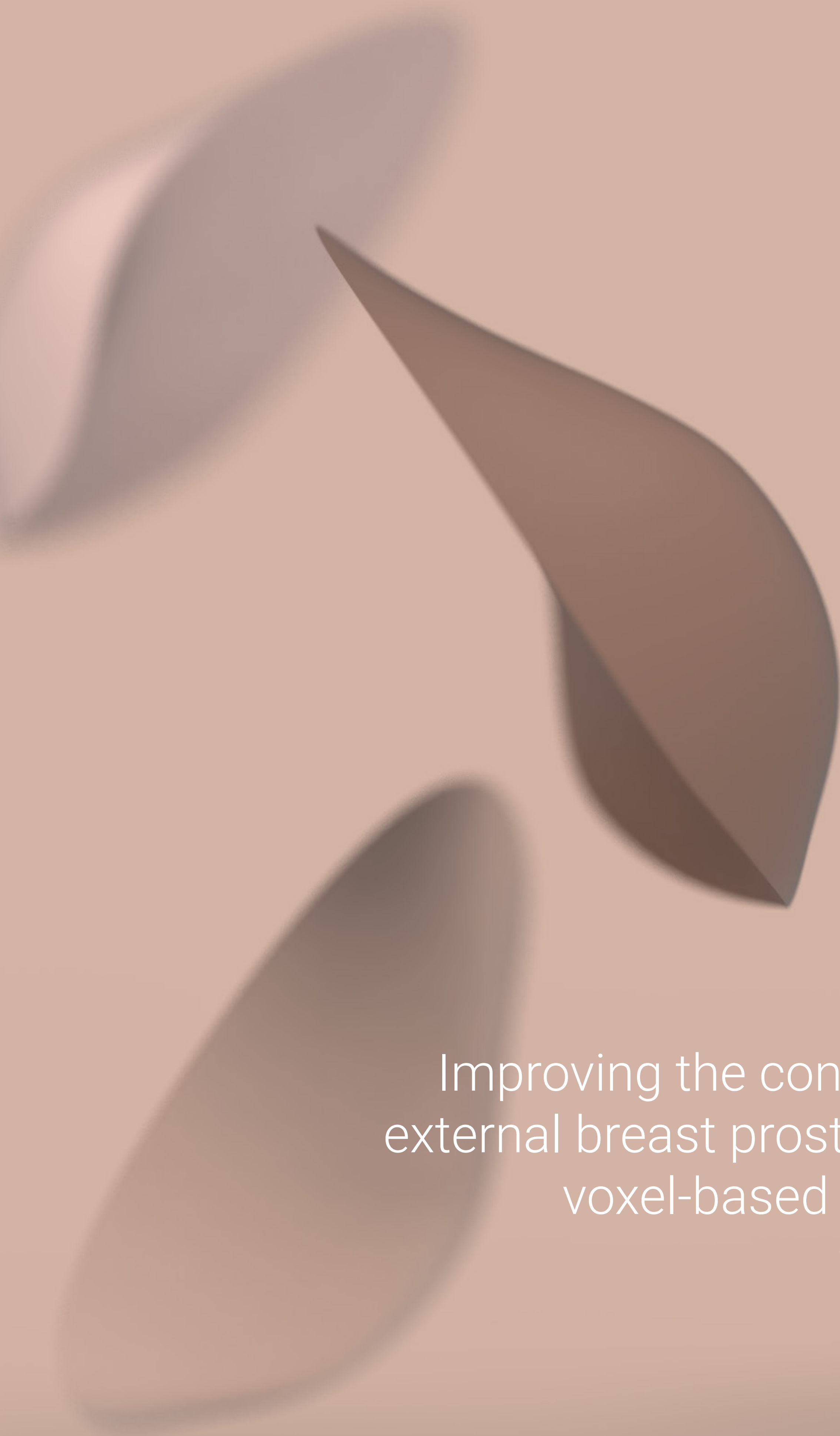
MSc. Integrated Product Design - Thesis
Faculty of Industrial Design Engineering
Delft University of Technology

TU Delft



Improving the consistency of external breast prostheses with voxel-based 3D printing

Yuka Reinoso Hayashi

Master Thesis
MSc. Integrated Product Design
Faculty of Industrial Design Engineering
Delft University of Technology

July 07, 2023
Yuka Reinoso Hayashi
5621593

Chair
Dr. ir. Doubrovski, E.L. (Zjenja)
Faculty of Industrial Design Engineering

Mentor
Dr. Kermavnar, T. (Tjaša)
Faculty of Industrial Design Engineering

Special thanks to
MSc. Dam, J.J.F. van (Joris)
Participating interviewees
Perfect Again Breast Forms
Borstkankervereniging
Cancer Research UK

TU Delft

Abstract

Eighty percent of women after mastectomy wear an external breast prosthesis either permanently or during the period before breast reconstruction. External breast prostheses replace the removed breast and aim to recreate the original body shape. However, while each woman has a different chest wall and scar topology, most commonly used are standard commercial prostheses, which often fail to provide comfort and symmetry to the wearer.

Given the risks and costs associated with elective reconstruction surgery, women who decide to use external breast prostheses should be offered options that are as well developed as their surgical alternatives.

This project envisions an external breast prosthesis design method that allows the efficient manufacture of personalized forms. 3D scanning and 3D printing are suitable techniques to create solutions tailored to each person's necessities. 3D scanning allows having a digital twin of the chest wall topology that helps create the geometry that perfectly matches an individual woman. 3D printing, on the other hand, eases the fabrication of patient-specific products. For this reason, this project considers 3D printing as a suitable technology for the production of personalized external breast prostheses.

Research has been conducted with breast care experts and women after mastectomy to explore the pain points associated with existing external breast prostheses, which helped identify several design opportunities. This project aims to achieve a specific main goal: To provide a realistic consistency of external breast prostheses to touch. Current solutions tend to be too stiff and hard, which makes them uncomfortable for the user.

Polyjet 3D printing offers the possibility to print with rigid, flexible, liquid, and gel-like materials. Furthermore, owing to the droplet-based working principle of this technology, it is currently possible to mix different materials with full control of the proportions and the design of the material distribution droplet by droplet. This allows achieving a mixture that works as a homogeneous material at a macroscopic scale and having tailored mechanical properties. This project approaches the challenge of external breast prosthesis redesign by exploring the possibilities and limitations of voxel-based Polyjet 3D printing; specifically, the different mixtures of liquid and gel-like materials encapsulated in an outer cover made with flexible material.

Extensive prototyping is performed throughout the project and compression tests are conducted to obtain quantitative data regarding the softness of prototypes and its similarity to a natural breast. Besides the objective information obtained from these tests, a user evaluation is conducted with ten participants to compare the objective data with human perception, which is ultimately more relevant for this topic due to the subjective nature of tactile experiences.

Preface

This research is conducted as part of my MSc. Integrated Product Design Thesis, within the academic context. Over the course of five months, I dedicated myself wholeheartedly to this work. The objective of this research is to initiate an improvement in external breast prostheses, ultimately enhancing the quality of life for their users.

I extend my appreciation to all the women that participated in this research. I am thankful to the experts for sharing their knowledge and giving advice. I am also grateful to organization managers for helping me reach participants. And most importantly, my deepest gratitude to all the women that use external breast prostheses and believed in this project. They shared their personal experiences with me and are the core of this project. Their positive and grateful attitude inspired me to give my best. This research is dedicated to them.

Despite the initial stage of this project, I view it as a significant first step towards improving external breast prostheses with 3D printing. I do believe in the potential of this project and honestly envision a future in which breast prostheses are personalized for each woman.

This research presented many challenges, both technically and personally. I faced many moments of powerlessness, but the purpose of this research kept me always determined to overcome any difficulty. My supervisors Zjenja and Tjaša always supported me in this and guided me through the process that has allowed me to provide the best result I could.

I gained experience in voxel-based 3D printing and material testing. Additionally, I developed the skills necessary to create a comfortable environment for women to share their experiences during sensitive interviews. I was able to integrate technical and human aspects in a project that is significant to me. In the future, I hope I can keep applying this integration to design. All I learned in this project exceeds by far my expectations. It energized and inspired me.

As you, reader, go through this research, I hope it evokes the same energy and inspiration I experienced during the project.

MSc Integrated Product Design - Thesis

Content

MSc Integrated Product Design - Thesis

1

Introduction & background

This research aims to improve the consistency of external breast prostheses using multi-material 3D printing. The goal is to present the embodiment of an infill that integrates opinions and perspectives of current prostheses users.

The project analyzes the use women do of these prostheses, finds points for improvement, and envisions an enhanced satisfaction of the users. These interactions are translated into physical properties that are sought through prototyping iterations.

External breast prostheses play an important role in the lives of women after mastectomy, as they affect their mental journey after the surgery. The psychological and physical effects such prostheses have on the users have been broadly researched by investigators, together with how their acceptance has been deeply influenced by the cultural and social context.

While the design of most external breast prostheses focuses on either providing a good fit to the woman's torso, or on having a very realistic look by matching the shape and colors of both the body and the nipple of the wearer's remaining healthy breast, aspects like their feeling to touch or reaction to movement have been neglected. This graduation project explores the needs and desires current external breast prostheses do not meet and proposes an improvement that can be implemented with Polyjet 3D printing.

Additive manufacturing using multi-material jetting (hereinafter referred to as "Polyjet 3D printing") allows for the use of a broad range of flexible materials, as well as experimenting with gels and liquids. Exploring different combinations of materials, geometries, and transitions can lead to a 3D-printed solution that provides external breast prostheses with an improved performance.

Knowledge about breast anatomy and physiology, external breast prostheses, and Polyjet 3D printing necessary for this project is explained in the following paragraphs.

BREAST ANATOMY AND PHYSIOLOGY

The adult female breast is a conical or teardrop shaped gland that sits over the second to sixth or seventh ribs, and contains from 15 to 20 lobes that are radially distributed. These lobes are subsequently composed of several lobules (McGuire, 2019). The lobes are linked to the nipple by lactiferous ducts, and the areola, a pigmented skin region, surrounds the nipple. The spaces between the lobes and ducts are filled with fat. Muscles are located under each breast and cover the ribs.

Anteriorly, the breast extends from below the clavicle to the sixth rib; and laterally, it extends from the sternum into the axilla. This axillary fat pad is known as the "tail of Spence". The superior part that extends from the clavicle to the nipple is known as the upper pole, and the inferior part below the nipple is known as the lower pole (Gabriel & Maxwell, 2020).

In addition, each breast contains blood vessels, as well as lymphatic vessels that lead to small, bean-shaped organs known as lymph nodes, which are found in clusters under the arm, on the collarbone, chest, and other parts of the body (a representation of the breast anatomy can be seen in Figure 1.1). The primary function of the female breast is lactation, which includes the synthesis, secretion, and ejection of milk.

EXTERNAL BREAST PROSTHESES

An external breast prosthesis (EBP) is a synthetic breast that can be directly attached onto the skin or worn inside a bra pocket (Cancer Council NSW, 2020). It replaces the breast removed during mastectomy and intends to recreate the woman's original physical appearance. It is presented in a broad range of materials, shapes, weights, and attachment methods that are explained in the *Problem definition* section.

POLYJET 3D PRINTING

Additive manufacturing processes are fabrication methods that build three-dimensional objects by adding materials layer by layer. A Computer-Aided Design (CAD) contains the geometry that is approximated by triangles when converted into a Standard Tessellation Language (STL) file. This STL file is then sliced, containing the information of each layer that is going to be printed.

The main advantages of additive manufacturing lie in the reduction of time, cost, and human interaction. As compared to subtractive manufacturing, it offers the possibility to build almost any geometry that could be difficult to machine (Wong & Hernandez, 2012). It also offers the possibility to print different geometries with no additional cost associated with it, which presents the main advantage of using additive

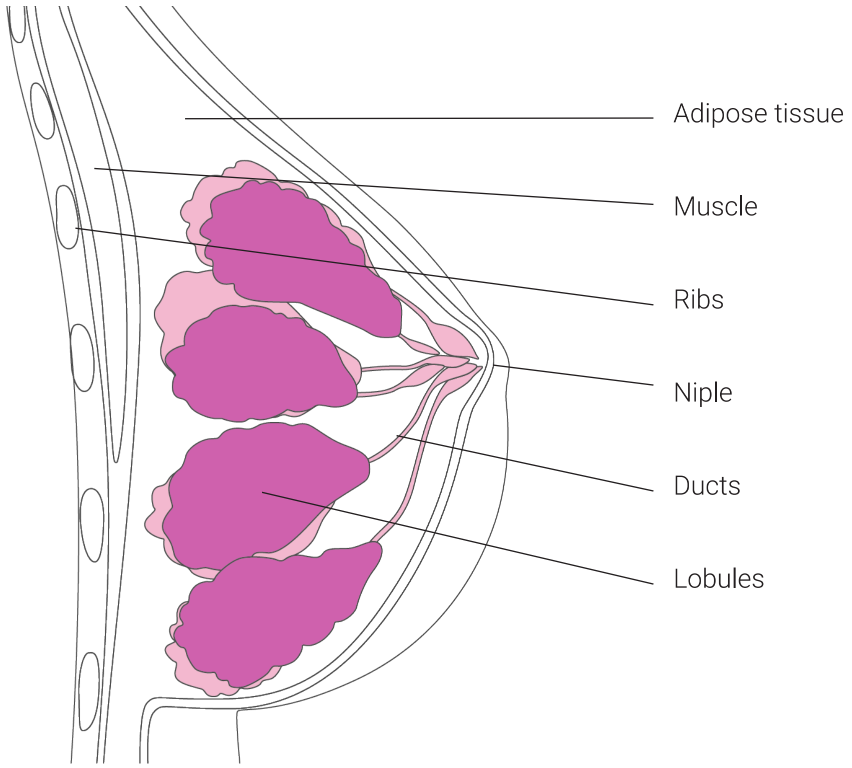


Figure 1.1. Anatomy of a breast.

MSc Integrated Product Design - Thesis

manufacturing to produce EBPs. The shape of the prosthesis can be personalized for each woman's scar topology with the help of 3D scanning and reverse engineering.

Additive manufacturing technologies can be classified according to their base material as shown in Figure 1.2 (Wong & Hernandez, 2012).

Polyjet 3D printing is one of the liquid-based, photopolymerization techniques. It uses multiple inkjet heads with nozzles that deposit concurrent droplets of photocurable material. Because each inkjet head can have a different material assigned, it is possible to print objects that combine up to six different materials, each of which can have different mechanical and visual properties. Each droplet of the corresponding material is deposited following a design geometry (Hayes et al., 2022). A roller levels each layer and removes the excess material. Simultaneously, ultraviolet (UV) light cures the material, hardening each deposed layer and forming the final part (Mora et al., 2022).

Because this technology deposits individual droplets, it is always necessary to use support material. When this material is not defined in the design as part of the component that is being printed, the printer will use a gel-like material as support. This gel can be removed once the printing process finishes.

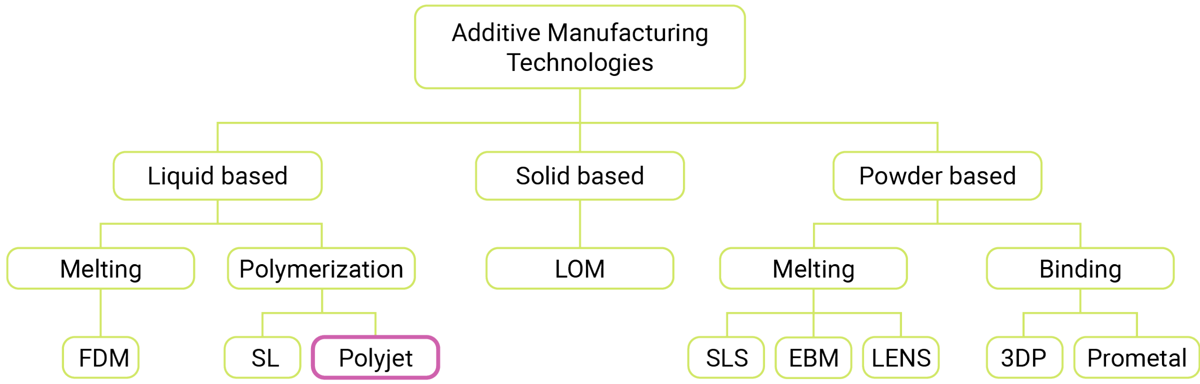


Figure 1.2. Three-dimensional printing processes classification according to Wong & Hernandez (2012).

2 Project scope & structure

PROJECT SCOPE

This project contributes to the fields of external breast prosthesis design and additive manufacturing. It explores the possible areas for improvement of current breast prostheses by exploring the existing pain points in user experience. It investigates the relevance of these aspects and sets priorities to the sought qualities based on their importance and practicality within the academic scope of the research. In the end, a solution that improves the performance of existing prostheses is proposed.

In the digital manufacturing field, the characterization of different material combinations, including flexible materials, liquids, and gels, is researched, tested, and explained. The physical perception of the prototypes is evaluated and used for further iterations to produce a solution that resembles the consistency and specific position and movement-related aspects - based on the insights from user research - of natural breast tissue.

PROJECT STRUCTURE

This project combines research conducted in two different fields; therefore, two different approaches are used. On the one hand, research is conducted into female users' personal experience with EBPs to define existing problems and formulate a design challenge. This research employs a context-driven, user-centered approach. It analyzes the current use and envisions a future one that is achieved through specific product qualities.

On the other hand, research is conducted in the digital manufacturing field, developing prototypes and iterations towards the goal formulated in the design challenge. The product qualities defined in human research are the drivers of several prototyping sessions. The first half of this research is exploratory, while the second half is narrower and aims to improve the results obtained in the first part following a specific direction. Relevant opportunities and design limitations of Polyjet 3D printing are explained throughout the report.

MSc Integrated Product Design - Thesis

3 Methods

The structure of the problem definition and the design challenge formulation related to human aspects follows the workflow outlined in the Vision in Product Design (ViP) method proposed by Hekkert and Van Dijk (2016). The Problem definition section explores current breast prostheses, the interaction users have with them, and how these interactions are affected by the context. After this, in the *Design challenge* section, the envisioned interaction is presented and the product qualities that are sought for this are explained. The specific steps of this methodology have been slightly modified to suit this project. An overview can be seen in Figure 3.1.

To define the problems current external breast prostheses present, three different areas are studied:

THE CONTEXT

The socio-cultural contextual situation where these prostheses currently are.

EXTERNAL BREAST PROSTHESES

The different types of prostheses and their relevant aspects.

WOMEN'S USE OF EXTERNAL BREAST PROSTHESES

It presents how this use occurs, the physical and psychological reaction, perception and opinion of women towards breast prosthesis. In this subsection, the problems, pain points, and areas for improvement are explored.

While the context and the existing types of prostheses are mainly explored through literature research, the interaction requires further methodologies. For this reason, in addition to literature research and extracting women's personal experiences from online blogs, meetings, interviews, and a survey were also conducted.

While the survey targeted specifically women after mastectomy with experience using EBPs, the interviews and meetings also targeted breast surgeons, breast care nurses, prosthesis fitters, and other professionals with related backgrounds.

Meetings were conducted with the following breast professionals whose names are not mentioned for privacy purposes:

- An expert in fit of wearable items and body shape and size data. She conducted her PhD research at the Delft University of Technology (TU Delft) in the context of a project titled "A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer" (Veitch, D., 2019).
- Two breast reconstruction surgeons.
- A breast prosthesis fitter at *Demagneet Lingerie*.
- The owner and founder of *Perfect Again Breast Forms*.
- A PhD Researcher EmmaJude Lyons and her mentor Dr. Kevin O'Sullivan, who are researching the possibilities of 3D printed external breast prostheses in a collaboration between the Rapid Innovation Unit at the University of Limerick (UL), the Symptomatic Breast Care Unit at the University Hospital Limerick (UHL), and the Mater Private Network's Mid-Western Radiation Oncology Centre in Ireland.

Research with participants was conducted with women after mastectomy. Interviews were held with 4 participants, and a survey was conducted with 18 women. All human research was approved by the Human Research Ethics Committee on March 24, 2023 (code: 2889).

Interviews

PARTICIPANTS

Four female volunteers participated in online, individual, semi-structured interviews that took approximately 30 minutes. The participants were recruited through the Dutch breast cancer association *Borstkankervereniging*, (who reached out to patient advocates and provided the contact information of women interested in participating), and through *Perfect Again Breast Forms* (who reached out to their clients and provided the contact information of women interested in participating).

TOOLS AND PROCEDURE

All participants gave their written consent before the beginning of the interview (the Informed Consent Form can be found in *Appendix 02*). Notes were taken during the interview, and audio recordings were used to retrieve important information that was not written down. The interview explores the most commonly used types of prostheses, how women use and perceive them, and how they affect the woman's daily life. The questions asked during the interview can be found in *Appendix 03*. The insights are explained throughout the *Problem definition* section of the report.

Survey

PARTICIPANTS

Eighteen female volunteers participated in the survey. They were recruited through the publication of the survey on the *Patient Involvement* website of *Cancer Research UK*, through *Perfect Again Breast Forms* (who reached out to their clients and provided the contact information of women interested in participating), and publications on social media.

TOOLS AND PROCEDURE

The survey was constructed using Qualtrics under the license provided by the educational institution. No personally identifiable information besides age and date of mastectomy was collected. The survey took approximately 10 minutes to complete. All participants needed to provide their informed consent on the first page of the survey in order to be able to access the questions. The survey explores the most commonly used types of prostheses, how women use and perceive them, and how they affect the woman's daily life. The questions asked during the survey can be found in *Appendix 05*. The insights are explained throughout the *Problem definition* section of the report.

The design and embodiment phase of this project followed a double-diamond structure (Figure 3.2). The process started with literature research that soon integrated exploratory prototyping and testing.

To evaluate consistency-related aspects of the prototypes, the "breast model number 3" from Dr. Daisy Veitch, who during her PhD developed six breast models for medical training to teach how to detect tumors through tactile examination, is used for comparison. This prototype (Figure 3.3) offers a medium breast consistency. This means it is in the middle of a soft breast-hard breast range. As this model is used for medical training purposes, the accuracy of its consistency is total, and therefore appropriate as a reference for this project. Both the exploratory and the conclusive research phases are

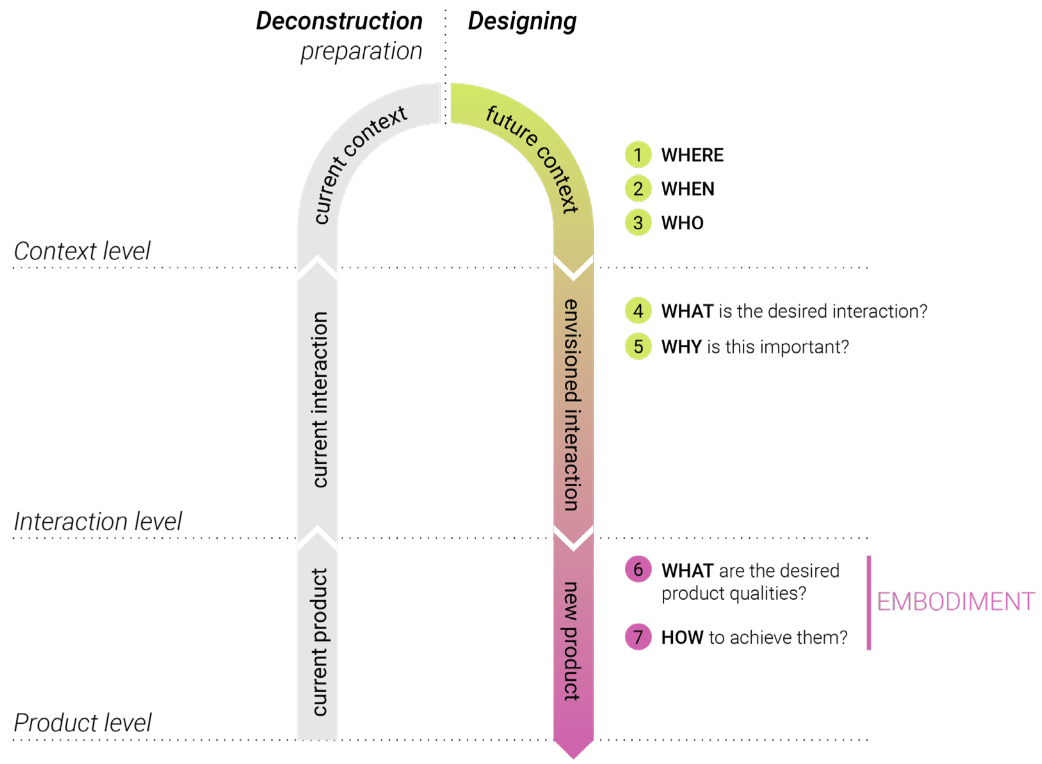


Figure 3.1. Method followed for the problem definition and the design challenge formulation phases of this project (based on Hekkert & Van Dijk, 2016).

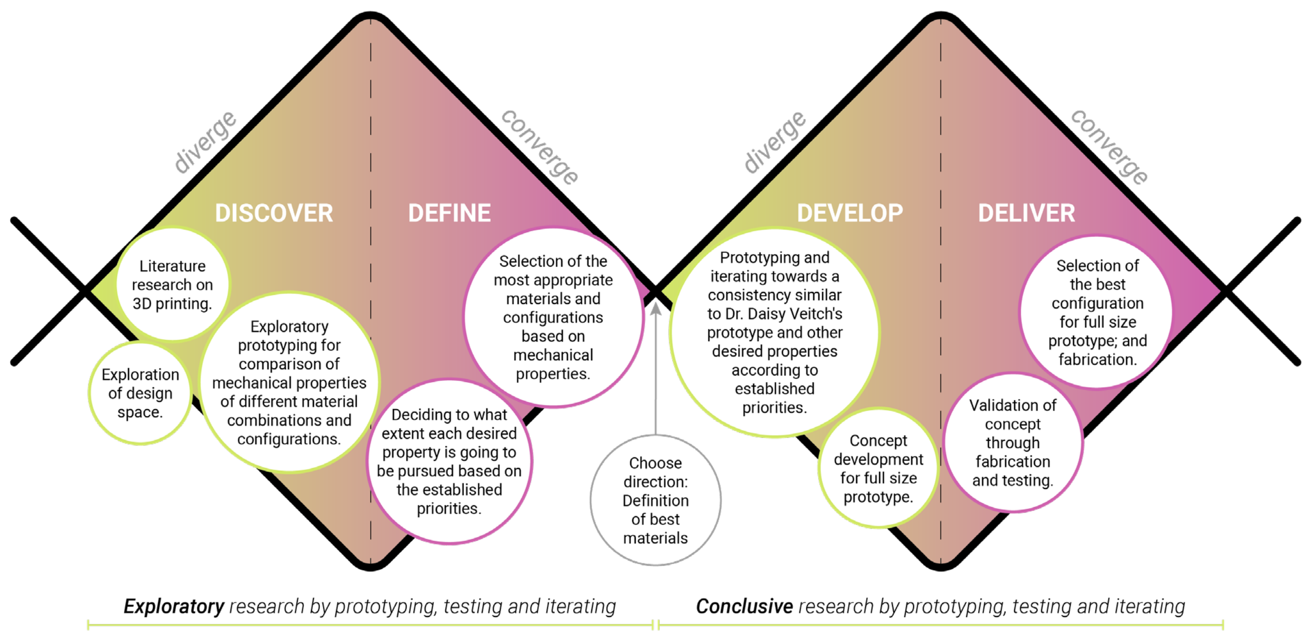


Figure 3.2. Structure and methodology followed in the design and embodiment phase of the project.

Figure 3.3. Breast model number 3 for training for tumor detection through tactile examination. Developed by Dr. Daisy Veitch in her doctoral thesis: A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer: Detecting Breast Disease using Palpation (Veitch, D., 2019).

explained in the *Design and embodiment* section.

For the evaluation and validation of prototypes, several compression tests were performed, where both prototypes and the reference model were subjected to the same force and their deformations were compared. Besides these objective tests, an evaluation with participants was also conducted. The objective of performing user validation was to understand whether the results obtained from the compression tests actually match people's perception. This was key, as the objective of improving the consistency of EBPs was for women to feel tactile similarity to a real breast, regardless of numerical results. The specific methods, tools, and setup of the validation user test are explained in the *User evaluation* section.

MSc Integrated Product Design - Thesis

4 Problem definition

Context

At present, breast cancer is the most common cancer in women worldwide, contributing to approximately one-quarter of the new diagnosed cases and reaching up to 2.26 million women in 2020 (WCRF International, 2022).

Of the women diagnosed with breast cancer, around 36% get a partial or total mastectomy (Fefferman et al., 2023). After the mastectomy, approximately 80% of women wear an EBP either permanently or during the period they wait for breast reconstruction (McGhee et al., 2020). The EBP replaces the removed breast and aims to recreate the original body shape.

Currently, some of the physical properties of these prostheses are far from meeting the needs and desires of the users, creating both physical and mental problems. Some personalized designs focus on offering a good fit to the woman's torso - by scanning the torso and recreating the shape of both the body and the scar - and/or a very realistic look - by matching the shape and colors of the body and the nipple to the remaining breast. However, most women opt for standard EBPs due to economic reasons, as in the Netherlands commercial alternatives are offered by the insurance every two years. In the desboth, personalized and standard EBPs, many other aspects like their feeling to touch (Maillo et al., 2020), adaptation to the woman's body position, temperature and humidity control, the prosthesis' reaction to the woman's movement, or good skin contact have been largely neglected.

External breast prostheses

Breast prostheses can be made of different materials, have different shapes, and offer different ways to be worn. Depending on these aspects, they offer varied physical properties that make them more suitable for specific women and activities. An overview of the types of external breast prostheses is presented in this section.

MATERIALS

Most prostheses are made of soft silicone gel encapsulated in a thin film. The silicone is whisked to incorporate air within the material, which gives it a soft consistency and makes it lighter. Then, it is molded to resemble the geometry of a natural breast or part of it, and might include a nipple outline (Types of Breast Prosthesis | Breast Cancer Now, 2022).

EBPs can also be made of cotton, foam, filled with polypropylene beads, or have an air chamber that can be adjusted by the user to ensure good fit and skin contact. Cotton prostheses are a lightweight alternative, while the foam and the polypropylene beads alternatives offer ventilation thanks to the air that can circulate through them as their biggest advantage (Been-a-Boob Beaded Breast Form (BABH), 2022). Having an air chamber is appropriate for women with more uneven chest walls (Cancer Council, N.S.W., 2020).

SHAPES

As happens with materials, prostheses are offered in a broad variety of shapes. They can be symmetrical - meaning that they can be worn either on the right or the left side -, or asymmetrical - which are more suitable for women who had a bigger amount of tissue removed, as they commonly include extensions to fit the upper chest or the area under the arm, and are therefore made for either the right or left side specifically. They can also have the shape of a teardrop, which is more appropriate for women whose breasts are fuller in the lower part and less full above the nipple (Types of Breast Prosthesis | Breast Cancer Now, 2022).

WEIGHT

Silicone prostheses are offered in different weights. A full-weight prosthesis matches the weight of the remaining breast and is designed to make the woman feel more balanced. Yet, if the breast is very big, this weight might be excessive. In these cases, it might be more suitable to wear a lightweight alternative. However, a common disadvantage of lightweight prostheses is that they can easily ride up, preventing them from being aligned with the other breast (Types of Breast Prosthesis | Breast Cancer Now, 2022). The importance of choosing a prosthesis with the correct weight is explained in the following subsection.

ATTACHMENT

A breast prosthesis is normally worn inside the pocket of a specialized bra. However, it is also possible to wear it simply by placing it in the cup of a normal bra. A less common alternative offers an adhesive inner surface that can be attached directly to the chest wall.

An overview of the different types of breast prostheses can be seen in Figure 4.1.

3D printed external breast prostheses: Overview

Maillo et al. (2020) 3D printed EBPs using thermoplastic polyurethane (TPU) filament in an Ultimaker FDM 3D printer. They decided to use this material due to its high elasticity, which they predicted would provide the softness sought in an EBP. They claimed their printed prosthesis to be similar in flexibility to traditional models and to be lightweight, as they reduced the weight to less than one third of their corresponding silicone full-weight alternative. While their design was considered comfortable, lighter, and less limiting regarding clothing choice, two of the three surveyed participants agreed that it did not feel natural enough to touch. This research suggests improving consistency as an evolution of their work.

Cruz et al. (2018) also intended to create a 3D-printed EBP with a realistic consistency following a biomimetic approach in which they followed a circular arrangement of cones that became bigger the closer they were to the back side of the prosthesis. They built a rapid prototype using acrylonitrile butadiene styrene (ABS) to ensure that it could be manufactured simply and economically.

Figure 4.1. Overview of the types of external breast prostheses (Cancer Council, N.S.W., 2020; Basko Healthcare, n.d.; Borstprotheses | LingerieService Marieke Vermaas, 2017; De Magneet Lingerie, 2023; Your Rules Prosthetics, n.d.; Amoena Nederlands | Amoena Lingerie, Badmode, Borstprothesen, Prothesen & Mastectomy Wear, n.d.; Mastectomy Bra and Post Surgery Bra Specialists - Nicola Jane, n.d.; Mastectomy Bras, Prosthetic Bra & Breast Forms | Mastectomy Shop, n.d.; Prothèse De Sein Externe Après Un Cancer À Nice, 2023).

Afterwards, their evaluation was made through a simulation using Finite Element Analysis, where they tested the deformation of the prosthesis in different body positions. Following this method, they achieved the expected deformations, which they claimed to be natural. Having a physical prototype that proves this deformability would have been very beneficial, especially considering the impact that both the manufacturing technique and small variations in features can have on the overall performance.

Helguero et al. (2021) modeled a personalized EBP using 3D scanning and built it with photopolymerization 3D printing. Their main objective was to offer greater skin contact than standard marketed alternatives to provide increased comfort, for which they created a personalized shape based on the scan of a mastectomized torso. They achieved a contact area six-times higher than what commercial options offer. The design of their prosthesis incorporated some curly tubes that provide flexibility and a solid interior, the diameter of which could be adjusted to match the desired weight. They evaluated the force that needed to be applied on the prosthesis to keep it attached to the body and the result was within the range that a standard bra can provide.

Finally, Emmajude Lyons and Dr. Kevin O'Sullivan are currently working on the development of 3D printed personalized external breast prostheses (see Figure 4.2). Using VAT polymerization with resin-based flexible materials, their main focus is on making the prostheses lightweight. They have three levels of customization in their designs: The front of the geometry, the back of the geometry, and the consistency. Their designs have an outer wall of 4 mm and host a lattice structure inside, whose voxel size is changed to modify the consistency. As a post-processing technique, they cover the printed prostheses with talcum powder to minimize stickiness of the material.

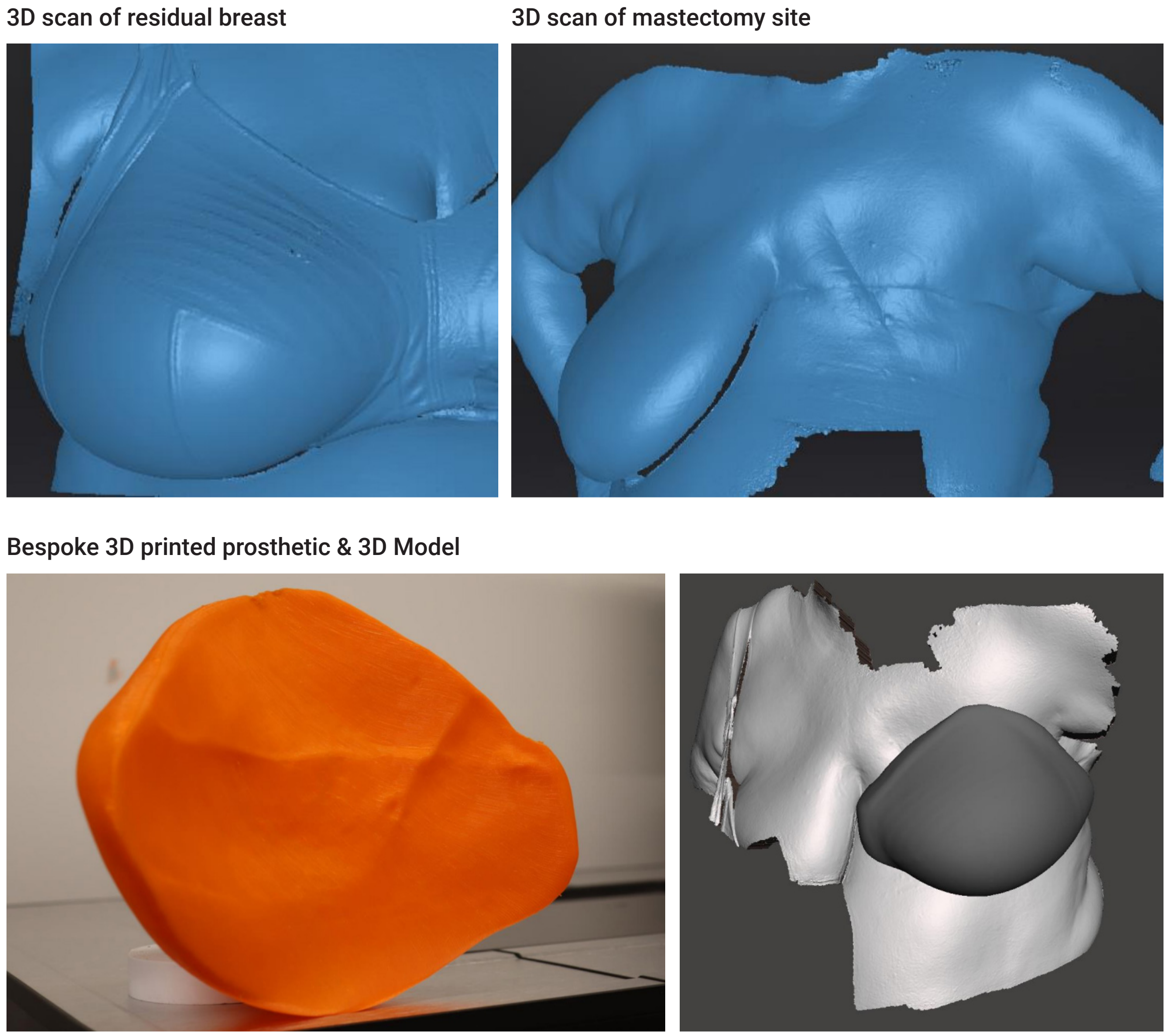


Figure 4.2. 3D printed external breast prosthesis developed by Emmajude Lyons and Dr. Kevin O'Sullivan.

MSc Integrated Product Design - Thesis

Use of external breast prostheses

The socio-cultural context creates an expectation of women that affects their psychological reaction after mastectomy and towards external breast prostheses. In this sense, the woman's cultural and social context cannot be separated from the personal mental journey she goes through.

Mastectomy causes a big change in the woman's body shape, which can cause a major effect on her self-image and decrease her sense of femininity (Roberts et al., 2003), leading sometimes to anxiety and depression (Jetha et al., 2017). External breast prostheses help to overcome this stress and improve her self-esteem (Jetha et al., 2017).

In the Western culture, the body image of an older woman is considered less important than that of a younger woman. However, women's femininity is not linked to age, but to gender (Jetha et al., 2017). This has been influenced by the symbolic link between breasts and sexuality, desirability, and affection that exists in this culture (Roberts et al., 2003), where breasts have been a universal symbol of womanhood (Reaby & Hort, 1995).

Aspects that contribute to a higher utilization of the prosthesis include higher level of education, living in a city, or being younger. In fact, younger and unmarried women tend to have more difficulty in adjusting after mastectomy, as compared to women of old age (Jetha et al., 2017).

External breast prostheses often have a very negative meaning attached to them. This is emphasized by the fact that they have to be worn and removed every day, and each of these actions can be experienced by the user as a reminder of the breast they lost (Jetha et al., 2017). The prosthesis is commonly perceived as a foreign object (Reaby & Hort, 1995).

Regarding the aspects that influence the satisfaction of women with their external breast prosthesis, Hojan (2020) classifies the age of the woman and the weight and size of the prosthesis as aspects that do not influence the woman's satisfaction. On the other hand, the time after mastectomy and the person that chose the prosthesis seem to be relevant factors. The more time it has been since the mastectomy, the more satisfied women are. In addition, women who chose the prosthesis themselves instead of having it chosen by a professional also experience higher levels of satisfaction.

However, there are inconsistencies regarding the relevance of the weight of the prosthesis. According to McGhee et al. (2020), 59% of women find full weight prostheses to be too heavy and report feeling pain and discomfort at the bra strap-shoulder interface. Moreover, women who wore a lightweight prosthesis reported higher overall prosthesis satisfaction. In addition, Hojan and Manikowska (2017) mention that 50% of women wear full-weight breast prostheses, while the other half opt for a lighter type. The fact that half of the women seek a lighter option gives additional indication of the importance of the weight.

Regardless of the influence of the weight on the overall satisfaction, it is also important to consider the needs from the health perspective. In the study conducted by McGhee et al. (2020), it was observed that decreasing the mass of the prosthesis only decreased the loading at the bra strap-shoulder interface when participating in locomotor activities, but not when standing still. They concluded that decreased loading did not decrease discomfort, nor perceived pressure. In fact, the erector spinae muscle activity on the mastectomized side and healthy side become significantly different after mastectomy. However, this imbalance was not affected by the weight of the prosthesis, meaning this weight does not contribute to posture changes in women after mastectomy (Hojan et al., 2016; Hojan & Manikowska, 2017). Healey (2003) also noted that there is no scientific evidence of skeletal misalignment or imbalance produced by non-weighted breast prostheses.

Although the weight of the prosthesis is not relevant from the health perspective, it is a relevant aspect in providing comfort and symmetry. According to the interviewed breast prosthesis fitter from *DeMagneet Lingerie*, the weight of the prosthesis should be just slightly lighter than the remaining breast. This is because when wearing the prosthesis in the bra pocket, the natural breast applies a force that pulls the bra following gravity. The breast prosthesis should balance this force to create symmetry. When the prosthesis is too light, it is pulled up by the bra and moved towards the center of the chest, resulting in an asymmetric shape. This phenomenon can be seen in Figure 4.3, where the image "a" represents the situation when using a full-weight prosthesis and the image "b" represents the situation when using a prosthesis that is too light.

Three of four women interviewed for this project pointed out that the weight of the prosthesis is one of the main reasons for discomfort. One of them mentioned that she could get used to it after a few months, but the other two needed to switch to lighter versions. The interviewed participants mentioned that the reason why the prosthesis should be lighter is that it is not directly attached to the body and therefore all the weight falls on the bra, which is then held by the shoulders. In addition, when one of the interview participants was asked about the phenomenon of a light prosthesis moving towards the center of the chest, she stated that only a slight displacement occurs, and the comfort gained by using a light version is worth this little asymmetry.

Six of the eighteen respondents to the survey mentioned that they felt pain in their shoulder, which is caused by the weight of the prosthesis. In fact, one of the participants in the survey, who used a full-weight silicone prosthesis, mentioned that it *"weighed down the bra on the affected side, causing a poor symmetrical finish under clothes. (...) The weight meant it would often fall out when bending forward and make that side of the body ache"*.

The bra plays a crucial role when choosing the right prosthesis for a woman, as the fitting process begins with selecting a bra that perfectly fits the remaining breast. The space created between the chest wall and the inside of the bra on the mastectomized side then defines the optimal shape of the EBP. This means that the shape is not defined by the remaining breast itself, but by the shape the remaining breast acquires inside the bra.

Whether the most suitable prosthesis should be symmetric or asymmetric depends on the shape of the healthy breast. If it is located mostly in the front part of the torso, a symmetric prosthesis might be suitable, while if it reaches far to the side of the torso as well, an asymmetric prosthesis might be more suitable. These insights were provided by the breast prosthesis fitter from *DeMagneet Lingerie*.

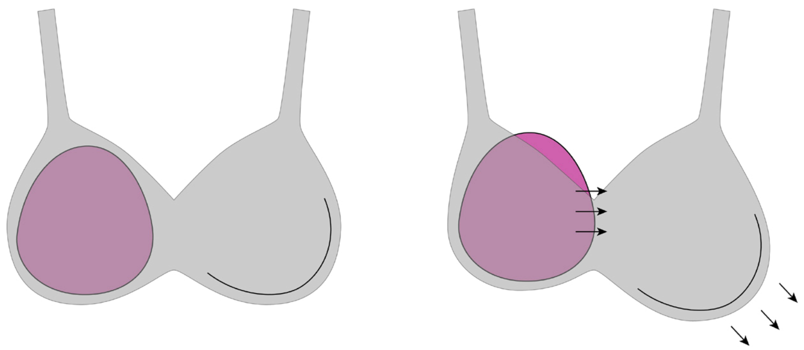


Figure 4.3. Effect of the weight of a breast prosthesis on body symmetry.

Reasons why women decide against breast reconstruction surgery

Of the 22 women who participated in the interview and survey, 12 decided not to have a reconstruction for their own personal reasons, while 8 were not eligible for breast reconstruction. Two participants underwent breast reconstruction and got the implant removed afterwards for health reasons. Figure 4.4 shows the distribution of the participants according to reasons for preferring EBPs over breast reconstruction surgery.

According to one of the breast surgeons a meeting was held with, the reasons why women might not be eligible for breast reconstruction include being overweight, excessive smoking, or having been irradiated during the treatment, among others. It is therefore possible to assume that 8 participants met at least one of these conditions.

The participants who voluntarily chose not to have a reconstruction justified their decision saying that they did not want to cause more harm to their own body going through another surgery, which implies more pain, longer time of recovery, and more risks. Four of them mentioned that they consider an implant as a foreign object, and they did not want such interference in their body. Interestingly, one of the interviewed participants mentioned that she would have liked to get a reconstruction with her own body fat, but she was too skinny to be eligible for this. A different interviewed participant, on the other hand, said that she opted for external breast prostheses because reconstruction surgeries with one own's body fat was not advanced when she was offered this option, so she felt insecure.

One participant mentioned that after two mastectomies on both sides in different years, she did not feel the need to have a reconstruction at her age (in the range between 61-70 years).

Two participants underwent reconstructions that failed after several weeks. They both got their implants removed. One of them said that after the removal, she felt *"sick of hospitals, infections, and wanted her body back."* She then considered the prosthesis a more convenient alternative. The second participant mentioned that the implant was creating a strong pressure due to the forced stretching of the skin that did not allow her to take deep breaths. She had to get her implant removed and used several types of EBPs since then.

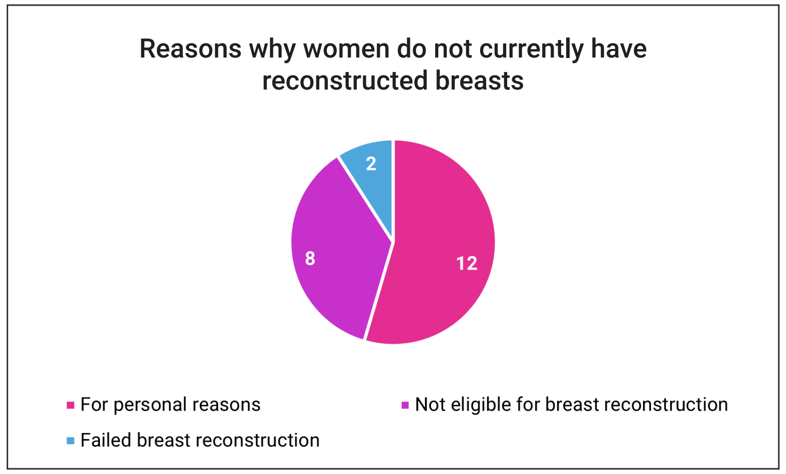


Figure 4.4. Reasons why women do not currently have reconstructed breasts.

Identified pain points associated with external breast prostheses

In relation to the consistency, one of the interviewed participants explained that both consistency and weight are important for her. While she needs to use polyurethane prostheses because they are lighter and therefore more comfortable, she would give up some of that lightness to have a more realistic consistency.

An uncomfortable situation women using EBPs sometimes experience occurs when they are wearing it within the swimsuit at a beach or pool and they lie down facing upwards. In this position, the natural breast tends to flatten, while the prosthesis does not change its shape. This causes a clear asymmetry that can make the woman feel uncomfortable.

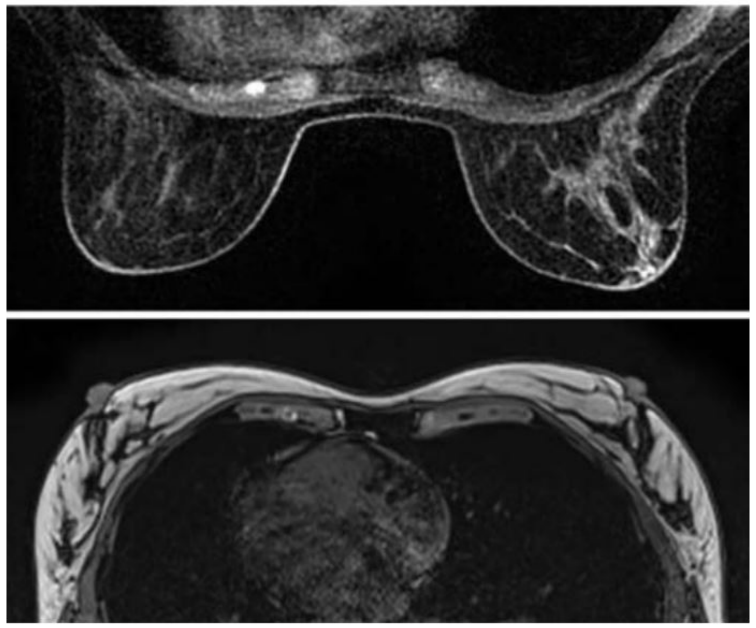


Figure 4.5. Two MRI transverse slices of the same 50-year-old patient taken at the same transverse height from different scans in two different postures, one lying prone (above) and one supine (below), showing a significant amount of breast tissue movement occurring during postural change (Veitch, D., 2019).

This insight derived from a meeting with Dr. Daisy Veitch, designer of the six breast models for medical training. Figure 4.5 shows an MRI of the same person at the same transverse height but in two different postures. The image at the top shows the section when the woman is lying down looking downwards (prone), and the image at the bottom shows the section when the woman is lying down looking upwards (supine). This figure shows how the shape of natural breasts changes depending on the body position of the woman (Veitch, D., 2019).

Although this is a common problem women face when using EBPs according to the conducted interviews as well, one of the breast surgeons a meeting was held with affirmed that the same problem also occurs in reconstructed breasts. This point was also supported by one of the interviewed women who underwent breast reconstruction. She stated that the implant is much firmer than the natural breast.

Another problem women commonly face when using EBPs is skin rash. The materials of the prostheses often facilitate sweating, which together with movement creates friction that produces skin irritation. This effect has been broadly identified and highlighted by several researchers (e.g., Jetha et al., 2017), confirmed by Dr. Daisy Veitch, and corroborated by 8 of the 22 participants who took part in this research. Participants mentioned that it is uncomfortable to wear the prosthesis because it causes excessive sweating in their mastectomy site. Hot weather, exercise, sweat, and friction are the main causes of this skin irritation according to the participants, which aligns with the insights from the literature research. One of the interviewed participants stated that this effect is especially pronounced when using an adhesive breast prosthesis, as the sweat reduces the effectiveness of the glue and the EBP would just fall off if not worn inside a bra. Figure 4.6 lists the main kinds of discomfort experienced by the participants.

According to Reaby and Hort (1995), many women experience embarrassing situations with their prosthesis due to displacement when engaging in physical activities. In fact, 4 survey participants and 2 of the interviewed women have endured uncomfortable situations related to the movement of the prosthesis. According to them, they *"fell out of the bra," "moved out of place," "slipped down,"* or *"fell down"* in public. Three out of the six participants experienced this when swimming. Such unwanted movements happen commonly, and together with the fact that some prostheses do not offer symmetry, they limit the woman's clothing choice; specifically, women tend to wear looser and high-neck options

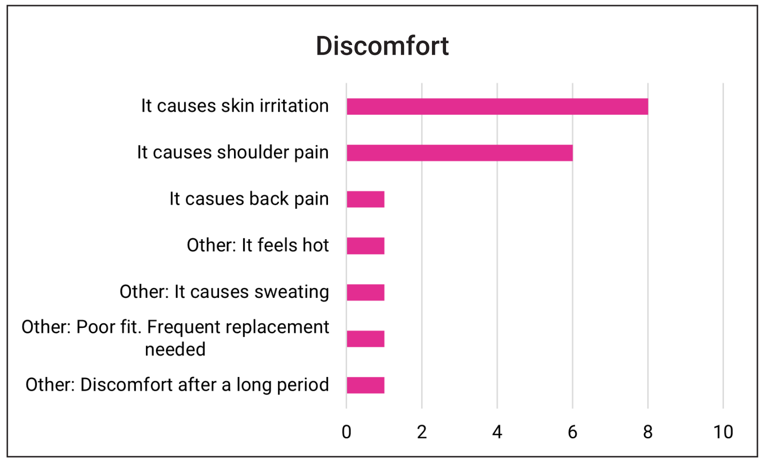


Figure 4.6. Discomfort caused by the use of EBPs.

Figure 4.7. Participation in activities.

(Jetha et al., 2017). Fourteen of the eighteen survey participants reported that they limit their clothing choice. The limitation of their clothing choice was included in a question that aimed to understand what kind of activities women stopped participating in after mastectomy. Surprisingly, participation in physical, social, and public activities was not influenced. These results can be seen in Figure 4.7.

Helguero et al. (2021) designed a personalized breast prosthesis to be made with photopolymerization 3D printing from a 3D-scanned mesh. Their focus was on increasing the contact area between the back part of the prosthesis and the torso of the woman, which generic designs not considering the patient's anatomy features like the scar's size and shape fail to achieve. Building the shape of the prosthesis from the scanned information and digitally measuring the contact area afterwards, they reported a contact area six-times higher than that of commercial options. This article reaffirmed a common problem stated by one of the breast surgeons a meeting was held with, who mentioned that one uncomfortable situation women using prostheses face is the lack of contact between the prosthesis and the torso, which makes them look like they have a hole in their chest. One of the survey participants mentioned that she has a concave chest wall in which her prosthesis does not sit. To solve this, she puts pants inside her bra to push the prosthesis out. Increasing the contact area allows the prosthesis to better adapt to the mastectomized body and provide a more natural appearance, as well as increased comfort (Helguero et al., 2021).

Although not mentioned by any participant, another problem typically associated with silicone breast prostheses is that they might emit a noise when struck. Often these prostheses are designed with a cavity in the rear side with the aim of making them lighter. This can lead to suction, the seal of which can be broken with physical activity, causing the EBP to emit a noise (Healey, 2003).

Polyjet 3D printing

3D printing of medical devices

Additive manufacturing offers advantages in the production of medical devices, such as cost-effectiveness of patient-specific product fabrication in a relatively short time. Geometrically and structurally complex geometries can be made in-house and on-demand (Kermavnar et al., 2022).

The use of additive manufacturing for medical devices is consistently considered beneficial, and is generally associated with increased procedure accuracy, reduced duration, and better quality of outcomes when compared with traditional techniques. On the other hand, common concerns additive manufacturing raises in this field are related to economic and clinical aspects. Using 3D-printed bone implants is estimated to cost between two- and five-times more than using conventional implants, due to the need for additional preoperative virtual planning, device design, and production of trials or variations (Kermavnar et al., 2021).

In medical devices in direct contact with the skin, smooth surface finishes are preferred, for which technologies like material jetting (Polyjet 3D printing) are appropriate (Kermavnar et al., 2022). Although the printed EBP will probably need to be covered by a soft fabric to be pleasant to touch or covered with talcum powder to avoid stickiness, it is important to consider the surface finish of the printed part.

Opportunity for Polyjet 3D printing

This technology allows using a broad range of materials, from rigid solid, to liquid, including any intermediate consistency like flexible solids or gels by mixing droplets of different materials in different proportions.

The accuracy of Polyjet printing also allows it to print narrow parts with customized rigidities, giving the possibility to design and fully control the physical properties and mechanical performance of what is being printed. The accuracy of the Stratasys J735 used for this project is 0.014 mm (Stratasys J750 3D Printer. Proto3000 Inc., 2023).

Due to these properties, Polyjet 3D printing presents a great opportunity to experiment with material combinations, gradients, lattice structures, and geometries that could allow creating a solution with a similar consistency and mechanical behavior as a natural breast tissue. Lastly, as other additive manufacturing technologies, it offers a great potential for personalization.

Design limitations of Polyjet 3D printing

Polyjet 3D printing, besides being an expensive manufacturing method, also presents other unfavorable conditions. While solid materials can be printed with great stability, the use of liquids presents several difficulties, especially when the walls and covers they are encapsulated in are made of flexible material. Printing big regions of liquid makes it necessary to have additional support around the walls of this region to provide steadiness. This support material helps the flexible walls not to deflect or rip when the roller presses them and removes excess material.

In addition, printing on top of liquids or liquid-gel combinations (using them as support) with flexible materials becomes especially restrictive, as deposited droplets may sink before they get cured. The roller also pushes the uncured material in the direction of the head's travel, which moves the liquid out of its intended region and contaminates adjacent curing layers. This leads to uneven surfaces that often do not entirely enclose the inner mixture. This phenomenon has been studied and reported by MacCurdy et al. (2016). Prototyping iterations shown in the *Design and embodiment* section of this report shows results of experiments with flexible materials. Specific iterations, results, and conclusions can be found in the *Design and embodiment* section.

Polyjet 3D printers deposit individual droplets of the selected materials. This working principle makes it necessary to always have a support material to print on. Depending on the geometry of the printed part, the type of support necessary is different, and heavy supports (which incorporate rigid material into the gel-like support material) are much stiffer and therefore more difficult to remove. While this does not present a bigger problem when printing simple geometries where the access to this support is easy, it makes printing intricate geometries like lattice structures very complicated.

MSc Integrated Product Design - Thesis

Discussion

As Healey (2003) suggests, given the risks and costs associated with elective breast reconstruction surgery after mastectomy, women who decide to use external breast prostheses should be offered options that are as well developed as their surgical alternatives. This requires a diversity of well-researched solutions that satisfy the needs and desires of women, who might have a great variety of preferences in terms of materials, weight, shape, and design.

The information obtained from participants in this research underscores the importance of the prosthesis when interacting with the outside world. Uncomfortable situations they experience due to their EBPs adds to their existing personal struggles dealing with the loss of a body part, which should not be minimized. While many women do not wear their prosthesis when they are alone at home and feel comfortable not wearing it with their close relatives, the need to wear it when they are outside and the amount, severity and impact of the shared negative experiences clearly proves the need for improvements.

Several pain points associated with external breast prostheses were identified. An overview of these problems and their prioritization in this project are presented in Figure 4.8.

The consistency of external breast prostheses is often too stiff, which means they provide an unrealistic sensation to touch. Softer prostheses with a consistency similar to a natural breast can help provide greater comfort, both physically and mentally, as they might also help the woman feel more confident in common daily activities, such as giving a hug. Therefore, providing a realistic consistency is the most prioritized goal tackled in this project.

Very closely related to the feeling to touch and the consistency of the prosthesis is the adaptation to the body position of the woman. As previously explained, body symmetry is often not achieved due to the lack of shape change of the prosthesis. Common concerns are related to lying down in public places like beaches or pools, where this asymmetry becomes too obvious, and therefore problematic for the wearer. This is an important aspect of an EBP, which makes providing shape adaptation to body position a crucial objective as well. Its priority is high, but secondary compared to achieving a realistic consistency.

From the health perspective, skin irritation is a common problem experienced by approximately half of the women that participated in this research. Providing ventilation to keep heat and humidity under control would be a valuable improvement. Although this was pursued, its priority was in third position.

It was interesting to see that six participants shared uncomfortable experiences related to the movement of their prosthesis, leading to the prosthesis becoming partially visible from outside or fully falling out of the bra. This is a common problem, but most probably the solution is not in the prosthesis itself but in the bra used. As mentioned by the breast prosthesis fitter from *DeMagneet Lingerie*, the steadiness of the bra is an absolute priority to be able to comfortably use an EBP. This situation worsens when swimming, for which the owner of the breast prosthesis business *Perfect Again Breast Forms* recommends using a zipped bra that fully encloses the prosthesis. Avoiding these unwanted movements is also a goal, although its relevance is low in this project because the focus would most likely need to be on the bra.

Lastly, providing good skin contact increases the comfort of a prosthesis. This contact cannot be ensured with marketed standard EBPs because the topology of the mastectomized area of each woman is different. The severity of this problem reaches the point in which women need to fill the space between their chest wall and the rear side of the prosthesis with cloth or other objects they find appropriate. The importance of offering personalized options becomes obvious, but this challenge is implicit in the use of additive manufacturing for the fabrication of these prostheses.

With the purpose of providing personalized EBPs, the envisioned design process of external breast prostheses starts with scanning the torso of the woman. If the woman had a unilateral mastectomy, the front shape of the prosthesis can be made by building the symmetric geometry of the remaining breast. If the woman had a double mastectomy, the front shape of the prostheses can be made based on the shape of the inner side of a bra. In both cases, the rear side of the prosthesis should be designed following the scar topology of the mastectomized area.

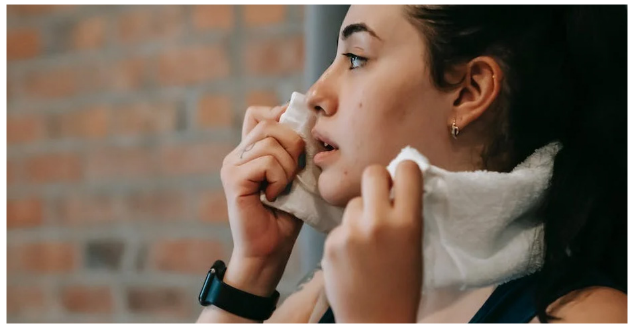
Additive manufacturing offers the possibility to personalize EBPs according to each individual's chest topology. While customizing the shape of the prosthesis can be achieved via 3D scanning and reverse engineering, other aspects like providing a consistency that is similar to the existing breast, avoiding excessive heat, or providing shape adaptation to the body position exclusively depend on the possibilities of 3D printing.

As previously explained, the Polyjet technique allows for printing of voxel-based designs that mix materials in a way that they become homogeneous at a macroscopic scale. This offers full control of the material properties and makes it possible to print mixtures of liquid and gel that could potentially provide the right consistency when encapsulated in a layer of flexible material. Lattice structures might also help provide deformability similar to a natural breast and ventilation.

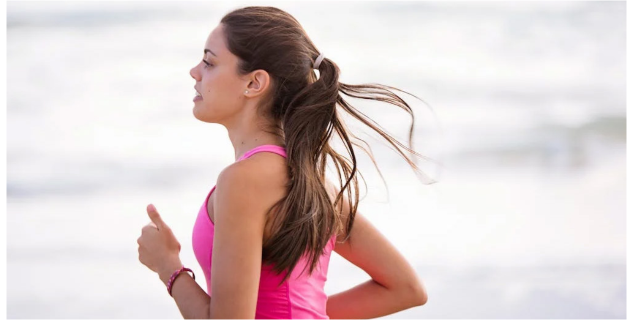
For this reason, this project aimed to explore the possibilities offered by Polyjet 3D printing and the limitations it presents.

1. Realistic feeling to touch

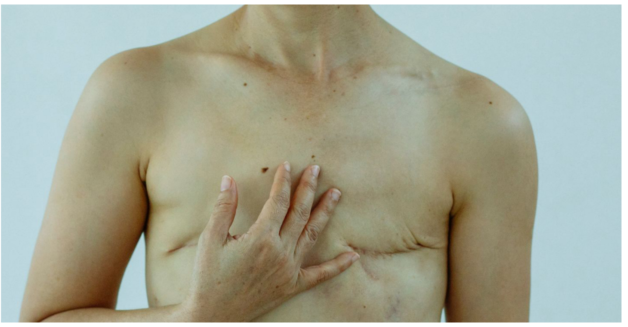
2. Shape adaptation to body position



3. Temperature and humidity control



4. Avoid unwanted movements



5. Increase contact area with skin

Figure 4.8. Identified problems and their priority in this project.

MSc Integrated Product Design - Thesis

5 Design challenge

As explained in the previous section, the three most relevant improvements this research project works towards are: (1) providing a realistic consistency, (2) providing shape adaptation to the body position of the woman, and (3) providing temperature and humidity control. Although avoiding unwanted movements of the prosthesis is also desirable, this challenge was not addressed because it would have required working on the mastectomy bra rather than on the prosthesis itself. On the other hand, providing increased skin contact is an improvement that is implicit in the use of additive manufacturing techniques, which often include 3D scanning and reverse engineering of existing body structures.

Having established these goals and their priority, the challenges for this project lie in the technical aspects: How can these qualities be achieved using Polyjet 3D printing? The design challenge is formulated as follows:

"Define the materials and the design of an external breast prosthesis produced with Polyjet 3D printing that offers a realistic consistency to touch, shape adaptation to body position, and temperature and humidity control."

6
Design & embodiment

Exploratory research

The exploratory prototyping phase included the embodiment and evaluation of several samples. For reproducibility purposes, technical drawings of the printed prototypes are added to *Appendix 07*.

Discover

Following the insights from literature research, three directions were explored during the discovery phase:

- Material combinations
- Lattice structures
- Interaction between gel and flexible geometries

DESIGN DIRECTION 1. MATERIAL COMBINATIONS

The droplet-based working principle of multi-material Polyjet printing offers the possibility of mixing materials. Designing droplet by droplet the material that is going to be deposited, it is possible to create parts that have a homogeneous combination at a macroscopic scale. For example, if the printer deposits 50% of support material (which is a gel-like composite) and 50% of liquid (cleaning fluid) following an even droplet distribution, the result will be a multi-material part that presents material properties falling between those of the two base materials (Bezek et al., 2022).

The design of this material distribution can be accurately customized, allowing to create homogeneous combinations, gradients of materials, and any kind of disposition. At the moment, a single part can incorporate up to two different materials combined at a voxel level, so experimentations mixing higher amounts are not explored in this project.

This aspect is especially interesting for this research, as a specific combination of support material (gel) and liquid could provide a consistency similar to that of breast tissue.

MSc Integrated Product Design - Thesis

EXPLORATORY PROTOTYPING PHASE 1

Before starting experimentation with mixed materials, a general exploration of how encapsulated gel, liquid, and air felt was intended to be researched. The pods designed for this exploration can be seen in Figure 6.1. These prototypes have the shape of a hemisphere. They were designed with this geometry because it was an efficient way for the flexible material to cover the inside gradually and minimize flaws while printing.

However, despite the geometry, the first printing process was stopped before finishing because the fluid of the liquid pod started to flow out (see Figure 6.2). This happened because the diameter of the hemisphere was too big to host a (purely) liquid pool with very little support. Though this prototype did not provide information about consistency, it was useful to understand the limitations of liquid printing and to get familiar with the printing and the subsequent cleaning processes.

After canceling this process halfway, the air pod was printed. Because of the droplet-based working principle of Polyjet printing, this sample was filled with support material when manufactured, which was then intended to be removed. This single sample worked therefore to test both the gel pod (before removing the support material from the inside) and the air pod (after removal). Both versions can be seen in Figure 6.3.

From these prototypes, it was possible to conclude that:

- The gel inside the pod was too hard compared to the consistency of breast tissue. However, this might have been influenced by the walls it was encapsulated in. The flexibility of the wall material (when the wall is 1 mm thick) is not enough to let the inner gel move outwards enough to resemble a breast consistency when pressed.

- When pressing the air pod (after the removal of the support material), the material did not recover the shape immediately. The pod would have needed to be hermetically closed to allow "force feedback" to immediately respond to the applied force.

- The shell was too light to deform by itself when its position was altered. It would therefore be necessary to add more weight or build a geometry that is not self-supporting.

- The first contact with the pod was too hard. This happened because of the geometry itself. A hemisphere is a double curved surface that is structurally very steady and therefore more force needs to be applied to make it collapse.

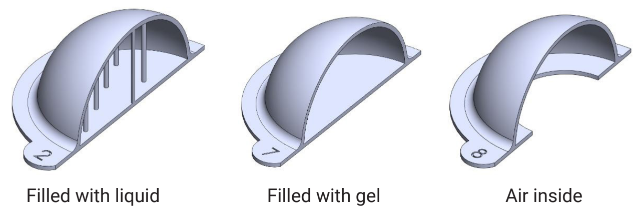


Figure 6.1. Pods designed for the Exploratory Prototyping phase 1.

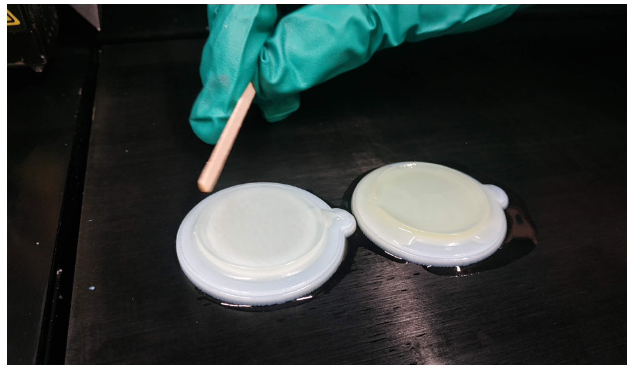


Figure 6.2. Liquid flowing out of the region when printing the pods for the Exploratory Prototyping phase 1.

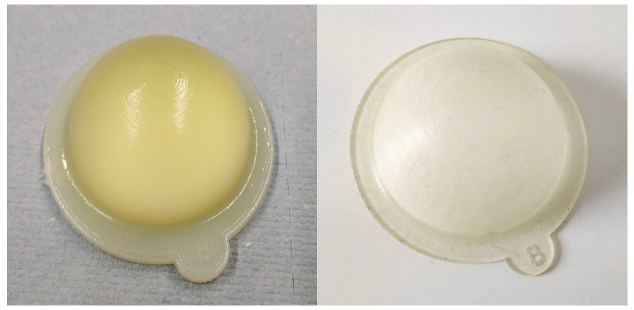


Figure 6.3. Pod filled with support material on the left and the same pod with air on the right. Both of them are part of the Exploratory Prototyping phase 1.

EXPLORATORY PROTOTYPING PHASE 2

These conclusions from a first prototyping session led to the need to explore combinations of gel-like materials and liquids. Because this voxel level design is done with the BitmapSlicing application in Matlab, a first sample with a gradient from 100% support material to 100% cleaning liquid was made.

This application allows setting two .stl files and applying a combination of two materials to one of them. Therefore, the approach was the following: one .stl was the outer shell that would be made of flexible material (Agilus30Clr) and encapsulate the gradually transitioning mixture of gel (SUP705) and liquid (M.Cleanser). The geometry of the .stl files is modeled and then selected in the BitmapSlicing application as .stl file A and .stl file B. The file A is the one that will have the mixture of materials, so in this case, the inner part. Then, an image that represents the material distribution of the multi-material part is designed and selected. For this specific sample, the image in Figure 6.4 was used. In the following step, all materials are selected. For the .stl file A, the first material will be put in the white parts of the selected image and the second material will be put in the black parts of it. Because the image is a gradient from white to black, this material distribution will also be a gradient. A third material is also chosen for the .stl file B. Then, the slicing process can be initiated. The result is a file containing bitmaps for each material (see an overview of the bitmaps generated for this sample in Figure 6.5). There is, therefore, one bitmap for each layer and for each material. In these bitmaps, the points represent the individual droplets. A white point means a droplet of that material will be deposited, while the black one means it will not. Because the support material will be printed by default when there is no droplet defined, the images with gradient for Mat. 2 (gel) in Figure 6.6 can also be made black and the result would still be the same.

The result was a sample (see Figure 6.6) in which the top cover was not printed correctly because the most liquid region was still very broad and the cover was fully horizontal, which complicated the printing process. However, the gradual transition from gel to liquid on the inside was printed correctly.

Figure 6.4. Gradient image used for gradual transition from gel to liquid materials.

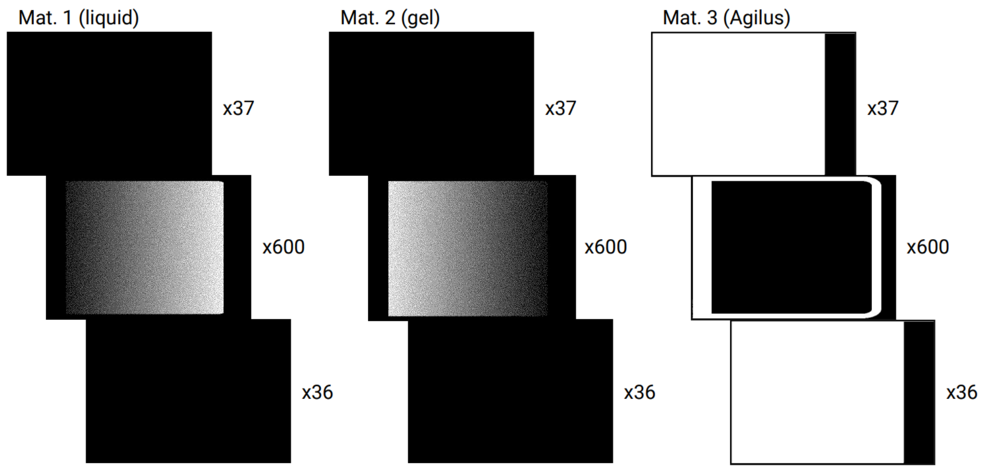


Figure 6.5. Overview of the bitmaps generated for the sample containing gradual transition from gel to liquid of the Exploratory Prototyping phase 2.

Figure 6.6. Sample containing gradual transition from gel to liquid of the Exploratory Prototyping phase 2.

MSc Integrated Product Design - Thesis

EXPLORATORY PROTOTYPING PHASE 3

The following step intended to explore the consistency of different proportions of gel and liquid combinations. To research this, a set of 10 samples with different percentages of gel and liquid were printed. The samples were printed with two different wall thicknesses to test how both the proportions of the inner material and the thickness of the membrane affected their feel to touch. Table 6.1 shows the reference of each sample, and Figure 6.7 shows the results.

The samples were printed upside down to avoid any problem printing the thin walls that meant to be the testing surface. Previous attempts at printing went wrong because combinations of liquid and gel where the amount of gel is insufficient present difficulties to build upper layers of solid material that enclose the mixture. By positioning the samples upside down, the thin layer lies below the liquid, so this problem will not affect the testing wall. In addition, the opposite side of the samples is designed in the shape of a pyramid to let the material at the top enclose the inner mixture gradually, facilitating the printing. The thickness of all the walls that are not the testing face are much thicker (3 mm) to minimize any risk of tearing. To make the printing more stable and ensure a smooth process, support material of 4 mm is located in the surroundings of the entire samples. This is achieved by modeling a thin layer of material on top of each sample (Figure 6.8). Because Polyjet printing cannot print anything without support, the software will by default assign support material to any undefined area below this layer. The results of these samples are explained in the following paragraph.

The samples B and G, with 75% gel (support material) and 25% liquid (cleaning fluid) already feel very soft. The samples A and F (100% gel) were printed without any flaws. The 45º angled roofs of samples B and G (75% gel) were printed without any flaws, but the top part, which was horizontal, presented some imperfections. However, the inner material was fully encapsulated. In the samples C and H (50% gel), both the horizontal and the angled roofs presented flaws, though it could encapsulate all the inner material. Lastly, the samples D, E, I, and J could not be fully closed even with a 3-mm thick flexible cover, so all the inner material was exposed. The sensation to touch did not considerably vary from the 75% gel - 25% liquid options to the ones that had lower gel concentrations. Instead, the thickness was more relevant, as the difference between having a 0.6-mm or a 1-mm thick membrane was considerable.

From these results, the following conclusions can be drawn:

- 25% of liquid is enough to provide a soft consistency. More liquid is not necessary because the sensation to touch barely changes and it would make the printing process more complicated due to the low performance of liquid as support to print with flexible materials on top.
- Proportions ranging from 75% to 100% gel should still be explored, as higher amounts of gel could provide a similar sensation while exhibiting better performance as support material.
- A wall thickness of 0.6 mm leads to better results than 1-mm walls in terms of consistency. However, a 0.6 mm layer could be too easy to tear. Therefore, this aspect should be further tested, and a compromise should be found.

	Wall thickness	
Proportions	0.6 mm	1 mm
100% support with grid - 0% liquid	A	F
75% support - 25% liquid	B	G
50% support - 50% liquid	C	H
25% support - 75% liquid	D	I
0% support- 100% liquid	E	J

Table 6.1. Reference of samples for support-liquid proportion and wall thickness testing.

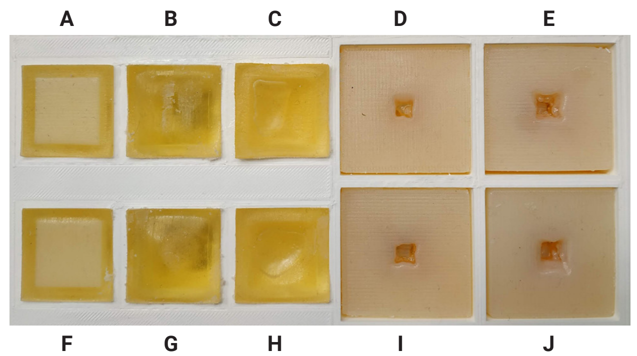


Figure 6.7. Samples for support-liquid proportion and wall thickness testing for the Prototyping phase 3.

EXPLORATORY PROTOTYPING PHASE 4

Based on these conclusions, the following step aims to find out if any higher percentage of gel in the mixture could still provide a consistency that is soft enough to resemble natural breast tissue. For this, three samples were printed with 100%, 90%, and 80% of gel in the mixtures. Compared to the previous models, the roof was made more horizontal, with an extrusion angle of 60º. This was done to simultaneously test the performance of these proportions to act as support for printing flexible materials on top. The thickness of the testing face was kept at 0.6 mm and the one of all the other faces remained 3 mm. It was again printed with the testing face on the bottom. The geometries prepared for this evaluation and the result can be seen in Figure 6.8. Starting from the left, the first sample was filled with 100% support material with no grid, the second sample was filled with a mixture of 90% support material and 10% cleaning fluid, the third sample was filled with a mixture of 80% support material and 20% cleaning fluid. Lastly, the sample in the left was also filled with 100% support material with no grid.

Conclusions from these samples are:

- All proportions performed perfectly as support for a flexible material roof with a 60º angle and 3 mm thickness. There were no flaws in any of the samples.
- The samples with 100%, 90%, and 80% of gel present gradual changes in their consistencies. However, when comparing the 80% gel mixture with the 75% gel mixture, the difference is not noticeable. The mixture ratio of 80% gel - 20% liquid might provide the softest consistency while performing well as support for flexible material.

Although the mixture containing 80% gel and 20% liquid provides a soft consistency together with good performance as support material for the conditions of the *Exploratory Prototyping phase 4*, the impact of the scale, both on the consistency and on the cover that uses this mixture as support, is still uncertain. It is hypothesized that bigger regions of this mixture will provide a softer sensation. For this reason, the next prototype is designed on a bigger scale with the same inner material. The geometry tries to replicate a teardrop shape but keeps the pad thin. This exploratory prototyping phase can be seen in the *Define* stage of this subsection.

Although the samples with percentage of gel lower than 80% were not properly enclosed, the consistency they would have has been predicted extrapolating the trend based on the samples with higher percentage of gel. For this, a compression test was performed with the samples with 80% gel, 90% gel, and 100% gel. This compression test was performed using a probe with a flat cap, a 6-mm diameter, and a circular cross section. The maximum force applied was 5 N and the speed at which the test was conducted was 50 mm/min. The results obtained for the three samples and the trendline that shows the prediction of the consistency of samples with lower amounts of gel can be seen in Figure 6.9.

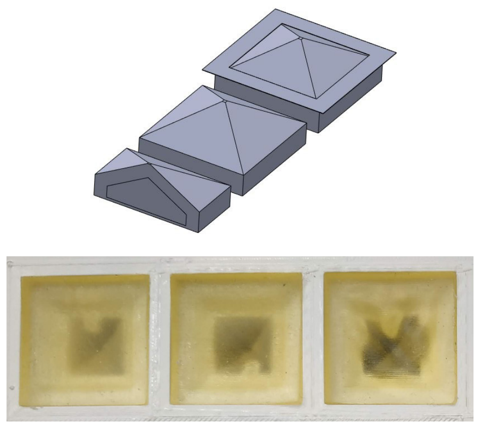


Figure 6.8. Geometries for 100%, 90%, and 80% gel mixture testing in the Exploratory Prototyping phase 4.

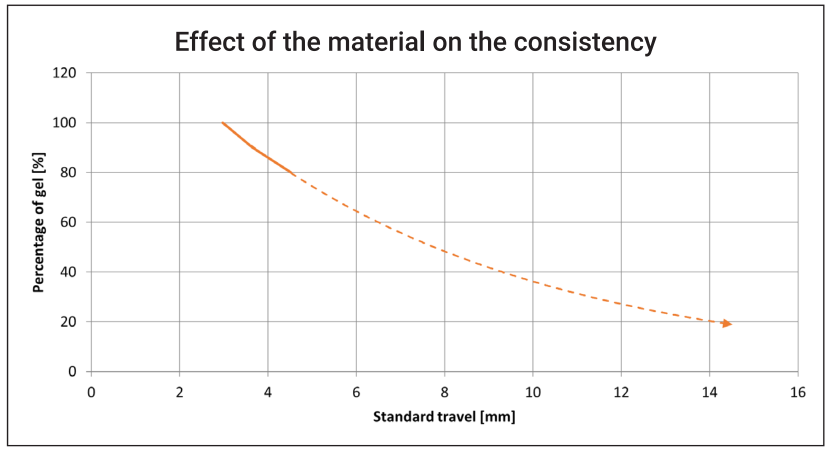


Figure 6.9. Effect of the material on the consistency. The graph shows the predicted standard travel under a force of 5 N in a test conducted at a speed of 50 mm/min in samples with percentages of gel lower than 80%. Results were obtained from three samples and the prediction was done with a power curve approximation.

DESIGN DIRECTION 2. LATTICE STRUCTURES

Lattice structures can be classified based on their cellular structure as stochastic, if they follow a random material distribution, or non-stochastic, if they are formed by the tessellation of a unit cell. These geometries can resist large deformations under high loading at low density levels (Mora et al., 2022).

Based on their performance, they can be classified as stretch-dominated or bending-dominated lattices. Stretch-dominated lattices have higher nodal connectivity and tend to be stiffer, while bending-dominated lattices have lower nodal connectivity and are ideal for energy absorption (Deshpande et al., 2001). When compressed, beam-based bending-dominated cells undergo bending deformations rather than tension and compression (Graziosi et al., 2022).

Design variables that affect the performance of a cellular solid according to Scheffler and Colombo (2005) and Graziosi et al. (2022), include:

- Topology and shape of the unit cells;
- Properties of the base material;
- Relative density of the lattice structure;
- Load orientation with respect to the lattice.

The base material used for all experimentations with lattices will be Agilus30Clr, which is the flexible material used by the Stratasys J735 Polyjet printer.

To choose the type of lattice structure, several considerations are taken into account. As this project aims to design a product that resembles breast tissue consistency as closely as possible, stiffness needs to be avoided. Therefore, honeycombs or octet lattice structures are not suitable (nTopology Learning Center, n.d.). Auxetic behavior is not sought as an overall property either because a negative Poisson's ratio would make the prosthesis behave differently than breast tissue. Namely, when breast tissue is pressed in a specific direction, the tissue is displaced to surrounding areas; so in the other directions, it does not compress, but expand. However, even if the prosthesis as a whole must not perform as an auxetic material, it is possible that auxetic regions help achieve the wanted consistency. Lastly, bending-dominated lattices are more suitable because their stiffness is lower.

The Kelvin cell is interesting to study because it mimics the geometry of foams and has a quasi-isotropic behavior. Together with the body-centered cubic (BCC), it is one of the most studied bending-dominated structures (Graziosi et al., 2022). Both the Kelvin cell and the BCC lattice structures store energy with their elastic deformation and quickly return to their original shape when the force is removed (Radius, 2022). Despite having these similar desirable characteristics for this project, they have a significantly different number of beams and nodes, making them interesting to explore (see lattices in Figure 6.10).

Lattice structures present geometries that are very challenging to print efficiently with Polyjet because they would require heavy support, which integrates a lot of rigid material within the gel-like support material and is therefore very difficult to remove. In an attempt to simplify the lattice while reaching a good result, the following logic is followed:

Having thin columns made of flexible material connecting two surfaces will allow relative movement between the surfaces owing to the bending of the columns (see Figure 6.11). This is prototyped and tested.

Three variants of samples that consisted of two plane surfaces connected by columns were printed. The diameters of the columns in the samples were 1 mm, 2 mm, and 3 mm, respectively. Figure 6.12 shows these 3 samples. It was possible to clearly observe that 1-mm columns are not suitable because they are too weak, which made removing the support material from the surroundings very difficult. Three columns were broken during this cleaning process. The samples with 2-mm and 3-mm columns presented, instead, feasible alternatives.

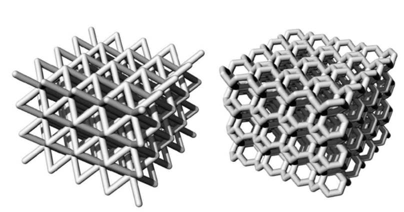


Figure 6.10. BCC lattice on the left and Kelvin cell lattice on the right.

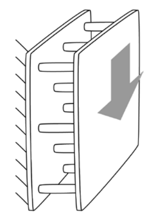


Figure 6.11. Lattice prototyping.

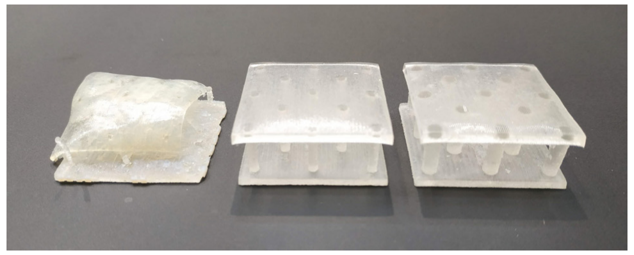


Figure 6.12. Column-based lattice structures with columns of 1 mm diameter (on the left), 2 mm diameter (on the center) and 3 mm diameter (on the right).

MSc Integrated Product Design - Thesis

DESIGN DIRECTION 3. INTERACTION BETWEEN GEL AND FLEXIBLE GEOMETRIES

One of the conclusions from testing the pod full of gel in *Exploratory Prototyping phase 1* was that the flexibility of the wall material is not sufficient to let the inner gel move outwards enough to resemble breast consistency when pressed. This effect is illustrated in Figure 6.13: When a force is applied, the material is pushed toward the surroundings, but the stiffness of the wall does not allow this pushed material to deform enough to provide the sensation of touching a soft material.

Leaving some open space with air that can go in and out could help achieve bigger deformation with the same force. Figure 6.14 illustrates this idea: When the force is applied, discrete points of flexible material press on the inner gel. The air between the touching points, which is represented in green in the Figure 6.14, provides the space into which the gel can easily relocate until the force is released.

To provide a more realistic sensation, making the surface where the force is applied flat could be helpful. In addition, making the discrete points that touch the gel sharper would allow displacing the gel material more efficiently. This can be seen in Figure 6.15.

This idea was also 3D printed, and the result can be seen in Figure 6.16.

The improvement in consistency this prototype offers is low when compared to the complexity it adds to the geometry. For this reason, this design direction is not further explored.

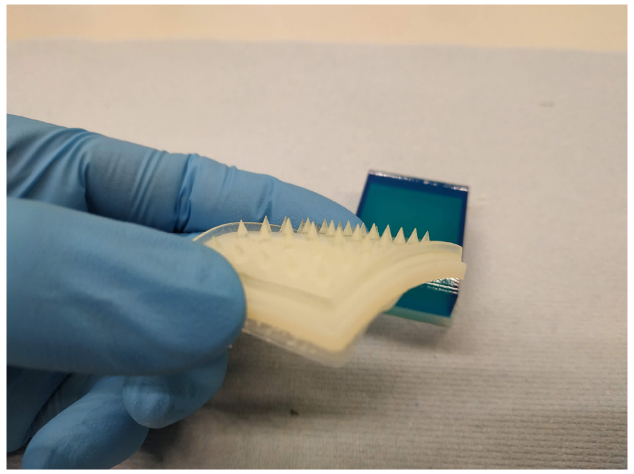


Figure 6.16. Sample to test the interaction between gel (support material) and discrete touching points made of flexible material (Agilus30Clr).

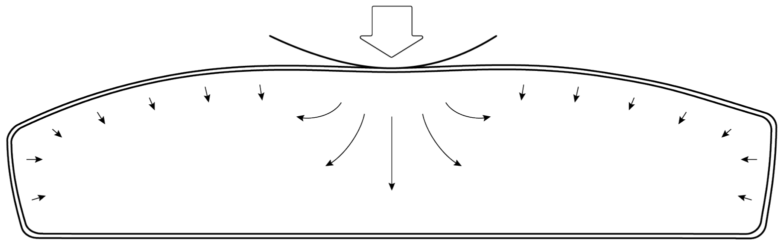


Figure 6.13. Effect of the shell material on the deformation of the inner material.

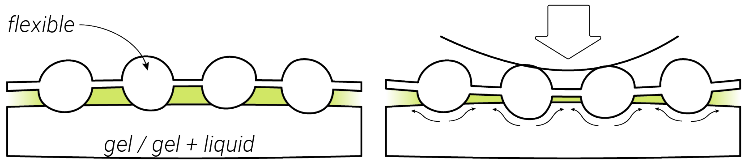


Figure 6.14. Discrete touching points allow efficient displacement.

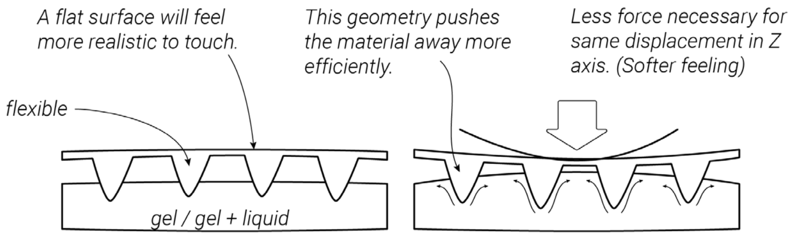


Figure 6.15. Sharper discrete touching points allow more efficient displacement.

Define

Having explored different material combinations, column-based lattices, and how flexible materials could transmit a softer sensation owing to its interaction with gel, results drove to the conclusion that a combination of a mixture of gel and liquid with column-based lattices could provide the wanted characteristics. This narrowed down the exploration and defined a clearer direction for further investigation.

Based on this, further samples were made.

EXPLORATORY PROTOTYPING PHASE 5

The *Exploratory Prototyping phase 5* intended to explore the effect of the scale on consistency while using the same material. For this, a bigger sample was printed, which had a teardrop shape and incorporated several columns in the interior. The columns were included to ensure printability of the part. A broad chamfer was incorporated in the corners defined by the columns and the top cover, so that the flexible material was printed on top of the gel and liquid mixture gradually, which decreased the risk of the top layer not being fully closed. A section view of the model and the result can be seen in Figure 6.17.

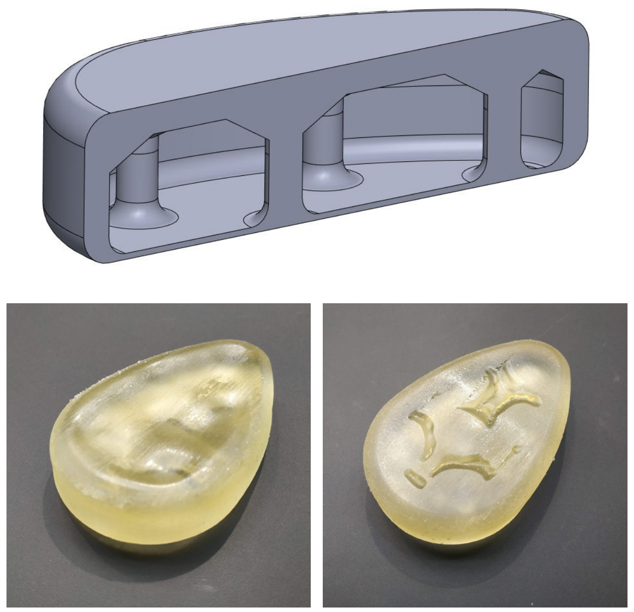


Figure 6.17. Teardrop-shaped sample. The testing surface is 0.6 mm thick and is printed on the bottom to ensure that the print will not fail due to its thinness. The image on the bottom left shows the testing face. The image on the bottom right shows the top cover (in the printing position), which is 3 mm thick. Flaws are visible in the parts that were horizontally printed on top of the gel-liquid mixture. Even if flaws are present, the material fully enclosed the inner mixture.

EFFECT OF SCALE ON CONSISTENCY: COMPRESSION TEST 1

To evaluate the effect of scale on the softness of the sample, a compression test was performed.

TOOLS AND METHODS

The setup of the compression test can be seen in Figure 6.18. The test was performed at a speed of 50 mm/min and the maximum force applied was 5 N. The diameter of the testing probe was 6 mm and the cap was flat.

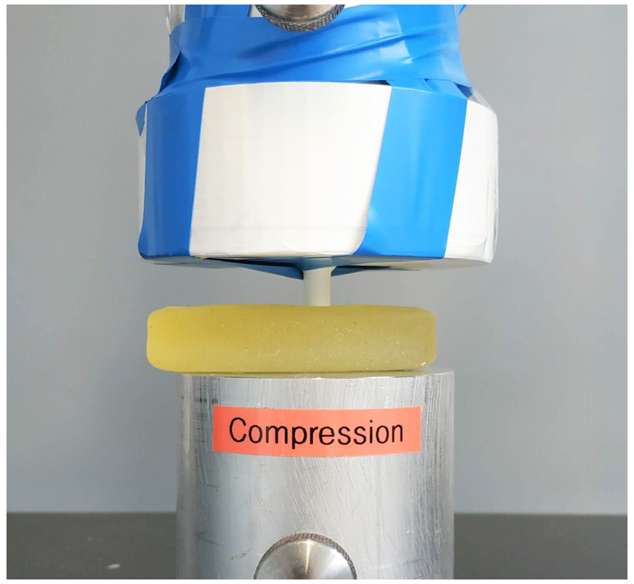


Figure 6.18. Experimental setup of the compression test 2 to evaluate the effect of the scale on the consistency.

Figure 6.19 shows the results of the compression test for the diamond-shaped sample with 80% gel 20% liquid, the teardrop-shaped sample with 80% gel 20% liquid, and the breast prototype from Dr. Daisy Veitch.

From the graph, it is possible to conclude that increasing the scale does increase softness. The curve that represents the teardrop-shaped sample might be affected by the columns in the geometry, which might have strengthened the sample and offered more resistance against compression. Despite this effect, the results lead to the conclusion that a bigger scale increases softness, allowing for more deformation under the same pressure. It can be expected, therefore, that larger, real-size samples would provide softer results. It is possible to observe that the curve that represents Daisy Veitch's prototype changes its slope when the travel is close to 15 mm. This can be explained by the fact that the testing probe was not long enough for such a big travel, causing contact between the prosthesis and the body of the testing probe. This phenomenon, which can be seen in Figure 6.20, has probably influenced the shape of the curve. Therefore, the curve should be considered inaccurate after the change of this slope.

From a user-experience perspective, the effect of the columns on the feeling to touch cannot be neglected. The columns create harder points on the testing surface that, when touched, provide a nodular sensation that should be avoided in the final result. To test if smaller touching points between the columns and the testing face provide a smoother sensation, a sample with columns that vary in diameter (becoming smaller as they get closer to the testing surface) was printed in the *Exploratory Prototyping phase 6*.

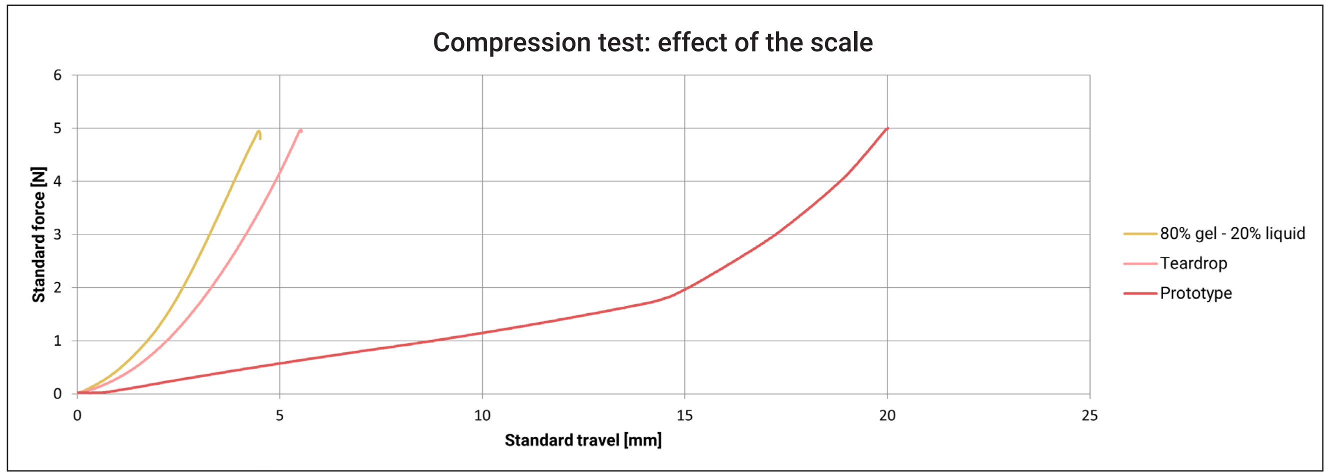


Figure 6.19. Compression test: effect of the scale.

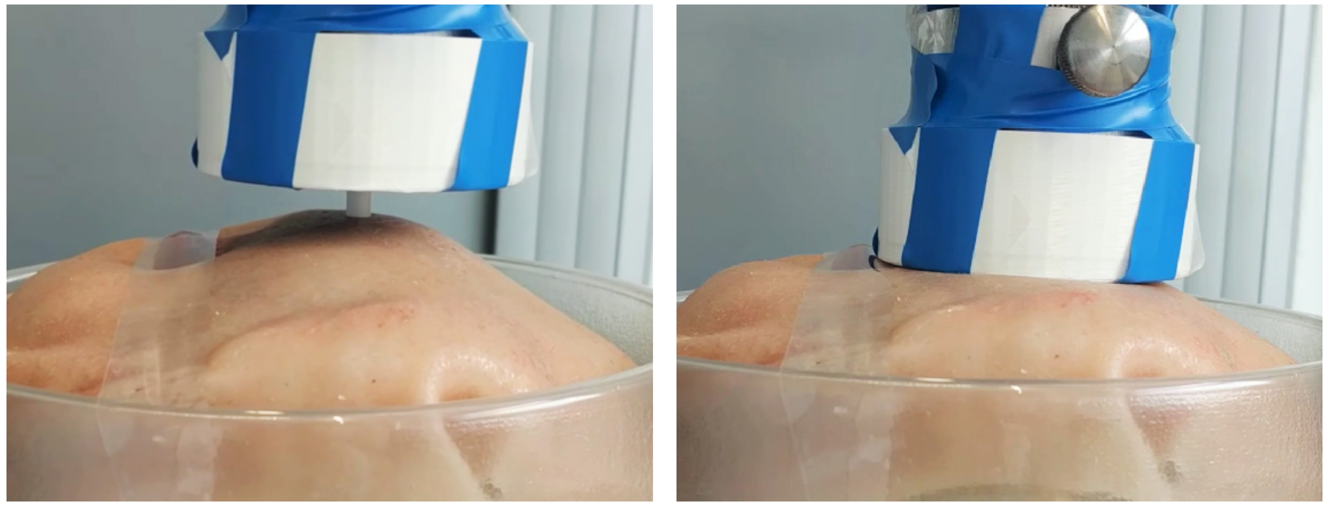


Figure 6.20. Unwanted contact between the prototype and the body of the testing probe.

EXPLORATORY PROTOTYPING PHASE 6

The sample tested in this exploratory prototyping phase can be seen in Figure 6.21, which also shows a cross section to visualize the thickness variation of the columns.

From this sample, it was possible to conclude that decreasing the diameter of the columns does not decrease the nodularity perceived when touching the testing surface. Therefore, it is possible to state that the outer layer of the final prototype should not have direct contact with columns or any other internal geometry printed using Agilus30Clr.

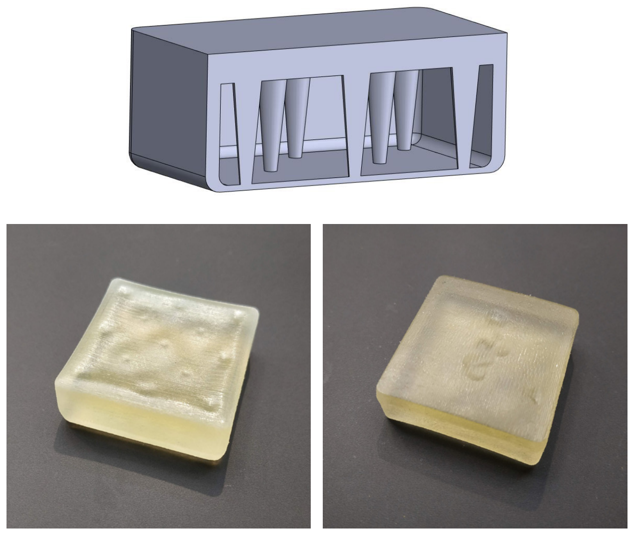


Figure 6.21. Sample with variation in the diameter of the columns. The testing surface is 0.6 mm thick and is printed at the bottom. The image on the bottom left shows the testing face. The image on the bottom right shows the top cover (in the printing position), which is 3 mm thick.

EXPLORATORY PROTOTYPING PHASE 7

The *Exploratory Prototyping phase 7* aimed to identify the minimum thickness the top cover needs to have when printing on top of a mixture with 80% gel 20% liquid. This information was necessary when printing a bigger-scale prototype. Samples were printed with top covers made of 1-mm, 2-mm, and 3-mm thicknesses. The results can be seen in Figure 6.22.

The results showed that, while all the samples could be enclosed by the printer, the 1-mm thick cover presented with considerably more flaws (“waves”) on the surface than the 2-and 3-mm thick covers. While this kind of flaw might not be too relevant for haptic sensation if the user does not have direct contact with it, it is possible to hypothesize that when printing at a bigger scale, these flaws could scale up as well, ultimately leading to a cover that does not fully enclose the inner liquid. In addition, while the middle sample offered a harder surface (compared to the 1-mm cover), based on the conclusions from the first compression test, it could be assumed that increasing the scale would provide a softer consistency.

It was therefore concluded that a 2-mm thick cover is appropriate to print on top of an 80% gel, 20% liquid mixture. Other considerations needed to be taken into account when printing the rear surface of the prosthesis, in order to achieve a smoother texture that presents no “waves”.

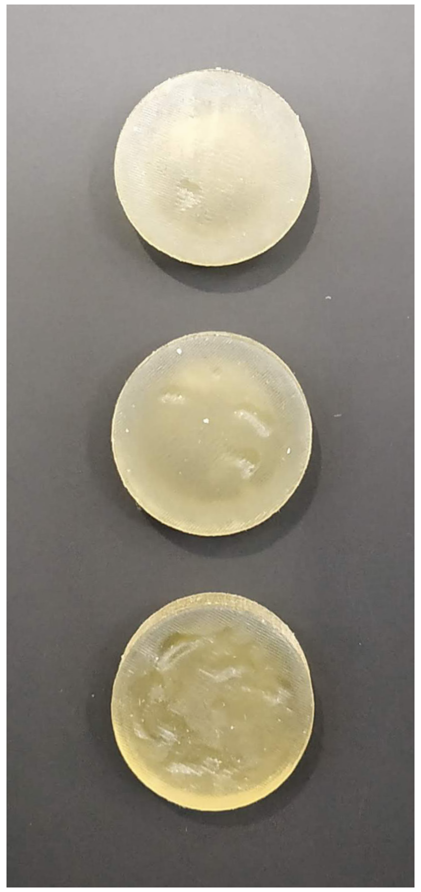


Figure 6.22. Samples printed to test how thin it is possible to print on top of a mixture with 80% support material and 20% liquid. The sample on top shows a 1 mm thick cover; the sample in the center shows a 2 mm thick cover; and the sample in the bottom shows a 3 mm thick cover.

EFFECT OF SCALE ON CONSISTENCY: COMPRESSION TEST 2

To test how the scale affects consistency, a set of samples were printed, and a compression test was conducted. As the volume of a sample can be varied in many ways, the influence of both the height and the diameter were evaluated. For this reason, two arrays of cylindrical samples filled with mixture were designed: a set of samples with the same diameter (40 mm) but different heights, and a set of samples of the same height (25 mm) but with different diameters. The samples and their dimensions can be seen in Figure 6.23. The testing surfaces of all samples were printed with a thickness of 0.6 mm and the mixture inside was 80% gel and 20% liquid. The walls had a thickness of 3 mm.

The height and diameter mentioned represent the overall dimensions, shown in Figure 6.24 in a section view. The volume of the inner mixture is therefore not directly represented by these values. It is important to note that the cylindrical wall and the bottom layer are 3 mm thick, and the testing wall (the upper surface) is 0.6 mm thick.

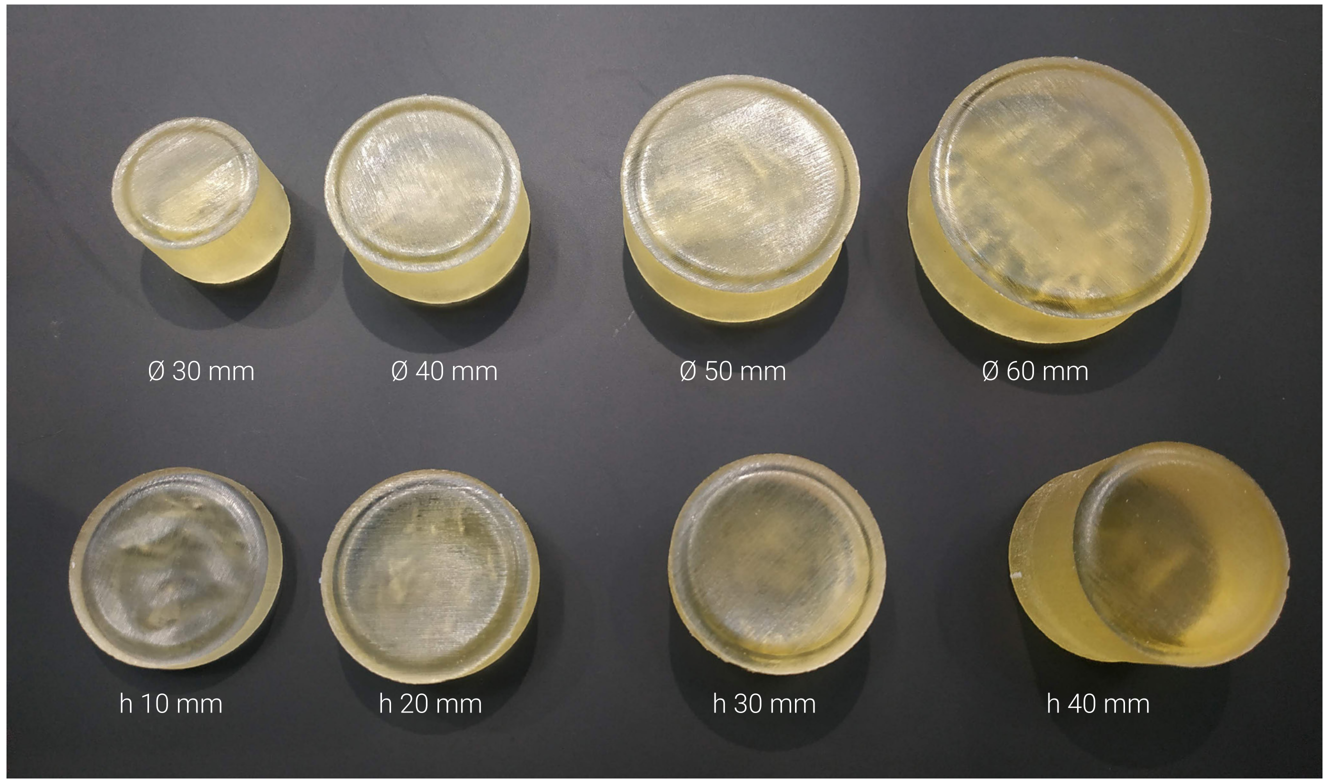


Figure 6.23. Samples printed to test the effect of the scale on the consistency.

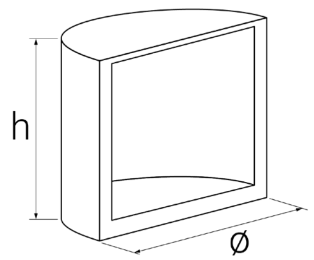


Figure 6.24. Dimensional definition of the cylindrical samples printed with the objective of testing the effect of the scale on the consistency.

MSc Integrated Product Design - Thesis

TOOLS AND METHODS

A second compression test was conducted to test the effect of the scale on consistency/ deformability of printed parts. In order to simulate a situation more similar to a hand touching a breast, a different testing probe was used. This probe was longer to avoid any unwanted contact that the deformation could cause between the sample and the horizontal surface of the probe. In addition, the diameter and the cap shape were also modified. To make it as similar as possible to a finger, a diameter of 16 mm and a hemispherical cap shape were used.

The 16-mm diameter was defined based on the mean forefinger breadth of Dutch female adults (31-60) measured in the middle of the distal phalanx (DINED, 2023), which is the furthest phalanx on the index finger (Maw et al., 2016). See Figure 6.25 for reference.

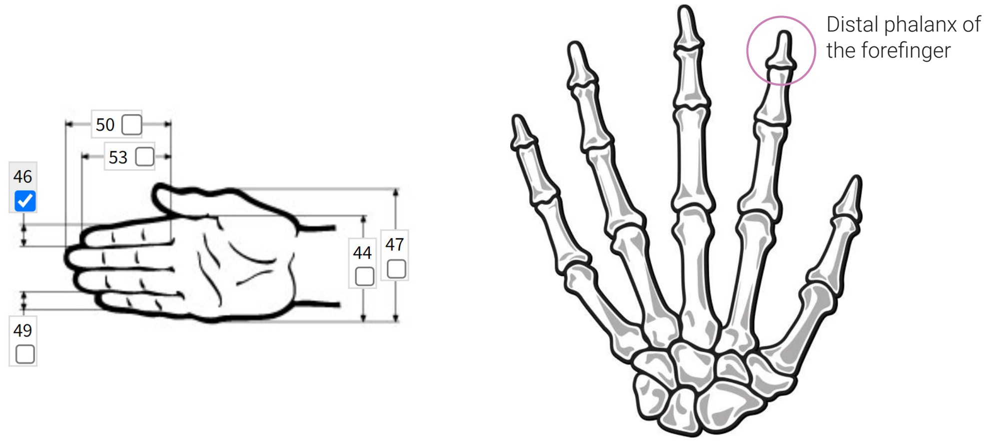


Figure 6.25. Distal phalanx of the forefinger (DINED, 2023; Maw et al., 2016).

The setup of the experimental test can be seen in Figure 6.26.

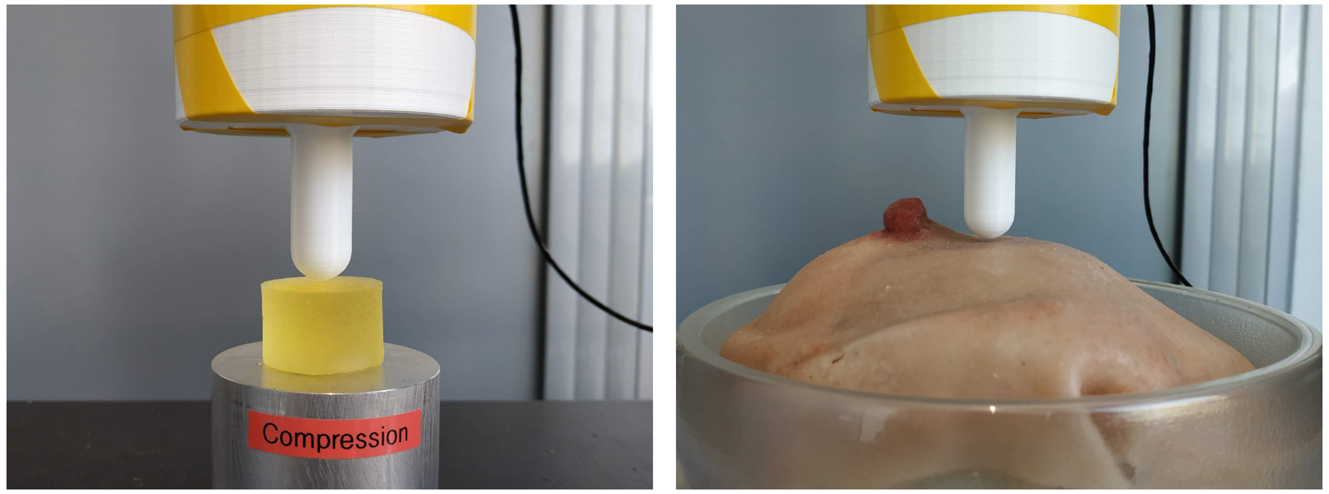


Figure 6.26. Experimental setup of the compression test 2 to evaluate the effect of the scale on the consistency.

The test was conducted with a probe speed of 50 mm/min, and a maximum force of 5 N was applied vertically. The results obtained on samples with the same diameter can be seen in Figure 6.27. The results obtained on samples with the same height are presented in Figure 6.28. The results obtained from the test are represented by continuous lines, while the dotted lines show a prediction of the travel under higher forces for each sample. These predictions have been made using a polynomial approximation, and despite being approximated as loyally as possible, they should not be interpreted as accurate results, but as an approximated prediction. Both the results and predictions were compared with the travel presented by the reference model from Daisy Veitch under the same testing conditions.

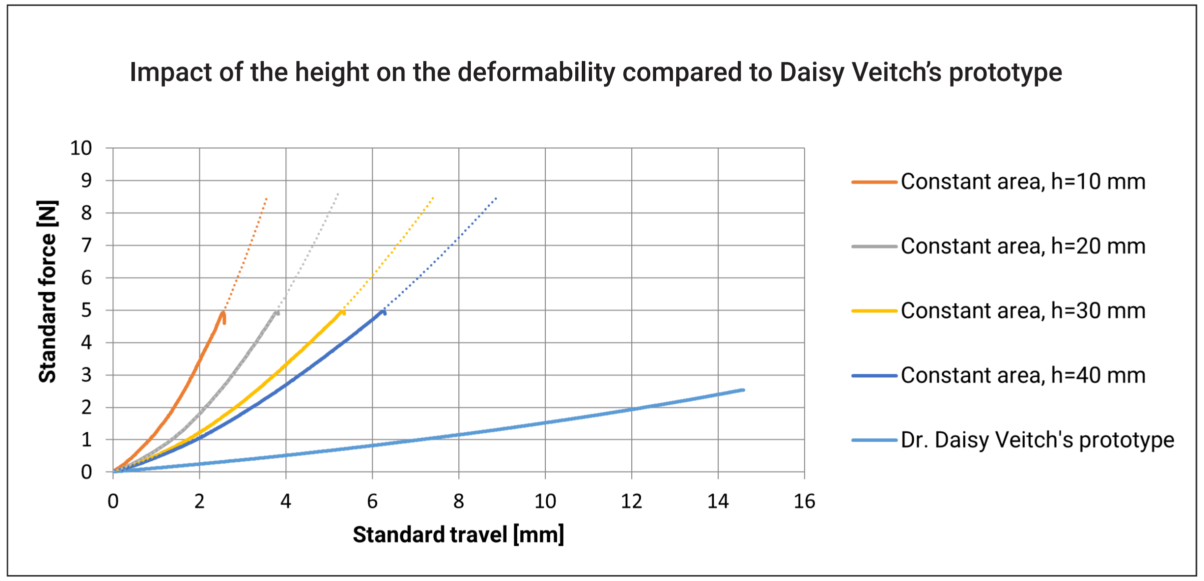


Figure 6.27. Impact of the height on the deformability.

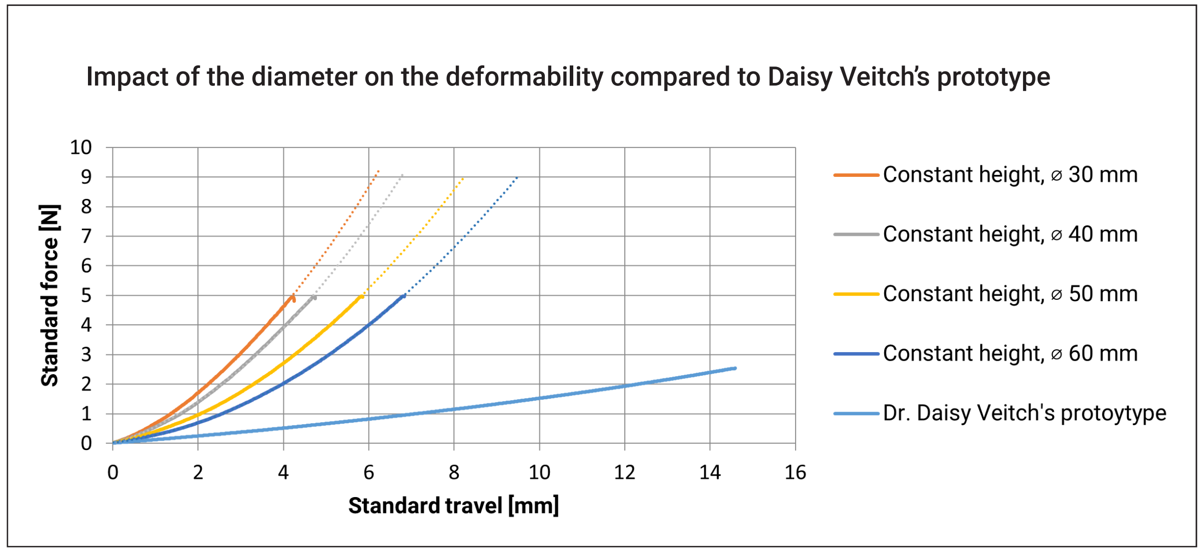


Figure 6.28. Impact of the diameter on the deformability.

To be able to make approximate predictions of consistency for cylindrical prototypes of other dimensions, trendlines were obtained from these results. These trends are shown in Figure 6.29 and Figure 6.30, where the x-axis shows the variation in height/diameter and the y-axis shows the standard travel under 5 N of force. Due to the distribution of the known points, a linear approximation was considered the most appropriate. However, it is important not to neglect the potential inaccuracies in this prediction, as only four points were used as reference and linear approximation might not necessarily be the best approach.

In these graphs, the points in pink represent where the reference model developed by Daisy Veitch would be located. The reference model has an approximated diameter of 200 mm and is 70-mm high. Based on the deformation this model experienced in the compression test, its travel has been determined using the average slope between 1.5 and 2.5 N and considering a linear growth up to 5 N. This was necessary because travel data for this model under a 5 N force was not measured during the compression test due to the travel limitation imposed, which made the probe stop moving before reaching 5 N.

When analyzing the graphs, it was possible to see that the slope of the graph predicting consistency based on the height of the sample is steeper. This means that by increasing the height of the cylindrical sample by 1 mm, a bigger increase in travel could be achieved than with a 1-mm increase in diameter. Therefore, height has a bigger impact on consistency than the diameter.

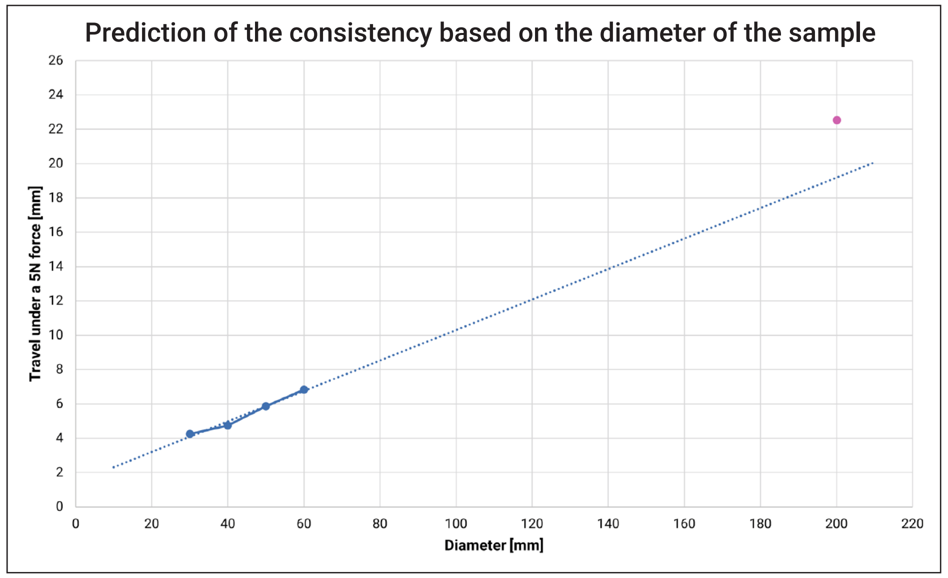


Figure 6.29. Prediction of the consistency based on the diameter of the sample.

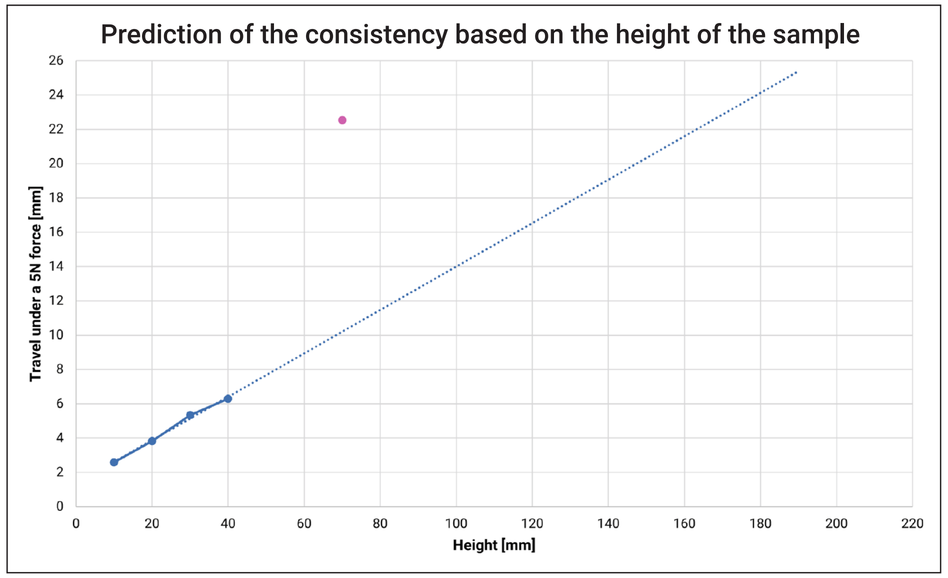


Figure 6.30. Prediction of the consistency based on the height of the sample.

These results allowed establishing general measurements of cylindrical samples with similar characteristics that would provide the same deformation as the reference model under a 5-N force. Given the same conditions, a 25-mm high sample would need to have a diameter of 235 mm to deform similarly as the reference model. On the other hand, a sample with the diameter of 40 mm would need to be 170-mm high to achieve this.

Furthermore, it is interesting to be able to predict the deformation for other forces applied. For this, two graphs that show the increase of deformation for each additional 1 N of force applied depending on the diameter/height of the sample were created (see Figure 6.31 and Figure 6.32). To make this estimation, the information shown in Figures 6.29 and 6.30 was used. More specifically, only the information belonging to the force range between 3 and 5 N was used. This is because this range presents a more linear tendency, while the deformation under forces lower than 3 N would make this estimation less accurate.

In the below graphs, the points in pink represent the travel under each additional 1N applied to the reference prototype from Dr. Daisy Veitch. To make this estimation, the force range used was from 1.5 N to 2.5 N, as opposed to the 3-5 N used for the estimation of the printed samples. The reason for this was the fact that deformation of the reference prototype under forces bigger than 2.5 N was not measured due to the limitation of the deformation, which made the compression stop before reaching the 5N force.

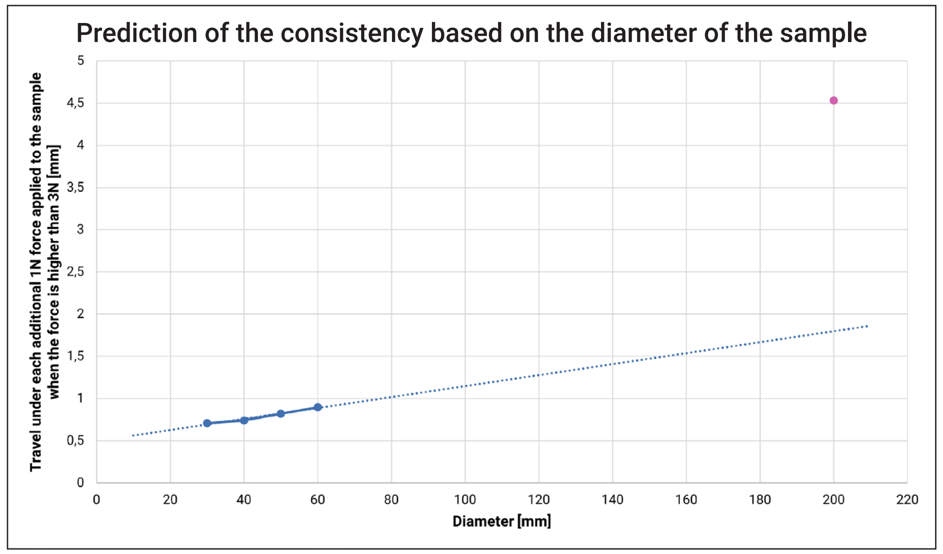


Figure 6.31. Prediction of the variation of the deformation under each additional 1N force applied based on the diameter of the sample.

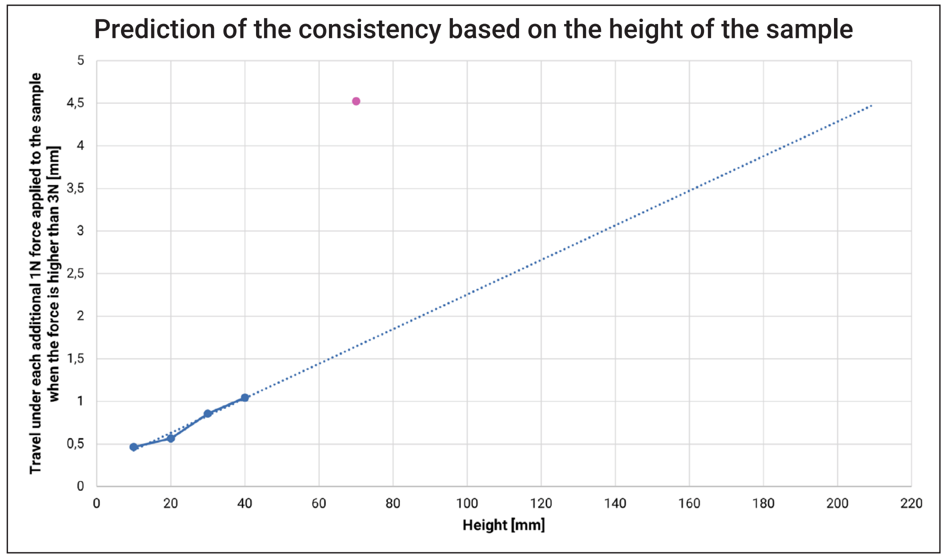


Figure 6.32. Prediction of the variation of the deformation under each additional 1N force applied based on the height of the sample.

MSc Integrated Product Design - Thesis

Discussion

This subsection discusses the conclusions obtained throughout the exploratory prototyping phase and their implications for future steps. For that, an overview of all prototypes is shown in Figure 6.33.

The first prototypes aimed to acquire a general understanding of the performance of different materials when 3D printed. Although the first trial left some unfinished wrecks due to a failure during the print, samples from later trials proved that having material inside the prototype is necessary to achieve immediate recuperation from deformation.

While it was clear from the beginning that printing with flexible material (Agilus30Clr) on top of liquid would present difficulties, mixing liquid with gel in a homogeneous fashion at a macro scale was possible. After printing several samples with different proportions of liquid and gel, it was concluded that a mixture of 80% gel and 20% liquid provided the softest consistency while performing well as support for flexible material. Mixtures with lower percentages of gel presented problems when printing flexible material on top: even in more favorable conditions, horizontal layers could not be closed, making their encapsulation impossible.

Two arrays with different external wall thicknesses (i.e., 0.6 mm and 1 mm) were printed to determine the appropriate thickness, from which it was possible to conclude that a wall thickness of 0.6 mm presents better results in terms of consistency, as they feel softer and are equally printable. Because these walls are very thin and printing them on top of any liquid-gel mixture could lead to imperfect results, all samples were printed upside down, with the testing surfaces at the bottom.

Column-based lattice structures were also manufactured to test their printability and whether they would be of relevance to this project. Lattices with columns of 1 mm, 2 mm, and 3 mm in diameter were printed. Due to their intricate geometry, they needed heavy support, which became difficult to remove. When removing the support material from the 1-mm column lattice, three columns broke, making this lattice highly inconvenient to use with Polyjet 3D printing. On the other hand, the 3-mm column lattice was too stiff and thus difficult to deform. Lattices with 2-mm columns were found to be most suitable for achieving shape deformation due to gravity.

Incorporating columns within the mixture that is used as support is also a possibility that helps printing smoother surfaces on top. However, these beams create a haptically perceptible nodular pattern on the testing surface, which is undesirable.

Lastly, the effect of the scale on consistency was tested through two different compression tests. The results of these tests confirmed that, as presumed, bigger volumes provide softer consistencies (higher deformations are achieved under the same force in bigger samples). The effect of increasing the volume of samples through an increase in diameter and through an increase in height were also contrasted. It was possible to conclude that the height of the geometry has a bigger impact on consistency than the diameter: increasing the height by 1 mm causes a bigger increase in deformation than increasing the diameter by 1 mm.

MSc Integrated Product Design - Thesis

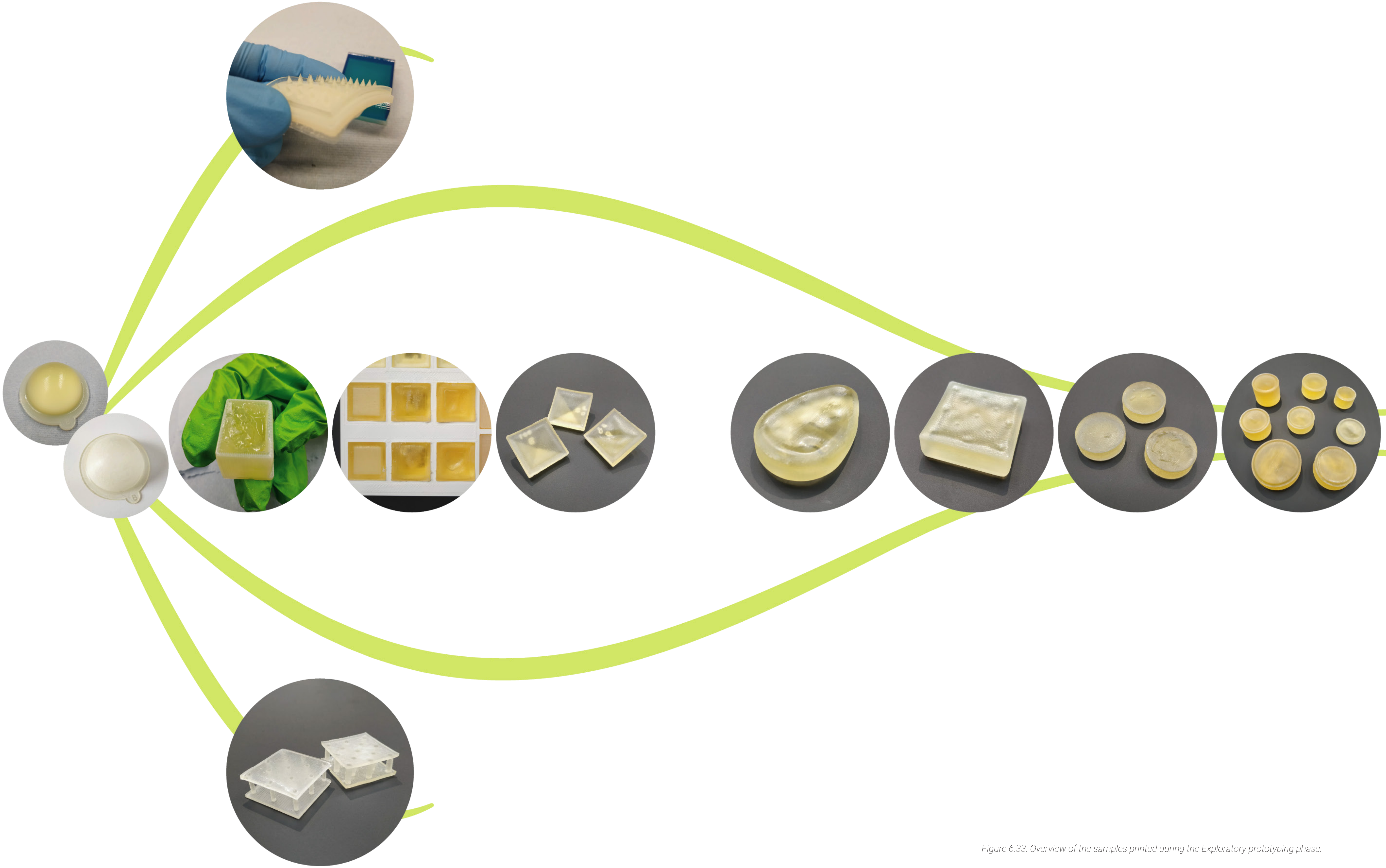


Figure 6.33. Overview of the samples printed during the Exploratory prototyping phase.

Direction

Before proceeding with Conclusive prototyping, a specific direction to follow was defined.

As explained, lattice structures add complexity to a design without necessarily providing advantages to the performance of the prosthesis. For this reason, the use of lattice structures was avoided unless they were proved to be beneficial.

Informed by the in-depth exploration in the Exploratory prototyping phase, a decision was made to use mixtures of gel and liquid for the development of new prototypes. These mixtures provide a softness that could potentially resemble the consistency of a real breast, granted that the internal structure of the prosthesis is designed correctly. As a starting point for the design of the interior, a biomimetic approach was considered appropriate. Following a general design based on the lobule distribution in a breast could help generate the desired consistency. To develop this approach, the first design was based on the model proposed by Cruz et al. (2018). Further information is specified in the *Conclusive prototyping* section.

To model the external shape of the prosthesis, the ideal process would include 3D scanning the torso of a woman after mastectomy and reverse-engineering a shape that is symmetrical to the healthy breast and perfectly conforms to the topology of the mastectomized area. For this project, it was not possible to access a 3D scan of a female torso after mastectomy, therefore, a tool developed by Dr. Toon Huysmans was used. This tool functions as a plug-in for Blender that generates statistical models of female torsos for each bra size, based on 3D scans of women wearing bras. The generated model is a mesh that can be then exported and used to reverse engineer the shape of the front side of the prosthesis. Because the models generated by this tool have both breasts, the rear side of the prosthesis cannot be designed based on any reference scan. Therefore, for this project, the rear side was modeled imitating the shape of existing silicone breast prostheses. The process is explained in more detail and visualized in the following section.

Conclusive prototyping

Develop

In the Conclusive prototyping phase, a specific direction was followed, characterized by the biomimetic approach explained in the previous subsection. Three iterations were conducted for partial prints of full-scale prototypes.

TOOLS AND METHODS

The breast forms were modeled using a specific bra size as a reference. In order not to use too much material, which would make the testing process more expensive, a small size was chosen: 70B. To base the model on a real shape, the Bra manikin tool was used which creates a statistical shape model of female breasts. These models are an average of several 3D scans of women with different bra sizes. When size 70B was selected, a model of the torso was created. The shape of breasts in this model was based on the shape that the breast would assume in a bra. As breast prostheses should be selected based on the space created between the bra and the chest wall, this was considered the most correct approach.

The torso model created by the Bra manikin tool was a mesh (see Figure 6.34). This mesh was then introduced to Rhinoceros, where, using Grasshopper, the breast was isolated from the rest of the torso, smoothed, and converted into a surface, which was then exported in the .stl format. This .stl file was then imported into Solidworks which allows for better creation of solids and posterior editions. There, reverse engineering was performed using surface modeling and following the shape of the imported surface for the front side of the prosthesis. The rear side of it was based on the shape of existing prostheses. The final digital model of the prosthesis is shown in Figure 6.35.

It is important to note that all prototypes in this phase were printed in a horizontal position with the front side of the prosthesis on the bottom and the rear side on top. This decision was made because the thickness of the front layer was only 0.6 mm, which, as determined in an earlier stage of the project, could not be smoothly printed on top of the mixture containing 80% gel and 20% liquid.

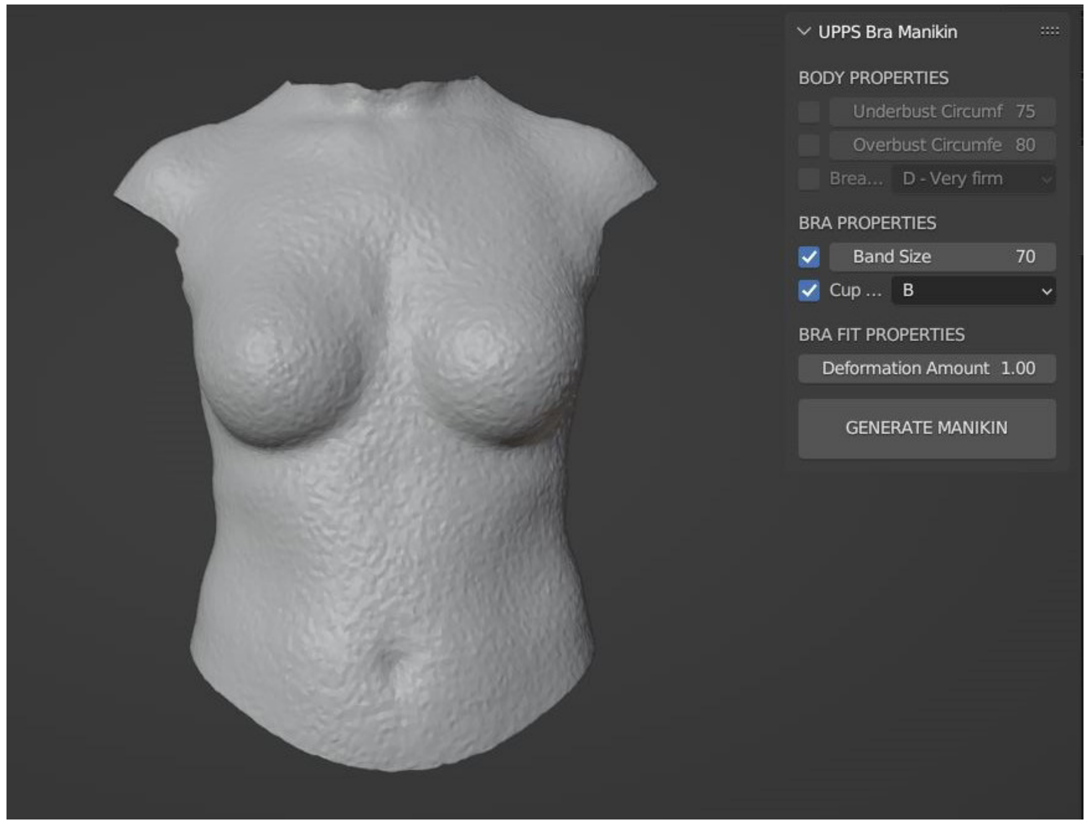


Figure 6.34. Mesh of statistical model of a torso using a bra size 70B created by the Bra manikin tool.

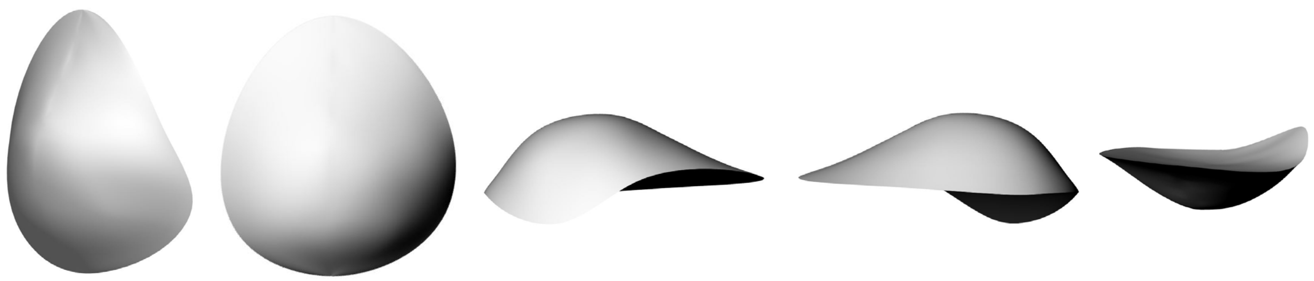


Figure 6.35. Shape of the prosthesis for bra size 70B.

CONCLUSIVE PROTOTYPING PHASE 1

As previously mentioned, a biomimetic approach was followed in this project as a starting point. The work published by Cruz et al. (2018), where the lobular arrangement of a real breast was imitated in the design of a 3D-printed breast prosthesis, was taken as a reference. Several features characterized the structure developed in their research:

- Cone-shaped geometries represented the lobes inside the breast;
- The lobes were distributed in a circular layout;
- The geometries representing the lobes gradually increased in size the closer they were to the rear side of the prosthesis;
- The arrangement of internal structures had an element of connectivity with the nipple.

To develop an approach similar to the one described in this research, the internal structure of the prosthesis was designed using cones with a similar arrangement. Three layers of cones were modeled following a circular distribution and the size of cones increased as they got closer to the rear side.

However, an important difference was incorporated in the design based on previous insights. As explained in *Exploratory Prototyping phase 6*, nodularity is perceived when discrete points are in contact with the outer surface. For this reason, the vertices of the cones should not be in direct contact with the outer front surface. Therefore, a compartment containing the mixture of 80% gel and 20% liquid was placed at the front of the prosthesis to separate the cones from the outer surface with the aim of preventing this nodularity. The structure designed for this prototype can be seen in Figure 6.36.

In Iteration 1, all the material that can be seen in Figure 6.36 was printed with flexible material (Agilus30Clr). All cavities were printed containing the mixture of 80% gel and 20% liquid. There were no empty spaces in this prototype.

For *Conclusive Prototyping phase 1*, only a slice of the prosthesis was printed, as there was no need to have the full breast form to get the necessary information. A vertical slice was considered appropriate because this would show the deformation both in standing and lying positions. The physical result can be seen in Figure 6.37.

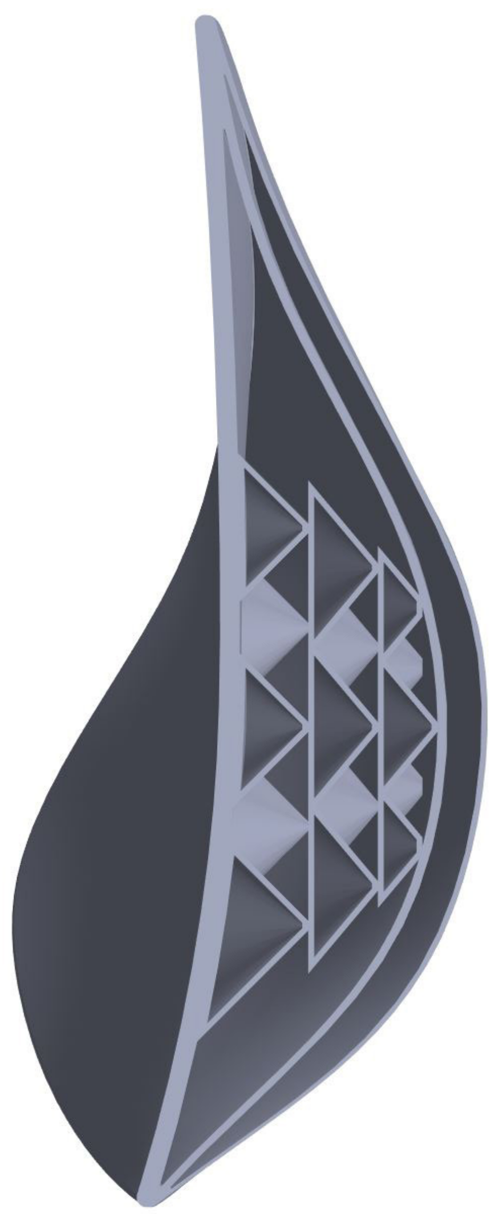


Figure 6.36. Internal structure of the full-scale model. Iteration 1.

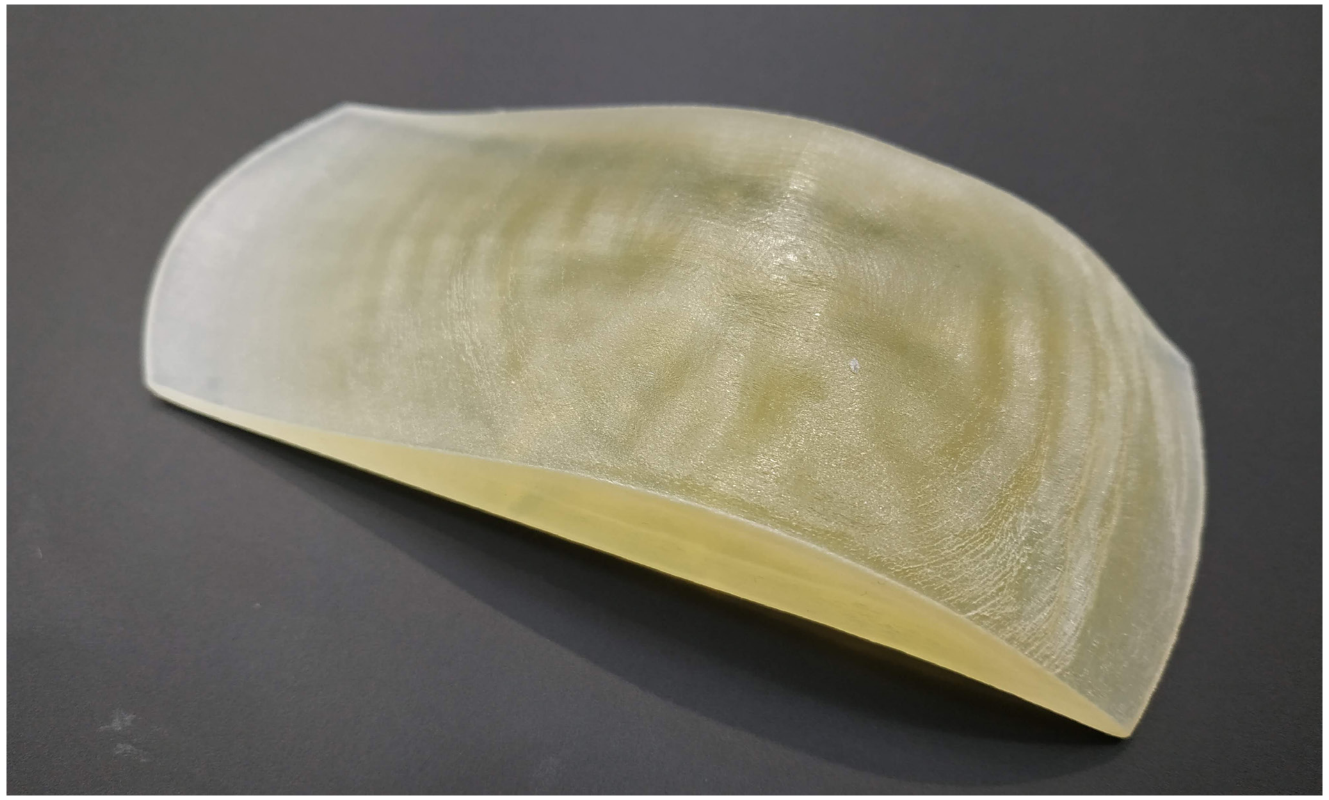


Figure 6.37. Prototype of a slice of a full-scale breast prosthesis for the Conclusive prototyping phase 1.

Results and conclusions from Conclusive Prototyping phase 1

When touching this prototype to compare it to Dr. Daisy Veitch's reference model, a clear difference in consistency could be perceived: the prototype was obviously harder. To numerically confirm that the consistency was inadequate, a compression test was conducted with this prototype. The results in comparison with the reference model can be seen in Figure 6.38.

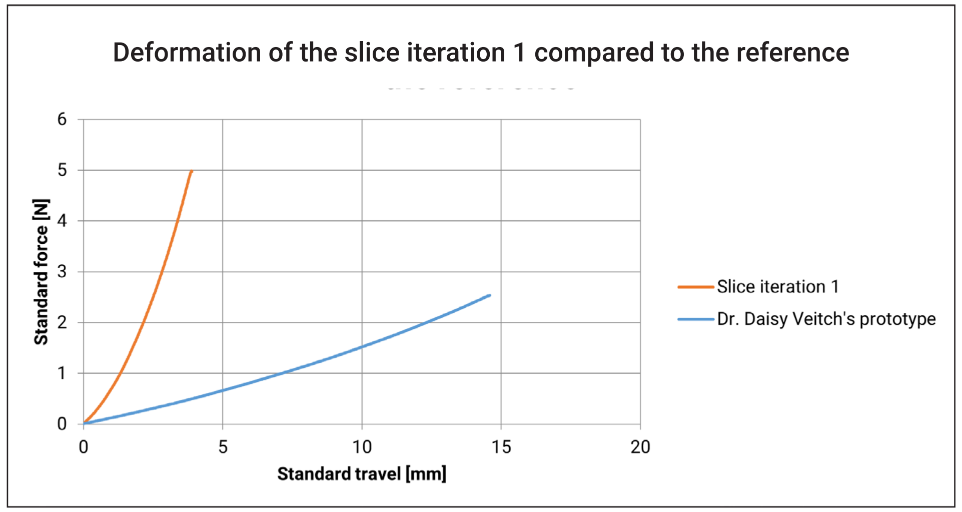


Figure 6.38. Deformation of the slice iteration 1 compared to the reference model from Dr. Daisy Veitch.

It was also possible to observe the lack of deformation when the position was altered (see Figure 6.39). Dots were drawn on the prototype to be able to compare the position of these dots when the prototype was in a horizontal position and when it was in a vertical position. Absolutely no change in shape occurred, as it is possible to see in the superposition of images: the position of dots coincides perfectly.

Factors influencing consistency were found to be related to the inner structure and its general layout. Four aspects were identified:

- Number of cones in the interior;
- Size of the cones;
- Wall thickness of the cones;
- Wall thickness of the 1-mm layer of Agilus30Clr (flexible material).

Having identified these aspects, their influence on consistency and how the consistency could be made softer were evaluated. This evaluation is presented in Table 6.2.

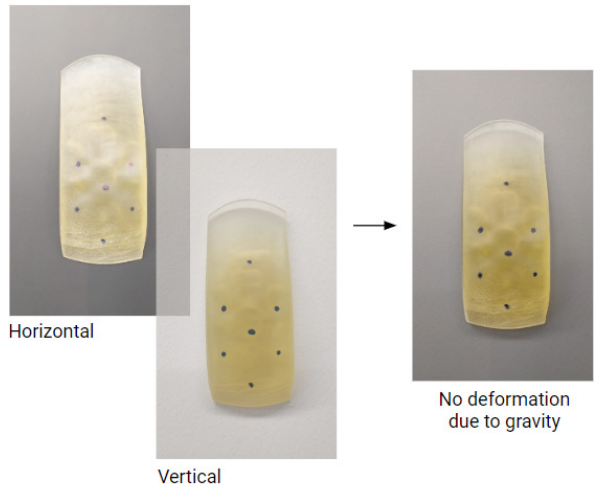


Figure 6.39. Deformation of the slice iteration 1 based on its own position. The image on the left shows the prototype in a horizontal position (picture taken from above). The image in the middle shows the prototype in a vertical position (picture taken from the front). The image on the right shows a superposition of both images with reduced opacity.

Factors influencing consistency			
Inner structure			Layout
Number of cones in the interior	Size of the cones	Wall thickness of the cones	Wall thickness of the 1-mm Agilus30Clr layer
How do these factors affect the consistency?			
Reducing the number of cones would make it softer.	Making the cones bigger would allow them to keep more mixture inside and therefore make the prototype softer.	The thinner the walls are, the softer they will be. However, there is a limit to printability and smaller thicknesses have not been tested.	The thinner the wall is, the softer it will feel.
Can this be improved? If yes, how? If not, why?			
Yes, there could be fewer cones.	Yes, the cones could be made bigger.	No. For printability reasons, the walls of the cones should be kept at 0.6 mm.	Yes, the 1-mm thick wall could be made 0.6-mm thick.

Table 6.2. Factors influencing the consistency of the prototype of Conclusive prototyping phase 1.

On the other hand, a potential factor influencing deformability due to change in body position could be the connectivity between the elements of the inner structure. As in lattice structures, where higher connectivity provides stiffer structures (Mora et al., 2022), cones being interconnected, as well as connected to outer layers were assumed to make the overall prototype stiff and prevent deformation. Connectivity could be reduced by removing the touching points between cones and between cones and outer layers.

MSc Integrated Product Design - Thesis

Although the geometry was modeled and sent to the printer with the exact properties shown in previous figures, there was no certainty that all parts would be printed accordingly. To verify whether the model was printed as planned, the prototype was cut open and the internal structure examined.

The internal material had a very gel-like consistency, rather than liquid consistency (see top left image in Figure 6.40), which supported the printability of this prototype. The 1-mm layer that separated the cones from the outer layer was printed correctly (see image in the top right in Figure 6.40). The cones in the interior were also printed according to the CAD model (see bottom image in Figure 6.40). The cones were also connected to each other and to other layers according to the digital model. This connectivity was purposely broken to remove the cones with the aim of verifying whether the cones themselves were printed correctly.

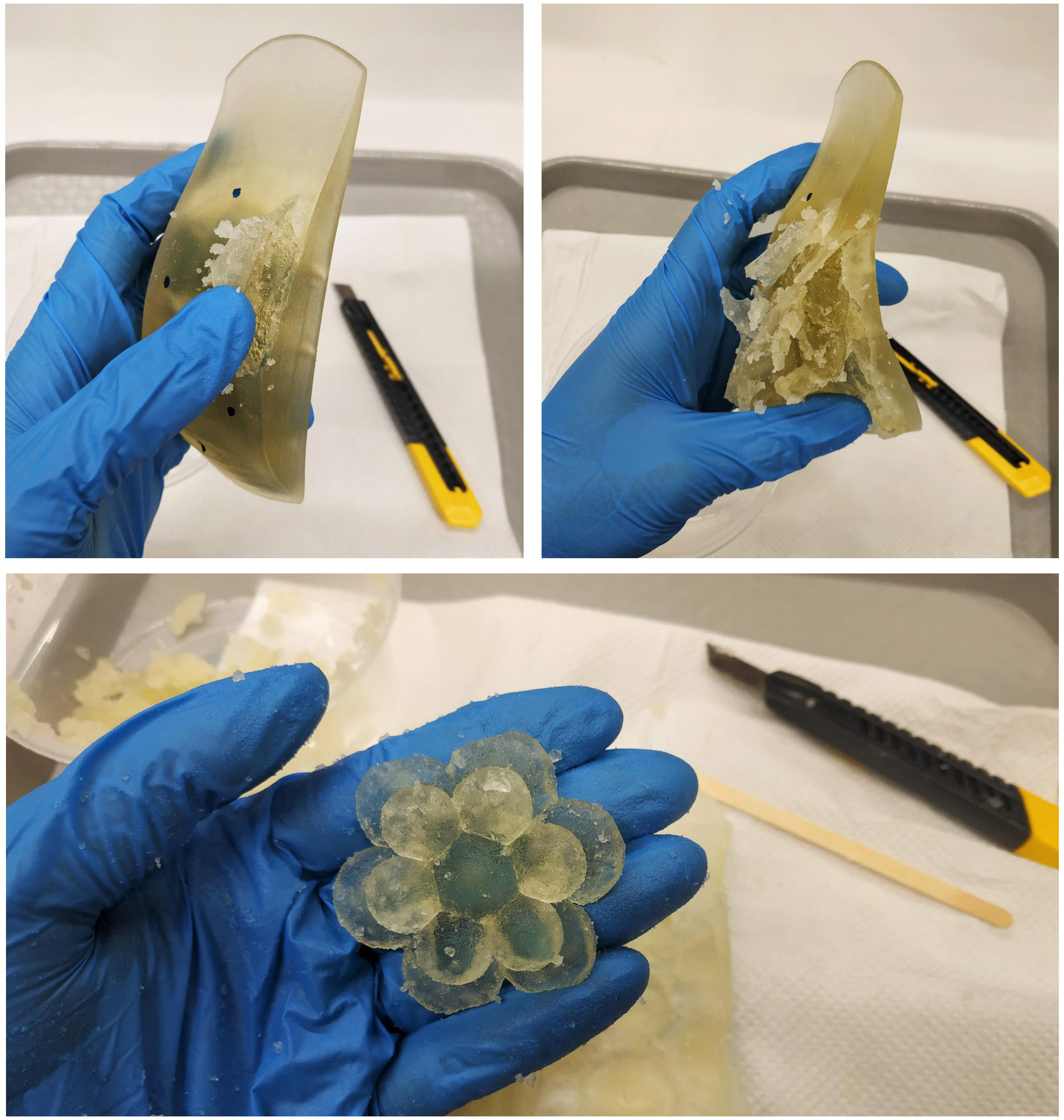


Figure 6.40. Checking the interior of the slice iteration 1. The image on the top left shows the inner homogeneous mixture with 80% gel and 20% liquid. The image on the top right shows the layer of flexible material that separates the cones from the outer layer. The image on the bottom shows the two superior layers of cones (out of three) that were printed in the interior.

CONCLUSIVE PROTOTYPING PHASE 2

Based on the insights from Conclusive prototyping phase 1, the design of the next iteration was modified as follows:

- The number of cones in the interior was reduced;
- The cones were made bigger;
- The 1-mm thick wall was made 0.6-mm thick;
- The connection between the elements in the interior was removed; all cones were entirely surrounded by the mixture and were not connected to outer walls.

The CAD model resulting from these changes can be seen in Figure 6.41. As for the previous iteration, all the material that can be seen was printed with flexible material (Agilus30Clr). All cavities were filled with the mixture of 80% gel and 20% liquid. There were no empty spaces in this prototype. Again, only a slice of the prosthesis was printed. The physical result can be seen in Figure 6.42.

Results and conclusions from Conclusive Prototyping phase 2

When touching this prototype, it was possible to clearly perceive that it was softer than the previous prototype, but still much harder than Dr. Daisy Veitch's reference model. While the factors influencing consistency were correctly identified, the influence of changes made to the design was still insufficient. To numerically confirm these affirmations, a compression test was conducted with this prototype. The results that compare both iterations to the reference model can be seen in Figure 6.43.

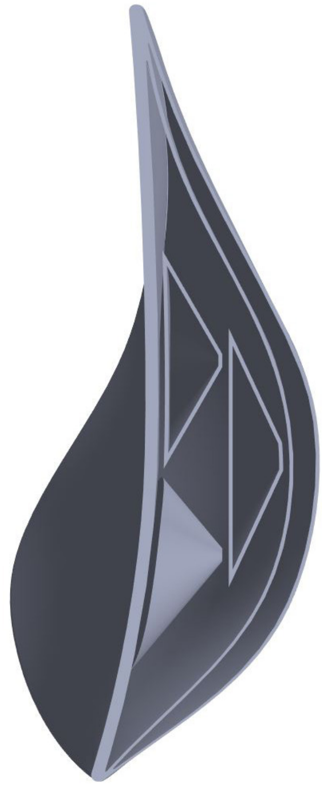


Figure 6.41. Internal structure of the full-scale model. Iteration 2.

Figure 6.42. Prototype of a slice of a full-scale breast prosthesis for the Conclusive prototyping phase 2.

Similar to the previous iteration, factors influencing consistency were related to the inner structure and the general layout. The following aspects were identified:

- Number of cones in the interior;
- Size of the cones;
- Wall thickness of the cones;
- Inclination of the walls of the cones;
- Wall thickness of the internal Agilus30Clr (flexible material) layer;
- Distance between the external front Agilus30Clr layer and the intermediate Agilus30Clr layer.

Having identified these aspects, their influence on consistency and how the consistency can be made softer are evaluated. This evaluation can be seen in Table 6.3.

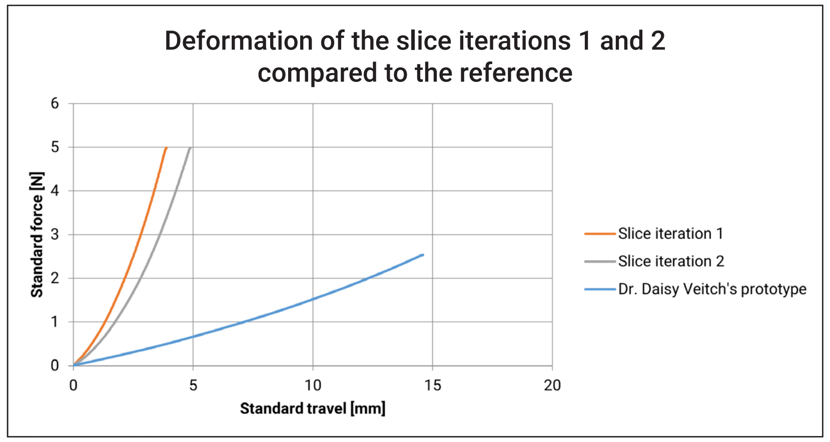


Figure 6.43. Deformation of the slice iterations 1 and 2 compared to the reference model from Dr. Daisy Veitch.

Factors influencing consistency					
Inner structure				Layout	
Number of cones in the interior	Size of the cones	Wall thickness of the cones	Inclination of the walls of the cones	Wall thickness of the internal Agilus-30Clr layer	Height of the mixture between the two external Agilus30Clr layers
How do these factors affect the consistency?					
Reducing the num-ber of cones would make it softer.	Making them bigger will allow them to keep more mixture inside and therefore make it softer.	The thinner the walls are, the softer they will be, but there is a limit to printability.	The more vertical they are, the stiffer they make the prototype.	The thinner, the softer it feels.	The higher, the softer it feels (according to the scale test).
Can this be improved? If yes, how? If not, why?					
Yes, there could be fewer cones.	Yes, the cones could be made bigger.	No. For printabi-lity reasons, the walls of the cones should be kept at 0.6 mm.	Yes, the angled wall could be made more hori-zontal, although this depends on the topology of the rear side of the prosthesis.	No. For printability reasons, the wall should not be thin-ner than 0.6 mm.	Yes, it could be made higher.

Table 6.3. Factors influencing the consistency of the prototype of Conclusive prototyping phase 2.

Before continuing with the redesign for iteration 3, the necessity of the Agilus30Clr wall that separates the cones from the outer layer was evaluated. As the connectivity between the cones and outer layers has been removed and the purpose of this wall was to prevent the nodular sensation when touched, it made sense to assume that this wall could be removed. This would allow having a bigger continuous volume of the liquid and gel mixture, which according to previous compression tests, should help provide a softer consistency.

As there were no requirements or limitations making this wall further necessary, a decision was made to eliminate it in the next iteration.

CONCLUSIVE PROTOTYPING PHASE 3

Based on the insights from *Conclusive Prototyping phase 2*, the design of the next iteration was modified as follows:

- The number of cones in the interior was reduced to just one big cone;
- The cone was made bigger;
- The wall that separated the cone from the exterior layer whose aim was to avoid nodularity was removed.
- To avoid any nodular sensation when pressed strongly, the vertex of the internal cone was rounded.

The model resulting from these changes can be seen in Figure 6.44. All external surfaces were printed with flexible material (Agilus30Clr), and all cavities were printed containing the mixture with 80% gel and 20% liquid. Like in previous iterations, only a slice of the prosthesis was printed. The physical result can be seen in Figure 6.45.

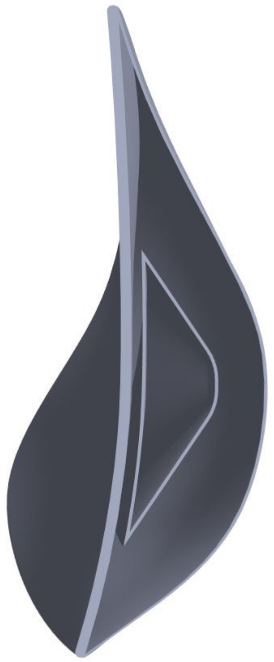


Figure 6.44. Internal structure of the full-scale model. Iteration 3.

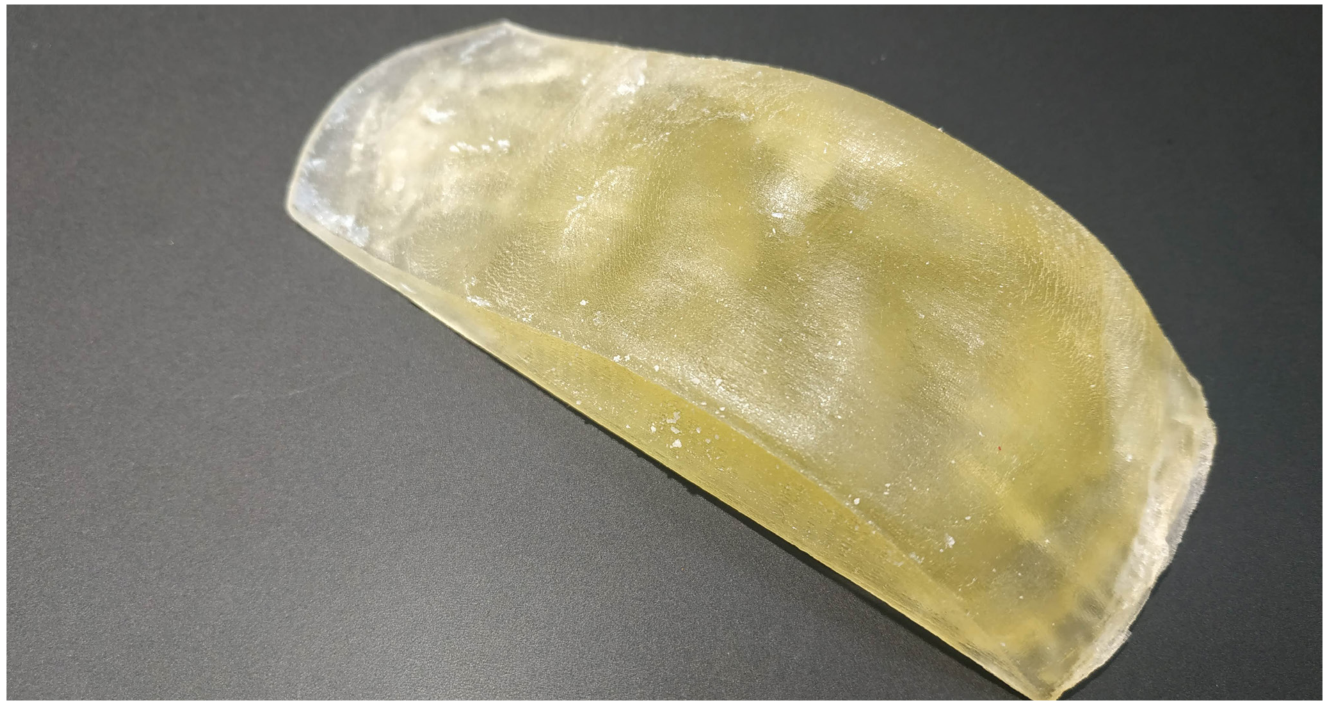


Figure 6.45. Prototype of a slice of a full-scale breast prosthesis for the Conclusive prototyping phase 3.

MSc Integrated Product Design - Thesis

Results and conclusions from Conclusive Prototyping phase 3

When touching this prototype, it was possible to perceive that it was much softer than the previous iteration, while still offering more resistance to deformation than the reference model. In Figure 6.46 the comparison of compression-test results across all iterations and the reference model is presented. Interestingly, for forces lower than 0.5 N, the last prototype demonstrated softer properties than the reference model, as the deformation under the same force was bigger in the printed sample.

Besides consistency-related aspects, it is important to note that this prototype presented some flaws. The front side of the prosthesis was ripped in two different points (see Figure 6.47). Whether this happened during the printing or during the removal of the support material is unknown. However, it could be hypothesized that removing the inner layer that separated the cones from the outer front layer (see Figure 6.48) might have had an impact on this incident by weakening the lower part where the front and rear layers of flexible material meet. Another possible reason might also have been just a punctual failure during the printing process.

All iterations contained cones in different numbers and sizes, and also all of them offered a harder consistency than the reference model. This led to thinking that having cones inside the breast form might not necessarily be the best idea. While they might help with printability, they might be the reason why softer consistencies more similar to a natural breast were not reached. It was, therefore, necessary to understand what the value of the cones was. From the product's performance perspective, would it be better not to have them? The *Conclusive Prototyping phases 4 and 5* explored this possibility.

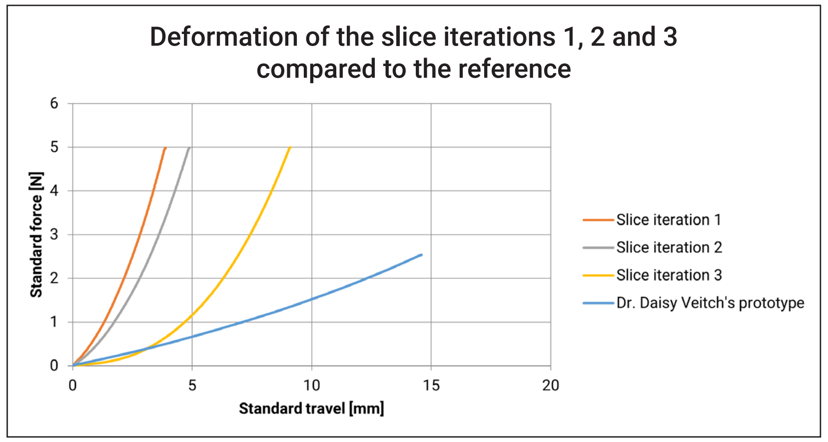


Figure 6.46. Deformation of the slice iterations 1, 2, and 3 compared to the reference model from Dr. Daisy Veitch.

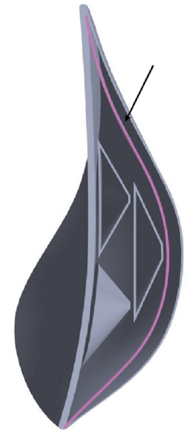


Figure 6.48. Layer of flexible material (Agilus30Clr) that separates the cones zone from the front zone.

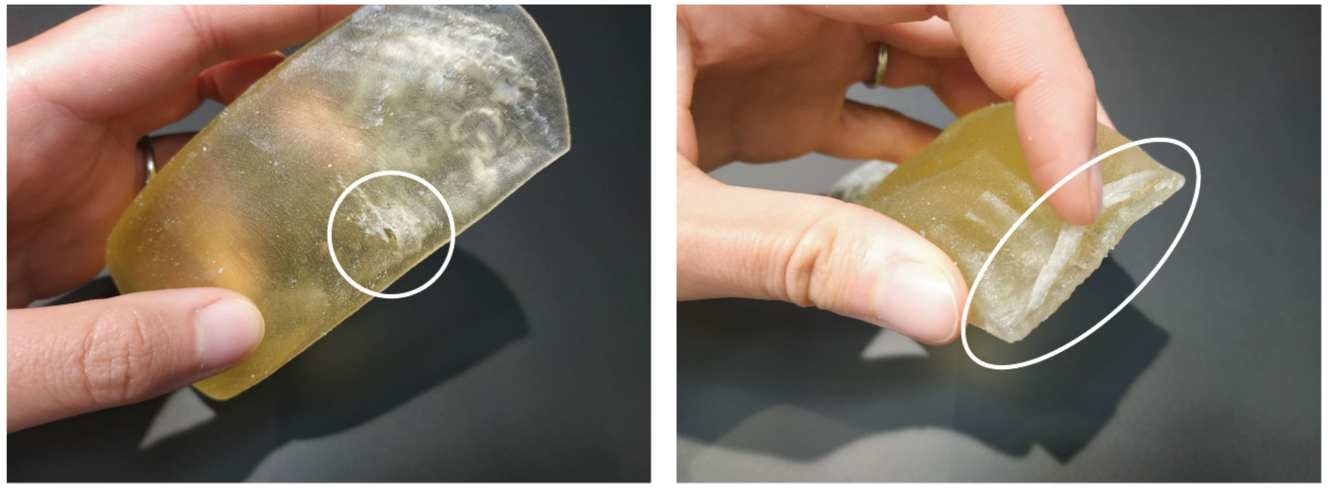


Figure 6.47. Rips in the models printed for the Conclusive prototyping phase 3.

CONCLUSIVE PROTOTYPING PHASES 4 AND 5

These prototypes intended to explore the performance of the prosthesis without the cones inside. Despite thinking they might help provide a realistic consistency by following a biomimetic approach and experimenting with several variations of the cones' layout, it seemed like they were not preventing the prototypes from acquiring a consistency that would be objectively close to that of a natural breast. For this reason, two more prototypes were printed. The models of these prototypes can be seen in Figure 6.49.

While the conclusive prototype 4 intended to explore consistency of the prosthesis without internal cones, it was not expected to be fully printable. It was expected to present the same problem as the conclusive prototype 3, which did not contain the compartment separating the cones from the outer part, and was hence ripped at the joint between the front and the back outer surfaces. The conclusive prototype 5 intended to explore a similar aspect by not having cones in the interior, but the inner flexible layer was preserved for the purpose of printability.

Figure 6.49. Internal structure of the full-scale model. Iteration 4 on the left; iteration 5 on the right.

Results and conclusions from Conclusive Prototyping phases 4 and 5

The printed results can be seen in Figure 6.50. Several flaws were apparent in both prototypes, as highlighted in Figure 6.51. While the conclusive prototype 4 was expected to present imperfections, prototype 5 was expected to be printed correctly. The fact that the last prototype was ripped as well gave an indication that the cones might be the elements reinforcing the interior of the prosthesis and providing a good support to print the rear side on top. This was considered in the design of the last prototype.

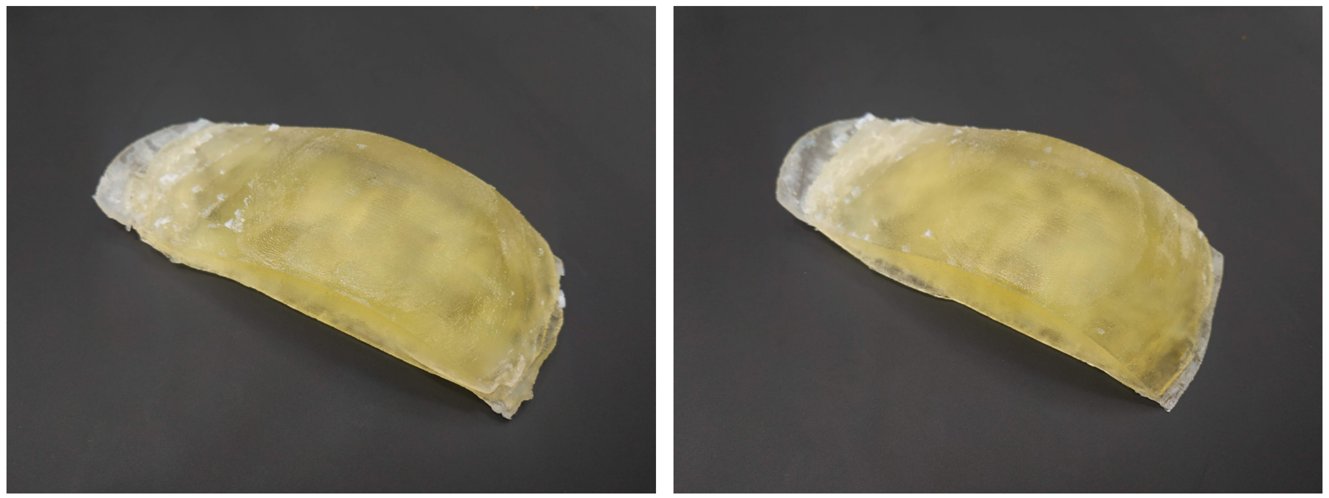


Figure 6.50. Prototypes of a slice of a full-scale breast prosthesis for the Conclusive prototyping phase: iteration 4 on the left, iteration 5 on the right.

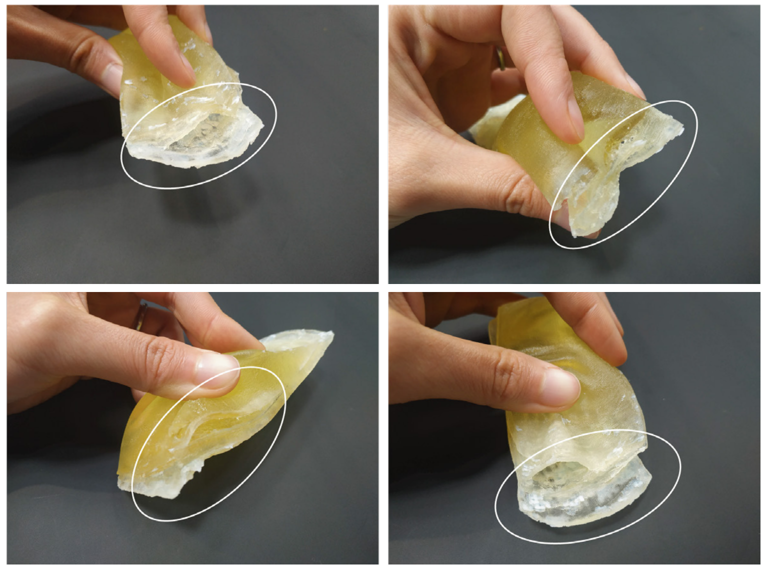


Figure 6.51. Rips in the models printed for the Conclusive prototyping phases 4 and 5.

Despite the flaws, the consistency of prototypes 4 and 5 was also examined in a compression test to gain better understanding. The results were as expected. The conclusive prototype 4 deformed more than the conclusive prototype 5 because it did not contain the internal layer of flexible material. These results can be seen in Figure 6.52. Similar to the conclusive prototype 3, for forces lower than 0.5 N, the conclusive prototypes 4 and 5 demonstrated slightly softer properties than the reference model, as they experienced bigger deformations.

As a showcase of the results obtained during the development phase of this project, an indicative evaluation of the prototypes' printability and consistency was performed (Table 6.4). Consistency was evaluated based on the results shown in Figure 6.52, and printability was estimated based on the size and severity of visible flaws.

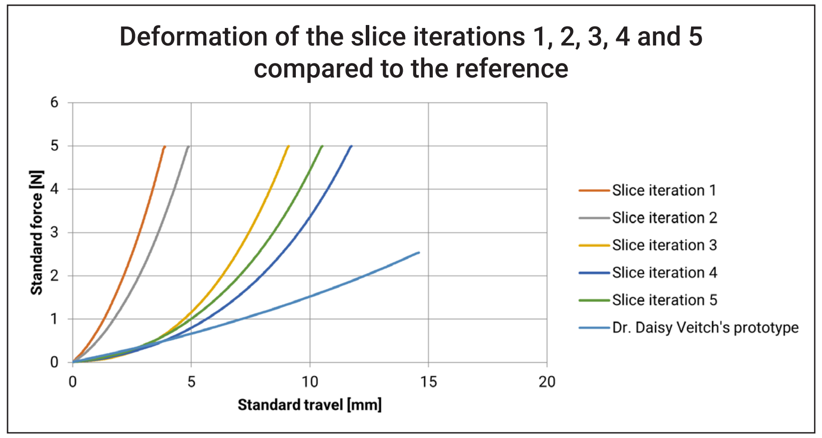


Figure 6.52. Deformation of the slice iterations 1, 2, 3, 4 and 5 compared to the reference model from Dr. Daisy Veitch.

	Consistency	Printability
Conclusive prototype 1	- - -	+ + +
Conclusive prototype 2	- -	+ +
Conclusive prototype 3	+	-
Conclusive prototype 4	+ + +	- - -
Conclusive prototype 5	+ +	- - -

Table 6.4. Indicative evaluation of the conclusive prototypes from the development phase.

From the evaluation, it was very clear that softer consistencies are not well printable for the chosen prosthesis designs. There was an obvious relation between the reduction of inner structures made with flexible material (Agilus30Clr) and the worsening of printability. There were two key aspects to consider:

- Printability is objective, and other designs of the interior should be considered to improve this aspect as much as possible without negatively affecting the consistency.
- The consistency evaluation was based on objective, measured information. Whether people are able to perceive those differences and how they are perceived could be very important for the project.

Deliver

For the design of the full-scale prototype, conclusions obtained during the conclusive prototyping iterations were taken into account. An overview of all CAD models is presented in Figure 6.53. The conclusive prototype 1 was proven to be too stiff due to the big number and small size of interior cones. The next iteration was softer but still stiffer than desired, also due to the effect of the cones. The consistency was softer in the higher and lower parts of the prototype because the distance from these points to the cones was bigger. The first two iterations were printed without any flaws. The conclusive prototype 3 was much softer according to the compression test. However, it presented some flaws in the parts where the front and rear side of the prosthesis meet. This delamination was assumed to have happened due to the elimination of the intermediate layer that previously separated the cones from the outer front part. Conclusive prototypes 4 and 5 were printed simultaneously. They both demonstrated softer qualities, but also very big flaws. The delamination was severe in both of them, and iteration 5 proved that the intermediate layer might not have been the only reason why the conclusive prototype 3 was not properly printed. In fact, it was possible to conclude that cones help enclose the cover more than the intermediate layer.

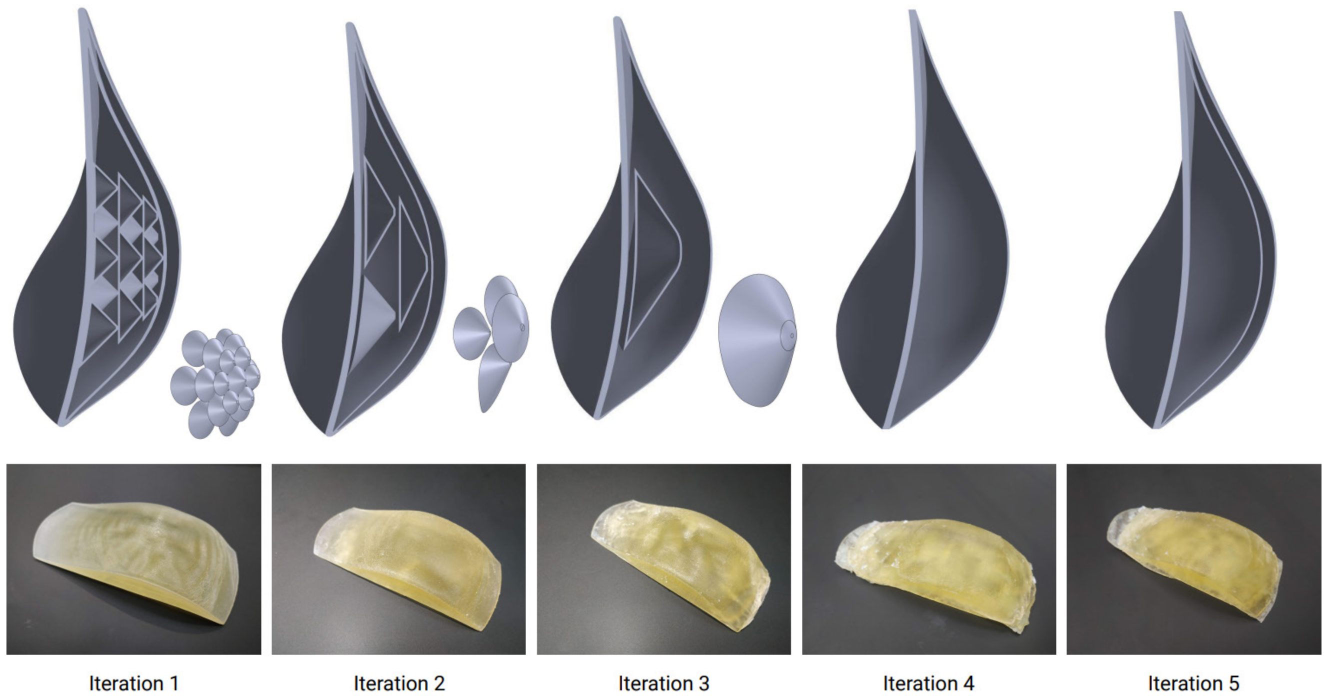


Figure 6.53. Overview of conclusive prototypes.

These full-scale iterations allowed concluding that the cones in the interior make the consistency harder, but they are desirable for printability reasons. The intermediate layer provides stiffness. Although it is not wanted from the consistency perspective, it helps printing the rear side (upper cover in printing position). Interestingly, it was possible to observe that printability was not a problem when printing the front half of the prosthesis, where flaws did not appear in any iteration. This is a positive observation; namely, while this is the most easily printable region, its consistency is heavily affected by including (flexible) solid material inside. It can then be stated that having (flexible) solid material at the front affects consistency negatively by making it harder, while it does not improve printability. Therefore, removing this material (Agilus30Clr) from the far front region might improve consistency without affecting printability.

Design decisions for the full-scale prototype were made according to the above conclusions. Cones were integrated in the design with a similar distribution as in the conclusive prototype 2, but they were only included in the rear side of the prosthesis. Cones were intended to help print the top (rear) cover. While the internal flexible layer was also preserved to some extent for good printability, the part closer to the front side of the prosthesis was removed. This was done to avoid harder consistency. In general, having Agilus30Clr (flexible solid material) close to the further front side of the prosthesis was avoided with the intention of keeping a soft consistency while not affecting printability. This model can be seen in Figure 6.54, and the printed result can be seen in Figure 6.55.

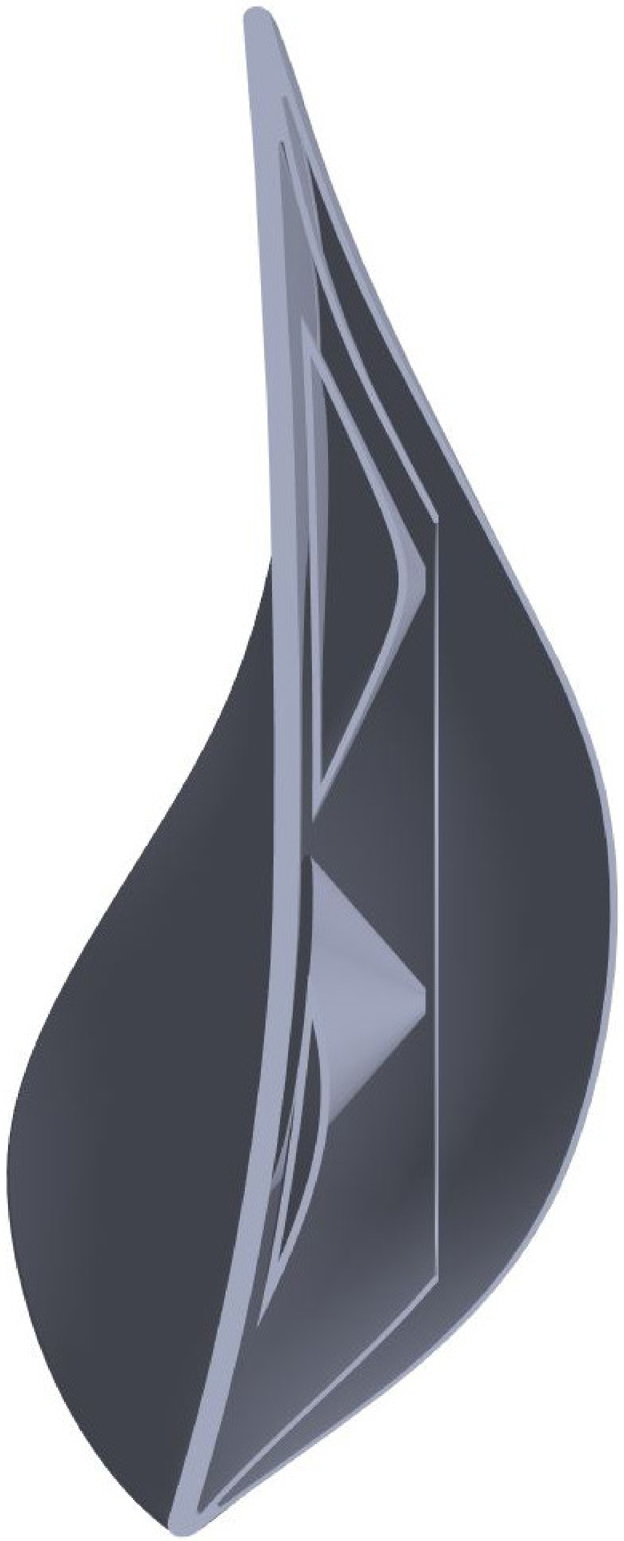
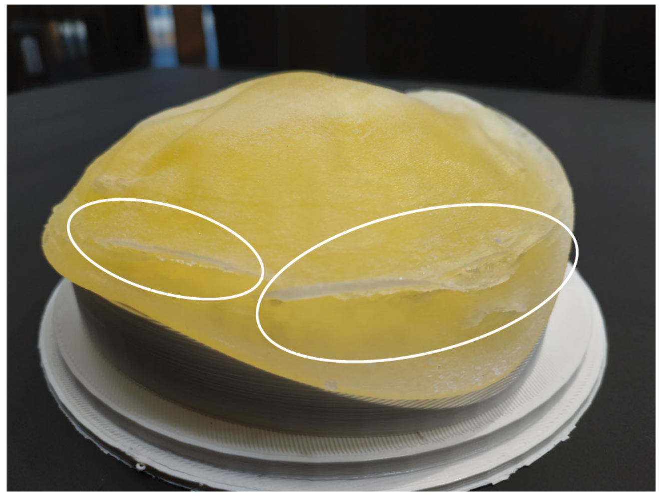


Figure 6.54. Model of full-scale prosthesis.

Figure 6.55. Printed full-scale prosthesis.

When inspecting the printed result, it was clearly visible that some flaws occurred during printing. Some rips due to delamination could be seen on the front side in the lower region close to the rear cover (see Figure 6.56, left image). The reason why this delamination might have happened is the high amount of continuous mixture in the area, which might have been scattered by the roller, making it more difficult for future layers of curable material to adhere to lower layers. This would have led to two consecutive layers of curable material not being attached to each other. Moreover, printability might have also been influenced by the fact that the cones were not attached to the rear cover of the prosthesis. This created a continuous horizontal layer of mixture that might have been too wide.

In high regions of the prosthesis, it was also possible to see air between the outer layer and the internal mixture (see Figure 6.56, right image). The front cover in this area might have had tiny slits from which part of the liquid inside might have flowed out. Losing internal material caused the volume of filling to no longer match the volume determined by the outer flexible cover. For this reason, in addition to having air inside, the cover was slightly wrinkled.



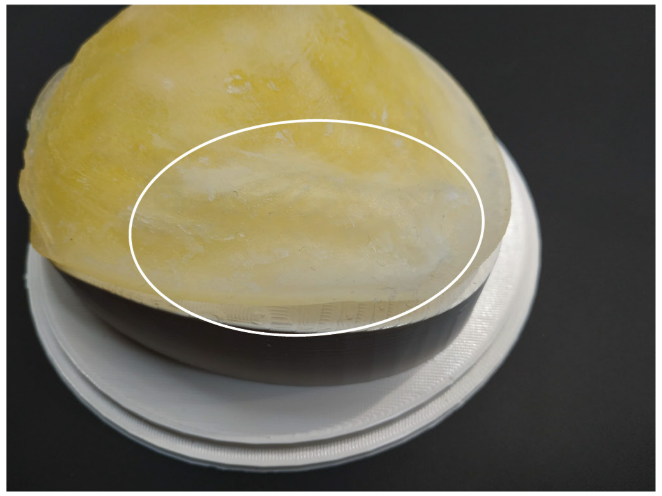


Figure 6.56. Flaws in the full-scale prosthesis. Delamination can be seen in the image on the left; air chamber can be seen in the image on the right.

To evaluate the value of this prosthesis from the consistency perspective, a new compression test was performed. The same settings and testing equipment were used as for the prior compression tests, namely:

- Applied force: 5 N
- Speed: 50 mm/min
- Probe: diameter = 16 mm; round cap

The result obtained can be seen in Figure 6.57, where it is compared against the curves obtained for the slice iterations and the reference model.

Evaluating the results, it is possible to see that the final prototype demonstrated the best qualities in terms of consistency. The curve that represents its travel is the closest to the reference and, in fact, for forces lower than 1 N, the printed prototype has softer properties than the reference model. However, a user test still needed to be performed to determine whether or not humans can even perceive these differences, as explained in the following section.

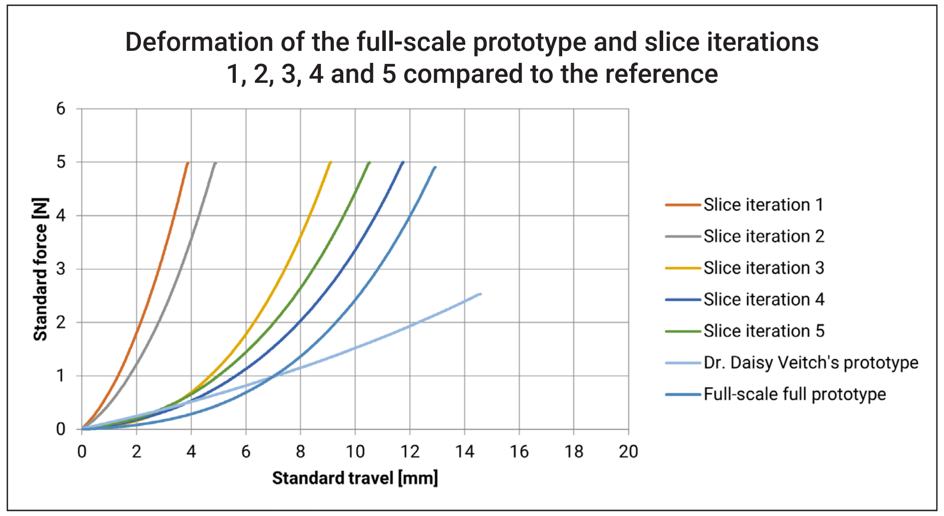


Figure 6.57. Deformation of the full-scale prosthesis compared to the slice iterations 1, 2, 3, 4, 5, and the reference model from Dr. Daisy Veitch.

7 Evaluation

Objective

Evaluation of the 3D-printed samples and final prototype was conducted with human participants to determine whether the consistency of the full-scale prosthesis is perceived as similar to the reference model, and to compare the perception of consistency with measured data. Although the compression tests provided numerical objective data regarding the consistency of samples and prototypes, it remained unknown whether the differences are noticeable by the users as well and whether the differences perceived coincide with the measured data. Therefore, the user test aimed to compare the consistencies of the full-scale prosthesis, the samples printed to test the effect of the scale on consistency, and the reference model, as perceived by the participants.

Softness is the human perception of a texture that is velvety, delicate, and bulky. Although it is related to visual, auditory, and olfactory senses as well, tactile properties are the most relevant. Two aspects can be evaluated regarding softness: surface softness and bulk softness. While surface softness is perceived by rubbing the fingers over a surface, bulk softness is related to the overall compressibility and stiffness (Wang et al., 2018). Although surface softness is also relevant to provide good product experience (especially in a product that might be in constant direct contact with the skin), the evaluation conducted in this project focused on bulk softness, which is related to consistency and the measured data.

MSc Integrated Product Design - Thesis

Tools, methods, and setup

The prototypes compared in this test include:

- The reference model from Dr. Daisy Veitch;
- The full-scale 3D-printed prosthesis (for bra size 70B);
- Eight samples printed to test the effect of scale on consistency.

Ten volunteers (5 women and 5 men) participated in this evaluation. They were all master students from the faculty of Industrial Design Engineering at the Delft University of Technology. The evaluation was conducted in an individual, onsite, structured interview that took approximately 20 minutes. All participants provided their consent to participate in the evaluation by signing the Informed Consent Form, which can be found in *Appendix 06*.

The objectives, activities, and expected results of the evaluation session can be seen in table 7.1. The printed samples were enclosed in custom-made cases with an aperture at the top, through which the participants palpated the testing surfaces. This decision was made to avoid biased perceptions led by the size of the sample, as reported by Wesslein et al. (2014). Moreover, visual stimuli have the potential to alter perceived tactile features, such as roughness, hardness, and stickiness (Yanagisawa & Takatsuji, 2015). Cases of samples from the scale testing array were equipped with codes that were meaningless to the participants, but allowed the researcher to know at every moment which sample was inside each box. These codes were as follows:

Samples with constant diameter/area and different heights:

- CAL (Constant Area Low)
- CALM (Constant Area Low-Medium)
- CAMH (Constant Area Medium-High)
- CAH (Constant Area High)

Samples with constant height and different diameters/areas:

- CHS (Constant Height Small)
- CHSM (Constant Height Small Medium)
- CHML (Constant Height Medium-Large)
- CHL (Constant Height Large)

Evaluation: User test			
	Objective	**Activity**	**Expected result**
1	Identify the potential differences between participants' perception of consistency and the objective measurements. Identify three samples from the scale testing array that resemble the softness of the reference model the most, according to human perception.	Participants palpated the eight samples of the scale testing array and were asked to order them from hardest to softest. They also palpated the reference model and were asked to select the 3 samples that felt most similar to the reference. They were also asked to state how confident they feel about their responses.	It was expected that participants would distribute the samples with the following order from harder to softer: CAL, CALM, CHS, CHSM, CAMH, CHML, CAH, CHL. They were expected to select the 3 softest samples CHL, CAH, and CHML (Figure 7.1) as the most similar to the reference.
2	Understand how the consistency of the full-scale prosthesis compares to the selected 3 samples from the scale array.	Participants compare the full-scale prosthesis to the best 3 samples from the array. They were asked to express their perception regarding consistency (i.e., whether they felt that the prosthesis was softer or harder). Note: the full-scale prosthesis was compared with the samples of the scale test before being compared to the reference model to avoid different surface textures influencing the comparison.	Participants were expected to say that the full scale prosthesis feels softer than the 3 samples of the scale testing array they had selected in the previous stage.
3	Understand how the consistency of the full-scale prosthesis compares to the reference model.	Participants compared the full-scale prosthesis with the reference model. They were asked to express their perception regarding consistency (i.e., whether they felt the prosthesis was softer or harder). Participants' responses in this stage were compared to those in the previous two stages to determine whether they logically complied with their earlier statements. If they did, it should be possible to distribute the samples, the full scale prosthesis, and the reference model linearly on a soft-hard scale. They were asked to incorporate both, the full-scale prototype and the reference model into the linear distribution they had made with the samples from the scale array.	Participants were expected to perceive the full-scale prosthesis as harder than the reference model.
4	Understand which aspects influence participants' perception of softness.	Participants were asked to elaborate on the other differences they had noticed between the scale testing samples, the full-scale prosthesis, and the reference model, and whether they felt like any of them influenced their perception of consistency.	Participants were expected to notice differences in aspects like surface texture and temperature.

Table 7.1. Overview of the user test for validating the full-scale prosthesis.

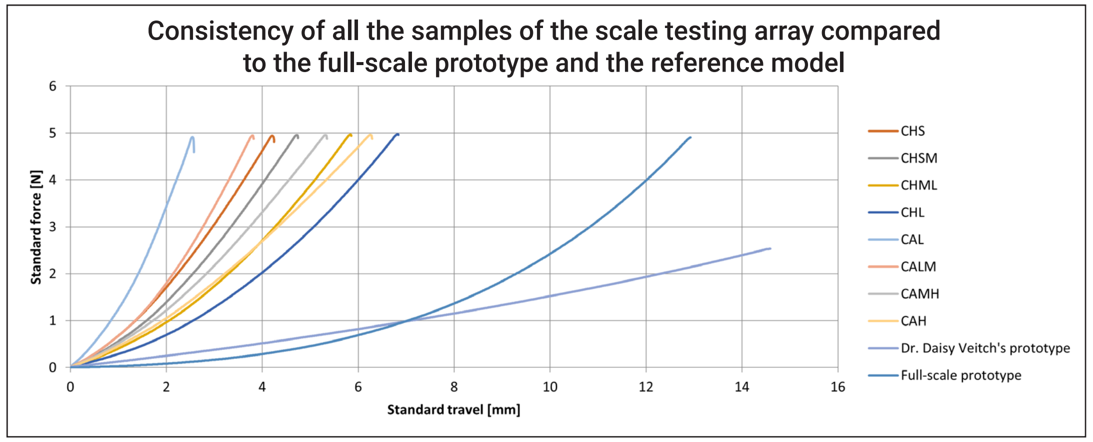


Figure 7.1. Consistency of all the samples of the scale testing array compared to the reference model.

Each sample of the scale array was placed on a base and covered with a 3D-printed cover. The bases had different heights so that the testing surfaces of all samples were at the same height. A round aperture in the middle of the cover was designed to be of sufficient size for a finger to be able to touch the sample comfortably without allowing participants to see the size of the samples inside; the diameter of the aperture was 25 mm. The complete set of samples can be seen in Figure 7.2.

Following the advice from Ms. Lyons and Dr. O'Sullivan, all printed samples were covered with talcum powder. This was considered appropriate because it reduced the stickiness of the surface, which was not intended to be part of the experience.

The possibility of heating the samples to body temperature was briefly considered, but was discarded because the objective of user evaluation was to compare the measured and perceived consistency. This comparison would not be valid if the samples were not tested under the same conditions. It is expected, however, that at higher temperatures, the deformation of the samples would be bigger; i.e., they would feel softer to touch.

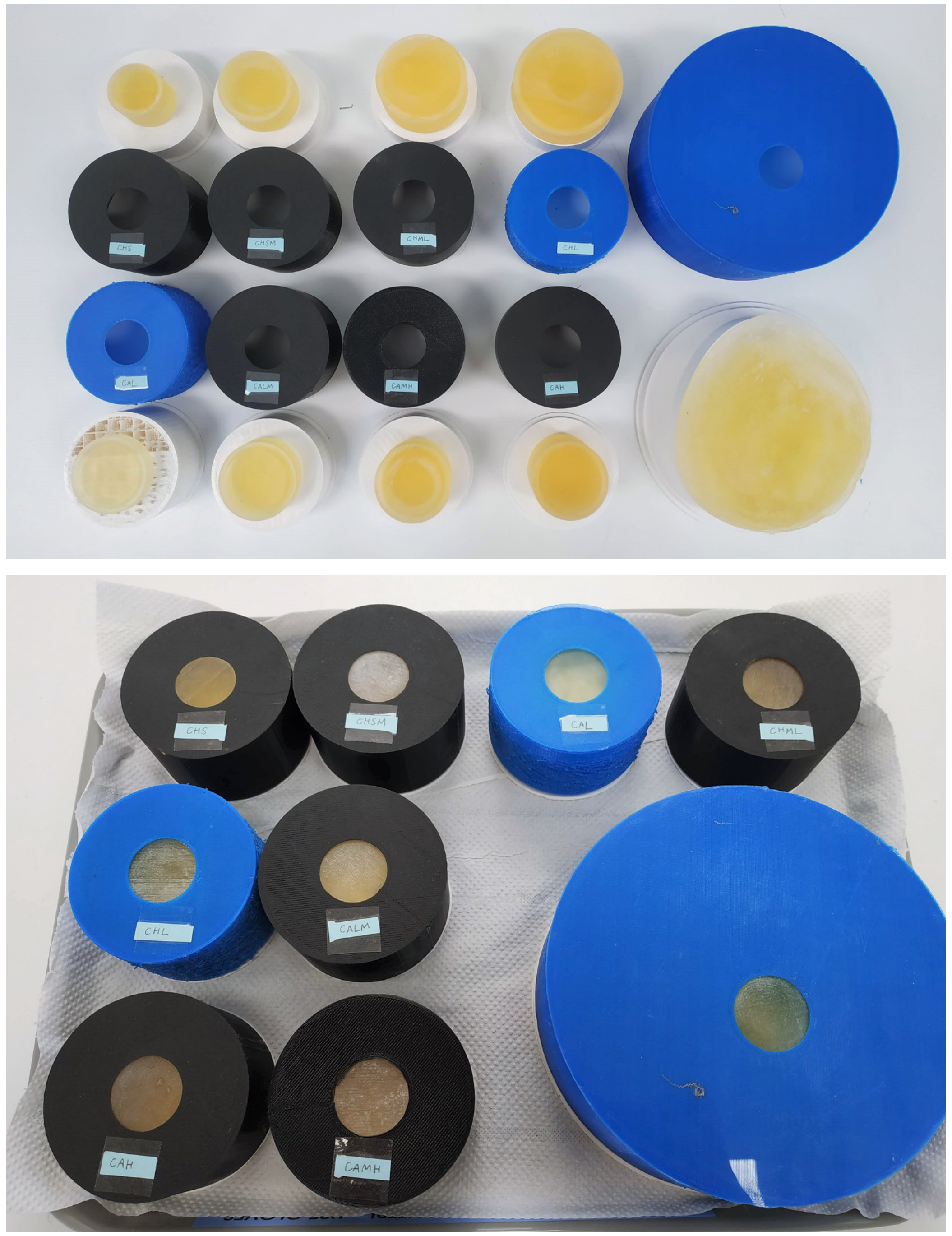


Figure 7.2. Set of printed samples used during the user evaluation session.

Results

The results obtained from the first activity, where participants ordered the samples of the scale testing array from hardest to softest, are shown in Table 7.2. The samples each participant claimed to perceive as most similar to the reference model from Dr. Daisy Veitch are highlighted in bold. An example of how the participants ordered them on a scale from hardest to softest can be seen in Figure 7.3.

Results from the user evaluation activity 1									
	Harder							**Softer**	**Confidence level (%)**
Expected order	CAL	CALM	CHS	CHSM	CAMH	CHML	CAH	CHL	
Participant 1	CAL	CHS	CALM	CHSM	**CAMH**	**CAH**	CHML	**CHL**	80%
Participant 2	**CAL**	CHS	**CAMH**	CALM	CHSM	CAH	**CHL**	CHML	80%
Participant 3	CHS	CAL	CALM	**CAMH**	CHSM	**CHML**	CAH	**CHL**	Confused about the softer ones
Participant 4	CAL	CHS	CALM	CHSM	CAMH	**CAH**	**CHML**	**CHL**	Confused about the ones in the middle
Participant 5	CAL	CHS	CALM	CHSM	CAMH	**CAH**	**CHML**	**CHL**	65%
Participant 6	CHS	CALM	CHSM	CAMH	**CHML**	**CAH**	CAL	**CHL**	90%
Participant 7	CAL	CHS	CALM	CAMH	CHSM	**CAH**	**CHML**	**CHL**	60%
Participant 8	CAL	CHS	CALM	CHSM	CHML	**CAH**	**CAMH**	**CHL**	Confused about the softer ones
Participant 9	CHS	CAL	CALM	CHSM	CAMH	**CAH**	**CHML**	**CHL**	Confused about the ones in the middle
Participant 10	CHS	CAL	CAMH	CHSM	**CALM**	**CHML**	**CAH**	CHL	90%

Table 7.2. Results from the user evaluation activity 1. The meaning of the abbreviations is as follows: CAL (Constant Area Low), CALM (Constant Area Low-Medium), CAMH (Constant Area Medium-High), CAH (Constant Area High), CHS (Constant Height Small), CHSM (Constant Height Small Medium), CHML (Constant Height Medium-Large), CHL (Constant Height Large).

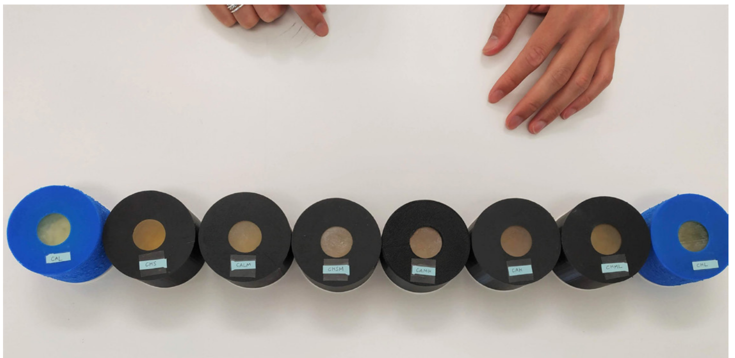


Figure 7.3. Result of the samples ordered from harder to softer according to participant 1.

In activity 2, participants compared the consistency of the full-scale printed prototype with the consistency of the three samples from the scale testing array that they claimed to perceive as most similar to the reference model. The results are presented in Table 7.3.

Most participants located the full-scale prototype somewhere between the samples they perceived as most similar to the reference model.

In activity 3, participants compared the consistency of the full-scale printed prototype with the consistency of the reference model. The results were as follows:

- Six people stated that the printed prototype felt harder than the reference model, although most of these participants mentioned that they felt extremely similar;
- Three people stated that the printed prototype felt softer than the reference model, but also mentioned that they felt very similar;
- One participant mentioned that during the first few millimeters of deformation, the printed full-scale prototype felt softer, but after a certain force was applied, the reference model felt softer because they did not need to increase the force applied to keep deforming it. This comment was very interesting because it perfectly aligns with the results obtained in the compression test.

Participants were then asked to incorporate both the full-scale prototype and the reference model into the array they built in activity 1. The results are shown in Table 7.4.

Results from the user evaluation activity 2				
	Harder			**Softer**
Participant 1	CAMH	CAH	CHL	FS
Participant 2	CAL	CAMH	FS	CHL
Participant 3	CAMH	CHML	FS	CHL
Participant 4	CAH	FS	CHML	CHL
Participant 5	CAH	CHML	FS	CHL
Participant 6	CHML	FS	CAH	CHL
Participant 7	CAH	CHML	FS	CHL
Participant 8	CAH	CAMH	CHL	FS
Participant 9	CAH	CHML	FS	CHL
Participant 10	CALM	CHML	CAH	FS

Table 7.3. Results from the user evaluation activity 2. The meaning of the abbreviations is as follows: CAL (Constant Area Low), CALM (Constant Area Low-Medium), CAMH (Constant Area Medium-High), CAH (Constant Area High), CHS (Constant Height Small), CHSM (Constant Height Small Medium), CHML (Constant Height Medium-Large), CHL (Constant Height Large).

Results from the user evaluation activity 3										
	Harder									**Softer**
Participant 1	CAL	CHS	CALM	CHSM	CAMH	CAH	CHML	CHL	FS	REF
Participant 2	CAL	CHS	CAMH	CHML	CALM	CHSM	FS	CAH	REF	CHL
Participant 3	CHS	CAL	CALM	CAMH	CHSM	CHML	CAH	FS	REF	CHL
Participant 4	CAL	CHS	CALM	CHSM	CAMH	CAH	FS	CHML	REF	CHL
Participant 5	CAL	CHS	CALM	CHSM	CAMH	CAH	CHML	FS	REF	CHL
Participant 6	CHS	CALM	CHSM	CAMH	CHML	FS	CAH	CAL	REF	CHL
Participant 7	CAL	CHS	CALM	CAMH	CHSM	REF	CAH	CHML	FS	CHL
Participant 8	CAL	CHS	CALM	CHSM	CHML	CAH	CAMH	CHL	REF	FS
Participant 9	CHS	CAL	CALM	CHSM	CAMH	CAH	CHML	REF	FS	CHL
Participant 10	CHS	CAL	CAMH	CHSM	CALM	CHML	CAH	FS	CHL	REF

Table 7.4. Results from the user evaluation activity 3. The meaning of the abbreviations is as follows: CAL (Constant Area Low), CALM (Constant Area Low-Medium), CAMH (Constant Area Medium-High), CAH (Constant Area High), CHS (Constant Height Small), CHSM (Constant Height Small Medium), CHML (Constant Height Medium-Large), CHL (Constant Height Large).

In activity 4, the participants were asked to elaborate on aspects they thought might have influenced the way they perceived the consistency. They mentioned aspects like:

- The size of the full-scale prosthesis and the reference model: they assumed that because they were bigger, they would also be softer, which might have biased them;
- Participant 6, who classified the lowest sample of the array with constant diameter (CAL) as one of the softest samples, explained that they felt it was soft because they *"could pinch it"*;
- Five participants mentioned that bouncing was different in the samples, the full-scale prototype, and the reference model: while the samples barely bounced the finger when pushed, the full-scale prototype felt more similar to the reference model in this regard; however, the full-scale prototype would need to be more bouncy to reach the properties of the reference model;
- Two participants also mentioned that they could see that the full-scale prototype had a more rounded shape rather than a flat testing surface, which might have affected their perception;
- Four participants stated that the texture of the reference model was different to the printed samples: one of them described the surface texture of the reference model as *"oily"*, which was not pleasant to touch;
- Four participants mentioned the temperature difference between the printed prototypes (warmer) and the reference model (colder).

Conclusions

SOFTER CONSISTENCIES ARE MORE DIFFICULT TO DISTINGUISH

Interesting observations were made during activity 1 of the user test. Five participants stated that the difference in the consistency between the harder samples was much clearer and easy to perceive, while noticing the difference in the softer samples and the ones in the middle part of the range was much more difficult. This was clearly noticeable by observing how much time they spent evaluating each kind of sample and how many times they switched the position between those samples in the array. Participants would quickly move the harder ones to one side, while they would repeatedly touch and compare softer samples.

A very interesting observation that proves this is that, while most participants were able to locate the softest and the hardest samples correctly, many of them switched the positions of the second and third hardest ones, the two in the middle of the range, and the second and third softest ones. This clearly shows the confusion participants experienced when evaluating the samples in the middle part of the range. One of the participants said: *"If I compare two samples that are distant on the scale, I can clearly feel the difference, but if I compare two consecutive samples, I have no idea which one is softer."*

Although participants were asked about their level of confidence in the way they distributed the samples, no direct correlation could be found between this level and the correctness of their distribution.

SOFTER SAMPLES ARE MORE SIMILAR TO A NATURAL BREAST

When participants compared the samples, they had distributed with the reference model, most of them automatically discarded the harder samples and started comparing how similar the consistency is of the softer samples. In fact, it was very clear that the samples with the most similar consistency to the reference model are the softest ones.

When palpating the reference model, four participants also mentioned that it was not necessary to increase the force applied to keep going further with the deformation. Instead, to deform the printed prototypes more, it was necessary to gradually increase the force. One of the participants described this effect saying that *"the softest part is outside, the inside is more solid."*

Seven of the ten participants categorized the reference model as softer than the full-scale prosthesis when introducing them into the array during activity 3, while three of them categorized them the opposite way. Regardless of which one was perceived to be softer, both of them were generally very close on the scale, suggesting that the difference in consistency was not overly noticeable to human touch. In fact, the difficulty of ordering them was noted by seven participants.

TRAVEL AND BOUNCING

An aspect that was discovered to be very relevant, as mentioned by half of the participants, is the bounciness of the prototypes. Bounciness was described by the participants as the force that the prototype returns to the finger and that makes it go to its initial position. This might be related to the elasticity of the flexible material used in the prints (Agilus30Clr), the shape recovery of which might be slower than that presented by the reference prototype.

When evaluating the consistency of a model, the bouncing it provides might be as relevant as the travel it allows when pressed - in this case, by a finger.

VISUAL CUES: INDICATIVE VS. MISLEADING

Three participants mentioned that part of how they evaluated consistency was visual. They were observing how much they could deform the samples (how far they could push the finger). They pointed out that this visual cue was key in their evaluation. Similarly, two participants stated that they felt that the deformation of the reference model was bigger because they could see that the side opposite to that being pushed was also being pulled. This gave them an indication of its softness.

The fact that a few participants mentioned this was especially interesting because four other participants were seen closing their eyes while palpating the samples. This suggests that, while visual cues are used to complement haptic sensation by some people, others perceive such cues as misleading, so they prefer to close their eyes.

Discussion

The results obtained at the user evaluation lead to conclusions that help define some changes and considerations that should be taken into account for the design of the final prototype. Although users were generally able to correctly distinguish samples in the softer range from samples in the harder range, they were not able to feel subtle differences. This was concluded from the fact that no one was able to distribute all the samples in the exact correct order.

The fact that samples with softer consistencies were considered the most similar to the reference model and that the full scale prototype belonged to that range shows the similarity of the consistency of the full scale prototype and the reference model. In addition, the fact that some participants found the reference model to be softer than the full scale prototype and other participants perceived them the opposite way leads to the conclusion that the final prototype does not need to be made softer than the full scale prototype already is. For this reason, and also due to the printability flaws the full scale prototype presented, it is possible to say that the focus of the design of the final prototype can be put on improving the printability of the prosthesis, rather than on changing its consistency.

8

Final result

Design of the prosthesis

The purpose of the final prototype is to make a prosthesis that offers a similar consistency as the full scale prototype while improving its printability. Design decisions are therefore made to improve printability without negatively affecting its consistency (making it harder). Such decisions are:

CONES WILL COVER A BIGGER PART OF THE REAR SURFACE

The intention is to increase as much as possible the area of the rear surface that has cones beneath it. Having cones below allows having smaller pools of mixture on top of which to print. This makes the print more stable and eases enclosing the inner material.

CONES WILL BE ATTACHED TO THE REAR COVER

This allows not having a continuous pool of mixture that hinders the print. As explained in the *Conclusive Prototyping* section, having such a wide pool of mixture can make the roller drag some of the incurable liquid material to the edges, not allowing the flexible material to properly enclose the mixture due to the effect of delamination.

MATERIAL GRADIENT WILL BE ADDED

By leaving the material mixture in the central part as it is and decreasing the amount of liquid material gradually as it gets closer to the edges of the breast form, liquid will less probably be dragged by the roller. The material gradient used can be seen in Figure 8.1. This decreases the chances of delamination.

NO FLEXIBLE MATERIAL WILL BE INCORPORATED TO THE FRONT REGION OF THE PROSTHESIS

The intention of not adding flexible material in the front region is to preserve the softness of the prosthesis as intact as possible.

These design decisions lead to the prototype whose section view can be seen in Figure 8.2.

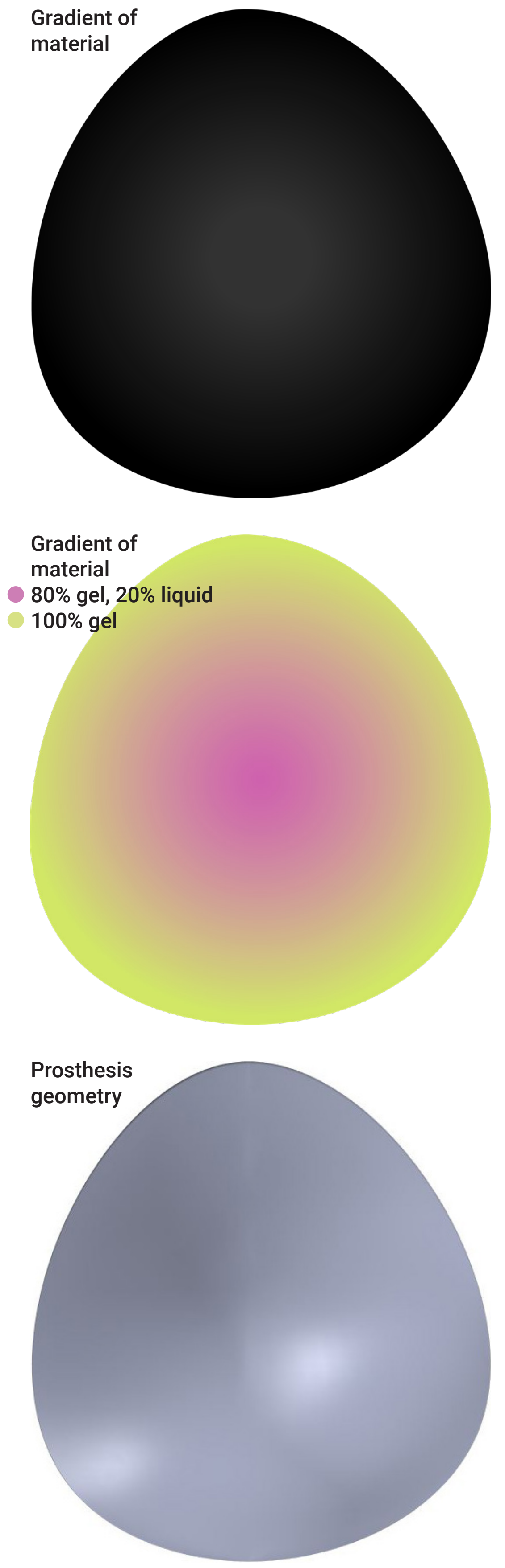


Figure 8.1. Material gradient applied to the inner mixture on top. This gradient was applied to the breast form shown on the bottom. Same gradient but represented with different colors for better visualization in the middle.

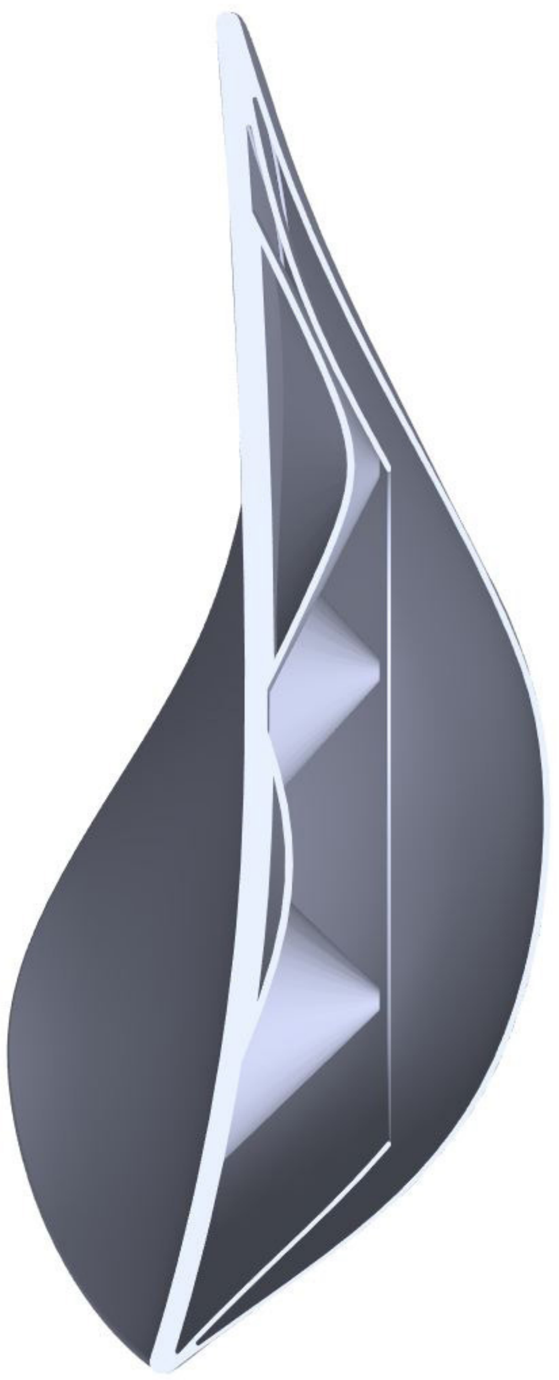


Figure 8.2. Section view showing the design of the interior of the final prototype.

Printing of the prosthesis

The printed final prototype can be seen in Figure 8.3. It is possible to see that the flaws in this prototype (see Figure 8.4) are smaller than the ones from the *Deliver* phase. Delamination happened in less spots and at a smaller scale. As compared to the previous prototype, this print did not lose liquid from inside during the fabrication process. This is the reason why the front surface is smooth -does not present wrinkles.

The application of a material mixture with a gradually changing transition from the center to the edges is noticeable to touch. Although the prosthesis is perceived to be softer in the center and become harder towards the edges, the consistency in the central area is again tested in a compression test. The objective is to have an accurate and objective comparison with the previous prototype. Results within the range defined by the previous prototype and the softer samples from the scale testing array are considered satisfactory.

The tools, setup, and methods used are the same as for previous compression tests performed. The result obtained can be seen in Figure 8.5, where the curves for the previous full scale prototype and for the reference model are also shown. As presented in the figure, the consistency of the final prototype is very close to the results obtained for the full-scale prototype. This is a positive result because while this prototype has much better printability, the consistency it provides is still close to the reference model. However, it is important to mention that this softness has been measured in the central part of the prosthesis. Closer to the edges, the amount of liquid is less and the amount of gel is higher, which means the consistency gets gradually harder.

Based on the results obtained, it is possible to conclude that in order to meet requirements both from product experience and from technical feasibility perspectives, adding a gradient of material to the mixture inside the prototype is beneficial. This gradient allows having a soft consistency in the central part of the prosthesis, which gets gradually harder towards the edges, while heavily reducing the flaws caused by delamination. Further visualizations of the final result can be seen in Figure 8.6.

The structure inside might also have influenced the improved printability. However, even if printability has been improved, it is still not perfect, as some flaws are still present. In following work related to this, further iterations should be done to avoid delamination while keeping the achieved softness.

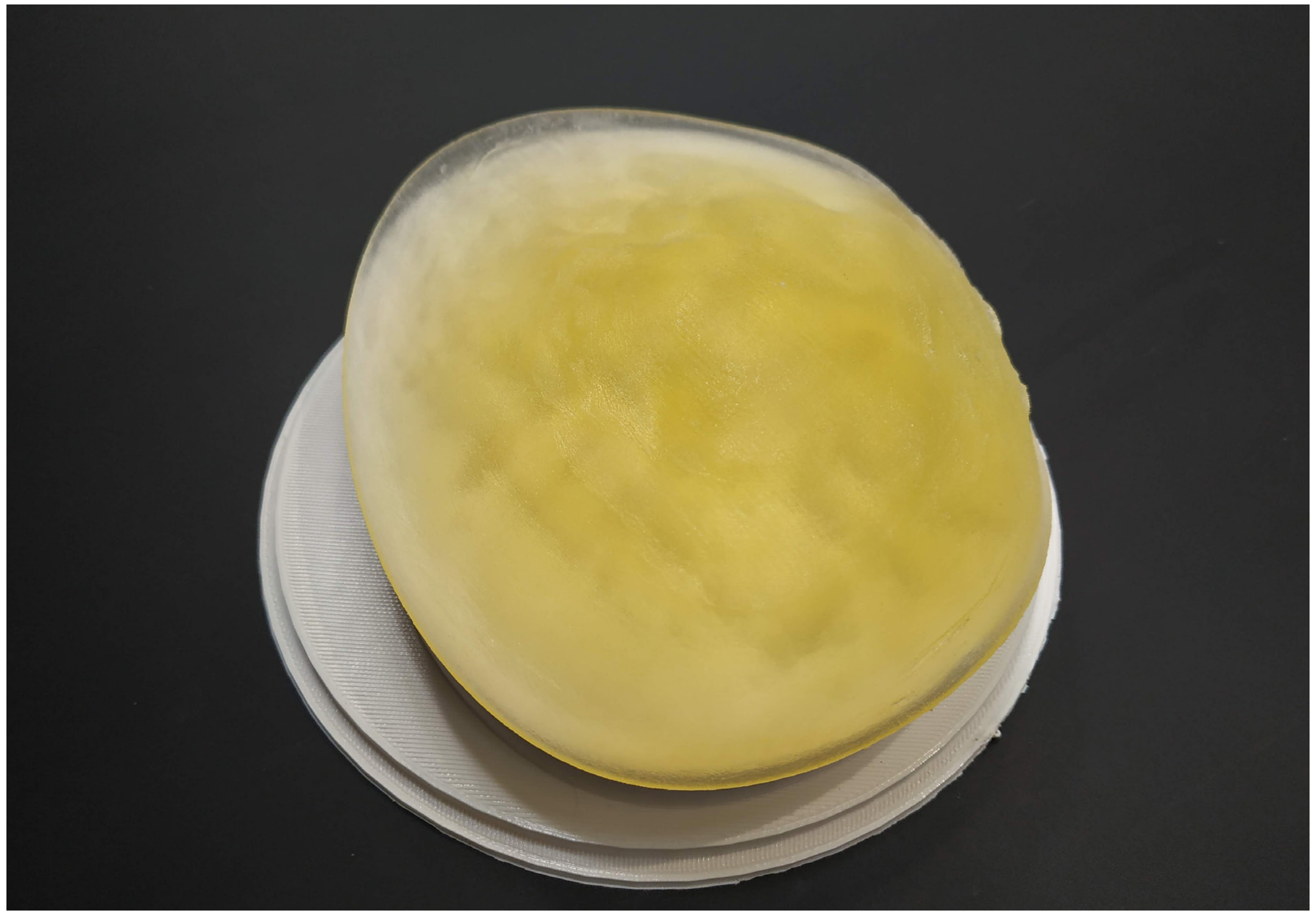


Figure 8.3. Final prototype.

Figure 8.4. Flaws due to delamination in the final prototype.

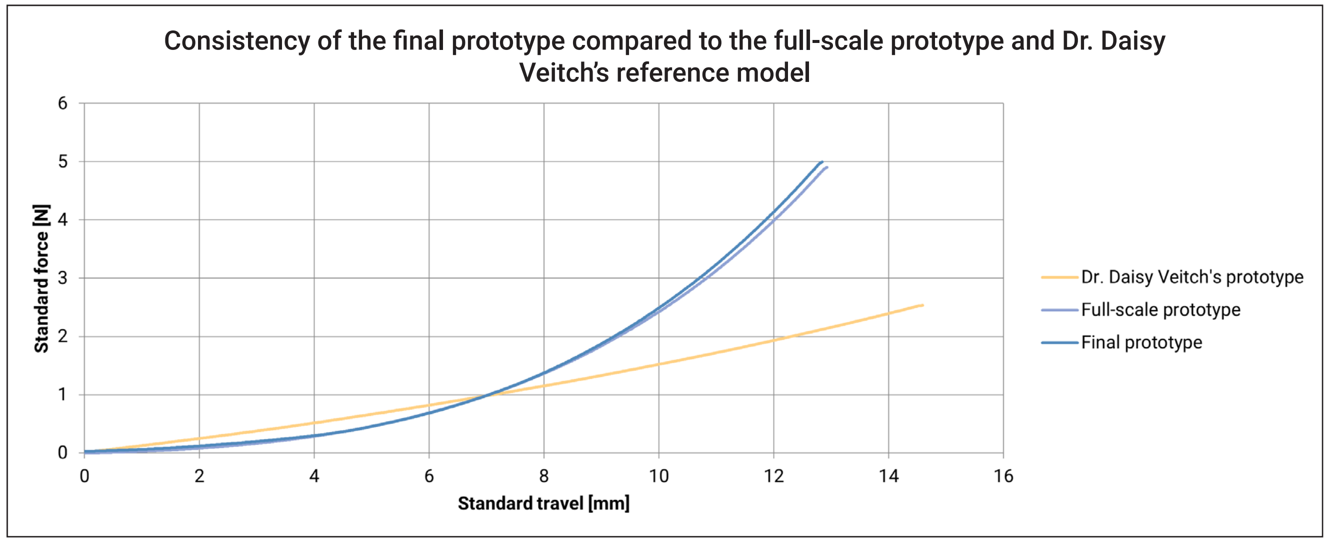


Figure 8.5. Consistency of the final prototype compared to the full-scale prototype and Dr. Daisy Veitch's reference model.

Figure 8.6. Final prototype being touched.

9 Critical analysis

Limitations & future opportunities

BREAST FORM MODELING

The breast shape that was modeled and used for testing and validation was obtained combining two different sources. On the one hand, the front side was designed based on a statistical model obtained from the Bra manikin tool, which makes it realistic and high-fidelity. However, on the other hand, the rear side was designed following the shape current external breast prosthesis have, as opposed to basing it on the chest wall topology of a specific mastectomized woman. These silicone prostheses that have been used as a reference are commonly modeled with a slightly concave rear geometry to make the prosthesis lighter.

NUMERICAL RESULTS

In the envisioned case in which 3D printed prostheses become feasible, they should be personalized for each woman's torso to make use of all the advantages additive manufacturing offers in this field. In such case, the final geometry of the prosthesis might be considerably different to the model printed and tested in this project, even for the same bra size. As the chest wall and scar topology of each woman is different, the resulting breast form could be either thicker or thinner, which will also affect its consistency. Therefore, the numerical results presented in this research must not be interpreted as exact measurements but as an approximated indication of consistency-related values that can be expected from a 3D printed breast form of similar characteristics.

PRINTABILITY

The percentage of the material used as filling of the prototypes of this project (80% gel, 20% liquid) might be too close to the limit of what can or cannot be used as support material for such big prototypes. In future work, it might be interesting to experiment with lower percentages of liquid, which might provide better results in the regions of flexible materials printed on top of the mixture. However, whether the new mixture will provide a consistency that is soft enough must be researched.

DURABILITY

The flexible material used to build the prototypes of this project was Agilus30Clr, which gets cured by UV light. Its exposure to UV light also after production will deteriorate the material over time. How it will evolve over the years is not known yet. According to the PhD researcher Emmajude Lyons and Dr. Kevin O'Sullivan, who are also investigating 3D printed external breast prostheses, it is possible that the flexible material becomes rigid over the years, as they experienced with the predecessor of Agilus30Clr: Tango. Although whether this will happen or not is not proven yet, this uncertainty should not be neglected. In fact, it is recommended to consider coating the printed part with a flexible varnish or coating to improve the durability over time (How to Optimize Tango & Agilus30 Material Performance | GrabCAD Tutorials, 2019).

VENTILATION AND TOUCH

Given the fact that the prosthesis might be in direct contact with the skin and ventilation is desired to provide temperature and humidity control, covering the prosthesis with cloth can be evaluated in further steps. This would not only help improve the product experience of the prosthesis by making it look and feel better, but also could help prevent the rapid degradation Agilus30Clr might present. In addition, this could be a good option to ensure the material safety of a 3D printed breast prosthesis. Although direct skin contact with Agilus30Clr is safe, any uncured trace can be toxic for the skin, leading to irritation. Also, the effect of long-term skin contact with this material is not well known, which added to the fact that cloth-like materials might be more pleasant to touch, gives a clear indication that having some fabric covering the prosthesis is a promising direction to research.

SHAPE ADAPTATION

No deformability was observed in the final prosthesis when the position was changed. This means that the second problem being tackled in this project has not been solved with the printed prosthesis. However, this print is a breast form for a bra size 70B, which is considerably small. It is expected that prints of similar characteristics will present slight deformations when the position is changed, meaning they will provide shape adaptation to body position. Whether this actually happens or not and to what extent this shape change is realistic will need to be researched in further work.

REAR SURFACE

The latest prototypes printed in this project present a rear side with irregular surface finishings. These irregularities were not considered important and they were purposefully not a relevant aspect to improve because due to printability complications and the initial stage of this research, having the prototype being printable was considered adequate enough.

10 Conclusions

This project shows the design and embodiment of a 3D printed external breast prosthesis that provides a soft consistency similar to a natural breast. Polyjet 3D printing has been proved to present great qualities to improve these prostheses using voxel-based design and personalizing their shape to the torso of each individual woman.

A similar consistency to a natural breast has been achieved thanks to mixtures of gel and liquid material at a 80-20% ratio. This mixture was then encapsulated in a cover made with flexible material. The inner structure of the 3D printed prosthesis originates from a biomimetic approach and allows meeting the two main requirements of this project: providing a soft consistency and being printable.

This research proves, therefore, that Polyjet (multi-material) 3D printing is a technology with great potential to be applied to the fabrication of external breast prostheses.

Furthermore, this project does not only serve the development of breast prostheses but also provides insights on soft tissue mimicking possibilities multi-material 3D printing offers, which could potentially be applied in other medical areas as well. It proposes a specific voxel-based design that achieves the consistency of a natural breast, which can be used as a reference for further investigations on soft tissue-like consistencies.

Following steps should further explore and improve the printability of these prostheses, which is hindered by the use of liquid in the interior. In addition, future work should be done to study to what extent shape adaptability is achieved with the proposed design by prostheses of bigger sizes. Lastly, having the prosthesis covered with a fabric is expected not only to help make it more pleasant to touch but also provide increased ventilation and temperature control, which should be studied in future development.

References

3 3D lattice structures: Design elements and mechanical responses. (2022). Fast Radius. Retrieved 21 February 2023 from https://www.fastradius.com/resources/3d-lattice-design-elements/

A Amoena Nederlands. Retrieved 22 February 2023 from https://www.amoena.com/nl/

B Basko Healthcare. Retrieved 20 February 2023 from https://basko.com/nl-nl

Been-a-Boob Beaded Breast Form (BABH). (2014). Nicola Jane. Retrieved 6 March 2023 from https://www.nicolajane.com/beenaboob-heart-prosthesis-babh/

Bezek, L. B., Chatham, C. A., Dillard, D. A., & Williams, C. (2022). Mechanical properties of tissue-mimicking composites formed by material jetting additive manufacturing. Journal of the Mechanical Behavior of Biomedical Materials, 125, 104938. https://doi.org/10.1016/j.jmbbm.2021.104938

Borstprotheses. (2017). LingerieService Marieke Vermaas. Retrieved 28 February 2023 from https://lingerieservice.nl/borstprotheses/

C Cancer Council NSW. (2020). Breast Prostheses and Reconstruction: A Guide for Women Affected by Breast Cancer. Cancer Council Australia. Retrieved 7 March 2023 from https://www.cancercouncil.com.au/wp-content/uploads/2014/05/Breast-Prostheses-and-Reconstruction-2020.pdf

Cruz, P. E., Hernández, F., Zuñiga, M. L., Rodriguez, J. A., Figueroa, R. I. A., Vertiz, A. P., & Pineda, Z. (2018). A Biomimetic Approach for Designing a Full External Breast Prosthesis: Post-Mastectomy. Applied Sciences, 8(3), 357. https://doi.org/10.3390/app8030357

MSc Integrated Product Design - Thesis

D Deshpande, V., Ashby, M. L. N., & Fleck, N. A. (2001). Foam topology: bending versus stretching dominated architectures. Acta Materialia, 49(6), 1035–1040. https://doi.org/10.1016/S1359-6454(00)00379-7

DINED. (2023). DINED Anthropometric Database. Retrieved May 15, 2023, from https://dined.io.tudelft.nl/en/database/tool

F Fefferman, M., Nicholson, K., Kuchta, K., Pesce, C., Kopkash, K., & Yao, K. (2023). Rates of Bilateral Mastectomy in Patients With Early-Stage Breast Cancer. JAMA Network Open, 6(1), e2251348. https://doi.org/10.1001/jamanetworkopen.2022.51348

G Gabriel, A., & Maxwell, G. P. (2020). Anatomy of the Breast. In Augmentation Mastopexy. Mastering the Art in the Management of the Ptotic Breast (p. 1). Springer. https://doi.org/10.1007/978-3-030-48226-8_1

Graziosi, S., Ballo, F. M., Libonati, F., & Senna, S. (2022). 3D printing of bending-dominated soft lattices: numerical and experimental assessment. Rapid Prototyping Journal, 28(11), 51–64. https://doi.org/10.1108/RPJ-03-2022-0095

H Hayes, B., Hainsworth, T., & MacCurdy, R. (2022). Liquid–solid co-printing of multi-material 3D fluidic devices via material jetting. Additive Manufacturing, 55, 102785. https://doi.org/10.1016/j.addma.2022.102785

Healey, I. R. (2003). External breast prostheses: misinformation and false beliefs. PubMed, 5(3), 36. https://pubmed.ncbi.nlm.nih.gov/14600672

Hekkert, P., & Van Dijk, M. (2016). VIP Vision in Design: A Guidebook for Innovators. BIS Publishers.

Helguero, C. G., Amaya, J. L., Maldonado, F., Acosta, J. A., Bravo, M., & Garzón, J. (2021). Design of Custom Breast Prosthesis for Additive Manufacturing Production. International Conference on Applied Human Factors and Ergonomics, 274, 74–81. https://doi.org/10.1007/978-3-030-80462-6_10

Hojan, K. (2020). Does the weight of an external breast prosthesis play an important role for women who undergone mastectomy? Reports of Practical Oncology & Radiotherapy, 25(4), 574–578. https://doi.org/10.1016/j.rpor.2020.04.015

Hojan, K., & Manikowska, F. (2017). Can the Weight of an External Breast Prosthesis Influence Trunk Biomechanics during Functional Movement in Postmastectomy Women? BioMed Research International, 2017, 1–9. https://doi.org/10.1155/2017/9867694

Hojan, K., Manikowska, F., Chen, B., & Lin, C. (2016). The influence of an external breast prosthesis on the posture of women after mastectomy. Journal of Back and Musculoskeletal Rehabilitation, 29(2), 337–342. https://doi.org/10.3233/bmr-150648

How to Optimize Tango & Agilus30 Material Performance | GrabCAD Tutorials. (2019, August 14). GrabCAD. Retrieved May 30, 2023, from https://grabcad.com/tutorials/pre-printing-tips-for-flexible-polyjet-materials

I Intro to Lattices: Graph Options. nTopology. Retrieved 21 March 2023 from https://learn.ntopology.com/latticing-course/1469708/scorm/69m1xu4ekq47

J Jetha, Z. A., Gul, R. B., & Lalani, S. B. (2017). Women experiences of using external breast prosthesis after mastectomy. Asia-Pacific Journal of Oncology Nursing, 4(3), 250–258. https://doi.org/10.4103/apjon.apjon_25_17

K Kermavnar, T., Guttridge, C. G., Mulcahy, N. J., Duffy, E., Twomey, F., & O'Sullivan, L. (2022). 3D printing in palliative medicine: systematic review. BMJ Supportive & Palliative Care, 1–10. https://doi.org/10.1136/bmjspcare-2021-003196

Kermavnar, T., Shannon, A., O'Sullivan, K., McCarthy, C. T., Dunne, C. P., & O'Sullivan, L. (2021). Three-Dimensional Printing of Medical Devices Used Directly to Treat Patients: A Systematic Review. 3D Printing and Additive Manufacturing, 8(6), 366–408. https://doi.org/10.1089/3dp.2020.0324

M Maillo, B. M., San, A. B., Bobo, P. A., Moreno, M. E. M., Haro, F. B., & Juanes, J. A. (2020). Methodology of custom design and manufacturing of 3D external breast prostheses. Eighth International Conference on Technological Ecosystems for Enhancing Multiculturality, Salamanca, Spain.https://doi.org/10.1145/3434780.3436586

Mastectomy Bra and Post Surgery Bra Specialists. Nicola Jane. Retrieved 12 April 2023 from https://www.nicolajane.com/

Mastectomy Bras, Prosthetic Bra & Breast Forms. Mastectomy Shop. Retrieved 12 April 2023 from https://www.mastectomyshop.com/

Maw, J., Wong, K., & Gillespie, P. J. (2016). Hand anatomy. British Journal of Hospital Medicine, 77(3), C34–C40. https://doi.org/10.12968/hmed.2016.77.3.c34

McGhee, D. E., Mikilewicz, K. L., & Steele, J. R. (2020). Effect of external breast prosthesis mass on bra strap loading and discomfort in women with a unilateral mastectomy. Clinical Biomechanics, 73, 86–91. https://doi.org/10.1016/j.clinbiomech.2019.12.027

McGuire, K. P. (2019). Breast Anatomy and Physiology. In Breast Disease. Diagnosis and Pathology (Vol. 1, p. 2). Springer. https://doi.org/10.1007/978-3-030-04606-4_1

Mora, S., Pugno, N. M., & Misseroni, D. (2022). 3D printed architected lattice structures by material jetting. Materials Today, 59, 107–132. https://doi.org/10.1016/j.mattod.2022.05.008

P Prothèse de sein externe après un cancer à Nice. (2023, January 27). Atlelier J'm Paris | Nice. Retrieved April 12, 2023, from https://atelier-jm.fr/prothese-sein-cancer-nice/

Protheselingerie. De Magneet Lingerie. Retrieved 29 March 2023 from https://demagneetlingerie.nl/borstprothese/

R Reaby, L., & Hort, L. K. (1995). Postmastectomy attitudes in women who wear external breast prostheses compared to those who have undergone breast reconstructions. Journal of Behavioral Medicine, 18(1), 55–67. https://doi.org/10.1007/bf01857705

Roberts, S. B., Livingston, P. M., White, V., & Gibbs, A. (2003). External Breast Prosthesis Use: experiences and views of women with breast cancer, breast care nurses, and prosthesis fitters. Cancer Nursing, 26(3), 179–186. https://doi.org/10.1097/00002820-200306000-00002

S Scheffler, M., & Colombo, P. (2005). Cellular Ceramics: Structure, Manufacturing, Properties and Applications. Wiley-VCH. Retrieved 16 March 2023 from https://application.wiley-vch.de/books/sample/3527313206_c01.pdf

Stratasys J750 3D Printer. Proto3000 Inc. Retrieved 29 March 2023 from https://proto3000.com/product/stratasys-j750/

T Triangle breast prosthesis. Your Rules Prosthetics. Retrieved 3 March 2023 from https://yourrulesprosthetics.com/nl/product/breast-prosthesis/

Types of breast prosthesis. Breast Cancer Now. Retrieved 22 February 2023 from https://breastcancernow.org/information-support/facing-breast-cancer/living-beyond-breast-cancer/your-body/breast-prosthesis/types-breast-prosthesis#:~:text=Most%20breast%20prostheses%20are%20made,may%20include%20a%20nipple%20outline.

V Veitch, D. (2019). A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer: Detecting Breast Disease using Palpation. [Doctoral thesis] https://doi.org/10.4233/uuid:d4b385c9-6d47-44f6-a959-4125825e7f06

W Wang, Y., Park, S., Zambrano, F., Pal, L., Venditti, R. A., Dasmohapatra, S., Pawlak, J. J., & Gonzalez, R. (2018). Relationship between human perception of softness and instrument measurements. Bioresources, 14(1), 780–795. https://doi.org/10.15376/biores.14.1.780-795

Wesslein, A., Spence, C., & Frings, C. (2014). Vision affects tactile target and distractor processing even when space is task-irrelevant. Frontiers in Psychology, 5. https://doi.org/10.3389/fpsyg.2014.00084

Wong, K. V., & Hernandez, A. M. P. (2012). A Review of Additive Manufacturing. ISRN Mechanical Engineering (Print), 2012, 1–10. https://doi.org/10.5402/2012/208760

Worldwide cancer data. World Cancer Research Fund International. Retrieved 6 March 2023 from https://www.wcrf.org/cancer-trends/worldwide-cancer-data/#:~:text=Breast%20cancer%20was%20the%20most,non%2Dmelanoma%20skin%20cancer).

Y Yanagisawa, H., & Takatsuji, K. (2015). Effects of visual expectation on perceived tactile perception: An evaluation method of surface texture with expectation effect. International Journal of Design, 9(1), 39-51.

MSc Integrated Product Design - Thesis

Appendices

01. Graduation Project Brief

Personal Project Brief - IDE Master Graduation

TU Delft

Improving the consistency of external breast prostheses with 3D printing — 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 13 - 02 - 2023 — 07 - 07 - 2023 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, ...).

Women who have gone through mastectomy often use external breast prostheses. Most of these external breast prostheses seem to focus on either having a good fit or having a good (realistic) "look". Prostheses could be improved providing a good "feel" as well. The objective will be to find what 3D printing technologies, materials, and patterns are the best for the filling of an external breast prosthesis to provide the feeling the woman wants. This project will be developed within the current socio-cultural context in developed European countries.

The stakeholders that will be involved in this project can be divided into two categories: from TU Delft with an academic interest in the project, and out of the educational area, with a practical interest.

Stakeholders out of the academic area:

Women that have gone through a mastectomy: within this group, women that use and do not use external breast prostheses will both be relevant. The experience of users will be relevant to know why they like using them, what their strengths are, and what the prosthesis means for them. They will also inform about the weak points and what could be improved. Their feelings towards using them will also be relevant. Women that do not use these prostheses will inform why they do/did not want to use them, which will be relevant to define the improvement areas. From the women that have gone through a mastectomy, understanding the meaning and perception of external breast prostheses within the current socio-cultural context both from their perspective and from their surroundings, will be relevant.

Breast cancer associations/ hospitals/ surgeons: They know potential end users and users experienced with external breast prostheses. They will potentially become the contact that allows to get participants for the research of this project.

Breast prostheses manufacturers: Talking with them will provide insights about the advantages and disadvantages of specific kinds of breast prostheses and their manufacturing methods, and considerations that will need to be taken into account in this project.

Specialised lingerie stores: They are experienced with different kinds of (non-stick) breast prostheses, so they will bring relevant information about the requirements or considerations for this project.

Stakeholders from TU Delft are:

Chair: Zjenja Doubrovski, expert in 3D printing and digital technologies. His interests might be in the innovation of infill structures of 3D printed materials, their application, and their physical properties.

Mentor: Tjaša Kermavnar, expert in medical and social sciences, and ergonomics. Her interests might be in the psychological and social aspects of the project.

3D printing Lab: They will provide the resources to experiment and research with high fidelity prototypes. This will guarantee the technological feasibility of the project.

space available for images / figures on next page

Personal Project Brief - IDE Master Graduation

introduction (continued): space for images

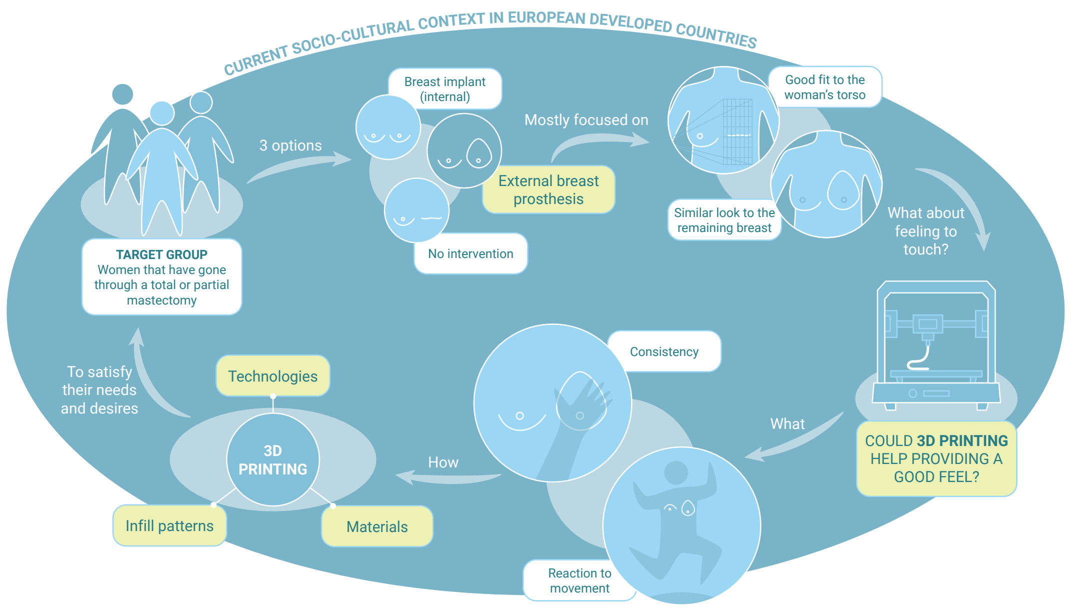


image / figure 1: Introductory overview of the project

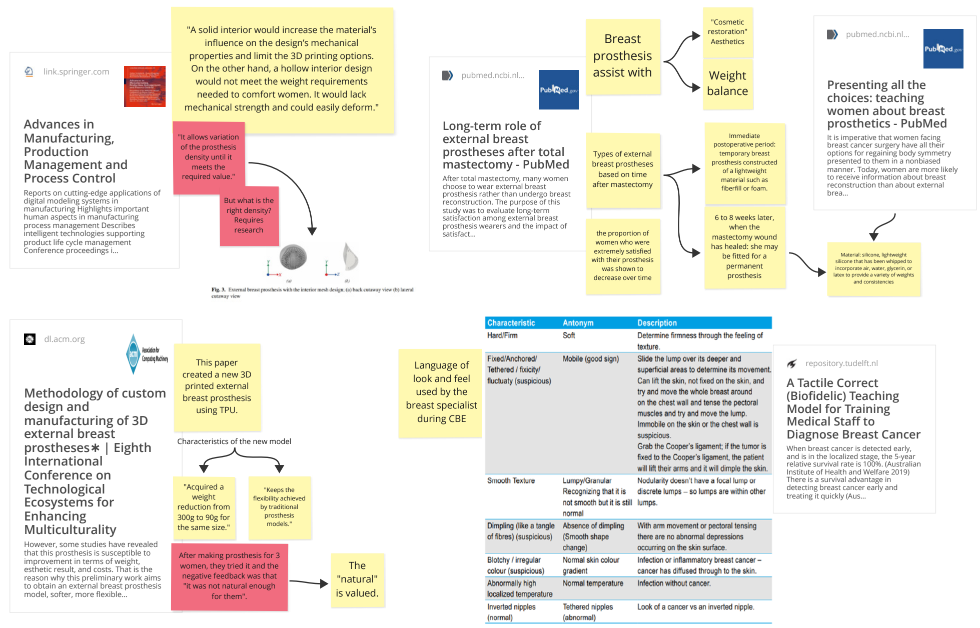


image / figure 2: Preliminary insights

Initials & Name YRH Reinoso Hayashi 6317 Student number 5621593

Title of Project Improving the consistency of external breast prostheses with 3D printing

MSc Integrated Product Design - Thesis

Personal Project Brief - IDE Master Graduation

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.

A solution will be designed for women that have gone through a total or partial mastectomy.

Current breast prostheses mainly focus either on having a good, personalized fit to the woman's torso, or having a realistic look. The fit to the woman is done 3D scanning the torso and the scar and building a shape that is symmetric to her remaining breast. The realistic look is achieved matching the colour of the prosthesis to the skin colour of the woman both in the body and the nipple. While looking realistic and being comfortable, they are mostly not realistic to touch or movement, which can potentially reduce the confidence of the user. Daily activities like giving a hug could make the woman feel uncomfortable.

Relevant context factors include the fact that breasts are not a functional part of the body. This might have been a reason why the development of external breast prostheses has not been further conducted up to now. Within the socio-cultural context in developed European countries, it is important to understand the meaning of the breast both from the woman's and the societal perspectives, which might not be possible to separate.

Other relevant factors lie on the technical aspects involved in making a breast have a density and consistency that matches women's desires. Materials and technologies that allow to get the sought features might not have been of interest for economical or technological reasons. However, cultural, ergonomic, and social aspects in favour of the patient also need to be considered and pursued.

In this project, the experimentation to reach the physical properties of the infill of external breast prostheses that are desired by women will be done exclusively with 3D printing technologies.

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.

I will investigate what materials, patterns, and multimaterial 3D printing technologies are the best to create a filling for external breast prostheses that provide the consistency the woman wants. The focus will be on the feeling to touch and reaction to movement and position.

Two areas will be investigated simultaneously, as they will affect each other.

1. Focusing on understanding what the woman wants from an external breast prosthesis -with special emphasis on its feel. The outcome of this research phases is expected to be the understanding of the role of the prosthesis in the woman's life. This will create a set of statements that define the woman's perception, expectations, and desires regarding the prostheses. These statements are expected to evolve as the other research field also creates input for this research.

2. Experimenting, testing, and iterating on prototypes with different patterns and materials to define the 3D printed infill that best matches the goal stated in the previous phase.

The expected outcome of this project is a 3D printed solution that represents the infill of an external breast prosthesis. It will be based on the result of all the previous research and supported by an evaluation and explanation of its physical properties. This solution will be defined by the material and pattern that performs the best according to women's wishes. Presumably, the result will have both a similar consistency to a real breast and reaction to movement.

Initials & Name YRH Reinoso Hayashi 6317 Student number 5621593

Title of Project Improving the consistency of external breast prostheses with 3D printing

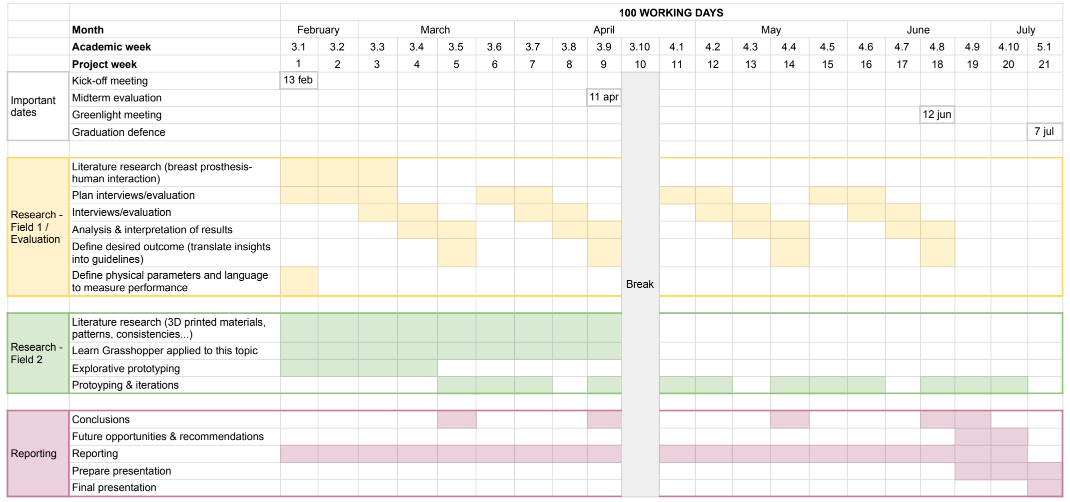
Personal Project Brief - IDE Master Graduation

TU Delft

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 13 - 2 - 2023 7 - 7 - 2023 end date



There are two research fields: one focused on understanding what the woman wants from the prosthesis, specifically related to the feeling to touch and reaction to movement and position; and one focused on the embodiment of the filling that will allow to create such consistency. The first one will involve conducting interviews with participants to know their preferences and have feedback on the prototypes. The second one involves translating the desired features into manufacturable physical properties and building them with the right materials, patterns, and technologies.

Both researches affect each other because the first one defines what the woman wants and the second one studies how to make that. They are both going to follow an iterative process where the prototypes will be tested by participants and the new feedback will again be applied in the next iteration, which will then be tested as well.

All the decisions will be documented and supported by research in a report, and the work will be presented publicly in the end of the project.

Initials & Name YRH Reinoso Hayashi 6317 Student number 5621593

Title of Project Improving the consistency of external breast prostheses with 3D printing

Personal Project Brief - IDE Master Graduation

TU Delft

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 feel personally motivated about this project because of previous interest in both 3d printing and prostheses. Because breasts are generally not a functional part of the body, I thought the meaning and the role of a breast prosthesis in a woman's life could be interesting to research, especially because her perception might be influenced by social expectations. The relevance of the context and its effect on the woman is a topic that sounds especially interesting. I think that researching about this will allow me to refine my interviewing and research with participants skills. Having initiated in this during the master, I would like to hone this ability learning how to establish a meaningful connection with participants. I think the fact that this is a sensitive and personal topic might make this experience especially enriching for me.

In a similar tone, I would like to work towards developing a deeper understanding of human interactions. I would like to learn how different contextual factors affect specific interactions, shaping people's perception. In this sense, this project offers the possibility to explore why the feeling to touch of an external breast prosthesis is important for a woman.

I also want to learn about the technicalities of how different materials and patterns provide different physical properties. Experimenting with varied 3D printing technologies will allow to prototype, test, and iterate on the features of the solution integrating the participants' feedback. Playing with different combinations of materials and printing settings will allow to generate gradually changing densities that might result in consistencies that are more similar to a breast's. Besides the learning of the technical aspects directly related to the project, I feel motivated towards learning in depth about the available 3D printing technologies as well. I would like to learn about their working principles and their technology, which I will indirectly do through the iterations of the configuration of all the settings and prototyping.

Improving my knowledge of Grasshopper (computational design software) will be necessary to create patterns that can then be 3D printed. This is something I am looking forward to, as I am interested in the design of customized solutions that can then be prototyped with digital technologies. I think this is the most appropriate software for this case because it allows to precisely manipulate geometries and parameters and to easily create complex designs, which will presumably be the case of the filling for the external breast prostheses. Because Grasshopper allows to digitally create intricate shapes and 3D printing allows to build a physical prototype of it, the combination perfectly fits the objective of this project.

FINAL COMMENTS

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

Initials & Name YRH Reinoso Hayashi 6317 Student number 5621593

Title of Project Improving the consistency of external breast prostheses with 3D printing

02. Informed Consent Form for interviews

Opening statement for online evaluations with women after mastectomy

You are being invited to participate in a research study titled *Improving the consistency of external breast prostheses with 3D printing*. This study is conducted at TU Delft by Yuka Reinoso Hayashi, and supervised by Dr. Tjaša Kermavnar and Dr. Zjenja Doubrovski.

Purpose
The purpose of this research is to understand the perception of and expectations regarding external breast prostheses from the perspective of women after mastectomy. The data will be used to formulate the requirements and wishes towards which innovation in 3D printing will be conducted.

Procedure
The study will be conducted through an online individual interview that will take approximately 30 minutes to complete. You are expected to talk about your personal perception and opinion regarding external breast prostheses, with special emphasis on their *feel to touch*, *change of shape according to body position*, *reaction to movement*, and *temperature and humidity control*. The interview will be audio-recorded.

Confidentiality
To the best of our ability, your answers in this study will remain confidential. We will minimize any risks by means of anonymization and by storing your personal information separately from the data obtained during the study. Upon signing this consent, you will be assigned a unique participant ID number; all information you provide during the study will be stored in an anonymized form under this number to protect your privacy. The audio recordings will be transcribed and deleted immediately after the interview. The collected data will only be used for scholarly purposes and de-identified research findings will be published in a MSc Integrated Product Design graduation thesis. No personally identifiable information or raw data will be shared outside the research group at any time. Upon the completion of the project, all materials containing personally identifiable information will be destroyed.

Participation
Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions and can ask to get data removed at any time before the end of the session.

Contact
If you have questions at any time about the study or the procedures, please feel free to contact the main researcher Yuka Reinoso Hayashi (email: y.reinosohayashi@student.tudelft.nl, phone: +34 680194370) or the responsible researcher Tjaša Kermavnar (T.Kermavnar@tudelft.nl).

Electronic consent
Please, specify below whether you agree to participate in this study.
Choosing ***"Yes, I agree to participate"*** indicates that:

1. I have read and understood the study information dated [17/03/2023], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.
3. I understand that taking part in the study involves:
    a. Sharing personal information (age, date of mastectomy) with the researcher.
    b. Answering a set of questions about my experience with/opinion on external breast prostheses.
    c. Having the researcher taking notes of the most relevant information.
    d. Having the audio of the session recorded with a voice recorder for consultation of information not written down during the session and for the transcription after the end of the session.
    e. After transcription, the voice recordings will be deleted.
4. I understand that the study will take approximately 30 minutes.
5. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) like age or date of mastectomy.
6. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach:
    a. Voice recordings will be destroyed after transcription.
    b. Written notes and transcriptions will be destroyed after completion of the project.
7. I understand that personal information collected about me that can identify me, such as age or date of mastectomy, will not be shared beyond the study team.
8. I understand that the (identifiable) personal data I provide will be destroyed after completion of the project.
9. I understand that after the research study the de-identified information I provide will be used for:
    a. Decision-making throughout the design process, with scientific and academic purposes only.
10. I agree that my responses, views, or other input can be quoted anonymously in research outputs.

If you do not wish to participate in this study, please decline participation by choosing ***"No, I do not agree to participate"***.

☐	*Yes, I agree to participate*	☐	*No, I do not agree to participate*

Name of the participant:

Signature:

Date:

03. Interview questions for women after mastectomy

The first part was an introduction from part of the researcher to explain the project's objectives, scope, and processes. The questions made to the participants afterwards are as follow:

1. How old are you?
2. How many years ago did you undergo mastectomy?
3. Do you currently use or have ever used an external breast prosthesis?
4. Why did you decide to use a prosthesis instead of having a reconstruction?
5. What kind of external breast prosthesis do you use?
6. Do you use a full weight or a lightweight prosthesis?
7. How do you wear your prosthesis?
8. Is your prosthesis symmetric or asymmetric?
9. Who chose your prosthesis?
10. Were you offered the possibility to choose a lightweight prosthesis?
11. Please, rate the following aspects about your prosthesis on a scale from 1 to 5:
    a. Very light 1 – 5 Very heavy
    b. Very soft 1 – 5 Very hard
    c. Very comfortable 1 – 5 Very uncomfortable
    d. Keeps my skin fresh 1 – 5 Makes me sweat
    e. I am very satisfied with it 1 – 5 I am very dissatisfied with it
12. Does the prosthesis cause you any physical discomfort?
13. Where does it cause you skin irritation?
14. When do you get skin irritation?
15. What would you say are the reasons why you get skin irritation?
16. When do you wear your prosthesis?
17. Do you still participate in the same activities as before the surgery?
18. Have you ever had any uncomfortable experience with your prosthesis?
19. Could you give any example of these uncomfortable experiences and explain how they made you feel? How did you react?

04. Interviews

Participant 1

Age: [51-60] years old
Mastectomy date: 10 years ago.

Why she decided to use external breast prostheses

She did not want to get a breast reconstruction because she felt they did not provide her with enough information, so she felt insecure. She did not know what the advantages and disadvantages of each option were. She preferred not taking the risk, as she knew that having an implant could also bring complications both during and after the reconstruction.

She had the possibility to have an implant, but she was not eligible for a breast reconstruction with her own tissue, which she would have considered, due to insufficient body mass. The fact that her only breast reconstruction option was having an implant, together with the fact that she didn't feel informed enough, made her decide not to get a reconstruction.

Her prostheses

She used a full-weight, non-adhesive, symmetric silicone prosthesis. In the beginning it caused her pain in the shoulder, but soon she got used to it and spent many years using a full-weight prosthesis very comfortably. However, she was recently offered a lightweight prosthesis and wanted to try it. Now she got used to the lightweight prosthesis and she feels like it is more comfortable. She feels it is also better when it is getting hot, because it causes her less skin irritation.

She only used a cotton prosthesis right after the surgery, but it was too light. She prefers having some weight.

She has another prosthesis made especially for swimming. It is also made of silicone but is a bit harder, less flexible.

When she wears her silicone prosthesis she feels as if the prosthesis was her own breast. She feels like if she was complete and the prosthesis belonged to her own body, and she doesn't think the cotton one would make her feel the same.

Prosthesis choice

To choose her prosthesis she went to a specialized shop, where they helped her choose the best one.

Opinion

She feels her prosthesis is light, soft, and comfortable. However, she still prefers not wearing it, especially when it is hot (for physical reasons), or when she is tired (for emotional reasons). In general, she is happy with her prosthesis.

Daily life

She does not mind if people "by accident" see the prosthesis from outside. It took her many years to not be ashamed to show on the beach that she only has one breast.

She wears the prosthesis when she dresses herself, regardless of whether she is at home or not, or if there are people or not. One of the activities she stopped doing was going to the sauna. She used to go, but after the mastectomy she feels a bit ashamed because people would look at her, making her feel uncomfortable. She prefers to keep it private.

She receives a prosthesis from the insurance every two years.

Participant 2

Age: [51-60] years old
Mastectomy date: 18 years ago.

Why she decided to use external breast prostheses

She had the option to have breast reconstruction. However, she did not want to have the silicone implant, and in her time the option to have breast reconstruction with her own tissue was just beginning which did not make her feel confident.For this reason, she decided to have an external breast prosthesis. Lack of information and development together with her own preference were the reasons to choose using an external breast prosthesis.

Her prostheses

She normally uses a full-weight, non-adhesive, symmetric silicone prosthesis. She prefers a full-weight option because she feels it is more balanced with her remaining breast. In the beginning, she used an adhesive silicone prosthesis. However, this used to cause her skin irritation because it made her sweat, which in addition made the glue not work. She prefers the non-adhesive option because the adhesive alternative falls when moving a lot or when swimming with it.

She also has a lightweight cotton prosthesis for swimming because that's more comfortable to wear under the wet swimsuit.

Prosthesis choice

She had help from a professional to choose the prosthesis, but there were only two options. The breast prosthesis is okay, but the feeling and the shape are not the same.

Opinion

Regarding both the weight and the consistency of her prosthesis, she would rank them in the middle of a range. She doesn't find the prosthesis comfortable because the feeling is not the same. In the beginning it used to make her sweat, but now it's fine (she does not use the sticky one anymore). To avoid other physical problems like pain in the shoulder, back and neck, she chooses the bra carefully. She is not very satisfied with her prosthesis.

Daily life

Now she uses the prosthesis always except to go to sleep. She has problems when doing sports because she has limitations in the movement of the arm due to the removal of the axillary lymph nodes, but she still participates in all social activities, although the prosthesis limits her clothing choice.

Uncomfortable experience: when she was swimming and her adhesive prosthesis just fell down. When you lie down on the beach the natural breast would flatten, while the prosthesis doesn't.

She would like the transition of the prosthesis to the torso to not be visually perceived, also matching the skin color perfectly. She believes shape adaptation would be a great added value.

MSc Integrated Product Design - Thesis

Participant 3

Age: [61-70] years old
Mastectomy date: 21 years ago.

Why she decided to use external breast prostheses

She had a reconstruction the same day as the mastectomy because she was recommended to do so by the medical staff. However, for her, "it was a disaster". First of all, the reconstructed breast was not like the breast she had lost, "it was nothing like a real breast, it is firmer". She got her implant removed after a few months. The prosthesis she uses doesn't feel real either, but she says "at least I can take it out at night and put it on the chair". The problem she had with the implant was that she felt it was too tight, she wasn't able to take a deep breath because her skin had to expand.

Her prostheses

She used full-weight, non-adhesive, asymmetric silicone prosthesis. She had a lot of radiation and her skin was very fragile, so she could not use an adhesive prosthesis.

Since years ago, she uses an asymmetric polyurethane prosthesis, which weighs one third of the silicone prosthesis. She prefers to use the lightweight polyurethane prosthesis because its lightness allows her not to feel like she is wearing a prosthesis, which is exactly how she wants to feel. Her polyurethane prosthesis is not adhesive, but it has gripability, and she wears it in a normal bra, so it is in direct contact with her skin.

Opinion

Her polyurethane prosthesis is as light as it can be. It is quite soft, but she would like it to have a more realistic consistency. However, she finds it extremely comfortable and it doesn't make her sweat. She's very satisfied, even if it is not perfect, "it is as good as it can get being a fake product".

Daily life

She wears her prosthesis in the morning and removes it at night, so she wears it all the time. This hasn't affected the activities she does in her daily life, although she thinks the situation would be different if she had been a sporty person. She generally doesn't limit her clothing choice, but "one has to be aware of what she wears". For example, zig zag or irregular patterns camouflage better the asymmetry, while stripes for example, would make it too obvious.

Participant 4

Age: [51-60] years old
Mastectomy date: 6 years ago.

Why she decided to use external breast prostheses

She did not have the chance to have a reconstruction due to both economic and health reasons. She is still considering getting a reconstruction, but the more time it passes, the less inclined she is towards getting it.

Her prostheses

She used full-weight silicone prostheses, but they were very heavy and also made her feel very hot. When it was cold, the silicone prosthesis was cold in the beginning when she wore it, then it became warmer through time.

Now she uses asymmetric polyurethane prostheses. She likes the fact that they are a lot lighter, but she still feels very hot with them. She used to wear them with a normal bra, but that causes her a lot of skin irritation, so she had to go back to using a mastectomy bra.

Prosthesis choice

She chose her prosthesis with the help of a professional.

Opinion

She thinks her polyurethane prosthesis is very light, although quite hard. She said she would give up part of the lightness to have a more realistic consistency. She finds it comfortable and less hot than the silicone option. Due to the light weight, she is very satisfied with it.

Daily life

She has to limit her clothing choice. She avoids encounters with a lot of people like pop-culture conventions, which she used to like but now she does not go anymore. She also avoids sexual relations after the mastectomy.

She wears the prosthesis when she goes out and when visits come home, unless they are close relatives or friends.

05. Survey questions

1. How old are you?
    a. ≤40
    b. 41-50
    c. 51-60
    d. 61-70
    e. 71-80
    f. ≥81
2. How many years ago did you undergo mastectomy?
    a. <1
    b. 1-3
    c. 4-10
    d. >10
3. Do you currently use or have ever used an external breast prosthesis?
    a. No.
    b. Yes.
4. Could you explain why you never used an external breast prosthesis? (This question only appears if the answer to question 3 is "No").
    a. Please explain… (To the end)
5. Why did you decide to use a prosthesis instead of having a reconstruction?
    a. I didn't have the option of breast reconstruction.
    b. I prefer using an external breast prosthesis. Please explain why…
6. What kind of external breast prosthesis do you use? (If you use more than one type of prosthesis, please, select all that apply).
    a. Silicone.
    b. Cotton.
    c. Filled with polypropylene beads.
    d. With an air chamber.
    e. Other.
7. Do you use a full weight or a lightweight prosthesis? (This question only appears if the answer to question 5 is "Silicone").
    a. Full weight.
    b. Lightweight.
8. How do you wear your prosthesis?
    a. It is adhesive.
    b. It fits in my bra pocket.
    c. Other.
9. Is your prosthesis symmetric or asymmetric?
    a. Symmetric
    b. Asymmetric
10. Who chose your prosthesis?
    a. I chose it myself.
    b. I chose it with the help of a professional.
    c. I let a professional choose it for me, although I was given the option to choose it myself.
    d. A professional chose it for me, I wasn't given the option to choose.

MSc Integrated Product Design - Thesis

11. Were you offered the possibility to choose a lightweight prosthesis? (This question only appears if the answer to question 10 is either "I chose it myself" or "I chose it with the help of a professional").
    a. Yes.
    b. No.

12. Please, rate the following aspects about your prosthesis on a scale from 1 to 5:
    a. Light 1 – 5 Heavy
    b. Hard 1 – 5 Soft
    c. Comfortable 1 – 5 Uncomfortable
    d. Keeps my skin fresh 1 – 5 Makes me sweat
    e. General satisfaction=very dissatisfied 1 – 5 General satisfaction=very satisfied

13. Does the prosthesis cause you any physical discomfort?
    a. No.
    b. Yes, it causes skin irritation.
    c. Yes, it causes neck pain.
    d. Yes, it causes shoulder pain.
    e. Yes, it causes back pain.
    f. Other. Please explain...

14. Where does it cause you skin irritation? (This question only appears if the answer to question 13 is "Yes, it causes skin irritation").
    a. In all my skin area that is in contact with the prosthesis.
    b. In specific parts of my torso. Please specify where…

15. When do you get skin irritation? (Choose all that apply) (This question only appears if the answer to question 13 is "Yes, it causes skin irritation").
    a. When the weather is hot.
    b. When I do exercise.
    c. When I cook.
    d. Other. Please explain…

16. What would you say are the reasons why you get skin irritation? (Choose all that apply) (This question only appears if the answer to question 13 is "Yes, it causes skin irritation").
    a. Because of the sweat.
    b. Because of the friction.
    c. Because of the material of the prosthesis.
    d. Other. Please explain…

The following questions are related to your daily life:

17. I wear my prosthesis … (Choose all that apply)
    a. At home when I am alone.
    b. At home when I am with my family.
    c. When I leave home.
    d. When I meet friends.
    e. In professional meetings.
    f. At work.
    g. When I exercise.
    h. When I sleep.
    i. I never wear my prosthesis.
    j. Other. Please explain…

18. Do you still participate in the same activities as before the surgery? (Choose all that apply)
    a. Yes, in all of them.
    b. I avoid activities that require movement.
    c. I avoid wearing the swimsuit in public pools and beaches.
    d. I avoid social encounters.
    e. I avoid body contact that could make others realize that I am wearing a prosthesis.
    f. I avoid sexual activities.
    g. I limit my clothing choice.
    h. Other. Please explain…

19. Have you ever had any uncomfortable experience with your prosthesis?
    a. No
    b. Yes

20. Could you give any example of these uncomfortable experiences and explain how they made you feel? How did you react? (This question only appears if the answer to question 15 is "Yes, I have").
    a. Please explain…

06. Informed Consent Form for User Evaluation

Informed consent form for on-site evaluation

You are being invited to participate in a research study titled ***Improving the consistency of external breast prostheses with 3D printing***. This study is conducted at TU Delft by Yuka Reinoso Hayashi, and supervised by Dr. Tjaša Kermavnar and Dr. Zjenja Doubrovski.

Purpose
The purpose of this research is to contrast the human tactile perception with the measured objective information regarding the softness of 3D printed samples. The data will be used to formulate the similarities and differences observed and to define possibilities of improvement both within and out of the scope of the project.

Procedure
The study will be conducted at TU Delft in one stage that will take approximately 20 minutes to complete. You will be asked to touch some samples and prototypes with your hands and evaluate their softness, establishing comparisons between different prototypes. You will be asked to think out loud and mention further aspects – also related to other senses – that might have affected your tactile perception and experience.

Confidentiality
Upon signing this consent, you will be assigned a unique participant ID number; all information you provide during the study will be stored in an anonymized form under this number to protect your privacy. The collected data will only be used for scholarly purposes and will be published in a MSc Integrated Product Design graduation thesis. No personally identifiable information will be shared outside the research group at any time.

As the activity will be on-site, the risk of a breach is low, but still possible. To the best of our ability, your answers in this study will remain confidential. We will minimize any risks by means of anonymization and by storing your personal information separately from the data obtained during the study. Upon the completion of the project, all materials containing personally identifiable information will be destroyed.

Participation
Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions and can ask to get data removed at any time before the end of the session.

Contact
If you have questions at any time about the study or the procedures, please feel free to contact the main researcher Yuka Reinoso Hayashi (email: y.reinosohayashi@student.tudelft.nl, phone: +34 680 19 43 70).

Consent
Please, specify below whether you agree to participate in this study.
Choosing *"Yes, I agree to participate"* indicates that:
- you have read the above information;
- you voluntarily agree to participate;
- you are at least 18 years of age.
If you do not wish to participate in this study, please decline participation by choosing *"No, I do not agree to participate"*. Choosing *"Yes, I agree to participate"* indicates that you agree to the points stated in the table below.

Explicit Consent points

A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION
1. I have read and understood the study information dated [31/05/2023], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.
3. I understand that taking part in the study involves: • Touching prototypes with the hand and giving my opinion on them. • Comparing the softness of the sample I perceive and order them in a range from softer to harder. • Having the researcher taking notes of the most relevant information. • Having the researcher taking photos where no recognizable features appear.
4. I understand that the study will take approximately 20 minutes.
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)
5. I understand that taking part in the study involves the following risks: • Being exposed to Covid.
6. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach: • Photos taken during the session and written notes will be destroyed after completion of the project.
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION
7. I understand that after the research study the de-identified information I provide will be used for: • Decision-making throughout the last phase of the design process, with scientific and academic purposes only.
8. I agree that my responses, views, or other input can be quoted anonymously in research outputs.

☐	*Yes, I agree to participate*	☐	*No, I do not agree to participate*

Signatures

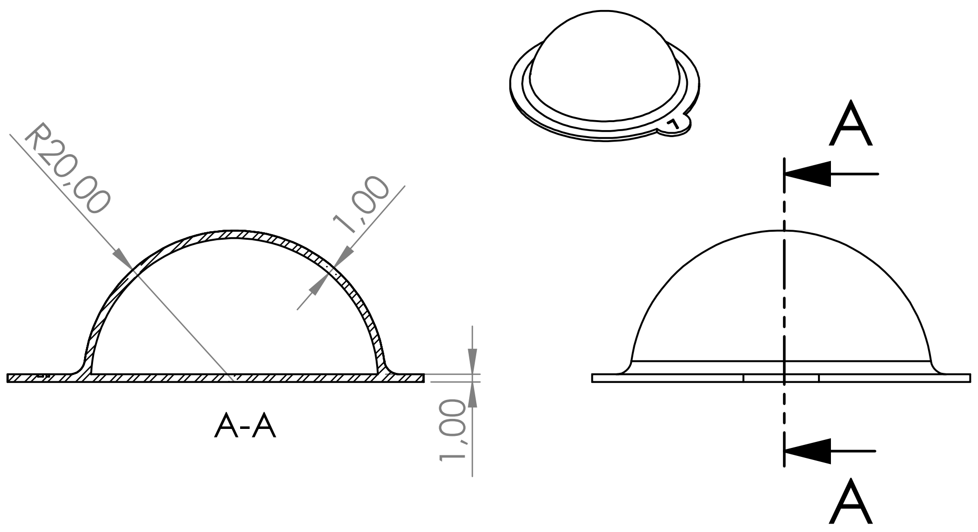
______________________ ______________________ ______________________
Name of the participant **Signature** **Date**

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

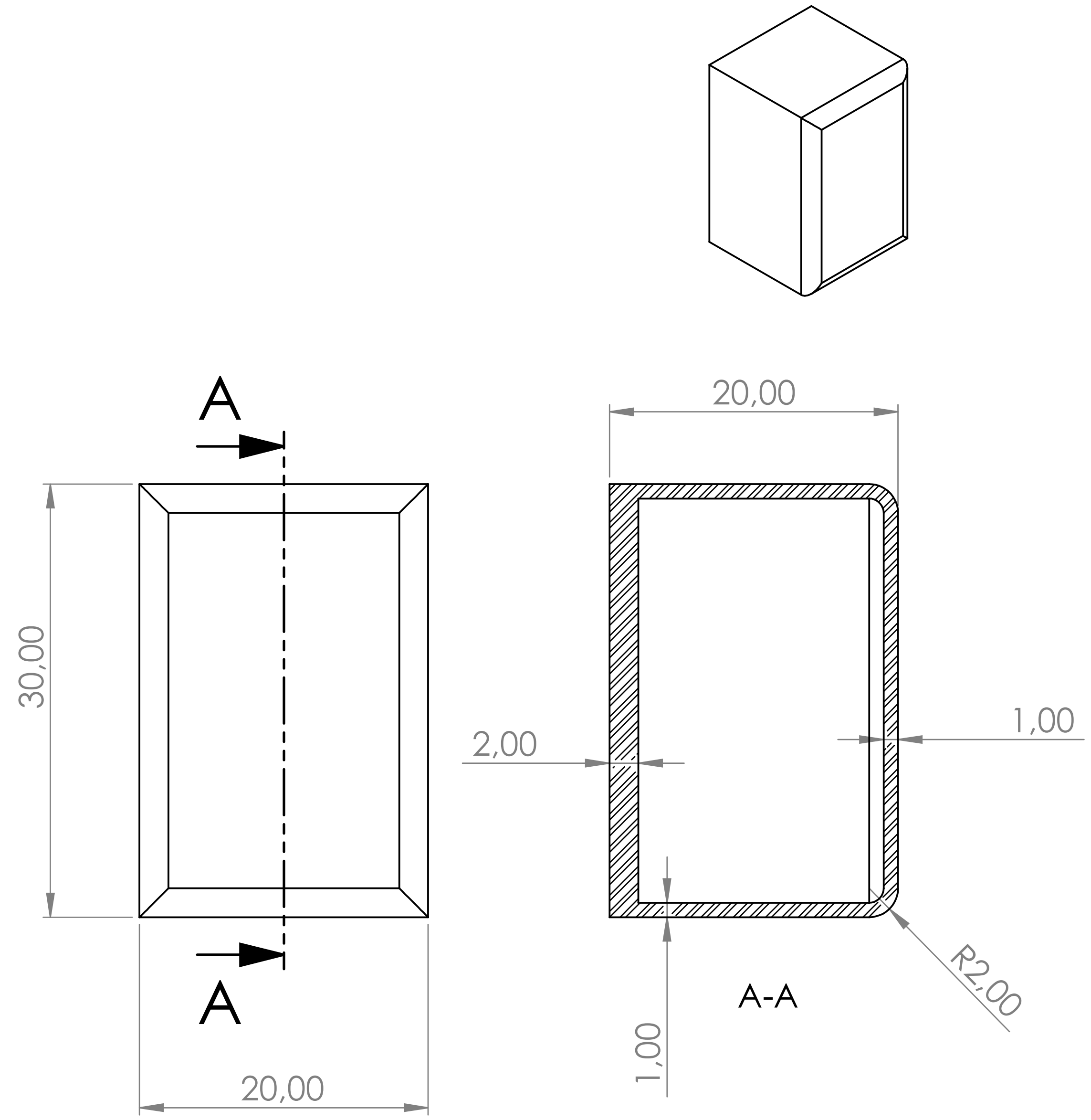
Yuka Reinoso Hayashi ______________________ ______________________
Researcher name **Signature** **Date**

Study contact details for further information:
Yuka Reinoso Hayashi, +34 680 19 43 70, Y.ReinosoHayashi@student.tudelft.nl

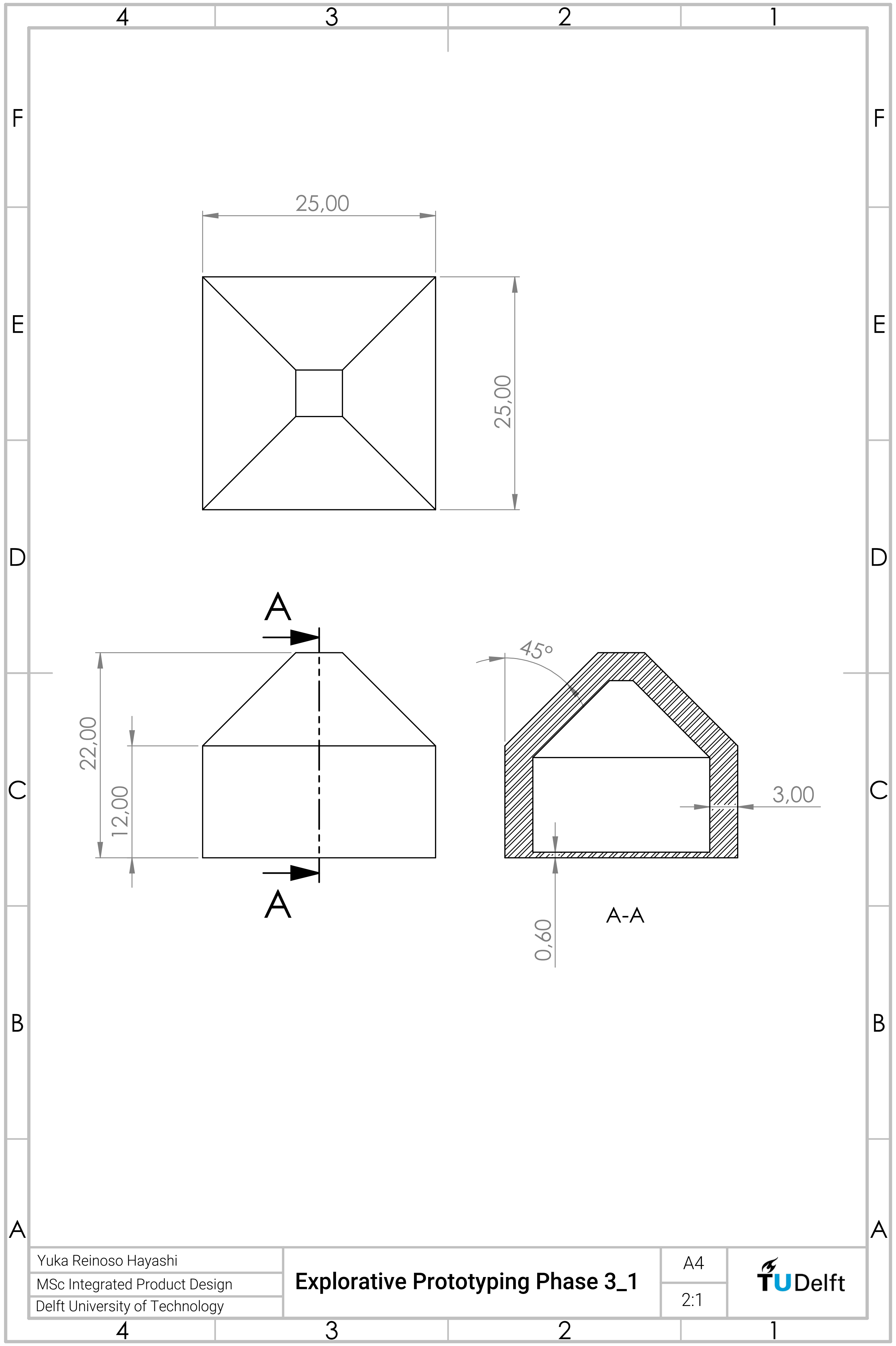
07. Technical drawings of the samples printed during the Exploratory Prototyping

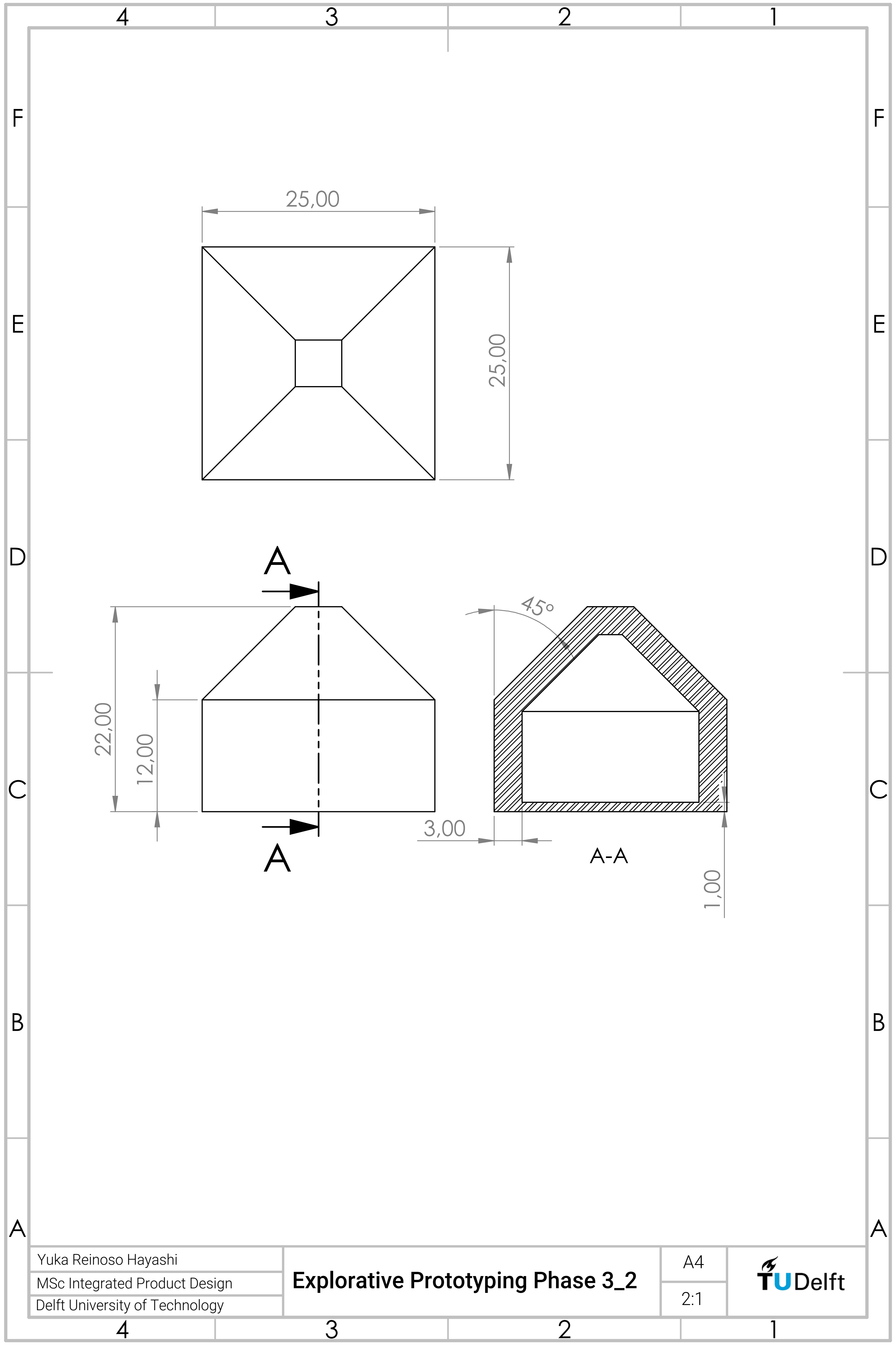


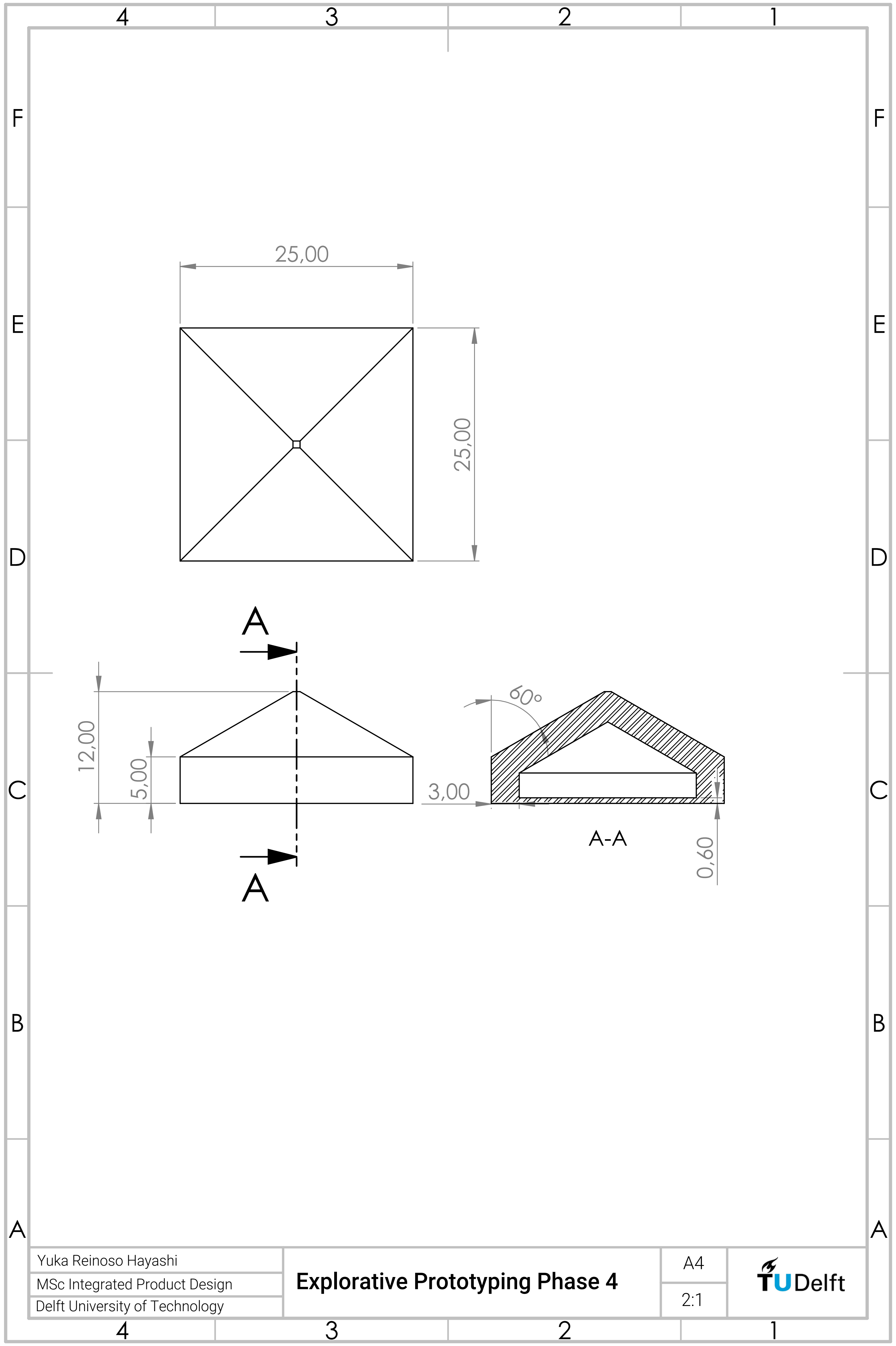
Yuka Reinoso Hayashi MSc Integrated Product Design Delft University of Technology	**Explorative Prototyping Phase 1**	A4 1:1	TU Delft

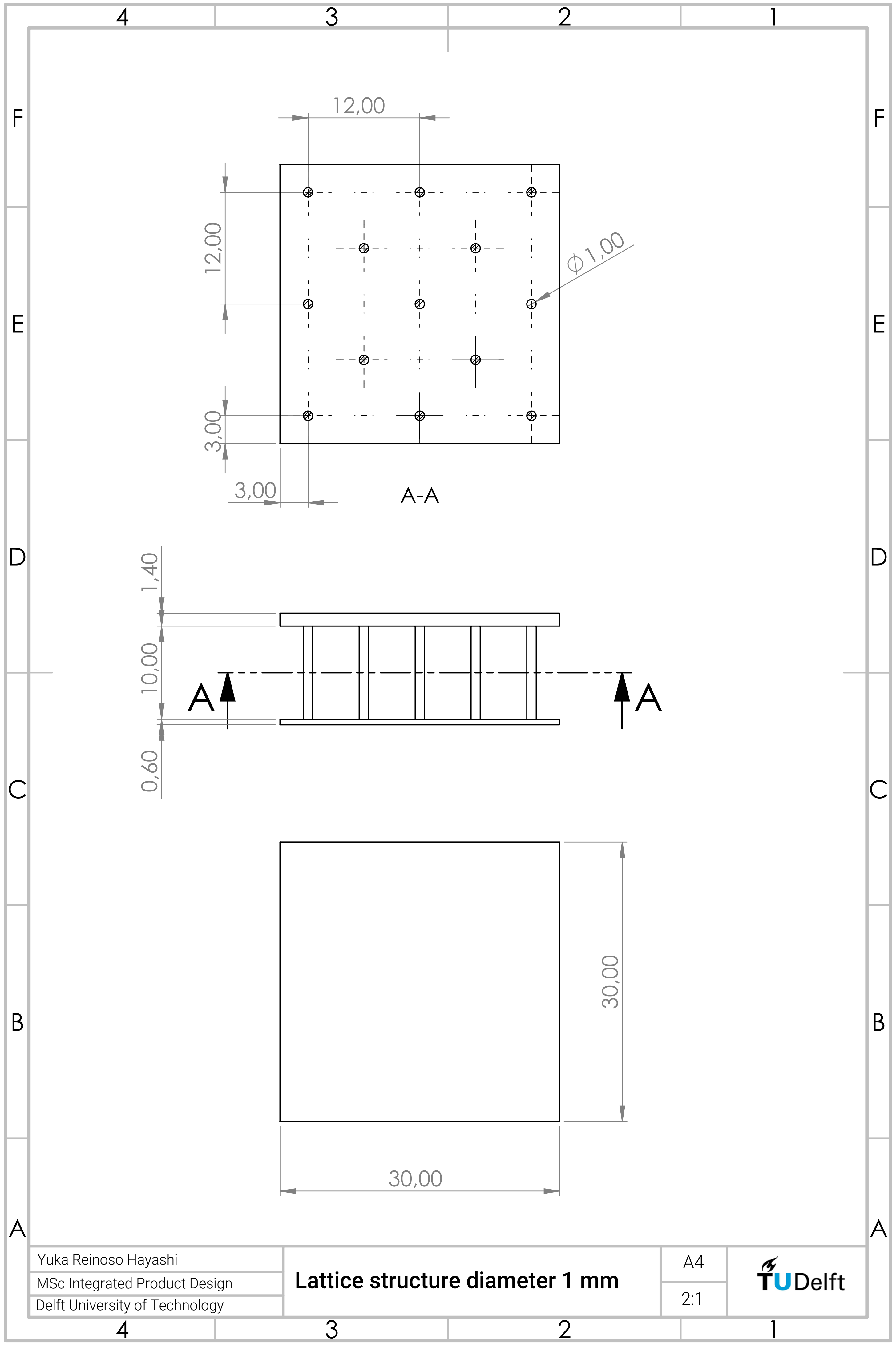


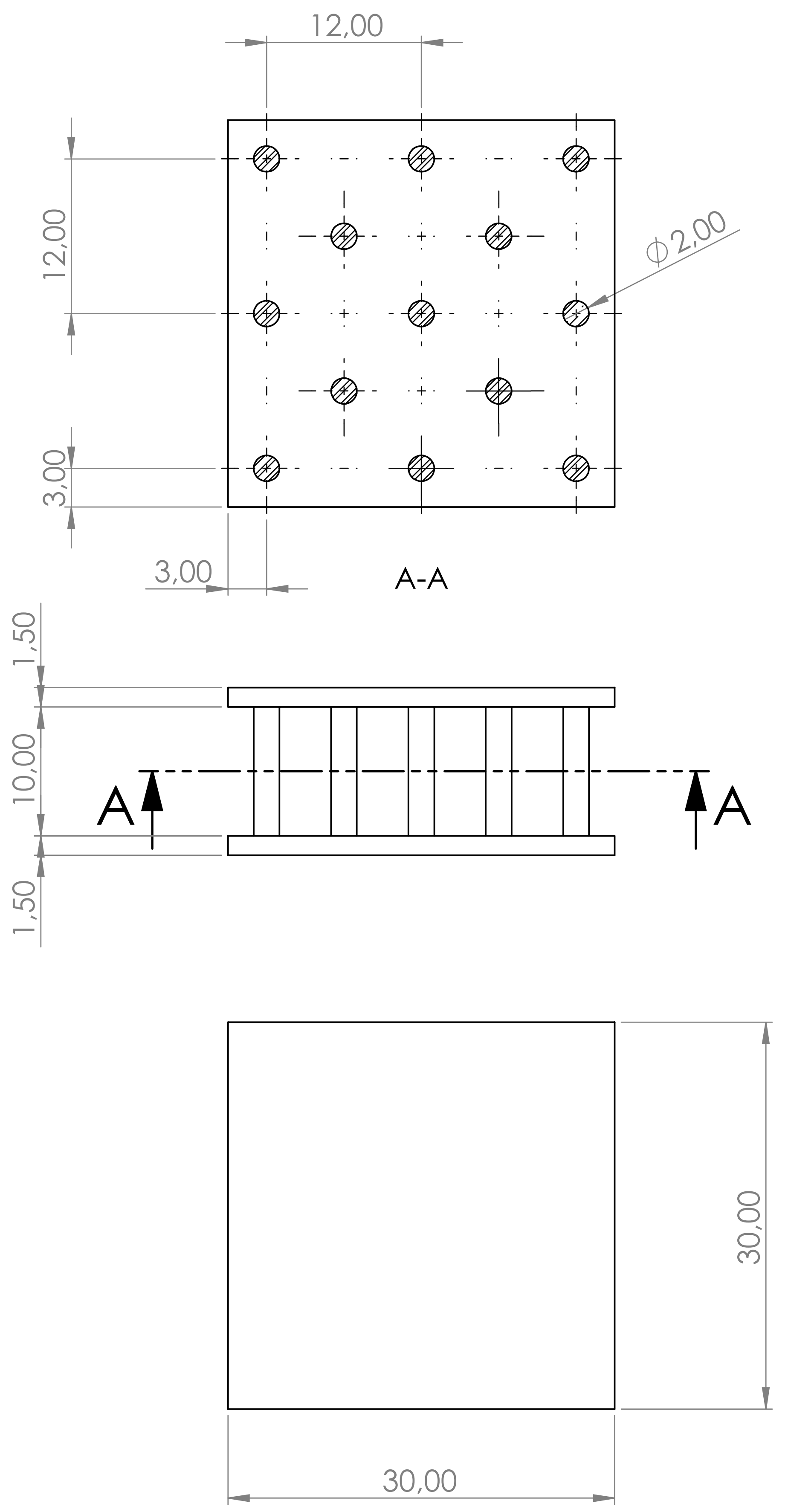
Yuka Reinoso Hayashi MSc Integrated Product Design Delft University of Technology	**Explorative Prototyping Phase 2**	A4 2:1	TU Delft


25,00
25,00
A
A
22,00
12,00
45°
3,00
0,60
A-A
Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology
Explorative Prototyping Phase 3_1
A4
2:1
TUDelft


25,00
25,00
A
A
22,00
12,00
45°
3,00
1,00
A-A
Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology
Explorative Prototyping Phase 3_2
A4
2:1
TUDelft


25,00
25,00
A
A
12,00
5,00
3,00
60°
A-A
0,60
Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology
Explorative Prototyping Phase 4
A4
2:1
TUDelft


12,00
12,00
ϕ1,00
3,00
3,00
A-A
1,40
10,00
0,60
A
A
30,00
30,00
Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology
Lattice structure diameter 1 mm
A4
2:1
TUDelft

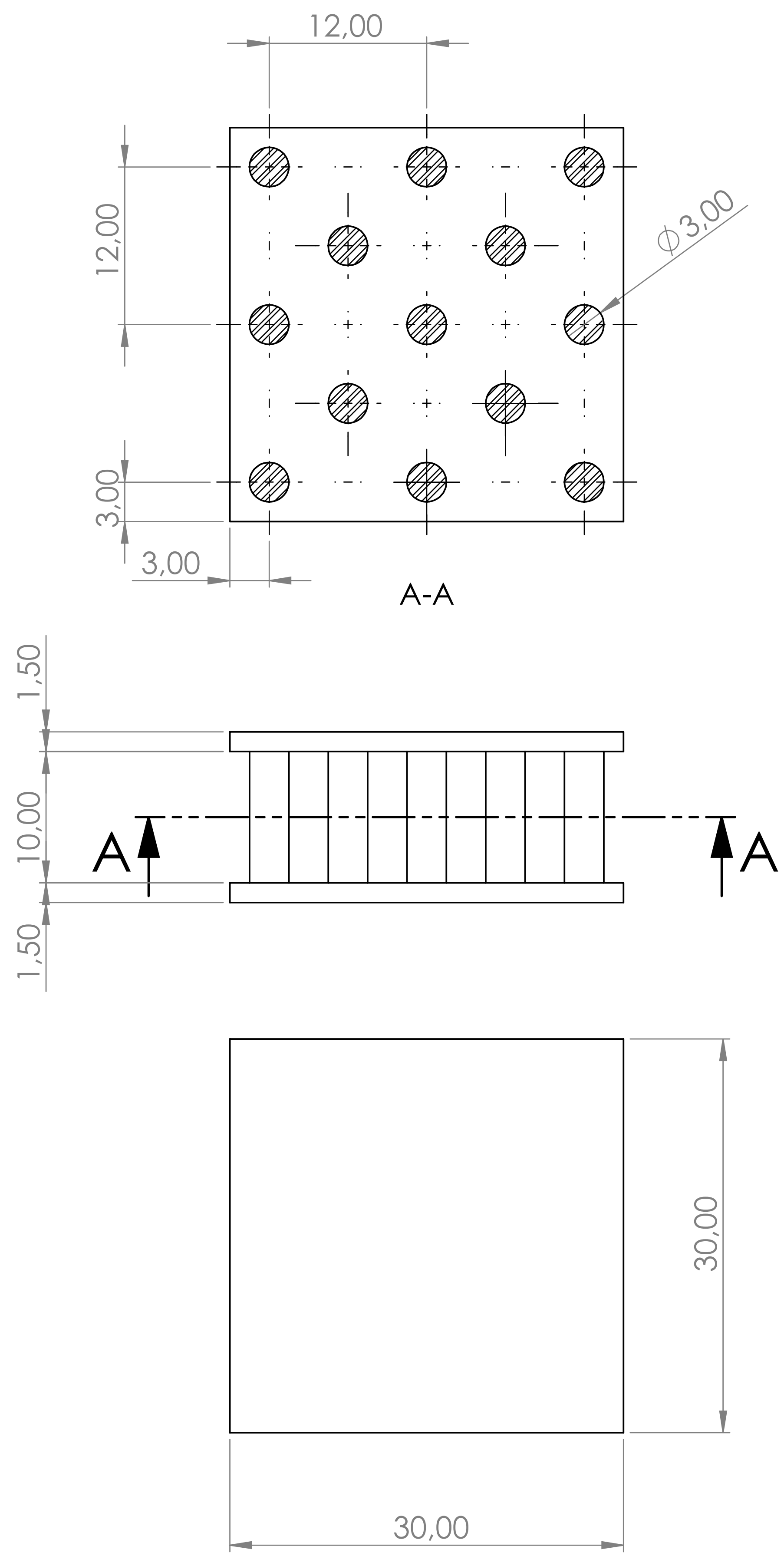


Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology

Lattice structure diameter 2 mm

A4
2:1

TUDelft

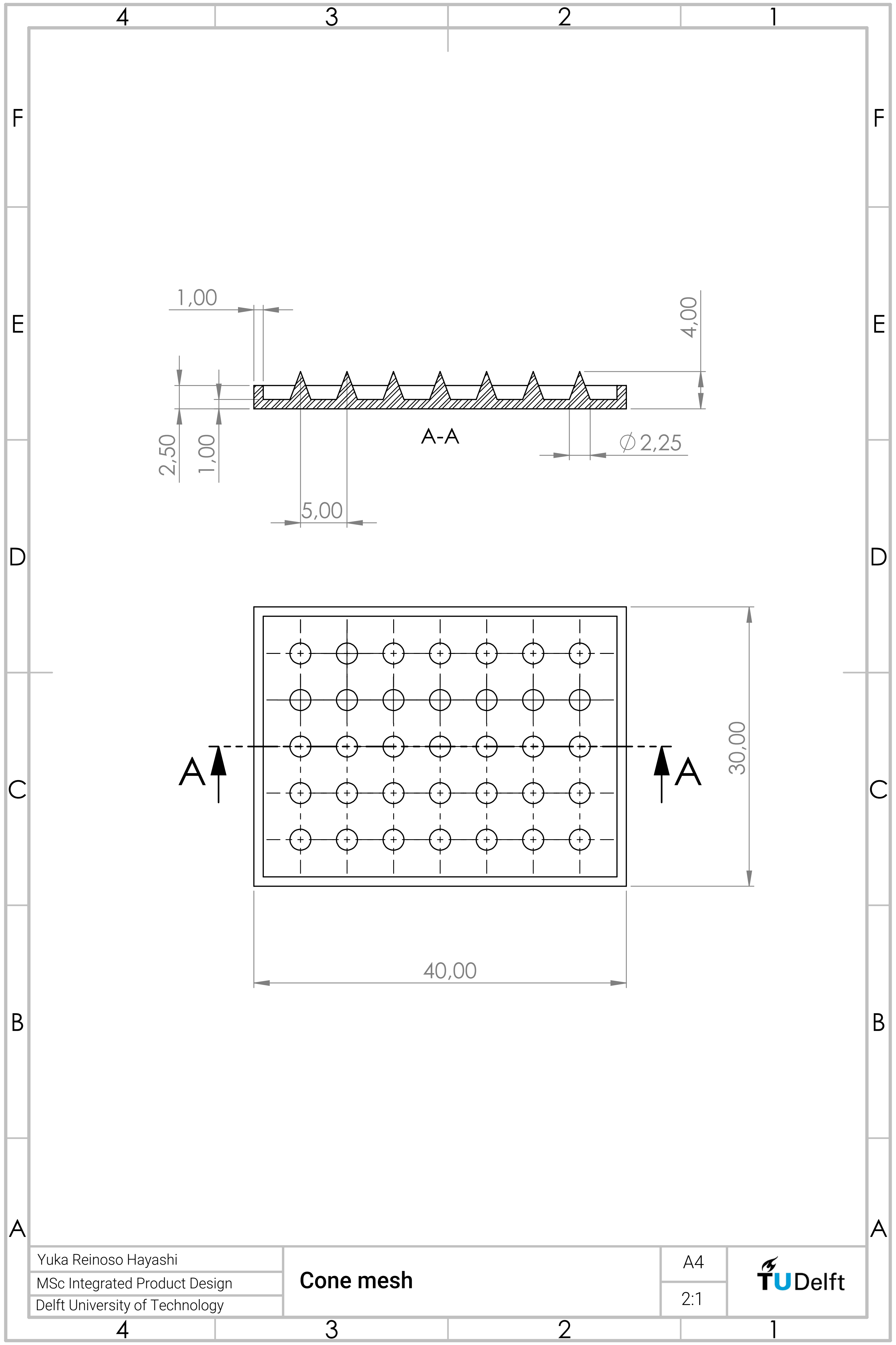


Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology

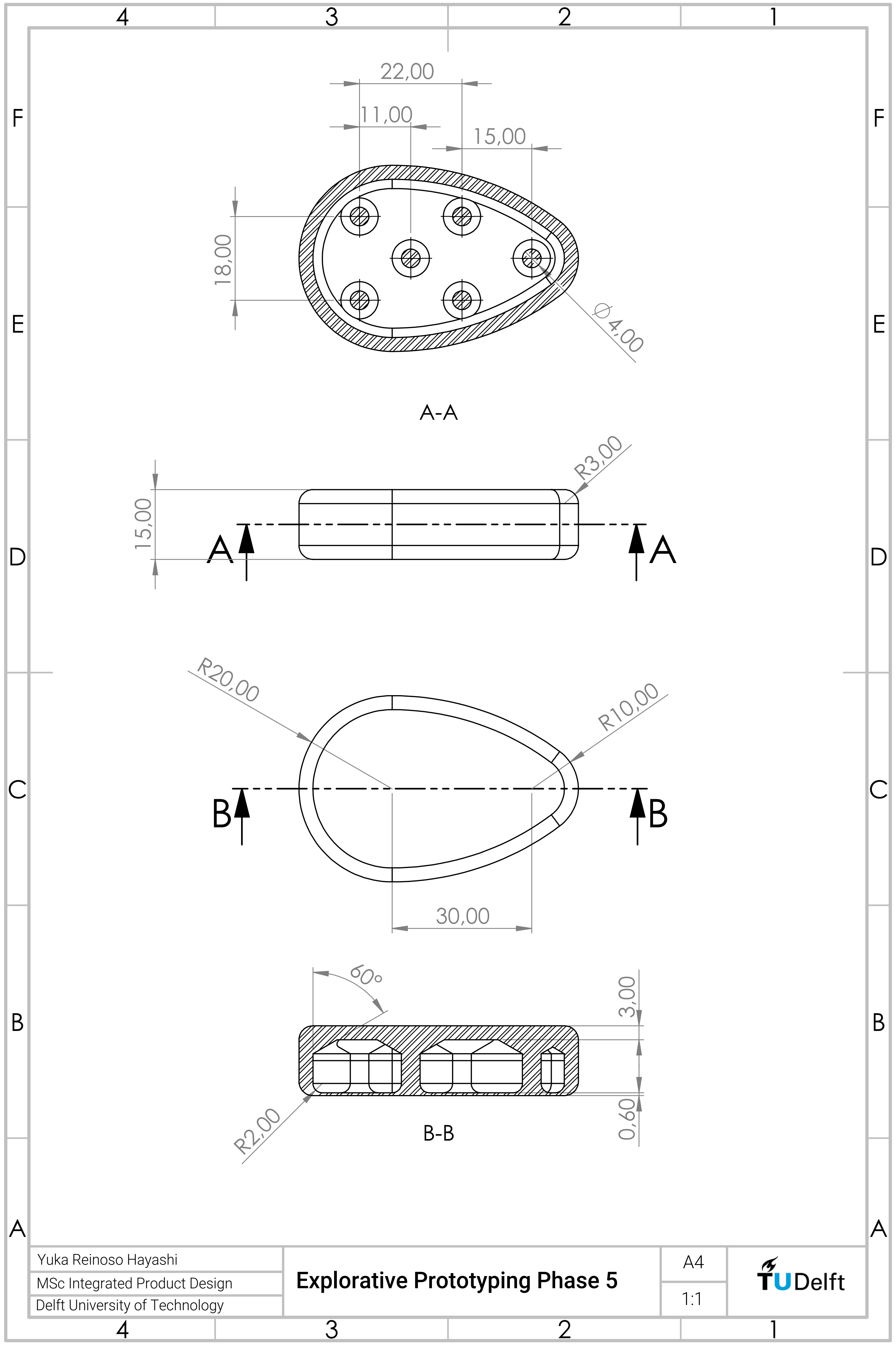
Lattice structure diameter 3 mm

A4
2:1

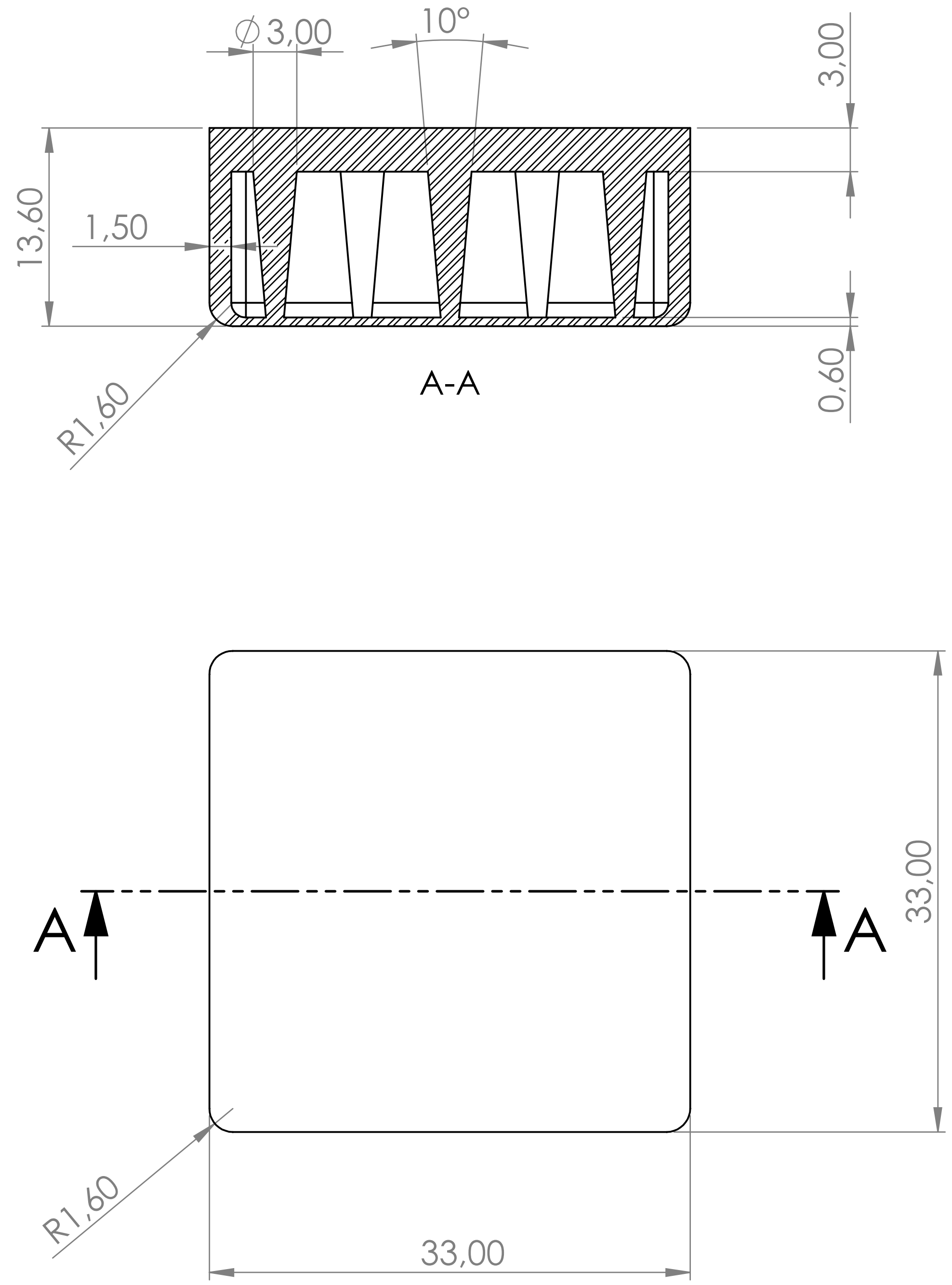
TUDelft



1,00
4,00
2,50
1,00
A-A
∅2,25
5,00
A
A
30,00
40,00
Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology
Cone mesh
A4
2:1
TUDelft



22,00
11,00
15,00
18,00
∅4,00
A-A
R3,00
15,00
A
A
R20,00
R10,00
B
B
30,00
60°
3,00
0,60
R2,00
B-B
Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology
Explorative Prototyping Phase 5
A4
1:1
TUDelft

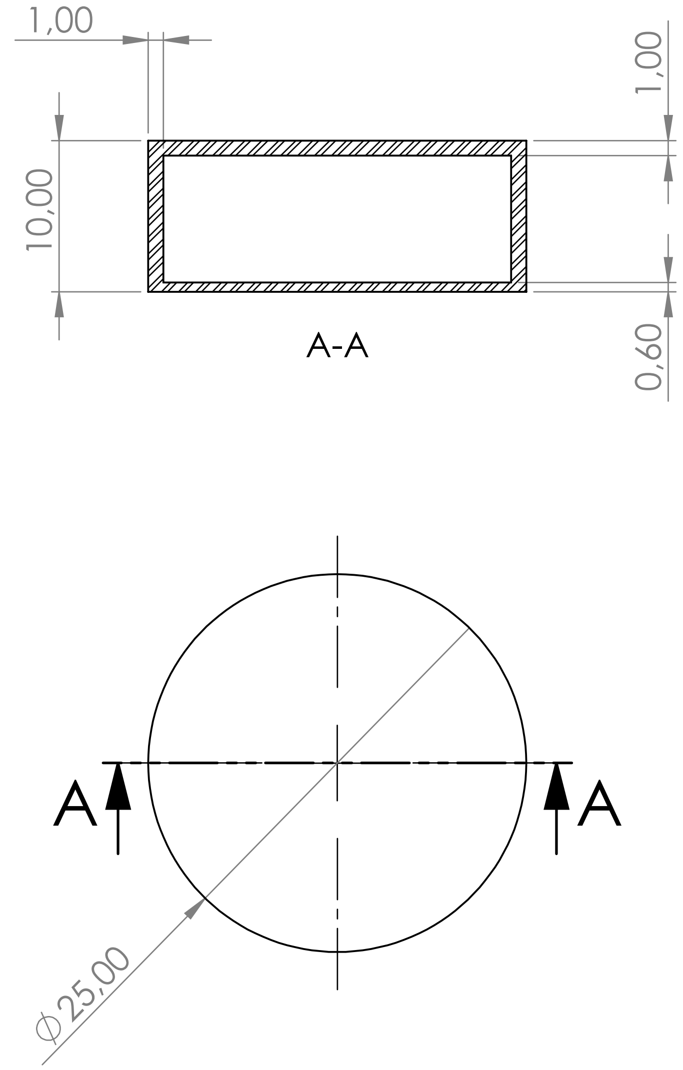


Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology

Explorative Prototyping Phase 6

A4
2:1

TUDelft

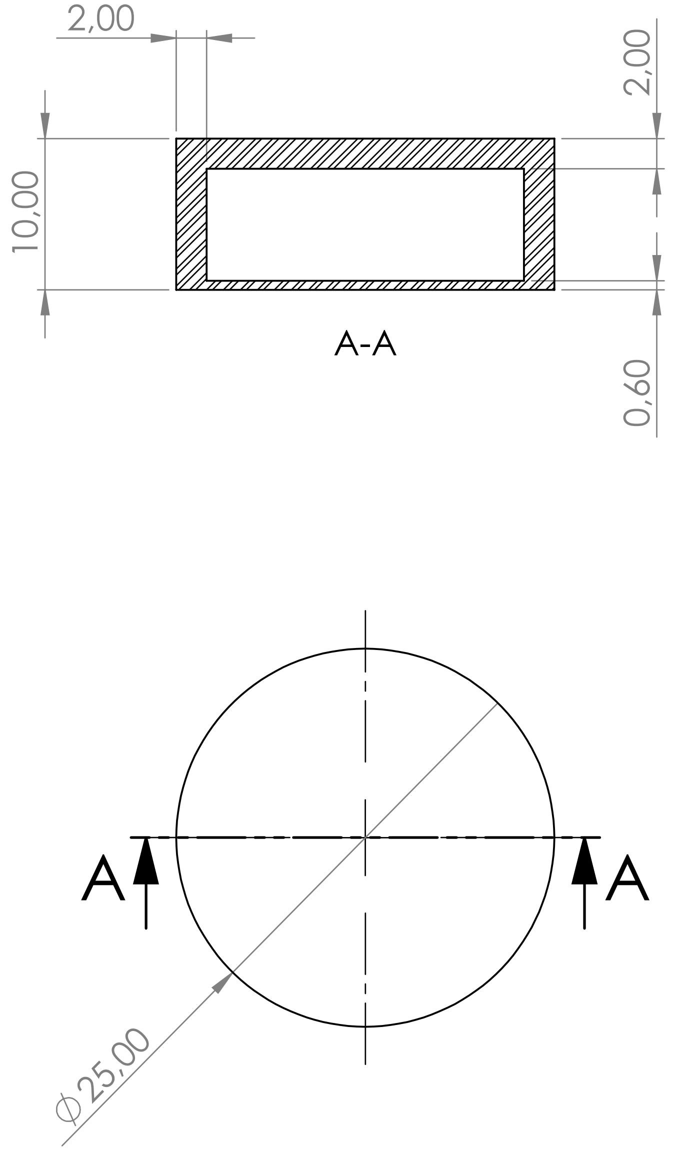


Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology

Explorative Prototyping Phase 7_1

A4
2:1

TUDelft

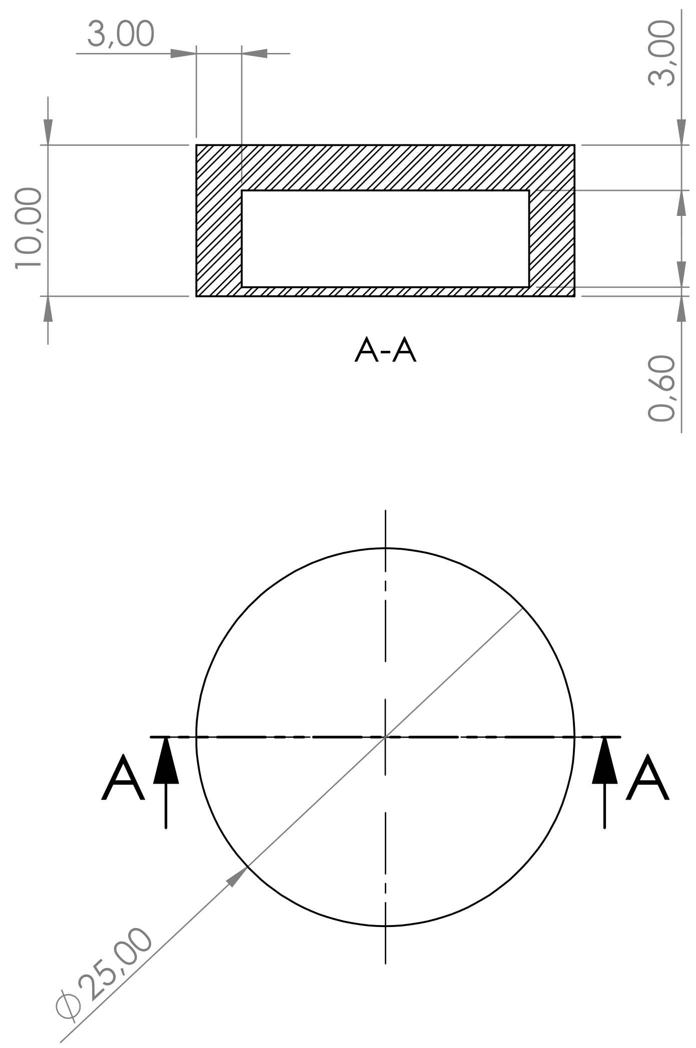


Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology

Explorative Prototyping Phase 7_2

A4
2:1

TUDelft



Yuka Reinoso Hayashi
MSc Integrated Product Design
Delft University of Technology

Explorative Prototyping Phase 7_3

A4
2:1

TUDelft

Yuka Reinoso Hayashi

MSc. Integrated Product Design - Thesis
Faculty of Industrial Design Engineering
Delft University of Technology