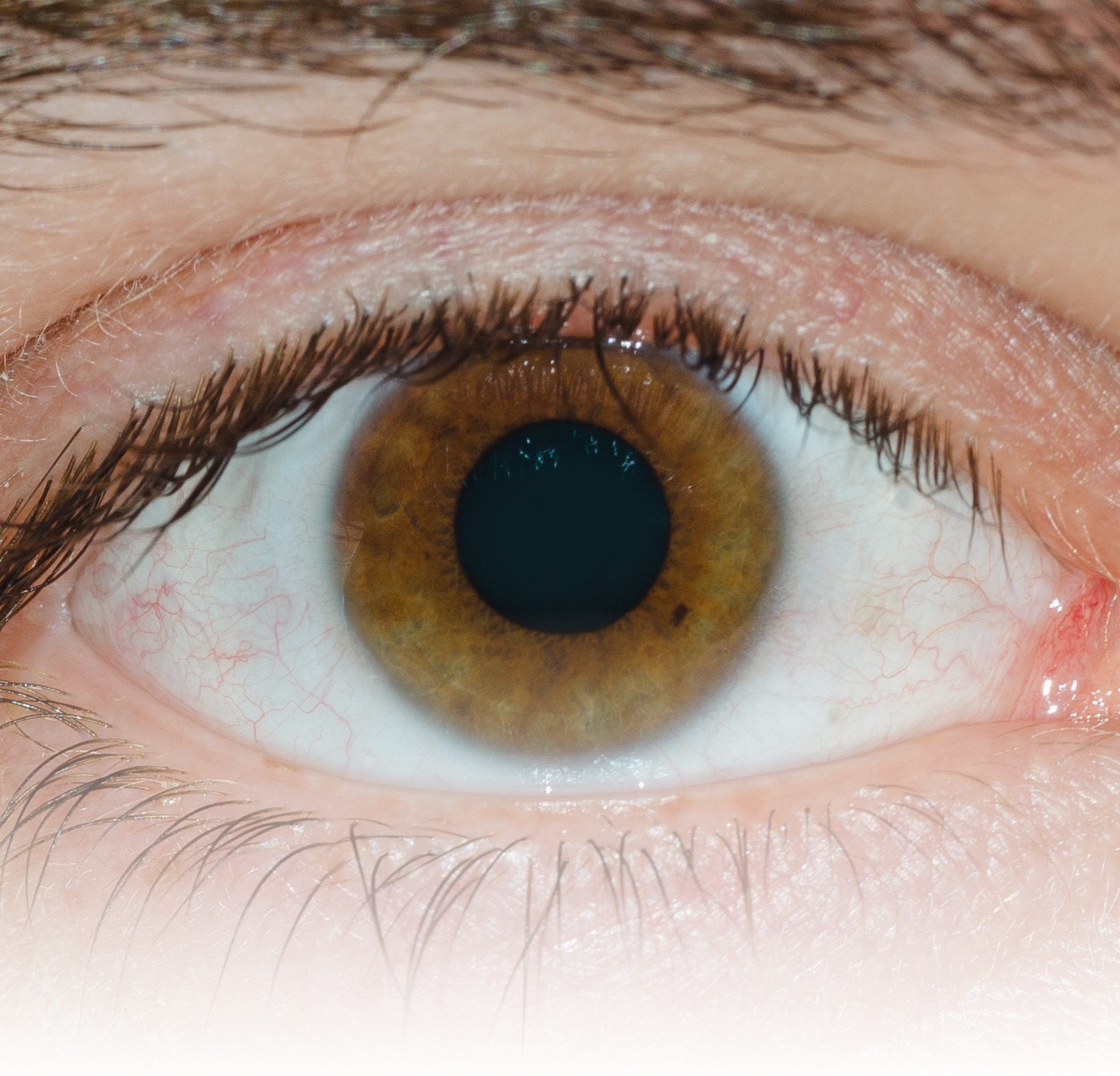

Creating ocular prosthetics using parametric 3D-modelling

Developing an new workflow for the parametric
3D-modelling of ultra-personalized ocular prosthetics.

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Master Thesis
by Jelmer Mulder

Final Report
Edition No 1
December 2022

Coaches
Daan van Eijk
Joris van Dam

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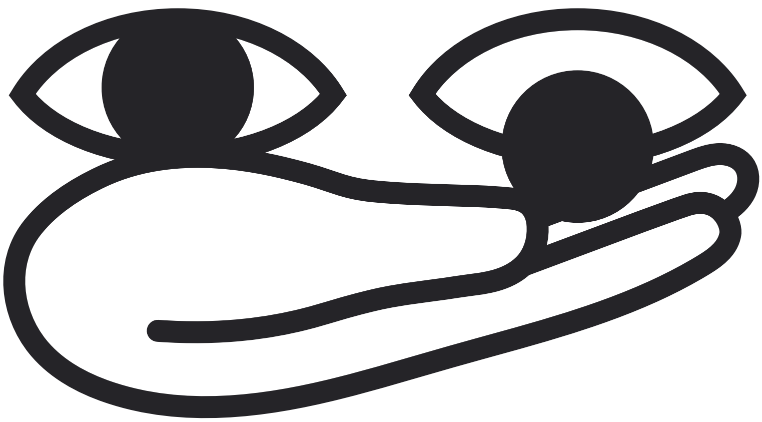

Creating ocular prosthetics using parametric modelling

Developing an new workflow for the parametric 3D-modelling of ultra-personalized ocular prosthetics.

Disclaimer
This master thesis is part of the master Integrated Product Design at the Industrial Design Engineering faculty of the University of Technology Delft in The Netherlands.

December 2022

Written by

J.A. Mulder
Industrial Design Engineering

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Advising company

Advising mentor: J. Remmers (Jelmer)
Adviser: Dr. D. Hartong (Dyonne)


Sclera
Thickness transparent layer
Limbus
Cornea

Acknowledgement

To everyone who was either involved in this project, I would like to say 'Thank You!'

To Jelmer Remmers, the ocularist, for being so enthusiastic and always willing to share ideas and opinions. It's because of him that the industry can move forward and innovate. Thank you for letting me join in on consultation sessions and showing me the intricacies of the profession.

To Sanne van der Horst whom I interviewed about the doctor side of things. Explaining me all the details that happen during and after surgery.

To Bertus van der Naagen, who I always could bother with another set of eyes to 3D-scan. Thank you for helping me with the scanning and thinking how to solve issues.

To Ilse Calis, my project partner who is now the other expert on ocular prosthetics in the faculty and whom I could always drink coffee and complain with.

To Joris, for his enthusiastic mentorship and helping me with the 3D-printing on the stratasys.
To Daan for being the chair and keeping me grounded for when I dived to deep in the technical details.

To my roommates, Jasper, Jelle and Titus for all the 'gezelligheid' during work in the office and the delicious lunches and 'bakkies' that came with it.

To my parents and my brother, for their continuous support and helping me in times of crisis.
To all my friends on the faculty who were always in for a coffee and a chat.

And to Sanne, for all her love and support.

"The eyes are arguably the most important part of the face, as this is where humans tend to focus when looking at someone. Eyes can convey emotions and foretell the actions of a person..."

Disney Research (2020)

Abstract

In the Netherlands roughly 20.000 people wear an ocular prosthetic as a consequence of losing their eye due to an accident or disease. An ocular prosthetic is a type of facial prosthesis that replaces an absent natural eye. The main goal of an ocular prosthetic is to provide an aesthetic replacement of a real eye. It does not restore the ability to see. During surgery the eye is removed and a empty socket is left. An ocular prosthetic is custom made to fit that socket.

These prosthetic eyes are made by highly-skilled professionals who are called ocularists. They do this through a labour-intensive manual production process. This process consists of several steps such as obtaining the shape of the empty socket, consulting with patients and painting a realistic iris, sclera and pupil by hand. Traditionally these prosthetics are made with an acrylate called PMMA using a series of plaster moulds.

However the industry is moving towards digital production. The starting point for this thesis was an article written in 2021 by a research team from the Amsterdam Medical Centre consisting of Annabel L.W. Groot, Jelmer S. Remmers, and Dyonne T. Hartong. This article featured a proof-of-concept of a fully coloured 3D-printed ocular prosthetic. This showed that creating an realistic prosthetic using 3D-printing is possible. The next steps are integrating this knowledge into the daily work of an ocularist.

The goal of this thesis was to develop a new workflow for an ocularist in order to create an ocular prosthetic suited for 3D-printing by using computer aided design. To increase the efficiency of production and to help the ocularist with digitalization a custom tool was developed in the form of a parametric model. This parametric model is able to automatically generate 3D-geometry of an ocular prosthetic using 3D-scans of ocular impressions or digital reference models. By inputting manual measurements, photographs and parameters the ocularist is able to create eyes which offer a personalized fit for every patient. Five ocular prosthetics have been made using the new workflow and parametric model. These were then validated by comparing the results with prosthetics who are made using the same input but with the traditional method. The 3D-prints showed great promise for a new fully digital way of creating ocular prosthetics having low surface deviations with the original prosthetics .

The next steps are testing with real patients and further developing the parametric model into a dedicated software tool for ocularists.

Most ocularists seem to be far away from producing fully 3D-printed prosthetics for customers but this thesis is a good first step in the digitalization of the ocularist practice.

Glossary

Ocularist	A person who makes and fits artificial eyes
Ophthalmologist	A doctor who specializes in eye and vision care.
Anophthalmic socket	An orbit not containing an eye- ball, but with orbital soft tissues and eyelid structures.
Prosthesis	Artificial device that replaces body part
CMP	Custom Made Prosthetic
AM	Additive Manufacturing, producing components by means of adding material.
3D printing	Synonym for AM
Cornea	The transparent layer forming the front of the eye protecting the iris and the lens.
Sclera	The white outer layer of the eyeball. At the front of the eye it is continuous with the cornea.
Limbus	The corneal limbus is the border between the cornea and the sclera.
Impression	The injection of material into the socket of a patient to get a volume which mimics the interior shape of the socket. This can be done with, or without eye present.

Table of contents

1. Introduction

This chapter introduces the project. It includes the background as to why this project exists. It will introduce the problem as a whole, the research questions that will be answered, the main stakeholders involved and the design process adopted for the duration of the graduation.

Figure 1. 3D-printed ocular prosthetics

1.1 Project introduction

In the Netherlands roughly 20.000 people wear a prosthetic eye as a consequence of losing their eye due to an accident or disease. An ocular prosthesis is a type of facial prosthesis that replaces an absent natural eye following disease or trauma. These prosthetic eyes are created by hand by highly-skilled professionals who are called ocularists. They do this through a labour-intensive manual production process. This process consists of several steps such as designing the shape of the prostheses, painting the iris to look realistic and making moulds.

In the western world almost all ocular prosthetics are custom-made. This is because the location, size, contour and colour have to be considered in order provide realism and symmetry to patients. Custom-made, hand-painted and individually constructed ocular prostheses have proven to be the most satisfactory ocular replacements. As there are not standard sized possible due to large variety. Customized fabrication however relies on skilled artists to recreate the iris and the white of the eye (sclera). It is a sophisticated and time-consuming process which involves a lot of manual labour. Only in recent years has there been a significant improvement in the production process with the introduction of digital technology.

A team coming from the Amsterdam University Centre (AMC), consisting of doctors, researchers and a ocularist, Jelmer Remmers, have developed a proof of concept, utilizing 3D scanning, digital modelling and 3D printing to digitize the process of making a prosthetic eye. Using open-source techniques and technologies they were able to 3D-print an prosthetic eye with a textured and coloured iris and sclera using an material-jet 3D-printer. The result is a fully coloured prosthetic which shows promise for the introduction of 3D-printing in the creation of ocular prosthetics. This prosthesis was made in 4 hours, reducing the labour time compared to conventional methods which is one of the advantages that 3D-printing can bring to this field.

The starting point for this thesis was an article written by the team from the AMC consisting of Annabel L.W. Groot, Jelmer S. Remmers, and Dyonne T. Hartong in 2021 . This article discussed the proof of concept of the 3D-printed prototype. Although ocular prostheses have been 3D-printed before, iris colour and texture are often manually added to the final product afterwards. As a starting point they used a 3D mesh of an ocular prosthesis made in the modelling software Meshmixer , combined it with a high-resolution digital photograph of a human eye which was processed in Photoshop. To achieve depth in the iris functions such as 'displacement mapping' and 'UV mapping' are used. Using a custom made bump texture height displacement of the mesh was possible to produce a textured and coloured iris and sclera. The result is an realistic lifelike prosthesis which is fast to fabricate. The process took 4 h, of which 2.5h was printing time.

This proof-of-concept study shows that the 3D-printing of realistic eye anatomy with coloured and textured iris and sclera in a single print job is possible. As until the publishing of this paper this complete method was not described before. The purpose of the paper was to develop a novel method of adjusting a photograph of a human eye for the 3D-printing of a ocular prosthesis. The shape of the 3D-model however was not taken into account. The prosthesis would not be able to fit a real patient. A recommendation by the ocularist was to find a way where a personalized shape could be made that fits the socket of a patient. This was the start of this graduation project.

The next steps which are stated in the research paper are optimizing the workflow, including optimizing the capturing and reproduction of the eye's appearance, and how to make a fitting and comfortable shape for the prosthetic. Making sure the eye fits right now takes a lot of testing and back and forth between the ocularist and the patient and the current manual process is prone to a lot of errors in the manufacturing.

1.1.1 Previous theses

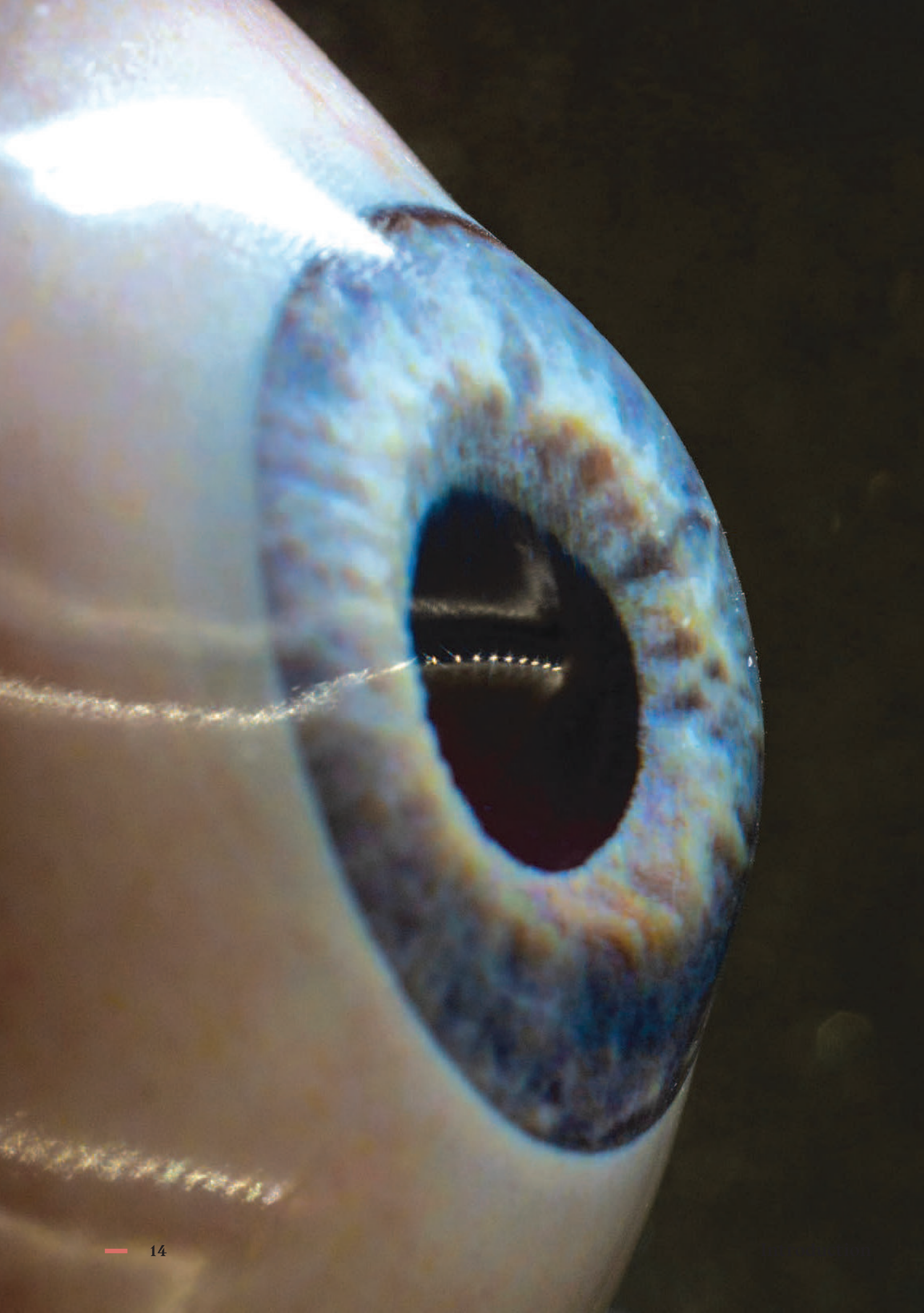
There have been other master thesis's done before about the subject of ocular prosthetics and also for the same research group of the AMC. One of these is the thesis of Ronald van der Beek. His research concerns crating an ocular prosthetic eye with dilating pupils. The goal was to simulate a pupil which can dilate and contract under different lighting conditions and which can be placed inside an prosthetics eye. One of the biggest differences in the appearance of prosthetic eyes compared with real eyes is the change in size of the pupil. Using a technique called electro webbing where you run an electric current through a fluid to change its hydro active properties he simulated an changing pupil. However this proved to be hard to implement in a real prosthesis due to the very small form factor. This research shows that innovation in the manufacturing of ocular prosthetics is happening. Another thesis by Jinyi Liu from electrical engineering builds on the work of van der Beek with a more detailed look at the technology behind electro wetting.

1.1.2 Problem definition

The original proof-of-concept for the 3D-printed ocular prostheses as described in the paper used a general shape for the prosthesis. One which is not modeled after a real socket but instead is made by hand to resemble an actual prosthetic.
In order to fully digitialise the process of creating ocular prosthetics using 3D modelling a method needs to be developed to model the geometry of the prosthesis.

This is the next step in the development of a new digital workflow. How do we translate the socket geometry to a well-fitting prostheses?

Figure 2. original 3D-printed ocular prosthetic



1.2 Project goal

The main goal of the project is to investigate and research how an ocular prostheses might be made using digital tools and state-of-the-art technologies with a focus on the geometry of the 3D model. The ocularist is interested in a new workflow for developing the ocular prosthesis using computer-aided-design (CAD) software. He believes that this is an area where good results can be achieved and which is not yet researched a lot.

The ocularist practice is traditional practice with ways of working which haven't changed a lot over the last years. Remmers is one of the most innovative in his field and he believes that the industry is ready to grow and adopt the new technologies of today.

1.2.1 Research questions

In order to innovate the fabrication of ocular prosthetics it is important to gain insight into the current manufacturing process. By uncovering the methods used new insights can be gained for opportunities in digitalization. The research questions of the first phase are:

RQ 1. What are ocular prosthetics, and how are they made?

RQ 2. To what extend is digital manufacturing implemented and what is the state-of-the-art method?

RQ 3. How do you translate the socket geometry to a well-fitting prostheses?

RQ 4. How do integrate new technologies into the current way of working?

Figure 3. CAD-model of ocular prosthetic

The primary research question of this thesis is:

How can an ocular prosthetic be designed for production with additive manufacturing?

How to adapt the process of creating an ocular prosthesis to these new technologies is the problem this thesis will focus on.

1.3 Approach

This thesis is split into four phases and takes an integrated design approach and uses methods described in the Delft Design Guide (Van Boeijen et.al., 2020).

Discover the problems, background and context principles that apply to the problem by researching the scope

Define the problem, background and context principles that apply to the problem by researching the scope.

Develop ideas and concepts that provide solutions to the problem areas.

Deliver a validated final design outcome.

Figure 4 provides a visual overview of where the different stages of the design process are presented in the report. It also highlights the applied methods and tools used during the project.

1.3.1 Background research

The background research consists of several parts that were conducted simultaneously during the first weeks of the project in order to answer research RQ 1 and 2 and to get familiar with the subject of ocular prosthetics.

- Literature research on ocular prostheses

This research is done to introduce the subject and to get familiar with all the important aspects that are linked to it. What are they and how are they made?

- Literature research on digital manufacturing of ocular prostheses

What is the current state of digital manufacturing in ocular prostheses? How is it integrated already, what research is being done or why isn't it being done more? Digital manufacturing also plays a role in other medical fields such as in dental. How far is it there? And what finding can we take from those fields?

- Interviews with specialists related to the subject

In order to get a proper understanding of the problem and solution space, expertise is needed. For this phase of the project two experts where consulted. Jelmer Remmers, the ocularist, and Sanne van der Horst, a ophthalmologist at the eye hospital Rotterdam. There where also conversation with people who own ocular prosthetics. Especially linked to the patient society: Vereniging oog in oog (source: https://ver-ooginoog.nl/)

- Research on commercially available digital technology

What are the different solutions that fit in a new workflow? Answers to these questions should point to areas for improvement and opportunities for design. As a result a new design process for creating an ocular prostheses using digital technologies will be presented.

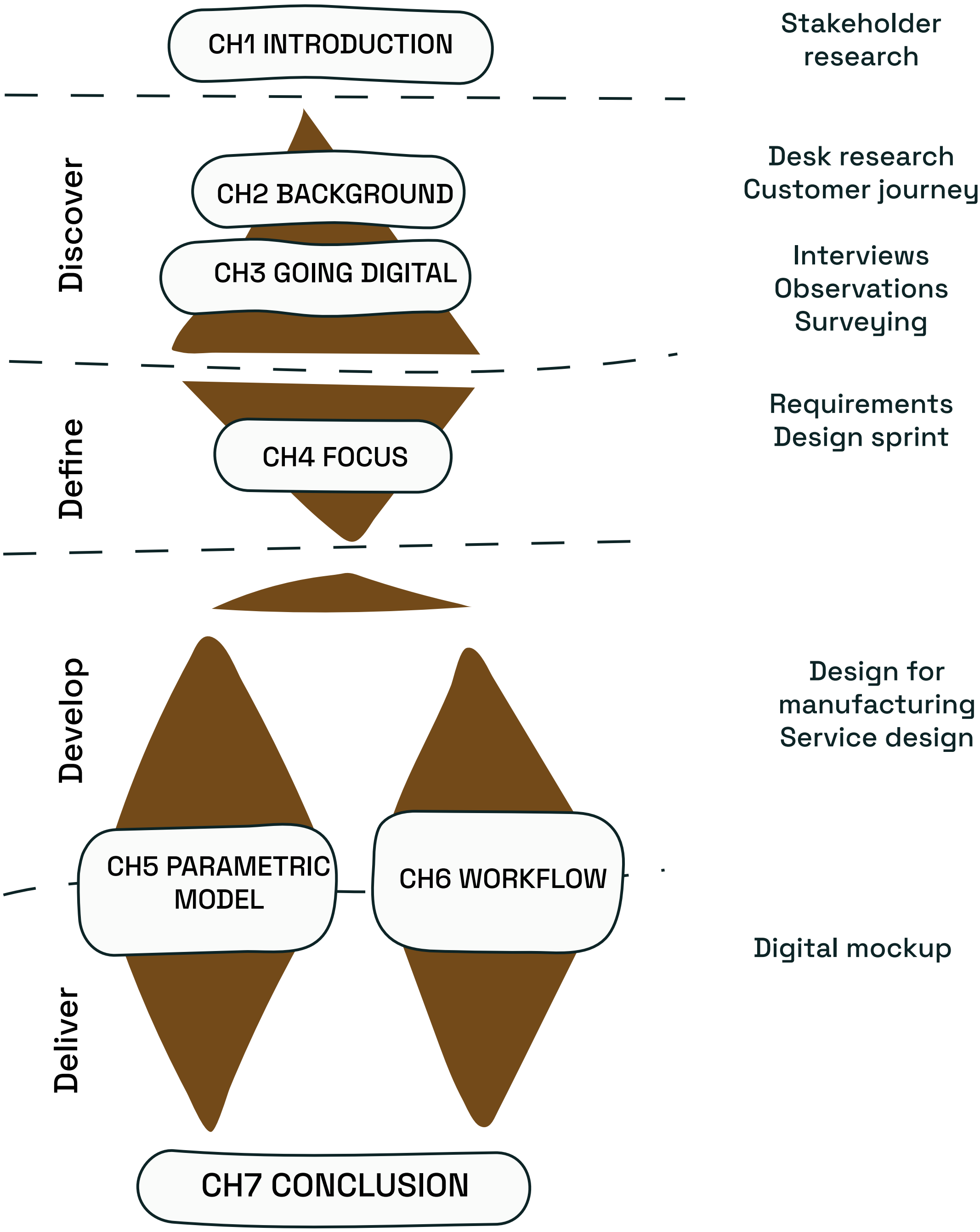


Figure 4. Project stages

1.4 Stakeholders

This project is done in collaboration between the Industrial Design Faculty at the Delft University of Technology and the Amsterdam Universality Medical Centre. There are several important people who are connected to this project

Jelmer Remmers | The ocularist
Remmers acts as the problem owner throughout the project. He is the one that invented the assignment and who is responsible for the previous research paper. He studied kinesiology and afterwards learned to become an ocularist. He has 11 years of experience in making ocular prostheses. Jelmer is specialized in the treatment of retinoblastoma and Microphthalmy / Anopthalmy (MICA). He is also part-time researcher on implementing (3D) technology in his field. Because of his wealth of knowledge there are frequent meetings with him to discuss the progress and ideas.

Dr. Dyonne Hartong & Emiel Romijn | The doctors
Dyonne is a ophthalmologist working at the Amsterdam University Medical Centre. She specialises in ocuplastic (eyelids) and orbita (eyesockets). She studied at the harvard medical school and UMCG in Groningen. Dyonne is part of the research group at the AMC and mostly interested in the connection the product has to the patient.

Emiel is a basic doctor who is researching to become an ophthalmologist. He will be responsible in researching the experience of the patient after this project. For example finding out if a 3D-printed prostheses is preferable above a normal one. He is also part of the same research group as Dyonne

Patients | Users
The target users of this project are people who after trauma or illness need an ocular prosthesis or who already have one. The patients are the users of the product. During the project some patients will be approached and interviewed on their experiences with prosthetic eyes. The final product should meet the needs of the users.

Prof. ir. Daan van Eijk & Joris van Dam | TU Delft Chair and mentor
Both supervisors for this project have differing areas of expertise that compliment each other well. Daan, who is professor in applied ergonomics and design at the TU Delft is there to help oversee the design process and implementing ergonomics in the project. He is also part of a research group on ultra-personalized products and services (UPPS) which specializes in developing personalised products using 3D data and smart systems.

Joris is head of the 3D-printing lab at the faculty of industrial design engineering. He is an expert on advanced manufacturing, robotics, digital fabrication and smart textiles. His technical knowledge will be useful throughout the project as using new digital fabrication techniques is the main goal.

Jelmer Mulder | Designer
As the author of this theses and carrying out the project, my role is to investigate how 3D modeling can play a role in the creation and fabrication of ocular prosthesis. What are the role of these prostheses in society and how do I improve the process for the ocularist? As a student of Integrated Product Design (IPD) I will be mainly focusing on the production processes en the development of a new digital workflow for the ocularist but also

maintain constant contact with all the stakeholders to ensure an optimal end product.

Ilse Calis | Graduation student
Fortunately there is another student who is working on a project closely linked to this one. Ilse is another graduation student from IPD. She is also working on the same subject of ocular prosthesis and in close contact with Jelmer, Dyonne and Emiel. Her focus is different from mine. The goal of her thesis is to improve the digital photography and 3D-printing workflow for the ocularist. How does the ocularist reach the most realistic results and what settings should you use for 3D-printing prostheses? Ilse's and my research will eventually be combined into one. Ilse and I will be working closely together in order to swap out ideas and findings.

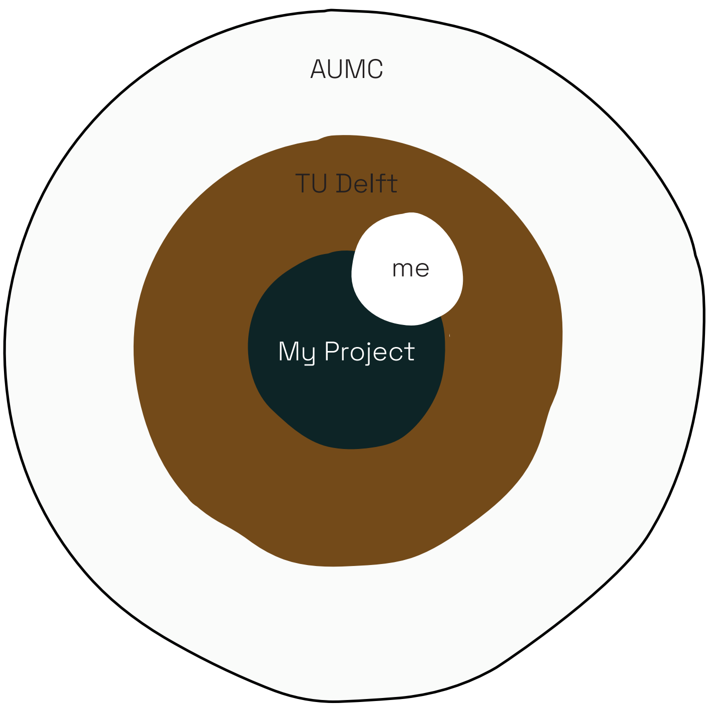


Figure 5. Stakeholders

2. Background

This chapter introduces the world of ocular prosthetics, how they are made, who makes them, their supply and demand and more background information.

RQ 1. What are ocular prosthetics, and how are they made?

Figure 6. Ocular prosthetics

2.1 The eye

This chapter is about eyes. In order to design ocular prostheses it is important to know the anatomy of eyes and how they work. Although prosthetic eyes do not emulate vision, they do need to look as realistically as possible. How do real eyes differentiate from prosthetic eyes?

2.1.1 Anatomy of the eye

In order to properly understand how ocular prostheses are made some general knowledge is needed on the anatomy of the eye. In order to create a lifelike representation the goal of an ocularist is to recreate the appearance of a real eye.

Looking into the anatomy of eyes choices can be made on what parts of the eye are important for this project and what information is needed later when creating prosthetics.

Eyes are organs located in the skull for the visual system. They provide us with sight, the ability to receive and process visual detail as well as other responses that are independent of vision. Eyes detect light and convert them into electro-chemical impulses. They do this by focusing light through an adjustable collection of lenses to form an image on the back of the eye.

Eye colour

People have very different shades and colours of eyes. This difference is especially large in the colour of the iris. In humans, pigmentation of the iris can vary between light brown to black depending on the concentration of melanin in the iris and the cellular density of the stroma. Which is the layer between the cornea and the iris. The appearance of blue, green and hazel eyes is a result from light scattering inside the stroma, similar to the phenomenon that accounts for the blueness of the sky. Neither blue nor green pigments are ever present in the human iris. This makes recreating lighter eyes difficult in ocular prosthetics.

Outside of the eye

The eye sits in a protective bony socket called the orbit. It is attached to six extra-ocular muscles. These muscles can move the eye up and down, side to side and rotate it. The extra-ocular muscles are attached to the white part of the eye, called the sclera. This is a strong layer of tissue that nearly covers the entire surface of the eyeball. The sclera is covered with tiny veins called capillaries. The sclera can change colour through the veins, for example is a person is tired the eyes are more red. How many veins and the orientation of them differs from person to person.

The surface of the eye

The surface of the eye and the inner surface of the eyelids are covered with a thin membrane called the conjunctiva. The eye is lubricate by tears and they make up three layer that together are called the tear film. Tears drain from the eye through the tear duct. Tears are needed to keep the eye from drying out and to wash away dirt and other debris.

The front of the eye

Light is focused into the eye through the clear dome-shaped front portion of the eye called the cornea. Behind the cornea is fluid filled space called the anterior chamber. This fluid is constantly being produced in order to maintain a constant eye pressure. Behind the cornea is the eye's iris. This is the coloured part of the eye. The dark hole in the middle is the pupil. Muscles in the iris dilate (widen) of constrict (narrow) the pupil to control the amount of light reaching the back of the eye. Directly behind the pupil sits the lens. The lens focuses light towards the back of the eye and can change shape to help the eye focus on objects up close. 70% of the eye's focusing power comes from the cornea and 30% from the lens.

The fornix conjunctiva is loose soft tissue lying at the junction between the palpebral conjunctiva, covering the inner surface of the eyelid and bulbar conjunctiva, covering the globe. This is the space between the eye and the eyelids.

Each eye has two fornices, the upper and lower. A fornix permits freedom of movement of the eyelids. This part of the anatomy is very important for making an prosthesis because after surgery this cavity increases in size and now offers the place where the prosthetic eye is placed.

Back of the eye

Light that is being focused into the eye by the cornea and lens passes onto the retina. This is light sensitive tissue in the back of the eye. A tiny specialized part is responsible for giving us our detailed central vision. The other parts provided peripheral vision. The cells on the back of the eye can perceive two different types of light, one for black and white and night vision, and one for colour and detail. The retina sends light as electrical impulses through the optic nerve to the brain.

Shape of the eye

Although some medical texts call the human eyeball a 'globe' just as our planet. The eye is spheroid rather than a true sphere. Our eyeballs are not perfectly spherical. A true sphere has the same diameter all around but a eye is generally less tall than it is wide. An adult eye has small variations in diameter and differ only by one or two millimeters with no significance difference between sexes

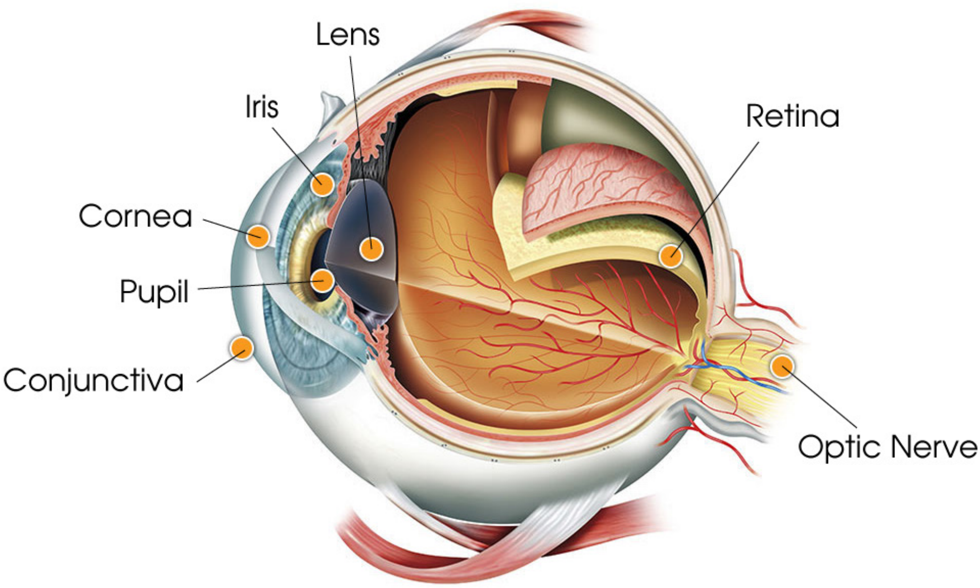


Figure 7. Anatomy of the eye

and ethnicities. Strong correlation has been found between the transverse diameter and the width of the orbit (r = 0.88). Bigger skulls often mean bigger eyes. Eyes also grow very rapidly and by the age of ~21, the eye has attained its full size.

2.1.2 Dimension of eyes

In order to get a feel for the size of the prosthesis and the geometry that are being used a research is conducted about the differences in dimensions of eyes. Although a lot of average or mean dimensions are available and exist, the perfect average eye does not. Every case is unique and making and perfectly average prosthetic will never fit and look good. These numbers however can give a good idea of the range of dimensions that are needed in the design.

The size of the iris varies from person to person with a range of 10.2 to 13.0 mm in diameter [4], an average size of 12 mm in diameter, and a circumference of 37 mm (Source: Iris Surface Deformation and Normalization)

Ocular prosthetic dimensions

Ocular prosthetics are not a direct copy of an eye. Contrariety to popular believe ocular prosthetics are not spheres or balls but are more shaped like shells.
Also the dimension of real eyes do not transfer directly onto the dimensions of prosthetics. This is because the implant that is placed after surgery has a smaller diameter then the original eyeball that was present. This biggest contributor to eye size is the size of the skull. Bigger eye sockets also mean larger eyes.

What is interesting is that the type of surgery, so enucleation or evisceration , has an effect on the resulting thickness of the prostheses. This research showed that evisceration leads to an marginal mean of thickness of 8.21 mm while Enucleation to an mean of 9.44 mm.

2.1.3 Conclusion

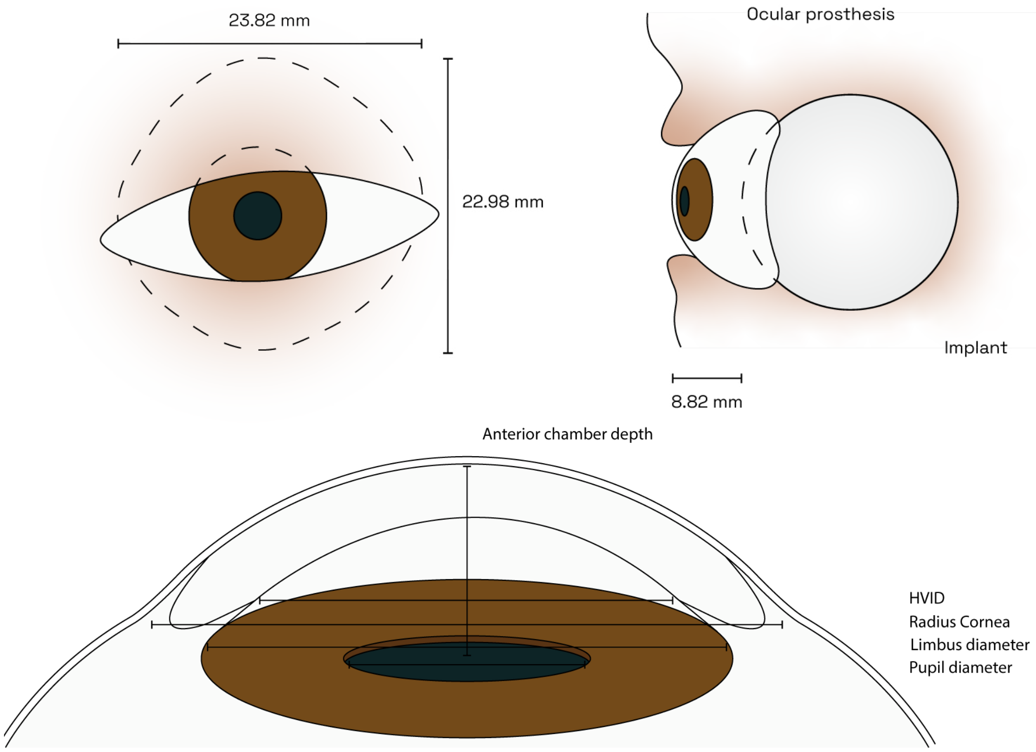
The eye is one of the most complex organs of humans. It not only provides us with the ability to see shape and color but also are known as 'windows to the soul'. Although the function is the same in every person, every eye is unique in its own way. Eyes are not spheres as is often mistaken but are irregular differ between left and right. The size of an eye does not correspond directly to the size of the prostheses. A better indication would be the width of the orbit and overall size of the skull.

The shape of the companion eye can not be copied one-on-one to get the front of a needed prostheses. The type of surgery has an effect on the resulting shape. Evisceration leads to a thinner prostheses and often a more stable one, offering more motility.

For the design,, sockets with grade 0 and 1 will be taken into consideration. The other sockets are out of scope for this project and it is recommended to work on those after this project. The dimensions of factors such as the iris diameter or the pupil width can be used for implementing the design.

"The pupil is seldom positioned in the centre of the iris but is usually upwards and inwards of centre"

The pupil is one third the size of the iris. And the iris is one half the size of the globe.



Measurement	Value
Tip of the Cornea	0.55 mm
Cornea radius	7.7 mm (SD ± 0.3 D)
Refraction index	1.3375
Anterior chamber depth (depth from 0 to front of lens)	3.1 - 3.2 mm
Horizontal Visible Iris Diameter (HVID)	10.2 to 13 mm
Lens (front of cornea till back of lens)	7.2 mm
Limbus diameter	3.7 ± 0.5 mm
Pupil diameter	1 to 8 mm

Figure 8. Relevant dimensions of the iris and ocular prosthetics

Key takeaways

- The eye is one of the most complex organs of humans.
- Eyes are not spheres but are shaped irregularly. They are wider then they are high.
- At 21 years, the eye has attained its full size.
- The pupil is one third the size of the iris. And the iris is one half the size of the globe.
- An ocular prosthetic is shaped like a shell.
- The cornea smoothly transitions unto the sclera, this is called the limbus.

2.2 Ocular Prosthetics

An ocular prosthesis is a type of facial prosthesis that replaces an absent natural eye following disease or trauma. In the Netherlands roughly 20.000 people wear an prosthetic eye as a consequence of losing their eye due to an accident or disease. The main goal of an ocular prosthetic is to provide an aesthetic replacement of a real eye. It does not restore the ability to see with that eye. They have been around for hundreds of years with drastic changes is their appearance ranging from eyes made of pure gold to wood. Nowadays most prosthetic eyes are made from two different materials. glass and plastic.

The plastic that is used for the production of artificial eyes is polymethyl methacrylate or better known as PMMA.

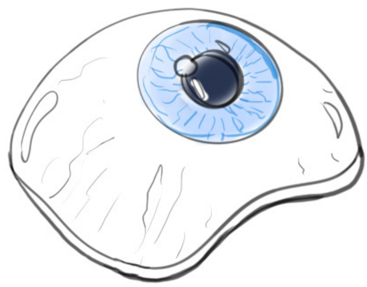
Plastic is chosen because it has few key advantages over glass namely:

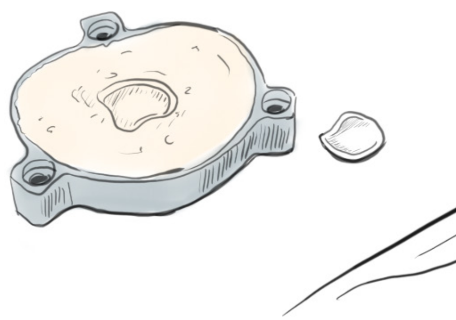
1. It is almost unbreakable. This is useful for children and athletes where there is a higher chance of the prostheses dropping.
2. It has the ability to be adaptable when needed. The socket is able to change shape and thus the prosthesis can change with it.
3. Long levity, plastic lasts a long time.

Whereas glass prostheses are very smooth, lighter, have a higher wettability and look more lifelike but are prone to breaking and not adaptable. The main advantage over plastic is also the manufacturing time. Glass prosthetics can be made within a few hours during one consult whereas plastic prosthetics costs a few days to make due to large variety of steps involved.

Important aspects of a good prosthetic are if it looks good, if the colour is correct and if the eye has motility, meaning if it can move in the direction where the patient is looking. Motility is partly a result of good surgical procedure but it is also closely linked to the match between the shape of the prosthesis and the interior shape of the socket.

Everybody with an ocular prosthetic needs a new one approximately every two years. This is due to changes in their physique and tissue that starts growing after the surgical removal of an eye. Also the prosthesis will show signs of wear over time such as fading, losing its shine and having scratches. Next to shape, the colour of somebodies eye can also





change by age. It is known that elderly people have more lightly coloured eyes then younger people.

An artificial eye can give people back their sense of identity and make someone feel whole again.

“You wear a prosthesis not in vain but because the trauma should not attract attention.” (Remmers, 2020)

“The goals of treatment with ocular prostheses are to restore facial aesthetics and self-esteem to anophthalmic patients.” (Goiato, 2014)

“The primary purpose of any ocular prosthetic rehabilitation is to regain eye socket volume and produce the illusion of a normal healthy eye and surrounding tissues.”

“As many as 18% of patients who wear orbital prostheses experience clinical depression and anxiety, and a further 21% have reported that they avoid being seen in public.”

Not attracting attention is a big goal. That is why it is important that if someone needs an artificial eye it matches their other companion eye. It should look as realistic as possible. This offers a challenge because eyes are very complex organs that are hard to replicate. Realism involves a lot of precise detailed work and expertise. Next to that, the prosthesis should also fit comfortably in the eye socket.

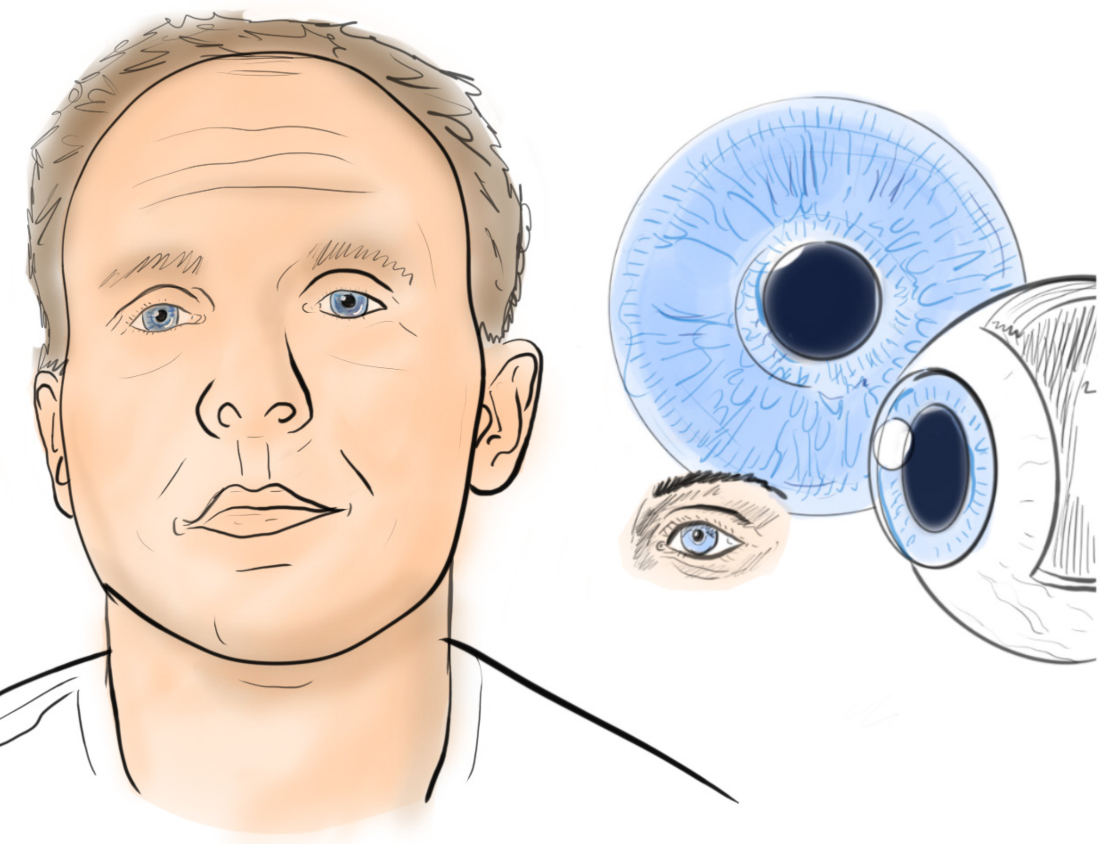


Figure 9. Ocular prosthetics

2.2.1 Different prosthetics

So when do you need an ocular prosthetic? If the situation of an eye is so dire that a person is in constant pain or if vision is almost totally lost an specialized eye doctor called an ophthalmologist can decide that someone needs an ocular prosthesis. There are different types of prosthesis which are useful to differentiate between for this project.

1. **A scleral lens,** this prosthetic is worn over a non-sighted eye. The shell is thinner than a regular prostheses and shaped like a contact covering the entire visible portion of the eye.
2. **A CMP**, custom made prosthesis. This prosthetic is worn inside the socket where the damaged or sick eye used to be and is thicker then a scleral lens.
3. **Stock prosthetics**, these are pre-made prosthetics which are readily available, inexpensive and can be fitted instantly though they ofter do not provide a good fit. These are mostly used in low-income countries and not in the Netherlands.

This project will focus on CMP's. Custom made ocular prosthetics. Because of their properties they lend themselves good for creating digitally.

2.2.2 Surgery

In some cases the eye needs to be removed with surgery. During surgery an implant is placed where the eye used to be. This implant comes in different sizes which depends on the size of the eye is being removed. The two main different surgical procedures are:

1. **Enucleation**, here the entire eyeball is removed and donor tissue for the sclera is needed. This tissue is reattached to the ocular muscles.
2. **Evisceration**, here the contents of the eye are removed but the original sclera is left intact.

The different surgeries have an effect on final shape of the prosthetic. The effect these different situations have on the prostheses is that the second method tends to lead to better motility and a usually a thinner prostheses. (van der Horst, 2022)

After the implant is placed. the mucous membrane is stitched over the implant and because the implant is smaller than an regular eyeball it leaves a empty space between the eyelids and the implant. This space is called: the anophthalmic socket (meaning, socket without eye). This is the place where the ocular prosthesis

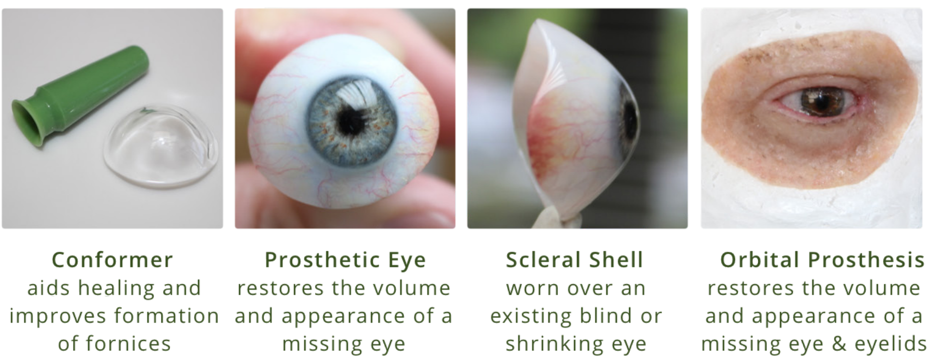


Figure 10. Ocular prosthetic types

will be worn. The prostheses should fit comfortably in the socket with the right balance between having a close fit and giving the eyelids room to move. The better the prosthetic fits the back of the socket, the better the motility and comfort.

2.2.3 Socket condition

An ocularist does not work alone, he/she often collaborated with an ophthalmologist and depending on how complex the situation is for the patient more teamwork may be needed.

There is an grading system in place to asses the complexity of the socket. If the socket is lined with healthy conjunctiva and has deep and well formed fornices the socket can be described a grade 0. This is an 'ideal' situation. Meaning that

Grade 0 and 1 are solvable by the ocularist.

Grade 2 and 3 need attention from an ophthalmologist and grade 4 and 5 need close collaboration between ocularist and ophthalmologist.

From grade 2 onward more personalized work is needed such as the use of conformers of multiple surgeries. This project focuses only on grade 0 and 1 sockets that the ocularist can work on.

Grade 0	Socket is lined with healthy conjunctiva and has deep and well formed fornices.
Grade 1	Shallow lower fornix or shelving of the lower fornix.
Grade 2	Loss of the upper and lower fornices.
Grade 3	Loss of the upper, lower, medial, and lateral fornices.
Grade 4	Loss of all the fornices and reduction of palpebral aperture in horizontal and vertical dimensions.
Grade 5	Recurrence of contraction of the socket after repeated trials of reconstruction.

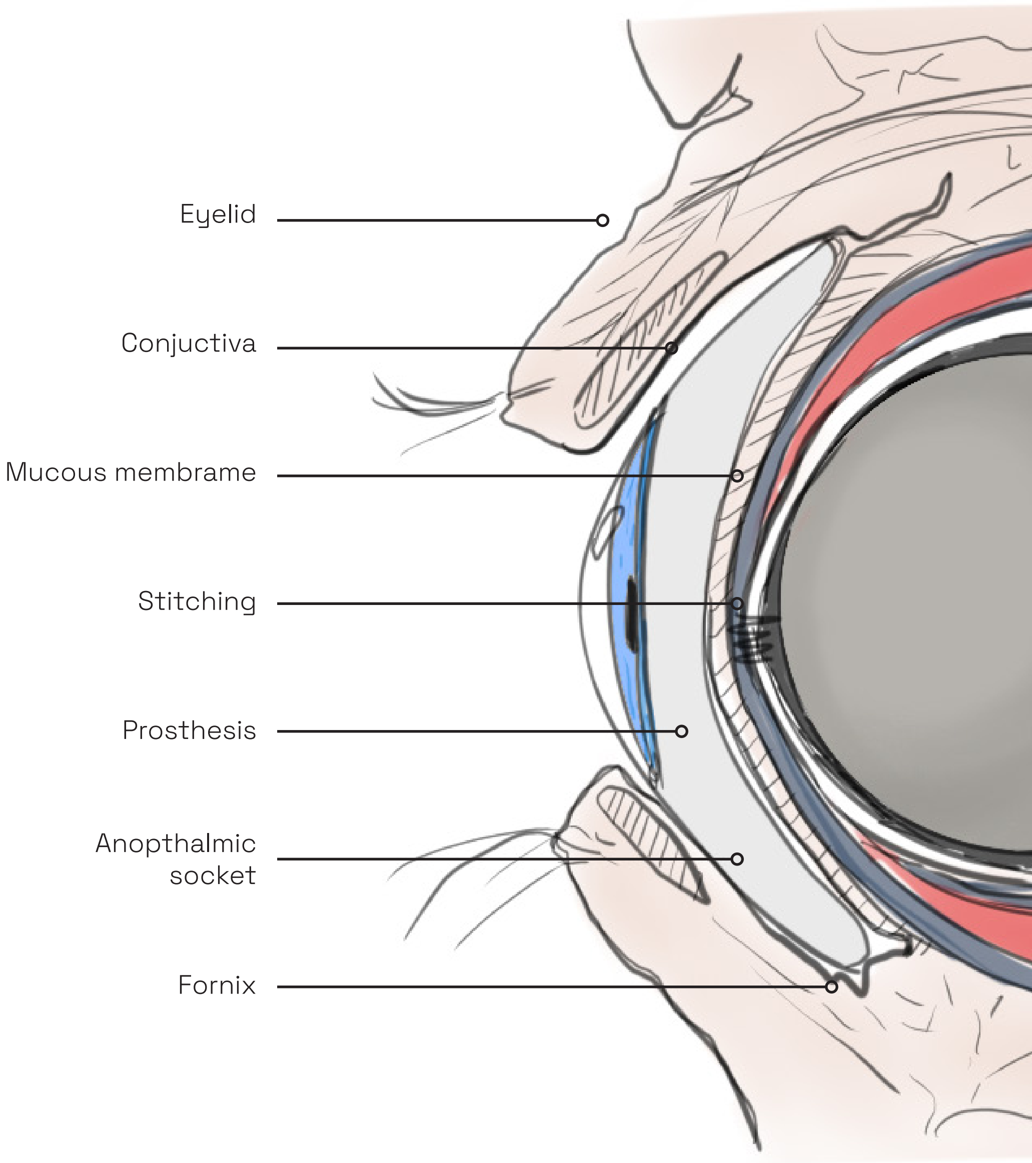
Figure 11. Grades of socket conditions

On the next page, a schematic drawing is presented showing a cut-out view of the anatomy of a socket with an ocular prosthetic. This is the result after an evisceration because the original sclera is still intact and connected the ocular muscles.

Key takeaways

- An ocular prosthesis is a type of facial prosthesis that replaces an absent natural eye following disease or trauma
- The goal is to retain eye socket volume and and produce the illusion of a normal healthy eye.
- The type of surgery has an effect on the shape of the final prosthetic.
- They are made by specialists called ocularists.
- Artificial eyes are made from Acrylic (PMMA) or cryolite glass.
- Different types of prosthetics exist, this thesis focuses on custom made prosthetics (CMP,s)
- Depending of the grade of the socket more collaboration with doctors can be needed.

2.2.4 Anatomy after evisceration



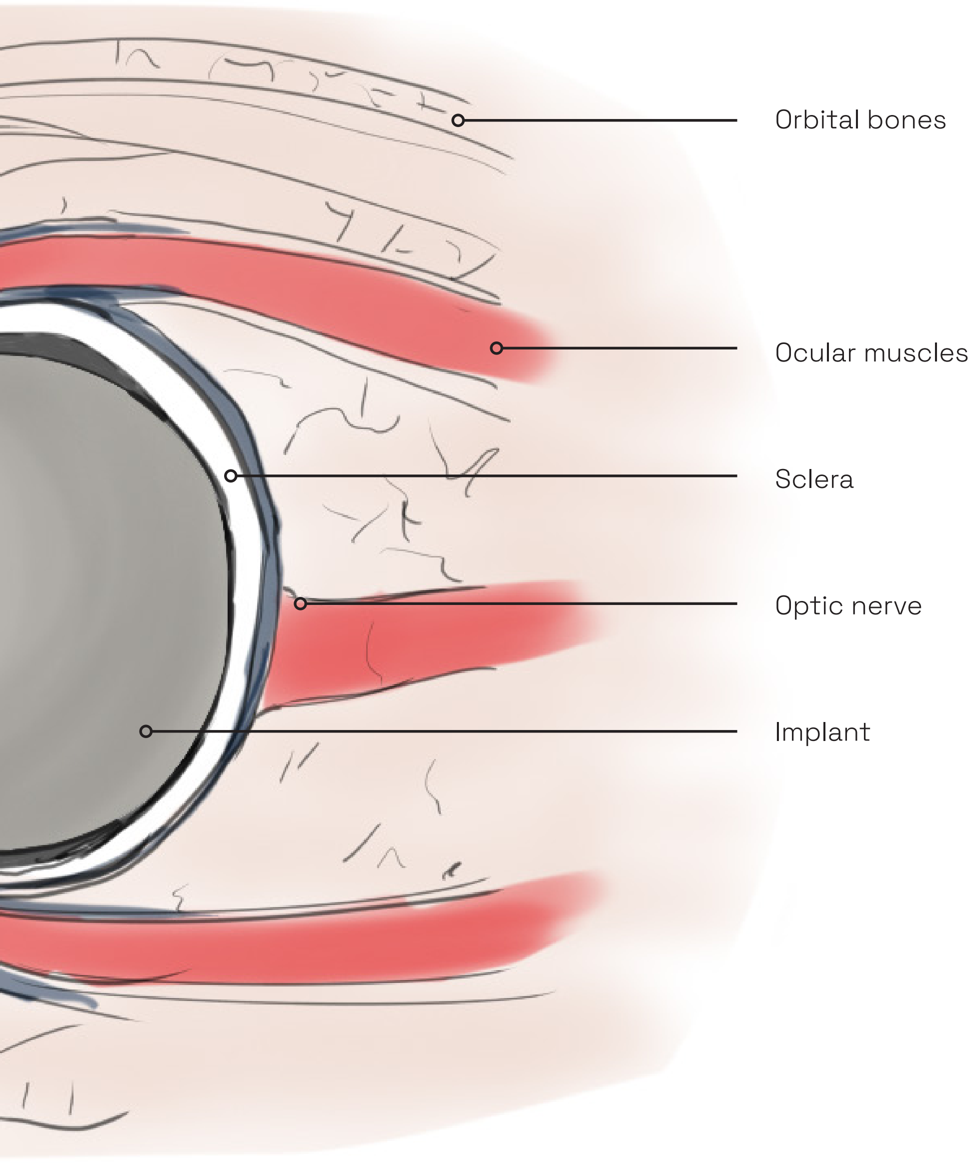


Figure 12. Anatomy after surgery

2.3 Supply and Demand

What does the market for prosthetics look like? How large is the demand and the supply? This chapter will begin with a look into the business side of an ocular prostheses company.

2.3.1 Supply

There are only a few people in the Netherlands who are capable of creating ocular prostheses. In the Netherlands prostheses made from glass are made by one German company: firma Müller. This is the oldest company with up top 155 years of experience and the only one with the skills in Europe to make good glass prosthetic eyes.

There are four different ocularist companies in the Netherlands who make them from acrylics. Het Haags Kunstogen Laboratorium (Axel Franken), Kunstogen (Frédérique Bak en Koen Smolders) and Jelmer Remmers.

Dutch health insurance companies reimburse the costs of the prostheses in the basic health insurance package once every two years.

According to Jelmer Remmers, a prostheses costs around €800 to make but these costs can go up to €1500 depending on the company. Private clinics can get more expensive. In the Netherlands every ocular prostheses is custom made, meaning using no stock shells are used. This is due to the differences the healed socket after surgery and the reason for removal in the first place. For example extra damage to the surrounding tissue.

A great advantage of custom made prostheses is the possibility of making it based on the geometry of the anophthalmic socket, which ensures maximum comfort for the patient. In addition to custom made prostheses, stock prostheses which are manufactured in a wide range of colors, sizes and shapes also exist. They are mass produced and their main advantage is their low price. They are mostly used in low-income countries and are used in areas where custom prosthetics are not available. They do not require a high level of expertise needed to make. The downside is that these prostheses often do not fit right and cause complications such as instability and infections. What is interesting is that in countries where these prostheses are being used most people have a similar dark eye colour. People with darker eyes have less noticeable details in their iris and thus are easier to replicate according to the ocularist.

2.3.2 Demand

Approximately 20.000 people in the Netherlands have and wear an ocular prosthesis due to an accident or a disease. Every person that wears an prostheses needs a new one every 2 years. This is due to the changes in physique of the visage, especially in the first years after surgery. Your face is always changing because there is a lot of soft tissue.

One of the reasons for an ocular prosthesis is a disease occurring in children: Microphthalmia. Yearly around 10 babies in the Netherlands are being born with one eye which is underdeveloped or missing. This rare disease leads to children needing an ocular prostheses from a very young ages. The Amsterdam UMC specializes in treating these children.

According to (Fortune, 2020) there is an increasing shift towards the adoption of cryolite glass ocular prosthesis. This is owed to the reflection provided by the glass mimicking the natural eye. Additionally, advancements in digital technology have enabled the quick and precise construction of such an ocular prosthesis. These factors have led to an increased interest in glass prosthesis in other countries such as Japan, Germany and the U.S.A.

According to the World Health organization (WHO), around 20 million people worldwide have blindness die to cataracts and additionally there is an expected rise in cases of glaucoma. The highest in Asian countries such as China, India and Japan. It is expected that if more people get diagnosed with these diseases that the demand for glass or acrylic eyes will rise. One of the biggest market driver is the technological advancements that are happening in the field. Prosthetic eyes have been around for centuries and will continue to do so in the future

2.3.3 Conclusions

People are always going to need ocular prosthesis as they did in the past and with an increase in wealth in lower-income countries is it expected that the demand for personalized prosthesis will grow. With technological advancements making it easier to manufacture realistic eyes more people will have access to a complete visage.

A high level of expertise is needed for the designing and fabrication of ocular prostheses. Giving ocularist the right tools will help them with suppling the higher demand.

Figure 13. Collection of ocular prosthetics

Key takeaways

- The demand for custom ocular prosthetics is growing, especially in non-western countries.
- A high level of expertise is needed for the designing and fabrication of ocular prostheses. Giving ocularist the right tools will help them with suppling the higher demand.
- Approximately 20.000 people in the Netherlands have and wear an ocular prosthesis.
- Stock standard sized prosthetics are used in low-income countries, but the demand for CMP's is growing.

2.4 The ocularist

Ocularists specialize in the fabrication and fitting of ocular prosthetics for people who have lost an eye following trauma or disease. The fabrication process for a custom eye usually involves taking an impression of the eye socket, shaping a plastic shell, painting the iris and then fitting the ocular prosthetic. There is no special training program of study for being an ocularist and ocularist may develop their skills from various background disciplines including medical, dental, biology and illustration.

2.4.1 Manual production

Currently being an ocularist included a lot of manual work. All the prosthetics are made by hand and the process involves a variety of different steps.

In this chapter an analysis is made on the traditional method of fabrication and the method employed by the ocularist.

For the purpose of effectively analysing and comparing traditional and possible methods of socket production, the process can be divided in three stages: **Measuring**, **Designing** and **Fabrication**. These stages can be further divided in 11 steps. Each stage has a variety of inputs, tools used and processes, but is characterized by a specific goal. Not all stages have to performed by the same person.

Measuring

The goal of the first stage, measuring is to obtain all the relevant information of the patient in such a way that it can be used in the next stages. The anatomy of the anophthalmic socket is recorded as is the companion eye. The ocularist also observes the companion eye of the patient and tries to find a close match from a batch of prosthesis. This is the stage where the patient is always present and involved.

Different methods exist for capturing the shape of the socket but the most common one is using an impression. An 'ocular tray' is placed in the empty socket of a patient. An ocular tray is a plastic retainer which hooks under the eye lids. A syringe is connected which is filled with impression material. The material is injected through the retainer and into the gap between the retainer and the eye. With the correct pressure this gives a clear and defined mold. This method can give vary accurate results and is also used for the creation of scleral lenses. During the impression it is important for the patient to look straight ahead and to move their eye as little as possible in order to get the best results.

Another method for measuring is using reference models. By trail and error and having a large sample of references, the ocularist can quickly find a close match in shape, iris colour and sclera colour from his collection. These models can be altered using wax to attain a desirable shape.

Each methods comes with their own advantages and disadvantaged and which one is chosen is based on the condition of the socket and the specific situation. For example if the socket of the patients is irregularly complex, the ocularist opts for using an impression. Whereas the resulting socket has a more 'standard' shape he chooses for using an existing prostheses and adapting that to the ideal shape.

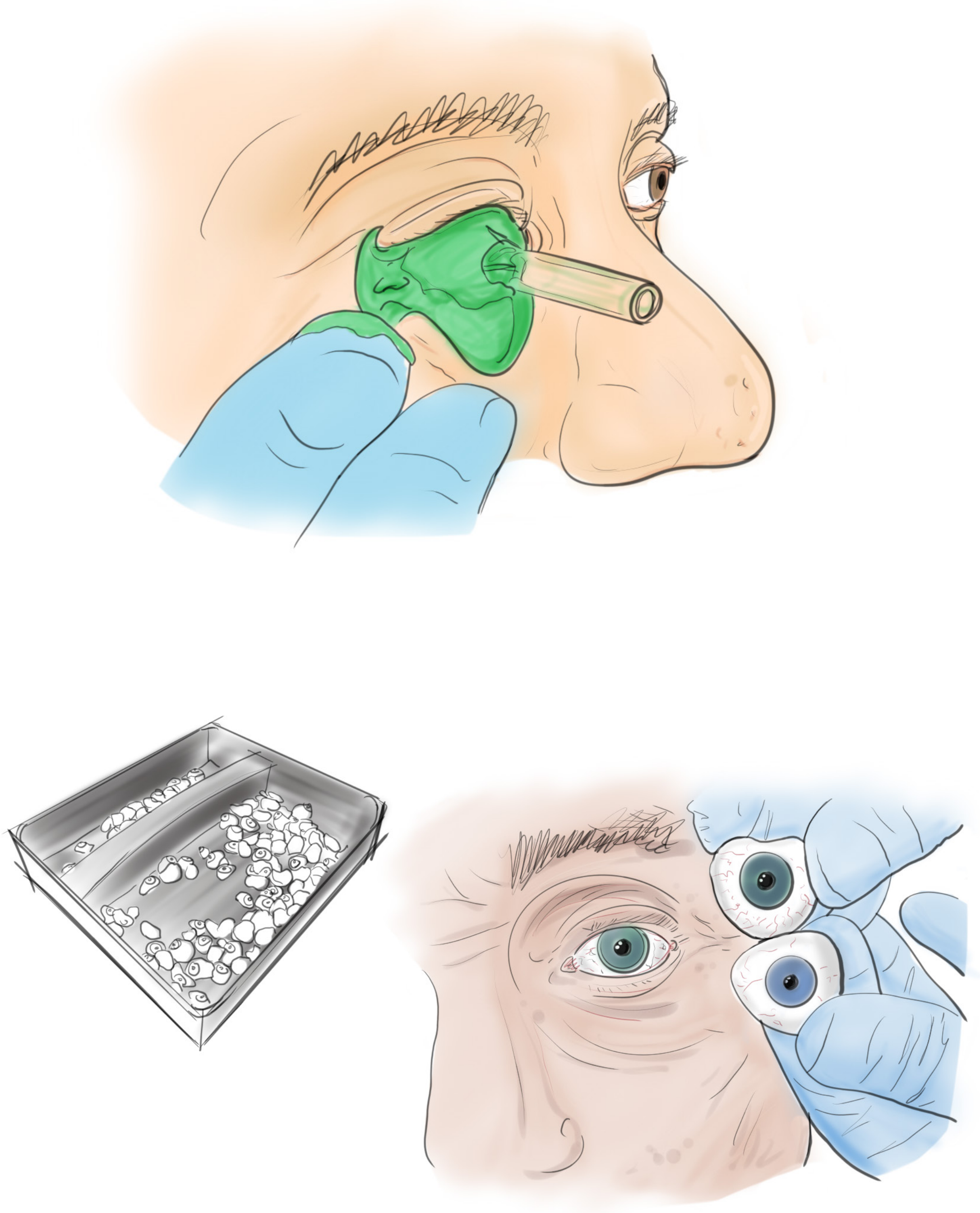


Figure 14. Different measuring methods

Designing

The purpose of the second stage, designing, is to translate the representative shape of the patients anophthalmic socket to a shape (traditionally with help of a mould) that can be used to fabricate the prostheses. The definitive shape is found by adding or removing material from a prosthesis and fitting it with trail and error. Sometimes a intermittent step is needed to find the correct gaze direction.

Fabrication

The end result is fabrication stage. The final shape of the prosthesis is molded using acrylic paste. Here a realistic iris and sclera are painted on the model before covering with a final glossy coating. Finally the prosthesis is fitted and polished to a fine shine.

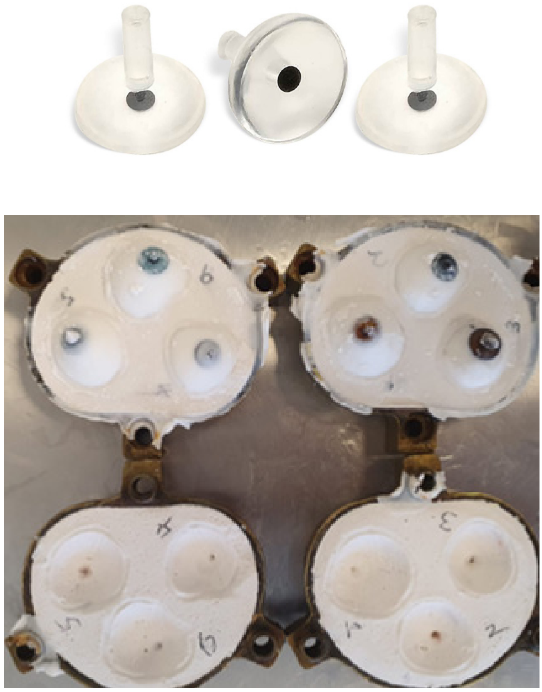


Figure 15. Iris disk and plaster mold

2.4.2 Literature

There is a large book about Clinical Ocular prosthetics, It not only covers prosthetic eyes but also the clinical procedures concerning eyes and anatomy. Chapter 5: 'Making and fitting prosthetic eyes' is the most relevant for this project. The chapter discusses the manufacture and fitting of custom-made (poly)methyl methacrylate (PMMA) prosthetic eyes. There are two types of prostheses, stock and custom. Few western countries use stock prostheses. Custom eyes improve the patients prospect for receiving a comfortable and aesthetically pleasing prosthesis with optimum motility.

The book states that ocularist need to undergo defective colour vision tests because this is important for delivering satisfactory results. A prosthetic eye is made up of two basic components - an iris/corneal unit and the white scleral body of the prosthesis. Whichever method is used for creating the iris/cornea, the process starts with the patient seated in a comfortable position facing good light. Ideally the light should be natural light (from a northerly direction in the northern hemisphere and from a southerly direction in the southern hemisphere) to avoid the sun's direct rays which have less blue than the light coming from the sky. The ocularist chooses for artificial light because this will result in more constant lighting conditions across different patients.

Anophthalmic sockets range from soft deep cavities (with small or non-existent orbital implants) and shallow fornices to those with shallow cavities containing convex or flat posterior aspects and deep fornices. The shape of the prosthetic eye is initially determined by the impression although it is not uncommon for the shape to be modified when molding the wax pattern later in the manufacturing process. A good impression extends fully into the fornices without over stretching the conjunctiva and accurately records the shape of the posterior aspect of the socket. Overextending may restrain the movement of the eye while under extended can lead to instability. The anterior shape of the prosthetic eye is not derived from the impression but is molded free hand to achieve its final contour in a later stage of the process. Figure 17 shows the recommended process of manufacturing an ocular prosthesis according to the book (Pine, 2015).

The difference between the method described in the book and the method of the ocularist Remmers is that after an impression is taken, Remmers uses a Micro-CT scanner to 3D-scan the impression. The impression is edited in the CAD software Meshmixer and the model is then 3D-printed for a first fit. This skips the first mold making and saves time. The most important step here is finding the right gaze for the prosthesis.

The measuring stage is arguably the most important stage in the process of making a prosthetic eye. The size of the eye, the direction of gaze, the curvature of the globe and the contour of the eyelids are determined during this stage. Similarity with the companion eye is very important and trade-offs can be made in order to increase the looks of the prosthetic. This can mean that the eyes will no longer be symmetrical to its companion but in the end will result in a better looking appearance. Tricks can be used such as making the iris larger to show more of the iris if the eyelids cover it too much.

The mold for the final prostheses is always produced oversized in order to accommodate tolerances for grinding and polishing away material in a later stage.

Figure 16. Ocular prosthetics

Steps	Task	Tools
First clinical session	Take an impression of the socket	Polyvinyl siloxane (PVS), Ocular tray
	Paint the iris disc to match the patient's iris	Finest grade oil paints (ivory black, titanium white, Vandyke brown, cobalt blue, yellow ochre, raw sienna and burnt sienna), sable hair brushes.
Laboratory processing	Cast the impression and make a wax pattern. Process or cement PMMA cornea over the painted iris disc and polish	Wax
Second clinical session	Insert the wax pattern into the socket. Mark the iris position and remove. Embed the iris/corneal unit into the wax pattern. Adjust and retry until size, shape and direction of gaze are correct	Putty
Laboratory processing	Key the iris/corneal unit and invest the wax pattern in dental plaster in a two-part metal eye flask. Remove the wax, pack the mould with white PMMA and process. Remove the PMMA eye, roughen the surface and cut back the cornea leaving a thin layer covering the painted iris beneath	Dental plaster, two-part metal eye flask, white PMMA
Third clinical session	Apply a second layer of paint to the iris and the scleral colours. Tease out red cotton thread and lay down conjunctival veins	Paint, red cotton
Laboratory processing	Dry the paintwork and process a clear PMMA veneer over the front of the eye. Polish to a high standard of finish	Clear PMMA Veneer, polisher
Fourth clinical session	Insert the completed prosthesis. Adjust and re-polish if necessary	
Follow up session	After 1 month of wear, inspect the prosthesis and make final adjustments as needed	

Figure 17. Manufacturing method according to literature

Key takeaways

- Making ocular prosthetics is long artisan process that involves a lot of manual work.
- All ocularists have their own unique way of working, this difference is also seen across countries.
- The two most common methods for attaining the shape are using references and taking an impression.
- Although novel, digital technologies are already being applied in the fabrication process.
- The final product is over-dimensioned to accommodate for corrections.
- A notable characteristic is the absence of standard metrics; the ocularist qualitatively defines pass-or-fail criteria for surface roughness, and color aesthetics using experience-based knowledge.

2.5 Customer Journey mapping

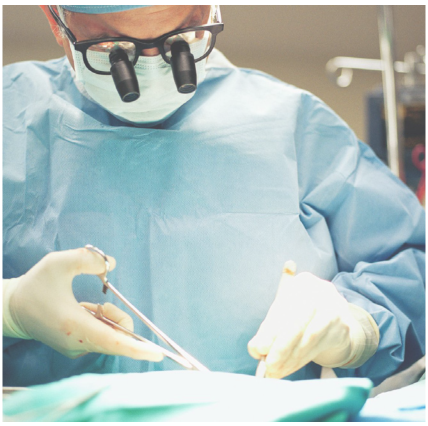
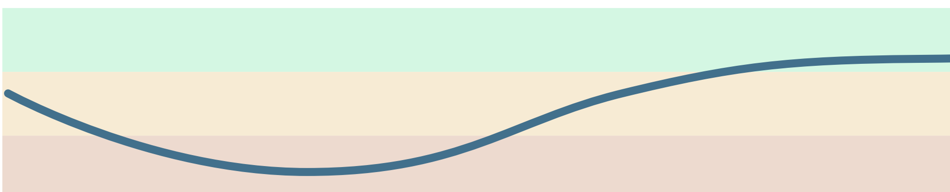
The next chapter is a detailed breakdown of all the steps that are performed by the ocularist for the fabrication of an ocular prostheses. It starts with consulting the patients and ends with the use of the final prosthetic. This is done using the method of customer journey mapping as described in the Delft Design Guide (Van Boeijen et.al., 2020).

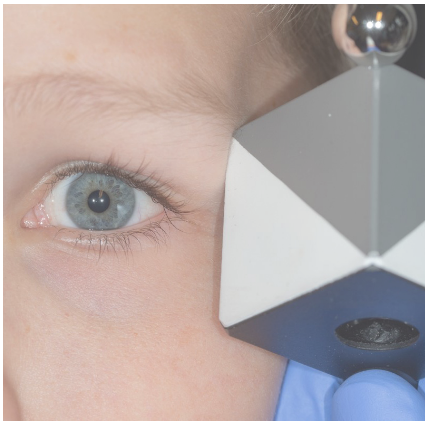
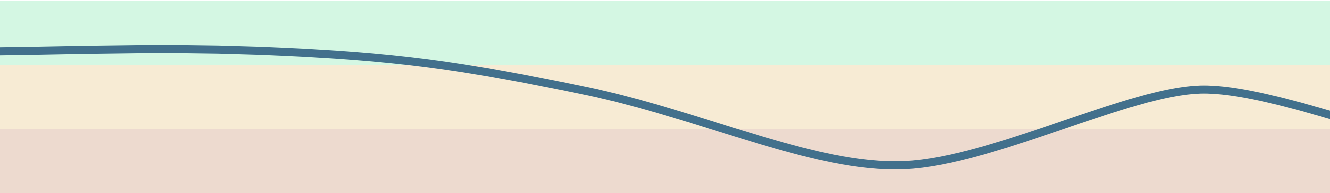
The main goal is to gain insight into all the stages the ocularist goes through while experiencing the service. It covers the emotions, goals, interactions and barriers he faces at each stage.

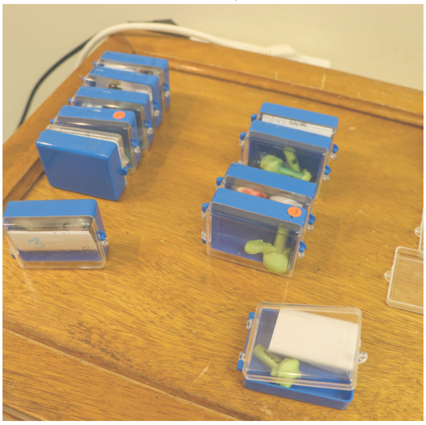
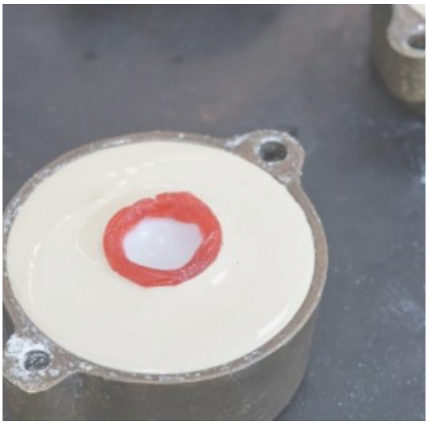
Important to note is that the process described is the process of the ocularist Jelmer Remmers and t does not translate directly to the approach of other ocularists. Every ocularist works in his or her own preferred way and while there are advised procedures, over time every ocularist develops their own way of working.

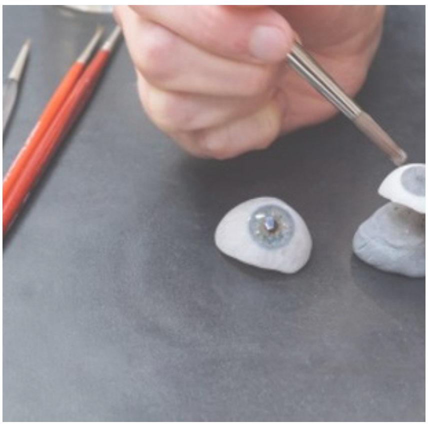
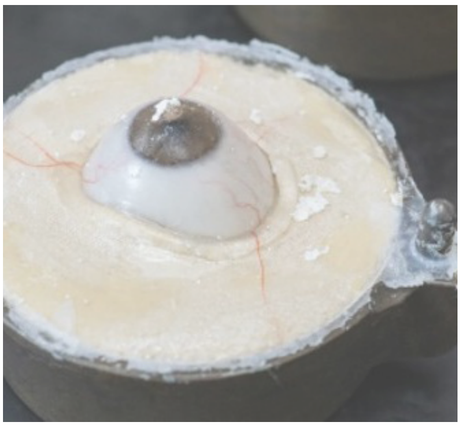
While the process is mostly similar for most patients there are some optional steps.

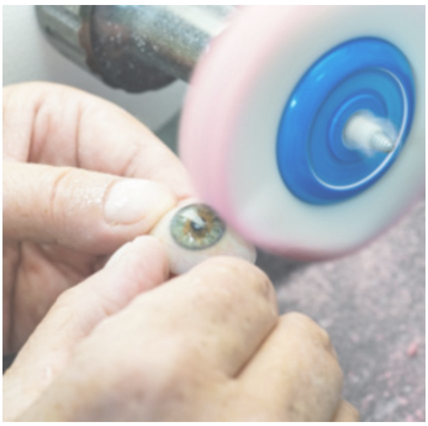
Figure 18. The ocularist at work

Phase	Surgery	Informing
Needs	• Improving the quality of life. • Giving back the feeling of being yourself • Preparing the patient for an ocular prosthesis	• Offering mental support for the patient • Expectation management. • Making plans for the treatment.
Activities	• It is determined if a patient needs surgery following an malignancy, born conditions, trauma or other causes. • A choice is made between enucleation or evisceration depending on the condition of the patient. • The patient undergoes surgery. • An implant is interested into the cavity.	• The patient comes to a consult with the ocularist. • The patients is informed on what is going to happen. • A decisions is made on what sort of prosthesis the patient is going to receive.
Time	?	4-6 weeks after surgery
Tools	Surgery tools	-
Visualization		
Likes	Surgery can affiliate issues.	The ocularist has a chance to make an personal connection with the patient.
Experience		
Pains	The surgery can be intrusive. Losing an eye can be a grieving pro-cess.	

Measuring	Comparing
• Capturing the companion eye for manufacturing. • Determining a correct pupil size for the prosthesis.	• Finding a starting point for manufacturing.
• The width of the Iris is measured • The width of the pupil is measured • A photo is taken of the companion eye using a calibration cube • The photo is calibrated using image processing software.	• The companion eye of the patients is being compared to an existing prosthesis. • A matching iris and sclera is selected if possible. • A matching prosthetic shape is selected if possible. • If the prosthetic almost matches, wax can be added or the prostheses can be grind down to alter the shape.
? A DSLR-camera, a calibration cube, Photoshop, calipers, form to fill in.	? Different prostheses in shape and size, wax, grinder
	
Having a digital image of the patient makes the painting process in the future easier. There is no need for the patient to be present in the manufacturing process.	A lot of time can be saved by using a reference. Only two consults are needed instead of
	
The lighting conditions are based on the indoor lighting of the workplace of the ocularist. Daylight is not taken into account. Experience with digital image processing is needed.	In order to find a suitable match, the ocularist needs a lot of different references.

Impression	Manufacturing
• Finding the perfect shape of the prostheses • Using a match is not possible due to an irregular surface.	• Making the prosthesis
• If no match can be found an impression must be made. • Putty is injected into the eye socket. • The impression is scanned. • The fit model is designed in CAD. • 3D-printing of the fit model. • The model is fitting to determine gaze direction.	• A plaster mold is made based on the comparison model or the 3D-print. • The Iris photo is printed in an iris disk. • White acrylate is pressed in the plaster mold. • The mold is heated to polymerize the acrylate.
?	2 weeks
Polyvinyl siloxane (PVS), ocular tray, micro CT-scanner, 3D printer, Meshmixer 	Plaster, two-part metal molds, iris disk, white PMMA, oven. 
Having 3D-data means the prostheses can be easily reproduced. The impressions is very good in capturing the shape of the back of the prostheses.	Multiple prostheses at the same time can be made.
“An extra consult is needed to find the correct iris position”	
Impression putty overfills the fornices and distorts the shape. Sufficient experience is needing in 3D modeling software. Most of the time the 3D-print needs rework.	The 3D-data used in the previous phase is not used anymore. Its a craft and a lot depends on the experience of the ocularist.

Painting	Manufacturing 2
• Making the eye as lifelike as possible by painting the iris.	• Giving the eye a natural reflection • Creating the cornea
• The iris of the half finished eye is painted on based on photographs. • Veins are added using fabric thread.	• The mold is ground out to make room for a new layer, add space for a cornea and to add tolerance • The eye is packed with a layer of transparent acrylate. • The edges are filed.
?	?
Waterbased paints, paint brushes, red cotton thread	Transparent PMMA, dremel
	
The red threads create very lifelike veins. Painting over the iris disk creates depth in the eye.	The transparent PMMA offers a realistic shine. The material is bio-compatible.
Using only a photo of the patient iris is not enough for a lifelike effect.	The mold needs to be ground out in order to accommodate tolerances for rework later.

Fine-tuning	Using
• Finalizing the prostheses • Giving the eye a shiny finish	• Instructing the patient on how to use the prostheses. • Instructing the patient on how to care for the prostheses.
• Final consult with the patient. • Make last additions and check if the fit and looks are correct.	• Clean the prostheses when needed, preferably not everyday. • Re polish at least once a year.
?	1 year
Polishing wheel	-
	
The process is done in presence of the patient.	The prostheses is easy to clean. The patients can feel whole again.
If the prostheses is ground to much and the transparent layer is gone, the prostheses is lost and the process needs to begin from the start.	Irritation and infections can build up over time if the fits is not perfect.

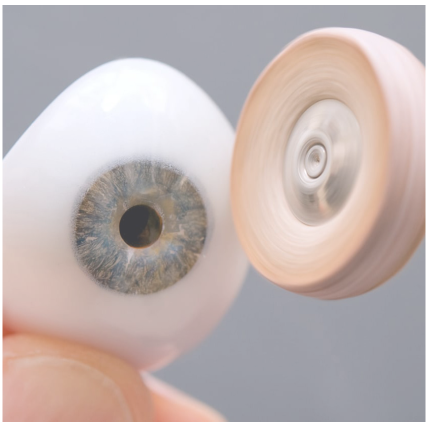
Evaluating

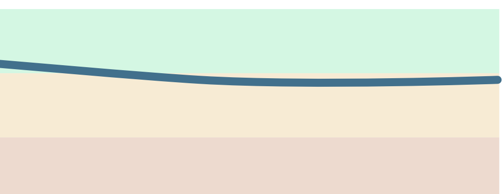
- Getting feedback on the work.
- Informing doctor when problems arise.

- Determine if a new prosthesis is needed after ~2 years.
- In case problems arise edit the eye or make a new prosthesis.

~2 years

Grinder, polishing wheel





Because of the physical process in order to make a new prostheses the process needs to start from the beginning.
The eye loses its shine over time with use.

Key takeaways

- The surgery can be intrusive.
- The lighting conditions are based on the indoor lighting of the workplace of the ocularist. and daylight is not taken into account.
- Experience with digital image processing is needed.
- In order to find a suitable match, the ocularist needs a lot of different references.
- Impression putty overfills the fornices and distorts the shape.
- Sufficient experience is needing in 3D modeling software.
- Most of the time the 3D-print needs rework.
- The 3D-data used in the previous phase is not used anymore.
- Its a craft and a lot depends on the experience of the ocularist.
- Using only a photo of the patient iris is not enough for a lifelike effect.
- The mould needs to be ground out in order to accommodate tolerances for rework later.
- If the prostheses is ground to much and the transparent layer is gone, the prostheses is lost and the process needs to begin from the start.
- Irritation and infections can build up over time if the fits is not perfect.
- Because of the physical process in order to make a new prostheses the process needs to start from the beginning.
- The eye loses its shine over time with use.

2.6 Psychological effects

Having your eye removed is a very intrusive procedure. It's not easy to make the decision to undergo surgery. The following statements are from a presentation Remmers gave to nurses on helping patients with their expectations and preparing them for living with an prosthesis.

- "Nobody can give you back your own eye."
- "The patients will always see 'a piece of plastic' and it is hard to realize that other people do see it that way."
- "You wear a prosthesis not in vain but because the trauma should not attract attention."
- "Motility is not a 100%. Short movements however are possible."
- "The periorbital area (area around the eyes) can show signs of asymmetry after a while."
- "There is more discharge then normal because it is a foreign body."

Their have been multiple documentaries and TV-programs made concerning Ocular Prosthetics. One of those is 'Ocularist' and it follows an ocularist in his practice. He talks about the implications of losing an eye and the effects it has om people. No matter how close artistically or how close in shape a prosthesis is always going to be inferior, they are never going to see.

"Depth perception is one of the physical losses, you also lose peripheral vision. Patients see different, their world becomes different. Your balance becomes different, you feel different. They are most aware of looking different." (Ocularist, 2003)

Most people accommodate their sight when their eye is lost after 3 to 6 months but some things will always be difficult. The loss of the dominant eye can slow down this accommodation process.

"It's a product that I'm producing, But the product isn't as important as to how they feel about themselves. When they enter here, they are missing something and when they leave, they are whole again. "

Remmers also describes the process of losing an eye as a grieving process. For some people it can be hard to realize that their eye will be removed and they will delay the procedure as long as possible.

The Dutch children show Klokhuis made an episode of their informative TV-show talking about ocular prosthetics. Here they follow a little girl who talks about her experience with her prosthetic. She talks about how it helps her feel whole again.

Children are sometimes bullied because they have an artificial eye. They are, after all, different from the rest. To prevent this, the ocularist sometimes makes eyes which do not match at all. For example, an iris with a galaxy in it or their favorite cartoon hero, Spider-man.

Figure 19. Child with galaxy eye

Key takeaways

- Losing an eye can be a grieving process.
- Losing an eye has not only a large emotional effect but also on sight, depth perception and balance.
- Realism is not always the end goal of a prosthetic, sometimes you want to stand out.

2.7 Key takeaways

These are the most important knowledge aspects from the background research.

The eye

- The eye is one of the most complex organs of humans.
- Eyes are not spheres but are shaped irregularly. They are wider then they are high.
- At 21 years, the eye has attained its full size.
- The pupil is one third the size of the iris. And the iris is one half the size of the globe.
- An ocular prosthetic is shaped like a shell.
- The cornea smoothly transitions unto the sclera, this is called the limbus.

Ocular prosthetics

- An ocular prosthesis is a type of facial prosthesis that replaces an absent natural eye following disease or trauma
- The goal is to retain eye socket volume and and produce the illusion of a normal healthy eye.
- The type of surgery has an effect on the shape of the final prosthetic.
- They are made by specialists called ocularists.
- Artifcial eys are made from Acrylic (PMMA) or crylite glass.
- Different types of prosthetics exist, this thesis focuses on custom made prosthetics (CMP,s)
- Depending of the grade of the socket more collaboration with doctors can be needed.

Supply and Demand

- The demand for custom ocular prosthetics is growing, especially in non-western countries.
- A high level of expertise is needed for the designing and fabrication of ocular prostheses. Giving ocularist the right tools will help them with suppling the higher demand.
- Approximately 20.000 people in the Netherlands have and wear an ocular prosthesis.
- Stock standard sized prosthetics are used in low-income countries, but the demand for CMP's is growing.

The Ocularist

- Making ocular prosthetics is long artisan process that involves a lot of manual work.
- All ocularists have their own unique way of working, this difference is also seen across countries.
- The two most common methods for attaining the shape are using references and taking an impression.
- Although novel, digital technologies are already being applied in the fabrication process.
- The final product is over-dimensioned to accommodate for corrections.
- A notable characteristic is the absence of standard metrics; the ocularist qualitatively defines pass-or-fail criteria for surface roughness, and color aesthetics using experience-based knowledge.

Workflow

- The surgery can be intrusive.
- The lighting conditions are based on the indoor lighting of the workplace of the ocularist. and daylight is not taken into account.
- Experience with digital image processing is needed.
- In order to find a suitable match, the ocularist needs a lot of different references.
- Impression putty overfills the fornices and distorts the shape.
- Sufficient experience is needing in 3D modeling software.
- Most of the time the 3D-print needs rework.
- The 3D-data used in the previous phase is not used anymore.
- Its a craft and a lot depends on the experience of the ocularist.
- Using only a photo of the patient iris is not enough for a lifelike effect.
- The mould needs to be ground out in order to accommodate tolerances for rework later.
- If the prostheses is ground to much and the transparent layer is gone, the prostheses is lost and the process needs to begin from the start.
- Irritation and infections can build up over time if the fits is not perfect.
- Because of the physical process in order to make a new prostheses the process needs to start from the beginning.
- The eye loses its shine over time with use.

Psychological effects

- Losing an eye can be a grieving process.
- Losing an eye has not only a large emotional effect but also on sight, depth perception and balance.
- Realism is not always the end goal of a prosthetic, sometimes you want to stand out.

3. Digitalisation

This chapter presents the key research findings on the initial analysis of the project scope.

RQ 2. To what extend is digital manufacturing already implemented and what is the state-of-the-art method?

Figure 20. The office of the ocularist


KLINION
SensiCare

3.1 Approach

With the background established a lot of information is gathered concerning eyes, prosthetics and the work of the ocularist.

One of the main challenges of this thesis is to transform the manual process of creating an ocular prosthetic into a digital process. Which technologies can help with that? What are the advantages and disadvantages? This chapter tries to answer these questions.

Starting by analysing the current digital process of the ocularist. What is he already doing in his practice and what steps are important for the final prosthesis?

What is the state-of-the-art in ocular prosthetic design? A literature study is done on the state-of-the-art methods for creating prosthetics using CAD/CAM tools.

After enough knowledge is gathered a new digital workflow for the ocularist can be proposed.

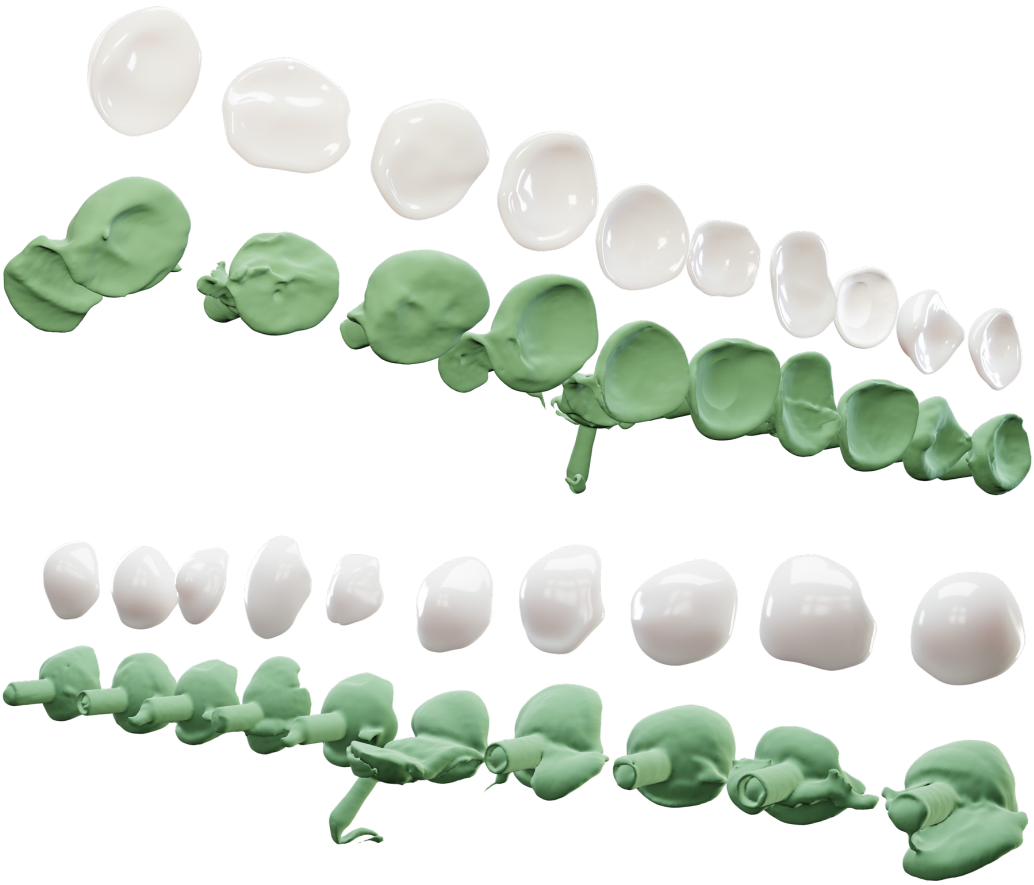


Figure 21. Ten impressions and their fitmodels

3.2 Current digital workflow

Looking back at the analysis on the current workflow of the ocularist differences can be found between his way of working and that of his competitors. The ocularist implemented digital production in some form in his work already. The comparison can be seen on the next page in figure 21.

Currently the ocularist already works using CAD and CAM tools. These tools are used during the design phase of the prosthetics. For this he uses a micro-CT scanner to scan the impressions. The reason he chooses for this kind of scanner is because these kind of scanners are widely used in hospitals. The scans are edited in the software Autodesk Meshmixer which is a program designed for editing and repairing meshes. The software is made by Autodesk (california) and currently not supported anymore.

With the tools provided by Meshmixer the ocularist designs a prosthetic which than can be 3D-printed using an SLA-printer. These models are mostly used for a first fit and to determine the location of the pupil. This step skips the wax try-in stage described in the traditional method. Appendix A describes in detail the ocularist goes trough for each prosthetic he designs.

The most important information that comes from the 3D-scan is the contour of the impression, the backside geometry , the thickness of the impression and the overall volume.
The scan can not be used in its entirety because of the way taking an impression works. The alginate creates a pressure inside the socket and thus disforms the socket when filling. Because the fornices are made from soft tissue that are the areas where the most distortion takes place. The back of the socket consists of the mucous membrane which is stretched over the implant. Here the impression does not disform that much. This means that the backside of the 3D-scan offers a good representation of the socket but the front not so much. This is where the expertise of the ocularist comes into play. The translation from the 3D-file from the scan into a first fit prosthetic which can be 3D-printed.

As a general rule the ocularist keeps in the back of his mind that the overall surface area of the prostheses should not change. This is due to the fact that the eyelids deform but not stretch. Figure 19 shows a collection of impressions and their corresponding processed fitmodels.

Key takeaways

- The ocularist already implemented 3D-scanning and printing into his daily practice.
- The most important information that comes from the scan is the contour of the impression, the backside geometry , the thickness of the impression and the overall volume.
- The overall surface area of the impression that is inside the socket does not change.
- The eyelids deform but not stretch.

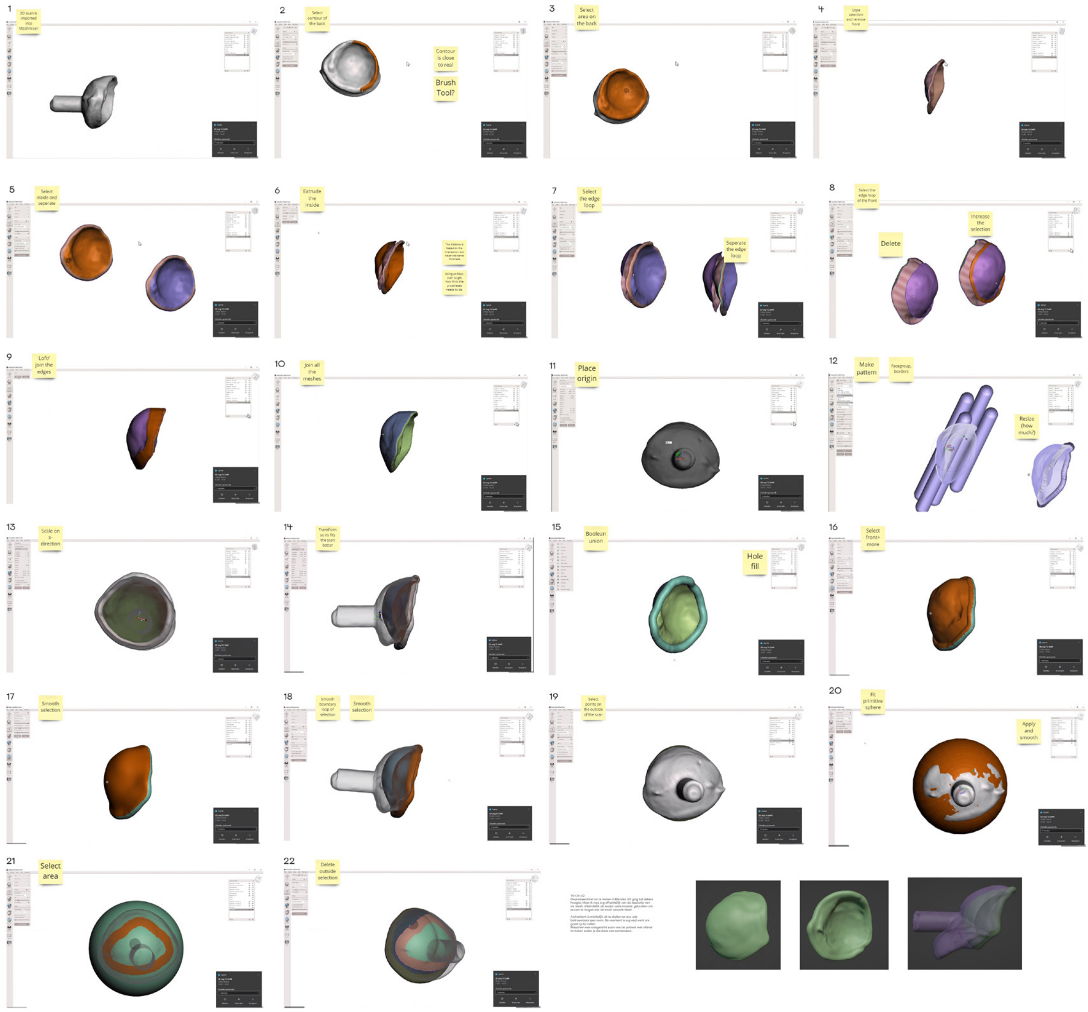
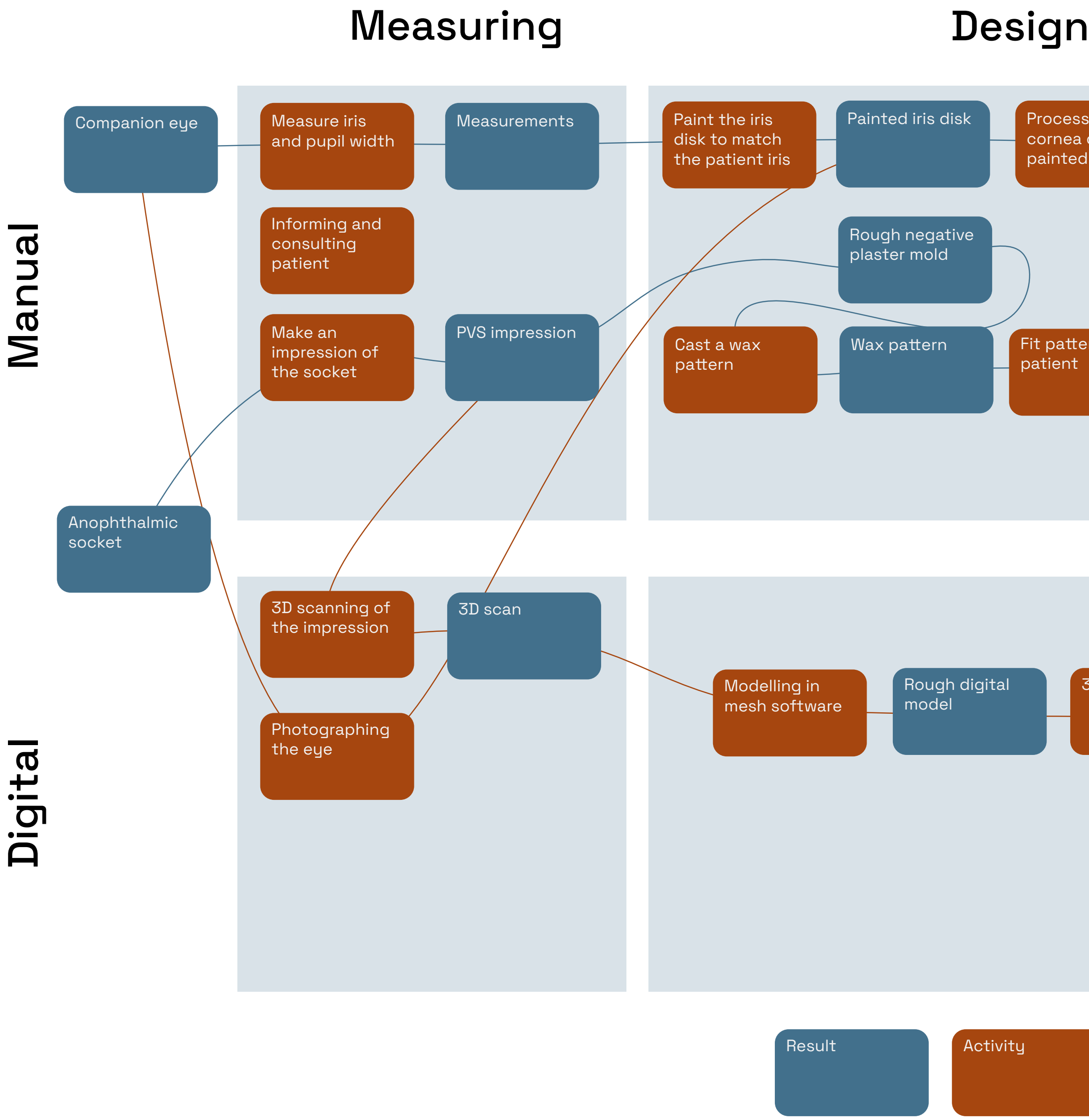


Figure 22. Digital workflow

The process the ocularist uses can be described by the following steps.

1. Load in the corresponding impression.
2. Select the backside contour.
3. Select the backside geometry within the contour.
4. Cut out the backside geometry.
5. Duplicate the backside geometry.
6. Offset the duplicated geometry. The offset is based on the desired thickness of the prosthetic.
7. Select edge loops and delete with offset on surface.
8. Loft front and backside geometry.
9. Join all the meshes.
10. Set origin point.
11. Thicken contour.
12. Scale on x-direction.
13. Transform so it fits the impression.
14. Smooth mesh.


Measuring
Design
Manual
Digital
Companion eye
Measure iris and pupil width
Measurements
Paint the iris disk to match the patient iris
Painted iris disk
Informing and consulting patient
Rough negative plaster mold
Make an impression of the socket
PVS impression
Cast a wax pattern
Wax pattern
Anophthalmic socket
3D scanning of the impression
3D scan
Modelling in mesh software
Rough digital model
Photographing the eye
Result
Activity

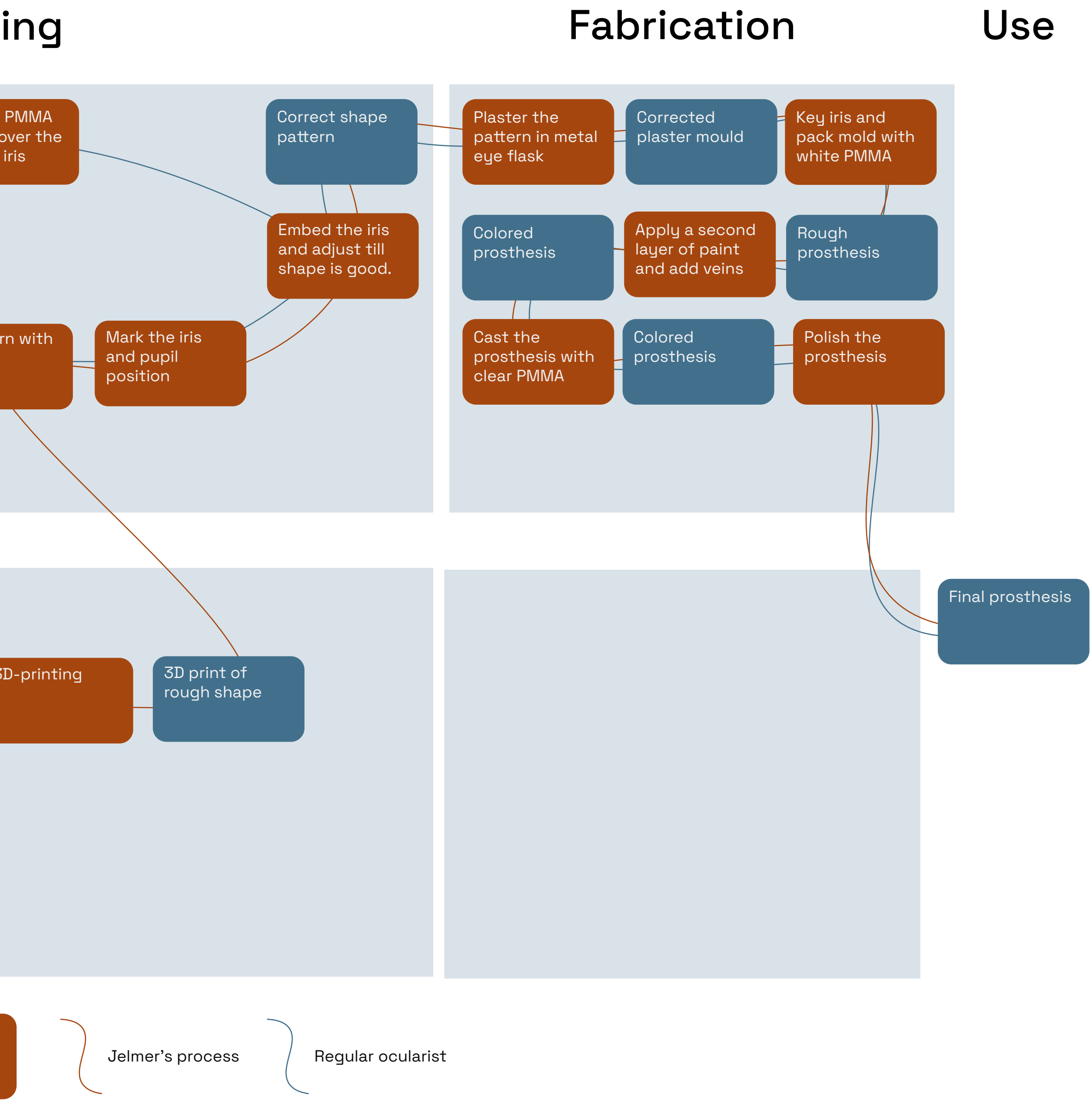


Figure 23. Workflow comparison

3.3 Articles

Ocular prosthetics have been around for centuries and will continue to do so in the future. This means that sometimes they will pop up in the media. This chapter explores the question: How do ocular prosthetics appear in the media?

First commercial 3D-printed eye

In 2010, a British company called 'Fripp design and research' collaborated with the Manchester Metropolitan University to design a method of fabricating prosthetic eyes using 3D-printing. The main goals of the project was to reduce the costs and fabrication times. They digitally created a design and overlayed it onto a 3D form using CAD software. To get a detailed looking iris they photographed the eye. The idea of the company was to start a business that could sell 3D-printed eyes. They created three different sizes: small, medium and large that people could customize and buy.

The main problem with this methods is that the only customization is the colour of the iris. The shape of the prosthesis is predetermined by the size that is bought. This is a problem for a good fitting prosthesis, however this could be a solution for low-income countries such as India where a lot of people lose an eye due to badly performed surgery. The advantages are the low cost and ease of manufacturing. The main challenge they encountered was the bio compatibility of the materials. They used a bio-compatible starch and silicone to build the soft tissue prosthesis. They then printed it from a mixture of gypsum and silica powder in full colour using a Z-Corp 510 machine and encased the form in resin. (Figure 25)

A London man (Steve Verze) has reportedly become the first person in the world to be fitted with a 3D printed prosthetic eye on November the 25th 2021. The eye was created by the British company Fripp.

Cuttlefish

Another research team, located in Darmstadt have developed a unique process to create a virtual model from a scan of the eye socket together with a photo of the healthy eye. This is made possible by the algorithms of Cuttlefish:Eye, a software solution from the Fraunhofer Institute for Computer Graphics Research IGD. In 2.4 second a non invasive scan of the socket can be made using a specially modified optical coherence tomography scanner. The software combines this with the photo of the companion eye and send this data to the printer. After printing the prosthesis is inspected and given a final polish. This would greatly improve the manufacturing times. However the prosthetic can only get as good as the software is because there is almost no human intervention in the process of design the prosthetic.

OCT-scanning

An American research group developed a methods of capturing an anophthalmic socket. They use non-invasive imaging using custom optical coherence tomography (OCT). This way high resolution data almost 'in vivo biopsy' can be collected and reconstructed in 3D. It is a proof of concept that does not use an alginate impression mold.

Figure 24. First commercial 3D-printed eye
Figure 25. Standard sizes of prosthetics
Figure 26. Prosthetic made with Cuttlefish

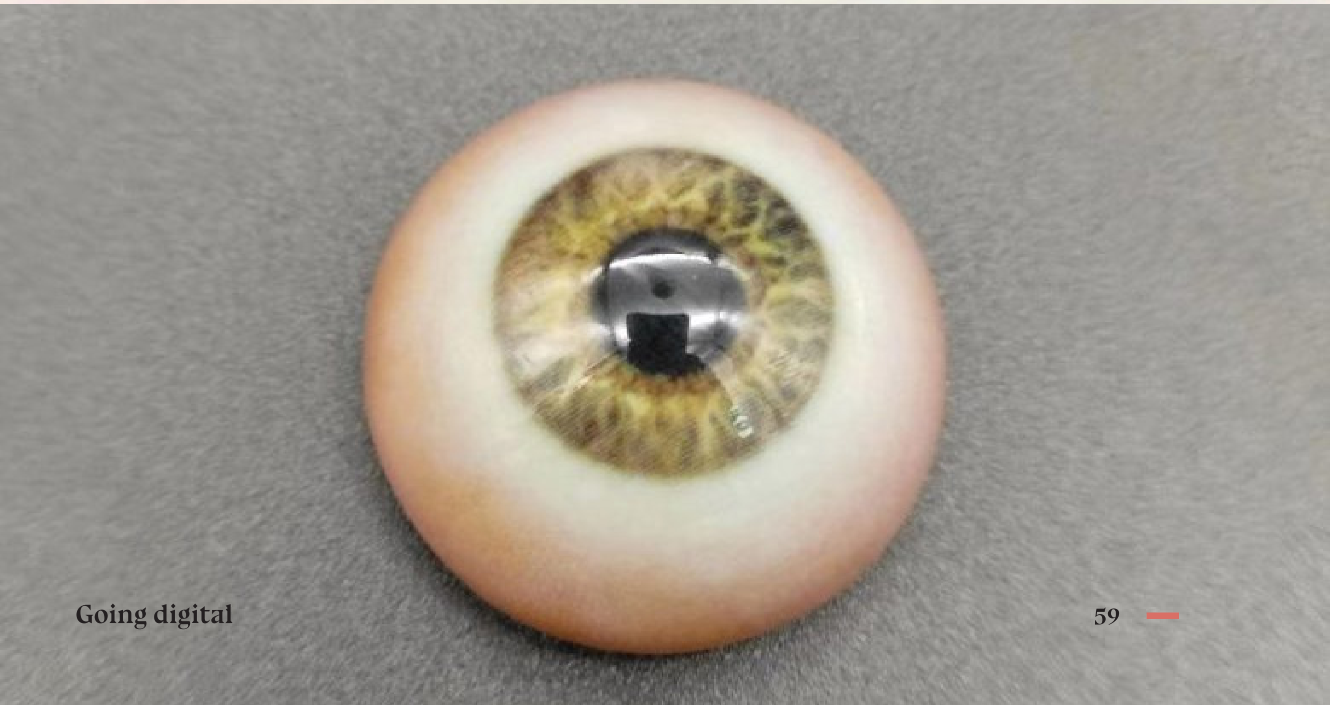


Figure 27. Voxel printing for ocular prosthetics

“We believe that AS-OCT will eventually replace alginate impression moulding required to manufacture a bespoke prosthesis. In this way a time-consuming, invasive and uncomfortable process can be replaced with a painless, non-invasive one that takes 2.4 s.”

Weta workshop

Another recent development is done by Weta Workshop, a special effects studio based in New Zealand who make props for film and the entertainment industry. They made props for films such as Lord of the Rings and Avatar. Tor Robinson, a design innovation student from Victoria University designed a workflow for 3D-printing eyes for realistic models and creatures using a polyjet printer. The Stratasys J750 is a multi material printer with the capability of printing on voxel levels. Using the 3D-modelling software Houdini she was capable of printing highly realistic eyes. The eyes made by Weta Workshop are mostly used for larger scale models. This means that they are not the same scale as a real human eye. It could be that printing on a smaller scale will result in loss of detail. Logically, these eyes are not made to fit a real human socket, but it is interesting to know what is capable using the right technologies and that achieving a high level of realism is possible using 3D-printing over other traditional methods.

Disney research

There are two papers done by Disney Research which are relevant to this project. One being a successor to the other. The first is called High-Quality Capture of eyes.(Disney, 2015) The goal the researchers had was to develop a way to capture the visual appearance of eyes for use in the entertainment industry. So far its shape has been mostly approximated inside Disney with gross simplifications. Each eye is different and personal intrinsics exist in every person. They developed a novel way to capture the white sclera, the transparent cornea and the colored iris. Combining al these captures into a complete model with shape and texture on a high level of detail. Creating photo-realistic digital humans is a long-standing challenge in computer graphics and capturing eyes always seemed to be a problem due to their high reflectivity and complexity. In the past eyes where assumed to be composed of two spheres. Their main motivation described in the paper is to increase the realism and to more closely match the eyes of the here character in their films.

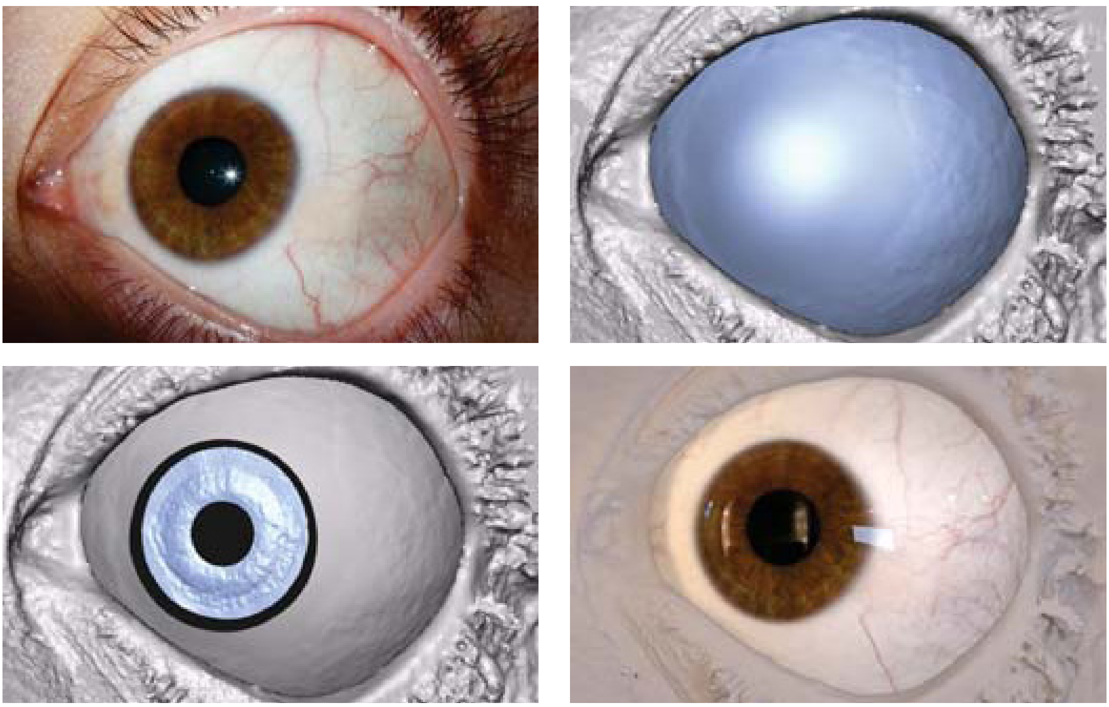
The researchers used a complex set-up to capture the eyes of actors in multiple positions. Although they claim it requires not a lot of effort. The actor has to lie down for 20 minutes and keep their eye open for most of the time while multiple cameras take photos from different angles with different lighting conditions.

They developed a piece of software which loads all the images and creates a 3D-model based on the visual aspects it captures.

Disney's research is mainly focused on animation and graphics. Meaning that their goal is to create lifelike, but unrealistic eyes. The difference with this project is that the prosthetic eyes need to be manufactured after they have been designed in the computer. This gives rise to a couple of questions. For example, Is this high level of detail needed in ocular prostheses. Because with Disney's software the model can get very detailed, but if the resolution of the 3D-printer can't handle this level of detail work is lost. The specific shape of the eyeball might be important for creating realistic characters but capturing the shape of the companion eye of a patients does not necessarily provide a good fitting prosthesis. This is due to the differences in sockets.

The second paper from Disney aims to develop a lightweight model that uses parameters in order to recreate eyes. Similar to the goal of this thesis. It uses a database of pre-captured eyes (from the previous research) to guide the creation of new eyes. Requiring as an input a single face 3D-scan or even a single photograph. Disney claimed to provide the full

Figure 28. Disney digitalization of eyes



database of eyes on their website but the link did not work. Contact was sought with the researchers to still look into the data but to no avail.

The paper gets very technical very quick and utilities a machine learning algorithm in order to achieve a shape that fits and resembles the input eye. It also automatically textures the iris and sclera. Their approach of using model fitting, and texture generating algorithms is out of scope for this project but serves as a inspiration for what could be achieved in the domain of ocular prosthesis.

Other fields

Dentistry is one of the field which is already widely affected by digital innovation. “Digital dentistry has caused disruption on many fronts, bringing new techniques, systems, and interactions that have improved dentistry. Innovation has spurred opportunities for material scientists’ future research.”(Rekow, 2019)

This lead to more restoration options leading to longer lifetimes and better aesthetics. Specialized CAD/CAM solution make same day restoration possible. There also exist special imaging scanner, specifically developed for capturing teeth.

Conclusion

But what does this mean for this project? All these previous examples show that there are a lot of people working on the digital representation of eyes and that people across disciplines are trying to get as close as possible to reality.

Especially the second paper from Disney shows that it is possible to develop a parametric model that can match the color and shape of eyes to reality.

Key takeaways

- There has only been one case where an 3D-printed eye was made for use by a real patient.
- More industries are interested in the 3D-modelling of artificial eyes.
- Technologies exist for capturing the geometry and looks of eyes.
- Customization so far is mostly used for the eye colour, not for the shape.
- Unrealistic eyes are also possible and sometimes even preferred as a result.
- It is possible to make a parametric model that can generate different eyes.

Figure 29. Parametric eye model

3.4 Digital manufacturing of ocular prosthetics

"Science and technology have revolutionized the fate of mankind in numerous ways, collaborating the knowledge in science and engineering with medicine has opened new doors for innovative health care." (Vasamsetty, 2020)

3.4.1 Introduction

Besides the design of the prosthetic itself, the production pipeline must also be designed to allow ocularist companies to provide the prosthetic to customers.
In this chapter the manufacturing process is considered. A literature study is done to assess the state of the art of digitalization in the fabrication of ocular prosthetics. A workflow is proposed to allow ocularist to produce 3D printed ocular prosthetics, even if they do not have a lot of experience with applying digital tools.

3.4.2 Digitalization

The use of Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) in prosthetic applications has been rapidly developing since the mid-1980s (Smith, 2001). These technologies show great benefit and are already in use across a spectrum of devices in the medical field such as ankle-foot orthoses and prostheses. Technologies which are commonly used are: additive manufacturing and 3D-scanning. 3D-printing allows models to be directly manufactured through the layer-by-layer addition of material. There are different categories of AM technology, each operating with different materials, deposition and curing methods and each one requiring different design considerations. The use of this technology has become common in several medical specialties such as dental aligners, hearing aids and other patient specific devices. It my provide the same benefits for orbital and ocular devices. Three dimensional scanning and printing can provide high accuracy, reduce product waste and improve quality. It also delivers shorter waiting times, design consistency, repeatability, quantifiable modification, and modern manufacturing. (Binedell, 2020) Research suggests the use of AM for prostheses is an emerging field. "The authors summarized that ocular prostheses were the most challenging to design and 3D print due to the complex anatomical features of the socket." (Farook, 2020)

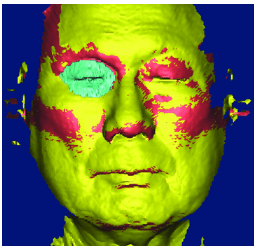
3.4.3 Literature study

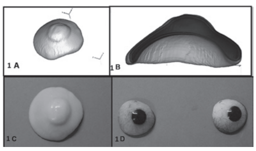
The next pages present an overview of the state-of-the-art research on the 3D-printing of ocular prosthetics. This study aims to address the issue by specifically focusing on the review of additively manufactured orbital and ocular prostheses. To provide a synthesized understanding of the current state, and highlight gaps in knowledge to use in the design.

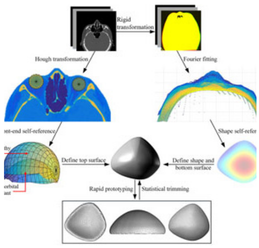
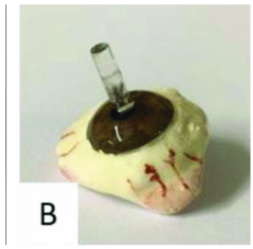
The researches are evaluated on their input data, the processing, the printing and the final end product. Each one showing different advantages and disadvantages.

3.4.4 Print applications

Collection of visuals showing the final results from the references of the table of the next page.
From left to right, top to bottom.

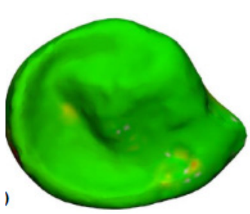










Year	Reference		Input Data	CAD Software
2004	1.	Conference	CT	Mimics, Freeform
2010	2.	Journal	3D scan	Rapidform XOS
	3.	Journal	3D scan, photo	Mimics, Magics
2013	4.	Journal	3D scan	–
2014	5.	Journal	MRI, 3D scan	Freeform
2016	6.	Conference	CT	Mimics, Geomagics
	7.	Journal	CT	Mimics
2017	8.	Journal	CT	Mimics, 3-Matic
2018	9.	Journal	CT	Rhinoceros 4.0, Reverse Engineering
2019	10.	Conference	3D scan	–
	11.	Journal	MRI	Rhinoceros
	12.	Journal	3D scan	Z Brush 4R7
	13.	Journal	3D scan, photo	ZBrush 4R7, Photoshop CS4
	14.	Poster	Original CAD model	Houdini
	15.	Journal	3D scan	–
2020	16.	Journal	3D scan, photo	3DS Max
	17.	Journal	CT	3D Slicer, Autodesk Meshmixer
	18.	Journal	3D scan, photo	Geomagic Studio12
	19.	Journal	Ultrasound	Tinkercad
2021	20.	Journal	CT	–
	21.	Journal	3D scan, photo	ZBrush 4R7, Photoshop CS4
	22.	Journal	3D scan	Autodesk Meshmixer
	23.	Journal	CT	Mimics, 3-Matic

3D Printer	Type	Material	Print Application
3D Systems ThermoJet	MJ	Wax	Orbital: prototype & mold
Stratasys Dimension	FDM	ABS P400	Facial prosthesis: prototype & mold
Z Corp Z510	BJ	Hybrid plaster ZP150	Orbital: mold
–	SLA	–	Orbital: mold
–	SLS	Polyamide	Facial prosthesis: end-use part
MakerBot Replicator 2X	FDM	ABS	Facial prosthesis (orbit & nose): mold
Stratasys Objet Connex350	MJ	Bio compatible MED 610	Ocular: prototype & mold
–	MJ	Bio compatible PMMA	Ocular: end-use part
–	FDM	PLA	Ocular: end-use part
Formlabs Form 2, Ultimaker 3, Markforged Mark Two, CI SAAM	SLA, FDM	v4 MMA resin, PLA, Nylon, ABS	Ocular: end-use part
Formlabs Form 2	FDM	PLA	Orbital: prototype & mold
Carima IM-96	DLP	FotoTec DLP.A resin	Orbital: mold
Carima DS131	DLP	FotoTec DLP.A resin	Ocular: mold
Stratasys J750	MJ	Vero (6x materials)	Ocular: end-use part (film)
Makerbot Replicator 2	FDM	PLA	Ocular: end-use parts
Stratasys J750	MJ	Vero (6x materials)	Ocular: end-use part
–	FDM	PLA	Ocular: patient model & mold
Ultimaker	FDM	ABS	Orbital: mold
Rokit Healthcare INVIVO	FDM	PCL/HA, PCL filament	Facial prosthesis: end-use part
–	–	–	Orbital: patient model & mold
Carima DS131	DLP	FotoTec DLP.A resin	Ocular: end-use part
Formlabs Form 2	SLA	RS-F2-GPGR-04 resin	Orbital: patient model & mold
Stratasys Objet Connex 350	MJ	Biocompatible MED 610	Ocular: prototype & mold

3.4.5 Results

As we can see in the table, there is already a substantial amount of work being done on implementing digital fabrication in the creation of ocular prostheses. However all the described research contains single use cases and does not go further than a proof-of-concept model most of the time. Work must be done on how to implement these technologies on a larger scale. The different references have also different print applications. The first ocular prosthetic being printed in 2016.

Further areas where research is required in order to move towards implementation of AM is related to the education and training of ocularists. The digital workflow which involves 3D scanning combined with CAD and setting up 3D printing is typically not the domain of the ocularist. Their expertise tends to be analogue and requires years of practical training. This was observed as the most common limitation across the articles. It will require short term collaboration with designers and engineers to develop hybrid workflows that mix the best of the digital and the analogue approaches.

Now that there is an overview of the current state of this technology we can find opportunities and limitations on the implementation.

Opportunities

- Manual steps in prosthetics fabrication can be replaced by digital methods, potentially saving time.
- Less discomfort to patients through use of medical imaging or 3D-scanning techniques.
- Weight reduction compared to traditional methods.
- Improved accuracy and fitting of prosthesis.
- Good realism of the eye.
- Ability to easily re-print the same components in the future.

Limitations

- End-use parts are not biocompatible and require coating with PMMA or used as a mould to cast.
- Experience in CAD technology is required, which is not part of a traditional skillset.
- Additive manufacturing (AM) times are slow.
- Rough parts require post-processing (polishing).
- There are challenges associated with using 3D scanners e.g. patient movement or scanning anatomy with hair.
- Expert manual skills are still required for some steps of the workflow
- CT scanning for the purpose of creating an prosthesis can increase harmful exposure to radiation.

Input data

The literature shows that **52%** of theses studies use 3D-scanning as an input in some sort of way, followed by CT-scanning. With singular case of using MRI imaging. Nowadays a wide variety of different 3D-scanners exist with different use cases. The researches used 3D-scanning on different objects, for example scanning an impression of the socket or scanning the entire face of the patient. Most 3D-scanners work with lasers or light, this makes scanning reflective objects difficult as the can reflect the light of the scanners. This is also the reason the scanning eyes is very hard to do

The biggest downside to CT-scanning is that a patients for fitting an prostheses can receive radiation damage and it is expensive. It did however provide very precise results which match the geometry of the socket very well due to no deformations taking place.

Another option for recreating the iris is digital imaging, Using easy techniques very acceptable results can be achieved. It requires minimal artistic skills and decreases treatment time. However, special digital photography equipment is needed. The ocularist is currently already working with photography in order to capture the look of the companion eye of the patient. Theses photographs can serve as a reference for painting the iris or as the iris themselves. Advantages are that the process is fast and can produce good results. The main disadvantage being that no depth can be created this way.

"Improving digital photography technique and using it as a starting point to potentially fabricate a CAD/CAM ocular prosthesis that could be constructed in one visit, a technique that would require no special skill, should be the goal for future ocular prosthesis construction." (Buzayan, 2015)

CAD software

The presented references use a variety of different techniques for creating the 3D model of the ocular prosthetic. This shows that there is not an industry standard method of using CAD. The software that is used also depends on the input methods chosen. For example when CT-scanning the files first need to be processed to turn the images into a mesh that can be edited.

According to the paper by Ye et al., in a self-referenced prototyping computation, an ocular prostheses is constructed from a combination of a top surface, shape contour, and a bottom surface. The top surface is derived from the outer region of the healthy eyeball recorded with CT scanning. The shape contour and bottom surface are computed from facial edges. This is the first case of automatically generating the geometry for an ocular prosthesis. The authors of this papers summarized that ocular prostheses were the most challenging to design and 3D print due to the complex anatomical features of the socket.

3D-printer

Fused deposit modelling (FDM) was the most dominant AM technology. It is surprising how popular this is due to FDM often being linked to poor surface quality with a typical minimum layer height of 0.1 mm. And ocular prosthetics requiring a smooth precise result. This can be explained by the commodity of this technology. FDM printers are cheap and easy to use. **63%** used 3D-printing for either moulds or parts of the prosthesis where **39%** used 3D-printing for the final model.

Also 3D-printing can produce a realistic eye and gives us the ability to re-print components. However not all 3D-printing techniques are suitable for this.

Material

The challenge in manufacturing a medical device with a 3D printer lies in selecting an appropriate material because the material must be bio compatible and the printed output is usually required to have a smooth and homogeneous surface

The material alone cannot determine whether a device is food safe or medical grade. Rather, the combination of the raw materials, design, surface finish, and handling of the part determines whether the application is biocompatible. It is recommended that in the future more research is done on the biocompatibility and the effect on appearance of the

3D-printing materials used . It also is expected that in the future the supply of biocompatible materials which are suited for the production of ocular prosthetics is sufficient.

3.4.6 Discussion

The current literature provides us with enough reason for developing a new digital workflow for the ocularist. A wide range of different techniques are used for creating realistic prosthetics. From these options a new workflow can be distilled.

The research showed that not all the steps are currently possible to digitize . That is why an hybrid workflow that mixes the best of digital and analogue approach for creating ocular prosthetics needs to be developed.

Key takeaways

- Manual steps in prosthetics fabrication can be replaced by digital methods, potentially saving time.
- Less discomfort to patients through use of medical imaging or 3D-scanning techniques.
- Improved accuracy, realism and fitting of prosthesis.
- Experience in CAD technology is required, which is not part of a traditional skillset.
- Expert manual skills are still required for some steps of the workflow
- End-use parts are not biocompatible and require coating with PMMA or used as a mould to cast.
- 3D-printing can produce a realistic eye and gives the ability to re-print components. However not all 3D-printing techniques are suitable for this.
- An ocular prostheses is constructed from a combination of a top surface, shape contour, and a bottom surface.
- Using photographs as input can speed up the process while offering good results.

Figure 31. 3D model of an ocular prosthetic

3.5 Key takeaways

These are the most important knowledge aspects from the related works.

Current digital workflow

- The ocularist already implemented 3D-scanning and printing into his daily practice.
- The most important information that comes from the scan is the contour of the impression, the backside geometry , the thickness of the impression and the overall volume.
- The eyelids deform but not stretch.

Articles

- There has only been one case where an 3D-printed eye was made for use by a real patient.
- More industries are interested in the 3D-modelling of artificial eyes.
- Technologies exist for capturing the geometry and looks of eyes.
- Customization so far is mostly used for the eye colour, not for the shape.
- Unrealistic eyes are also possible and sometimes even preferred as a result.
- “Usually the iris of the prosthetic eye should just touch the lower eyelid and be partially covered by the upper eyelid”

Digital manufacturing of ocular prosthetics

- Manual steps in prosthetics fabrication can be replaced by digital methods, potentially saving time.
- Less discomfort to patients through use of medical imaging or 3D-scanning techniques.
- Improved accuracy, realism and fitting of prosthesis.
- Experience in CAD technology is required, which is not part of a traditional skillset.
- Expert manual skills are still required for some steps of the workflow
- End-use parts are not biocompatible and require coating with PMMA or used as a mould to cast.
- 3D-printing can produce a realistic eye and gives the ability to re-print components. However not all 3D-printing techniques are suitable for this.
- An ocular prostheses is constructed from a combination of a top surface, shape contour, and a bottom surface.
- Using photographs as input can speed up the process while offering good results.
- The typical resin thickness used for the artificial sclera ranges from 2 to 10 mm. The colorless resin layer varies from 1 to 3.5 mm thickness.
- “Fabricated in acrylic resin, artificial eyes should be aesthetically pleasing, scratch-resistant, and adequately polished.” (Goiato, 2014)
- The irises of the natural and prosthetic eyes should be well aligned in the same plane. The eyelids should be similar in shape, and the eyelid openings should be the same.

4. Focus

This chapter presents the key research findings on the initial analysis of the project scope.

RQ 3. How do you translate the socket geometry to a well-fitting prostheses?

Figure 32. Office of the ocularist

4.1 Design direction

Out of the research on the transition of manual ocular prosthetic production to digital production, a design direction emerged. This direction was defined in consultation with the Ocularist in order to provide a clear target for this project.

Design Goal A:

Develop a new workflow to create ocular prosthetics using 3D-modelling.

The goal of this design project is to enable ocularists with the right digital tools to provide customers 3D-printed ocular prosthetics that are easy to manufacture, easy to use, good looking, user friendly and affordable.

This direction was based on the observation that while the 3D printing of ocular prosthetics has been done before there was no clear method for the 3D-modelling. And that only in one case a 3D-printed prosthetic was used in a real use-case. Combined with the fact that the current digital steps of the ocularist are repeatable for most of the prosthetics The discussion is made to develop a new workflow for the ocularist to create ocular prosthetics easier and faster.

In other researches the full potential of computer aided design and manufacturing was not achieved due to only partly replacing the steps in production and not tackling the entire pipeline. The new proposed workflow aims to bring the entire production phase of making ocular prosthetics to the digital realm while keeping the important hand-knowledge of the ocularist in view. Because some steps cannot be digitalized and will always need a personal approach.

Design goal B:

Design and validate a tool that leads to more efficient production and reproduction and that gives a more iterative character to the creation of ocular prostheses.

To assist the ocularist with the new workflow a tool will be designed.
As a tool the decision is made to create a parametric model that can give the ocularist the right amount of freedom during the designing phase while automating the repeated steps.

As a combination of CAD and manual methods, a parametric digital model can be fed manually measured data combined with tweakable parameters. Each measurement is an input of a variable of a parametric model. The advantages of this methods are that low tech equipment can be used to measure and that is does not require a radical change in procedure. However the more complex the geometry or the socket condition becomes, the harder the measuring. This problem can be resolved by instead of manually scanning, 3D-scans of an impression or reference model can be used.

One of the most common reasons to use a parametric design methods is to customize a design to fit a user's specific anthropometry. Another could be to assist people without CAD skills to make their own design or to automate an iterative design process.

4.2 Design criteria

From the research on the digital fabrication of ocular prosthetics a compromised list can be formed of requirements an ocular prosthetic needs to adhere to. This list of requirements will serve as a starting point for developing a new digital workflow for the ocularist.

4.1.1 Design Goal A

A new and improved workflow for creating ocular prosthetics has the following criteria:

1. The workflow should assist the ocularist with automating repeatable steps.
2. The workflow should offer an iterative character to the design phase.
3. The workflow should assist the ocularist without requiring extensive CAD-knowledge.
4. The workflow should produce feasible. viable and desirable solutions.
5. The workflow should keep the hand-based knowledge of the ocularist.

4.2.1 Design Goal B

A properly fitted and acceptable custom ocular prosthesis has the following characteristics,

1. Retains the shape of the defect socket.
2. Prevents collapse or loss of shape of the lids
3. Provides proper muscular action of the lids
4. Prevents accumulation of fluid in the cavity.
5. Maintains a palpebral opening similar to the natural eye.
6. Mimics the coloration and proportions of the natural eye.
7. Has a gaze similar to the natural eye
8. Offers a close adaptation to the tissue bed to use the full potential of the implant to produce movement
9. Minimize the possibility of infection by avoiding voids in the socket.
10. Accumulated geometric error and precision characteristics dimensions must remain under 0.5mm (S. Beiruti 2019)

5. Workflow

The parametric model is the first outcome of this design project and is the direct result of the first project goal defined in chapter 4

DG A: Develop a new workflow to create ocular prosthetics using 3D-modelling.

Figure 33. The ocularist at work

5.1 Proposed workflow

For this thesis a new workflow for designing and creating ocular prosthetics has been developed and tested.

An overview of this is shown in figure 34. The visual shows the proposed production activities for an ocularist not currently applying any digital production.

The transition involves the addition of a 3D-scanner, software that generates prosthetic geometry based on a 3D-scan, a digital twin, and a Polyjet 3D-printer to its production toolkit. Instead of the manual production of ocular prosthetics the production will now be done by a multicolour 3D-printer. This provides a lot of opportunities but also challenges to the production.

In short, the workflow starts the same as before with an consult after surgery. Here the ocularist evaluates the specific situation of the patient and chooses how to measure the socket. He can choose between taking an impression for complex sockets or using a reference for simpler sockets. If opted for using an impression, it can be 3D-scanned and loaded as input for the parametric model. In case of the reference model, the corresponding digital twin can be selected.

Using these inputs combined with other measurements and photographs, the ocularist uses the parameters of the model to design an ocular prosthetic. When he is done, the prosthetic can be exported for 3D-printing and then can be fitted. If the prosthetic is not satisfactory enough the previous steps can be repeated.

The proposed workflow is divided in the same sections as is done for the literature research in chapter 3.4.

Input

As an input the ocularist can choose between two different methods: an impression or an reference model.

Taking the impression is done in the same way as it is currently done and the final result is 3D-scanned. The most important data from this scan is the backside geometry, the thickness and the contour.

If the socket geometry is 'standard' enough the ocularist can decide to opt for using reference models to determine the shape and colour of the new prosthetic. These reference models exist physically and digitally. They have a digital counterpart, a digital twin. This way the ocularist can work faster and more efficiently.

To validate the idea of using 3D-scans and digital twins as input experiments were conducted. See chapter 6.6

CAD

Instead of introducing a specific CAD software solution which the ocularist needs to learn a new method is chosen. Namely a parametric model that can automate the steps the ocularist takes. Giving him the right amount of freedom while also assisting during the design phase.

3D-printer

For printing the ocular prosthetics the Stratasys J750 is used in this thesis. This is a material jetting printer that is capable of printing multicolour objects with different materials. This printer is possible to print very accurately with reaching layer thicknesses of 0.014mm. It is recommended that a printer with similar qualities is used because ocular prosthetics are very detailed objects, especially the colour.

Material

This thesis chose to focus on the geometry of the prosthetic so the materials that were used are kept out of the research. It is recommended that more studies on bio compatible materials is done because this is an area in which multicolour 3D-printing is lacking

Application

The goal for application is to have the final print be the final prosthetic. With only needing some extra finetuning steps such as the removing of support material and polishing.

As this thesis solemnly focuses on the geometry, the final print application is a colourless prosthetic.

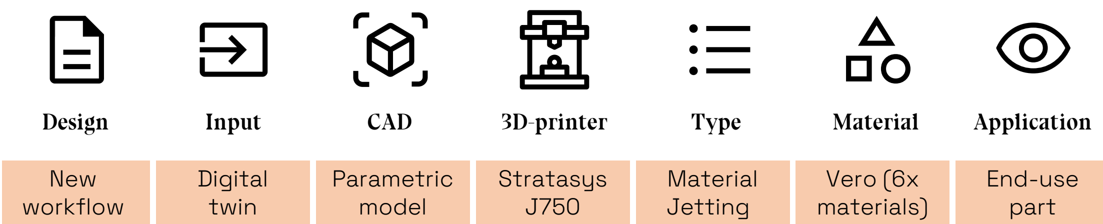


Figure 34. Proposed workflow

5.2 3D-scanning

As input for the new workflow it is proposed to use 3D-scanning. Experiments were conducted to test the application in the case of ocular prosthetics. The 3D-scanning can be divided into two different stages.

The scanning of impressions

This is the stage that the ocularist currently already uses. It is advised to integrate this into the new workflow because taking impressions is still the industry standard when it comes to making ocular prosthetics. Also these impressions lean themselves very well for 3D-scanning due to their material. Their matte appearance is easy to capture with a variety of different scanners.

The scanning of references

To capture the shape complexity of and for creating the digital twins, reverse engineering methods were used. [Píška 2009] describes reverse engineering as follows:

"Reverse engineering is characterized by the opposite sequence of activities to the classical production process. In the classic process, the designer creates a CAD design of a virtual part model on the basis of the underlying materials, which becomes the template for the production of the physical part. In reverse engineering, there is a physical object at the beginning, which is digitized into model data with which the designer can continue to work with data processing systems as needed."

Artec 3D which belongs to the group of contactless scanners and operates of optical digitalization was used for scanning. The scanner is designed for 3D measurement and part inspection. The Artec Space Spider is specially designed for recording and capturing small objects and intricate details of large industrial objects. Originally designed to be used in the international space station, to scan the prosthesis, the Artec Space Spider industrial 3D scanner was used

3D point accuracy	0.05 mm
3D resolution	0.1 mm
Object size	>5 mm
Texture resolution	1.3 Mpx
Scanning speed	7.5 fps

For successful scanning, the acrylic prosthesis had to be prepared. "By providing a suitable fixture to secure the prosthesis during scanning, this operation can be greatly streamlined." [Vocílka 2017]. Due to its glossy surface, it was necessary to apply a chalk coating to the surface. The coating surface must be thick enough to counteract the reflectiveness but small as possible or distortion of the object may occur.

Scanning was performed on a rotary table on which the prosthetic was placed. To keep the prosthetic upright it was wedged in Playdoh clay.

Digitization was performed with a set of scans in the scanner software. The scanner automatically creates a point cloud in the Artec 3D software and translates this point cloud to a 3D-model. After a full rotation the prosthesis was

Figure 35. 3D-scanning reference models

inverted and the scan was repeated for the other side of the object. Finally the point cloud is reviewed to remove interference from the surroundings and to close potential holes.

Figure 37. Artec Space Spider

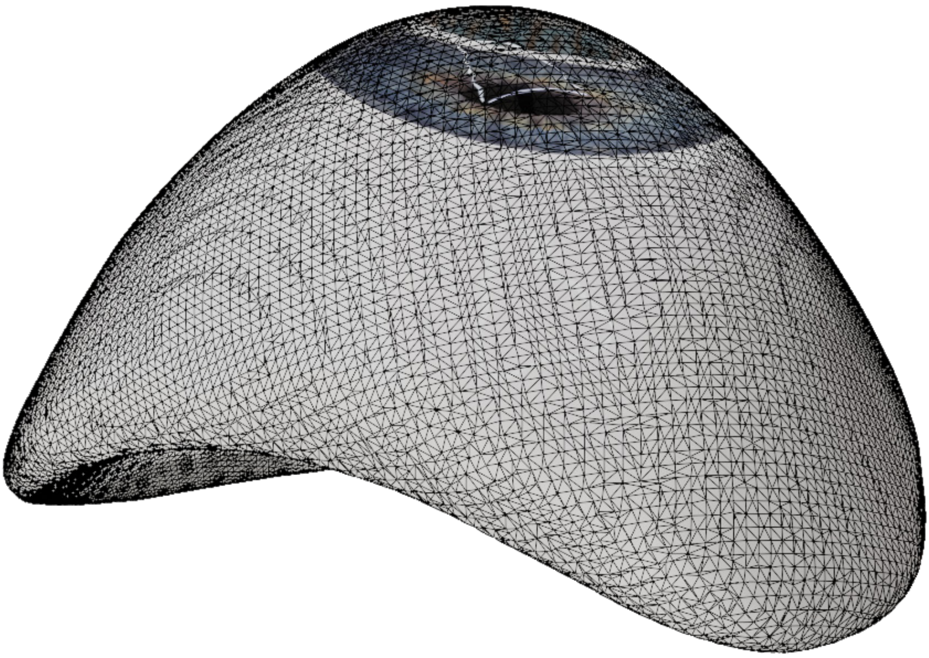


Figure 36. Textured 3D-scan

5.3 Digital twin

A digital twin is a virtual representation of a real-world physical system or product (a physical twin) that serves as the indistinguishable digital counterpart of it for practical purposes. A digital twin can, but not must necessarily, be used in real time and regularly synchronized with the corresponding physical system with the use of sensors and smart technology.

There are multiple subtypes of digital twins. In the case of this design it will involve a digital twin instance (DTI). The DTI is the digital twin of each individual instance of the product once its manufactured.

An example of digital twins is the use of 3D modelling to create digital companions for the physical objects. It can be used to view the status of the actual physical object, which provided as way to project physical objects into the digital world.

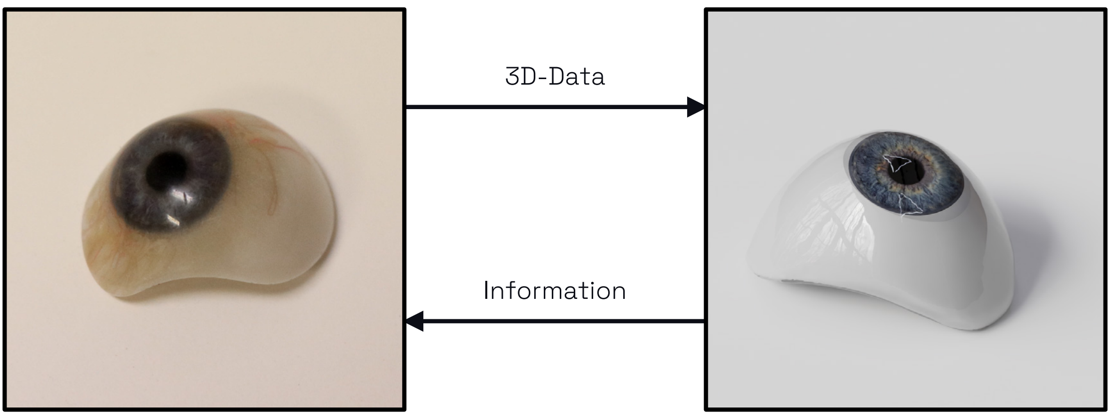
The physical manufacturing objects are virtualized and represented as digital twin models seamlessly and can be closely integrated in both the physical and cyber spaces. They can act in a both mutually beneficial manner. In the case of ocular prosthetics this means having 3D-representations of a collection of physical prosthetics. A digital library matching its physical counterpart

When the ocularist chooses for using references to determine the prosthetic shape he can use the digital twin of the corresponding reference.

f.e. the ocularist chooses prosthetic number 8. In the computer he can then load the digital prosthetic number 8 in the parametric model.

Which models have a digital twin is decided by the ocularist himself. This collection can also change from one ocularist to another. Offering each ocularist their one personal collection will increase the support for adapting the new workflow.

To test the viability of the digital twin a comparison study is done to check the differences between the original reference prosthetics and the final 3D-print.

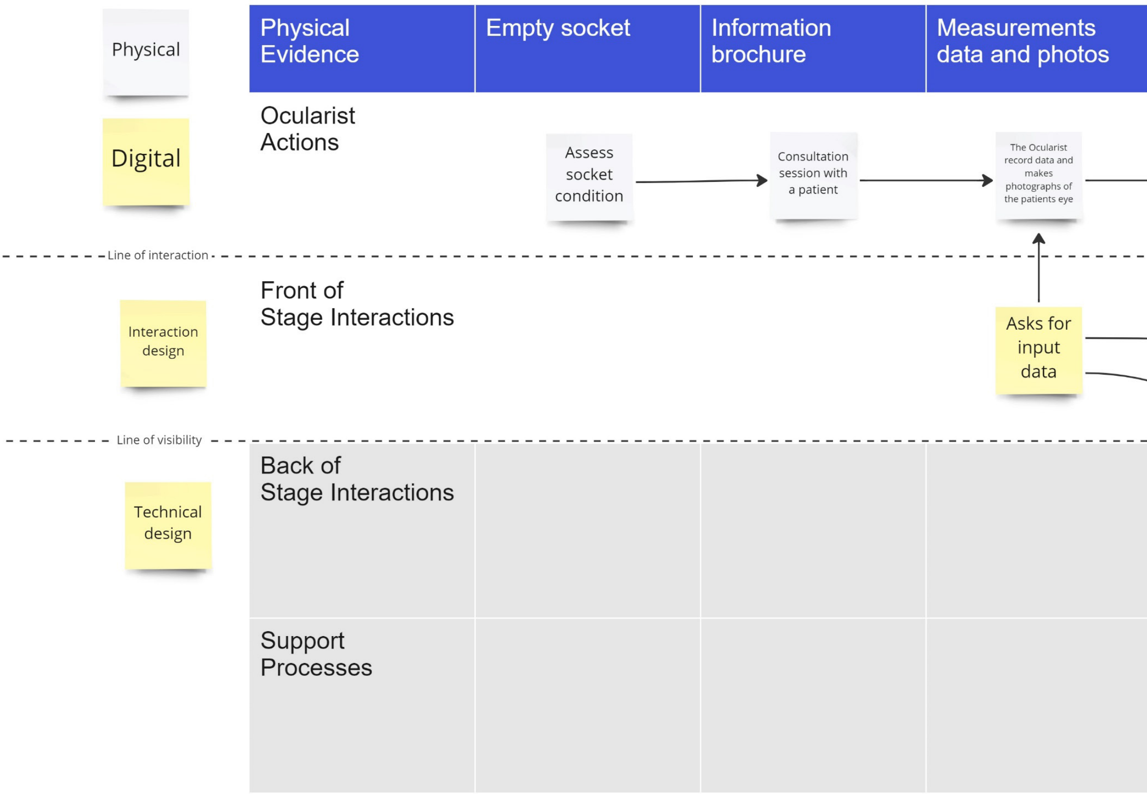


Physical collection

Digital collection

5.4 Service design blueprint

Figure 38 shows the designed process in which the ocularist interacts with the new workflow.



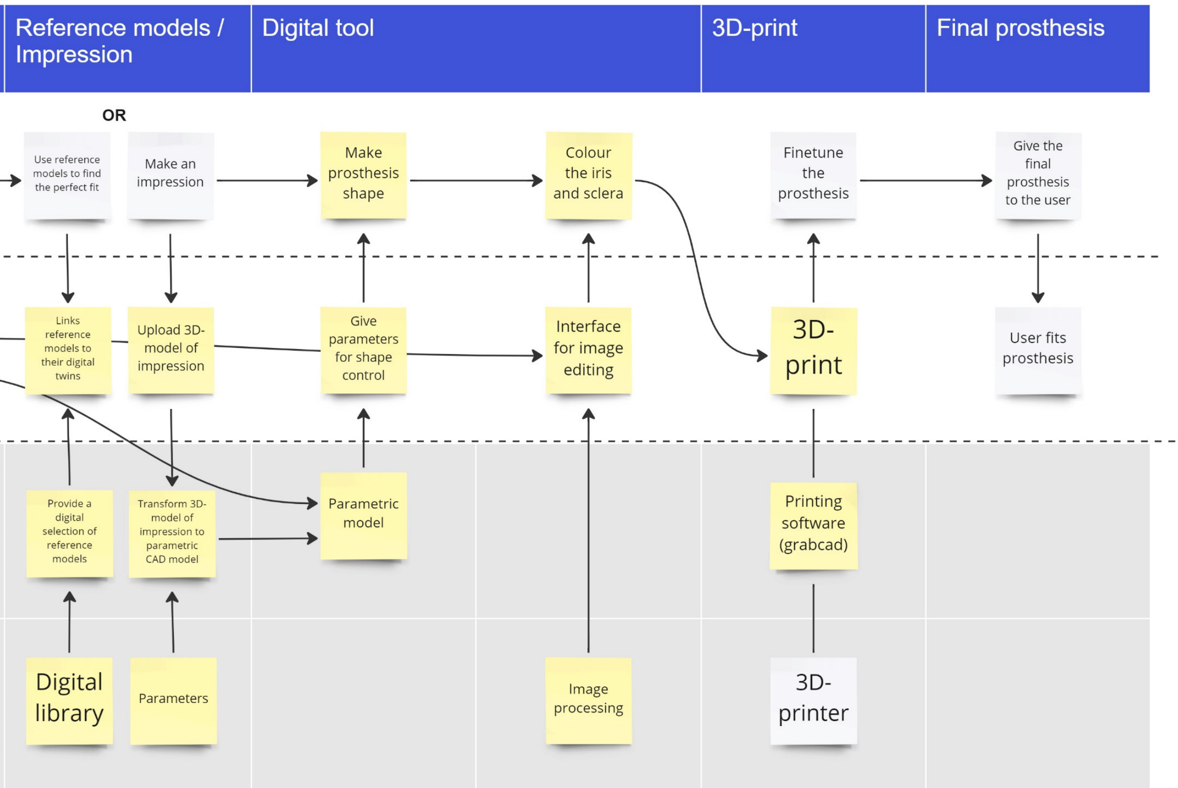
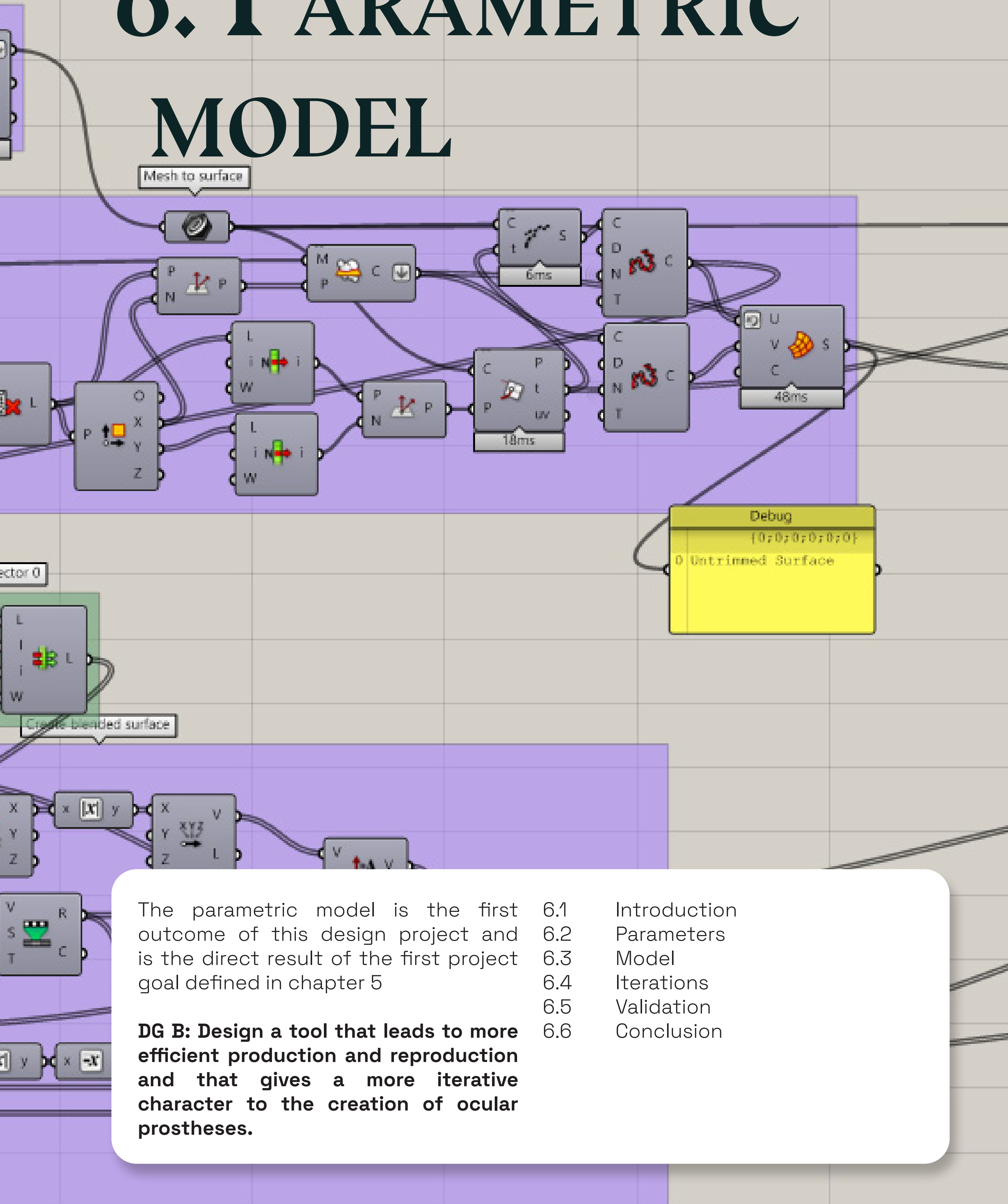


Figure 38. Service design

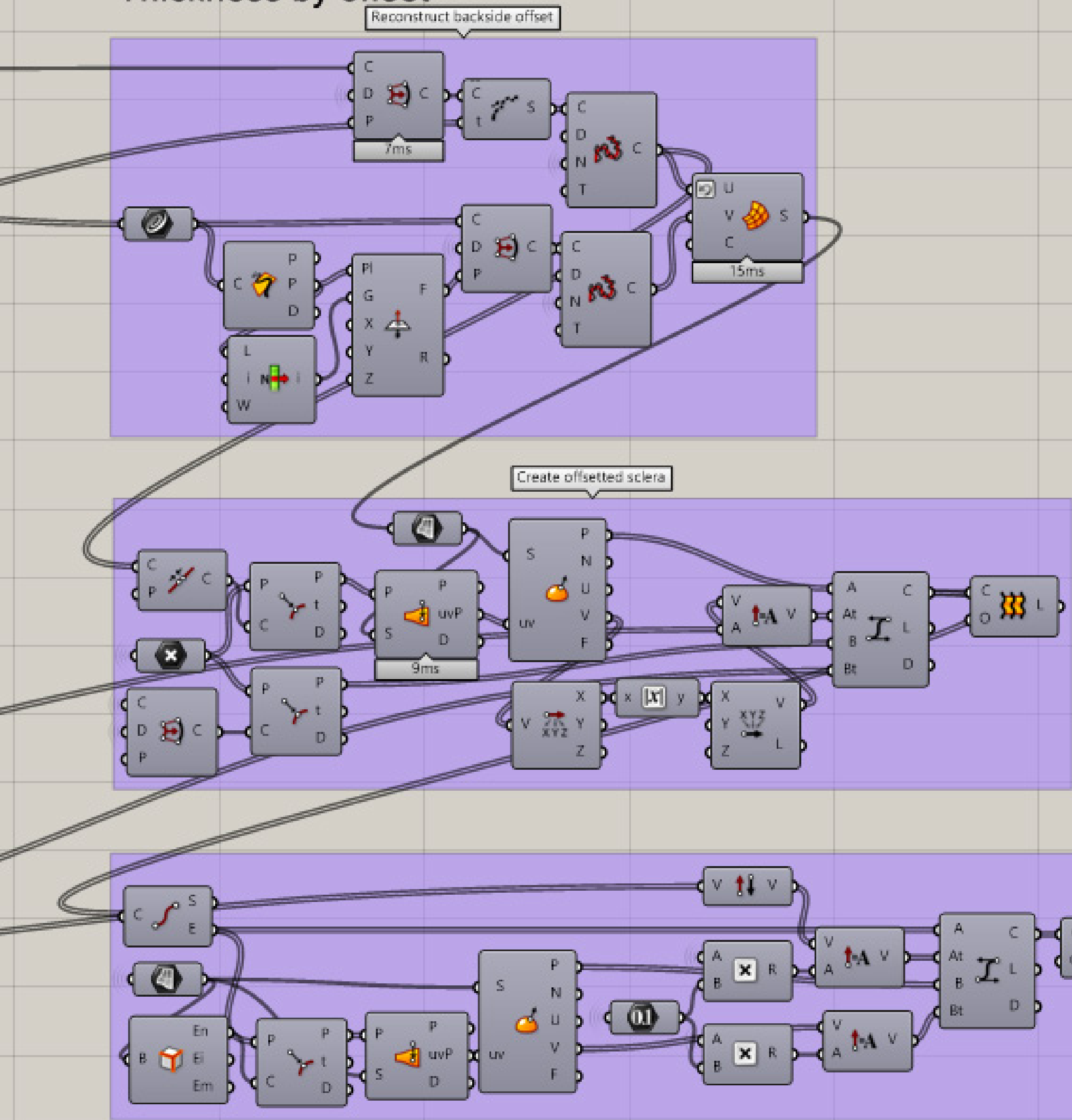
6. Parametric model



The parametric model is the first outcome of this design project and is the direct result of the first project goal defined in chapter 5

DG B: Design a tool that leads to more efficient production and reproduction and that gives a more iterative character to the creation of ocular prostheses.

Thickness by offset



6.1 Introduction

A tool is designed in the form of a parametric model which is able to generate a prosthetic based on a 3D-scan, measurements and tweak-able parameters.

What is a parametric model?

As a combination of CAD and manual methods, a parametric digital model can be fed manually measured data. Each measurement is the input of a dimension variable of a parametric model. Advantages of this method is very low-tech equipment can be used for measuring. Downside is that a sufficient parametric model and interface must be developed first. Moreover, the more complex the geometry, the more laborious the measuring becomes. But instead of manual measuring we can utilise data from the 3D-scan of the impression as input for the parametric model.

Parametric design is a design method where features are shaped according to algorithmic processes, in contrast to being designed directly. In this method parameters and rules determine the relationship between design intent and design response. The term parametric refers to the input parameters fed into the algorithms.

Parametric modeling can be divided into two main types:

- Propagation-based systems, in which algorithms result in final shapes that are unknown. They are based in initial parametric inputs using a data flow model.
- Constraint systems, in where final constraints are set and algorithms are used to satisfy these constraints.

For this project a propagation based system will be used. Requiring the 3D-scan data of a impression as input for the algorithm.

Systems that allow the user to directly construct and manipulate the dependency graph are the most powerful. Such graph-based systems include Bentley's Generative Components and Rhino Grasshopper. Both of these systems support implicit multi-operation iteration using nested list data structures. Meaning that data flows from node to node.

In order to prototype the behavior of the parametric model, Rhino Grasshopper is used.

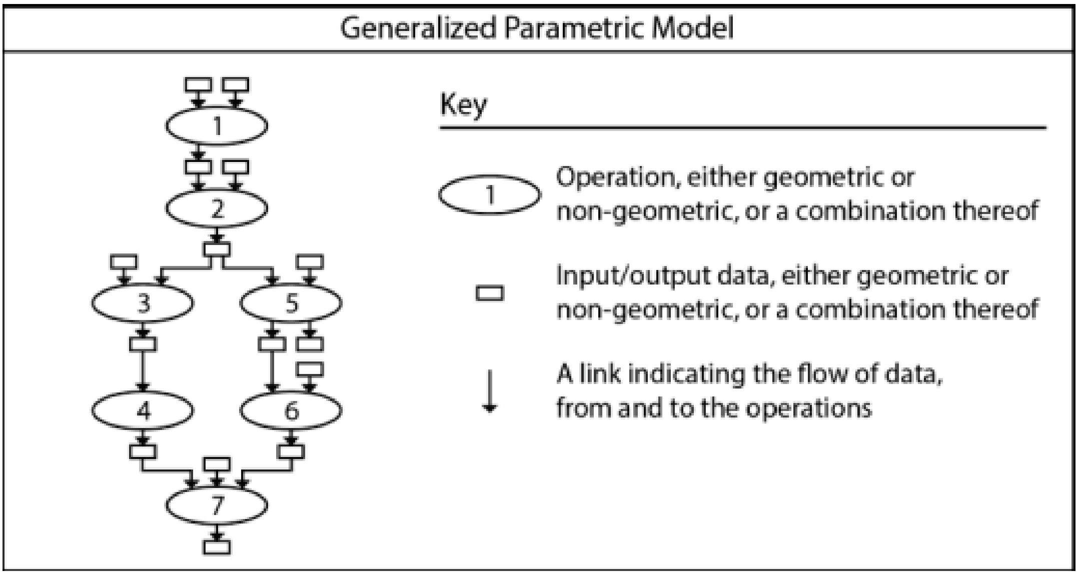


Figure 39. An example of an GPM graph

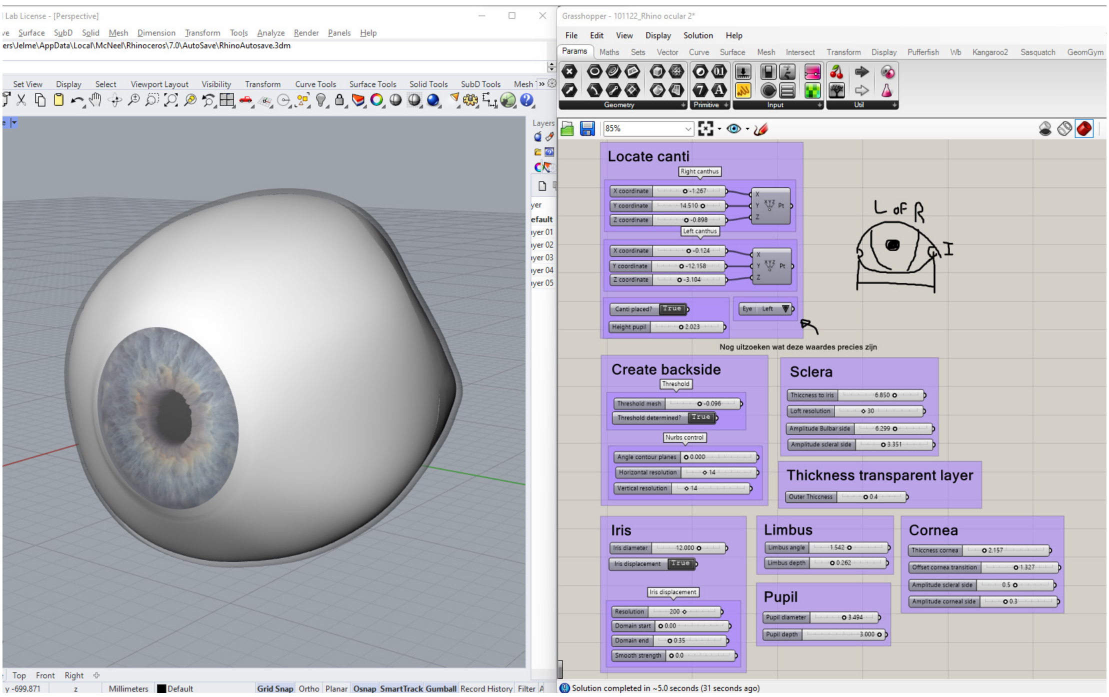


Figure 40. The parametric model

6.2 Parameters

Left or Right

Iris diameter

Iris bump map

Iris displacement

Iris colour

Pupil diameter

Cornea thickness

Pupil depth

Cornea transition curvature

Pupil height

Left canthus coordinates

Right canthus coordinates

Thickness to iris disk

Thickness transparant layer

Sclera resolution

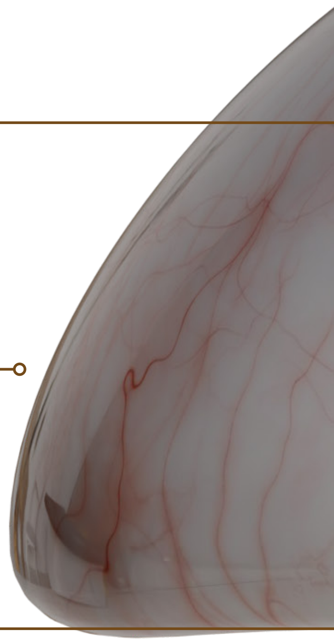
Sclera curvature corneal side

Sclera curvature bulbar side

Backside geometry threshold

Backside horizontal resolution

Backside vertical resolution



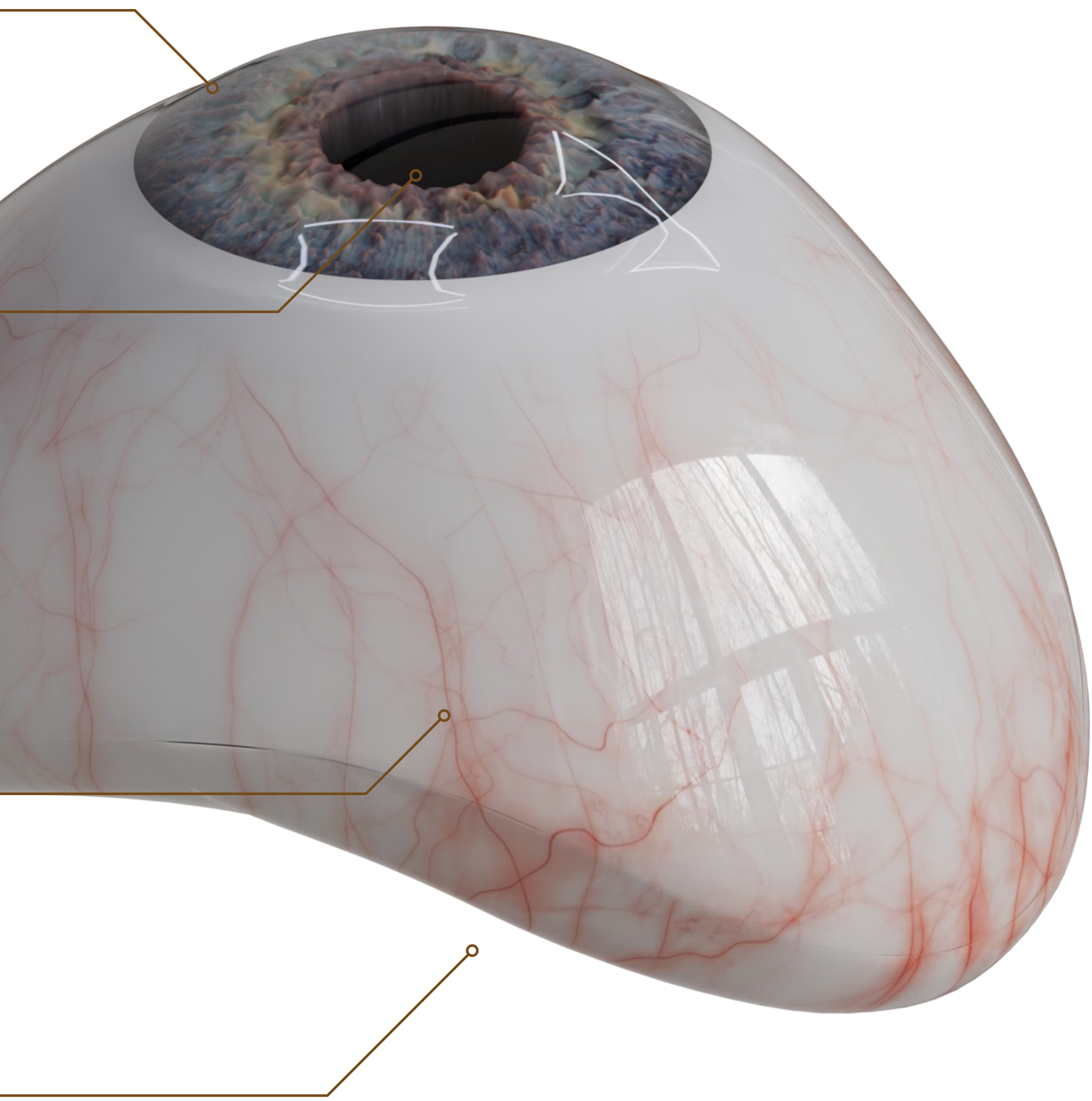


Figure 41. Render of an ocular prosthetic

6.3 Model

With the parameters that are found a model can be build that can generate an prosthetic from these parameters.

The model is designed in such as way that it guides the ocularist through the different steps because some parameters need to be determined before others in order for the model to work. This is because too many variables are interdependent of each other.

6.3.1 Parameters

Locate canti
- XYZ location of the right canthus (eye corner)
- XYZ location of the left canti
- Canti placed? (True/False)
- Pupil height
- Eye (Left/Right)

Create backside
- Threshold mesh backside
- Threshold determined (True/False)
  Mesh to NURB control
- Angle contour planes
- Horizontal resolution
- Vertical resolution

Sclera
- Thickness to iris plane
- Loft resolution
- Amplitude bulbar side
- Amplitude scleral side

Iris
- Iris diameter
- Iris displacement (True/False)
  Iris displacement
- Resolution
- Height start
- Height end
- Smooth strength

Limbus
- Limbus angle
- Limbus size

Pupil
- Pupil diameter
- Pupil depth

Cornea
- Thickness Iris plane to cornea
- Offset cornea transition
- Amplitude scleral side
- Amplitude bulbar side

Outer layer
- Thickness transparent layer

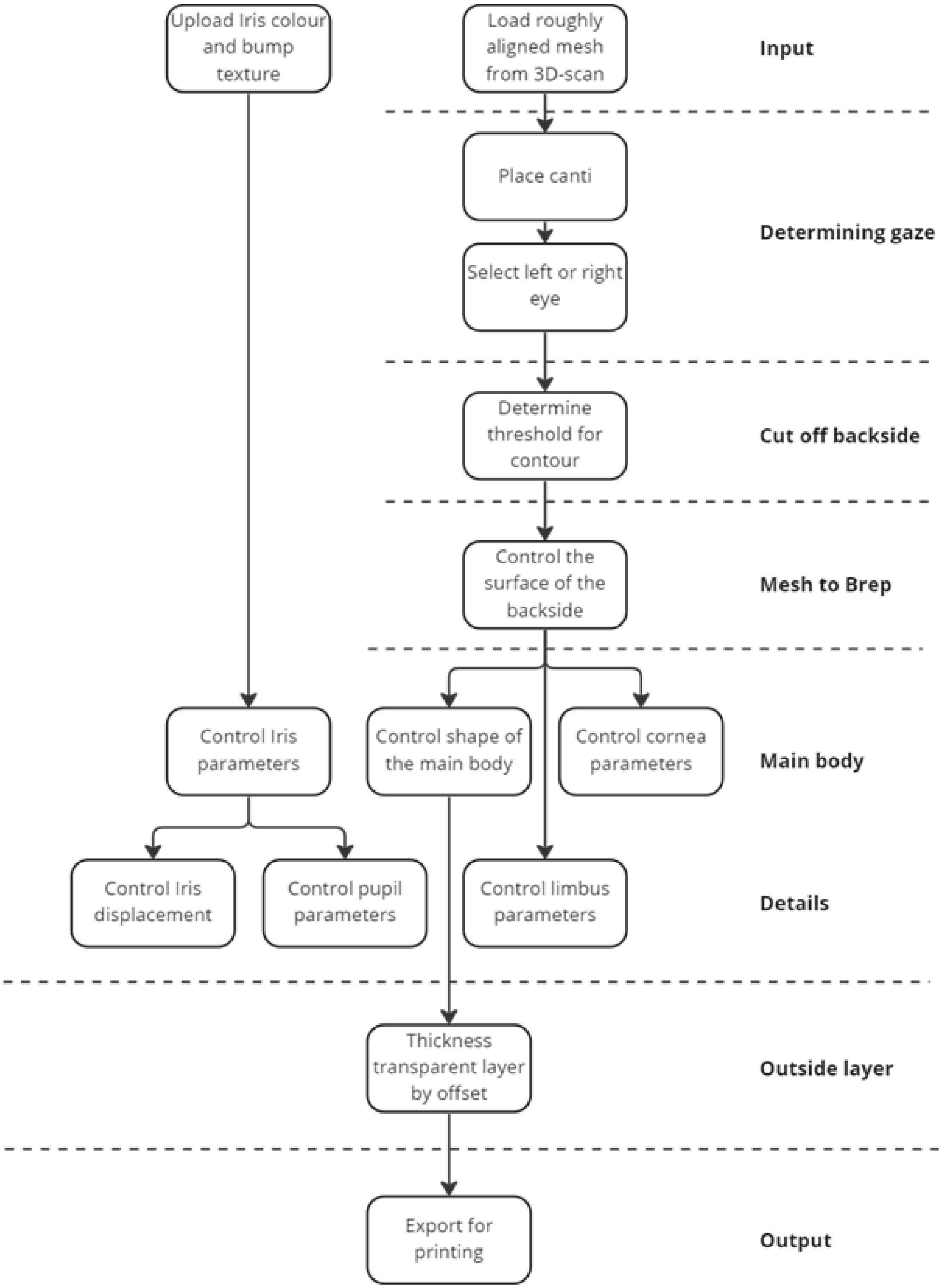
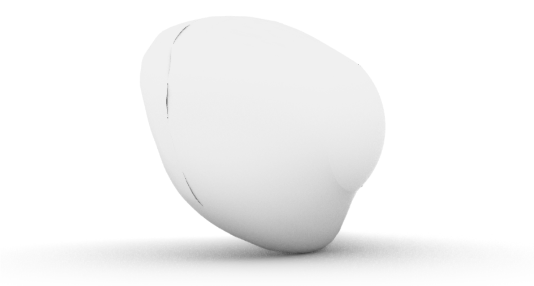
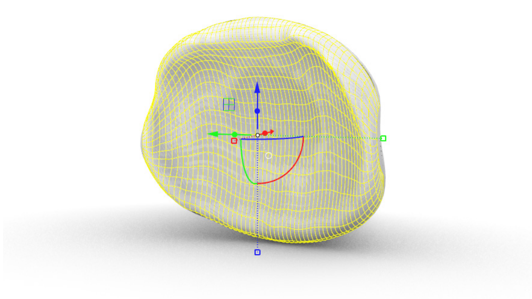


Figure 42. Flowchart of parametric model

6.4 Iterations

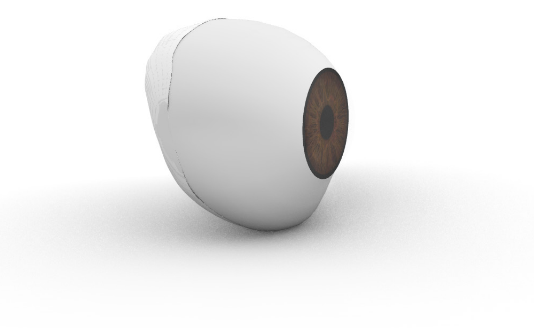
This spread summarises the several iterations that have been designed and tested in various ways in order to come to the final design.

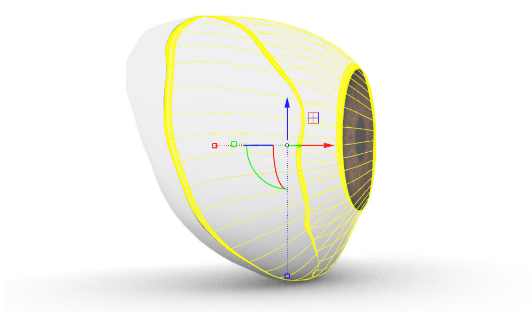




Iteration 1

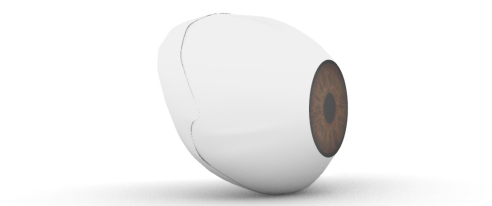
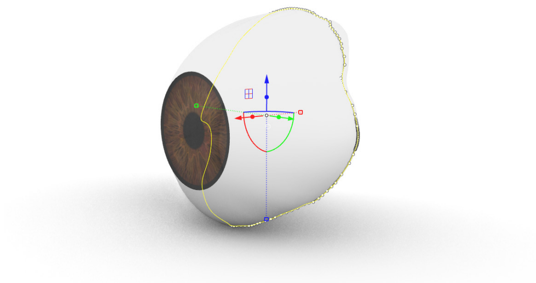
- 3D-scan is manually loaded in Grasshopper.
- Geometry is automatically generated in Grasshopper
- Contour is selected by choosing a project direction.
- Mesh is translated to NURBS.





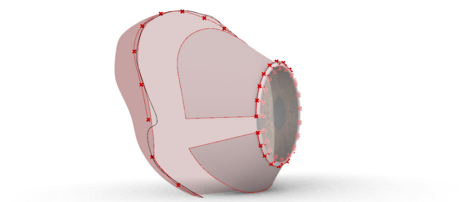
Iteration 2

- Iris is added
- Different approach for creating the sclera.

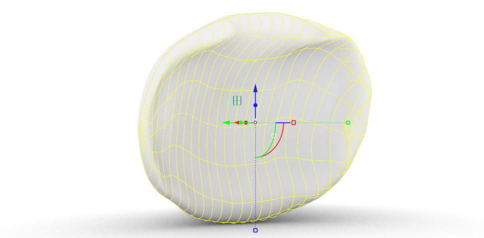
Iteration 3

- More close fit between backside and front geometry.

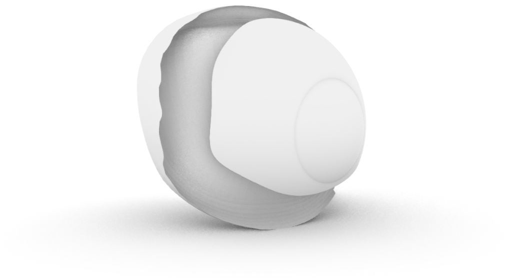
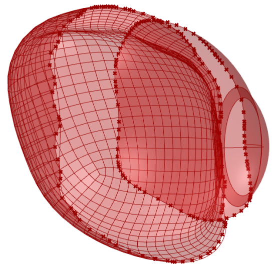
Iteration 4

- Trying different approaches for translating mesh geometry into curves and surfaces.
- Tests with different inputs, different impressions.
- Added canthi control to better determine gaze.

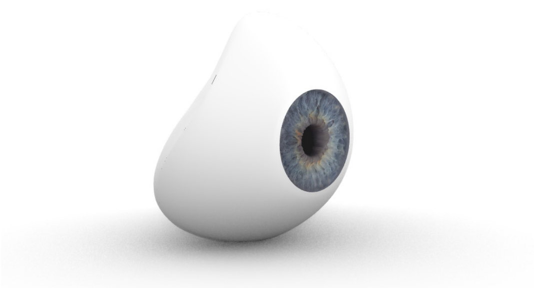
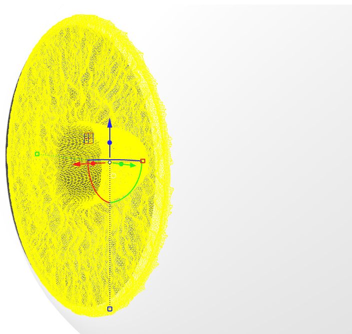
Iteration 5

- Cleanup of nodes, imoproved run time of the model.
- Added more control for the back and front side translation to NURBS.

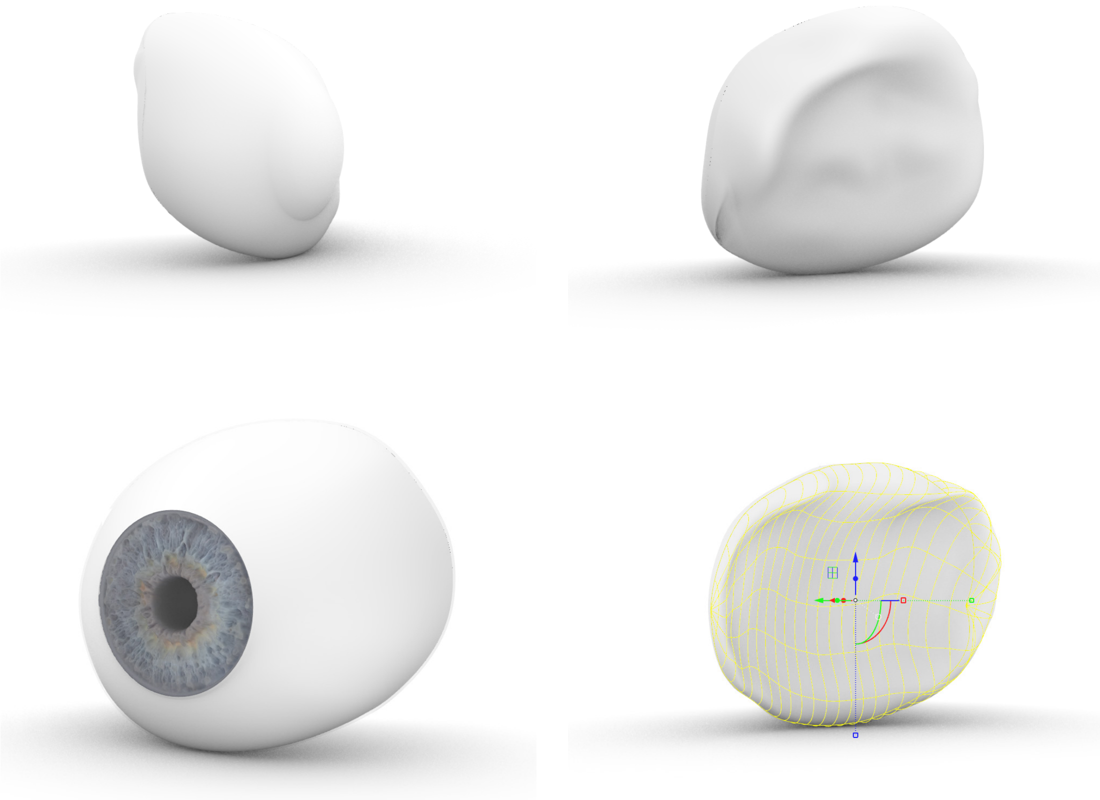
Iteration 6

- Different more lightweight approach for translating Mesh to NURBS.
- Added a limbus
- Problems with smooth surface transition

Iteration 7

- Model works with reference models and other impressions.
- Added more parameters for more control of the main body.
- Added displacement and color mapping to the iris.
- Added control to the curvature of the sclera.



Iteration 8

- Smoothed out the surface transitions.
- Added more parameters for more precise control.
- Added a transparent layer with offset.
- Created a flow in the Grasshopper file for usability.
- Added control for pupil depth and diameter.
- Values in the parameters now correspond to realistic values based on literature.

6.5 Validation

A comparative study using real use-cases and reference models. This experiment will focus on the viability of the parametric model. Does the model function properly and can it perform sufficiently according to the ocularist.

In order to quantitatively assess the performance of the model a mesh comparison study is performed to check if the model is a good substitution of the workflow of the ocularist.

Research objective & research questions

- Is the parametric model able to achieve similar results in the geometry of ocular prosthetics as achieved with traditional methods?

6.5.1 Method

Participants

For this study three cases of different participants are used who are owners of ocular prosthetics (n=3). Their names will not be used in this research for privacy reasons and will be referred as participant 1, 2 and 3. These three participants are of different age ranging from approximately 18 years to 65 years old and have worn the prosthetic for different amounts of time. For all three the participants this is not their first prosthetic. They have been selected based on their preference of collaborating with this research. All three cases have different eye colours. Light brown, dark brown and blue.

Stimuli & equipment

Digital equipment

- 3x 3D-scan of impressions
- 3x Digital model of edited scan used for fitting
- Meshmixer
- Blender
- Rhino Grasshopper
- GOM inspect

Physical equipment

- 5x Prosthetics
- Moulding paste
- Clay
- Artec Space Spider 3D-scanner

Procedure

In order to test the output of the parametric model the corresponding 3D-files need to be gathered. To capture the shape of the final prosthesis a mould can be made from the prosthetic using moulding paste. This is done because the prosthetic is still in use and this way the shape of the prosthetic can be captured quickly and participant is not without their prosthetic for a prolonged period.

The other (n=2) prosthetics are also scanned with the Artec Space Spider. Because this scanner has an resolution of 0.1mm it is able to capture the shape of small objects such as ocular prosthetics. The Artec Space Spider is a high-resolution 3D scanner based on blue light technology which means that it has trouble with scanning reflective objects. In order to properly capture prosthetics they first need to be coated with a matte layer. For this layer, drying shampoo is used based on the recommendation from B. Naagen. The shampoo covers the prosthetic in a thin layer of white material. Figure 35 shows the coated prosthetic. To keep the prosthetic upright, it is fixed in clay. Playdoh is used for this because it does not harden and is able to be reshaped if needed.

The prosthetics need to be scanned at least two times. This is because the part of the model which is currently in the clay cannot be scanned. The model will be washed, flipped and the coating will be reapplied for the second scan.

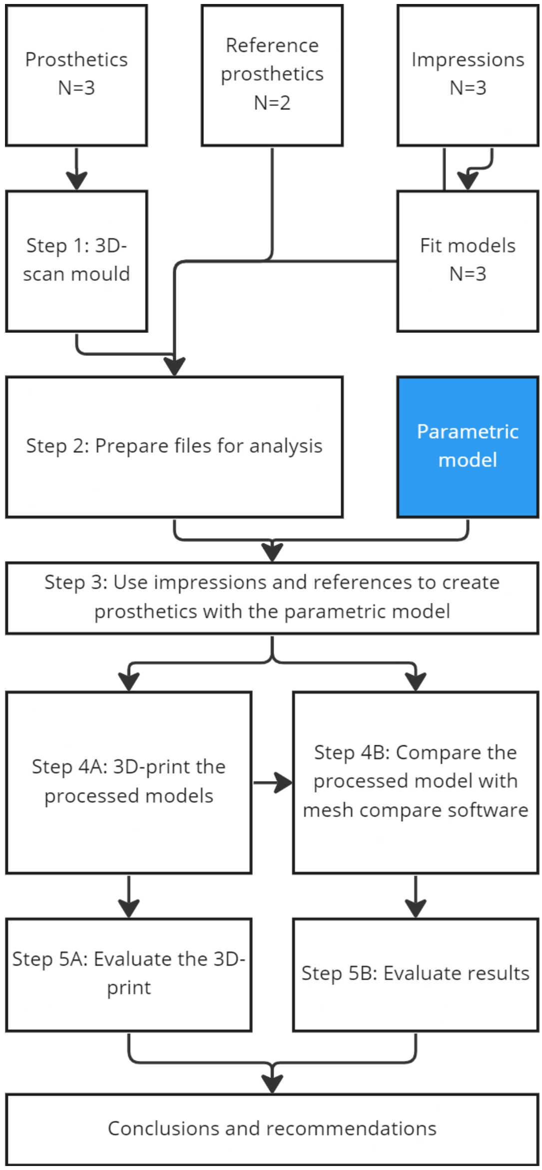
Another important factor is the overhang in the backside of the model. Because of the angle the 3D-scanner is placed in, it is important that the model does not have large overhangs or otherwise the scan will show artifacts. .

Step 2 (file preparation):
The files need to be prepared. For this the 3D-scanned negatives of the prosthetics need to be aligned so an positive shape can be found. This positive shape will resemble the prosthetic. (This shape will be influenced by the methods of alignment.)

For the 3D-scans of the prosthetics, the output from the 3D-scanner needs to be edited in the software provided by Artec Studio.

The models are only rotated and transformed, nu further edits are done.

These moulds can then be 3D-scanned using an handheld 3D-scanner. This is done to digitalize the shape. From these models the geometry of the final prosthetic can be derived.



Data analysis
Using GOM inspect, software that is able to compare the differences between mesh geometry a quantitative assessment can be made on the accuracy and trustworthiness of the parametric model.

6.5.2 Interview

An interview is held with the ocularist in order to qualitatively assess the parametric model. For this a rating form is used for each prosthetic (see Appendix B). The ocularist is asked to rate each sample on a 5 point Likert scale ranging from very dissatisfied to very satisfied.

- How do you rank the smoothness or the level of detail in the 3D-print?
- How do rank the geometry of the socket side (backside) of the prostheses?
- How do you rank the geometry of the corneal side (front) of the prostheses?
- How much do you feel the addition of a cornea adds to the prostheses?
- How do you rank the final result?

General questions
- What do you feel went well?
- What do you feel went less well?
- What would you do differently next time and why?
- What do you think about the weight?

Results

Figure 45 shows the combined results of all the five prosthetics. A scale from -100% to 100% is used meaning if the total is 100 that all the prosthetic are rated at least satisfactory.

- Overall pleased with the results of the parametric model, especially the models based on impressions.
- The cornea is often tóó pronounced which affects the overall smoothness of the models.
- The live-preview during designing is an important feature to utilize the hand-based knowledge of the ocularist.

The conclusion from the evaluation with the ocularist led to the following points:
- The cornea transition needs to be less noticeable. This does not mean that the added cornea is a redundand function, the extra thickness is needed to properly position the upper eyelid.
- Prosthetics made with impressions often lead to lighter eyes, which is more comfortable and preferable.
- Reference models can only be used for simple round sockets, so both options are necessary.
- The parametric model needs an extra step to better determine the pupil location.
- More then 50% of the prosthetics are scleral prosthetics, the added functionality would benefit a lot of people.
- The ocularist wants more control over the contour. The contour needs to be able to scale and move.

Figure 43. Result of 3D-scanning moulds

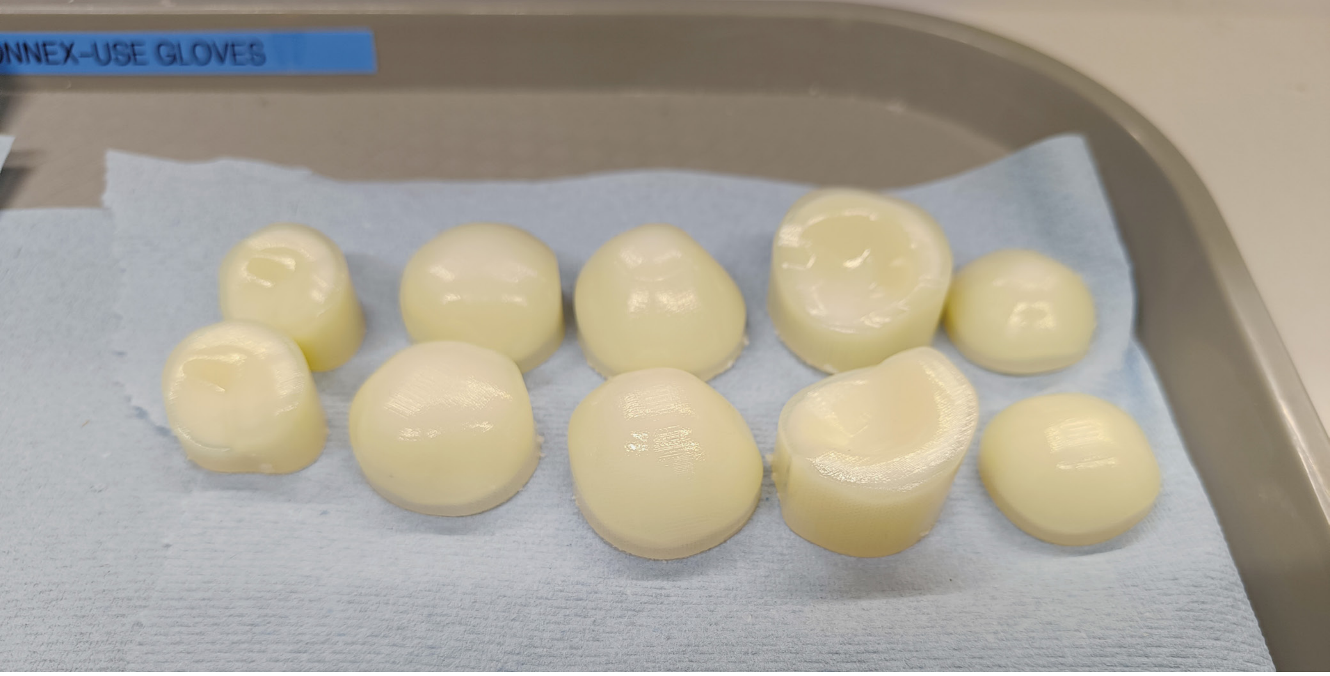


Figure 44. Prosthetics pre-processing

Overal high satisfaction but opinions on the cornea are neutral and satisfaction about the smoothness of the prosthesis is variable.

Replies to the rating form on the evaluation of (n=5) 3D-printed samples from the parametric model. The evaluation is done by an ocularist.

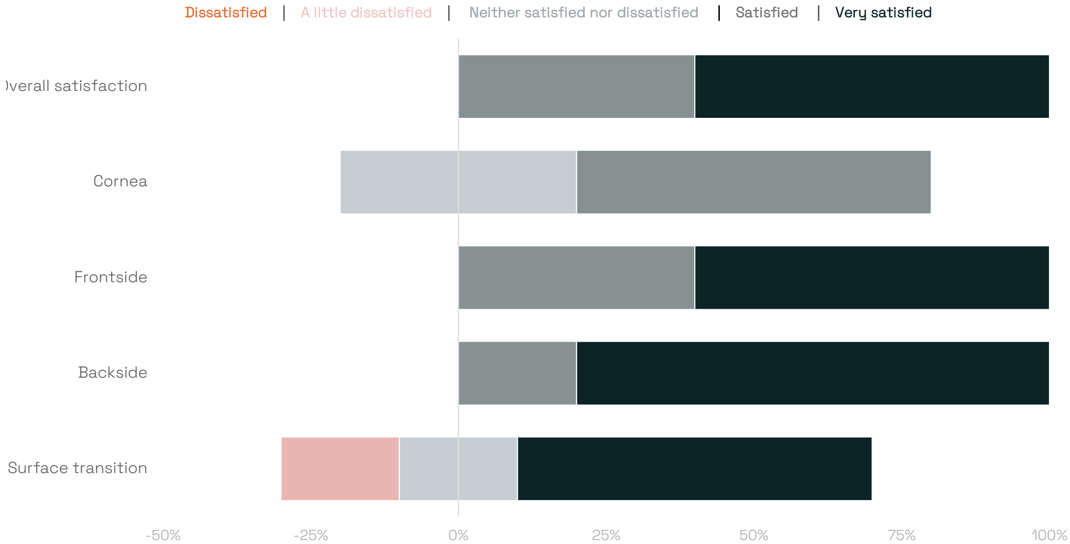
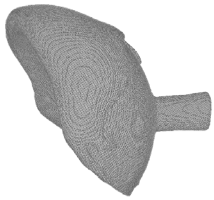
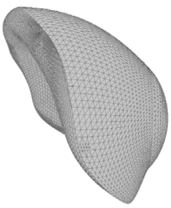


Figure 45. Results from evaluation with ocularist

6.5.3 Prosthesis 1 (Impression)





	Print vs CAD	Print vs Fitmodel	Print vs Orginal
Max distance (mm)	0,29	1,21	9,6
Min distance (mm)	-0,26	-1,4	-2,17
Mean distance (mm)	0,01	0,06	1,71
Distance std deviation (mm)	0,07	0,44	0,81

Opinion Ocularist

Weight (g): 4,33

Smoothness	**Back geometry**	**Front geometry**	**Cornea**	**Overall Satisfaction**
Very satisfied	Very satisfied	Very satisfied	Neither satisfied nor dissatisfied	Very satisfied

Results

Comparing the 3D-model of prosthesis 1 with its CAD model shows that the the accuracy of the 3D-printer is high. With an standard deviation of only 0.07 millimeter, which is negligible and matches the accuracy the company Stratysis states on their website. The biggest differences are located on the edges. This can be explained by looking at the CAD-model. On that location a sharp graphical error occurred, a transition between the back geometry and the front. Because the 3D-printer cannot handle non-zero geometry it combated this error by simply blending the two shaped together. The differences between the CAD-model and the 3D-print can also be linked to the export setting of the modelling software, in this case Rhino 3D.

The print can also be compared with the fitmodel made by the ocularist which uses the same input. The back geometry is similar to the fitmodel. The largest differences are the cornea protruding outwards in the print and the contour being smaller.

The difference between the print and the original prosthesis is a lot bigger. The original prosthesis is quite a bit smaller than the fitmodel. This is possibly the because of the manual production steps which often tend to result in a smaller prosthetic due to the material that needs to be removed in the final steps. The max distance of 9,6 mm is an error because that overall width of the model is ~30mm

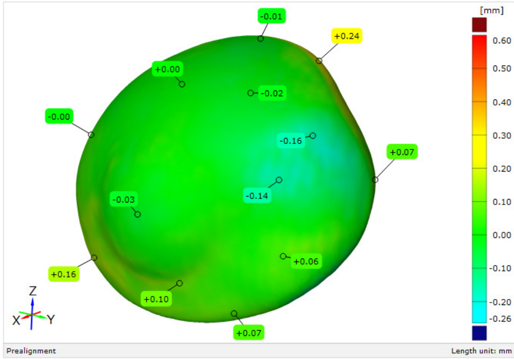


Figure 46. 3D-print vs CAD

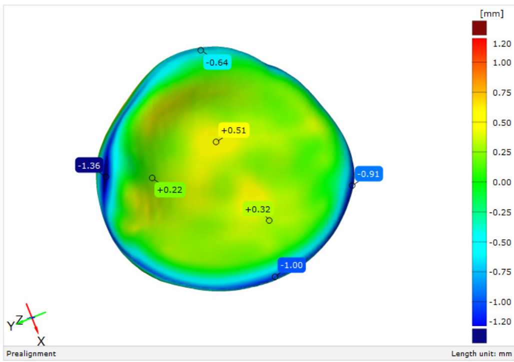


Figure 47. 3D-print vs Fitmodel

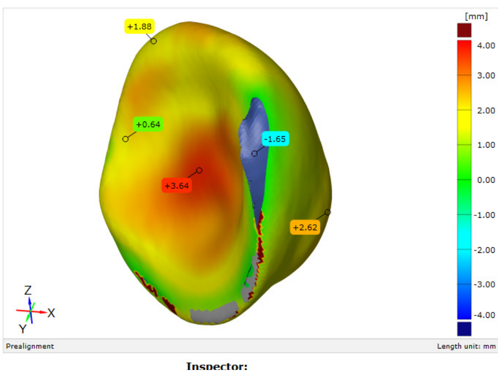
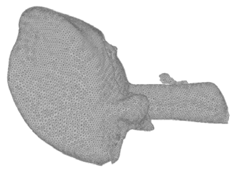
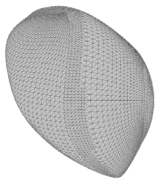


Figure 48. 3D-print vs Original

6.5.4 Prosthesis 2 (Impression)





	Print vs CAD	Print vs Fitmodel	Print vs Orginal
Max distance (mm)	0,19	2,75	10,0
Min distance (mm)	-0,14	-1,63	-0,75
Mean distance (mm)	-0,03	0,70	3,73
Distance std deviation (mm)	0,04	0,62	1,66

Opinion Ocularist

Weight (g): 4,75

Smoothness	**Back geometry**	**Front geometry**	**Cornea**	**Overall Satisfaction**
Very satisfied	Very satisfied	Satisfied	Satisfied	Very satisfied

Results

At first the alignment of the meshes didn't work, this was because the surfaces of the output of the parametric model where not merged properly. This final fine-tuning step would be a recommendation to automate in the future.

The print compared to the CAD-model is smoother which results into the surfaces blending over. Here are also the biggest surface deviations.

Compared to the fitmodel the backside geometry is more uniform. The fitmodel shows a larger difference between the valleys and peaks of the backside.

Difference between the 3D-print and the fitmodel is that print has a more uniform curvature of the front. This is not always preferable as the socket might also be shaped differently.

The output of the parametric model deviates a lot from the original prosthetic.. It is bigger. Interesting is that the fitmodel the ocularist made also bigger is.

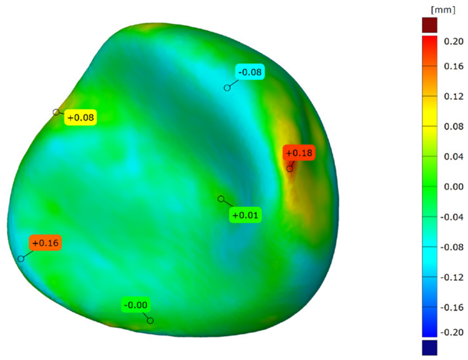


Figure 49. 3D-print vs CAD

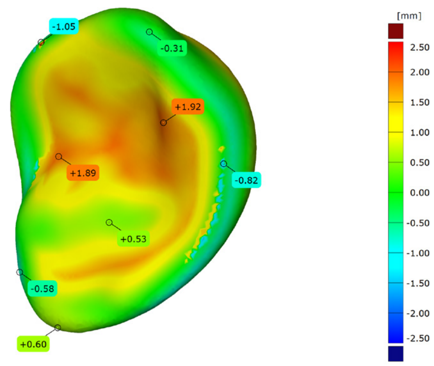


Figure 50. 3D-print vs Fitmodel

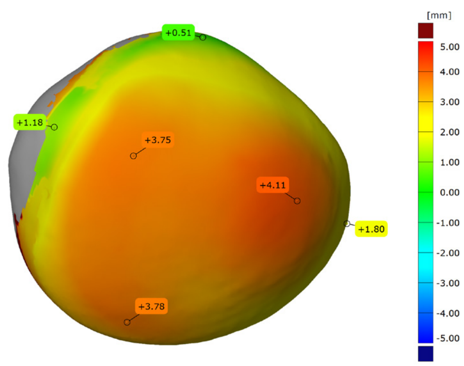
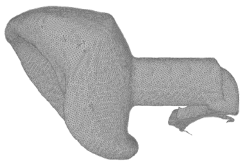
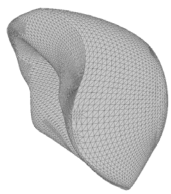


Figure 51. 3D-print vs Original

6.5.5 Prosthesis 3 (Impression)





	Print vs CAD	Print vs Fitmodel	Print vs Orginal
Max distance (mm)	0,33	3,50	9,18
Min distance (mm)	-0,17	-1,00	-0,84
Mean distance (mm)	0,01	1,22	1,45
Distance std deviation (mm)	0,08	0,66	0,74

Opinion Ocularist

Weight (g): 5,12

Smoothness	Back geometry	Front geometry	Cornea	Overall Satisfaction
A little dissatisfied	Satisfied	Very satisfied	Neither satisfied nor dissatisfied	Satisfied

Results

After 3D-printing the prosthesis is still very similar in geometry to the CAD model showing little to no deviation. The biggest changes occur at the edges and on sharp features. The sharp features are lost due to how the model is printed. In order to achieve a matte appearance the entire model is covered in support material and during removal might damage the print. However this is not an issue as sharp features are not preferable in the final prosthetic.

Prosthetic 2 has one protruding feature which also causes the largest deviation, a sharp point on one of the edges. This point can be lead back to a modelling error in the parametric model and is not part of the impression geometry. On the front of the prosthetic is also another high deviation. Just as with prosthetic #1 this is the result of the sclera feature in the parametric model.

The same protruding point appears in the comparison with the original prosthetic. The final prosthetic is also a lot smaller. The small dark red spot correspond to the very thin mesh of the original prosthetic. It is possible that the software has trouble processing those parts.

A comment from the ocularist was that the transition between the back and the front of the prosthetic could be smootherr. However he also commented that this could be helped during grinding and polishing.

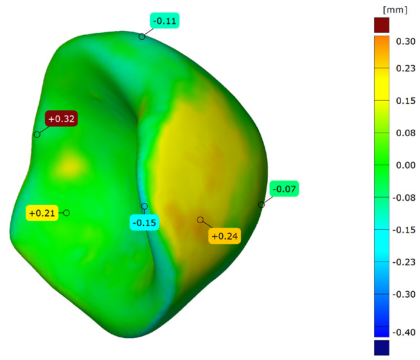


Figure 52. 3D-print vs CAD

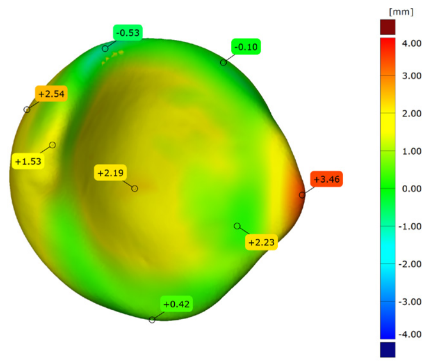


Figure 53. 3D-print vs Fitmodel

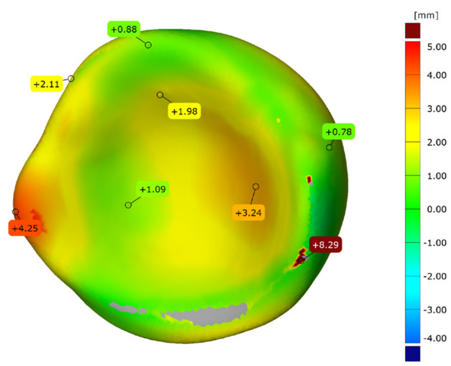
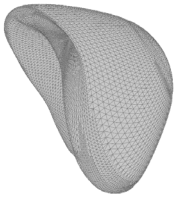


Figure 54. 3D-print vs Original

6.5.6 Prosthesis 4 (Reference)




	Print vs CAD	Print vs Fitmodel	Print vs Orginal
Max distance (mm)	0,31	-	0,48
Min distance (mm)	-0,20	-	0,63
Mean distance (mm)	0	-	-0,01
Distance std deviation (mm)	0,05	-	0,16

Opinion Ocularist

Weight (g): 4,7

Smoothness	**Back geometry**	**Front geometry**	**Cornea**	**Overall Satisfaction**
Neither satisfied nor dissatisfied	Very satisfied	Satisfied	Satisfied	Satisfied

Results

Prosthetic #4 is made based on a reference model. Figure 55 shows the comparison between the final 3D-print and the CAD-model. The maximum deviation is 0.3mm so it is falls in the tolerances. The area where the deviation is the largest are also the areas where the scanning process encountered the biggest difficulties because here the original model is the thinnest.

Comparing the 3D-print with the original prosthetic an almost zero mean distance is achieved. For the most part do the two models overlap but the largest deviation still appear at the edges and borders of the prosthetics.

The ocularist was overall satisfied with the model. Especially how close it looked compared to the reference model. The biggest commentary was the addition of a cornea. The original reference model had a smooth transition between cornea and the sclera and in the 3D-print the transition is more pronounced. The caused the score for the smoothness to drop.

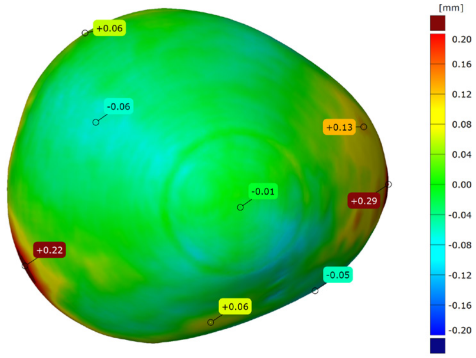


Figure 55. 3D-print vs CAD

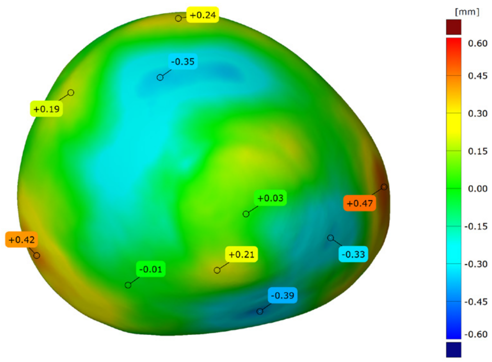


Figure 56. 3D-print vs Original

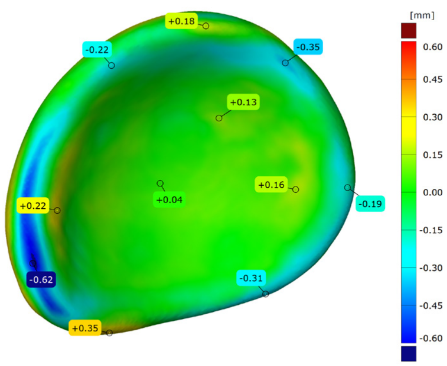
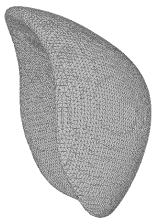
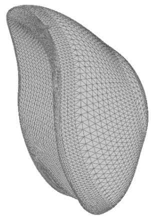


Figure 57. 3D-print vs Original

6.5.7 Prosthesis 5 (Reference)





	Print vs CAD	Print vs Fitmodel	Print vs Orginal
Max distance (mm)	0,27	-	0,47
Min distance (mm)	-0,25	-	-0,54
Mean distance (mm)	-0,01	-	0,07
Distance std deviation (mm)	0,04	-	0,16

Opinion Ocularist

Weight (g): 1,88

Smoothness	Back geometry	Front geometry	Cornea	Overall Satisfaction
Very satisfied	Very satisfied	Very satisfied	Satisfied	Very satisfied

Results

The 3D-print deviates very little from the original prosthetic. The only problem areas are the thin edges of the prosthetic.

Prosthetic #5 is very well rated by the ocularist. This is because of the smooth transitions between the front, the backside and the cornea. Also shows the prosthetic a good balance between a complex and simple form. Especially this balance is important is making ocular prosthetics.

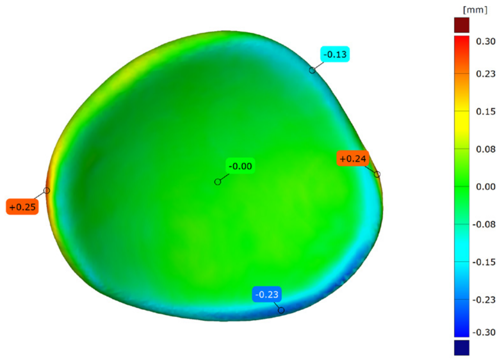


Figure 58. 3D-print vs CAD

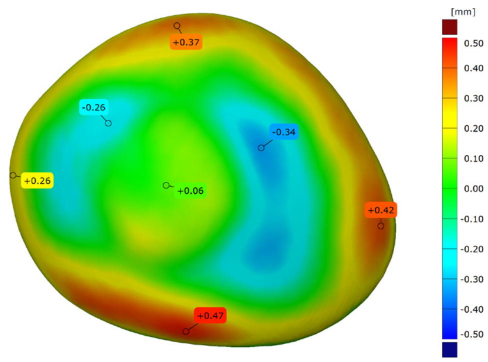


Figure 59. 3D-print vs Original

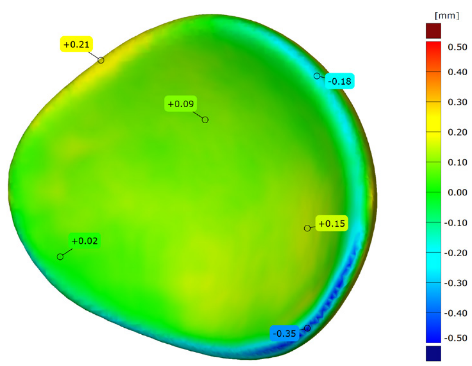


Figure 60. 3D-print vs Original

6.6 Conclusion

Reference contour
Both of the prosthetics based on the a reference model showed the largest deviation on the contour of the prosthetic. There they differed from the original models. This change can be led back to the 3D-scanning process. The edges are often very thin and during scanning the 3D-scanner had trouble recognizing those areas.

Quadrants
The front of the prosthetics which come from impressions are too uniformly shaped. An extra feature is needed which divides the sclera in quadrant offering control over each quadrant. This is neede because the ocularist needs the freedom to change the shape of the proshetic is such a way. For example, making the prosthetic larger on the top pulls the eyelids upwards and reveals more of the iris.

Oversimplification
The traditional methods of fabricating an ocular prosthetic often lead to over simplification. The detail that is gained with taking an impression is lost during the manufacturing process. This is caused by the molds being often not very precise and the fact that the prosthetic needs to be fine tuned and polished later.

Results

- Largest deviations are on the contour of the prosthetics. These areas are also the hardest to 3D-scan properly.
- Socket geometry (backside) matches well between the print and fitmodel from the ocularist
- The original prosthetic is always thinner than the print.
- Digital twins have little deviation (mean distance <0,1mm)
- The front of the prosthetics are too uniform.

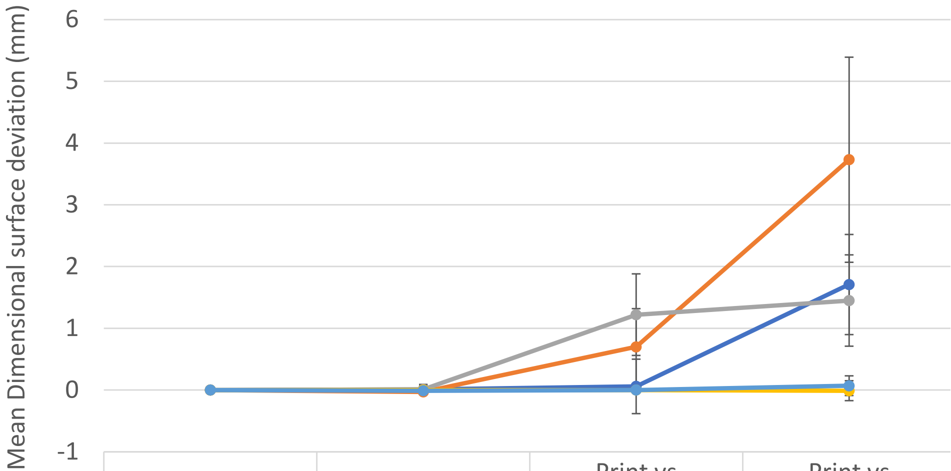
The front of the prosthetics which come from the parametric model are too uniformly shaped. In order to properly position the prosthetic in the eye socket the ocularist needs more control of the curvature of the front. The prosthetic can be divided into quadrants (left, right, up, down) to provide more freedom

Research into manual and digital manufacturing methods resulted in an overview of the state-of-the-art methods of integrating digital tools into ocular prosthetic production. Together with the finding that 3D-scanning and mulit-colour 3D-printing can deliver a very realistic ocular prosthetic the choice to design a new workflow for creating ocular prosthetics was made.

The proposed production process, combining manual and digital production has successfully been applied partly in cooperation with an ocularist. The choice was made to design an parametric model which automates the repeatable steps of the ocularist while still keeping the hand based knowledge in view.

Two different methods for input were chosen. 3D-Scanning an ocular impression to obtain the interior geometry

Surface deviations where able to be kept to an minimum but this was very much depended of the input of the model.



	Print	Print vs CAD	Print vs Fitmodel	Print vs Orginal
Impression 1	0	0,01	0,06	1,71
Impression 2	0	-0,03	0,7	3,73
Impression 3	0	0,01	1,22	1,45
Reference 1	0	0	0	-0,01
Reference 2	0	-0,01	0	0,07

Figure 61. Surface deviation of prosthetic designs

7. Recommenda-tions

This chapter contains recommendations on how to proceed with the work done in this thesis and what subject need additional research.

7.1 Recommendations

The end of this graduation project is still only situated at the start of the integration of digital technology in the ocular prosthetic profession. Based on the conclusion from this project, recommendations will be formulated regarding what a good approach willl be for the next step for the feasibility of an entire digital production.

System approach

There need to be changes on the way the industry looks at the making prosthetic eyes. Instead of a normal patient by patient basis the practice could be viewed at with a system approach. CMP's are unique in a way that will they are tailor made for everyone they still contain a lot of similarities with each other. Finding these similarities cannot only done with expertise but also with an extensive collection of different prosthetics.

By recording all the prosthetics that are made over time a library can be formed with all the possible options for ocular prosthetics. This library will grow over time and from all these prostheses new parameters can be derived with the help of algorithms. Instead of manually determining parameters. This way all possible variant of prosthetics can be generated with only knowing a few measurements.

For example a set could be developed of 10 of the most used prosthetics in the Netherlands. This is different from the current set of the ocularist because these are his own preferred shapes.

A next step could be to research on how to create such a library. By 3D-scanning different types of prosthetics and translating those to new parameters.

Testing with real people

One of the biggest hurdles for this thesis was evaluating the final shape of the prosthetic. Because parameters can be determined based on research and findings from conversations with the ocularist but the final evaluation can only be done by inserting the prosthetic into a real socket.

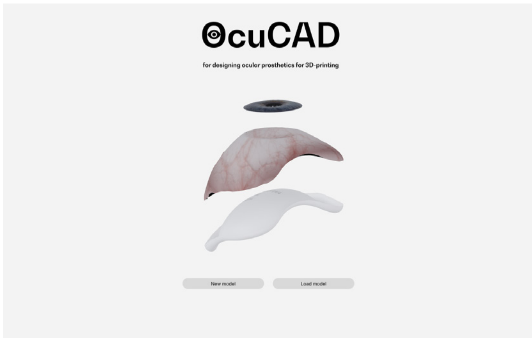
Luckily this is the plan of the research group of the AMC, to test the prosthetics in-vivo in real cases. Only there you can evaluate the final fit and comfort. No patients were available during this theses due to the sensitive nature of the prosthetic and the medical procedures required to get clearance for testing with patients.

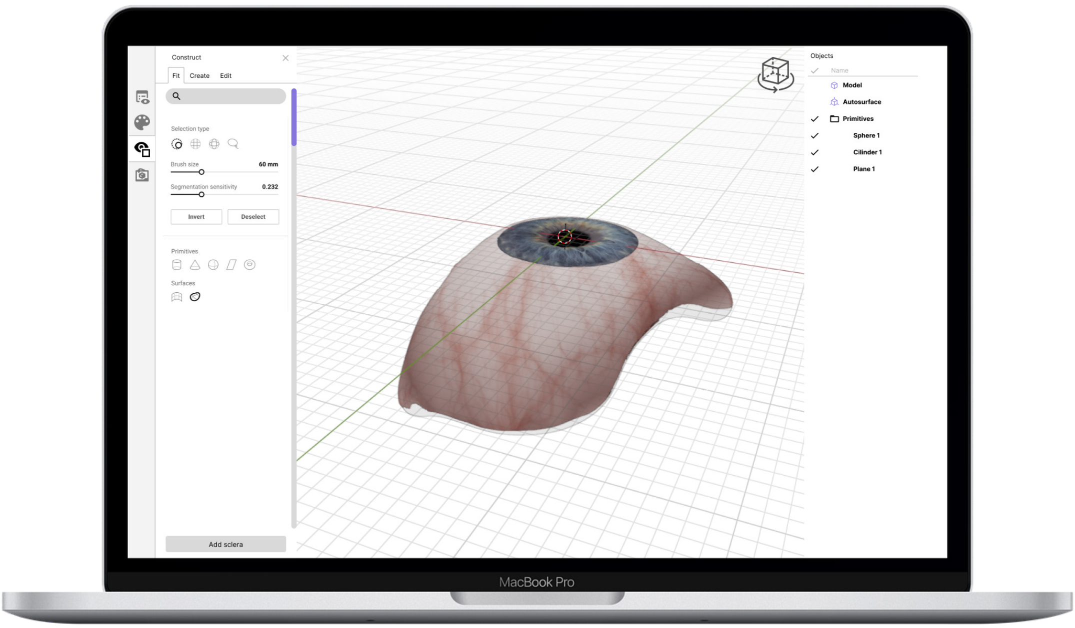
One of the researches used an model made from silicone to test fit a prosthetic. This could be a recommended step in further testing and developing the parametric model.

7.1.1 Dedicated tool

As a recommendation the parametric model can be developed into a dedicated tool. For example in dentistry this is already happening. Here CAD and CAM tools are used for creating and improving dental restorations. It increases the speed of design and creation, the convenience and simplicity. However it often involves extra time and costs.

A dedicated software solution can lower the barrier for other ocularist with less digital experience to start digitizing their practice.





7.1.2 Extra step for pupil location

From the interview with the ocularist came that as a recommendation an extra step needs to be added to better determine the pupil location. This was not sufficiently added to the model.

An intermittent step needs to be added by 3D-printing a prosthetic with an grid.

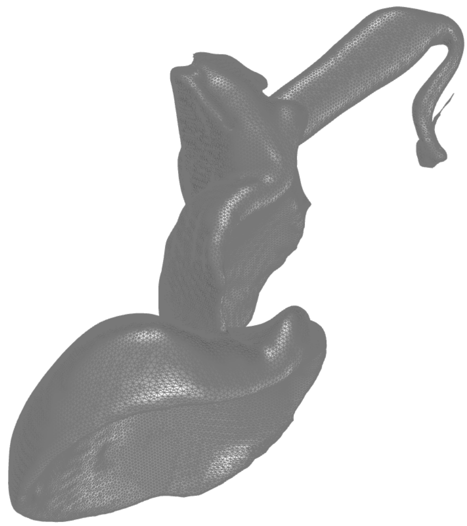
1. Print grid on model for fitting
2. Mark estimated pupil location
3. Take a photo from straight on
4. The flash falls on the pupil
5. Use that location in the parametric model for the pupil location

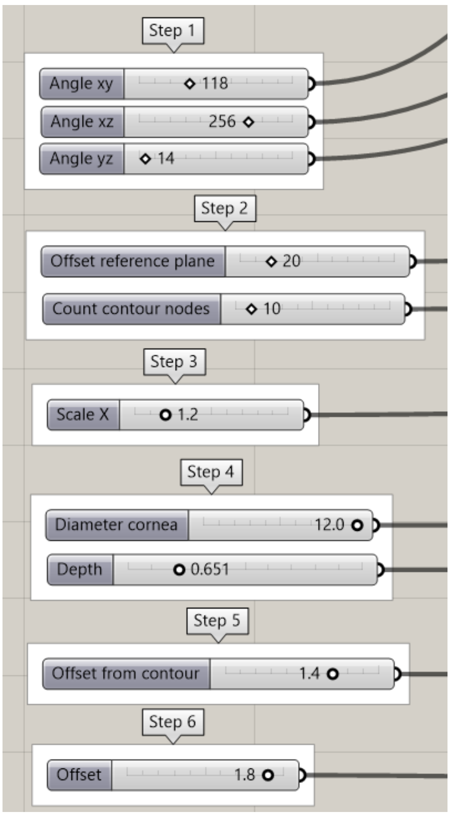
7.1.3 Add sclera control

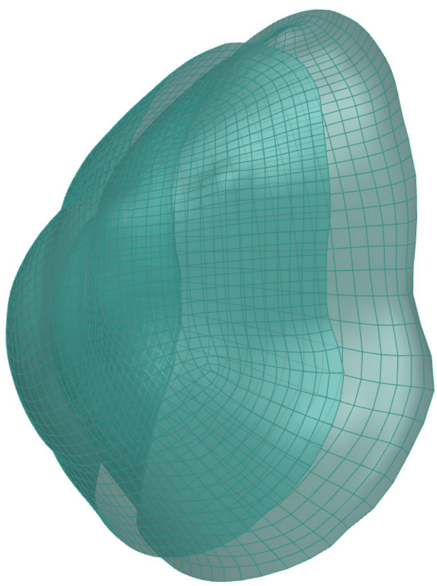
The parametric so fat does not contain any information concerning the color and texture of the sclera. An addition to the parametric model could be the implementation of an parametric sclera model. With parameters to control the shade, amount of veins visible and vein complexity. This was out of scope for this project but important for creating an entirely digital workflow.

7.1.4 Scleral prosthetic model

It is recommended to develop a separate model which is able to generate scleral prosthetics. These kind of prosthetics are made in different way compared to regular CMP's. A start is made on a model which is able to replicate the design guidelines provided by the ocularist. The model is co-developed with the ocularist and needs to be further worked on in collaboration with lens manufactures.







7.2 Reflection

Learning goals

Now that the project is finished I can reflect back on the learning goals I set for myself in the project brief. In the project brief I stated that generative modeling has always interested me but I never had the opportunity to incorporate it into project. I believe that this project was a very good start with that. I can now see the effectiveness and usefulness of generative design and I expect and hope to continue using it in my professional career. During this thesis I learned to use a whole new software for me, Grasshopper and I can say that I became quite adept in it. I hope to continue learning more.

3D-printing was something else that I stated in my project brief. Little did I know that the type of 3D-printing is was going to work with was quite different from the kind I was familiar with. Luckily I had help for this. Joris and Ilse could help me with the 3D-printing if needed and I learned the beginning on how to design for poly-jet printing. Looking back I would have wanted to start with 3D-printing earlier in the project because I believe I only scratched the surface and could have utilised it more.

Another point was that I wanted to set-up a proper experiment and become better in research, especially the practical part. To my knowledge I managed it, although it being not very extensive. I am happy with the results of the desk research and I believe that is done extensively. But I also believe that the research on the viability of the design is somewhat rushed. Because it all came together later in the planning than I anticipated I lacked in the analysis of the final experiment. So something to keep in mind for future project is planning extra time in the end for when things don't go as planned.

Knowledge
I believe I had an extensive research phase in this thesis that went into great detail on what ocular prosthetics are, how they are made and how to incorporate digital production. All these findings led to design criteria and key take-aways to use for final design

Methods
I used appropiate and meaningfull methods during the project. Escpecially in the analysis of the gathered research. The choice of methods could be better for the evaluation of the design.

Project results
The validation of the parametric model is one of the strong suits of this thesis. Although it would have been better to test with real patients, this was impossible for the scope of this project. The new workflow is made for the ocularist and as he stated is going to be used in his daily practice. It increases the efficiency and which the ocularist can design new prosthetics. The next step would be to optimize the workflow to be useful for more ocularists to increase the viability.

Communication
The writing in the thesis is sufficient but I would not say it is ready for publication. Due to time constraints in the end not all the writing is polished. I also believe that the report could be thinned out, because now it is quite extensive.
The connection with the client was very good, with timely meeting to discuss the progress and co-decide on ideas. We could get along well which helped with communication and honesty.

Project management and planning

Planning and project management is not my strong suit. This is something which I was aware of when beginning this thesis but still caused me troubles in the end. I do believe I can make autonomous decisions well but Ideally I operate better in a team, not alone. My coaches were able to help me with the project management. Pointing out moments and methods to use. If compared to my original planning the project took a few weeks longer with one of the week being a holiday which lasted a week longer then expected. The overtime was something which I believe could have been prevented by being more assertive on my own schedule. Now the workload increased the longer the project lasted while ideally it was more equally spread out.

8. Appendix

This chapter contains the appendices
for more detailed information.


KLINION
SensiCare

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8.2 Appendix A

8.2.1 Surgery

During the first step of the process a person undergoes surgery, this is performed by a specialist, an ophthalmologist. Here an implant replaces an eye of the patient. There are two sizes, 10mm and 12mm. The doctor will use the largest one that fits. After the surgery the doctor places a conformer in the resulted socket, this is to prevent the tissue of contracting during the healing process. This would lead to problems when trying to eventually fit an prosthesis. According to ophthalmologist Sanne van der Horst there are three sizes of conformers that are used. These conformers are thin for more comfort and won't fill the socket properly as a regular prosthesis would. In the first few weeks the socket will change a lot only when it is stable a start can make on making a new eye.

8.2.2 Informing

Around 6-8 weeks after surgery the socket is healed and won't deform much anymore. The patient consults an ocularist. The ocularist walks the patient through the whole process and tries to inform as best as possible. This is a moment where the ocularist can make a personal connection with the patient. Because the patient needs to return multiple times it is best if he/she feels comfortable.

Having one of your eyes removed is not an easy choice to make and some people will wait till the last moment before the situation gets even worse. That is why it is necessary that the patient is as informed as possible on what will happen.

8.2.3 Measuring

The goal of the ocularist now is to measure the patient and get as much data as possible. This is done by taking a photo of the companion eye of the patient using a special lighting set-up. Jelmer uses an SLR camera with a macro lens for close-up shots. On the camera two flashes are mounted that evenly lit the eye. He also uses a calibration cube specially made for photography in order to get the right greytones. The photo is shot in a RAW image format in the highest resolution as possible in order to prevent loss of detail.

Photographing eyes poses a couple problems. Eyes are very glossy and reflect light that shine on them. With a camera flash, the ocularist tries to minimize the reflection because these will be edited out later in the computer. Good practice is to let the reflection fall in the pupil. Because the pupil will be replaced with pure black in the computer anyway. Pupils will dilate and contract based on how much light hits the optical nerve in the back of the eye. This means that pupil size will never be the same and is constantly changing in healthy eyes. Thus a standard size for the pupil will be chosen.

8.2.4 Comparing

In this step the ocularist compares the other eye of the patient with eyes from his collection. He looks at the color of the sclera, the amount of veins present and the color of the iris. He also makes an estimation on the shape of the prostheses. Based on how the socket healed he can make a estimated guess. If he thinks that the prostheses will fit, the patient tries the prosthesis. Based on how the prosthesis sits in the socket and by asking the patient about comfort, the ocularist can either add wax to the prosthesis on places where its needs to be bigger or grind away the acrylic on places where it is too tight. Sometimes these steps are enough and a sufficient shape can be found this way using trail and error. Jelmer now marks which example to use for the colours and which for the shape for processing later. As Jelmer pointed out, there is a collection of prostheses which he uses more frequently then others. Approximately 10 are used very frequent.

8.2.5 Impression

If no good match can be found for the shape an impression must be made. This is done by injecting alginate into the empty socket using a syringe and a ocular impression tray. The putty fills the socket completely and deforms the soft tissue of the eyelids. It also overflows out of the corners of the eye. The putty takes a couple seconds to harder after which it can be taken out of the patients eye.

Jelmer pointed out that other ocularist often make impression for every patient. The reason he does not have to this is because of his large collection of models and his expertise in assessing if a prosthesis will fit or not. The impression is then labeled and stored for future use.

After the consult Jelmer 3D-scans the impressions he made using a micro-CT scanner. The impression is then edited in the computer and he 3D-prints a model which will be used for fitting in a later consult with the patient. When fitting the model, Jelmer can add wax or grind away material to eventually arrive at the perfect shape. The prosthesis should not be too tight because this will prevent it from moving but it should also not be to loose because it then will not fit right and could fall out. All these choices on where to add and where to take away material are what makes it hard being an ocularist. As Jelmer pointed out these thing are only learned by experience over time and it will take a lot of tries to get it right eventually.

Using the 3D-printed fit model he also looks at the gaze and the location of the pupil. The pupil is always located a bit closer to the side of the eye that faces the nose. This fit model is then given to his colleague Julios for fabrication and painting.

8.2.6 Manufacturing

Now the prostheses is ready for manufacturing. This is done by his colleague Julios Veizaj. He is and artist and technician and responsible for the painting of the iris and casting of the prosthesis. A plaster mold is made based on the fit model that Jelmer made. This is done using a two part metal mold. Multiple prostheses can be cast at the same time. When the mold has hardened the fit model is taken out and white acrylate is pressed in together with an iris disk.

An iris disk is a small piece of transparent PMMA where the iris is painted on. Jelmer uses a special technique for this using a photograph as a base layer for the painting. This not only serves as a guide for Julios but also gives the iris a depth that otherwise could not have been achieved.

8.2.7 Painting

Using the photograph as an reference the iris is painted to be a close as possible match to the patients companion eye. For this process the artist uses painted which have a lot of pigments in order to make the colours pop.

Veins are added to the prostheses using thin cotton threads. Matching the other eye one on one is not needed but it is important to achieve the same amount of veins. The white acrylate can also be painted. For example people who have darker skin tone also have more pigment in their eyes and elderly often have more gray in there sclera.

8.2.8 Manufacturing 2

Using the same mold the eye is cast again in transparent arcylate. But not before a concave hole is ground out to make space for the cornea. The PMMA used offers a realistic shine and is bio compatible.

8.2.9 Finetuning

The prosthesis is polished to a fine sheen using multiple steps of polishing wheels. This is important for the life-like appearance of the prostheses. This is also the place for final corrections.

Jelmer stated that he over dimensions his prostheses because he knows that he will always need to adapt the final shape. And material is more easily taken away then added. A risk is if the prostheses is filed too much, the transparent layer could be gone and manufacturing has to start all over again.

8.2.10 Using

The patient is instructed on how to use and take care of the prosthesis. The ocularist show how to put in and take out the eye and how to keep it if it is not being used.

The prosthesis needs very little care and can be held in at all times. Due to the tear ducts wetting the eye, there is also no need for eye drops.

The patient should return to the ocularist at least every year to repolish the prostheses because over time it will lose its shine and will 'gray' out.

8.2.11 Evaluating

After two years the patient comes back for another consult to get a new eye. Here the prosthesis is evaluated and the process can start over again. Jelmer uses the current prosthesis a reference point for the new one.

8.2.12 Conclusion

I now have a complete understanding of the whole process of manufacturing ocular prostheses. How they are made and what are the pain points during the process. Using these, choices can be made on what to focus on for the design.

The 10 prostheses Jelmer uses a lot for fitting might be a good start for 3D-modeling. Being able to select a model and editing its digital twin could be a good start for the design of a prosthesis.

The patient is only present a handful of times. In Jelmer his process even less then as the process in literature where the patient is also present during the painting phase. On the one hand it is convenient for the patient to have to spend as little time as possible at the ocularist. On the other hand, this interaction between patient and ocularist may be a major factor in the patient's fate that he will receive a good prosthetic eye. Human interaction between patient, ophthalmologist and ocularist must be taken into account when implementing digital production. Due to the dynamic of the socket and soft tissue the ocularist service does not stop after delivery of the eye.

When considering implementation of digital production, these factors should be kept in mind. No matter how good the design of a ocular prosthesis may be, it will probably have to be repaired, adjusted or even discarded. Solutions which make these decisions easier or cheaper will be most attractive to ocularists.


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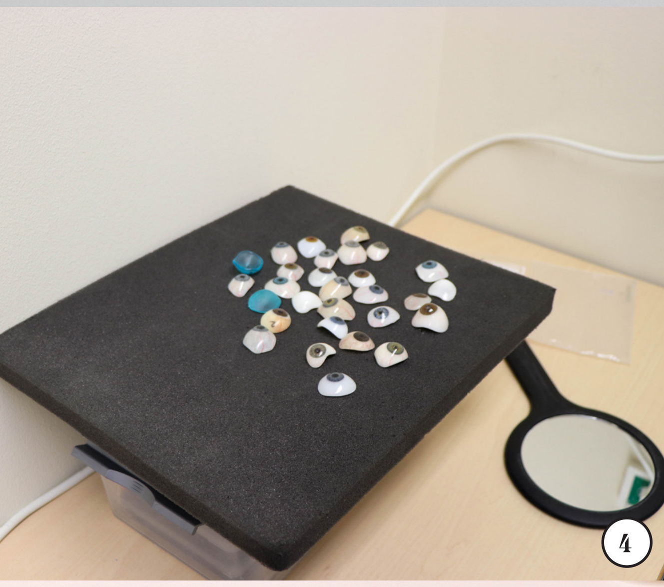
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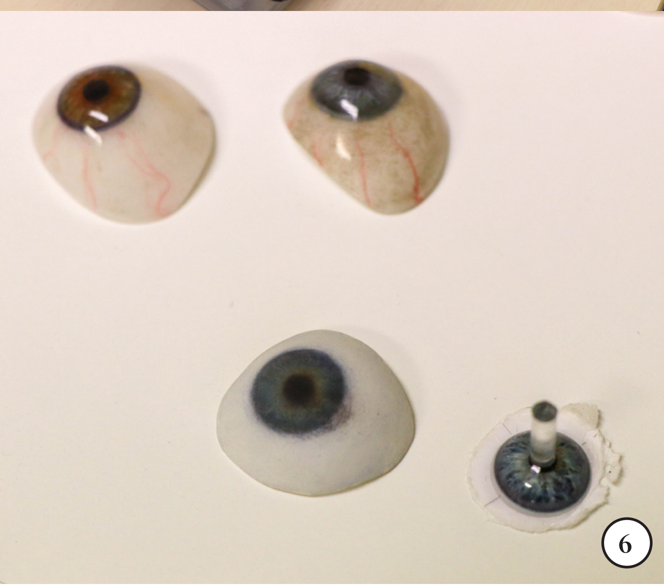
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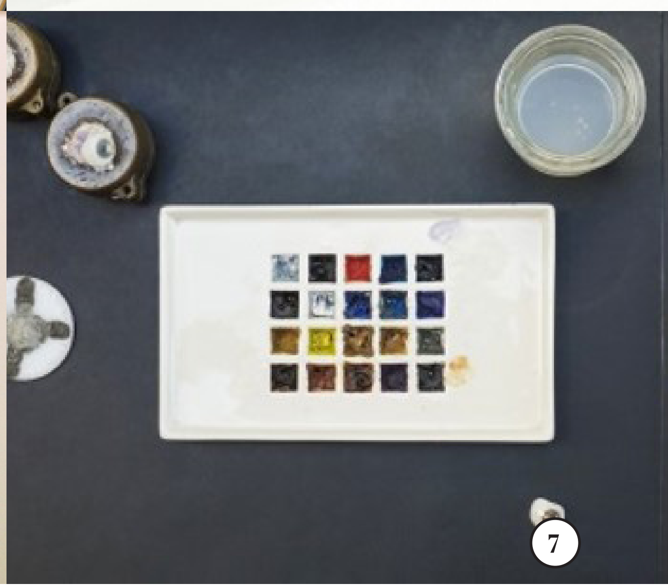
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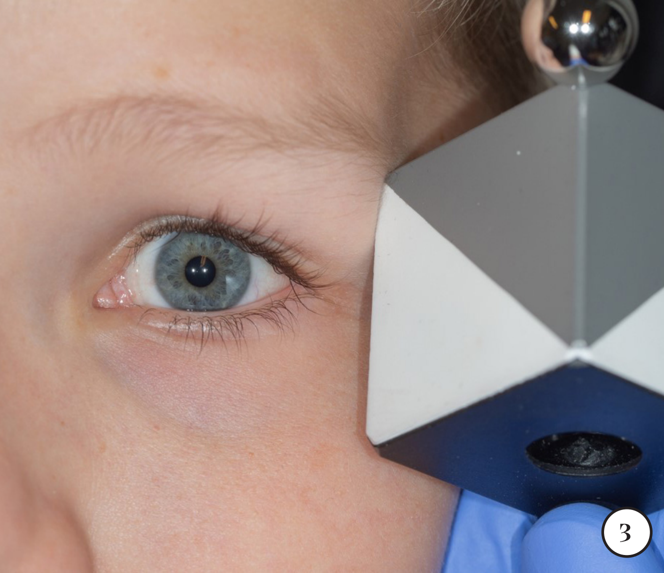
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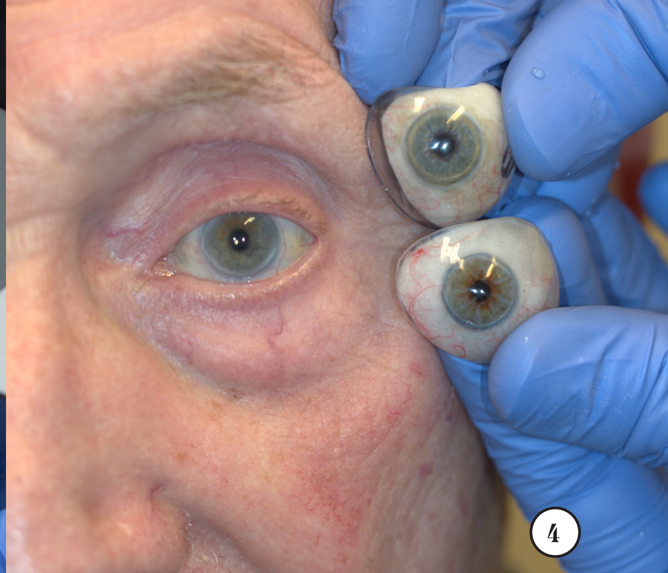
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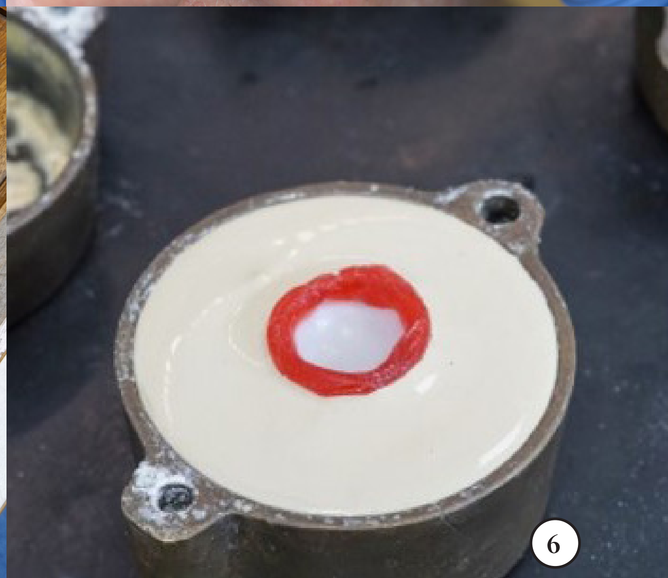
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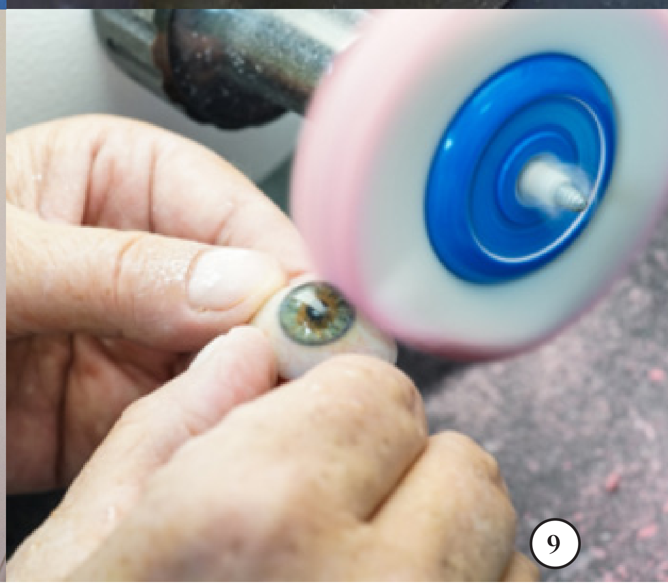
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8.3 Appendix B

Rating form 3D-prints

Please evaluate the samples you received on the aspect listed below. Think about your own performance and the eyes made by hand by yourself. Reflect upon this with the help of the points below.

Try to think about to what extent the 3D printed samples match the current handmade eyes. Look for improvements or opportunities

Use a separate form for each sample

Ratings

	Very dissatisfied	A little dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
How do you feel about the smoothness or the level of detail in the 3D-print?	○	○	○	○	○

	Very dissatisfied	A little dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
How do you feel about the geometry of the socket side (backside) of the prostheses?	○	○	○	○	○

	Very dissatisfied	A little dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
How do you feel about the geometry of the corneal side (front) of the prostheses?	○	○	○	○	○

	Very little	Little	Some	A fair amount	A great deal
How much did you feel the addition of a cornea adds to the prostheses?	○	○	○	○	○

	Very dissatisfied	A little dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
How satisfied are you with the final result?	○	○	○	○	○

In general:

- What do you feel went well?
- What do you feel went less well?
- What would you do differently next time and why?
- What do you think about the weight?

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DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

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Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy". Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: Mulder
initials: JA given name: Jelmer
student number: 4440498
street & no.:
zipcode & city:
country:
phone:
email:

Your master programme (only select the options that apply to you):
IDE master(s): ★ IPD | DfI | SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: Honours Programme Master
specialisation / annotation: Medisign | Tech. in Sustainable Design | Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Daan van Eijk dept. / section: HCD
** mentor: Joris van Dam dept. / section: SDE
2nd mentor: Jelmer Remmers
organisation: Jelmer Remmers Ocularist
city: Grou country: the Netherlands

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Daan van Eijk date 03 - 06 - 2022 signature

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 36 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 30 EC

List of electives obtained before the third semester without approval of the BoE

★ YES all 1st year master courses passed

NO missing 1st year master courses are:

name C. van der Bunt date 13 - 06 - 2022 signature C. van der Bunt Digitally signed by C. van der Bunt Date: 2022.06.13 09:55:30 +02'00'

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: ★ APPROVED NOT APPROVED

Procedure: ★ APPROVED NOT APPROVED

comments

name Monique von Morgen date 21 - 06 - 2022 signature

Initials & Name JA Mulder Student number 4440498

Title of Project Creating ultra-personalized ocular prosthetics using 3D-modelling

Creating ultra-personalized ocular prosthetics using 3D-modelling — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 01 - 06 - 2022 | 01 - 11 - 2022 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

In the Netherlands roughly 20.000 people wear a prosthetic eye, as a consequence of losing their eye due to an accident or disease. These prosthetic eyes are created by highly-skilled ocularists, through a very labor-intensive manual production process. Prosthetic eyes are a cosmetic addition and can help the appearance of these patients and five them back a sense of identity. It can help patients feel whole again. It is very personal for most patients who have a prosthetic eye. They don't want people to know you have one. There is an urge to appear normal and feel yourself, despite the disability.

The Amsterdam University Center (AMC), consisting of doctors, researchers and ocularists, have developed a proof of concept, integrating 3D scanning digital modeling and 3D printing to digitize the process of making a prosthetic eye*. Using common open-source techniques they were able to 3D-print an prosthetic eyes with a textured and colored iris and sclera using an polyjet 3D-printer. This way an prosthesis can be made in 4 hours, reducing labor time compared to conventional methods. 3D printing can offer many benefits including easy reproduction, customization and adaptability. Every patient needs a new eye approximately every two years due to changes in their physique. This means that new prostheses need to be made, computer aided design (CAD) could assist is this process.

The next steps which are stated in the research paper are optimizing the workflow, including optimizing the capturing and reproduction of the eye's appearance, and automatic generation of a fitting and comfortable shape for the prosthetic. Using generative design even faster results can be achieved. Making sure the eye fits right now takes a lot of trail and error. Research in this is very much still in it's early phase so effort is needed in order integrate these technologies into the process of creating an ocular prosthesis.

Important aspects of the prosthetic are if it looks good, if the color is correct and if the eye has motility, so if it can move in the direction where the patient is looking. Motility can be handled by good surgical procedure.

The stakeholders important to this project are:
an ophthalmologist, a doctor who performs ocular surgery.
an ocularist, an expert who fabricates fake prosthetic eyes.
the patient, a person with and ocular prosthesis.

*Groot, A. L. W., Remmers, J. S., & Hartong, D. T. (2021). Three-Dimensional Computer-Aided Design of a Full-Color Ocular Prosthesis with Textured Iris and Sclera Manufactured in One Single Print Job. 3D Printing and Additive Manufacturing(6), 343–348.

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introduction (continued): space for images

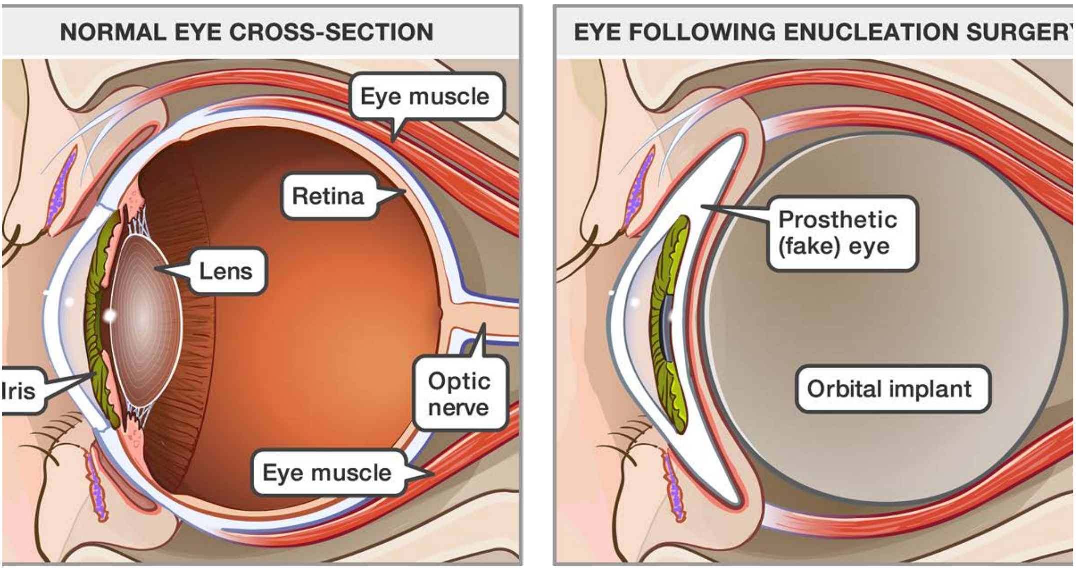

image / figure 1: Comparison between an healthy eye and and a prosthetic eye

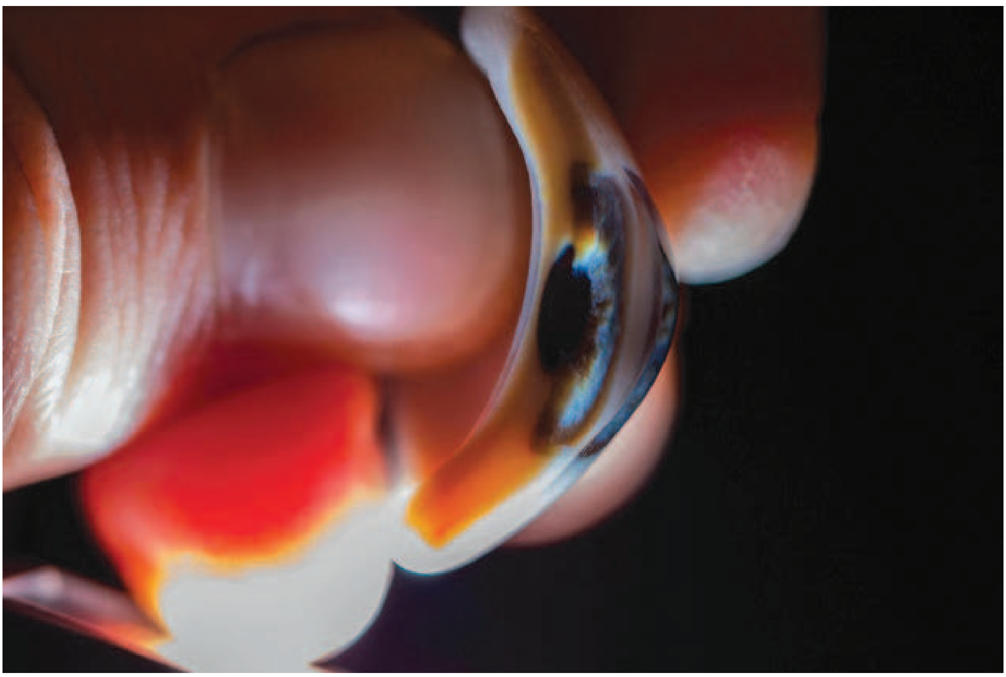

image / figure 2: One of the researchers holding a cross section of the 3D-printed prosthesis.

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

As pointed out by the ocularist, one of the most challenging areas in fabricating the ocular prostheses is the fitting and the shape of the prosthetic. Because everybody is unique and everybody's eyes slightly differ, every prosthetic is also unique. That is why there is a need for ultra-personalized ocular prostheses. Every two years a new prostheses is needed. During my graduation I want to focus on using generative design in order to create an new workflow of creating an ocular prostheses.

So: How can technologies such as 3D-scanning, 3D-printing and generative design be used in order to effectively create an personalized ocular prostheses.

Subquestions:
1. How does the current process of creating and fitting an ocular prostheses work?
2. How can generative design take a role is this?
3. Which technologies are best suited for a new 3D process?
4. How do you handle bio compatibility?

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

To research/design a new process of creating an ocular prosthesis using three dimensional computer aided design and generative 3D modeling.

My focus will be on the geometry of the eye. Capturing, modeling and reproduction. Implementing technologies such as Rhino grashopper, 3D scanning and 3D printing using an polyjet printer.

The result of the thesis will be a new process for the fabrication of prosthetic eyes grounded by research on generative design the current workflow and tested using prototypes.

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PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 1 - 6 - 2022   1 - 11 - 2022 end date

The analysis will consist of a few different steps starting with literature research about ocular prosthetics. I want to know what the current state is of the technologies and practices. Next I want to find out what the cultural perception is of people who have prosthetics, the history behind them and how they feel about it. This is achieved by interviewing patients on their experiences.

Next I want to analyse the 3D-data provided by the ocularist and map the whole process he goes through when fabricating an ocular prostheses. Find relevant technologies in the field of 3D scanning, 3D printing and generative design and find out how this can be implemented into the current practice. On my midterm I will finish with an analysis on the implementability of generative design and an envisioned journey map on the procedure on how to handle 3D fabrication. I'll be gone on vacation for two weeks after which I will spend my time on developing and experimenting with an 3D modeling workflow. Then prototyping using a polyjet 3D printer and finally testing (if the medical committee agrees).

During the academic break I will be working 4 days a week and otherwise 5 days.

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MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I enjoy using 3D modeling programs and I use them for my studies but also for my own company where I make product visualizations.

Generative modeling is something that always interested me but I never had the change to work with. This would be a good opportunity to learn that.

3D printing is something I am very competent with and I think that using this technology in this way can really help the lives of a lot of people. I believe that a project like this can have an real impact on the wellbeing of others.

I would like to learn on how to set-up and conduct such a research project in technology and to translate that into tangible solutions.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

The project will be done partly in collaboration with colleague Ilse Calis. Her research will be focusing on the appearance of the prosthetic. The final goal is to combine our findings.