Cover Design for Osseointegrated Prostheses

Master’s thesis in Industrial Design Engineering

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Cover photo: Render of the result

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Abstract

This paper reports the design process of a cover for osseointegrated myoelectric prostheses. The main purpose of these prostheses is to rehabilitate amputees by restoring as much of the lost function as possible and this is thus what previous development has focused on primarily. Consequently, aesthetic considerations have been neglected, and, whilst the functional usability may be the major benefactor for psychological acceptance of the prostheses, it has lately been suggested that the appearances also have an affect; that more novel designs, regarding the prostheses as ornaments rather than replicas, could further enhance perceived quality of life by having a positive impact on how amputees see themselves as well as how others look at their disability.

The idea that quality of life for the amputees could be increased by the aesthetics of prostheses was what motivated the project. To understand how the external design alters the experience of wearing and encountering a prosthesis, relevant scientific publications were reviewed, and perspectives of amputees studied in presence on social media and through interviews. A concept designed for an enhanced experience of use, satisfying of the criteria elicited in the research, was then developed iteratively though ideation and prototyping. The result is a functional prototype.

Acknowledgements

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1. Introduction

The outsourcer of the project was *Integrum*; a Swedish Med-Tech company based in Gothenburg that develops an attachment system for prosthetic limbs called the *e-OPRA™*. The system is osseointegrated — meaning that it has a load-bearing artificial implant in direct structural and functional connection with living bone — with a rod, or abutment, shooting out of the residual limb to hold a prosthesis. Contrary to conventional prostheses, the e-OPRA™ has no socket; an enclosure that holds the prosthesis in place by pressuring the residual limb. Without this socket, prosthetic use with the e-OPRA™ is more comfortable as it increases range of motion; provides better stability; and, in some cases, restores proprioception - the sense through which the position and movement on the body is perceived (Potter, 2016). Figure 1 shows the e-OPRA™ next to a modern socket prosthesis.

The e-OPRA™ has a technical appearance. It is a clear case of 'form follows function' as a result of being developed for improved usability, where the different parts are stacked, making it appear segmented. As the residual limb shows (which is not the case for socket prostheses), some patients have expressed feeling exposed, or "naked" when using it (interview, 2020/02/12).

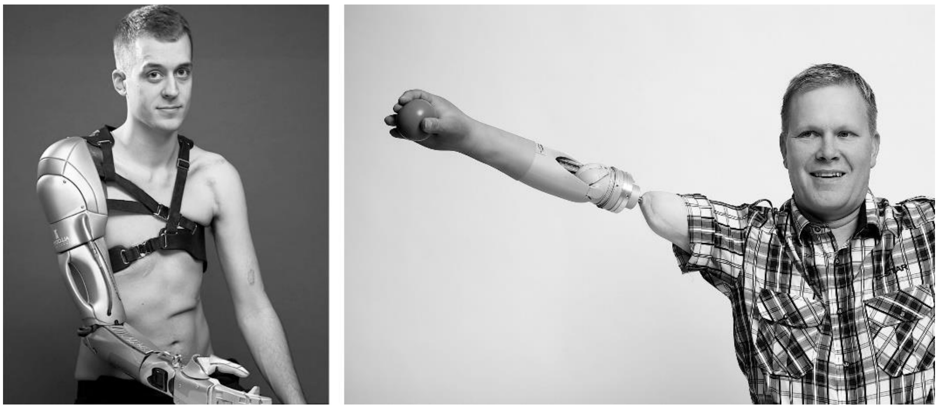

Figure 1. Modern socket prosthesis (left) and the e-OPRA™ (right)

1.1. Objective

The objective of the project was to design a cover for the e-OPRA™ for an enhanced experience of use, and the goal was to deliver a functional prototype of high fidelity, which would allow for Integrum to finalize a dialog with a manufacturer for setting up production.

1.2. Restrictions

All residual limbs are unique and Integrum lack the resources to make custom covers for each individual patient. Hence the cover would need to exist in predetermined sizes. Neither were their resources enough for allowing an altering of the current hardware design, meaning that the cover would have to be attachable to the e-OPRA™ as it was.

The project was also restricted to only consider and merge the transition 'residual limb to prosthesis', as the robotic prostheses connected to residual limbs with the e-OPRA™ are designed by third party *Ottobock* and thus outside the design space.

Finally, there was a delimitation from concerning relevant certificates necessary for a complete implementation, *e.g.* CE marking, as the primary focus was to develop a concept.

1.3. Approach and Planning

The method of approach and planning was the conventional design process, *i.e.* that of *IDEO* (UserTesting Blog, 2020), with the idea to diverge and converge the scope continuously to assure accuracy and progress towards the goal, whilst still allowing wider explorations in areas deemed relevant and interesting. This method is called the Double Diamond (Justinmind, 2018), and figure 2 shows how it was applied in this design project. A more detailed explanation of how the process was planned is presented in appendix 1: Planning Report.

The planning report was essentially a supportive document that cleared out what needed to be done, and when, and established a common understanding of how to proceed at any given moment. Parallel to the planning report (and of more use once the project was live) was a 'to-do' list in the form of a live updated *Trello* board (a browser-based planning tool). Because the process was iterative, and adaptive to the outcomes, especially in the phases of ideation and concept development, the agile format of the to-do list was well suited.

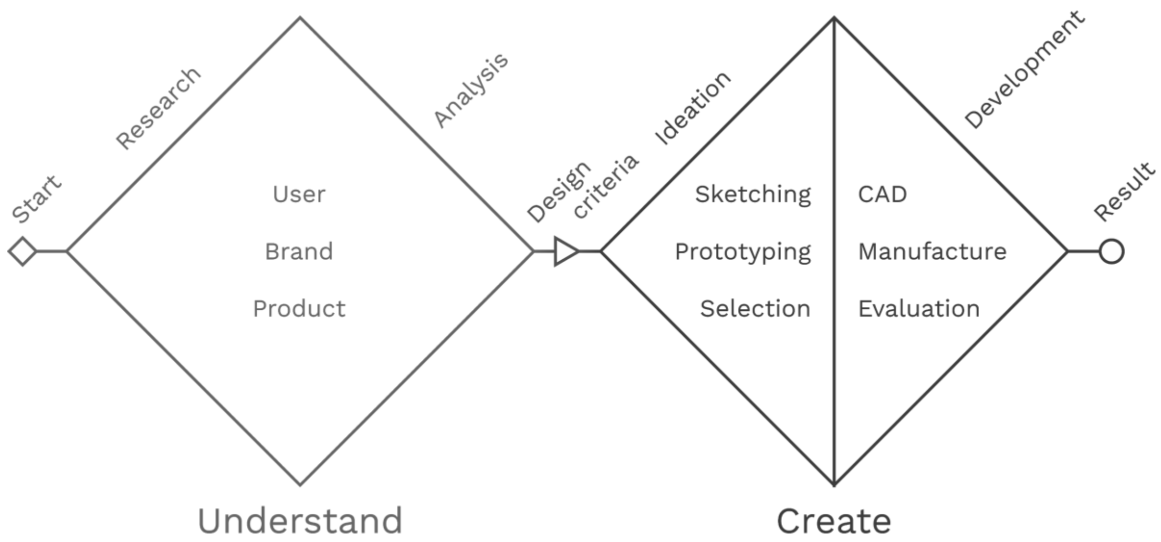

Figure 2. The design process

2. Research

The research consisted of literature reviews, benchmarking, interviews, and aimed to close knowledge gaps and elicit notions of interest regarding prostheses and their use. This phase defined the problem and established design criteria — a manageable format of elicited conclusions — which were to contribute to the relevancy of concepts later generated in ideation; aiming to make the design direction coincident with patient expectations.

These design criteria also supported objectivity in later evaluation of the concepts and is an acknowledged way of working in product development, allowing the forming of informed opinions and broadening of perspectives according to Milton et al. (2013).

2.1. Prosthetic Use

The use of prostheses is a way for amputees to facilitate the execution of Activities of Daily Living (ADL), which are routine activities people tend to do every day without needing assistance (Currie et al. 2017). There are eight ADL: (1) Food Preparation; (2) Feeding; (3) Personal Care; (4) Housekeeping; (5) Shopping; (6) Driving and Transport; (7) Leisure; and (8) Others. According to Vergara et al. (2014), around five hours per day are spent completing these ADLs using the hands. This excludes all the other non-essential activities that people do every day also using their hands, and it is thus not difficult to imagine how the loss of a limb and the strive to regain independence can be challenging. Around 36% of amputees suffer from depression (Advancer Technologies, 2016), which relates to the psychological acceptance of the situation (of prosthetic use) and previous work done in the field has focused on the restoring of lost function to tackle this. As a result, the aesthetics of prostheses have been neglected to a large extent, and whilst van der Kaaden (2018) found this aspect of the products to be secondary for most users, Sansoni et al. (p 975, 2014) noted that "many users are unsatisfied with the aesthetics of their prostheses" and found that it indeed has an effect on psychological acceptance; that "prosthetic users, wearing prostheses perceived as aesthetically attractive, are more confident with their personal body perception and, consequently, gain a psychological well-being" (Sansoni et al. p. 983, 2014).

As prostheses with their appearance carry the capability of enhancing a positive feeling and promote acceptance of the new limb, they ought to be designed accordingly. Regarding the visuals of artificial limbs, Sansoni et al. (p. 976, 2014) proposes considering them a "special and intimate product"; a "bridge between a product and a real limb [...] with which the user establishes an emotional relationship." Undeniably, osseointegrated, thought-controlled robotic prostheses are one of the most intimate human-machine interactions existing today.

The idea of neurologically bridging the prosthesis to the body relates to the emerging science field of prosthotology - a thought concept interpreting prostheses as new "proper parts" of the body, rather than external entities (Bache, 2008). It aims to illuminate the gap between the technology and the philosophical dimension, by posing the question: *Where does a person start and stop?* According to Bache (2008), there has been a clinical and cybernetic advance in prosthetic technology, with improved materials and components, whilst oppositely, the philosophical dimension has remained the same. Osseointegration is considered a healthy addition to the balancing of the two, as it makes the posed question vague. Coincident with prosthotology, van der Kaaden (2018) found and proposed that putting on a prosthesis should feel like putting on a part of yourself, making yourself complete, and according to Sansoni *et al.* (2014), the design of a prosthesis will enable aforementioned forming of a good bond with the user if it manifests characteristics that make it objectively attractive, with a touch of personality and novelty. Objective attractiveness in the context relates to anatomical coherence — a preservation of the holistic symmetry of the human body — and was suggested already in the 1980s (Hanson *et al.* 1983). The product novelty would according to Desmet (2003) amount to a deviation from conventionality; a raising of curiosity; an appraisal of unfamiliarity; yet evoking of a harmonious and pleasant feeling all the same.

Regarding the promotion of a feeling proud to wear the prosthesis, van der Kaaden (2018) emphasized how it relates not only to aesthetics, but also to the being a user of the technological marvel that is myoelectric robot prostheses. Myoelectric being a term for electric properties of muscles, which in the case of a prosthesis means that it is thought-controlled - when the patient thinks about flexing a muscle, motors in the prosthesis are triggered and a movement is generated (Ottobock, 2020). Van der Kaaden (2018) then suggested that the osseointegrated connections should not be entirely hidden behind a cover design and that more revealing concepts may be of interest to pursue.

Besides these aspects of psychological acceptance related to the exterior design of a prosthesis, there are physiological ones; mainly function and comfort of use. Considering that these issues are what the science field of today aspires to solve, the project focused more on ensuring not to inhibit any of the already established use benefits provided with the e-OPRA™ use, it would be undesirable to regress the technology of Integrum back to socket-level.

A related phenomenon is the phantom sensation that amputees commonly experience in their amputated limbs. Thought to be caused by a mixing of signals from your brain or spinal cord, these sensations can sometimes be painful, giving rise to Phantom Limb Pain (PLP), which approximately 70% of amputees suffer from (NCBI, 2019). PLP can manifest itself in a variety of different ways, e.g. sensations of burning, twisting, itching, or of pressure, but will diminish in frequency and duration for most amputees within the first six months post-surgery. It is, however, known to have remained for several years for a minority, and can be triggered anew when the residual limb contacts external objects. According to NCBI (2019), there is evidence suggesting that amputees using myoelectric prostheses suffer less from PLP, as their brain perceives an answer from movement signals. These effects are yet to be studied more, but other established PLP related benefits of osseointegrated prosthetic use is how it does not contact the sensitive residual limb and is hence recommended for patients who have problems with PLP provoked by socket attachments. Thus, it is critical for the cover to avoid skin contact, not only of the residual limb, but also of nearby body parts. It meant that it had to consider the range that osseointegrated prostheses allow and not extend so to risk jabbing against e.g. the ribs.

Besides the PLP, other problems related to constant skin contact and lack of airflow in worn products (that further emphasize how the cover must give way) are ingrown hair, rashes, skin irritation, odour, erythema, blisters, ulcers, and skin thickening etc. (Currie et al. 2017).

As seen in figure 3, most amputees have had underlying disease causing the need for surgery. In contrast, patients of Integrum are mainly amputees as a result of trauma and are described as heavy-duty workers curious about the forefront technology. Furthermore, osseointegration requires the patient to be of good health; at a maximum 70 years of age (as bone quality deteriorates); and weigh less than a 100 kg (van der Kaaden, 2018). This is due to the surgery being a demanding procedure for the body, and prosthetists — the doctors working with the appliance of prostheses — generally recommend socket solutions at first.

In the surgical procedure for fitting the implant that makes the system osseointegrated, the soft tissue of the residual limb is retracted so that the bone (bones if below elbow, or below knee amputation) emerges. The bone is then drilled and threaded axially (figure 3) and the titanium abutment screwed in position. The nearby skin is then extended over the bone and into contact with the abutment and the aperture closed.

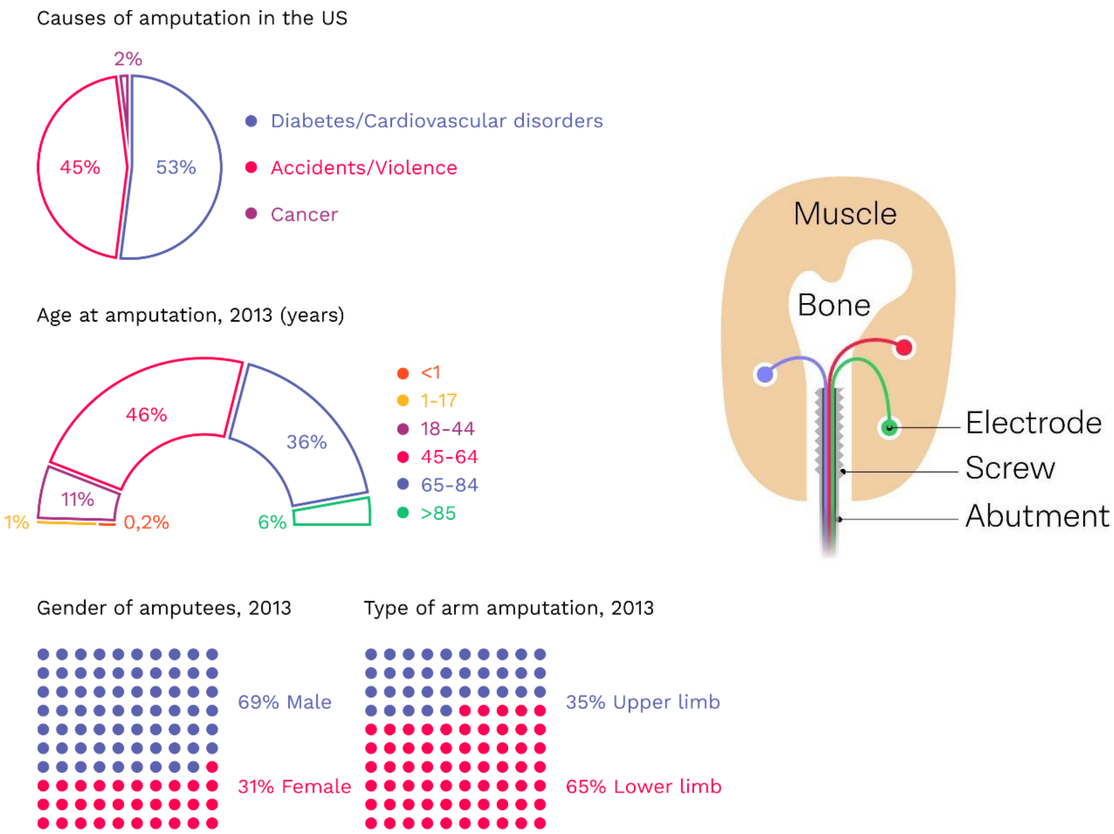

Figure 3. General amputation statistics (Amputee Coalition, 2016) and osseointegration

2.2. The e-OPRA™

When the patient has recovered, a prosthesis can be attached to the abutment with a clamp. Between this clamp and the artificial limb is an aluminium spacer that accommodates for the distance between the residual limb and the next missing joint, which is unique for each individual, to make the appearance more anatomically correct and improve congruency in use.

The e-OPRA™ is the latest in the product line of Integrum and contrary to conventional solutions for myoelectric prostheses, it does not utilize surface electrodes put on the residual limb for picking up the signals. Instead it wires tiny cables through the abutment from electrodes implanted in the muscles of the residual limb to a part placed between the clamp and the spacer called the Artificial Limb Controller (ALC). This makes for a direct, bidirectional communication interface between the myoelectric prosthesis and the nerves and muscles of the patient. The ALC unit has an elliptically shaped exterior and houses three vertically stacked circuit-boards, which converts the naturally generated input into a digital signal (Mastinu *et al.* 2017) that triggers motors in the prosthesis to generate a mechanical output - a movement. The accuracy in determining what movement the patient intends to do makes for a complex system, and one function of the e-OPRA™ is to correlate the force of a muscle flex to the strength of the mechanical output, *e.g.* a hand grip. The ALC part also has a port for connecting to a computer, making it easily accessible for technicians to update the software.

When an osseointegrated prosthesis is used, the muscles of the residual limb move up and down as they flex and relax. There is thus a need for space allowing this between the prosthesis and the limb, and the abutment would hence make for a bad cover platform (not to mention how the cover must remain out of contact with the residual limb).

The clamp is the second consecutive part descending, and it needs to be accessed and openable from all angles, as the placement of it is made according to the personal preference of patients. Furthermore, the prosthesis attachment to the abutment was not in scope to be altered in this project and hence neither is the clamp a suitable platform for the cover.

The ALC protects the delicate technology inside, and the external shape derives from a need of having it applicable for both upper and lower limb cases of amputation. This design makes it indented over the spacer and attaching a cover to it would function (given that the port for connection is accessible) if there were an interior structure of the cover reaching for it.

The spacer is considered to be the best cover platform as it, in contrast to the ALC, would need no extra material, and as an empty cylinder, completely malleable for future versions of the cover to alter its shape for improved fitting. See figure 4. The spacer is also of a constant diameter and has no moving parts.

It is worth mentioning that attaching the cover directly to the prosthesis itself also would be possible, but as the prostheses used vary in shape and sometimes have moving parts right next to the e-OPRA™, it is unsuitable.

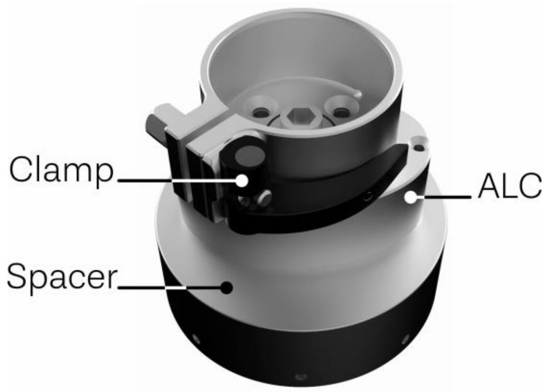

Figure 4. The main components of the e-OPRA™

2.3. The Brand of Integrum

Whilst Integrum is mainly focused on improving the functional and comfortable use of prostheses, progressing the science field of myoelectric control with their e-OPRA™, there is a brand image that the cover should be coherent with. To understand which visual expressions would be representative of Integrum, a brand analysis was performed through a brief review of online presence and in interviews with a representative of the company.

The webpage of Integrum mixes imagery of nature with detailed descriptions of how their product works. The choice of colour and font gives a crisp graphical appearance, and the nature theme suggests active lifestyles. The vision and the mission of Integrum read as follows: “Our vision is to continuously lead the improvement of medical devices using evidence based development” and “Our mission is to provide safe medical devices that will improve quality of life for individuals with amputations” (Integrum, 2020).

In a meeting with the Mechanical Engineer of Integrum (meeting, 2020/02/12) it was understood that besides being a functionality driven company, with a firm foothold in research and clinical studies, Integrum values safe and robust solutions which their patients can use reliably over time.

Considering that the products of Integrum are a traditional case of ‘form follows function’ there was no clear form language available to align the design direction to. As such, it was asked what car manufacturer design values Integrum considers to be closest to. The answer was *Volvo*, and it was deemed relevant to review how they convey their similar values and user centred focus in their form language as a makeshift comparable for aesthetic expressions. Volvo was found to manifest robustness and safety through organised geometrical structures, that on a detailed level are more organic; there are barely any straight lines, and the surfaces are all concave or convex. See figure 5.

Figure 5. Integrum (top) and aesthetic details of Volvo (bottom)

2.4. Benchmarking

Benchmarking is a method used to learn from similar and contemporary projects. It reviews what it was in those projects that worked, and what did not, in order to form references, or benchmarks, for improving the product (Larsson, 2007).

In benchmarking with contemporary projects, it was identified that the vast majority of modern prostheses tend to fall into the category of either being fashionable or technological, with the former inclined towards aesthetics with a clear foundation in arts and architecture, and with the latter exploring, and expanding on the function from a technical perspective. Two good examples of functional cases are that of a ballerina's toe-position, built so to push for the next step and giving stability and balance with a heavy rubber base, and the 'Immaculate Prosthesis' by Hans Alexander Huseklepp (2009), that expands on the natural motions of a joint. See Figure 6.

These two separate fields are both coherent with what van der Kaaden (2018) found: That patients lean towards preferring their prostheses designed as ornaments rather than imitations of anatomical human limbs, yet value function highly. The Guardian (2018) interviewed amputees, and an interesting notion was from user Angel Giuffria, who explained that before she had an ornament prosthesis — custom made by her preferences in a highly technical manner with see-through cables and circuit boards *etc.* (see figure 5) — she would wait for people to notice that her prosthetic arm, an anatomical replica, was indeed not a real arm, and then bring up the subject of being an amputee.

Figure 6. Ballerina's toe-position (left), immaculate prosthesis (right), and Giuffria (bottom)

2.5. Trendspotting

Trendspotting is the identification of new and emerging trends. To accommodate not only for what aesthetics would manifest the brand of Integrum, nor for what is relevant only today, but also for what the users of prostheses desire and expect of the near future, a trendspotting was performed. It was initiated with the analysis of amputee social media influencers, who are present on multiple platforms, and to try and understand how these portray their disability and how others react to this in the commentary field, an *Instagram* (an image-based social media) account was made and six accounts with different presentations followed.

Generally, these lifestyle profiles would emphasize positivity and optimism through inspirational quotes and display of pictures of attractive people, or demanding situations such as climbing or trail running. The first type of profiles would often show posts that match items and clothing with prostheses in fashionable ways and use other words than “amputee” to describe themselves. The other type of profiles was more about action, grit, and ability. This appeared coherent with what was currently available on the market, with some prostheses mimicking anatomical limbs, and others made solely for function, with tools like claws instead of anatomical hands, or springing blades instead of legs, to facilitate ADL. Most of the posts portrayed younger people, estimated to be in their 20s to 40s. However, regardless of age, gender, and type of profile, there seemed to be a consistent ‘don’t hide’ spirit.

Besides these accounts of personalities sharing their everyday, manufacturers of custom-made prostheses were also present on the platform, *e.g. @prostheticguy*, a maker of more art styled covers, and *@alleles*, who have “removing stigma 1 stylish prosthesis cover at a time” written in their presentation. These two creators both appeared to want to shift the immediate reaction amputees get from “oh my God, what happened to you?” to “oh, that’s really cool!” and in such a way desire prostheses to be more of a fashion statement; something that advances the form field much like what happened in the design evolution of eyewear in the last century. Profile @alleles explained how they want to explore “the idea of turning a handicap into a high-performance, cybernetic fashion statement”.

Reddit (the internet forum), mainly non-imagery based, was browsed for threads regarding the aesthetics of prostheses, and user *pioneer9k* made a post asking for fashion advice — how to dress stylishly with his two blade legs — and got a lot of replies. The other users of the forum consistently gave him praise for his cool looking prostheses, and commented that he ought to dress in ‘tech-wear’, a style of futuristic clothing that makes use of high-tech fabrics for breathability and water resistance *etc.* for comfortable and variable use, yet minimalistic in appearance. Tech-wear would match with his artificial legs and make him look more “cyborg,” which all, including the original poster, appeared to agree was what he should be aiming for (Reddit, 2018). Another post by a user *that_one_amputee* provoked a discussion regarding whether to flaunt or hide the prosthesis, and it was unanimously agreed that the former was superior. Like user *pioneer9k*, *that_one_amputee* was encouraged to go for a sleek and minimal look with tech-wear (Reddit, 2015). This relates to the notion of Angel Giuffria of having the prosthesis honest to what it is, so not to evoke a social discomfort.

Articles of the BBC told a similar story: Sian Green-Lord, an aspiring model who lost her leg in a traffic accident, was unable to wear high heels until she made a unique prosthetic leg out of an old Louis Vuitton bag (BBC, 2020). Her leg is a good example of a prosthesis designed as an ornament with the more fashionable approach, and of flaunting rather than hiding.

Bella Tadlock, an eleven-year-old who was the first person to receive a robotic prosthesis with a *Star Wars R2-D2*0 design, made for function with an aesthetic that is honest to what it is — a robot (or a droid) — is a good example of a prosthesis designed as an ornament with the more technological approach (BBC, 2020).

Figure 7. *@Hopscotchampion* (top-left), Bella Tadlock (bottom-left), *@xoexxapoian* (top-right), and Sian Green-Lord (bottom-right)

2.6. Speculative Design

Diverging on the trainspotting, it was decided to consider speculative design. Neeley et al. (2016) write that "The practices [of speculative design] seek to challenge narratives about probable futures, allowing organizations to openly explore various possible futures as a way to better understand alternatives and preferable directions forward," and it was considered as a means to look further into the future of the aesthetics of prostheses.

A popular video game series that according to the Verge (2016) "is all exploring human augmentation" is *Deus Ex*. The aesthetics in the game have received positive feedback and the developers have teamed up with engineers to make the prostheses of the game a reality, without the added weaponry. Like the two creators of prostheses present on Instagram, the developers of the game want to make prostheses that amputees are proud to wear. Their form language is, as can be expected of a sci-fi video game series, highly technological. However, a critical success factor for this type of speculative design is the need for a firm foothold in reality. Auger (p. 12, 2013) states that "if [a concept] strays too far into the future to present implausible concepts or alien technological habitats, the audience will not relate to the proposal resulting in a lack of engagement or connection. In effect, a design speculation requires a bridge to exist between the audience's perception of their world and the fictional element of the concept." Meanwhile, this is where the value of speculative design resides and Auger (p. 14, 2013) found that the "paradoxical reaction humans have that invoke a sense of familiarity whilst at the same time being foreign [...] is a complex and difficult reaction to manage but when achieved responses to the design concept tend to be both meaningful and strong". This infers that the concept must be presented comprehensively in a fine balance between realism and fiction. However, it might be strong in the wrong way and out of context in the case for prosthesis, as this cognitive dissonance relates to the 'uncanny' of Sigmund Freud, see below.

Figure 8. Prostheses of Deus Ex

2.7. The Uncanny Valley

When designing a product that has human-like attributes, it might end up unintentionally uncanny and the phenomenon 'Uncanny Valley' should be taken into account. It was identified in the 70s by professor Masahiro Mori and suggests that a person interacting with a sufficiently realistic humanoid robot, will experience a feeling of eeriness and revulsion (IEEE SPECTRUM, 2019). The idea draws form the notion of Freud of the uncanny, applying it to human-like objects. Freud believed that the contrast between the expectation of something familiar and the realisation that the thing is strange causes an intense feeling of alienation or cognitive dissonance (Freud, 1919/2005). Robotic prostheses are abiotic, yet we viscerally expect a life in them that is not present, and this can make the situation incongruent. The reaction decreases as the human likeness increases, but right before that, at a human likeness score of 75-85%, there is the depression that is called the Uncanny Valley. Unfortunately, it is right in this range that commercial prosthetic hands are located, see figure 9 below.

There are three design principles suggested to avoid the Uncanny Valley. Firstly, the design features should be matching on a holistic level, as a mixing of nonhuman and human characteristics may provoke an uncanny appearance (Ho *et al.* 2008). Secondly, this appearance should also match the behaviour and ability of the object; Goetz *et al.* (2003) found that if an object looks like a device, users will not expect more of it and contrary, if the object is too human-like, users will expect too much. This leads to an uncanny uncertainty in how to act. Thirdly, human proportions and texture are only to be used together, or the object will be uncanny. For example, artists will typically enlarge eyes or other facial features to make a person in an illustration more beautiful, but this would be uncanny if done on a robot (MacDorman *et al.* 2009).

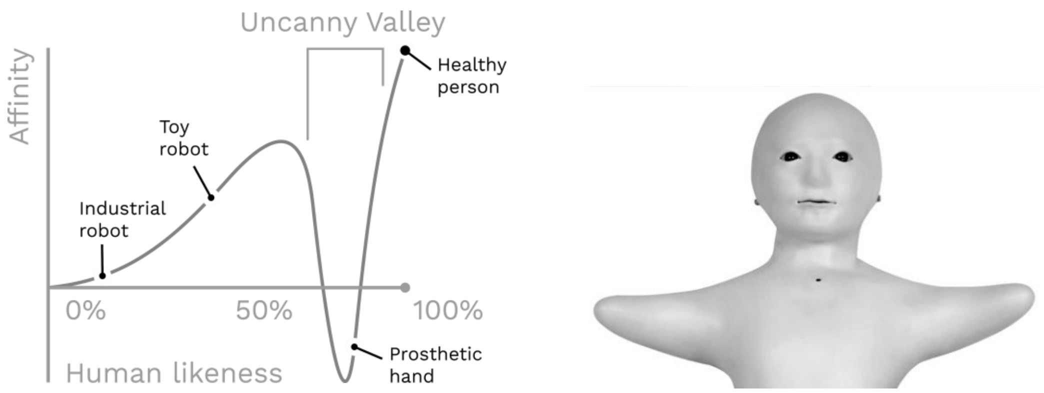

Figure 9. The Uncanny Valley and 'Telenoid' - IEEE SPECTRUM ranked as the uncanniest in 2019

2.8. Mood-board

To scope out the middle ground between the two different preferences of fashionable or technological, and understand how to incorporate the varying features of the two in a single design concept so to accommodate the desires of the majority of the patients of Integrum — regardless of gender, age, and preference — a mood-board was made. It is a means to describe a sought after feeling and is a valuable source for inspiration in later ideation (Edholm, 2011). See figure 10.

From left to right, the prostheses of the mood-board go from technological to more fashionable. Currie *et al.* (p. 8, 2017) states that "The overall goal of prosthetics is to help normalize amputees" and that "[...] prosthetic arms give amputees the ability to once again manipulate their surroundings in a more 'normal' fashion." As the technological expressions were not perceived as particularly safe, with aggressive, machine-like features that seemed unsuitable for most of the ADL, and the expressions of fashion to the left, not sufficiently promoting of capability and active lifestyles, with an appearance interpretable as frail in beauty, the examples in the middle section were interesting; they were found to incorporate a certain level of the technological whilst still appearing fashionable, or organic, and seemed to show a resemblance in appearance with the form language of Volvo, and thus relevant with what had been established as a comparable for how Integrum wanted their brand conveyed: robust and permitting of action, yet kind, safe, and with a 'human touch'.

Figure 10. The mood-board and the 'exiii handiii' prosthesis of the middle section

2.8. Interviews and Observation of Use

Interviews and observations aimed to elicit the expectations of the users, and a total of four subjects (A-D) were interviewed in a semi-structured format with the aid of an interview guide, see appendix 2: 'Interview Guide'. With this format the interviews aimed to be more like discussions, where the subjects could affect the direction of the topic which increases the chance of having a common problem previously unnoticed, being noticed (Kylén, 2004).

Subject A (interview, 2020/01/28) is a Swedish man in his 50s, working in manufacturing. He is a user of the e-OPRA™, and regarding what aspects of prostheses that are the most important to him, and what he expected of future solutions, the patient emphasized the function. As of now, the wrist of his prosthesis must be twisted manually, and the elbow is locked in fixed positions by the pulling of a string. The second most important aspect of the system for the patient is durability. When asked about the design, the patient expressed a desire for the prostheses to be more honest to what they are and that a more technical appearance, particularly that of *Iron Man* (character of *Marvel)*, would be nice. Sometimes he covers his prosthesis using a fabric sleeve, though not for aesthetic purposes but to prevent objects from falling into it when working. The patient considers the attaching and detaching of the prosthesis easy, however, in a later discussion with the Electrical Engineer of Integrum (interview, 2020/01/29), this was pointed out as the most risky of all use scenarios, as it potentially can damage the connection nodes in the abutment and evoke the need for a second surgery. The problem is that the prosthesis can be attached in multiple different ways and that the patient relies on visual markings for putting it on correctly. Even when the patient has learned what is correct and does it with care, the nodes commonly end up being damaged.

In comparison to an interview, which gives reflective answers on the aspects of use, an observational study of a use test with subject A provided raw data and an opportunity to identify subconscious behaviour patterns or problems. The user tests were done according to a standardized evaluation tool, the Southampton Hand Assessment Procedure (SHAP), which includes the picking up of coins, moving of mugs, cutting of clay, folding of pages, opening of jar lids, and pouring of liquid - basically fine precision motoring abilities. During the observation it was clear how much the muscles of the residual limb move when flexed and relaxed during prosthetic use.

Subject B (interview, 2020/02/12) is a Swedish woman in her 40s, working as an engineer, and a user of the e-OPRA™ system, though a new one. It is her first myoelectric prosthesis and it has not yet been calibrated; she has yet to fully explore the function of it. The patient suffers from her residual limb being very sensitive and the cause of pain when in contact with external objects. Therefore, she has undergone the surgery for an osseointegrated solution instead of a socket one. However, as her residual limb is no longer covered by an enclosure, she feels exposed, or "naked", using the new system. Van der Kaaden (2018) found that the abutment sticking out of the residual limb in an osseointegration can be a strange and uncommon sight for others, and that patients feel how people are staring more now than when they wore a socket prosthesis. The patient considers functionality the most important aspect of the prosthesis and she expects it to be even better in the future; that she will be able to adjust the prosthesis and swap it for different functions, *e.g.* she would have one for horseback riding and another for typing. For the aesthetics, she would want it to be more coherent with the anatomy of her body - more symmetrical and proportionate.

Subject C (interview, 2020/03/03) is a Swedish woman in her 20s, a student. She is the user of conventional socket prostheses, yet an important source of information regarding the aesthetics. The user values function the most and mentions the advantages of having her prostheses waterproof. She has broken a few in her lifetime due to her active lifestyle, so durability is considered the second most important aspect. Regarding the aesthetics of prostheses, she mentioned how she was happy when she as a child for the first time received an anatomically correct foot prosthesis with toes. It also allowed her to wear flip-flops which was a pleasant novelty. Expanding on the aesthetics, the user experiences sexism in the design of prostheses; that most of them tend to be shaped from a male leg. She would appreciate it if there were more feminine designs available. She also expresses a concern of how she experiences a societal norm that wishes for amputees to not stand out but to be more normal. She wishes for the initial reaction of the people she meets in her everyday life to be that her prostheses look "cool," and said that they are an aid that give her the ability to walk, run, dance, jump, and live a normal life which should be celebrated and not "shunned." Angel Giuffria, of The Guardian (2018) interviews, similarly explained how "Stigma implies that there is something we should be embarrassed about, and we are not." For the future the user expects prostheses to have interchangeable cosmetics so she can match her clothes, and have changeable functions to enable wearing of high heels *etc.*

Subject D (interviewed 2020/02/04) is a Spanish man in his 50s, working as a service auxiliary. He uses a conventional socket prosthesis that is an anatomical replica because he feels the function of the robotic prostheses do not work well enough yet, and he just wants to look symmetrical. The user expresses the importance of the impression of the people he meets every day, and in the summertime, he shaves his other arm to match the prosthesis. He expects future prostheses to be of a higher quality; more detailed, but also with better durability.

Figure 11. Subject A performing the SHAP

2.9. Manufacturing and the Importance of Material

The most significant problem in mass production of prostheses is that every individual and residual limb is unique. This affects the design, and size or a length that is wrong may detriment the usability and thus the psychological acceptance. Traditionally, prostheses have been custom-made from heat-curing and room temperature vulcanizing silicones and polymethyl methacrylate resins (Hanson et al, 1983). These translucent and colourless silicone polymers are opacified with base colours added to match the skin tone of an amputee and one noted downside of these materials is their inability to be further colourized after being shaped, to fine-tune the matching and promote acceptance of the prosthesis. What was usually done to compensate for this was to spray paint the prosthesis, but the results would wear and start to peel over time, leaving a less desirable appearance. This is a good example of how important it is to consider not only how the cover must fit and match the patient well, but also how it will wear over time.

Modern prostheses are more often made of carbon fibre, or plastics with low melting temperatures to facilitate form fitting to the users (Currie *et al.* 2017). This gives a low weight, but that is, however, not always desired; it is not uncommon for amputees to request more mass (Opedge, 2014). Regarding other functional aspects of the materials, patients wish for it to be soft and with no edges close to the residual limb (interview, 2020/01/28). They also think that having too hard a shell could be dangerous for others, as they have experienced poking holes in bed sheets with the abutment. Van der Kaaden (2018) suggested a soft outside and a padded inside.

Framing what materials and processes to use defined the borders of feasibility for ideation. Considering the batch size was to be small, 3D printing was a good option; it is initially less expensive than injection moulding, and the form complexity can increase without additional costs. It also decreases the number of steps in assembly and, furthermore, was the platform on which to later prototype and thus an easy transition for when realizing production.

The two most common materials used in 3D printing are Acrylonitrile- Butadiene-Styrene (ABS) and Polylactic Acid (PLA). ABS is accessible, relatively inexpensive, and has good mechanical properties. PLA shares these attributes, but is also biodegradable, being made of a natural starch (Protolabs, 2020).

When browsing for more materials possible to 3D print, FilaFlex™ was encountered. Previous browsing from before the decision to use 3D printing had identified 3mesh, a spacer fabric, as a suitable material choice for its lightweight, cushioning abilities, and breathability. FilaFlex™ is an elastic plastic with similar attributes that can be printed with regular printers if set up correctly; FilaFlex™ requires an altering of the printer setup with a modified feeder, and the material must be prepared in a slow heating process.

As for methods, the two common are (1) Fused Deposition Moulding (FDM), with rolls of filament heated and extruded in layers through a nozzle, and (2) Stereolithography (SLA) with resin in trays being hardened layer by layer when exposed to UV light. A promising method emerging in 3D printing is Poly-Jet, which can print multiple materials simultaneously; *e.g.* an elastic over a stiff or of different colours. It carries the potential to enhance 'Design for Assembly' (DFA) solutions by printing the varying parts of a design, with their unique functions, at once (Protolabs, 2020).

3. Design Criteria

The project converged as the notions elicited in the research were interpreted, condensed, and ultimately listed in a table of design criteria as functions, restrictions, and wishes. Multiple sources of the research indicated similar trends, and this phrasing and listing was a means to form a simpler dataset; a guideline for the ideation. The process was iterative and table 1 shows the 3rd and final version of the list.

It had been established that the current aesthetic of the e-OPRA™ and the accompanying Ottobock prosthesis do not match the form language Integrum aims for, nor what their patients desire. Integrum needs a cover for the e-OPRA™ that manifests their brand, and the users want their artificial limbs to be designed as ornaments rather than anatomical replicas (which with mannequin looks and feels of associated materials falls into the Uncanny Valley). The cover design should contribute to making the prosthesis a product that the patients feel proud to use and show, with a slight technically inclined appearance and organic touch. It should make the prosthesis be within the desired range of affinity, and it should hold a level of objective concinnity - not subject to fashion, cultural or personal trends (Sansoni, 2014). If fulfilled, the new design would be superior to the current.

Table 1. Design criteria

#	FUNCTION	DESCRIPTION
1	Cover the transition	To prevent the patients from feeling naked, to shield the sensitive technology, and to give the system a more unified appearance.
2	Protect the residual limb	So, no external objects contact the sensitive area and provoke PLP.
3	Comfortable use	By leaving space for muscles of the residual limb to move freely, allowing for physical activities, being light, and easy to attach/detach with one hand.
4	Allowing airflow	So not to gather excessive heat during hot seasons or exercise.
5	Durable in all-condition	By having a durable construction and materials that are not susceptible to the elements - be it sun or rain *etc.*
6	Easy to wash	For maintaining good hygiene.
7	Prevent dirt from gathering	So, to stay pristine longer after wash.
8	Filling up clothes	So not to make the transition visible through depressions in worn fabric.

#	RESTRICTION	DESCRIPTION
1	Not disabling any function	As the functional benefits of the e-OPRA™ is what the patients value the most.
2	Be safe	So not to harm primary, nor secondary users.
3	Provide symmetry	So, to give the system a, to the body of the patient, unified look.
4	Considerate of e-OPRA™ parts	So that these fit well within and need no alteration to hold the cover.
5	Non-damaging for clothes	So that the cover does not poke holes or tear worn clothes quickly.
6	Adaptable to cross-sections	Be it upper or lower arm amputations.
7	Considerate of manufacturing	For the cost to be cheap and require little time.
8	Accessible hardware	So, the technicians of Integrum easily can do their job during the regular follow-ups.

#	WISH	DESCRIPTION
1	Please aesthetically	By being designed as an ornament, fitting to different prostheses, attractive regardless of age and gender, and by having objective concinnity.
2	Avoid the Uncanny Valley	By making it clear what it is.
3	Represent Integrum	By manifesting a robustness, reliability, trust, and a user centred focus in the design.
4	Be simple	So, to minimize risk of failure and maximize ease of use.
5	Have a good perceived quality	By having a good finish and of pleasant touch and having use elements that feels nice to interact with.

4. Ideation

At the outset of ideation, the project diverged with a creative workshop to challenge preconceptions of the problem evoked by the research. It involved design students not related to the project as their elementary understanding of the case would keep their creativity unhindered by predetermined beliefs of feasibility or relevance. After a warm-up exercise, the six participants were given the first task of the workshop: *To conceptualize a futuristic prosthesis influenced by the forms and functions found in nature* - an aspiration to incorporate a basic level of biomimicry, as nature is considered inherently concinnitive (Sansoni, 2014). Upon completion after a set time, the workshop proceeded into the second task: *To envision what it would be like to wear the ideated prostheses in a set context, e.g. brewing coffee at work or socializing at a dinner party, and try to specify at what point the conveniences of these futuristic aids would be overshadowed by their uncanniness, i.e. answering the question of when would the incongruence become intolerable for secondary users.* The resulting material of the workshop inclined towards an exploration of various functions rather than the sought-after forms. This might be due the instructions having been misinterpreted, but, regardless, it generated ideas outside of the previous conception, served well as a “kick-off,” and elicited that: (a) It seems like the uncanniness of robotic prostheses relates more to the function than the form, and (b) being able to change the form depending on activity or occasion would make the artificial limb more useful.

Before approaching a generation of concepts in a structured manner, it was decided that a short session of ‘brain drawing’ (Dhillon, 2006) was to take place; it was executed in 10-minute intervals on printed overlays, and the generated ideas were later incorporated in coming ideation matrices. Figure 12 samples a result.

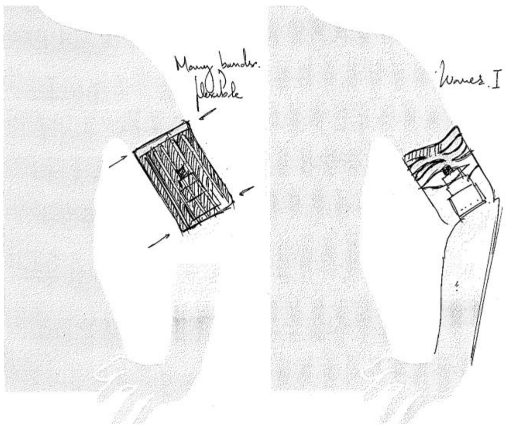

Figure 12. Sample of the brain drawing

4.1. Method of Integrum

Integrum was developing their own strategic means for concept generation, which aims to assure that no ideas go unthought of by structuring the work for a holistic approach. The method aims to make the result fulfil a certain standard for med-tech products. As the cover was a simpler product than what is regularly developed at integrum, a simpler version of the Integrum method was adapted for this project.

The first step of the method was to abbreviate elicited design criteria by rephrasing them into one verb followed by one noun, *e.g.* ‘provide - symmetry’ or ‘protect - residual limb’. It was then identified which of these new criteria were functions, and if multifaceted, divided into sub-functions phrased in the same format. The functions of the project are listed in table 2.

The reworked criteria then served as a basis for exploring solutions in the second step, during which each of the listed functions were ideated for individually, *e.g.* the function to ‘protect - residual limb’ was thought to be possible through a cushioning, shielding, or an all-together prevention of external objects contacting the sensitive body part. The function ‘attach to - existing hardware’ was thought to be possible through clip-on mechanisms, screws, or magnets *etc*.

The third and final step of the method, or rather, the final lockstep of one iteration, was to categorize and list the generated solutions on the two axes of a matrix. This relates the solutions to one-another, and, when combined, extrapolates new concepts. Upon completion the matrix is reviewed to see if any ideas are missing. Figure 13 illustrates the consecutive lock-steps of the method, diverging and converging.

Table 2. List of criteria rephrased as functions

#	**Verb**	**Noun**
1	Cover	Transition
2	Protect	Residual limb
3	Please	Aesthetically
4	Comfortable	Use
5	Endure	All-condition
6	Easy	Wash
7	Allow	Air flow
9	Prevent	Dirt
10	Removeable	One handily

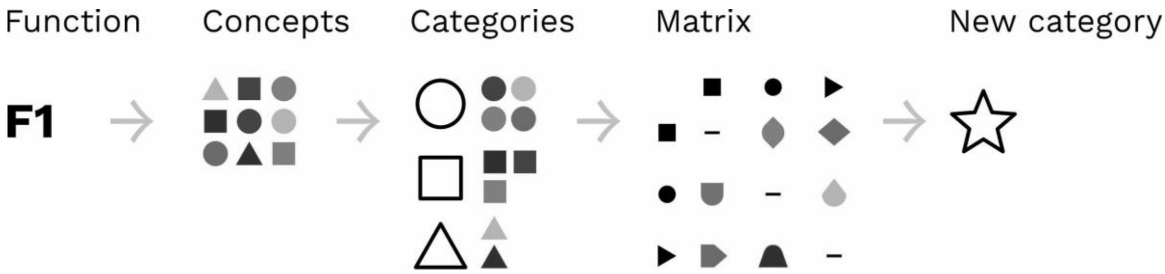

Figure 13. Adapted method of Integrum

4.2. First Matrix

The results of brain drawing were added to the first matrix, which is presented in appendix 3: First Matrix. Continuous creative work filled in most of the remaining locations and when a redundancy was noticed in that later concepts started to resemble ones already generated, this first iteration of structured ideation was deemed saturated, and the result were categorized in 10 groups of concepts: (1) Scales; (2) Open Air; (3) Tubes; (4) Folding Flaps; (5) Apertura; (6) Snap-on/Wearable; (7) Active Sunday; (8) Panels; (9) Miscellaneous; and (10) Fiction/Speculative. See Figure 14.

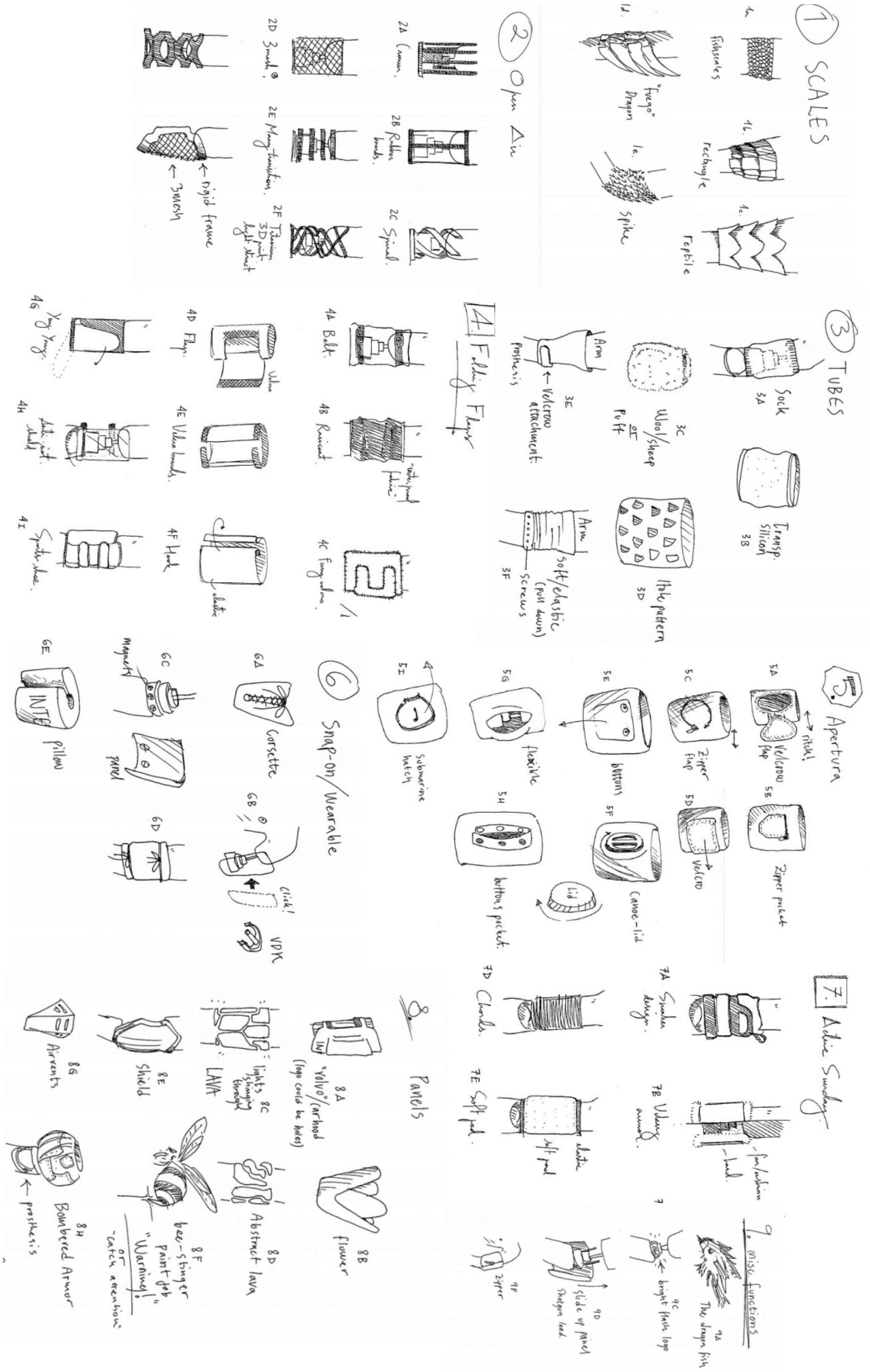

Figure 14. Concept groups of the first iteration

4.3. Second Matrix

In the second iteration, the 10 concept groups were listed on the axes of a new matrix, and, as the combining of concepts got more complicated, simplicity was pursued. The second matrix is presented in appendix 4: 'Second Matrix'.

Again, it was ideated until a redundancy was noticed and the results were categorized. This time there were six concept groups (A-F), defined on a more detailed level, with considerations of feasibility further explored: (A) The snap-on pillow - a soft cushioning foam with a slit opening for closing around the e-OPRA™; (B) The elastic tube - a breathable fabric sleeve that is similar to the "do it yourself" covers already used by the patients; (C) The organic mesh - a open structure that promotes breathability, made of the 3D printable *FilaFlex™* material; (D) the rigid frame - a protective frame that holds the spacer fabric *3mesh™* and allows breathability and is lightweight yet protective; (E) the turtle - a concept with a soft inside and a hard outside, a sort of mix between concept B and F; and lastly, (F) the buttoned wrap-around collar - providing extra durability and protection. See figure 15.

In the first iteration, elimination and development of concepts occurred intermittently in the creative work and was intuitive and heuristic. For this second iteration, it was decided that the opinions of Integrum were to be considered in that process, and hence a meeting was set up. In preparation for this, the six concept groups of A-F were refined visually with sketches of a higher fidelity. Having them represented equally well and in one colour palette intended to promote a non-biased evaluation. Appendix 5: '6 Concepts' presents the ideas more thoroughly with their respective pros and cons.

Rather than being our ultimate design proposals, these concepts served the purpose of further identifying the needs of Integrum and scope out whether the present design direction was something they believed in. With these concepts, the discussion with Integrum evoked more ideas that previously had gone unnoticed, were elicited. These were to be incorporated in the consecutive iteration, which would be the final.

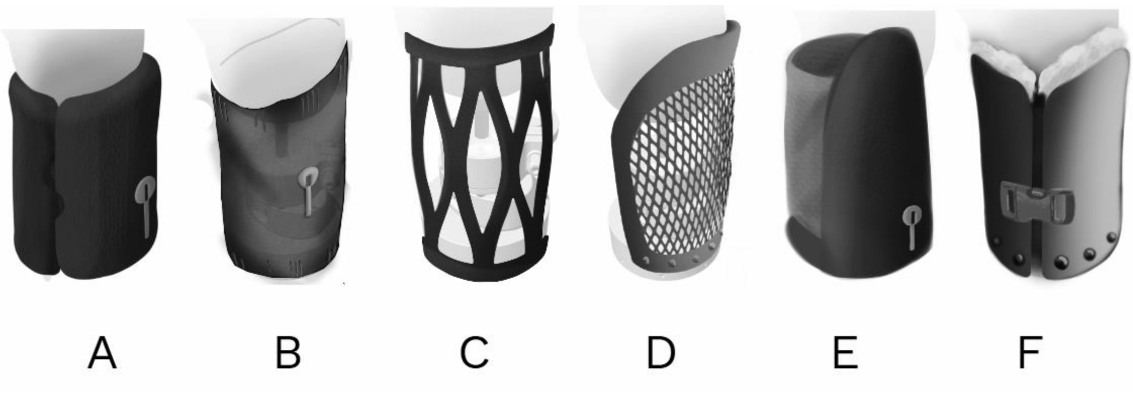

Figure 15. Concept groups of the second iteration

4.4. Choice of Concept

The meeting concluded that concept A, B, and F were to be discontinued; A and B for being too simple, interpreted as too much of a "quick-fix", and F for its resemblance to a cervical collar, something that purposely discourages movement, giving a "wounded" appearance. Concurrently, concept C, D, and E, were to be further explored and combined in a configuration of panels held together by an elastic mesh/hinge. Their form language appealed to Integrum, and they were deemed more feasible for production. This established a clear direction for continued development, and as such no new matrix was made. Instead the continued work focused on sketching solely, analogue and digital. At this point it was aspired to construct to minimize the processing and assembly needed in manufacturing, and the means by which the cover would be attached to the e-OPRA™ was further explored. It was also suggested in the meeting that the cover should feature an inner opening to facilitate the attaching and detaching by enabling access to the clamp.

In a conventional design process the generated ideas would be listed in an evaluation matrix according to *e.g.* Pugh, or Pahl and Beitz (Johannesson et. al, 2004), in order to choose what concepts to pursue. However, as the concepts presented were not seen as ultimate design proposals of which one were to be chosen, but rather a means to provoke a discussion and further scope out what Integrum envisioned with the cover, intentionally leaving room for implementation of the resulting ideas evoked, it was deemed that this expert insight and help in choice of direction would suffice at this stage of the design.

We also had the idea of involving users at this stage, but it was decided to instead develop the concepts further and have functional prototypes ready for the testing first. As the function is what the users value the most, we thought that this would generate the most valuable feedback.

5. Concept Development

Earlier ideation had generated several ideas regarding how the chosen concepts could be attached. These are presented in appendix 6: Ideated Attachments. Upon continued brainstorming on these they were generally found to require extra material and multiple parts or had inferior pleasure of use in *e.g.* lack of haptic feedback or perceived quality. In the pursuit of simplicity, it was easy to heuristically scope out which solutions were superior and of relevance, and there were two that did not require mechanisms; clips and magnets. Both ideas explored the possibility of modifying the design of the spacer slightly, so to make for a better attachment, however, as one of the design restrictions was to not alter the current hardware, it was made so that the magnetic attachment would have a magnetic band attached to the spacer by glue, and the clip-solution would fit around the ALC. See figure 16.

The implementation of a DFA aspect in this phase aimed to decrease cost by simplifying manufacturing, by seeking a solution of few parts and intuitive assembly steps (Boothroyd *et al.* 2002). Chang *et al.* (2013) claim that DFA mainly is of relevance when considering construction details, as this is where it can be measured and evaluated. However, the project desired to relate it to the core of the design and thus it was considered at this earlier stage.

Kelley (2001) claims that it is good to fail often so to reach success earlier, and many of the first prototypes made were rather 'Pretotypes' - meaning that they derived from an imagined design and had their function backtracked to feasibility for realization (Pretotyping 2018). These pretotypes were of paper and served the purpose of enabling better communication within the collaboration whilst also exploring forms.

The first real prototypes had their shape derived from these pretotypes and were of *Styrofoam* and *Kapa®* foam board. These materials took longer to process, but were more robust, which was necessary when used for trying out attachments. At this stage, the dimensions were related to reality using a mock-up residual limb and a 3D printed e-OPRA™ serving as a replica of the system. The physical modelling was crude, using mainly a hobby knife and a glue gun to swiftly try out different configurations, but did so efficiently.

Figure 17 shows how magnets were put into one of the prototypes of Kapa® to try the magnetic attachment. These magnets would pull to the magnetic band — a rubber mass strip infused with chips of magnets — and one major benefit of this solution was how the placement of the magnetic poles of the band run lengthwise (WDT, 2020), allowing two different positions in height for the cover, see figure 17.

In these trials, the load carrying capability and the strength of the self-adhesive fixation of the magnetic band was evaluated. The first try used a band with the magnetic pull strength of 14 g/cm^2, which proved to be insufficient. The adhesive fixation attached well to the paper prototype, but not plastic, nor metal. The second try used instead a band with the magnetic pull strength of 92 g/cm^2, that was not self-adhesive, but attached using contact glue instead.

Five types of super magnets of varying strengths were tested in combination with the bands, and through trial and error we found that the best solution was using the stronger band with magnets of a diameter of 20 mm and a thickness of 3 mm. It made the attachment strong enough for steadily holding the cover in place - able to withstand being jabbed against or jerked without falling of - yet easily removable. However, only having a patient use the cover with the e-OPRA™ (for some time) in their everyday life can determine if it is good enough.

The process of attaching the cover was fast; the magnets snapped in place with a pleasing sound and feel and would self-align into position. If one magnet failed during use, it would also self-align back in position, and having magnets in sockets left the cover with few nooks and crannies, improving the cleanability of it. Compared to clips, however, magnets are more expensive and require an additional step in assembly.

For trying the clips concept, two differently scaled ones were designed and 3D printed, see figure 18. It was examined what dimensions would make for a snug fit without play yet requiring but a reasonable amount of force for attachment. Though cheap and easy to manufacture, the clips required precise dimensioning not to give play or difficulty in attaching/removal. They may also wear over time and will absorb potential impacts; transferring the force of a hit into the e-OPRA™ system rather than yielding. Through trial and error, and using the design criteria as reference, it was clear that magnets would provide the best attachment as they (a) allow more than one way of fitting to the spacer; (b) improve cleanability; (c) provide a pleasant feel when attaching; (d) have no play; and (e) will truckle rather than strain the osseointegration if hit. As such, a complete concept for aesthetics and attachment had been established and the project proceeded into a defining of details.

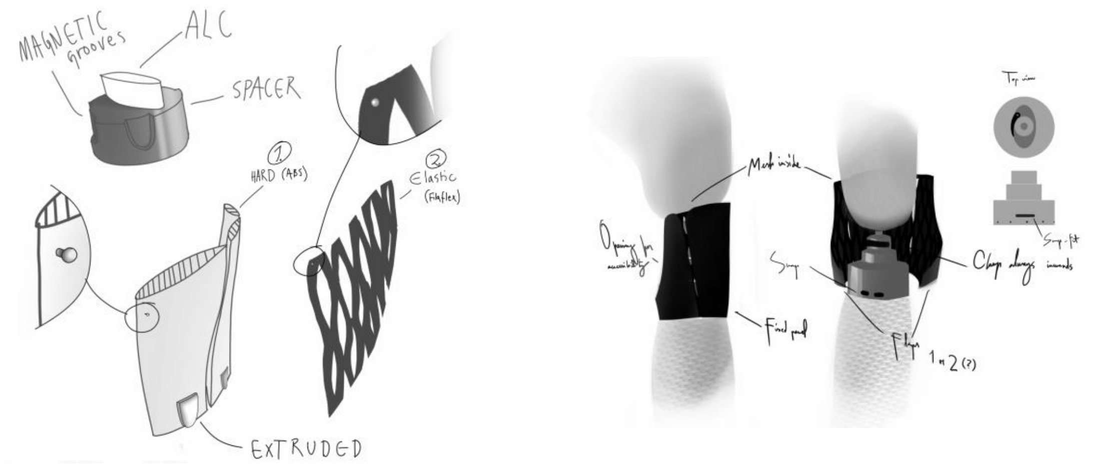

Figure 16. Concept for magnetic- (top) and clip attachment (bottom)

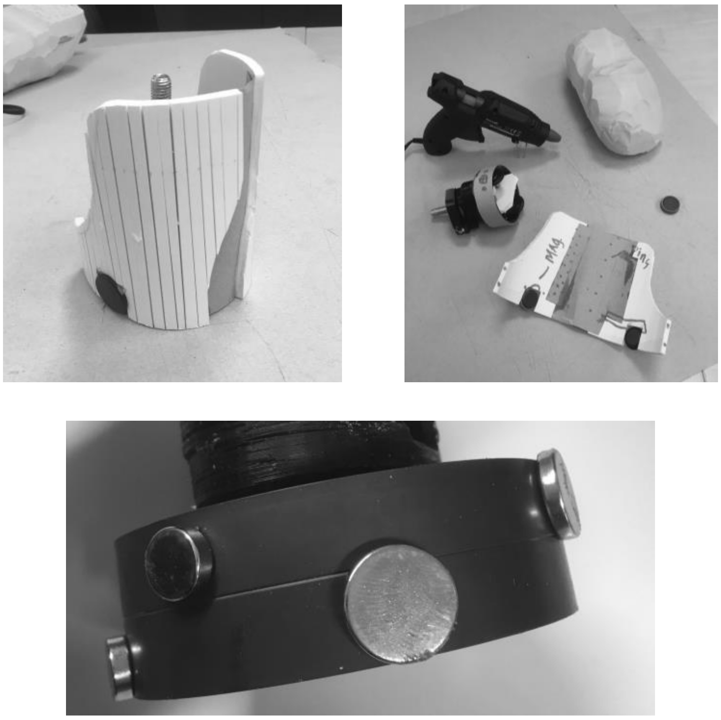

Figure 17. Paper prototype and the height positions of the magnetic attachment

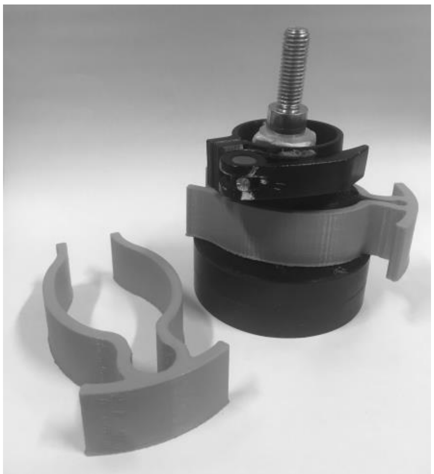

Figure 18. Clip attachments on the ALC

5.1. Form Exploration

The project diverged when expanding on details of the form. The aspiration was to portray the brand with technological features yet within human symmetry. For the latter, it was considered what contours of muscles — which would have been had they not been amputated — could make for the split-line hinges in the cover, see figure 19. Several panel configurations supporting anatomical coherence and ease of use were ideated in sketching and a second round of paper pretotyping, see figure 20, and the line dividing the panels came to be inspired by the boundary of the biceps and the triceps. As the cover was to be adaptable for the varying heights accommodated for by the spacer, a possible solution for scalability was suggested at this stage as well. This iteration is presented in appendix 7: ‘Form exploration’.

The ideas were then visualized vectorially in 2D to facilitate modelling in CAD as reference image planes, and figure 21 shows a panel configuration proposal composed of three panels for an improved usability with additional hinge ease the closing and opening of the cover.

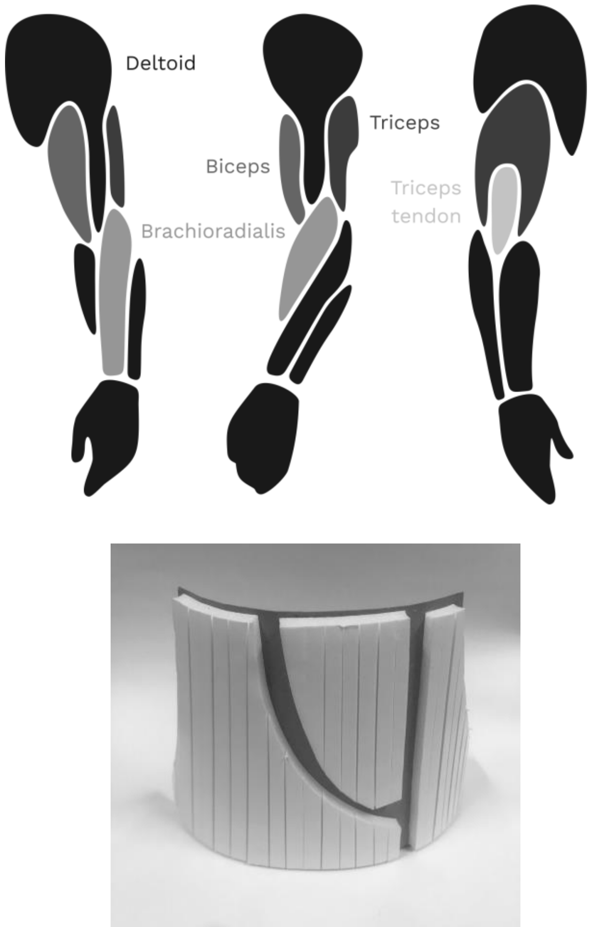

Figure 19. Simplified diagram of the upper arm muscles and a muscle-inspired configuration of panels in a paper pretotype

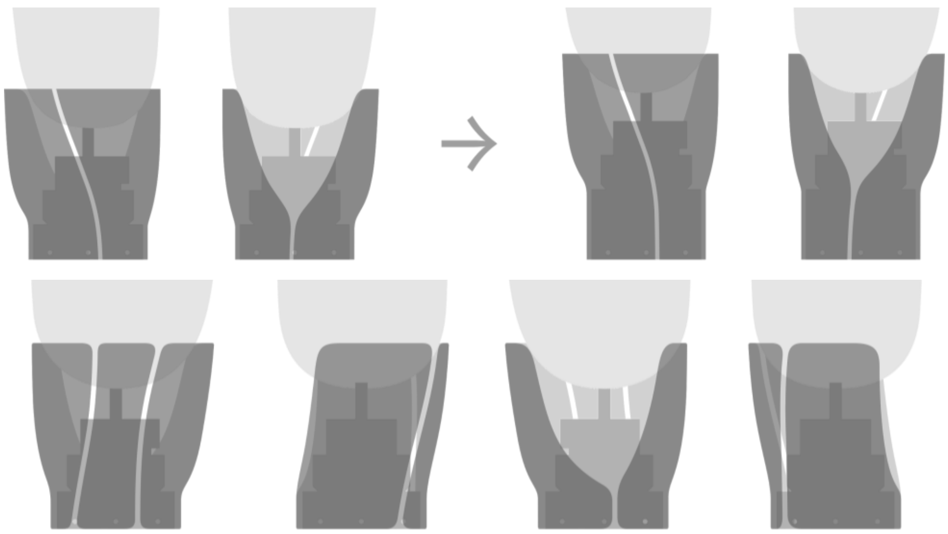

Figure 20. 2D vectorial representation of a panel configuration and proposal for scaling

5.2. CAD and Prototyping

The process shifted into CAD to make models for communicating the idea with Integrum and manufacturers and incorporate the points of view of these stakeholders. Simple models and renders were prepared using the 3D conceptualization software *Rhino 6* and the render engine *Keyshot 9*. Figure 21 shows the model that was further developed. At this stage it was realized that a Poly-Jet printing would improve both durability and DFA and was hence suggested to the manufacturer.

Concurrently, a quick print of a cover, of low-fidelity and half-scale was prepared to get a feel for the form and to try the strength of a print. It was realized that the weak points are the straight edges — perpendicular alterations in thickness — parallel to the print plane, as these would easily crack. Figure 21 shows the print with a crack.

The feedback for the models was that (a) the diameter of the cover should not exceed the one of the spacer, as it might inhibit movability; (b) the height of the cover should not exceed above the lower end of the abutment, to assure there is no contact between the cover and the residual limb; (c) the different heights ought to be accommodated for by expanding the top end of the cover rather than the bottom; (d) a further promotion of a technological expression could take its form in a feature inspired by the air intake of a car - it would not fulfil that function, but accentuate the concavity where the triceps transcends into the elbow by adding a non-tangent edge; (e) increase the size of the back aperture to facilitate opening and closing and make room for the ribs, without compromising the shape of the panels too much.

The feedback and the physical testing was synthesized into a second iteration of the 3D modelling using *Autodesk Alias AutoStudio* for optimal surface accuracy. Four new design features were (1) triceps-shaped stylized edge, inspired by a car surface; (2) sockets for the magnets; (3) greater radii for the upper panel corners than for the bottom, expressing the transition from organic to technological; and (4) faded pattern in the elastic hinge for the same reason.

Five manufacturers were contacted for insights regarding feasibility in printing the model with Poly-Jet. It resulted only in discussions regarding cost, and as the price asked for exceeded the project budget, it was decided to split the model into the two materials of hard panel and elastic hinge and print using the available printers instead.

The result is shown in figure 22. It was successful in function, having a strong connection achieved with the magnets and near complete embracing of the e-OPRA™ for a snug and tight fit; it did not move upon light to medium pressure. Testing the prototype resulted in 10 items for improvement to modify for the second iteration: (1) Small, upside down shelves of the inside of the cover, to rest on the spacer, would further inhibit misalignment under pressure; (2) a U-shaped inside aperture would allow a more comfortable opening of the clamp, and further assure no nearby body parts are jabbed during use; (3) The elastic hinge should go further inside the panels to improve durability; (4) The thickness of the elastic hinge should increase, and the fading hole pattern removed to also improve durability; (5) The hinge should extend all the way to the horizontal borders of the panels for aesthetic reasons; (6) Larger and deeper sockets for the magnets would accommodate for how the print shrinks during cooling and enhance the fit to the spacer; (7) The two elastic hinge parts are to fuse into one and be attached to the harder panels by pins and glue; (8) Further increase the radii at the top end edges, to avoid sharp points of collected force if in contact with the residual limb; (9) Remove one panel to only have two, for increased durability and decreased risk of failure by having fewer parts; (10) The stylized edge in the back ought to be sharper, and hence more protruding for a more technical look.

Involving patients at this stage would have been reasonable and likely generated valuable feedback. Unfortunately, it was not possible as patient contacts were conducted by Integrum and no further visits were planned.

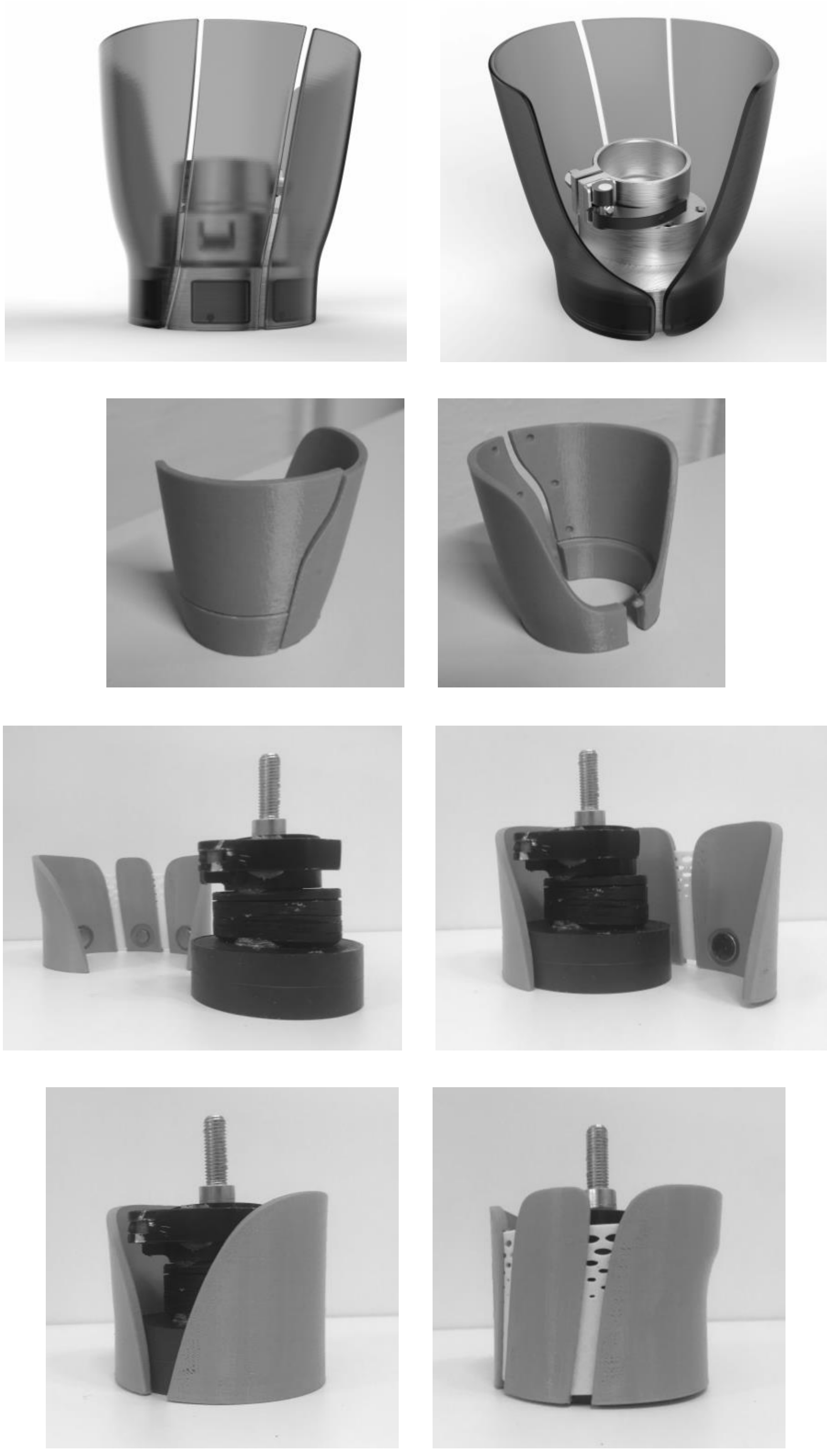

Figure 21. 3D rendering of the 'Muscle' concept, the first print (note the crack), and the first hi-fi prototype

6. Result

The final design is smoother and rounder than the previous iterations and has a larger aperture on the inside for improved usability. It consists of 5 unique parts; the back panel; the front panel; the elastic hinge holding the two together; 6 pins, which fixate the elastic part; and 5 magnets, of dimension 20 x 3 mm. There is also the magnetic band glued to the spacer for attachment.

The panels and the elastic hinge are 3D printed, whilst the magnets and the magnetic band are commercially available off the shelf, and the assembly of the cover is done in three steps: (1) The fitting of the elastic hinge, (2) fixing it and the magnets using contact glue, and (3) the gluing of the magnetic band to the spacer. The first step consists of inserting the flaps of the elastic hinge into the slits of the panels; the second step is done by applying the glue to the 5 sockets of the magnets, and the 6 holes for the pins, and the putting these in place (care has to be taken so to make the polarity of the magnets face the same way); and the third and final step consists of cutting the magnetic band to the length of 235 mm and then gluing it onto the spacer. These steps are graphically explained in illustrations in figure 23.

Ideally, the design would consist of only 4 unique parts by having it printed with Poly-jet instead. This would have both the panels and the adjoining elastic hinge print concurrently, and thus eliminating the need for pins and their associated step in assembly. However, considering the Poly-jet printing technology is yet novel and not widely available, this was not an option in this project. Manufacturers with the necessary tools were identified and contacted, but the price offered exceeded the project budget. Instead, as an alternative, the final design was quickly re-designed and slightly altered for a version to print in FilaFlex™ material solely. It also simplified the design and improved assembly by having the fitting of the magnets as the single step. It also has a decreased risk of failure by utilizing the least amount of unique parts.

The two functional prototypes resulting from the project are shown in figure 24, and figure 25 shows a *Photoshop* render of a black version when worn. The all elastic version is thought to be superior from a functional perspective, and it is also cheaper to produce. The one with stiff panels has a better perceived quality however, and the haptic feel of attaching and removing is superior. The form language varies little and is thought to be minimalist, promoting objective concinnity, and basic enough to make it an easy match regardless of clothing preferences.

Figure 22. Final cover design

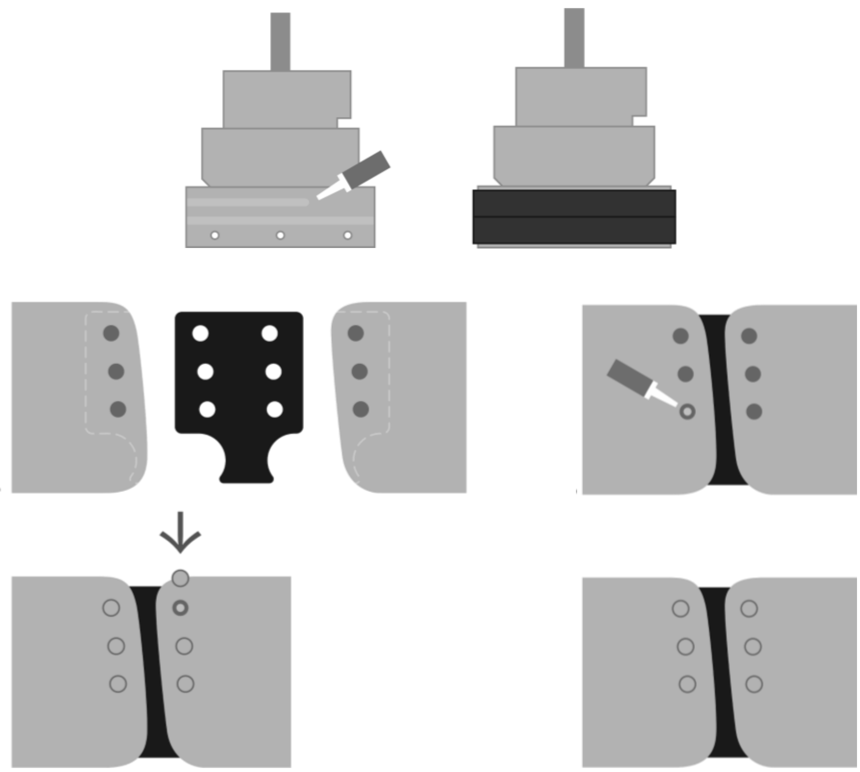

Figure 23. Step-by-step gluing of the hinge to the panels

Figure 24. Final prototypes, elastic (top) and stiff (middle)

Figure 25. Photoshop rendering

7. Discussion

The approach chosen for the project was well suited at large. Delays and backtrackings had been predicted and were accommodated for in the planning with buffer times, and the continuous converging pushed the project forward.

At a more detailed level, however, looking into the individual phases, there are some comments to be made. The first regards the research, which was broad and served as a good foundation on which to later ideate, but, in hindsight, has the relevancy of some findings debatable. An issue that needs to be addressed is how about 88% of the target group is above the age of 40 (Amputee Coalition, 2016), yet the scope considered mainly the younger users. To a large extent, this is the result of the younger being more present on social media and in internet forums, which served as the major basis for gathering information. The purpose of the trendspotting and the speculative design, which took place in these areas, was to frame what would make for a future proof design, though at the risk of setting out on a direction which would lead to something most of the current users would not appeal to. To some extent, this was balanced out by the wish of the design criteria of achieving objective concinnity and suitability regardless of age or gender. However, what this would infer on an aesthetic level was not as elaborately explored as what was asked of for the future. This notion was partly lifted under the section regarding speculative design; how the concept cannot stray too far into the future, if to be comprehensible and approved, and the concept generation sought simplicity accordingly. The minimalist appearance of the result is thought to be gender neutral, but this is however a subjective opinion.

As for the method for ideation and selection of concepts, the adapted approach of Integrum worked well. It generated a wide array of unique ideas and the consecutive converging was easy using the matrices. The phase of ideation can usually be tangled and confusing, but this method makes it structured and organized and we see its potential use in other design projects, *e.g.* for when designing processes or user interfaces.

The idea of listing the concepts for evaluation according to conventional methods, *e.g.* that of Pugh (Johannesson et. al, 2004) was discarded as the expert insight was deemed sufficient. It would, however, have been valuable to confirm the speculations of the experts using the acknowledged methods. As the concepts were many, combined, and multiplied into new ones, it may be that, though the approach was structured, some potentially valuable solutions have been lost.

The later concept development phase used CAD to refine the idea. Surface modelling was a slow process, and when a model is printed there is a need for precision for exactness in surface continuity. Time was lost due to this, and it may have been that the project shifted into the 3D visualization too quickly. Johannesson et. al (2004) advocate a ‘front-heavy’ process, in which thorough foundational work is made in advance to facilitate the later. Though the research explored widely, and so too the beginning of ideation, it may have been of value to have done the same for concept development. Regardless, the project was seen all the way through.

When relating the result to the design criteria, a notion is immediately provoked and needs addressing: *The very first requirement listed is not fulfilled* - it reads to ‘cover the transition’ and the designed cover does not. It is not a mistake, however, but a good example of how different requirements of the project conflicted and priorities had to be made. Even the needs of a single stakeholder, *e.g.* patients desire to cover the transition, but not contact the residual limb, and valuing of function and movability, seemed impossible to fulfil simultaneously; this example would require a cover that covered the residual limb, but did not touch it, nor was in the way.

Integrum also had their own idea of what the main purpose of the cover was. It, similarly, emphasized the importance of the cover not inhibiting movability, nor touching the residual limb, but rather than covering the transition the main purpose would be to fill up the space, with the argument that as long as it is homogenic, it is aesthetically pleasing. Research had indeed probed that anatomical coherence is of utmost importance, but this neglected that some patients feel exposed wearing a sight that may be strange to others. It creates a conflict of what the feeling of proudness to wear means, and, whilst Integrum would argue that the select few patients of theirs are all proud of the technology as it is, it does not address the feeling "undressed." As a result of conflicting requirements, it was decided that as long as the cover is functional, durable, and filling up of the space, the design is adequate.

Other requirements concerned the protection of the residual limb. Initially a cushioning shield was considered and many of the concepts circulated the idea of having a soft padding. It had been found in interviews that some sort of soft outside would also be preferable to reduce the risk of hurting others. However, considering the cover was to be simple, and speculated to be worn a lot under clothes and during summertime, airflow and light weight were deemed more important. The idea of using multiple layers of different materials was discarded and it was decided to work with the form of it for improved safety instead.

Managing conflicting requirements can be difficult and problematic in a design process. Even though the project had a few to consider, it was quite clear how to prioritize. As some requirements potentially could cause pain if ignored, these were the most pressing, and when there was uncertainty, Integrum was consulted.

Throughout the design process the emphasis has been to not inhibit any function. The most likely problem was that the solution would regress the technology back to socket level, and hence the result does not enclose the residual limb and takes care not to poke out. It was also important to avoid harsh corners or edges where the cover could jab the residual limb, and potentially provoke PLP. The rounds at the top were also used to emphasize how that is the organic end of the transition. Comparably, the lower end of the cover was made straighter to align with the mechanical elements of the artificial limb. An argument can be made that the mixing of the two elements was to be avoided, if to stay out of the uncanny valley. Nonetheless, it was considered to be within the desired range of affinity.

Regarding the durability, which was the second most important aspect, the lack of points or edges ensured that no straining forces could accumulate; rounds were carefully placed, and edges smoothed even where there was no risk of contact with the residual limb or other body parts. This also improved the cleanability of the cover; with few nooks and crannies where grime can gather that also allows easy wiping.

The requirement of comfortable use relates to this and was mainly considered from the functional point of view, *e.g.* by having the attaching and detaching easy and quick. It was in a later iteration made so that the prosthesis could be put on and taken off even with the cover attached to promote this, and the airflow was enhanced by the hollow inside.

The result is adaptable for future development; the split-lines designed can easily be altered to align with other contours of muscle groups in other limbs, and considering that the attachment is to the spacer, the cover would fit with the same attachment. The one size of the final concept is made for the most common spacer dimension. The idea is that it sets the format for the cover proportions and that it easily can be scaled in versions to fit the other use cases.

Whether or not the design is a success is difficult to say. Due to circumstances outside the control of the project, it was impossible to conduct user tests. These would have occurred intermittently throughout the process to assure the direction of development was towards relevancy and would have helped evaluate the final result.

Regarding actual user cases, it is also worth mentioning that the glue used in the cover may be unsuitable for worn products. Contact glue can be harmful as it may contain endocrine disruptors and this needs to be considered in further development through biocompatibility testing.

A final thought of reflection relates to restrictions put in the beginning of the project. An argument can be made that the cover could have been further promoting psychological acceptance, enhancing experience of use, if the artificial limbs of Ottobock had been within the design space. Much of the research indicated that this is where the larger issues regarding the aesthetics of prostheses reside.

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Appendices

Appendix 1
Planning Report

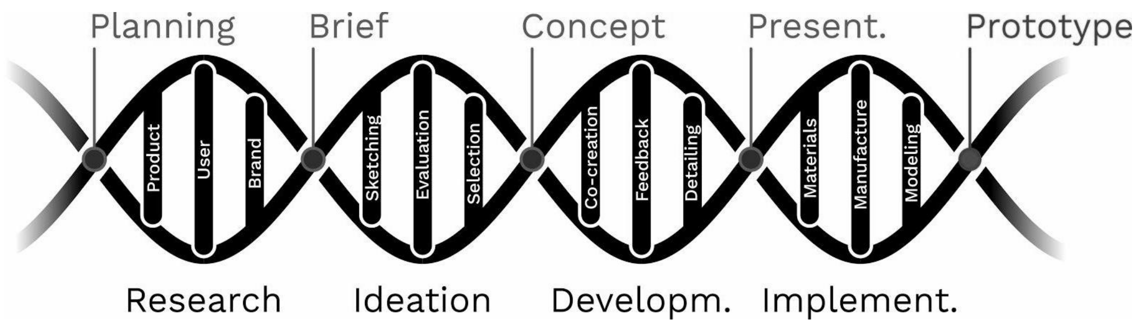
Master Thesis: Cover Design for Robotic Prosthesis
Students: Anton Hörling & Iñigo Uriarte Peña

Robot prostheses of today have a technical appearance. Improving the aesthetics with a cover could make a big impact on how patients see themselves as well as how others look at their "disability".

The Objective of this thesis is (a) to understand how the design of a prosthesis alters the experience of wearing and encountering it, and (b) to design a cover for an enhanced pleasure of use and deliver the material needed for the outsourcer to finalize a dialog with planned manufacturer and set up production.

The academic objective is (c) to conduct this project with an evident connection to current research on the topic, (d) to incorporate methods and approaches presented in the courses of the MSc program, and (e) to document the process in a report for examination.

22th of January 2020



27/1 - 21/2: Research

The research phase will examine previous work done on the topic (*e.g.* van der Kaaden, E. (2018). e-AD: enhanced attachment device), and thus identify notions of interest to pursuit.

It will analyse the existing solution of Integrum, and in that way generate technical restrictions for the coming design (*e.g.* regarding where the prosthetists need access; where fixings could be placed; what cost limits there are, *etc.*).

It will conduct a brand analysis, so to identify how Integrum markets itself; what the core values are and how these are communicated (*e.g.* in what colours and what words *etc.*). The brand analysis will outline a form language and thus aid the process of designing a cover that manifests itself as an Integrum product. It will consist of a meeting with the marketing department and a review of the company's online presence will make parts of it. Ethical questions will also be reviewed at this stage, and regard questions like whether it is agreeable or not to have a visible company logo on this type of product.

A market comparison will be conducted to examine the solutions of other companies, as this will provoke discussion about—and allow inspiration by— alternative ideas.

The history of prosthesis will be researched briefly for inspiration, alongside with the DIY movement of ornamenting one's own. Relevant aspects of biomimicry will possibly be researched superficially for the same reason.

The basics of human limb anatomy will briefly be studied so to understand how the widths and cross-sections of human limbs vary, but also to get an insight in how *e.g.* weight and other aspects of the design can be altered in order to make its feel more aligned with the patients' visceral expectations of it.

Considering regulations for medical products is a vast topic, it will be partially delimited, and only looked at so to superficially understand what limits there are when designing for this purpose.

User interviews regarding the UX of the product and its current flaws will be conducted, as a first-hand understanding of the patients' needs and wishes will contribute to the relevancy of the design.

A look into common everyday tasks may open up for ideas of expanding on the function of the prosthesis by implementing additional features for enhanced usability and will hence be considered. In regards to enhanced usability, how the system can give feedback to aid use, and how that would take form (*e.g.* in visuals or sounds), will also be examined.

The research phase will generate a brief with criteria and is considered a gateway; it is to be approved by the outsourcer and the supervisor before the project will proceed.

24/2 - 13/3: Ideation

The ideation phase will Include sessions of brainstorming, sketching, and form exploration, and will seek to find a solution that considers the functional needs elicited from the research phase in an aesthetically pleasing format. Methods will include cooperative exercises, *e.g.* the 3-6-5 method, and possibly involve other design students. Other examples of methods may be the 'fishtrap method' or the 'perfect day scenarios' *etc.*

The ideation phase will end with a concept evaluation that, with the aid of the brief and criteria, and possibly pugh-matrices, will select the one deemed superior. It is considered a gateway, and all the concepts in the final round of selection will be shared with the outsourcer, so as to allow them to influence the course of the design process.

16/3 - 3/4: Concept Development

The selected concept will be further refined by a look into materials, so to know what is best suited, *e.g.* for the medical regulations; for constant skin contact (what is comfortable and not sweaty); what is light yet durable enough, *etc.*

It will look into manufacturing and start exploring what companies are available and set a date for when to supply them with blueprints of the design. It will also explore what forms a chosen production method allows and how that affects the concept.

It will include 'Lo-fi' prototyping for user involvement; sessions of co-creation for ideas and feedback to implement. Additionally, a risk analysis will start to take shape in this stage.

The concept development phase will end with an elevated fidelity of the concept, which will be shared in the coming ‘bottleneck’ phase.

6/4 - 17/4: Interim Presentation

A session of physical co-creation with Integrum has the purpose to get feedback and generate additional ideas to the concept. These notions will then be implemented through iterations of the ideation and concept development phase. This will lead to yet another concept evaluation and selection process, which at this time heuristically will include the aspect of sustainability as an evaluation criteria.

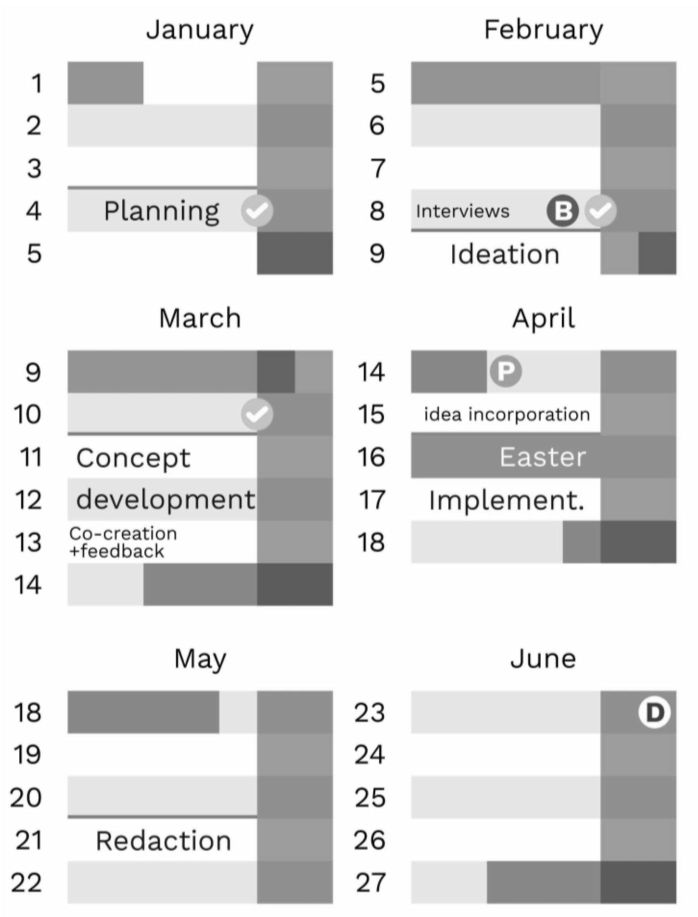
The presentation phase will result in blueprints, which are a gateway.

20/4 - 15/5: Implementation

The planned manufacturers are supplied with the blueprints a dialog for production initiated. The phase will further adapt the solution to what’s possible with the tools available for said manufacturer and hopefully generate custom made ‘Hi-fi’ prototypes for the interviewees. Evaluation of these will generate user feedback. Implementing this feedback and visualizing the final result in renderings is the final delivery to Integrum.

18/5 - 29/5: Buffer and Documentation

This phase is planned so as to allow for delays and corrections of mishaps. It will also finalize the report for hand-in.



Appendix 2
Interview Guide

Name:

Age:

Profession:

How long since the accident:

(Hur länge sedan var olyckan?)

Have you had any other prosthesis than this current? What type?

(Har du haft en annan protes än denna, vad för någon?)

How long have you had your current prosthesis?

(Hur länge har du haft din nuvarande protes?)

Is it better than the previous? In what way?

(Är den bättre än föregående, på vilket sätt?)

What did you expect of the prosthesis?

(Vad förväntade du dig av protesen?)

Was there something about its use that surprised you?

(Var det något med användningen som förvånade dig?)

When you first got it, what were your initial reactions to the design, form, colour, feel of your prosthesis? *etc.*

(När du fick protesen, vad var dina första reaktioner på design, form, färg, känsla? etc.)

Are there occasions during which you don't use it // How often do you put on and remove your prosthesis a day?

(Vilka tillfällen använder du inte protesen // hur ofta tar du av och på den?)

Do you experience any difficulty while putting on and removing the prosthesis? it is easy

(Upplever du några svårigheter med att ta av och på protesen?)

Are there situations that require different settings/functions?

(Finns det situationer som kräver olika inställningar, funktioner?)

Would you value being able to change the appearance of the prosthesis depending on the occasion? Casual, formal, sporty *etc.*

(Skulle du vilja kunna byta utseendet beroende på tillställningen, formell, sportig etc.)

When and why are you frustrated with this solution?

(När och varför blir du frustrerad på den här lösningen?)

Are you using any modifications, self-made additions?

(Använder du några hemmagjorda modifikationer till protesen?)

Have you ever shared a story about its use?

(Har du någon gång delat en berättelse om användandet med vänner eller familj?)

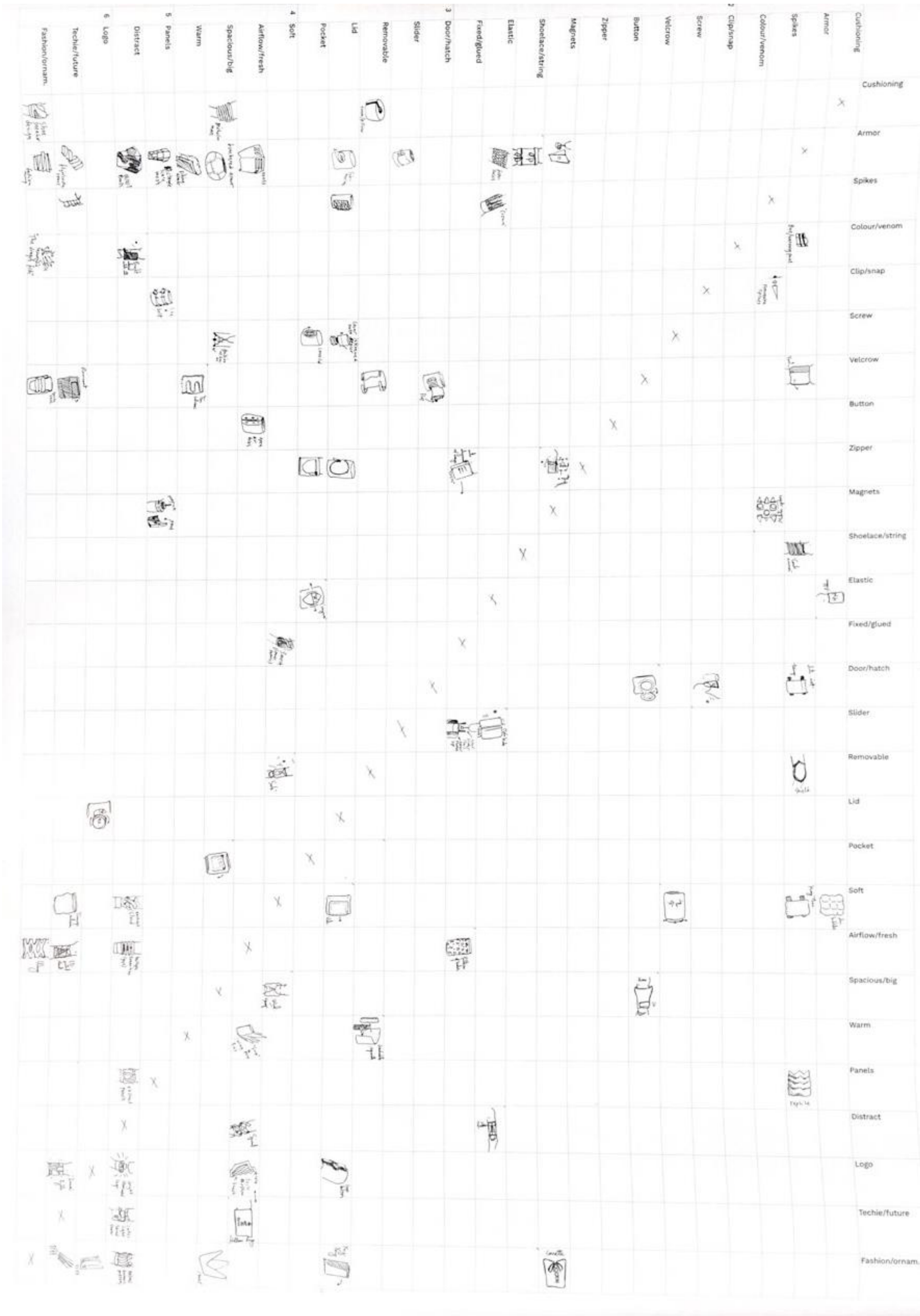
If you could change anything about the prosthesis to make it better, what is currently missing // What do you expect future prosthesis will look like, feel like?

(vad skulle du ändra för att förbättra protesen, vad saknas? Vad förväntar du dig av framtidens proteser, hur ser dom ut, hur känns dom?)

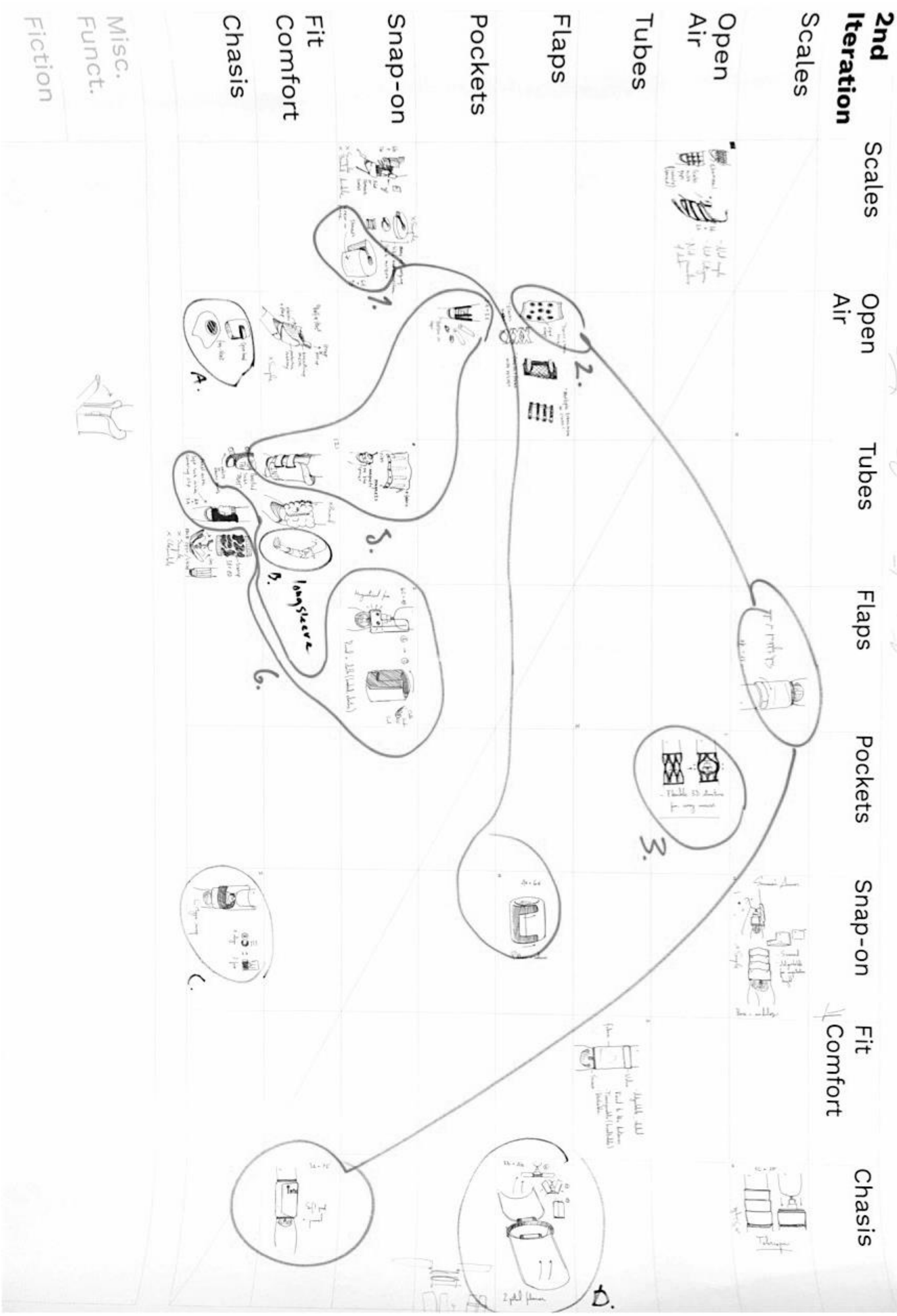
Would you value additional features in the prosthesis? *e.g.* increased strength, a torch, a knife, a screwdriver

(Skulle du vilja ha några extra funktioner, till eller i protesen, för att utöka dess användningsområde? Isåfall, vilka?)

Appendix 3
First Matrix

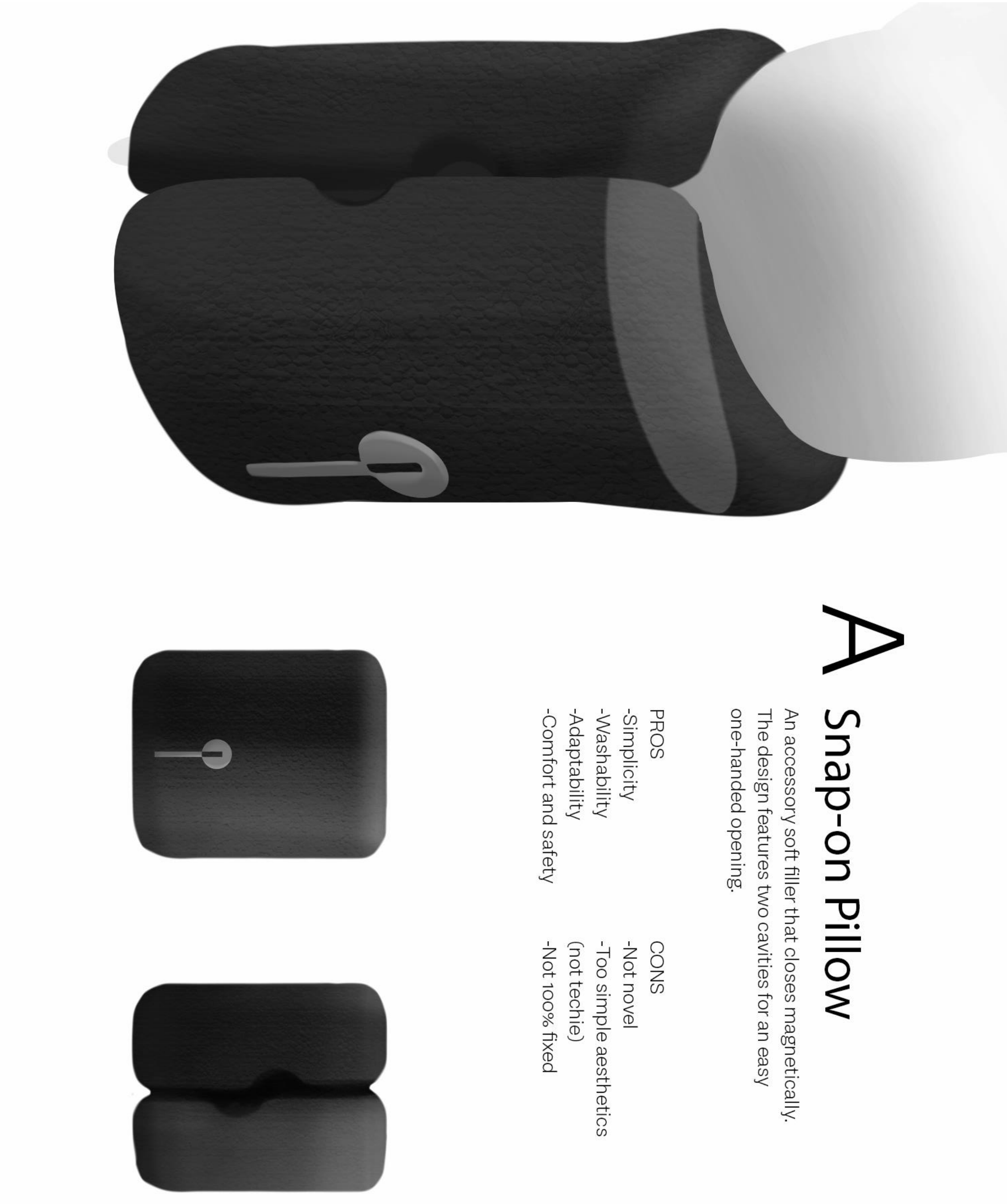


Appendix 4
Second Matrix



Appendix 5

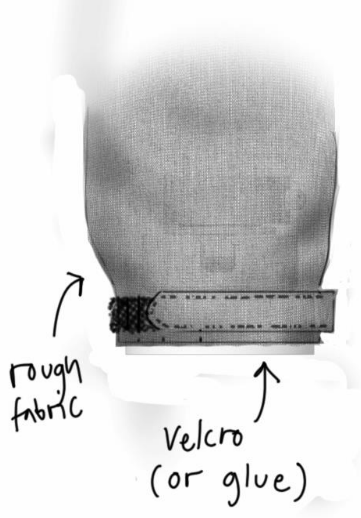
6 Concepts

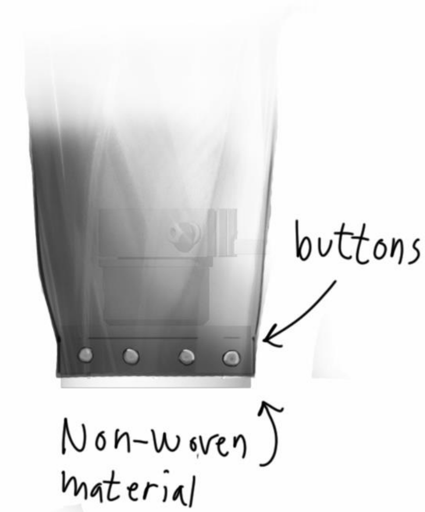


B Elastic Cloth Tube

One of the patients already use this solution, mainly to prevent things from falling into the prosthesis.
The tube, or sleeve, could be made long and extend all the way down to the wrist/ankle of the prosthesis to give a more unified look.

PROS	CONS
- Simple	- Not protective
- Easy to adapt for individuals	- Not durable: elastics may wear
- Washable	- Will not fill up clothes
- Light	- Not novel
- No need for fixation (?)	

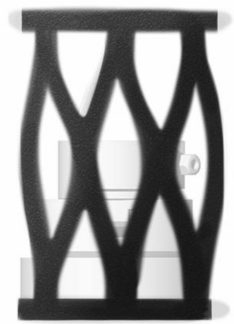




C Elastic Frame

An airy, light and open structural mesh elastically fixed in both ends.

PROS	CONS
-Lightness & simplicity	-Difficulty to wash
-Adaptability (if 3D printed)	-Not novel
-Trendy (fashionable + techie)	-Not protective
-Low cost	-Could not be all-condition
-Customizability	

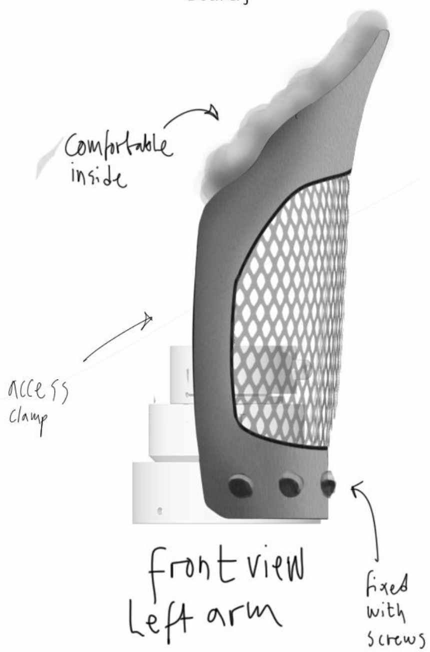


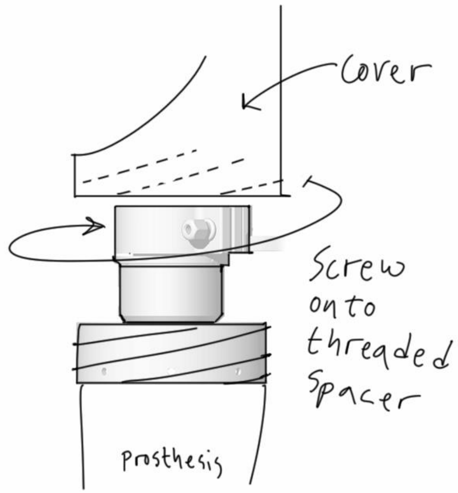
D Lacrosse

A rigid frame holds a softer mesh in place. The idea is that the frame will protect the sensitive areas and that the mesh will cover the transition yet allow airflow.

PROS
- Breathable
- Light
- Sturdy

CONS
- Needs remodelling, or different size standards to fit all
- Potentally difficult to wash



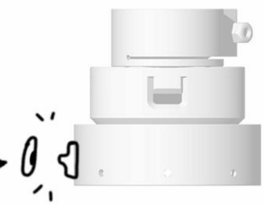



E
Turtle
A hard shell placed on the outer side permanently fixed to the system. The inner is covered wit a cloth, possibly attached with: velcro, zipper, clip...
PROS
-Protects while comfortable
-Helps the alignment
-Simplicity
-Breathability
CONS
-Could be difficult to adapt
-The attachment could wear
Integrum

F Collar

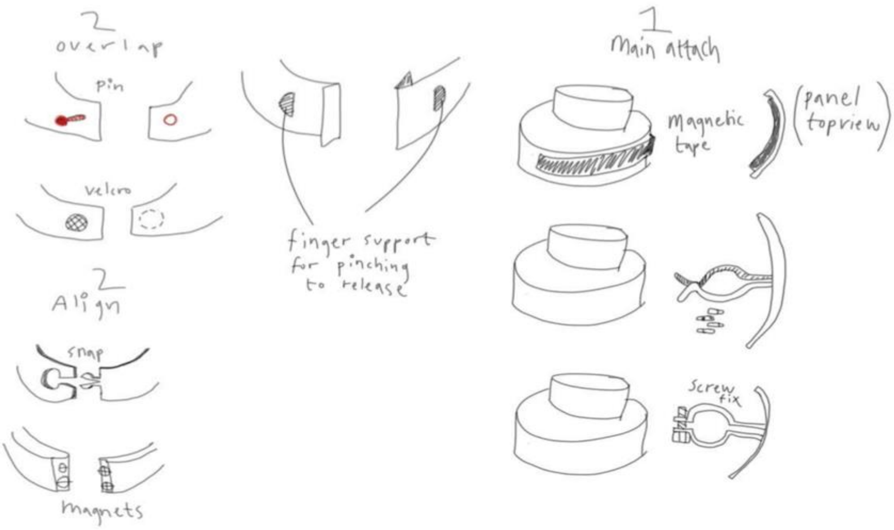
An elastic, yet stiffer, outershell protects a cushioned inside. Similar to a slalom boot or a neck brace on a basic level, but this concept can take many different forms.

PROS	CONS
- Safe and protective	- Potentially not simple
- Can portray Med-Tech, hence honest	



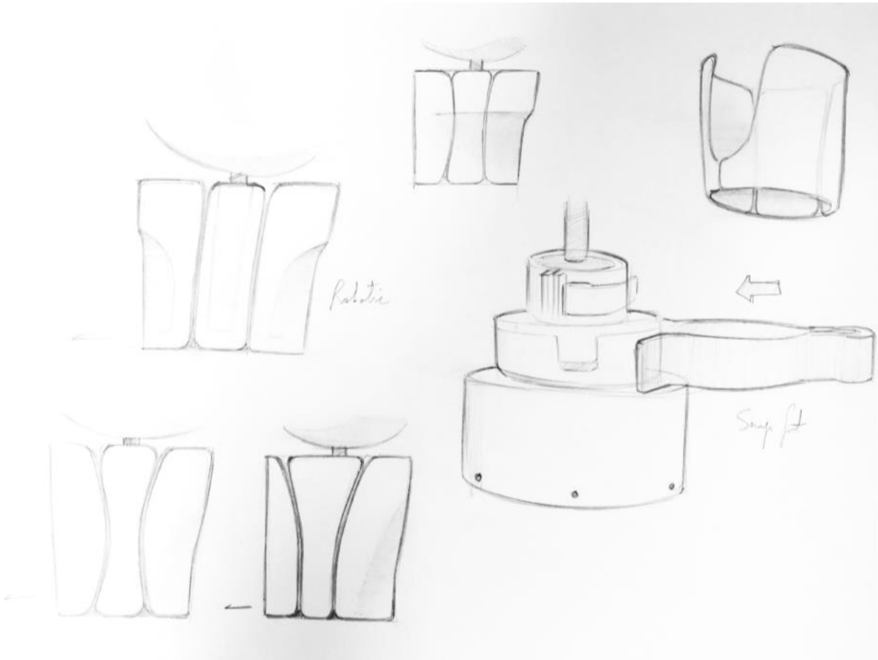
Appendix 6
Ideated Attachments

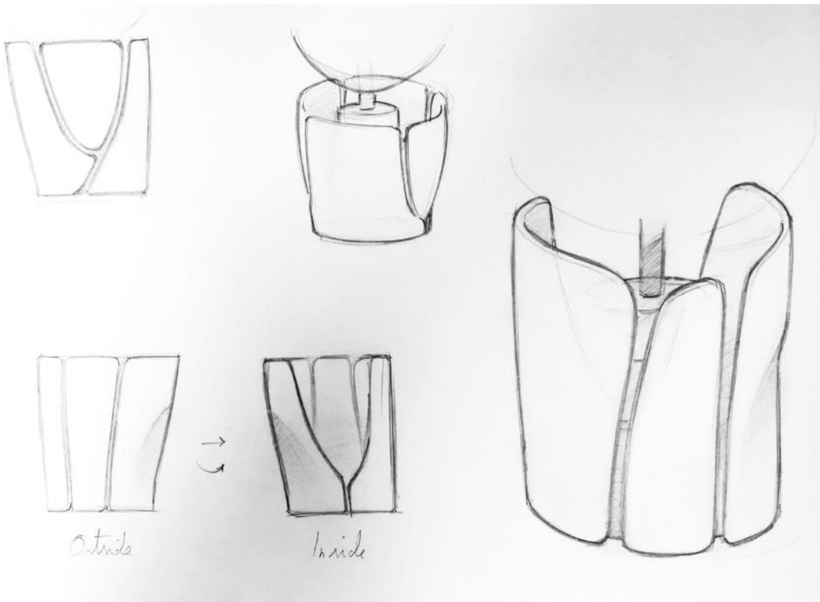
Type	Variations	Pros	Cons
Pins	- Hard print - Punched belt	- DFA - Haptic feedback - Multiple fits	- Durability - Fine tolerances - Difficult to use with one hand
Velcro	- Glued Patch - Band	- Cheap - Ease of use - Replaceable	- Will wear - Cheap feel - Inferior pleasure of use
Snap	- Onto e-OPRA™ - To itself	- DFA - Ease of use - Haptic feedback	- Durability - Fine tolerances - Play
Permanent	- Glue - Screws	- Durable - Ease of use	- Access problems - Restricting
Magnets	- Band - Socket Magnets - On YX/YZ plane	- Ease of use - Haptic feedback - Cleanability - Superior pleasure of use	- Non-DFA - Expensive

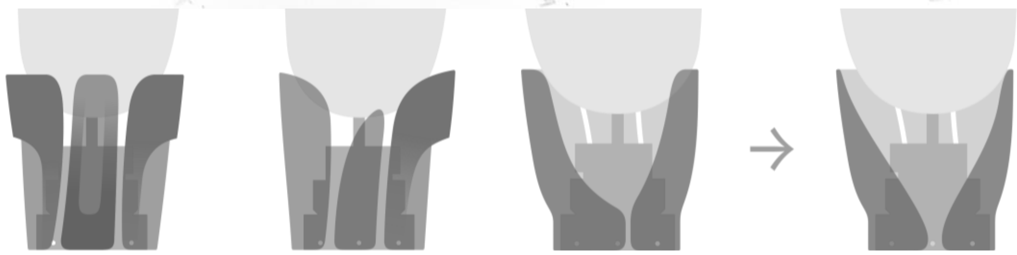


Appendix 7
Form Exploration

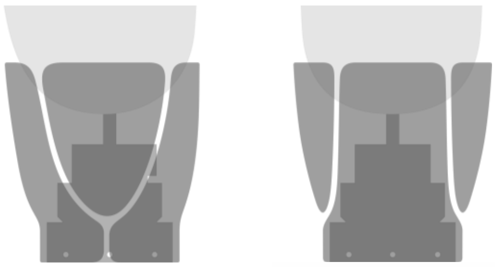
Much of the form exploration was done through sketching, perhaps the most agile way to perform it, allowing easy communication and quick projection of ideas.

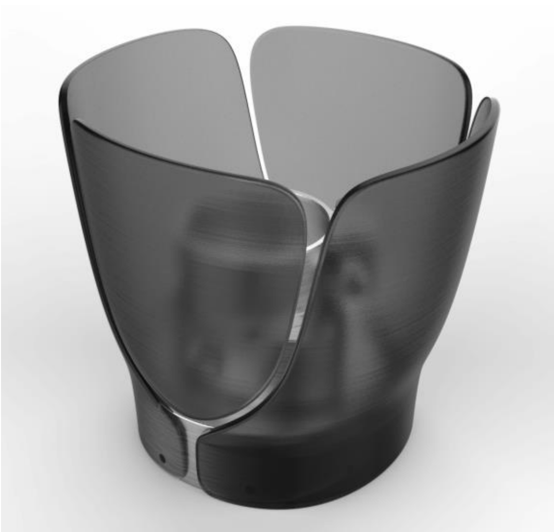






The ‘Tulip’ concept was a symmetrical form that moved off the organic lines of muscles and softened their shape to resemble the flower that named it, with the inner “petal” removable for access. It was discarded as it did not ease the closing and opening as much as the ‘Muscle’ concept, which hence served as a better foundation on which to further develop the form. Displayed below are also the tangent line of a car body.





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