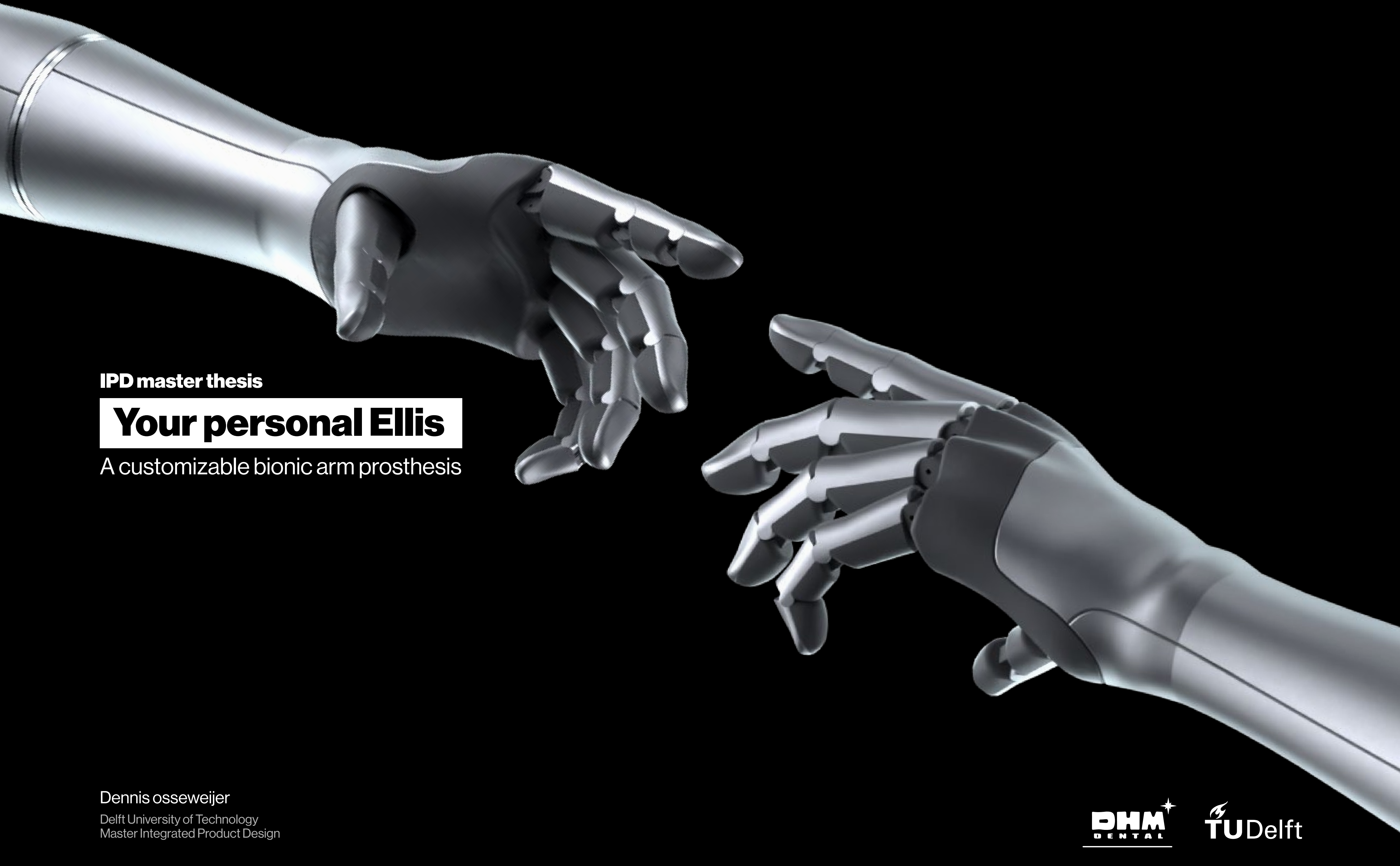


IPD master thesis

Your personal Ellis

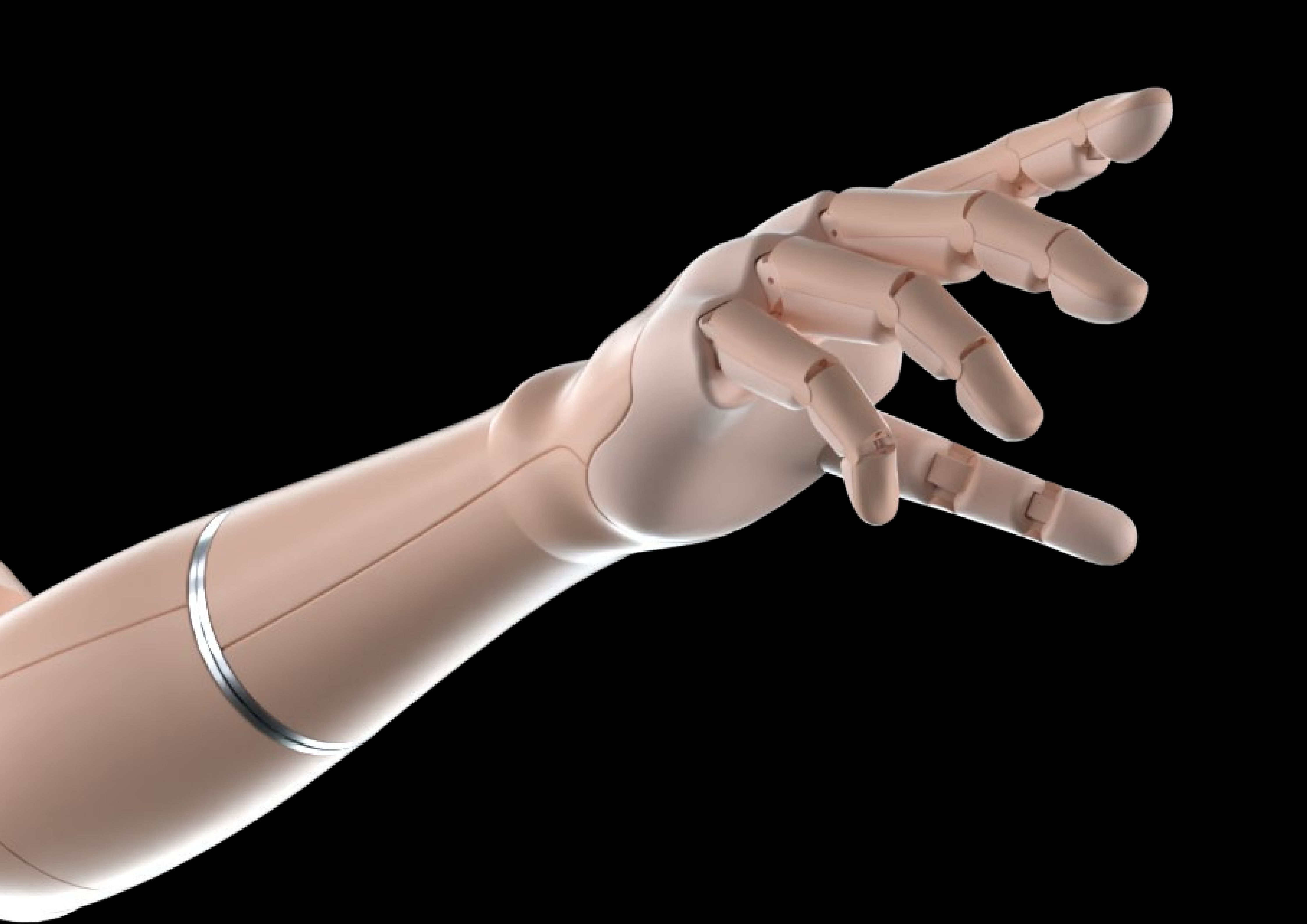
A customizable bionic arm prosthesis

Dennis osseweijer

Delft University of Technology
Master Integrated Product Design

DHM DENTAL

TU Delft



Summary

In this master integrated product design graduation project a design concept is created for an osseo-intagrated customizable bionic arm prosthesis, which can serve as a stepping stone for the development of this product called 'Ellis'.

There is a lot of development going on in the domain of bionic upper limb prostheses. A major innovation is the use of osseo-integration and using myoelectric sensors to actuate fingers with muscles and connecting tactile sensors to the nervous system to 'restore human touch'. In this master thesis an embodiment concept is made for a osseo-integrated bionic arm prothesis for trans humeral amputees.

An initial exploration was done on parametrically designing embodiment with Altair CAD software provided by desin8. However this has not been further applied in the project as this was not deemed important.

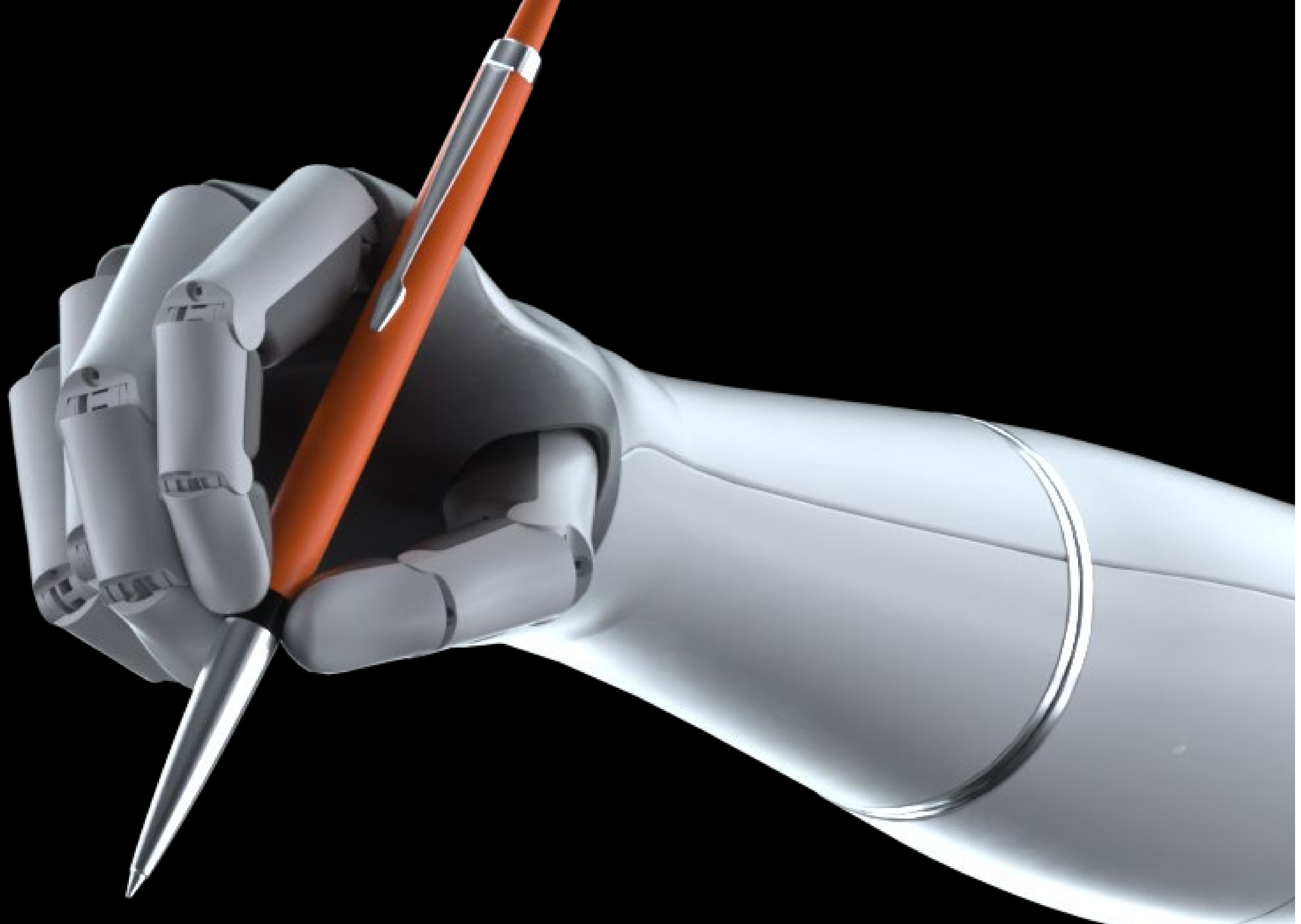
The design is the result of an extensive analysis of the state of the art, interviews with the target group and experts, analysis of anthropometric ergonomical capabilities and dimensions and an analysis to human touch. The state of the art analysis shows great opportunity in terms of customizability and gives a clear overview of the market segments. Furthermore performance capabilities such as strength, durability and unique selling points are investigated. Target group interviews show user needs and desires. Notable is the desire for an appealing design, customizability options and matching prosthesis dimensions. Including sensory feedback adds immense value to the prothesis since this add to the sense of body ownership; the product belonging to the body.

The findings of these analyses served as a framework for the design and were translated to main drivers. The main drivers for the prosthesis are: Customizability, mobility, modularity, tailor-made, durability and aesthetics.
With the drivers in mind multiple ideation sessions have taken place in which solutions were brainstormed for the prosthesis. The best solutions based on discussion and looking at the drivers were selected for further embodiment and prototyping.

The result is a design that is customizabile due to its modular approach and can be tailor-made to the users dimensions. This modular approach also allows for easy replaceability of wearing and tearing components. It is designed to have an aesthetical appeal and resemble human arm form characteristics. The arm can mimic antropometric ergonomical movements such as finger flexion and extension, ab-/adduction, a wrist rotation and an elbow rotation. The design is built in such a way that crucial components are protected from water and dust and is therefore durable.

The design is assessed on its feasibility, viability and desireability. In terms of feasibility it is assessed whether the product is producible and if it meets the required drivers. For viability the business side of the product is evaluated; although it is an expensive product for a very niche market it can be viable as long as the price and value is in balance and can therefore be covered by health insurance, otherwise very wealthy individuals have to acquire the arm themselves. The desirability is assessed by showing the product to the target group, the main conclusion is that some prefer a discrete design and some an expressive one. This product is created more for the expressive individual. The user states that allowing to customize the prosthesis makes that the prosthesis really belongs to him.

The result of this integrated product design master thesis is a design concept that explores multiple important aspects for a prosthesis such as customizability, modularity and aesthetics and can serve as a stepping stone in the development of this bionic arm prothesis called 'Ellis'.



Glossary

Within this project some very specific and technical termonology is used. Therefore this glossary is provided to clearify the meaning of some of the used termonology.

A

- Amputation - Surgical removal of all or part of a limb, an organ, or projecting part or process of the body.
- Amputee – a person who has lost all or part of an arm, hand, leg, etc., by amputation.
- Additive manufacturing – industrial production name for 3D printing
- ADL – Activities of daily life
- Anthropometric – the measurement of the size and proportions of the human body
- Aesthetics – the study of the mind and emotions in relation to the sense of beauty

B

- Body ownership – The sensation that something belongs to the body.

C

- CAD model – A computer-aided design model
- Customizability – The option to make personal modifications
- Cinema 4D – 3D modelling software

D

- DoF – Degrees of freedom – meaning the number of independent variables that define its configuration or state.
- Dorsal – situated at the back

E

- Exteroception – sensitivity to stimuli that are outside the body
- Embodiment – a tangible or visible form of an idea

F

- FDM Printing – Fused Deposition Modeling is 3D printing method

H

- Hydrodipping – A method of applying printed designs to three-dimensional surfaces

M

- MDR – Medical device regulation

O

- Osseointegration – Phenomenon where an implant becomes so fused with the bone that they cannot be separated without fracture

P

- Palmar – relating to the palm of the hand
- Prosthesis – A device designed to replace a missing part of the body
- Proprioception – Perception or awareness of the position and movement of the body
- PCB – Printed circuit board
- Phalanx – The finger is build up out of three bones called phalanxes. The phalanx closest to the hand is the proximal phalanx, followed by the middle phalanx and the tip being the distal phalanx.
- Phantom limb pain – Pain felt in the area where a body part has been amputated

S

- Somatotopic – A specific part of the body associated with a distinct location in the central nervous system
- SLA printing – Stereolithography is a 3D printing technique which uses UV light to build a 3D solid out of resin

T

- Tactile feedback – Mechanisms responding to touch

Table of contents

01
Introduction

The past decade there have been massive developments in the domain of bionic prosthetic limbs. Osseointegration, closeloop sensory feedback and personalisation for prostheses could soon be a reality for amputees.

In this master thesis an embodiment of a bionic arm prosthesis has been developed fit for osseointegration, integration of sensory feedback and personalisation in the form of appearance and dimensions.

Stakeholders

This project is a collaboration between the company DHM dental bv and the TU Delft.

DHM dental with its respective designers: Maarten den Hartog and Pamela Musch. Furthermore DHM Dental adn R&D crew Willem van Rossum; Daan den Hartog; Joris van Oers and Jan Timmers.

OTN implants with Henk van de Meent. Henk is responsible for the placement of the osseointegrated implants.

TU Delft commitee consisting of Erik tempelman (associate profesor IDE) as chair and Joris van Dam (Researcher IDE) as coach.

And ofcourse myself, Dennis Osseweijer, IPD master graduate student.

This product is developed for combined use with wired osseointegration implant BADAL E which is currently in development by OTN Implants B.V.

Relevance

Current prostheses on the market lack proper sensory tactile feedback and options for customizability and personalization of the product. However these are two crucial elements for product acceptance and performance. This thesis explores the possibility for integrating these elements into a feasible and viable product and could serve as a stepping stone for the developments in the domain of bionic prostheses.

Confidentiality

Certain details have been left out of this document for confidentiality reasons, such as internal technological components and materials.

What to expect

This document presents the development of an osteo-intergratred arm prosthesis embodiment.

- Chapter 2 describes the assignment and scope of the project and the deliverables.
- Chapter 3 focusses on the context of the assignment.
- Chapter 4 describes the approach of the project
- Chapter 5 contains the analyses. More in depth details on the analyses are presented in appendix 5.
- Chapter 6 Summarizes and concludes the findings from the analysis into six drivers.
- Chapter 7 presents the ideation phase. Embodiment solutions are generated for the prothesis functions.
- Chapter 8 Showcases the concepts that were generated from the ideation phase.
- Chapter 9 Discusses the concept choice. The concepts are being discussed with the company and the best concept is chosen to further develop.
- Chapter 10 Covers the embodiment phase. Here the product is made in detail within CAD software.
- Chapter 11 describes the prototyping phase. In this phase the embodiment model is prototype and different materials and functionalities are tested.
- Chapter 12 shows the final product.
- Chapter 13 covers the validation phase. the product is assessed on feasibility, viability and desireability.
- Chapter 14 concludes the report. The proces and

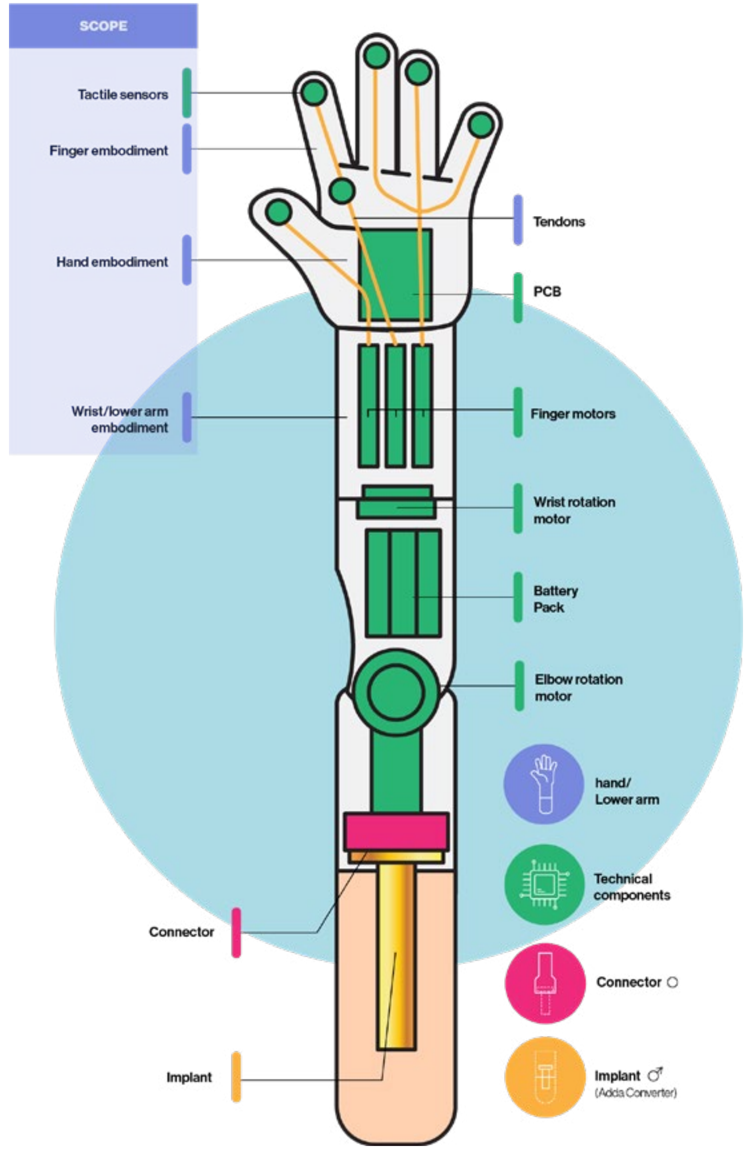


Figure 2.1: Product architecture and Project scope

Design an embodiment for an osseointegrated arm prosthesis with closeloop tactile feedback and myoelectric controlled actuators and has a biomimicral appearance.

02 Assignment

This chapter presents the objectives, scope and deliverables of this graduation project.

2.1 Problem definition

As mentioned briefly in the introduction, there are major developments in the domain of bionic prosthetic arms. Osseointegration enables the possibility for connecting tactile sensors with the peripheral nervous system. This allows for integrating tactile feedback in arm prostheses. One of the main missing features for commercially available arm prosthese according to a paper by Raspopovic et al. (2021).

An embodiment needs to be designed for a bionic prosthesis that makes use of this technological principle. The embodiment needs to house motors that actuate the fingers, a motor that actuates the wrist rotation, a motor that actuates the elbow motion, a battery pack, a PCB and several tactile sensors.

Furthermore current models oftentime do not match the users residual limb dimensions and allow for very little personalisation through customization of the product.

2.2 Project description

DHM dental bv has asked me to **design an embodiment for an arm prosthesis that makes use of the osseointegration principle and houses tactile sensors and actuators and has a biomimicral appearance.** Figure 2.1 shows an overview of the product architecture.

2.3 Focus areas

Focus areas of this project are:

- Modularity - Product must be tailor made to different human arm dimensions.
- Wearing and tearing of parts.
- 3D printing and suitable materials
- Biomimicry - Product must resemble the human arm and mimic human body features.
- integration of motors, sensors and electronics.

2.4 Scope

The scope for this master thesis will consist of the embodiment design for the fingers, hand and wrist/lower arm of the prosthesis. This can also be seen in figure 2.1

2.5 Product function

The product has to fulfill certain functions, the intended behaviour of the product in the widest sense of the word, as stated by the Delft Design Guide (2010). This is the foundation of the design proces. See appendix 2 for more in depth.

2.5.1 Technical function

Product has to assist the user in activities of daily life (ADL). Must mimic the human hand and arm ergonomical capabilities. Must provide tactile feedback to the user.

2.5.2 Psychological function

Losing a limb has a huge psychological impact on a person. The product has to help decrease the negative psychological impact the loss of a limb has.

2.5.3 Social function

Amputees often experience social insecurety. Appearance looks 'off' and participating in social habits (e.g. handshakes) can sometimes be difficult. Therefore the arm must resemble the human arm in appearance (biomimicry) and assist in social habits.

2.5.4 Economic function

Prostheses are often covered by insurance, since the loss of a limb is most of the time caused by accidents or diseases and prostheses are very expensive. The product has to be viable and make a profit, but should still be coverable by insurances.

2.5.5 Cultural function

Since the arm is a part of the human body, it is extremely personal. The product has to be able to feel personal and reflect the users personality.

2.6 Deliverables

- Explorative analyses
- CAD model of fingers, hand and lower arm/wrist
- Prototypes of fingers, hand and lower arm/wrist
- Product renders
- Product poster
- Thesis report

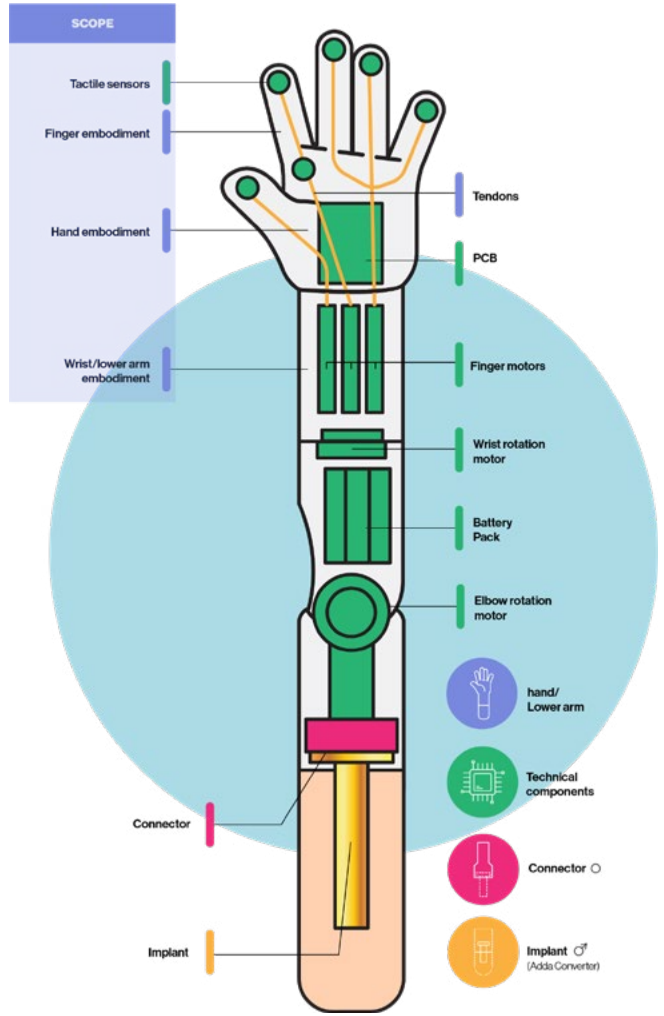


Figure 3.1: Team roles and their focus

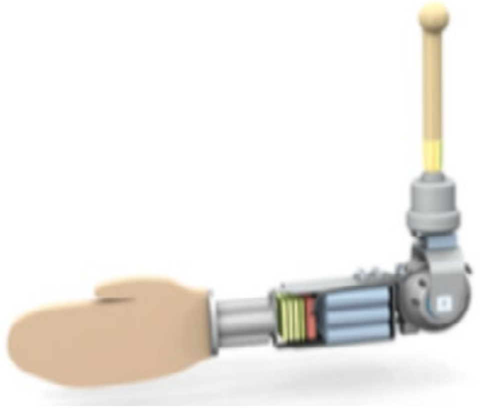


Figure 3.2: Basic visual of prosthesis principle provided by DHM Dental bv.

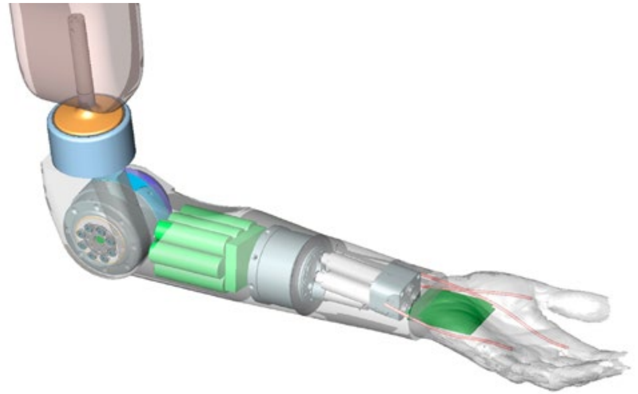


Figure 3.3: Starting prototype for the assignment (after short break)

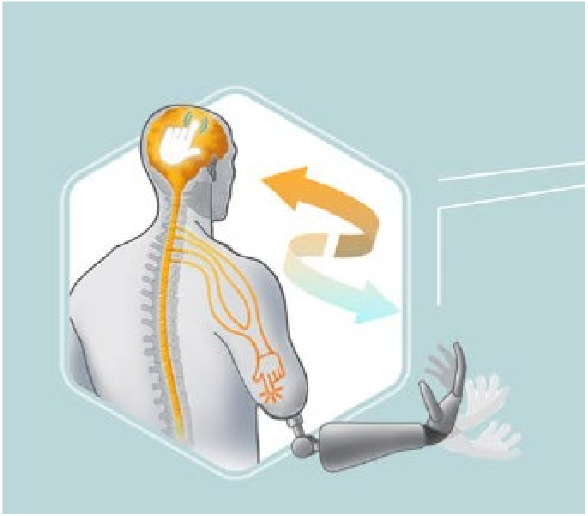


Figure 3.4: Osseointegrated Implant - close loop sensory feedback and Myoelectric muscle controlled actuation principle.

03
Context

The project consists of a multidisciplinairy team which works together on the design of an osseointegrated arm prosthesis.

3.1 Project team

The product is divided in four major components: The implant, the connector, the motor controls and the overall embodiment. The prosthesis is designed with a multidisciplinairy team where each member focusses on their major component. However there is ofcourse internal communication to make sure everything works and fits together.

Implant

The implant is designed by OTN implants.

Arm prosthesis

The arm prosthesis is developed by DHM Dental. The scope of my project is the embodiment of the prosthesis (finger, hand and lower arm). Thes will determine the appearance of the product, but also I also have to take in account that all the internal components fit inside.

3.2 Internal components

Osseointegrated Implant

The titanium implant is integrated in the humeris which is the big bone present in the upper arm of a person.

Close loop sensory feedback
From the implant neural electrodes are attached to the somatosensory peripheral nerves. This allows for the output of signals. Tactile sensors can be integrated in the system and send signals to the nervous system. A sense of touch can be restored in this way because the nerves corresponding to the individual fingers still exist there. OTN Implants states that there are over 28 output signals available.

Myoelectric muscle controlled actuation
The use of myelectric sensors to measure muscle contractions and translate in to the actuation of motors is a very popular method to allow the actuation of prostheses. This is often done with the use of an EMG band around the upper arm of the user. The remaining muscle tissue can be used to input signals, this allows for actuating motors connected to the fingers. This prosthesis will integrate the EMG system internally through the implant. OTN implants states that there are 5 input signals available.

Connector

The connector part is used to attach and detach the prosthesis to the implant and to a charging connector.

Elbow motor

The elbow rotation motor is for allowing the arm to make a natural elbow bending motion.

Battery pack

The battery pack located in the lower arm powers all the electronical components and can be recharged.

Wrist rotation motor

For the radial motion of the arm there is an torque motor in the middle of the lower arm. This allows for 180 degrees of wrist rotation.

Finger motors

The product is equiped with several motors that are connected to the fingers in order to flex and extend them.

Tactile sensors

Tactile sensors are integrated in important tactile areas of the hand and connected to the PCB.

PCB

The product is equiped with a PCB which is responsible for all the data conversion of the sensors and actuators.

3.3 discussion

The starting point of the project already allows for defining some important requirements for the product:
- The product must house all the technical components
- The product must be able to perform a wrist rotation motion
- The product must be able to perform an elbow rotation motion
- The motions of the prosthesis have to be done with the use of 5 output signals

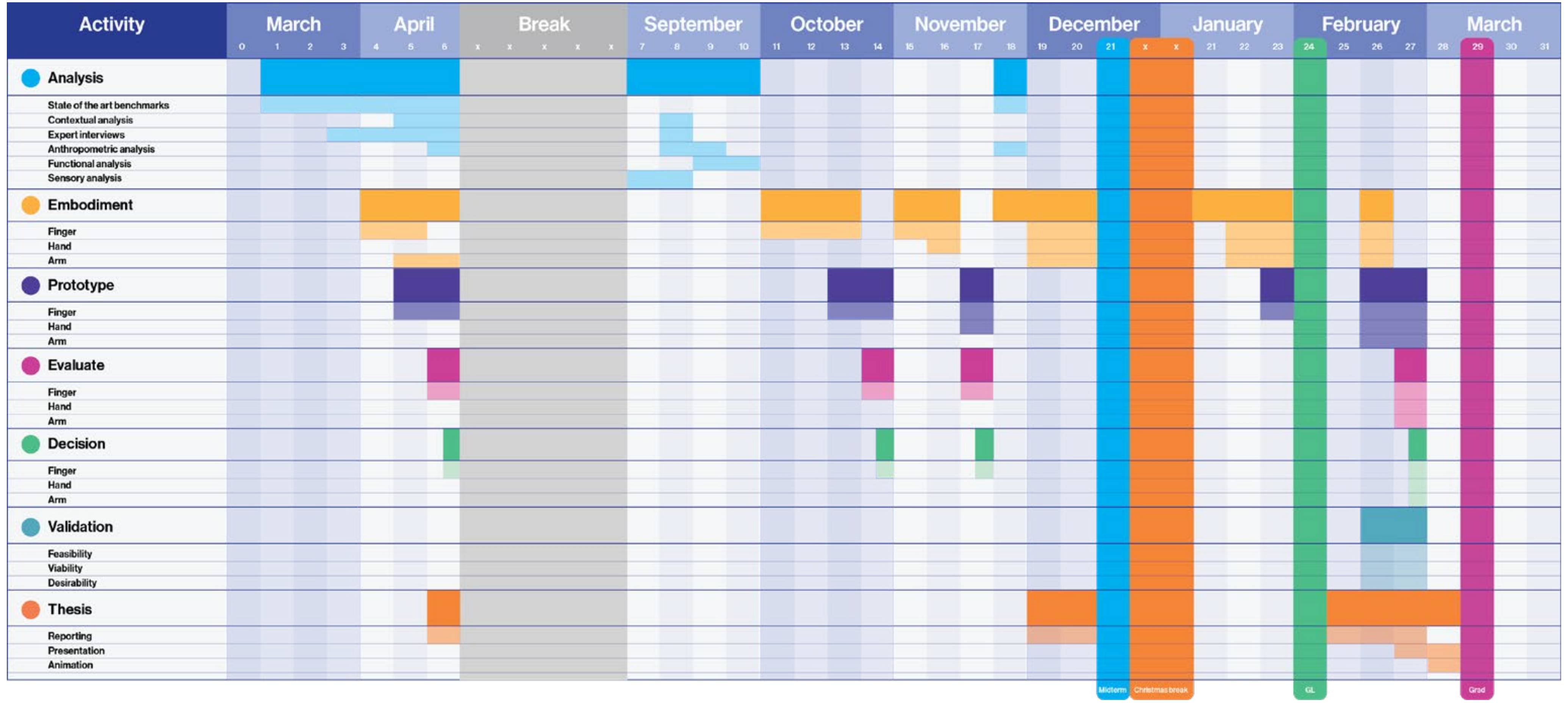


Figure 4.1: Overall project planning

04
Approach

This chapter describes the approach that has been used in this project.

For this master thesis the basic design cycle is used in combination with a concurrent engineering approach in which the internal structure and the external embodiment of the product were designed simultaneously.

Analysis

based on the ultimate function the product and each sub part of the product has to fulfill certain matters can be analysed. The outcome of this analysis results in a program of requirements. This program of requirements can be used to assess the product design solution.

Synthesis

In the synthesis phase a lot of ideas are generated that could potentially fulfill the desired product functions. These ideas are generated in brainstorms together with DHM. The ideas are translated into provisional designs.

Simulation

The provisional design is prototyped in order to simulate behaviour and properties of the design.

Evaluation

The provisional designs are assessed on the defined criteria to evaluate the value.

Decision

Once the provisional design is assessed a decision is made, either continue with the design or iterate on it and create a better one.

In reality this is more a fluent process where quick ideation takes place and is quickly prototyped to test some product qualities and is then evaluated and quickly results into an iteration of the concept, but in the end it comes down this this basic design cycle process. This process is executed for each part of the product finger, hand and arm. Sometimes multiple iterations take place one a product part.

The finger has had the most attention and went through the most iteration cycles. Due to time limitations the hand and arm had less ireations.

Planning

The project originally started in March 2021, and was set out to finish in september. However the graduation project has been on hold from April until September. All parties agreed on this break and the project developed in the meantime. This was actually a good thing because there was more embodiment opportunity after the internal architecture was developed further.

The project continued in September and was planned to finish in March with a 4-day work week. Figure 4.1 shows an overview of the entire planning.

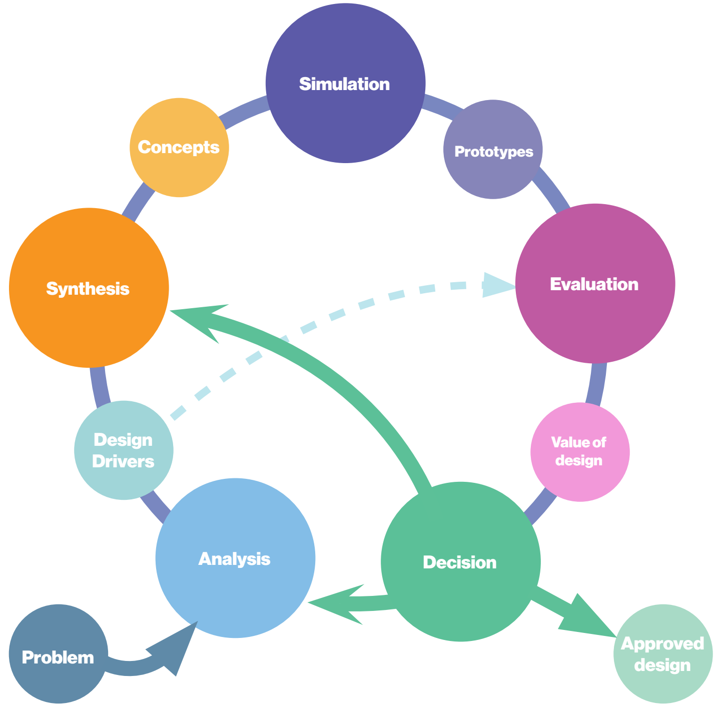
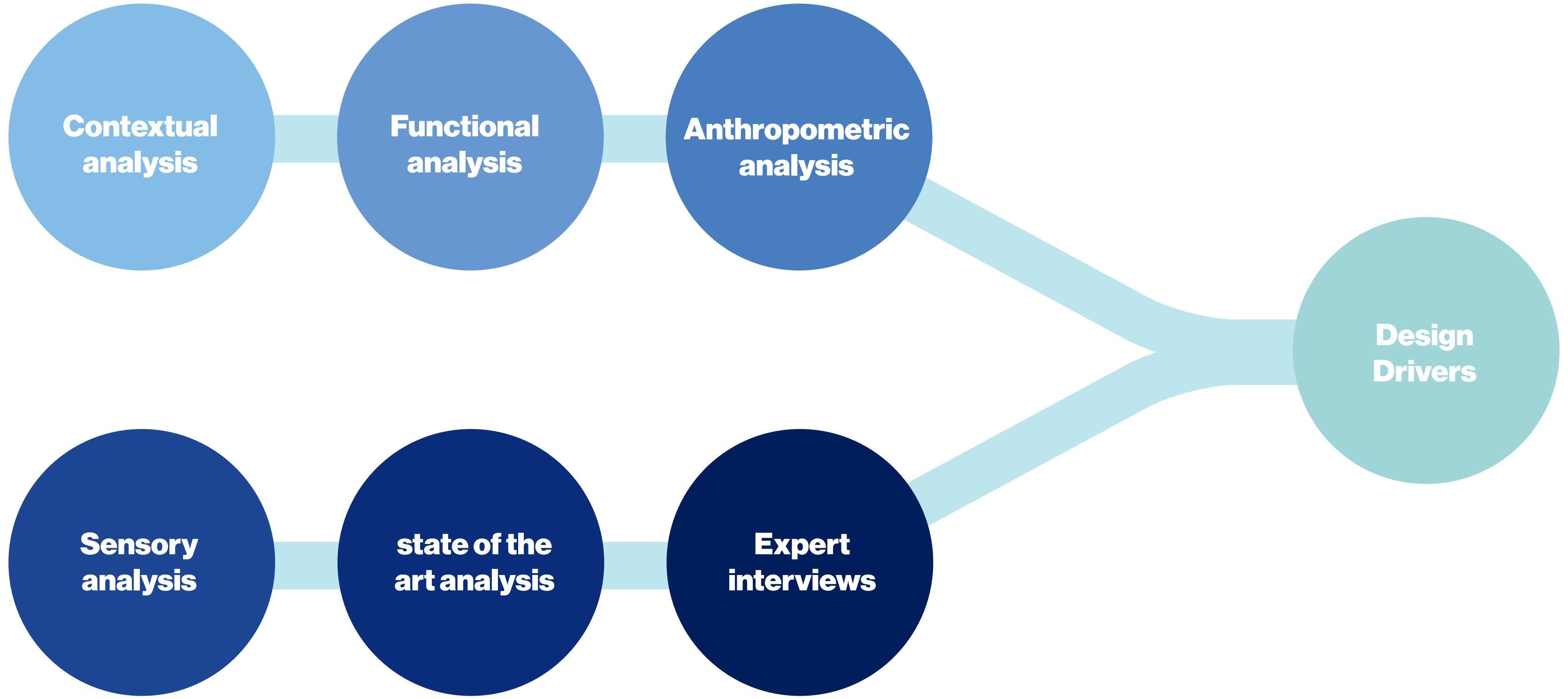


Figure 4.2: Basic design cycle



05

Analysis

Several topics have been analysed for this project. These topics include a contextual analysis, a functional analysis, anthropometric analysis, sensory analysis and state of the art benchmarking.

The analyses are done in order to find answers to specific research questions which need answering for developing the product and also to define the criteria necessary for the product to be succesful.

Contextual analysis

- Who is the target group and what are their needs and wishes?
- What is the psychological impact of an amputation?
- What is the process of receiving a prosthesis?

Functional analysis

- What are all the components?
- What are the component functions?
- where are the components located?

Anthropometric analysis

- What are the ergonomical capabilities of fingers, hands and arms for P5 to P95?
- What are the anthropometric dimensions of P5 to P95 of human fingers, hands, arms?
- What are the most used grips?
- What is a small hand?

Sensory analysis

- How does human touch work?
- What is the value of human touch?
- what are optimal tactile sensor locations?

State of the art benchmarking

- What best practices are out there?
- How do they perform?

Expert interviews

- How did Scott Summit approach his design for personal prosthetic legs?
- How did Evan Kuester assists Scott in his design for personal prothetic limbs?

Bert Pot

Age 58

Occupation None

Amputation Trans-radial

Bio

Bert Pot is someone who never gives up. After his accident in 2006 he was worried he could never drive a motor cycle again. However he did not give up, and is riding again!

Hobbies

Driving motor cycle, designing, carpentry

Pain points

Prosthesis weight

Needs

Prosthesis may be expressive
Prosthesis must be water resistant
Prosthesis must be customizable
Prosthesis must be aesthetitcally pleasing

Personality

Creative, solution-oriented, perseverend

Lisa Jansen

Age 26

Occupation Student

Amputation Trans-humeral

Bio

Lisette Coolen is a student who works as a service employee. She uses here prosthesis for little everyday tasks such as eating, tieing shoelaces and typing.

Hobbies

Volleybal

Pain points

Product dimensions are not ideal

Needs

Prosthesis may be appearant but not too much.
Prosthesis appearance is incredibly important.

Personality

Helpful, cheerful, patient

Figure 5.1: Personas of prosthesis users

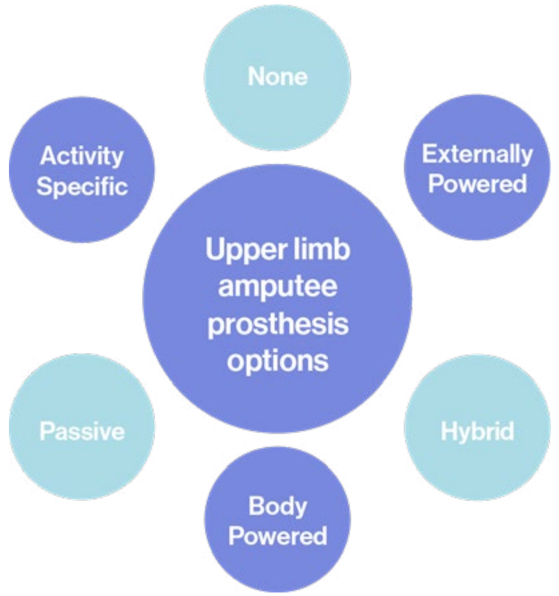


Figure 5.2: Types of prosthesis options

5.1 Contextual analysis

In this chapter the target audience and psychological effects of limb loss are investigated.

5.1.1 Introduction

The goal is to better understand the target audience and their needs and wishes and the pyschological effects of an amputation.

5.1.2 Method

In order to better understand the target audience I visited one of the most experienced prosthesis user in the Netherlands, Bert Pot. Also I set out an online survey which brought me in contact with Lisa Jansen (real name not mentioned due to privacy).

Furthermore I read many papers of scientists which conducted interviews with amputees and also watched youtube videos of amputees explaining how they experience their prostheses.

5.1.3 Results

The key takeaway of the interview with Bert Pot is that his prosthesis allows him to basically do everything another person would do with two hands.

However he mentions that in order to have sufficient grip with the prosthesis he has to put a silicone glove on it. This glove also protects the glove against water. Unfortunetaly the gloves break very fast, impair the movement and look not very appealing.

Furthermore Bert always has to look at what he is doing, since the prosthesis does not provide any tactile feedback, other than that he feels some resisance in the remainder of his limb.

Another key takeaway from the interview was the desire to customize his own prosthesis. Bert is a creative individual and likes to express himself. The current option he has is putting a custom print on his socket.

Lisa also claims to attach alot of value to the appearance of the prosthesis. However the prosthesis does not have to be extremely expressive, but it is not a problem if people can see it is a prosthesis. Preferrebly a natural look.

Lisa also mentions that dimensions of the prosthesis are often not ideal and that the weight can be a problem.

Body ownership

In addition to loss of function, limb amputations pose a significant threat to a person's body image. Zbinden et al. (2021). A distorted body image has also been correlated with "decreased life satisfaction, quality of life, activity levels and overall psychological adjustment" (Gallagher et al. 2021).

Directly measuring the body image has proven to be difficult. Therefore a way to assess change in the body image is to study the sense of ownership of the prosthesis. Ownership is stated to be an aspect of self-awareness related to experiencing parts of our body belonging to ourselves. An article by Wijk et al. (2015) state that the problem is that Prosthesis are not experienced as a part of the body, but rather a foreign part, a tool or a fake hand.

Identity

Wijk et al. (2015) also states that the relationship between prosthesis and person is often expressed as part of ones identity rather than part of one's body.

Appearance

Furthermore many prosthesis users express a desire for neater looking prosthesis. Current models are considered big and clumsy. Color is also considered important since the material gets dirtsy easy and is hard to clean.

Prosthesis procedure

When a patient has had their amputation there is a trajectory with a professional who will figure out the goals and needs of the patient and deciding on what kind of prosthesis will satisfy those needs. In the Netherlands there is the PPP; Prothese prescriptie protocol. The image shows an overview of available types of prosthesis options.

Discussion

All the information gathered can be translated into requirements and drivers. Key requirements are stated here:

- Product must have sufficient grip
- Grip parts must not easily wear and tear
- Worn and torn grip parts should be replaceable
- Product must provide tactile feedback
- Product must allow user to express identity
- Product must have an appealing appearance
- Product must match the dimensions of the user
- Product must weight may not be uncomfortable
- Product must be experience as part of the body
- product must not look dirty very quickly
- product must be easy to clean
- product must be customizable

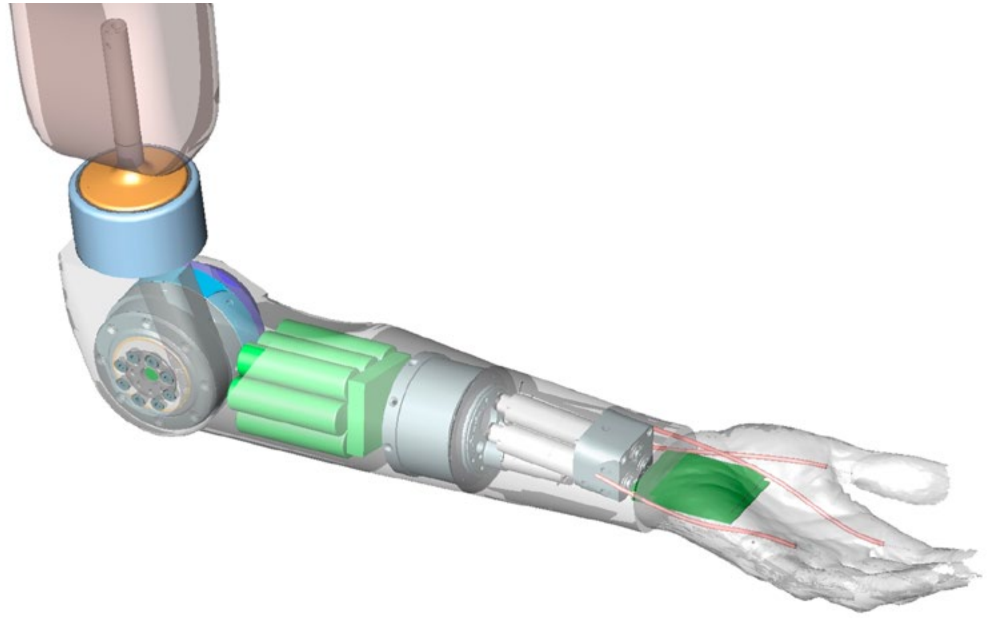


Figure 5.4: Arm packaging model provided by DHM Dental bv.

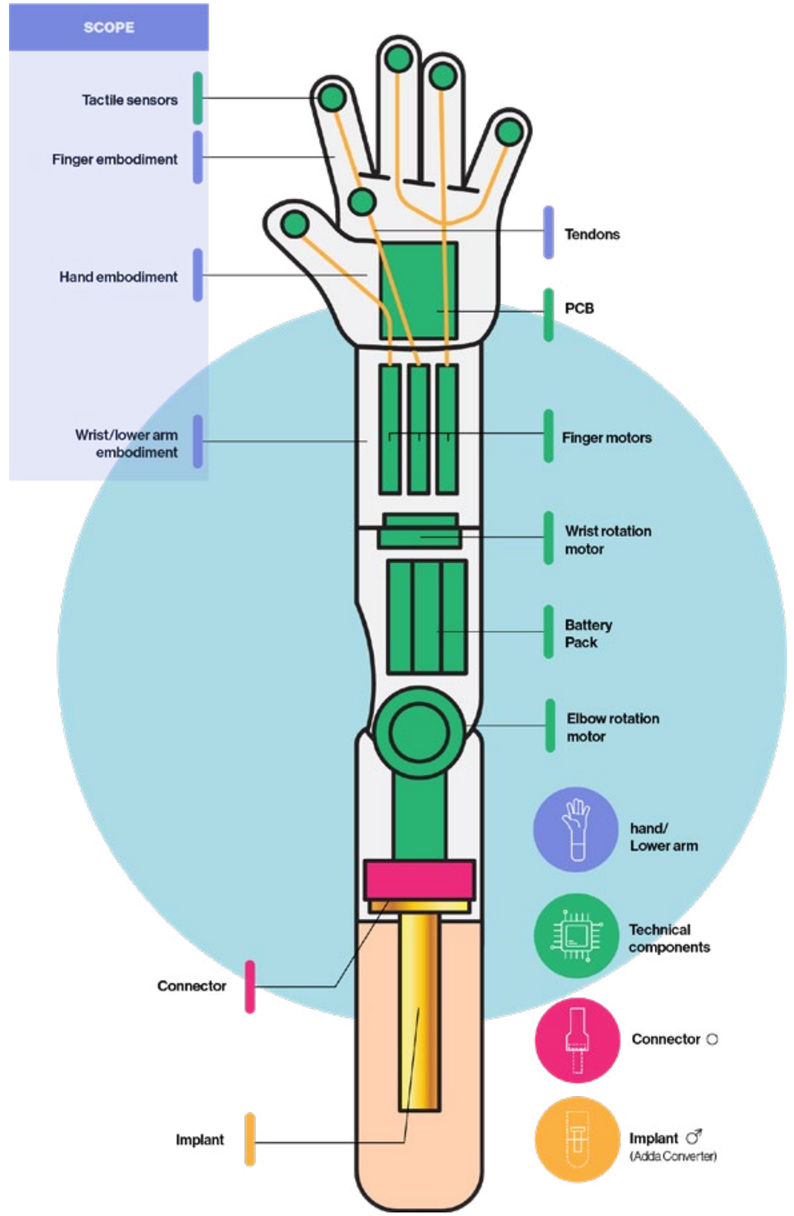


Figure 5.5. Component overview

5.2 Functional analysis

In this chapter a functional analysis of the product is executed. This will help later with the ideation.

Introduction

The goal of this functional analysis is to determine what functions each part of the prosthesis has.

Method

The major components within the scope to be designed are the fingers, hand and wrist/lower arm. For each component the functions are being analysed.

Finger functions

- Flexion and extention
- Abduction and adduction
- Grip
- Exert force
- manipulate objects
- exteroceptive sensing
- Housing tendons
- Housing tactile sensors

Hand functions

- Help manipulate objects
- Exteroceptive sensing
- Grip
- Housing PCB
- Housing tactile sensors
- Hold fingers

lower arm functions

- Wrist rotation
- Elbow rotation
- House finger Motors
- House wrist rotation motor
- House elbow motor
- House battery pack

Discussion

Having an overview of the functions can assists later on in the ideation phase.

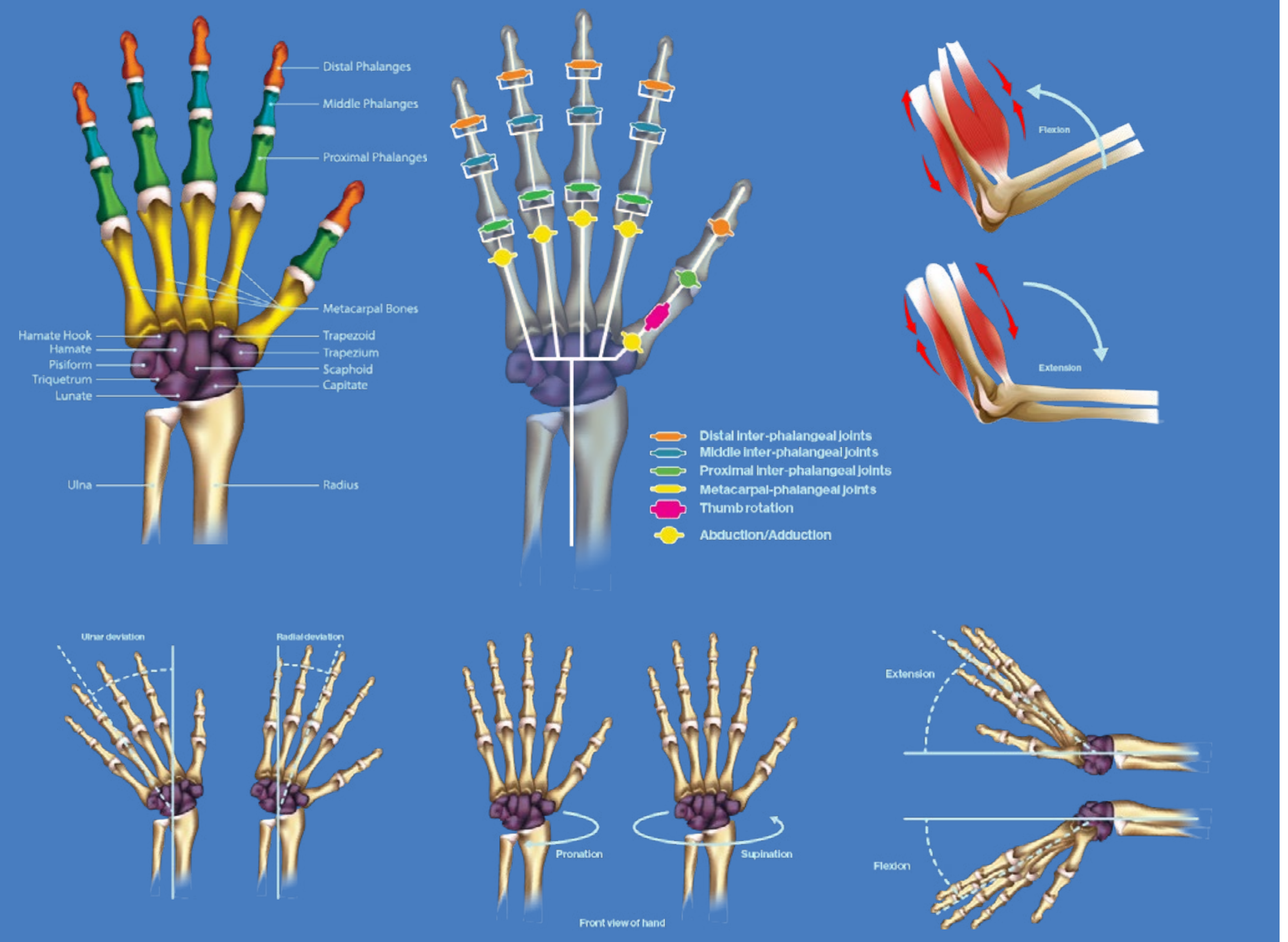


Figure 5.6: Arm ergonomic capabilities

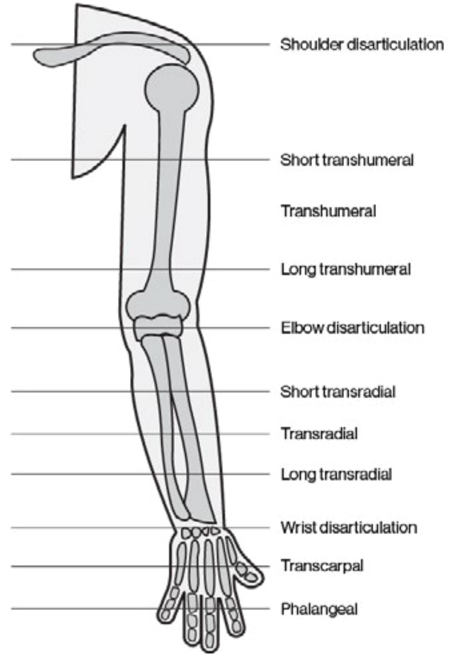
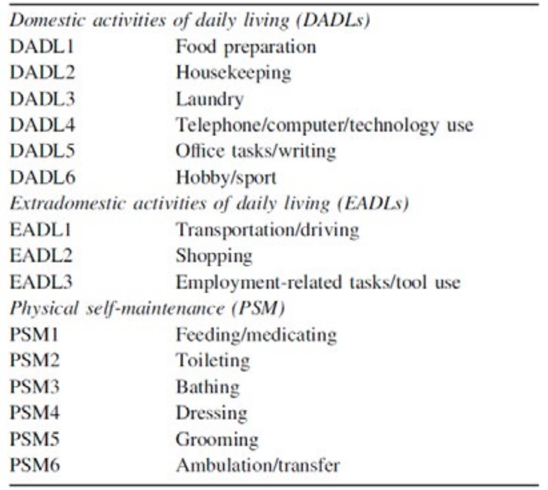


Figure 5.7: Types of amputations



Domestic activities of daily living (DADLs)	
DADL1	Food preparation
DADL2	Housekeeping
DADL3	Laundry
DADL4	Telephone/computer/technology use
DADL5	Office tasks/writing
DADL6	Hobby/sport
Extradomestic activities of daily living (EADLs)	
EADL1	Transportation/driving
EADL2	Shopping
EADL3	Employment-related tasks/tool use
Physical self-maintenance (PSM)	
PSM1	Feeding/medicating
PSM2	Toileting
PSM3	Bathing
PSM4	Dressing
PSM5	Grooming
PSM6	Ambulation/transfer

Figure 5.8: Activities of daily life

5.3 Anthropometric analysis

This chapter explores ergonomical and anthropometric data required to understand the capabilities and dimensions of hands.

Introduction

Human hands and arms differ in sizes and ergonomical ranges of motion. For the prosthesis it is important to know for instance how a finger flexes and extends, or what is a small hand for example. Since the prosthesis will be taillor-made it is paramount that we can make sure that all the components will also fit in the smaller hand sizes. Furthermore it is interesting to understand what the most common used hand grips are.

Approach

Papers have been read to find anthropometric data on hand and arm dimensions and motion capabilities ranging from P5-P95.

Fingers

Jarrassé et al. (2014) describes a kinematic model of the capabilities of the human hand.
According to the paper the human hand has 28 DoF.

Each finger has 4 DoF. A flexion/extension excursion between phalanxes (Proximal Inter-Phalangeal hinge joints (PIP) and Distal Inter-Phalangeal hinge joints (DIP)) along with 2 DoF at the MetaCarpal Phalangeal (MCP) saddle joint (flexion-extension and abduction/adduction mobilities).

The thumb has 5 DoF: 2 Flexion-extension mobilities thanks to the Proximal Inter-Phalangeal and MetaCarpal-Phalangeal hinge joints and at least 2 DoF at the level of the saddle joint between the carpus and metacarpus (trapeziometacarpal joint). In addition to these mobilities, the thumb exhibits a pseudo-rotation allowing 3 DoF.

Wrist

The wrist is capable of making the following motions:

- Flexion/extension
- radial deviation/ulnar deviation
- pronation/supination

Elbow

The elbow is capable of performing a flexion and extension motion.

Grips

According to a paper by Earley et al. (2016) the grips people use most commonly in ADL (activities of daily life) are the following:

1. Chuck grip
2. Fine pinch
3. Key grip
4. Power grip
5. Hook grip
6. Tool grip

More in depth infor about grips can be found in appendix 1.

Anthropometric data

Table sheets of anthropometric dimensions and ergonomical capibilities of P5-P95 can be found in appendix 5.3. these have been analysed in order to determine different arm dimensions to make sure components can still fit in the arm.

Amputations

Amputation can be performed on a variety of locations of the arm. Figure 5.7. shows the locations and their corresponding names. The prosthesis is designed for trans-humeral amputees.

ADL's

ADL's give an insight in most common activities humans perform in daily life. This can help to understand in what situations and interactions the prosthesis is begin used. Figure 5.7. shows a list of common ADLs by Dollar et al. 2012.

Discussion

All this anthropometric data can be translated into valuable requirements for the prosthesis:

- Fingers must perform a flexing and extending motion
- Wrist must be able to make a pronating motion
- Wrist must be able to make a supination motion
- Elbow must be able to make a flexion and extension motion of atleast 160 °
- Hand weight should not exceed 610 grams
- forearm weight should not exceed 1720 grams
- Upperarm weight should not exceed 2500 grams
- Product should be able to perform atleast the 6 most used grips

Further reading in appendix 1

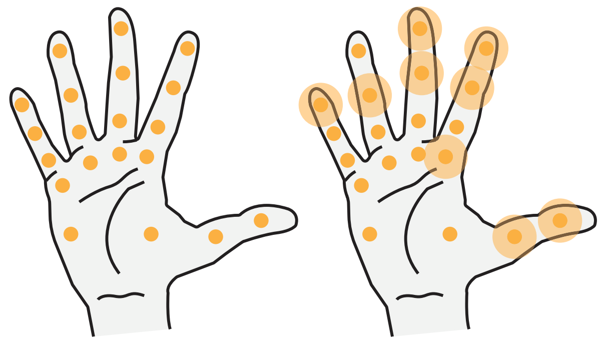


Figure 5.9: Suggested sensor locations by Kargov et al. (2016). Right image indicates location with highest force exretion.

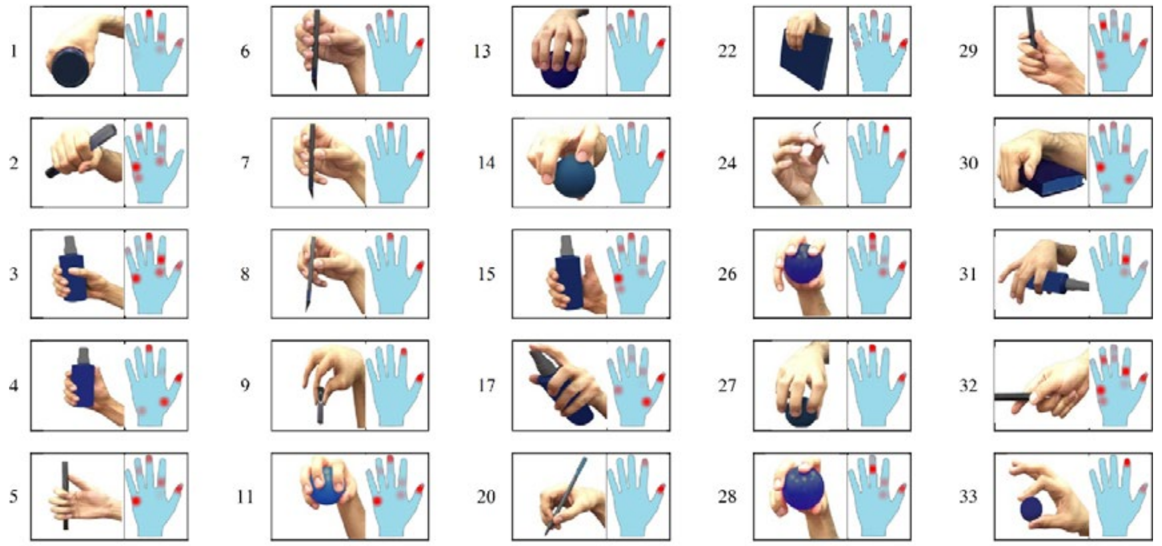


Figure 5.10: Abbassi et al. (2016)

Prosthesis handling

Sensory feedback improves prosthesis handling and functionality

Body ownership

Sensory feedback increases sense of body ownership

Phantom limb pain

Sensory feedback decreases phantom limb pains

5.4 Sensory Analysis

A deep dive in how human touch works and what it means.

Introduction

This chapter investigates the working principle of tactile feedback, the effect of tactile feedback and certain sensor solutions. This is done in order to understand how it can be implemented in the prosthesis and why it is necessary.

Method

The information was gathered by reading papers and watching videos.

Results

The human sense of touch allows us to asses the size, softness and texture of the objects that surround us and with which we interact.

Human touch

The human body is capable of sensing proprioceptive (kinesthetic) and exteroceptive (cutaneous) feedback. Proprioception is when a sensory receptor is responding to stimuli originating inside the body. Exteroception is when a sensory receptor is responding to stimuli originating outside of the body. For example touch or heat.

Value of human touch

Raspapovic et al. (2021) states that sensory feedback is mentioned by upper-lim amputees as one of the main missing features of commercial prostheses, as they are not able to execute confident grip forces or undertake fine manipulations. An article by Wijk and Carlsson (2015) even states that lack of sensory feedback and inadequate embodiment are among the reasons for rejection of available commercial prosthesis.

However integration of sensory feedback in hand prostheses is claimed to improve their functionality and the users' sense of body ownership as stated by Wijk et al. (2015).

An interview with several amputees resulted in the conclusion that prosthesis are not experienced as a part of the body, but rather a foreign part, a tool or a fake hand. Prosthesis with sensory feedback however caused a strong emotional experience and also resulted in an experience of body ownership. The fine sense of touch on the surface of the prosthesis is what makes it a part of the amputee.

An article by Pierce (2020) states that when we hug or feel a friendly touch on our skin, our brains release oxytocin, a neuropeptide involved in increasing positive, feel-good sensations of trust, emotional bonding and social connection, while decreasing fear and anxiety responses in the brain at the same time.

Phantom Limb Pain

Lack of physiological feedback from the remaining extremity to the brain also generates phantom limb pain, which is experienced by 50-80% of the amputees as stated by Flor et al. (2006)
Phantom limb pain is pain perceived as arising from the missing limb due to sources other than stimulation of nociceptive neurons that used to innervate the missing limb (Ortiz-Catalan, 2018). An article bij Wijk et al. (2014) states that integration of tactile feedback reduces phantom limb pains.

Sensor locations

Kargove et al. (2016) did research to the optimal location of pressure sensors and thermistors within a hand prosthesis. The result of the paper is shown in the figure 5.9.

Desired outcome

The ideal outcome for a hand prosthetic is to have somatotopic matched feedback – when the input to a specific part of the prosthesis is experienced in the same lost body part (wijk et al. 2021).

However Neural stimulation should be able to provide sensory feedback that is functionally effective and highly natural, as the naturalness of the feedback plays a pivotal role in prostheses acceptance (Graczyk e al. 2016).

Therefore all the communication between the controller, stimulator and prosthesis sensors need to be in quasi-real time with an unperceivable delay (as in the mammalian somatosensory system) as mentioned by Raspopovic et al. (2021)

Discussion

The analysis shows that integration of sensory feedback can have a huge impact on the performance and experience of the prosthesis.

All the information gathered can be translated into requirements and drivers. Key requirements are stated here:
- Product must provide exteroceptive feedback
- Product must have tactile sensors in the fingertips
- Product must have tactile sensors in the proximal phalangial palmar area
- Sensors must have force range of atleast 0.1-0.9 [N] during manipulative tasks (Dahiya et al., 2009)
- Product must have some sort of somatotopic matched feedback
- Communication between controller, stimulator and prosthesis sensors must be in quasi-real time

Further reading in appendix 1

Express user identity

Use form, color and material to express the user identity in the prosthesis

Nature is symmetry

Symmetry is everywhere in nature and makes things look natural

Fashion statement

Make prosthesis more expressive by thinking of it as a fashion statement

5.5 Expert interviews

In this chapter I will discuss all the interviews I had. Why I had them. And what was relevant information for the project.

5.5.1 Introduction

The most prominent interviews I have had were the ones with Scott Summit, Evan Kuester and Bert Pot.

Scott Summit is a pioneer in the domain of customized prosthetic limbs.The goal with Scott Summit was to understand what his philosophy was with the incredible leg prosthetics he created and how he approached this.

Evan Kuester is an industrial designer and worked together with Scott. the goal was to learn how he helped Scott Realize the design of these legs and how he approached designing such personal products.

5.5.2 Method

With each interview I prepared some questions and topics I wanted to discuss and then I had an open conversation were the questions and topics were merely guiding and inserted when it felt appropriate.

5.5.3 Scott Summit

Hiding vs embracing

Scott Summit stated in the interview that there are basically two kinds of prosthesis users.

1. The user who prefers to hide it
2. The one who embraces it

Scott decided to focus on the group that embraces it and wanted to turn the prosthesis into a very personal product that expresses the user identity. This is done by including the user in the design process. Having interviews and discover what the user likes and what expresses this identity. The result is incredible looking leg prostheses which express the users identity with clever use of form, colour and material.

Nature is symmetry

In nature symmetry is everywhere: we have two eyes, two ears, two nostrils and all mostly in balance. If things are not enough in balance it starts to look 'off'.

Scott mentioned that oftentime prostheses do not match the users dimensions and in that way look unnatural. The hand is too big, or too small. The arm looks too long etc. If the prosthesis is desired to look natural it should be in balance with the users dimensions.

5.5.4 Evan Kuester

Evan Kuester has helped Scott with the realization of the personal leg prostheses. I was really curious to the workflow he implemented to create these extremely organic products.

Mesh modelling

He explained that he used a mesh modelling technique in Rhino, which allows to create organic shapes in an easy way. I tried to use the mesh modelling technique aswell and was able to design a hand and a prototype rather quickly. The upside is that one can kind of clay the organic hand shape quite easily. The downside was that it is less accurate in terms of dimensioning therefore this technique possibly serves best to create an underlayer for the final design. More about this in chapter 10.

Get to learn the user

Evan also elaborated on the process of involving the user in creating a personalized prosthesis. He explains that the best way to approach it is with a good conversation. Understanding the user and what the user likes in terms of aesthetics and look and feel. A good technique is to ask about other products and brands the person likes, in order to discover what kind of look and feel the user likes. Also asking the person to describe their personality in a few key words can help understand what kind of expression the product should convey. All this gathered information can then eventually be translated in a product vision.

Discussion

What does this mean for the project? The insights can be used as an inspiration for the product. Furthermore some requirements can be translated from the interviews:

- Product must have an option for people who prefer to hide the prosthesis
- Product must have an option for people who want to embrace it
- Product must be able to express user identity
- Product dimensions must be in balance with user dimensions

Inspirators:

- mesh modelled designs can serve as an underlayer for the final model
- The user can be included in the design process to create a personal product
- product form, colour and material can be used to express user identity


Modular Prosthetic Limb


Luke Arm


i-Limb


Bebionic


Nexus


Zeus Hand


Taska Hand


Vincent Evolution


Esper

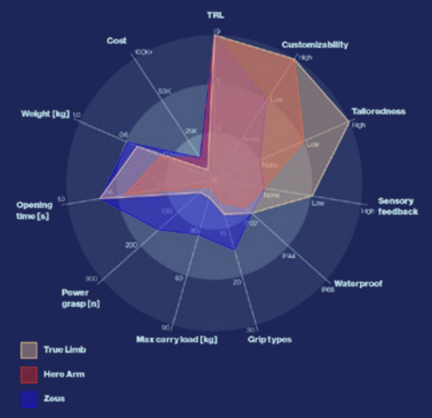

Zhe Xu Hand


Hero Arm


True Limb


Michelangelo


Ability Hand

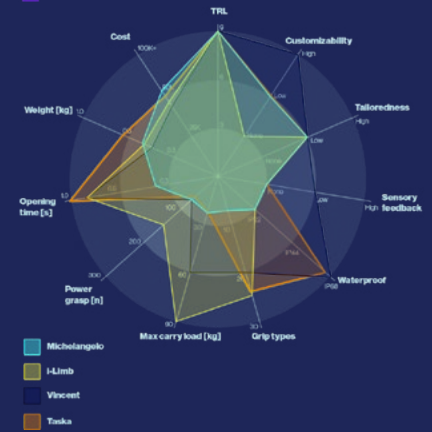


Lower market segment (6k-19k)

Whats noticable in the affordible low end segment is that customizability and tailoredness score very high. This is due to the use of additive manufacturing techniques. This also makes the products low weight. A negative thing that is noticable is the low performance statistics (carry load, power grasp, grip types, waterproofness).

Middle market segment (20k-39k)

In the middle segment one can also find customizability options and medium tailoredness options. These hands all have standard sizes to choose from. Also one can see introduction of sensory feedback and higher IP values. Also higher performance statistics.



Higher market segment (40k-90k)

The expensive segment is a little upgrade from the middle segment. Materials are often more durable and sophisticated.Performance values tend to be higher and all models have several models to fit users different hand dimensions. Often there are more extras such as apps and adaptive grip.

Figure 5.11: State of the art graphs

5.6 State of the art benchmarking

In this chapter the state of the art is being discussed. 14 arm prostheses have been analysed and benchmarked.

5.6.1 Introduction

Research has been done to the state of the art in order to create a benchmarking, learn from best practices, translate relevant learnings to drivers and recommendations for the to be designed product.

5.6.2. Method

14 arm prostheses have be analysed and benchmarked based on the following parameters:

- TRL (technical readiness level)
- Customizability
- Tailoredness
- Sensory feedback
- Waterproofness
- Grip types
- Max carry load and grasp forces
- Opening time
- Weight
- Price

Information has been gathered from company websites, papers, videos of prosthesis users, and product manuals.

5.6.3. Results

The state of the art benchmarking results in a lot of valuable information. The key findings are elaborated per category.

Customizability

Most models allow for 3-4 standard body panel colors. Otherwise a range of cosmetic skin tone sleeves. Hero Arm offers customized embodiment themed panels. But in general most models do not allow for much integration of personality.

Tailoredness

Most models offer a range of sizes going from small, medium to large. Sockets are designed to match the users stump.

Sensory feedback

Sensory feedback is not available in the majority of the models. Some models have little form of haptic feedback. The MPL arm is most advanced in this area and contains a multitude of tactile sensors.

Waterproofness

The majority of models is not waterproof on its own and require a protection glove. The models that are waterproof have IP 67 ratings. Ability, Taska and Vincent are highest scoring in this area.

Grips

The prosthesis models offer grips ranging from 4-32 grips. In reality only 4 grips are used most of the time. more grips does not necessarily mean better.

Loads and forces

There is quite a difference in maximum load and forces within the available models.

	Lateral force [N]	Power grasp[N]	Finger load [kg]	Carry load [kg]
Lowest	15	50	6.8	8
Mean	63.5	181	19.4	49
Highest	112	312	32	90

Table 5.1: Loads and forces overview

Opening time

Opening time of the hand prostheses lay between 0.5 to 1.0 seconds. The ability hand however was able to perform a closing time of 0.2 seconds, alloweing to catch objects in mid air.

Weight

Weight of prosthesis hands vary between 0.35 and 0.67 [kg].

Price

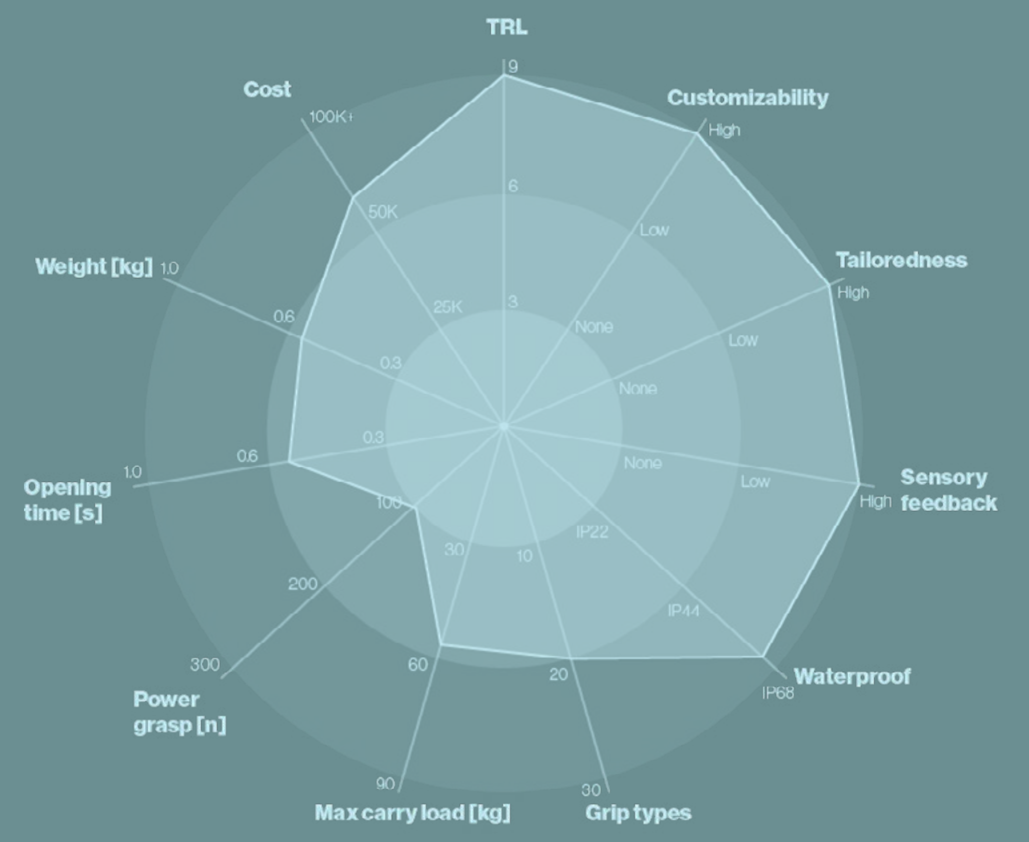
Cheapest commercialy available models price vary around 6k and 15k euros. Then there is a middle market segment of around 20k to 40k euros. The most expensive models cost around 40 to 90k euros.

Discussion

The analysis of the state of the art has resulted in a lot of valuable data and insights that can serve as criteria for the product or inspiration for certain design solutions. more gathered insights can be found in appendix 5.6.
translated requirements:

- Product must atleast have IP67 rating
- Product hand must not weigh more than 0.67 [kg]
- Product closing time must not exceed 1.0 seconds
- Product must be able to perform atleast 4 grip types (power, key, hook and fine pinch) but preferably 6 (Early et al., 2016).
- Product must have atleast a carry load of 50 [kg]
- Product must atleas have afinger load of 20 [kg]
- Product must atleast have a power grasp of 180 [N]
- Product must atleat have a lateral force of 63.5 [N]
- Product must atleas provide 3 standard sizes
- Product must have more then 4 color options
- Product must have customizable body options

Further reading in appendix 1



Tailor-made
Product tailor-made to users anthropometric dimensions

Durable
IP 67 Water- and dustproof, UV-resistant and shock-absorbent

Customizable
Allowing the user to customize the prosthesis to make it more personal

Mobility
Product must be able to perform human hand movements

Modular
Replacebility of easily wearing and tearing parts and internal maintenance

Aesthetics
Product must have appealing appearance and biomimicral elements

06
Main drivers

In this chapter all the gathered data from the analysis phase is concluded nto 6 main drivers for the product. A full list of the requirements can be found in appendix 6.

Tailor-made

Product must be tailor-made to the patient. DHM Dental bv has stated in their design brief that is desired for the product to be tailor-made to the user. This means that the product has to be easily alterable to the users dimensions. Also this has concequences for the production techniques used. Therefore DHM Dental has stated that the embodiment parts have to be produceable with 3D manufacturing techniques.

Customizable

Current prostheses are quite basic and only come in 2 or 3 predefined colours. A trend shows that this can be more personal, as has been proven by Scott Summit and also talking with the target group has shown a desire to express oneself with the prosthesis. The prosthesis therefore has to have options for customization.

Modular

Product parts tend to get dirty and break down quickly, such as the silicone glove of the iLimb or the sleeves of the michelangelo that gets dirty. It is a requirement that the prosthesis is easily cleanable and that parts that break down are easily replaceable.

Durable

The state of the art has shown that some of the models have IP67 ratings which is an important unique selling point, because the product can be used easily in conditions that involve dust or water, without having to wear protective sleeves. The prosthesis must apply for an IP67 rating for the components that are prone to damage due to water or dust.

Mobility

The prosthesis has to be able to perform human ergonomic hand and arm motions, which are investigated in chapter 5.3. This includes the 6 most used grips, the finger flexion and extention, the wrist rotation and the elbow rotation.

Aesthetics

Analysis on the target group has shown that there is a desire for a neat looking product. Current models are considered big and clumsy looking. Furthermore DHM has stated to want a prosthesis design that resemble human hand figures and has an aesthetical pleasing appearance.

Define H2's

Brainstorm solutions

Explorative drawings

Morphological chart

Combine solutions to concepts

07

Ideation

In this chapter I will describe how the ideation has been done. The brainstorms we have had. the most relevant sketches. and how decisions were made. Since the product has been devided into three main parts it will be presented in this way. Finger, hand, arm. And also a part customizability.

The ideation was quite a fluent process sometimes, with spontaneous brainstorms with DHM dental, exploring solutions and assessing ideas on the spot. The product essentialy was divided in three parts: fingers, hand, arm. Every part of the prosthesis has their own challenges.

Finger

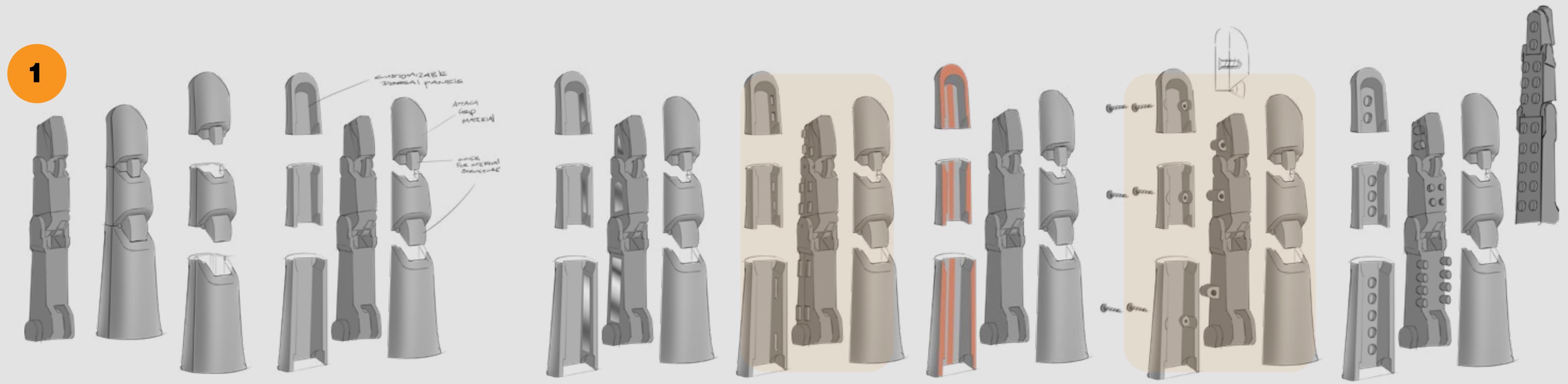
The biggest focus was on the design of the fingers. This part of the hand showed to be very intricate and complicated. Also what made it more challenging is that the final principle of how the finger was going to look and work was not yet fully defined. The main focus points were the replaceability of wearing and tearing parts, integration of grip material, protection of technical components, customizability options and required mobility.

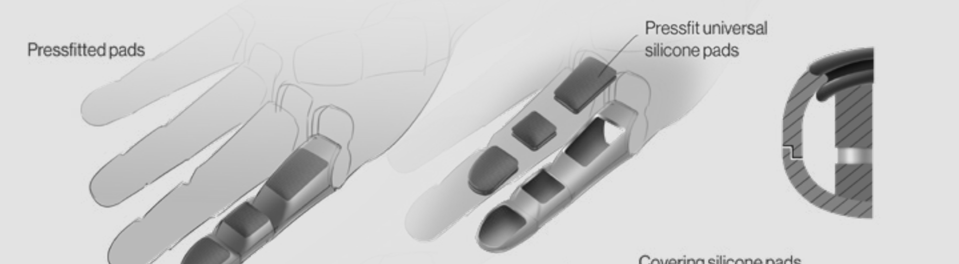
Hand

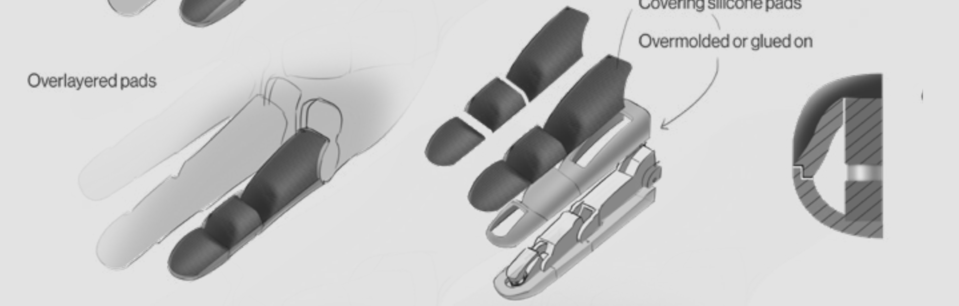
The hand houses the fingers and thumb and houses the PCB system. The challenge is to create a connection from finger to hand that looks organic and human like and still provides the required finger motion. Furthermore the hand needs to provide grip.

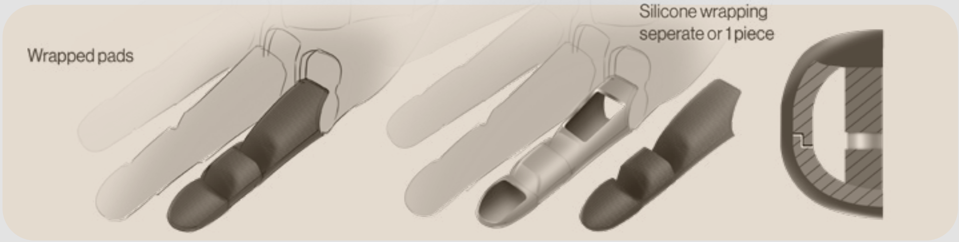
Arm

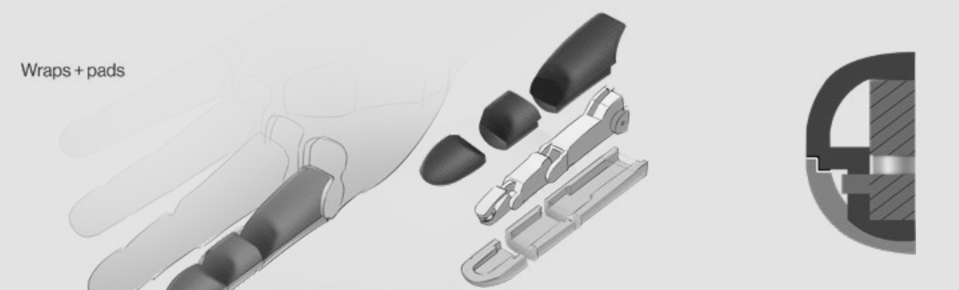
The arm houses the finger motors, wist motor, elbow motor and battery pack. Quite a packaging. However the shape of the human arm is quite simple. The challenge is to design the arm in such a way that this packaging still fits but that the arm is still modular in dimensions.

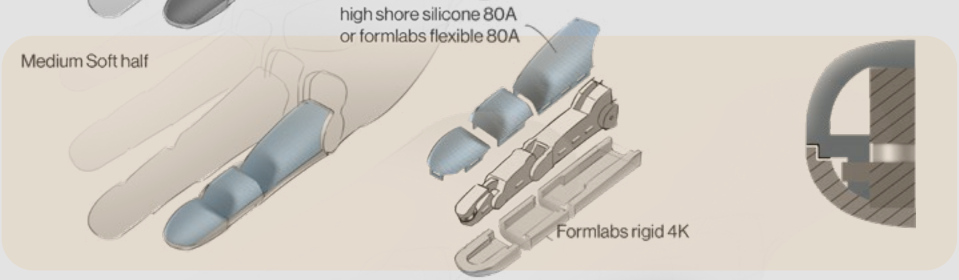


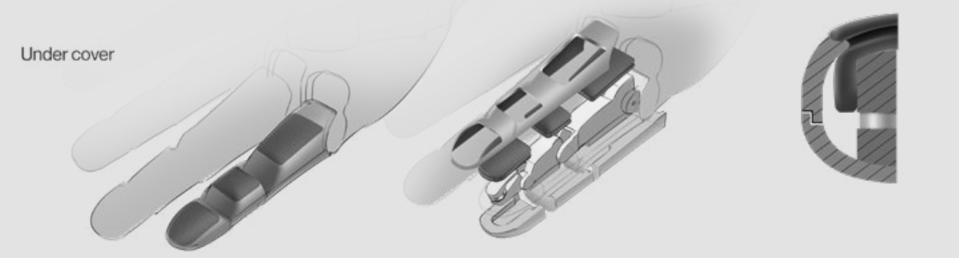












7.1 Finger ideation

The finger is a challenging part of the human body, since it is small, detailed and has a sophisticated motion as explored in chapter 5. During this project multiple concepts of the finger have been developed since the entire principle of the finger has changed from a linked beam system to a string actuated system. In this chapter the final ideation iteration cycle is discussed. Additional sketches can be found in appendix 7.

The challenge

The main functions of the finger are:

- Perform flexion and extension motion
- House tactile sensor
- house tendons
- Provide grip

The main requirements for the finger are:

- Must be accessible for maintenance by manufacturer
- Wearing and tearing parts must be replaceable by user
- No visible screws or bolts
- User may not access sensors and tendons
- Must include customizibility options
- Must be able to operate a touch screen
- Finger must be adjustable to user dimensions
- Fingers must have enough grip to hold everyday items without slipping

Full overview of requirements can be found in appendix 6

The major questions that needed design exploration are:

- How to make wearing and tearing parts replaceable?
- How to add parts with grip to the finger?
- How to protect technical components?
- How to add customizibility in the finger?

Motion

In order to be able to make the flexion and extension motion the finger has to be able to fold in a clever way. The solution for this was to have little cuts in the finger that allow the finger to have space to fold into. The basic principle was defined here. More elaborate info is presented in chapter 10.

Protective mainframe

The product houses vulnerable components such as tactile sensors and an intricate tendon system that allows the finger to flex and extent, explained in chapter 5.2. Therefore the idea of a protective mainframe is created. The mainframe houses all the vulnerable parts and is not accessible for the user. See sketch 1.

Modular design approach

Since the product has easily wearing and tearing parts the product ideation was focussing on a modular design approach. Once the idea of a mainframe was established that could house all the necessary components such as tactile sensors and tendons, the ideas for modular embodiment panels was quickly born.

Grip

Furthermore the product required to have sufficient grip on the parts that interact with objects and that are not allowed to easily slip out of the hand. Therefore certain grip parts are needed. In appendix 7 a H2 ideation can be found of ways to integrate grip in a product. Together with DHM it is decided that the use of a high friction material such as silicone, TPU or formlabs flexible material is desired to integrate grip.

Sensors

Besides that the finger is equiped with tactile sensors on locations defined in chapter 5.3. These tactile sensors need to be able to be actuated. Therefore the idea is that at those locations softer material is used that can easily deform when interacting with objects. This combines perfectly with the high friction material idea.

Assembly

Now that the overall principle of the mainframe with modular embodiment panels was created the following challenges emerged:

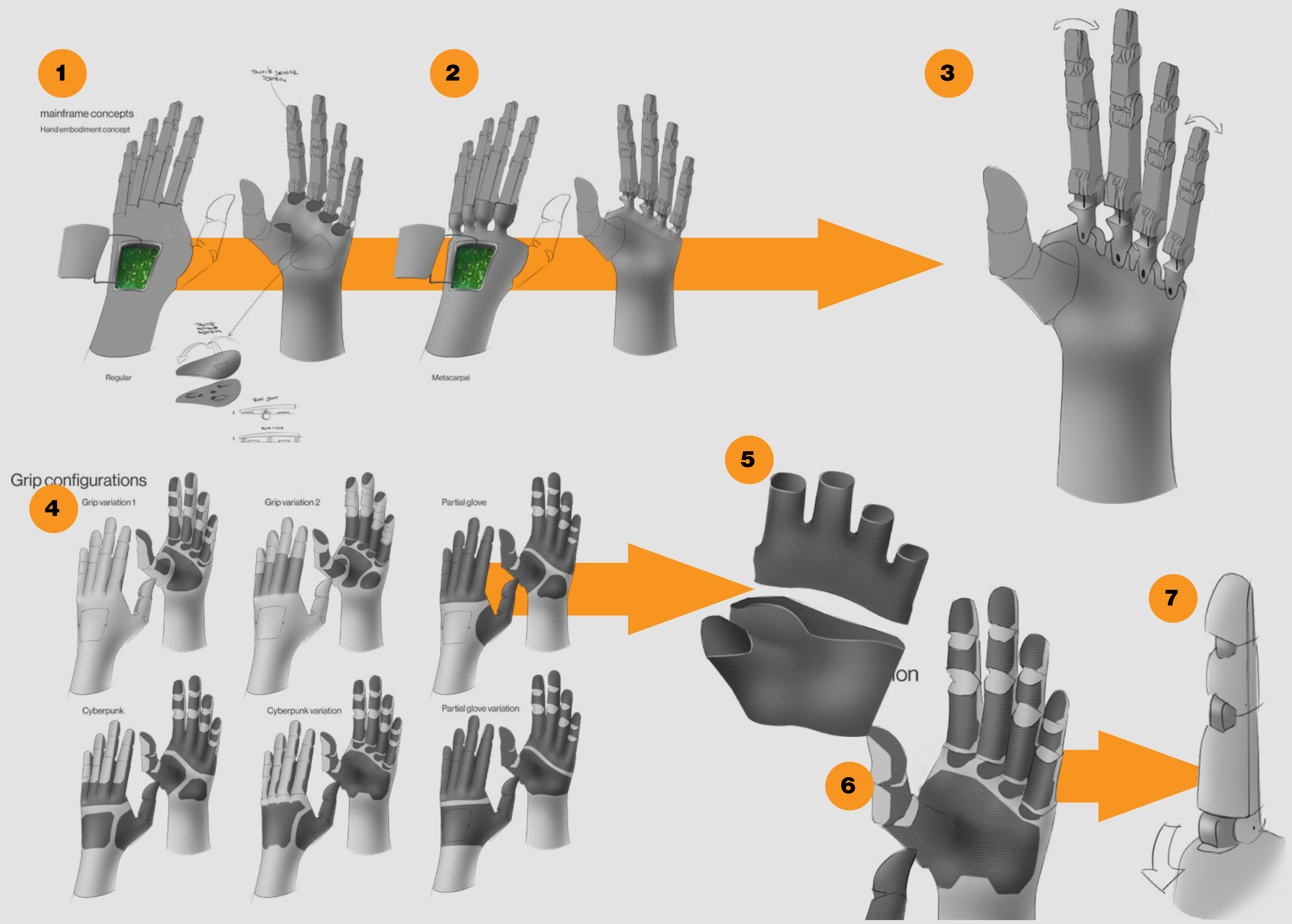
1. How do you attach the panels to the mainframe?
2. How do you attach the grips to the mainframe?

Figure on the left page shows explorative sketches for the finger embodiment.

Discussion

The ideation process consisted of multiple brainstorms together with DHM Dental bv and were often iterative. However the figure on the left is basically a conclusion of all these brainstorms. Out of all these ideas , 2 ideas for the grip solution were picked to be further developed. These were the silicone wrapped pads and the medium soft-half pads. These were chosen because they seemed most promising and feasible. Other criteria taken into account are customizability, amount of parts, ease of maintenance.

in terms of assembly of the panels the screw principle and snapfit principle were picked for further development. These were picked sinced they were deemed as strongest solution.



7.2 Hand ideation

The biggest challenge for the hand is the transition from fingers to hand. A human hand has skin, which covers the intricate systems that allow us to make all the dexterous hand movements. It is challenging to imitate skin, which leads to some parts of the design being open. You do want to maintain a uniform shape though.

The challenge

The main functions of the hand are:

- House fingers
- House thumb
- House PCB
- House tactile sensors
- Provide grip

The main requirements for the hand are:

- The hand must house the PCB
- The hand must have enough grip to hold everyday items without slipping
- The hand must have a biomimicral appearance
- The fingers must be able to make an abducting and adducting motion.
- Wearing and tearing parts must be replaceable by user
- Technical components may not get wet

Full overview of requirements can be found in appendix 2.

Mainframe

The idea for the hand is also that of a protective mainframe that houses the PCB system and tendons. This mainframe can be watertight and made only accessable for maintenance. Sketch 1 shows this idea of a mainframe. On this mainframe fingers and panels can be attached. A hatch on the dorsal side of the hand (see sketch 1) can be opened to access the PCB. This hatch can be made watertight with a watertight seal.

Finger hand connection

The fingers are connected to the mainframe with a hinge system. This hinge system allows the fingers to make a flexing motion (see sketch 1).

Ab- /adducting finger motion

The fingers have to be able to flex into the hand, but there is also a desire for a ab- and adducting finger motion. There have been explored two ways to achieve this finger motion as can be seen in sketch 2 and 3. sketch 2 shows a hinge system on static beams that can abduct and adduct due to material flexibility. This however was later iterated to become a hinged beam system as is illustrated in sketch 3. Another challenge that arrises from this idea is how to create an embodiment around this.

Grip

The hand needs to provide grip. Therefore mutltiple grip configurations have been explored. The main grip configurations are that of a semi glove, that is flexible enough to move along with the motion of the fingers (see sketch 5). Furthermore what this idea also solves is the general hand shape that is formed due to the skin. Human fingers are actually pretty long, but the skin covers a lot of the space between the fingers and make them appear shorter. If this skin is not there this will result in oddly long looking fingers, which is a risk for protheses.

The other configuration is more of an open design as can be seen in sketch 6. However an opening like this is undesireable. This was later on iterated to use the same principle as the fingers where the mainframe seamlessy slides into the gap as can be seen in sketch 7.

Discussion

The main outcome of the finger ideation was the concept of a mainframe, how the finger would be connected to the hand and how the grip parts of the hand would be configured.

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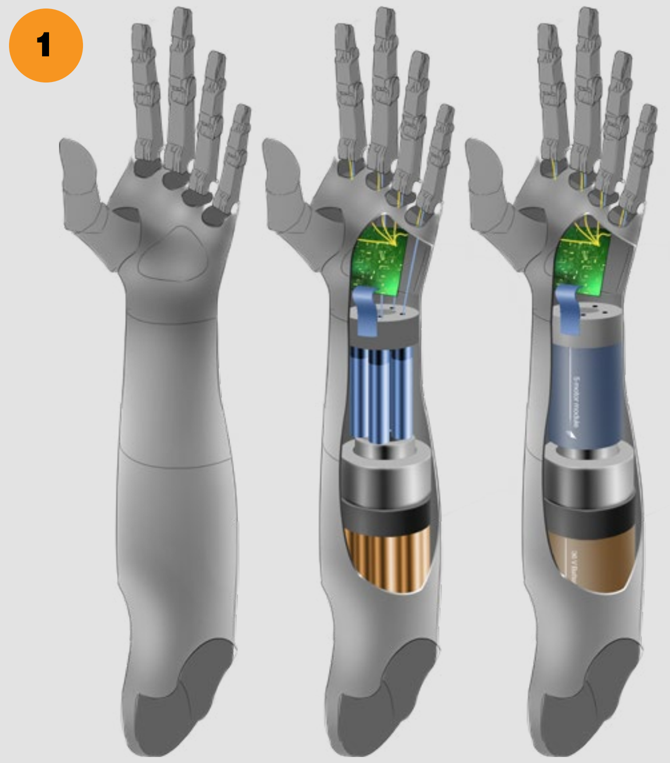


2

3

4

5

7.3 Arm ideation

The arm in terms of shape is less of a challenge compared to the finger and hand. However the big challenge here is having enough space to house all the tech components while maintaining an option for a modular design. Besides that there is a desire to add some customizability options.

The challenge

The main functions of the arm are:

- Housing motors
- Housing wrist rotation motor
- Housing battery pack
- Perform wrist rotation motion
- Housing elbow rotation motor
- Perform elbow rotation
- Have a human like appearance

Protective mainframe

Since the product has components prone to getting wet protective mainframe idea is also applicable for the arm. This mainframe could have a standard format which is changeable to different arm dimensions. (see sketch 1).

Modules

Since a standardize mainframe is used one can think of creating modules (see sketch 2) for the motors and battery pack. This allows for compact packeging design. If the mainframe gets to small because of a very small arm size a smaller motor module can be used for example which uses less motors, or a smaller battery pack which has less capacity.

Customizable panels

The mainframe having a standardized shape opens the opportunity to add external panels that define the overall arm shape. Since these panels are attached externally the shape and form and color of these panels can be customized and in that way customize the appearance of the arm.

Assembly

A few ideas were generated for attaching the panels to the mainframe such as magnets, snapfits and a screw system.

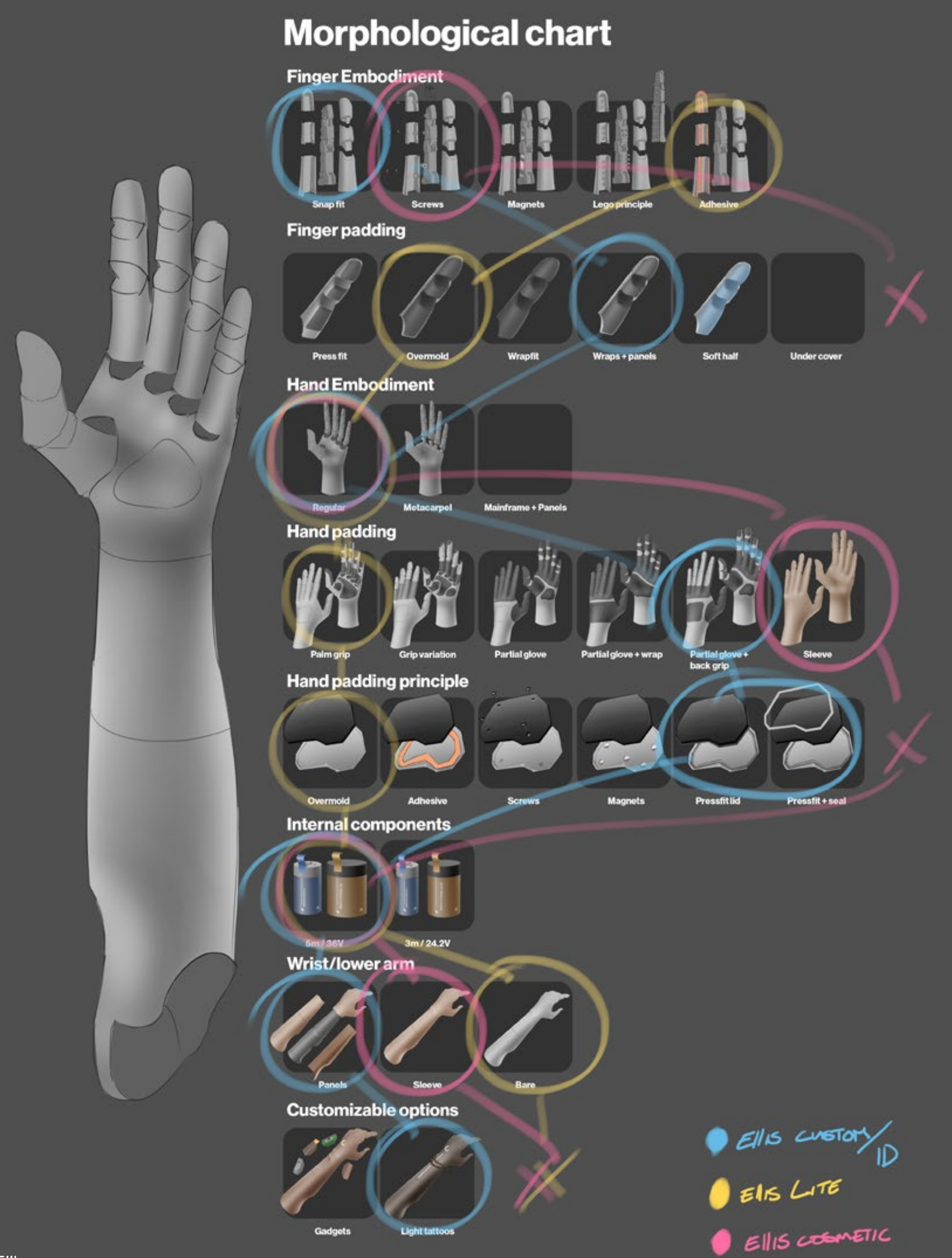
Features and gadgets

One could imagine wanting to add light features to the prosthesis that indicate battery life for example. But this concept can also be used to add aesthetical features such as a light pattern/tattoo. By integrating a LED underneath the panels and have the embodiment be thinner at that point in order to let the light through.

In the interview with Bert Pot he was talking about wanting to integrate a watch in his prosthesis or an LCD screen which could display pictures of this family. The idea of a modular system of interchangeable gadgets could be implemented in the arm.

Discussion

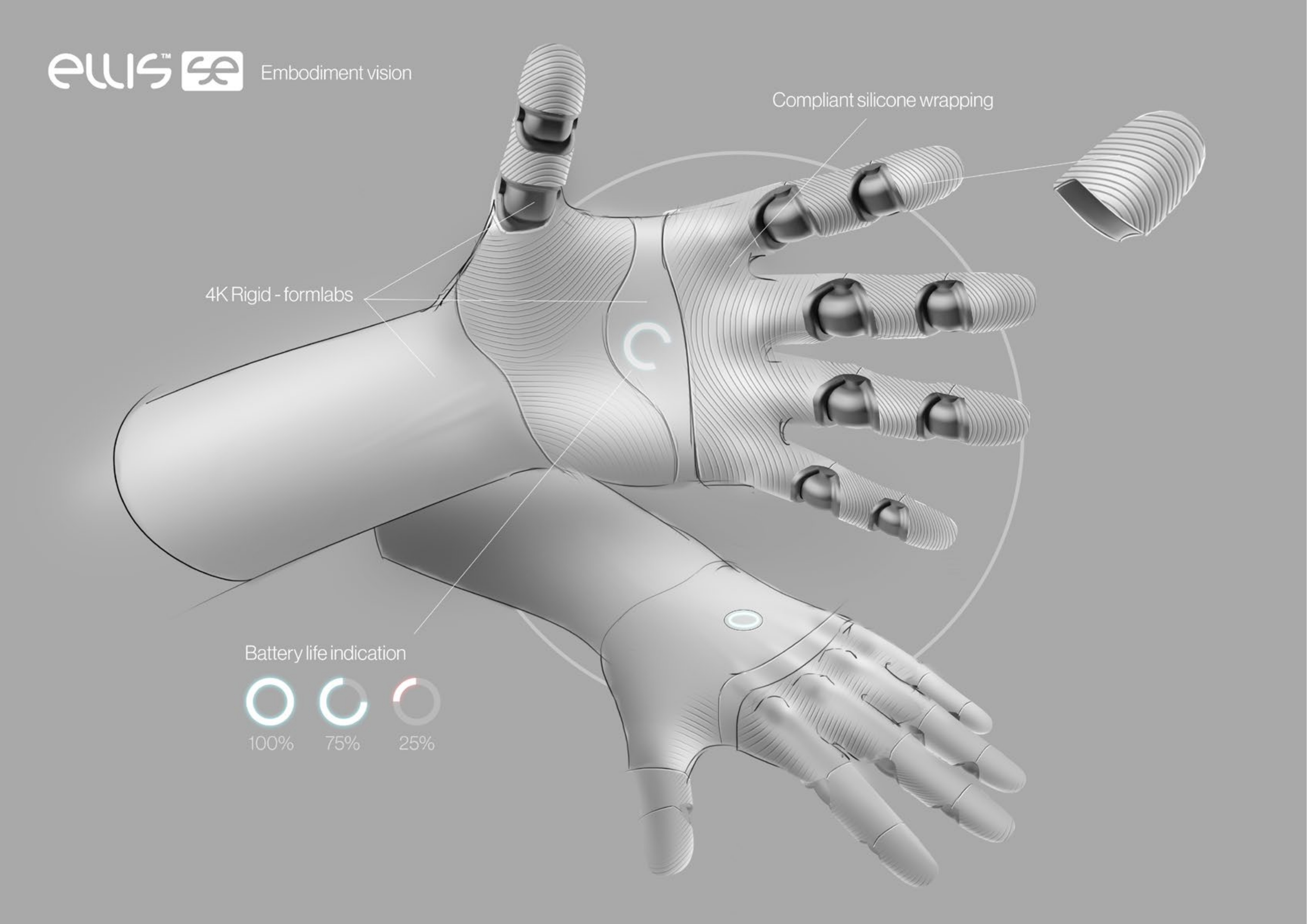
The ideation for the arm did not go very broad. This is due to the focus being more on the finger. However still an interesting idea of the mainframe with interchangeable panels holds a lot of potential for the product and allowed for major customizability options.



08
Concepts

Combining all the ideation solutions several concept proposals were made. however these concepts are the result of combining specific design solutions within the archetype of an arm prosthetic. Therefore they do not differ to much, its mainly details.

Visual on the left page shows a morphological chart of all the main ideation solutions for every different part of the hand. By combining the solutions different concepts were generated.



8.1 Ellis Concept 1

The first Ellis concept uses a compliant silicone principle to create the illusion of human skin at locations where the fingers move.

Finger

The first ellis concept made use of a silicone grip wrap system. The finger consists of a hardbody mainframe with grip pads wrapped around. Between the grip pads and the mainframe tactile sensors are placed. See appendix 3 finger wrap concept. Within this mainframe the tendons and springs are located. This principle is made by DHM Dental. The joint sections are covered with a rounded surface to avoid big gaps. These rounded surfaces slide into the mainframe. The grip pads have a texture that is inspired by a finger print.

The grip wraps can be replaced if damaged. The grips are possible to be customized in different colours and can be changed if the user decides to want to wear another color. The user can simply wrap the grip off the finger and place a new one.

Hand

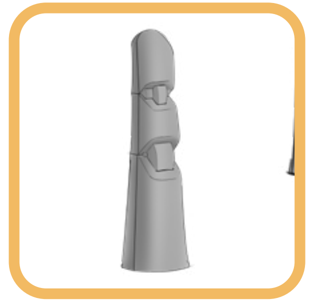
The connection between the fingers and the hand is covered by a stretching grip semi glove. The semi glove helps to create the hand form. In a real human hand there is skin between the fingers which make the fingers look smaller. In reality fingers are longer that and start at your knuckles.

The same stretching silicone 'skin' principle is applied at the thumb. In this way if the thumb moves the silicone deforms with this motion. This grip wraps all around the palmar and dorsal side of the hand.
The hand has a bettery indicater in the palm with the use of an LED placed underneath the hardbody which shines through. On the dorsal side of the hand a power on/off button is located.

On the dorsal side of the hand there is a maintenance hatch underneath the grip wrap. This maintenance hatch allows to access the PCB assembly.

Arm

The arm is a hard body shell which houses the major tech components such as the motors and battery pack. The hardbody can be customized to have one custom color. In this way certain themes can be created as can be seen in figures below.


Fixed finger embodiment

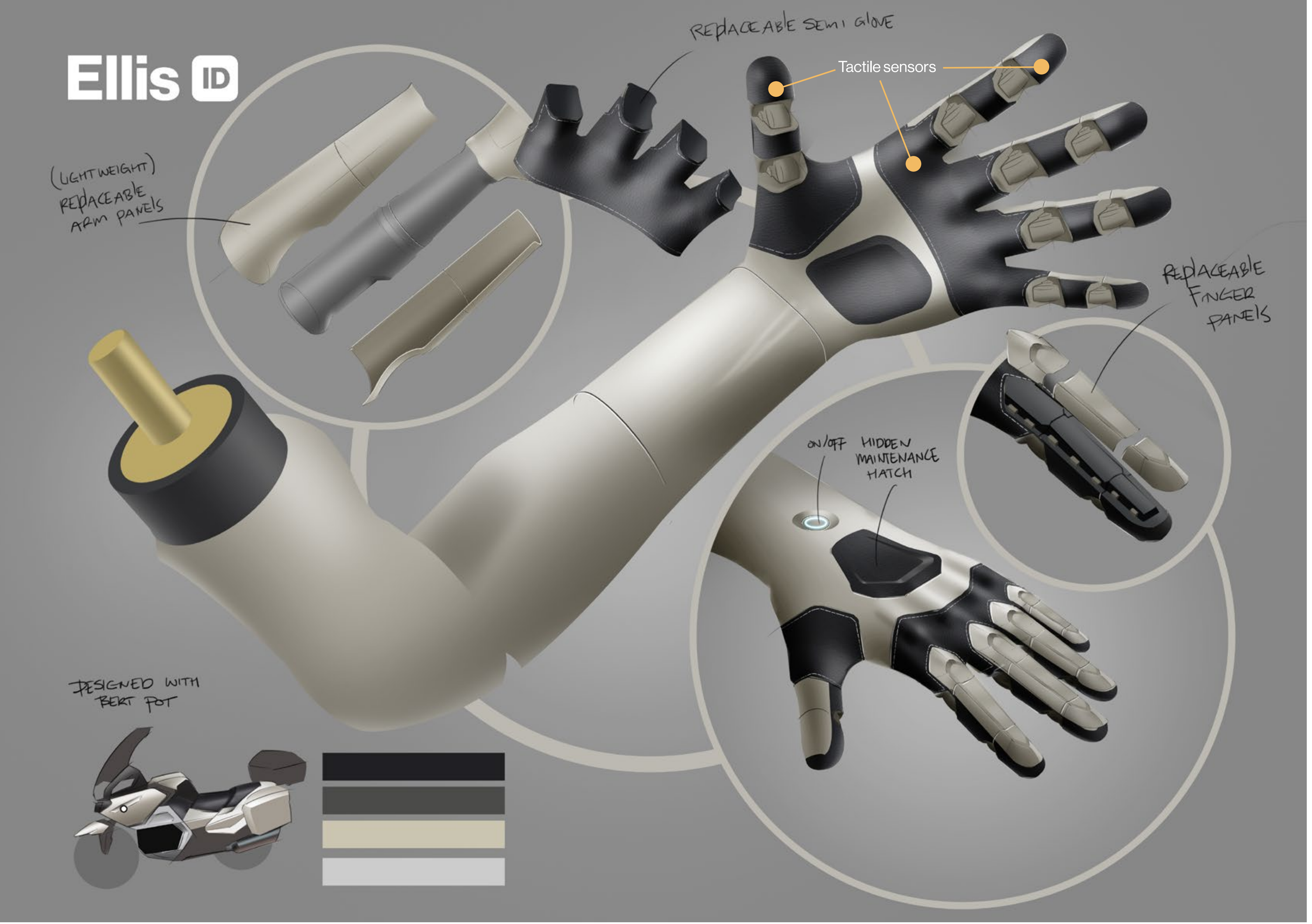

Wrapped grips


Mainframe


Compliant wrap grip


Pressfit lid


Fixed arm embodiment



8.2 Ellis ID

The Ellis ID is a modular approach for a bionic arm prosthesis. All the external panels and grips are replaceable and this allows for flexibility in the product appearance.

Finger

The finger makes use of a compact mainframe which house the tendons, springs and tactile sensors. On this mainframe grips and panels are attached. The dorsal panels are hardbody and attach with the use of a snapfit principle. The grips are made of a soft material such as silicone or flexible 80A from formlabs. The grips wrap into designated cutouts and are secured due to the hardbody panels enclosing them.

These panels and grips define the external appearance of the finger. This principle allows for a lot of customizability options since the panels can be customized in terms of form and color, as long as they can be still attached to the mainframe. Same counts for the grips. Since the tactile sensors are integrated in the mainframe, this mainframe is a solid and protected part, which is made inaccessible for the user, to avoid the user damaging it. The user is allowed to disassemble the modular panels and grips if they break down or if the user decides to change the products' appearance.

Hand

The arm consists of a mainframe which houses all the major tech components such as the finger motors, wrist rotation motor and the battery pack. This mainframe is watertight and inaccessible by the user. On top of this mainframe external panels are placed which define the appearance of the arm. The panels can be customized in form and color. The panels are attached to the mainframe with the use of magnets and can be easily changed by the user if the user decides to clean the panels or change the appearance by placing another set of panels.

Arm

The hand makes use of the compliant silicone skin principle.

Sensors

Tactile sensors are located at the fingertips and the proximal phalanxial palmar ares of the fingers. These tactile sensors are integrated in the mainframe and inaccessible by the user.

Identity

Due to the high customizability options it is possible to alter the appearance a lot and therefor allow the user to personalize the prosthesis. This is inspired from the concept of Scott Summit with the leg prosthesis.

Together with Bert Pot we made a custom prosthesis design vision. The design is inspired by the BMW motor cycle of Bert. Bert loves his motor cycle and the design of it. Bert was very positive about the design vision that was made and loves the concept of this customizability.

This personalization of the prosthesis could be done for every individual user and makes the product more personal and therefore more a part of the user; it adds to the user identity.


Snapfit


Wraps + panels

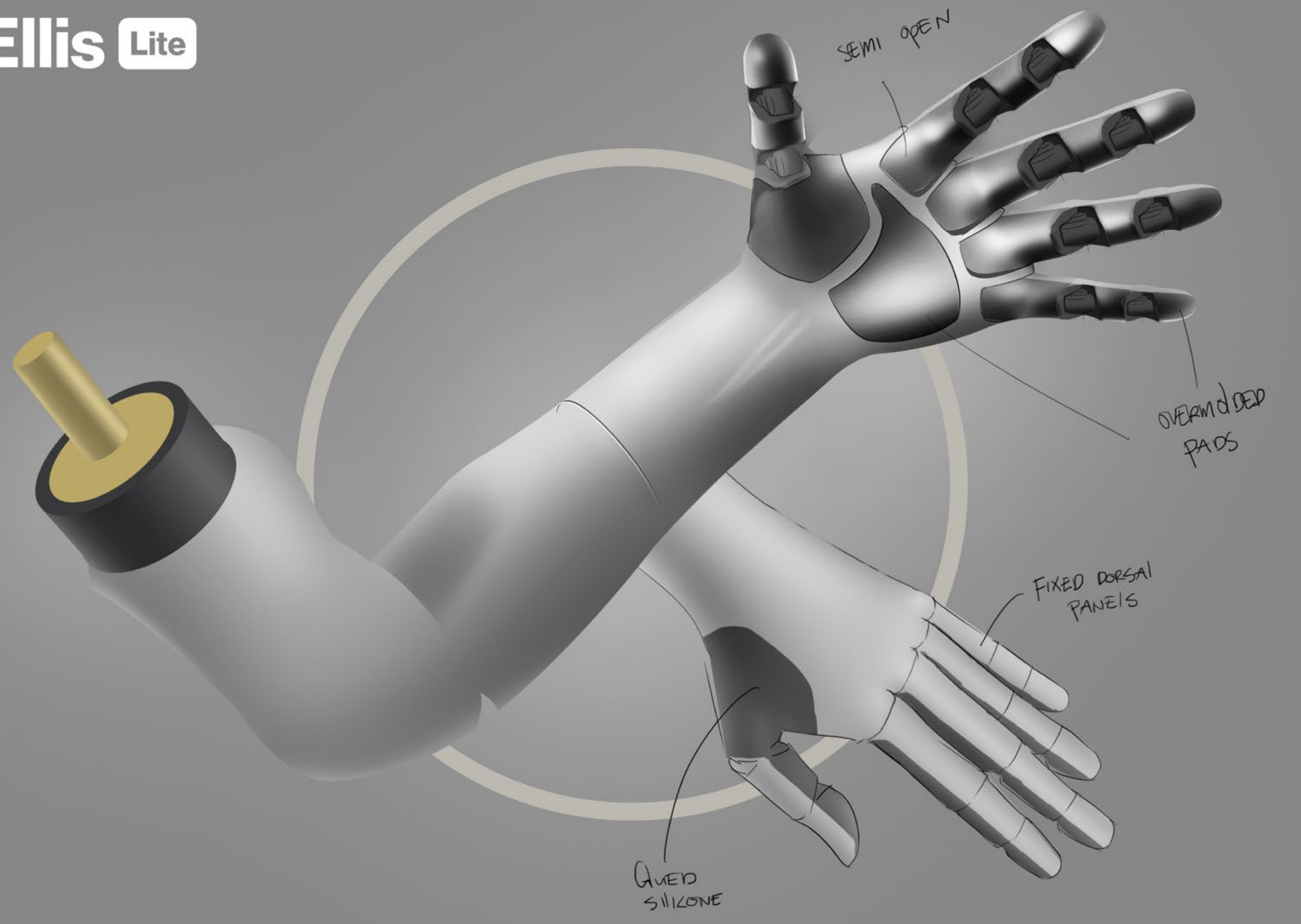

Mainframe


Compliant wrap grip


Pressfit lid


Replaceable panels

Ellis Lite



8.3 Ellis Lite

The Ellis Lite is more a basic model and has no modular and customizable parts.

Finger

The finger uses a mainframe with attached panels and overmolded grips. The panels and grips are not detachable by the user. Tactile sensors are located at the finger tips and proximal phalanxial palmar areas of the fingers.

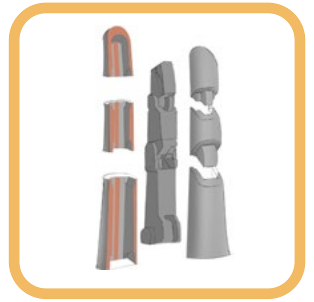
Hand

The fingers are connected to the hand with the use of hinges. The holes. that are required for the finger to move into because of the flexing motion. are seamlessly filled up by the finger mainframe. This is to create a uniform embodiment form.

The hand has a fixed grip pad over molded on the hand palm hard body that houses tactile sensors underneath to provide tactile feedback on the hand palm.

Arm

The arm is a standard hard embodiment that houses the major tech components. This embodiment is not accessible by the user and is made watertight.


Adhesive

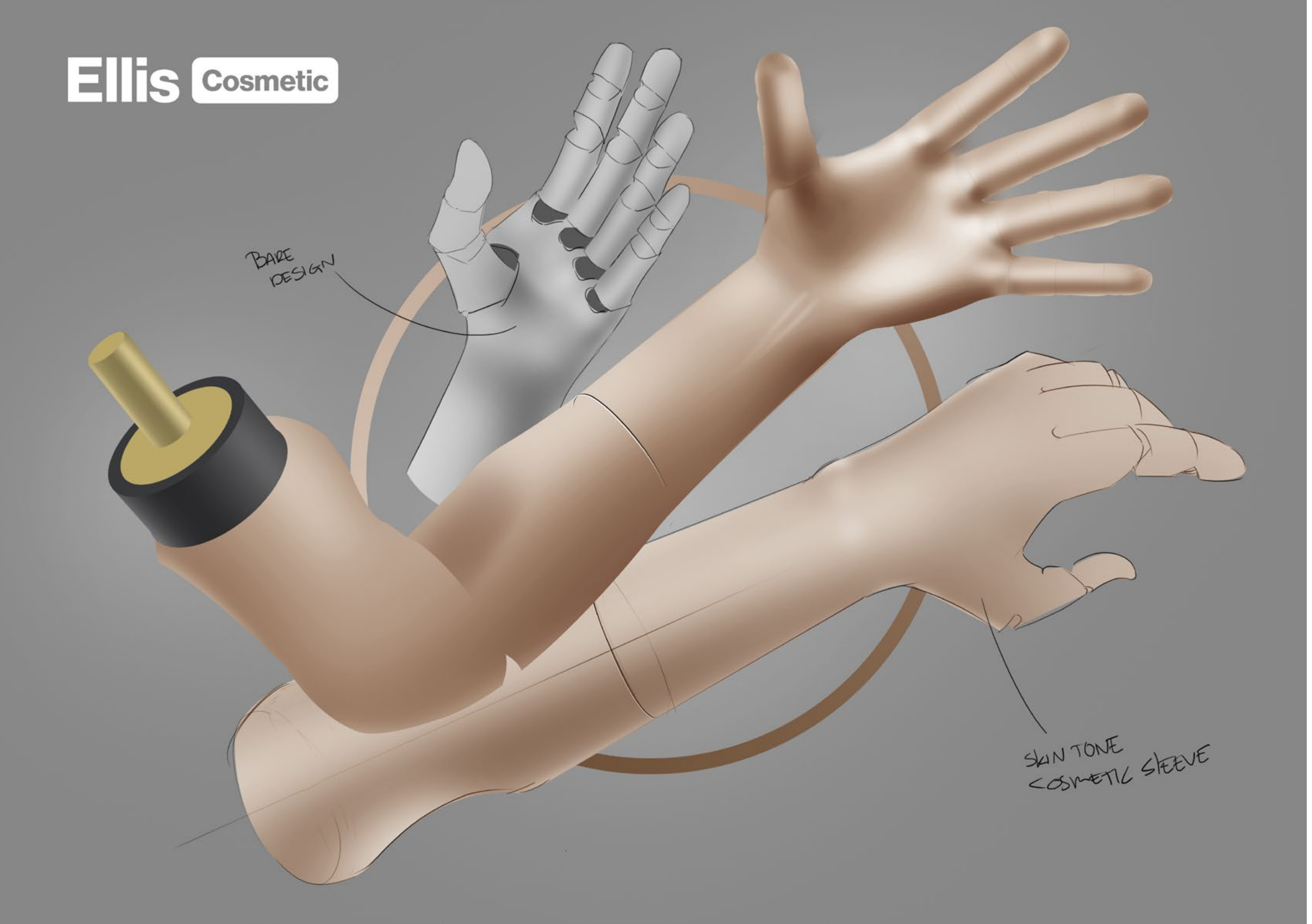

Overmold


Mainframe


Compliant wrap grip


Overmolded pads

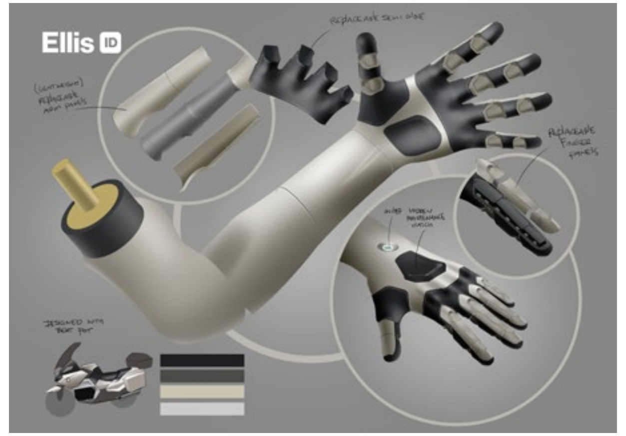

Replaceable panels

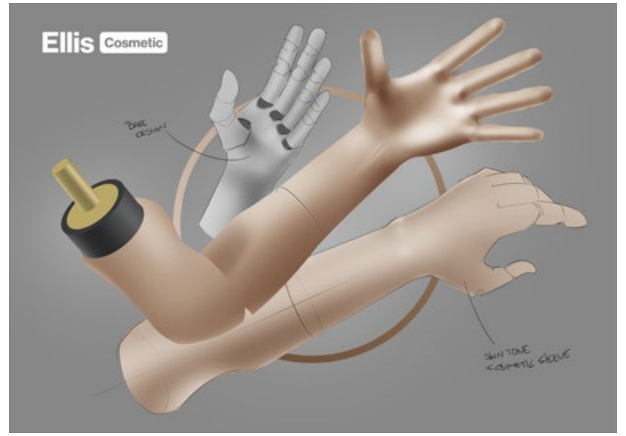


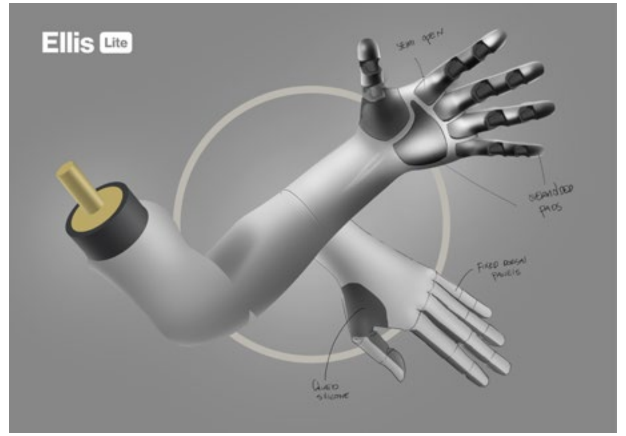
8.3 Ellis Cosmetic

The Ellis cosmetic is a bare model which is covered by a cosmetic sleeve in order to create a cosmetic human hand appearance.

The Ellis cosmetic is not a very elaborate concept. It is a minimalistic mainframe hand which allows to be covered with a sleeve. However there is a part of the target group that preferes a cosmetic model, therefore the Ellis Cosmetic is also one of the concepts.







Ellis ID

	-2	-1	+1	+2
Customizability			■	■
Dimensions			■	
Weight		■		
Amount of parts		■		
Mobility			■	
Grip			■	
Durability			■	
Modularity			■	

Ellis Cosmetic

	-2	-1	+1	+2
Customizability			■	
Dimensions			■	■
Weight			■	
Amount of parts			■	
Mobility		■		
Grip			■	■
Durability	■	■		
Modularity			■	

Ellis Lite

	-2	-1	+1	+2
Customizability			■	
Dimensions			■	
Weight			■	■
Amount of parts			■	
Mobility			■	■
Grip			■	
Durability			■	■
Modularity	■	■		

Customizability	Meaning how customizable the concept is
Dimensions	Dimensions means
Weight	Weight meaning the result the concept will have on the weight of the product
Amount of parts	Amount of parts meaning how many individual parts the concept includes
Mobility	Meaning the rate in which the product is able to move freely
Grip	Meaning how good the grip quality of the concept is probably going to be
Durability	meaning how likely the product is going to last long
Modularity	Meaning how easy it is to disassemble the product for maintenance

09

Concept choice

Concept choice decision making process will be explained here

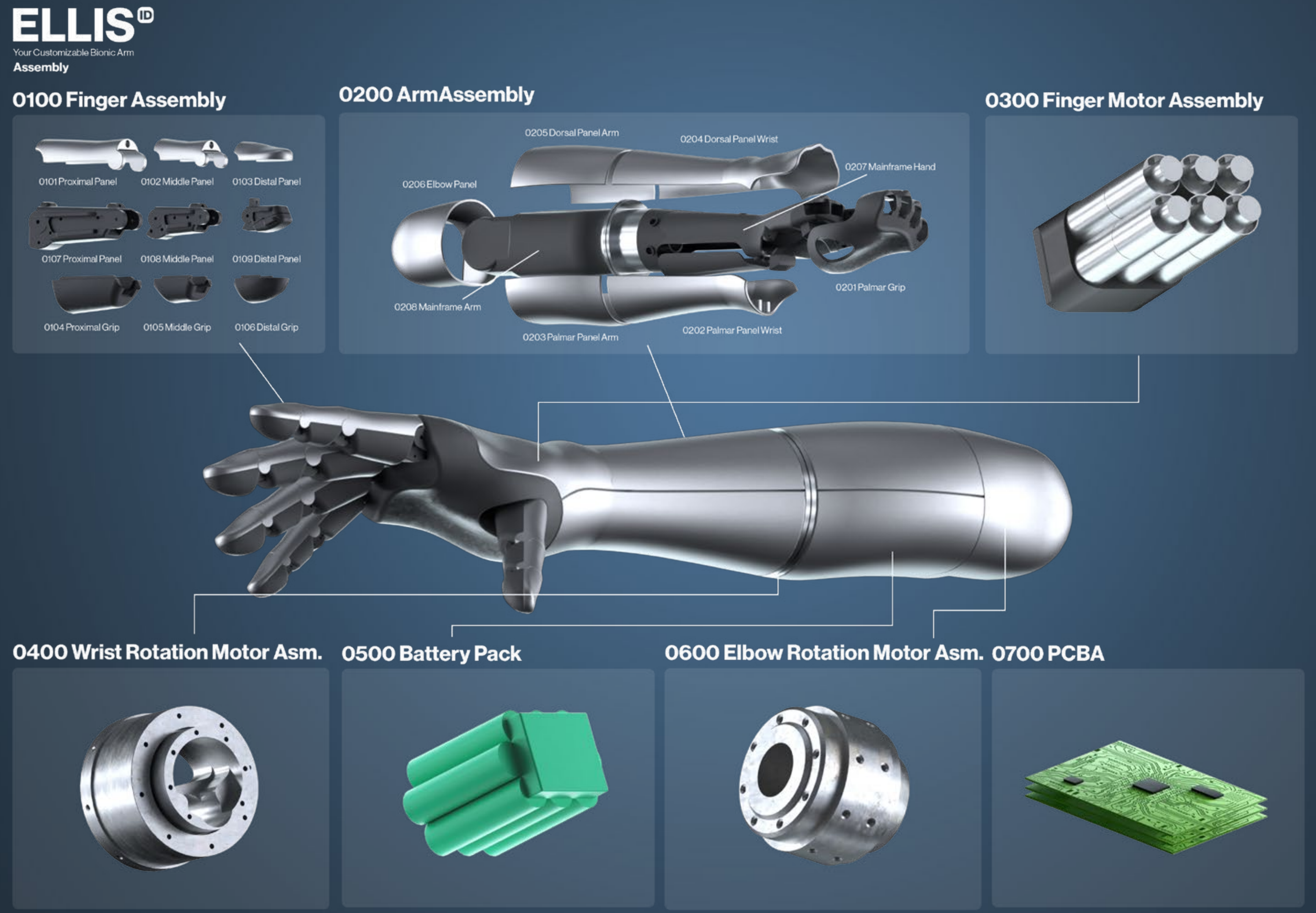
The concept sketches served as a tool to discuss and think of a final concept to develop for the embodiment. The image on the left page shows a quick use of a harris profile to asses the individual concepts, however the choice was more based on a discussion of what deemed most realistic and feasible.

The final concept is the result of combining several solutions of the multiple concepts that were deemed promising. The most promising concept was that of the Ellis ID. The Ellis ID was taken as a basis and some adjustments were made.

For example the snapfit principle of the dorsal finger panels was changed into a sliding principle.

The compliant grip wrap was changed for an approach that looks more like the principle used in the Ellis Lite.

However during the embodiment phase the model developed aswell, this was an ongoing iterative process. The Ellis ID served as the main inspiration for the embodiment.



10

Embodiment

In this chapter the final embodiment design is presented. In chapter 9 the final concept is chosen to be further developed. This is the Ellis ID, a modular customizable bionic arm.

However this final embodiment design is the result of multiple iterations. For example the finger went through about 7 iteration cycles and has changed drastically during the project.

10.1 Detailed product lay out

In this chapter the product embodiment is discussed in detail.

Exploded view

An exploded view of the product is presented showing every part within every sub assembly.

0100 Finger assembly

The finger assembly consists of the hard body panels, the mainframe and the soft body grips pads. The soft body grip pads are wrapped on the mainframe and the hardbody panels slide over the mainframe to secure the grips.

0200Arm assembly

The arm assembly consists of a mainframe housing 0300 finger motor assembly, 0400 wrist rotation motor assembly, 0500 Battery pack, 0600 Elbow rotation motor and the PCB assembly.

On the arm mainframe thearm panels are attached with the use of magnets. The arm panels define the arm form and are customizable in shape and color.

0201 palmar grip

The palmar grip is attached to 0200 arm assembly and provides as a soft grip for the palmar side of the hand. It also is the connection point between the fingers and the hand in terms of embodiment form.

0300 Finger motor assembly

The finger motor assembly is connected to the fingers with the use of tendons. The type of motor is not mentioned due to confidential reasons.

0400 Wrist rotation motor assembly

The wrist rotation motor allows the arm to make a wrist rotation motion. The type of wrist rotation motor is not mentioned due to confidential reasons.

0500 Battery pack

The battery pack is located in the back of the lower arm. The type of battery is not mentioned due to confidential reasons.

0600 Elbow rotation motor

The elbow rotation motor is located at the elbow and allows the arm to make an elbow rotation motion. The type of elbow rotation motor is not mentioned due to confidential reasons

0700 PCB Assembly

The PCB assembly is located in the hand and is responsible for computing all the input en output data. More details on the PCB is not mentioned due to confidential reasons.

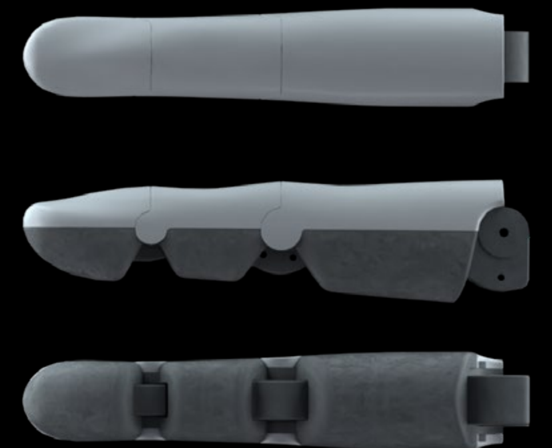


Figure 10.1: Finger views. The sideview shows integration of knuckles in the embodiment.

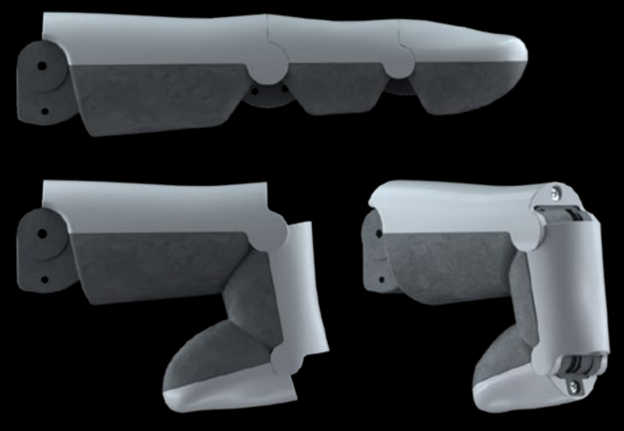


Figure 10.3: Mobility - Flexion motion

Figure 10.2: Finger exploded view

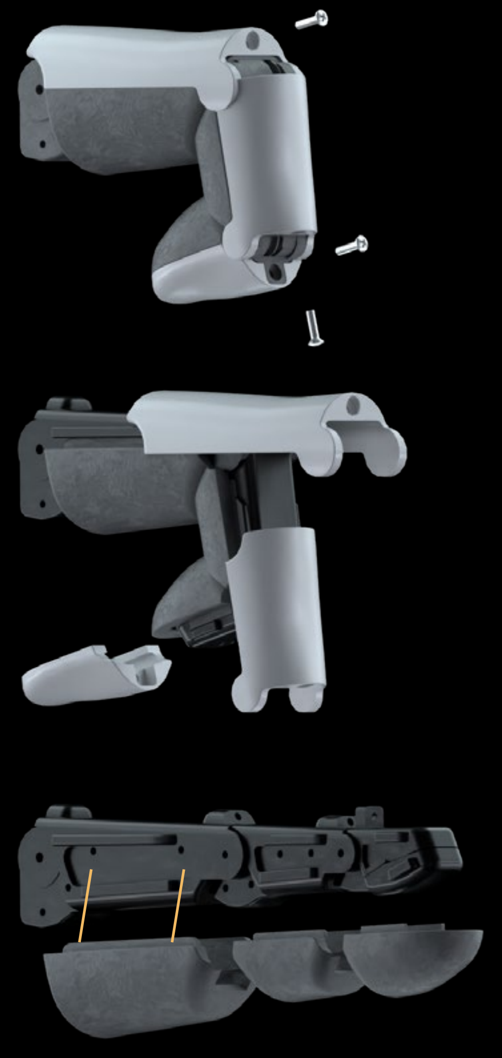


Figure 10.4: Disassemble steps of modular panels

0100 Finger assembly

The embodiment design of the finger went through multiple iteration cycles due to changes in the movement principle or learnings from prototypes. the figure above illustrates this design evolution. Appendix 10 elaborates deeper on the individual embodiment designs. In this chapter the final design is mainly discussed.

Finger principle

The fingers has evolved from a kinematically linked beam system to a tendon principle. This principle was chosen for the following reasons:

1. Easier to create enclosed and therefore watertight design.
2. Higher mobility.
3. According tot tests by DHM Dental the kinematic bar system showed low power
4. The linked beam system requires many gaps, this is not aesthetically pleasing.

The tendon principle works basically like a real finger works. A cord pulls on the tip of the finger en through a clever mechanism of pulleys the finger is being flexed. The extension motion is caused due to internal springs that pull the finger back.

This mechanism is created by DHM Dental bv and is out of scope for this project. System principle is not illustrated due to confidentiality reasons.

Finger mainframe

The finger consists of a mainframe which houses the tendons, sensors, springs and ball bearings. This mainframe is watertight and therefore protects the internal components from water and dust. Furthermore the mainframe is inaccessible for the user, which prevents the user from accidentally breaking important components.

Palmar grips

The palmar side of the finger consists out of replaceable grips. The grips are wrapped onto the mainframe and fit perfectly into little gaps in the mainframe see figure 10.4. The palmar side of the hand has a lot of interaction with objects and therefore needs to provide sufficient grip to prevent objects slipping out of the hand. Furthermore the sensors underneath the grips need to be actuated during interaction. Investigated materials are silicone, TPU and the formlabs flexible, due to their flexible and high friction characteristics.

The grips are supposed to have a customizable color and grip texture. Texture can add a little to the friction but is mainly an aesthetic feature. A paper by Cadoret et al. (1996) states that friction coefficient has more influence on grip force used during object manipulation than texture.

Chapter 11 investigates the performance of the different grip materials and the limitations.

Dorsal panels

The dorsal side of the fingers consists of hard body replaceable panels. The panels can smoothly slide on and off the mainframe and serve to hold the palmar grips in place.

Furthermore the panels have embodiment form elements that represent those of a human finger, such as the knuckles and the overall organic shape of the finger. Also the joint area is covered by this round shape which allows the different phalanxes to smoothly rotate, without breaking the form.

The panels are secured with the use of a small M1.6 screw and M1.6 nut to ensure that the panels won't fall off during use.

Investigated materials for the panels are formlabs rough, formlabs rigid 4K and PLA. These materials have been prototyped and can be found in chapter 11.

Tailor-made

The finger embodiment can be altered in size by elongating or widening the mainframe and its related panels and grips

Mobility

The fingers can make a flexing and extending motion due to the clever design of the mainframe. With this it is kept in mind that the gaps are minimalised and the shape of the finger stays as uniform as possible. The phalanxial mainframe parts can rotate perfectly into each other and the corresponding panels and grips connect seemlessly with this motion.

The fingers are also able to make an ab- and adducting motion due to way the hinges are connected to the hand mainframe. This is further elaborated in 0201 palmar grip.

Model

The design is made in Solidworks. The creation steps are further elaborated in appendix 3

Discussion

It is important to use enough tolerance with sliding and wraping parts to ensure that the parts can be attached and detached smoothly. Furthermore prototypes must be made to decide on what material is most suitable for all the parts.

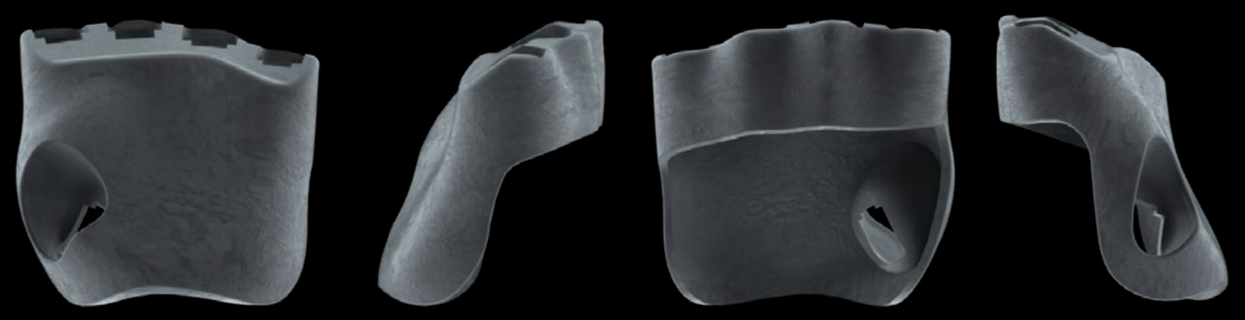


Figure 10.5: Hand palmar grip views.

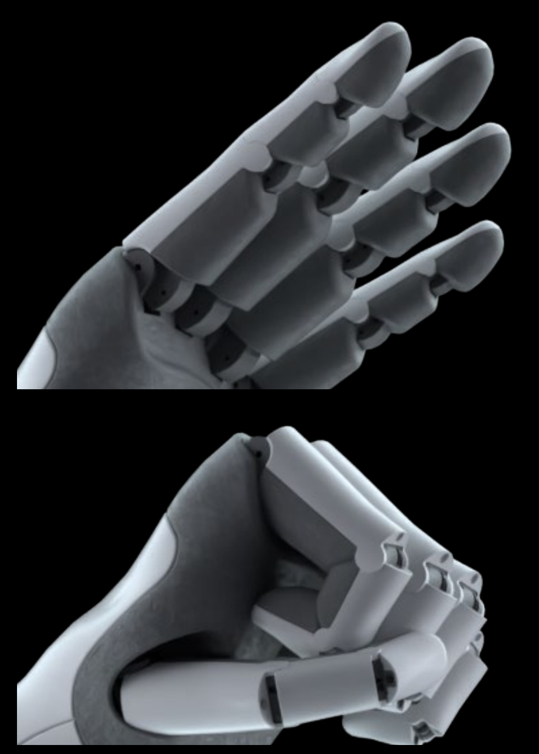


Figure 10.7: Finger flexion

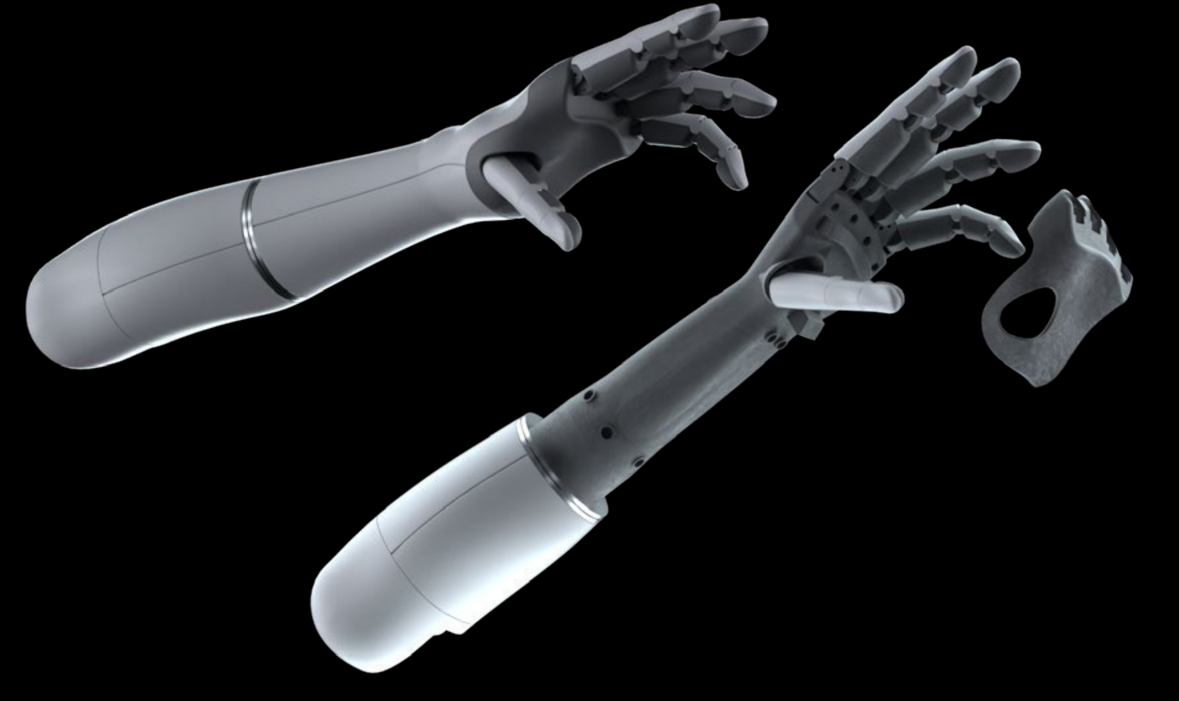


Figure 10.6: Hand exploded view

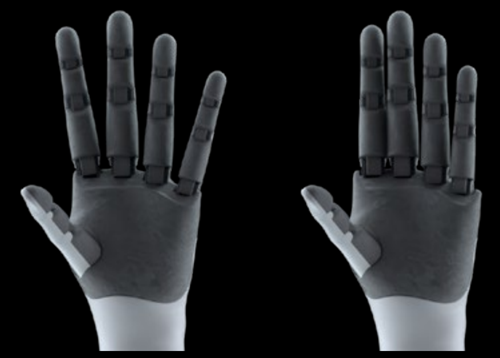


Figure 10.8: Finger ad-/adduction

0201 Palmar grip

The hand is the connection point of the fingers with the rest of the arm. The challenge here was to have a uniformous transition from finger to hand and integrate the thumb in a clever way. The result is a flexible semi glove with organic human inspired form features and cutouts that provide space for the fingers to move into, without breaking the form of the hand too much.

There have been some iterations on this design. The iteration is elaborated in appendix 3.

Material

It is decided that this part is made from a flexible material with high friction characteristics. The palm requires grip, since it interacts with objects. Furthermore integrated tactile sensor need to be actuated. Moreover the fingers need to make a flexion motion and ab-/adduction motion and therefore need to have some space to move. The flexible material can deform if needed for the fingers to perform this motion.

Material that might be suitable for this part are TPU, silicone or formlabs flexible. These materials are investigated in chapter 10.

Hand Mainframe

The hand mainframe houses the PCB assembly and tendons go through this part. Furthermore tactile sensor will be integrated in the palmar area of the mainframe.

The fingers are attached to the mainframe with the use of hinges. The hinges themselves allow the finger to make a flexing motion. The hinge connection to the mainframe allows the finger together with the hinge to make an ab-/adduction motion.

Finger connection section

At the finger connection point a cutout has been made that allows the fingers to flex into the hand palm. At first this where just massive gaps for the fingers to move into. This solution is more enclosing and makes the hand more a uniform whole.

Furthermore there are little cuts in the top of the part through which the fingers stick out. And the mainframe fills up the gap perfectly. In this way there is limited amount of gap.

Thumb section

For the thumb an organic cutout is designed that allows the thumb to flex and extent, but still tries to maintain a uniform whole, integrating the thumb in the embodiment. It needs to be tested wether the thumb can perform the required range of motion. Furthermore this area might be prone to becoming dirty sinds small things like crumbs can get stuck in there. However one could easily clean this with some water or compressed air, just like you would clean a keyboard.

Model

The model is made with solidworks and the full development steps are elaborated in appendix 3.

The model has been made with a wall thickness of 2mm. However prototype testing should determine wether this is thick enough.

Assembly

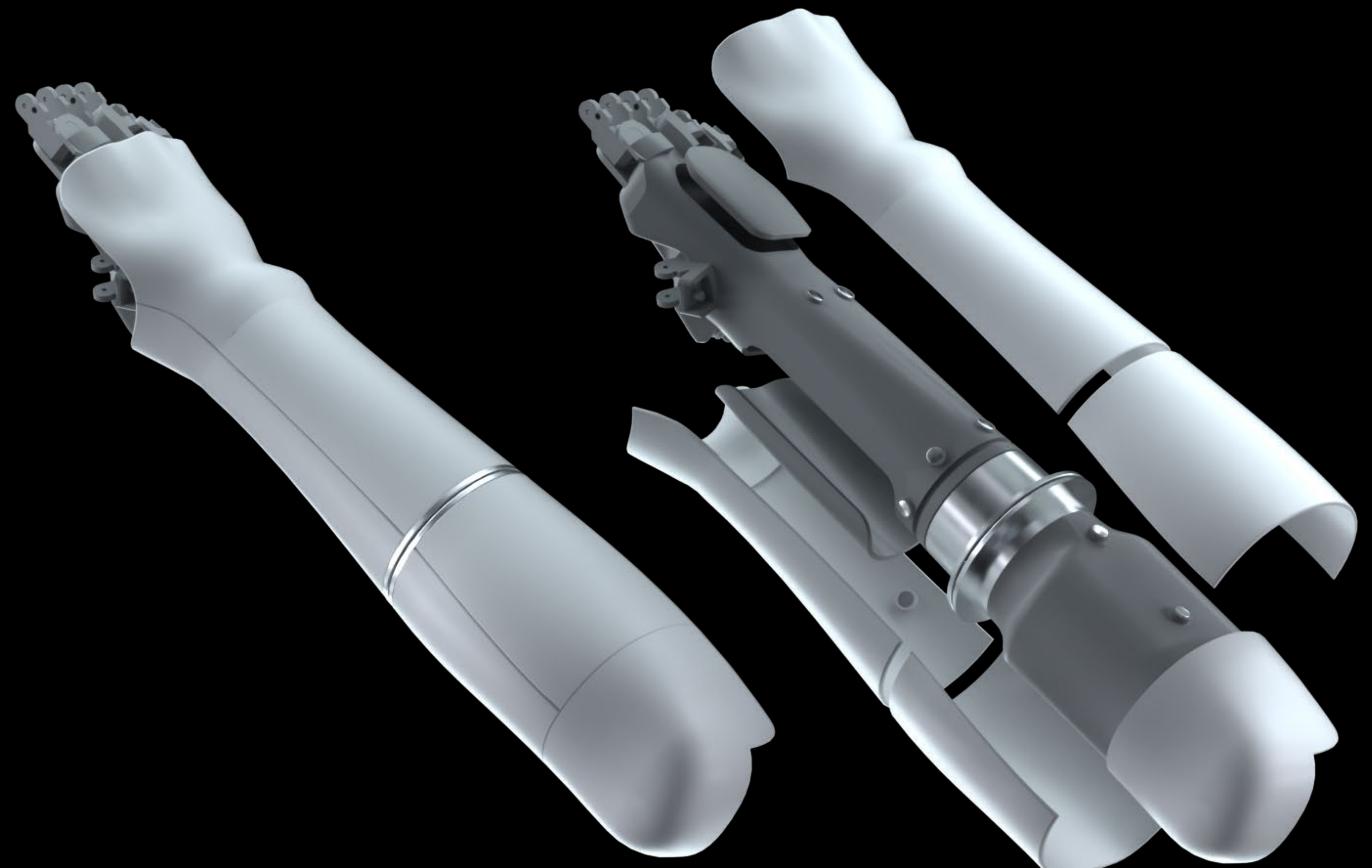
The flexible semi glove wraps around the mainframe and is fastened. The way the part is fastened is not defnitive yet. However a proposel has been made to secure the part with the use of screws. Another proposal is to have it secured with a lid, that is pressed into a cutout.

Appearance

Human hand characteristics are integrated in the product form. The dorsal side of the part includes the tendons and bones which can be seen in a human hand. And the palmar side follows the same palmar shape of a human hand with the thumb in a slight forward angled position.

Discussion

hinge detail of the fingers has not been finished. Due to time limitations this part of the product looks a bit bare. It is adviced to look into this detail. Could be solved by adding some of the hand material to cover up this hinge area.



0200 Arm assembly

The arm assembly consists of the palmar and dorsal panels, 0201 palmar grip and the mainframe.

Arm mainframe

The principle of the mainframe is that this is designed to be waterproof. Prefereably IP67 based on the requirements defined in chapter 5.

The mainframe houses alll the technical components such as the finger motors, wrist rotation motor, elbow motor, PCB assembly and the battery.

The mainframe can be opened for maintenance by the manufacturer, not by the user. This is to prevent the user from damaging any important technical components.

Onto this mainframe the palmar and dorsal panels are attached.

Palmar and dorsal panels

The palmar and dorsal panels define the shape of the arm. Human arm characteristics are integrated in the embodiment form, because one of the requirements of the prothesis is that it should resemble the human arm.

Features such as the radial bone which can be seen in the human arm and the overall shape of the lower arm muscle are incorporated in the embodiment. Furthermore a little hint of the tendons in the dorsal panel is included which blends into the palmar grip part.

Material

The prothesis is desired to be not too heavy since the weight of the prothesis will pull on the implant, if it is too heavy the implant can break or the user can experience discomfort. The MPL prothesis investigated in chapter 5 has a weight of 4.9 kg. The prothesis is not adviced to weigh more then this weight.

Therefore the material to use for the arm panels should be strong and light weight. DHM Dental has stated to prefer materials that are 3D printable. Investigated materials for the panels are formlabs rough, formlabs rigid 4K and PLA. These materials have been prototyped and can be found in chapter 11.

Assembly

The panels are attached to the mainframe with the use of strong cilindrical magnets. The magnets have a diameter of 7 mm and height of 3.5 mm. They can hold up to 14N. The magnets fit into small sockets, located on the mainframe and the panels. The magenets are glued on to the panels.

These magnets were selected because of their size and strength ratio. The panels weigh approximately 35 grams each which is about 0.35 N. This means that the magnets can easily hold the panels. In chapter 11 it is tested wether this principle works and wether it is stong enough.

Embodiment

The panels have a wall thickness of 2 mm. This thickness is chosen as a general rule of thumb to provide strong enough wall thickness for a plastic part. However prototyping has to show wether the part is strong enough. This model does not contain any ribs or reinforcing added material. It is recommended to include this in the model to provide more strength and stiffness.

Model

The model has been made in solidworks. Appendix 5.3 shows an overview of the process of creating this part.

Discussion

The magnet principle makes it extremely easy to replace the embodiment panels and therefore customize the arm within seconds. However the panels should not come off too easily. Therefore it is important to test this and define if a more tight securing of the parts is necessary. This has been done in chapter 11.

In the model the panels obviously align perfectly. However 3D prints can have little deviations and the panels might not have a perfect fit. It is important to make sure that this alignment is accurate, in order to ensure that it looks seemless.

The overall embodiment form has a very human like appeal. However it can be valuable to test this with an aesthetics test. This has been done in chapter 13.

10.2 Customizability exploration

Some customization exploration is done with the CAD model in terms of color, texture and form.

Color

The product color can be easily customized due to the modular nature of the product. there are several ways to achieve the color of the product.

Formlabs color kit

On can use a color resin and print in the color that is desired. However this technique with the formlabs cartridges is not ideal. Since in order to achieve a different color, according to the formlabs website, one must use the formlabs color kit and blend this with the cartridge. This means that the entire cartridge can now only print that color, which is limiting. This technique however is more promising for the soft flexible 80A parts. Since these are harder to treat after wards due to the flexibility.

Spray paint

Another option is to sand the parts, prime them and then use a spray paint and a protective coating. However this can be quite time consuming. It is rather cheap though.

Hydro dipping

Another technique that is promising for customizing a product appearance is hydrodipping. A technique well known for the customization of parts in the automotive industry.

Hydrodipping is done by adding a thin film with a color or print on it to a big bath of water and then dip the part into that. The thin film will adhere to the part seamlesly. Afterwards the product is treated with a protective coating.

Costs for custom films from china cost 10€ and take 2-3 weeks to arrive. The dipping of all the prosthesis panels will cost around 350€. Usually the product is also sanded and primed before going in the dip. This is included in the price.

Finish options are: satin, gloss or thermologic. Thermologic is a relative new technique. A thermologic finish can be a color that disappears depending on the temperature. For example an arm can have a black finish. But if the temperature outside rises the arm reveals the hydrodip print that is underneath. In this way the product can have a changing appearance.

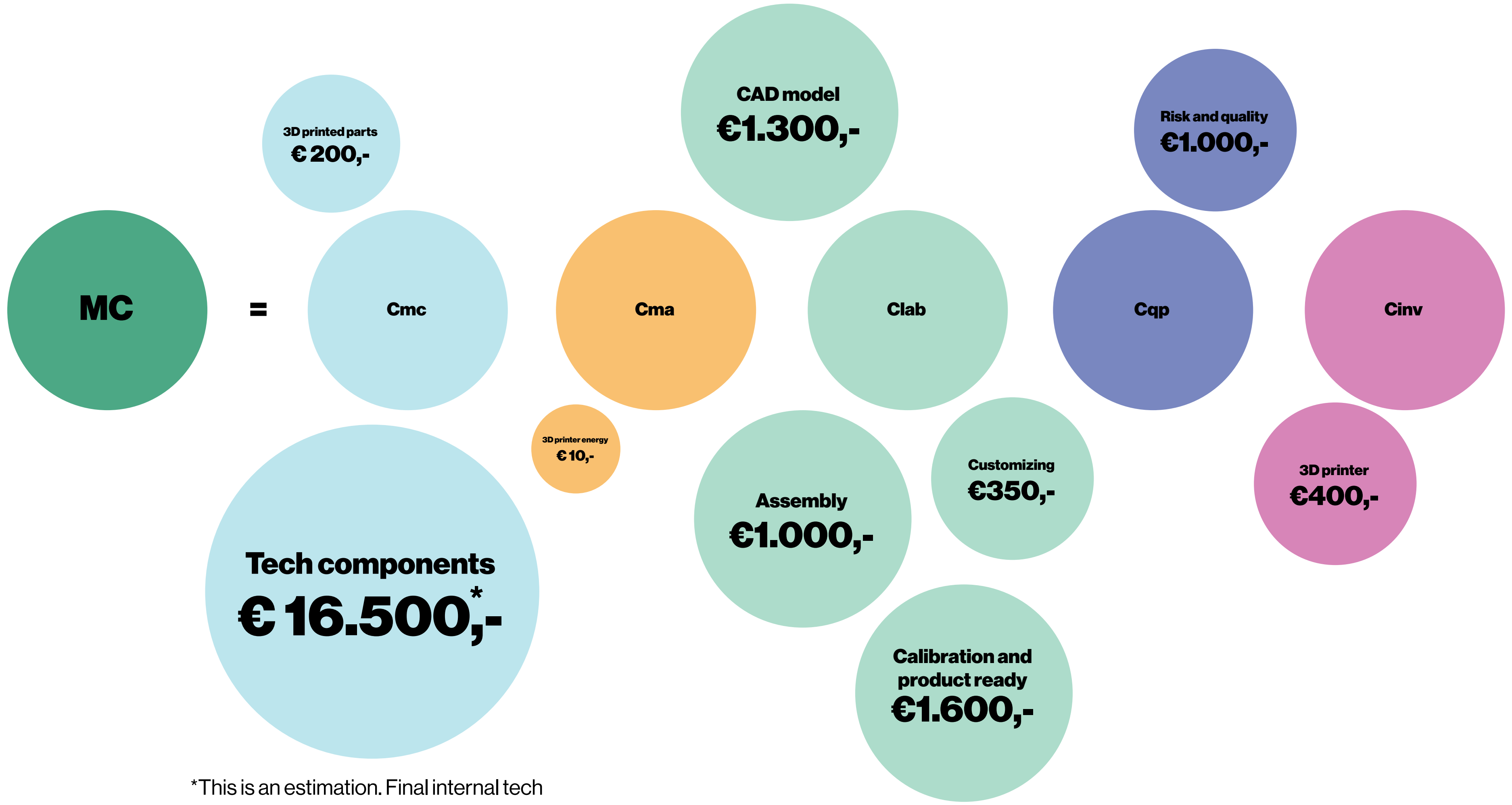
color and pattern options are basically endless. there is basic colors in every possible hue but also famous looks like carbon fibre, camo or a tattoo sleeve. There is also options for a pearlescent or iridescent look. Hydrodipping has been tested in chapter 11 on the dorsal panel of the prototype with a shiny carbon fibre finish.

Textures

texture can be added to the flexible grip parts. This has both an appearance function but also a performance function. Solidworks has an option which allows to add custom textures to surfaces which can then be 3D printed.

Light elements

It is possible to integrate light features by having thinner sections in the panels and install LEDs underneath. This can be used to create useful feedback such as a battery indicator, but can also serve as an aesthetic feature such as a light tattoo.



*This is an estimation. Final internal tech components have not yet been defined.

10.3 Cost price estimation

In this chapter an prediction of the cost price of the product is being determined.

Method

For this cost price prediction a formula is used as stated in NSFD (Tempelman et al. 2022). The formula is as follows: **MC = Cmc + Cma+ Clab + Cqp + Cinv**

The production volume is: **10 arms/year**

MC

MC is the manufacturing cost. NSFD describes the MC as 'the cost of turning materials and components into a functioning product that is packaged and ready to be shipped from the factory to its final customer, using machines, labour, and investments dedicated to that purpose.'

Cmc

Cmc is the cost of all the materials and components that need to be bought, per product. The product consists of 3D printed parts and bought components. There are some components that are standard such as the screws, nuts, magnets, ball bearings and axis. But there are also some product specific components such as the wrist rotation motor, the elbow motor and the PCB assembly. Some components also need to be treated such as the body panels which get a color and protective finish.

In the excel sheet the rigid 4K and flexible 80A are used as 3D print material to estimate the cost price of the 3D printed parts.

Since the specific tech components are not definitive an educated estimation is made for these prices.

Cma

Cma is the cost of all the machine and assembly operations, per product. The machines used for the production are the 3D printers and tools required to finish the parts such as drilling machine and sanding paper. The electricity bill for a 3D printer that has to print for 100 hours is probably around 100 euros if you estimate 10 cents per hour.

Clab

The labour involved in this product is for the CAD model, the assembling and maintenance of the product, the 3D limb scan, the finishing of the parts such as the hydrodipping and activities such as calibrating the prosthesis and training for the patient.

Cqp

A medical device requires a strict quality control, as is stated in the MDR. Quality management, risk management and testing of the device are all costs that should not be forgotten. Althought the quality and risk management applies for the overall product, every product needs to be tested indivdually according to the MDR and ISO22523, this is further elaborated in chapter 13.

Cinv

inventory costs are the 3D printer and the tools. Furthermore there are licenses that have to be acquired for the CAD software.

Discussion

The most expensive parts for this poduct are the tech components and the labour costs. The labour costs of making the CAD model optimized for changing dimensions should not be underestimated. This can be a very time consuming effort and can increase the cost of the product. However this is adviced to do, to avoid extensive costs for adjusting the model to all the different dimensions.

The tech components are net yet definitve, therefore an estimation has been done for these components. The end price can differ entirely if cheaper motors are being used, but it is just not possible to say, because this has not been decided.

For the full cost price estimation excel sheets see appendix 10.5

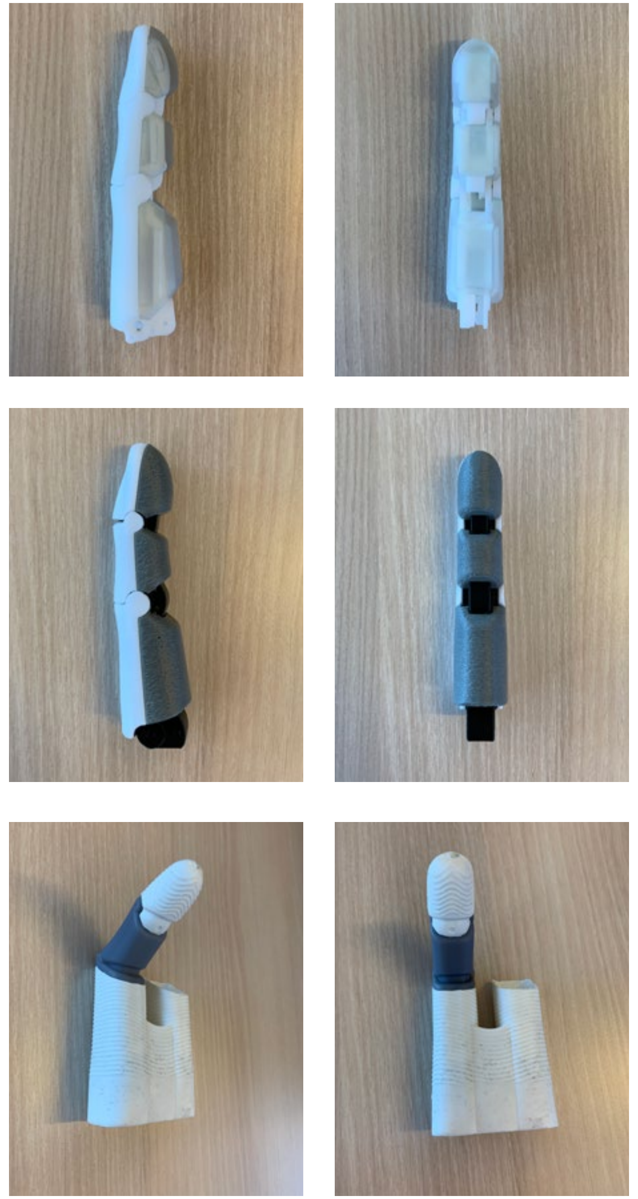


Figure 11.1: Grip material prototypes

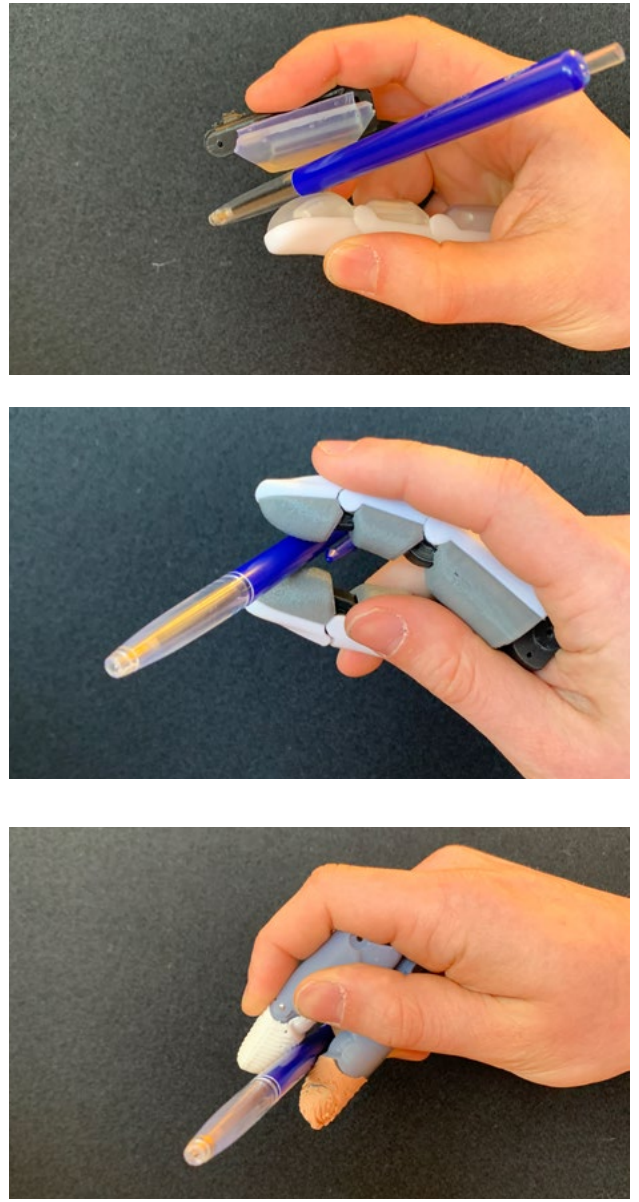


Figure 11.2: Simple grip test

Figure 11.3: Grip material scratch test. Cuts made with simple kitchen knife.

Figure 11.4: Coloring flexible 80A. Soaking in IPA and alcohol ink.

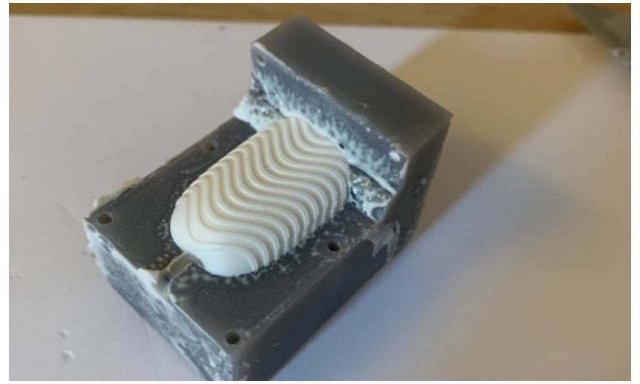


Figure11.5: Silicone molding process. Silicone 50A Distal finger gip wrap.

11
Prototyping

Certain parts of the products were prototyped in order to validate its function, material quality and appearance.

11.1 Finger prototype

For the finger multiple prototypes have been created to test functionality, appearance and material qualities.

Goal

Based on the Loughbourough Ideation cards the goal of the prototype is defined. For this prototype a functional model is made. The finger prototype had multiple test goals:

- Replaceability principle of panels and grips.
- Overall finger movement.
- Overall appearance of product.
- Friction qualities of the grip parts Flexible 80A, TPU95A, Silicone 50A.
- Material quality of formlabs tough, formlabs rigid 4K and PLA.

Palmar finger grips

The palmar grip panels are created with three different production techniques. The flexible 80A was printed with the formlabs form 2 SLA printer. The TPU 95A was printed with a creality ender 2 FDM printer. The silicone 50A was created with a silicone molding technique.

The requirements for the grips are:

- They provide sufficient grip to prevent objects from slipping out of the hand.
- They need to be customizable in color and texture.
- They need to be soft enough to actuate sensors.
- They need to be replaceable.

Grip

A small test with the prototyped grips shows that the formlabs flexible 80A does not provide much grip, the surface is relatively slippery. Also the parts are very hard, a thinner wall thickness might resolve this issue.

The TPU 95A shows poor grip qualities. The material is very hard and provides very little grip support. Wall thickness of 1.2 showed that be very hard. wall thickness of 0.8 feels better to the hand and has nice soft feel.

The silicone 50A shows the best grip qualities of the three. The material really tends to add friction and holding objects like a pen is possible without it immediately slipping out, unlike the TPU and Flexible material.

Customizable

The flexible 80A can be customized in form. Textures can be added within the 3D CAD model and then printed. However adding color to the material seems an issue. Formlabs does not provide a legitemate way to give the material a solid color. When tested by DHM dental, by adding formlabs color kit. the prints failed due to alteration of the material properties. Another option investigated was to soak the flexible part in an IPA and alcohol ink bath. This was a method suggest by formlabs, however the results of this were dissapointing and the material remained transparent.

The TPU 95 A ccan be customized in form. Textures can be added in the model and FDM 3D printed. Also color is alterable depending on the colour filament that is used.

Silicone 50A have also proven to allow custom textures. Textures integrated in the mold translate perfectly into the product. The silicone can be altered in color by adding pigments. Pigments can be mixed to create different colors.

Sensor actuation

Sensor actuation has not been tested elaborately and is suggested to be done more extensively. Some test have been done with different shores. Furthermore a brief test had been done with the silicone grip on the mainframe, actuating a sensor. See appendix 11 for results.

Replaceability

The replaceability of the grip pads shows to be quite easy. A user test has been done for the replaceability of the grip pads and panels and can be found in appendix 13.

Material quality

The silicone tends to be quite sticky and attracts dust. It is adviced to use color that does not look dirty quickly. Furthermore the silicone is very prone to getting cut. A simple knife stroke instantly cuts through the material. The flexible performs better against knife strokes, but leaves very visible scratches. The TPU also withstands the knife strokes and leaves little scratches.

Discussion

It can be concluded that both the TPU and the flexible material do not provide desireable grip qualities. Silicone however shows promising. Furthermore silicone has good customizability possibilities. However more elaborate grip testing is advised. the downside of silicone is that it is very prone to cuts. It is adviced to dive deeper into silicones and find a solution that has the desired grip capabilities and resistance to cuts. Inspiration can be taken from kitchen gloves.

Choosing for silicone will mean that molds have to be created and that a good molding process has to be achieved by DHM Dental. DHM can always choose to outsource this process. The silicone molding process can be found in appendix 11.2.

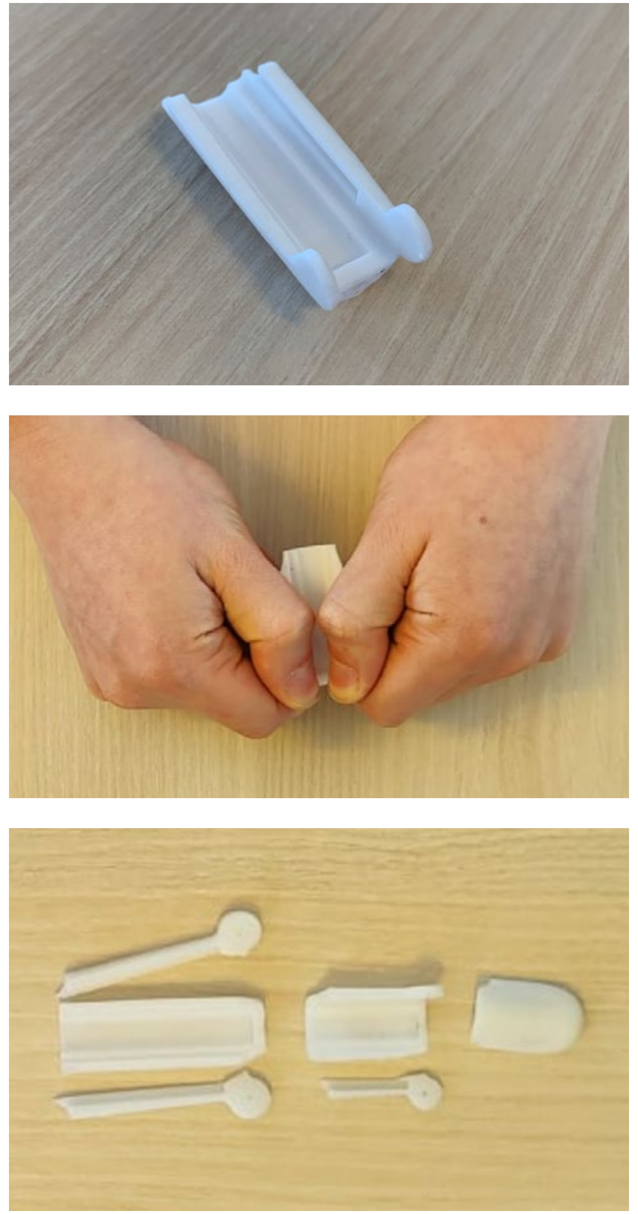


Figure 11.6: Bend test

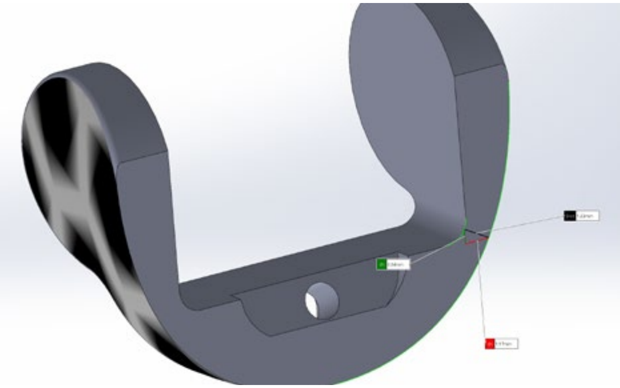


Figure 11.7: Wall thickness

Figure 11.8: Hidden screw

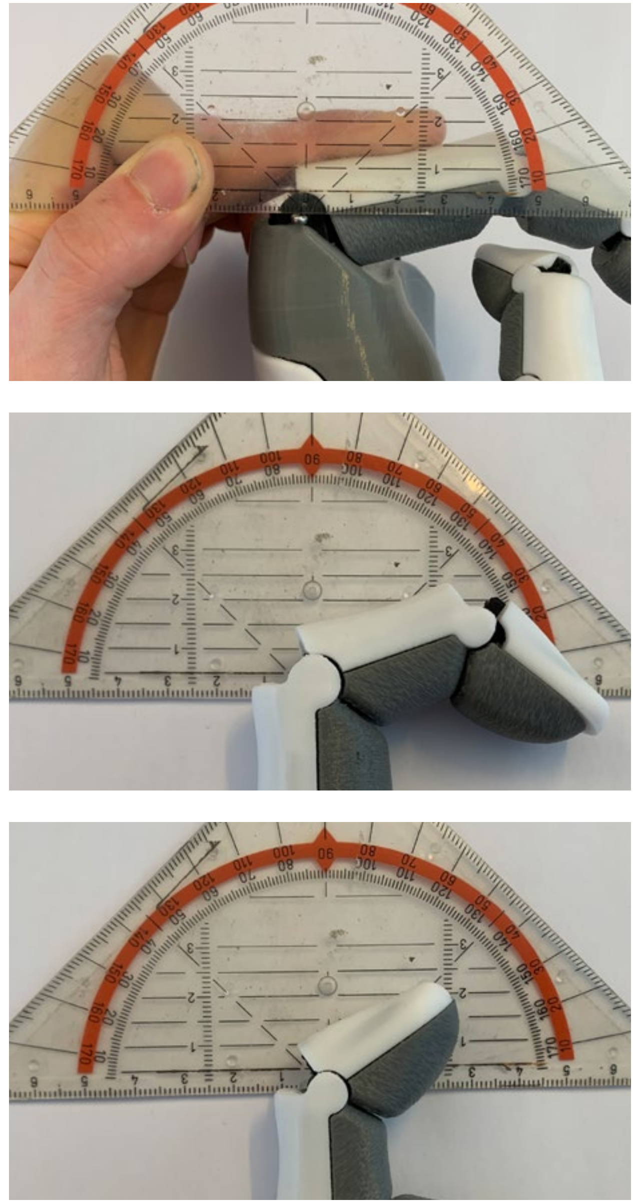


Figure 11.9: Finger flexion capabilities test

Dorsal finger panels

The dorsal panels have been prototyped in PLA, rough and rigid. PLA has been made with a creality ender 2 FDM printer. The rough and rigid are created with the formlabs form 2 SLA printer.

The requirements for the panels are:
- They need to be replaceable.
- They need to be customizable in color.
- They need to be safely secured.
- They need to be cleaneable.

Replaceable

The overall principle of sliding the panels onto the mainframe and securing the grips works very well. The panels slide smoothly. At first this was a bit tight, but with a tolerance of 0.15mm this works like a charm. Appendix 13 shows the results of a user test where were asked to simulate this interaction of replacing the panels. The participants showed to quickly understand how it works and were easily able to perform the action, with one hand.

The principle of a snapfit was also tested. The principle did work but it is quite small detailing due to the parts being pretty small. Also the intereaction of taking of the panels is harder and is predicted to be hard to do with one hand.

Customizable

The SLA prints by formlabs have limited flexibility in color customizability. This is because in order to have specific color one would have to create the material cartridge entirely in that color. The formlabs color kit allows to create any color you want, but u would need a seperate material cartridge for each color, which is expensive.

For the FDM prints there are a lot of choices in filament colors allowing for flexible customizability.

Both FDM and SLA printed materials are able to be spraypainted or hydrodipped in order to customize the appearance. This would require sanding, priming and then spraying or dipping the parts.

Material quality

FDM prints are always a bit rough, even with a small nozzle size and will therefore always need some form of sanding to smoothen the part. SLA printed parts tend to come out very smoothly out of the printer and require very little maintenance in that aspect. However the support leave some spots. These need to be sanded off.

The parts have been exposed to some force to test how they perform. The PLA shows to be quite strong and does not break easily when trying to bend the product at critical points. Also standing on the parts does not seem to break it.

The rigid 4K is very stiff but also super brittle. The parts tend to break extremely easily where the design is critical. The prototype was tested by bending it and broke almost instantly. However it is important to say that the moddle was not optimized at that point and the critical part was relatively thin. Nontheless this does not change the fact that the rigid 4K is very brittle. It can be concluded that when opting for this mtterial one must take into account sufficient wall thickness.

The Tough material shows to be more flexible and therefore doesnt break as easily as the rigid 4K when being bend. However again, this model had a critical small wall thickness. The PLA part was moddeled with a wall thickness of 1.3 mm. It is recommended to stay close to this wall thickness to prevent the part from breaking. Appendix 11.3 shows the material properties of the tested materials.

Discussion

The sliding principle of the panels works very good and is very intuitive, as can be concluded from the user test in appendix 13.

SLA prints come out more smoothly then the FDM prints. Rigid 4K shows to be very brittle compared to the Rough material that is more flexible. The PLA shows to be quite strong and does not easily break when putting pressure on critical points. A wall thickness of atleast 1.3 mm is adviced.

Further testing is recommended on dishwasher proofness and exposure to heat. PLA is expected to deform when heated too much. Furthermore the principle of the screw has not been tested extensively due to limited time, it is adviced to also test this.

Finger motion

For the finger motion the flexion range was determined with the FDM prototype see figure 11.9. The fingers are not able to perform full anthropometric motion however they come close. The proximal phalangial joint. can perform a flexion motion of 78°. The middle phalangial joint can perform a flexion motion of 69°. The distal phalangial joint can perform a flexion motion of45 °.The middle and distal phalangial joints cannot perform a full 90° flexion due to the limitations of the mainframe motion. As long as the hand can perform the required grips, this should not be an issue.

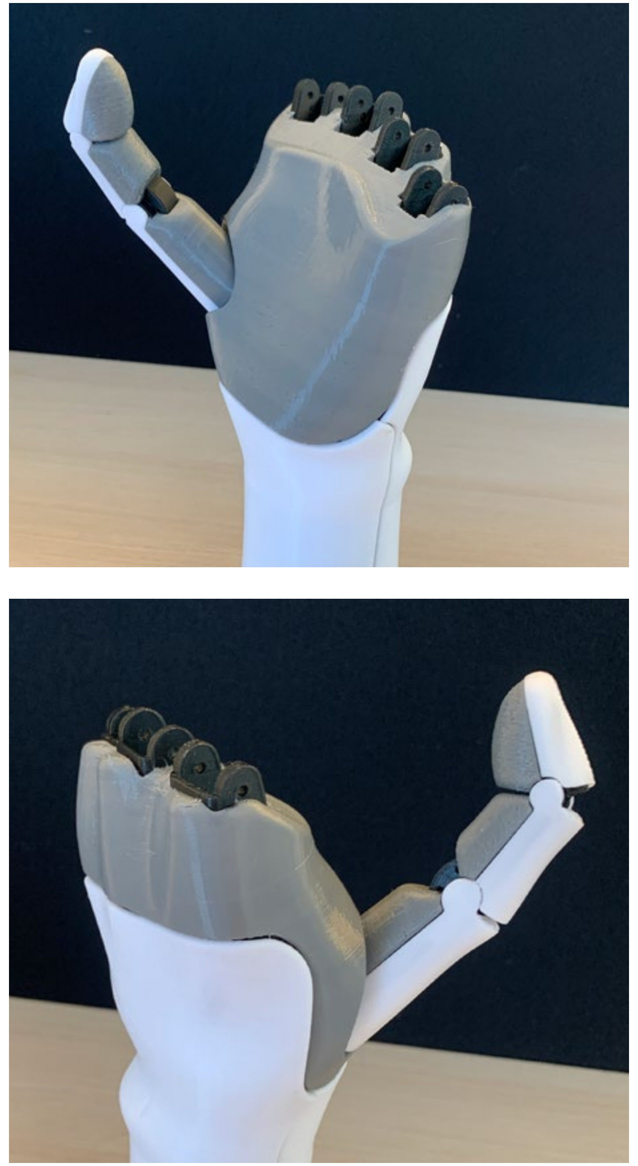


Figure 11.10: Hand grip

Figure 11.11: form connection panels and grip

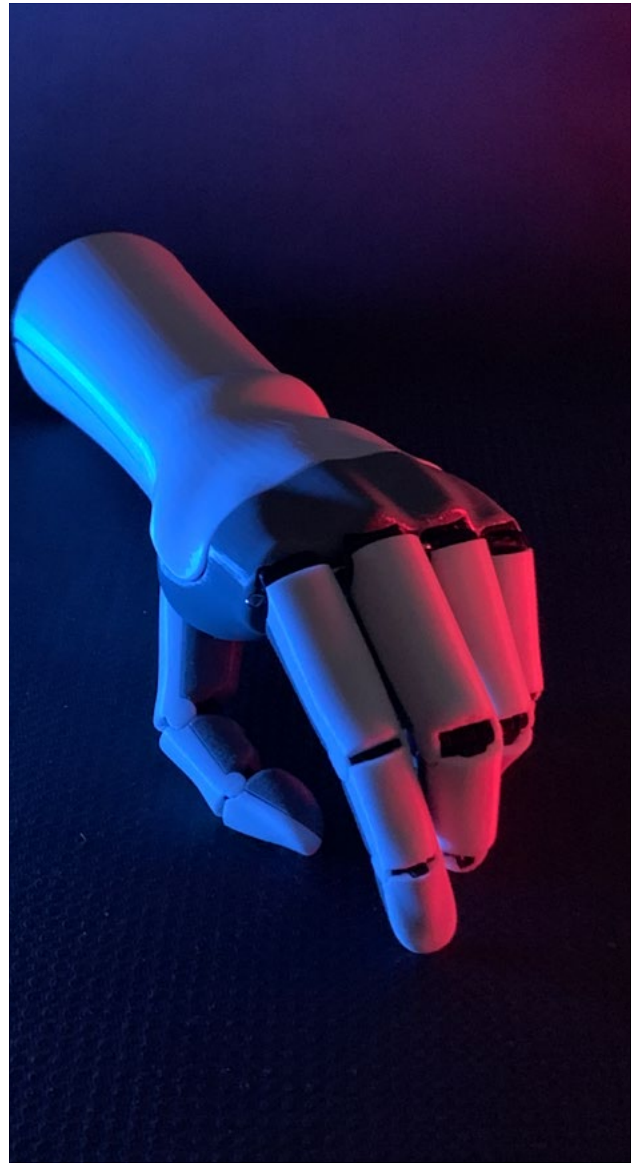


Figure 11.12: form connection panels and grip

11.2 Hand prototype

For the hand the flexible grip has been prototyped. This part covers most of the hand palm and the upper portion of the dorsal side of the hand.

Goal

Based on the Loughbourough Ideation cards the goal of the prototype is defined. The prototype is a functional prototype. The goal of the prototype is:

- Assess finger motion capabilities
- Assess material performance
- Assess replaceability
- Assess overall appearance

Flexible palm grip

The flexible palm grap is prototyped with an FDM printer using 95A TPU filament.

The requirements for this part is:

- Needs to be replaceable.
- Needs to be customizable in color.
- Needs to be safely secured.
- Needs to be cleaneable.
- Needs to show human hand features

Modularity

The TPU part is quite stiff. Getting the part on the mainframe is possible, but it is a little hassle. It is expected to be easier with a more flexible material. Also the part is only able to be put on the mainframe if the fingers are not attached.

Material quality

As for material quality the same conclusions as for the TPU grips apply here.

Aesthetics

The part has quite an interesting shape due to its organic nature and it flows perfectly into the design together with the palmar and dorsal panels. However, since the material is flexible, in the prototype it tends to bend inside or outside a little, disrupting the seemless organic shape. It is paramount that the part is secured very tightly in order to maintain this seemless shape, preventing it from bending at the edges.

Regardless of that little detail the human features like the knuckles and tendons which can be seen in a human hand that are included in the grip part and the dorsal panel form a nice unity in the product and create a form flow. As can be seen in figure 11.11.

Mobility

The hand grip is the connection point between the hand and the fingers. It is designed in such a way that the fingers can flex into the part without disrupting the shape of the hand to much. Furthermore the fingers are able to make an ab-/adducting motion. However due to time limitations that has not been included in this prototype. However due to the fact that the grip part is flexible it is expected that the fingers can move a little. This has to be tested though.

Discussion

The part in itself shows to be promising. It was probably one of the most complicated parts to create. Although appearance wise the part is good, the material does not have the desired properties yet. It is adviced to try the formlabs flexible and silicone. It is expected that silicone is the best candidate since it has the best grip characteristics. However it should also be durable enough and not break down by a simple knife cut. Also it should be furthe detailed how the part is attached to the mainframe, preventing it from deforming and breaking the overall shape.

Figure 11.13: Snap on magnet system

Figure 11.14: Hydrodip dorsal panel prototype test

Figure 11.15: Flexible TPU wrap system by Papenburg Orthopedics

11.3 Arm prototype

The Ellis arm consists of a mainframe with detachable arm panels that are connected with the use of strong magnets.

Goal

Based on the Loughbourough Ideation cards the goal of the prototype is defined. The goal is to have a functional model and also partly appearance model. Goal of this prototype:

- Assess magnet covers principle
- Assess customized panels look and feel
- Assess panel hydro dip quality
- Assess overall appearance

Arm panels

The arm panels are attached to the mainframe with the use of a magnet system. This has been prototyped with the use of FDM PLA printed arm panels. Within these panels designated spots have been modelled were magnets can be glued in with a diameter of 3mm and a height of 1.5 mm. The magnets were attached to the panels with the use of a glue gun. The same principle was applied to the mainframe.

The panels snap satisfyingly to the mainframe and have quite a good hold. The user test (appendix 13) also showed that people experience this interaction as satisfying. However bumping into something or applying too much force on it will make the panel come off.

Material quality

The panels have only been printed in PLA. PLA is not the strongest material and the shell of the arm only has a thickness of 2 mm. one could easily break this panel if too much force is applied to it.

Furthermore the prints are not 100% accurate, causing the panels to not fit seemlessly onto each other, and this can be seen in the model. This is undesireable.

Appearance

The panels have human arm characteristics integrated in the design. In the prototype this gives the product a very human look and it also feels organic and human. This has further been assessed in appendix 5.

Customizability

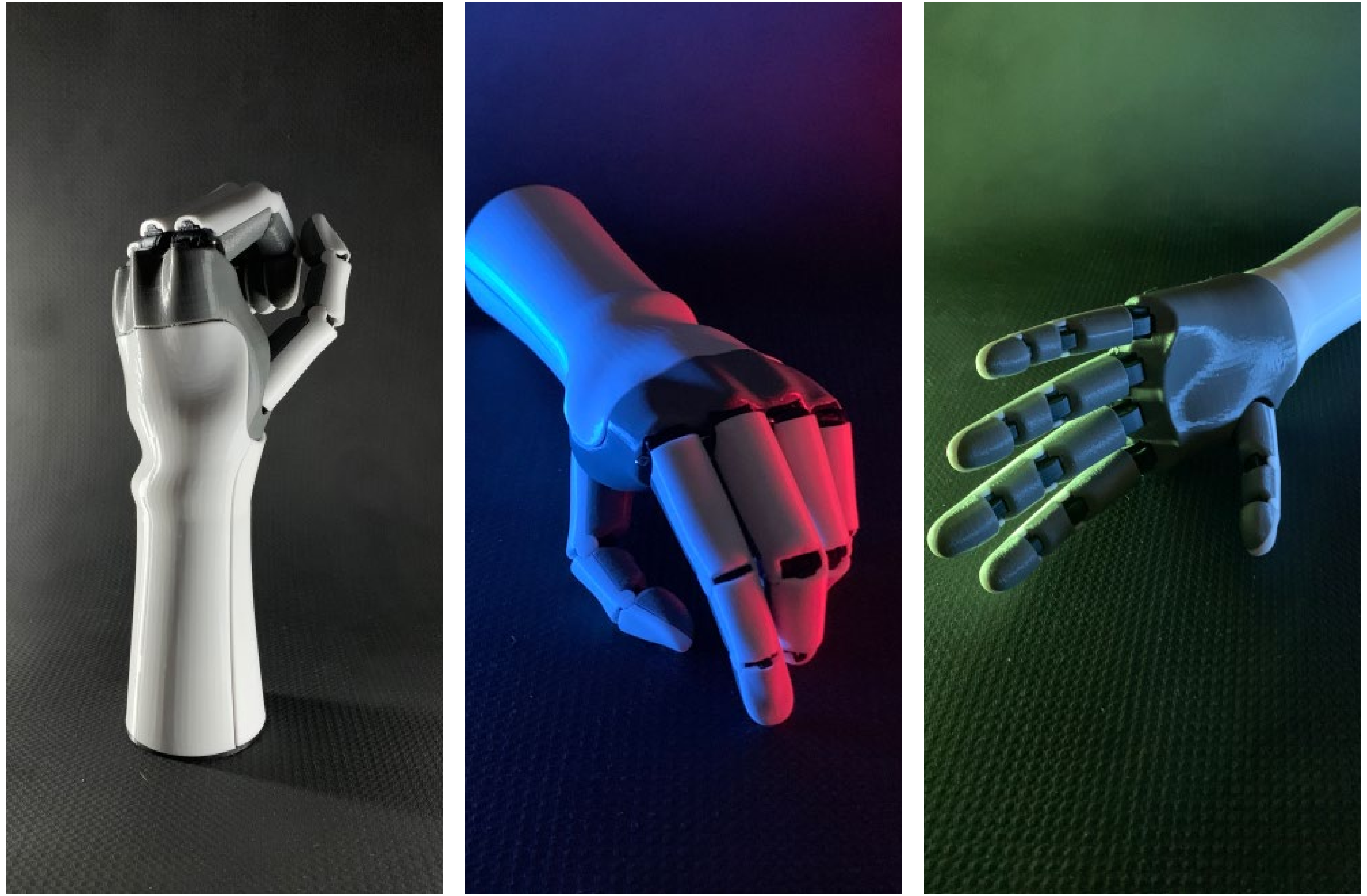
The dorsal panel of the arm has been tested for a hydro dip finish. Appendix 11.4 explains the hydrodip process more in detail. This was done to test the quality of this customization process. The result can be seen in figure 11.4. The part has been dipped at SK dipping in Rotterdam.

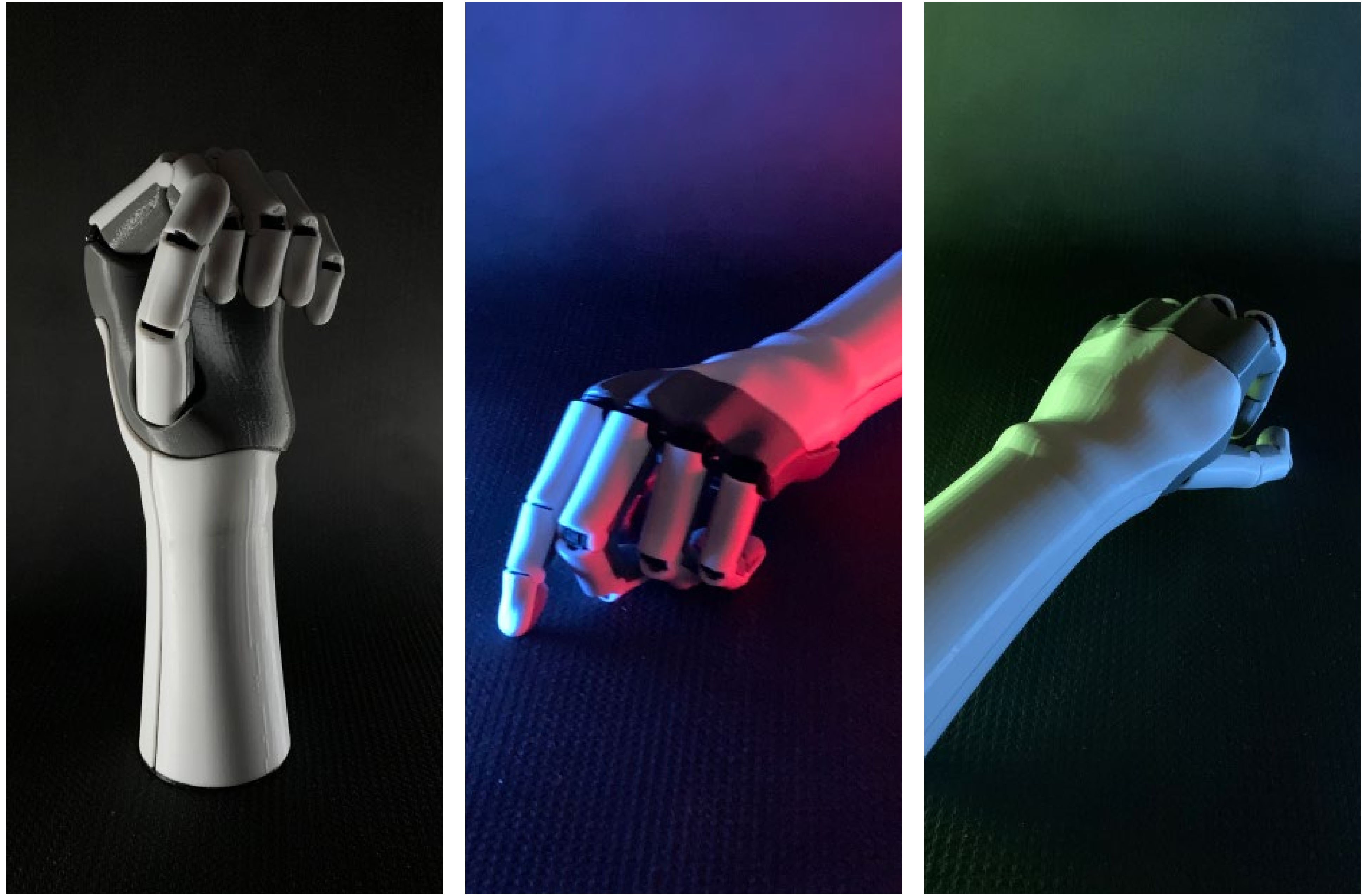
The hydro dip finish looks very good. For this prototype a carbon fibre print was chosen with a glossy finish coating. From a distance the part looks as though to be made out of real carbo fibre. When looking closer you can see it is actually a print.

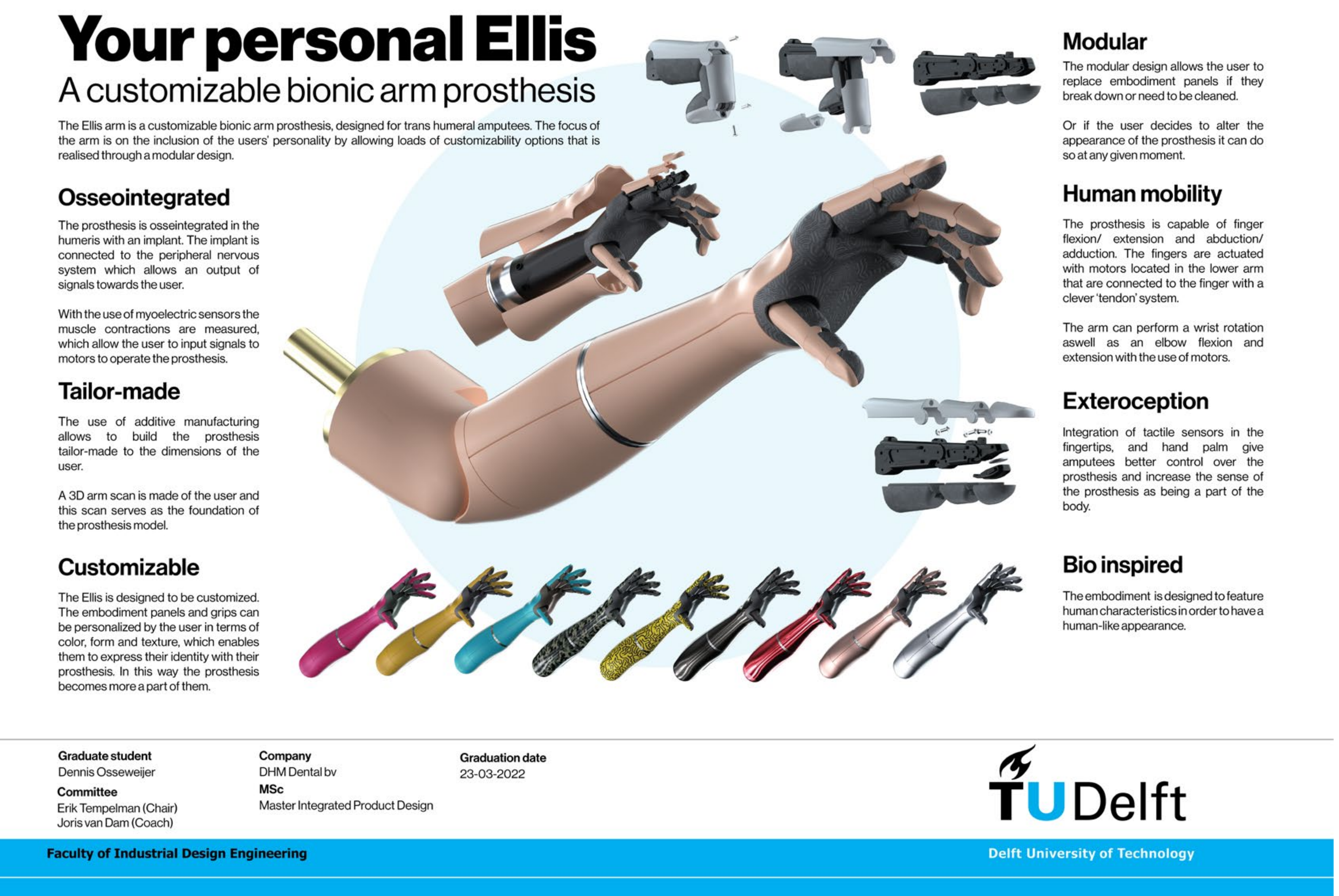
Discussion

The arm panels have been prototyped only in PLA. It is adviced to try other materials such as the tough with the SLA printer. Another option could be nylon, since this is much stronger then PLA.

Although the hydrodip finish looks extremely good and allows for great customizing options, the downside is that it scratches really quick. Over time this might look ugly. Another material that might be worth investigating is TPU. This also allows for a different principle to attach the part to the mainframe since it is flexible and can therefore be wrapped around the product, as was done by Papenbrug Orthopedics. See figure 11.5.







Your personal Ellis

A customizable bionic arm prosthesis

The Ellis arm is a customizable bionic arm prosthesis, designed for trans humeral amputees. The focus of the arm is on the inclusion of the users' personality by allowing loads of customizability options that is realised through a modular design.

Osseointegrated

The prosthesis is osseintegrated in the humeris with an implant. The implant is connected to the peripheral nervous system which allows an output of signals towards the user.

With the use of myoelectric sensors the muscle contractions are measured, which allow the user to input signals to motors to operate the prosthesis.

Tailor-made

The use of additive manufacturing allows to build the prosthesis tailor-made to the dimensions of the user.

A 3D arm scan is made of the user and this scan serves as the foundation of the prosthesis model.

Customizable

The Ellis is designed to be customized. The embodiment panels and grips can be personalized by the user in terms of color, form and texture, which enables them to express their identity with their prosthesis. In this way the prosthesis becomes more a part of them.

Modular

The modular design allows the user to replace embodiment panels if they break down or need to be cleaned.

Or if the user decides to alter the appearance of the prosthesis it can do so at any given moment.

Human mobility

The prosthesis is capable of finger flexion/ extension and abduction/ adduction. The fingers are actuated with motors located in the lower arm that are connected to the finger with a clever 'tendon' system.

The arm can perform a wrist rotation aswell as an elbow flexion and extension with the use of motors.

Exteroception

Integration of tactile sensors in the fingertips, and hand palm give amputees better control over the prosthesis and increase the sense of the prosthesis as being a part of the body.

Bio inspired

The embodiment is designed to feature human characteristics in order to have a human-like appearance.

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Dennis Osseweijer

Committee
Erik Tempelman (Chair)
Joris van Dam (Coach)

Company
DHM Dental bv

MSc
Master Integrated Product Design

Graduation date
23-03-2022

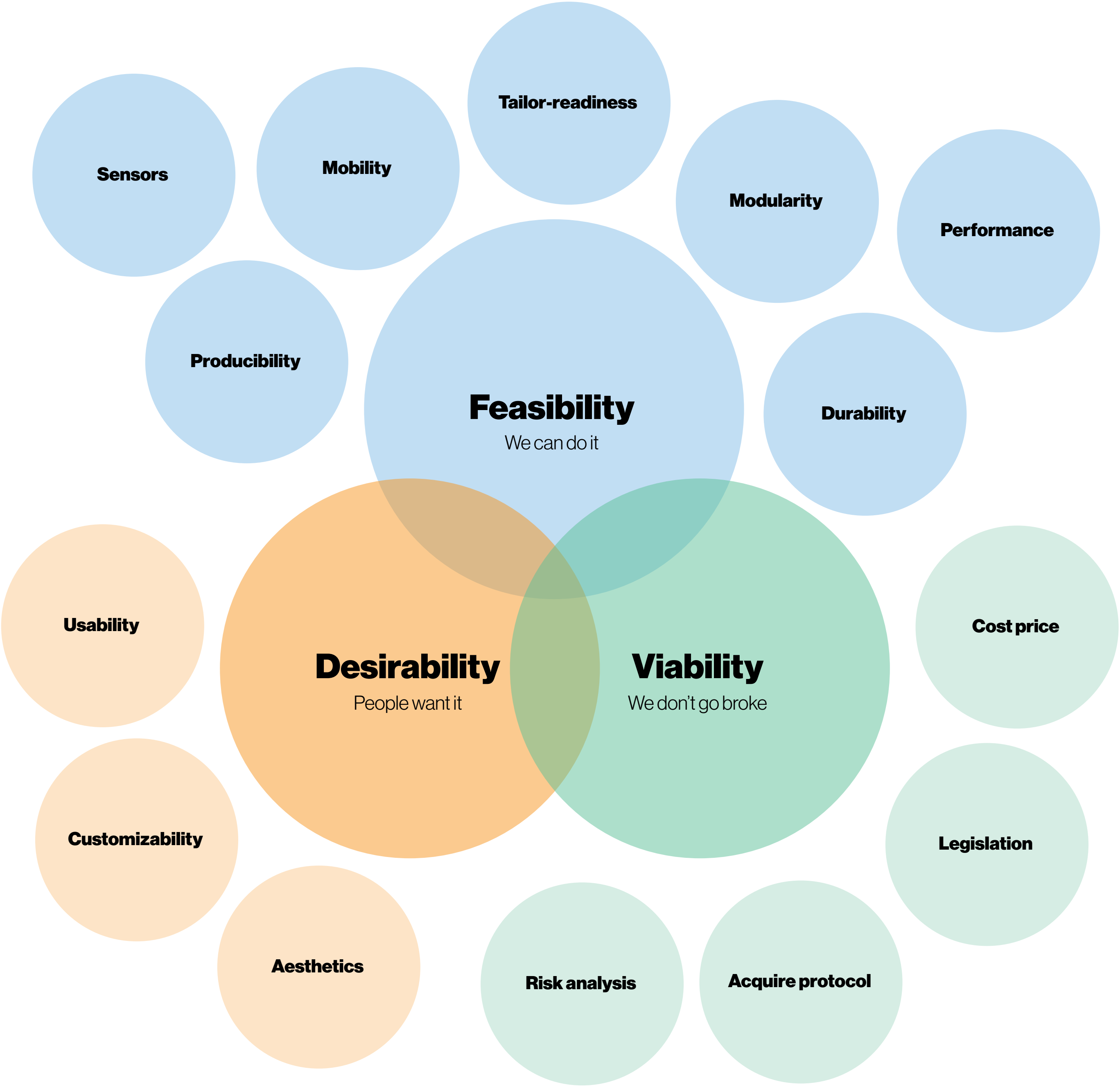
TU Delft

Faculty of Industrial Design Engineering

Delft University of Technology

12
Product presentation

Final product presentation.



13
Validation

In this chapter the validation of the product will be discussed. For a product to be succesful it needs to feasible, viable and desireable.

Feasibility

For feasibility it is interesting to investigate wether it is possible to produce the product. Do we have the resources, do we have the required partners. Do we meet the drivers related to the feasibility of the product.

The things investigated for feasibility are:
- Producibility
- Mobility
- Tailor-made readiness
- Modularity
- Durability
- Performance
- Customizability

Viability

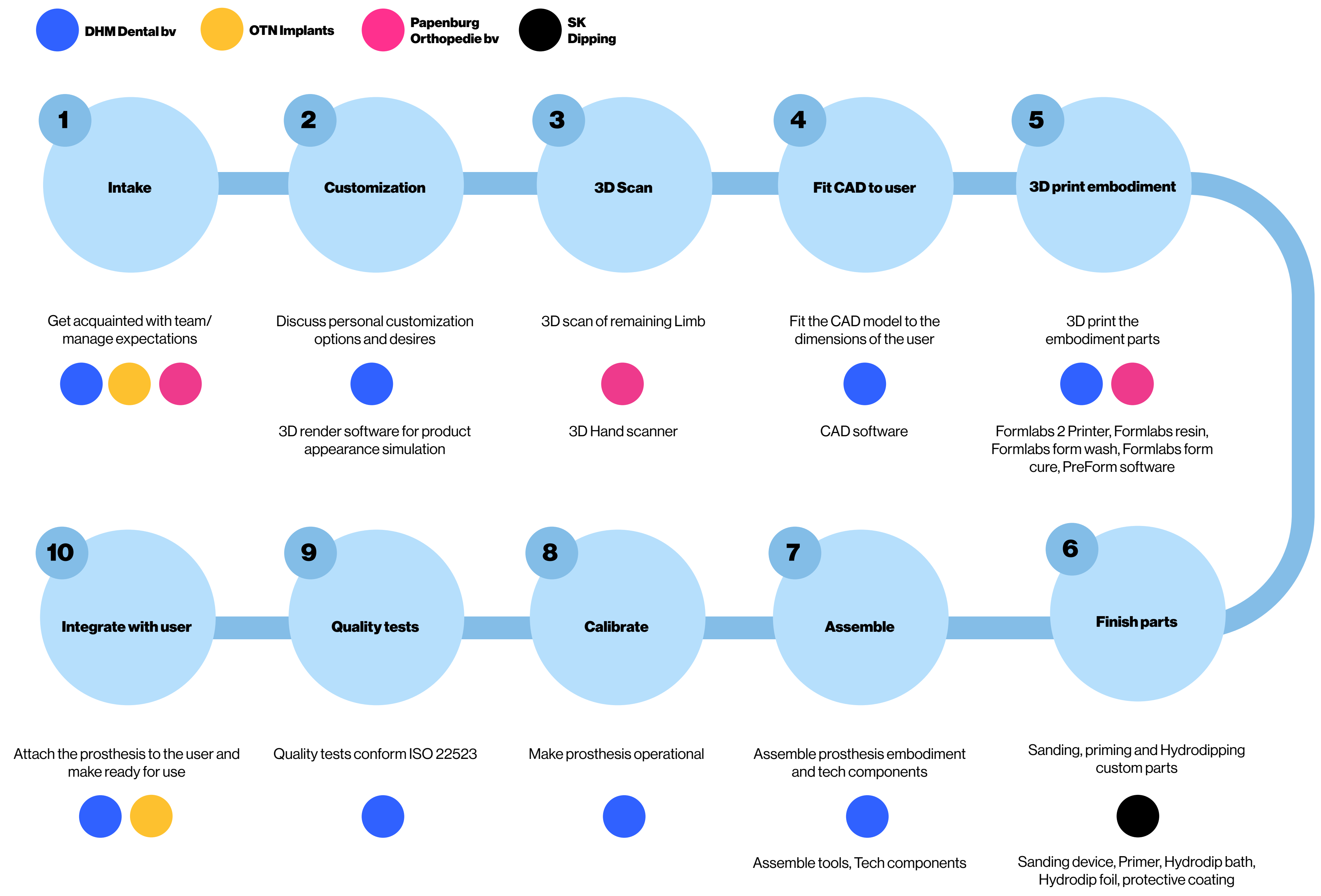
Viability covers the bussiness aspect of the product. The product has to have a financially stable business case. The product has to sell, otherwise it is worthless. The product also has to meet certain standards to be introduced to the market because it is a medical product.

The things investigated for feasibility are:
- Cost price
- CE legislation
- Risk analysis

Desirability

Desireability is about wether the product fulfills the users needs. If the user doesnt like the product, it will be rejected.

The user needs that are investigated here are:
- Customizability
- Aesthetics
- Usability



13.1 Feasibility

Can DHM dental produce this product. Does it have the required resources? Do we meet all the requirements? Do we need other companies to create specific parts?

Producibility

Figure on the left page shows a simplified overview of the key production process steps with its required resources and/or partner responsible.

1. In step 1 the whole team can get acquainted with the patient and discuss the process of creating the prosthesis.
2. In step 2 DHM Dental and the patient can create a vision for the design appearance of the prosthesis. It is good to establish in the beginning before diving into the CAD model. This step has been simulated with Bert Pot and can be found in chapter 13.3 Desirability.
3. The next step is to acquire a 3D scan of the remaining arm of the patient, which serves as an underlayer for the dimensions and arm type of the prosthesis. Papenburg Orthopedics owns a sophistitaced 3D body scanner and is experienced with making body scans due to their leg prosthetics business.
4. In step 4 the CAD model is altered to fit the 3D arm scan. If the CAD model is setup modular and parametrical enough it can be easily altered to fit the dimensions of the user. However this requires a really strong and sophisticated CAD model.
5. Once the CAD model is finished the embodiment parts are ready to be 3D printed. The prototypes of the SLA prints have shown that it is feasible to use this production method. Also the material quality of the prints show to be promising.
6. The 3D printed parts are a bit rough and need finishing. Also the outer embodiment parts require the custom finish. SLA prints are very smooth, but have some rough points where supports are needed for the print. These can be sanded of and covered with a smooth primer. The hydrodip company SK dipping has shown that a hydrodipped part looks of high quality.
7. Once every part is finished the product is ready to be assembled. Tech components are installed in the right place. Although out of scope for this project, Daan and Willem have shown to be able to make a working prototype of the motor components. With further development this shows to be promising and will work.
8. Once all the components are in place the product can be turned on and calibrated.
9. Quality tests are mendatory to comply with the ISO22523 for prosthesis.
10. Once the product is ready to go it can be integrated with the user and made operational. This part is also out of scope and has yet still to prove to work. This is a step that has to be validated further down the road of this entire project.

It can be concluded that the required resources and partners for the production steps are within reach for DHM Dental bv and that the process steps within this project scope are feasible.

Tailor made

The product is to be tailor made to the user dimensions. A bigger arm is not a problem since every component will fit easily. The challenge is smaller hand and arms. It is tested if a P5 arm can still house all the required components, however this was done with components that have already been changed in size again. It is therefore adviced to look at the P5 arm size table and check if the components that are going to be used will still fit in the mainframe. Otherwise the mainframe has to get bigger.

Modular

The prosthesis is designed to be modular. Wearing and tearing/customized parts can be replaced by the user. The process of disassembly has been tested with a user test and can be found in chapter 13.3 desirability. This process has shown to be easy and satisfying.

Durability

The state of the art analysis in chapter 5 has shown that in order to compete with the other models it is required that the prosthesis is atleast IP67 certified which means that water and dust cannot penetrate the product were it is crucial for components not to get wet. Although not tested the design has been created in such a way that all components prone to getting damaged by water are conceiled and protected with the use of the watertight mainframe. The further development of this mainframe is out of scope. It is recommended to prototype this and make sure it is IP67 certified.

Furthermore the product is prone to getting dirty. It is desired that the product is easily cleaneable. Although there is not enough time to do a full scale cleanability test, it has been tested whether the material used for the replaceable parts is dishwasher proof and can therefore be easily cleaned. The SLA printed parts show get clean easily in the dishwasher without damaging. A bigger test for this is recommended with multiple cycles.

Furthermore parts are prone to bumping into everyday objects and damage and scratch. Therefore it was tested how scratch resistant the parts are. The hydrodipped parts show to be scratch resistant when bumped into objects multiple times. Also scratching the part with a car key leaves only minor scratches.

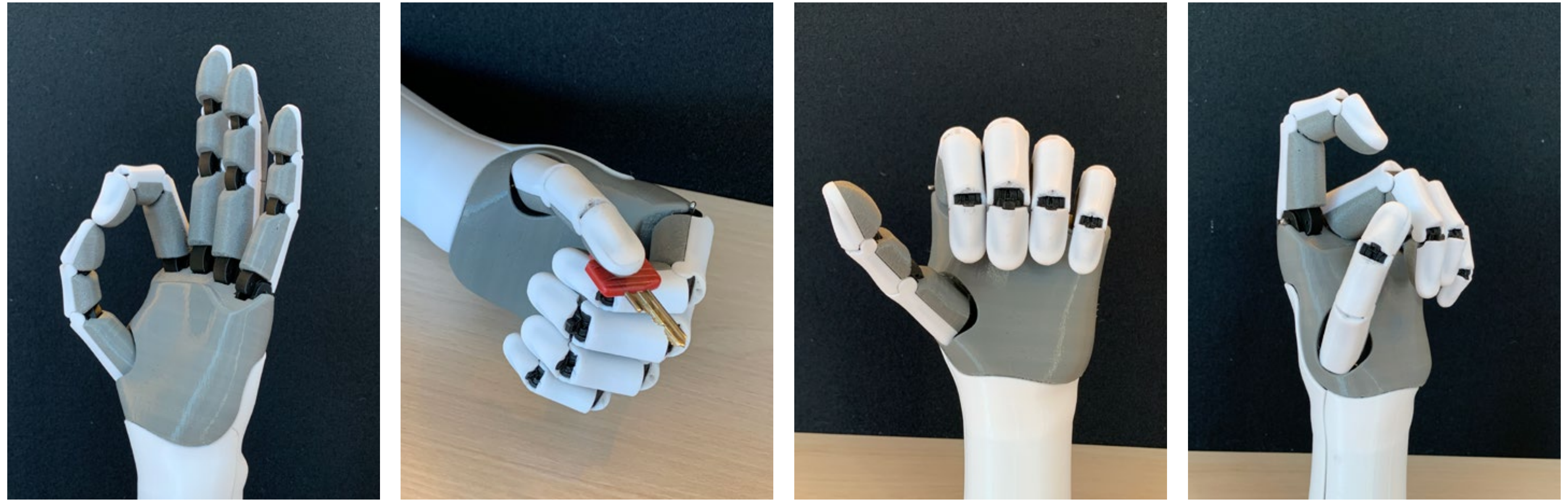


Figure 13.1: Grip types from left to right: Fine grip, key grip, hook grip, tool grip. Note this model is not actuated by motors.

Figure 13.2: Finger flexion capabilities test

Figure 13.3: Pololu Force sensing resistor 0.25".

Mobility

In terms of mobility the prosthesis must be able to perform a set of specific motions. These motions were defined in the analysis phase of chapter 5.

Grips

The prosthesis is required to be able to perform atleast the 6 most used grips in ADLs defined in chapter 5. 6 most used grip according to Earley et al. (2016):

1. Chuck grip
2. Fine pinch
3. Key grip
4. Power grip
5. Hook grip
6. Tool grip

The prototype shows that it is able to perform a fine pinch, key grip, hook grip and tool grip. Power grip and chuck grip are not possible due to the thumb not being able to move into an opposing position. It is recommended to have this possibility for the thumb, as it allows to create more grip variations and atleast the 6 most commonly used grips.

Finger motion

The fingers are not able to perform full anthropometric motion however they come close. The proximal phalangial joint. can perform a flexion motion of 78°. The middle phalangial joint can perform a flexion motion of 69°. The distal phalangial joint can perform a flexion motion of45 °.The middle and distal phalangial joints cannot perform a full 90° flexion due to the limitations of the mainframe motion. As long as the hand can perform the required grips, this should not be an issue.

Wrist motion

The wrist must be able to perform a pronation and supenation motion. Analysis in chapter 5 shows that according to DINED 2021 a P95 wrist pronation is 139.5 degrees and a wrist supenation is 118.9. Since the wrist can theoratically rotation 360 degrees this requirement is met. However cables that go through the arm should not get messed up during this motion. This should be taken into account.

Elbow motion

The elbow must be able to perform a flexion and extension motion. DINED (2021) shows that P95 females can perform a extension motion of 90degrees and a flexion motion of 75.9 degrees. The embodiment of the elbow is out of scope for this project. In furtger development of the arm it should be taken into consideration that the arm can perform this range of motion, in order to mimic anthropometric ergonomic motion.

Performance

The product has to be able to carry certain weights and needs to have sufficient grip.The state of the art analysis in chapter 5 has shown the performance of competitors.

Grip

It is required that items used in ADL do not easily slip out of the hand. the 95A TPU FDM printed grip pads have been tested on their grip. However these have shown not always provide desireable grip. Objects sometimes easily slipped out. The flexible 80A showed more grip than the TPU 95A. The silicone grips however showed to provide the best grip. It is recommended to use a lower shore material then 95A.

Strength

The product has to be able to carry certain weights and needs to have sufficient grip.The state of the art analysis in chapter 5 has shown the performance of competitors. However DHM Dental bv has made the following requirements for the prothesis:

- Hook grip 30 [kg]
- Force on wrist 12 [kg]
- Force on handpalm 12 [kg]

ISO 22523 shows guidelines for testing the strength of the product. Unfortunately there is not enough time in this project to perform this test. Since the product is not yet equiped with the motors. It is recommended to perform this test to validate whether the product matches the strength requirements.

Sensors

The analysis in chapter 5 has shown that a gentle touch is around 0.1 [N]. The polulu tactile sensors are capable to sense forces as small as 0.2 [N]. The sensors come close. Further sensor testing is still required on the full prototype model.

Conclusion

Product shows to be producable. The key activities, resources and partners have been explored and show to be feasible. Since the product is in such an early development state the process might obviously change and new partners or resources might have to be acquired.

The product shows to meet most of the set requirements and drivers. It needs some modifications at some points. And some more elaborate testing on some points is required such as strength tests and durability tests.

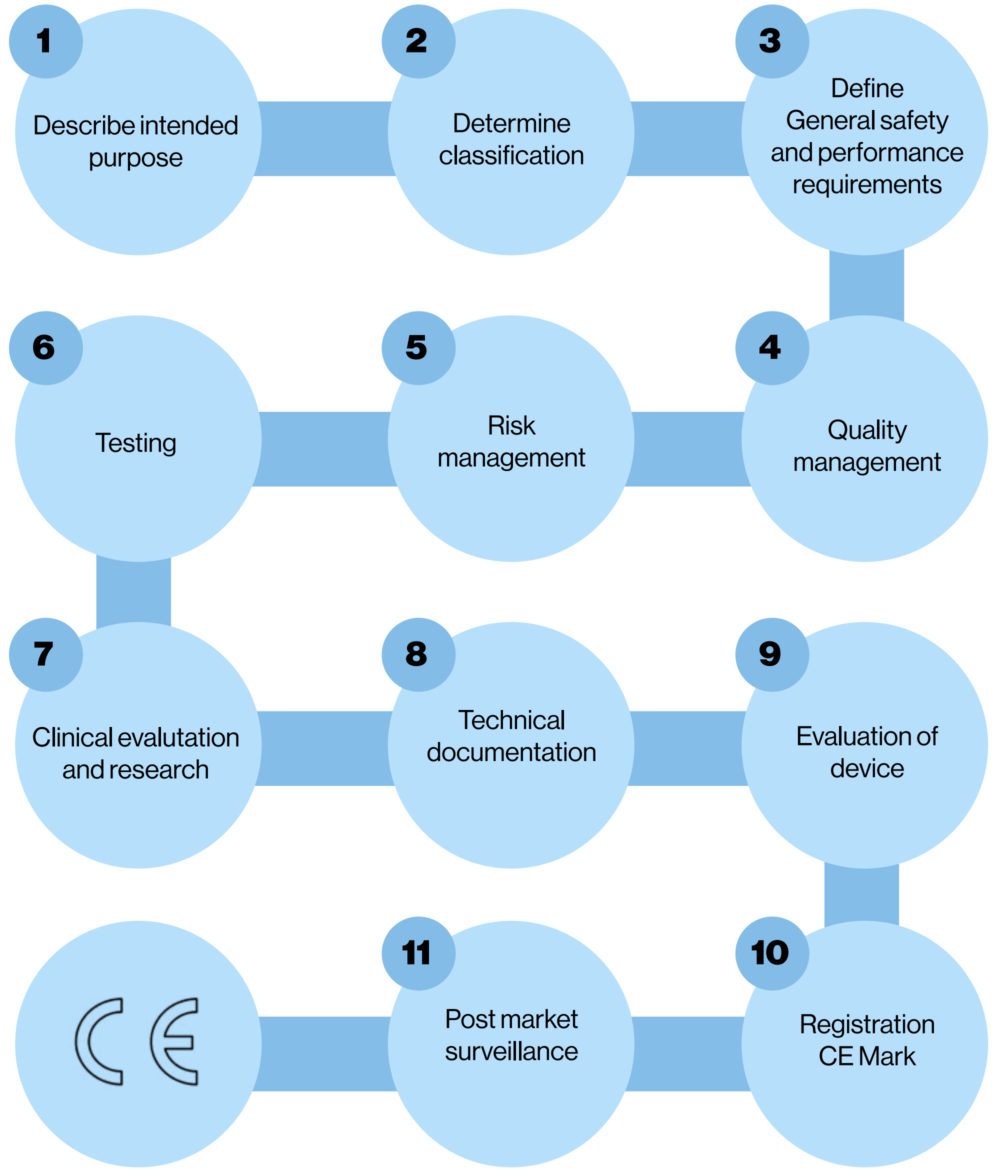


Figure 13.4: CE Roadmap

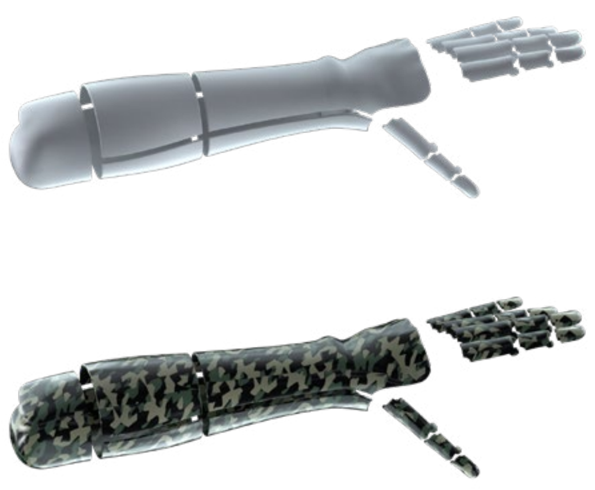


Figure 13.5: Ellis starterbundle - 1 set regular panels + 1 set custom panels.

Figure 13.6: Expand Ellis appearance panels by acquiring a new set. Custom keith Haring for example.

13.2 Viability

In this chapter the product viability is assessed. The main question here is: Does the product have a viable business case? The cost price determined in chapter 10.3 is used to determine whether the product can be viable. Furthermore there has be a consultation with medical product viability exper Tessa Souhoka. Besides this expert consultation a docter responsible for prostheses has been cosulted at the Erasmus MC to validate the product.

Financial

Prostheses can be extremely expensive and often have to be covered by a healthcare insurance plan. In order to receive a prosthesis the patient needs to go through an entire protocol. In the Netherlands there is the 'PPP' (prothese prescriptie protocol).

The cost price has been estimated in chapter 10. Factors that influence the cost price the most are the Tech components and the Labour costs. However the tech components are not yet definitive, therefore the cost price is a rough estimation. With the estimation made currently the cost price for the prosthesis is €20-25k. A rule of thumb is to multiple this by a factor 3-5 as stated by NSFD (Tempelman, 2022). This will result in a price of €80-100K. This is excluding the costs of acquiring the implant and also excluding taxes.

This is within the range of the iLimb. As long as the Ellis has enough value to be selected it can be viable within this price range, otherwise the healthcare insurance plan will not cover the costs for acquiring an Ellis. That would mean that patients will have to buy their own Ellis and there is not many people who can easily spend €100K out of pocket on a robotic arm. However the Ellis arm is extremely innovative and is disrupting the field of prosthesis with the integration of tactile feedback and its options for customizability. Therefore it is safe to say that the Ellis does have a lot of unique selling points that might help in the selection procedure.

Another business case are the customizable panels. The print costs for the panels are around 60€; the hydrodipping costs are 350€. This means that the production price of 1 set of customized panels costs €410. If the product is sold with a factor 2, the product will cost around €800,-. The full prosthesis can be initially sold with 1 set of regular panels (a lot cheaper) and 1 set of customized panels like a starterbundle. If the patient decides to want more customized panels it can order a new set for €800,-. €800,- might seem like a lot of money, but we are talking about someones arm. One might expect that someone finds a lot of value in being able to alter the appearance of their arm. This is validated in chapter 13.3 desireability.

Legislation

An interview was held with medical product validation expert Tessa Souhoka about the validation of this prosthesis. Medical products have to meet specific medical legislations in order to be viable. The most important ones for this product is the CE marking, the MDR and the ISO 22523.

ISO 22523

ISO 22523 describes requirements and performance tests specifically for upper limb prostheses. In appendix 5 the important requirements are described. Furthermore the ISO 22523 PDF will be provided to DHM Dental.

CE Roadmap

In order to obtain a CE certification for a medical device the product has to meet certain standards and requirements. CEtool.nl provides a 11 step roadmap to achieve this CE certification. In appendix 5 these steps are described and also in figure 13.4.

there are four classifications for medical devices: I, IIa, IIb and III. The classification is based on risk. Higher risk for a patient if a product fails results in higher classification.

Based on the rules of the MDR Annex VIII the prosthesis is a class IIa active therapeutic device.

Discussion

Is the product viable? It could be. As long as it has more to offer then the current protheses within the price range of 80-100K. Is the customizable panel side business viable? If the value of having customized prosthesis appearance is high enough and people see value in having multiple sets of customized panels costing €800,- , then yes.

Furthermore it has to comply with all the regulations of the MDR and ISO22523. However it is hard to say this early in development of this project, where many choices still have to be made and there is basically just a first prototype. However it is valuable to keep a viable business case in mind, to avoid any unexpected surprised which might ruin the product launch later on in the product development.

		Severity				
		Negligible	Limited	Moderate	Severe	Critical
Occurrence	Improbable	Low	Low	Low	Medium	Medium
	Remote	Low	Low	Medium	Medium	High
	Occasional	Low	Low	Medium	Medium	High
	Probable	Low	Medium	Medium	High	High
	Frequent	Low	Medium	High	High	High

Figure 13.7: FMEA rating guide provided by DHM Dental

A13.3 FMEA

A risk analysis has been done together with DHM Dental. The potential risk of the design and use are examined. This was an open brainstorm where stimuli were provided such as the prototype and images of the product.

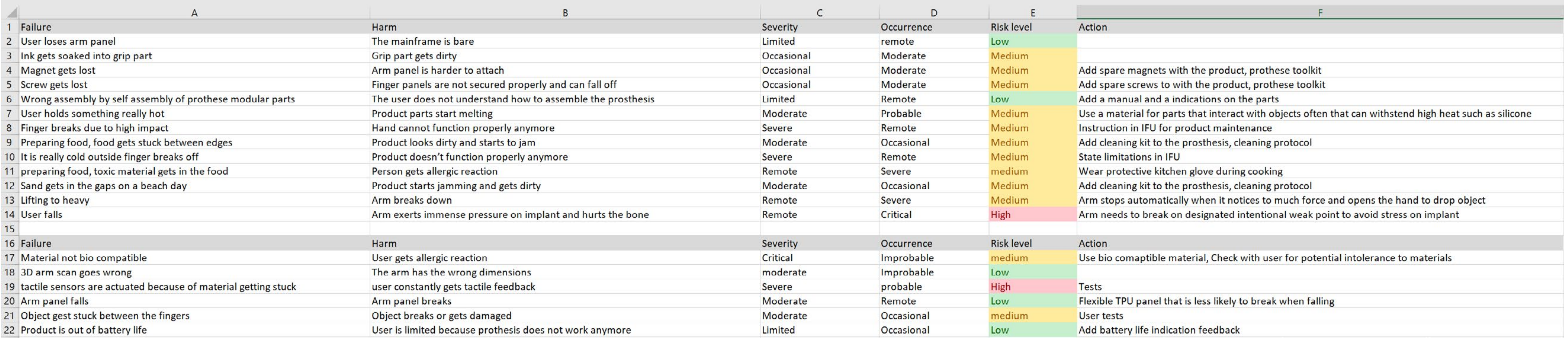
Hazards were brainstormed for use and design and were written down on a sticky note and placed on big white sheets. For each risk the potential effect has been brainstormed. For each effect the Occurence and Severity are rated based on the table of figure 13.7. If the result is medium of high it means that the risk and effect require action.

Discussion

A lot of the failures and harms can be preventing by stating in the IFU what the limitations and proper use of the prosthesis are.

other solutions is providing instruction manuals for certain specific tasks such as replacing the panels or a cleaning and repair kit with cleaning tools and spare parts.

Some actions require user tests to figure out the severity.



	A	B	C	D	E	F
1	Failure	Harm	Severity	Occurrence	Risk level	Action
2	User loses arm panel	The mainframe is bare	Limited	remote	Low	
3	Ink gets soaked into grip part	Grip part gets dirty	Occasional	Moderate	Medium	
4	Magnet gets lost	Arm panel is harder to attach	Occasional	Moderate	Medium	Add spare magnets with the product, prothese toolkit
5	Screw gets lost	Finger panels are not secured properly and can fall off	Occasional	Moderate	Medium	Add spare screws to with the product, prothese toolkit
6	Wrong assembly by self assembly of prothese modular parts	The user does not understand how to assemble the prosthesis	Limited	Remote	Low	Add a manual and a indications on the parts
7	User holds something really hot	Product parts start melting	Moderate	Probable	Medium	Use a material for parts that interact with objects often that can withstend high heat such as silicone
8	Finger breaks due to high impact	Hand cannot function properly anymore	Severe	Remote	Medium	Instruction in IFU for product maintenance
9	Preparing food, food gets stuck between edges	Product looks dirty and starts to jam	Moderate	Occasional	Medium	Add cleaning kit to the prosthesis, cleaning protocol
10	It is really cold outside finger breaks off	Product doesn't function properly anymore	Severe	Remote	Medium	State limitations in IFU
11	preparing food, toxic material gets in the food	Person gets allergic reaction	Remote	Severe	medium	Wear protective kitchen glove during cooking
12	Sand gets in the gaps on a beach day	Product starts jamming and gets dirty	Moderate	Occasional	Medium	Add cleaning kit to the prosthesis, cleaning protocol
13	Lifting to heavy	Arm breaks down	Remote	Severe	Medium	Arm stops automatically when it notices to much force and opens the hand to drop object
14	User falls	Arm exerts immense pressure on implant and hurts the bone	Remote	Critical	High	Arm needs to break on designated intentional weak point to avoid stress on implant
15						
16	Failure	Harm	Severity	Occurrence	Risk level	Action
17	Material not bio compatible	User gets allergic reaction	Critical	Improbable	medium	Use bio comaptible material, Check with user for potential intolerance to materials
18	3D arm scan goes wrong	The arm has the wrong dimensions	moderate	Improbable	Low	
19	tactile sensors are actuated because of material getting stuck	user constantly gets tactile feedback	Severe	probable	High	Tests
20	Arm panel falls	Arm panel breaks	Moderate	Remote	Low	Flexible TPU panel that is less likely to break when falling
21	Object gest stuck between the fingers	Object breaks or gets damaged	Moderate	Occasional	medium	User tests
22	Product is out of battery life	User is limited because prothesis does not work anymore	Limited	Occasional	Low	Add battery life indication feedback

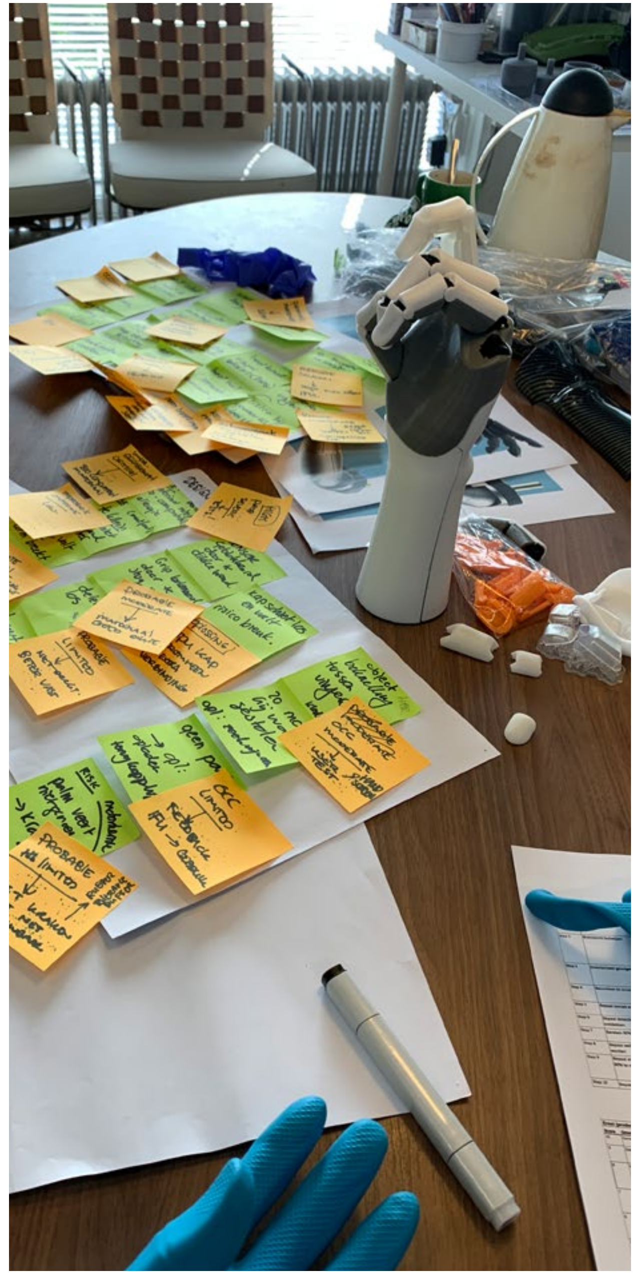


Figure 13.8: Custom designs Bert Pot

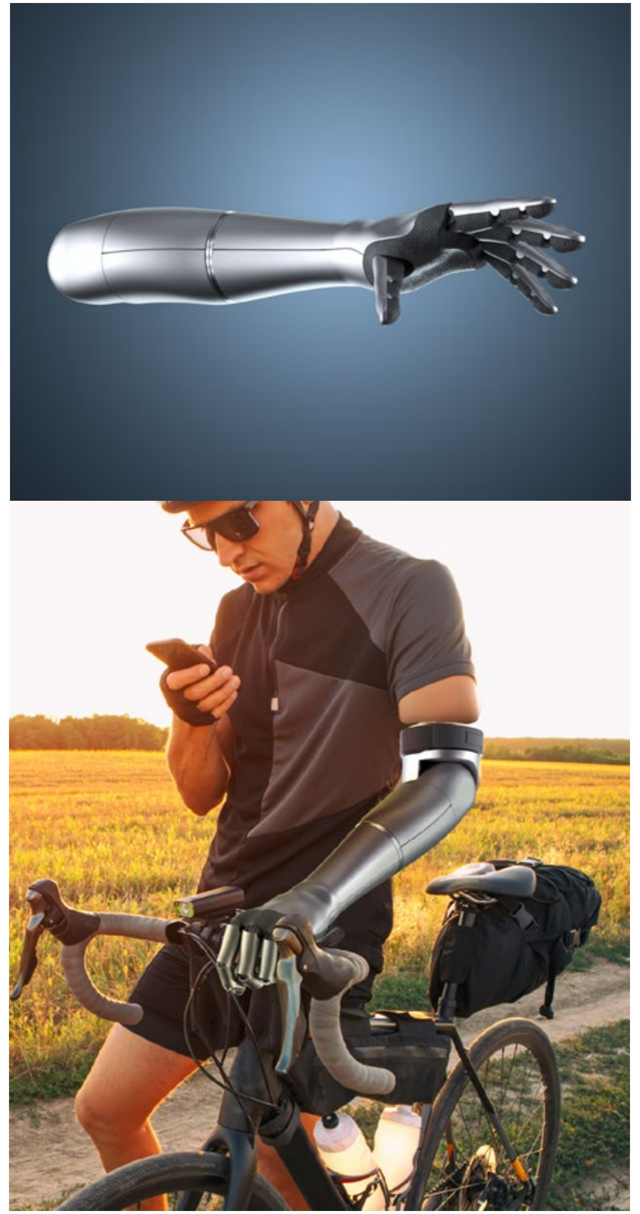


Figure 13.9: Aesthetics conclusion

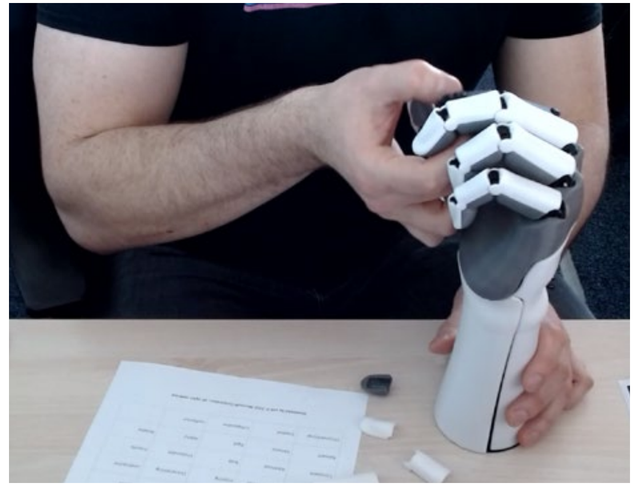


Figure 13.10: Usability research

13.3 Desirability

For the product desirability it is important to determine wether the user is happy with the solution. The question is: Did we solve the right customer problem. The customer desires that were focussed on fulfilling are customizability, aesthetics and modularity.

13.3.1 Customizability

One of the desires for prosthesis users is that of customizibility in order to express themselves. For this validation the product has been presented to Bert Pot and together we designed 4 custom designs for him.

The conclusion of this interview and colaberative design session was that he sees great value in the broad option for custom designs and that this will increase the acceptance of prosthesis. he stated:'In this way the prosthesis really belongs to me'.

When asked what custom designs he would like to have he stated that he would base it on different occassions. On a bright summer day Bert would prefer a bright yellow design. On a more regular work day Bert would like a cool camo print or a tattoo sleeve. Another design could be a photo of his family integrated in the arm panels. Bert could also see himself play around with the different covers and make combinations, the options are endless. This flexibility he thinks is 'amazing'.

Ofcourse this is the opinion of someone who likes an expressive design. When interviewing Lisette she indicated that she likes the design, but that she would prefer an arm that looks more cosmetic, thus rather with a sleeve. Therefore it is important to note that this prosthesis design is not for everyone.

13.3.2 Aesthetics

Another desire is for an aesthetical pleasing and neat design. A way to assess the aesthetics of a product is by using the 9 moments of product experience.

Human product interaction can be categorized in three different levels: micro, macro and meta level. Aesthetics has been assessed based on unity, variety, typicality and novelty. Meaning as the perceived character of the product and emotion the perceived emotion the product evokes.

A questionaire has been executed for assessing the perceived product appearance on a micro level. 16participants ranging from age 23 to 61 were asked to answer questions assessing the product on micro level for its aesthetics, meaning and emotion. Full research can be found in appendix 13.

It can be concluded that the participants were overall positive about the perceived appearance. The product is perceived as a uniform whole. But is still interesting enough by the use of different materials that add variety to the design. The product is recognizable and comprehensable, but still looks innovative and futuristic.

The product looks innovative, futuristic and clean. Which are quite positive characteristics. However as stated in chapter 5 there are two different kinds of prosthesis users, the ones that want to hide it and the ones that want to express it. It is understandable that the prosthesis might not be the right fit for prosthesis users that want it to be more discrete.

The product evokes postive emotions such as proud, inspiring and exciting. This is because it is very innovative and a development for a noble cause. Negative emotions are due to the tragic related to prostheses. People feel bad for that.

13.3.3 Usability

For usability the interaction of replacing the modular body panels has been tested. 6 participants have been asked to perform the replacing of the panels only using one hand. They were asked to think out loud and afterwards to point out 5 words from a product reaction card sheet that describes the interaction they had with the product. They were then asked to elaborate on the chosen words.

It can be concluded that the interaction is quite straight-forward and easy to learn. It requires some learning curve, but after a while every understands how to do it. After that it is even perceived as satisfying.

Some recommendations are to add indication marks in the grips that indicate how to part should be orientated.

Another advice was to include some sort of ikea manual that explains the intereaction that gives the user some guideline when it is first encountering the product.

Discussion

It can be concluded that the product concept has value. The inerview with prosthesis user Bert Pot clearly showed that he was excited about it and that the cutomizability is a great addition as he stated:'In this way the prosthesis really belongs to me'. However it is advised to assess the concept on more prosthesis users.

In terms of aesthetics the research showed overall positive reactions to the appearance on a micro level.

The modular parts showed easy to disassemble and assemble, as can be concluded from the usability research. However more thorough usability research is advised, when the product is in a further development stage.

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Conclusion

There is a lot of development going on in the domain of bionic upper limb prostheses. A major innovation is the use of osseo-integration and using myoelectric sensors to actuate fingers with muscles and connecting tactile sensors to the nervous system to 'restore human touch'. In this master thesis an embodiment concept is made for a osseo-integrated bionic arm prothesis for trans humeral amputees.

The design is the result of an extensive analysis of the state of the art, interviews with the target group and experts, analysis of anthropometric ergonomical capabilities and dimensions and an analysis to human touch. The state of the art analysis shows great opportunity in terms of customizability and gives a clear overview of the market segments. Furthermore performance capabilities such as strength, durability and unique selling points are investigated. Target group interviews show user needs and desires. Notable is the desire for an appealing design, customizability options and matching prosthesis dimensions. Including sensory feedback adds immense value to the prothesis since this add to the sense of body ownership; the product belonging to the body.

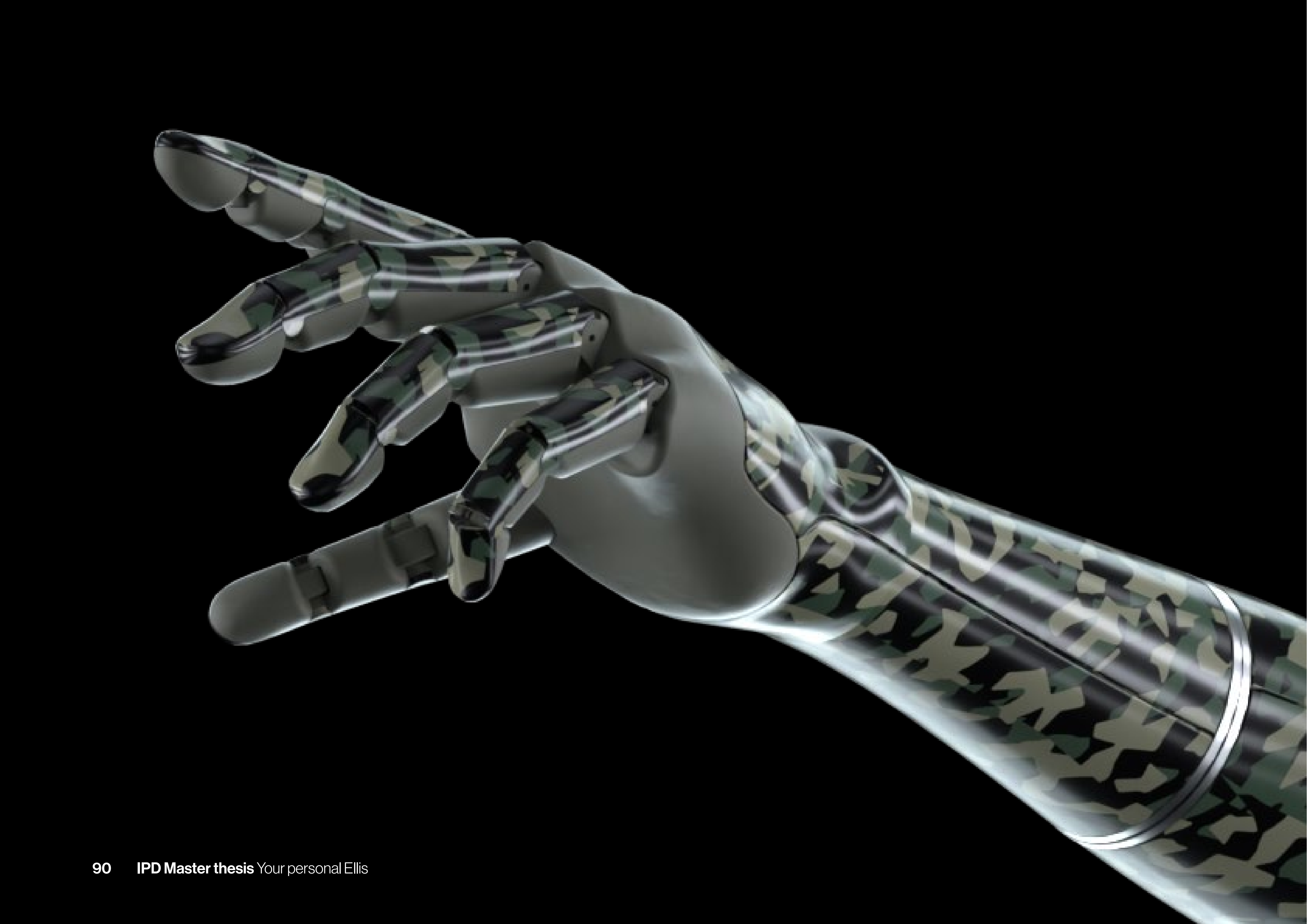
The findings of these analyses served as a framework for the design and were translated to main drivers. The main drivers for the prosthesis are: Customizability, mobility, modularity, tailor-made, durability and aesthetics.

With the drivers in mind multiple ideation sessions have taken place in which solutions were brainstormed for the prosthesis. The best solutions based on discussion and looking at the drivers were selected for further embodiment and prototyping.

The result is a design that is customizabile due to its modular approach and can be tailor-made to the users dimensions. This modular approach also allows for easy replaceability of wearing and tearing components. It is designed to have an aesthetical appeal and resemble human arm form characteristics. The arm can mimic antropometric ergonomical movements such as finger flexion and extension, ab-/adduction, a wrist rotation and an elbow rotation. The design is built in such a way that crucial components are protected from water and dust and is therefore durable.

The design is assessed on its feasibility, viability and desireability. In terms of feasibility it is assessed whether the product is producible and if it meets the required drivers. For viability the business side of the product is evaluated; although it is an expensive product for a very niche market it can be viable as long as the price and value is in balance and can therefore be covered by health insurance, otherwise very wealthy individuals have to acquire the arm themselves. The desirability is assessed by showing the product to the target group, the main conclusion is that some prefer a discrete design and some an expressive one. This product is created more for the expressive individual. The user states that allowing to customize the prosthesis makes that the prosthesis really belongs to him.

The result of this integrated product design master thesis is a design concept that explores multiple important aspects for a prosthesis such as customizability, modularity and aesthetics and can serve as a stepping stone in the development of this bionic arm prothesis called 'Ellis'.



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Recommendations

Despite aspects being analyzed and explored it is recommended to further explore on some areas.

Now that a first embodiment prototype has been made one can explore multiple materials. In this thesis for the hard body parts SLA printed rigid 4k and Tough have been explored and FDM printed PLA. However the Rigid 4K showed to be brittle, despite looking very good appearance wise. The PLA has negative material characteristics such as that it deforms under heat and in general FDM printed parts have to be sanded thouroughly before they like smooth.

Therefore it is adviced to explore other materials such as Nylon, which is also used in other prosthesis as was discovered in the state of the art analysis.

Furthermore regarding the grip parts the TPU and flexible showed dissapointing results. The silicone however showed promising grip characteristics. Silicone requires creating molds and could be done by DHM themselves. It is worth to further investigate the silicone molding proces.

In this thesis a silicone with a shore of 50A is used. However this could be a bit too soft. It is recommended to try out a shore 60A or 70A aswell. Wall thickness of 1 - 1.5 mm was used for the silicone grips. This showed to be very thin and rupturing quickly. Recommended is to look into thicker wall thicknesses such as 2-3 mm.

Durability

It is unfortunate that it was not possible to attach the motor to the finger prototype. If at a further stage of the project this is possible it is recommended to execute performance tests following the guidelines of ISO22523 to see how strong the construction is.

Sensors

In terms of sensors this project scratched the surface by doing some small tests with sensors and silicone and their actuation. However it is recommended to have a more elaborate sensor test with the finger mainframe setup combined with the grips. Interesting information is to figure out the effect of the different grip materials and wall thickness on the sensor actuation performance.

Tailor-made

It is recommended for the CAD model to build this up in a really optimized and modular way. If the arm is set out to be tailor-made to every user it can save up a lot of time if the CAD model can be easily changed to the users dimensions. Recommendation is to invest time in an optimized model to save time later on.

Customizability

In terms of appearance customizability the hydro dipping has been explored. Hydro dipping shows to be promising but is more expensive then a spray paint finish.

Assembly

The modular panels disassembly process seems to be working good. The usability test shows that people are able to do this with one hand and understand how to do it quickly and find it satisfying. However the screw system has not been included in this test. It is therefore advised to check how this screw and nut principle performs.

Mobility

The fingers show to have good flexion and extension motion freedom. However the thumb in this model cannot move properly due to not enough space in the palmar grip. It is recommended to look into this and make this hole bigger. Furthermore regarding the thumb, the arm shows to be able to perform 4 of the 6 major grips (explored in the anthropometric analysis). The other 2 grips require an opposing thumb motion. It is recommended to look into this to ensure the prosthesis can perform enough grips.

Viability

It is calculated that the custom panels can cost around €800,-. This is quite expensive, but the value seems to be big if we look at the interview with the target group. It is worth to look into wether the target group is willing to pay this amount of money for the customized panels. However the panels which are made by Papenburg Orthopedics cost €750,- and these prove to sell aswell.

Furthermore the prosthesis has to comply with the MDR and the ISO22523 regulations. Although looked into briefly within this project it is recommended to take this into account early on to avoid any problems later on in the product development. Also if you want to apply for a CE marking the product has to meet a whole set of requirements and has to go through a whole process, it is recommended to keep this in mind.

It is hard to say something really concrete about the final product price, since many choices still have to be made about the final components and materials being used. However the market research shows that the most expensive prosthesis fall into the €90k range. It is important to keep in mind that most amputees will not be able to afford their own prosthesis and that this is being covered by healthcare insurance plans. The amputee goes through a whole process to acquire a prosthesis

and the healthcare insurance has to decide whether the value of the prosthesis is enough and fits the amputee before they will cover the costs. It is recommended to have a clear overview of this process to make sure the prosthesis has a big chance to be picked for coverage. The PPP (prothese prescriptie protocol in the Netherlands) show the entire protocol which is followed for acquiring a proshesis.

Desireability
It is clear that there are two kinds of protheses wearers, the ones that want to hide it and the ones that want to show it. The prothesis designed in this project is made for the ones that want to show it. Although assessed with one prothesis wearer (Bert Pot), which was very enthusiastic about the concept, it is advised to assess its desireability on more prothesis users. It is unfortunate that I was not able to get in contact with more prothesis users, despite multiple efforts through the patient association.

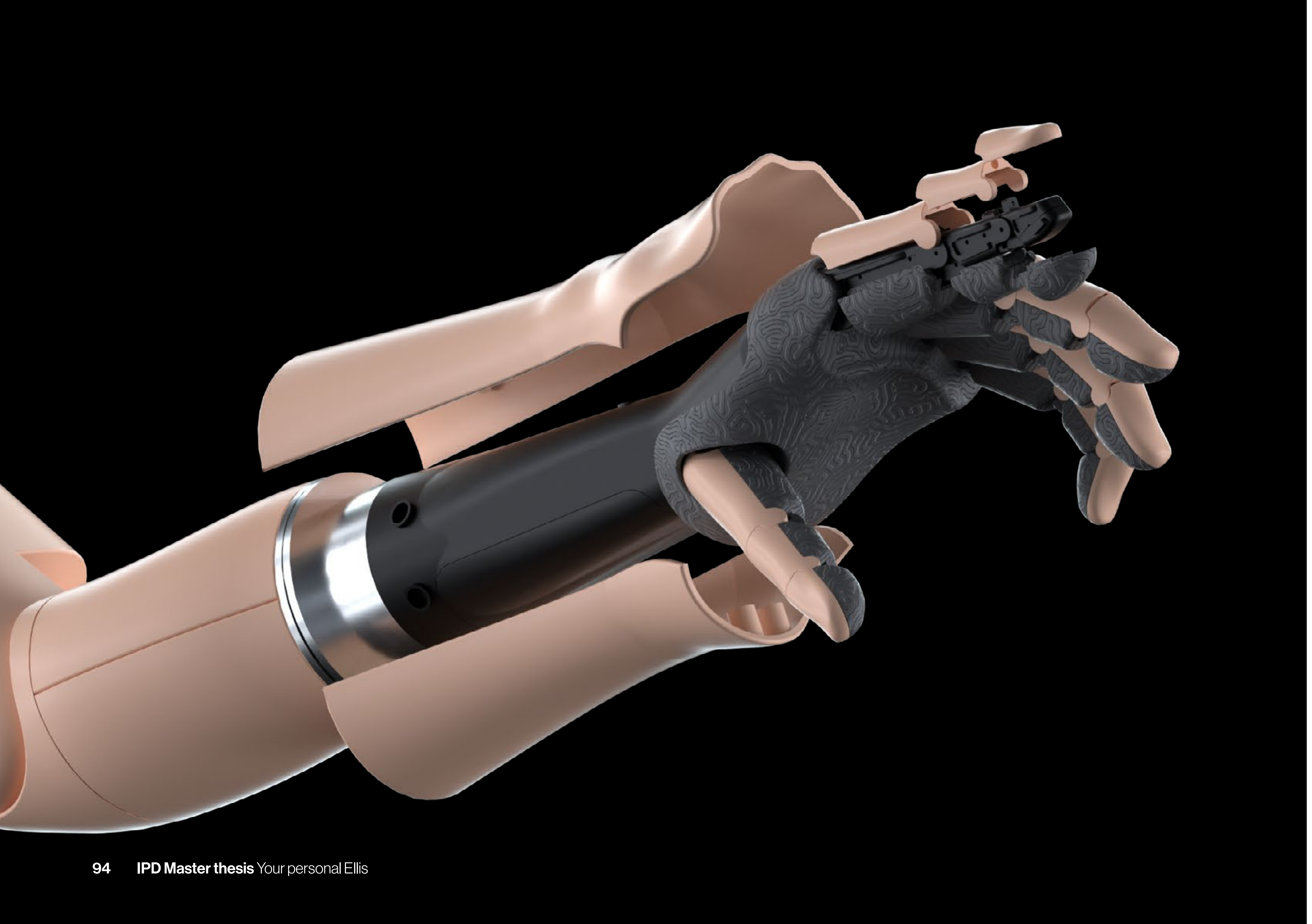
Design specific
The replaceable panels show to function properly with the magnets, however if the prothesis bumps into something a panel can come off. This is undesirable because the panel can fall and might damage. It is recommended to explore a second attachment like a snapping or sliding system which makes the panel attachment a bit more secure.

It is recommended to add an instruction manual that explains how to replace the modular parts. Furthermore adding indications on the modular parts that show where they are supposed to be attached is advised.

It is recommended to create toolbox for the prothesis which contains spare parts and tools that can be used to repair and maintain the prothesis. This can be perfectly accompanied with a cleaning kit. A proper instruction manual can be a good addition to this aswell.

The embodiment still has some spots that need some finishing touches. For example the proximal joint area that connects the finger with the hand is still a little open. It is recommended to cover this up. Furthermore the palmar grip is not fully defined on how it will be attached to the mainframe. For now it wraps around and stays in place, but at the edges it can deform and will break the product form. It is advice to secure the grip part at the edges. A proposal was done to attach it with lids and screws, however this was not fully embodied due to time issues.

Risk
The FMEA showed that some risks can occur with the prothesis design. A lot of these risk can be averted by stating the proper use and performance in the IFU. However it is recommended to do some tests on bio compatibility of materials to avoid allergies and test risks such as objects getting stuck between the fingers or tactile sensors not being actuated properly.



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Reflection

Acknowledgements and a reflection on this challenging but really cool and learnful project.

Acknowledgements
I'd like to firstly acknowledge Erik Tempelman. Erik has really helped me through this project, which had many ups and downs. The project came with many challenges and resulted in some hard moments. However Erik was always there to help me and guide me were needed and that helped me greatly. Also a lot of wise lessons, tips and useful connections were provided and were of great value.

Secondly I'd like to thank Joris van Dam, my coach, who was always there to guide me with the project and discuss certain approaches and tools and help me to realize that I should manage my time and deliverables. This however is still something I should work on.

Thirdly I'd like to thank Maarten den Hartog and Pamela Musch for their hospitality, the tools they provided me and all the things they taught me. Maarten and Pamela are great designers who were always very energetic and enthusiastic during the brainstorms, it was sometimes hard to mingle. I'd also want to apologize for the way the project started off after the break. The performance and communication was inadequate at that moment and I was not happy with how it was going. This however was greatly due to personal situations, but is nonetheless something I would have wanted differently. However I have really tried to turn the tide and go full effort on the project to deliver results that are valuable for the development of the prosthesis.

Fourthly I'd like to acknowledge The Productivity Company for providing me office space to work on this graduation project. Especially Tom Lindsen, who immediately agreed, when I asked him if I could move my work setup to the office. Furthermore Christian Doppert, a dear colleague and friend, who supported me morally during the project.

Furthermore I'd like to acknowledge Marius Langer, a dear friend, who helped me greatly by allowing me to use his 3D printer for the FDM prototyping. This printer was available 24 hours-a-day and allowed me to rapidly prototype the model.

I'd like to acknowledge Orlando Sardaro, for bringing me in contact with DHM Dental and therefore getting this project.

Finally I'd like to acknowledge my roommates, my friends and family, who supported me throughout the project. Especially Carola Weijers and Rik Brouwer, who occasionally checked in on me to see how I was holding up.

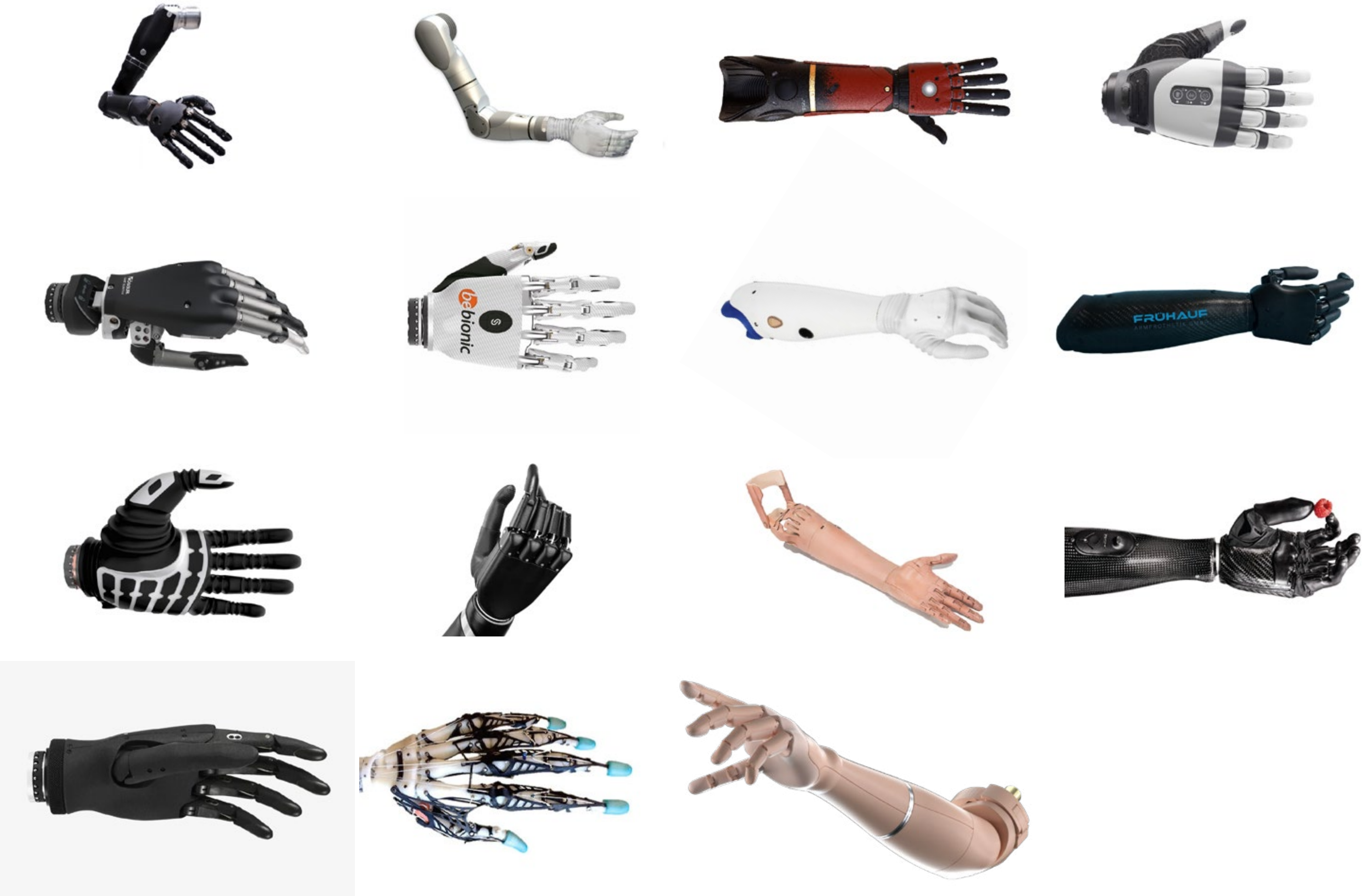
STARR reflection

Situation
For the master integrated product design at the faculty of Industrial design engineering of the TU Delft I had to write my master thesis. This project was done during the COVID-19 Pandemic. The project was done together with DHM Dental BV located in Arnhem and my TU Delft committee. Due to the pandemic half of the project was done from home and the other half I worked at a flex office in Rotterdam. Occasionally I went to Arnhem for physical meetings and prototyping.

Task
I was asked to work on the development of an embodiment for a bionic arm prothesis which is connected to a patient with the use of osseointegration.

Action
I performed analyses on the context, ergonomics, functions, state of the art and I had expert interviews to discover the domain of this topic. These learnings I translated into drivers which served as a framework for the product design. With this in mind I started an ideation to explore solutions for the product. These ideas were converted to concepts. Out of the concepts a final concept was picked to further develop for the embodiment. This embodiment was made in CAD and later on prototyped to validate the function and performance. In the end the overall design was assessed on feasibility, viability and desireability.

Result
Analysis show the desires of prosthesis wearers for a neat looking prosthesis that allows the user to express their personality. An embodiment is created that proposes solutions for a modular and customizable bionic arm prosthesis.



Reflection

This project was perhaps the most complicated thing I have done during my studies. This had to do with multiple factors. This project was done during the COVID pandemic which caused several limitations such as working from home, digital meetings and limited physical contact moments. What I have learned about myself is that I cannot work properly from home. I do not seem to be able to focus at home and therefore the first 10 weeks of the project my productivity was inadequate. This caused for a major delay of proper results and caused the rest of the project to be quite rushed and caused for some delays.

Moreover the big break during the project caused me to have a hard time getting back into the project. A lot had changed and I was actually quite lost on where I had to start again. This resulted in me working on stuff that was actually a waste of time. The big mistake I made was that I only had a brief meeting with DHM about the updates, I should have gone to the company physically immediately. This is a big learning point.

Furthermore working on such a complex product with a team that is working remotely and only has occasional meetings is plainly very hard. This sometimes caused that we were not on the same page and working on different things entirely, cause we were unaware of what the other was doing. If I ever encounter a complex project like this I will be weary for this and make sure that I can work more closely with the team. Daily stand-ups would also be a good addition for this, to make sure that everyone knows what they are doing and if people need anything from each other.

With new projects to come I will immediately assess the feasibility, viability and desirability to check if the project is even worth working on.

I have learned many new things within solidworks which I am really proud of. I never thought I would be able to design such a complex and organic product within solidworks, which is overall a very geometric modelling tool.

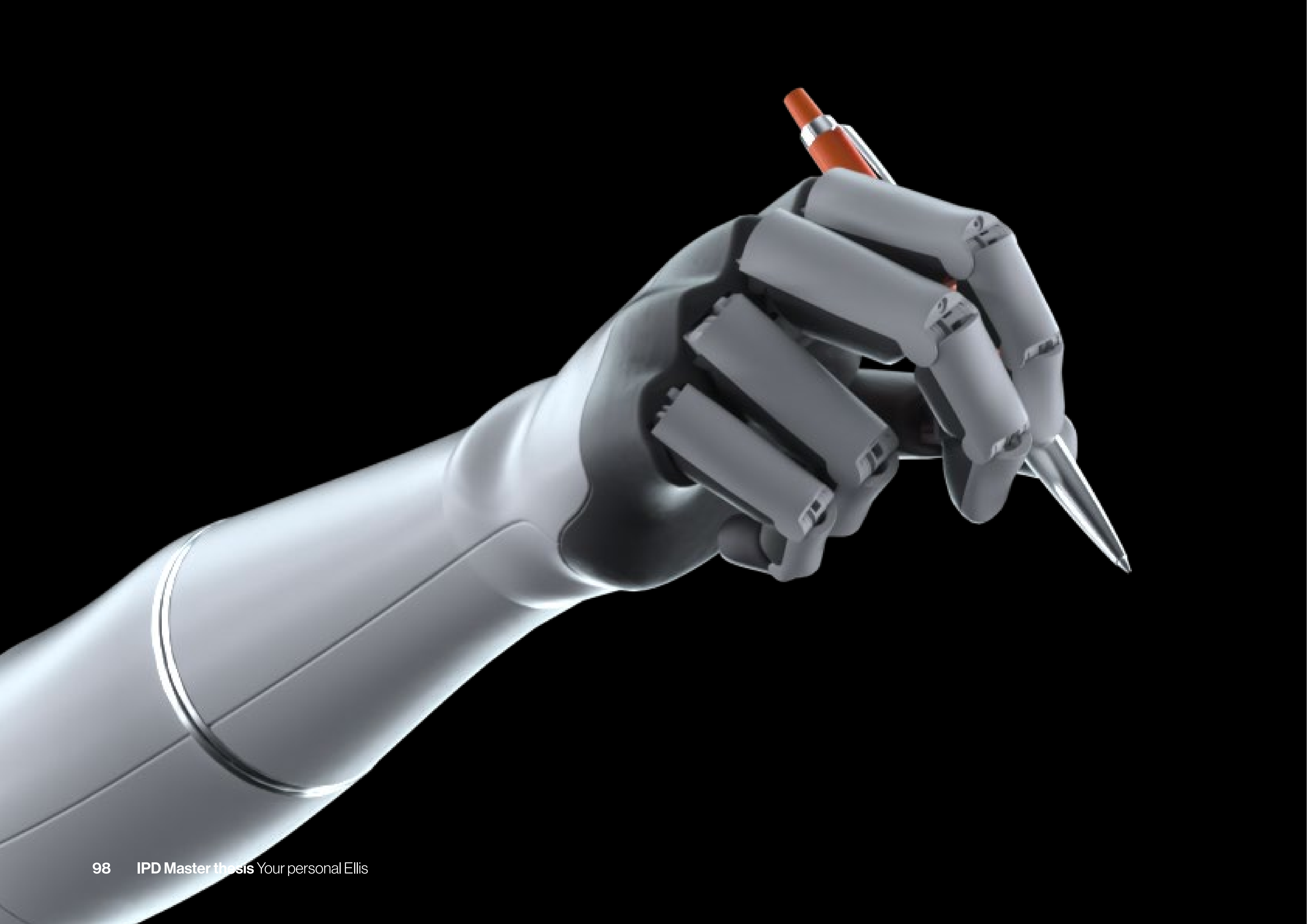
Furthermore I have been reminded again what a design project entails and how many important steps it includes. This project has shown me the importance of feasibility, viability and desireability, which I lacked to have learn properly during the master. I would have wanted that I focused earlier on the viability during this project, but it got to me only at the end of the project.

Additionally I learned how to make molds for silicone casting. Which is a pretty complex process at first but after the third mold design I got the gist of it.

Another thing I have learned is that with a project where time is so limited as this one, it is important to divide the focus on all the important topics and also set boundaries for the scope. A mistake I made was lingering to long on certain aspects, while losing time to do other things, but also adding new things to the scope. This obviously results in lack of time and delays. With next projects I will spend more focus on defining the scope and balancing time management on each topic.

Closing words

This project was a big challenge, filled with ups and downs, during a very uncertain time, which has taught me a multitude of valuable lessons. It was hard, I wanted it to be better, but I value what I've learned. I hope that I have contributed some value to the domain of prosthesis and that the development of the prosthesis will result in a product that will make the life of people who life with an amputation better.



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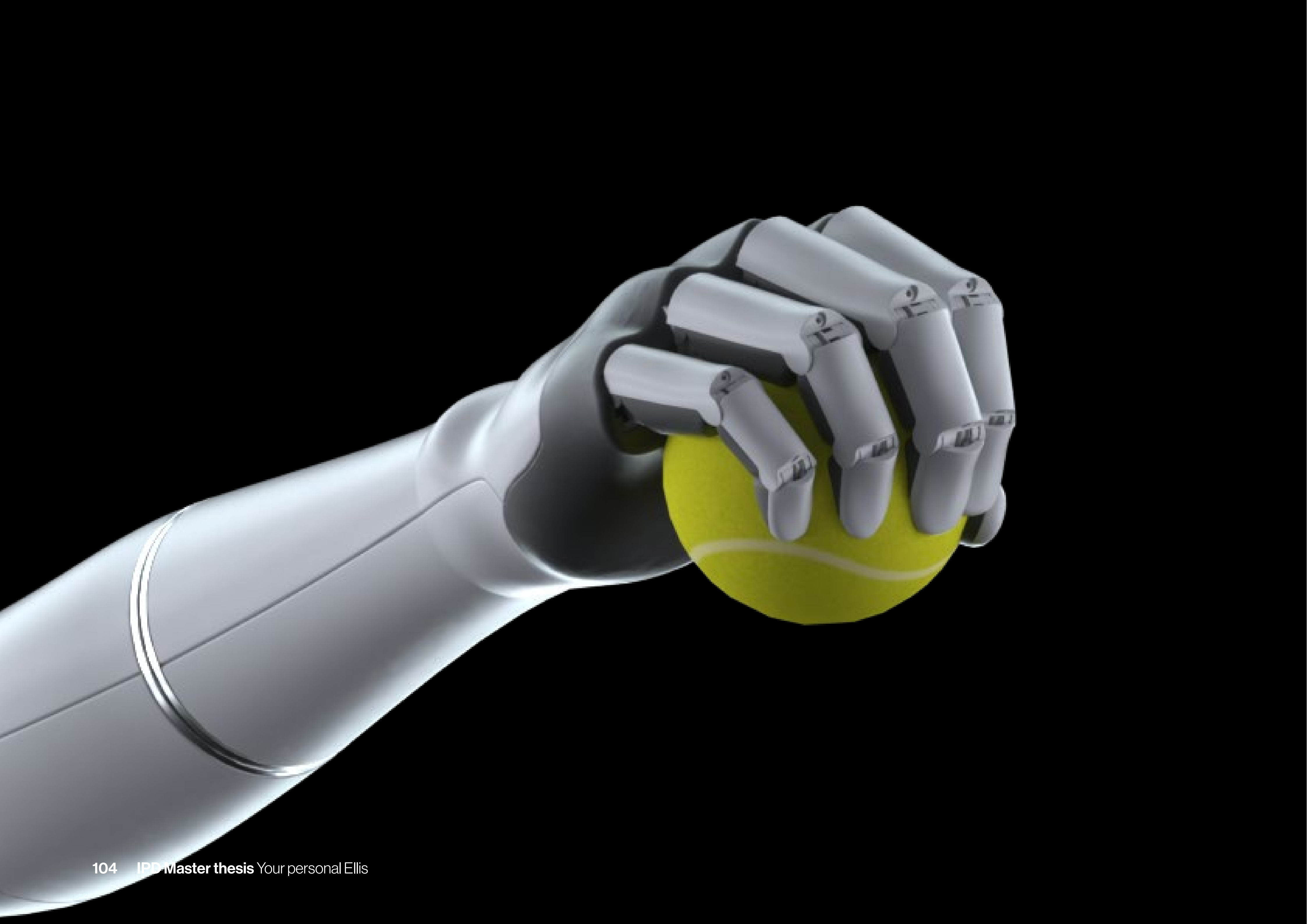


Appendices

Here the appendices start

A1.1

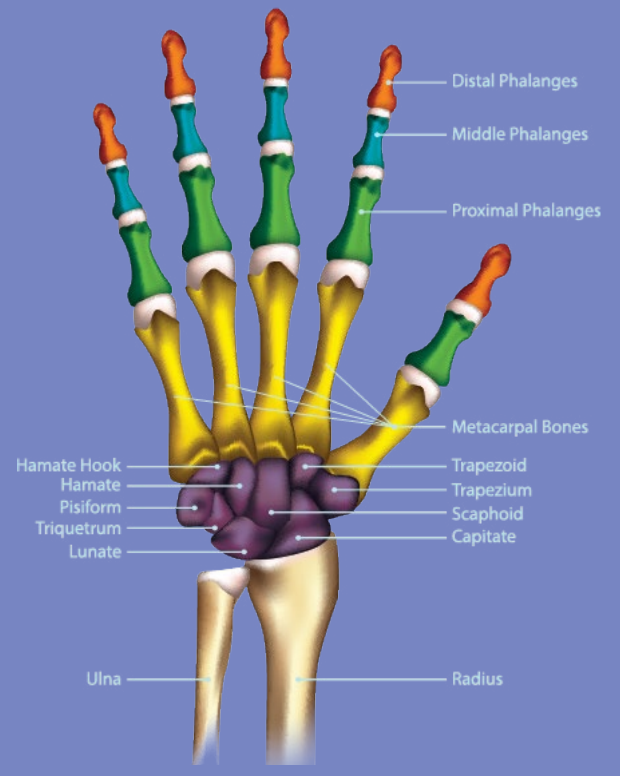
Anthropometric Analysis

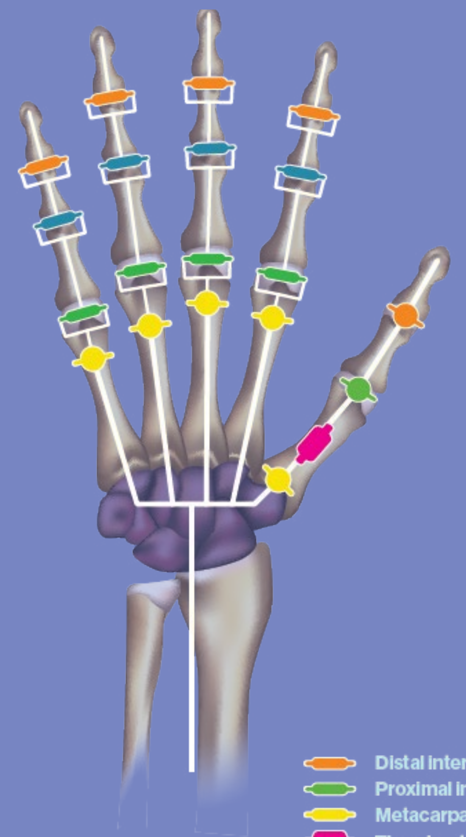
In this chapter the human hand and arm anatomical capabilities and dimensions are analysed.

Hand anatomy

Dunai et al. (2020) explains in their paper that the human hand consists of carpal bones, metacarpal bones, proximal, middle and distal phalanges. All fingers are based on four bones: metacarpal bone, proximal, middle and distal phalange. The thumb only consists of two phalanges.

The image on the right shows all the bones in the human hand its names.





🟧 **Distal inter-phalangeal joints**
🟩 **Proximal inter-phalangeal joints**
🟨 **Metacarpal-phalangeal joints**
🟪 **Thumb rotation**
● **Abduction/Adduction**

Fingers

Jarrassé et al. (2014) describes a kinematic model of the capabilities of the human hand. According to the paper the human hand has 28 DoF.

Each finger has 4 DoF. A flexion/extension excursion between phalanxes (Proximal Inter-Phalangeal hinge joints (PIP) and Distal Inter-Phalangeal hinge joints (DIP)) along with 2 DoF at the MetaCarpal Phalangeal (MCP) saddle joint (flexion-extension and abduction/adduction mobilities).

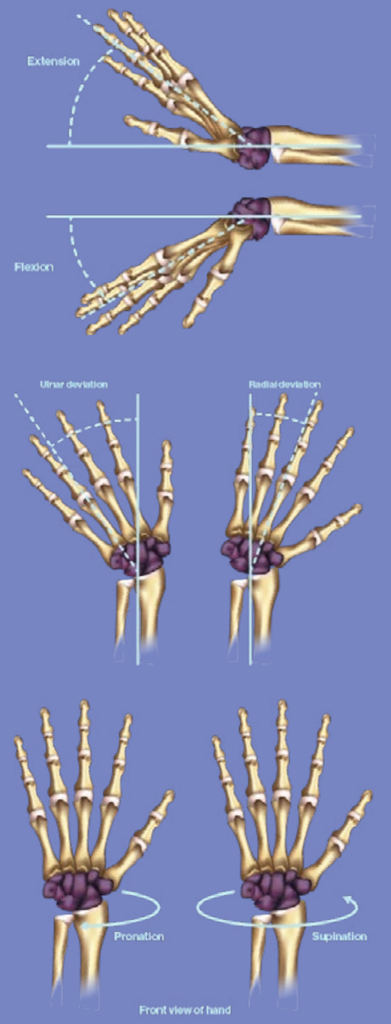
The thumb has 5 DoF: 2 Flexion-extension mobilities thanks to the Proximal Inter-Phalangeal and MetaCarpal-Phalangeal hinge joints and at least 2 DoF at the level of the saddle joint between the carpus and metacarpus (trapeziometacarpal joint). In addition to these mobilities, the thumb exhibits a pseudo-rotation allowing 3 DoF.

Wrist

The wrist is capable of making the following motions:

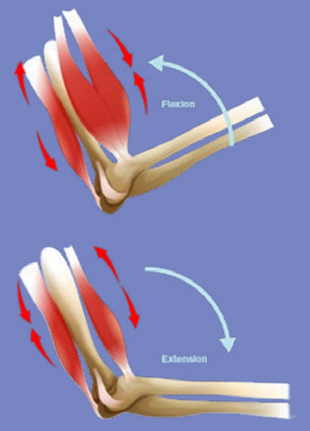
- Flexion/extension
- radial deviation/ulnar deviation
- pronation/supination

Pronation and supination will be included in the arm prosthesis.



Elbow

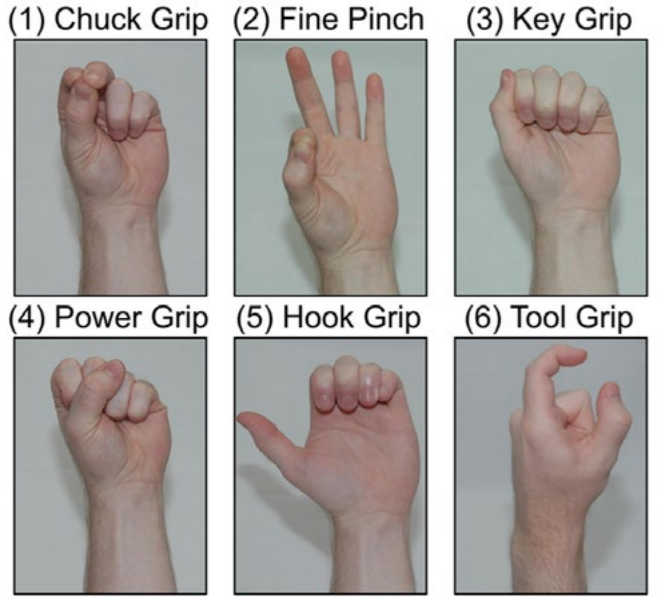
The elbow is capable of performing a flexion and extension motion.



Grips

According to a paper by Earley et al. (2016) the grips people use most commonly in ADL (activities of daily life) are the following:

1. Chuck grip
2. Fine pinch
3. Key grip
4. Power grip
5. Hook grip
6. Tool grip



FigureA1.1: 6 most used grips

Bebionic grips

The instruction manual of the bebionic by Ottobock explains their grips. This can be insightful for the grips for the Ellis prothesis.

Tripod

When the thumb is opposed, the hand closes into Tripod Grip with index and middle fingers meeting the thumb. Ring and little fingers continue to close until they meet resistance or the close signal stops. This type of grip allows users to pick up, hold and manipulate a variety of everyday objects such as car keys, coins, jar lids and pens.

Power

With the thumb opposed, all four fingers close into the palm untilthey meet resistance or the close signal stops. When fingers areapproaching a fully closed position, the thumb drives in to cover thefingers for additional grip security. This pattern allows round objects such as a ball or a piece of fruit to be held securely. This grip can also provide a handshake. Cylindrical shaped objects such as bottles, home and garden utensil handles are also held easily and securely.

Finger Adduction

The fingers of the hand move together naturally as the fingers close. This allows the user to securely grip thin objects, such as cutlery or a toothbrush, between the fingers to achieve function in a different plane. Finger Adduction is most functional with the hand in Power Grip but can also be achieved with the hand in Key Grip and Pinch Grip.

Hook

With the thumb in opposed position, a partially closed Power Grip provides Hook Grip.This is ideal for carrying a shopping bag or briefcase. Hook Grip can also be achieved by closing the fingers from the relaxed hand position.

Active index

With the thumb opposed Active Index Grip will grasp the handle of an object with the middle, ring and little fingers and secure the grip with the thumb. The index finger will then close – this may be positioned over the lever of the device held such as a spray bottle, it also offers the ideal finger position for typing. The index finger is under independent user control and may be positioned accordingly. To exit Active Index, an open signal will fully open the index finger before the other fingers and thumb release their grip.

Pinch

The thumb only contacts index finger and is used for the fine manipulation of objects. To achieve this grip it is necessary for the thumb to be manually repositioned by the practitioner/technician so that the thumb only contacts the index finger

Precision closed

This grip can be used in situations similar to the Precision Open Grip, but where extended fingers would be obstructive, such as working at a desk. Initially the middle, ring and little fingers close into the palm. The thumb moves to the midpoint of its range and pauses. The Index is then active and under user control. (To achieve this grip it is necessary for the thumb to be manually repositioned by the practitioner/technician so that the thumb only contacts the index finger.)

Precision open

With the thumb opposed, the index finger meets the static thumb allowing the user to pick up and manipulate small objects. When this grip is selected and a close signal is applied, the thumb closes to the midpoint of its range and pauses. The index is then active and under user control. The middle, ring and little fingers remain extended. (To achieve this grip it is necessary for the thumb to be manually repositioned by the practitioner/technician so that the thumb only contacts the index finger.)

Key

In the non-opposed thumb position, the four fingers partially close. The thumb then closes onto the side of the index finger. The thumb position may be raised and lowered without moving the other four fingers allowing for release, capture or reposition of the object being gripped. This pattern is ideal for carrying paper or letters, using a spoon and for holding a thin flat object such as a plate, a credit card or a key.

Finger point

With the thumb in the non-opposed setting, the user can move to Finger Point position. The middle, ring, and little fingers close against the palm and the thumb moves against the middle finger. With this grip, typing on a keyboard or input pad, pressing a bell or a button can be achieved.

Open palm

With the thumb in the non-opposed position the hand may be fully opened to provide a flat palm suitable for carrying a tray or a plate.

Mouse

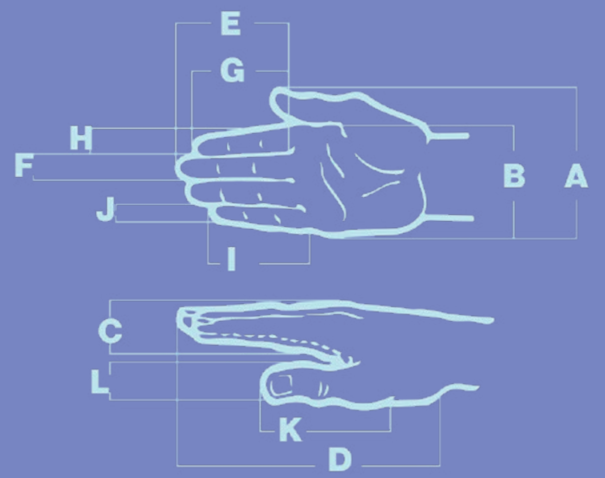
The thumb and little finger close to hold the side of the mouse, with the middle and ring fingers providing stability. The index finger closes on to the mouse button and then backs off to provide the button press. Each close signal will give a mouse click whilst an open signal will release the mouse.

Conclusion

The bebionic provides many different grips. But according to a paper by Earley et al. (2016) the grips people use most commonly in ADL (activities of daily life) are the following:

1. Chuck grip
2. Fine pinch
3. Key grip
4. Power grip
5. Hook grip
6. Tool grip

it is adviced to first focus on these key grips. Later on the grips can be programmed to create the more elaborate grips.



Hand Dimensions

	Limb Parameters [mm]	P5	P25	P50	P75	P95
A	Hand width (+thumb)	88	97	103	109	118
B	Hand width (without thumb)	73	80	85	90	97
C	Hand thickness	16	22	26	30	36
D	Hand length	166	178	187	196	208
E	Middlefinger length					
F	Middlefinger width					
G	Index finger length					
H	Index finger width	14	16	17	18	20
I	Pink Length					
J	Pink width					
K	Thumb length					
L	Thumb width	19	21	22	23	25

A,B, C, D, H, L: DINED 2021 - Dutch adults dined 2004 age 20-60 male and female mixed

Arm Dimensions

	male					
	Limb Parameters [mm]	P5	P25	P50	P75	P95
A	Elbow-grip length	331		364		397
B	Elbow -finger tip length	450		493		536
C	Shoulder-elbow length	337		366		394
D	Wrist circumference	162		177		193
E	Bicep circumference	294		332		369
F	Forearm circumference	274		301		327
G	Wrist breadth	51.6				62.3
H	Elbow breadth	67.5		74.0		82.0

A,B: DINED 2021 - Dutch adults dined 2003 age 18-30 male
C, D, E, F: NASA American male 2000 age 40
G: Cakit et al. (2012)
H: Narancic et al. (2001) Age 18-74

	Female					
	Limb Parameters [mm]	P5	P25	P50	P75	P95
A	Elbow-grip length	294		324		354
B	Elbow -finger tip length	406		439		472
C	Shoulder-elbow length	272		298		324
D	Wrist circumference	137		150		162
E	Bicep circumference					
F	Forearm circumference	199		220		241
G	Wrist breadth	45.5				54.9
H	Elbow breadth	60.0		66.0		74.0

A,B: DINED 2021 - Dutch adults dined 2003 age 18-30 female
C, D, E, F: NASA American female 2000 age 40
G: Cakit et al. (2012)
H: Narancic et al. (2001) Age 18-74

Joint excursion

	male					
	Joint motion [degrees]	P5	P25	P50	P75	P95
A	Wrist flexion	56	65	72	79	88
B	Wrist extension	59	68	74	80	89
C	index finger flexion	42	51	58	65	74
D	Wrist pronation	78.2				116.1
E	Wrist supination	83.4				125.8
F	Elbow flexion	140.5				159

A, B, C: DINED 2021 - Dutch adults 20-30 male

	Female					
	Joint motion [degrees]	P5	P25	P50	P75	P95
A	Wrist flexion	56	65	72	79	88
B	Wrist extension	59	68	74	80	89
C	index finger flexion	42	51	58	65	74
D	Wrist pronation	82.3				118.9
E	Wrist supination	90.4				139.5
F	Elbow flexion	144.9				165.9

A, B, C: DINED 2021 - Dutch adults 20-30 female

Weights

	Weights [g]	P5	P25	P50	P75	P95
A	Hand [g]	460		530		610
B	Forearm [g]	1180		1450		1720
C	Upperarm [g]	1600		2500		2500
D						
E						
F						
G						

A, B, C: NASA Anthopometry and biomechanics 2000

Force exercise

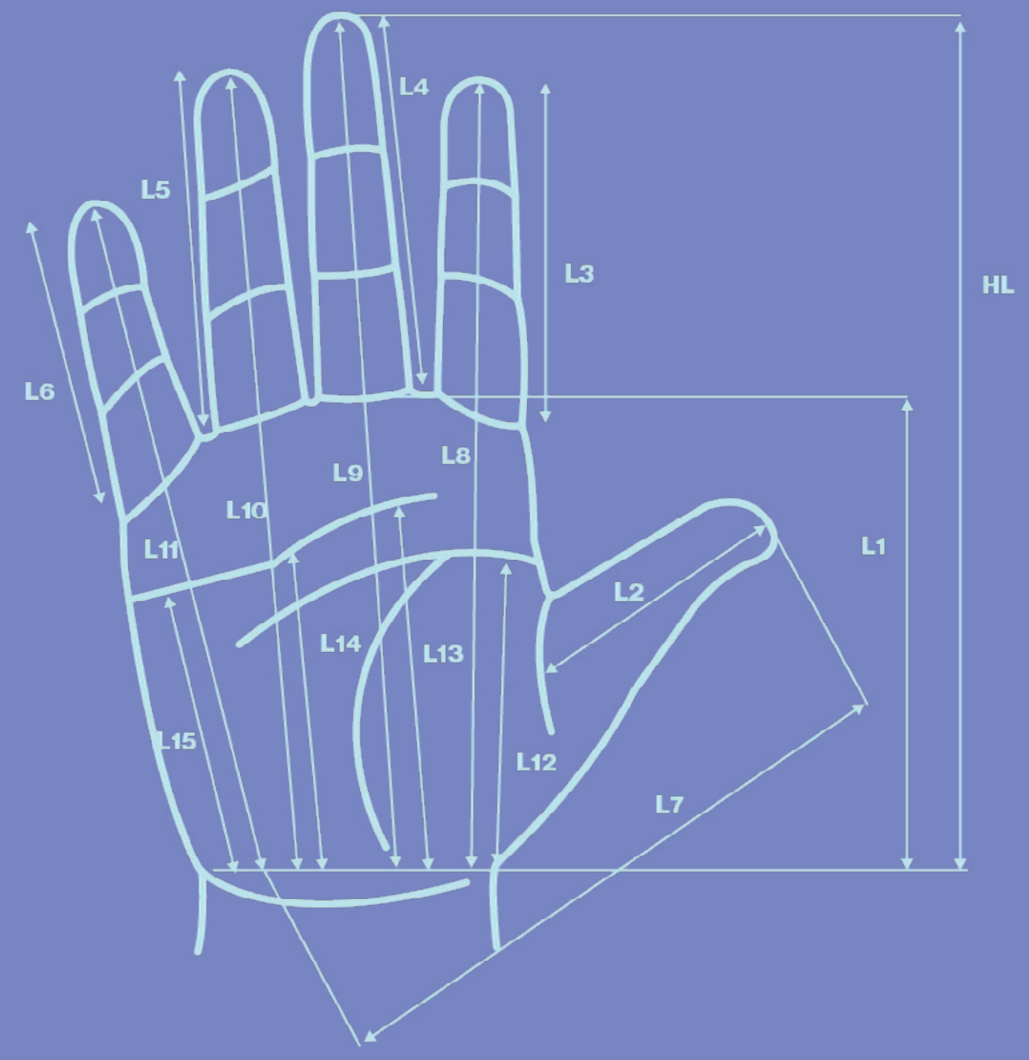
	Force exercize	P5	P25	P50	P75	P95
A	Maximum gripping force [N]	231	350	432	514	633
B	Pulling force 1 hand [N]	151	232	389	346	427
C	Torque with two hands [Nm]	4	6	7	8	10
D						
E						
F						
G						

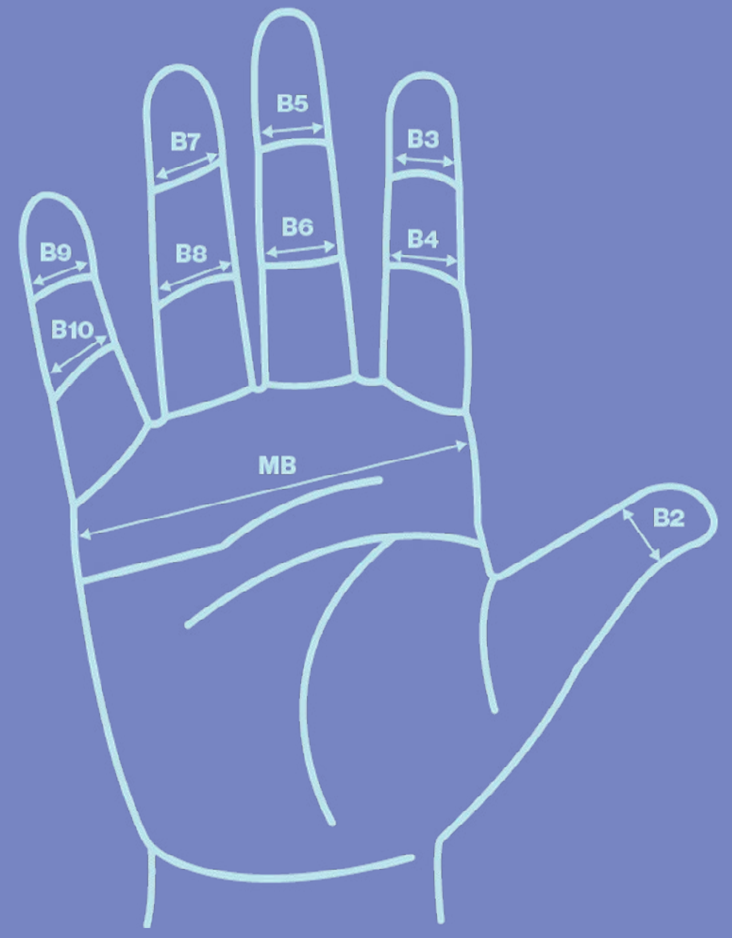
A, B, C: DINED 2021 - Dutch adults 20-30 male and female mixed

Hand Dimensions

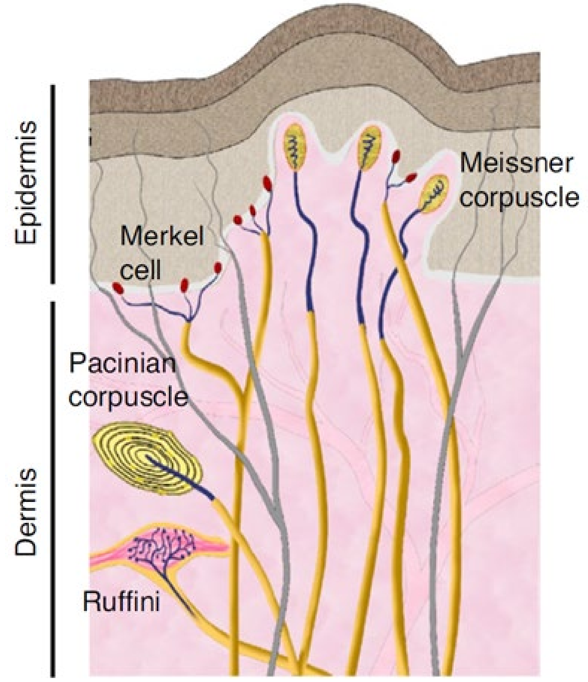
		Female					Male				
	Hand parameters [mm]	P5	P25	P50	P75	P95	P5	P25	P50	P75	P95
MB	Palm breadth	71.8	73.6	75.5	78.3	80.6	76.0	80.0	83.0	85.0	89.0
B3	Index distal interphalangeal joint breadth	13.8	14.4	15.5	16.2	17.4	15.8	16.8	17.6	18.6	19.8
B4	Index proximal interphalangeal joint breadth	16.0	16.6	17.9	18.6	19.7	18.2	19.3	20.2	21.1	22.4
B5	Middle distal interphalangeal joint breadth	13.6	14.2	15.5	15.9	17.1	15.6	16.6	17.4	18.2	19.3
B6	Middle proximal interphalangeal joint breadth	15.5	16.2	17.4	18.1	19.3	17.8	18.9	19.8	20.7	21.8
B7	Ring distal interphalangeal joint breadth	12.5	13.1	14.2	14.8	15.9	14.5	15.5	16.2	17.1	18.2
B8	Ring proximal interphalangeal joint breadth	14.7	15.3	16.5	17.1	18.5	17.1	18.0	18.8	19.7	20.9
B9	Pinky distal interphalangeal joint breadth	11.6	12.1	13.3	13.8	14.9	13.7	14.6	15.3	16.0	17.0
B10	Pinky proximal interphalangeal joint breadth	13.1	13.7	14.9	15.5	16.6	15.3	16.1	16.9	17.6	18.5
L2	Thumb length	52.0	56.0	58.0	61.0	65.0	58.0	63.0	66.0	69.0	73.0
L3	Index finger length	58.0	61.0	64.0	67.0	70.0	63.0	68.0	71.0	74.0	7.0
L4	Middle finger lengt	65.0	68.0	71.0	74.0	78.0	71.0	76.0	79.0	83.0	88.0
L5	Ring finger length	60.0	64.0	66.0	69.0	73.0	67.0	71.0	75.0	78.0	83.0
L6	pinky finger length	48.0	51.0	54.0	56.0	60.0	53.0	58.0	61.0	65.0	69.0
L7	Thumb tip to wrist length	105.0	111.0	115.0	121.0	128.0	117.0	125.0	130.0	136.0	144.0
L8	Index tip to wrist length	145.0	151.0	156.0	162.0	170.0	160.0	169.0	175.0	181.0	190.0
L9	middle tip to wrist length	153.0	159.0	164.0	170.0	178.0	168.0	177.0	183.0	190.0	200.0
L10	ring tip to wrist length	144.0	150.0	155.0	161.0	169.0	160.0	168.0	174.0	181.0	191.0
L11	pinky tip to wrist length	123.0	129.0	134.0	140.0	147.0	136.0	145.0	151.0	158.0	167.0
L12	index metacarpal link length	58.0	61.0	64.0	67.0	71.0	66.0	70.0	72.0	76.0	80.0
L13	Middle metacarpal link length	65.0	69.0	72.0	75.0	80.0	70.0	76.0	80.0	84.0	90.0
L14	Ring metacarpal link length	59.0	63.0	66.0	69.0	74.0	65.0	70.0	74.0	78.0	83.0

Antropomorphic data of hand paramaters Rincón-Becerra & Garcia Acosta (2020)

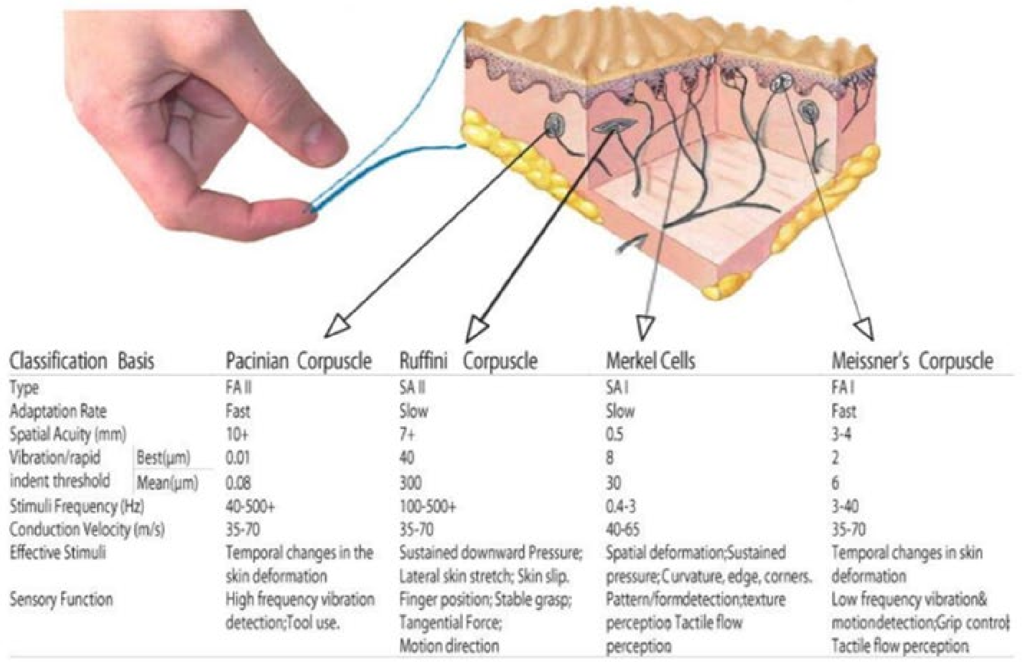




A1.2
Sensory analysis



FigureA1.2: Human touch receptors



Classification Basis		Pacinian Corpuscle	Ruffini Corpuscle	Merkel Cells	Meissner's Corpuscle
Type		FA II	SA II	SA I	FA I
Adaptation Rate		Fast	Slow	Slow	Fast
Spatial Acuity (mm)		10+	7+	0.5	3-4
Vibration/rapid indent threshold	Best(µm)	0.01	40	8	2
	Mean(µm)	0.08	300	30	6
Stimuli Frequency (Hz)		40-500+	100-500+	0.4-3	3-40
Conduction Velocity (m/s)		35-70	35-70	40-65	35-70
Effective Stimuli		Temporal changes in the skin deformation	Sustained downward Pressure; Lateral skin stretch; Skin slip.	Spatial deformation;Sustained pressure;Curvature, edge, corners.	Temporal changes in skin deformation
Sensory Function		High frequency vibration detection;Tool use.	Finger position; Stable grasp; Tangential Force; Motion direction	Pattern/formdetection;texture perceptioo Tactile flow perceptioo	Low frequency vibration& motiondetection;Grip control Tactile flow perception

FigureA1.3: Human touch receptors

A5.4 Sensory Analysis

A deep dive in how human touch works and what it means.

Human touch

In order to be able to mimic the human touch for a prosthesis its self-evident to first understand how the human touch actually works.

The human body is capable of sensing proprioceptive (kinesthetic) and exteroceptive (cutaneous) feedback. Proprioception is when a sensory receptor is responding to stimuli originating inside the body (described in an article by Santos-Longhorst (2019) as a continuous loop of feedback between sensory receptors within our skin, joints and muscles sensing effort, force and heaviness of our actions and positions and responds accordingly). it tells the brain where body parts are and what they are doing. The sense of movement and posture of the arm and hand for example. Exteroception is when a sensory receptor is responding to stimuli originating outside of the body. For example touch or heat.

The somatosensory system is responsible for our sense of touch. This system consist of an immense network of nerves and receptors located in the skin. Within this system we can distinguish four different types of receptors: Mechanoreceptors, Proprioceptors, pain receptors and thermoreceptors.

Tactile sensation is one of the most important components of mechanosensation and is carried out by specific sensory formations localized in the skin and known collectively as cutaneous sensory corpuscles or receptors (Zimmerman et al. 2014)

Raspapovic et al. (2021) describes four types of cutaneous mechanoreceptors, which adapt differently to mechanical stimuli and responses to electrical stimulation. The four types of mechanoreceptors are Merkel's cell, Meissner's corpuscle, Pacinian's corpuscle and Ruffini's corpuscle.

Merkel's cell and Meissner's corpuscle can be found in the Epidermis, which is the top layer of the skin. These are the most sensitive mechanoreceptors. These receptors are responsible for detecting gentle touch and the texture of an object.

Pacinian corpuscle and Ruffini are located deeper in the dermis and along joints, tendons and muscles. These sensors are responsible for experiencing sensations of vibration and stretching of skin.

The value of human touch

There are approximately 15,900 upper limb amputations performed in the US annually. And in Europe this amount is around 6,311. The upper limb prosthetic devices currently available do not provide natural sensory information and are therefore often rejected.

A research done by Raspopovic et al. (2021) states that sensory feedback is mentioned by upper-limb amputees as one of the main missing features of commercial prostheses, as they are not able to execute confident grip forces or undertake fine manipulations.

The lack of physiological feedback from the remaining extremity to the brain prevents the correct integration of the prosthesis in the body perception of the person. This induces low prosthesis embodiment and increased cognitive effort while using the devices, which affect their acceptability and ultimately reduce user confidence in the prosthesis. Lack of sensory feedback and inadequate embodiment are among the reasons for rejection of available commercial prosthesis. (Wijk and carlsson, 2015)

Lack of physiological feedback from the remaining extremity to the brain also generates phantom limb pain, which is experienced by 50-80% of the amputees as stated by Flor et al. (2006)

Phantom Limb pain Phantom limb pain is pain perceived as arising from the missing limb due to sources other than stimulation of nociceptive neurons that used to innervate the missing limb (Ortiz-Catalan, 2018).

Movements become inaccurate and unstable in the absence of 'sense of touch' is stated by Dahiya et al. (2015). This was investigated by having participants put their hand on an ice block, which resulted in tactile information from mechanoreceptors not being available to the brain. It was observed that even though volunteers could see what they were doing, they could no longer maintain a stable grasp of objects.

Sensory feedback in hand prostheses is also claimed to improve their functionality and the users' sense of body ownership as stated by Wijk et al. (2015). An interview with several amputees resulted in the conclusion that prosthesis are not experienced as a part of the body, but rather a foreign part, a tool or a fake hand. Prosthesis with sensory feedback however caused a strong emotional experience and also resulted in an experience of body ownership. The fine sense of touch on the surface of the prosthesis is what makes it a part of the amputee.

Psychological effect of human touch

An article by Pierce (2020) states that when we hug or feel a friendly touch on our skin, our brains release oxytocin, a neuropeptide involved in increasing positive, feel-good sensations of trust, emotional bonding and social connection, while decreasing fear and anxiety responses in the brain at the same time.

Restoring body image by increasing ownership

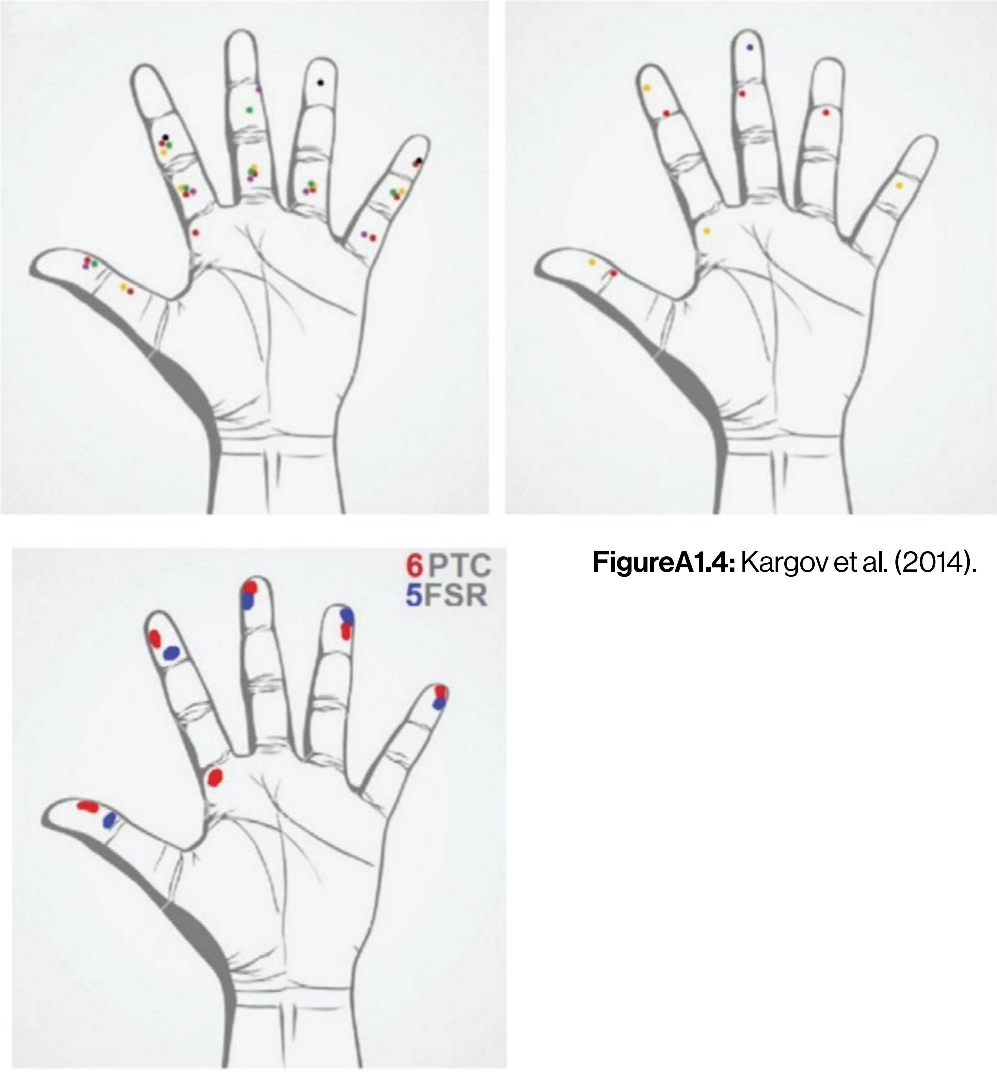
In addition to loss of function, limb amputations pose a significant threat to a person's body image. Zbinden et al. (2021) states that the body image represents the perceptual, conceptual, and emotional aspects of our bodies in our mind. Limb loss immediately affects the perceptual and conceptual representation: the stored structural description of the body substantially mismatched the received visual somatosensory feedback.

Moreover, the exclusion from social rituals like handshaking, and prejudicial attitudes towards disabilities, can damage the emotional aspects of the body image and lead to a negative relation towards a missing limb.

A distorted body image has also been correlated with "decreased life satisfaction, quality of life, activity levels and overall psychological adjustment" (Gallagher et al. 2021).

Directly measuring the body image has proven to be difficult. Therefore a way to assess change in the body image is to study the sense of ownership of the prosthesis.
Ownership is stated to be an aspect of self-awareness related to experiencing parts of our body belonging to ourselves. The phenomenon of the 'rubber hand illusion' (RBI) is a perfect example where a sense body ownership can be achieved with an object that is not part of our actual body.

A neurocognitive model has been created by Taskiris et al. (2010) based on this RBI in which steps are described in order for body-ownership to arise. The first step compares the visual congruency of the prosthesis to a concept of a biological limb stored in the body image. The second step postural features of the prosthesis are compared to the current body posture. The third and last step comprises multisensory integration of available afferent information. The article states that if all three comparators match, ownership over the prosthesis arises.



FigureA1.4: Kargov et al. (2014).

Optimal sensor location

Mirkovic et al. (2014) did research to the optimal location of pressure sensors and thermistors within a hand prosthesis. This was done by having 25 participants touch objects while not seeing them.

Upon touching the object they were asked to place dots on a screen, where an image of a hand was presented, indicating where "feeling" of the certain feature of an object grasped was characteristic. Participants had a limited amount of dots to place.

The colours represent different objects that were being touched. In the second image the dots indicate the intensity of stiffness.

The final outcome of all the objects being tested and their corresponding locations for touching is represented in the image on the right. These locations would represent ideal locations for placing tactile sensors in order for humans to recognize objects.

kargov et al. (2016) did research to the locations on the hand which apply the most force when manipulating everyday objects. Abassi et al. (2016) confirms this. The figures on the right show the locations that are providing the most force exertion doing object manipulation.

Conclusion

The results of the research by Kargov et al. (2016) and Abassi et al. (2016) canbe used in the decision making of picking the locations for tactile sensors within the prosthesis. These locations will be most important to have tactile feedback since they are crucial for object manipulation and awareness.

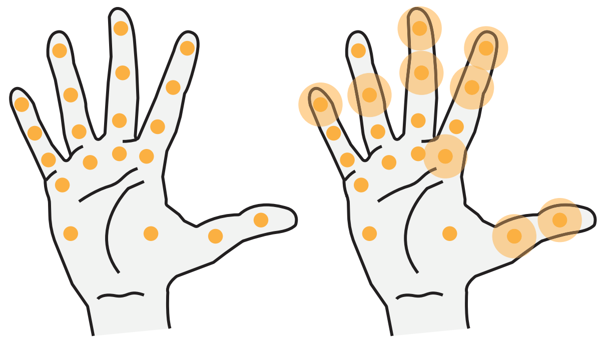
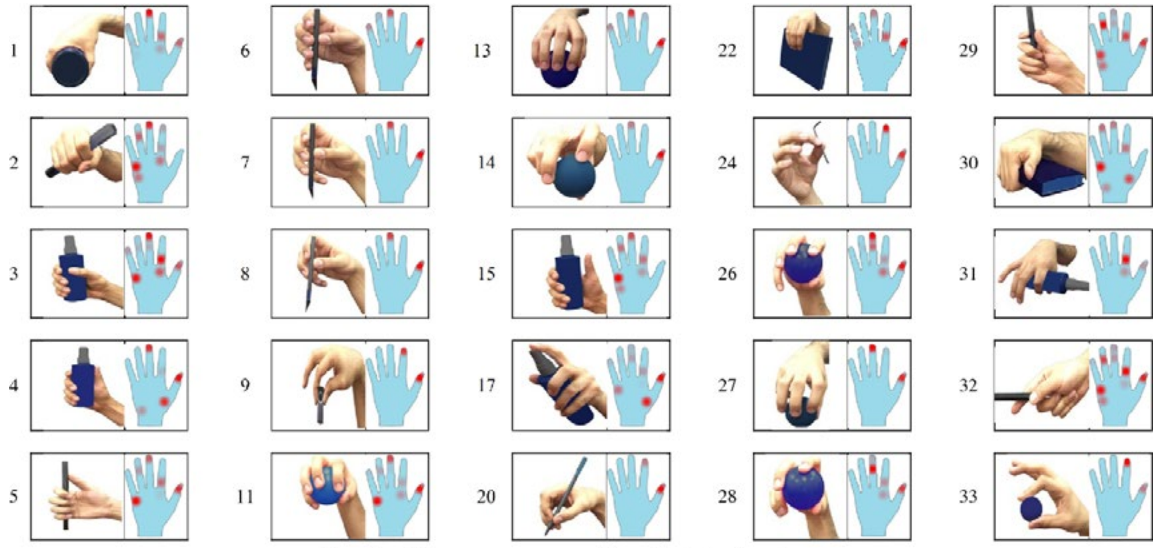


Figure A1.5: Suggested sensor locations by Kargov et al. (2016). Right image indicates location with highest force exertion.



FigureA1.6: Grip pressure locations by Abbassi et al. (2016)

Desired outcome

The ideal outcome for a hand prosthetic is to have somatotopic matched feedback – when the input to a specific part of the prosthesis is experienced in the same lost body part (wijk et al. 2021).

However Neural stimulation should be able to provide sensory feedback that is functionally effective and highly natural, as the naturalness of the feedback plays a pivotal role in prostheses acceptance (Graczyk e al. 2016).

Therefore all the communication between the controller, stimulator and prosthesis sensors need to be in quasi-real time with an unperceivable delay (as in the mammalian somatosensory system) as mentioned by Raspopovic et al. (2021)

Finger human touch capabilities

Dahiya et al. 2015

241/cm2	**700 Hz**
Mechanoreceptor density	Frequency range of vibration
0.1-0.9 N	**<1 mm**
Range of force during normal manipulative tasks	Spatial resolution

Sensor overview

The overall function and advantages and disadvantage of the three most common types of sensors.

Piezoresistive	**Piezoelectric**	**Capacitive**
Change in resistance	Strain (stress) polarization	Change in capacitance
Advantages	**Advantages**	**Advantages**
Flexible Highe spatial resolution Good sensitivity Low noise Low cost Simple electronics	Flexible Workability Chemical stability Good high-frequency response	High spatial resolution Good frequenc response Long term drift stability High sensitivity Low temperature sensitivity Low power consumption
Disadvantages	**Disadvantages**	**Disadvantages**
Large hysteresis Low frequency response Low repeatibility	High temperature sensitivity Poor spatial resolution Dunamic sensing only Simple electronics	Severe hysteresis Stray capacitance Complex electronics Noise susceptible

Sensor types

There are many tactile sensors available on the market. But which one is the best to get the job done? This sub chapter investigates this question.

Zhou et al. 2021 describes in their paper that tactile sensors are based on various principles, including piezoresistivity, piezoelectricity, capacitance, optoelectricity, strain gauge and so on. They describe the three most common principles to be: capacitance, piezoresistivity and piezoelectricity.

Piezoresistive type

Zhou et al. 2021 explains that a pressure-sensitive element whose resistance varies with applied force constitutes piezoresistive sensors. In general, the working principal of a resistive tactile sensor is to transduce external physical information to resistive signals measured by current, voltage and resistance.

Piezoresistive sensors are the most widely used tactile sensors due to their simple structure, low power consumption and high performance. Piezoresistive sensors have proven their application for detecting force, acceleration, temperature, friction and displacement.

Tactile sensors can be used to mimic tactile functions of the human body such as perceiving multiple external information such as pressure, prickle roughness and temperature

Piezoelectric type

The change of resistance in piezoelectric tactile sensors depends on how large a voltage potential is generated when deforming the crystal lattice. For various materials, especially certain crystal, sensitivity depends on crystal structure. Piezoelectric-based pressure sensors rely on the piezoelectric effect when dipoles form an internal polarization under pressure.

Capacitive type

Capacitive sensors consist of two conductive plates with a dielectric material sandwiched between them. A capacitive sensor constantly monitors the electrical capacity of the touch area. A human finger works as a conductor and upon touching the sensor surface it will result in a distortion of the electrostatic field.

Conclusion

Lack of tactile feedback is among the reasons for prosthesis rejection. Including tactile feedback improves product handling, body ownership and decreases phantom limb pains.

Research by Abassi and Kargov can serve as guidance for picking the locations for tactile sensors.

Research by dahiya et al. 2015 can serve as a guideline for picking the appropriate tactile sensor to immitate human touch.

A1.3

State of the art Benchmarking

Research has been done about the state of the art of hand prosthesis. A list of the most prominent existing solutions have been benchmarked based on Price, TRL, Customizability, Adaptability, Performance (Watertightness, Feedback).

Also mechanical and functional insights have been gathered regarding design solution examples. This resulted in an overview of the current market and are translated into criteria and opportunities.

5.6.2. Method

14 arm prostheses have be analysed and benchmarked based on the following parameters:
- TRL (technical readiness level)
- Customizability
- Tailoredness
- Sensory feedback
- Waterproofness
- Grip types
- Max carry load and grasp forces
- Opening time
- Weight
- Price

Information has been gathered from company websites, papers, videos of prosthesis users, and product manuals.


Modular Prosthetic Limb


Luke Arm


Hero Arm


Taska Hand


i-Limb


Bebionic


Michelangelo


Vincent Evolution


Nexus


Zeus Hand


True Limb


Ability Hand


Esper


Zhe Xu Hand

Benchmarks

	TRL	Customizability	Tailoredness	Sensory feedback	Waterproof (IP)	Grips	Lateral force [n]	Power grasp [n]	Finger load [kg]	Carry load [kg]	Open time [s]	Weight [kg]	Cost [x1000 Eu]	Adapt grip	Prop speed	Auto grip	Trans Radial	Trans Humeral	Shoulder	App
MPL	7	1	3	3	67	16	112	312		16	0.3	4.8	420	Yes	Yes	yes	yes	yes	yes	no
Luke	8	1	1	1	52	6						4.7	100	Yes	Yes	no	yes	yes	yes	no
Hero	9	3	2	1	20	4				8	0.5	0.35	15	no	yes	no	yes	No	no	yes
Taska	9	2	2	1	67	23	22	50		20	1.0	0.67	50	yes	yes	yes	yes	yes	no	yes
i-Limb	9	1	2	1	22	24		136	32	90	0.8	0.52	45	Yes	Yes	yes	yes	yes	no	yes
Bebionic	9	3	2	1	22	14	26.5	140.1	25	45	0.5	0.59	32	yes	yes	yes	yes	yes	no	yes
Michelangelo	9	2	2	1	22	7	60	70		20	0.37	0.51	55	No	Yes	No	yes	yes	no	yes
Vincent	9	3	2	2	68	20	15	60			0.8	0.41	40	yes	yes	No	yes	yes	no	yes
Nexus	9	3	2	2	44	24	22	80	16	90	0.7	0.59	25	yes	yes	yes	yes	yes	no	
Zeus	9	2	1	1	22	14		152		35	0.7	0.56	13	no	yes	no	yes	yes	no	
True Limb	9	3	3	2	22	6			6.8	13.6	0.7	0.5	6	no	yes	no	Yes	no	no	yes
Ability	9	2	2	2	64	32				23	0.2	0.47	27	no	yes	no	yes	yes	no	yes
Esper	8	1	2	1	22						0.8	0.41	15	no	yes	no	Yes	Yes	no	

TRL = Technicall readiness level

1. Basic principles observed
2. Technology concept formulated
3. Experimental proof of concept
4. Technology validated in lab
5. Technology validated in relevant environment
6. Technology demonstrated in relevant environment
7. System prototype demonstration in operational environment
8. System complete and qualified
9. Actual system proven in operational environment

Customizability

1. None - Product has no options for personal customization.
2. Low - Product offers for little customization (e.g. Colors)
3. High - Product offers color customization, customized glove, customized panels

Tailoredness

1. None - there is only 1 size
2. Low - product has a few different sizes to match the users dimensions
3. High - the product is tailormade to match the users dimensions

Sensory feedback

1. None - there is no form of sensory feedback at all
2. Low - Product has little form of sensory feedback in terms of vibrations or haptic feedback upon touching objects
3. High - Product has advanced exteroceptive sensory feedback

Waterproof (IP)

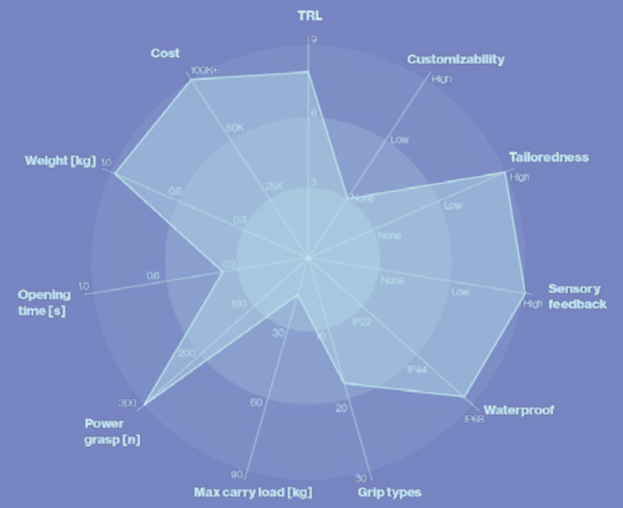
IP 20. Protected from touch by fingers and objects greater than 12 millimeters/ Not protected from liquids.

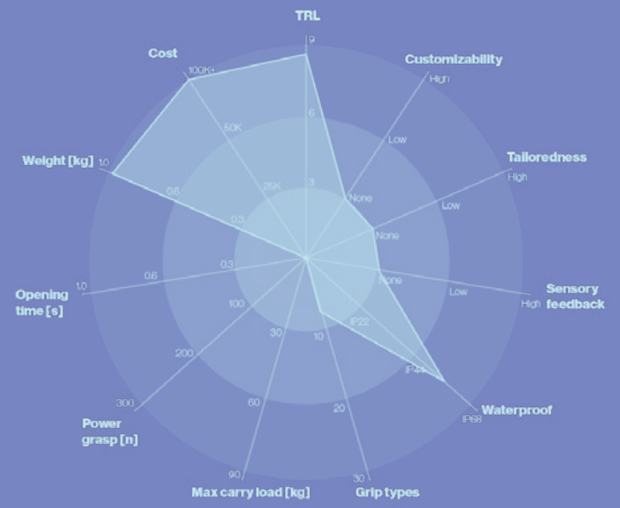
IP 22. Protected from touch by fingers and objects greater than 12 millimeters/ Protected from water spray less than 15 degrees from vertical.

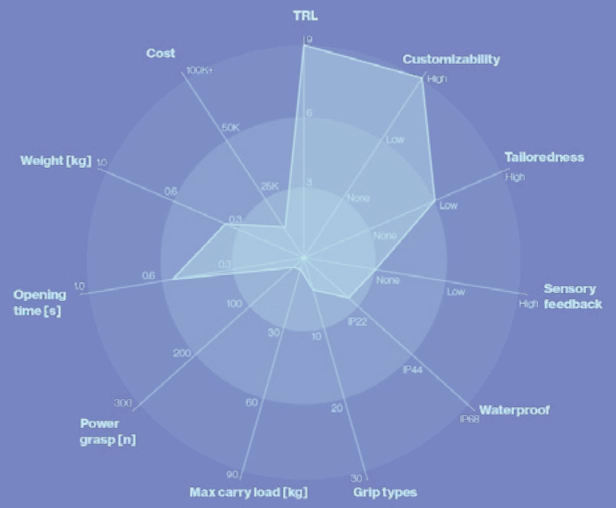
IP 44. Protected from tools and small wires greater than 1 millimeter/ Protected from water spray from any direction.

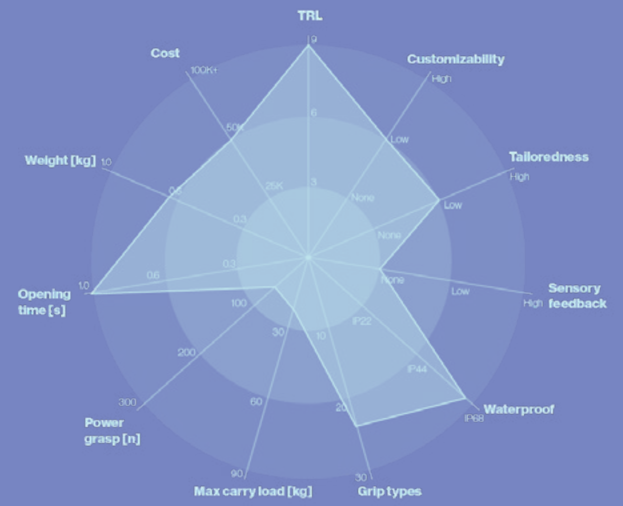
IP 67. Protected from total dust ingress/ Protected from immersion between 15 centimeters and 1 meter in depth.

IP 68. Protected from total dust ingress/ Protected from long term immersion up to a specified preasure.

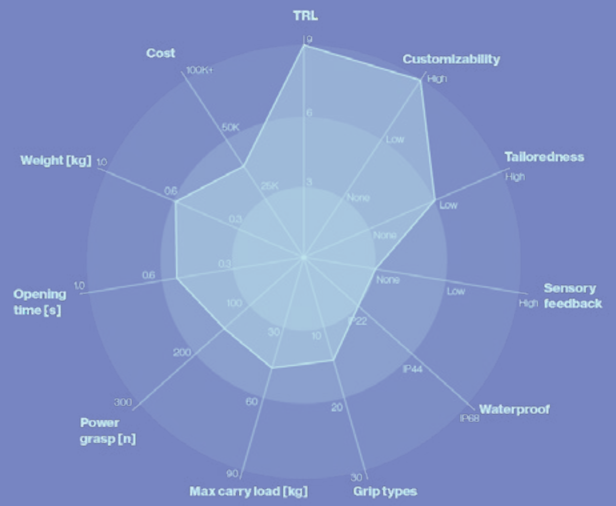

TRL
9
6
3
Customizability
High
Low
None
Tailoredness
High
Low
None
Sensory feedback
High
Low
None
Waterproof
IP68
IP44
IP22
Grip types
30
20
10
Max carry load [kg]
90
60
30
Power grasp [n]
300
200
100
Opening time [s]
1.0
0.6
0.3
Weight [kg]
1.0
0.6
0.3
Cost
100K+
50K
25K

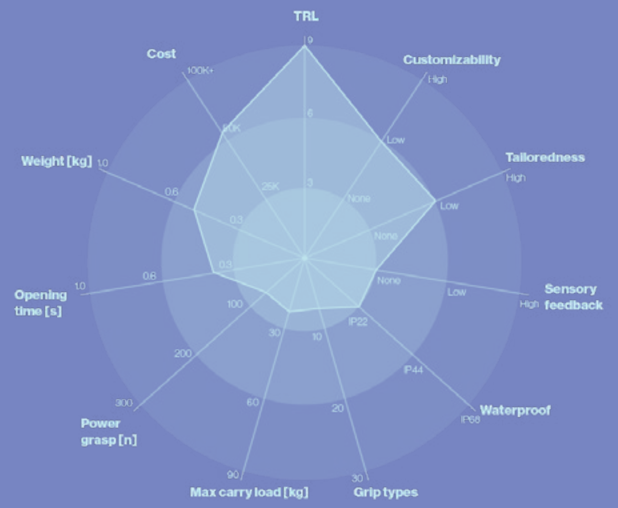

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

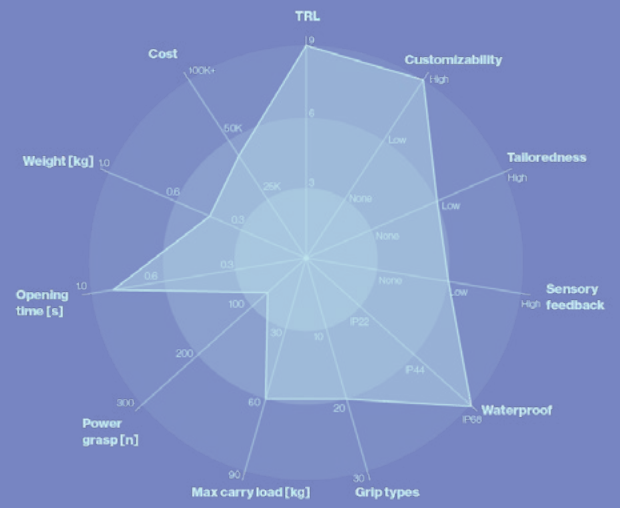

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

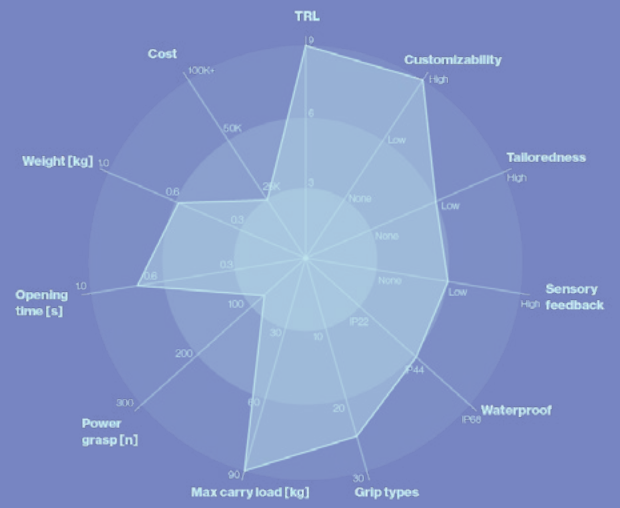

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

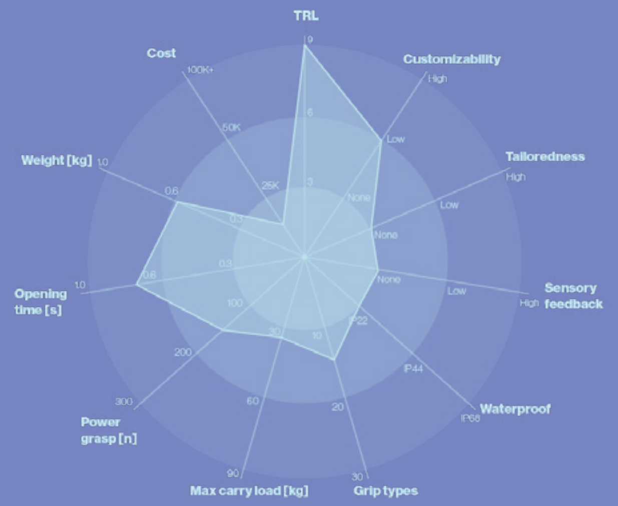

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

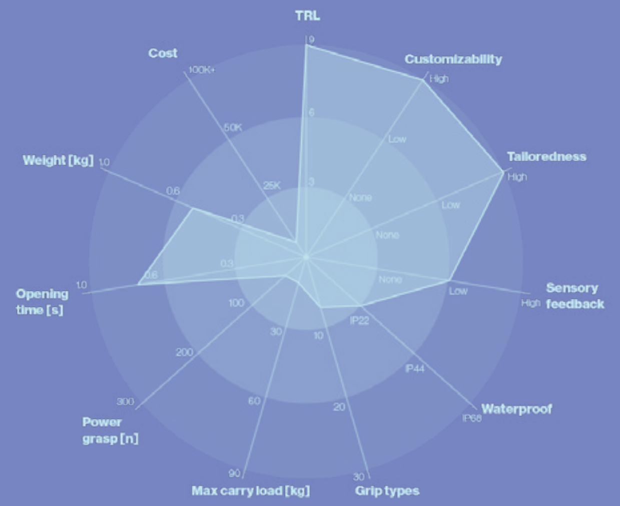

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

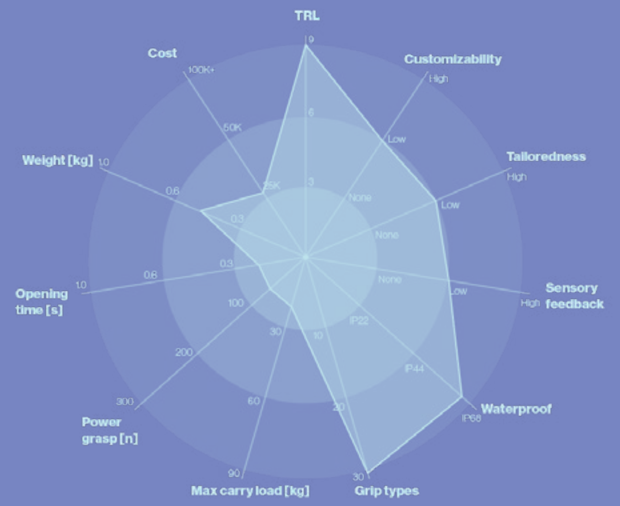

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

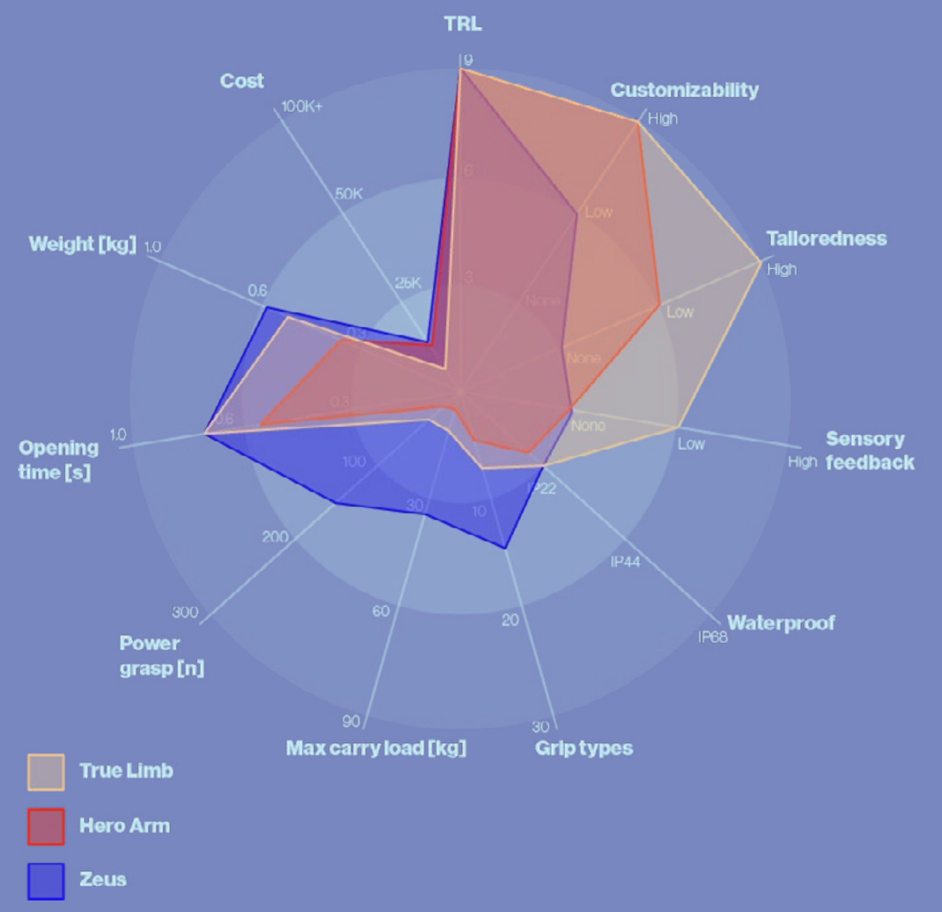

TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost


TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost


TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost


TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost


TRL
Customizability
Tailoredness
Sensory feedback
Waterproof
Grip types
Max carry load [kg]
Power grasp [n]
Opening time [s]
Weight [kg]
Cost

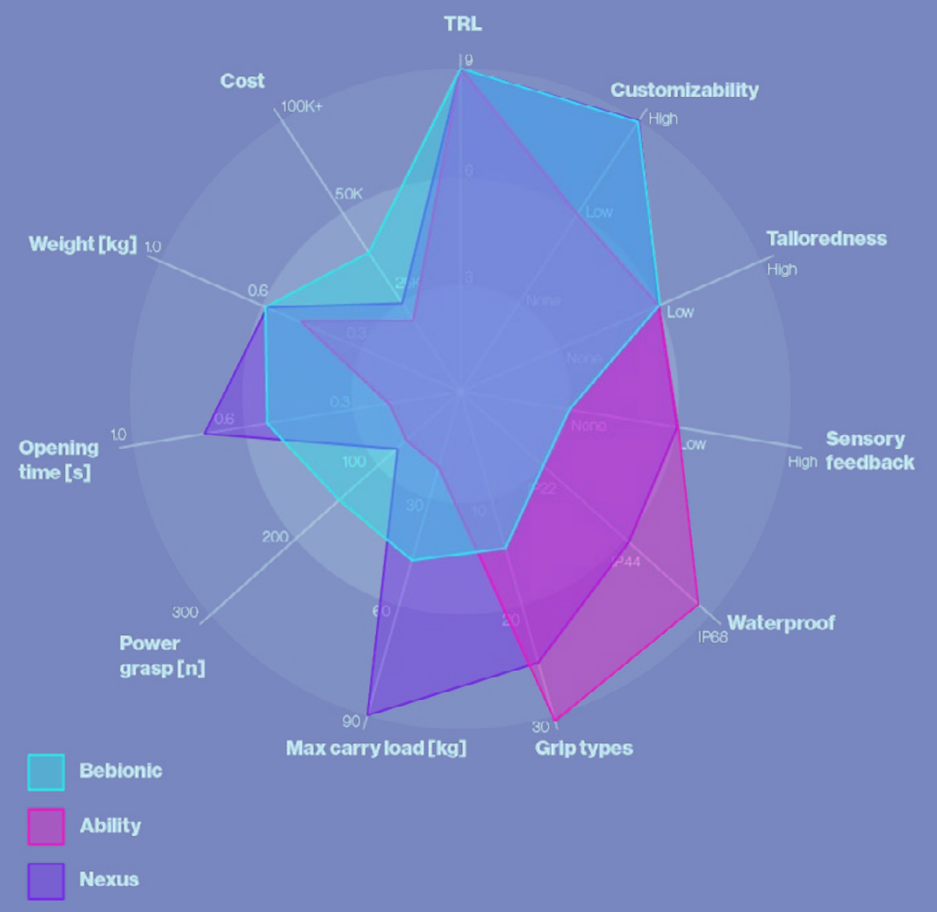


Affordable segment

(6k-19k)

Whats noticable in the affordible low end segment is that customizability and tailoredness score very high. This is due to the use of additive manufacturing techniques. This also makes the products low weight. A negative thing that is noticable is the low performance statistics (carry load, power grasp, grip types, waterproofness).

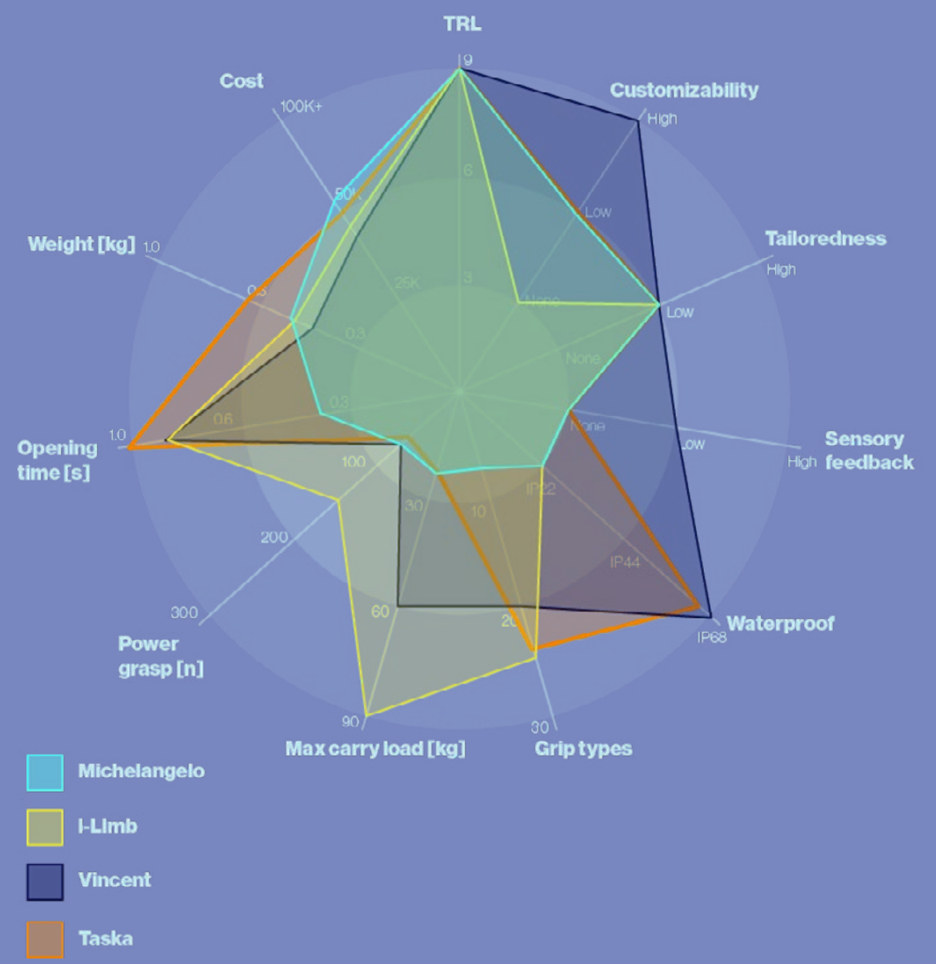
The cheaper hands are often not compatible with 3rd party arm attachments, which causes them to not be available for people with a trans humeral amputation.
Also no adaptive grip and auto-grip features are found in the lower end models.



Middle segment

(20k-39k)

In the middle segment one can also find customizability options and medium tailoredness options. These hands all have standard sizes to choose from. Also one can see introduction of sensory feedback and higher IP values. Also higher performance statistics.

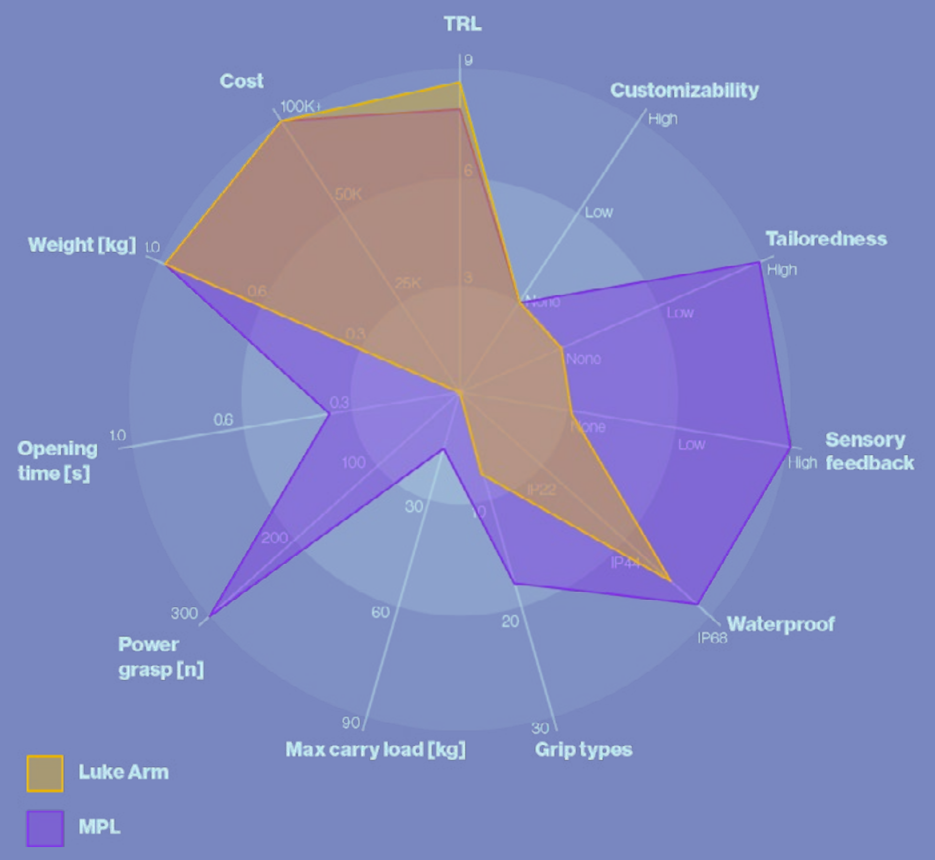


Expensive segment

(40-90k)

The expensive segment does not differ much from the middle segment. Materials are often more durable and sophisticated, but not necessarely. Performance values tend to be higher and all models have several models to fit users different hand dimensions.

The hands in this segment are quite comparible. The Taska and Vincent are more focussed on durability.
The i-Limb more on strength and carry load.
No eye for customizability at all.



Unaffordable segment

(90k+)

The unaffordable segment is also still one thats in development. the MPL arm is so advanced that it outperforms almost all the other hands in terms of power, speed, dexterity, durability and sensory feedback.

Conclusion

Customizability

In terms of customizability there is still a lot of opportunity. Most of the products on the market show only little options.

- a few color options of the body panels
- customized body panel options
- skin tone body panel options
- skin tone sleeve options
- Integrating 'gadgets' in arm (watch)

Only the Hero Arm and the True limb take it so far to provide customized embodiment form!

- Embodiment panels that resemble certain themes

The Ellis arm could stand out in the market by providing atleast custom coloured body parts.

Some arms allow for integrating a personal gadget such as a watch.

Take it a notch further would be allowing customizability of embodiment form.

Tailoredness

Looking at the state of the art there are four options out there in terms of fitting the product to the user.

1. 1 size fits all
2. several sizes M, S, L
3. Several sizes hand palms and phalanges which can be connected to create a hand closely tailored to the hand of the user.
4. Custom designed hand matching the exact hand dimensions of the user.

Although the interview with Bert Pot stated that he didnt care match about his i-Limb not matching his other hand, Scott Summit addressed that symmetry in nature is an important factor for making things appear 'natural'.
Since a lot of people with prosthesis care about the appearance and looking 'normal' one could think it an important USP to allow for custom designed dimensions for the hand dimensions.
Downside is that this takes a lot more time to develop ofcourse making the product more expensive, which is a big issue in this market.

Sensory feedback

Sensory feedback is still very much in its children shoes. So far the majority of models dont have any form of sensory feedback, which makes operating it much harder. The models that do have feedback only have as little as some vibrations or haptic feedback.

Ellis will be able to stand out incredibly with the closed loop sensory feedback system that will be integrated.

Waterproof

Most models on the market are not water or dust proof at all. This limits the use of the prosthesis. The more durable models have IP ratings of 67 which allows for more use environments and actions.

If Ellis wants to compete with the high end segment of the prosthesis market it has to atleast have an IP rating of 67.

Grips

The prosthesis models offer grips ranging from as little as 4 - 6 untill a massive amount of 32. In reality user only use about 4 grips in the majority of the time. And every now and then some extra grips for special activities. Thus saying that more grips does not necessarily means better.

It is important that Ellis can atleast perform the 6 major grips:

1. Chuck grip
2. Fine pinch
3. Key grip
4. Power grip
5. Hook grip
6. Tool grip

Loads & forces

Maximum loads and forces have been examined. Some prosthesis are extremely strong and some are rather weak.

	Lateral force [n]	Power grasp[n]	Finger load [kg]	Carry load [kg]
Lowest	15	50	6.8	8
Mean	63.5	181	19.4	49
Highest	112	312	32	90

Ellis should be able to perform necessary ADL's and should therefore not be weak. The graph shows the lowest, highest and the mean values for common loads and forces.

It is logical to have the values atleast around or above the mean values to compete in the market. Although a power grasp of 181 is rather high. A human hand during normal manipulative tasks exerts 70 [n] in a power grasp.

Opening time

Some hands show to be extremely quick with opening and closing. The majority of hands opens in around 0.5-1.0 seconds.

An outlier is the ability hand with 0.2 seconds. Extremely fast! The biggest advantage with that is that you can catch things mid-air.

To compete with the market standards the Ellis arm should atleast be able to open or close within 0.5 seconds.

Weight

Weights of the hand prostheses vary between 0.35 and 0.67 [kg]. The average weight of a human hand is 0.46 [kg].

The Ellis hand cannot weigh too much ofcourse since this will cause a heavy momentum and stress on the implant. A weight between the 0.46 and 0.67 seems desirable and reasonable.

Cost

The cost price of prostheses has been a big issue. Many people are not able to afford a 50K prostheses. Therefore there is also a cheaper market segment with prostheses ranging from 6k to 15k. Often these protheses are very weak and only usable for simple manipulative tasks.
The higher market segments of 20 to 50K offer obviously higher quality performance products which are also more durable.

If the Ellis arm is able to outperform the higher market segment models in the important areas it is more than justified that it costs around or more than that price. Which would mean a cost price of around 50-70K.

Adaptive grip & proportional speed

The higher segment models also seem to have functions like adaptive grip, anti-slip and proportional speed.
Adaptive grip means the fingers stop moving after having reached a certain level of resistance while grabbing an object.
Anti-Slip means that the hand can add extra force when it notices that an object is slipping out of the grasp
Proportional speed means that the hand opens and closes faster or slower depending on the amount of muscle tension is exerted to the EMG

Ellis needs to have all these functions in order to compete with the top segment of the market.

Configuration

Most of the protheses on the market are designed in such a way that they are compatible with 3rd party arms. This means that one can attach their hand to either a trans radial or a trans humeral arm, making it available for a bigger part of the market.

This obviously does not go up for the Ellis arm since this one will be connected with the use of osseo integration. Which is a very novel way of connecting arm protheses. Therefore an entire arm has to be designed for this hand by ourselves. It is considerable to design an arm for either trans-radial and trans-humeral amputedusers. In this way a bigger market segment can be addressed.

App

Most of the arms also come with an app which allows for adjusting settings, monitoring performance or customizing grip patterns.

An application which allows to monitor performance and adjust settings seems like a benificial and necessary option to include in the future.

Other learnings

Tendon cords

Several hands such as the Hero arm, True Limb and the i-Limb make use of cords inside of the finger which serve as tendons.

When the motors pull on these tendons, which are connected to the distal phalanx, the finger rotates around certain axis. In order to move the finger back to its natural position there are small springs located at the joint sections of the phalanges.

A disadvantage is that in most of the hands I've encountered that use this mechanism the cords are visible and vary prone to being damaged or break.

On the other hand the tendon system is more accurate to the real function of the hand. The experimental hand by Zhe Xu uses 3 tendons per finger, simulating almost all finger functions of a real finger.

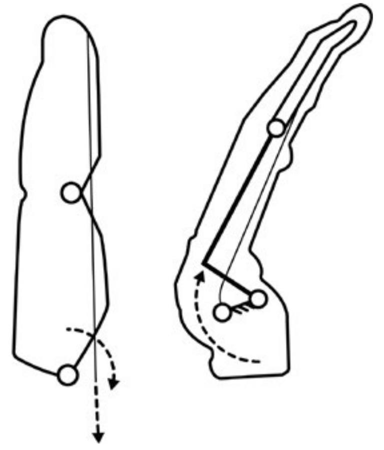
Solid 1 DoF

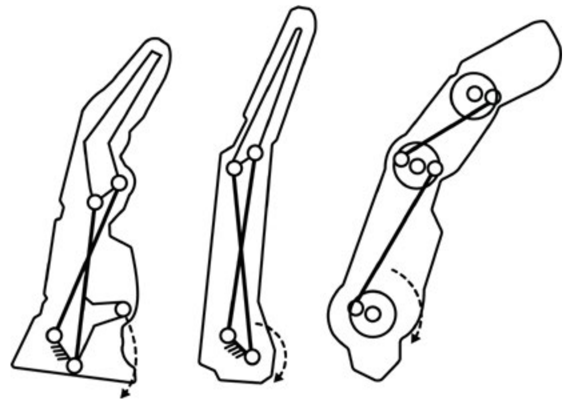
The Michelango by Ottobock has quite a simplistic approach. The finger is shaped in predefined angle and is only actuated at the MCP joint. This allows the finger to have only 1 DoF.

Kinematically connected

One of the most used approaches in all the hands that have been examined are is with a kinematically connected bar system.

This is seen in for example the Bebionic, Vincent Evolution and MPL. The advantage of this system is that is robust and very direct. Also the finger can be actuated more accurately in both flexion and extension motion, whereas this is harder with a cord system.

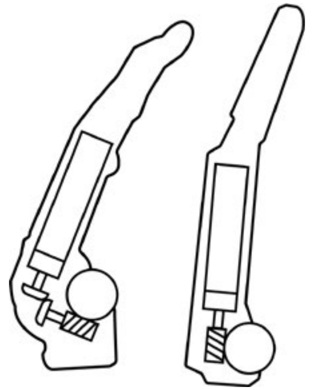




Actuation solutions

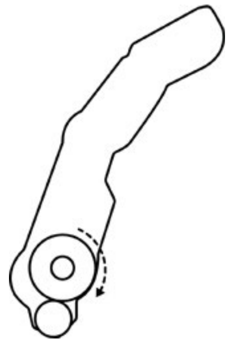
Motor in finger

In terms of actuation solutions there are several different options. I've seen both linear motors and rotational motors in all kinds of different places of the hand and even in the fingers. Showcased here are the i-Limb and the Vincent Evolution



Motor in MCP joint

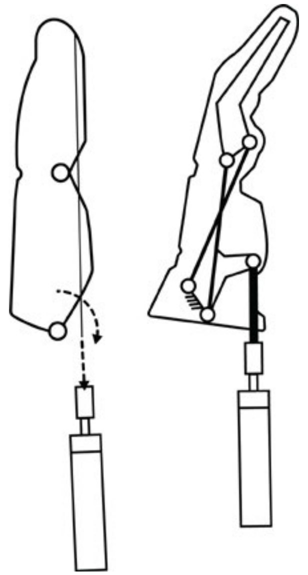
For finger flexion and extension the MPL uses a small brushless DC motor with a cycloidal drive (torque ratio of 341:1).



Motor in MCP joint

Many of the models have the motors located in the hand palm and pull on the fingers with a linear motion. As illustrated in figure x this is how it is done for the Hero Arm and the Bebionic.

The michelangelo has an even more unique approach. This hand has only 1 giant motor in the and palm that actuates all the fingers and the thumb at the same time.



Pneumatic

None of the commercially available hands had pneumatic actuation. They do exist, but these are mostly experimental and have never made it to the market.

MPL Arm

John Hopkins University

The MPL (modular prosthetic limb) is a project funded by DARPA with over 15 years of R&D to create the best arm prosthesis out there.

The MPL is an osseintegrated mind controlled arm with sensory feedback. With the use of an EMG band muscle signals are read to control the actuators.

Configuration

Configuration options: Wrist, trans radial, trans humeral, shoulder

The MPL is designed to be extremely modular, hence its name. It comes with an option for people with a wrist amputation, trans lateral, trans humeral amputation and shoulder disarticulation.

7	**TRL**	Technical readiness level Ranging 1 - 9
Low	**Customizibility**	Product appearance customizibility option by user
High	**Tailoredness**	Rate in which product is tailor-made to user
High	**Sensory feedback**	The rate in which the arm is able to give sensory feedback
IP 67	**Waterproof**	Grade in which the product is waterproof

Performance

16	Grips
112	Lateral pinch [N]
112	three jaw pinch force [N]
312	Power grasp [N]
16/20.4	Carry load in [kg], bicep curl [kg]
120	Upper arm joint speed [deg/s]
120	Wrist join speed [deg/s]
300	Hand open close time [ms]
4.8	Total weight [kg]
3.6	Upper arm + battery [kg]
1.2	Hand + wrist [kg]
16	Battery [V]

420	**Cost**	x 1000 €
tba	**Production year**	Year in which the product is released for consumer use

https://www.jhuapl.edu/Prosthetics/ResearchMPL
https://bionicsforeveryone.com/atom-touch-from-atom-limbs/#lift-capacity-strength

Technical readiness level

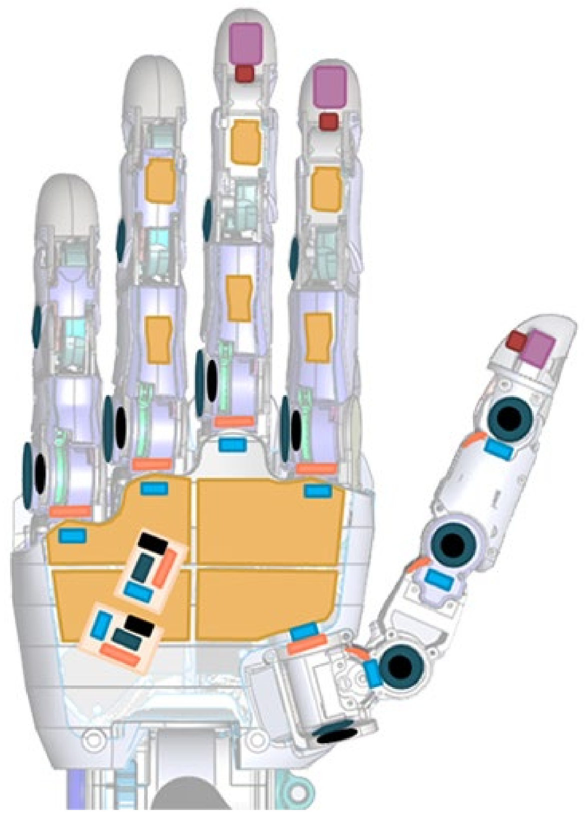
The MPL arm is not yet ready for the consumer market. It has been tested with over 20 participants and the prototype has proven its functionality in operational environment. The product scores a 7 on the TRL. But as of yet the product is not launched on the consumer market yet.

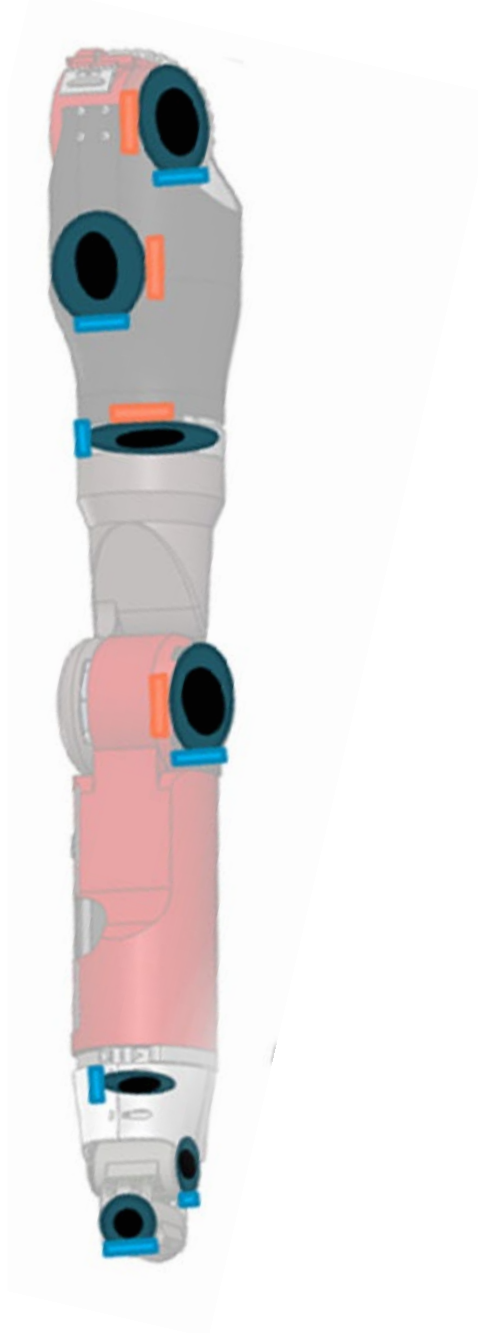
Customizability

Two variations of the MPL cosmesis were developed: the work glove, a functional covering that is less expensive and more durable, and the standard glove, a fully realistic cosmetic cover that includes artistic detailing to resemble a natural limb and spectrally insensitive color formulations.

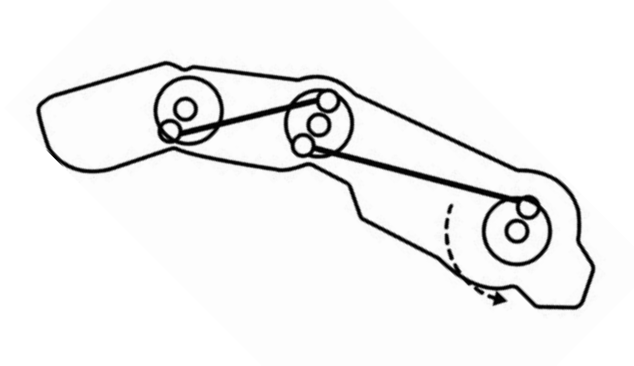
Sensory feedback

There are over 100 sensors in the MPL of which a total of 10 different sensors. The sensors allow for targeted sensory reinnervation. This gives the user back a sense of touch. These sensors give feedback of force, vibration, fine point contact and even temperature/heat flux.





■	Absolute Position Sensor (21)
■	contact Sensor (10), Torque Sensor (14)
■	Torque Sensor
■	Joint Temperature Sensor (17)
■	3-Axis Accelerometer(3)
■	3-Axis Force Sensor (3)
■	Incremental Rotor Position Sensor (17)
■	Drive Voltage Sensor (17)
■	Upperarm Drive Current Sensor (7)

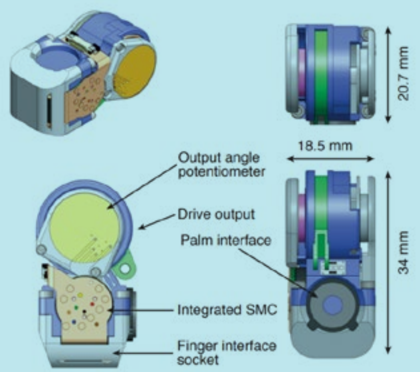


Technology breakdown

The MPL is a very technological advanced product. In this section the technology and principle of the arm is examined. The MPL is designed to be modular, meaning that the hand is operationable as an arm but also as a hand only for hand amputees. This required all hand actuation to be located in the hand. he product scores a 7 on the TRL. But as of yet the product is not launched on the consumer market yet.

Metacarpophalangial joint (MCP joint)

For finger abduction and adduction actuation within the metacarpophalangeal (MCP) joint the MPL uses a small burshless DC motor with a three-stage planetary drive (torque ratio of 352:1), which allows for two actuated degrees of freedom whilst maintaining the required torque (Johannes



Finger

For finger flexion and extension the MPL uses a small brushless DC motor with a cycloidal drive (torque ratio of 341:1). The MCP Cycloidal Drive in the finger is kinematically connected with the joint of the middle phalange with the use of a beam and this joint is then connected to the joint of the proximal phalange.

Thumb

The paper states that an effective thumb for a dexterous hand requires 4 degrees of freedom (Johannes et al. 2011).

The thumb uses four three-stage planetary drives with associated SMC (Small motor controllers) which allows for four actuated degrees of freedom.

Hand palm

The handpalm contains 2 PCBs. This location was chosen to enable full modularity of the arm. In this way the MPL is able to be used for any level of arm amputee.

Wrist

The wrist has three drives: rotation, abductions/adduction and flexion/extension.

Lower arm

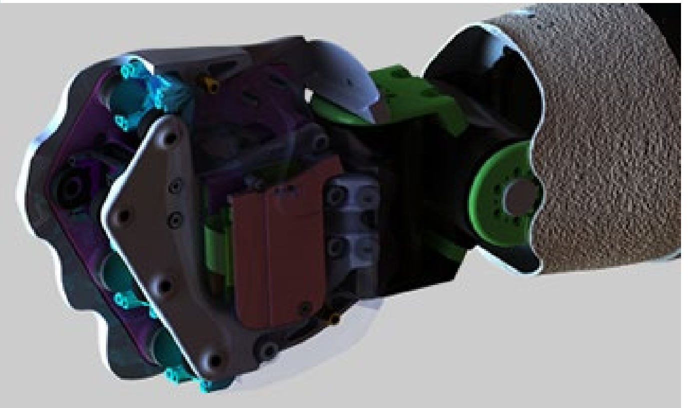
The lower arm contains the elbow joint which is able to flex and extent with the use of a small torque motor.

Upper arm

The upper arm contains the shoulder with two drives which enable abduction/ adduction and flexion/extension of the upper arm.

Battery

The MPL is a very technological advanced product. In this section the technology and principle of the arm is examined. The MPL is designed to be modular, meaning that the hand is operationable as an arm but also as a hand only for hand amputees. This required all hand actuation to be located in the hand. he product scores a 7 on the TRL. But as of yet the product is not launched on the consumer market yet.



Luke Arm

Mobius bionics

The Luke Arm (inspired by star wars character Luke Skywalker) is a DARPA funded project for a multiarticulated arm prosthesis.

The Luke arm is operated with the use of EMG electrodes and a foot mounted interial measurement unit. The arm is attached either with osseo integration or a socket.

Configuration

Configuration options: Wrist, trans radial, trans humeral, shoulder

The Luke arm is designed to be modular. It comes with an option for people with a wrist amputation, trans lateral, trans humeral amputation and shoulder disarticulation.

TRL

8

Technical readiness level
Ranging 1 - 9

Customizibility

Low

Product appearance customizibility option by user

Tailoredness

Low

Rate in which product is tailor-made to user

Sensory feedback

Low

The rate in which the arm is able to give sensory feedback

Waterproof

IP 52

Grade in which the product is waterproof

Performance

6	Grips
N.A.	Lateral pinch [N]
N.A.	three jaw pinch force [N]
N.A.	Power grasp [N]
N.A.	Carry load in [kg]
N.A.	Upper arm joint [deg/s]
N.A.	Wrist join speed [deg/s]
N.A.	Hand open close time [ms]
4.7	Shoulder [kg]
3.4	Humeral [kg]
1.4	Radial [kg]
14.8	Battery [V] Li-ion (7000 mAh)

Cost

100

x 1000 €

Production year

2016

Year in which the product is released for consumer use

Technical readiness level

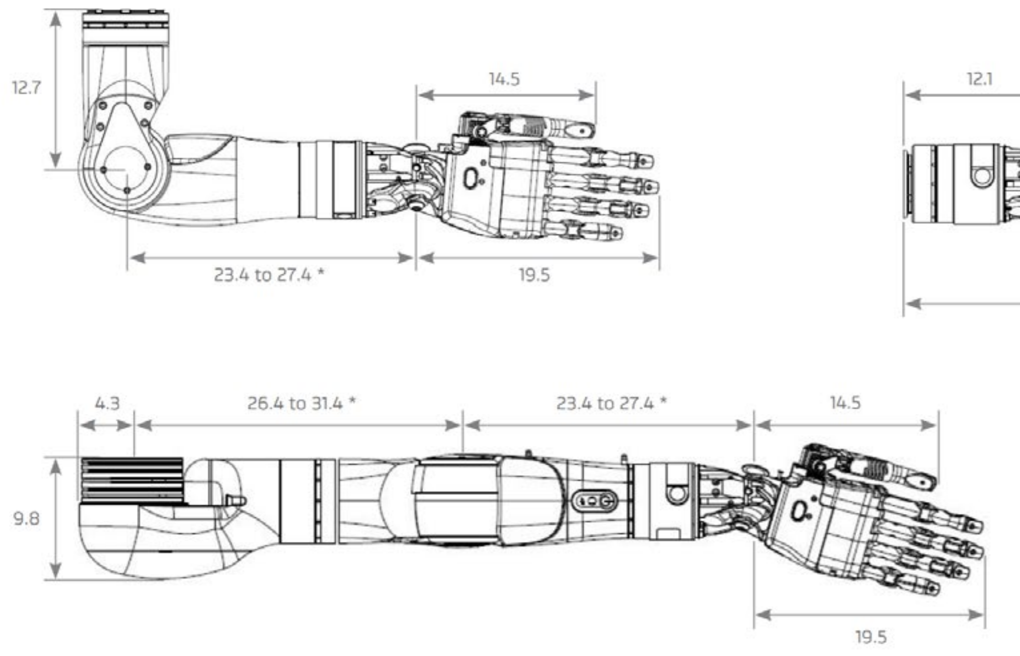
The Luke arm has ben launched in 2016 for consumer use.

Customizability

The luke arm is not customizable, but does come with a silicone glove.

Sensory feedback

The luke arm has simple sensors in the thumb and finger tips which give a vibrating feedback to the users body.



All Dimensions in cm

* Available in 1 cm increments

Hero Arm

Open Bionics

Open bionics is a startup in Bristol. Their mission is to turn disabilities into superpowers.

The Hero arm is a myoelectric actuated prosthesis for trans radial amputees that uses a fitted socket to attach to the prosthesis to the user. Most of the parts are made using additive manufacturing.

Configuration

Configuration options: Trans radial

The Hero arm is only available for people with a trans humeral amputation. The socket is tailor made to fit the user.

9	**TRL** Technical readiness level Ranging 1 - 9
High	**Customizibility** Product appearance customizibility option by user
Low	**Tailoredness** Rate in which product is tailor-made to user
None	**Sensory feedback** The rate in which the arm is able to give sensory feedback
IP 20	**Waterproof** Grade in which the product is waterproof

	Performance
4	Grips
N.A.	Lateral pinch [N]
N.A.	three jaw pinch force [N]
N.A.	Power grasp [N]
8	Carry load in [kg]
no	Auto grip
no	Adaptive grip
yes	Proportional speed
~1	Hand + arm [kg]
0.28	Small hand [kg]
0.34	Medium hand [kg]
0.35	Large hand [kg]

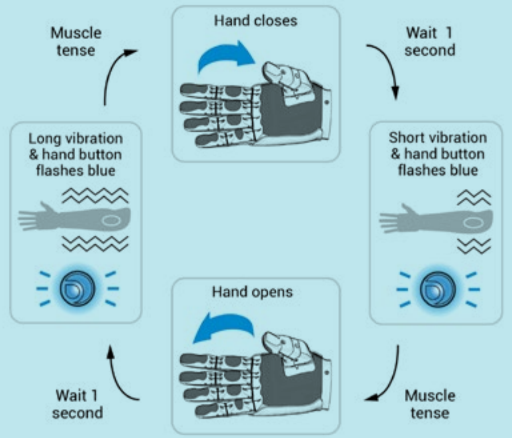
15	**Cost** x 1000 €
2018	**Production year** Year in which the product is released for consumer use

Technical readiness level

The Hero Arm was launched in 2018 and has been used by many users already.

Customizability

When purchasing a Hero Arm by Open Bionics, one can choose to put stylized covers (different colours, themes and patterns) on the prosthesis. Some covers have even been custom designed with a different shape to fit a theme (e.g. deus ex arm). This allows for high customizability and personalization of the product. Because the covers are attached with the use of strong magnets they can be removed, replaced and washed.



Spectrum Covers - Customisable £119.99

Custom Hero Arm Cover

Arm side

Which arm do you want to customise?

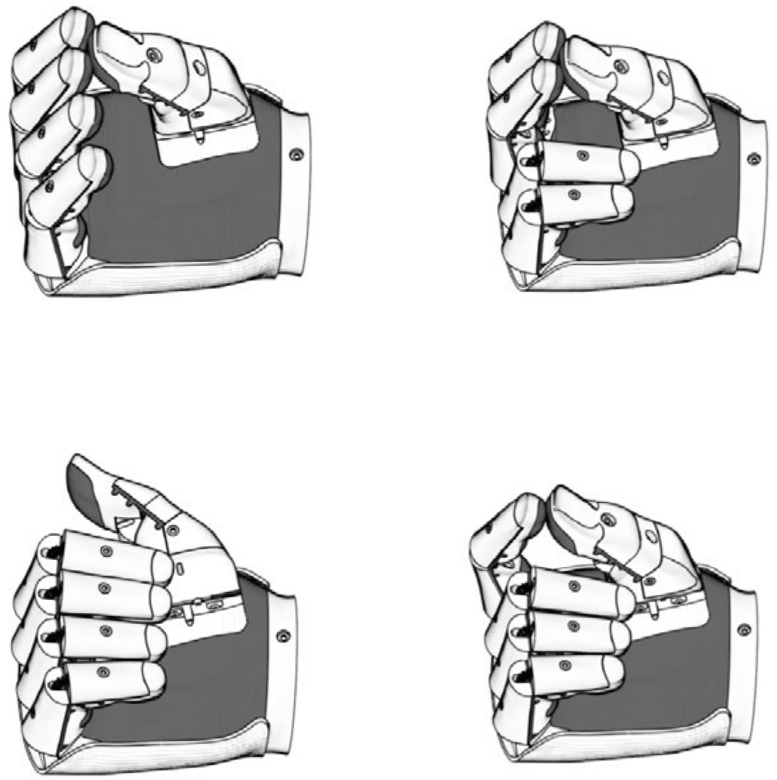
Right Left

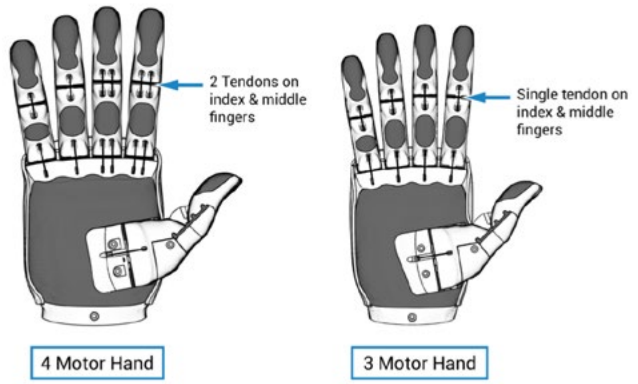
Hand cover - choose your colour

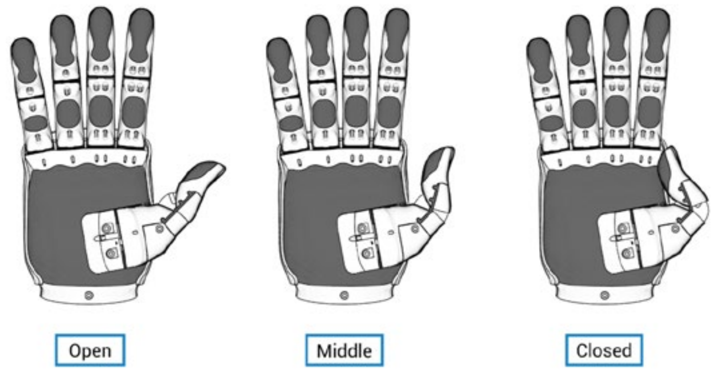
Inside cover - choose your colour

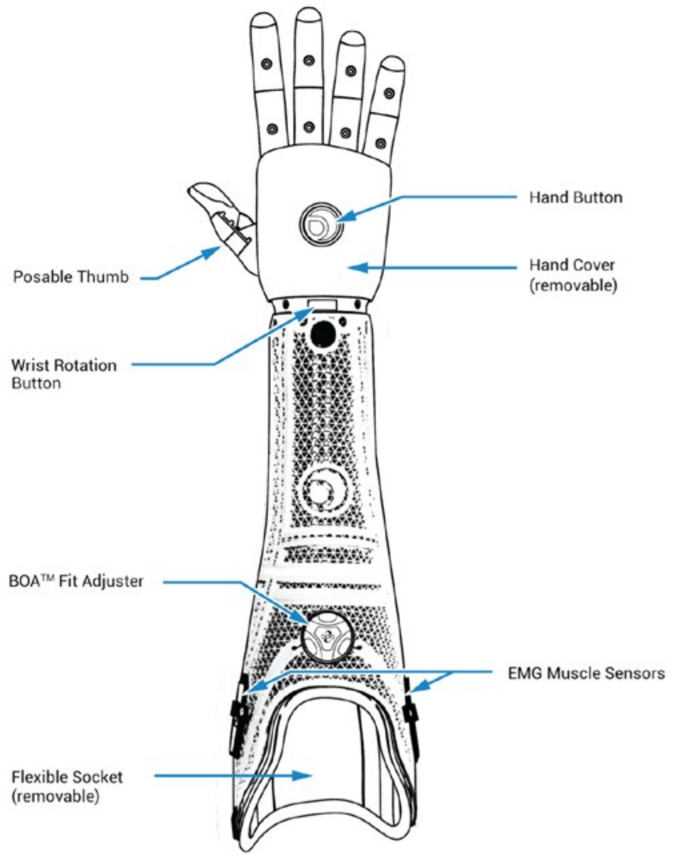
Outside cover - choose your colour

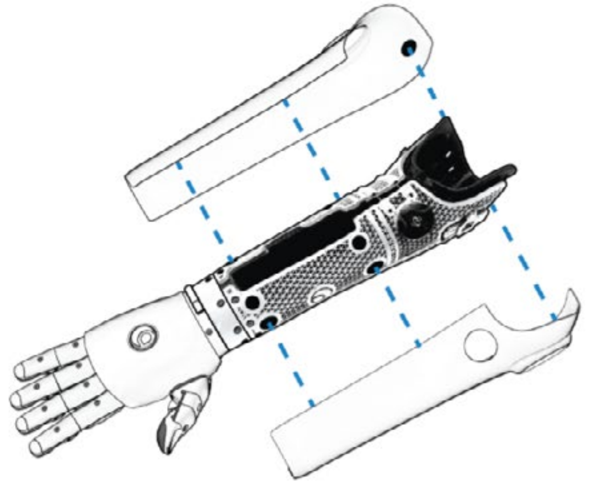
the look and style of it, we've got a customizer
so you can design them yourself, change the

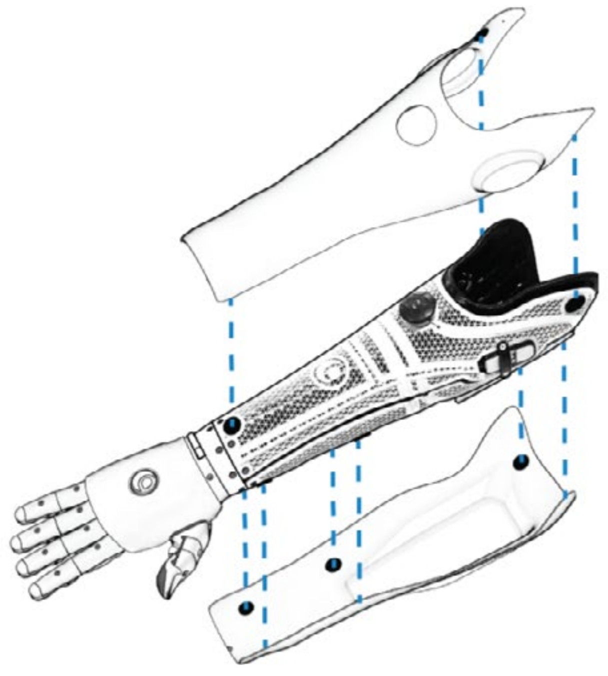












Grips

The Hero arm is able to perform 4 different grips. The hook, the fist, the pinch and the tripod.

In order to switch between grips the user has to press a button. The user will then feel a vibration and see a light flicker a few times.

Drivetrain

The medium and large version of the hero arm come with 4 PQ12-63-12-P Linear Actuator motors and the small one with 3 motors. With the 3 motors version the index and midddle finger are actuated together.

Fingers

The hero arm uses only 2 phalanges for the fingers. The fingers are connected with a flexible plastic. The fingers are actuated by the linear actuator motors which are connected to the finger with a cable which functions as a tendon. Between the joints there are little springs that allow the finger to move back to its neutral position.

Production

The hero arm by Open Bioinics was designed to be cheap and affordable. With the use of lightweight 3D printed parts and smart and modular architectural solutions. The main material used for the embodiment is Nylon-12

Taska Hand

Taska Prosthetics

De Taska Hand is a sturdy, robust and waterproof prosthesis created by Taska Prosthetics.

The Taska Hand is the first ever fully waterproof hand prosthetic. Integrated wrist with passive rotation and flexion. Available in three different colours. Using EMG elektrodes to articulate the fingers.

Configuration

Configuration options: Trans radial, trans humeral

The Taska hand is compatible with 3rd party transradial and transhumeral solutions:

- **Espire elbow pro**
- **Utah Arm 3+**
- **Ottobock dynamic arm+**

9	**TRL** Technical readiness level Ranging 1 - 9
Low	**Customizibility** Product appearance customizibility option by user
Low	**Tailoredness** Rate in which product is tailor-made to user
None	**Sensory feedback** The rate in which the arm is able to give sensory feedback
IP 67	**Waterproof** Grade in which the product is waterproof

Performance

23	Grips
22.0	Lateral pinch [N]
N.A.	three jaw pinch force [N]
~50.0	Power grasp [N]
20	Carry load in [kg]
98	Finger speed [deg/s]
63	Thumb speed [deg/s]
1.0	Hand open close time [ms]
yes	Adaptive grip
yes	Proportional speed
yes	Auto grip
0.67	Weight [kg]

50	**Cost** x 1000 €
2020	**Production year** Year in which the product is released for consumer use

Technical readiness level

Taska Hand was launched in 2020 and is used in the USA and Europe by many users already.

Customizability

The Taska hand is available in 3 color tones: white, black and sand. Furthermore one can choose from 3 sizes: S, M , L.

Grips

The taska hand can perform 23 different grips. in reality only 4-5 grips are used most of the time. The most prominent grips are show on the right. these are the power grip, lateral pinch, bipod pinch, relaxed and keyboard grip.

i-Limb (Q)

OSSUR

i-Limb comes in 3 models: Access model, the Ultra model and the more advanced Quantum model.

The OSSUR i-Limb is a multi-articulated hand prosthesis which uses EMG electrodes. The hand comes with an app that allows for programming grip patterns and monitoring real time hand performance feedback.

9 | **TRL**
Technical readiness level
Ranging 1 - 9

None | **Customizibility**
Product appearance customizibility option by user

Low | **Tailoredness**
Rate in which product is tailor-made to user

None | **Sensory feedback**
The rate in which the arm is able to give sensory feedback

IP 22 | **Waterproof**
Grade in which the product is waterproof

Configuration
Configuration options: Trans radial

	Performance
24	Grips
N.A.	Lateral pinch [N]
N.A.	three jaw pinch force [N]
136	Power grasp [N]
90	Carry load in [kg]
32	Carry load per finger [kg]
N.A.	Wrist join speed [deg/s]
0.8	Hand open close time [s]
Yes	Adaptive grip
Yes	Proportional speed
0.52	Weight [kg]
7.4	Battery [V] (Li-polymer 2000mAh)

90 | **Cost**
x 1000 €

2020 | **Production year**
Year in which the product is released for consumer use

Technical readiness level

The i-Limb comes with accasional upgrades and newer models. Right now the i-Limb quantum is the latest model and is available around the world.

Customizability

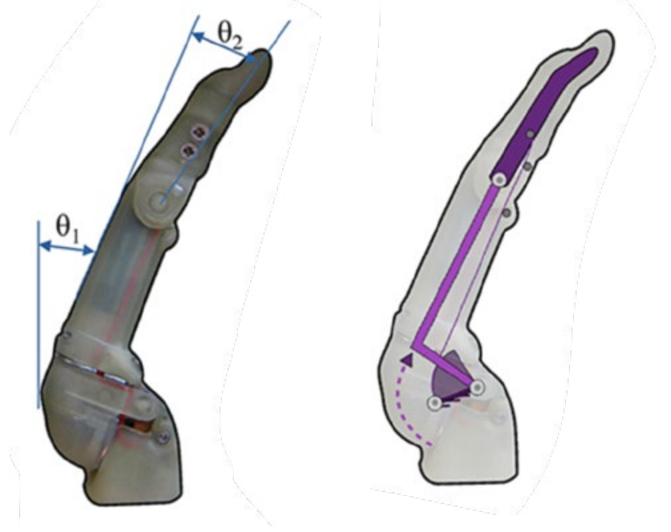
The i-Limb offers no customizability options. The only thing they offer is a glove you can put on it. The glove adds grip and makes the product more waterresistant.

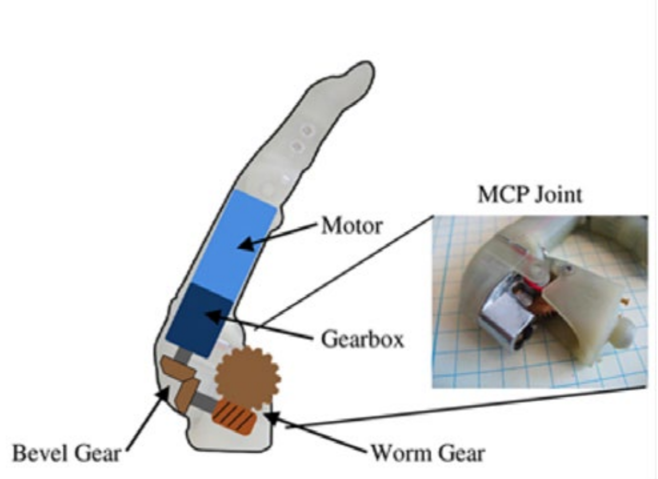
The glove tends to break rather quickly though and looks not very aesthetic or cosmetic at all.

Small

Medium

Large





Technology breakdown

Finger

The fingers are actuated by a motor which is located in the proximal phalanx of the finger, just like the Vincent Evolution. The difference is that the i-limb uses a bevel gear transmission. This causes the knuckle area to be quite large. The distal phalanx is also connected to the MCP joint with a cable. When the finger is actuated this cause the distal phalanx to rotate aswell.

Thumb

The i-Limb Ultra and Quantum come with powered thumb that can abduct and adduct and also flex and exten allowing for a total of 18 grip patterns for the Ultra and 24 grip patterns for the Quantum.

Motor

The iLimb and iLimb Pulse use a Maxon GP 10A with metal 64:1 three-stage planetary gear reduction before entering into a 1:1 set of bevel gears and finally a 25:1 custom worm drive located at the base of the fingers

Wrist

The i-Limb models are all compatible with the i-Limb wrist option.

Battery

Rechargeable lithium polymer; 7.4 V (nominal); 2000 mAh capacity;

Aut-grasps

The i-Limb uses automatic stalling of fingers for ideal grip. Sensors measure the resistance and act accordingly, this also allows for Auto-grasp which prevents user from unwantingly dropping objects if a musscle is shortly triggered accidentally.

Finger movement speed

0.8 [s]

Software

Ossure allows 4 different methods of controlling the i-Limb. These methods are: Application, EMG signals, Gesture contrl and proximity.

the My i-Limb app allows the user to connect to the hand via bluetooth. Within this app the user can control quickgrips. This app can also be connected to a smart watch, which allows easy acces of the quick grips, which is handy for less frequently used grip patterns.

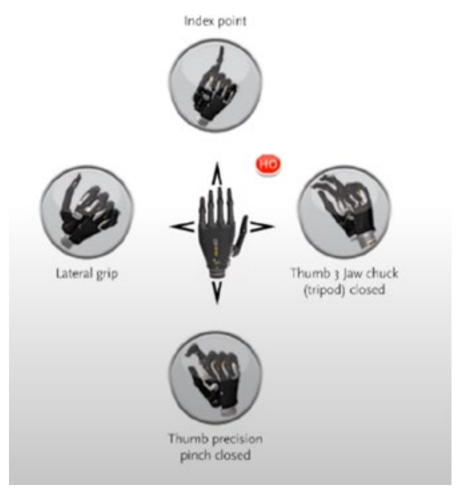
Within the app the user can also set-up certain grip patterns for different activities such as cooking, work-out or office.

Another smart feature Ossur has integrated is gesture control. moving the hand in a certain direction triggers predefined grip patterns.

Another smart feature is the so called grip chip. these are chips that can be placed around the house or office which, if the arm moves within a close proximity of the chip, triggers a certain predefined grip.

Training

ossur provides training for the arm which is devided in three stages:
Stage 1: Opening and closing
Stage 2: Accessing multiple grips
Stage 3: Advanced options



Device Weight			
	Extra Small	Small	Medium/Large
QWD	472g/1.04lbs	512g/1.13lbs	528g/1.16lbs
WD	432g/0.95lbs	472g/1.04lbs	488g/1.08lbs
Flexion Wrist	572g/1.26lbs	612g/1.35lbs	628g/1.38lbs
Friction Wrist	467g/1.03lbs	507g/1.12lbs	523g/1.15lbs

Bebionic

Ottobock

Configuration

Configuration options: Trans radial, trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes in S, M and L sizes.

9	**TRL**	Technical readiness level Ranging 1 - 9
High	**Customizibility**	Product appearance customizibility option by user
Low	**Tailoredness**	Rate in which product is tailor-made to user
None	**Sensory feedback**	The rate in which the arm is able to give sensory feedback
IP 22	**Waterproof**	Grade in which the product is waterproof

	Performance
14	Grips
26.5	Lateral pinch [N]
36.6	three jaw pinch force [N]
140.1	Power grasp [N]
45	Max carry load [kg]
25	Finger carry load (hook) [kg]
90	Max vertical load (knuckles) [kg]
0.5-1.0	Hand open close time [s]
0.6	Large hand [kg]
0.59	Medium hand [kg]
0.57	Small hand [kg]
7.4	Battery [V] (Li-polymer 2000mAh)

32	**Cost**	x 1000 €
2017	**Production year**	Year in which the product is released for consumer use

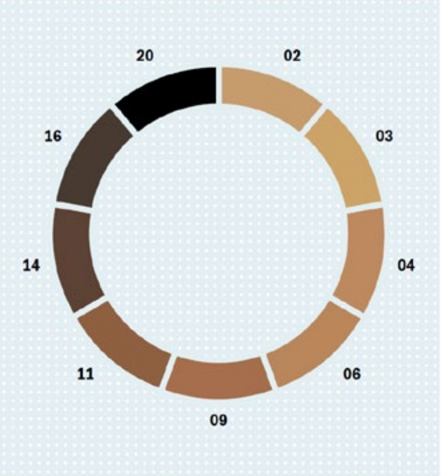
Technical readiness level

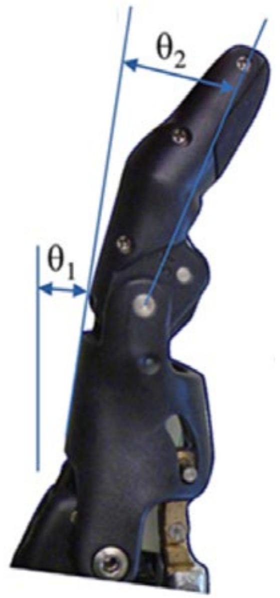
The Bebionic by Ottobock system has been proven in operational environment and produced for the market. Therefore the Hero Arm scores a 9 on the TRL score.

There seem to be some durability complaints about breaking fingers with the Bebionic. But this seems to be a problem in general with bionic hands.

Customizability

Bebionic comes with customizable covers or silicone skin tone sleeves (9 different skin tones). Without sleeve there is options for black or white.





Technology breakdown
The Bebionic is one of the more advanced robotic prosthetic arms on the market. It offers 14 different grip patterns allowing for crucial grips such as:
Power grip
Active index grip
pinch grip
hook grip
prcesion closed grip
tripod grip
precsion open grip
open palm grip
mouse grip
column grip
key grip

motor
Custom Linear drive from reliance precision mechatronics (Belter et al. 2013).

Finger
The bebionic uses a form of a four-bar linkage system. It is actuated at the metacarpophalangeal (MCP) joint and the proximal and middle/distal phalange follow. This is illustrated in figure on the left. **Also the middle and distal phalange are made out of one piece** which is very common for hand prosthetics. The motor located at the MCP joint allows for flexion and extension of the finger.

Thumb
The thumb can be actuate to flex and extent but to abduct and adduct the thumb has to be manually moved. This allows for more grip patterns.

Wrist
The Bebionic comes with four different wrist setups.

EQD wrist
The EQD wrist allows the hand to be removed with rotating action. The user can quickly rotate and remove or attach terminal devices as required.

Short wrist
The Short wrist consists of a low-profile connectorforapplications where there is a long residual limb. A Shortwrist lamination assembly is supplied with these hands.The hand can be rotated against a constant friction,which can be adjusted by the user. For use when length isan issue. Supplied with a lamination ring.

Multi-flex wrist
The Multi-flex wrist offers passive wrist movement in alldirections and the ability to lock in 30° flexion, 30° extension or a neutral position. Lateral deviation remainsavailable while the wrist is locked in the preferred flexionangle.

Flexion wrist
The Flexion wrist is a versatile flexion device that allowsthe wearer to easily lock or unlock the wrist position andreposition the wrist in either a flexion or extensionposition. Offers 30° in either direction and can be lockedin each of the three positions.

Battery
Bebionic comes with a 2200mAh / 7.4 V battery. Dimensions: 18.5x36.5x70 mm.

Finger movement speed
0.5 [s]

Michelangelo

Ottobock

The Michelangelo can be fitted with 6 different skin tone PVC gloves. The gloves are reported to break rather quick.

Configuration

Configuration options: Trans radial, trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes in S, M and L sizes.

9	**TRL** Technical readiness level Ranging 1 - 9
Low	**Customizibility** Product appearance customizibility option by user
Low	**Tailoredness** Rate in which product is tailor-made to user
None	**Sensory feedback** The rate in which the arm is able to give sensory feedback
None	**Waterproof** Grade in which the product is waterproof

	Performance
7	Grips
60	Lateral pinch [N]
15	Neutral grip [N]
70	Power grasp [N]
20	Max carry load [kg]
N.A.	Finger carry load (hook) [kg]
N.A.	Max vertical load (knuckles) [kg]
0.37	Hand open close time [s]
No	Adaptive grip
Yes	Proportional speed
0.51	Weight [kg]
11.1	Battery [V] (Li-Ion 1500mAh)

55	**Cost** x 1000 €
2011	**Production year** Year in which the product is released for consumer use

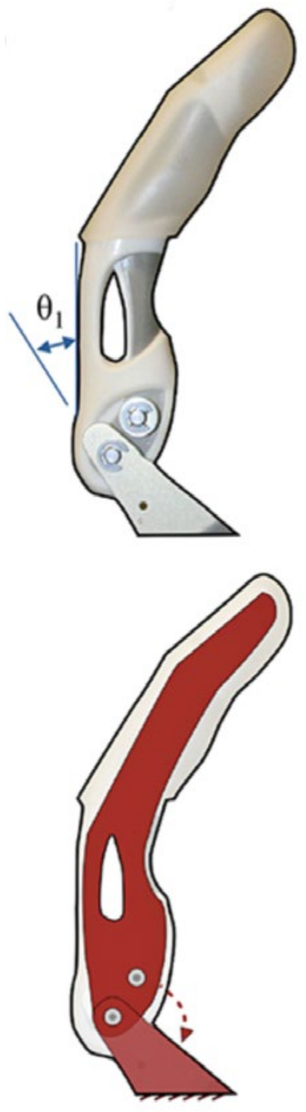
motor
The Michelangelo hand uses one large custom modified brushless Maxon EC45 motor housed directly in the center of the palm to control flexion/extension of all five fingers and one smaller motor in the proximal portion of the thumb to control thumb abduction/adduction. (Belter et al. 2013)

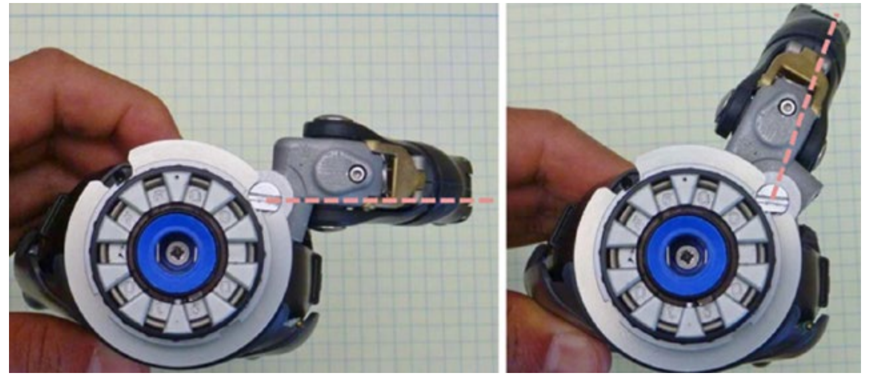
Finger
The michelangelo finger consist of a single finger segment which is actuated at the MCP joint.

Thumb
The thumb is actuated with a second motor. This motor arranges the abduction and adduction of the thumb by actuating against a worm wheel. This small motor changes the path that the thumb will take when the main motor actuates to close the hand either in a palmer or lateral grasp (Belter et al. 2013).

Battery
Ottobock states that the battery life should last up to 20 hours when fully charged. Full charge time is approximately 3.5 hours. Therefore the hand should be recharged everday day.

Wrist rotation
A unique feature of the Michelangelo by Ottobock is the wrist rotation system, which most prosthesis lack. This system allows for a more natural motion and positioning of the hand.





Vincent

Vincent Systems

The Vincent Evolution 4 is the latest model of Vincent Systems.

The vincent evolution is one of the few myoelectric multi articulated hands with sensory feedback. It has been designed to be very lightweight with only 0.41 kg. furthermore it is IP68 certified.

Configuration

Configuration options: Trans radial, trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes in XS, S, M, L and XL and a special child size.

9	**TRL** Technical readiness level Ranging 1 - 9
High	**Customizibility** Product appearance customizibility option by user
Low	**Tailoredness** Rate in which product is tailor-made to user
Low	**Sensory feedback** The rate in which the arm is able to give sensory feedback
IP 68	**Waterproof** Grade in which the product is waterproof

Performance

20	Grips
15	Lateral pinch [N]
N.A.	Neutral grip [N]
60	Power grasp [N]
N.A.	Max carry load [kg]
N.A.	Finger carry load (hook) [kg]
N.A.	Max vertical load (knuckles) [kg]
0.8	Hand open close time [s]
Yes	adaptive grip
Yes	Proportional speed
0.41	Average weight [kg]
8	Battery [V] (Li-polymer 2600mAh)

40	**Cost** x 1000 €
2019	**Production year** Year in which the product is released for consumer use

Technical readiness level

The vincent evolution has proven its value in the market and scores a 9 for technical readiness level.

Customizibility

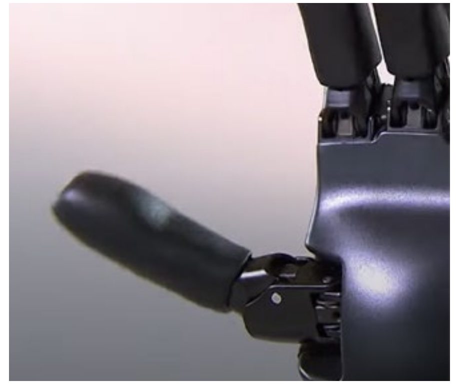
The vincent evolution is available in 4 different tone variants: Blue, Magenta, skin tone and black. It can also be worn with a cosmetic glove.

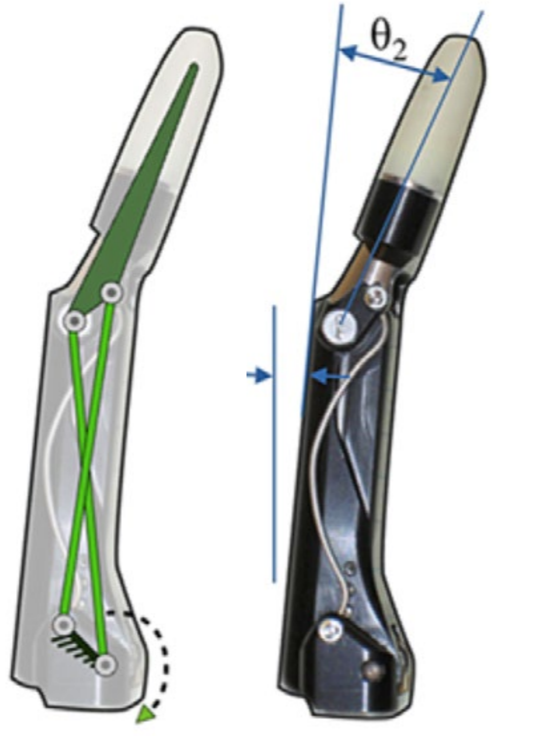
Material

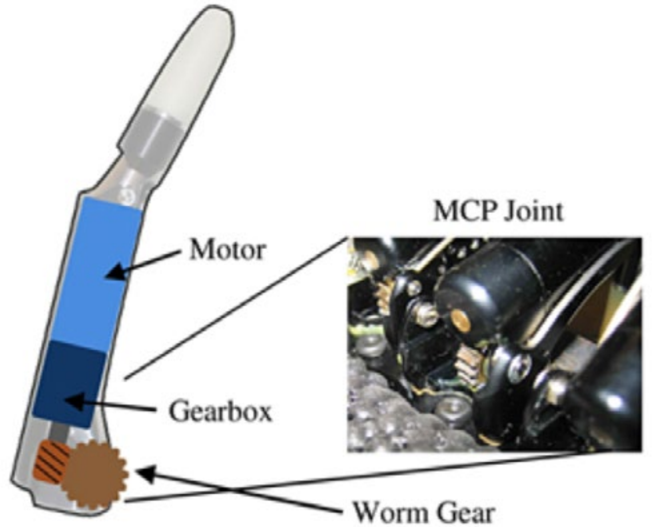
stainless steel and a high-strength magnesium-aluminum alloy.

Feedback

The Vincent has sensors in the finger tips that give vibration feedback to the user. It gives feedback upon touching an object and also indicates how much pressure is used.







Technology breakdown

motor

The Vincent Evolution model covered in an article by Belter et al. 2013 uses a Maxon DC series 10 motor with metal 64:1 three-stage planetary gear reduction before entering into a 1:1 set of bevel gears and finally a 25:1 custom worm drive located at the base of the fingers. (Belter et al. 2013)

Fingers

What is unique for the Vincent Evolution hand is that the motors that actuate the fingers are actually inside of the proximal/middle phalanx. With a worm gear transition conencted with a normal gear the flexion and extension is executed, as is illustrated in figure on the left.

Thumb

The thumb is able to adduct and abduct with the use of small motor which connects the thumb and the handpalm. Flexion and extension is done with the same principle as the fingers.

Wrist

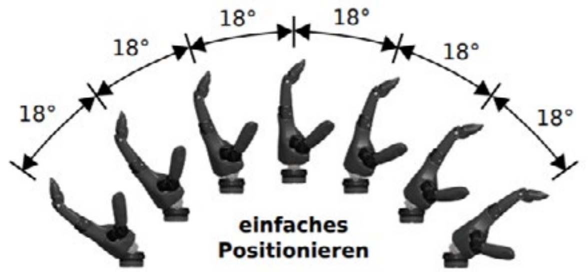
The vincen evolution also comes with a rotation wrist option, which allows flexion and extension of the wrist and rotation around the longitudinal axis of the arm. The wrist is put in to the desired angle manually.

Battery

The Vincent Evolution comes with two different battery sizes.
VINCENTaccu flex 420 nano with 420 mAh
VINCENTaccu flex 1290 with 1290 mAh
They are flexible and very flat (4 mm thick). They are rechargeable with a USB C charging cable and adapter.

Software

There is certain software application available for the Vincent Evolution. This software allows the training of certain grips and is quite advanced.



Nexus

Covvi

The Vincent Evolution 4 is the latest model of Vincent Systems.

At Covvi the goal is not only equipping amputees with the latest upper-body prosthetic tech but also with something that users can customize in a way that speaks to their personality. Something that is undeniably them.

Configuration

Configuration options: Trans radial, trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes in S, M, L.

9	**TRL** Technical readiness level Ranging 1 - 9
High	**Customizibility** Product appearance customizibility option by user
None	**Tailoredness** Rate in which product is tailor-made to user
Low	**Sensory feedback** The rate in which the arm is able to give sensory feedback
IP 44	**Waterproof** Grade in which the product is waterproof

	Performance
24	Grips
22	Lateral pinch [N]
N.A.	Neutral grip [N]
80	Power grasp [N]
90	Max carry load [kg]
16	Finger carry load (hook) [kg]
yes	Auto grip
	Hand open close time [s]
yes	Adaptive grip
yes	Proportional speed
0.57	Average weight [kg]
7.4	Battery [V] 1600 [mAh]

25	**Cost** x 1000 €
2019	**Production year** Year in which the product is released for consumer use

Customizability

The Nexus arm comes with a choice in a variety of different colours for the HDPE covers (gloves).

Feedback

The Nexus has sensors in the finger tips that give vibration feedback to the user. It gives feedback upon touching an object.

Docking station

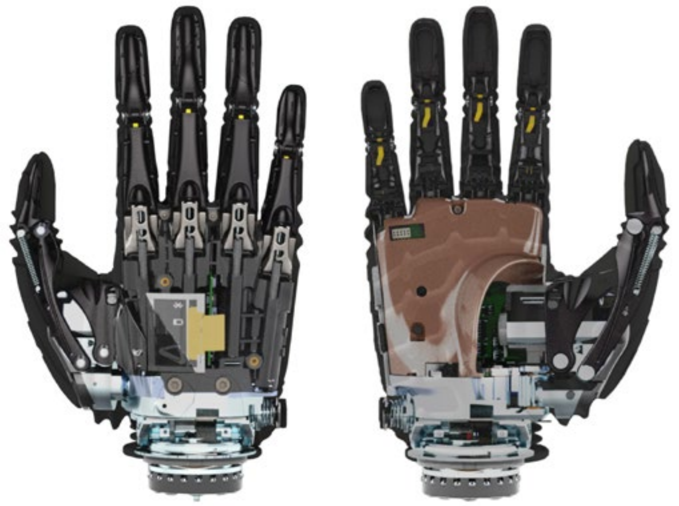
The Nexus by Covvi comes with a handy display unit that can be used to assist with the programming of the hand. Also the hand can be charged in this unit with the use of USB-C charging.

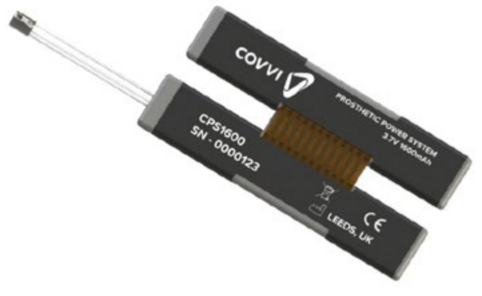
Battery

The Nexus uses a light and flexible battery solution that follows the contours of the limb. It is charged with USB-C. Details: 7.4v 1600mAh, 2xCELLS. The hand also has a little screen that features the battery life.

Elektrodes

The Nexus electrodes operate at a 30-250 Hz frequency band.



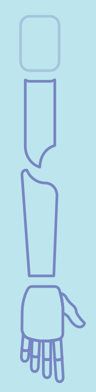


Zeus

Aether Biomedical

The Zeus is one of the cheaper models on the market

The Zeus offers 12 standard grips and 2 extra customizable grips. The covers are fully customizable. The design is modular and parts are easy to repair or replace. It has the highest power grip of all the models on the market with a whopping 152 [N]!



Configuration

Configuration options: Trans radial, trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes in one size.

9 — **TRL**
Technical readiness level
Ranging 1 - 9

Low — **Customizibility**
Product appearance customizibility option by user

None — **Tailoredness**
Rate in which product is tailor-made to user

None — **Sensory feedback**
The rate in which the arm is able to give sensory feedback

None — **Waterproof**
Grade in which the product is waterproof

	Performance
14	Grips
N.A.	Lateral pinch [N]
N.A.	Neutral grip [N]
152	Power grasp [N]
35	Max carry load [kg]
N.A.	Finger carry load (hook) [kg]
50	Max vertical load (knuckles) [kg]
1.5	Hand open close time [s]
Yes	Adaptive grip
Yes	Proportional speed
0.56	Average weight [kg]
7.4	Battery [V] (Li-Ion 2200mAh)

13 — **Cost**
x 1000 €

2020 — **Production year**
Year in which the product is released for consumer use

Customizability

The covers are fully customizable in terms of color or personal print.

True Limb

Unlimited Tomorrow

The true limb is designed to match the users residual limb and being accessible in price.

True Limb is one of the most affordable models on the market and also the one that is most tailered to the user. With customizable skin tone and tailor made hand design. Opposed to that it is also quite weak and often used only by kids.

9	**TRL** Technical readiness level Ranging 1 - 9
High	**Customizibility** Product appearance customizibility option by user
High	**Tailoredness** Rate in which product is tailor-made to user
Low	**Sensory feedback** The rate in which the arm is able to give sensory feedback
None	**Waterproof** Grade in which the product is waterproof

Configuration

Configuration options: Trans radial

The True limb comes with a personal designed socket to fit the residual limb.

	Performance
6	Grips
N.A.	Lateral pinch [N]
N.A.	Neutral grip [N]
N.A.	Power grasp [N]
13.6	Max carry load [kg]
6.8	Finger carry load (hook) [kg] (index)
	Max vertical load (knuckles) [kg]
	Hand open close time [s]
Yes	Adaptive grip
0.5	Average weight [kg]
	Battery [V] (Li-Ion 2200mAh)

6	**Cost** x 1000 €
2020	**Production year** Year in which the product is released for consumer use

Technical readiness level

The True Limb is market ready and scores a 9 in TRL. It is currently only available in the USA and Canada

Customizability

The Truelimb can be customized with a range of 450 skin tone colours.

Material

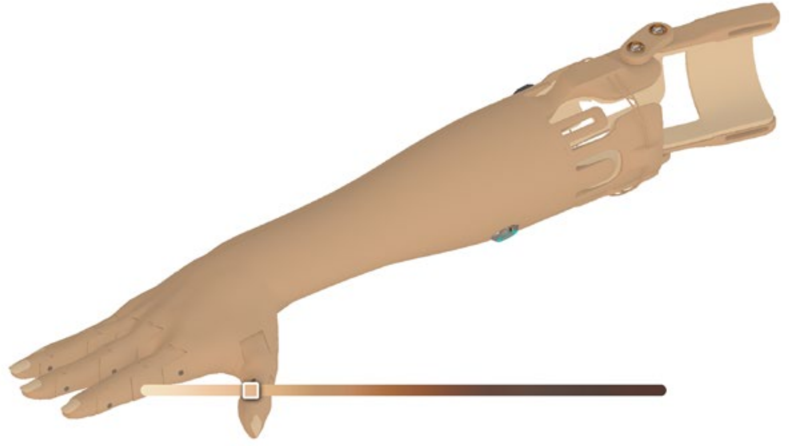
MJF 3D printed PA12 nylon

Technology

Most prosthesis use myoelectrice sensor to detect muscle movements to translate into hand movements. The True limb uses another technology which they called TrueSense. This system senses changes in muscle topology and with 32 sensors it has a 360 degree view around residual arm.

Feedback

Smal haptic feedback upon touching objects.



Ability Hand

Psyonic

The Ability hand focusses on durability, weight, responsiveness, sensory feedback, water/dust resistance

The Ability hand is currently one of the few hands which offers sensory feedback and is splash water resistant. Also its the fastest closing hand with 200 [ms].

Configuration

Configuration options: Trans radial, Trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes in size S and L

9	**TRL**	Technical readiness level Ranging 1 - 9
Low	**Customizibility**	Product appearance customizibility option by user
Low	**Tailoredness**	Rate in which product is tailor-made to user
Low	**Sensory feedback**	The rate in which the arm is able to give sensory feedback
IP 64	**Waterproof**	Grade in which the product is waterproof

Performance

32	Grips
N.A.	Lateral pinch [N]
N.A.	Neutral grip [N]
N.A.	Power grasp [N]
23	Max carry load [kg]
N.A.	Finger carry load (hook) [kg] (index)
26	Max vertical load (chassis) [kg]
0.2	Hand open close time [s]
No	Adaptive grip
Yes	Proportional speed
0.47	Average weight [kg]
7.4	Battery [V] (Li-Polymer) 2000 mAh

27	**Cost**	x 1000 €
2020	**Production year**	Year in which the product is released for consumer use

Technical readiness level

The Ability Hand is market ready and scores a 9 in TRL. It is currently only available in the USA.

Customizability

The ability hand is available in 5 different carbon fiber colours.

Material

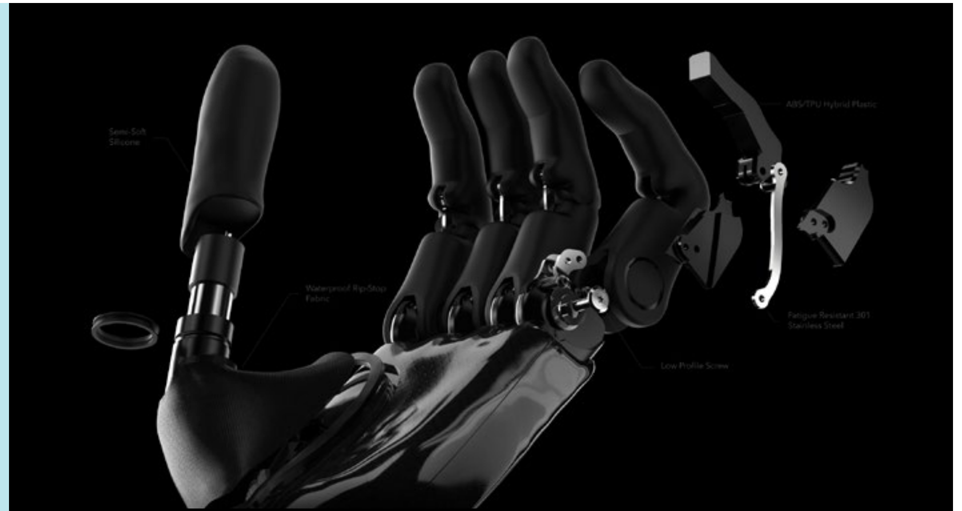
Fingers are made from durable silicone and rubber. Hand body made from carbon fiber.

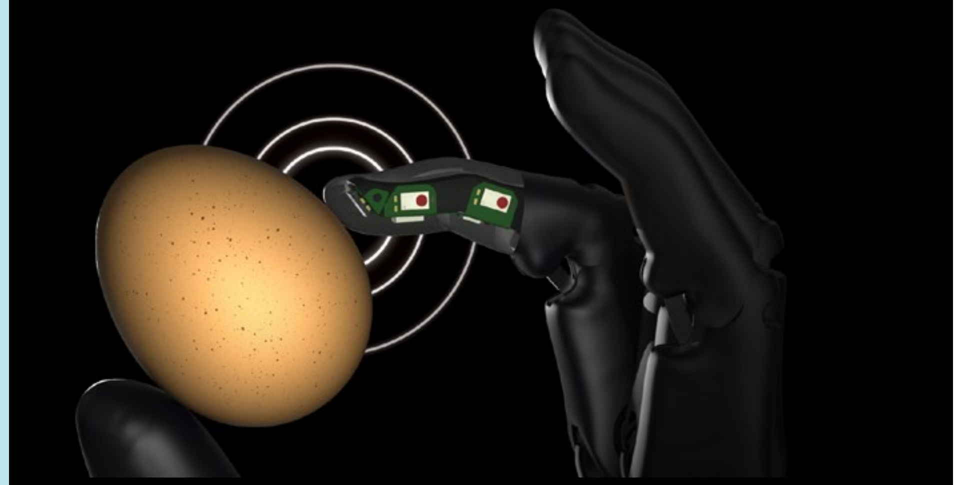
Feedback

The Ability Hand has sensors in the finger tips that give vibration feedback to the user. It gives feedback upon touching an object and also indicates how much pressure is used.

Conditions

The ability hand is stated to function properly between 50°C and -5°C.
With an IP64 rating it means that the hand is protected from total dust ingress and water spray from any direction.





Esper

Esper Bionics

Configuration

Configuration options: Trans radial, Trans humeral

transradial and transhumeral solutions.:
- **Ottobock dynamicArm+**
- **Ottobock ErgoArm**

3rd party:
- **Espire elbow pro**
- **Utah Arm 3+**

The hand comes with 5 sizes of phalanges and 5 sizes of palms with which the user hand size can be replicated

8	**TRL**	Technical readiness level Ranging 1 - 9
None	**Customizibility**	Product appearance customizibility option by user
Low	**Tailoredness**	Rate in which product is tailor-made to user
None	**Sensory feedback**	The rate in which the arm is able to give sensory feedback
None	**Waterproof**	Grade in which the product is waterproof

Performance

N.A.	Grips
N.A.	Lateral pinch [N]
N.A.	Neutral grip [N]
N.A.	Power grasp [N]
N.A.	Max carry load [kg]
N.A.	Finger carry load (hook) [kg] (index)
N.A.	Max vertical load (chassis) [kg]
0.8	Hand open close time [s]
N.A.	Adaptive grip
N.A.	Proportional speed
0.41	Average weight [kg]
N.A.	Battery [V] (Li-Polymer) 2000 mAh

15	**Cost**	x 1000 €
2022	**Production year**	Year in which the product is released for consumer use

Zhe Xu Hand

By Zhe Xu

Configuration

There is only a hand configuration

4	**TRL**	Technical readiness level Ranging 1 - 9
None	**Customizibility**	Product appearance customizibility option by user
None	**Tailoredness**	Rate in which product is tailor-made to user
None	**Sensory feedback**	The rate in which the arm is able to give sensory feedback
None	**Waterproof**	Grade in which the product is waterproof

Performance

All	Grips
N.A.	Lateral pinch [N]
N.A.	Neutral grip [N]
N.A.	Power grasp [N]
N.A.	Max carry load [kg]
N.A.	Finger carry load (hook) [kg] (index)
N.A.	Max vertical load (chassis) [kg]
N.A.	Hand open close time [s]
N.A.	Adaptive grip
N.A.	Average weight [kg]
N.A.	Battery [V]

None	**Cost**	x 1000 €
None	**Production year**	Year in which the product is released for consumer use

A2
Requirements

This chapter covers all the requirements which are generated. The requirements are clustered using pugh's checklist.

1. Performance

Req ID.	Requirement	Source
1.1	Elbow must be able to perform a flexion motion of 45 degrees and extension of 90 degrees	
1.2	Wrist must be able to perform a pronation motion of 90 degrees and supination of 90 degrees	
1.3	Product must provide tactile exteroceptice feedback to the user at the finger tips and upper palmer area	
1.4	Product must provide form of proprioception to the user	
1.5	Must be able to lift a weight of 20kg with a hook grip	
1.6	Must have a finger grip of 12.5 N	
1.7	Must have a thumb grip force of 22.0 N	
1.8	Must keep functioning in wet environment with a rating of IP67	
1.9	Must have an option to be turned on/off	
1.10	Must be able to inform user about battery status, preferebly on the outside of the embodiment	
1.11	Fingers must have enough grip to not let slip everyday items out of hand, also in wet environments	
1.12	Must be able to communicate errors when detected by the controller	
1.13	Battery must last an entire day with intended use	
1.14	tactile sensors must be able to sense from atleast 0.1 N (gentle touch)	
1.15	Sensors may not get wet	

2. Maintenance

Req ID.	Requirement	Source
2.1	Wearing/tearing parts must be able to be replaced by the user within 15 minutes with the use of simple tools such as a screwdriver	
2.2	Internal components (finger motors, wrist motor, PCB, Battery, Elbow motor and 'tendons') have to be accessible by the maintenance engineers	
2.3	Parts prone to getting dirty must be easy to clean with regular means such as a sponge or a cloth with soap	
2.4	wearing and tearing parts replacement must be able to be performed with 1 hand	
2.5	Product must be able to be send back to factory for maintenance	
2.6	maintenance of hardware (sensors, battery, motors) must be possible with a special tool (not by end user)	

3. Environment

Req ID.	Requirement	Source
3.1	Parts that interact with hot objects must be able to withstend a heat of 80 degrees Celsius without breaking (e.g. a hot pan or hot water)	
3.2	Product must be able to withstend heavy rain without breaking down (IP67)	
3.3	Product must be able to go underwater (30 mins 1m is IP67) without breaking down	
3.4	hardware and electronics must be protected from dust and water (IP67)	
3.5	Product must not break down when exposed to high heat of the sun (40 degrees)	

4. Life in service

Req ID.	Requirement	Source
4.1	Product must function properly for atleast 5 years with intended use before breaking down (with maintenance and repairs in between)	

5. Target product cost

Req ID.	Requirement	Source
5.1	Product may cost around €75K (end user price ex. VAT)	
5.2	Replaceable wearing/tearing parts may cost around 150,- EU	

6. Transportation

Req ID.	Requirement	Source
6.1	Package of product must protect product while being transported to the user from the manufacturer	
6.2	Product must be able to be safely transported when not being worn	

7. Packaging

Req ID.	Requirement	Source
7.1	Product must be presented to the user in a secure packaging which contains all components, necessary tools and instruction manuals	
7.2	packaging must be able to be used to safely store the arm for travel or transport	

8. Quantity

Req ID.	Requirement	Source
8.1	Must be able to produce 10 arm prosthesis annually	
8.2	production is a tailor made production	
8.3	parts must be able to be produced in batches per user	

9. Manufacturing facilities

Req ID.	Requirement	Source
9.1	Most of the embodiment parts must be designed for 3D printing production technique	
9.2	grip pads may be produced by 3D print and/or injection moulding	
9.3	designed embodiment parts may not be bigger then the formlabs printer size of DHM Dental	

10. Size and weight

Req ID.	Requirement	Source
10.1	The weight of the embodiment must not be more then 2.5 kg - weight of hardware in kg	
10.2	Lower arm length must match arm length of the user	
10.3	Finger lengths must match finger length of the user	

11. Aesthetic and appearance

Req ID.	Requirement	Source
11.1	The product must resemble basic characteristics of patients other arm (biomimicry)	
11.2	The product must offer possibility for personalization of certain parts to fit person identity	
11.3	The product must have design characteristics that are derived from science fiction/future studies	
11.4	The lower arm must have an option for cosmetic sleeve coverage	
11.5	products movements must resemble human arm (biomimicry in function of movements)	

12. Materials

Req ID.	Requirement	Source
12.1	The product must have material with enough friction and grip on parts that interact with objects	
12.2	The product must have a material that allows for the use of touchscreens at a logical location	
12.3	Product must be produced from materials that can withstend water	
12.4	Product must must be produced from materials that can withstend chemicals such as soap and oil	
12.5	Material which will interact with the human body should be biocompatible and thus not harm living tissue	

13. Product life span

Req ID.	Requirement	Source
13.1	Product is expected to be produced for 5 years with a warranty period of 1 year	
13.2	product's replaceable parts are expected to be produced for 5 years	

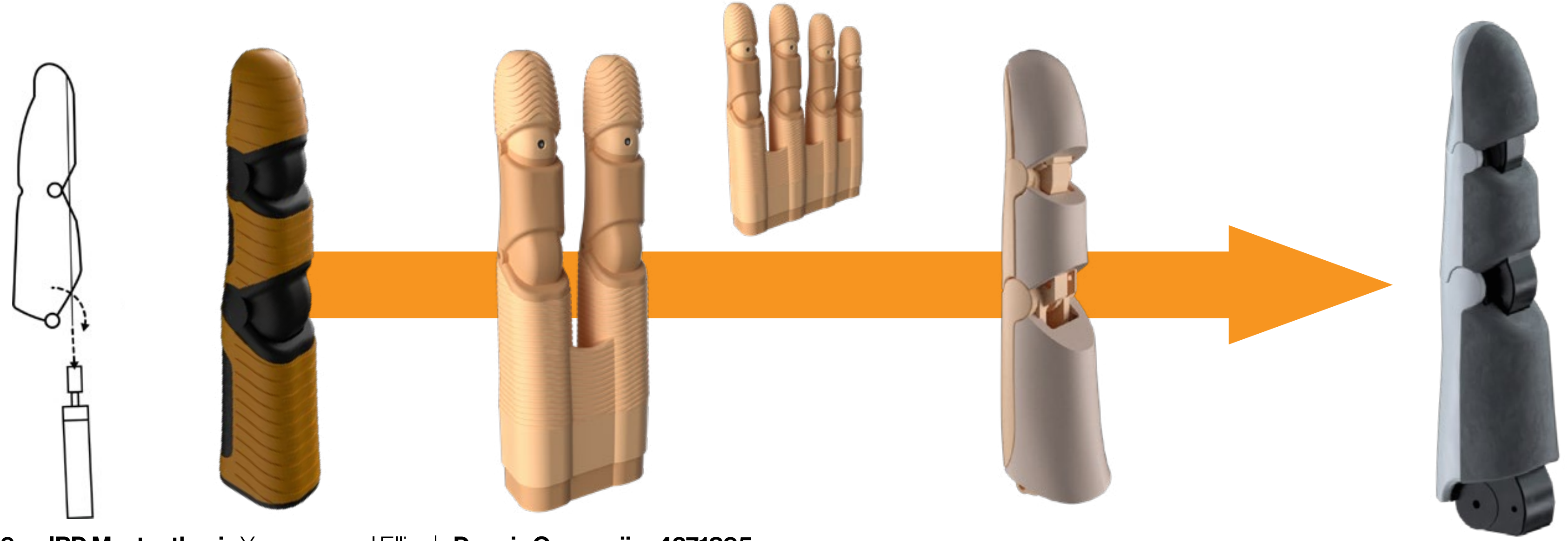
14. Ergonomics

Req ID.	Requirement	Source
14.1		
14.2		

15. Quality and reliability

Req ID.	Requirement	Source
15.1		
15.2		

After the break from the project the finger principle changed from kinematic linked bar system to a cord system.



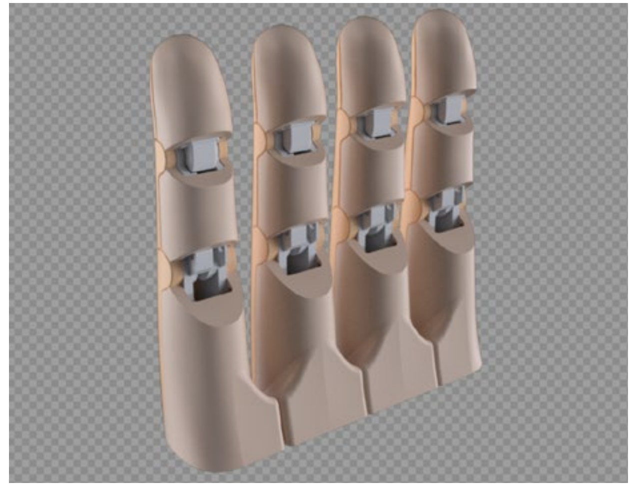
A3
Embodiment

A5.1 Finger iterations

The finger went through multiple iterations during the project due to changes in the mainframe. The embodiment changed alongside with this development. In this appendix chapter the evolution of the Ellis finger is shown.

Embodiment iterations

1. The first embodiment design was with a kinematic linked bar system with three pahalanxes. The model showed to be quite hard to model and had the major disadvantage of have big gaps. This model was made to have a first exploration with modelling a finger. Get a feel for the shapes and dimensions of a finger. It was made using mesh modelling. It could soon be concluded that mesh modelling is a handy tool to create organic shapes, but is awful for precise systems such as a linked kinematic bar system.
2. The second embodiment was inspired by the bebionic. The bebionic joined the distal and middle phalanx in a specific angle. This model was made to learn from the system that is used by a competitor design. Furthermor this model was also prototyped, which was a first exploration with 3D SLA printing. Learnings from this were that the outcome of the SLA prints actually look really smooth and are very suitable for the organic shapes.
3. After the big break in the project the system of the finger changed from a kinematic linked bar system to a cord system and with that the entire embodiment changed aswell. It was now possible to make a more enclosed embodiment design, which is much more desireable, because it is not optimal to have big gaps and holes in the design in which things can get stuck. In this finger design the embodiment is shelled and within this shell the cords, sensors and springs are integrated. The grips were made with a wrapping principle and the internal components would be accessible with the use of hatches. See appendix 3 finger wrap concept for more elaboration.
4. An alteration on this concept was to have the proximal grip connected in order to create a surface that covers the upper palmar area of the hand. This part was intended to be flexible and could deform with the finger movements. However this idea was later rejected because it was thought not feasible due to too much stretching of the material. Also attaching the material to the hard embodiment could be an issue.



Pre final iteration

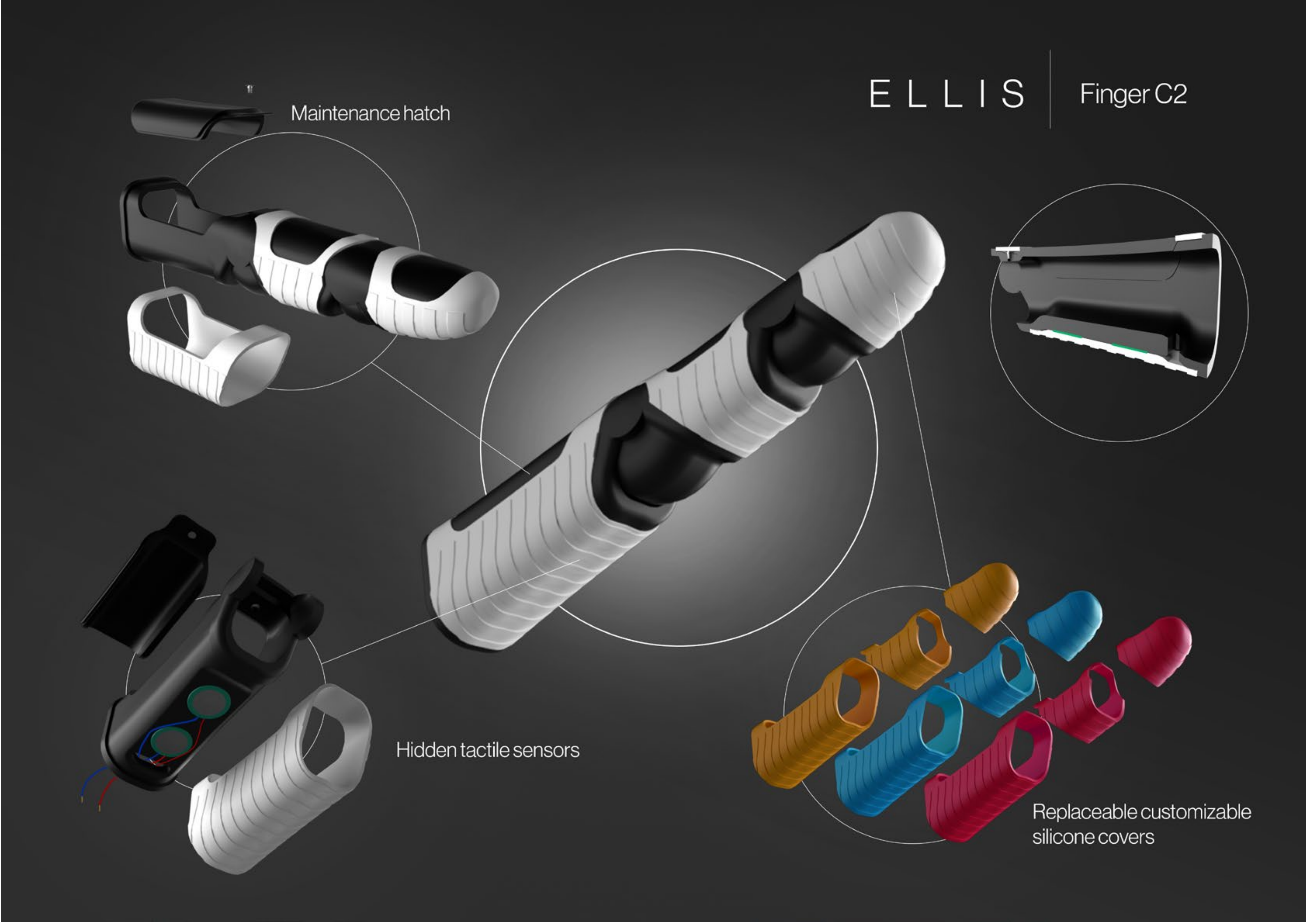
The last iteration is based upon a mainframe with modular embodiment panels. Within this embodiment concept some iterations have taken place. For example the distal grip was first modelled to bend a bit upwards in order to have more grip surface. However this gave complications with the disassembly of the parts. Therefore this was remodelled to be a straight line.

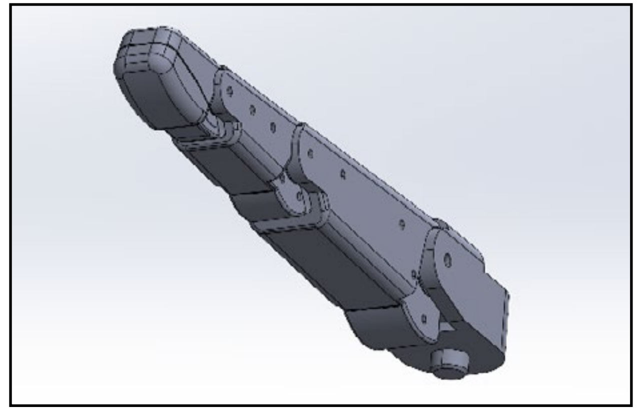
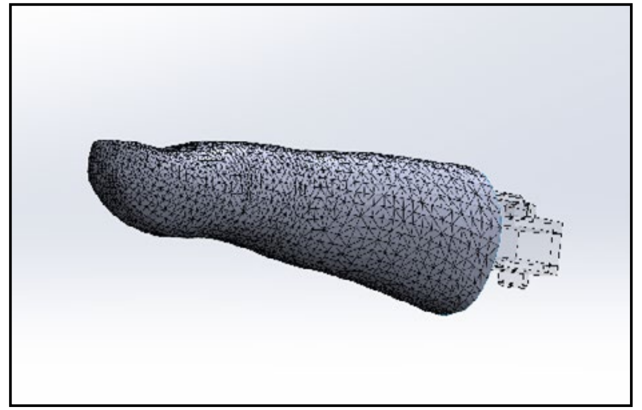
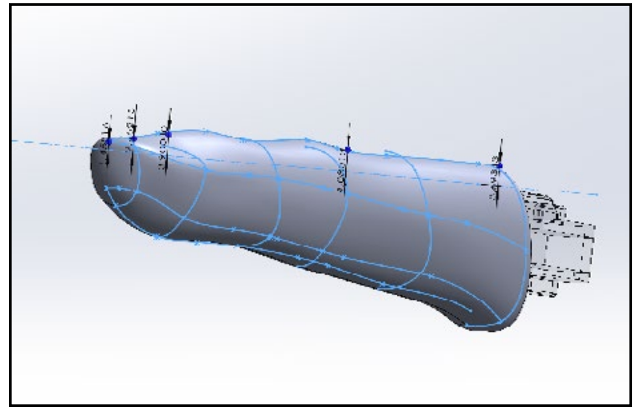
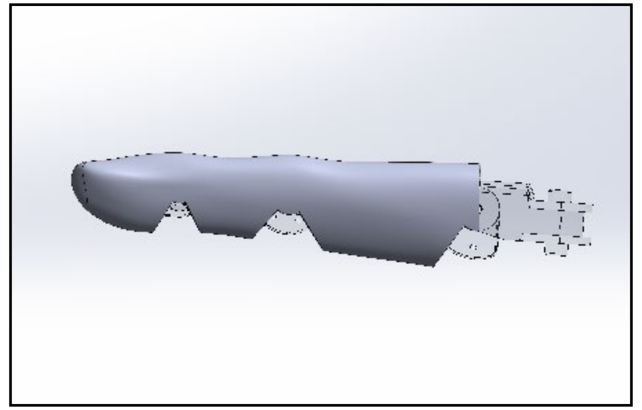
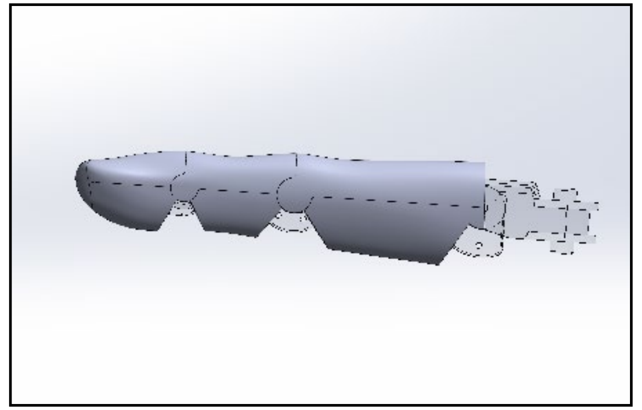
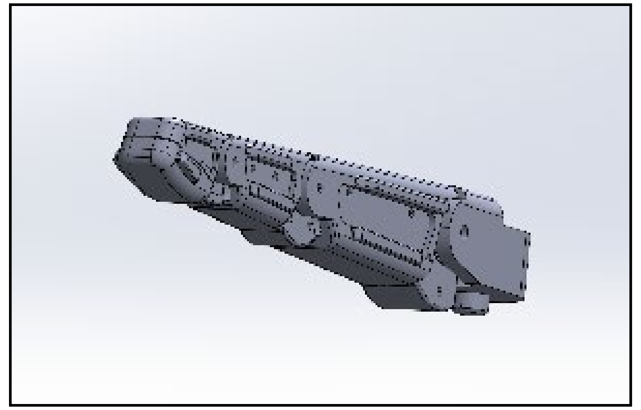
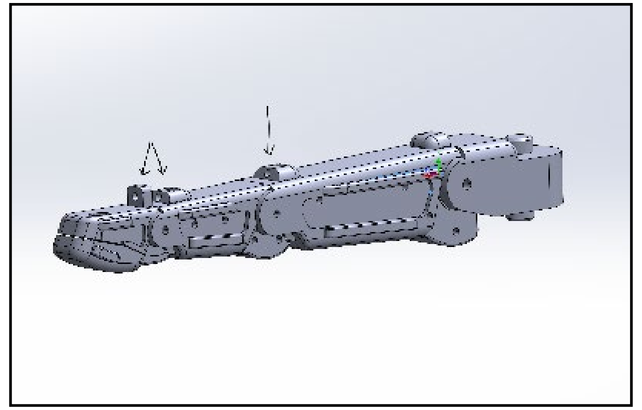
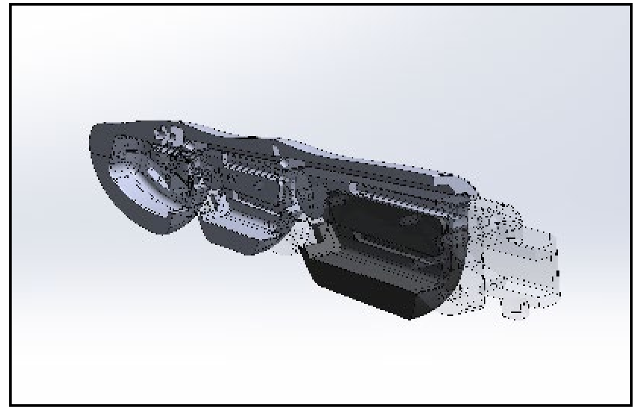
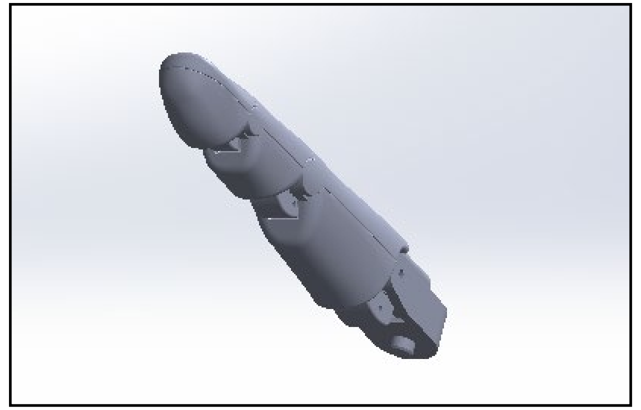
Furthermore the proximal phalanx was first modelled to have a semi connecting surface with extending surfaces. However this looked unpleasant and was therefore rejected.

Final iteration

In the final iteration the mainframe was edited to make sure all the gaps are neatly enclosed without compromising the motion.

Also the assembly mechanisms of the panels and grips are optimized. This embodiment is elaborated in chapter 10.


ELLIS
Finger C2
Maintenance hatch
Hidden tactile sensors
Replaceable customizable silicone covers

A3.2 Finger model

The finger model is created in solidworks. In this appendix chapter the steps of the creation are elaborated in a global way. It is not an easy task to create such an intricate and organic product in CAD software and certain detailing and tools requires extra explaining. But this is a simple overview of the process.

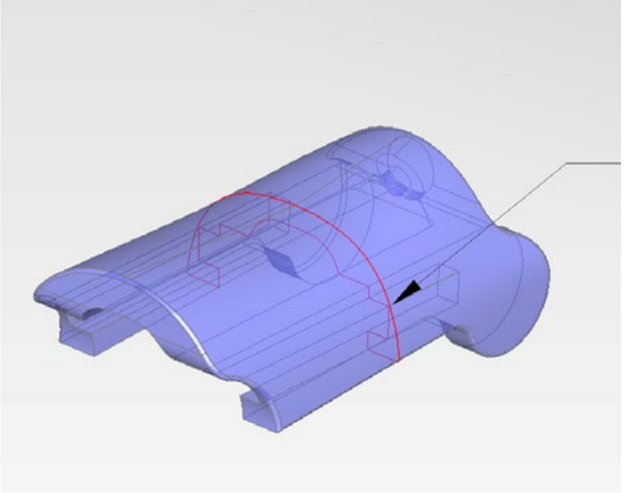
Modelling steps

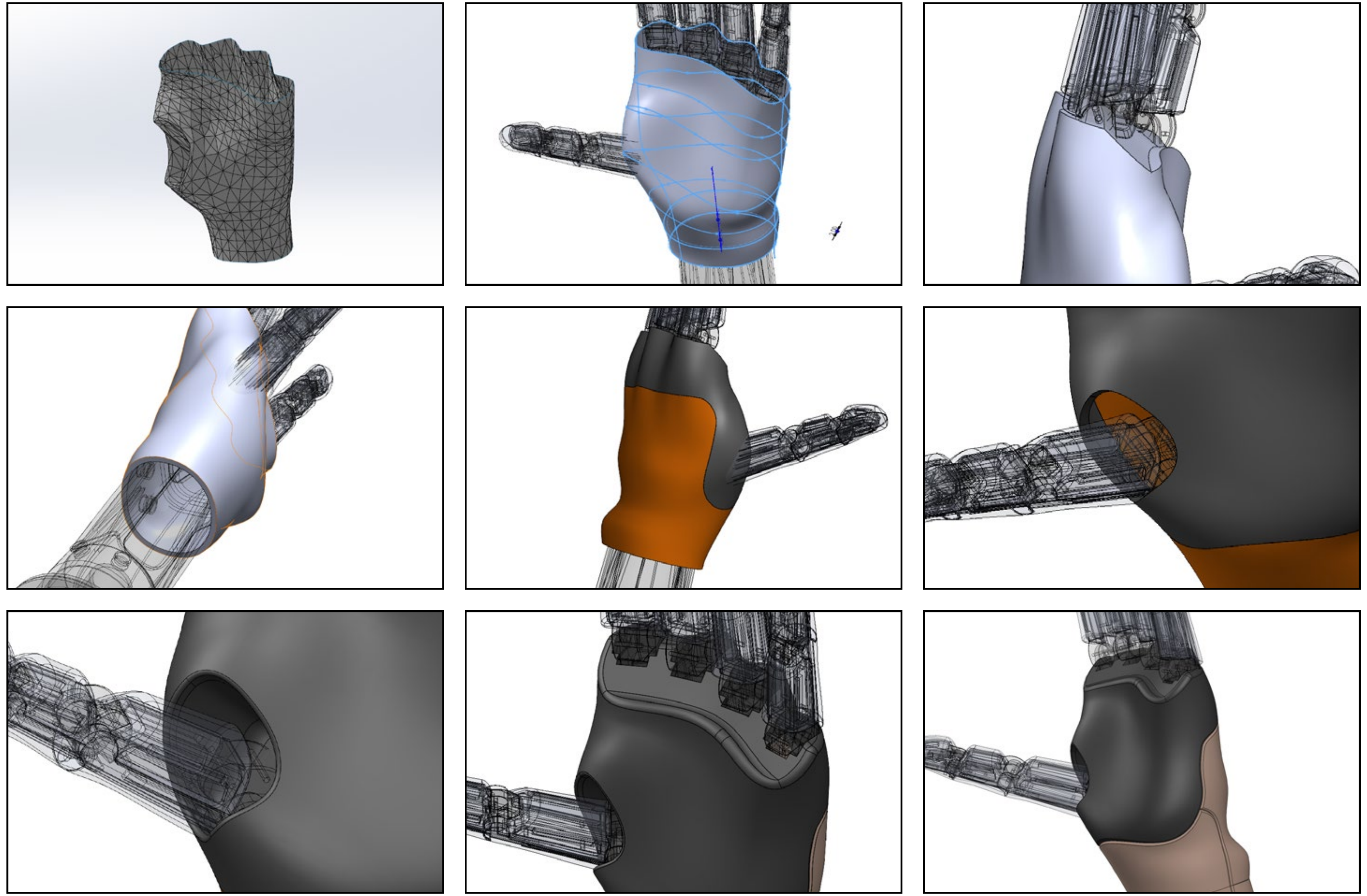
1. The start of the model was the mainframe. This mainframe serves as a guide for the dimensions and dictates where the finger is supposed to rotate and have split sections.
2. Within Cinema 4D a finger model was mesh modelled. This software is easier to model organic shapes. This model was imported in solidworks and served as an underlayer for the shape.
3. The underlayer is traced by 3D splines. It is made sure to use enough splines to define the entire organic shape of the body. The splines are then connected with a loft. A tip is to set up these splines in such a way that it is possible to alter them later on the process. This was very helpful, because the shape has changed a few times in order to fit components and provide enough thickness of material to avoid product failure, see imageon the right.
4. Once the organic finger shape is modelled it is time to make sure the finger can move. Therefor cuts are made at the places where the finger has to make a flexing motion. The mainframe dictates here the location of the rotation points and amount of degrees for the motion.
5. The next step is to divide the finger into the seperate components and decide the hinge points. The finger is split in dorsal and palmar panels. And the proximal, middle and distal phalanges are now defined. The middle section line goes straight through the rotation axis.
6. Now on the mainframe the sliders and cutouts are designed on the mainframe in order to have the panels sliding and the grips stick onto the model. The sliders have a thickness of 2mm and are tapered to the end with a thickness of 2.15mm. The depth is 1.5 mm. The cutouts for the grip pads are 1 mm in depth. These dimensions were chosen to make sure that the material is thick enough to not break.
7. beside the sliders and cutouts there are also features on top of the mainframe for the crews. The holes are designed to fit an M1.6 screws and cutouts are created to house a M1.6 nut.
8. Since all the sliding and attachment features are now modelled on the mainframe, the next step is to create a cavity in the finger parts. The mainframe was cutout of the solid mainframe with a 0.15 mm tolerance. This tolerance was chosen to make sure the parts fit onto each other smoothly.
9. The final step is to smoothen edges with fillets, to avoid sharp edges and make it look better.

Discussion

Creating this finger was extremely challenging and I constantly had to expand the limits of my CAD skills. Therefore I learned a lot. Nontheless the model can still be optimized. Certain smart constraints can be added and the model can be optimized in a sense that it is easier to modify the dimensions for different finger sizes. It is advised for DHM Dental to make an optimized model that is easy to alter, otherwise this will take an extreme amount of time per individual arm.

If the model can be build in such a way that you only have to alter the dimensional paramaters and everything reshapes accordingly, that would be a huge time and money saver.





A3.3 Hand model

The hand model is created in solidworks. The hand is a very challenging shape to create in CAD software such as solidworks because solidworks usually builds up shapes geometrically. However smart tools allow to create organic shapes such as a hand. The following 9 steps globally explain how to hand was built.

Modelling steps

1. The model starts off with a mesh modelled hand shape within Cinema 4D. This serves as an underlayer.
2. The second step is to build splines alongside this underlayer. In this way the shape is translated from a mesh model to a smooth surface.
3. The surface is knitted and made into a solid. The next step is to create a cutout for the fingers to make the flexing motion.
4. The part is then shelled. A shell thickness of 2mm has been used here. This is a common wall thickness standard for plastic parts.
5. The part is split into a hard body part and a soft body part using the split tool. The shape is chosen in this way because it was desired to have large strong surfaces without any fragile edges. Also the soft part goes all around the top section of the hand, because the fingers are allowed to move also in a ab-/adducting motion. The flexible material allows the fingers to do this.
6. The next step is to create a cutout for the thumb to be located and move.
7. The thumb hole is closed with a smort lofted surface and this surface is connected to the main body.
8. Holes are created on the locations were the fingers will be. The holes are carefully made, in order to make sure that the fingers are able to move properly.
9. The last step is to add fillets to the sharp edges to finish up the parts.

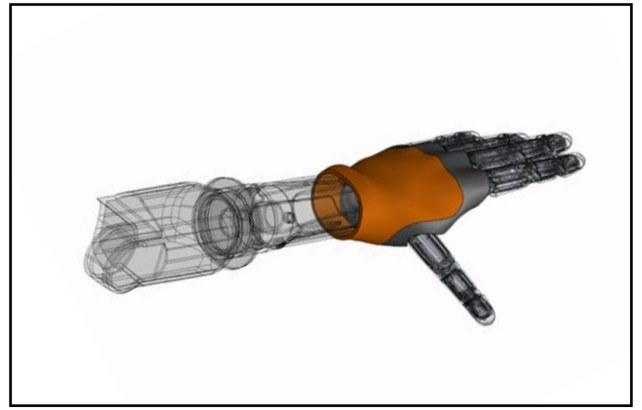
Discussion

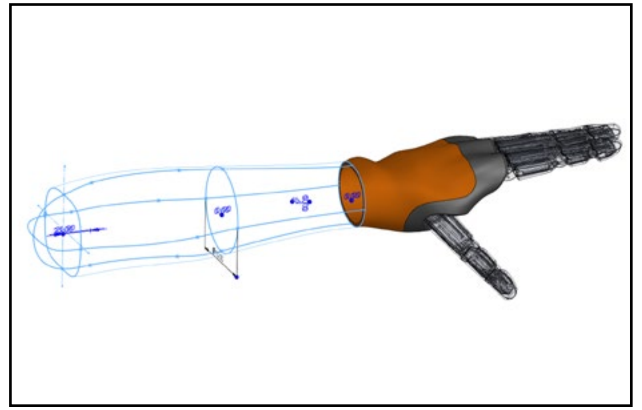
The dorsal side of the hand is hard body panel. This part is later connected to the arm and is elaborated in appendix 5.4.

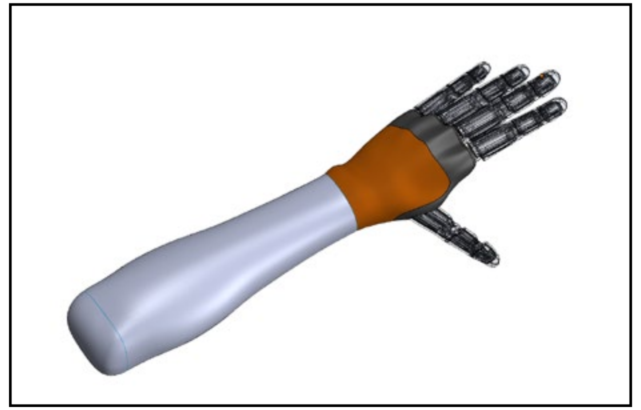
The palmar grip is connected to the mainframe. A proposal was made with the use of screws and surfaces that get pressed into place.

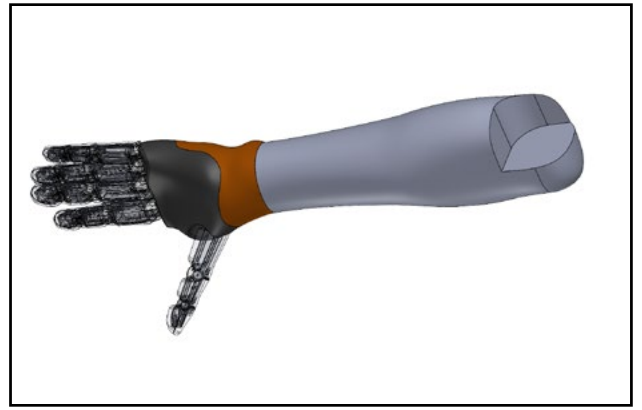
The hand is the result of an earlier iteration which had two seperate grip pads. Figure on the right shows what this looks like. However after evaluating with DHM Dental it was decided that this was not ideal, because some parts had pretty thin embodiment, which is prone to failure. Furthermore this design had a lot of parts. It is desired to have not too many parts. Therefore it is decided to have the palmar grips as one connect uniform piece.

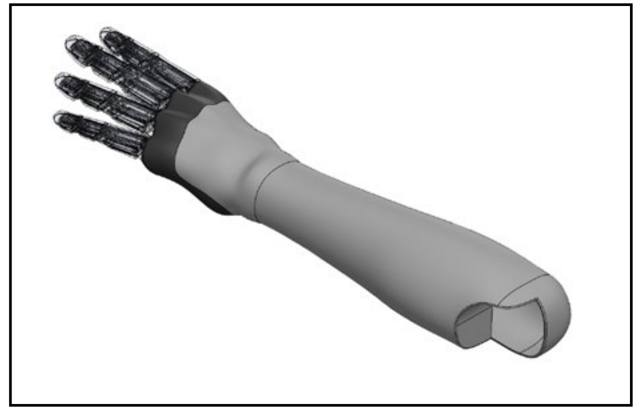
The human features in the hand embodiment can still be altered due to the spline build up. In this way it is possible make them more appearant or less appearant. For example the radial bone that is sticking out might be a bit to exeggerated and can be tomed done a little. Some counts for the tendon features on the dorsal side of the hand.

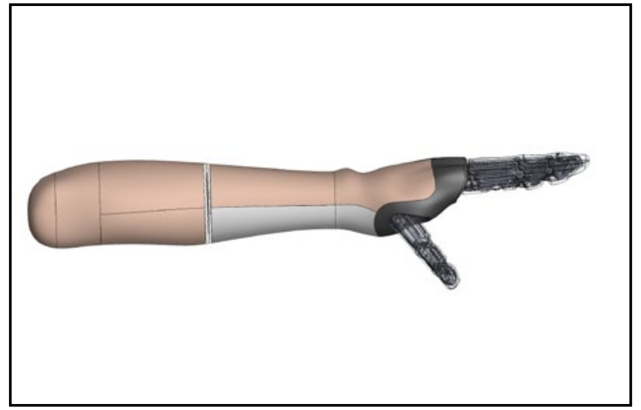


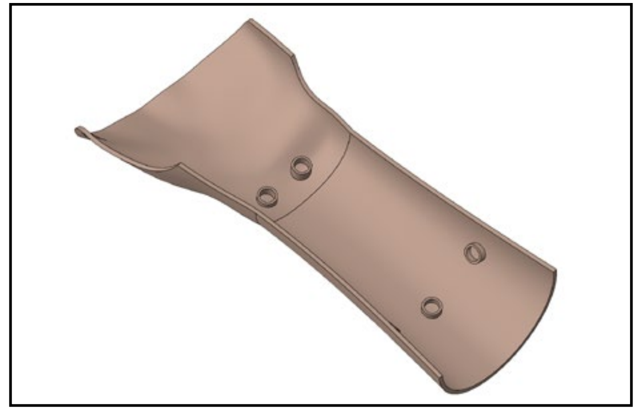


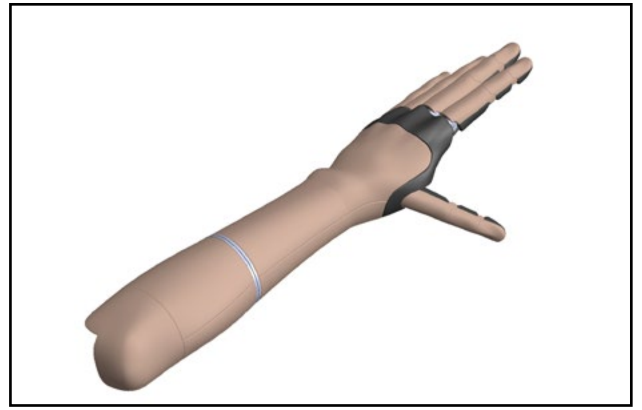












A3.4 Arm model

The arm was created in solidworks. Since the creation of the finger and the hand taught me so much, the creation of the arm was a bit easier. The arm is build up out of 3 section sketches and 6 splines along the outside defining the shape. The modelling steps are elaborated here.

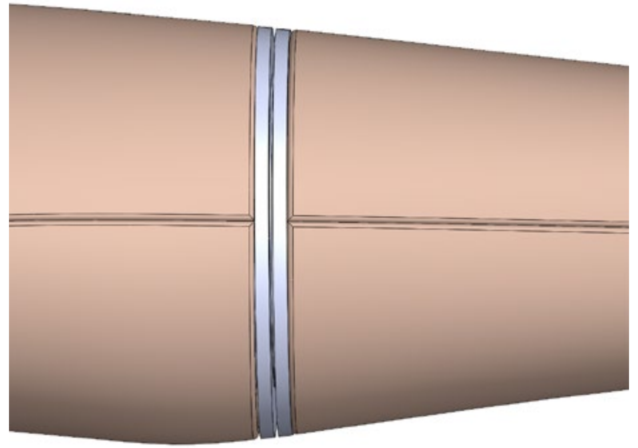
Modelling steps

1. The mainframe serves as an underlayer for the dimensions of the arm.
2. The arm is build up out of 3 cutsection sketches and 6 splines that define the outside shape. For reference images from the internet were used and the 3D arm scan of Maartens' arm.
3. The splines are connected with a loft and closed and knit to a solid body.
4. The section where the elbow rotation motor is supposed to come is cutout.
5. The model is shelled and combined with the hand mode. The wall thickness is 2mm. A common used wall thickness for plastic parts.
6. The model is split in half deviding the arm in a palmar and a dorsal side. At the spot were the wrist rotation motor is located the arm is also split, because otherwise the panels could not rotate.
7. Material is added at the spots were magnets are placed. The diameter is 7 mm and the height is 3.5 mm, based on the selected magnets.
8. Finish up the model with fillets.

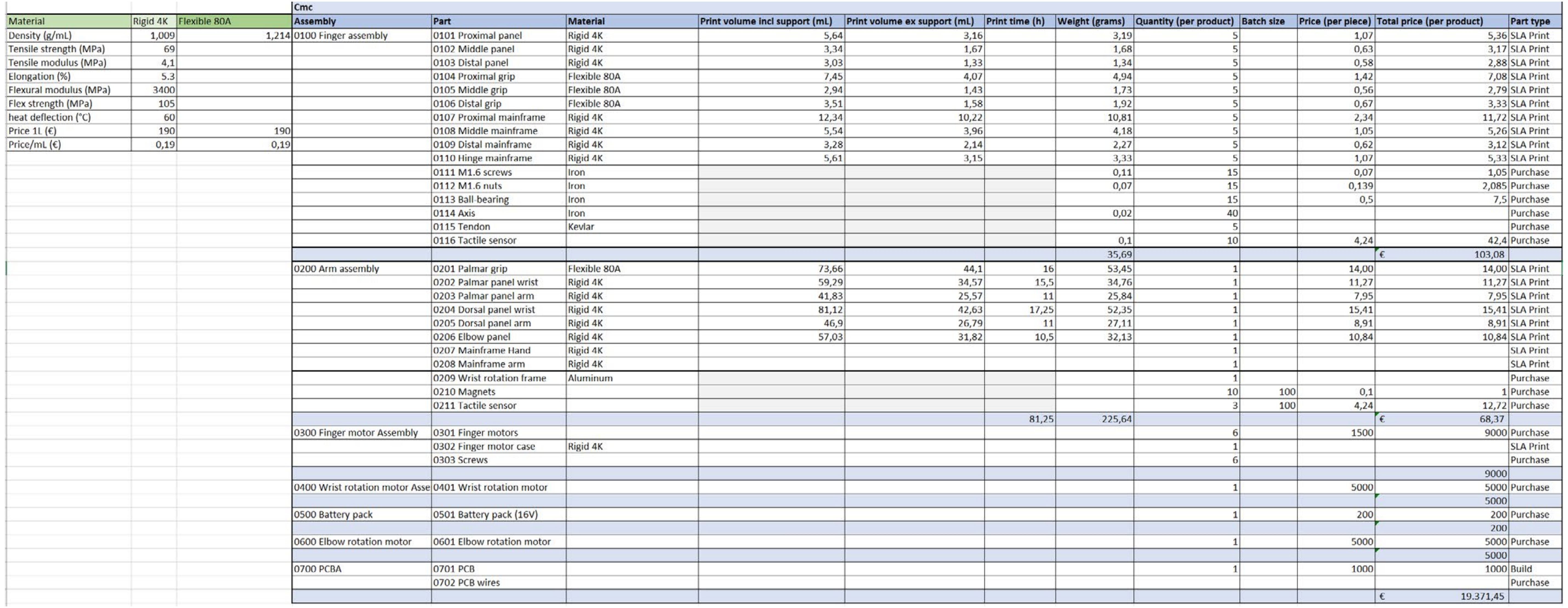
Discussion

The arm is very adjustable due to the spline buildup. The arm can be made to look more muscled or more slim. The only restriction is that the mainframe has to fit inside the arm embodiment.

It is important that the panels connect perfectly, in order to create a seamless uniform shape. Since the arm rotates at the wrist, it is important that the arm is precisely circular at this location, otherwise it will look odd when rotating the arm. There has been made a big cutout at this location and material from the mainframe with the wrist rotation system can be seen here. This is the aluminum mainframe body. This is done to make sure the panels can connect seamlessly there and ensure a uniform emobodiment shape, since 3d printed plastic parts can always have little deformations, the aluminum will be perfectly round.



A3.5 Cost price estimation
Excel sheets



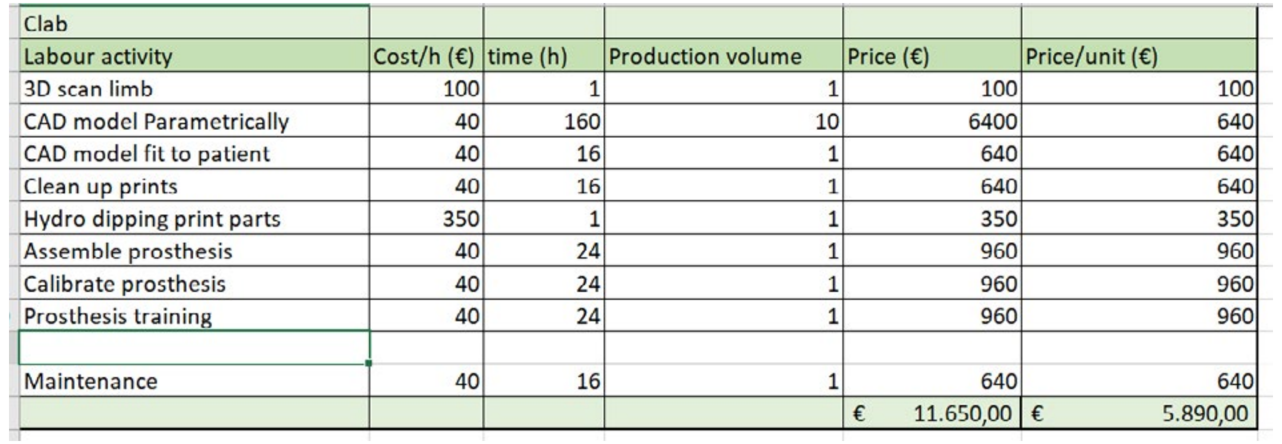
Material	Rigid 4K	Flexible 80A
Density (g/mL)	1,009	1,214
Tensile strength (MPa)	69	
Tensile modulus (MPa)	4,1	
Elongation (%)	5.3	
Flexural modulus (MPa)	3400	
Flex strength (MPa)	105	
heat deflection (°C)	60	
Price 1L (€)	190	190
Price/mL (€)	0,19	0,19

Cmc

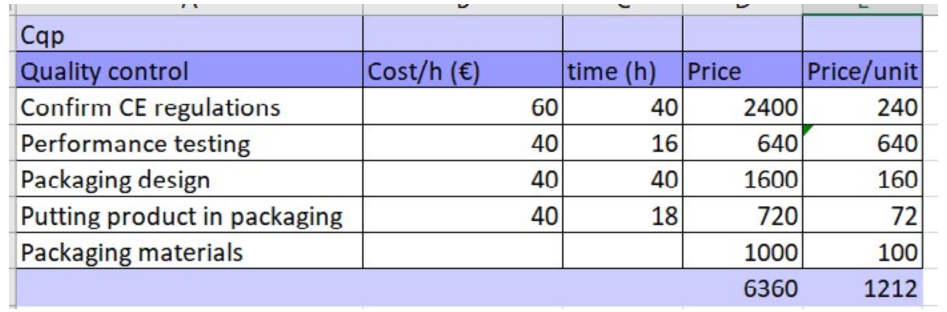
Assembly	Part	Material	Print volume incl support (mL)	Print volume ex support (mL)	Print time (h)	Weight (grams)	Quantity (per product)	Batch size	Price (per piece)	Total price (per product)	Part type
0100 Finger assembly	0101 Proximal panel	Rigid 4K	5,64	3,16		3,19	5		1,07	5,36	SLA Print
	0102 Middle panel	Rigid 4K	3,34	1,67		1,68	5		0,63	3,17	SLA Print
	0103 Distal panel	Rigid 4K	3,03	1,33		1,34	5		0,58	2,88	SLA Print
	0104 Proximal grip	Flexible 80A	7,45	4,07		4,94	5		1,42	7,08	SLA Print
	0105 Middle grip	Flexible 80A	2,94	1,43		1,73	5		0,56	2,79	SLA Print
	0106 Distal grip	Flexible 80A	3,51	1,58		1,92	5		0,67	3,33	SLA Print
	0107 Proximal mainframe	Rigid 4K	12,34	10,22		10,81	5		2,34	11,72	SLA Print
	0108 Middle mainframe	Rigid 4K	5,54	3,96		4,18	5		1,05	5,26	SLA Print
	0109 Distal mainframe	Rigid 4K	3,28	2,14		2,27	5		0,62	3,12	SLA Print
	0110 Hinge mainframe	Rigid 4K	5,61	3,15		3,33	5		1,07	5,33	SLA Print
	0111 M1.6 screws	Iron				0,11	15		0,07	1,05	Purchase
	0112 M1.6 nuts	Iron				0,07	15		0,139	2,085	Purchase
	0113 Ball-bearing	Iron					15		0,5	7,5	Purchase
	0114 Axis	Iron				0,02	40				Purchase
	0115 Tendon	Kevlar					5				Purchase
	0116 Tactile sensor					0,1	10		4,24	42,4	Purchase
						35,69				€ 103,08	
0200 Arm assembly	0201 Palmar grip	Flexible 80A	73,66	44,1	16	53,45	1		14,00	14,00	SLA Print
	0202 Palmar panel wrist	Rigid 4K	59,29	34,57	15,5	34,76	1		11,27	11,27	SLA Print
	0203 Palmar panel arm	Rigid 4K	41,83	25,57	11	25,84	1		7,95	7,95	SLA Print
	0204 Dorsal panel wrist	Rigid 4K	81,12	42,63	17,25	52,35	1		15,41	15,41	SLA Print
	0205 Dorsal panel arm	Rigid 4K	46,9	26,79	11	27,11	1		8,91	8,91	SLA Print
	0206 Elbow panel	Rigid 4K	57,03	31,82	10,5	32,13	1		10,84	10,84	SLA Print
	0207 Mainframe Hand	Rigid 4K					1				SLA Print
	0208 Mainframe arm	Rigid 4K					1				SLA Print
	0209 Wrist rotation frame	Aluminum					1				Purchase
	0210 Magnets						10	100	0,1	1	Purchase
	0211 Tactile sensor						3	100	4,24	12,72	Purchase
					81,25	225,64				€ 68,37	
0300 Finger motor Assembly	0301 Finger motors						6		1500	9000	Purchase
	0302 Finger motor case	Rigid 4K					1				SLA Print
	0303 Screws						6				Purchase
										9000	
0400 Wrist rotation motor Asse	0401 Wrist rotation motor						1		5000	5000	Purchase
										5000	
0500 Battery pack	0501 Battery pack (16V)						1		200	200	Purchase
										200	
0600 Elbow rotation motor	0601 Elbow rotation motor						1		5000	5000	Purchase
										5000	
0700 PCBA	0701 PCB						1		1000	1000	Build
	0702 PCB wires										Purchase
										€ 19.371,45	

Cma

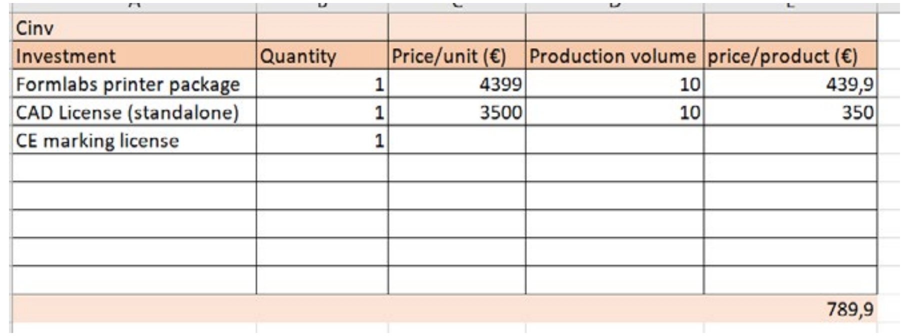
Machine	Cost/h €	Hours	Cost total
Formlabs 2 3D printer	0,1	100	10



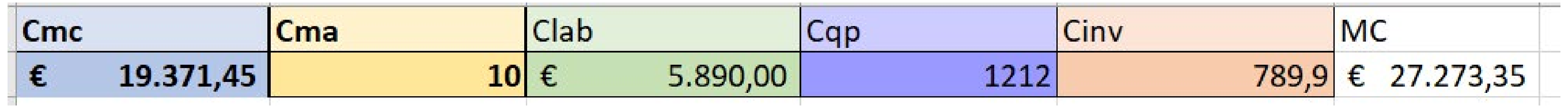
Clab					
Labour activity	Cost/h (€)	time (h)	Production volume	Price (€)	Price/unit (€)
3D scan limb	100	1	1	100	100
CAD model Parametrically	40	160	10	6400	640
CAD model fit to patient	40	16	1	640	640
Clean up prints	40	16	1	640	640
Hydro dipping print parts	350	1	1	350	350
Assemble prosthesis	40	24	1	960	960
Calibrate prosthesis	40	24	1	960	960
Prosthesis training	40	24	1	960	960
Maintenance	40	16	1	640	640
				€ 11.650,00	€ 5.890,00



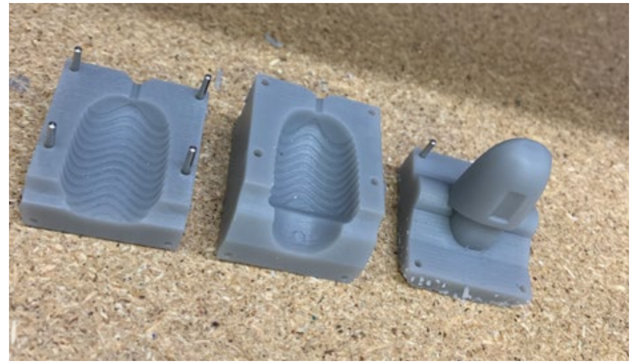
Cqp				
Quality control	Cost/h (€)	time (h)	Price	Price/unit
Confirm CE regulations	60	40	2400	240
Performance testing	40	16	640	640
Packaging design	40	40	1600	160
Putting product in packaging	40	18	720	72
Packaging materials			1000	100
			6360	1212



Cinv				
Investment	Quantity	Price/unit (€)	Production volume	price/product (€)
Formlabs printer package	1	4399	10	439,9
CAD License (standalone)	1	3500	10	350
CE marking license	1			
				789,9



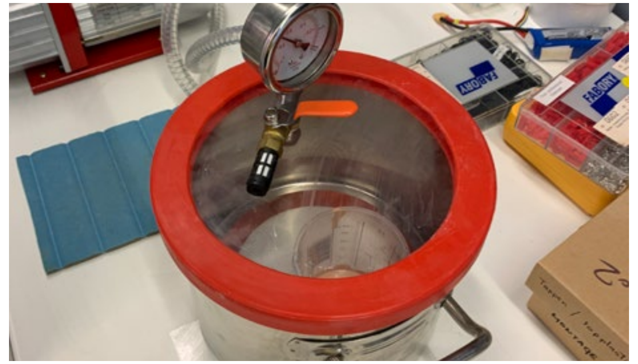
Cmc	Cma	Clab	Cqp	Cinv	MC
€ 19.371,45	10	€ 5.890,00	1212	789,9	€ 27.273,35



Step 1: 3D print the silicone molds

Step 2: Apply release agent to molds

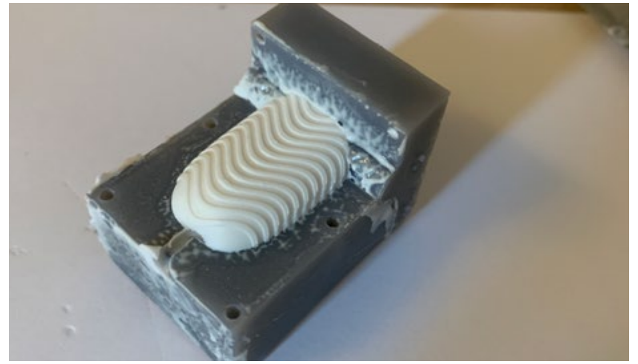
Step 3: Mix the A component with B component



Step 4: Vacuuming the silicone (3 times)

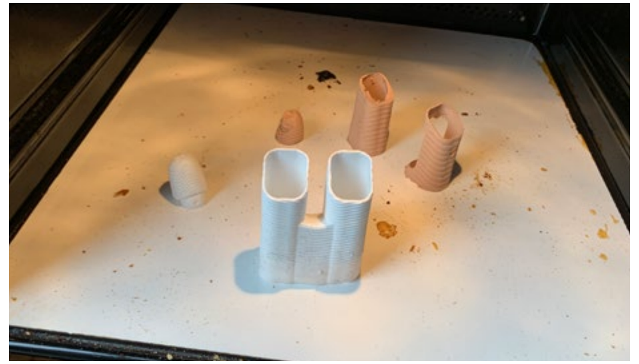
Step 5: Cast the silicone

Step 6: Let the silicone harden 24 hours



Step 7: Carefully open mold

Step 8: Take silicone part out of mold



Step 9: 2 hours in the over on 100 degrees celsius

A4

Prototyping

A4.1 Silicone molding

For the grip pads a silicone molding process is done. The steps are discribed and the results are discussed.

Method

Molds have been modelled in solidworks and are 3D SLA printed with the formlabs 'Tough' material.

Silicone has been acquired from 'Silicones and more' with a shore of 50A. It is a 2 component silicone. This silicone in itself is transparent. Pigments have been acquired, which can be blended through the silicone to alter the color.

Procedure

The figures on the left show the procedure that has been followed to cast the silicone.

1. 3D print the silicone molds. The silicones from silicones and more do not tend to shrink. Therefore there has not been added any tolerance to the cavity. If however the silicone is stated to shrink it is adviced to keep in mind this tolerance. Make sure that the molds align perfectly with the use of pins. Furthermore it is adviced to add some tolerance between the mold parts, otherwise fitting the parts onto each other can be a struggle.
2. It is adviced to use a release agent to prevent the silicone from sticking to the molds. Silicones and more offers a release agent which works very good with the printed molds and the used silicone. Do not breath in the release agent, as it is toxic and can cause fatigue and drowsiness.
3. The silicone components A and B have to mixed 1:1. It is adviced to figure out in advance how much silicone is needed for the casting. This prevents any waste of silicone. Stir the silicone with a rotating motion for about 5 minutes to make sure the components are mixed properly
4. The stirring can cause bubbles to appear in the silicone mixture. Vacuuming of the silicone is adviced to ensure a smooth result without any bubbles. Vacuuming multiple times is adviced. In this case 3 times was enough.
5. Cast the silicone by injecting it into the mold with pressure. Make sure that there are air holes in the model, to ensure that the air can go out while casting the silicone.
6. Once the silicone is casted, let the mold harden for 24 hours.
7. Carefully open the mold using a spatula or other tools.
8. Carefully take the silicone part out of the mold. The silicone is very flexible so it is possible to wrap and deform the part in order to get it out.
9. The last step is putting the silicone part in the over for 2 hours on 100 degrees to make sure the silicone hardens even more and solidifies fully.

Discussion

The silicone parts came out pretty well. However the process was sometimes quite messy and sometimes the casting failed due to the silicone not fully spreading thourgh the mold. It is adviced to optimalize the molds and use more pressure for the casting to ensure better results. Another option is to outsource this process to a company which has more experience with this.

In terms of material quality, the silicone is very flexible and easy to wrap around objects. The textures inside the mold translate very well onto the surface of the silicone part. Downside is that the silicone is very prone to cuts, and breaks quite quickly if it is too thin. Also the silicone is quite sticky and attracts dust and gets dirty rather quickly. Silicone cast for this project was 1.2 mm wall thickness.

Also mixing color has to be done with the proper mixture ratio . This is stated in the instructions manual of silicones and more. If not properly mixed the material gets a weird

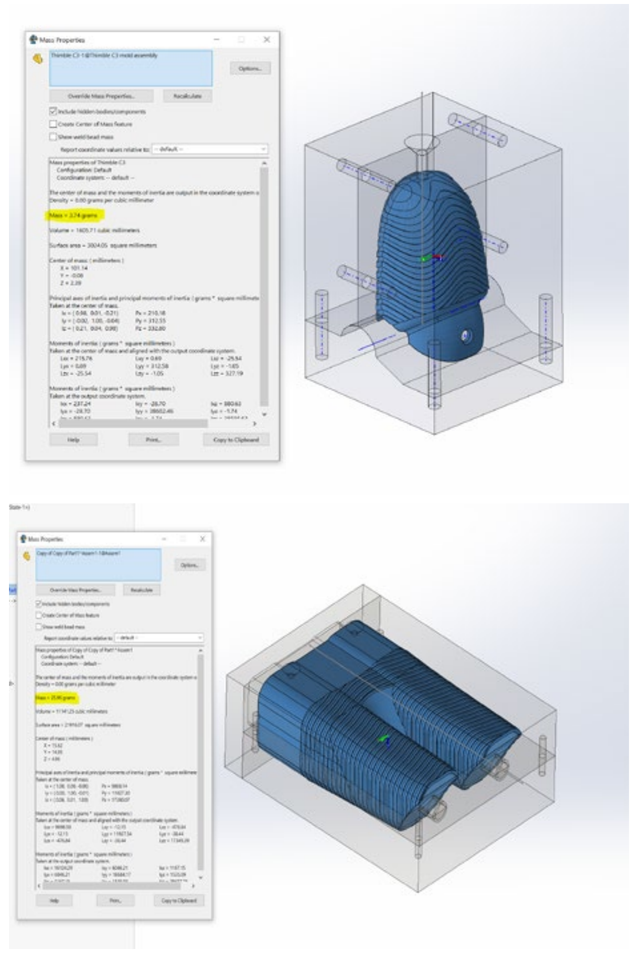


Figure A4.3. Mold designs in solidworks

A4.2 Hydrodipping

The hardbody panels have been customized using the hydrodipping process. The company contacted for this job is SK Dipping, located in Delfshaven, Rotterdam.

Process

1. For the hydrodipping the part is first made ready. The parts are sanded if needed and then primed.
2. After the priming the product gets a base paint color.
3. When this is dry it goes into the hydrodip bath with the custom film. The film adheses onto the part. The hydrodip company has stated that the parts need to be onto a frame in order to dip them properly in one go. Therefore a frame needs to be designed for this process.
4. Once this is dry the part is coated with a 2K coat (SprayMax 2K).

Price

The price for the entire process of hydrodip customizing one set for one arm costs 350€.

Bio compatibility

The 2K SprayMax coating is a product usually used in the automotive industry. Since the product is a medical device and will be in contact with human skin the coating should be bio compatible. The safety regulations of the 2K SprayMax coating have been checked and it is not stated to cause any dangers once the coating is hardened. I takes 12 hours to dry once it has been applied to the object twice.

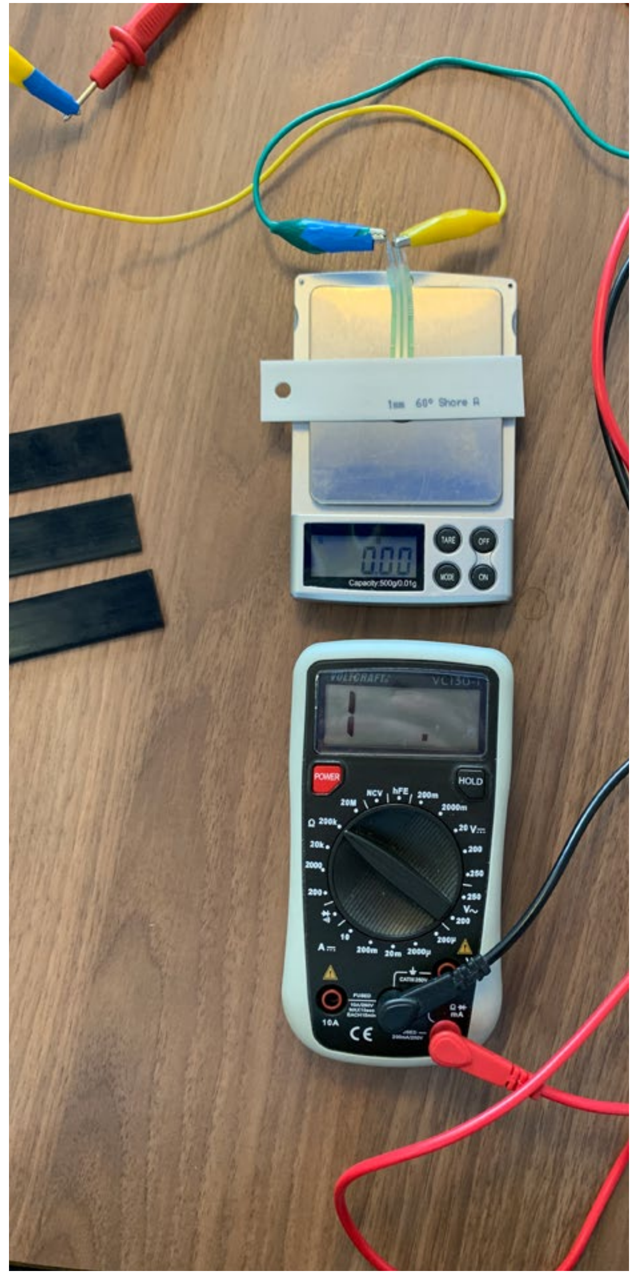
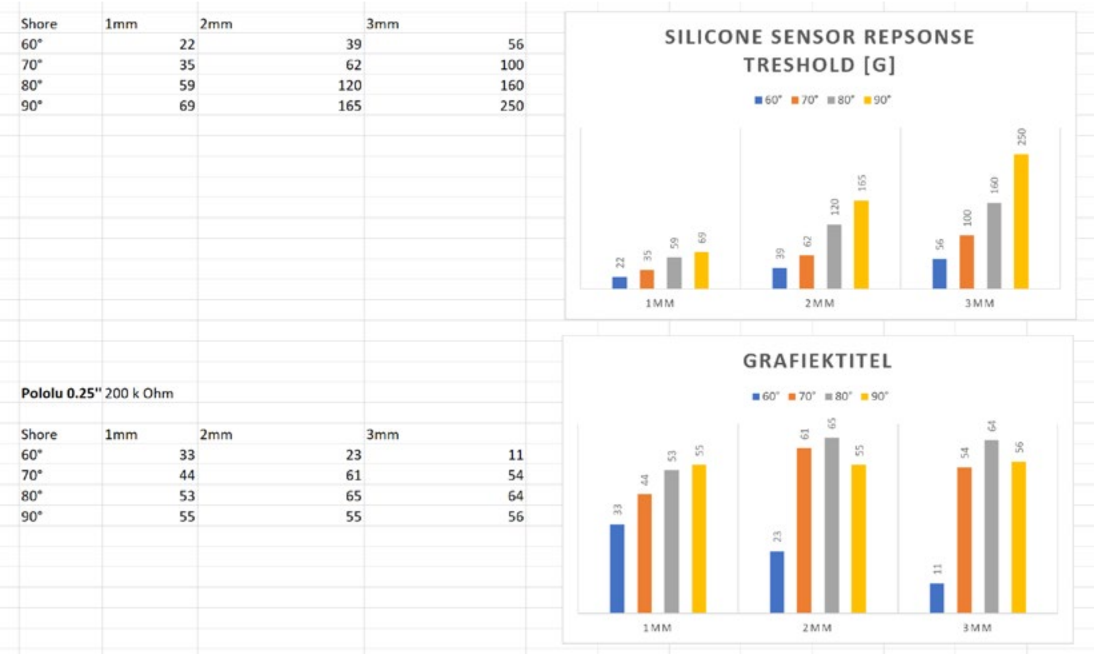


Figure A4.1. Sensor test set up

Figure A4.2. Pololu Force sensing resistor 0.25”.



Shore	1mm	2mm	3mm
60°	22	39	56
70°	35	62	100
80°	59	120	160
90°	69	165	250

Pololu 0.25" 200 k Ohm

Shore	1mm	2mm	3mm
60°	33	23	11
70°	44	61	54
80°	53	65	64
90°	55	55	56

A4.3 Sensor test

A simple test has been done with two tactile sensors. The singletact sensor and the Polulu 0,25”.

Method

The sensors are stuck to a weight with double sided tape. Silicone with a certain thickness and shore are placed on top. The sensor is actuated by pressing on to it. The required force to actuate the sensor is measured.

Stimuli

Four different shore silicones were used each with three different thickness. Shores used are 60, 70, 80 and 90A and thickness varied from 1, 2 and 3 mm.

Procedure

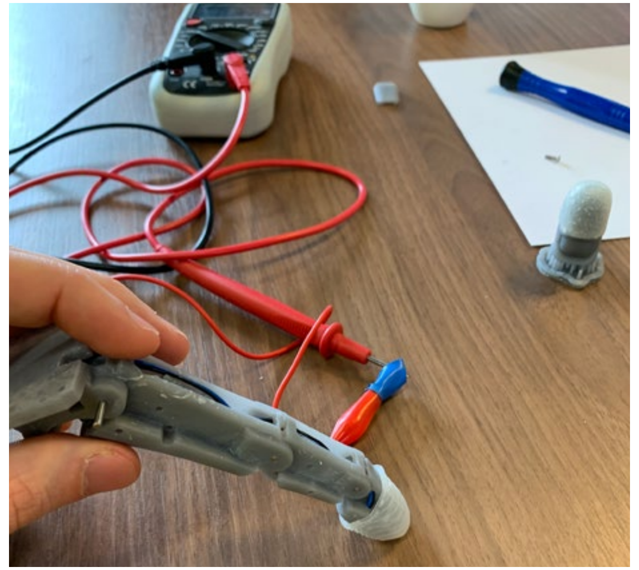
1. The silicone was placed on the weight
2. With a pencil it was pushed
3. the pressure was measured in grams

Results

The results show that the singletact sensor requires more force with a higher shore and wall thickness. The polulu sensor however is quite similar for different shores.

Discussion

Please not that this was a very brief and quick test, just to see how the sensor behaves when actuated underneath a piece of silicone. It is advised to do a more elabore pressure test with the hand prototype.



Sensor within the finger model with a solicone grip wrap. The sensor actuated when the finger was pressing on the table.

A5
Validation

A5.1 CE Roadmap

In order to obtain a CE certification for a medical device the product has to meet certain standards and requirements. CEtool.nl provides a 11 step roadmap to achieve this CE certification.

The 11 steps of the roadmap are the following:

1. Describe intended purpose
2. Determine classification
3. Define general safety and performance requirements
4. Quality management
5. Risk management
6. Testing
7. Clinical evaluation and research
8. Technical documentation
9. Evaluation of device
10. Registration CE mark
11. Post market surveillance

For this thesis step 1,2,3 and 5 will be done.

Intended purpose

The intended purpose describes everything the product is supposed to do and also what it is not supposed to do. IEC 62366-1:2015 also suggests to identify the most important characteristics related to use, to ensure that the intended purpose of the medical device is understood. Therefore the device's intended use, intended users and intended use environments have to be included.

IEC 60601-1:2013 describes that the intended use should include: Medical indication, intended patient group, probable body part, probable user profile, intended use environment, functioning principle and other intended use.
This creates a framework for the device. Everything that is described in the intended purpose needs to be proven, this will therefore result in tests that need to be done.

Medical indication

The medical indication is in this case an upper extremity amputation. More specifically trans humeral amputation.

Intended patient group

The intended patient group is therefore upper extremity amputees. However the device is specifically for patients with an osseointegated implant.

Probable body part

Upper extremity limbs

intended user profile

The user profile inclused humans with a trans-humeral amputation and an osseointegrated implant with implanted electrical components that are connected with muscle tissue and nerves.

Functioning principle

The device includes a powered elbow, wrist and fingers and a multitude of sensors including tactile sensors The device is controlled by osseointegrated implanted electrical components connected to the muscles and nervous system. The functional analysis dives deeper into these steps.

Intended use

How is the device intended to be used. IEC 62366-1:2015 describes the definitions of use.

- Abnormal use: conscious, deliberate act or deliberate omission of an act that is counter to or violates normal use.
- Normal use: operation, including routine inspection and adjustments by any user, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those medical devices provided without instructions for use.
- Use error: user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user
- Correct use: normal use without user error.

Conclusion

Summarizing the above: This medical device is an upper extremity prosthesis including a powered elbow, wrist and fingers and tactile sensors controlled by implanted electrical components and is intended to replace a partially amputated upper extremity for patients with an osseointegrated implant.

Classification

There are four classifications for medical devices: I, IIa, IIb and III. The classification is based on risk. Higher risk for a patient if a product fails results in higher classification.

Based on the rules of the MDR Annex VIII the prosthesis is a class IIa active therapeutic device.

A5.2 ISO22523

General safety and performance requirements

Medical devices have to meet certain general requirements. These requirements can be found in the MDR (medical device regulation). These requirements are very general and do not cover all the requirements. ISO 22523:2006 covers more requirements specific for external arm prostheses. These general requirements are interesting for DHM Dental. However for the scope of this project the focus is more on the specific ISO 22523:2006 requirements.

ISO22523:2006

The ISO 22523 norm describes external limb requirements and test methods. The requirements are being described in this subchapter.

Risk management requirements

ISO 22523 describes that possible hazards associated with a prosthetic or an orthotic device can endanger the user. Therefore the manufacture shall establish and maintan a process for identifying those hazards and evaluating the associated risks, controlling these risks and monitoring the effectiveness of control. This risk management process shall include the following elements:

- Risk analysis
- Risk evaluation
- Risk control
- Post-production information

It is suggested to use ISO 14971 as a guidance for the risk management process

Materials

ISO 22523 states that in prosthetic devices every effort shall be made to use materials which minimize the risk of propagation of flames or production of toxic gases, as it is of particular importance to disabled persons who may not be able to escape from a fire.

If however the clinical requirements for the prosthetic prevent the use of materials which minimize the risk of proagation of flames or the production of toxic gases the device shall be supplied with a warning and a description of the precautions necessary to reduce the risk.

Biocompatibility

Materials that come into contact with the human body shall be assesd for biocompatibility, taking into account the intended use and contact by those involved in user care or transportation and storage of the product.

Contaminants and residues

All materials used in the prosthetic device shall not cause the user to be exposed to cytotoxicity, irritation and sensitization when that device is being used in the intended manner.

Infections

The manufacturer shall specify the means by which a prosthetic device's body surface can be cleaned.

Resistance to corrosion and degradation

If the strength of a prosthetic device, or the saefty of the user or an attendant, may be affected by corrosion or degradation, risk analysis shall be used to determine the most appropriate protective measures.

Performance

The ISO 22523 norm states certain requirements regarding the performance of the prosthesis. The main requirement is that a prosthetic device shall have the strength to sustain the loads ocurring during use by amputees in the manner intended by the manufacturer for that device according to his written isntructions on its intended use.

The manufacturer must determine which strengths are appropriate:

- Fatigue strength: The cyclic load which can be sustained for a prescribed number of cycles
- Proof strength: The static load representing an occasional severe event, which can be sustained and still allow the prosthetic device to function as intended
- Ultimate strength: The static load representing a gross single event, which can be sustained but which might render the prosthetic device thereafter unuseable.

The manufacturer shall specify the strength level considered appropriate. For strength levels the state of the art benchmarking can be used as a guidance.

The manufacturer shall specify the method of test to be applied. ISO 22523 describes a few test setups which can be used as a guidance.

Discussion

Some important requirements of the ISO have been displayed here. It is just more convenient to have a look at the ISO22523 document and make sure the prosthesis complies.

FigureA5.1: Provided stimuli

A5.3 Aesthetics research

Perceived product experience of a customizable bionic arm prosthesis

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TU Delft coach: Joris van Dam[a]
Company: DHM Dental BV[b]

Abstract

This paper presents research about the perceived product appearance experience of a customizable bionic arm prosthesis. The product is assessed on the perceived aesthetics, meaning and emotion on a micro level.

Keywords

Product experience; prosthesis; aesthetics; meaning; emotion; appearance; customizable.

Introduction

One of the concerns of prosthesis users is that current prosthesis models are considered big and clumsy and that there is a desire for neater looking prostheses (Wijk et al. 2015).

The bionic arm prostheses that is developed together with DHM Dental BV is desired to have an aesthetical appearance.

A way to assess the aesthetics of a product is by using the 9 moments of product experience.

Human product interaction can be categorized in three different levels: micro, macro and meta level. Micro meaning the product form (shape, colour, texture, dimensions, materials). Macro meaning the product function (use, mechanisms, activities). Meta meaning the product in a specific context (other products, locations).

The product experience on every level can be categorized in aesthetics, meaning and emotions.

Aesthetic can be divided into two categories: perceptual and cognitive (Hekkert et al. 2014). Perceptual determinants include symmetry, simplicity, harmony, proportion, balance, unity and variety. Perceptual determinants like symmetry, unity and simplicity aid in processing the object as a whole. This fluent process results in pleasurable feelings. Determinants like variety and complexity make a design more interesting and therefore more aesthetically pleasing. Cognitive determinants are typicality and novelty.

Meaning is about the characteristics of a product, like a cute cup or a though motorcycle. Emotions is about the emotion that is perceived by the user.

The first research question is:
“Does the bionic arm prosthesis have an aesthetical pleasing apperance?”

For this research 2 hypotheses are formulated:
H0 The product is perceived as aesthetically pleasing.
H1 The product is not perceived as aesthetically pleasing.

The second research question is:
“What is the perceived meaning of the bionic arm prosthesis”

The third research question is:
“What is the perceived emotion of the bionic arm prosthesis”

The fourth research question is:
“How much does the prosthesis resemble a human arm?”

Method

The research is conducted with an online questionaire. The questionaire contains both quantitatieve and qualitative questions.

Participants

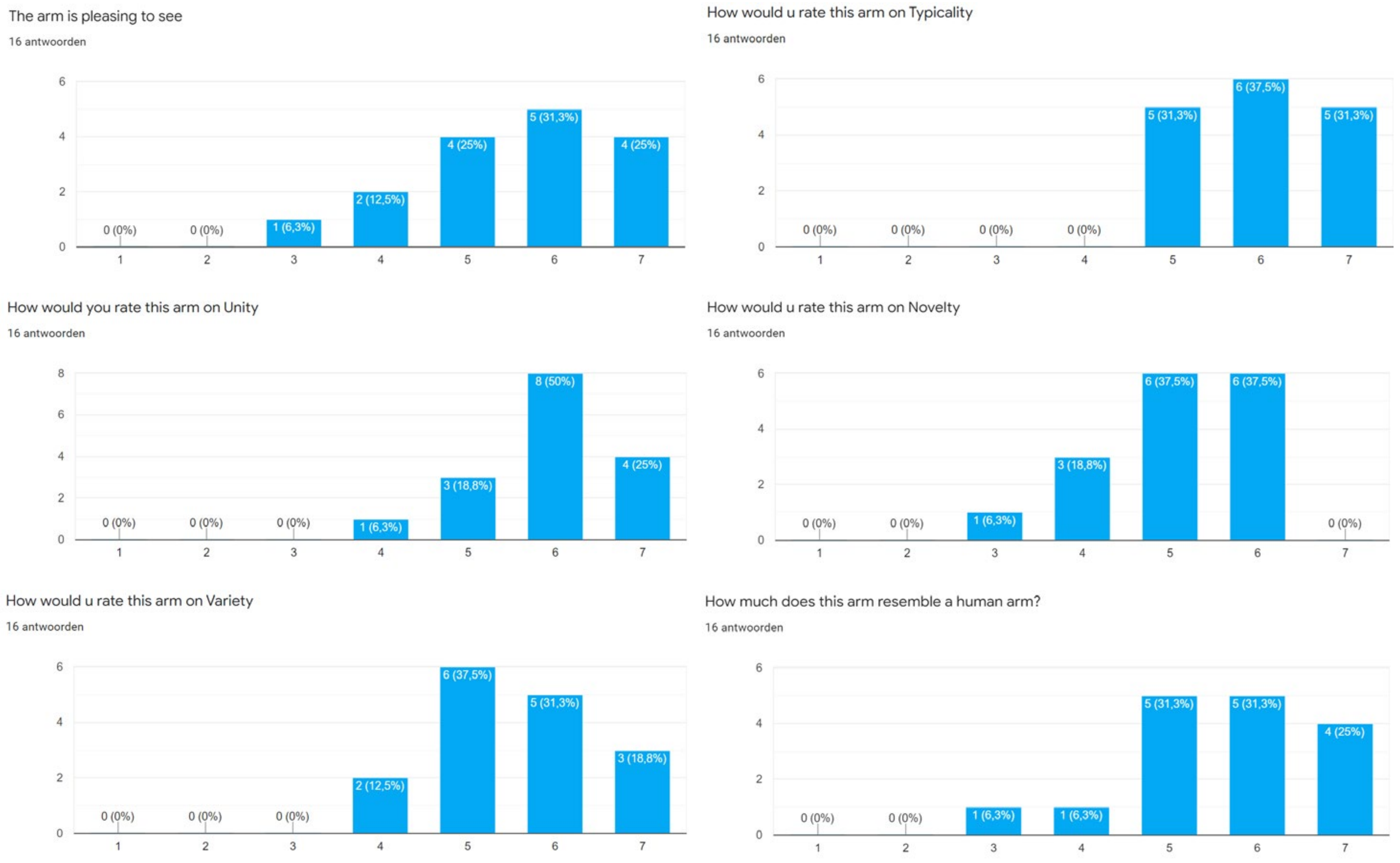
The participants (N=16) consist of sixteen people, a mix of male and female with age ranging from 23 to 61 with a variety of differen occupations. Eventhough these participants are not the target group, they are still people who will encouter the product and have an opinion about its perceived appearance.

Stimuli

During the research the participants are shown visuals, and animations of the product. The provided stimuli visuals can be found in figure A5.1.

Apparatus

The tool used for the survey is a google forms questionaire which people answered on their pc or smartphone.



FigureA5.2: Graph result of the questionaire

Procedure

Participant is presented with the online survey. participant is first presented with the stimuli.

Afterwards the participant is asked to fill in the perceived pleasure of appearance with a 7 point likert scale and elaborate briefly why they made that decision.

The following four questions are about unity, variety, typicality and novelty. For these topics the participant is asked to fill in a 7 point likert scale and elaborate on their decision.

The next part is about the perceived resembles of the prosthesis with that of a real human hand. again the participant is asked to fill in a 7 point likert scale and elaborate on the decision.

Following is an open question about the perceived meaning of the product. The participant is asked to decide what character or meaning the product evokes. The participant is asked to elaborate on this choice.

Finally the participant is asked to address a certain emotion the product evokes. Again the participant is asked to elaborate why.

Measures

In this research quantiative data variables are measured for perceived aesthetic pleasure, unitiy, variety, typicality, novelty, biomimicry with 7 point likert scales, ranging from 1 (Strongly Disagree) till 7 (Strongly Agree).

Qualitative data is gathered by asking participants for elaboration on their choices. The qualitative data is examined and is used to better understand what participants think of the product.

Results

Pleasing appearance

The results show that the product scores a 5,6 on perceived pleasant appearance. Although this is a simple measure to determine perceived pleasant appearance it can nontheless be concluded that people find the product appealing.

Elaborative comments state that the simplistic look makes the product appealing. That it is in balance with the rest of the corpus. That it looks nice and well put together. Some even find it elegant.

A negative comments is that the connected mechanism where the arm joints with the body looks bad. Because it looks bulky and doesnt match the rest of the design.

Unity

The design scores a 6 on unity. Which means that the product is perceived as a coherent whole. The fluent process of perceiving something as a coherent whole often results in pleasurable feelings as stated by Hekkert et al. 2014.

Comments by the participants state that nothing stands out in a way that it distracts from its intended presentation. It has a seamless feel, although there is made use of different components and materials.

Variety

The design scores a 5,6 on variety. variety is what makes a product more interesting to look at.

Comments show that the custom designs add great to the variety within the design and make it interesting to look at. Furthermore the difference in materials add to the variety and looks good.

Another comment states that there is more variety to distinguish it as more than a simple replacement of an arm; the curves and details that mimic those of a natural arm add greatly to this.

Typicality

The design scores a 6 on typicality. Typicality means that a product is familiar and recognizable. It can be concluded that people find this product familiar and understand what it is.

Elaborative comments state that is recognizable as an arm, but that it is not just copying it but instead has a high tech feel. Another comment states that it resembles the look of semi-futuristic design for prosthetics often used in video games, but does not feel alien or unfamiliar.

Some comments also state that they have not encountered a product like this before, but that it is very easy to comprehend what it is and what it does.

Novelty

The arm scores a 5 in novelty. Novelty means that a product looks very innovative or new. 5 is stille a relative high score, meaning that the product is still perceived as quite novel.

The comments elaborate on this. It looks new in terms of technology, but the concept of prosthesis is not new. It is not the first bionic arm ever created. Also similar designs have been seen before, but not as futuristic and innovative as this one.

However the customizibility is stated as something people have never seen before and perceived as something that is innovative.

Human arm resemblance

The arm resemblance scores a 5,6. Meaning that the resemblance is good.

Participants state that it looks ‘natural’ and that although it is not a copy of a human arm, it gets very close.

What is notable is that most of the participants elaborate that the form looks very human, but that the colours or custom prints that are not skin like make the arm look less human and more machine like.

Meaning

Participants where asked to address characteristics that define the arm best. Words that are adressed to it are: Futuristic, high-tech, cool, interesting, powerful, gadget, manly, superhero, strong, natural, innovative, useful, exciting, mechanical, appealing, clean, classy, balanced, robust.

Some perceive the arm as to be stronger than a human arm and have more moving freedom.

Emotion

When asked what emotion the arm evokes the following emotions were stated: Optimistic, strong, proud, empowering, inspiring, excited, sad, unhappy.

The positive emotions were mostly due to the fact that prosthesis is giving someone back some functionalities of the arm. Seeing developments in this field make people feel empowering and inspired since it is such a noble cause.

The sad and unhappy emotion is related to the fact that limb loss is very tragic and that the participants feel bad for that.

Discussion

The amount of participants is quite low with only 16. Furthermore it would have been interesting to have amputees fill in the questionaire aswell. I have contacted the association for amputees, but I got no respondends sadly. However with the participants that have filled in the questationaire it is still possible to say something about the perceived appearance on a micro level. It is adviced thought to test this on a broader audience.

In terms of stimuli it would have been even more valuable to have a full appearance model. In that way the people can interact with the object and look around it. In this way they can say more about the design in terms of the way the product feels in terms of texture and materials for example.

Conclusion

It can be concluded that the participants were overall positive about the perceived appearance. The product is perceived as a uniform whole. But is still interesting enough by the use of different materials that add variety to the design. The product is recognizable and comprehensable, but still looks innovative and futuristic.

The product looks innovative, futuristic and clean. Which are quite positive characteristics. However as stated in chapter 5 there are two different kinds of prosthesis users, the ones that want to hide it and the ones that want to express it. It is understandable that the prosthesis might not be the right fit for prosthesis users that want it to be more discrete.

The product evokes postive emotions such as proud, inspiring and exciting. This is because it is very innovative and a development for a noble cause. Negative emotions are due to the tragic related to prostheses. People feel bad for that.

Figure A5.3: Physical prototype

Figure A5.4: Test setup

A5.4 Usability research

Experience of replacement of modular body panels of a bionic arm prosthesis.

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Abstract

This paper presents research about the experience of replacing modular body panels of a bionic arm prosthesis. In this research participants were asked to perform the replacement of body parts and share their experience.

Keywords

Product experience; prosthesis; modularity, replaceability, body panels,

Introduction

The product is designed to be very modular due to the desire for customizability and replaceability of wearing and tearing parts. For this research the goal is to assess the experience of replacing the body panels of the product prototype.

The research question is:
"How is the interaction of replacing body panels experienced?"

Method

Participants are given the prosthesis prototype and instructions on how to replace the panels and grips. They are asked to think out loud while performaing the handling. Afterwards the participant is asked to pick 5 words from the product reaction card sheet (see figure A5.5. and elaborate on the chosen words.

Participants

The participants (N=5). 5 participants were asked to participate in the usability test. Age ranged from 24-34 with various different occupations such as food technologist, IT developer, marketeer and copywriter.

Stimuli

Participants are presented with the prototype and an image of the product with its customizability options.

Apparatus

A webcam with built in microphone is used to film the interaction with the product.

Measures

The participants are asked to think out loud and they remarks are being recorded. Furthermore the participants pick 5 words from a product reaction sheet.

Procedure

Participant is presented with the prototype. A short introduction explaining the product and its function is given. Afterwards a short demonstration of how to the panels are supposed to be detached and assembled is given.

After this introduction the participant is asked to perform the disassembly of the index finger. Participant is asked to think out loud while performing this interaction.

Afterwards the participant is asked to pick 5 words from the product reaction cards sheet and elaborate why they picked those.

Results

Participants seem to struggle at first, but there is a clear learning curve. Once they manage to find out how to do it becomes very easy and the participants are actually enjoying it: 'its like a little fidget toy'.

The hard panels seem to be able to get off really easily. The grips however sometimes give trouble. Some participants make the mistake of not putting the grip pad of the proximal or middle phalanx in the right orientation. Furthermore people have to figure out how much force is necessary to remove the grip parts. After a couple of times it becomes easy. For example participant 5 learned really quickly how to do it (see video of usability test participant 5)

Sometimes the fingers can be in the way when trying to take the panels. However the actual model is supposed to be able to abduct the fingers, which would give more space for the interaction.

Words that have been picked are the following:

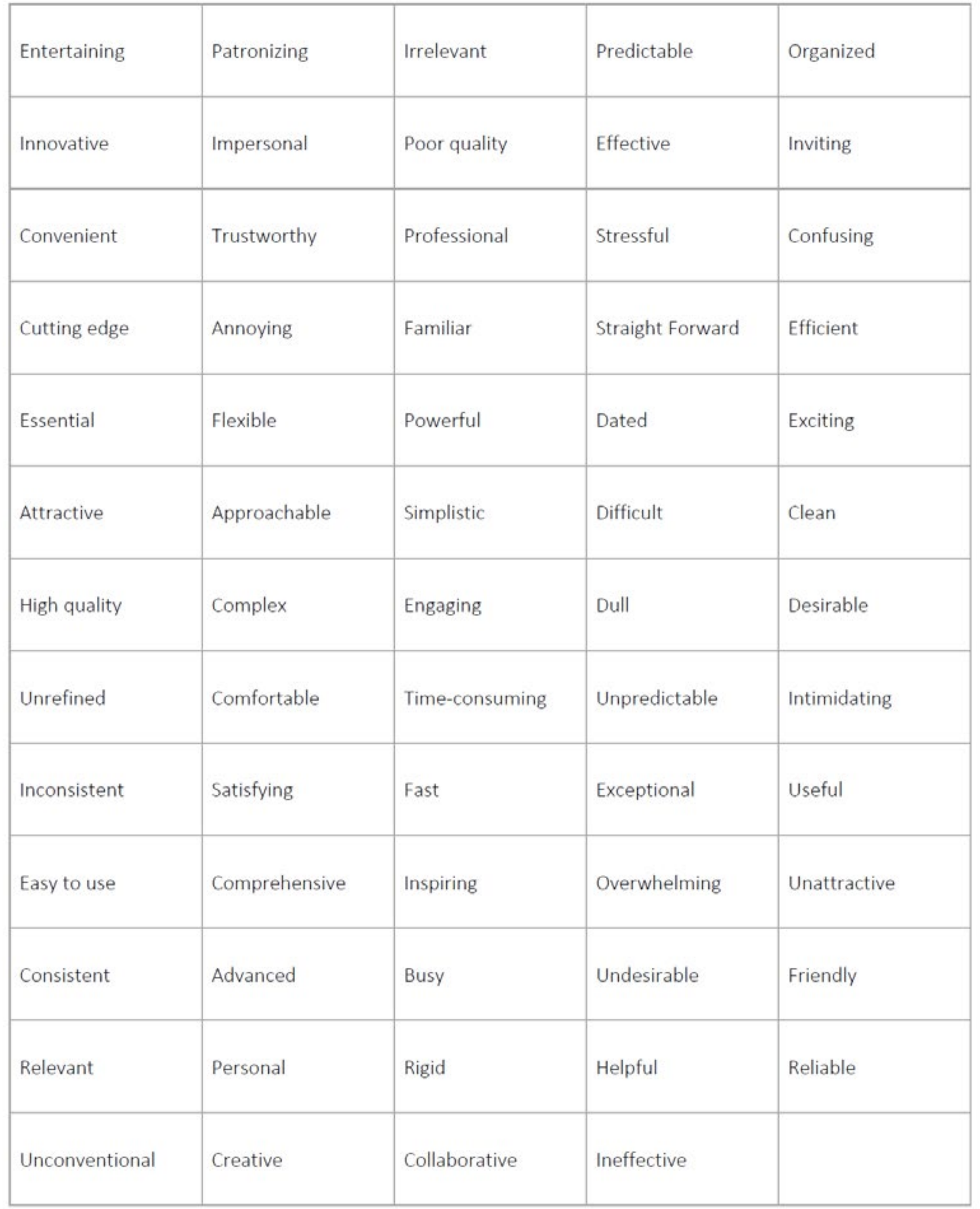
Satisfying: because it is easy to do once the participants understand how to do it. 'If you don't know how it works it is difficult. But after a while you understand it easily and the rest comes in easily. It slides nice.'

Systematic: Because it is a very systematic approach of handlings to do it.

predictable: After a while it is very straightforward and quite predictable how it works.

effective: It is effective because it does exactly what it has to do.

Engaging: It is engaging because you have to focus to perform it correctly.



Entertaining	Patronizing	Irrelevant	Predictable	Organized
Innovative	Impersonal	Poor quality	Effective	Inviting
Convenient	Trustworthy	Professional	Stressful	Confusing
Cutting edge	Annoying	Familiar	Straight Forward	Efficient
Essential	Flexible	Powerful	Dated	Exciting
Attractive	Approachable	Simplistic	Difficult	Clean
High quality	Complex	Engaging	Dull	Desirable
Unrefined	Comfortable	Time-consuming	Unpredictable	Intimidating
Inconsistent	Satisfying	Fast	Exceptional	Useful
Easy to use	Comprehensive	Inspiring	Overwhelming	Unattractive
Consistent	Advanced	Busy	Undesirable	Friendly
Relevant	Personal	Rigid	Helpful	Reliable
Unconventional	Creative	Collaborative	Ineffective	

Figure A5.5: Micro soft product reaction cards

Straight-forward: It is clear how it works. The grip panel takes some learning to understand. One of the participants mentioned an 'ikea like' manual would be a great addition.

Time consuming: A participant stated that although it is straight-forward it might be time consuming to replace every part. However it is probably not something people will be doing everyday. If so, it will take probably about 15 minutes and it adds a lot of value, so spending that time could actually be worth it.

convenient: It is convenient that it is possible to replace all the parts. Easy to have several standard parts for the user that can easily be replaced

Creative: The modularity is perceived as creative and something they have not seen before.

Efficient: Perceived as an efficient way to easily replace a part if it breaks down.

Predictable: Participants state that looking at the product already reveals partly how it is suposed to be dissassembled.

Dated: One of the participant stated that the sliding mechanism of the dorsal panels is perceived as a bit dated. The participant would expect more of a snapping magnet system as is used in the arm panels.

Rigid: The grip panels experience was perceived as a bit rigid. One has to discover the material qualities and how many force can be applied in order to remove the parts.

Clean: Particpant states that the design is perceived as clean. Not many small gaps that could trap dirt. Everything fits quite seamless and neat.

Fast: Participant 5 states that the interaction is very fast and if you do it for a couple of times you can do it with your eyes closed.

Consistent: All the parts have the same way to be taken of. For example all the panels slide, all the grips wrap.

Easy: It is perceived as very easy to learn and to execute.

Discussion

There was a clear difference in learning curve and skill with removing the modular parts. However overall everyone managed to quickly understand and manage to do it. This could be due to the fact to some have done the interaction with the index finger and some with the middle finger. The index finger is a bit more rough due to the print quality and can therefor be a bit harder to disassemble.

The number of participants is not very high with only 5 participants. However this can be seen as a pilot and bigger more extensive research is adviced. Eventhough the participants were asked to perform this intereaction with one hand, it is ofcourse important to also test this with the actual target group.

Furthermore due to time limitations the screw that is supposed to be in the design was not taken into consideration. For full usability research the screw has to be added into the interaction.

Conclusion

It can be concluded that the interaction is quite straight-forward and easy to learn. It requires some learning curve, but after a while every understands how to do it. After that it is even perceived as satisfying.

Some recommendations are to add indication marks in the grips that indicate how to part should be orientated.

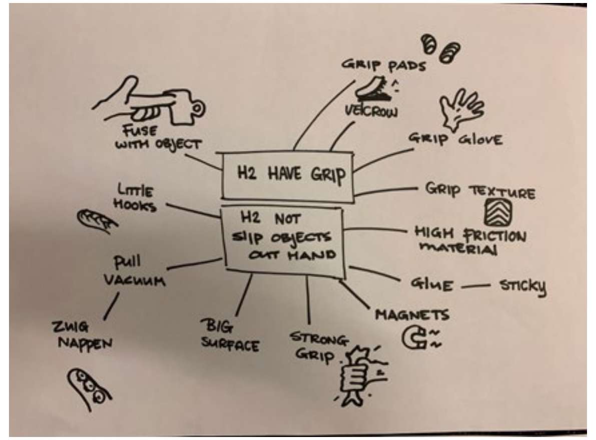
Another advice was to include some sort of ikea manual that explains the intereaction that gives the user some guideline when it is first encountering the product.

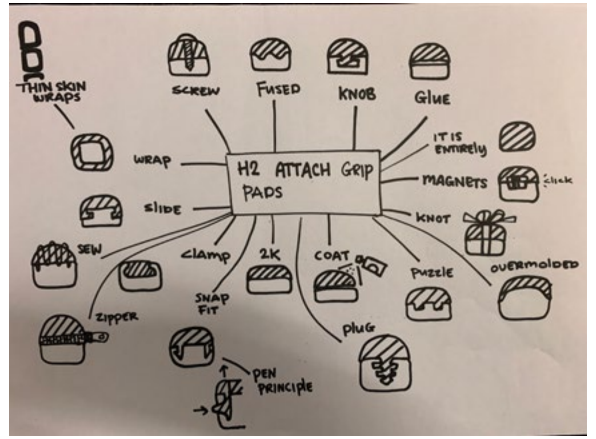
Form collage.
This served as Inspiration for the embodiment design

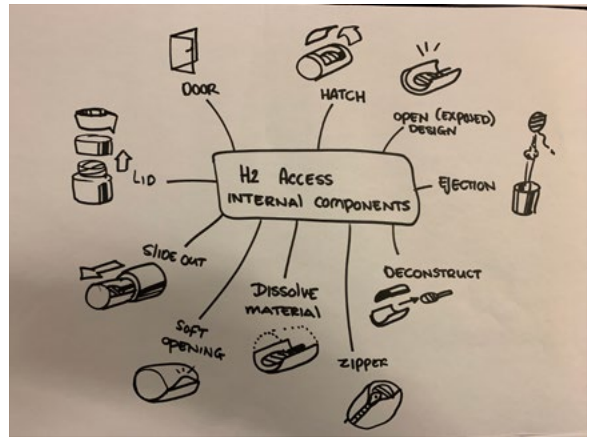
A6

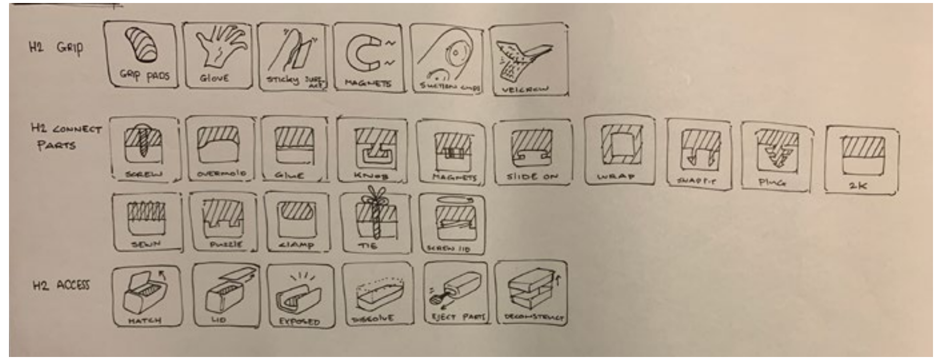
Ideation

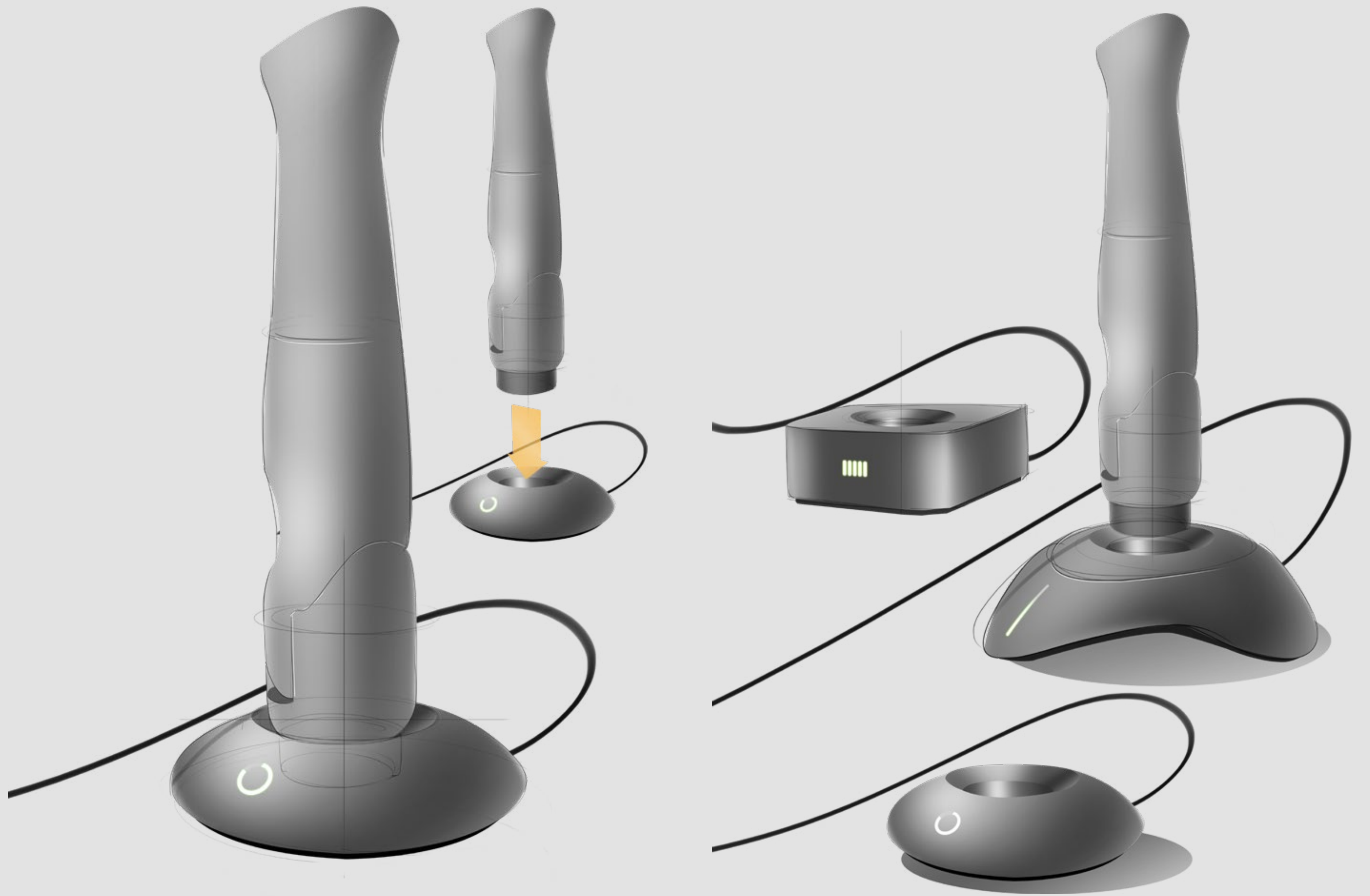
The 'How to' tool was used to come up with solutions for different functions of the prosthesis finger. These 'how to' solutions were later on combined with a morphological chart to come up with different combined ideas.Figures on the right show the sketches used for this.



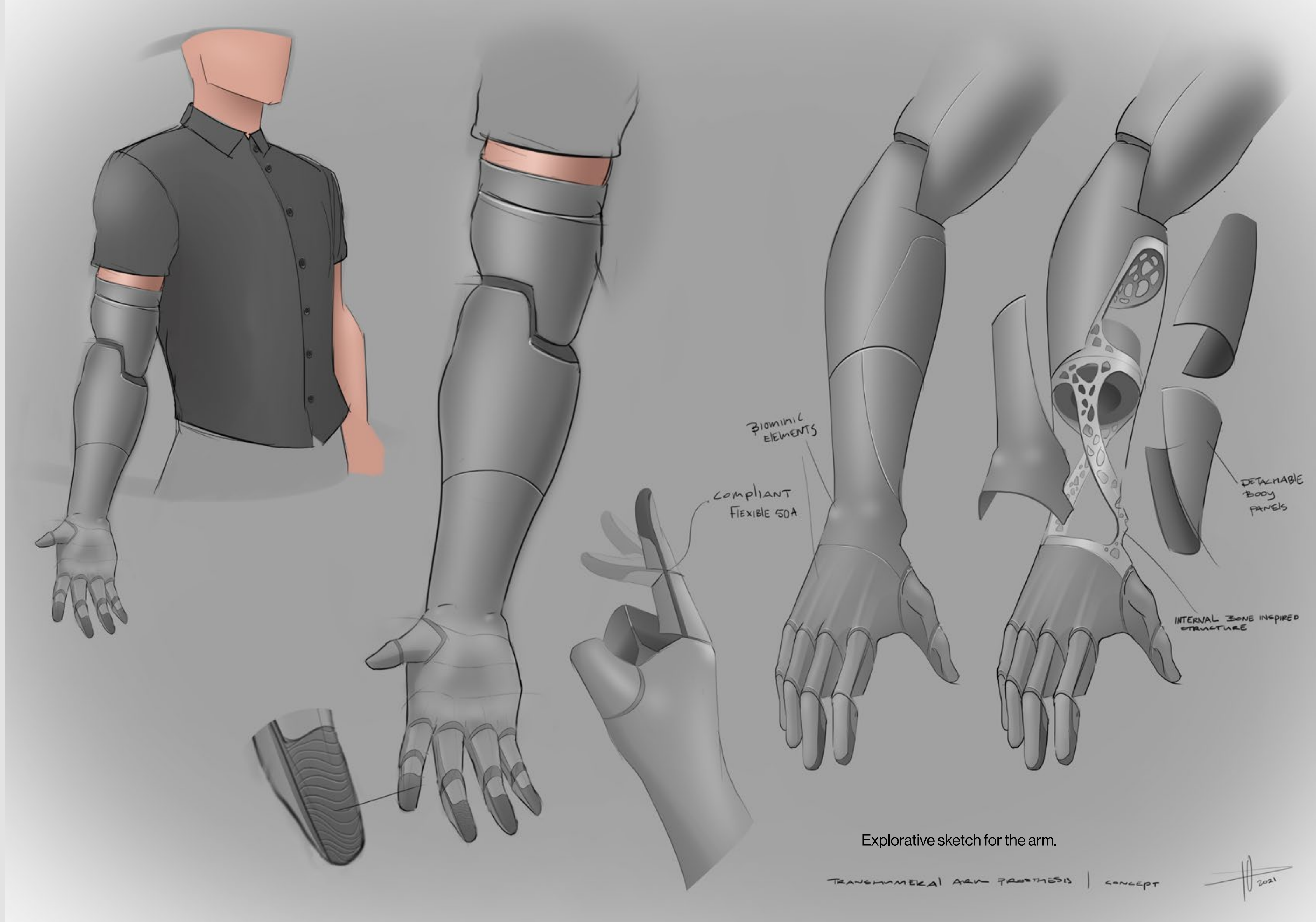








Explorative sketch for a prosthesis docking station design.



Explorative sketch for the arm.

In this master integrated product design graduation project a design concept is created for an osseo-intagrated customizable bionic arm prosthesis, which can serve as a stepping stone for the development of this product called ‘Ellis’.