Development and Usability Testing of a Custom Positioning Surgical Guide for Soft Tissue Breast Reconstruction

by

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Abstract

Breast cancer is the most common cancer in women with more than two thousand new cases diagnosed every year in Alberta [1]. Women endure both physical and psychological hardship from the disease and treatment. Surgical treatment often includes a mastectomy that removes the entire breast. Breast reconstruction surgery, either immediate or delayed, is considered to improve the rehabilitation process. Despite advancements in surgical reconstruction, the current methods to pre-operatively plan for a symmetrical outcome are limited, and the final result is a subjective assessment done by the surgeon intraoperatively. Other factors effect the surgical outcome such as how well the tissue heals, and how much fat resorbs over time. The challenge in precisely predicting the postoperative result comes from the nature of soft tissue and its surgical manipulation. Therefore, revisional surgery following breast reconstruction is common.

The purpose of this project is to improve the understanding of surgical design and simulation in breast reconstruction and its applications benefits in a soft tissue manipulation. This is explored within two main objectives. The first objective is to develop a process for designing and fabricating a patient-specific surgical guide. The second objective is to evaluate the guide's usability in a guide fitting session.

A single case feasibility study was conducted. The participants included a patient with a unilateral mastectomy and a plastic surgeon. An interview with the surgeon was done to determine the design criteria of the surgical guide. A surface scan of the patient's torso was taken. A custom surgical guide was designed and fabricated. The guide's usability was tested in a guide fitting session. The results of this study include: 1) a design decision matrix determining the required design criterira, 2) the design workflow created to develop the patient-specific surgical guide, 3) the surgical guide both as a physical component and the numerical measure of volume estimate, 4) seven themes from the thematic analysis of the guide fitting session: 4.1) comparision of design techniques, 4.2) location of the inframammary fold, 4.3) positioning landmarks, 4.4) posture , 4.5) changes in weight affecting soft tissue, 4.6) imaging technique, 4.7) materials.

This approach of evaluating the use of virtual planning to improve surgical outcome is inspired by the well-established 3D digital planning protocols for jaw reconstruction at the Institute for Reconstructive Sciences in Medicine (iRSM).

Preface

This thesis is an original work by Jumana Joury. The research project, of which this thesis is a part, received research ethics approval from the Health Research Ethics Board of Alberta – Cancer Committee, Project Name: University of Alberta Research Ethics Board, Project Name "Development and Usability Testing of a Surgical Design Guide for Autologous Breast Reconstruction", No. HREBA.CC-17-0314 , September 8th 2018.

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I would like to express my sincere gratitude to the Institute for Reconstructive Science in Medicine (iRSM) for providing the modeling tools, working space, imaging equipment, materials and fabrication facilities; all that was needed to create and test the guide. For their technical assistance in learning the modeling software, I would like to thank Heather Logan and Andy Grosvenor. From day one Heather Logan's advice and mentorship was most valuable. I appreciated Lindsay McHutchion's assistance in the data acquisition and her continued encouragement to succeed. I truly valued Carolyn Kincade for keeping the mood light and always finding a way to make me laugh. Dr. Jana Rieger's thoughtful and kind advice gave me continuous encouragement. Dr. Suresh Nayar's wealth of experience was inspirational.

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1. General Overview of the Thesis

1.1. Introduction

Breast cancer accounts for 22.9 % of invasive cancers in women [2]. The surgical treatment of breast cancer often includes a mastectomy that removes the entire breast or breast-conserving surgery (BCS) which removes the cancerous tumor but not all of the surrounding healthy breast tissue. The type of surgical procedure chosen depends on the size, location and type of tumor, the size of the breast, and the patient's choice based on a recommendation from the surgeon. Advancements in treatment have increased the patient five-year survival rate to 89.7%. [3].

One of the outcomes of breast cancer treatment is the change in the patient's native anatomy. A reduction in breast size, changes to the breast shape, or complete breast removal are some of the physical changes that the patient might experience from their treatment. In addition to coping with the physical changes, women endure emotional stresses from the disease and its treatment. [4] Together these changes may adversely affect the patient's quality of life.

Breast reconstruction is often a part of the overall treatment process. There are a variety of reconstruction techniques now available. Autologous breast reconstruction uses the patient's own tissue to recreate the breast mound. The Transverse Rectus Abdominis Myocutaneous (TRAM) flap and its various modifications is the most common technique used for autogenous breast reconstruction [5]. The Deep Inferior Epigastric Perforator (DIEP) flap - a modification of the TRAM flap - involves taking tissue from the patient's lower abdominal region based on the position of the perforating vessel to create a breast mound [6]. This is often paired with a procedure on the contralateral breast to improve symmetry [7]. The challenge in precisely predicting the postoperative results arises from the nature of the breast soft tissue and the surgical challenges in reshaping the breast on each side. Despite advancements in surgical technique to improve flap survival rate, current methods to evaluate breast symmetry both preoperatively and postoperatively are limited to subjective assessment.

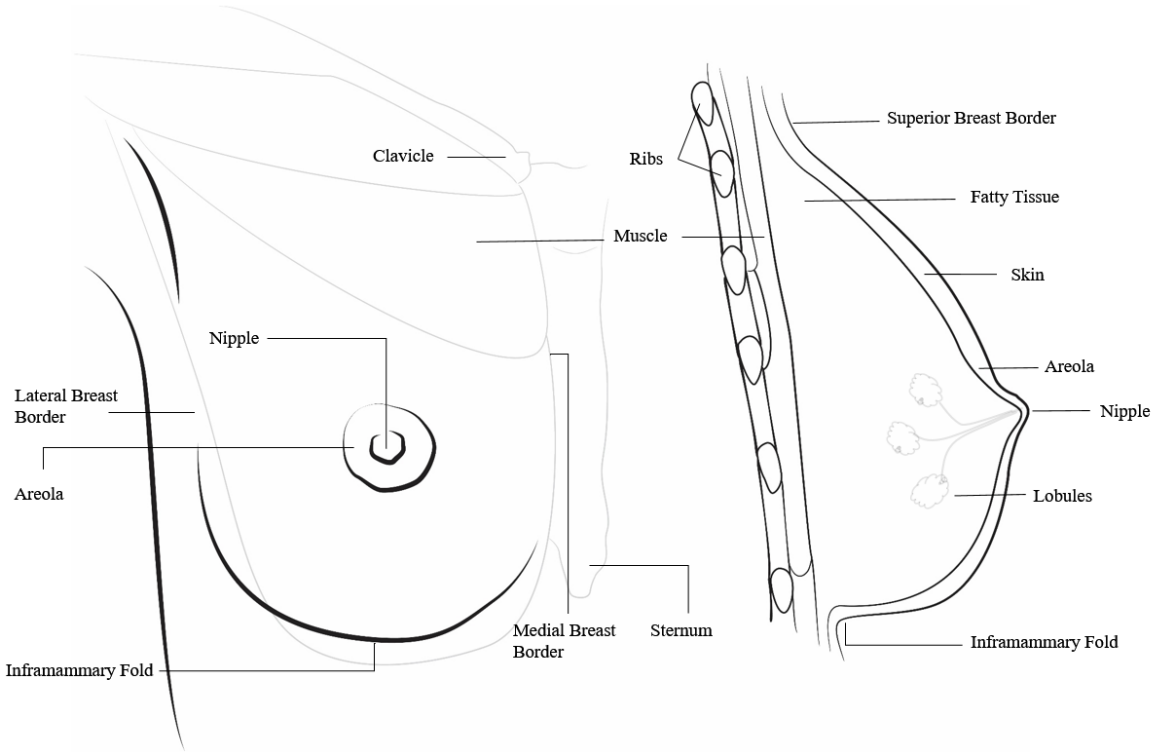


Figure 1-1 Breast Anatomy[1]

The anatomical structure of the female breast is primarily composed of fatty tissue, skin, and glandular structures. Figure 1-1 illustrates the anatomical structures of the breast. The breast is defined by four main borders, the medial border, lateral boarder, superior border and the Inframammary fold (IMF). It is attached to the chest wall by the pectoralis fascia muscle and the overall shape is determined by the skin volume, breast tissue, and supporting ligaments. Skin deformation and stretching play a major role in the final reconstruction outcome, and often multiple surgical procedures are required to achieve an acceptable symmetry in breast shape and volume [7] [6].

The traditional methods of evaluating breast reconstruction include 2-D digital photography, volume measurement techniques such as water displacement, and plaster or thermoplastic casting [8]. Measuring the efficacy of the reconstructive procedure is usually limited to a visual examination post reconstruction [9]. In current practice, plastic surgeons are highly dependent on visual examination and surgical perception to achieve symmetrical reconstruction outcomes. Clinical challenges persist given the subjectivity requried of the current reconstructive technique. The current subjectivity in the reconstruction technique poses clinical challenges. These challenges

[1] Breast Anatomy Figure adapted from National Breast Cancer Foundation, Breast Anatomy and How Cancer Starts. February 5th 2019, https://nbcf.org.au/about-national-breast-cancer-foundation/about-breast-cancer/what-you-need-to-know/breast-anatomy-cancer-starts/

include defining the footprint of the healthy breast and the reconstructed breast, and locating the reconstructed breast appropriately on the chest wall. The lack of planning tools to accurately predict the shape, volume and position of the soft tissue for breast reconstruction is the principal issue addressed in this project. This research aims to assess the potential of virtual surgical planning (VSP) and its role in patient-specific modeling of soft tissue in breast reconstruction.

1.2. Literature Review

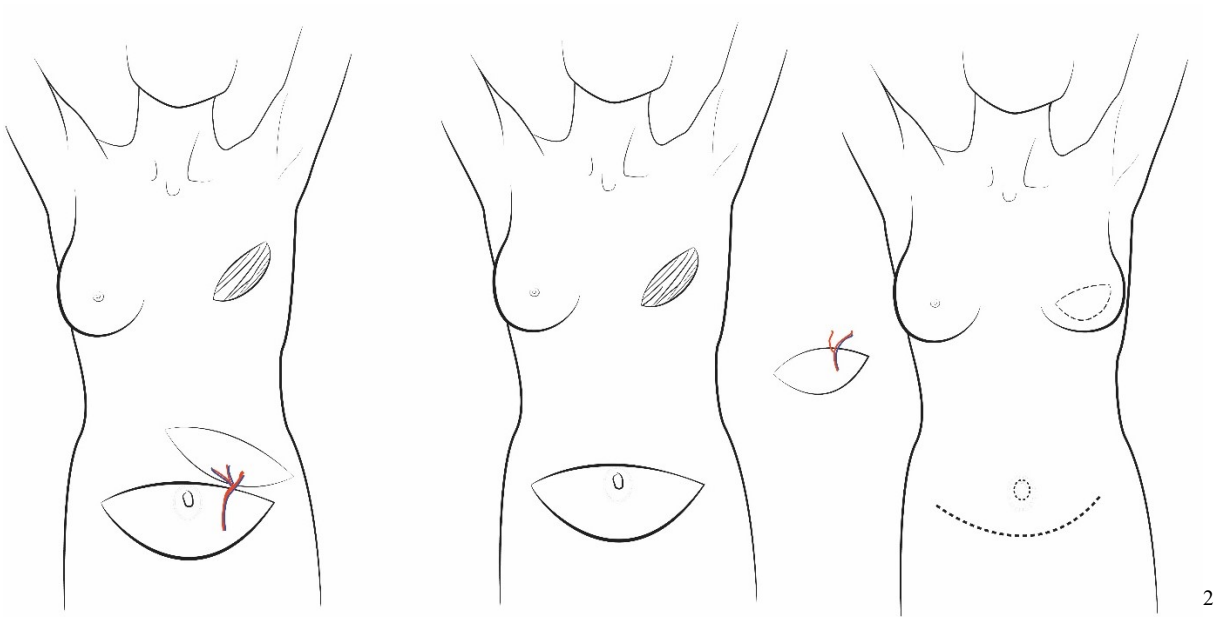
In this section, the background literature related to surgical planning in breast reconstruction and current advancements in soft tissue modeling are examined. A review of the literature is divided into three sections. The first section defines the various surgical techniques in breast reconstruction and examines the difference between autologous and alloplastic reconstructive techniques. The second section examines the application of 3D digital modeling in preoperative planning and its current application in soft tissue reconstruction. The third section examines the current status of engineering modeling of soft tissue. The review of different models will focus on how the existing technology has been of use in a clinical application. By understanding the barriers to usability, it is possible to identify the existing gaps in designing technology geared towards addressing these clinical challenges.

1.2.1. Breast Reconstruction Techniques the Difference Between Autologous and Alloplastic Reconstruction

The various techniques of breast reconstruction are categorized into three main groups. The first group, alloplastic reconstruction, uses soft tissue expanders and silicone gel implants. The second group, autologous reconstruction, uses a patient's own tissue. The third group uses a combination of both [10]. To better understand the reconstruction outcomes, a review of each technique and its application is required. The use of silicone gel implants following soft tissue expansion works better when reconstructing smaller breasts. The implant's position is related to the thoracic wall (chest wall), and an implant is more ridged than native breast tissue resulting in the less change in the shape of the breast when the patient changes posture from upright to laying down. The breast shape from the implant will change less with a change in a patient's posture. This technique will not allow the recreation of as much ptosis or drooping of the breast [7]. The defined shape of the implants allows the surgeon to better visualise the reconstructed breast profile. However the overall symmetry of the outcome is influenced by other factors including the implant positioning and the patient's chest wall profile. The second technique, using vascularized autologous tissue, uses a skin and soft tissue flap as a breast replacement and requires shaping and contouring to create the breast mound. An example of this is the deep inferior epigastric perforators (DIEP flap) technique. The DIEP flap technique often requires a two-team surgical approach. During surgery, one team will harvest the flap from the abdomen carefully

taking into consideration the location of the blood supply vessels, while the second team prepares the reconstruction site which includes defining the breast footprint on the chest wall. The third, and final, technique is a combination of both. This alternative is used in the situation where the patient lacks adequate flap tissue volume, or skin laxity is insufficient to accommodate the soft tissue or implant [11].

A unilateral mastectomy is the removal of one breast. The intact breast is defined as the contralateral breast. A DIEP flap autologous reconstruction procedure, as seen in Figure 1-2, involves taking tissue from the patient's abdominal region to reconstruct the missing breast. This is often paired with a symmetrization revision procedure of the contralateral breast to achieve a desirable outcome.



[2]

Figure 1-2 Abdominal Flap Reconstruction Technique

Understanding the differences in the implant reconstruction procedure and the autologous reconstruction procedure is an important stage in design research. In the case of an alloplastic reconstruction several considerations are taken into account when choosing the prosthesis. The shape and profile of the prosthesis are categorized as high-rise or low-rise projection. In their planning surgeons currently take the prostheses and place it next to the healthy breast prior to the operation to find the best match of shape and size. The challenges in planning for an alloplastic reconstruction include introducing material with different properties than the normal breast. An alloplastic reconstruction will vary in its behavior in relation to the healthy breast. This challenge is common, and is more pronounced in patients

[2] DIEP Flap autologous reconstruction procedure, Adapted From: John Hopkins Medicine , Breast Center , Reconstructive Breast Surgery Options: https://www.hopkinsmedicine.org/breast_center/treatments_services/reconstructive_breast_surgery/options.html

with higher body mass index. In autologous reconstructions where the tissue flap is harvested from the patient, the reconstructed breast will have more similar attributes to the normal breast. A current challenge in surgical planning is in trying to estimate the shape of the reconstructed breast considering the variations in chest wall, breast projection, quantity of soft tissue material and the effect of gravity on soft tissue.

1.2.2. The application of 3D digital modeling in preoperative planning

The next section of the literature review is an evaluation of how 3D digital modeling enhances the surgical planning process and the key findings in the application of VSP. The use of medical imaging is well established in the field, however using segmentation tools to identify specific anatomical structures and creating patient-specific 3D models is a new method in digital planning [12]. When using a 3D digital planning technique, it is important to define a standardised method of comparing preoperative and postoperative measurements [13]. One attempt at developing a standardized method of comparison in 3D planning was established by Oren et al. Their research in mammometrics is a proposed method to objectively analyze surgical results [8]. Surface measurements are taken of the breast shape and volume. Measurements between pre-defined points on the breast surface in the 3D model quantify the size and shape of the soft tissue. A surface model of the breast is one of the simplest visual models as identified by Amit et al. ; there are many levels of complexity associated with developing a mathematical model of the breast [14]. The complexity of the model increases with the introduction of parameters defining various tissues, fat characteristics, and body interactions. Throughout the design of digital models to support surgical planning, considering the complexity required to achieve the clinical objective is critical. Creating a model with complexity suitable to the clinical need will be an ongoing challenge in the field.

1.2.2.1. Tissue Shaping Molds

A study conducted by Uros et al. the team created a workflow for producing a new breast replica cast (NBRC) for 12 participants. The design of the cast was based off of patient specific models obtained from laser scans. They used the 3D models to design a cast of the healthy breast to define the shape and volume needed for the reconstructed breast. The novelty of the idea is inspiring to future planning techniques, but their model is much limited to creating a replica shape of the existing breast [15]. The fabrication process of the mold was costly and cumbersome, as it involved several stages of subtractive manufacturing and a final step of vacuum forming. Tomita et al. in Osaka, Japan also introduced this technique of mirroring the breast profile and creating a mold to shape tissue. The group utilised the ease of additive manufacturing to create shaping molds for five single pedicle flaps and six double pedicle flaps. A

strong positive correlation of $r^2 = 0.95$ between the estimated total flap volume (ml) and actual total flap weight (g) was reported [16]. The use of a tissue shaping mold has proven to be a supportive tool in reconstruction cases, mostly when the reconstruction involves mirroring of the healthy side. Often the case that the reconstruction is also followed by a symmetrization procedure to change the healthy breast and match the reconstructed size. With introducing a symmetrisation procedure, the challenge of achieving symmetry becomes more complicated, as the plastic surgeon is trying to match a moving target.

1.2.2.2. Tissue Vascularisation

Gacto-Sanchez et. al developed a digital planning technique to improve the perioperative outcome of the blood richness in the abdominal flap. Using a comparative study with 70 patients, they evaluated outcomes using Computed Tomography (CT) imaging to identify the blood vessel locations in the flap in comparison to the free hand technique. The outcomes of using CT imaging included reducing surgical time by approximately two hours and a higher flap survival rate [17]. This study demonstrates the promising application of a CT based approach in assessing the flap tissue.

1.2.3. Current status of soft tissue engineering modeling

Defining what has currently been done in the biomechanical modeling of soft tissue is relevant to the work of this thesis as it demonstrates another approach to model simulation. The computer simulation in gravity deformation models are designed to demonstrate to the user the change in breast tissue with the effect of gravity. This is one of the many approaches that can be taken in digital planning.

The biomechanical modeling of soft tissue has been a prevalent interest in engineering and computer science. Finite Element (FE) analysis is a numerical method for modeling how the object of interest reacts to real-world forces [18]. An example for this application would be predicting the change in shape of the breast as it's affected by the downward pull of gravity, predicting the shape of the breast following to volume expansion, or estimating the pressure on the tissue induced by the tool of the incision. There are several levels of complexity in determining the properties and constraints of a predictive model, which include defining the material properties, defining the solver algorithms as well as establishing the appropriate boundary conditions. A study by Eder et al. applied 12 material properties proposed in the literature to FE simulation models derived from prone Magnetic Resonance Imaging (MRI) breast imaging of healthy participants [18]. Based on their findings several of the proposed material parameters in the literature treat the soft tissue as too stiff compared to real breast tissue, preventing adequate deformation in response to gravity. However, from their results, two materials

showed modeling properties that best fit the gravity deformation behavior: a Hyper-elastic Neo-Hookean model proposed by Tanner et al. [19] and a Hyper-elastic Neo-Hookean model proposed by Rajagopal et al. [20]. Eiben et al. developed a simulation methodology to demonstrate the breast shape changes in a breast conserving surgery; their numerical predictions were compared with a clinical trial showing a strong correlation of the model's ability to simulate the change in volume [21]. Finally, an advanced modeling technique for breast reconstruction is evident in work published by Joachim Georgii et al. at the Technical University of Munich School of Medicine. The Computer Aided Plastic Surgery (CAPS) project focuses on modeling the breast to visualize the soft tissue to implement computer-aided surgery (CAS). Through this project, the group developed a workflow to demonstrate the utility of taking a surface scan, setting landmarks, defining the breast volume, generating a Finite Element model, introducing external implants to the breast contour, and finally simulating the change breast profile as the volume increases [22].

1.2.3.1. Commercial Software

In addition to the advancements in research, there is an emerging market of breast tissue-virtual modeling software packages. Examples of this include Vectra XT by Canfield and the Temporal3dMD Torso System. The Vectra modeling tool is designed to show a visual representation of simulated outcome by overlaying the preoperative image with various breast implants [23]. This tool has proven to be useful for reconstruction applications. However, there are limitations to the utility of a predictive model as it could provide false expectations to the patients and fail to consider patient age and skin ptosis variability. The Temporal3DMD Torso System is a motion capture system that generates a series of 360-degree thorax models over a period of time. It captures the breast movements, posture and dynamics by taking a 3D image at time intervals e [24]. This system provides the user with the ability to track the change in breast shape as the patient moves.

1.2.4. Summary

Based on the literature findings, there is evidence to support the positive outcomes of using digital modeling for surgical planning. Table 1-1 is a summary of the literature review regarding the studies that demonstrate work in VSP and designing patient specific models for breast reconstruction. Various levels of model complexity demonstrates the variability in the application of current modeling tools. The advantages of developing a patient-specific 3D model for pre-operative surgical planning of hard tissue are well established [12]. However, there is opportunity to extend the field of surgical design and simulation in the treatment pathway for soft tissue breast

reconstruction. A gap in the literature is evident in the lack of surgical planning to aid in locating the reconstructed breast relative to the healthy breast to achieve a symmetrical outcome.

Table 1-1 Summary of Literature Review Section 1.2.2 and Section 1.2.3

	Authors	Number of Patients	Digital Model	Surgical Intervention Type	Imaging Type	Surgical Design and Simulation Technique
1	Oren et al.	1	Breast	Non	3D Surface Imaging	Measurements between points on the breast surface in the 3D model are used to measure size and shape of soft tissue
2	Uros et al.	12	Breast	Autologous reconstruction (TRAM/DIEP)	3D Surface Imaging,	New Breast Replica Cast (NBRC) mold of the breast created based off of a patient specific surface scan. The negative shape of the breast was CNC milled in a wooden block, then the shape of the mold was vacuum formed.
3	Tomita et al.	11	Breast, Abdomen	Autologous Reconstruction 4 Single Pedicle 5 Double Pedicle	3D Surface Imaging,	Used digital modeling to create breast molds for flap reconstruction, and estimating abdominal flap volume. Breast molds were 3D printed. Strong correlation between total flap volume (ml) and actual flap weight (g).
4	Gacto-Sanchez et al.	70	Abdomen	Autologous Reconstruction (DIEP)	CT Imaging w/contrast	A comparison between freehand technique and using CT scans to identify blood vessels in the abdomen. Results: reduced surgical time, higher flap survival rate.
5	Eder et al.	18	Breast	Non	3D Surface Imaging , MRI	Developed a model to asses 12 material properties, in the current literature, in an Finite Element model simulating the change in soft tissue in the breast.
6	Eiben et al.	4	Breast	Breast Conserving Surgery (BCS)	3D Surface Imaging, MRI	Workflow integrating MR images and 3D surface scans in a mechano-biological model to demonstrate the change of breast shape in (BCS)
7	Georgii et al.	Unknown	Breast	Breast augmentation w/ silicone implants	3D Surface Imaging	Software development of a model simulating augmentation mammaplasty based on solely a 3D surface scan. A finite element model is generated to simulate breast implants and gravity deformation of the soft tissue.

1.3. Purpose and specific objectives of the study

The purpose of this study is to examine the feasibility of designing a patient-specific surgical guide to intraoperatively support a plastic surgeon with a delayed unilateral mastectomy reconstruction. There are two objectives to this study. The ***first*** objective is to develop a patient-specific surgical guide, by creating the design workflow and fabrication process. The ***second*** objective is to evaluate the guide's usability in a guide fitting session. One patient with a unilateral mastectomy was recruited, and one plastic surgeon was consulted throughout the project.

2. Development of a Weighted Decision Matrix for a Patient-specific Surgical Guide

2.1. Problem Definition

In the current practice, plastic surgeons are highly dependent on their visual examination and surgical perception to achieve the most symmetrical reconstruction outcome possible. The current subjectivity in the reconstruction technique poses clinical challenges [25]. Those challenges include defining the footprint of the healthy breast and the reconstructed breast, and locating the reconstructed breast appropriately on the chest wall. There is a lack of planning tools to support the plastic surgeon with accurate planning and executing of the reconstruction [6]. The principle issue addressed in this chapter is defining the design criteria of planning tools. The design focus of this chapter is on answering the question: What design criteria are required in a surgical guide developed to support plastic surgeons with planning and executing breast reconnective surgery?

2.1.1. Guide Development Workflow

Concept development of a new guide design can be a complex process. It is important to define a protocol to follow throughout the process. Figure 2-1 is a model of the adopted workflow for developing a custom surgical guide to support plastic surgeons in planning and executing autologous breast reconstruction.

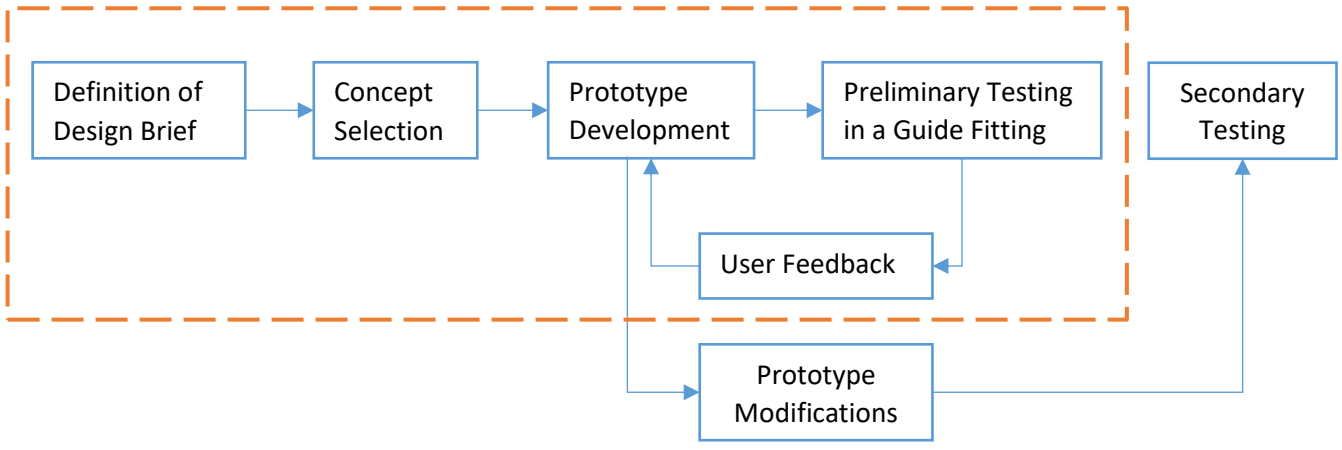


Figure 2-1. Design Process Workflow

2.1.2. Design Brief

A design brief is a tool created as a formal definition of the client's needs, the design problem statement, required design deliverables to meet those needs, and the project constraints including budget and time. A design brief was used to guide the direction of the project

and ensure proper communication between the client and the designer. There are multiple approaches to defining a design brief; it is important to consider the clinical input, engineering solutions and surgical design methodology throughout every phase proposed in the workflow. The relationship between the designer and the client is established in the design brief. In this project the primary researcher is the designer and the "client" is the plastic surgeon who is the primary user of the surgical guide. The primary researcher conducted a semi-structured interview with the plastic surgeon to discuss the desired design criteria to develop a prototype of the custom surgical guide.

2.2. Methods

The semi-structured interview was video recorded to capture the discussion between the primary researcher and the surgeon. Intelligent Verbatim Transcription method was used to transcribe the video. Intelligent Verbatim Transcription focuses on conveying the meaning in the discussion, omitting words such as 'um' , 'so' , 'you know' that are often said in a conversation but do not add any meaning in a written text [26]. Seven themes emerged from a thematic analysis of the interview.

2.3. Thematic Analysis Results

Theme 1: Breast Reconstruction Procedure Background

During a complete mastectomy procedure, the surgeon is likely to remove most, if not all, of the natural landmarks of the breast. Specifically the inframammary fold (IMF), the medial boarder, the lateral boarder and the superior aspect. This results in a significant change between the profile of the healthy breast, and the remaining flat chest. In this case, the surgeon is often left to assess the best possible positioning of the reconstructed breast based on a visual assessment of the healthy breast. This current approach is subjective. There are many considerations taken into account during the decision making process Appendix 1 [1 min 13 s – 7 min 18 s] including:

1. The change in breast shape between the upright position used for planning, and the supine position in surgery
2. Any distortions or issues of healing due to the mastectomy, this is highly dependent on the patient's body habitus
3. Changes in the surgical plan developed prior to any incisions, specifically adjusting to the shape of the chest wall when new tissue planes are opened intraoperatively
4. Challenges in visualizing the exterior shape of the breast while shaping the internal pocket of the breast intraoperatively
5. Estimating the required volume of the reconstructed breast compared to the healthy breast
6. Estimating the required volume of the reconstructed breast compared to the healthy breast through visual assessment

7. Locating the breast landmarks and the challenge in estimating the breast dimensions.

Theme 2: Planning Breast Reconstructive Surgery Deliverables

Three main deliverables are considered in planning a breast reconstructive surgery: volume estimation, shaping the soft tissue, and positioning the breast footprint, all of which interplay to achieve the best desirable outcome for the patient. Surgical planning for soft tissue reconstruction is adaptive in nature. Often the surgical plan changes as the surgeon opens new tissue planes, changes tissue margins and harvests tissue to create a new breast mound. Adjusting for the volume changes, tissue shape, and the breast positioning intraoperatively is challenging Appendix 1 [7 min 48 s – 10 min 11 s]. The current methods of planning are highly dependent on the surgeon's expertise in defining the best solution to meet all three deliverables. The plastic surgeon's clinical expertise and experience will drive the decision making process during surgery. The purpose of a custom designed surgical guide is to assist the surgeon in the planning process and has the potential to eliminate (lesson) the need for intraoperative adjustments.

Theme 3: Important Measures to Include in the Guide Design

An important criterion of the guide is to provide the surgeon with information on where the breast borders ie. IMF, medial, lateral and superior extents of the breast mound should be positioned Appendix 1 [10 min 34 s – 11 min 20 s]. This problem tends to be more pronounced with the reconstruction of bigger tissue flaps where the lateral border is too far lateral, and the IMF border poorly defined due to the ligaments being destroyed when the mastectomy was performed. It is important to consider the shape of the guide and how it will indicate the position of the borders on the inside of the incision pocket Appendix1 [11 min 30 s – 12 min 57 s].

Theme 4: Volume Estimation

The challenge in volume estimation is the visual quantification of breast size. Comparing the size of the breast to an alloplastic implant visually is an approach currently used, however this gives a very rough estimate. Creating appropriate breast volume that has similar characteristics to a normal breast is a challenge in both autologous and alloplastic reconstruction. The challenge comes from needing to consider two volume estimates in planning the reconstruction. The first estimate is the volume difference comparing the healthy breast to the reconstructed breast. The second estimate to consider is the absolute volume of the reconstructed breast. This number is useful in estimating the required size of alloplastic implant. Currently surgeons resort to visual assessment to estimate the volume in cubic centimeters (cc). The estimate can vary based on the surgeon's experience and best judgement Appendix 1 [20 min 30s – 21 min 45 s].

Theme 5: Breast Shape

The challenge in shaping the reconstructed breast stems from the malleability of soft tissue. One of the main issues in shaping the reconstructed breast depends on the variation of the breast shape when the patient is lying down compared to sitting upright Appendix 1 [21 min 45 s – 22 min 30 s]. Gravity affects the symmetry of the reconstruction. Surgical planning is often done while the patient is upright the landmarks are drawn on the patient marking the resection freehand. Once the surgery commences the patient is supine. During the surgery the surgeon could have the patient is lifted to an upright position to compare the reconstruction to the non-treatment breast, this increases the risks to the patient while under anesthesia.

A challenge in shaping the breast comes from asymmetries in the chest wall. The curvature of the chest wall is a part of the foundation that defines the shape of the breast. In the case of chest wall asymmetries it is difficult to define the variables that will affect the overall shape of the reconstructed breast. CT would provide more information to the surgeon in the planning stage. However, this is seldom used as ordering a CT scan to address this concern is considered unnecessary exposure to radiation for a small gain in knowledge Appendix 1 [16 min 0 s – 17 min 22 s]. The surgeon must therefore examine the patient visually. Here the assessment is subjective, and the information is of limited use prior to surgery.

Theme 6: Materials

Material samples were presented to the surgeon for comparison. The comparison was based on rigidity, color, and surface finish. Both opaque and clear materials were approved, with a preference for clear material to allow for marking on the guide with colored pen. The guide should have a smooth surface. The surgeon's input on material rigidity was: "I think the material has to have a certain stiffness to it, rigid enough to hold a certain shape and avoid distortion when affected by the pressure induced by the tissue or the flap positioning." Appendix 1 [13 min 31s – 15 min 50 s]

Theme 7: Registration Markers

When the guide is positioned on the patient's torso, it must register in the same location consistently. The surgeon is likely to place the guide, take it off, and place it back on several times during the surgery so both accuracy and precision are important factors to consider. Appendix 1 [25 min 55 s – 26 min 51 s]. The registration markers will be unique for each patient, based on their bony landmarks or skin composition. The guide must register to the opposite breast. Because it is unclear which registration markers are the most suitable it

would be preferable to include the greatest number of markers possible for testing. Questions regarding the registration markers and the supine or upright orientation of the patient arose Appendix 1 [27 min 0s – 28 mins 50s].

2.4. Developing the Weighted Decision Matrix

A set of optimal design criteria is defined based on the seven themes that resulted from the interview with the surgeon. The criteria encompasses the challenges in defining shape, volume estimation, and positioning. It also considers the practicality of using the guide in the operating theater. The defined criteria in Table 2-1 includes:

Table 2-1 Justification of Design Criteria

	Criteria	Justification
1	Sterilization	The guide has to be sterilize-able since it is used in the OR
2	Registration Repeatability	The guide must be positioned on the patient's torso in a repeatable manner, ie in the same location each time.
3	Indicator of IMF	In order to achieve correct positioning the guide must indicate the location of the breast borders: IMF , Lateral border , Medial border and Superior extent
4	Indicator of Lateral Border	
5	Indicator of Medial Border	
6	Indicator of Superior Extent	
7	Volume Estimate	A volume estimate would support the surgeon with planning the shape of the breast.
8	Projection Profile	It would be an asset if the guide can demonstrate the projection profile of the breast
9	Chest Wall Contour	The guide must follow the chest contour of the patient. This is do so as the guide fits well on the patient's torso to indicate positioning.
10	Ease of Use	The guide should be intuitive and easy to use
11	Material Rigidity	The material should not deflect, and withstand low pressure values as the surgeon places the guide
12	Color	User preference if the guide is transparent or opaque
13	Ease of Manufacturing	The manufacturing process should be simple and straight forward
14	Fabrication Time	The fabrication time should be low (1 – 2 days)
15	Cost	Must be of affordable cost
16	Internal Indicator of IMF	To support the surgeon with defining the internal IMF border

A weighted decision matrix is created using the criteria mentioned above. A weighted decision matrix is a tool to compare design concepts based on a fixed criteria, where each concept would be ranked on its level of importance [27]. A weight value is first assigned to each variable. Then a rank of importance from 1 to 5 is given, with 5 being the most valuable. The weighted decision matrix is an evaluation tool to compare the proposed concepts. The matrix can be seen in Table 2-2, this tool will be used to evaluate design concepts in Chapter 5 section 4.

Table 2-2 Weighted Decision Matrix

	Criteria	Ranking	Weight	%
1	Sterilisable	5	0.0943	9.43%
2	Registration Repeatability	5	0.0943	9.43%
3	Indicator of IMF	4	0.0755	7.55%
4	Indicator of Lateral Border	4	0.0755	7.55%
5	Indicator of Medial Border	4	0.0755	7.55%
6	Indicator of Superior Extent	2	0.0377	3.77%
7	Volume Estimate	3	0.0566	5.66%
8	Projection Profile	2	0.0377	3.77%
9	Chest Wall Contour	3	0.0566	5.66%
10	Ease of Use	4	0.0755	7.55%
11	Material Rigidity	3	0.0566	5.66%
12	Color	2	0.0377	3.77%
13	Easy of Manufacturing	3	0.0566	5.66%
14	Fabrication Time	3	0.0566	5.66%
15	Cost	2	0.0377	3.77%
16	Internal indicator of IMF	4	0.0755	7.55%
	Sum Total	53	1.0000	100.00%

2.5. Limitations of a Weighted Decision Matrix

A weighted decision matrix defines the design parameters and constraints. It is a tool that prioritises the defined criteria based on its importance to the design. It is valuable in ranking multiple design concepts. However, this method has limitations. It is often difficult to place a “weight” or value on a certain deliverable, leaving the designer to make as educated guess. Finally, the weighted decision matrix does not have the means to evaluate the user’s experience while using the guide. For example, how the user felt emotionally if

they were pleased, frustrated, content with the design. It lacks the ability to encompass how the user interacted with the product. Despite these limitations, developing a Weighted Decision Matrix is a useful tool in comparing design concepts and quantifying the differences with a numerical value.

2.6. Discussion

Designing a patient-specific surgical guide for breast reconstruction is an emerging field. It is unknown what design criteria must be used to define the purpose and shape of the guide. Therefor an interview with a plastic surgeon was conducted to discuss the guide's purpose and utility. A thematic analysis of the interview revealed seven main themes. From those themes the design criteria was defined. The defined criteria includes: sterilizability, registration repeatability, indicator of IMF, indicator of lateral border, indicator of medial border, indicator of superior extent, volume estimate, projection profile, chest wall contour, ease of use, material rigidity, color, ease of manufacturing, fabrication time, and cost. The ranking was based on the level of importance as a number from 1 to 5. There are limitations to the weighted decision matrix, however in this case having a set of design criteria was advantageous. The weighted decision matrix will be referenced throughout the design process of the patient-specific surgical guide.

3. Design Process

3.1. Introduction

The first study objective (defined in chapter 1 section 1.3) is to develop a patient-specific surgical guide, by creating the design workflow and fabrication process. This chapter will address the question: What is the process involved in developing a workflow for designing a patient-specific surgical guide to support a plastic surgeon with breast reconstructive surgery? The motivation of this chapter is to give a step by step illustration of the surgical guide's design workflow and to discuss the chosen imaging and modeling tools and considerations on how to improve the developed workflow for future revisions.

Design Concept Introduction

Based on the thematic analysis of the interview with the surgeon in Chapter 2 (Development of a Weighted Decision Matrix for a Patient-specific Surgical Guide) seven themes emerged. From these themes 15 design criteria were identified. The design process started with familiarizing the shape and proportions of the patient's torso (from the neck to the navel). A midline was drawn passing through the center of the clavicles to the navel. Distance measurements were taken from the healthy breast to the midline. Those measurements gave an indication of the potential size of the guide. Markers were placed at the location of critical design features such as IMF, lateral border, superior extent, patient freckles and other defined criteria. Then lines were drawn to connect the markers. This initial approach lead to three main design concepts which are the focus of this chapter.

Design concept A: Volume Estimation.

This was based on the analysis of Theme 4: Volume Estimation. Providing a volume value to support a plastic surgeon in estimating the required size of alloplastic implants was emphasized.

Design concept D: Positioning Guide.

The second design concept is a guide that could provide the location of the IMF, medial and lateral borders, and superior extent. This was based on the analysis of Theme 3: Important Measures to Include in the Guide Design, Theme 6: Materials, and Theme 7: Registration Markers. Those themes indicated 1) the shape will fit externally on the patient's torso, 2) the surgeon will use the shape to mark the location of the breast borders, 3) the guide must have a certain material stiffness to withstand the external pressures of the tissue flap placed on the guide.

Design concept C: Incision Pocket Guide.

The third design concept is a guide that would fit in the incision pocket that the surgeon creates when opening the tissue flap. The surgeon first creates a pocket between the patient's muscle (chest wall) and the skin. The surgeon then sutures the breast borders internally in that created space pocket. This was based on an understanding of the surgical procedure that came from watching multiple surgeries, as well as the analysis of Theme 1: Breast Reconstruction Procedure Background, Theme 3 and Theme 6. The themes indicated:

1) The guide shape needs to be small enough to fit in the incision pocket
2) The guide will be used to indicate the breast borders from inside the incision pocket
3) The guide will be clear in color preferably to allow for marking with a surgical marker.

3.2. Methods

A single case feasibility study was conducted. One female patient with a unilateral mastectomy was recruited and consented to participating in the study. The steps regarding the patient were outlined in the Patient Consent Form (HREBA CC-17-0314), Appendix 2. The patient involvement included an imaging appointment, and a surgical guide fitting session. The imaging session is discussed in this section, and the surgical guide fitting session is discussed in Chapter 5. The specific goal of imaging appointment session and the guide fitting session are:

1. To obtain a patient specific 3D model of her torso – this will be used to design the guide
2. To test the guide's usability: by the surgeon positioning the guide on the patient's torso

3.2.1. Imaging Session

The imaging appointment took place in a private room at the Medical Modeling Research Lab (MMRL), at the Institute for Reconstructive Sciences in Medicine (iRSM), Misericordia Community Hospital. The scanning setup was explained to the patient. This included the camera placement, the technology and scanning protocol. The patient was invited to change her upper garments to a robe, in the changing room inside the scanning room. Then, the clinical assistant palpated and placed 3D acrylic markers on the patient's clavicle (collarbone), and sternum (breastbone).

The 3dMD (Atlanta, Georgia, USA) is a surface imaging system that captures the surface topography. Obtaining the patient's skin pigmentation and surface features is key to photogrammetry. The 3dMD's six camera system is set up on a frame to capture the

patient's torso from all angles. The camera setup can be seen in Figure 3-1. The 3dMD computer system stitches separate images together to generate a complete surface model.

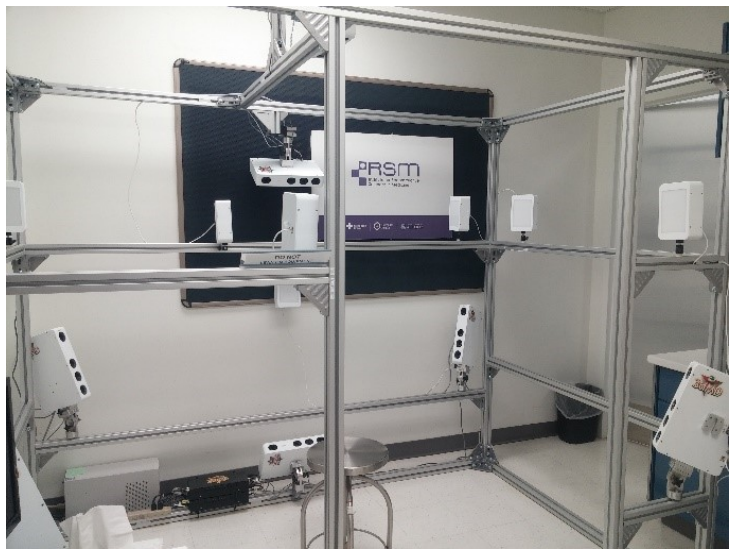


Figure 3-1. 3dMD Setup

The shape of the breast changes naturally as the patient is standing, leaning forward or backwards, and depending on the arm positions as well [18]. Knowing this, an imaging protocol was developed to try and captures a range of variations in the shape of the breast at different postures. Scans were recorded with the patient in five different postures:

1. The patient's arms were adducted parallel to the body at zero degrees (Figure 3-2)
2. The patient's arms were partially abducted at 45 degree angles to the body
3. The patient's arms were abducted perpendicular to the ground at 90 degrees
4. The patient was leaning posteriorly at approximately a 20 degree angle
5. The patient was instructed to lift her healthy breast to expose the inframammary fold

These five postures were chosen to simulate the changes in soft tissue in various scenarios. Often people walk with their arms resting at the zero degree position. This is the neutral upright position, as well as the position where surgical marking and assessments are made. The 90 degree and 45 degree positions represent the arm positions of the patient on the operating table. Here the surgeon was interested in studying the effect of the difference in arm position on the location of the IMF. This was done to understand the relation between the position of the IMF and the position of the patient's arm, to evaluate if the position of the IMF would shift upward with raising the arm. The fourth position where the patient was tilted back 20 degrees exposed the IMF during the scan. The scan where the patient was asked

to lift her breast to expose the IMF was intended to show the borders of the breast, however the soft tissue was deformed to an extent that the breast borders were compromised and these scans were not used. Figure 3-2 shows the postures recorded in the first three scans.

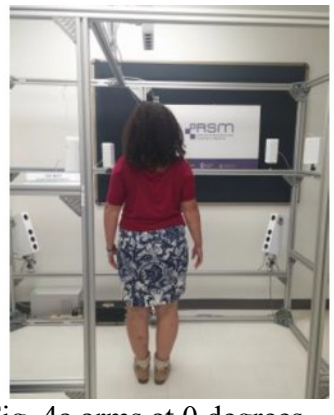


Fig. 4a arms at 0 degrees


Fig. 4b arms at 45 degrees


Fig. 4c arms at 90 degrees

Figure 3-2. Imaging postures

The chosen postures are a sample of a range in change of soft tissue shapes based on the movement of the breast. The goal here is to capture a variety of postures to better understand the factors involved in measuring soft tissue 3D models. This is the first step in creating a scanning protocol which is needed to establish a consistent method of collecting data. The accuracy of the postures meet the need of acquiring the breast in different positions.

3.2.2. Volume Estimation

A design method was developed to estimate the volume of the healthy breast from the torso surface scans. The goal of this section is to answer design questions regarding volume estimation. The questions are twofold: 1) What is the influence of the patient's posture to volume estimate? 2) What is the influence of surface shell closure method to volume estimate? Scans in four different postures were captured, and three different methods of closure were tested.

Volume Estimation Workflow

Delineating the breast footprint from the colored scan was the first step in estimating the breast volume. An .stl file of the patient's torso was imported into Freeform® modeling software (Geomagic® Freeform®, 3D Systems, Cary, NC, USA) as a Mesh file format. The surgeon then verified the footprint profile and adjusted the borders if needed. Using the Mesh file format the shape of the breast within the breast footprint was highlighted and copied into a new component, Figure 3-3.

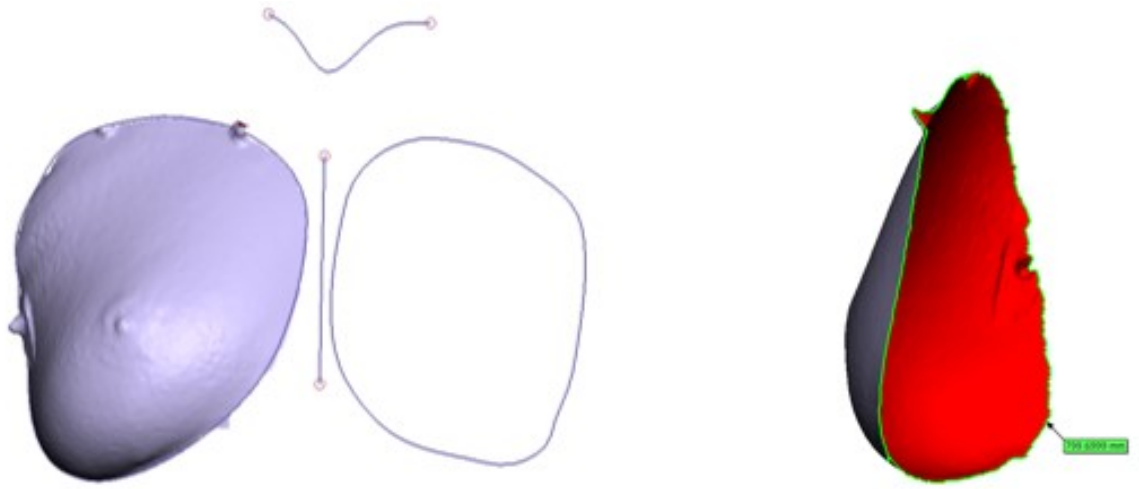


Figure 3-3 Breast Mesh Shell

The shell of the breast shape is closed by a surface generated by an algorithm. A comparison of three computer algorithms of computing closures was done, a tangent method, a curved method and a flat method. A 2D representation of the closure methods is in Figure 3-4.

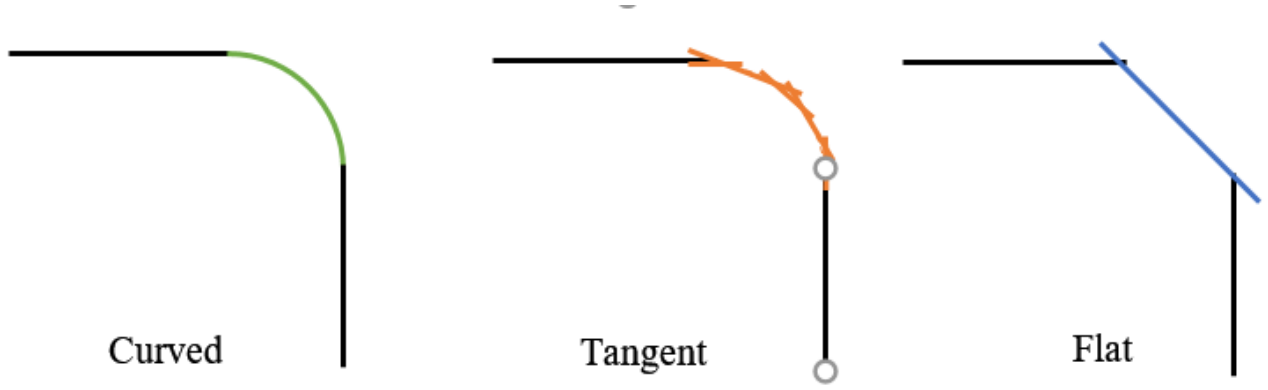


Figure 3-4 2D Closure Methods Comparison Between Curved Line, Tangent Lines and Flat Line

In the curved algorithm the closure method follows a smooth trajectory of the corner. In the flat algorithm the closure pattern is a flat surface that connects one point to the other. Finally, in the tangent method the closure is composed of multiple small flat planes angled at a tangent to the curve that connects the two points. A 3D example of this can be seen in Figure 3-5 with the open space in the corner of the cube.

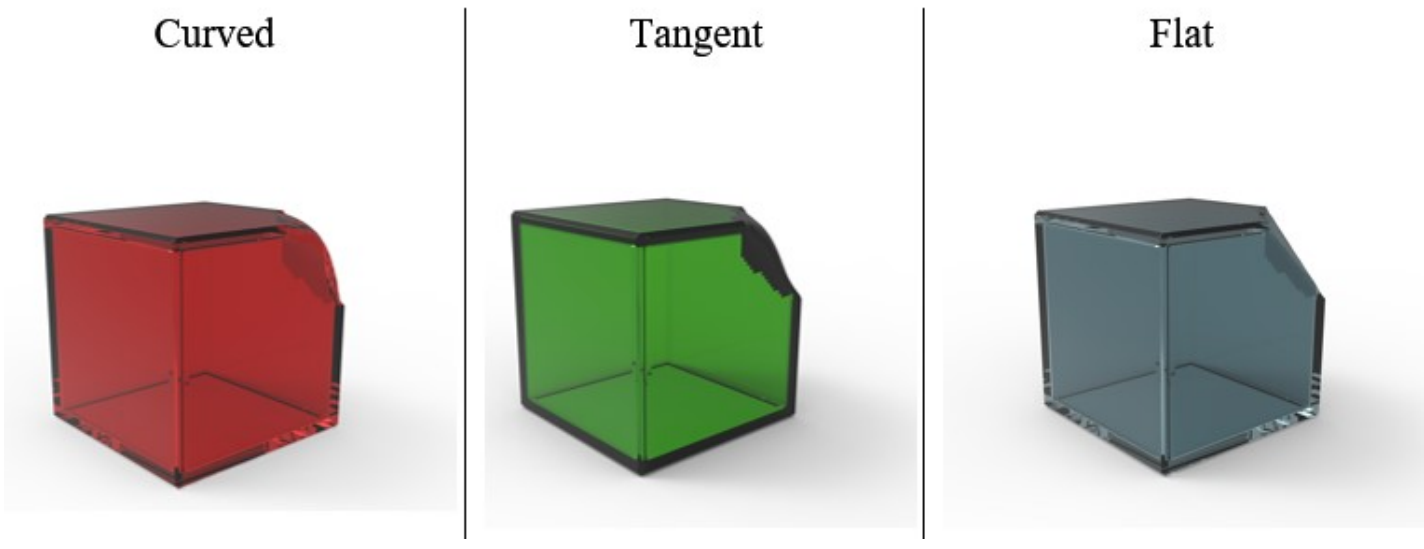


Figure 3-5 3D Cube Surface Closure in a Curved Shape , Tangent Combination of Planes and Flat Plane

A hole at the corner of the cube was removed, and the cube was closed in the three different methods. In the flat method the closure surface is composed of multiple 2D plans. In the tangent method closure surface is curved with partial restraint, formed by a combination of multiple small planes aligned at a tangent to one another. Finally, in the curved closure an organic shape with unrestrained curvature covering the surface.

These three closure algorithms were used to close the breast shell shape in Figure 3-6.

Figure 3-6 Breast Closure in Curved, Tangent and Flat Algorithms

The resulting shape of the breast closures in the three different forms of algorithms is very similar. If examined closely the flat closure shows two flat planes the first covering the upper half the second covering the lower half of the opening. There is minute differences between the curved and tangent closures. This is consistent with the with a strong similarity in volume estimations in Table 3-1.

Regarding the second question "What is the influence of surface shell closure method to volume estimate?" the volume of every scan was measured by all three methods, and a comparison was done. And to address the first question "What is the influence of the patient's posture to volume estimate?" a total of eleven scans were taken, and volume was calculated for seven of them. Three scans were in the zero degree position, two scans in the 90 degree position (one of those scans failed), two scans in the 45 degree position (one of those scans failed), and two angled back scans as in Table 3-1.

Table 3-1 Volume Estimates in Cubic Centimetre

Scan Name	**Scan Description**	**Volume Measurement Curved (cm^3)**	**Volume Measurement Tangent (cm^3)**	**Volume Measurement Flat (cm^3)**	**Mean Volume Across Different Methods**
180215135412	0 Deg	1081	1082	1047	1070±20
180215133021	0 Deg	1076	1075	1045	1065±18
180215134228	0 Deg	1064	1065	1030	1053±20
180215135720	90 Deg	1079	1080	1079	1079±0
180215135014	Failed Scan (90 Deg)	N/A			
180215140508	45 Deg	1116	1117	1078	1104±23
180215140661	Failed Scan (45 Deg)	N/A			
180215140715	Angled Back	829	1064	1027	973±126
180215140951	Angled Back	1154	1155	1106	1139±28
180215140241	IMF Lift 1	N/A			
180215140001	IMF Lift 2	N/A			
Mean Volume Across Different Positions		1057±105	1091 ±33	1059±29	

Discussion

The questions regarding the impact of posture and closure type on the volume estimate remains somewhat open. The mean values in the vertical column represent the mean across different closure methods. For all the values except for the first Angled Back scan (180215140715) the standard deviation is below 30 cm^3. This is a good indication that choosing a single algorithm of the closure options would be appropriate. To choose one of the three methods the designer would conduct a visual assessment of the breast shell and the shape of the enclosed plane, ensuring that the surface is water tight, smooth and does not include any shape anomalies like cylinders or cones that can be formed a part of the closing algorithm.

The measurement of mean volume values across different scan positions addresses the question: "which scan position should be used to estimate breast volume?". This question should not be answered purely by a numerical comparison. It is important to understand the nature of soft tissue changes as well. When soft tissue moves, the shape enclosing its volume changes. This changes in shape can be captured in several ways using surface scans. One case can be that the scan captures the shape representing the volume stretched out, and the next scan captures a shape showing the same volume compressed in a ball. Here the same volume is being measured, and represented in different shapes. Therefore, volume measurement should not be based on just one scan, but rather on an average of values from multiple scans.

The volume enclosed in scan 18021514071 is an anomaly. Since the shape is closed by an automatic algorithm it is possible that curvatures on the edges of the shell caused surface indentations. It is up to the designer's expert judgment to evaluate the shape and determine if the volume estimate is within range of the remaining scans.

Finally, the reported volume estimate to the surgeon is 1060 ± 30 cm^3. Overall the posture matters in calculating the volume; the flat closure gives the lowest SD suggesting that it is robust for postural changes in volumetric estimate. In surgical design and simulation a volume estimate is relevant as it provides the surgeon with further knowledge about the patient's body. Having a volume estimate could be useful in estimating the size of the harvested flap in autologous reconstruction or the size of implants in alloplastic reconstruction.

3.3. Surgical Guide Results

Two positioning surgical guides designed met the criteria outlined in design concept D, they were designed using two different techniques: Mirrored Scan Technique and Tissue-Fitting Technique. The guides where compared for usability and fit during the guide fitting session. The incision pocket guide designed to meet the criteria outlined in concept c was a shape that attached to the guide's above to complete the assembly.

Tissue-Fitting Technique Workflow

The tissue-fitting guide is the first technique used to design the positioning surgical guide. The first step in creating a guide using the tissue-fitting technique is to translate optical surface scan data to a virtual design of the guide. The torso model is imported from the photogrammetry system (3dMD) to Magics® modeling software (Magics®, Materialise, Leuven, Belgium) where the surgical markings on the surface are delineated manually to create a stereolithography (.stl) file containing the overall surface geometry and the markings overlaid on the surface. A 3dMD torso scans in obj format was imported into Magics®, Figure 3-7.

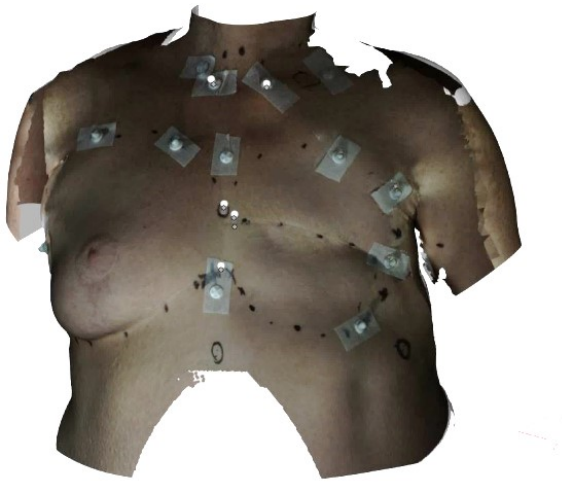


Figure 3-7 3dMD Torso scan with Markers

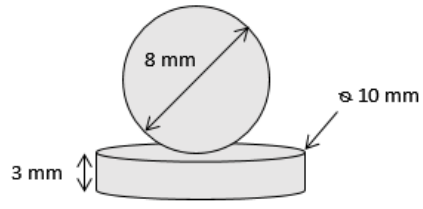


Figure 3-8 Positioning Marker Drawing

The surgical markings (surgical pen and taped markers) were used as a guide to outline the shape of the breast footprint. The positioning markers, Figure 3-8 were designed to be placed over the markings by pen so as the camera would capture the 3D shape of the sphere as a location of importance on the scan. Markers were placed on the boarders of the breast footprint as well as the clavicles.

Using the selection tool in Magics® an outline of the breast footprint was created, Figure 3-9, and extruded 1 mm. This is done to create a feature on the patient's torso, this feature of the breast footprint will be visible in an .stl format of the torso.

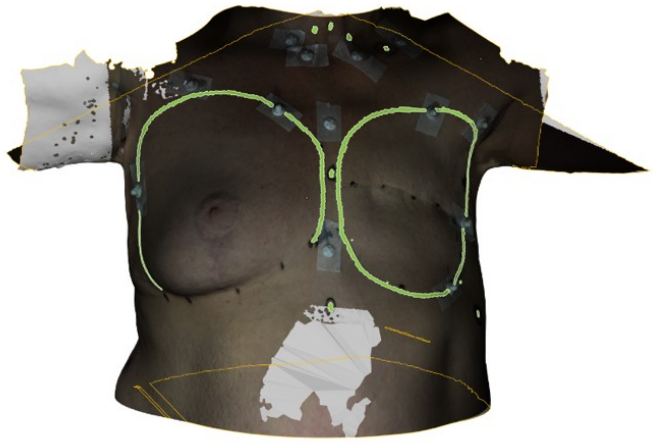


Figure 3-9 Outline of Breast Footprint

Once the breast footprint is embossed on the patient's torso the model is exported from Magics® and imported into Freeform®, Figure 3-10. Using the curvature tools the outline of the breast footprint is outlined Figure 3-11.

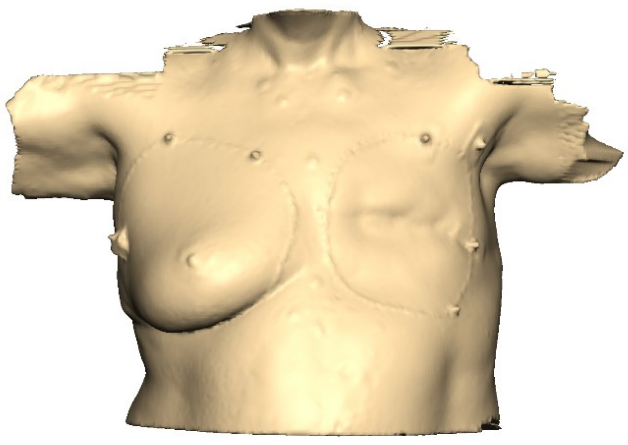


Figure 3-10 Breast Footprint Embossed

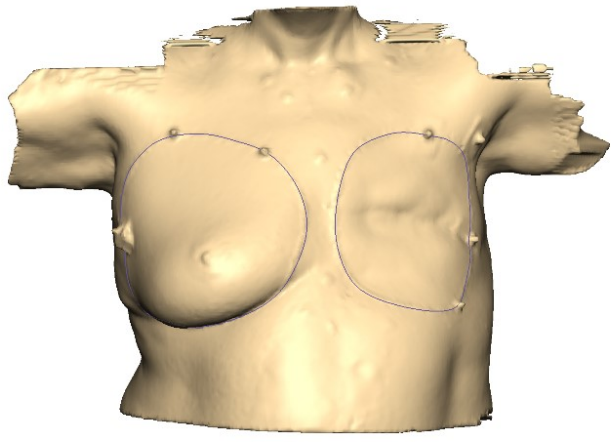


Figure 3-11 Breast Footprint Curvature

This method was repeated for four scans, one for each of the patient's scans in the 0 degree position, 90 degree position, 45 degree position and angled back, Figure 3-12.

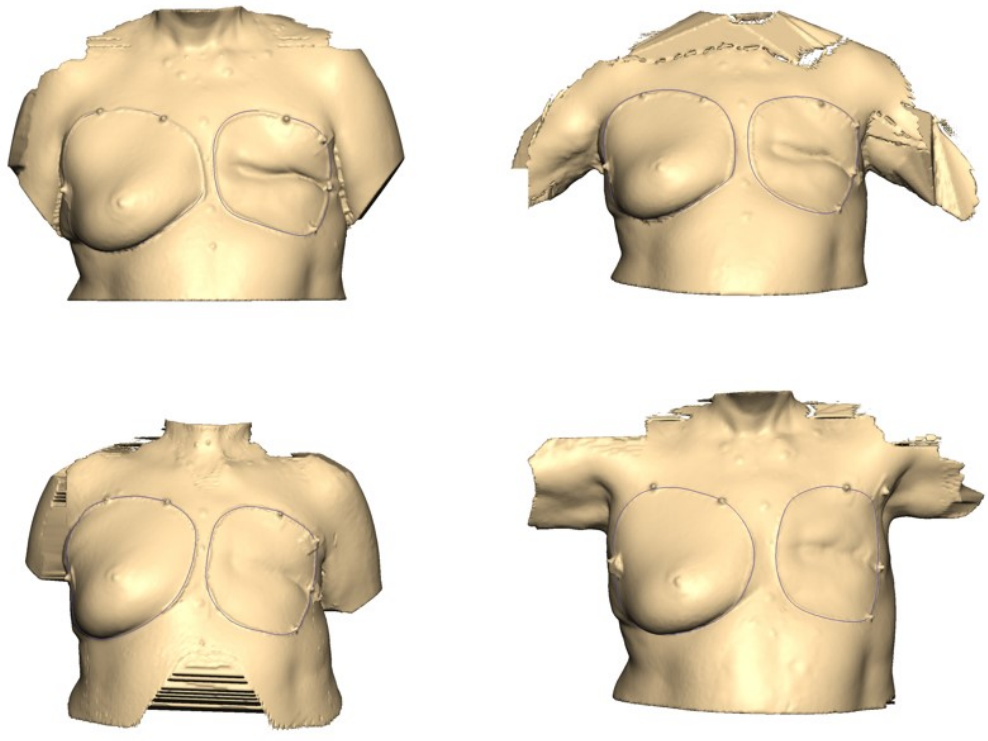


Figure 3-12 Footprint Curvature on 0, 90, 45 and angled back scans

The researcher and the surgeon met to review the results. Deciding on which scan to use for the guide design was a crucial step to moving forward with the design process. The discussion included a comparison of the IMF position on each of the scans and it was noticed that the IMF on the 0 degree scan was lower than the one on the angled back scan. The change in shape of the mastectomy scar tissue was also considered as the tissue seems stretched out in the scan where the patient is angled back and the scan where her arms were at 90 degrees. This raised the question whether or not the reconstructed IMF would move in a similar way. The task of choosing one scan to base the design off is challenging because the soft tissue presents itself differently in each scan. Together the team chose to use the scan with the closest resemblance to the posture of the patient on the operating table. The Angles Back scan showed the clearest image of the IMF and the patient's arms were to the side as they would be in surgery. It is possible that during the reconstruction procedure the patient will be lifted to a seated position and the shape of the reconstructed breast be evaluated then as well. Therefore, the Angled Back scan seemed to have the best features of IMF location, as well as the color tone in tissue markers such as freckles.

Using the curvature tool in Freeform® Plus a curved shape seen in Figure 3-13 was designed on the patient's torso. The curvature of the shape was based off the markings of the breast footprint. Here the lines that define the contours of the shape represent the location

of the lateral border, inframammary fold and medial border. The shape extends to the suprasternal notch, which was chosen as a landmark to locate the guide on the patient's torso in the guide fitting session.

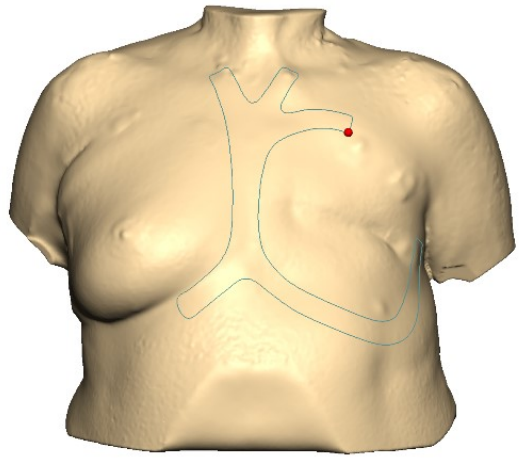


Figure 3-13 Line Design of the Tissue-Fitting Guide

Once the shape of the curves were finalized the area of the shape was selected and copied into a new piece. A 7 mm external offset was created from the new piece. A Boolean Subtraction operation was performed to remove the geometry of the angled back scan from the offset piece. This was done to ensure that the guide fit intimately on the torso scan and any excess material was removed. Finally the external shape of the guide was carved using the sculpting tools Figure 3-14.

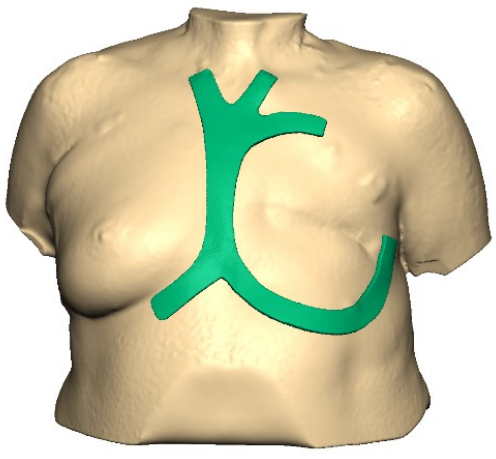


Figure 3-14 Tissue-Fitting Guide

Mirrored Scan Technique Workflow

The mirrored scan method was the second technique used to design the positioning guide. Using the plane tool a midsagittal plane was created in the center of the scan to give an accurate axis for mirroring. Using the mirror tool the healthy breast and remaining scan anatomy was mirrored to the mastectomy side Figure 3-15.

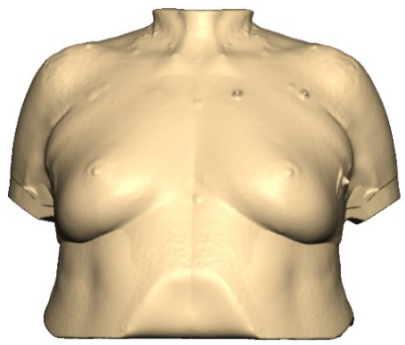


Figure 3-15 Mirrored Torso

The mirrored scan represented an ideal reconstruction based on a purely symmetrical outcome for the reconstructed breast. The curve tool was used to mark the shape of the guide. The borders of the shape such as the inframammary fold and the lateral border followed the profile of the mirrored breast seen in Figure 3-16. Once the curved outline was designed, the shape was verified by the surgeon. Using a similar method to the first technique described in this selection, a 7 mm offset was created and Boolean operations and sculpting were implemented to create the shape of the final guide in Figure 3-17.

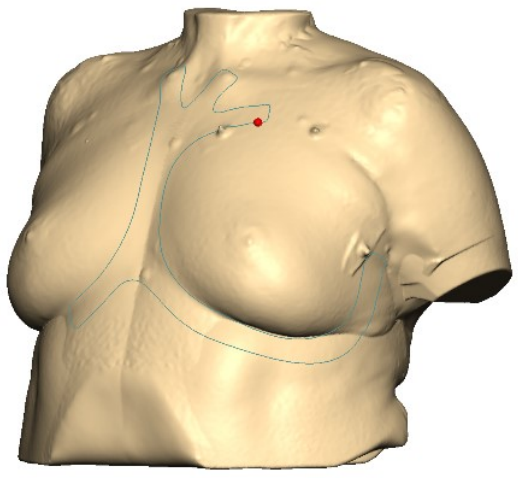


Figure 3-16 Curvature on Mirrored Torso

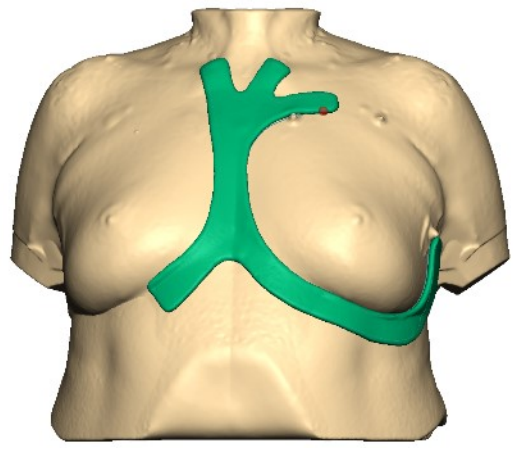


Figure 3-17 Mirrored Scan Guide

Comparison of the Tissue Fitting Guide and the Mirrored Scan Guide

There are strong similarities between the tissue fitting guide and the mirrored scan guide. Both of which extend to mark the medial border, IMF, lateral border and superior extent. However, the difference in the design technique created subtle differences in the shape and projection of the guide. The tissue fitting guide sits flat on the patient's chest, while the mirrored scan guide projects outward to indicate the curvature of the breast. The two guides are overlaid to demonstrate the differences and similarity in Figure 3-18. The tissue fitting guide is in the color green and the mirrored scan guide is in beige. The mirrored scan guide projects 34 mm that indicates the difference between the lateral extents.

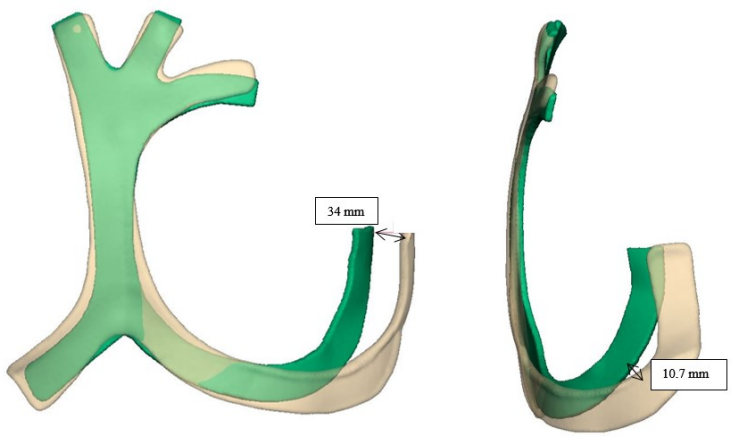


Figure 3-18 Comparison of Tissue Fitting Guide and Mirrored Scan Guide

The shape of the mirrored scan guide on the scan used to design the tissue fitting guide can be seen in Figure 3-19, this demonstrates the breast projection on the lateral extent.

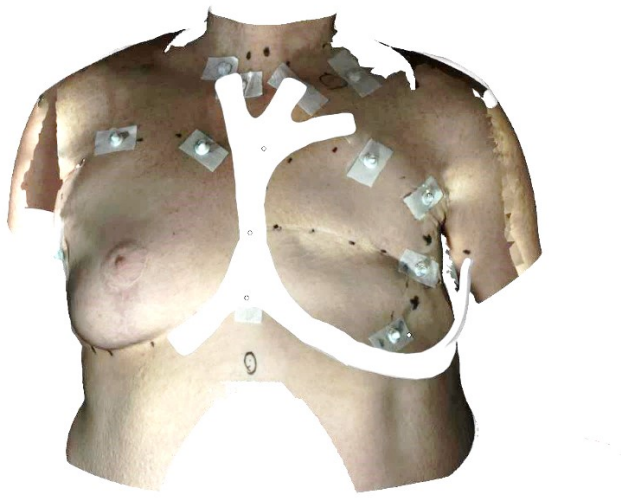


Figure 3-19 Mirrored Scan Guide Projection from the Unilateral Mastectomy Scan

The difference in design techniques was also prominent when the guides were fabricated and assembled. The projection in the mirrored scan guide was present in comparison to the tissue scan guide.

Incision Pocket Guide Workflow

The incision pocket guide workflow was design to meet the criteria of Design Concept C. The first step in creating the incision pocket guide is outlining the shape of the guide using the curvature tool in Freeform® (Figure 3-20). The shape follows the IMF curvature but is offset 1 cm inward. This is done to allow for tissue thickness once the guide is inside the incision pocket. The guide is designed with a tab that anchors into the positioning guide. By connecting the guides together their position is set on the patient's chest. The second step in creating the guide is selecting the area within the curvature, copying it as a new piece, and creating a 5 mm external offset. A Boolean subtraction operation of the patient's torso from the offset piece was performed, similar to the steps in the positioning guide. Finally, the clip in connection of the guides was designed with two pins.

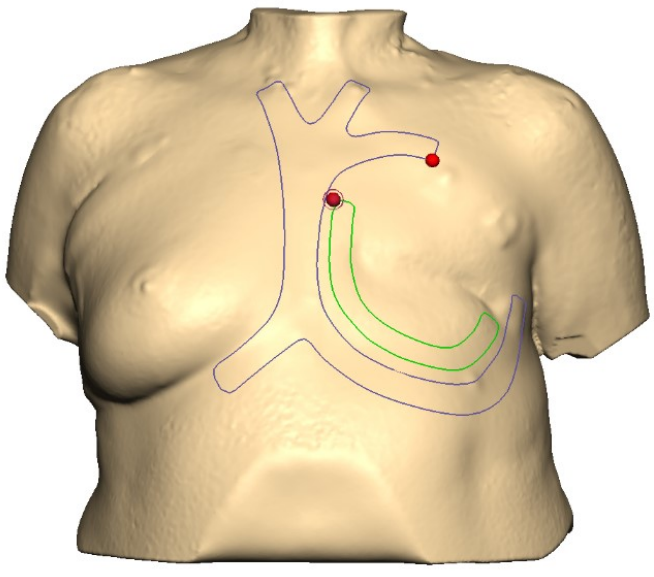


Figure 3-20 Guide Curvature

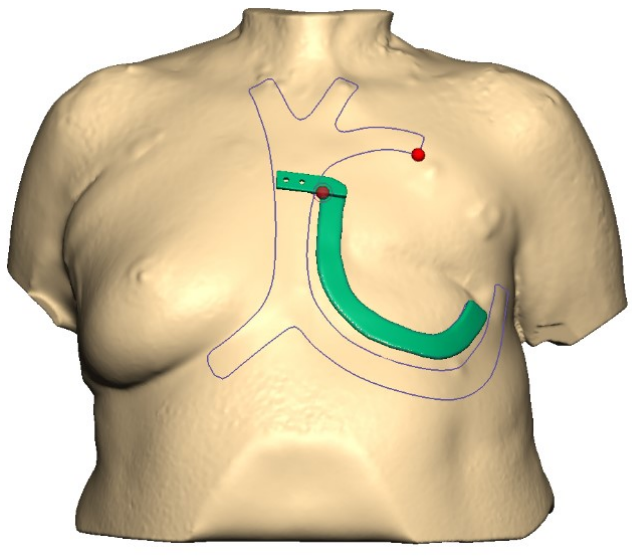


Figure 3-21 Incision Pocket Guide

Assembly and Detailing

The designed guides have organic shapes with multiple curvatures. This resulted in multiple support structures to achieve the designed curvatures. As well as the size of the guide was a challenge when trying to orient the shape on the 3D printer's platform. Modifications to the designs were made to simplify the build. The positioning guides were divided into three pieces. The piece connection was designed using Autodesk Fusion 360 as seen in Figure 3-22. A sliding connection was chosen for ease of assembly.

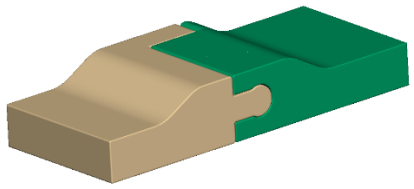


Figure 3-22 Connection Design

A test of joint connection fit was conducted to measure the required design tolerance. The connection design was prototyped using a 0.15 mm offset between the male and female pieces and a 0.25 mm offset between the pieces. The 0.15 mm fit showed a tighter tolerance and was still within the printer's specification limits, therefore it was chosen. The joint design was imported into Freeform® and incorporated into the positioning guide as seen in Figure 3-23.

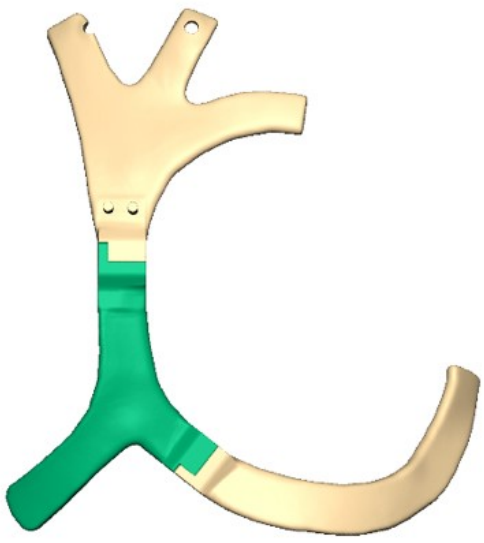


Figure 3-23 Positioning Guide Assembly

To position the registration markers the designed guide was exported from Freeform® and imported into Magics®. The angled back scan was chosen, and the guide was overlaid on to the patient's torso. Registration markers were placed over surface features such as freckles, moles and the mastectomy scar edge (Figure 3-24).

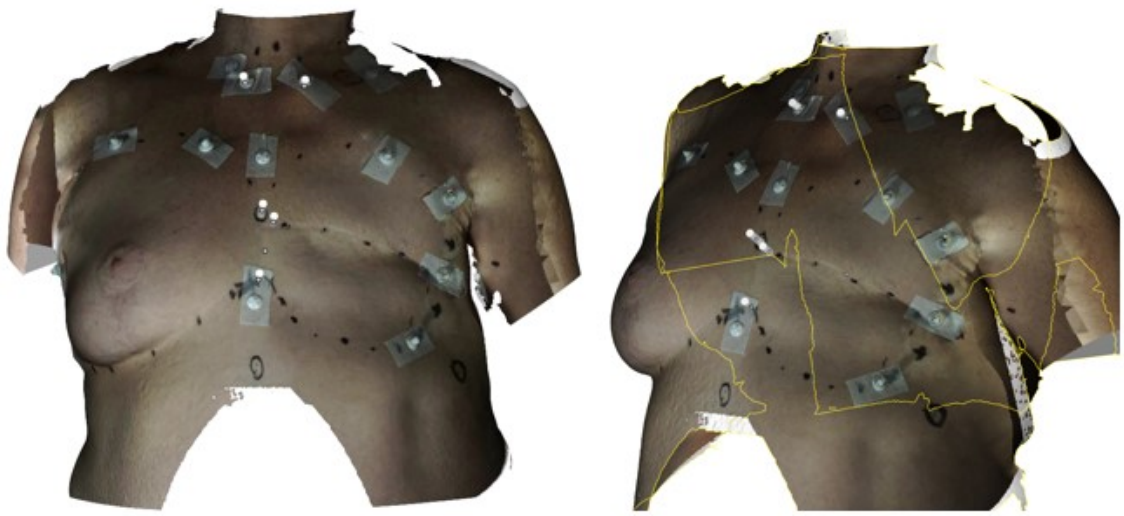


Figure 3-24 Registration Markers Positioning

Once the markers were positioned, their location was saved in CAD space and exported into Freeform®. Using the Boolean tool the markers were deducted from the surgical guide resulting in the final CAD shape of the tissue-fitting guide with registration markers (Figure 3-25)

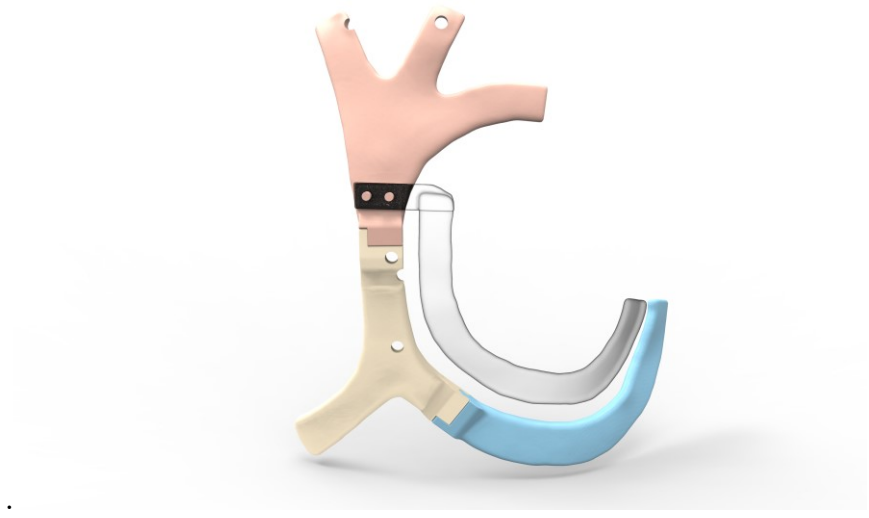


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Figure 3-25 Tissue-Fitting Guide with Registration Marker Holes

The completed guide was imported into Magics® where an identification label was added to each piece of the guide indicating the piece name, number and position. .

3.4. Summary

Three design concepts were developed: a) volume estimation, b) positioning guide, c) incision pocket guide. These concepts were based on the thematic analysis of the interview with the surgeon. A scanning method was developed to capture the changes of the soft tissue shape resulting from changes in the patient's posture. The first analysis done was to estimate the volume of the breast. This was compared across the multiple postures as well as the three different shell closure algorithms. The volume calculated across the different closure methods was 1030 cm^3 with a standard deviation of 30 cm^3. Thus, the choice of closure method may be left to the discretion of the designer. Regarding posture, the result of taking an average of all the different postures is the suitable method of analyzing volume. This is done to account for the changes in volume measurement caused by the change of soft tissue shape with the posture. The developed design concepts are a toolkit that is composed of the tissue fitting guide, mirrored scan guide, pocket incision guide and a volume estimate table. Together they provide the surgeon with additional information to support in the planning and execution of breast reconstruction procedure. The designs could be adaptable to suit both an alloplastic and autologous reconstruction.

4. Surgical Guide Manufacturing

The specialism of surgical design and simulation combines the skills of design and modeling with knowledge from surgical expertise to address a patient-specific surgical problem [28]. Head and neck reconstruction, hand and wrist surgery, and ear and nose reconstruction routinely use patient specific surgical guides [29] [30] [31]. The surgical planning relies on 3D modeling software's, additive manufacturing, vacuum forming, and CNC milling [29] [32] [33]. Advancements in rapid prototyping technology have led to a greater accessibility to this method of fabrication at a relatively low cost.

With the various fabrication methods available, it is important to determine what factors must be considered in choosing a method of fabrication. Fabrication time, material type, fabrication cost, and available resources were the constraints in this workflow as seen in Figure 4-1. A model of how this workflow could be practically implemented is proposed in Chapter 6 section 1.

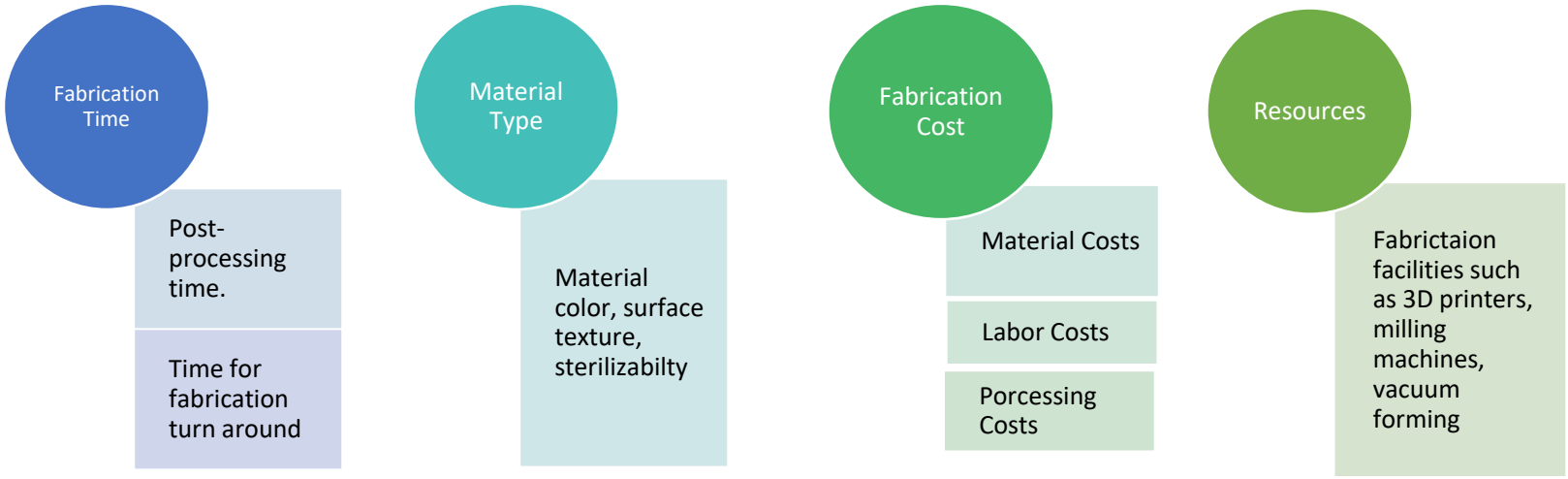

Figure 4-1 Factors that Influence the Fabrication Process

4.1. Additive Manufacturing

Additive manufacturing, also known as three-dimensional printing (additive manufacturing), is a fabrication process where an object is created by adding material layer by layer [34]. This approach of manufacturing differs from milling, also known as subtractive methods

of manufacturing [35]. Additive manufacturing can be done with materials like nylon, ABS, and resin or metals such as stainless steel, gold, silver and titanium [36]. In the medical field plastics are commonly used in manufacturing low cost prosthetics, medical models, and medical equipment [37]. Fused deposition modeling, also known as material extrusion, a 3D printing method where the 3D printer takes a spool of plastic filament, melts it, and extrudes the plastic on a platform, building the part layer by layer [38].

4.2. Vacuum Forming

Vacuum forming, also known as thermoforming, can be used to produce surgical guides [15]. The process involves heating a plastic sheet until it softens and placing the softened sheet over a ridged mold; once the plastic is draped over the mold, a vacuum seal is applied sucking the plastic sheet onto the mold [39]. Undercuts may appear but are not desirable and must be avoided to prevent the plastic sheet from being retained into the mold [40]. When designing a male mold it is advisable to include a positive draft angle 10--20 degrees to ease with the process of separating the plastic sheet from the mold [41].

4.3. Additive Manufacturing Fabrication Workflow

The fabrication process for the surgical guides utilized 3D printing and vacuum forming. The 3D Printers chosen was the Connex Objet 350. Printing on the Connex in Vero-White material was selected for the following reasons:

- This method and material are validated for sterilisation
- A smooth surface finish in the 3D Printed components
- Vero-White material has been used in similar applications for surgical guides for positioning osseointegrated implants
- Vero-Support material dissolves readily making the post processing steps straight forward
- Availability of this fabrication method in-house at the Institute of Reconstructive Science in Medicine (iRSM)

The first step in the 3D printing workflow is to prepare the model to print by ensuring it has the right number of shell components and surface triangulations. This is done in Magics® by following the wizard fix tool (Figure 4-2).

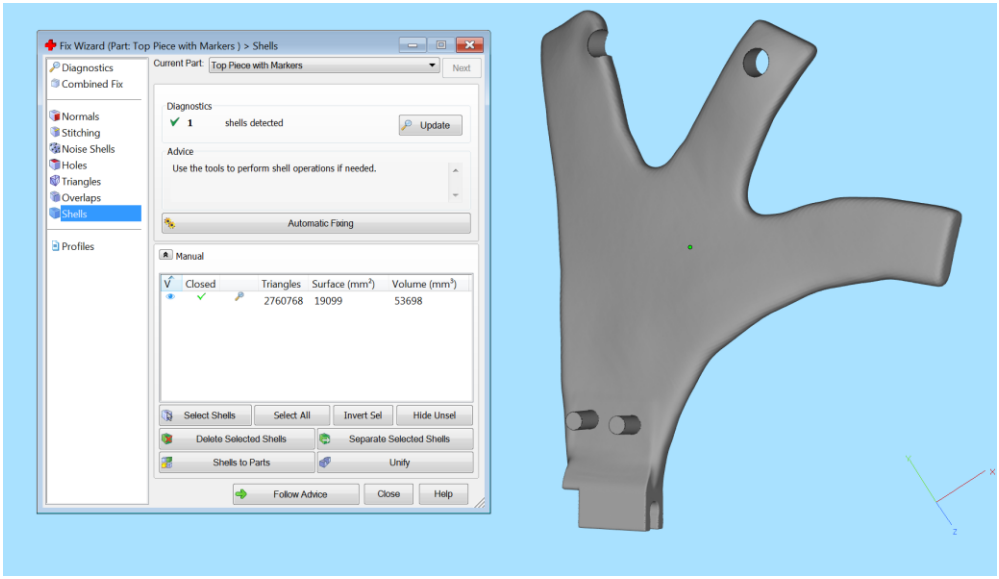

Figure 4-2 Preparing Components for Printing Using Fix Wizard Tool

Once the models were ready to print, they were imported onto the Connex 3D Printer's build platform. Their orientation on the platform was set for an optimized build with the minimal support material and the quickest build time (Figure 4-3).

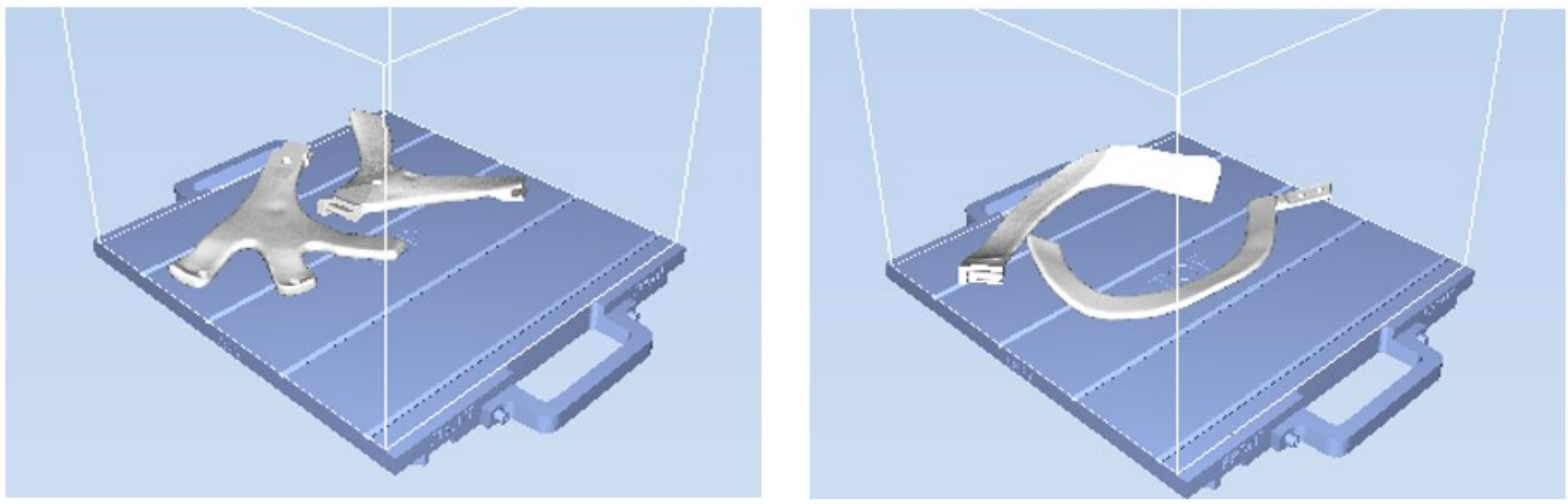

Figure 4-3 Orientation of Components on the Build Platform

Seven components comprising two completed guides were 3D printed. The build was set up in stages over the course of two days. The printing time for a single guide takes roughly a day. Figure 4-4 demonstrates the completed components on a build platform. The parts are displayed on a platform of another printer. The Connex platform was in high demand at the time.

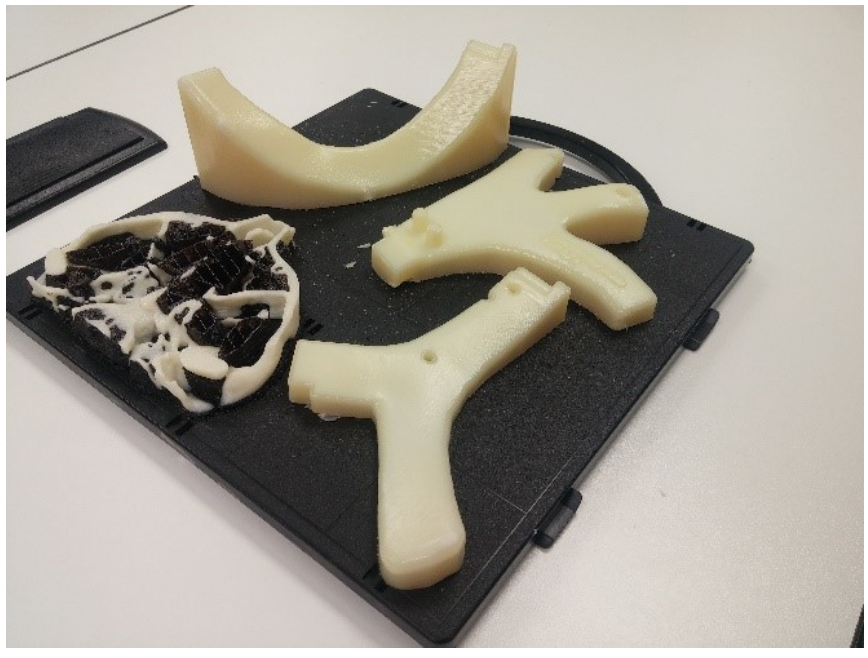

Figure 4-4 Printed Components on the Build Platform

The components were removed from the build platform and post-processed. Post-processing involved scraping off the support material as seen in (Figure 4-5).

Figure 4-5 Scraping Off the Support Material

The surface of the Vero-White material was then cleaned with a solution soapy water. Figure 4-6 is an image of the cleaned parts. The clean guides are shiny, smooth and the locking system fits together well.

Figure 4-6 Cleaned Surface of 3D Printed Guide

4.4. Vacuum Forming Fabrication Workflow

Vacuum forming was the preferred fabrication method for the incision pocket guide. This is one of the components of the complete surgical guide. The incision pocket guide required significant rigidity and transparency as indicated in Chapter 2 Section 2.3 Theme 6.

The first step in the vacuum forming process was to create the mold on which the component will be shaped. The shape of the component was translated into a male mold with a draft angle of 20 degrees to avoid undercuts. As seen in Figure 4-7.

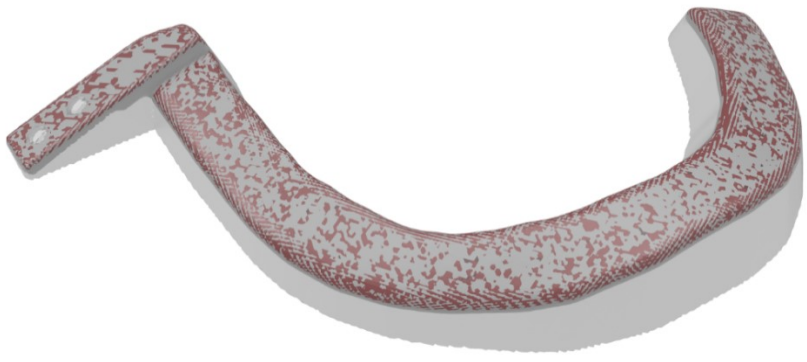

Figure 4-7 Male Mold with a Draft Angle

The mold was then additive manufactured with a flat base to fit flush on the platform. There was no support material required, as seen in Figure 4-8. Additive manufacturing the mold was a more efficient means of fabrication compared to CNC milling the shape.

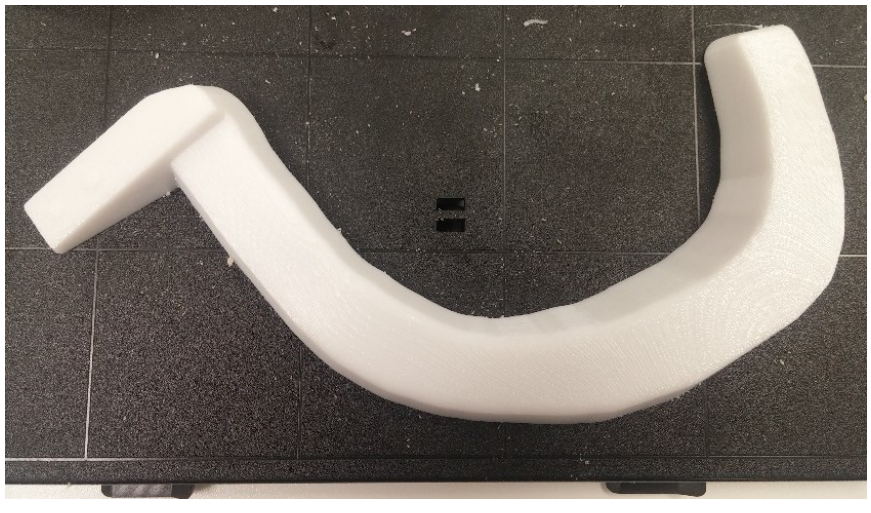

Figure 4-8 Printed Mold

Once the 3D printed mold was off the platform it is placed in the vacuum forming machine. A 3 mm sheet of Lexan was heated and suctioned down to take the shape of the mold, Figure 4-9

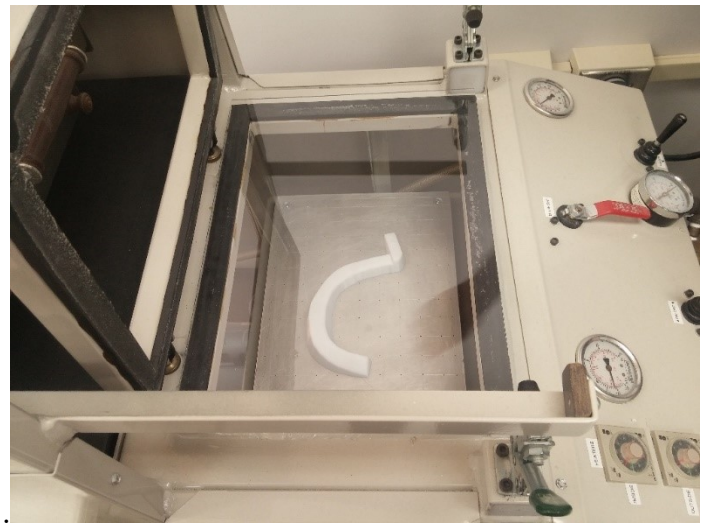

Figure 4-9 Mold in Vacuum Form Machine

The Lexan sheet was removed from the vacuum form machine with the mold pressed in. The mold was then peeled out of the formed plastic as seen in Figure 4-10.

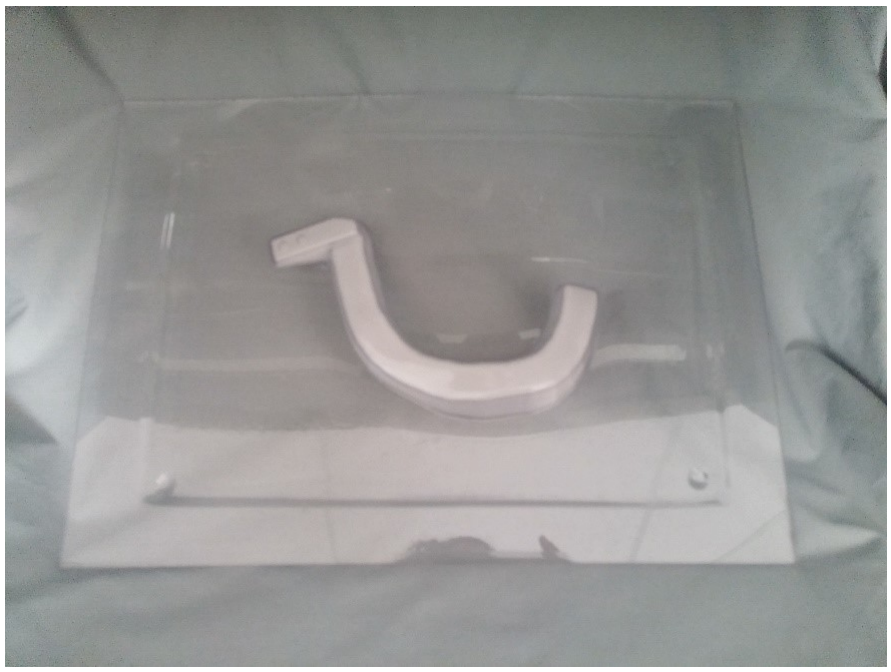

Figure 4-10 Lexan Sheet Formed onto the Mold

Once the forming process was complete the shape's borders are trimmed using a hand piece as seen in Figure 4-11.

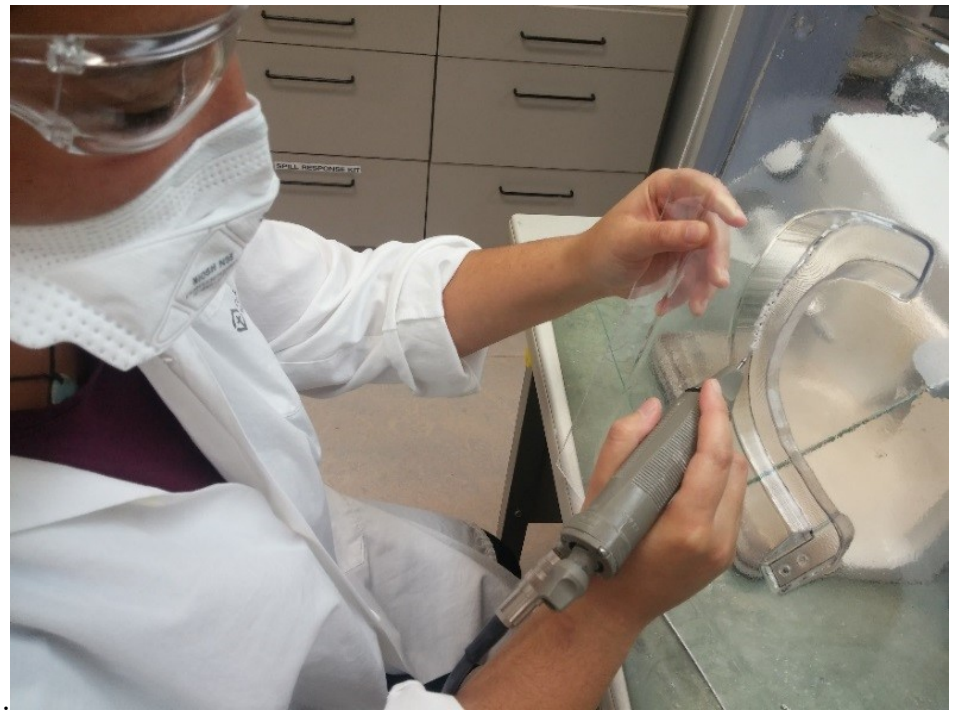

Figure 4-11 Trimming Down the Excess Material

The edges of the guide were smoothed using a flame torch achieve a smooth finish as seen in Figure 4-12.

Figure 4-12 Incision Pocket Guide

This fabrication process is very labor intensive as it involves several stages of heat forming, trimming and polishing. In order to optimize this in the future the guide would be 3D printed out of clear resin.

The final guide is assembled in Figure 4-13.

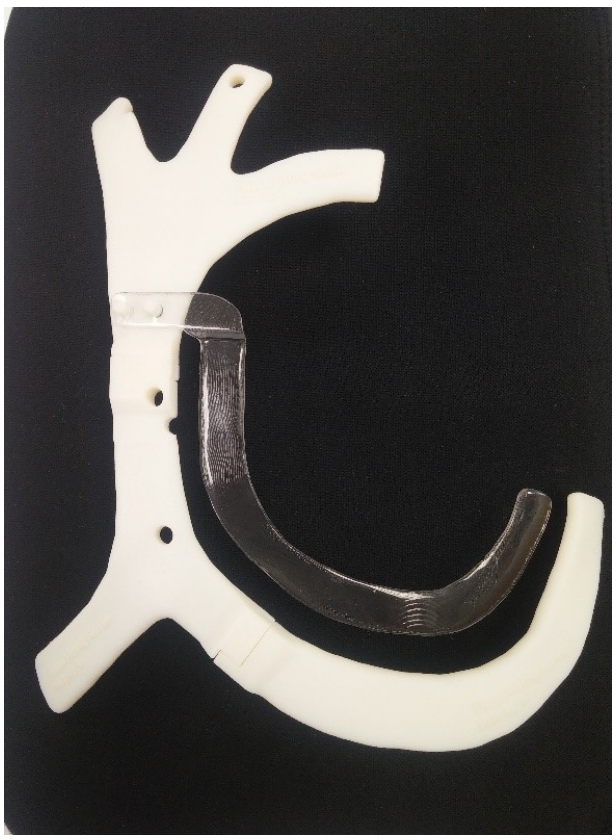

Figure 4-13 Final Guide Assembly

4.5. Cost Estimate

Cost is an important consideration in the overall design and fabrication process of the surgical guide. The cost estimate is based on the cost of Vero-White and support material required for fabrication. These items are outlined in the Table 4-1:

Table 4-1 Cost Estimate

	Tissue-Fitting Guide	Mirrored Scan Guide
VeroWhite Material (g)	379	368
Support Material (g)	451	299
Material Costs of 3D Printing*	168.25 $	152.15 $
3mm Clear Lexan - Sabic Polymershapes	3.10 $	3.10 $
3D Printed Mold for Vacuum Forming	30.11 $	30.11 $
Total Costs	201.46 $	185.36 $

The cost estimate excludes the time and resources for designing the surgical guide, as well as the 3D printing time.

The considerations for a manufacturing workflow include the material type, ease of application, time and overall resolution of the product. Additive manufacturing and vacuum forming were the two methods choses to take the design from a concept on screen to a tangible physical model. Multiple fabrication pathways could be applicable, including CNC milling and silicone mold forming. These approaches are not optimal, would require extra time and material in exchange for minor improvements in dimensional accuracy. Developing an optimal workflow is key to ensuring overall success in implementation. An alternative avenue that could be considered is printing the guides using the Form2 printer in sterilisable clear resin. This would be an option worth exploring in the future.

5. Guide Fitting Session

The design process of this surgical guide followed the ten key principles of User-Centered Design (UCD). As discussed in Chapter 2, UCD is a process that focuses on developing a tool from the human user perspective of how will it be used [42]. By employing the concepts of UCD the designer aims to provide a tool that delivers a user-friendly experience. This is important when it comes to designing tools for surgeons. An intraoperative guide will be used in a high pressure, fast pace environment that requires the utmost concentration by the user. Testing the guide's usability at various stages in the design process enhances the connection between the guide and the user. To apply an iterative process of design a user testing session was included in the form of a Guide Fitting Session. The purpose of the guide fitting session was to test the guide's usability in an environment that simulates surgery in the OR.

5.1. Methods

The guide fitting session had three phases: preparatory, surgical simulation and 3dMD imaging. The first two will be discussed here, and the 3dMD session will be in the following section.

5.1.1. Guide Fitting Session Setup

The guide fitting session was setup in the Patient Education Room at the Institute for Reconstructive Sciences in Medicine (iRSM). The setup emulated the OR by having a chair with the capability to recline to a supine position. The patient's torso was exposed allowing the surgeon to position the guide. A video camera setup on a tripod was used to capture a video of the surgeon using the guide. The video included the patient's torso and excluded her face. The researcher prepared a surgical guide user manual (Appendix 3) with instructions for the surgeon on how to position the guide.

5.1.2. Surgical Simulation

The surgeon invited the patient to change into the surgical robe and lay on the chair. The researcher started the video recording, and handed the guides to the surgeon. The surgeon first tested the positioning guides (tissue-fitting technique and mirrored scan technique) in the supine position and then in an upright position. The surgeon then tested the incision pocket guide. The surgeon then took a marker and marked the location of the breast borders in relation to the positioning guide. Once all the markings were complete, the patient and the researcher went to the 3dMD room and recorded surface scans. The researcher conducted a final interview with the surgeon. Overall, the fitting session, imaging session and interview took three hours to complete.

5.1.3. Video Analysis

There were three videos from the guide fitting session and two videos from the interview session. The videos were transcribed in Intelligent Verbatim as with the initial interview in Chapter 2 section 2.2 A thematic analysis was conducted based on the transcription in Appendix 4 and Appendix 5.

5.2. Thematic Analysis Results

Seven themes emerged: 1) Surgical Design Technique, 2) Inframammary Fold, 3) Positioning Landmarks, 4) Posture, 5) Changes in Body Weight, 6) New Imaging Protocol, 7) Materials

Theme 1: Surgical Design Technique

Summary of the theme: Comparison between the tissue-fitting technique design and the mirrored scan guide design.

The lateral extent of the surgical guide was designed to address the challenge of creating the lateral border. As expressed by the surgeon in: “The problem before with breast reconstruction is the tendency to create the breast mound too far lateral. And to get tricked into thinking that the lateral fatty tissue is breast tissue.” Appendix 4 [4 min 34 s – 4 min 55 s]. A comparison between the lateral extent of the tissue-fitting guide and the lateral extent of the mirrored scan guide showed a gape was present between the guide and the patient’s skin in the mirrored scan guide, while no gap was present in the tissue-fitting guide.

In other words, the tissue-fitting guide marks the extent of the breast footprint on the surface and the mirrored fitting guide marks the space that needs to be filled to acquire the desired breast volume Appendix 4 [5 min 03 s – 5 min 55 s].

Based on the surgeons’ feedback [6 min 02 s in Appendix 4] it would be useful to test both guides intraoperatively. The tissue-fitting guide would be used first to draw the breast border on the patient’s torso before incision. Then the mirrored scan would be used to reference the projection of the breast off the patient’s flat torso. The lateral extent would be used to shape the tissue mount with autologous reconstruction or guide the expansion of volume in a tissue expander. Figure 5-1 and Figure 5-2 represent the lateral extent of the tissue fitting guide and the mirrored scan guide respectively.

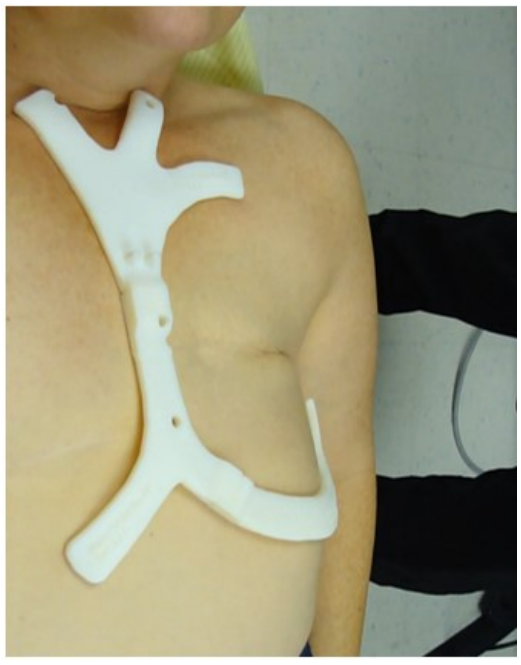

Figure 5-1 Lateral Extent of Tissue-Fitting Guide

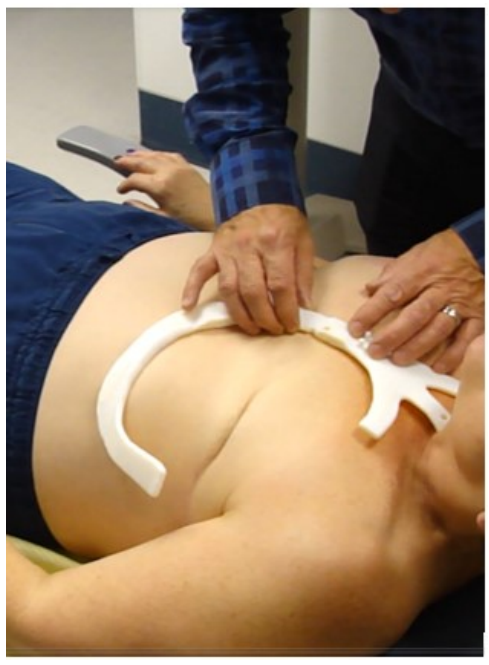

Figure 5-2 Lateral Extent of Mirrored Scan Guide

Theme 2: Inframammary Fold

Summary of the theme: The position of the guide relative to the inferior pole of the breast and the inframammary fold (IMF).

The guide was oriented medial to the mastectomy scar and markers matched the skin lesions. The surgeon observed that the guide is related to the inferior pole of the breast rather than the IMF [20 mins 45 s]. The IMF is higher than the inferior pole of the breast, thus the guide sits lower than the real IMF border on the patient's torso. The position of the guide relative to the inferior pole of the breast and the IMF can be seen in Figure 5-3 and Figure 5-4 respectively.

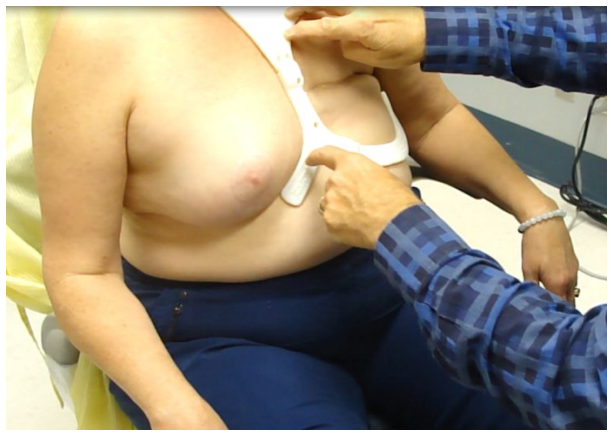

Figure 5-3 Inferior pole of the Breast

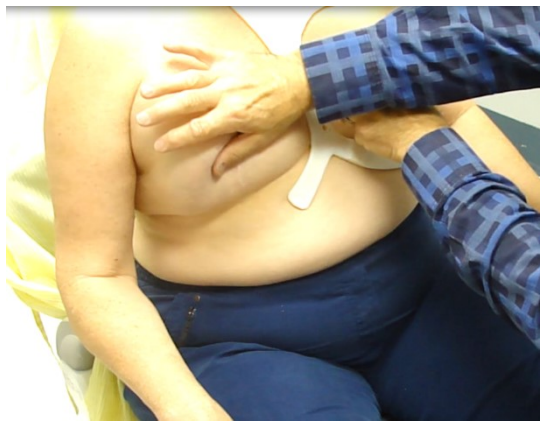

Figure 5-4 Guide Relative to IMF

From this observation the surgeon posed the question “Can we do a 3dMD scan lifting the breast but not distorting the IMF so that we could accurately know its position relative to the other side?” Appendix 4 [21 min 09 s – 22 min 02 s]. The surgeon then attached the incision pocket piece to the guide. Here the piece the surgeon would use to mark the IMF internally was too low on the patient’s torso relative to the healthy breast.

Theme 3: Positioning Landmarks

Summary of the theme: an assessment of the accuracy of the seven different positioning landmarks designed in the guide. The positioning landmarks were designed to incorporate patient specific freckles and moles. They were also based off the shape of the breast and the location of mastectomy scar. The shape of the design included an extent that indicated the location of the IMF on the healthy breast.

Superior Extent Landmarks

The surgeon described those landmarks as a bit confusing Appendix 4 [23 min 10 seconds]. The position of the guide did not fit well on the location of the clavicles due to the asymmetry between the bones. There is also the issue with the width of the clavicles being a variable distance apart based on the patient’s arm positions. The shape of the clavicles were not prominent enough to locate the guide, Figure 5-5. It was concluded that for this patient the positioning landmarks at the clavicles were inaccurate. A slight rotation at the top point in the guide could lead to a larger change in position at the bottom of the guide Appendix 4 [23 min 15 s – 24 min 47 s].

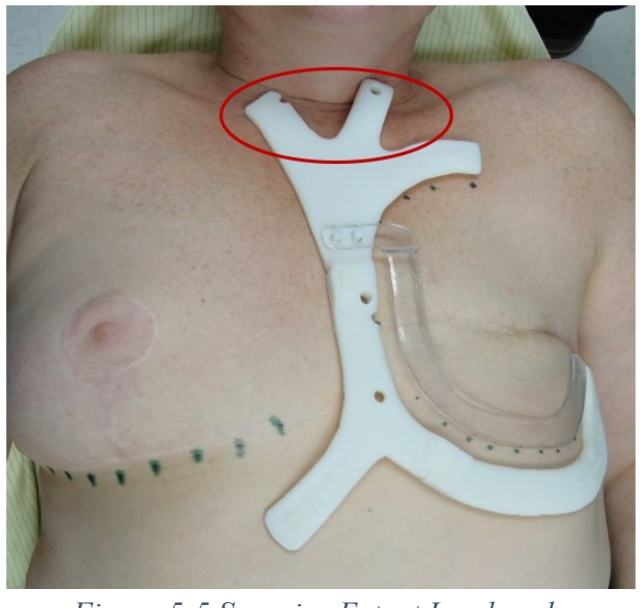

Figure 5-5 Superior Extent Landmarks

Freckles and Mastectomy Scar Markers

The holes fit well over the freckle markers and the landmarks were easily identified. Using two markers locating the freckles and one marker locating the mastectomy scar created a triangulation between all three points, (Figure 5-6). This allowed the guide to be well positioned on the patient's chest Appendix 4 [2 min 52 s]. The location of the markers was in the center of the guide making them relatively close to the guide's extremities.

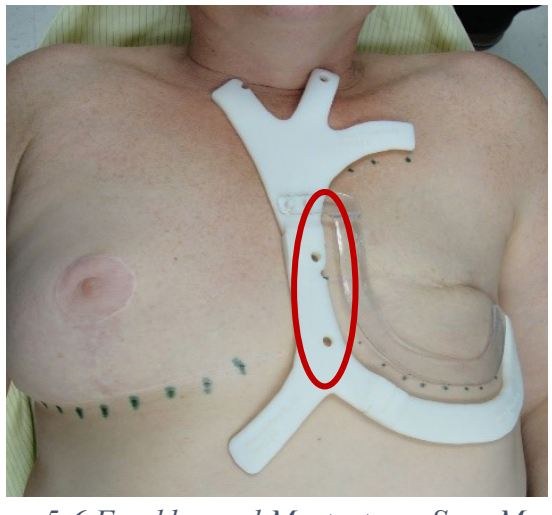

Figure 5-6 Freckles and Mastectomy Scar Markers

IMF locator on the healthy breast

The purpose of the arm extending to the left of the guide was to wrap around the IMF border of the healthy breast. While the patient is laying down the breast naturally shifts in position and droops laterally; thus the arm sits lower than the original marking of the IMF border, Figure 5-7. The design concept of having the guide extend to follow the IMF of the healthy breast is correct, however in this case the arm sat lower than the patient's IMF the border. The designed guide's position was shifted downward.

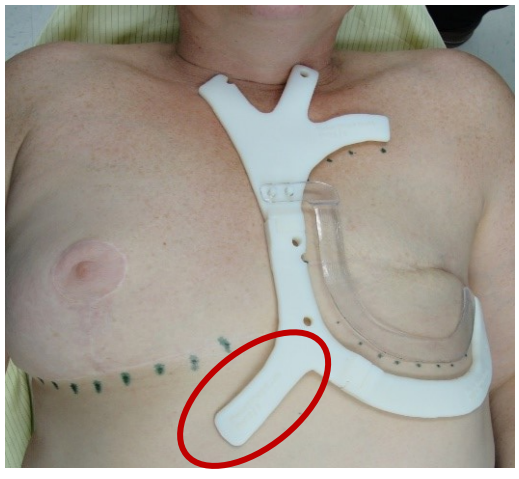

Figure 5-7 Position of IMF locator on the Healthy Breast

Theme 4: Posture

Summary of the theme: A comparison of guide in relation to different body postures (supine vs. upright) as well as a (90 degree vs 0 degree) arm position.

Theme 4: Positioning the guide sitting up vs. laying down

A comparison of locating the IMF border was done while the patient is sitting up and lying down. Here two marking were made, one in green while the patient is lying down, and one in red while the patient is sitting up. The findings show that the markings in green indicate the location of the IMF lying down, and the markings in red to indicate the location of the IMF sitting up overlapped, Figure 5-8. This shows that the location of the IMF while lying down is in the same position as the location of the IMF while sitting up.

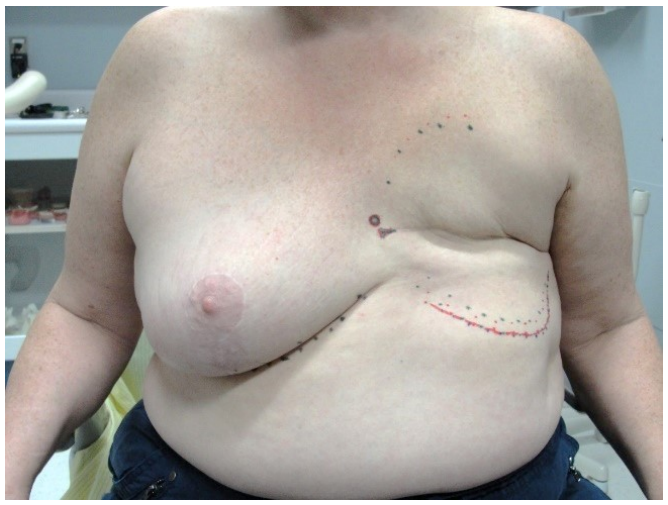

Figure 5-8 Comparison of IMF location supine vs. upright

It came as a surprise that there was minimal change. " I think it was interesting when we compared the positioning of the IMF and the position of the mastectomy scar, and the proposed IMF site all relative to whether the patient was sitting or supine didn't change a whole lot which was a bit of a surprise because I was expecting it to be more of a change. That is good because it takes away the concern of doing the scan while the patient is standing and the surgery while the patient is sitting" Appendix 5 [0 min 58s – 1 min 31s].

Arm positioning at 0 degrees vs. 90 degrees

Placing the guide with the patient's arms positioned at 0 degrees parallel to the body, and at 90 degrees perpendicular to the body were compared. The location of the IMF was found to be the same in the two positions. Here the IMF did not move relative to the position of the arms, however the superior extent of the breast was pulled higher when the arms were raised to a 90 degree position.

This is relevant because the patient's arms would be placed at 90 degrees to her body during surgery Appendix 4 [1 min 23 s – 1 min 56 s. Video M4H03207].

Theme 5: Changes in Body Weight

Summary of theme: The effect on well-being and change in body weight on the fit of soft tissue guides.

Designing for soft tissue guides can be affected by patient body weight changes. As described by the surgeon: "Let us say that your arthritis got worse and you did less and less exercise, you became a little more depressed ate more [……] and suddenly put on 25 lbs, then that changes all the relation to the guides. Or you exercise more and the opposite happens, you to lose weight. There would be an effect of the change in lifestyle on body weight and the fit of soft tissue guides." Appendix 4 [24 min 47 s – 26 min 10 s]. The initial 3dMD scans were taken in February and the guide fitting session was done in October. In those nine months the patient's body may have changed for multiple reasons. Therefor it is recommended that image acquisition, design and fabrication all happen within a month of testing or surgery.

Theme 6: New Imaging Protocol

Summary of theme: Based on the findings of the location of the breast pole creating a false IMF border a new imaging protocol was developed.

This was done by marking the location of the IMF with one marking color (green) and the location of the breast pole on the patient's chest with a second color (black). Then having the patient's breast taped in a position to raise the breast enough to expose the IMF border rather than the breast pole Appendix 4 [0 min 10 s – 1 min 46 s], this can be seen in Figure 5-9

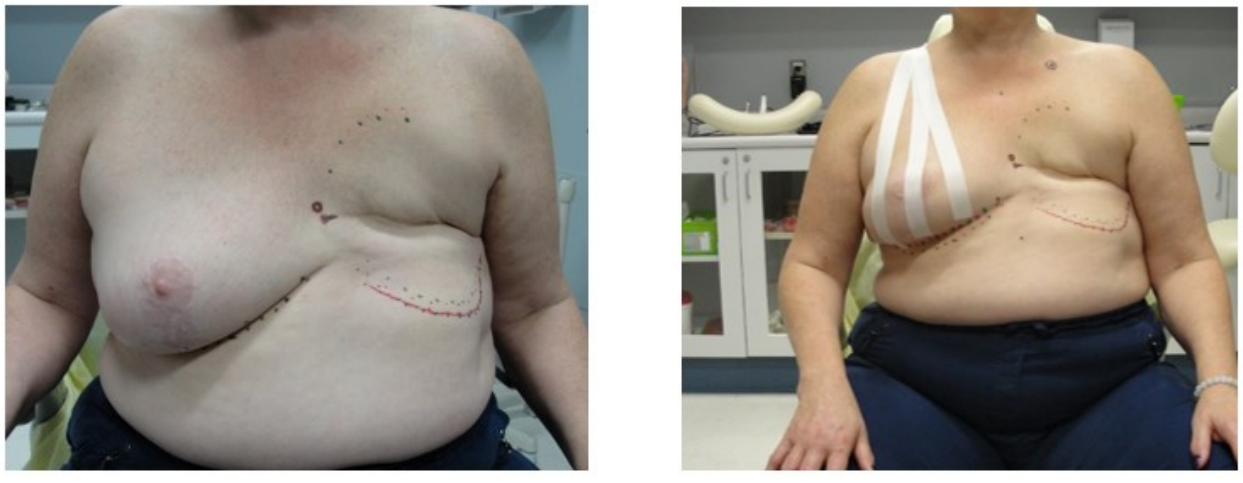

Figure 5-9 Taped Breast to expose IMF

As expressed by the surgeon “The biggest thing to improve on and I think we were able to figure out how to do that, was to differentiate the difference between the inferior pole of the breast and the IMF. I think it is important to have clearly delineated the normal IMF on the normal side which will make it as accurate as possible on the reconstructed side.” Appendix 5 [1 min 58s – 2 min 39s]

Theme 7: Material

Summary of theme: Feedback on the guide’s material and its appropriateness

The surgical guides were 3D printed except for the incision pocket guide, which was vacuum formed. Vacuum forming was labour intensive. In the interview the surgeon confirmed that additive manufacturing would be appropriate for all the guides and that vacuum forming process was unnecessary Appendix 5 [2 min 45s]. The surgeon commented that the guide was overdesigned considering the limited forces that the guides are subjected to. It was suggested that the guide thickness could be reduced. The reduction in thickness of the guide would have an impact on the overall costs associated with fabrication. Appendix 5 [6 min 59 s – 9 min 02 s].

5.3. Guide Fitting Session Summary

The guide fitting session tested the usability of the guide in the initial stages of design revisions. Having a physical guide that the surgeon can manipulate was important to evaluate aspects such as positioning, accuracy, shape, material and ease of use. The seven themes that emerged from the guide fitting session and the interview provided insight on aspects of the guide that were well designed and other aspects that could be improved upon in the next revisions. The surgeon’s feedback is an important step in the Design Process Workflow defined in Figure 2-1 Chapter 2. Gaining user feedback sparks new ideas for design iterations and model improvement.

The guide fitting session was the step prior to testing the guide in the OR. The relevance of what was learned regarding the guide's location markers, positioning of the IMF and the relation of the guide to the inferior pole of the breast all lead to the creation of an improved prototype in the next step. This allows the study team to avoid errors in the guide design when it is actually used in the OR, which is a future goal of this project.

The feedback gathered from the guide fitting session relates back to the criteria defined in the Weighted Decision Matrix [WDM] and the seven themes that were defined from the initial interview. The discussion in the guide fitting session answered the questions that emerged at the early stages of this project regarding guide registration, shape of the breast borders, guide material and volume estimation.

Moving forward, the next design iteration will be based on 3dMD scans taken with the new imaging protocol where the patient's breast is lifted to expose the IMF without distorting it. The shape of the guide will be changed to incorporate the surgeon's feedback.

5.4. Discussion

The chosen design concept and guide prototypes are the first stage of this design process. The work of this project sparked the initial ideas to approach the design problem of designing a custom surgical guide to support plastic surgeons with positioning the reconstructed breast.. There are limitations to the chosen design process. The research process included a single case study with the feedback of one surgeon. Moving forward to strengthen the project multiple design concepts would be evaluated by multiple surgeons. The robustness of the work would increase, however this would require a larger scope of work.

A comparison between the developed positioning guide concepts and the current work in the literature is done, to highlight the similarities and differences of different surgical planning approaches.

5.4.1. Concept 1: Breast Implant Projection and Shape

The shape and profile of a silicon implant is considered in alloplastic reconstruction. There are categorise of the projection profiles, high-rise or low-rise. In the planning process the surgeon and the patient discuss implant options by visually examining the implant next to the healthy breast. In comparison with the designed guide, the shape is not included in the design concept as the specific focus was on positioning of the breast. The lateral tail of the guide demonstrates a portion of the projection of the breast at the lateral border. Here there is minimal focus on the shape of the breast, this is rather left to the expertise of the surgeon.

5.4.2. Concept 2: Breast Surface Measurements

There is the potential to develop a method of breast surface measurements with the use of patient specifics scans and medical models of the breast. Taking measurements between pre-defined points on the breast surface in the 3D model quantify the size and shape of soft tissue, is a concept of Mammometrics developed by Oren et al [8]. The predefined points in Mammometrics specifically were not applied in this case, however the use of other surface measurements to design the surgical guide were utilized. Measurements of shape and volume of the breast, as well as the relation of the position of the guide to the shape of the breast.

5.4.3. Concept 3: Complexity of the Breast Model

It is a engineering challenge to create a suitable complexity of a model to match the desired clinical need. For example a gravity deformation model is designed to predict the change in shape of the breast as it is affected by the downward pull of gravity. The parameters of a model such as that are different than the parameters of the surface model used to design the positioning guide. The clinical need for this case was to design a tool to support the surgeon with positioning the breast despite the challenges with change of breast shape due to gravity. The focus was on the exterior surface of the torso model rather than its internal composition. Both models are suitable to their specific needs, however they vary in complexity.

5.4.4. Concept 4: Custom-made Cast Surgical Guides

Custom-made Cast Surgical Guides have been developed by Uros et al. The team created a workflow for designing and fabricating a new breast replica cast (NBRC) for 12 participants [15] They collected patient specific surface scans of all 12 patients with a unilateral mastectomy, and used the 3D models to design a cast of the healthy breast to define the shape and volume needed for the reconstructed breast. In their fabrication workflow they used a CNC mill to extract the negative shape of the mold and a vacuum forming procedure to create the mold. The novelty of the idea is inspiring to future planning techniques. In their approached they focused solely on the shape and the profile of the breast and left the positioning of the soft tissue to the expertise of the surgeon. In comparison to the approach taken in this study the focus of the work was on the positioning and volume estimate of the breast. This is an example were different design problems lead to different ideas regarding the same general concept of designing a custom surgical guide to support plastic surgeons with breast reconstructive surgery.

5.4.5. Concept 5: CT Imaging to Identify Blood Vessels

Finally, another approach to using patient specific imaging to preoperatively plan a breast reconstruction surgery is through the application of CT imaging to identify the blood vessesl location in the flap in an autologous reconstruction. This approach could be adopted as well as taking the 3dMD surface scan if that is the preferred path of reconstruction. Identifying the blood vessels through scan segmentation could be additional information provided to the surgeon along with designing the custom positioning guide.

6. Future Directions

There are several lessons learnt throughout this project. Those include: 1) better understanding of the design challenge, 2) Identifying the suitable design requirements to meet the challenge. A digital modeling pathway was developed based on the work with a surface imaging system and various modeling software. A fabrication path was chosen and tested, and the guide fitting session and user testing of the guide highlighted the importance of new imaging protocol. All of those lessons have lead to future directions. This chapter will focus on how to incorporate this workflow into a clinic as well as introduce future design concepts.

6.1.1. Steps to incorporate this workflow in a clinic

One of the ultimate goals of this project is to develop a workflow that can be incorporated in the clinic. In order for this work in developing surgical guides to support plastic surgeons with breast reconstructive surgery is carried forward it needs to be adopted by a team in a clinical setting. The available resources could vary, however there are keystone personnel in the workflow.

Firstly, the plastic surgeon identifies the surgical need for a surgical guide, and conveys that to the designer in a meeting. The surgeon's role is to provide the clinical insight on the surgical procedure, identifying the patient's breast footprint, provide feedback on the guide design, and approve the final guide prior to fabrication. The designer's role is to communicate with the surgeon to understand the clinical need, setup the imaging session and collect 3D surface model, design the guide and consult with the surgeon, oversee the guide fabrication, and finally prepare the guide to go to surgery. The patient's role is to go the imaging appointment where she will meet the surgeon and the designer. This is inspired by the project workflow defined in Figure 6-1.

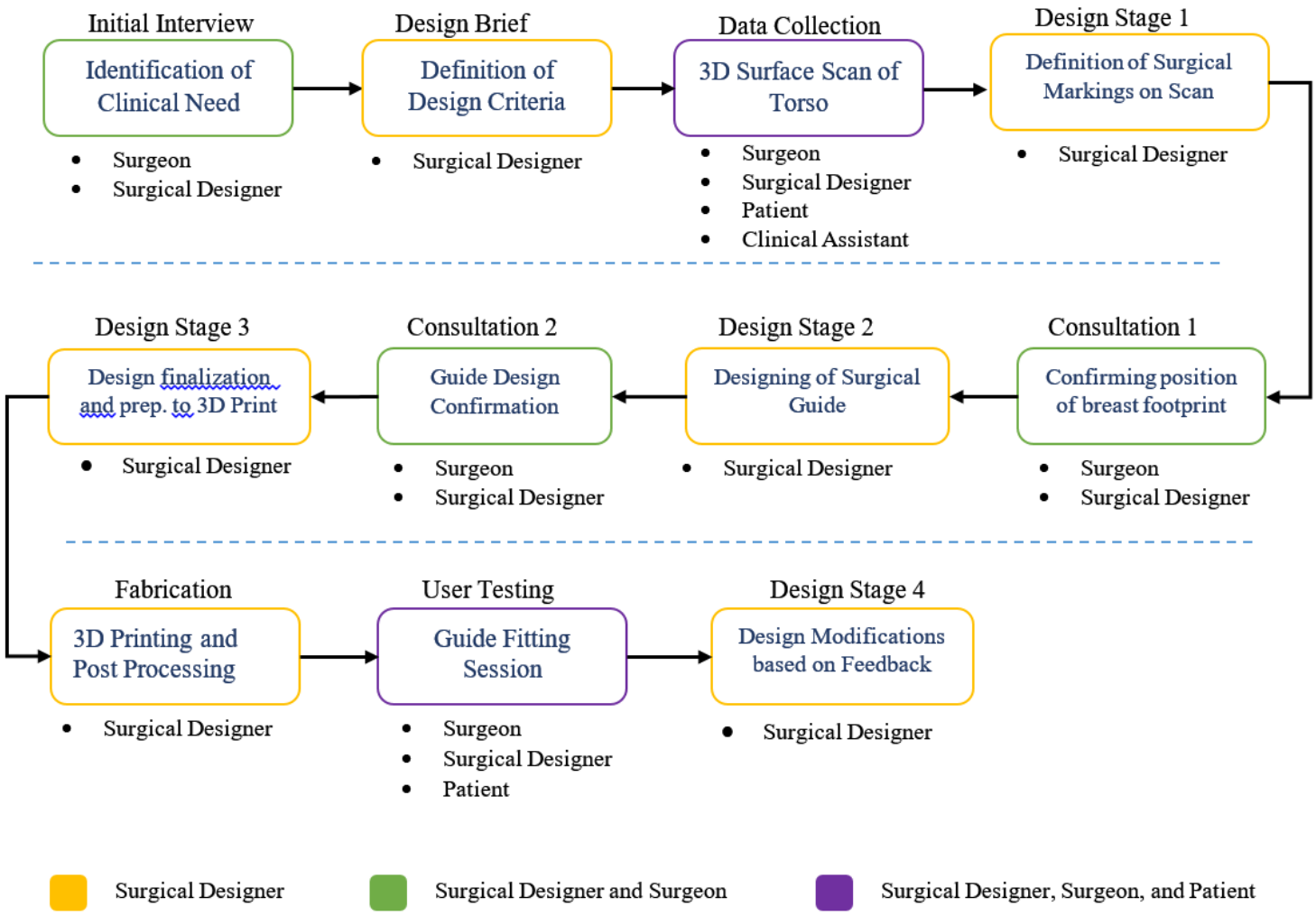

Figure 6-1 Project Workflow Highlighting the Stages of Work and Individuals' Roles

Some steps taken throughout the project brought insight to establishing a design process, and can be excluded from the clinical workflow to streamline the process. The guide fitting session was a useful method to test the guide's fit. This step can be eliminated in future cases once a design method and imagining protocol has been vetted numerous times. Figure 6-2 is a proposed workflow to be integrated in the clinic. There are five phases A – E from the start of the data collection to the surgery day. Once the imaging data is acquired the guide design, fabrication and steraliation will take a week. Table 6-1 is an estimation of the required resources including hardware, software and people needed for each case.

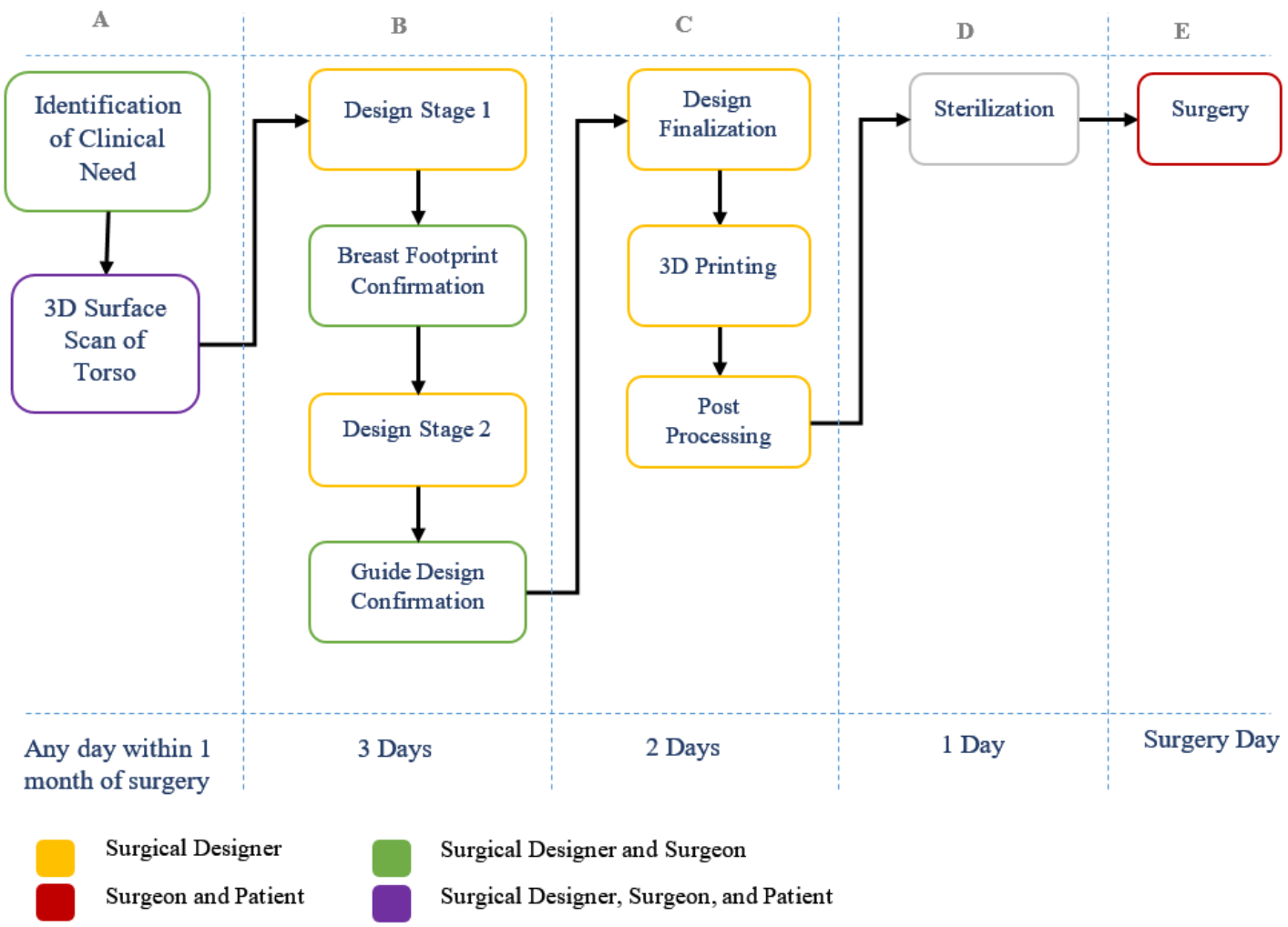

Figure 6-2 Surgical Design Workflow of Integration into a Clinic

Table 6-1 SDS Workflow Table of Resources

Table of Resources Required For Work flow Phases					
	A	B	C	D	E
Hardware	Surface Imaging System, 3D printed Markers	Computer, Haptic Feedback Device	Computer, Haptic Feedback Device, 3D Printer	Guides must be transported to hospital site if the clinic is in a different location. Then the sterilization procedures.	Surgical Guides Other surgical equipment
Software	Imaging software with the ability to generate a 3D model from 2D pictures	Modeling software: For large size / quality files in organic shapes	Modeling software: with the ability to handle large size / quality files in organic shapes 3D Printer Software		N/A
People	Patient, Surgeon Designer	Surgeon Designer	Designer		Patient Surgeon

6.1.2. Future Design Concepts

The guide fitting session provided opportunity for the surgeon to give feedback on the guides usability. While testing the guide it was evident that the imaging protocol needed to be revised. Figure 6-3 demonstrates a 3D model of the patient in the revised imaging protocol with the patient's breast lifted to expose the IMF. This is the start to re-designing a new concept for the surgical guide. A new concept will be designed (concept B) and compared to guide design (concept A). The Weighted Decision Matrix developed in Chapter 2 is used as the evaluation tool.

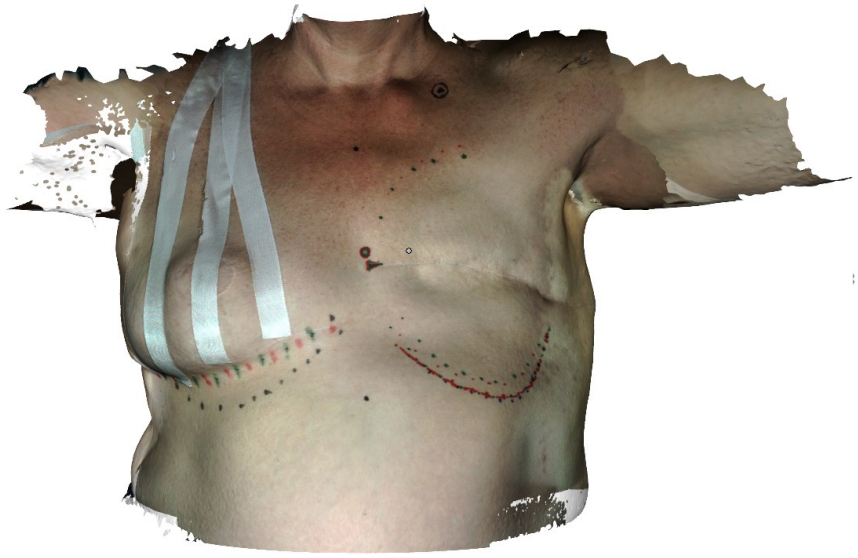

Figure 6-3 3D Patient Model in the Revised Protocol

A similar workflow is adapted to the positioning guide in (concept B), Figure 6-4. The scan was first mirrored to show the shape of the breast on the mastectomy side. The curvature tool is then used to draw the shape of the guide tracing the IMF border on both sides of the breast. This was inspired by the surgeon's input given at the guide fitting session. Positioning markers are drawn to include the patient's freckles, mastectomy scar and radiation tattoo. This would allow the guide to be positioned in reference to the healthy breast.

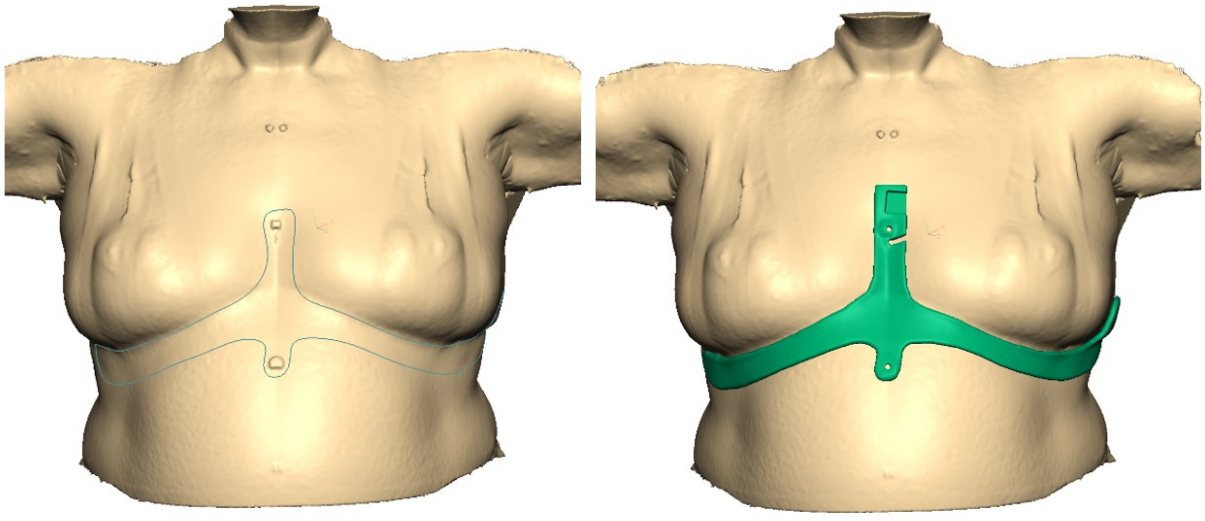

Figure 6-4 Model Design Concept B

The inspiration from which the design concept came from can be seen in Figure 6-5 where the surgeon is demonstrating the required shape with other pieces.

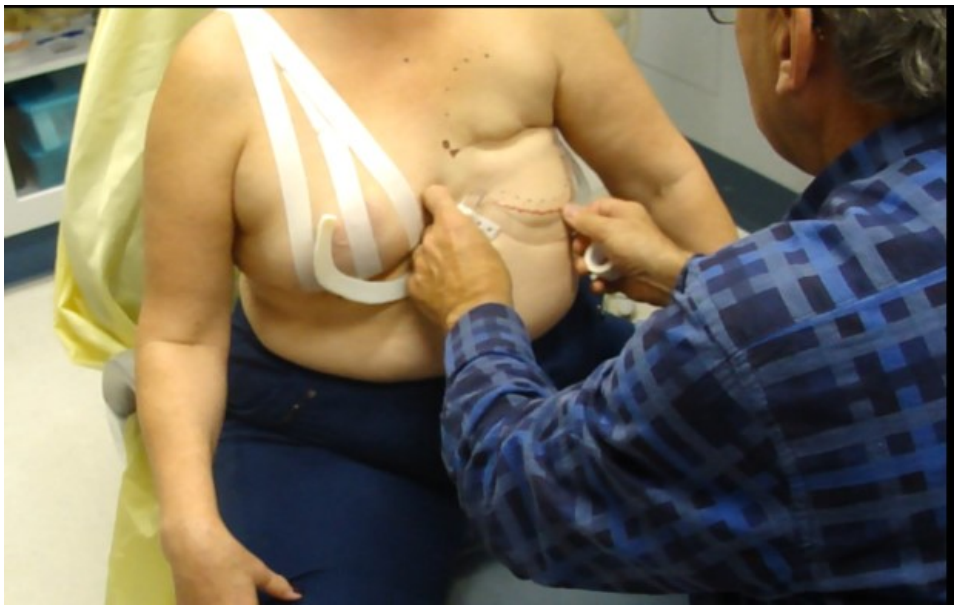

Figure 6-5 Model Inspiration During Guide Fitting Session

Figure 6-6 shows the shape of the guide positioned over the patients scan. The guide is composed to two pieces: first the wing shape component, and second the internal pocket guide adapted to fit the new design.

Figure 6-6 Guide Concept B Overlaid on Patient Scan

Weighted Decision Matrix Evaluation

Design concept A and design concept B (Figure 6-7) were presented to the plastic surgeon to be evaluated using the weighted decision matrix. The raking scale was: Excellent + 2, Good +1 , Neutral 0, Poor -1 , Fail -2 . The surgeon was asked to rate the each guide based on their best understanding of the design concept, aspects such as the manufacturing time / cost were rated by the designer.

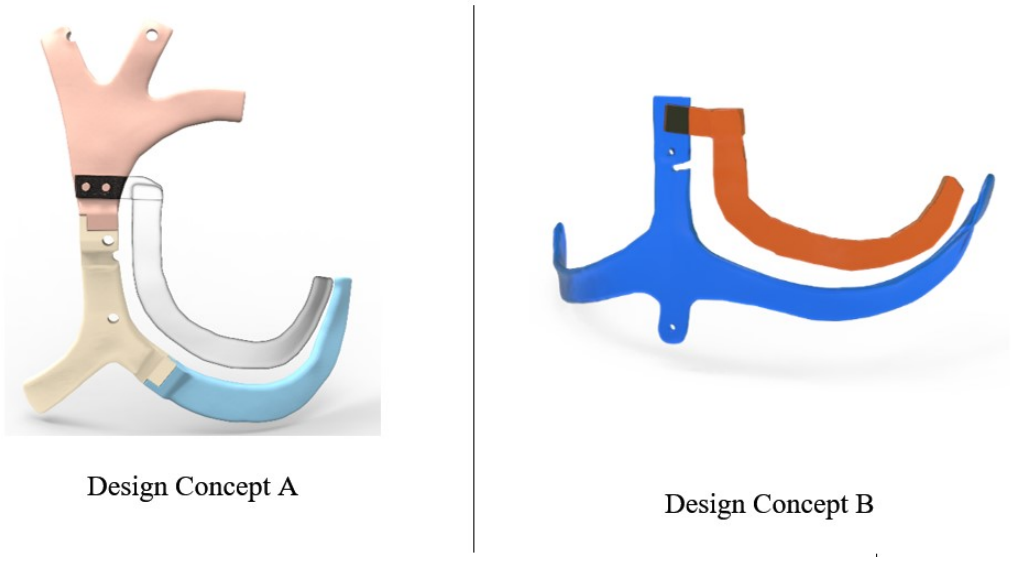

Figure 6-7 Design Concept A and Design Concept B

Table 6-2 demonstrates the scores of the WDM, and Table 6-3 shows the ranking justifications. The original copy of the WDM is attached in Appendix 6.

Table 6-2 Weighted Decision Matrix Results

				Design Concept A		Design Concept B	
	Criteria	**Importance**	**Weight %**	**Rating**	**Score**	**Rating**	**Score**
1	Sterilisable	5	9.43%	2	0.19	2	0.19
2	Registration Repeatability	5	9.43%	1	0.09	2	0.19
3	Indicator of IMF	4	7.55%	-1	-0.08	2	0.15
4	Indicator of Lateral Border	4	7.55%	0	0.00	0	0.00
5	Indicator of Medial Border	4	7.55%	1	0.08	2	0.15
6	Indicator of Superior Extent	2	3.77%	1	0.04	-2	-.08
7	Volume Estimate	3	5.66%	0	0.00	0	0.00
8	Projection Profile	2	3.77%	0	0.00	0	0.00
9	Chest Wall Contour	3	5.66%	2	0.11	1	0.06
10	Ease of Use	4	7.55%	1	0.08	2	0.15
11	Material Rigidity	3	5.66%	1	0.06	1	0.06
12	Color	2	3.77%	1	0.04	1	0.04
13	Easy of Manufacturing	3	5.66%	1	0.06	-1	-0.06
14	Fabrication Time	3	5.66%	0	0.00	0	0.00
15	Cost	2	3.77%	1	0.04	-2	-0.08
16	Internal indicator of IMF	4	7.55%	2	0.15	2	0.15
	Sum Total	53	100.00%		**0.86**		**0.92**

The results of the WDM show that design concept B has a higher score rating at 0.92 points and concept A is at 0.86. Concept design B is an improved version of the design. In comparison to concept design A the design features are closer to meeting the evaluation criteria. A comparison such as this quantifies the difference in approaches. The traditional use of a WDM is to compare design concepts that are at the same stage of production, (both concepts A and B would not have been tested yet). The use of the WDM here is an adaptation of from its original use.

Table 6-3 Weighted Decision Matrix Justification

			Design Concept A		Design Concept B	
	Criteria	**Weight %**	**Rating**	**Justification**	**Rating**	**Justification**
1	Sterilize-able	9.43%	2	3D Printed in Sterilize-able material	2	3D Printed in Sterilisable Material
2	Registration Repeatability	9.43%	1	Excluded Tattoo Location Markers	2	Included Tattoo Location Markers
3	Indicator of IMF	7.55%	-1	Based on the old imaging protocol	2	Design with using the new imaging protocol
4	Indicator of Lateral Border	7.55%	0	Both A and B have the same lateral extent	0	Both A and B have the same lateral extent
5	Indicator of Medial Border	7.55%	1	The medial border is define from the clavicle to the sternum the if the guide was pivoted to one side the error in angulation is large	2	The guide is designed with the improved protocol, shorter definition of the border allows the surgeon more control of the angulation of the guide
6	Indicator of Superior Extent	3.77%	1	Indicates Superior Extent	-2	Does not Indicate the Superior Extent
7	Volume Estimate	5.66%	0	A table for volume estimate will be included with A and B	0	A table for volume estimate will be included with A and B
8	Projection Profile	3.77%	0	Designed on a torso model excluding projection	0	Designed on a torso model excluding projection
9	Chest Wall Contour	5.66%	2	Large surface area of chest is considered	1	Low surface area of the chest is considered
10	Ease of Use	7.55%	1	It was adequate when tested	2	Using the tattoo markers would be easier for registration
11	Material Rigidity	5.66%	1	Both guides will be made of the same material	1	Both guides will be made of the same material
12	Color	3.77%	1	There is flexibility choosing the color for both	1	There is flexibility choosing the color for both

13	Easy of Manufacturing	5.66%	1	Designed pieces are easily oriented on the build platform	-1	The wing shaped design requires more work to orient on the build platform
14	Fabrication Time	5.66%	0	17.4 hours of 3D printing build time + 1 hour of post processing	0	17.2 hours of 3D printing build time + 1 hour of post processing
15	Cost	3.77%	1	3D printing cost of the guide material and time 171.35 $ CAD	-2	3D printing cost of the guide material and time 217.05 $ CAD
16	Internal indicator of IMF	7.55%	2	Both guides incorporate an internal IMF indicator	2	Both guides incorporate an internal IMF indicator
	Design Concept continuation to next stage			**No**		**Yes**

The WDM is a method that allows for an in depth evaluation of design concepts in a structured approach. By comparing the 16 design criteria for both guides the rater is encouraged to think critically about the design concept and the opportunities for design improvement. This example has showed how a comparison between design concept A and concept B, concept B is more superior and is designed to better suit the design challenge. This is a first step evaluation tool, the guide must be still be fabricated and tested.

7. Summary and Conclusions

The purpose of this research project was to examine the feasibility of designing a patient-specific surgical guide to support a plastic surgeon in delayed unilateral mastectomy reconstruction. The objectives of the study were met by, developing the surgical guide workflows and the guides, and evaluating the guide's usability in a guide fitting session. The guide fitting session's purpose was to study the guide's suitability in supporting a surgeon with breast reconstruction surgery.

7.1. Research Project Summary

A semi-structured interview was conducted with a plastic surgeon to discuss the development of a surgical guide for breast reconstruction. From the thematic analysis of the initial interview with the surgeon seven themes emerged: 1) Breast Reconstruction Procedure Background, 2) Planning Surgery Deliverables, 3) Measures to Include in the Guide Design, 4) Volume Estimation, 5) Breast Shape, 6) Materials, 7) Registration Markers. These seven themes define the fifteen design criteria of the Weighted Decision Matrix, a tool used to compare design criteria with different levels of importance. Three design concepts were introduced: A) Volume Estimation, B) Positioning Guide, C) Incision Pocket Guide. Following that, three corresponding design workflows were developed to create each of these design concepts. The guides were fabricated using a combination of additive manufacturing and vacuum forming, the fabrication methods were chosen based on: 1) meeting the design deliverables defined by the plastic surgeon, and 2) available fabrication resources. Finally the guides were tested in guide fitting session, here the guide's accuracy, precision and usability were evaluated. This initial prototype successfully registered on the patient's torso, and consistently defined the breast borders. However due to the imaging technique that was used, the inframammary fold was indicated lower than the inframammary border on the healthy breast. This inspired the development of a new imaging technique. Six themes emerged from the guide fitting session and the follow up interview: 1) Surgical Design Technique, 2) Inframammary Fold, 3) Positioning Landmarks, 4) Posture, 5) Changes in Body Weight, 6) New Imaging Protocol, 7) Materials. These themes severed to provide feedback on the guide and future improvements in the design.

7.2. Limitations and Alternatives

The study included some limitations regarding the participants, the data collection, guide design and fabrication. The signal case feasibility study narrows down the scope of addressing a specific design challenge through working with a specific person. This approach is user focused and is an initial start Consulting with more than one surgeon would lead to different design approaches as

each user would be unique. It is recommended that the surgeon using the guide would have direct input on the guide design as each surgeon might choose to work differently.

Another limitation is in the data collection phase. Taking a surface scan captures the color and shape of the soft tissue in a specific posture. However a surface scan does not include the internal features such as the muscles, ribs and fatty tissue. The estimate of volume that is calculated is limited in accuracy since it is missing the depth of soft tissue that is not captured in the scan. Having color in the surface scan is one of the advantages as it permits the definition of markers to position the guide. The color would not be a feature in an MRI or CT scan.

During the guide design and fabrication process some limitations in a single modeling software lead to the switching back and forth between different software. The 3D scans of a torso is a large file and requires a high level of computational power to work with. This limits the ability to use some modeling software restricting the designer to limited options. One of the design limitations is that the guide is designed and fabricated out of a solid structure, there is limited capacity to design a strut structure to reduce the weight, build material and cost of fabrication.

Finally, the main limitation from a user testing perspective is that the guide was tested once in the design process. There are opportunities for design improvement as seen in Chapter 6 section 2. New ideas or possibilities arise with every stage of user testing, the guide fitting session was insightful. Testing the new design concept in another guide fitting session would be recommended as a step prior to surgery.

7.3. Applicability on a Broader Scope

The focus of this project was to address breast reconstruction surgery in a unilateral mastectomy patient population. From the findings of the guide fitting session it is evident that the design concepts have a broader scope of application.

Firstly, the design concepts could be adapted to address a different patient population in breast reconstruction. For example, a patient with a double mastectomy where the shape of the two breasts could be designed using a custom surgical guide. These design concepts could also be applied in the case where a reduction will be done to the healthy breast, and surgical guides would be designed for the reduced and reconstructed breasts. When working with soft tissue the design challenge will be unique to every case and the

designer will have to adapt the workflow. It is possible to utilise tools such as 3dMD scanning, sculpting and curvature design to reshape the workflow to meet the need of a given design challenge.

Regarding the imaging technology that could be utilised, this project used surface imaging with a color depiction of the patient's surface features. One limitation of a surface scan is the lack of depth of the soft tissue that would be captured in a CT or MRI scan. The use of MRI would be preferred over a CT, as it captures the soft tissue well without the exposure to radiation. However, if one were to use an MRI scan exclusively vital information regarding guide registration would be missing. It would be ideal to have a surface scan registered to an MRI scan. In order to achieve this the scanning postures should be similar. This could be achieved using a hand held surface scanner to take a scan while the patient is laying down.

Three of the six themes that emerged from the guide fitting reflect concepts on a scope wider than breast reconstruction: 1) Surgical Design Technique, 3) Positioning Landmarks, 5) Changes in Body Weight. Those themes are applicable to other areas of surgical guide design. An example of the work that is currently done is the use of curves or a mirroring tools to recreate a missing facial feature like a partial nose or an ear. The positioning landmarks chosen using patient's skin landmarks (moles and freckles) is applicable to the design of surgical guides for facial reconstruction. Surgeons could then use surface markers and skin lesions to reference the position of the guide. Finally, changes in body weight greatly affect a patient's torso. Since soft tissue is constantly moving and adapting it would be difficult to predict how body weight changes would affect the soft tissues of the torso. As such the guide should be designed close to the surgery date.

7.4. Future Directions

This project is a part of a larger objective to test the guide's usability in the OR. The ultimate goal of this line of research is to develop and validate a service model that supports plastic surgeons in breast reconstruction as proposed in Chapter 6. Future directions for this project include fabricating design concept B and testing the proposed workflow in a clinic setting.

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Appendix 1: Transcription of Initial Interview

Interview with Surgeon

Major Themes from interview:

J: I would like to start with understanding the limitations of the current surgical technique, a highlight of some of the challenges in the current planning and executing of reconstructive surgery?

G: 1 min 13 s – 7 min 18 s

So we are talking about reconstructing a breast in someone who has had a complete mastectomy, who has a reasonable breast on the other side who we would use as a normal reference. When you have a mastectomy you remove a lot of the natural landmarks of the breast, in particular the IMF, medial and lateral borders of the breast and the superior aspect. It is also a challenge because when you are reconstructing a patient they are in the supine position, however when you asses the patient they are usually sitting or standing. For the aesthetics of the reconstruction procedure, you ideally would like the reconstruction would be as good as possible irrespective to whether the patient is supine or upright. In addition to that, the mastectomy can produce some distortions to the area regarding the issues of healing or the flap development and depending on the body habitus of the patient. If their BMI higher, it becomes increasingly challenging not only to make a breast but also position it in the right location. So traditionally the surgeon will use the opposite breast for their landmarks, but this is a fairly subjective process. So then there is the issue of planning before any incisions have been made, and the issue of once you've new tissue planes opened up, how do you know what is the right amount, and right direction of opening up the tissue planes? And then you have the problem of what you see on the outside vs what you see what you see looking underneath the tissue planes. As the surgeon would see when they are doing a reconstruction, whether it is putting a soft tissue expander or breast implant or some type of autologous flap. So reconstructing the breast to optimize the result is more than just producing a mound of some sort. Certainly the ability to get a better reconstruction in terms of techniques and things that are currently available, because the breast is a 3D organthat changes dimensions depending on the patient's position, and it also depends on what is inside there. So if you have an abdominal TRAM flap that is basically fatty tissue that will behave more like a normal breast when you are supine or sitting than if you have a soft tissue expander in. It does not behave the same as the normal breast. So the bigger the normal breast, the poorer the result of that type of technique can be. But regardless of the technique, to try to optimize, it would be nice if the surgeon could as accurately as possible do the reconstruction on the correct part of the chest and then limit the problems with asymmetry related to that. Then the issue is more how do I make it an adequate breast volume, that has a similar characteristics to a normal breast. then you have the issue of where to put the breast, and the issue of what is the difference between what you see on the outside vs. what you see on the inside, and once you have the outline of the breast, is there some means you can use, some of the modeling / 3D imaging techniques to know what volume you need. And then the last issue is the dissensions to create the volume so that you could have 2 breasts with similar footprints with similar volumes but the dimensions could be different and the breasts could look different. It is a more challenging problem than some of the boney reconstructions, because bone reconstructions would have the same dimensions where the patient is vertical or supine. That is one of the reasons why soft tissue reconstructions are much more subjective and the idea is to try to come up with some means, like we are trying here, to make the reconstruction as accurate as possible.

J: Where do you think a 3D model could be most useful to support in one of the challenges that have been identified?

G: 7 m 48 s – 10 m 11 s

You want to evaluate the breast volume, and positioning as separate aspects. Each aspect has its specified challenges. If you imagine building a house, if the foundation isn't right then it doesn't really matter what you do above there it won't be right. So you start with the foundation, which is what we are talking about in terms of put the breast on the chest wall. Then from there you can talk about what you can do to build upon it to be more accurate. If a person is obese and has a heavy abdominal panes for example that will pull down your IMF, and will be a difference whether the patient is supine vs vertical. If you are doing a TRAM flap, so you take out a defect of abdominal tissue and then you close it, when you close it you are pulling down on the IMF on the normal side, so where do you want the IMF to be on the mastectomy side. The thinner the person is – this probably doesn't change quite as much – then you are less likely

to use a TRAM flap because they have less abdominal tissue. Every patient is unique, in this type of breast reconstruction there are so many variables that make each one unique. So anything that could be done to standardize things could be a good thing.

J: As a surgeon, what do you think would be important criteria to have in the guide?

G: 10 min 34 s – 12 min 57 s

If it can provide you information on where you want the IMF to be, and where you want the medial extent and lateral extent and superior extent of the breast mound. Typically the problem tends to be with bigger flaps is that they tend to be too far lateral and you don't have as sharp of an IMF on the other side because all the ligaments have been destroyed when the mastectomy has been performed. When you add to it, if there is some means that you could have the guide somehow underneath the flap to show you were the fold is. Depending on how thick the mastectomy is, where you say it is going to be internally vs on the surface maybe would be hard to judge. I think those criteria would be helpful to the surgeon.

J: So it is more of a concept that could show you exterior and interior location?

The inside will be where you are going to be doing the suturing , and either insetting your flap or putting the soft tissue expander and deciding where the medial, lateral and superior boarders will be. So if you make the breast pocket too big then it is not going to magically shrink down to be smaller. Right off the bat you have a different template. Going back to the house analogy, if on one of them the foundation is not the same, then no way the reconstruction will be.

J: In terms of the material, I have a few samples here. Those are an idea of some of the material that could be used:

G: 13 min 31 s – 15 min 50 s

I think the material has to have a certain stiffness to it, rigid enough to hold a certain shape and avoid distortion when affected by the pressure induced by the tissue or the flap positioning.

It will be important to use material that could be referenced to a point, to ensure the precision of the marking locations.

The fact that it is clear would be helpful, so we could mark it or color it in appropriate spots.

I think it has to be harder, the pressure from tissue or flaps can distort this enough that you lose the accuracy of.

This would be too flexible, hard to reference to a point [Yellow mat]

Something that is solid to all you to have some flexibility to go into a pocket, but once you let it go it goes back to its original shape. It is not going to fatigue or become inaccurate.

Taking into consideration a big area that needs to be covered on the chest, this results in having long arms to connect certain distances. Making sure that the measured lengths, and designed angles are accurate. Without the effect of long moment arms, or deviation due to flexure / elasticity. I think some of these softer ones, you have to consider that you have a fairly big area there is going to be some long moment arms. So a few degrees of deviation from one area could greatly affect another location.

Clear would be helpful – mark it or color it in the appropriate spots

J: With a tool like this, because the chest wall is contoured, should the guide as well take the curvature of the chest wall?

G: 16 min 0 s - 17 min 22 s

One of the inaccuracies that you have to check for in the examination beforehand is the underlining chest wall asymmetries. The incidents of that are subtle. If it is not really obvious on a close clinical exam, I am not sure if you would really need to get a closed CT scan. But it needs to be considered when the designer and the surgeon are looking at the patient. The other interesting thing, in comparison to the bony stuff, a few millimeters doesn't make… a few millimetres in a bony jaw reconstruction could make the difference of whether the

occlusion is in the appropriate position. However, with the breast that is less of an issue. The surgeons aims to be as symmetrical and accurate as possible, but with soft tissue there is a bit more latitude.

J: So for example the template would sit flat on the chest wall of the patient would that be acceptable?

G: 17 min 37 s – 18 min 30 s

No, I think we have to go along the curvature, it will have to fit with the curvature of the patient's chest. That is part of the way it will register with the chest wall, the tight fit alignment is needed to show the proper marking locations. If you are just holding something clear and looking down then that is not a whole lot more accurate than what the surgeon can do by just looking at it by just looking from one side to the other. Assuming that the underlyng chest wall is relatively symmetrical, and that chest has some curvature and the IMF has curvature and the lateral extent is going to be closer to the operative table than the medial, it is a very 3D foundation so the guide needs to take that into account; the 3D dimensional architecture of the other side.

J: If we consider a surface scan from a 3dMD there would be the difference in the thickness of the skin from the surface to when you go internally with the location of the IMF inside the pocket, should that play a role ?

G: 19 min 19 s

Yeah that would be fine.

One of the issues from the surface scan is the lack of definition of the internal anatomy, and so the difference in defining the curvature of the chest based on the contour of the skin wrapping around the area of the breast rather than the exact curvature from the bony structure of the chest wall.

J: How about considering the projection of the breast?

Through our discussion we've identified the importance of locating the breast boarders, such as the IMF, medial, lateral and superior borders. What other information could be useful in creating custom surgical guide? How about volume, and or projection?

G: 20 min 30 s – 22 min 55s

So the next thing that potentially could be helpful would be the volume, so a measure of the volume of the normal side vs. the abnormal side. That is making the assumption that the normal side is not something that is going to be altered in the near future… which often it requires something done as well. That could change the dimensions of the desired breast, for the women with a smaller breast or has had some sort of procedure to their normal side – whether it would be a breast lift or a breast reduction – so that would be your "stable side" to compare to, then the next thing would be what sort of volume. So if you have got some sort of soft tissue expander, the next thing down the road is knowing what is the estimated number of expansion – so 400 cm^3 , 600 cm^3 … - now if you imagine the shape of the normal breast when they are supine and how that changes when they are vertical. With the reconstructed breast you could have the same volume in the supine patient, but when they sit up one side could stay with those dimensions and the other could change dramatically. That would be the next challenge to consider, if you reconstruct a breast with their own tissue in an autogenous reconstruction, it tends to behave more like a normal breast. So on bigger breasted women that would be more likely to occur. When you do a lift on the normal side it does tighten up the skin, but these are all factors that sort of run into how good the ultimate result is going to be.

J: So considering we would have a guide that would have both information in terms of projection, volume and location.

G: 23 min 6 s – 25 m 25 s

The potential could be that you could use the volume part of the – you could use it subsequently say you are putting a soft tissue expander in somebody and you are putting in X number of cc's but you are not really sure if it is enough or not. So if you have a clear acrylic mold that sits on top of the breast that is a volume of 650 cc's as you expand then you will be able to tell when am I at a symmetrical volume point of view, not an ultimately dimensional point of view – rather the 3D volume, when am I close.

Because then the other confounding variable is the fact that you reconstruct a breast and the patient is wearing a good bra it is helping produce the dimension. The surgeon is producing the volume so in theory if you have good volume, in a bra that makes it similar for dimensions then that would give a better result.

Because then we think of result, an excellent result is reasonable symmetry in someone who is naked vs. a good result in someone who has reasonable symmetry while wearing a bra or a bathing suit or some sort of supporting garment. Then a poor result is when someone has obvious miss match in terms of one reconstructed breast related to the other.

In terms of what you are telling patients of what they can expect, and sometimes it is predicable beforehand to know that it will be very difficult to get an excellent result just because of the body habitus – so if you inform the patients ahead before the surgery then that is good. It makes it sound that you have some experience and giving them the head's up so they are not disappointed. But if you have some sort of tool that could help you have less women in that group, then that would be good. Which hopefully this guide could.

J: Based on the custom made tools with other types of reconstruction, what are some of the limitations that you've experienced when those tools were first developed?

G: 25 min 55 s – 26 min 51 s

Certainly, there are always surprises that you don't think of so I think some of the issues will be having a very reproducible registration point so that it is consistent. Because when you… intraoperatively you may put it on, take it off, put it on again many times during the procedure – so if it doesn't sit on the same spot each time then if you are off five mm in the suprasternal notch when you get down to the IMF with that length of a leaver arm that could be problematic – with an awful lot more than 5 mm – this would put you in a situation that could be worse off than a trained surgeon's eye.

J: What would be the ideal registration markers?

G: 27 min 0s – 28 min 50 s

I guess that is what we are going to try and find out, this can be different for each patient depending on what bony landmarks that are available or would easily be identified. So with some patients if they are thin it is easy to identify the suprasternal notch, medial clavicle, or some sort of scar or skin lesion that is going to be consistent that could be used. I think that is what we will need to put some thought into, or try to see with each individual patient. Also take into consideration how much will it register with the opposite breast – is it going to be some sort of J shape that is going to register from the SSN area , or on the right breast will it be registered from 2 o'clock to 7 o'clock in reference to the left chest. The more registration points that we can figure out, then the more consistent it would be when positioning it on the chest each time.

Then from here it would be interesting to see when you are thinking about this, or designing it on the patient supine then based on a 3dMD scan – here you think you have it registered appropriately, then the patient lays down again. The question here would be what kind of differences are there? Are they going to be predictable, or are they unpredictable – we can find out if a certain parameter is going to be more consistent or less consistent when going from a change in positioning.

J: As we are coming close to an end with this interview, from a broader perspective what impact could you predict this project would have?

G: 29 min 25 s – 30 min 4 s

I think it would have very good potential to help the reconstructive surgeon in the clinical circumstance when we talked about with a mastectomy, and the secondary reconstruction. It may be beneficial for the case of an immediate reconstruction as well…..

J: Can you tell me more about any considerations for the sterilization process?

G: It would be important to consider how sterilization could affect the shape of the guide. This includes the chemicals or heat that is used during the sterilization process. The question would be if the shape or the curvature of the guide would be effected? This is a

step worth comparing in the guide fitting session where a sterilized guide would be compared to the non-sterile guide and both would be compared to the actual model.

Appendix 2: Patient Consent Form

INFORMED CONSENT – Patient Participant

Title of Project:
Development and Usability Testing of a Surgical Guide
for Autologous Breast Reconstruction

Principal Investigator	Dr. Daniel Aalto, PhD Assistant Professor, Faculty of Rehabilitation Medicine, Department of Communication Sciences and Disorders, University of Alberta / Research Scientist at the Institute for Reconstructive Sciences in Medicine (iRSM) Email: aalto@ualberta.ca Tel: 780-492-8938
Co-Investigator(s)	Dr. Jason P. Carey, PhD Professor, Department of Mechanical Engineering University of Alberta Dr. Gordon Wilkes, Faculty of Medicine and Dentistry, Department of Surgery, Division of Plastic Surgery – Breast Reconstruction. Heather Logan, Surgical Design Simulationist, Institute for Reconstructive Science in Medicine (iRSM) – Adjunct Assistant Professor, Faculty of Rehabilitation Medicine.
Study Coordinator	Jumana Joury, Master's Student Rehabilitation Sciences Program, Specialisation in Surgical Design and Simulation Faculty of Rehabilitation Medicine, University of Alberta
Clinical Assistant	Lindsay McHutchion, Anaplastologist, Institute for Reconstructive Science in Medicine (iRSM)

Sponsors / Funders: University of Alberta

Non-Emergency Contact Numbers:

Those are noted at the end of the document in the section heading "Who Can I Contact for Questions?"

Background Information for This Study:

A team of researchers from the Faculty of Rehabilitation Medicine at the University of Alberta is collaborating with the Institute of Reconstructive Science in Medicine (iRSM) to develop a breast reconstruction surgical guide, and evaluate its usability by Plastics Surgeons performing breast reconstructive surgery. The guide development process will include consulting with a surgeon, creating a concept prototype, and evaluating the guide usability in a guide fitting session. This study will not involve any surgery.

You are asked to be a participant in our study for the Development and Usability Testing of a Surgical Guide, for Autologous Breast Reconstruction. This will entail using 3D modeling to support surgical planning in autologous breast reconstruction. If you decide to participate, your participation will help the research team in the prototyping stage of developing a custom surgical guide to support plastic surgeons with autologous breast reconstruction.

The focus of this study is understanding how 3D modeling can be used as a tool to assists Plastic Surgeons. Digital modeling and surgical planning for bone reconstruction surgery has proved to improve the treatment pathway. However, digitally designing and simulating soft tissue reconstruction, specifically in the application of autologous reconstruction, has not yet been well developed

Why Is This Study Being Done?

This study is being done to develop a patient-specific surgical guide to support plastic surgeons in planning, and executing a delayed unilateral mastectomy reconstruction.

The guide design would be evaluated during a surgical guide fitting session. Here the surgeon will test the guide's usability and provide feedback to the designer.

What Are Other Options If I Decide Not to Participate In This Study?

As a patient, your participation in this study will not have any effect on your path of treatment. This guide fitting session is only a demonstration of how the prototyped guide would be used. This will not have any effect on your actual surgery procedure, the reconstruction technique that the surgeon would use, or the expected reconstruction outcome.

How Many People Will Take Part in This Study?

Two participants: One patient, and one surgeon.

What Will Happen During This Study?

During this study one plastic surgeon, and one patient with a unilateral mastectomy will be recruited. The study will include the following:

1. A Semi-Structured Interview with the Surgeon Participant to inform the researcher regarding an optimal guide design
2. An Imaging Appointment with the Patient Participant to obtain a 3D patient model
3. A Patient-specific Surgical Guide is designed, and fabricated based on the specifications identified by the Surgeon in the interview
4. A Surgical Guide Fitting Session with both the Surgeon and Patient Participant will take place to test the guide usability
5. A Follow-Up Semi-Structured Interview with the Surgeon Participant will demonstrate the guide design process, and discuss further improvements to the design concept.

A detailed explanation of the steps involving the patient can be seen below:

Imaging Protocol:

The imaging appointment will take place in a private room at the Medical Modeling Research Lab (MMRL), at the Institute for Reconstructive Science in Medicine (iRSM), Misericordia Community Hospital. The study coordinator will explain the scanning setup, including the camera placements, the technology and the scanning protocol to the patient. The scan recorded will be a surface scan that uses photos to create a digital 3D model. There is no radiation exposure involved in this type of scanning.

The patient will then be invited to change her upper garments to a robe, in the changing room inside the scanning room. Then, the clinical assistant will palpate and place 3D acrylic markers on the patient's clavicle (collarbone), and sternum (breastbone). A series of scans will be taken of the torso region with arm in different positions: 0 degrees, 45 degrees and 90 degrees.

A total of six postures will be scanned. During the first three scans the patient's torso will be completely exposed. The following three scans patient will be asked to wear a thinly lined, or unlined bra of their own, with an external prosthesis to demonstrate the aesthetics of a reconstructed breast.

Surgical Guide Fitting Session:

The surgical guide fitting session will include the patient participant, surgeon participant and study coordinator (Jumana Joury). The guide fitting session will take place in a private examination room at the surgeon's clinic or iRSM. The study coordinator will start the session with introductions, then explain the purpose and procedure of the session. The coordinator will start Video recording the session. The patient will lay down on the exam table, and the surgeon will stand as they would in the operating room. The study coordinator will then hand the custom designed guide to the surgeon, with verbal instruction explaining how it is used. The surgeon will place the guide as it would in the operating room. Once the information is clearly presented to the surgeon, the study coordinator will step back to observe how the surgeon interacts with the guide, and note any feedback (through body language or verbal) that the surgeon gives regarding the guide design, and / or usability. The guide fitting session is expected to take 15 – 60 minutes. A blanket will be available to give to the patient in the case they feel cold while being undressed during the session.

Possible Benefits:

There are no direct benefits to the participants. However, based on the results of the study, it is it is hoped that a surgical design and simulation process can be established to support autologous breast reconstruction in the future.

Possible Risks:

As a patient participant, there is the potential of having feelings of social or emotional discomfort (nervousness, stress, or unease) during the 3dMD scanning procedure and the guide fitting session.

Efforts to mitigate this possible risks include creating a safe environment. The scanning session will take place in a private room where only you (the patient), the researcher and clinical assistant will be present. The researcher will explain the scanning procedure to you, then invite you to change to a robe in a changing room.

Once you are comfortable with the procedure, and you have had a chance to ask questions, the researcher will guide you through the scanning protocol. If the face is included in any of the scans, the 3D image will be cropped to contain only the torso. The files of your scan will be saved using a participant code to protect the privacy of (you) the participating patient. The participating patient (you) will inspect the 3d images and will have an option for a retake or withdrawing from the study.

As a Patient, there is also possible risk of feeling nervousness or unease in the Guide Fitting Session. Efforts to mitigate this possible risk include creating a safe environment in during the Guide Fitting Session, as well. The Guide Fitting Session will take place in a private examination room. This session will only include (you) the patient participant, surgeon participant, and the study coordinator.

During the Guide Fitting Session the study coordinator will invite you to lay down on the exam table, as the surgeon would demonstrate using the designed guide in the operating room. The session is expected to take 15 - 60 minutes, which will be timed by the research coordinator. A blanket will be available, in the case you feel cold, throughout the session. Slight discomfort could be felt as a result of having the guide placement by the surgeon being gently pressed on your chest wall. However, this should not result in any bruising, and should have minimal to non- long lasting discomforts.

The research coordinator will start the guide fitting session with introductions, and explain the purpose and procedure of the session. The session will only start once both (you) the patient, and the surgeon participants feel comfortable to participate in the provided environment.

Possible Reproductive Risks:

Not Applicable In this Study

What Are My Responsibilities as a Study Participant?

- Inform the research coordinator at any stage during the study if you have any questions, concerns, or wish to end your participation in the study.

- Attend the 3dMD Scanning Session (1 Hour time commitment)

- Bring a thin Bra with minimal or no padding to the 3dMD Scanning Session

- Attend the Guide Fitting Session (1 Hour Time Commitment)

Will There be any long-term follow-up involved with this study?

No, there will not be any long term follow up with this study.

Can I Choose to Leave this Study Early?

Yes, as a participant you can withdraw from the study at any point without giving a reason. After the guide fitting session is completed, you will no longer be able to withdraw from the study.

How Will My Personal Information be Kept Confidential?

All video and photographs recorded will not have names attached to the files. Videos and photographs will be kept on a server behind AHS firewall. Questionnaires and data collection forms will not have names attached to them. The only place where a participant's name will occur is on the consent form. The consent forms will be kept in a locked room at the University of Alberta, in the study binder.

Will There Be Any Costs Involved with Participating in This Study?

Taking part in this study may result in additional personal cost to you, for example:
- There might be a cost associated with coming to the hospital for the appointment. For example, parking or transportation. We will reimburse you for your travel up to a maximum of $10 per visit.

- You may miss work as a result of participation in this study.

Will I Be Compensated For Participating in This Study?
If you decide to participate in this study, you only will be reimbursed for study-related expenses such as parking, up to a maximum of $ 10 per visit.
What Are my Rights as a Participant in this Study?

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form you do not give up any of your legal right against the hospital, investigators, sponsors, nor does this form relieve these parties from their legal and professional responsibilities.

Is there a conflict of Interest Related to this Study?

Dr. Daniel Aalto, Dr. Jason Carey, Dr. Gordon Wilkes, Ms. Heather Logan, Ms. Lindsay McHutchion, and Ms. Jumana Joury declare no conflict of interest.

Who Can I Contact for Questions?

If you have questions about taking part in this study, or if you suffer any research-related injury, please contact the lead investigator or a co-investigators at the University of Alberta. You can reach those people by:

Daniel Aalto, PhD	780-492-8938
Name	Telephone
Jumana Joury, MSc. Student	709-770-7009

Name Telephone

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at:

Telephone: 780-423-5727 Toll Free: 1-877-423-5727

CONSENT

Title of Project: Development and Usability Testing of a Surgical Guide for Autologous Breast Reconstruction

Principal Investigator(s): Dr. Daniel Aalto Phone Number(s): (780) 492-8938
Co-Investigators: Dr. Jason Carey, Dr. Gordon Wilkes, Ms. Heather Logan
Study Coordinator: Jumana Joury

	Yes	No
Do you understand that you have been asked to participate in a research study?	☐	☐
Have you read and received a copy of the Information Letter?	☐	☐
Do you understand the benefits and risks involved in taking part in this study?	☐	☐
May we take a surface scan of your torso?	☐	☐
Do you agree to us using de-identified pictures and the 3D model created from the scan of your torso in future presentations or publications?	☐	☐
Do you agree to the use of the video recordings for research purposes?	☐	☐
Do you agree to the use of the guide designed, based on your 3D model, for teachings or presentations?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without any negative consequences?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand that your name will not be associated with any of the data collected today?	☐	☐
Do you understand who will have access to your records, including personally identifiable health information?	☐	☐

_____

Who explained this study to you? _____

I agree to take part in this study: YES ☐ NO ☐

Signature of Research Participant _____

(Printed Name)_____

Date:_____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee_____

Date: _____

*** You will be given a copy of this signed and dated consent form prior to participating in this study. ***

Appendix 3: Guide Fitting Session Manual

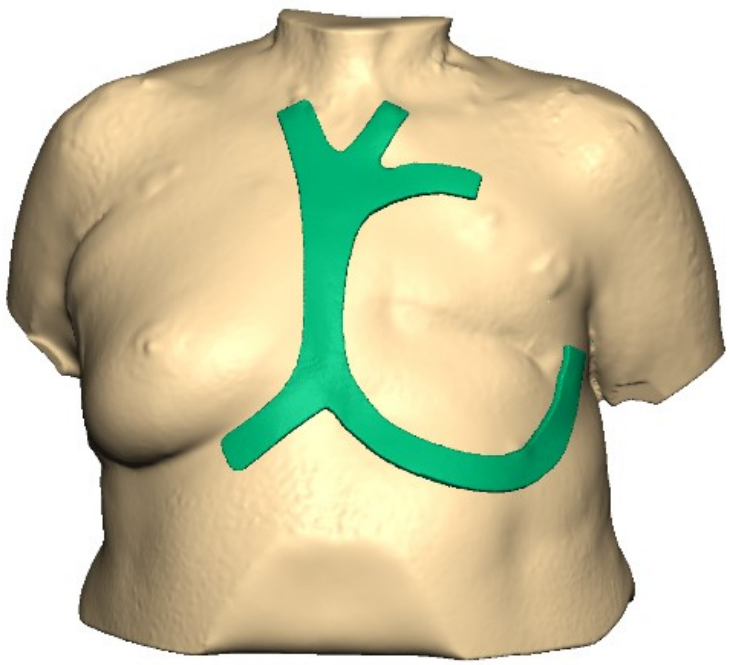
Surgeon Follow-Up Interview Structure

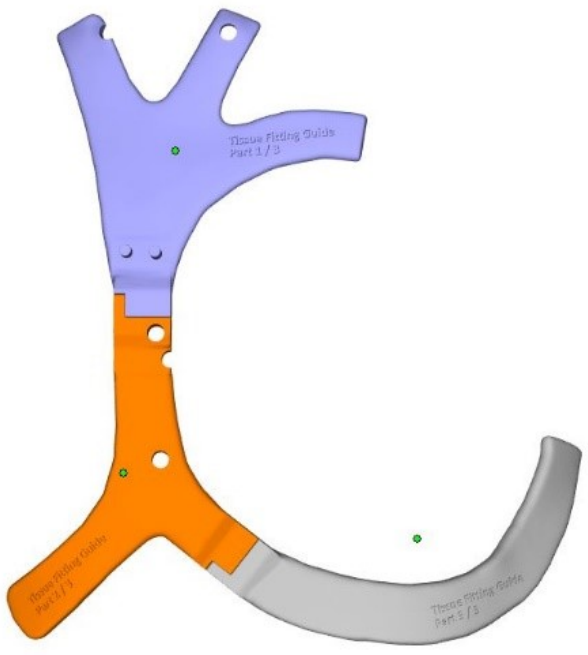
Conducting Semi-Structured Interviews: Adopted from Theodore Zorn, OXFAM Research Guidelines
https://itp.nyu.edu/classes/fungus/interview_technique/conductingInterviews.pdf
Reference Group: Plastic Surgeons Specializing in Breast Reconstruction

1. **Contact Participant**
2. **Arrange Time and Setting Post Surgery 1 and Surgery 2**
3. **Conduct Interview**
    1. State Purpose
    2. Consent and Recording
    3. Opening question: "I'm interested in learning about the utility of the patient-specific guide to support autologous breast reconstructive surgery. Can you tell me about your experience in using the guide during the Guide Fitting Session?
    4. What were some of the main challenges you noticed?

       Here is a demo of how the guide was designed ** visual demo of the guide design, and fabrication process **

    5. Compare and contrast question: How could the guide be improved?
    6. Imagining: Where would you like to see the future of this go?
    7. Impact: What impact do you think this could have?
    8. Come to a conclusion: Would you like to ask any questions?
    9. Participation Thank you
4. **Thematic Analysis**
5. **Report:** Compile a combined report and decide the future step to take.




Tissue Fitting Guide
Part 1 / 3
Tissue Fitting Guide
Part 2 / 3
Tissue Fitting Guide
Part 3 / 3

Volume Estimation

Scan Description	**Volume Curved (CC)**	**Volume Tangent (CC)**	**Volume Flat (CC)**
0 Deg	1,081	1,082	1,047
0 Deg	1,075	1,075	1,044
0 Deg	1,063	1,064	1,030
90 Deg	1,079	1,079	1,079
90 Deg Failed			
45 Deg	1,116	1,117	1,077
Angled Back	828	1,063	1,026
Angled Back	1,154	1,155	1,106
IMF Lift 1			
IMF Lift 2			
Mean Volume Across Positions	1,057	1,091	1,058
% Deviation from the Mean	1.13 %	2.07 %	0.95 %

Appendix 4: Guide Fitting Session Transcription

Video: M4H03203

1 min 17 seconds

- The surgeon takes the guide and places it on the patient's torso

G: Just lift your chin up just a bit. So how is this to be placed ?

J: The two things that I marked over here are the freckles and the mastectomy scar. So this mole is in there (pointing at the guide)

G: What about the top two holes right there ?

J: Those two would be…

P: you might want to lower the head down if it is coming too high.

G: Are you okay lying like that ? If you need a break let us know

P: No, it is good.

J: It seems like the guide is longer.

2 min 02 seconds

G: Can we put the head rest down, adjust the chair?

- Chair angulation adjusted.

2 min 26 seconds

G: so what is that there ? (pointing to the superior registration markers on the guide)

J: Those were the markers that we have had from before where you placed two markers on her chest.

G: So those were artificial markers that I put on there?

J: Yes

2 min 52 seconds

G: The guide orientates nicely there.

- Switching to a mirrored scan guide

G: could you just hold that tightly there ? I am just going to take a look from the floor to see how the lateral aspect looks.

4 min 34 seconds

G: You can see that the normal female breast if you look there is an area where there is fat. This is where the breast sort of ends. But women always have an area right here.

P: Our fat

G: it is called a tail of Spence. The problem before with breast reconstruction is the tendency to create the breast mound too far lateral. And to get tricked into thinking that the tail of Spence is breastrather than this border being the end. If we compared the mirrored scan guide with the tissue fitting guide, where the tail of the guide you can see that the mirrored scan guide the tail is in the air.

So the tail is marking the extent of the breast on the healthy side, were there is breast tissue already. The other one (Tissue fitting guide) is marking the extent. If you are doing the breast reconstruction, then you would be filling that space up to the point of where the tail is in the air.

It would be almost interesting intraoperatively you would first make your marking with the Tissue Fitting Guide, then if you are doing autologous reconstruction where what you got is ultimately what you have then it would be interesting to see if this gap closes, or if you are putting a soft tissue expander in then you might use this later as you expand the breast so to give you some sort of a guidance to when to stop expansion.

J: Would you say that both are potentially useful ?

G: I think so, now let us try these with the patient sitting up.

7 min 19 seconds

Chair adjustment

8 min 16 seconds – 19 min 37 seconds

The camera was facing the patient's back and the dialog is set out of context

19 min 55 seconds

G: We should have brought you a Halloween mask to hide your face from the camera, (chuckles) – speaking to the patient.

P: Is my face in it?

J: No now your face is not in it.

20 min 45 seconds

G: We are orientating the guide to the medial mastectomy scar and the lesions on the skin. So you could see that this guide here is more related to the inferior pole of the breast not the IMF. The other side of the guide (IMF on the reconstructed side) sits nicely on the chest wall. So the concern is that the IMF on the healthy breast is higher than the inferior pole of the breast. The question becomes, can we do a 3dMD scan lifting the breast but not distorting the IMF so that we could accurately know its position relative to the other side.

G: because when we add the piece that would be the part that is internal during the surgery. Intraoperatively this ideally would be were you would place the extent of your dissection underneath the skin flap. But again you could see that that would make the IMF too low.

J: It looks like here, that the IMF on this side matches up with the inner lining of the guide.

G: Well but this is too curved. If you to do that it would be more like coming out.

22 min 43 seconds

G: other thing to note is any patient who has had radiation treatment they usually have these little tattoos. We use methylene blue intraoperatively which will go away within a week. But these here are permanent and can be used as another reference point for the patient because it is going to be consistent just like the moles.

23 min 10 seconds

J: (Pointing to the superior reference points) – Are those reference points useful ?

G: I would say that they are a little bit confusing in the sense that if you are going to use markers there is another tattoo from radiation or picking a couple of skin lesions that are consistent and using those. Because the medial head of the clavicle there is

asymmetry and one side is more prominent than the other. Even just the width of them they are not as explicit. Unless the clavicles were so prominent you had a 3D cap that would just cover over it. Even then you could see that it wouldn't take much to move it, so a little bit of movement at the top would make it a huge change at the bottom. So you would have to have several good reference points.

So why don't we do the same process now with the patient supine

24 min 47 seconds

G: That would be another thing, if you have all those surgeries done. Let us say your arthritis got worse and you did less and less exercise and became a little more depressed and ate more. Then suddenly all of a sudden you put on 25 pounds that then changes all the relation to the guides. Or you have your hip done and you decide to exercise more so that would be the opposite. There would be an effect of the change in lifestyle on body weight and the fit of the soft tissue guides.

26 min 19 seconds

- Patient is supine

G: So you can see now that the patient is supine that the IMF distance extrapolated straight across is higher than the location of the guide. So what we should do in the preoperative planning I would say to mark this (IMF border) while supine in one color and we can try that. Then mark it with her sitting up in another color. Then seeing what the difference is. Let's do the marking now

J: Looks like we have what we need for now.

28 min 05 seconds

G: Now the other thing you notice is that the amount of play in the joints is an aspect of concern. This joint moving should be avoided.

J: Yeah, that shouldn't be there. That could be easily fixed

J: So now the best thing to ask is how do we design the guide to reflect the true border of the IMF?

Video M4H03207

- The patient is sitting up and the surgeon has placed the markers of the IMF on the patient's torso.

G: (Talking about the type of surgery that she would have) We would probably put in a tissue expander. The problem is the fact that you had a bit of radiation so the stiffness and tightness is much higher. You can't get the same degree of ptosis . Our goal is when you have a good supporting bra it looks similar. When you don't have anything on, the reconstructed side would be much more taught than the healthy side.

P: Something to think about

1 min 23 seconds

G: Can you have your arms out please? (Placing the guide on the patient's torso) So let us just see here. (Evaluated the location of the IMF with arms at 90 degrees) And now bring your arms down again. Now raise your arms to 90 degrees again. Bring them down again, and up again. So the location of the IMF doesn't change that much. (the surgeon marked the location in blue marker)

1 min 56 seconds

J: So we know that the position doesn't change that much, but everything with the guide design is shifted down. So what we need to do is fix why it is shifted down.

G: Because everything is based off of the inferior pole of the breast instead of the IMF

J: The scans that I designed this off of is when the patient was laying back. So I think that would have counted for the elongation

G: was she laying back partially? can you try to emulate that ?

The way to check it though would be to put markings of where the IMF border is, and then see what happens you extend backwards. So if it is taking of the marking of this line (inferior pole of the breast) rather than this line (IMF border)

3 min 12 seconds

J: Could we mark where the breast meets the skin if the patient was sitting normally upright?

G: Okay, for fun let's take a different colored marker. Let us mark the inferior contour of her breast in black. And let us put black markings on the mastectomy side and if it shows that all the planning is symmetrical then it answers that question.

- (Marks the black border at the angle perpendicular to the skin so it is strait on)
- Stop to get alcohol swabs to clean it up

Video M4H03212

- The patient's breast is pulled up with bandage tape

G: If you did a 3dMD scan with her breast pulled up like that. If you knew when you were doing your 3dMD that you are picking up this line (line of IMF) then everything else would

J: Would be a lot different.

G: Yeah, so the other thing I would do is mark the tattoos and skin lesions, here is one radiation marker, and here is the second radiation marker. So I would want to pick up those.

J: Are we okay with having the guide be a bit bigger or bulkier to capture those positioning markers?

G: Why can't it just be a thin arm reaching out? and forget about the arm reaching out here (pointing to the clavicle)

1 min 46 seconds

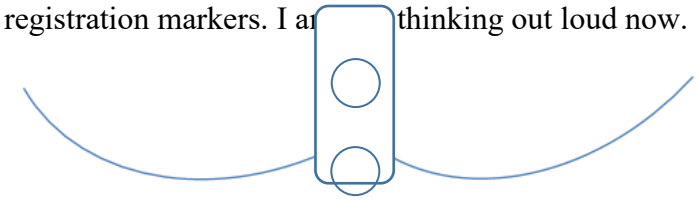
G: What you need to think about is to choose markers that are consistent. For example if you had a patient with an elevated mole. Something to use to create a triangulation of some sort. You don't have to capture all the markers just a few would be reasonable.

Cause the other thing, I mean let us say you had a guide that showed an IMF marker that went to here (so an IMF marker that extends from the healthy breast and over to the mastectomy side and triangulated with the skin lesions / mastectomy markers)

I am just trying to think, for registration points – because it is usually pretty straight forward to see where that IMF is

3 min 03 seconds

If you imagine two pieces of the guide like this (pointing two shapes of the guide and setting up against the curvature of the IMF) If you imagine that this sits like that , and this goes up like that and then there is a piece that has a hole there and there for registration markers. I a thinking out loud now.



J: So let us assume this is gone, (taking apart the guide and placing the pieces without the superior component).

G: Then you would have to decide whether or not you want anything that would go to the superior extent. But you don't want this all big chunk of stuff that would make it bulky.

J: So would you have the guide that goes inside of the IMF attach to this edge here ?

G: The one for the incision pocket?

J: Yeah, that is why I designed this to go higher than the mastectomy scar.

G: It would be worth trying.

J: Definitely, I think each guide would be specific to the patient. This might work for this case and it would be very different for another.

G: Well it would be worthwhile to try even. If it was with the same patient various kinds of guides and different shapes to see which one would fit best intraoperatively or preoperatively when we do this kind of planning. To see whether or not there would be an advantage of one or the other.

5 min 23 seconds

J: I can make the guides be built into parts, so it could have 2 or 3 parts that would assemble and dissemble whatever pieces.

P: Custom made just for me

J: A few things that I would like to have: A 3dMD scan that shows the breast pulled to expose the IMF. A scan with the guide on the patient's chest. So those are the two that I would like to get before we wrap up here.

6 min 19 seconds

J: As for volume: I estimated volume and for each scan in 3 different ways. And across that the average volume estimate from the mean the percent deviation is around 3%.

G: So it is around 1000 cc

J: Yes it is around 1000 cc

7 min 14 seconds

G: So you want to do those scans, have you got pictures of what you need ?

J: Yes let us take a couple

Appendix 5: Final Interview Transcription

Interview with Dr. Wilkes

Video M4H03217

0 min 10 s – 1 min 44s

J: Overall in general what did you think of the guide fitting session?

G: I thought it went quite well, that we learned a lot and it brought up some things that we haven't thought of . I think the physical guide is good, it is just a matter… it is a matter of the difficulty in ensuring the initial scans adequately delineate the IMF rather than the curvature of the breast mound itself.

Video M4H03218

0 min 28 s – 0 min 58 s

G: Registration of the guide on the patient is important. Using consistent markings like skin lesions, the mastectomy scars or tattoos are all reference points that could be useful in positioning the guide. The closer the registration points are to where the guide is the more accurate the guide is going to be.

0 min 58 s – 1 min 31 s

G: I think it was interesting when we compared the positioning of the IMF and the position of the mastectomy scar, and the proposed IMF site all relative to whetherthe patient was sitting or supine didn't change a whole lot which was a bit of a surprise because I was expecting it to be more of a change. That is good because it takes away the concern of doing the scan while the patient is standing and the surgery while the patient is sitting.

1 min 31s – 1 min 46 s

G: Also while comparing the position of the IMF and the mastectomy scar while the patient has her arms at right angle with the body which is the position they would be in on the OR table. Again there wasn't much of a change with the position or with the patient sitting, so that was important to know.

1 min 58s – 2 min 39 s

G: The biggest thing to improve one and I think we were able to figure out how to do that, was to differentiate the difference between the inferior pole of the breast and the IMF. I think it is important to have clearly delineated the normal IMF on the normal side which will make it as accurate as possible on the reconstructed side.So I think that was the biggest lesson learnt and then the minimal change in the position of the IMF in relation to the arm position and the patient's physical position. In my mind those are the key changes.

Materials of internal pocket guide 2 min 45s

J: With the incision pocket guide, does it matter if it was 3d printed of vacuum formed?

G: 3D printing should be fine. With the incision pocket guide the main thing to be discussed is to make sure that the gap that there is is sufficient to allow it to register on the external prosthesis but well enough to fit into the internal pocket.

J: How much of a gap do you think we will need?

G: Well it depends on the patient. Basically it depends on the thickness of the skin and soft tissue on that flap that you lift up inferior to your mastectomy scar. So if somebody has a higher BMI they would have a thicker flap and that would have to be compensated for. Otherwise you can't register the internal guide with the external guide.

– 4 min 09 s

– Registration of the internal pocket guide: 4 min 37 s – 5 min 36 s

The internal pocket guide wouldn't necessarily have to register to the external guide, it could be registered to external points itself. It wouldn't necessarily have to go on the tissue fitting guide component. It might be easier to manipulate it if the guide went into the pocket itself and registered with some skin lesions or markers. Have it be separated from the other component.

Then you wouldn't have to worry about the thickness of the step deformity to get it in, that would be one advantage. and two you wouldn't have to deal with some sort of a sandwich guide.

Material: 4 min 37 s – 5 min 36 s

The flexibility of the vacuum formed guide might make it less accurate than the 3D printed guide since it could get bent by the surgeon while the guide is being manipulated inside of the pocket

J: Material wise is the guide ok ?

6 min 59 s

G: Yeah it is fine. From a material perspective the chosen material is suitable, from a cost effective point of view…

J: Oh I forgot to tell you how much they cost, with the adjustment that they have done with the pricing the whole guide is 300 or a bit less.

G: That is good, The thickness of the guide is solid so they seem to be overdesigned that can be reduced in terms of thickness. In terms of cost for materials. It is not something that requires an excessive amount of strength. It won't be left in the patient's body. It is not going to be subjected to a great deal of forces, it is only going to be marked on and it is job is done. We could consider going down by half the thickness

J: I think with keeping it that thickness it was basically just an estimate, this can be thinner for sure. It is now 7 mm and can be brought down to 4 mm.

G: The least material the better.

9 min 02 s

J: I did the volume calculations, and I did them based on different scans. Roughly 1050 cc , as a number is that in any way useful ? or do you want that number in a form of a shape?

G: Well, Yes and Yes. Let me explain. So the volume of the other side being measured is really important. Because if you are reconstructing with a tissue expander it would be good to know the volume estimate of the breast you are trying to match. Then you plan to over expand the pocket to stretch the tissue and replace that with a smaller size of a prosthesis. So you might put a prosthesis in that is around 1000 cc, but you might want to stretch the breast tissue to 1300 ccs to start with. So that would help you from a volume point of view.

Then there is a question we know that the actual dimensions of the breast even though the volume stays the same the actual dimension change when the patient is supine vs sitting up. Whether it is upper pull fullness or lower pull fullness and so ultimately if we could control not only volume but the 3D dimensions with the reconstruction that well help with getting closer to the shape of the healthy breast.

So the absolute number might be helpful in terms of expanding the breast tissue. If you were doing an autologous reconstruction with your own tissue the overlay that would give you the volume on the table would be of help.

Again with some of theses things until you have the opportunity to use them intraoperatively it is hard to say which ones would be the most value and what will not be.

12 min 22 s

J: Moving forward do you think we might be able to use the guide intraoperatively of design an new guide for another patient with an upcoming surgery?

G: Yeah , yeah I think that we would. So if the guide today was off of the IMF that we marked out, then I would think that it would be something that you would probably use right away. So the question would become whether or not you would use the same sort of form with the markings which we had which will be fine. And we discussed more of a gull wing type of design as well for accuracy. Those are all things we would have to play around with to see if there is a difference in ease of creating it from a designer's perspective, or the ease of use from the surgeon's perspective. And weather there is any perceived difference between the accuracy of either designs relative to the IMF.

So we are talking about taking this design and using it for the footprint of the breast that you are reconstructing. Then can you further develop the model so that not only you have the footprint then you have the guide that helps you build the shape on top of it. So you first have the foundation, then you consider what is the shape of the first floor going to be. Because you can have your foundation but you make it different dimensions and still have the same volume of living space but you could have a completely different shape. That would be the next potential benefit of using it, or helping you hopefully get a more accurate result intraoperatively.

14 min 39 s – 15 min 51 s

J: I think that covers it all; we talked the cost, fabrication and next steps of what we will do so I will work on redesigning the guide. Hopefully we can take it to surgery.

Do you think there is an opportunity to present this to the plastic surgeons ?

G: For sure, I would once you have got the next guide made, I wouldn't do it based on this, we know the design error in this that we could fix. So if you have the potential of porotype B and you know that would be better, why would you present prototype A.

J: Thank you, I think that covers it all. I can't think of anything else honestly.

G: Sounds good.

Appendix 6: Results of Weighted Decision Matrix

					Concepts A		Concept B	
	Criteria	**Ranking**	**Weight**	**%**	**Rating**	**Score**	**Rating**	**Score**
1	Sterilisable	5	0.1020	10.20%	~~2~~		~~2~~	
2	Registration Repeatability	5	0.1020	10.20%	1		2	
3	Indicator of IMF	4	0.0816	8.16%	-1		2	
4	Indicator of Lateral Border	4	0.0816	8.16%	0		0	
5	Indicator of Medial Border	4	0.0816	8.16%	1		2	
6	Indicator of Superior Extent	2	0.0408	4.08%	1		~~0~~ ×2	
7	Volume Estimate	3	0.0612	6.12%	0		0	
8	Projection Profile	2	0.0408	4.08%	0		0	
9	Chest Wall Contour	3	0.0612	6.12%	2		1	
10	Ease of Use	4	0.0816	8.16%	~~0~~ 1		2	
11	Material Rigidity	3	0.0612	6.12%	~		~	
12	Color	~~2~~ 1	0.0408	4.08%	~		~	
13	Ease of Manufacturing	3	0.0612	6.12%	1		-1	
14	Fabrication Time	3	0.0612	6.12%	0		0	
15	Cost	~~2~~	0.0408	4.08%	1		~~-2~~	
	Value Total	49	1.0000	100.00%				
	16 / Internal IMF Measurement				2		2	

Ranking:

+ 2 : Excellent ------- +1 : Good ---------- 0 Neutral ---------- -1: poor ---------- -2: Complete Fail