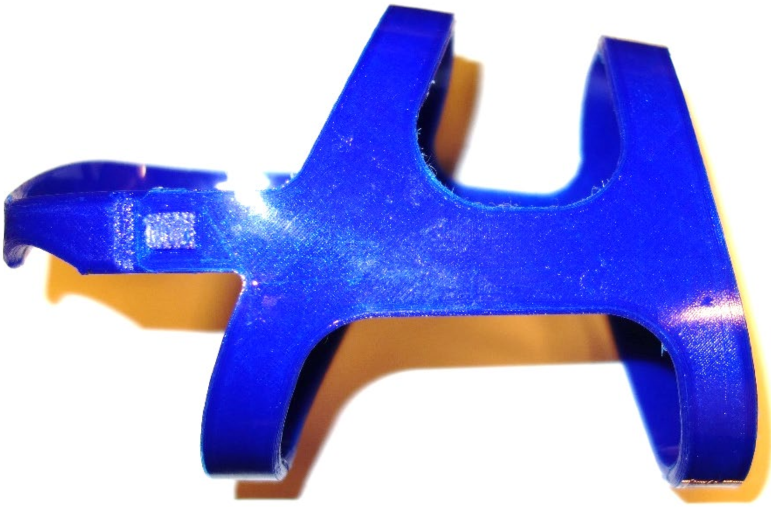
An AM optimised transradial interface for low-income countries

MSc Thesis by Matthijs Mazereeuw



Delft University of Technology

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Biomedical Engineering – BioMechatronics

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"Now and better is better than perfect and never"

- Someone not me

Summary

Additive manufacturing of prosthetic arms has been explored by the scientific community, humanitarian projects and online communities. Despite this increasing interest, the technique has not been adopted at large. The large number of widely varying designs and lack of patient trials are likely factors. This is unfortunate, because the low cost at which a custom made design can be fabricated with additive manufacturing (AM) is promising; especially for developing countries. For those countries in particular the high price and necessity for a prosthetic technician limits an individuals' access to a prosthetic device greatly. This graduation study aimed to design a transradial prosthetic interface specifically for AM technology, optimized for a low-income setting.

Out of several concepts, it was decided to follow the design principle of the WILMER Open Socket. Its airy design that takes advantage of bony prominences for suspension best fit the desired application. With an aimed application in low-income countries, it was decided to create a design that was easy to print. A compelling solution to this problem was to print the entire socket flat and subsequently fold it around the residual limb. This required a flexible yet strong material. TPU 95A filament and an Ultimaker 3 FDM printer were used for this study. Two locking mechanisms were designed specifically for reassembly and donning/doffing. The final design consists of three separate parts that can be assembled with these locks one-handed. Strength test were performed as well validating adequate performance of the interface.

Contents

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Outline

In order to graduate from the master BioMedical Engineering at the Delft University of Technology, students are asked to complete a project individually. 35 ECTs worth of time is to be invested in the project. Another 10 ECTs are reserved for literature study on the subject to prepare. The literature study for this project titled "Additive manufacturing of transradial prosthetic interfaces – A review" has been included in the Appendix. This thesis report is structures as follows:

Chapter 1 – Scientific paper

The background, methods and results of the transradial interface design process are presented in a concise scientific publication format.

Chapter 2 - Appendix

The Appendix is structured as follows:

A – Literature study

B – Report of LIVIT visit

C – Design criteria and validation

D – Context

E – In depth design process with photos

F – Ultimaker specifications and settings

G – Engineering drawing

An AM optimised transradial interface for low-income countries

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Abstract

Prosthetic devices remain inaccessible for many amputees in low-income countries. The lack of trained professionals and resources to fit a prosthetic (interface) are principle reasons. The low cost at which additive manufacturing technology (AM) is able to produce a custom made part could change this. As such, the aim of this study was to design an AM transradial interface specifically for low-income countries. It was decided to adopt the WILMER Open Socket design for AM. The interface was not manufactured in its final form. Instead it was decided to print the interface perfectly flat and reassemble it post-manufacturing for increased print reliability and optimal material properties. Flexible yet durable TPU 95A filament was chosen for this purpose. Reassembling the separate pieces occurred with two different locking mechanisms, which were designed specifically for this purpose. These locks were validates using tensile strength tests. The fully assembled interface was tested as well in two different orientations to validate its strength. In contrast to traditional interface fitting, the new design requires merely anthropomorphic measurements, as the actual surface of the residual limb remains mostly uncovered. This study proposes a different approach to AM prosthetic interface design. The fabrication method has been embraced fully, resulting in a comfortable, visually appealing, and durable design for low-income and challenging settings.

Keywords: WILMER Open Socket; Additive manufacturing; Transradial; Prosthesis; Prosthetic interface; Socket; 3D printing; Below-elbow; Amputee; Developing country

I Introduction

I.I Background

A transradial prosthesis is connected to the residual limb with an interface. Traditional prosthetic interface fabrication requires a skilled orthopaedic technician to manually ensure a good fit with the residual limb[1]. This time consuming manual labour is estimated to account for 83-86% of the total cost of a conventionally produced interface[2].

As the entire process is often manual without Computer Aided Design (CAD), no records are kept of previous attempts. As a result the entire process has to be repeated for replacements or adjustments[3]. The possibility of using additive manufacturing (AM) to build CAD prosthetic interfaces has been explored since the 1990s[4,5]. Since then many designs have been created by scientists and enthusiasts alike.

Research has focussed on improvements such as variable compliant areas to relieve pressure[6,7], thermal assessment[8] and the application of Finite Element Analysis(FEA)[1,9,10]. Projects that utilize AM for the production of prosthetic hands and forearms could incorporate above-mentioned research findings in their interface design. After all, poor design can cause discomfort and skin issues, which are experienced by an estimated 75% of the amputees[11], and can cause patients to abandon the prosthesis altogether[12].

AM interface designs aren't limited to scientific literature. Online open-source AM communities like e-NABLE[13], www.thingiverse.com, and www.3print.com allow enthusiasts to create and share their designs with ease. This combined with the high availability of entry-level 3D-printers leads to a large collection of AM interfaces.

A 2017 review by Ten Kate et al.[14] indicated that in roughly halve the cases Velcro is used to connect and tighten the prosthesis to the residual limb. In other cases an existing socket was used. A study performed in preparation for this project indicated that AM transradial interfaces can be subdivided into two categories: patient-specific and mechanically adjusted. The former uses 3D scanners to digitize the residual limb and create an anatomically contouring prosthetic interface. The latter is mostly scaled to potential wearers with anthropomorphic measurements and fastened with Velcro straps. While designs that rely on Velcro straps for suspensions are not necessarily inferior to more (traditional) anatomically contouring variants, the possibility of AM to provide a uniquely tailored design is not fully utilized either.

The potential lower cost and required material could make AM interfaces a viable alternative if factors like reliability and durability are similar to their traditional counterparts. These advantages could also make them accessible for amputees living in low-income or- developing countries. Especially if the interface can be fitted easily. Only 5-15% of amputees who need assistive technology actually receive it in low-middle income countries[15]. The lack of income and trained prosthetist are potential factors.

I.II Problem statement

Traditionally produced prosthetic interfaces require a skilled orthopaedic technician to manually ensure a good fit with the residual limb[1]. AM interfaces could make interfaces more accessible in challenging settings by eliminating this requirement and bringing down costs that come with it. Current solution however do not take full advantage of the technology.

I.III Objective

The objective of this study was to design a transradial prosthetic interface specifically for AM technology. The aimed application in challenging low-income settings has also been taken into account.

II. Materials and Method

Design criteria were established first. In order to solve the design problem, four concepts were conceived for this project. These concepts were valued with a weighted decision matrix, resulting in a winning concept.

II.I Establishing design criteria

Three approaches have been used to establish user requirements. The first was a visit to LIVIT orthopaedics at Erasmus MC, Rotterdam; a company with significant experience in fitting prosthetics to amputees. A report on this visit can be found in the Appendix. The second is a review on additive manufactured interfaces. Both scientific and non-scientific sources (e.g. humanitarian projects, design sharing websites) have been reviewed (Appendix A). Lastly, prosthetic interface designs for transradial cases were studied that have been fabricated with techniques other than AM. The following design criteria were chosen:

1. Able to be fit without a prosthetist

The lack of prosthetist in developing settings does not allow a professional to fit an interface. The new interface should be able to be fitted without.

2. Allow for post-print alterations

Raymon Wijman (LIVIT) explained that in almost all cases, small changes are made to the initial socket design. Reasons given for this necessity are errors or misjudgements to the positive model, problems in the fabrication of the check socket, and the fact that a perfect socket based on a well-adjusted positive model does not always result in a perfect fit. For example; during the visit, a patient requested the range of motion to be increased at the cost of suspension.

3. Airy

Perspiration inside the interface is the most common cause of reduces quality of life and skin problems in the lower limb.[16] One could assume this to be a similar issue in the upper limb.

4. Comfort

It has been agreed that the most important factor in amputee rehabilitation is in fact appropriate socket fitting[17,18]. Improper fit could lead to many conditions, such as pain, blisters, edema, pressure ulcers, and sometimes flat necrosis and osteomyelitis[19,20]. The prosthesis should also be lightweight.

5. Durable

The interface should not fail during everyday activities. Neither should water, UV, dirt, or grease leave lasting damage.

6. Easy donning and doffing

The interface should be donned and doffed with one hand easily.

7. Easy to print

The challenges a developing setting brings are not limited to money or trained personnel. Power outages and changing environmental conditions should have a limited influence on the manufacturing process.

8. Cosmesis

Unconventional designs such as the WILMER Open Socket (Delft University of Technology) are also fitted by LIVIT. However, the airy design that allows over 75% of the skin to be exposed looks unnatural and negatively affects appearance. Low profile will also be a focus to improve cosmesis and interaction with clothing.

9. Unreliant on distal part of residual limb

Raymon Wijman also noted the wide variety of residual limb shapes. This variety is most prominent in the distal part both in terms of shape and length. Without a trained professional, a new design will have to be unreliant on this part of the body.

II.II Conceptualization

Four concept design were made. The main focus was on form and function, not materials.

Concept A - Traditional design with options

This design borrows heavily from the traditionally produced transradial socket. An anatomically contouring design without a liner. Stromshed[2] used a similar design made from Nylon 12 with a universal wall thickness. The primary goals of this new design were to allow for post-print alterations and implement spatial variable stiffness at critical areas (Figure 1; highlighted in yellow).

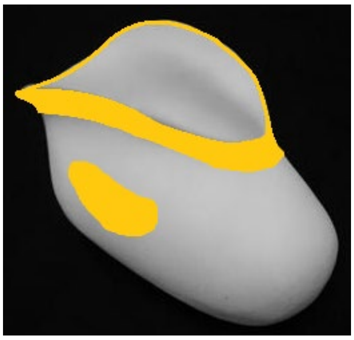

Figure 1. Concept A. Source: Image modified from Strömshed (2016)

Concept B - AM version of WILMER Open Socket

The WILMER Open Socket prevents sweat and heat accumulation by covering only areas that contribute

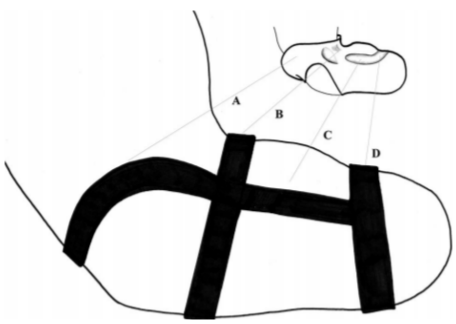

Figure 2. Concept B illustration, from Lake (2008)

to suspension and weight bearing.[21] This feature will have to be kept despite a radically different production method. Less bulky features and cosmesis are other attention areas.

Figure 3 Hero Arm by OpenBionics. Source: https://openbionics.com/hero-arm/

Concept C - AM liner covered by a hard cover

This concept draws heavy inspiration from the Hero Arm by Open Bionics.[22] An AM highly flexible, rubber-like liner is combined with a hard cover. Both components are perforated with small holes to prevent sweat accumulation.

Concept D – AM mould filled with another material

Material choice is limited by the types of filament FDM printers can handle. Another limitation of the technique is potential delamination as a result of print orientation. As indicated by Sjoerd te Slaa of the 3D Innovation Lab, Amsterdam UMC, both weaknesses can be overcome by producing an AM mould instead. A mould can be filled with a non-AM material, e.g. silicone.

II.III Weighted decision matrix

The weighted decision matrix lists all design criteria (Table 1). Weighting factors are listed in the second column. Most weight was given to ease of print, durability, and to ability to fit without a prosthetist with the intended application of the interface in mind. Criteria like biocompatibility and being waterproof have not been listed, as all designs have to comply with these criteria fully or were covered by other criteria.

Overall concept B scored highest with 115 points, followed by concept D and A. Concept D was hardest to grade. In contrast to the other concepts, it is mostly a production method which could be applied to many shapes. A big drawback is the hollow structures a mould inherently consists of. Especially if these are full of hard to remove support structures. Interestingly concepts C scored lowest, despite being based on a design that has already been released. Print complexity and lack of durability thanks to the large number of parts are at fault here. Concept B scored especially high on criteria with high weights and highest overall and was thus continued with.

Table 1. Weighted decision matrix

Criteria		Concept **A**		Concept **B**		Concept **C**		Concept **D**	
	Weights	Rating	Total	Rating	Total	Rating	Total	Rating	Total
Able to be fit without prosthetist	5	2	10	4	20	3	15	3	15
Allow post-print alterations	2	5	10	1	2	1	2	1	2
Airy	3	2	6	5	15	3	9	2	6
Comfort	4	4	16	4	16	4	16	5	20
Durable	5	2	10	4	20	3	15	5	25
Easy donning and doffing	2	2	4	4	8	2	4	3	6
Easy to print	4	1	4	5	20	1	4	1	4
Natural forms/visually pleasing	3	5	15	3	9	3	9	4	12
Unreliant on distal part residual limb	1	2	2	5	5	2	2	4	4
Total			79		115		76		94

II.IV Elaboration of the winning concept

The WILMER Open Socket consists of two rings that envelop the residual limb (Figure 4). The rings are spaced out and connected with hollow metal shafts. A condyle brace locks into the metal shafts, locking the interface to the residual limb. The build in locking mechanism allows the users to adjust the tightness of the fit. The metal bars are covered with soft material for increased comfort.

The placement of the rings and condyle brace has been done with anatomical landmarks in mind. Figure 2 demonstrates the strategic placement. The socket has been received very well by most children it has been fit to.[23] The bulky structure has been listed as one of the main disadvantages.[24] Raymon Wijmans (LIVIT) listed this as one of the main reasons amputees abandon the prosthetic interface as well. The bulkiness is the direct result of the mechanism it houses, which allows users to adjust the tightness easily. Growing children benefit most from this feature. It helps to accommodates growth of the limb and is required for don and doffing.

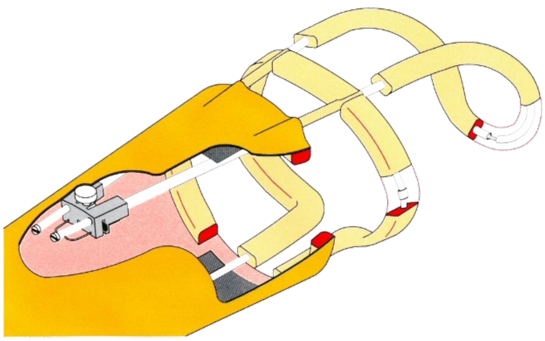

Figure 4. WILMER Open Socket. Source: tudelft.nl

The WILMER Open Socket could not simply be fabricated with AM. Foam covered metal bars and an intricate locking mechanism do not lend themselves well for the technique. In other words; significant changes had to be made to the design. It was decided to go back to the basic shapes that the WILMER Open Socket consists of. As explained before, it is believed that the intended fabrication process should also be incorporated into the design. For this reason, benefits, drawbacks, and limitations were explored first.

II.V Fabrication process

With an intended application in low-income countries, it was decided to opt for a widely available AM technique; fused deposition modeling (FDM). Selective laser sintering (SLS) has also been considered. Overall SLS building times are lower[25,26] and accuracy higher[26,27]. However costs are higher[26] compared to FDM and the 3mE faculty of the Delft University of Technology houses many Ultimaker FDM printer. Appendix F shows Ultimaker printer specifications. Typically the build plate of a FDM printer represents the x- and y-axis of the build. The Z-axis stands perpendicular to the plane these axes create. FDM printers build parts by stacking layers of material in the z-direction. The bond between these layers is relatively weak which leads to anisotropic characteristics.[28] In a similar fashion, the orientation in which the FDM printer lays down material (raster orientation) causes a part's tensile strength to vary in different directions.[28] Although many other parameters affect part strength, these inherent anisotropic characteristics affect the mechanical properties of a part. This weakness can not prevented. However its effect can be minimized. One way to achieve this is choosing the print orientation in such a way that the direction it will be loaded most heavily in is not in line with the z-axis. This is easy enough for simple shapes and parts loaded in a single direction. Parts with complex shapes and loaded in multiple directions are far more complex. Changing the part's orientation is not always possible either, as it could result in excessive amounts of support material or weaknesses elsewhere. A similar case can be made for support material, which an open design like the WILMER Open Socket requires a lot of. Supporting scaffolds can be hard to remove, require post-processing, cost time and material, and can cause dimensional inaccuracies[29,30]. Dissolving support material does address some of these problems, yet complicates the printing process as it would require dual extrusion. In other words, the interface's design could not be conceived without thinking of the resulting printing process and its consequences.

On way of avoiding both z-direction load and support material completely is by creating a completely flat print and subsequently form it in its desired WILMER-esque shape. This method does bring challenges regarding reassembly. However, the aforementioned issues that a flat print addresses are critical in the challenging settings this interface is likely to be used in and thus continued with.

When stripped to its core, the WILMER Open Socket envelops the residual limb with material strips. If these strips were flexible and cut open on one side, the interface would lie relatively flat on a surface. Figure 5 illustrates an impression of the concept. This would allow the design to be printed flat, although reassembly was still required.

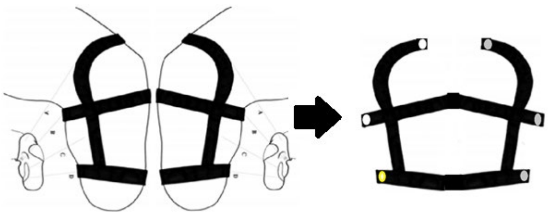

Figure 5. Early concept of flat fabrication. Images taken from Lake (2008).

II.VII Material selection

The WILMER Open Socket remains the same shape, donned or not, as a result of to the metal bars that run through it. Conversely, the new design had to achieve the same with a material that could be bend around the residual limb. Three options were considered; use a flexible filament, print microstructures to achieve flexibility[31], or achieve flexibility by limiting material thickness in z-axis. The latter limits the interface's durability and possible design dimensions. Microstructures are highly challenging to print with the aimed printer and presumably do not lend themselves well to outdoor use. A flexible filament was chosen in the end. Thermoplastic polyurethane (TPU 95A) and MakerPoint MP FLEX 45 (MP FLEX45) have similar material properties (chemical/grease/abrasion resistance and flexible[32,33] and were thus explored further.

Multiple test prints were manufactured in order to find the ideal combination of material stiffness and flexibility. Overhang angle limitations were also explored as it limits possible design dimensions. A list of test prints, slicing and printer settings are listed in Appendix F.

Two main challenges emerged when printing with MP Flex45; build plate calibration and the feeder. Active levelling (automatic calibration) put the plate slightly to far from the nozzle, resulting in relatively narrow material lines that did not connect. This was fixed by manually calibrating the build plate ever so slightly closer to the nozzle. The Ultimaker 3 feeder pushes material towards the nozzle. MP Flex45 filament clogged the feeder on multiple occasions, probably due to the filament's high flexibility. Manually unrolling the filament from the spool alleviated this problem somewhat. TPU 95A is manufactured by Ultimaker itself. As expected, the filament was handled far more reliably and thus continued with. The aforementioned test prints indicated that flexibility was very similar to that of MP Flex45 when identical print settings (e.g. fill pattern, fill ratio, line width) were used. The test prints were also created to find the minimal infill ratio required with the intend to save material and manufacturing time. Low infill ratios led to undesirable permanent deformations when the material was folded over and were thus avoided.

II.VIII Software & hardware

An Ultimaker 3 FDM printer was used for this project. Appendix F shows Ultimaker printer specifications and settings. Tensile strength tests (section III.IV) were performed on a Lloyd LR5K testing machine. SketchUp Free (Trimble Inc. version 18.0.16975 64 bit) was used for proof of concept CAD modelling. SolidWorks 2017 was used for CAD modeling of subsequent designs. Ultimaker Cura (version 3.3.1) was used for slicing and print settings.

II.IX Proof of concept

A proof of concept was created first. Paper strips were fitted around the author's arm. Placement of these paper strips were based on Figure 5. When satisfied, the paper interface was cut open, resulting in a relatively flat outline of the interface. A one-to-one scale copy was subsequently created in SketchUp Free. An early version of the type A locking mechanism (section III.III) was then fitted into the design along the cutting lines. Unfortunately, the flat interface dimensions exceeded the maximum build

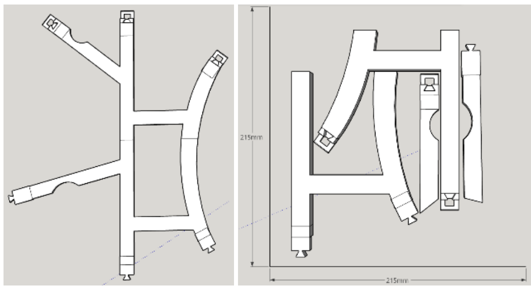

Figure 6. CAD of prototype. Left: intact. Right: split up to fit Ultimaker 3 maximum build dimensions

dimensions that an Ultimaker 3 printer offers (x:y=215x215mm). A printer with larger build dimensions was not available for this project. For the prototype, the interface was simply cut-up, to be reassembled with adhesives and/or tape. MP

Figure 7. Manufactured and fitted proof of concept

FLEX45 was used for the prototype because it was readily available. It proved unreliable to print with for larger prints. The Ultimaker filament feeder tends to warp the highly flexible filament and subsequently gets clogged as mentioned before. It results in deformed prints, which was especially problematic for the locking mechanism. Another downside was the fact that adhesives do not work well with MP FLEX45, which is why tape was used (see Figure 7). The interface requires material deformation for donning which doesn't work well with adhesives to begin with (most become hard and brittle). With the aim to fabricate the interface in challenging settings, post-processing and additional materials were undesired. Neither were long fabrication times. Power outages and changing environmental conditions negatively influence fabrication process. This first prototype took approximately 14 hours to manufacture. This could be lowered with the amount of material to the printed (e.g. wall thickness, infill ratio, dimensions, supports), print speed (e.g. layer height, travel speed) or by using a material that can be printed faster.

III. Results

III.I In depth design

The shape of the first prototype resembled the metal bars structure of the WILMER Open Socket. Its exact dimensions were based on a paper interface fit around the residual limb. That paper interface however wasn't perfectly flat when cut open. Neither is the outer surface of a residual limb. To guarantee that interface could be printed perfectly flat it was decided to select a shape that is both a suitable approximation of the residual limb's shape and could be unrolled/flattened for the next iteration. It was decided to opt for a truncated oblique cone. Figure 8 illustrates the thought process.

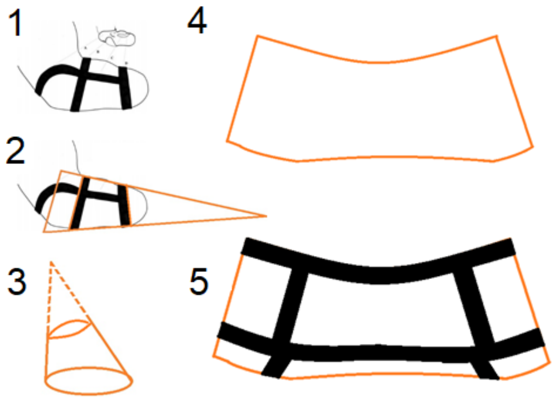

Figure 8. Thought process on CAD process.

The following dimensions of the residual limb were required, see Figure 9. These are highly dependent on the shape of the residual limb.

A. Distal ring: Distal circumference (roughly 35 mm distal of antecubitis – 80 mm distal of olecranon, dependent on residual limb length). It promotes weight bearing on the distal part of the residual limb.

B. Connecting strip: Connection between two rings for increased weight bearing.

C. Proximal ring: Proximal circumference (just distal of antecubitis and olecranon). Utilizing this bony prominences enhances anterior-posterior stability.

D. Condyle brace: Elbow flexed 90°; connect on line A just above epicondyles running over cubital fold to same point other side. This brace ensures that the interface doesn't slip of towards distal. Following bony prominences ensures rotational stability.

E. Locations medial/lateral epicondyle of the humerus

A, B, and C together form the truncated oblique cone on which the majority of the interface was drawn. Lines C and D run next to the epicondyles and intersect just distal of them. These structural placements were largely based on a description by Lake (2008)[12].

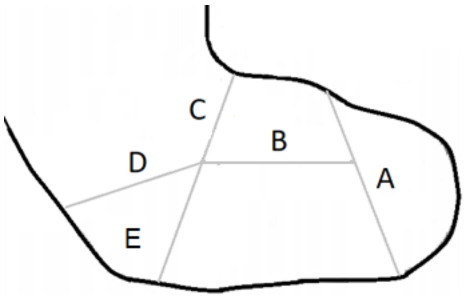

Figure 9. Required dimensions of the residual limb

The material strips were 15 mm wide and 4 mm thick, because sturdiness of the similarly dimensioned prototype seemed appropriate. For this iteration Ultimaker TPU 95A filament was used. Printing with TPU 95A proved to be more reliable during the test prints and thus selected for the detailed design. Its characteristics are comparable to MP FLEX45. Print duration was a concern with the first prototype. Thicker material layers negatively affects build resolution, yet brings down fabrication times greatly. The performance of the interface's locks are most affected by a lower resolution. A small test print indicated that locks (section III.III) performed well with 0.2 mm layers, which was thus chosen. The flexibility of the material will allow the interface to form to the residual limb as long as the circumference corresponds.

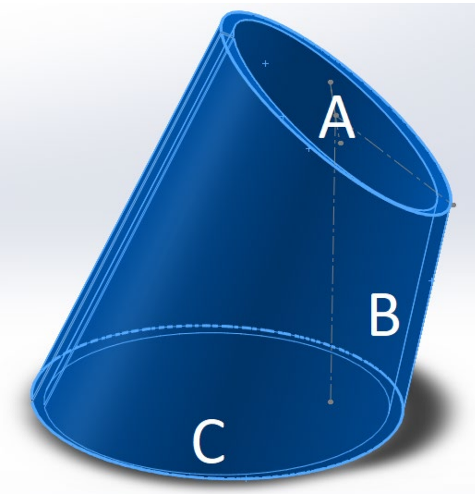

Figure 10. Truncated oblique cone to be flattened.

Computer Aided Design (CAD) was carried out in SolidWorks 2017. A truncated oblique cone was created first (Figure 10). The base's circumference was based on the circumference required for the proximal ring (Figures 9/10: line C). The closest distance between the two rings (Figures 9/10: line B) determined the location of the distal ring. The angle between line B and each of the rings is set at 110°, though that could be changed according to the size and shape of the residual limb.

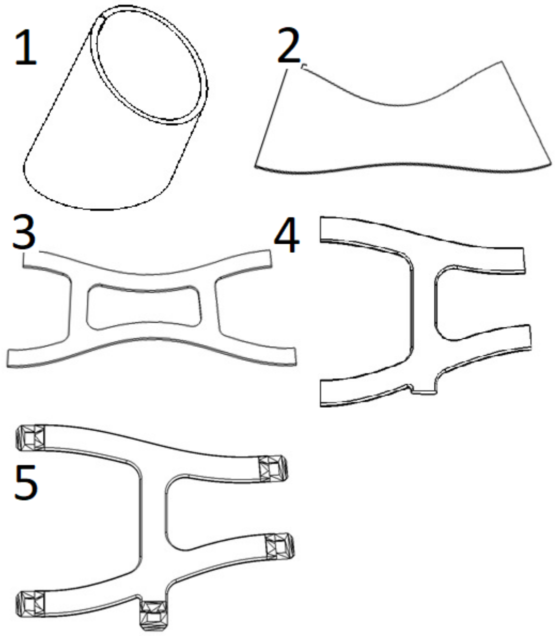

Figure 11. CAD process

Figure 11 illustrates the CAD process. (1) A truncated oblique cone was created as described before. (2) A small cut along its length allowed the "sheet metal" feature to be used and flatten the cone. (3) The interface outline was drawn on the resulting flat surface and subsequently cut out. The dimensions of the material strips were kept the same as in the proof of concept; 15 mm wide and 4 mm thick. (4) As noted before, the flat interface's dimensions exceeded that of the Ultimaker 3 build plate. The solution for this project was to cut the interface in half. A small extension was placed on the proximal ring for the condyle brace connection. The interface corners had to be softened to improve the interface's ergonomics. Fillets were no option when build perpendicular to the build plate. It would create overhang angles greater than 45° which requires support structures. Instead chamfers were implemented with a 45° angle. Fillets were implemented for stress relief in areas of sharp geometry changes in the x-y plane. (5) Type A and type B locks described in the next section were then attached to the ends to allow for reassembly.

A condyle brace was designed as well. It connects with a type A lock on the proximal rings, just above the epicondyles on the medial side of the elbow joint. The other side of the brace connects to the corresponding spot on the lateral side with a type B lock. Cut-outs were implemented around the epicondyles to promote medial/lateral and rotation stability. Appendix G displays the dimensions of the different sections.

III.III Design of locks

The interface could not be fit on the build platform completely flat. The design therefore had to be split in parts, which then after fabrication were joined together. In order to make the AM process as unlikely to fail as possible, only design iterations that use same type of material as the overall interface were explored. Two options were considered; temporary and permanent fixations. Permanent fixations were required for reassembly of the interface post-print. Temporary fixations were required for donning and doffing. As forces mainly pull the two pieces of material away from each other, tensile strength was the main focus. Adhesives and soldering irons were also explored for permanent fixations. However none appeared to lead to a reliable bond.

Design requirements for both joining mechanisms were:

- The locking mechanism should not make the interface more bulky or draw unnecessary attention to itself.
- The two sides of the joint should not be able to move relative to each other while the interface is being worn.
- Should be easy to print.
- Small gaps which could result in skin injury or pain should be avoided.
- It should be possible to open and close the joining mechanisms with one hand.
- The forced print orientation should not affect the lock negatively.

The flexible material properties required for bending the interface around the residual limb proved to be an obstacle for the joining mechanism. For instance snap joints, which would have been a great option for temporary joining, do not work well with flexible materials. The reason being that snap joints rely on temporary deflection of a protruding part that subsequently catches in a depression in a mating component[34]. A protruding flexible part is simply not stiff enough remain in place. Alternatively, the flexible material could be printed thick enough to minimize the flexible properties. The downside here is that it would require space, which is not readily available in the interface design. Lastly, fabrication imperfections easily affect snap joint performance easily. The goal was to print the interface perfectly flat. As such, the locking mechanism had to be printed in this orientation as well. In other words; the locking mechanism had to be designed with this restriction in mind. Support structures were not desired either. They are likely to leave supports marks on the locks, negatively affecting their performance. Two types of locks were designed: one to be used in the rings and another connected to the condyle brace. The former was mostly used for reassembly, while the latter was to be used primarily for don and doffing. The full exploration of locking mechanisms can be found in the Appendix.

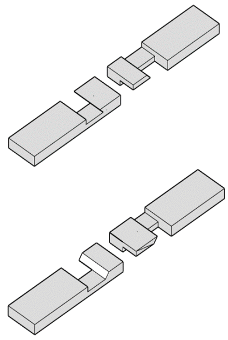

Figure 12. First lock design

The first attempt (Figure 12) fit together well. When pulled away from each other however, the flexible material started to move outwards at the joint causing the lock to fail. Additionally, when locked in place and bended, parts of the lock moved towards the skin. This would likely be uncomfortable to the wearer.

Lock A – reassembly lock

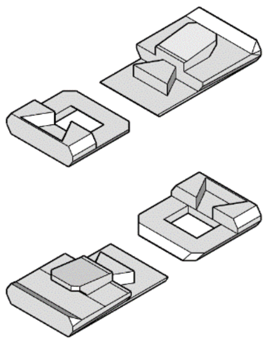

Figure 13. Lock A

For the second iteration interface the locks depicted in Figure 13 were implemented. It was inspired by Japanese carpentry, specifically the “Koshikake aritsugi” joint[35]. This distinctive woodworking approach connects beams of wood with complex interlocking joints. The above mentioned variant specifically implements the dovetail joint principle. The additional material underneath inspired the addition of a loop and inclined block. The loop on side B catches behind the inclined block of side A after which the dovetail joint connects. The latter principle is noted for its tensile strength, which makes it ideal for this purpose. The joint has been optimised to be bended around the residual limb as well, with the loop side of the lock facing away from the skin. The thin layer of material placed under the dovetail joint ensures that skin will not get caught in the lock when pulling forces are applied. In line with the design requirements, the locks’ dimensions barely exceed that of the 15x4 mm material strips and do not require any support material.

Lock B – donning- and doffing lock

Lock A had to withstand pulling forces while being bend around the residual limb. The triceps cuff lock on the other hand had to resistant tension solely in line with the lock. It also had to be easy to operate, as it facilitates donning and doffing of the interface. Side A is placed over side B. Pulling the two sides away from each other forces them to connect and stay in place. Pushing the two sides together allows the wearer to disconnect them. The dimensions of this lock exceed those of the overall interface slightly and do require a small amount of support material. Several test prints however proved this to be no problem for this particular design.

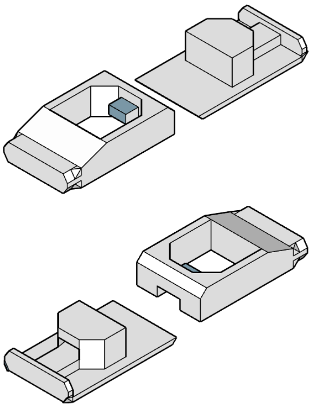

Figure 14. Lock B

III.IV Forearm & hand connection

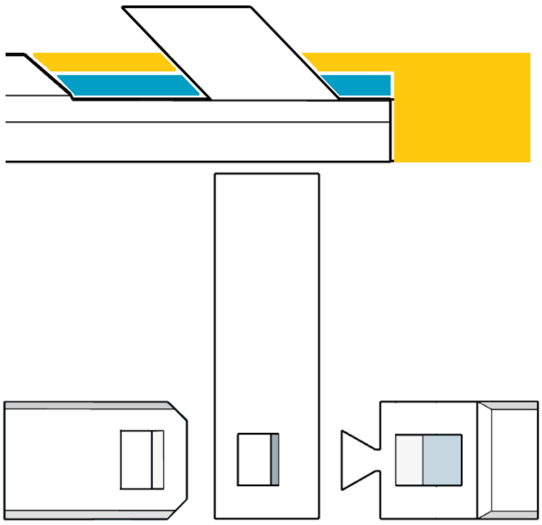

Figure 15. Forearm & hand connection

The preferred manufacturing method and printing orientation did limit the options for the attachment of a prosthetic forearm/hand. For example, when the half that incorporates the loop sides of lock A is assembled, the side that is printed last faces the skin. In other words, it is not possible to add some sort of locking mechanism on top of the interface. It would significantly complicate the printing process and likely add support structures. The print orientation of the other half does allow for additional structures to be created on top. However this would increase the height of the interface. Instead it was decided to incorporate the connection into the locking mechanism itself.

The principle is displayed in Figure 19. The inclined block height was increased to make room for another slice of material to fit, which is to be connected to the forearm/hand. The 1mm thin material strip is placed over the inclined block, followed by the loop to lock it in place. Bending this lock to follow the curvature of the residual limb strengthens the lock.

III.V Manufacturing and post-processing

As explained in section II.V, the orientation of the material fibers that a part consists of determines its mechanical properties. As laid out by Dawoud et al. (2016)[36] though, there seems to be little consensus on the matter. For example, where some report little influence of layer thickness on mechanical properties[37], other report the opposite[38]. The same contradiction applies to raster angle; where some studies suggest an influence[28,39,37] and others minimal[40] or no influence of pattern[38]. More consensus applies to infill ratio, where an higher infill ratio generally increase a part's tensile strength[38,41,42]. Another parameter of interest is optimal print temperature for the strength of a part[39,43].

These settings could not simply be copied for this project. Higher infill ratio's also increases stiffness, print times, and the amount of material that is required. As explained in the Appendix, a 45% infill ratio was chosen based on the test prints created early on. Higher infill ratios would undeniably increase the interface's tensile strength, however this was not required. The interface's weakest parts were the locks. For this reason, it was more important to ensure high infill ratio's in the locks and subsequently test their tensile strength (section III.VI). Print orientation could not be incorporated either. Forces act on the interface in many different directions, in contrast to samples displayed above. Print temperatures could not be transferred either. The melting point of TPU 95A is set at 220 °C, higher than ideal temperatures listed by Xiao and Gao[39], who used a different type of TPU. The influence of print temperature was not tested for this project. Instead the manufacturer's recommended print temperature was used.

The total manufacturing time of the prototype was 7 hours and 23 minutes divided over three prints using the settings described in Appendix F. Figure 16 shows the three different parts that the interface consists of. The two H-shaped parts form a forearm gauntlet. The long strip of material is the condyle brace. Figure 17 illustrates the interface fully assembled, which can be done one-handed. Minimal post-processing was required. Ultimaker Cura software recommended settings advised to use a brim to ensure sufficient build plate adhesion. This was easily removed with scissors. The minimal amount of stringing that resulted from movement of the print head was removed by hand. Small amounts of support material in Lock B was removed with small tweezers. No sanding was required.

Figure 16. Interface before assembly.

Figure 17. Fully assembled interface

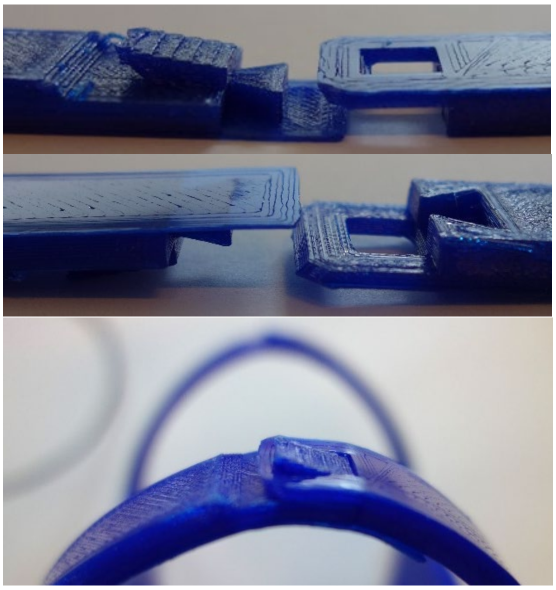

Figure 18. Lock A components and while bend

Figure 19. Lock B

III.VI Strength test

Method

Strength tests were performed for both locking mechanisms in order to test their performance. The Lloyd LR5K testing machine was used to this end. Clamps on both sides of the locks connected to the machine, which subsequently pulled them apart, testing the tensile strength in the process (Figure 20). Lock B was designed to be loaded while supported on one side by the residual limb. In drastically alters its performance. Similarly lock A was designed to be loaded while bend around the residual limb. This configuration causes a force to be applied by the residual limb on the lock, ensuring that the dovetail joint remains in place. To better mimic the loading conditions the locks would be subjected to, a polylactic acid (PLA) buckle was designed to be used during the tests (Figure 20; left and middle). It forced the locks to form around an arc while the load was applied by the machine. The downside to the buckle was the added friction. It likely caused a slight overestimation of the locks' performance during the tests. Fillets and chamfers were implemented to reduce friction and minimize the buckle's influence of

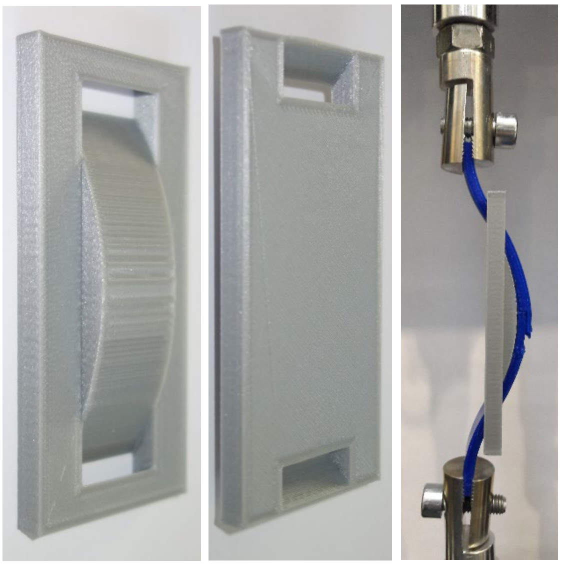

Figure 20. Tensile strength test setup. Left & right: PLA buckle; Right: test setup

the test results. Real-life wearing conditions lead to widely varying loading conditions. For this test however, only quasi-static loading conditions were applied. The locks were elongated at a rate of 5 mm/min until the point where they disconnected, either with or without permanent deformations. Samples were only subjected to multiple test if the locking mechanism remained functional, up to ten in total.

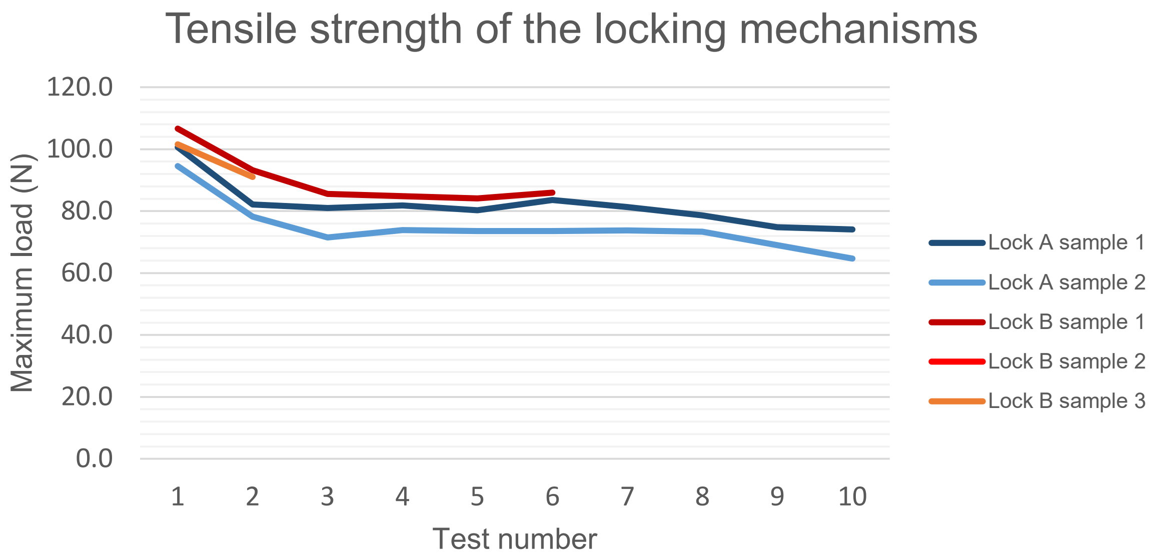

Figure 21. Tensile strength test results

Results

The results of the tensile strength tests are displayed in Figure 21. Both samples of the type A locks and the first of the type B locks were produced with the settings displayed in the Appendix. Unfortunately lock B samples 2 and 3 were produced with slightly different settings (lower temp., crisscross infill). Type A locks did not break when they failed. Instead the loop disconnected from the inclined block, with barely noticeable permanent deformation. This allowed the tests to be repeated the intended ten times. Maximum loads of 100.6 N and 94.5 N were achieved with samples 1 and 2 respectively. Their maximum load capacity decreases 28.9% between the first and tenth test on average. The largest changes occurred between the first and second tests (17.2% on average). Lock A decreased performance could be attributed to slight permanent deformation at the loop, making it more prone to disconnect from the inclined block.

Type B locks overall performed better at the first round of testing, achieving maximum loads of 106.6 N, 95.1 N, and 101.6 N. The latter two were printed with suboptimal settings and the results show. Sample 2 lasted only one round of testing, and sample 3 only two. The correctly printed sample lasted six rounds of testing. Here too maximum loads decreased especially much between the first and second tests (12.6%). Contrary to the type A locks however, significant delamination occurred after the sixth test, after which the lock was deemed unusable.

Strength test were also performed on the fully assembled interface to test its performance when subjected to everyday life loads. A concrete cast of the authors elbow was created for this purpose using plaster bandage mould (Appendix F). This cast was then fixed to a workbench after which the interface was donned. Two metal bars were fixed on the interface to attach the weights on. It extended 30 cm from the distal part of the interface to mimic the placement of the load when a prosthetic hand would be attached. Two test setups were used, inspired by the thesis project by Marina Pogosian[44]. Axial force was tested in the first setup, and radial force in the second, mimicking holding a bag with zero degrees anteflexion in the shoulder/elbow extended and elbow flexed 90° respectively. Weights were added in increments of 0.5 kg, up to an intended 10 kg. This limit was based on the likely maximum loading condition in activities of daily living (e.g. heavy grocery bags, luggage, and weight lifting). Clear permanent deformation, breakage or other obvious device failure would have ended the test pre-emptively. Unfortunately the temporary fixation of the extension failed at a weight of 8 kg in the radial force test condition. The interface showed no signs of permanent deformation however.

IV – Discussion

A transradial prosthetic interface has been designed for low-income countries. In contrast to many earlier attempts, the fact that the interface would be produced with AM was fully integrated into the designing process. The decision to create an AM version of the WILMER Open Socket led to an interesting choice. Print the interface in its final shape or print the interface perfectly flat for optimal material properties. The latter did require reassembly post-manufacturing but was nevertheless chosen as critical factors like print reliability and optimal material properties benefited from it greatly.

Overall this design philosophy led to satisfactory results. A completely flat print proved to be reliable and resulted in durable prints. The production method did create its own challenges. Material choice for instance became limited to flexible yet durable variants. Luckily TPU 95A fit all criteria and thus no compromises had to be made. Another obstacle to the design philosophy was the need for a locking mechanism. Designing the locking mechanism proved to be more complicated than expected. TPU 95A is very flexible. This combined with the fact that dimensional accuracy was limited meant that a forgiving yet good performing design had to be made. On top of that, the flat print and forced print orientation limited design options. After all, unideal printing orientations of the locks would have defeated the whole purpose of printing flat. Both locking mechanisms overcame these challenges. Lock A was able perform well while bend around the residual limb. Another advantage was that it did not negatively affect the curvature of the circles. Neither did it substantially exceed the overall interface dimensions. Lock B had to perform under different circumstances. It did not have to be forced around the residual limb yet had to be opened and closed far more often. The resulting lock managed to sustain loads considerable loads. Operating it one-handed also proved to be effortless. Lock A and B were able to sustain loads up to 100.6 N and 106.6 N respectively. Their performance did drop significantly as testing continued. The advantage of lock A was the fact that permanent deformations were minimal even when it failed, allowing continued testing and thus daily usage. Lock B on the other hand did suffer from delamination, even with the intended printing conditions. The biggest contributor to tensile strength of a 3D-printed part appears to be mass[42,41,38], although print temperature[45], nozzle size and flow rate[43] influence the tensile strength of a FDM part as well. One could assume these parameters would influence the performance of the TPU locks as well, however optimal print parameters were not examined for this study.

A drawback to the new interface is the inability to lock the condyle brace at different position. It allowed the WILMER Open Socket to be tightened or loosened whenever to fit the wearer's preference. It also allowed the interface to "grow with" children. The locking mechanism that facilitated this option did bulk up the interface considerably. It was not a primary goal of this project to facilitate this option as well. Although not integrated into the design, an alternative option does exist. One could manufacture condyle braces of different lengths. They can be interchanged easily, are fabricated in a little over an hour, and require only ~9 grams of TPU filament.

The flat AM WILMER Open Socket was unfortunately not fitted on amputees. Their experience wearing the interface could have identified weaknesses and possible improvements. It is recommended for a future study to do so. The quasi static tensile strength test results do not necessarily translate well to real-life wearing conditions. Cyclic loading tests would give more insight the interface's long-term performance and is thus recommended. Another recommendation for future studies is the forearm connection. Although a possible solution to the limited flat build dimensions was given in section III.IV, more research has to be undertaken on this subject.

The total manufacturing time of the entire interface was 7 hours and 23 minutes. It weighed a mere 57 grams, which translates to a material cost of 5.47 euros. Material cost however is only a small fraction of the actual cost a 3D printed part. Cost factors like labour, power usage, and location have to be taken into account for fair comparisons. Nevertheless, this study presents a durable, easy to print, and easy to size transradial interface that lends itself especially well to usage in low-income countries.

V – Conclusion

This study proposes an alternative approach to AM interface design. The fact that the interface was to be produced with AM led to the decision to print the interface in three separate, perfectly flat parts. Two different locking mechanisms, each optimized for their intended application allowed reassembly. This interface can be manufactured in roughly 7 hours and 23 minutes at a material cost of just 5.47 euros. This coupled with the fact to simple anthropomorphic measurements are all that is required for fitting the interface makes the design a good fit for low-income countries and challenging settings.

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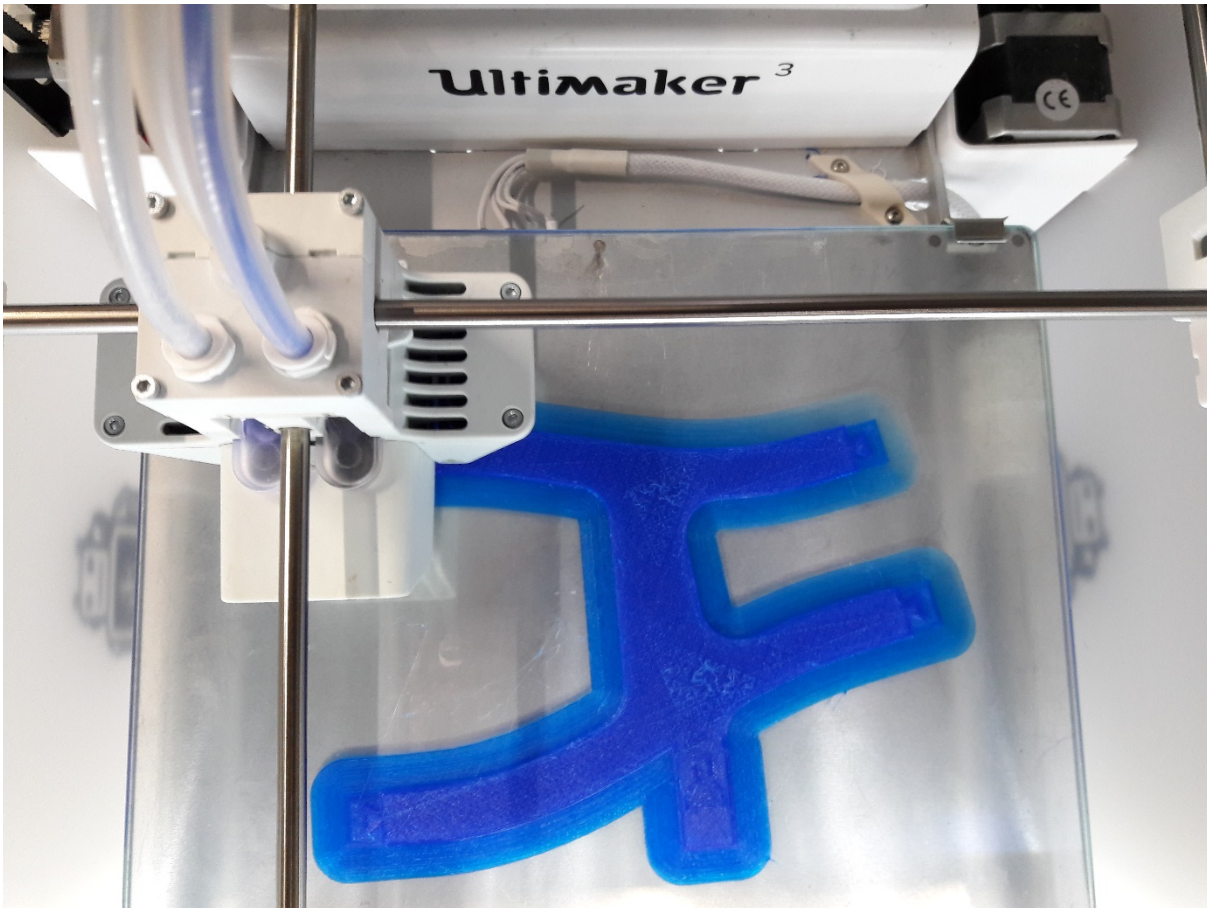
Appendix



Contents

A – Literature study

Additive manufacturing of transradial prosthetic interfaces – A review

Matthijs Anne Mazereeuw

Abstract

Objective: This review aims to provide an overview of transradial prosthetic interface designs fabricated with additive manufacturing. Scientific literature, design sharing websites and projects have all be included. Design principles will subsequently be identified. Additionally manufacturing techniques and the application of these designs will be discussed.

Method: Searches for scientific studies were performed on PubMed, Scopus, and Web of Science. Other designs were found on websites and in a recent review.

Results: In total 19 designs have been included in this review. These have been categorised as being anatomically contouring or mechanically adjusted. The former was mostly used in scientific studies, the latter by online communities and humanitarian organizations.

Conclusion: A large number of additive manufactured transradial prostheses exist, however the prosthetic interface appears to be an afterthought in most cases. Design considerations and motivation for certain choices is rarely given as a result. This is unfortunate, as prosthesis comfort is often rated at least as important as prosthesis hand function.

Keywords: socket, prosthetic interface, 3D-printing, additive manufacturing, upper limb, transradial

Introduction

Traditional prosthetic interface fabrication requires a skilled orthopaedic technician to manually ensure a good fit with the residual limb[1]. This time consuming manual labour is estimated to account for 83-86% of the total cost of a conventionally produced interface[2]. The other major contributor is material. A plaster cast, positive model and check socket are all required for the fabrication of the final socket. As the entire process is often manual without Computer Aided Design (CAD), no records are kept of previous designs. As a result the entire process has to be repeated for replacements or adjustments[3]. Some prosthetists do utilize CAD software to aid in the designing process. In those cases the CAD model that is obtained with a 3D scanner will be imported into a CNC milling machine to obtain a physical positive model[4].

The possibility of using additive manufacturing (AM) to build CAD prosthetic sockets has been explored since the 1990s[5,6]. Since then many designs have been created by scientists and enthusiasts alike. Research has focussed on improvements such as variable compliant areas to relieve pressure[7,8], thermal assessment[9] and the application of Finite Element Analysis(FEA)[1,10,11]. Poor design can cause discomfort and skin issues, which are experienced by an estimated 75% of the amputees[12], can cause patients to abandon the prosthesis altogether[13]. Projects that utilize AM for the production of prosthetic hands and forearms could incorporate above-mentioned research findings in their socket design to prevent these problems. However, a 2017 review by Ten Kate et al.[14] indicated that in roughly halve the cases Velcro is used to connect and tighten the prosthesis to the residual limb. In other cases an existing socket was used. Designs that rely on Velcro straps for suspensions are not necessarily inferior to more (traditional) anatomically contouring options, the possibility of AM to provide a uniquely tailored design is not utilized either. After all, a major advantage of AM is that production cost is related mostly to the required material rather than part complexity or number produced, meaning that there is no cost penalty to unique sophisticated designs in terms of fabrication[15]. The potential lower cost and required material could make AM sockets a viable alternative if factors like reliability and durability are similar to traditional counterparts.

AM interface designs aren't limited to scientific literature. Online open-source AM communities like e-NABLE[16], www.thingiverse.com, and www.3print.com allow enthusiasts to create and share their designs with ease. This combined with the high availability of entry-level 3D-printers leads to a large collection of AM interfaces. Other researchers have recently made overviews of prosthetic socket designs. Chen et al. (2016)[17] recently wrote a review, however upper limb sockets were not considered. Ten Kate et al. (2017)[14] did consult both scientific literature and websites for AM upper limb prostheses, but was not focused on sockets. Phillips et al. (2015)[18] wrote a review as well, but focussed on upper limb prostheses for resource-limited settings exclusively, no matter what fabrication method.

Problem statement

No review of AM produced upper limb prosthetic interfaces exists that includes scientific literature, websites and humanitarian projects.

Objective

The goal of this review is to give an up to date overview of AM prosthetic interface designs for transradial amputees. Both scientific literature and websites will be consulted. Pros and cons from different design principles will be discussed in an attempt to illustrate in which direction the field could best progress.

Method

Search strategy

Computerised searches on PubMed, Scopus, and Web of Science were performed on the 2^{nd} - 6^{th} of April 2018 respectively. Preliminary searches indicated a lack of studies that focus on an AM prosthetic interfaces exclusively. This led to the decision to broaden the search for all studies on AM upper limb prosthetics regardless of the sockets' importance in the overall study. Whether this included a transradial prosthetic interface would be reviewed after. Search terms were similar across all three platforms. The exact Boolean combination of keywords per database is given in the Appendix.

An internet search was also performed. The following websites were fully explored: www.enablingthefuture.org, www.3ders.org, and www.thingiverse.com. These websites allow volunteers and enthusiasts to share and alter open-source prosthetic designs. Additionally a search was performed on www.google.com, searching for 3D printed upper transradial sockets specifically, and a 2017 review by ten Kate et al.[14] was used as it included AM prostheses from websites as well.

Inclusion criteria

Due to the large number of contributors and small number of original design principles, not all designs that were encountered on websites were included. The goal of this study is to identify design principles and how they function. With that in mind, designs that represent a large collection with minor variations were chosen and included. For example, the RIT arm[19] by e-NABLE[16] has been modified by many contributors on the website www.thingiverse.com, yet only the original has been included. For the sake of meaningful comparison among results, only transradial sockets will be included. Literature studies en website designs that did not describe the socket at all or specify whether it was fabricated with AM have also been excluded. Sockets that were fabricated with a technique other than AM have also been excluded. Although not specifically searched for, results and references with principles that could be applied on transradial interfaces, like FEA of transtibial sockets, were consulted. The designs will subsequently be categorized and findings of the creators shared.

Results

Search results

1985 scientific sources resulted in total. This large number is a direct result of the relatively broad search strategy, discussed earlier. Based on the title alone roughly 90% could be excluded. Abstracts were read of the remaining titles. If relevance was still unclear the entire article was checked as well. Five unique designs have been included in this review. Naturally, references that were encountered in literature were also considered, but yielded no additional socket designs. Www.google.com, the listed websites, and ten Kate et al. (2017) produced fourteen included designs. Table 1 gives an overview of all included prosthetic interfaces. Two types have been distinguished; anatomically contouring (6) and mechanically adjusted (12). Although the latter is often scaled to the user, its main method of suspension and adhesion to the residual limb is adjustable Velcro straps. Remarkably enough, the socket part of the prosthesis was in almost all cases described in far less detail than the hand section. Elaborate motivations and design considerations were lacking as a result.

Table 1. Overview of AM sockets found in literature and on websites

Author/project	Type of socket	Material	Printer	Process	Notes
Socket designs in scientific literature					
Gretsch et al. 2015[20]	Anatomically contouring	ABS	MakerGear M2 desktop 3D printer	FDM	The gel liner and socket are attached to the residual limb through friction alone.
Herbert et al. 2005[3]	Anatomically contouring	Polypropylene	Z Corporation Z402 3-D printer	FDM	Dried in low-temperature oven and infiltrated wit PU resin to increase mechanical properties
Radosh et al. 2017[21]	Anatomically contouring	ABS and TPU	MakerBot Replicator 2X	FDM (dual extrusion)	Rigid core (ABS) and elastic shell (TPU). TPU is sold under the commercial name of NinjaFlex
Yoshikawa et al. 2015[22]	Mechanically adjusted	ABS	Fortus 250mc, Stratasys Ltd.	FDM	Inner side lined with high frictional fabric (DAIYA KOGYO Corp.). Available in four sizes
Zuniga et al. 2017[23]	Mechanically adjusted	PLA	Ultimaker 2 or Uprint SE Plus by Stratasys	FDM	Very little information on the socket.
Socket designs in other sources					
Bachelor project[24]	Mechanically adjusted	PLA	XYZ Da Vinci 1.0, Dimension SST 1200es, Makerbot Replicator 2, and Sindoh 3D printer	NS	Inside struts lined with EVA foam for comfort
Exiii Inc.: - HACKberry[25] - handiii COYOTE[26]	Mechanically adjusted	ABS recommended[27]	Designed for UP! Plus2 printer[28]	FDM	Two similar open-source designs. Handiii COYOTE is and earlier prototype
Hero Arm[29]	Anatomically contouring	NS	NS	FDM	FDA approved. Removable, breathable socket. Can compress and expand for comfort. Includes flexible liner.
Ivania 2.0[30]	Mechanically adjusted	Nylon 12	NS	SLS	Intended to be used as ornamentation first.
JD-1,2,3[31]	NS	NS	NS	SLS	A few different iterations. None appear functional.
Limbitless solutions Bionic Arm[32]	Mechanically adjusted	ABSplus	Stratasys printer	FDM	Socket scaled to the user after which minor tweaks can be done.
Project Daniel (2.0)[33]	Mechanically adjusted	PLA	MakerBot Replicator 2	FDM	
Stromshed 2016[2]	Anatomically contouring	Nylon 12	EOS Formiga p110	SLS	Material is added and removed digitally according to marked anatomical areas
The LifeArm[34]	Mechanically adjusted	NS	NS	NS	The forearm section is fastened over a ‘’regular’’ liner with Velcro. Combined with thermoplastic triceps cuff
The RIT arm[19]	Mechanically adjusted	ABS or Nylon recommended	N/A	FDM	
The UnLimbited Arm 2.0[35]	Mechanically adjusted	PLA	N/A	FDM	
Unlimited Tomorrow[36]	Mechanically adjusted	PLA	N/A	FDM	
Victory Hand Socket[37]	Anatomically contouring	PLA	Ultimaker 2+	FDM	A plaster model fitted by a prosthetist is scanned. Used in combination with regular liner

Abbreviations: NS: not specified, PLA: polylactic acid, ABS: acrylonitrile butadiene styrene, FDM: fused deposition modeling, TPU: thermoplastic polyurethane, SLS: selective laser sintering, EVA: thermoplastic polyurethane, TRAC = transradial anatomically contoured, N/A: not applicable

Anatomically contouring designs

Three scientific studies and two other sources created patient-matched devices. Only Strömshed[2] and the Victory Hand covered (part of) the elbow as well. Herbert[3] and Radosh[21] created exact limb replicas, similarly to traditional transradial sockets. Gretch[20] created a custom socket, made to fit over a traditional liner, while the Hero Arm[29] custom made the liner and socket themselves.

Transradial anatomically contoured (TRAC)

Figure 1. Transradial anatomically contouring socket by Strömshed (2017). a) Smooth design. b) Lattice pattern design.

Strömshed[2] used a combination of a supracondylar and supraolecranon socket. This combination ensures sufficient suspension, comfort, stability and pressure distribution[38]. The design mimics the traditionally manufactured interface to a large extent. Utilizing bony prominences means that liners or sleeves won't be necessary. The socket still covers the residual limb completely, which could result in heat accumulation problems. According to Strömshed[2] prominent bony landmarks and the thin tissue that covers it could be a source of problems of not taken into account. To prevent this Strömshed used an iSense 3D scanner[39] mounted on an iPad to obtain a 3D model of the residual limb, complete with premade markings of relevant anatomical structures. The markings indicated where material should be digitally added or removed to provide the best fit. The socket is fabricated from 2mm thick Nylon 12 using SLS technology. A lattice pattern covered socket variation was also produced (Figure 1; right). The smooth solid part and lattice pattern both were made 1mm thick. The overall decreased wall thickness should increase flexibility while stability is preserved. Based on data from the Orthopedic company worked with it was estimated that 45% of all transradial cases could use 3D-printed Nylon 12 instead of the conventional manufacturing method. Strömshed[2] used two case studies, both of which resulted in satisfied patients.

Figure 2. Transradial anatomically contouring socket by the Victoria Hand Project. Left: Hand Forearm Socket. Right: Victoria Hand Suspension Socket. ref:victoriahandproject.com

The Victory Hand (Figure 2) is produced by 3D scanning a rectified plaster positive mould made by a trained clinician or prosthetist. Scanning a plaster cast instead of the residual limb itself is less prone to errors resulting from involuntary movements. The scan is then combined with an equation driven Forearm Socket using CAD software and subsequently printed. Similarly to body powered mechanically adjusted sockets a triceps cuff is used in combination with the forearm socket. A variation of the socket for short-limbed transradial amputees (Figure 2: right) has also been produced with increased support. It appears to utilize supracondylar suspension. This organisations' device and the Unlimited tomorrow hand[36] are the only included devices to use myoelectric actuation for the hand.

Exact limb replicas

Figure 3. Exact limb replica by Herbert et al. (2005)

In this category, in contrast to the TRAC design, bony prominences are not utilized to ensure suspension, which means that a liner is often still necessary. Leather-rubber liners have been associated with unpleasant high perspiration and thermal environment in the socket[40], a problem that could be reduced with different liner material and thickness[41]. Two scientific studies produced an exact limb replicas[3,21]. Herbert et al.[3] scanned the residual limb using the TracerCad Premier Prosthetic system (OrthoEurope, Oxforshire, UK) and modelled the socket with SolidView Pro CAD software (Solid Concepts, Inc, Valencia, CA). A uniform wall thickness of 2 mm was used. Herbert[3] fitted two transtibial and one transradial prosthesis. Patients experienced these to be as comfortable as those made by traditional methods. Strength and durability of the produced sockets remained untested.

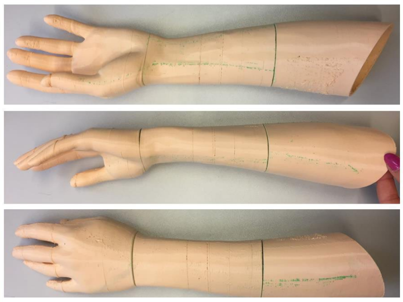


Figure 4. Exact limb replica by Radosh et al. (2017)

Radosh et al. (2017) scanned the residual limb and subjected the resulting mesh to an offset operation[21]. This small additional space was made for ergonomic purposes, as the stump can change volume in time. In contrast to all other designs, the goal was to have a cosmetic prosthesis. It was also the only study that took advantage of dual extrusion FDM. It allowed the authors to combine a rigid ABS core with an elastic thermoplastic polyurethane (TPU) shell. The authors did not specify whether a liner is necessary.

Other anatomically contouring designs

Figure 5. Hero Arm liner and removable outer socket. ref:openbionics.com/hero-arm/

Gretsch et al. (2016)[20] developed a socket that directly connects to the compartment that houses the electronics. The custom-made socket requires a gel liner made by a prosthetist. Friction holds the socket in place. Furthermore, the authors states that the socket can be scaled. This allows users to easily print a new one with age. The Hero Arm by Open Bionics features a liner as well. Its fabrication method and material are not specified on the website. In contrast to traditional liner, this one has openings throughout to increase ventilation. The overlaying socket is breathable as well thanks to an open mesh structure. The socket is also compressible and expandable for increased comfort by simply turning a small wheel on the side.

Spatially variable stiffness

Anatomically contouring the residual limb has been used in many AM produced transtibial cases[7,8,10,15,42]. Researchers have attempted to vary the stiffness of the socket in order to distribute pressure on the residual limb optimally. Variable wall thickness has been used to achieve spatial variable stiffness[7], which leads to considerably less pressure on the residual limb[8]. Another approach was the implementation of spiral compliant areas backed by a diaphragm spring over bony prominences[15]. These springs increased the overall size of the socket, impacting cosmesis negatively. Comotti et al. (2017) achieved varying stiffness by changing the infill ratio, pattern, and orientation in each part of the socket[43]. This principle has not been adapted to AM transradial cases yet.

Mechanically adjusted designs

The mechanically adjusted design principle has been adopted mostly by humanitarian projects and online communities like e-NABLE. Many variations exist. In most cases a triceps cuff is hinged to a forearm gauntlet. Straps or Velcro tighten it to the body. The Peter Binkley method[44] can be used to measure a patient's required prosthesis scaling factor from a photo and subsequently scale an e-NABLE device accordingly. For body powered models, hand actuation is often achieved by bending the elbow. Cables run through the forearm gauntlet connect the hand and triceps cuff. A harness has also been used (LifeArm) to make the grasping function independent of elbow position. The Unlimited Tomorrow hand[36] (Figure 6) uses myoelectric actuation, but uses the gauntlet/triceps cuff combination as well. In contrast to many e-NABLE designs, some non-AM components like metal screws are required for assembly.

Figure 6. Mechanically adjusted Unlimited Tomorrow Hand. ref:blogs.msdn.microsoft.com

Figure 7. The UnLimbited Arm. ref:http://enablingthefuture.org/team-unlimbited-arm/

E-NABLE's Team UnLimbited body powered arm[35] is sized to fit each patient. Three separate measurements on the non-affected arm allow anyone with a 3D printer to scale the prosthesis. Additional required materials are 20mm wide double sided Velcro to be weaved through the slots (see Figure 7), Dr Scholl Moleskin Plus Padding for lining the cuff and inside the forearm, and ≤1mm uncoated fishing line for the tendons. Although the half-open design covered with Velcro might not be optimal in terms of cosmesis, it does allow heat and sweat to get away easily on one side.

Figure 8. Mechanically adjusted Lifearm by 3Dlifeprints. ref: 3dlifeprints.com

The LifeArm by 3D LifePrints combines a thermoformed cuff with a forearm section. Whether this forearm is custom made or available in a few different sizes is unclear. A conventional liner is still required. Velcro straps on the proximal rim of the forearm fasten it to the body.

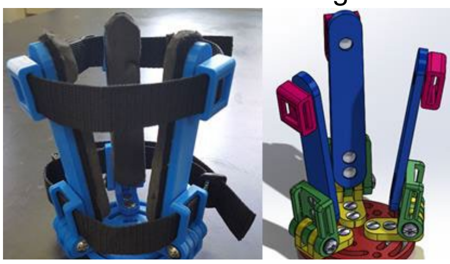


Figure 9. Mechanically adjusted design by students from the Worcester Polytechnic Institute

A very different approach was used by students from Worcester Polytechnic Institute[24], see Figure 9. Three EVA foam covered struts are tightened over the residual limb by an overlaying strap. The circular base plate connects to the prosthetic hand section. The elbow can not be used to actuate a prosthetic hand, as the socket does not cover it. Yoshikawa et al. (2015) used a similar design principle available in four different sizes. The forearm section of the prosthesis extends over the residual limb to form two plastic sheets lined with high friction fabric (DAIYA KOGYO Corp.). An overlying belt tightens the arm to the body. Fortunately the socket is washable.

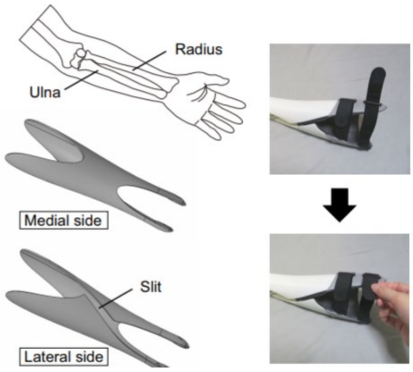


Figure 10. Mechanically adjusted Rehand design Yoshikawa et al. (2015)

Japanese based device startup Exiii Inc. produced the handiii (COYOTE[26]) and more recent Hackberry[25]. The handiii COYOTE is designed to fit every transradial amputee. Detailed information of the sockets' method of working is not specified, but it appears to clamp onto the residual limb with two plastic sheets. The latest iteration, HACKberry, is fastened to the residual limb with straps (which also house an infrared sensor). An advantage of the open-source HACKberry, is that the socket is not crucial to the workings of the hand. Other types of sockets and traditionally made sockets could thus be adapted to fit the hand. This possibility is discussed on the Exiii forums as well[45].

Figure 11. handiii (left), handiii COYOTE (middle), and HACKberry (right) by Exiii Inc. ref: techinasia.com

A weakness of mechanically adjusted sockets without liners and triceps cuff is that all forces that pull on the socket have to be compensated for by high friction foam and/or tight Velcro straps. While some of the listed designs are scaled to fit each patient, they are still largely dependent on a simple Velcro strap. One could argue that AM is not the most efficient fabrication method for such designs. A small number of different sizes could be fabricated with injection moulding at a faster rate against a lower price.

<u>Non-AM produced sockets</u>

Transradial sockets fabricated using techniques other than AM have advanced for years[46]. Early designs such as the Muenster-type[47] and Northwestern-style[48] sockets enveloped the residual limb completely. The former was focussed primarily on anteroposterior stability at the cubital fold to achieve self-suspension[13], while the latter utilized medial-laterial stability mostly to accommodate longer residual limbs and increase range of motion (ROM). Later designs targeted heat and sweat accumulation in the socket by exploring open designs. The ergonomic socket design concept[49] and subsequent WILMER open socket design[50] strategically place tubes around anatomical structures to ensure suspension and ROM with minimal contact. The ¾ transradial socket achieved these goals by removing the non-contributory section covering the elbow[51].

<u>Prosthetic socket for low-income countries</u>

Is has been estimated that less than 3% of people in low-come countries with disabilities have access to required rehabilitation services and devices[52]. A new approach is required to address this problem. While AM sockets were considered costly early on[5], more recent studies state low manufacturing costs as one of the main advantages[3,53]. AM arms cost only around 50-150 USD[16,21,34] in material. This amount is much higher when labour costs are considered[2,21].

Organisations such as e-NABLE[16] and the Victoria Hand Project[37] have created AM upper limb prosthetics with low-income countries in mind. The UnLimbited Arm[35] is an open-source design by the e-NABLE community that can be printed by anyone and sized to fit the individual using three measurements. Distribution of the arms is not regulated. Many versions of their designs exist thanks to a large online community. In contrast, the Victory hand design is not available online. The non-profit organisation (Victoria Hand Project) run by a team from the University of Victoria provides files only to collaborators. They team with local clinical partners. Local staff is trained and equipment is set up. Subsequent support and follow-up ensures success. The downside to the Victory hand is its dependence on a trained prosthetist. Instead of 3D scanning the residual limb itself, a plaster model is created the traditional way. The rectified positive is then 3D scanned and combined with an equation driven forearm socket in CAD software and printed.

AM prosthetics for developing countries have more shortcomings, even when no trained prosthetist is required. Printing a prosthetic hand takes a long time and will occupy a printer for the entire duration. Power-cuts during this long production will result in product failure and varying climate conditions affect the production process negatively. Additionally, finding trained professionals to operate the printers in the first place can be challenging.


Figure 12. LN-4 mechanically adjusted design. http://www.rotarykenton.co.za/ln-4-give-hope-give-hand/

While the focus of this review is AM produced sockets, progress in the field should not neglect non-AM solutions. Mass produced off-the-shelf prostheses/sockets could be more cost-efficient than customized sockets printed locally. One such case is the LN-4 prosthetic hands by the Ellen Meadows Hand Foundation. Instead of creating a unique hand for each individual, qualifications are set relating to the minimum length of the residual limb, age, and skin condition[54].

<u>*Printing techniques and materials*</u>

Printing technique

Fused Deposition Modelling (FDM) was the most common printing technique followed by Selective Laser Sintering (SLS) among the results. Biomechanical performance of FDM transtibial sockets has been verified[55], which motivated Herbert et al. (2005) to use it as well. FDM is known to have long fabrication times[56,57], which Herbert et al. overcame by building a customized FDM machine with a wider nozzle, sacrificing some accuracy in the process. Radosh et al. (2017) lists good strength and shape and dimensional accuracy as motivations for choosing FDM. Low cost and it being the most widespread method are also mentioned. Mainly humanitarian organisations don’t always specify their motivation to use FDM, but one can assume that it’s low cost and widespread use were taken into account. Gretch et al. (2016) and Yoshikawa et al. (2015) did not motivate their choice to use FDM. SLS was used by Strömshed[2]. It was deemed most suitable for AM sockets because of the techniques’ high accuracy, xyz-direction quality, good surface finish and little required post processing. Overall SLS building times are lower[56,58], accuracy higher[58,59], and costs higher[58] compared to FDM. Intended implementation of the AM sockets will thus determine the most suited technique.

Materials

The choice of material is limited by the AM technique. As a result the most common FDM materials Acrylonitrile Butadiene Styrene (ABS) and Polylactic Acid (PLA) were used in most projects. PLA allows for sharper features and is biodegradable[60]. Structural stability however is lacking with moisture and high temperatures present[61,62]. ABS has higher ductility and can thus be employed for high end use[60]. Printing with ABS is more changeling. None of the authors who utilized ABS motivated this choice[20,21,63]. The UnLimbited Arm by e-NABLE used PLA for its thermoplastic capabilities. Subsequent thermoforming allows for personalized fitting of the triceps cuff. The organisation aims to print parts totally flat, as it will aid with strength, print time and removes the need for support material[64]. The Victoria hand project's choice fell on PLA mainly because it is easier to print with than ABS[65], a quality that is highly important when less experienced 3D printers need to be able to print as well. A UV resistant and slightly stronger version of ABS also exists; Acrylic Styrene Acrylonitrile (ASA). Another prosthesis by e-NABLE is the RIT-arm, which is recommended to be printed with either Nylon or ABS[66].

Nylon (a.k.a. polyamide or PA) can be used in FDM, SLA and SLS printers. Also used by Strömshed (2016), it is known for its high strength and flexibly, excellent long-term constant behaviour, and biocompatibility[67]. Printing with Nylon is more challenging to print with than PLA and ABS[68]. Nylon is also more hygroscopic than both ABS and PLA, which means that humidity will be easily absorbed by the filament. Affected filament will negatively affect the print. Desiccant bags or containers can be used to prevent moisture from affecting the filament. When organisation intend to print locally in challenging conditions however, Nylon might not be suited. 3D LifePrints develops their material in-house[69]. Advantageous properties include enhanced resistance to microbiological attack, hydrolysis, UV, and availability in ten skin colours.

Another material option is Thermoplastic PolyUrethane (TPU). Compatible with a FDM printer, this flexible, highly elastic, and hard-wearing material[70] could well be incorporated into a design. A downside, as pointed out by Radosh et al. (2017), is that TPU is relatively hard to print with. As a result, their printing process had to be supervised constantly. A variety of TPU is ThermoPlastic Copolyester (TPC). It is not as commonly used as TPU, but is more resistant to UV exposure[70], an important quality for outdoor products that many other materials lack.

<u>*Ensuring reliability and validity of AM sockets*</u>

Few studies assess the efficacy and effectiveness of AM manufactured upper-limb prosthetics[71]. Case-studies are included occasionally. Goh et al. (2002)[72] completed 250 000 cycles of sinusoidal loading on a transtibial AM socket without observable delamination or cracks between layers. Solely proof-of-concept is more often demonstrated[71]. This is not sufficient to ensure safety for patient usage, especially for transtibial cases. Extensive follow-up studies and device testing will be required in the future. The Food and Drug Administration (FDA) anticipate that AM devices will be subjected to the same requirements as non-AM devices of the same type, with rare exceptions[73]. In the transition from digital to physical, AM execution can greatly impact the quality of the device. As such, the FDA indicates that control limits should be established to ensure that predetermined requirements are met[73]. Influence of build volume placement, support material handling, slicing, build path setting, machine parameters, and environmental conditions all impact the fabricated device and should documented. Organisations like e-NABLE do not have to conform to FDA regulations, as they do not charge patients for the prosthetics and inform users of potential risks. The Hero Arm by Open Bionics is the only FDA approved device in this review.

Finite Element Analysis

A way of ensuring quality of the manufactured device is finite element analysis (FEA). FEA has been used for transtibial socket designs in many cases[1,7,11,53,74]. Using FEA, Rogers et al. (2001) were able to successfully predict the area most likely to fail. Similarly Faustini et al. (2006)[53] performed structural analysis using FEA to ensure structural reliability of a compliant socket. Experimental tests showed that the force that lead to socket failure was within 3% of the FEA predicted value. Just as with Rogers[7], the predicted peak stress region corresponded with the region of failure. Compression deformation test indicated less strong predictions, especially closer to failure loads. One of the given limitations is the varying pressure profile among patients. Results from a FE model by Lee et al. (2005)[75] suggests a relation between peak pressure and pain triggered. Interestingly, a thick layer of soft tissue did not translate to higher load-tolerant ability as one would expect. Computer simulations have also been used to predict socket fit[74]. In this way designs can be evaluated before they are actually printed. Given the irregular geometry of the stump interface and that the contact surface changes with tissue deformation nonlinearly, modelling and simulating socket-stump interaction remains challenging[1].

Manufacturing problems could lead to socket failure, regardless of FEA results. Inter-layer bonding strength ultimately determines the strength of the product. A suboptimal printing process could (e.g. heat, build speed) affect this bond and allow the socket to fail. Another thing to keep in mind is the decreased tensile strength of laminated polypropylene compared to polypropylene sheets[72]. In other words, AM socket require thicker walls compared to traditional manufactured sockets from the same material.

Discussion

The literature search showed that the majority of scientific studies regarding AM sockets is focused on transtibial cases. Some findings such as the application of Finite Element Analysis can be transferred to transradial sockets. Others like design principles less so, because they largely depend on anatomical shapes and loading patterns. Scientific literature on AM transradial sockets seemed to favour the anatomically contouring devices. Humanitarian organisation and online communities favoured mechanically adjusted designs. The lack of available 3D scanners and the required expertise of such a design are a possible reason for that. It could also be the result of the goal. If the socket is to replace and compete with sockets created by well-trained prosthetist, a design that mimics the qualities of the already existing non-AM devices might be preferred. On the other hand, if the device is to fit a large number of potential wearers at the lowest cost and required expertise possible, a mechanically adjusted design might simply be the better option. However there is no arguing that CAD/CAM could improve the process for personalized designs, no matter the intended application. Alterations to a digital scan of the residual limb can be made indefinitely and stored. Subsequent AM lowers both production cost and time, thanks to a largely automated process with minimal manual labour.

The strength of AM lies in its relatively low cost for a customized product. Using AM for prosthetic parts that are always the same size is inefficient. Long manufacturing times and less consistency in quality compared to other techniques like injection moulding being prime examples. AM can also be combined with other manufacturing techniques to overcome its weakness. For example, King et al. (2015) achieved speed and customization of a prosthetic hand by combining AM with injection moulding[76]. After all, injection moulding is faster and cheaper for large quantities. Anthropomorphic data was used to come up with 3 standardized gauntlet and finger sizes[76]. These are to be attached to a customized AM palm to ensure satisfactory patient fit.

The biggest weakness of AM socket literature and thus of this review is the lack of follow-up information. This hinders progress in the field as it becomes unclear is which direction improvements could be best achieved. Especially in scientific studies, occasionally a couple of patients will be fit with the design and their experience is described. Findings and weaknesses that become apparent from experience are not described. Humanitarian organisation like the Victoria Hand project and Project Daniel do fit the prosthesis to a large number of amputees. Neither the design philosophy nor experience of wearers are made available by these organisation unfortunately. Another weakness is the lack of focus on the socket section of an AM prosthetic arm. While function of the hand section are undoubtedly important, discomfort strongly associated with abandonment of the prosthesis[13].

With the AM field being relatively new, one would expect it to mimic design principles from existing socket solutions, which is not the case. Strömshed[2] created a socket most comparable to advanced TRAC designs created with other manufacturing methods. Herbert et al. (2005) on the other hand followed the design philosophy of traditional sockets most closely. This illustrates that AM sockets' lower costs is beneficial to middle- and high income countries as well. Proof-of-concept is not enough to ensure that quality is not sacrificed for this reduction is cost, thus thorough testing of AM sockets is necessary. The prosthesis industry could benefit greatly from this.

Conclusion

This review identified 18 different prosthetic socket designs produced with additive manufacturing. These sockets could be roughly categorized as anatomically contouring or mechanically adjusted. The former uses 3D scanners to digitize the residual limb in order to create a tightly fitting prosthetic interface, while the latter is mostly scaled to potential wearers with anthropomorphic measurements. Scientific studies favoured the former. Humanitarian organizations and online communities more often opted for a mechanically adjusted solution, where Velcro straps fasten the prosthesis to the residual limb. Their more forgiving fit and less required expertise are possible reasons for this choice.

FDM was the AM technique of choice in almost all cases. A motivation for this choice was not always given, but the relative low cost of FDM technology, its widespread use, and good product properties appear to be the main reasons. ABS and PLA were the most used materials. While Nylon is the material best fit for sockets, ABS and even more so PLA are easier to print with thanks largely to lower print temperatures and non-hygroscopic filament[77]. Especially in challenging environmental and working conditions faced by humanitarian projects.

Although a reasonable number of transradial AM sockets exist, their strength and long term usability remains largely unproven. This can generally be attributed to the lack of patient trials. Combined with the fact that the socket section of AM prosthetics appears to be an afterthought creates a situation where the field progresses unfocussed and inefficiently. Instead, an interface should be created that takes advantage of the strengths of AM; affordable, possibly complex, unique designs. Subsequent patient trials are crucial. Identified strengths and weaknesses will then guide others on how to proceed. AM has the ability to facilitate affordable personalized prosthetic interfaces to citizens worldwide and thus should be explored fully.

Appendix

PubMed: 898 results

((((((("Prosthesis Design"[Mesh] OR prosthes*[All Fields] OR prosthetic*[All Fields]))) OR ("Artificial Limbs"[Mesh] OR limb prosthes*[All Fields] OR artificial limb*[All Fields] or artificial extremit*[All Fields] OR arm prosthes*[All Fields] OR artificial arm*[All Fields])) OR ("Prosthesis Fitting"[Mesh] OR prosthesis fitting*[All Fields] OR prosthesis adjustment*[All Fields])) OR ("Amputation Stumps"[Mesh] OR amputation stump*[All Fields] OR residual limb*[All Fields] OR stump[All Fields])) OR (socket*[All Fields] OR prosthetic interface[All Fields]))) AND (("Printing, Three-Dimensional"[Mesh] OR three dimensional printing*[All Fields] OR three-dimensional printing*[All Fields] OR 3 dimensional printing*[All Fields] OR 3D print*[All Fields] OR 3D-print*[All Fields] OR additive manufacturing*[All Fields] OR rapid prototyping[All Fields]))

Scopus: 939 results

(((TITLE-ABS-KEY (additive AND manufacturing) OR TITLE-ABS-KEY (three AND dimensional AND printing) OR TITLE-ABS-KEY (3 dimensional AND printing) OR TITLE-ABS-KEY (3d AND print*) OR TITLE-ABS-KEY (3d-print*) OR TITLE-ABS-KEY (rapid AND prototyping))) AND ((TITLE-ABS-KEY (prosthe*) OR TITLE-ABS-KEY (artificial AND limb*) OR TITLE-ABS-KEY (artificial AND extremit*) OR TITLE-ABS-KEY (artificial AND limb*) OR TITLE-ABS-KEY (stump*) OR TITLE-ABS-KEY (residual AND limb*) OR TITLE-ABS-KEY (socket*) OR TITLE-ABS-KEY (prosthetic AND interface*)))) AND NOT ((TITLE-ABS-KEY (dental) OR TITLE-ABS-KEY (zirconia) OR TITLE-ABS-KEY (teeth) OR TITLE-ABS-KEY (pelvi*) OR TITLE-ABS-KEY (ocular) OR TITLE-ABS-KEY (acetabul*) OR TITLE-ABS-KEY (cemented) OR TITLE-ABS-KEY (uncemented) OR TITLE-ABS-KEY (total AND knee AND prosthe*) OR TITLE-ABS-KEY (total AND hip AND prosthe*) OR TITLE-ABS-KEY (total AND knee AND arthroplast*) OR TITLE-ABS-KEY (total AND hip AND arthroplast*) OR TITLE-ABS-KEY (cranial) OR TITLE-ABS-KEY (nose) OR TITLE-ABS-KEY (skull) OR TITLE-ABS-KEY (mandable))) AND (EXCLUDE (EXACTSRCTITLE , "Journal Of Prosthetic Dentistry")) AND (EXCLUDE (SUBJAREA , "DENT")) AND (EXCLUDE (LANGUAGE , "Chinese")) AND (EXCLUDE (SUBJAREA , "BIOC"))

Web of Science: 148 results

(Prosthe* OR artificial limb* OR artificial extremit* OR artifical arm* OR stump* OR residual limb* OR socket OR prosthetic interface) AND (3d printing OR 3d-printing OR three dimensional printing OR additive manufacturing OR rapid prototyping) AND (upper limb OR upper arm OR forearm OR arm OR elbow OR hand OR wrist OR transradial OR radial OR finger)

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B – Report of LIVIT visit

In order to establish the user requirements for a new interface design, a visit has been made to the orthopaedic company LIVIT. Cosmetic, body-powered, and myoelectric prosthetics are all supported by the company. Orthopaedic technician Raymon Wijmans has been working at the company for xx years and was happy to answer all questions.

The use of CAD/CAM technology for transradial patients

Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) is already implemented at LIVIT. Raymon explained that it is common practice for transtibial, but not for transradial cases. This probably has to do with the relatively low number of transradial patients. Other reasons given by Raymon are the relatively large number of patients who abandon the prosthesis, thus don't require new ones, or don't get one in the first place. A prosthetic interface and hand that better support the wearers demand could possibly lower these numbers.

Though likely to be of relatively low quality compared to what is possible with more recent technology, 3D scans of good fitting transradial sockets have been made by Raymon. The resulting library of designs was aimed to aid the prosthetist in making a later/replacement socket. CAM has not been applied yet for the fabrication of the actual socket.

Advice for an AM design

Raymon explained that in almost all cases, small changes are made to the initial socket design. Reasons given for this necessity are errors/misjudgements to the positive model, problems in the fabrication of the check socket, and the fact that a perfect socket based on a well-adjusted positive model doesn't always result in a perfect fit. For instance, during the visit, a patient requested the range of motion to be increased at the cost of suspension. If an AM interface does not allow for post-processing a new socket will have to be created to implement the changes. This is undesirable. Even though AM interface materials are relatively cheap, prints are time consuming. A future solution will have to allow for small alterations post-printing to improve fit.

Another advice was regarding cosmesis. Unconventional designs such as the WILMER Open Socket are also fitted. However, the airy design that allows over 75% of the skin to be exposed looks unnatural. The metal beams also tend to be visible through clothing. Raymon clarified that heat is mostly a problem in a liner when air is able to form between the skin and liner. The pockets heat up, which causes discomfort. If a printed liner is to be included in the final design, these airy pockets will have to be prevented

The intended application of the prosthetic hand should also be kept in mind. The intended application of the interface being low-income countries, a single design should be usable in as many application as possible. As Raymon explained, plastic interfaces without liners are used, but are limited in their suspension strength. The large area of high friction surface liners provide is simply unmatched. A future design should attempt to achieve considerable suspension despite being all plastic.

Raymon also noted the wide variety of residual limb shapes. This variety is most prominent in the distal part both in terms of shape and length. This will obviously complicate the goal of a universal design. Ideally the distal part of the design will have to be adjustable. Also, the design should not rely too much on the distal part for suspension and the like.

In short the following design criteria have been identified:

- Allows for small alterations post printing to improve fit in critical areas that affect the overall interface shape minimally
- Airy without affections cosmesis
- Achieve considerable suspension with only plastic materials
- The design should not rely on the distal part for suspension
- The distal part of the design should be adjustable/forgiving

C – Design criteria & Validation

All design criteria are listed in the table below. In the second column a short description is given, discussing whether or not the criteria have been met. Criteria like waterproof and self-suspension had to be met fully, not to a certain degree. They have not been included in the criteria for this reason.

Table D.1 Design criteria validation

Design criteria	Validation
Able to be fit without prosthetist	Thanks to the forgiving flexibility of the material and few required dimensions of the residual limb, a prosthetist is not necessary
Allow post-print alterations	As was predicted in the weighted decision matrix, this criterion has not been met. Only concept A met this criterion thanks to the implementation of a thermoplastic filament. Small imperfections can be corrected with sanding paper for instance. This advantage of this design is that the condyle brace can easily be sized up or down and reprinted, because the interface is printed is separate parts.
Airy	Similar to the WILMER Open Socket, the majority of the skin remains uncovered.
Comfort	TPU 95A's flexibility will aid in the comfort of the interface. Chamfers at the edges and a thin slap of material to protect the skin from the type A locks should help as well.
Durable	TPU 95A is manufactured by Ultimaker. It is advertised as being exceptionally wear and tear resistant, having high impact strength, and resistance to oils and chemicals. The strength test validated some of these claims.
Easy donning and doffing	The condyle brace is locked by a type B lock, which can be operated with one hand. This allows easy donning and doffing.
Easy to print	Thanks to the flat print design, very little support material is required. Small print imperfections are unlikely to ruin the interface, thanks to a forgiving locking mechanism, which is the most critical part in terms of required accuracy.
Natural forms/visually pleasing	The interface is only 4 mm thick, up to 6 mm at the type B lock.
Unreliant on distal part residual limb	The distal part of the residual limb is not covered by the interface.

D – Context

This master thesis is part of a larger project:

Accessible prosthetics through 3D printing and a smartphone app

Paul Breedveld, Faculty of Mechanical, Maritime and Materials Engineering (3mE), Biomechanical Engineering department

Combining modern advances in smartphone technology with the seemingly unlimited possibilities of 3D-printing, we aim to create easy access to prosthetics for amputees in Third World countries. We will develop an advanced, free IOS/Android app that scans the amputee with a smartphone camera and completely automates the complex prosthetic design process ending in design drawings for a 3D-printer that manufactures a well-fitting prostheses. In this project we will not only generate new, fundamental knowledge on automatic designing and manufacturing, we will also collaborate with a number of charity organisations to stimulate local initiatives in 3D printing and to optimize the prosthetic supply chain.

Source: https://www.tudelft.nl/en/2015/tu-delft/delft-global-research-fellowships-science-and-technology-to-tackle-global-problems/

More information can be found on the following websites:

http://globalstories.tudelft.nl/story/paul-breedveld/

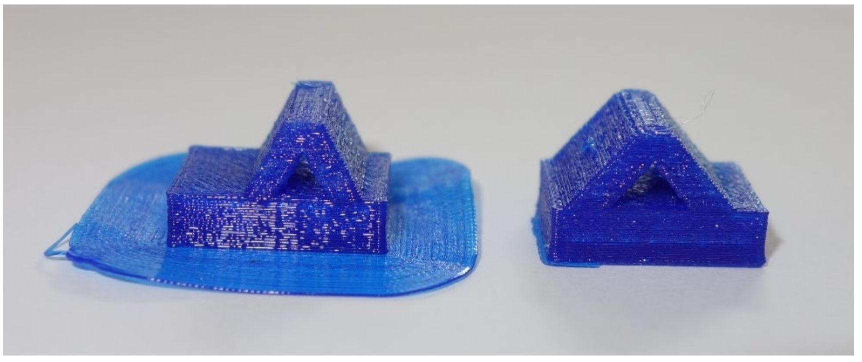
https://www.bitegroup.nl/research-projects/accessible-prosthetics/accessible-prosthetic/

E – In depth design process

This section provides a more in depth view of the design process. Test prints are shown first, followed with the locking mechanism, and lastly assembly of the final interface design.

Test prints

Figure F.1: Overhang tests. Left: 30°, right 45°.



F. 1

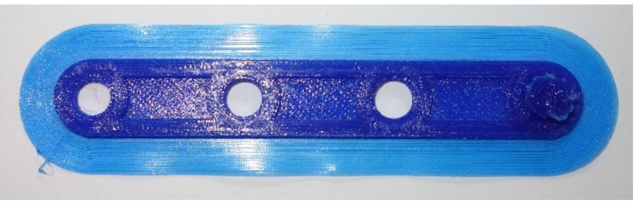
Figure F.2: exploration in printing the rings intact.

F. 2

Locking mechanism

Three locking mechanism approaches were attempted; snap-fits, Japanese carpentry inspired, and a strongly altered dovetail joint. The latter was used in the final design.

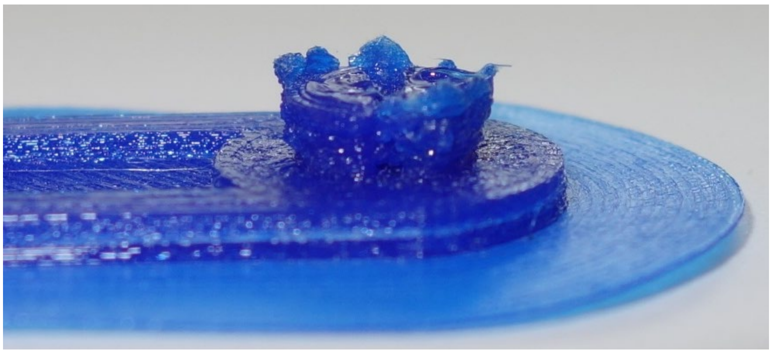
Snap-fit



F. 3

Only design iterations that use same type of material as the overall interface have been explored; TPU 95A. As explained in the middle section of this thesis report, snap joints, which would have been a great option for temporary joining, do not work well with flexible materials. The reason being that snap joints rely on temporary deflection of a protruding part that subsequently catches in a depression in a mating component (bron plastic snap fit design). An attempt has been made though.

Eiki Martinson released several joining mechanisms (bron). All have been made suitable for printing, ABS especially. The snap-fit pivots is one of them. Printing it in TPU 95A indicated a unique limitation. The protruding hub extends the most in z-direction. As a result, the layers of this small part are laid on top of each other in rapid succession. This does not allow a layer to cool and set sufficiently before the next layer of molten filament is laid on top, resulting in dimensional inaccuracies and an unfunctional snap-fit. It demonstrates how easily snap-fits can become ineffective when supports structures or impractical build sequences occur.



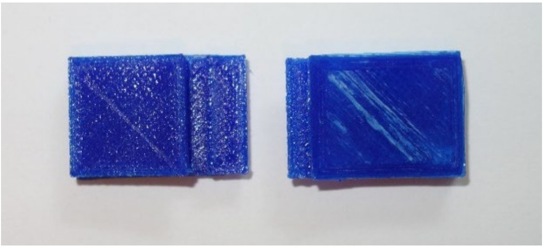
F. 4

Bron eiki martison:
http://eikimartinson.com/engineering/3dparts/#dovetail

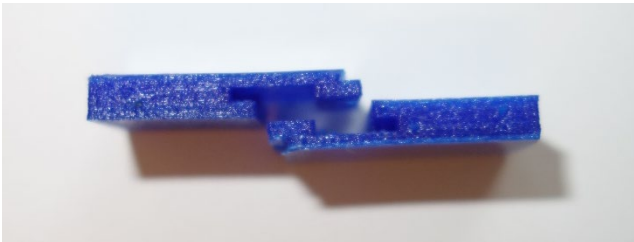
Japanese carpentry inspired

Another inspiration came from Japanese carpentry. This distinctive woodworking approach connects beams of wood with complex interlocking joints. A few design have been taken from the book “Wood joints in classical Japanese architecture” by Torashichi Sumiyoshi and Gengo Matsui.

Rabbeted oblique scarf splice (Okkake daisen tsugi)

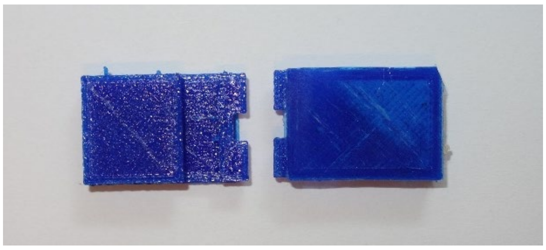


F. 5



F. 6

Blind stubbed, housed rabbeted oblique scarf splice (Shiribasami tsugi)



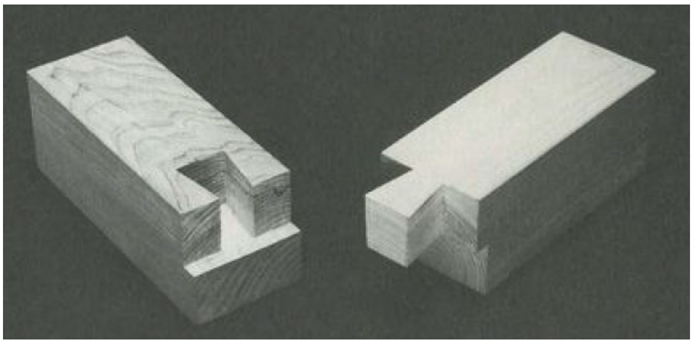
F. 7

F. 8

Neither of the locks possesed the required dimensional accuracy for these locks to work. Even when a connection was possible, their allignment was limited (Figure F.9). They also failed when bend, a critical limitation. Dimensional accuracy could be improved with thinner layers, however, support material at critical areas was still required.

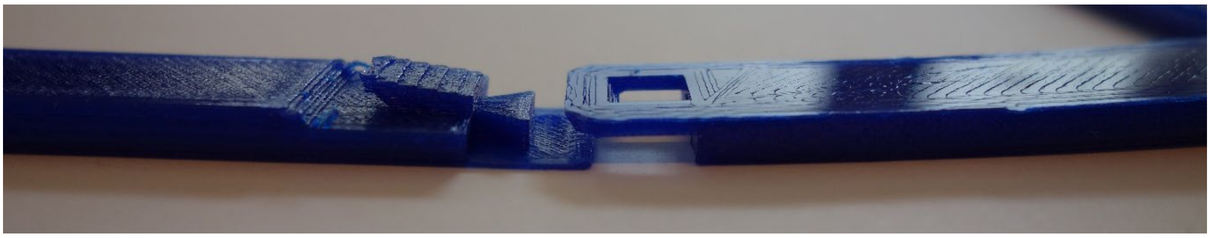
F. 9

Altered stepped dovetail joint

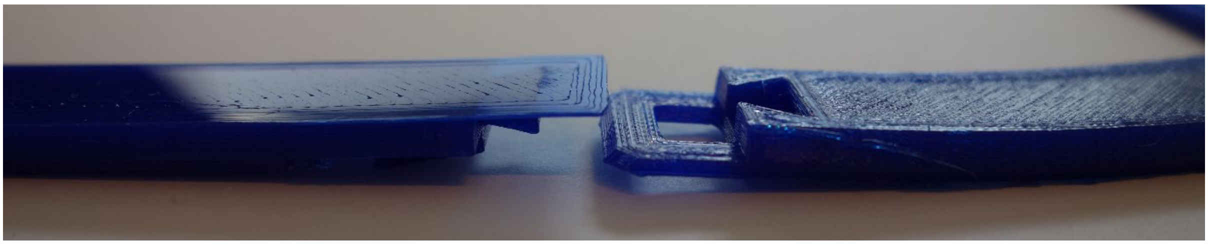


F. 10

The “Stepped dovetailed splice (Koshikake aritsugi, Figure xx) inspired the eventual Lock A used in the flat AM WILMER Open Socket. As can be seen from Figures xx and xx, the stepped dovetail is still there. The joint did not perform well when bend around, as required. In an attempt to fix this problem, the step depth was increased to make room for a loop to form, complemented with a block on the other side behind which it could catch. A thin slap of material was added underneath the dovetail to ensure skin could not get caught in the lock.

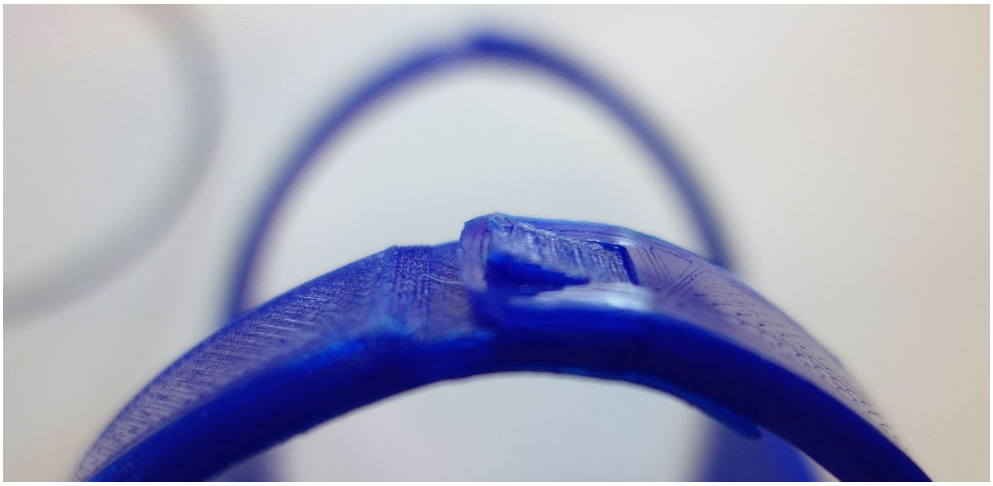


F. 11



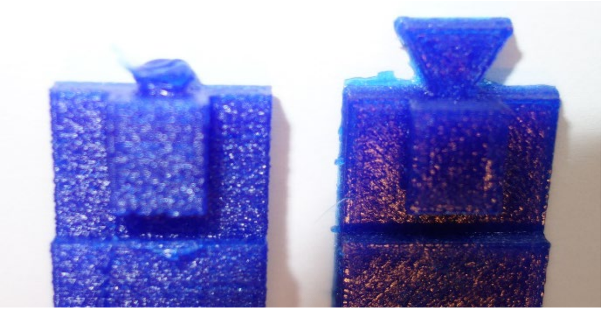
F. 12

As Figure F.13 illustrates, it performs well when bend. The lock's flexibility is similar to that of the material strips. This ensures that the material folds around the lock.

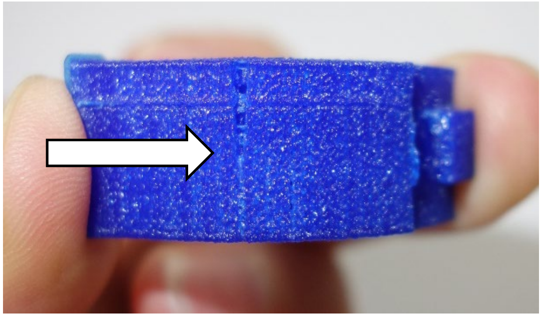


F. 10

The lock is truly optimised for this specific print orientation. Figures F.14 and F.15 illustrate the way print orientation and anisotropic material properties affect the quality of the lock respectively. The print orientation leads to a similar problem that occurred with the snap-fit lock. This print orientation leads to easy delamination when the material is bend as required.



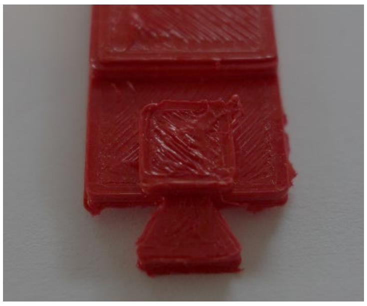
F. 14



F. 15

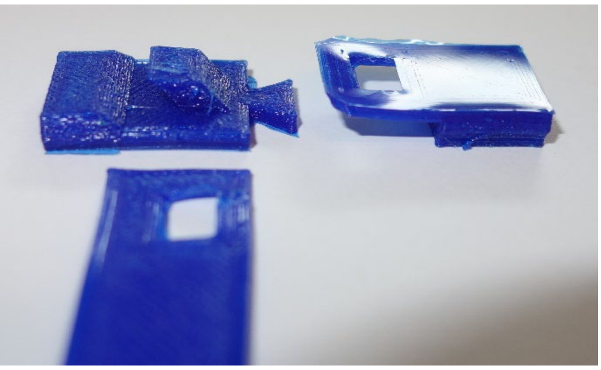
Figure F.16 shows lock A which came loose of the build plate made with MP FLEX 45, resulting in innacuracies. Figure F.17 shows the same part, printed with the same material and settings but remained in place. This problem occurred on more than one occasion with MP FLEX45.

F. 16



F. 17

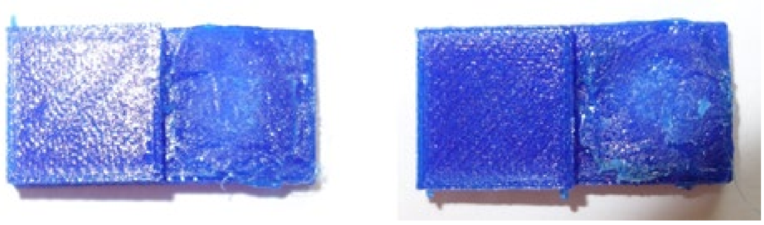
Figures F.18 and F.19 illustrates the possible integration of a forearm/hand connection in type A locks.



F. 18

F. 19

Figure F.20 shows the result of two samples welded together and subsequently pulled apart. This required little effort.



F. 11

Detailed picture of type B lock.

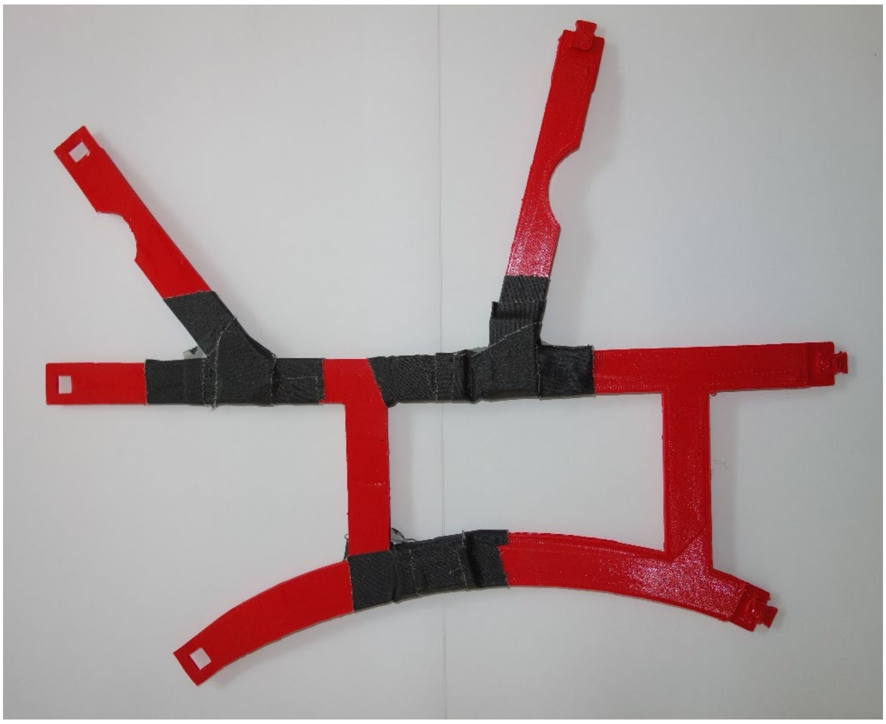
F. 12

Assembled interface

Prototype 1 – proof of concept

Figure xx. Fully assembled prototype made out of MP FLEX45. No locks were implemented yet for reassembly post print. As adhesives did not provide sufficient strength, a combination of adhesive and tape was used.

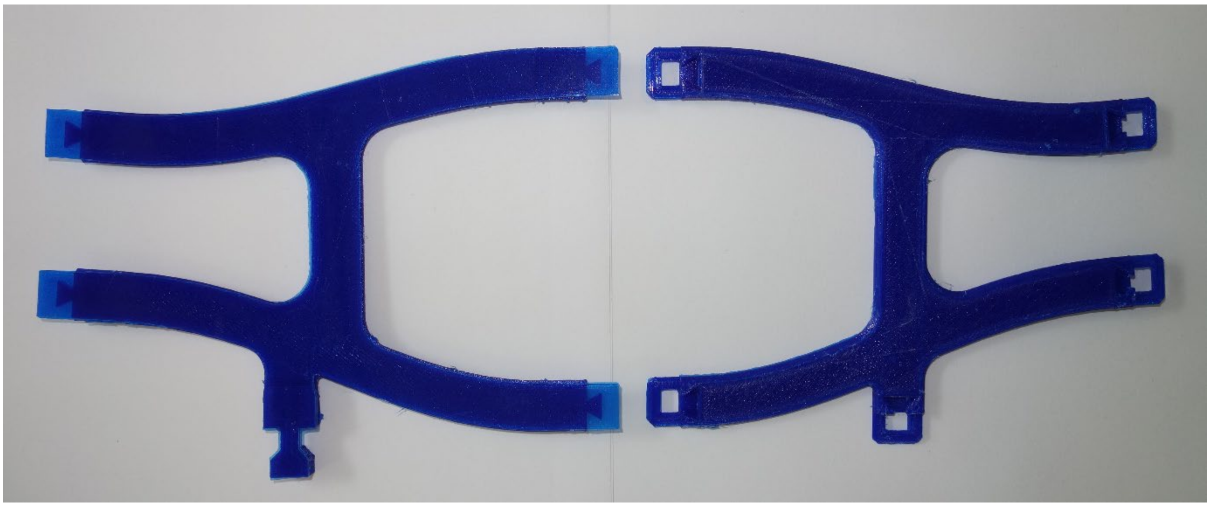
F. 13



F. 14

Prototype 2

The assembly steps of the second iteration are shown in Figures F.24-27.



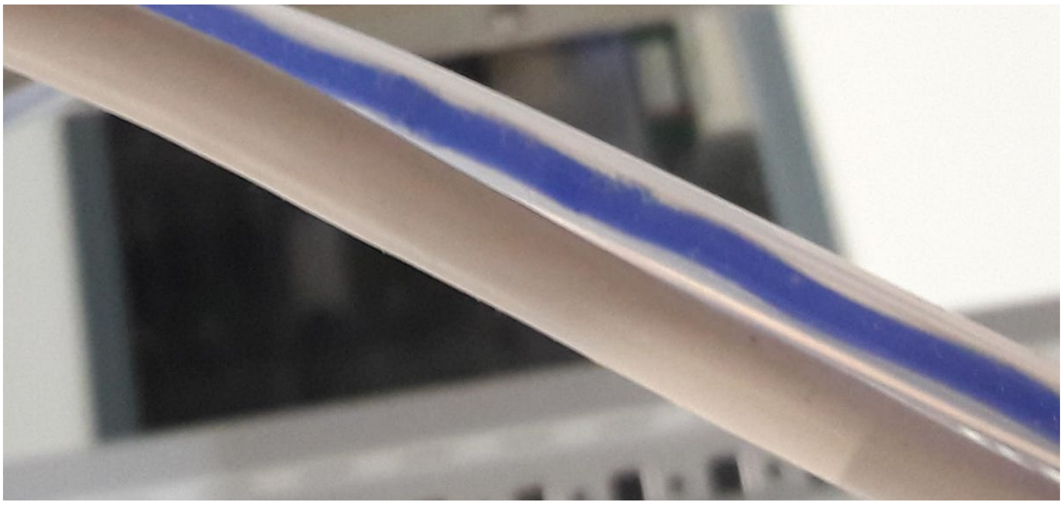
F. 24

F. 25

F. 26

F. 27

Although the Ultimaker 3 feeder could handle TPU 95A better than MP Flex 45, occassional problems did occur. Apparently extruder 2's feeder had slightly different settings, and required manual unrolling of filament from the spool to prevent clogging.



F. 27

Plaster bandage mould based on the author's elbow (F. 28) and subsequent concrete cast (F. 29).

F. 28

F. 29

F – Ultimaker specifications and settings

Ultimaker specifications

Table G.1. Specifications comparison of Ultimaker printers

Printer	Technique	Nozzle diameter (in mm)	Filament diameter (in mm)	Nozzle temp (in °C)	Build plate temp (In °C)	Official supported materials*	Build volume
Ultimaker 2	FDM	0.4	2.85	180-260	50-100	PLA, ABS	223/223/205 mm
Ultimaker 2+	FDM	0.25/0.4/0.6/0.8	2.85	180-260	20/50-100	PLA, ABS, CPE	223/223/205 mm
Ultimaker 3	FDM Dual extrusion	0.4 standard (can be changed?)	2.85	180-280	20-100	Nylon, PLA, ABS, CPE, PVA	Left nozzle: 215/215/200 mm Right nozzle: 215/215/200 mm Dual extrusion: 197/215/200 mm
Ultimaker 3 Extended	FDM Dual extrusion	0.4 standard (can be changed?)	2.85	180-280	20-100	Nylon, PLA, ABS, CPE, PVA	Left nozzle: 215/215/300 mm Right nozzle: 215/215/300 mm Dual extrusion: 197/215/300 mm
Ultimaker 5S	FDM Dual extrusion	0.25/0.4/0.8	2.85	180-280	20-140	PLA, Tough PLA, Nylon, ABS, CPE, CPE+, PC, TPU 95A, PP, PVA, Breakaway	330/240/300 mm

Information extracted from official Ultimaker manuals (ultimaker.com)
* Open Filament System, third party filament is supported, however Ultimaker filament recommended

Test prints

Table G.2. Test prints

Print No.	Material	Dimensions	Layer height	Infill ratio
1	MP Flex45	100x15x4 mm	0.2 mm	40%
2	MP Flex45	100x15x2 mm	0.2 mm	40 %
3	MP Flex45	100x15x4 mm	0.2 mm	25%
4	TPU 95A	100x15x2 mm	0.1 mm	45%
5	TPU 95A	100x15x4 mm	0.1 mm	45%
6	TPU 95a	30° angle	0.2 mm	45%
7	TPU 95a	40° angle	0.2 mm	45%
8	TPU 95a	45° angle	0.2 mm	45%

Ultimaker Cura (version 3.3.1) settings

Unlisted settings have not been set manually.

MakerPoint FLEX45

Quality	
Layer height:	0.2 mm
Shell	
Wall thickness:	1 mm
Top/Bottom Thickness:	1 mm
Infill	
Infill density:	25%
Infill pattern	Triangles
Material	
Printing temperature	245 °C
Build Plate temp.	80 °C
Flow	100%
Retraction enabled	
Retraction speed	40 mm/s
Speed	
Print speed	20 mm/s
Travel speed	100 mm/s
Travel	
Avoid printed parts when printing	
Travel avoid distance	3 mm
Z hop when retracted enabled	
Cooling	
Enable print cooling	
Support	
Generate support enabled	
Support extruder	1
Support placement	everywhere
Support overhang angle	60°
Support pattern	Zig Zag
Build Plate Adhesion	
Enable prime blob	
Build plate adhesion type	Brim

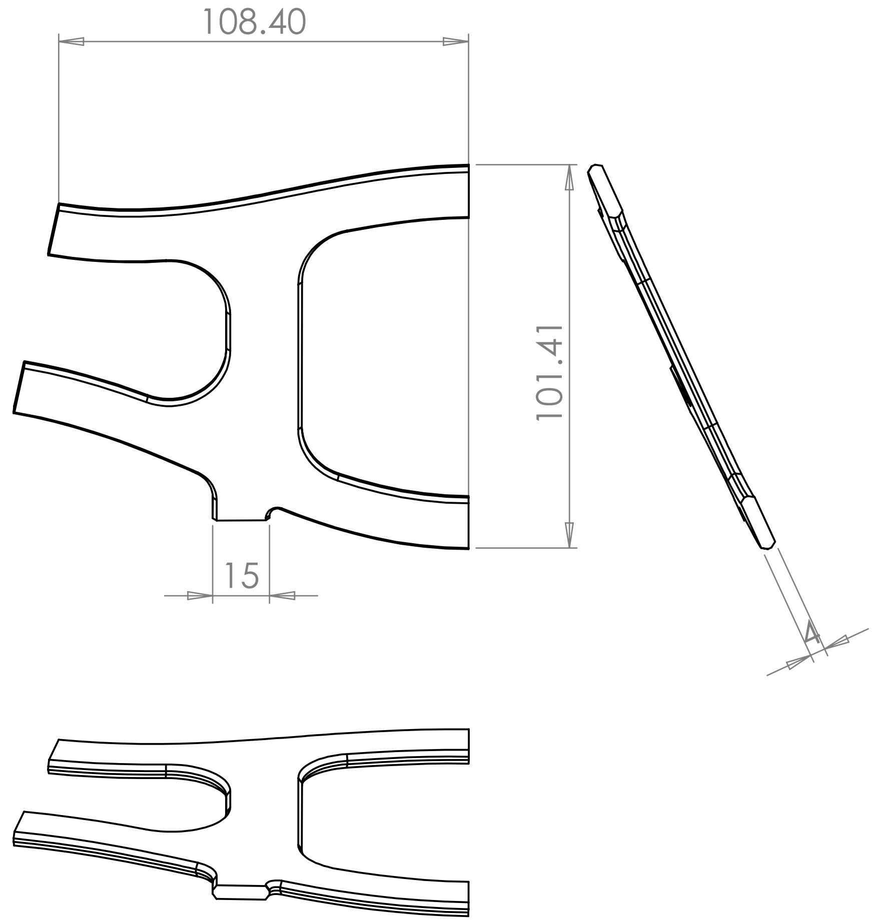
Build plate adhesion extr.	1
Brim width	6 mm

Ultimaker TPU 95A

Quality	
Layer height:	0.2 mm
Shell	
Wall thickness:	1 mm
Top/Bottom Thickness:	1 mm
Infill	
Infill density:	45%
Infill pattern	Cross 3D
Material	
Printing temperature	235 °C
Build Plate temp.	60 °C
Flow	106%
Retraction not enabled	
Speed	
Print speed	25 mm/s
Travel speed	300 mm/s
Travel	
Avoid printed parts when printing	
Travel avoid distance	1.5 mm
Z hop when retracted enabled	
Cooling	
Enable print cooling	
Support	
Generate support enabled	
Support extruder	1
Support placement	everywhere
Support overhang angle	50°
Support pattern	Zig Zag
Build Plate Adhesion	
Enable prime blob	
Build plate adhesion type	Brim

Build plate adhesion extr.	1
Brim width	6 mm

G – Engineering drawings



UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:	DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING

REVISION

	NAME	SIGNATURE	DATE
DRAWN			
CHK'D			
APPV'D			
MFG			
Q.A			

TITLE:

MATERIAL:

DWG NO.

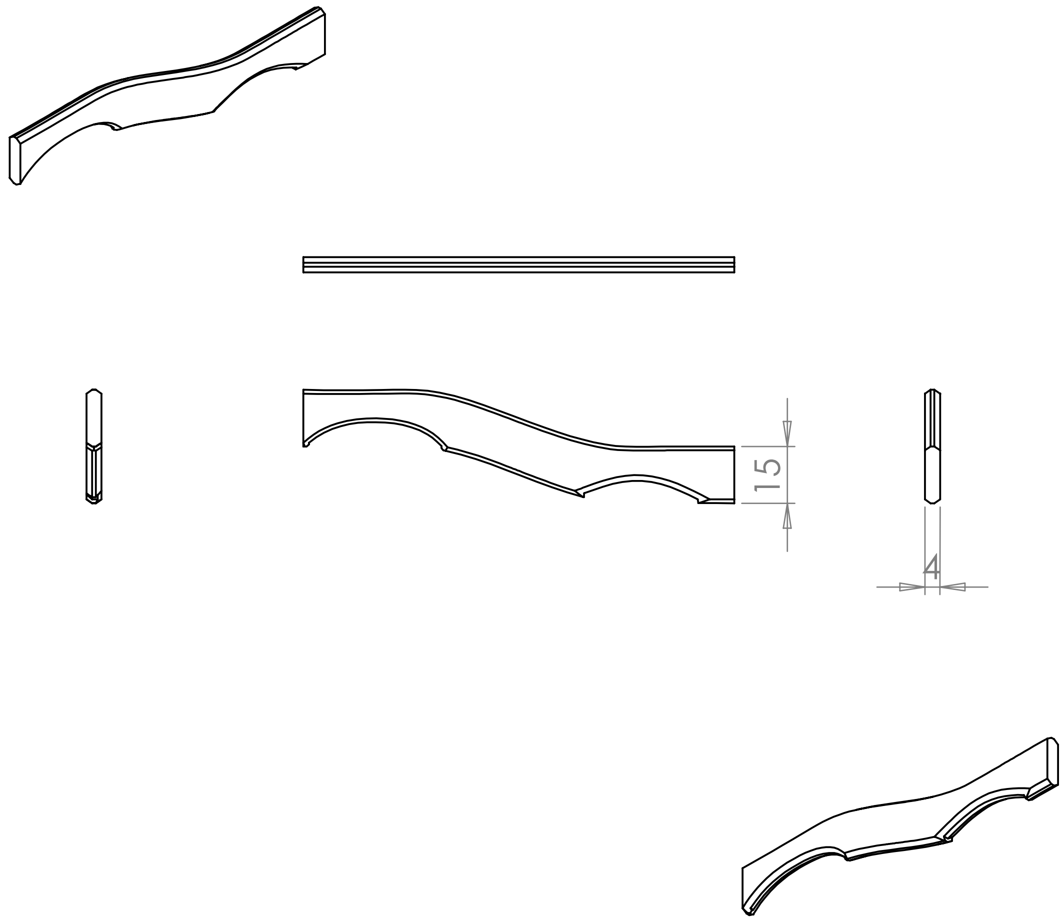
Flattened half 1

A4

WEIGHT:

SCALE:1:2

SHEET 1 OF 1



UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
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FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

	NAME	SIGNATURE	DATE
DRAWN			
CHK'D			
APPV'D			
MFG			
Q.A			

MATERIAL:

WEIGHT:

TITLE:

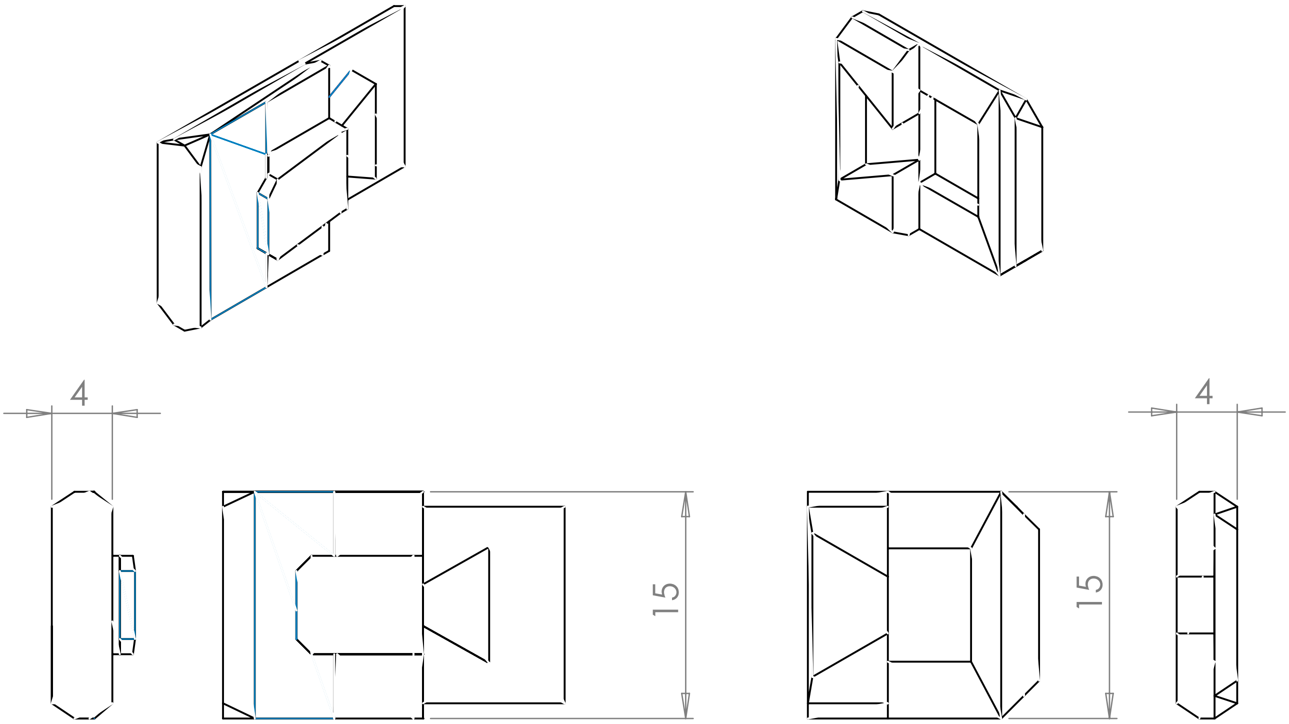
DWG NO.

Condyle brace

A4

SCALE:1:2

SHEET 1 OF 1



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	NAME	SIGNATURE	DATE		
DRAWN					
CHK'D					
APPV'D					
MFG					
Q.A					

TITLE:

MATERIAL:

WEIGHT:

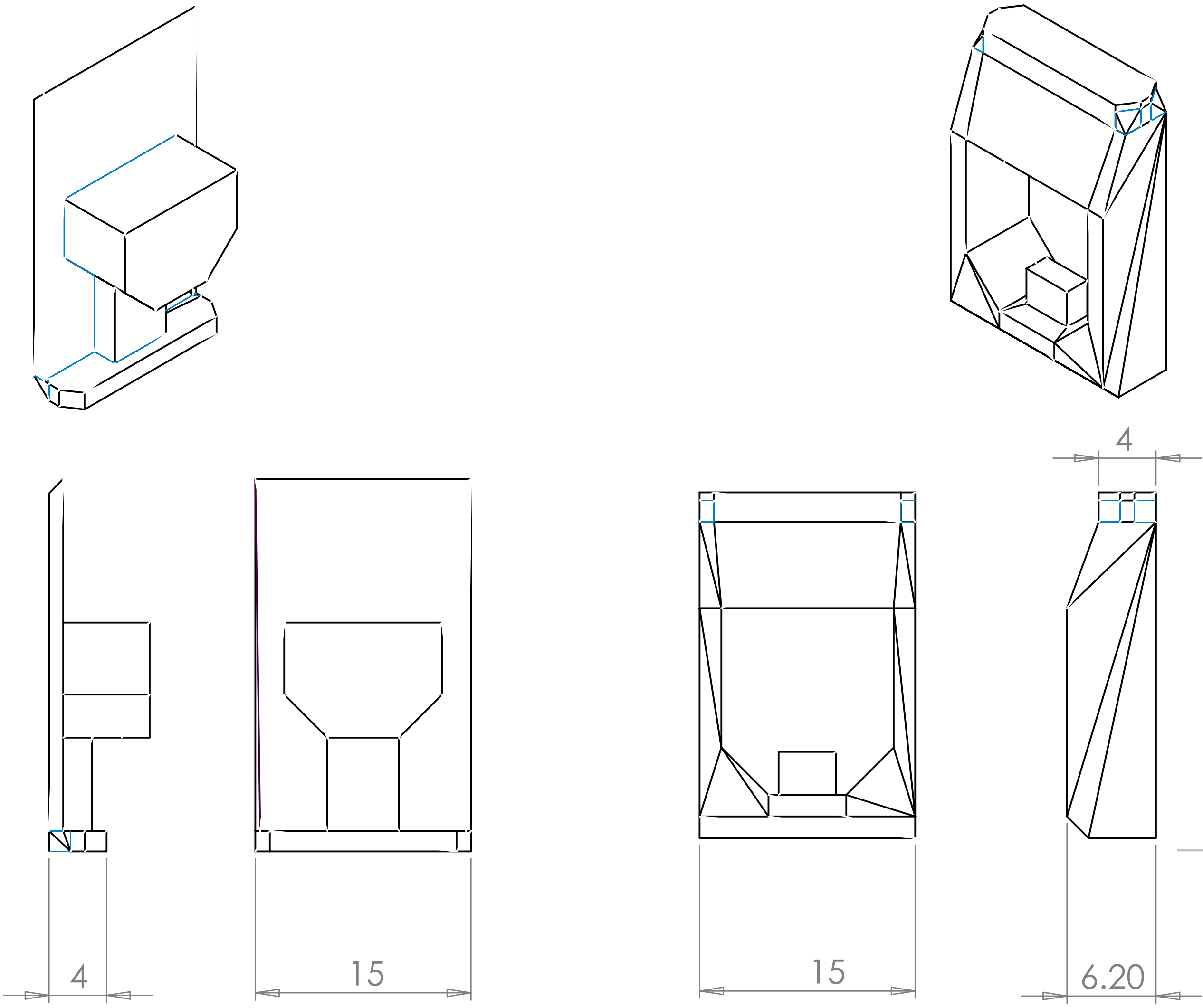
DWG NO.

Lock A

A4

SCALE:2:1

SHEET 1 OF 1



UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES:
LINEAR:
ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

	NAME	SIGNATURE	DATE
DRAWN			
CHK'D			
APPV'D			
MFG			
Q.A			

TITLE:

MATERIAL:

DWG NO.

Lock B

A4

WEIGHT:

SCALE:2:1

SHEET 1 OF 1