the forearm, but not on the upper arm. This might be solved by having the cushioning layer individual adjusted, that only a hole is cut for the specific electrode position for each patient, after the best place for the electrode is selected. Another solution proposed in an interview is the closure of the holes with lids. The lids could be attached similar to the bridges. These lids would have the disadvantage of making the socket less breathable and heavier.

Distal cap:

The addition of a distal cap was suggested in the interviews from an orthopaedic technician. It should increase the comfort as well as the stability. This cap needs to be able to change its position along the longitudinal direction. This can be achieved by using something similar to the rail system. The rails for this new system could be attached to the already existing rails or to the quick disconnect adapter or on the outside or inside of the radial part. Each of these propositions would have advantages and disadvantages.

For example if they were to attach to the inside of the radial part, it is difficult to find a good arrangement with the cushioning material. If they were to be mounted on the outside, holes would be necessary for them to go through the radial part. Multiple rails would be necessary if they are attached to the quick disconnect adapter, which could have a negative impact on its stability.. The

connection to the other rails might not always be possible, for example if the socket is in the shortest configuration.

Casing battery and cables:

One should also keep in mind that a final design should be able to encase the battery and the cables. This would decrease the risk of getting caught on something and protect the components from excessive wear. A casing for the battery should not be a problem. The cables could for example be put between the hard shell and the cushioning 3MESCH. This could decrease the comfort and lead to pressure marks. An alternative idea is to attach the cables to the fins and at least partially cover them there.

Canals for Tubing:

Since now the best-suited positioning of the RevoFit™ Tubing is found, small walls could be added to the outside of the hard shell. There the tubing should be fixated, small holes in the fins should be added for the tubing to go through. This would simplify the process of mounting the RevoFit™ Tubing considerably and provide a more stable bond. The disadvantage could be that the hard shell might loose a bit of the flexibility in the radial direction, but this should only be a minor effect. Also the tubing could no longer be mounted as flexible.

BOA system

There might also be an even better suited BOA systems available as a fastening mechanism. The RevoFit2™ is rather large. It was criticised in the interviews for standing out to much, which could lead to abrasive wear. Smaller

and flatter ones could thereby be advantageous. Also there are some which do not need a tubing. Since one critic was that the RevoFit2™ needs a not marginal force to be opened, there might also be some systems available where less force is necessary.

The position of the High Power Boa® Reel could also be changed. Especially the one on the humeral part was criticised, since it poked some participants in their side. By moving it to the back of the *BeneFit* socket, the socket would be symmetric and the High Power Boa® Reel would certainly no longer be able to poke the patients side. A disadvantage could be that the High Power Boa® Reel would be more difficult to access.

In an interview it was suggested, to move the most proximal tubing on the radial part to a more distal position. This could increase the range of motion, but it could also decrease the stability. Therefore it might not be the best idea since stability seems to be of more importance than range of motion (see chapter 4.2.1)

Fixation of electrodes:

In a few interviews it was empathized that the electrode position should be as flexible as possible. In the current model they have three discrete options for their position along the longitudinal axis and can be adjusted continuously along the radial direction. To make them freely adjustable along the longitudinal axis one could sacrifice the continuous radial adaptability and offer some discrete options for the radial direction, so simply using the same system only turning it 90 degrees. To make them both in longitudinal and radial direction freely adjustable no easy solution comes to mind.

Since the electrodes only have a depth of 4,5 mm under the arms and the hard shell is 3 mm tick as well as the cushioning 3MESCH spacer material, the electrodes, which are fixated by the bridges, are just able to establish skin contact, because the spacer material is pressed together. The bridges currently use the 3MESCH spacer material as a spring to push the electrodes to the skin. As can be seen in picture B of figure 52 this works, since a pressure mark from the electrode is clearly visible.

Still it would be preferable to have the electrodes penetrate deeper into the socket, but also be able to be pushed back elastically. This would secure the skin contact more firmly. By using an elastic material for the bridges and have the bridges connected to the electrodes directly like the arms currently do, this might be achieved.

In an interview it was suggested to connect directly the electrodes to the socket, by also modelling the arms of the electrodes to the radial part. This would have the advantage that the electrodes could be mounted more easily and quicker, but also the disadvantage that then only discrete electrode position would be possible and no longer a continuous change of the position. Also the elasticity of the electrodes going back would no longer be possible and these arms might be a weak point. If an arm was to break, the positioning of an electrode at this point would no longer be possible and therefore the whole radial part would need to be exchanged.

Another idea suggested in an interview was the addition of a removable cushioning pad, which can fixate another electrode. Such a pad has been fabricated out of 3MESH spacer material and can be seen in figure 53. The 3MESH was cut in the appropriate form. The outer textile shell and inner plastic

tubing of the RevoFit2^{TM} Tubing were cut open on one side. The outer textile shell and four pairs of snap fasteners were sewn on. The pad can be attached to the *BeneFit* socket by first threading the inner plastic tubing onto the laces, placing them into the textile shell and closing the snap fasteners.

Figure 53: additional pad for fixation of an electrode, above on the left: open, inner plastic tubing, outer textile shell and snap fasteners are visible; above on the right: closed; below: mounted on laces with electrode attached

Elbow joint:

There was no real consensus whether the double hinge joint needs more stability or more flexibility or has already the right middle ground. One suggestion which should not be too difficult and expensive to test is using longer plates of the double hinge joint. Also multiple length options could be provided to a patient and changed without much effort, so that the amputee could decide which suits him the best.

The double hinge joint of the tested *BeneFit* socket has a large width. This was chosen so that neither the arcs nor any other part of the double hinge joint can touch the skin of or around the elbow. But this rather generous width has the disadvantage, that it sticks out and therefore could get caught on something or poke the patient a little bit in their side. A smaller width would be preferable, but here also a compromise has to be found, so that it does not get to small and start touching the skin or even worse collide with the patients arm in certain positions.

Material:

That the 3MESH spacer material is pleasant enough for the patients themselves is not a given, which was questioned/reviewed in the interviews. Longer tests with amputees would be necessary to determine this question. A suggestion was the addition of small individual silicone patches for each patient. This could take some time and might complicate the procedure.

Additional remarks:

An interviewee commented that the design should be as modular as possible. It should be feasible that if multiple designs of different parts are available, that all are combinable.

Another remark mentioned in an interview was to reduce the screw connections. Screws have the advantage of being easily available and replaceable. They can be adjusted just as needed. In a later product of course different solution could replace them.

5 Conclusion

In this thesis an adjustable, temporary, transradial prosthetic socket, called the *BeneFit* socket, was designed. With the added adaptability of the sockets size it should be easier to fit more patients within the “Golden Period” and thereby improve their quality of life.

Following the production and assembly of the socket’s various components, a survey was conducted to evaluate it benefits and possible shortcomings.

The socket consists of two layers, a 3D printed hard shell made from Onyx and a cushioning 3MESH spacer material. The diameter of the socket can be changed. The length can be adapted using the rail system. Electrodes can be placed into the holes of the prosthesis and fixated there by bridges.

The *BeneFit* socket does not have a fixed centre of rotation and thereby adjusts to the individual anatomical rotational axis of the patients elbow. It is biocompatible. The design can be considered light-weight as it does not exceed 500 grams. With the fastening mechanism it is possible to switch between a relaxed state and a tightened state.

From the survey one can see that the *BeneFit* socket is judged to be quite satisfactory. It scores rather well for the easiness with which it is donned and doffed and for the breathability. It scores worse in safety, stability and security, comfort and range of motion, but not too badly (between more or less satisfied and quite satisfied). In the survey no participant ever marked one point as being not satisfactory at all.

Of course the design of *BeneFit* socket should undergo some changes. The most important one being the scaling down of the dimension in diameter and length.

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7 Appendix

Product Specifications: Markforged Mark Two

Material Datasheet: Composites/Onyx

Questionnaire: amputees and experts (in German)

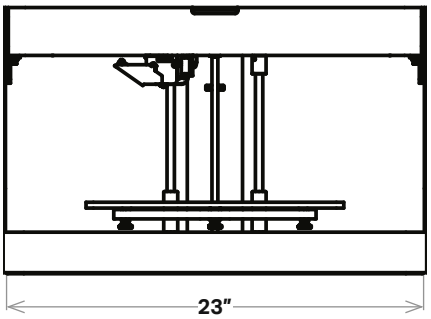
PRODUCT SPECIFICATIONS

Mark Two (Gen 2)

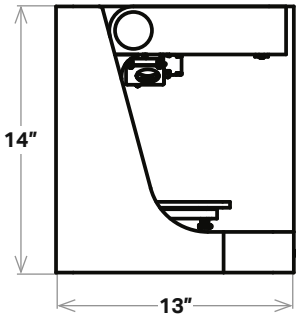
Replace machined aluminum tooling—jigs, jaws, and fixtures—with stronger parts for a fraction of the price. The Mark Two combines our unique continuous carbon fiber reinforcement with workhorse reliability for versatile parts with 26x the strength of ABS, ready same-day for use straight off the printer.

Printer Properties	**Process**	Fused filament fabrication, Continuous Filament Fabrication
	Build Volume	320 x 132 x 154 mm (12.6 x 5.2 x 6 in)
	Weight	16 kg (35 lbs)
	Machine Footprint	584 x 330 x 355 mm (23 x 13 x 14 in)
	Print Bed	Kinematic coupling — flat to within 160 µm
	Extrusion System	Second-generation extruder, out-of-plastic detection
	Power	100–240 VAC, 150 W (2 A peak)
	RF Module	Operating Band 2.4 GHz Wi-Fi Standards 802.11 b/g/n
Materials	**Plastics Available**	Onyx, Nylon White
	Fibers Available	Carbon fiber, fiberglass, Kevlar®, HSHT fiberglass
	Tensile Strength	800 MPa (25.8x ABS, 2.6x 6061-T6 Aluminum) *
	Tensile Modulus	60 GPa (26.9x ABS, 0.87x 6061-T6 Aluminum) *
Part Properties	**Layer Height**	100 µm default, 200 µm maximum
	Infill	Closed cell infill: multiple geometries available
Software	**Supplied Software**	Eiger Cloud (Other options available at cost)
	Security	Two-factor authentication, org admin access, single sign-on

FRONT VIEW



SIDE VIEW



* Continuous carbon fiber data. **Note:** All specifications are approximate and subject to change without notice.

MATERIAL DATASHEET

Composites

Markforged

Composite Base	Test (ASTM)	Onyx	Onyx FR	Onyx ESD	Nylon
Tensile Modulus (GPa)	D638	2.4	3.0	4.2	1.7
Tensile Stress at Yield (MPa)	D638	40	41	52	51
Tensile Stress at Break (MPa)	D638	37	40	50	36
Tensile Strain at Break (%)	D638	25	18	25	150
Flexural Strength (MPa)	D790[1]	71	71	83	50
Flexural Modulus (GPa)	D790[1]	3.0	3.6	3.7	1.4
Heat Deflection Temp (°C)	D648 B	145	145	138	41
Flame Resistance	UL94	—	V-0[2]	—	—
Izod Impact - notched (J/m)	D256-10 A	330	—	44	110
Surface Resistance (Ω)	ANSI/ESD STM11.11[3]	—	—	10^5 - 10^7	—
Density (g/cm³)	—	1.2	1.2	1.2	1.1

Markforged parts are primarily composed of Composite Base materials. Users may reinforce parts with one type of Continuous Fiber.

Dimensions and construction of test specimens:

- Tensile: ASTM D638 type IV beams
- Flexural: 3-pt. Bending, 4.5 in (L) x 0.4 in (W) x 0.12 in (H)
- Heat-deflection temperature at 0.45 MPa, 66 psi (ASTM D648-07 Method B)

1. Measured by a method similar to ASTM D790. Composite Base -only parts do not break before end of flexural test.

2. Onyx FR is UL 94 V-0 Blue Card certified down to a thickness of 3mm.

3. Surface resistance measured on multiple part surfaces using recommended print settings by an accredited third party test facility. See Onyx ESD technical data sheet for more details.

Continuous Fiber	Test (ASTM)	Carbon	Kevlar®	Fiberglass	HSHT FG
Tensile Strength (MPa)	D3039	800	610	590	600
Tensile Modulus (GPa)	D3039	60	27	21	21
Tensile Strain at Break (%)	D3039	1.5	2.7	3.8	3.9
Flexural Strength (MPa)	D790[1]	540	240	200	420
Flexural Modulus (GPa)	D790[1]	51	26	22	21
Flexural Strain at Break (%)	D790[1]	1.2	2.1	1.1	2.2
Compressive Strength (MPa)	D6641	320	97	140	192
Compressive Modulus (MPa)	D6641	54	28	21	21
Compressive Strain at Break (%)	D6641	0.7	1.5	—	—
Heat Deflection Temp (°C)	D648 B	105	105	105	150
Izod Impact - notched (J/m)	D256-10 A	960	2000	2600	3100
Density (g/cm³)	—	1.4	1.2	1.5	1.5

Dimensions and Construction of Fiber Composite Test Specimens:

- Test plaques used in these data are fiber reinforced unidirectionally (0° Plies)
- Tensile test specimens: 9.8 in (L) x 0.5 in (H) x 0.048 in (W) (CF composites), 9.8 in (L) x 0.5 in (H) x 0.08 in (W) (GF and Kevlar® composites)
- Compressive test specimens: 5.5 in (L) x 0.5 in (H) x 0.085 in (W) (CF composites), 5.5 in (L) x 0.5 in (H) x 0.12 in (W) (Kevlar® and FG composites)
- Flexural test specimens: 3-pt. Bending, 4.5 in (L) x 0.4 in (W) x 0.12 in (H)
- Heat-deflection temperature at 0.45 MPa, 66 psi (ASTM D648-07 Method B)

Tensile, Compressive, Strain at Break, and Heat Deflection Temperature data were provided by an accredited 3rd party test facility. Flexural data was prepared by Markforged. Inc. These represent typical values.

Markforged tests plaques are uniquely designed to maximize test performance. Fiber test plaques are fully filled with unidirectional fiber and printed without walls. Plastic test plaques are printed with full infill. To learn more about specific testing conditions or to request test parts for internal testing, contact a Markforged representative. All customer parts should be tested in accordance to customer's specifications.

Part and material performance will vary by fiber layout design, part design, specific load conditions, test conditions, build conditions, and the like.

This representative data were tested, measured, or calculated using standard methods and are subject to change without notice. Markforged makes no warranties of any kind, express or implied, including, but not limited to, the warranties of merchantability, fitness for a particular use, or warranty against patent infringement; and assumes no liability in connection with the use of this information. The data listed here should not be used to establish design, quality control, or specification limits, and are not intended to substitute for your own testing to determine suitability for your particular application. Nothing in this sheet is to be construed as a license to operate under or a recommendation to infringe upon any intellectual property right.

MATERIAL DESCRIPTIONS

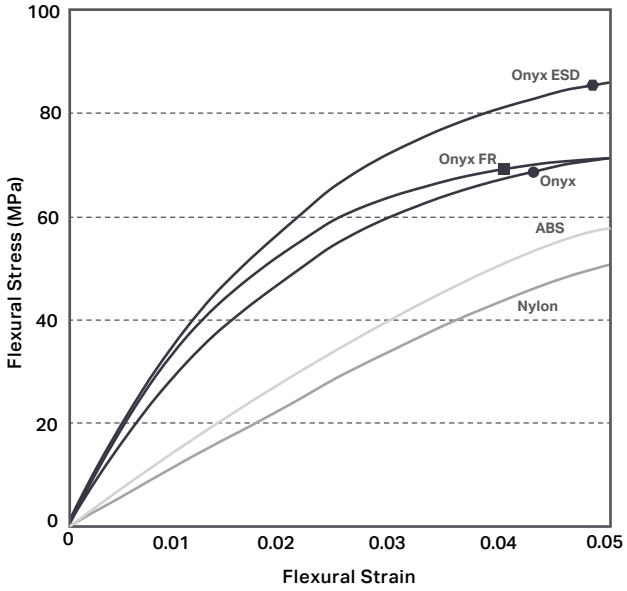
Composites

Markforged

Markforged composite printers are capable of Continuous Fiber Reinforcement (CFR) — a unique process that reinforces FFF parts with high-strength continuous fibers. A CFR capable machine uses two extrusion systems: one that extrudes Composite Base material in a standard FFF process, and a second for long strand continuous fibers that are laid down in-layer, replacing FFF infill.

Composite Base

Markforged Composite Base materials print like conventional FFF thermoplastics. They can be printed by themselves, or reinforced with any of our continuous fibers, including Carbon Fiber, Kevlar, and Fiberglass.



Onyx — Flexural Strength: 71 MPa

Onyx is a micro carbon fiber filled nylon. It's 1.4 times stronger and stiffer than ABS and can be reinforced with any continuous fiber. Onyx sets the bar for surface finish, chemical resistivity, and heat tolerance.

Onyx FR — Flexural Strength: 71 MPa

Onyx FR is a Blue Card certified UL94 V-0 material that possesses similar mechanical properties to Onyx. It's best for applications in which flame retardancy, light weight, and strength are required.

Onyx ESD — Flexural Strength: 83 MPa

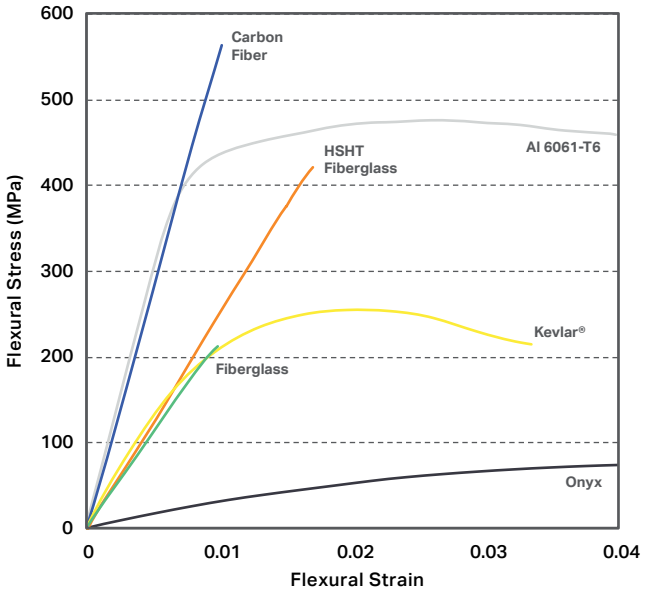
Onyx ESD is a static dissipative safe variant of Onyx — meeting stringent ESD safety requirements while offering excellent strength, stiffness, and surface finish. It's best used in applications that require ESD safe materials.

Nylon — Flexural Strength: 50 MPa

Nylon White parts are smooth, non-abrasive, and easily painted. They can be reinforced with any continuous fiber and work best for non-marring work holding, repeated handling, and cosmetic parts.

Continuous Fiber

Continuous Fibers are laid down on the inside of parts through a second fiber nozzle. They cannot be printed by themselves — instead, they are used to reinforce parts printed out of a composite base material like Onyx.



Carbon Fiber — Flexural Strength: 540 MPa

Carbon Fiber has the highest strength-to-weight ratio of our reinforcing fibers. Six times stronger and eighteen times stiffer than Onyx, Carbon Fiber reinforcement is commonly used for parts that replace machined aluminum.

Fiberglass — Flexural Strength: 200 MPa

Fiberglass is our entry level continuous fiber, providing high strength at an accessible price. 2.5 times stronger and eight times stiffer than Onyx, Fiberglass reinforcement results in strong, robust tools.

Kevlar® — Flexural Strength: 240 MPa

Kevlar® possesses excellent durability, making it optimal for parts that experience repeated and sudden loading. As stiff as fiberglass and much more ductile, it can be used for a wide variety of applications.

HSHT Fiberglass — Flexural Strength: 420 MPa

High Strength High Temperature (HSHT) Fiberglass exhibits aluminum strength and high heat tolerance. Five times as strong and seven times as stiff as Onyx, it's best used for parts loaded in high operating temperatures.

Teilnehmer-Code:	
Geschlecht:	
Betroffene Seite:	
Länge von der Ellenbogenbeuge bis zur Spitze des Stumpfes:	
Umfang des Unterarms (5 cm entfernt von Ellenbogenbeuge):	
Umfang des Unterarms (10 cm entfernt von Ellenbogenbeuge):	
vergangene Zeit seit dem Verlust der Hand:	

Bitte geben Sie eine erste Einschätzung ab, wie zufrieden Sie mit den folgenden Eigenschaften des Prothesenschaftes sind. Dafür bitte die Nummer einkreisen oder markieren, welche am besten Ihren Zufriedenheitsgrad beschreibt. Bitte lassen Sie keine Fragen unbeantwortet. :

1	2	3	4	5
gar nicht zufrieden	nicht sehr zufrieden	mehr oder weniger zufrieden	ziemlich zufrieden	sehr zufrieden

Wie zufrieden sind Sie mit:

1. den Dimensionen (Größe, Länge, Breite) des Prothesenschaftes? *Kommentare:*	1	2	3	4	5
2. dem Gewicht des Prothesenschaftes? *Kommentare:*	1	2	3	4	5
3. der Leichtigkeit mit der der Prothesenschaft an- und ausgezogen werden kann? *Kommentare:*	1	2	3	4	5
4. wie stabil, sicher und fest der Prothesenschaft ist? *Kommentare:*	1	2	3	4	5
5. der Haltbarkeit (Widerstand gegen Abnutzung) des Prothesenschaftes? *Kommentare:*	1	2	3	4	5
6. wie luftdurchlässig der Prothesenschaft ist? *Kommentare:*	1	2	3	4	5
7. wie bequem der Prothesenschaft ist? *Kommentare:*	1	2	3	4	5
8. wie effektiv der Prothesenschaft ist (der Grad zudem der Prothesenschaft Ihre Bedürfnisse erfüllt)? *Kommentare:*	1	2	3	4	5
9. der Bewegungsfreiheit mit dem Prothesenschaft? *Kommentare:*	1	2	3	4	5
10. wie gut der Prothesenschaft passt (Anpassung der Dimensionen an Sie): *Kommentare:*	1	2	3	4	5

Unten befindet sich eine Liste der zehn Eigenschaften von Prothesenschäften. Bitte wählen Sie welche **drei Eigenschaften** für Sie generell **am wichtigsten** sind. Markieren Sie diese bitte mit einem X in der entsprechenden Box.

☐	1. Dimensionen	☐	6. Luftdurchlässigkeit
☐	2. Gewicht	☐	7. Komfort
☐	3. Leichtigkeit des An- und Ausziehens	☐	8. Effektivität (Grad zudem Ihre Bedürfnisse erfüllt werden)
☐	4. Sicherheit, Stabilität und Festigkeit	☐	9. Bewegungsfreiheit
☐	5. Haltbarkeit	☐	10. Anpassung

Kommentare oder Vorschläge (z.B. gibt es eine spezielle Funktion oder Eigenschaft die Ihr Prothesenschaft haben sollte). Abgesehen von den hier abgegeben Kommentaren können Sie auch im anschießenden Interview auf Punkte genauer eingehen:

Teilnehmer-Code:	
Geschlecht:	
Berufsgruppe:	
Arbeitserfahrung/ -dauer in dem Bereich:	

Bitte geben Sie eine erste Einschätzung ab, wie zufrieden Sie mit den folgenden Eigenschaften des Prothesenschaftes sind. Dafür bitte die Nummer einkreisen oder markieren, welche am besten Ihren Zufriedenheitsgrad beschreibt. Bitte lassen Sie keine Fragen unbeantwortet. :

1	2	3	4	5
gar nicht zufrieden	nicht sehr zufrieden	mehr oder weniger zufrieden	ziemlich zufrieden	sehr zufrieden

Wie zufrieden sind Sie mit:

1. den Dimensionen (Größe, Länge, Breite) des Prothesenschaftes? *Kommentare:*	1	2	3	4	5
2. dem Gewicht des Prothesenschaftes? *Kommentare:*	1	2	3	4	5
3. der Leichtigkeit mit der der Prothesenschaft an- und ausgezogen werden kann? *Kommentare:*	1	2	3	4	5
4. wie stabil, sicher und fest der Prothesenschaft ist? *Kommentare:*	1	2	3	4	5
5. der Haltbarkeit (Widerstand gegen Abnutzung) des Prothesenschaftes? *Kommentare:*	1	2	3	4	5
6. wie luftdurchlässig der Prothesenschaft ist? *Kommentare:*	1	2	3	4	5
7. wie bequem der Prothesenschaft ist? *Kommentare:*	1	2	3	4	5
8. wie effektiv der Prothesenschaft ist (der Grad zudem der Prothesenschaft Ihre Bedürfnisse erfüllt)? *Kommentare:*	1	2	3	4	5
9. der Bewegungsfreiheit mit dem Prothesenschaft? *Kommentare:*	1	2	3	4	5
10. wie gut der Prothesenschaft passt (Anpassung der Dimensionen an Sie): *Kommentare:*	1	2	3	4	5

Unten befindet sich eine Liste der zehn Eigenschaften von Prothesenschäften. Bitte wählen Sie welche **drei Eigenschaften** für Sie generell **am wichtigsten** sind. Markieren Sie diese bitte mit einem X in der entsprechenden Box.

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Kommentare oder Vorschläge (z.B. gibt es eine spezielle Funktion oder Eigenschaft die Ihr Prothesenschaft haben sollte). Abgesehen von den hier abgegeben Kommentaren können Sie auch im anschießenden Interview auf Punkte genauer eingehen: