Augmented Reality Environments for Oncoplastic Breast Surgery

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I declare that this document is an original work of my own authorship and that it fulfils all the requirements of the Code of Conduct and Good Practices of the Universidade de Lisboa.

Acknowledgments

This work is dedicated to my grandfather, who although might not be here to see how far we've come, has been the one I would like to honor with this work that I have dedicated myself so profoundly. I wish he was here for me to look into those blue eyes and tell him that we've made it and that what comes next looks even better. He set up the example of resilience and strength. Only love can make us move this much, empowering us to do good and to carry on the hard times. Honesty, hard work, and ambition are fundamental to success. Learning those things from people you love and admire, takes you through the roughest paths without ever giving up.

To my parents, who have always been my light. Many times along the way there were doubts, insecurities, and fears that would try to overcome my motivation and strength. But they did not surpass my parents' love, encouragement, and support over all these years. It wouldn't have been possible without you by my side. Having you caring and staying with me in such key phases of my life, will find me forever grateful. You are the people I love the most, and the people I hope to make the proudest. You both are such good-hearted and hard-working people. You are the personification of joy and love. Still to this day, I don't know how I got so lucky. Thank you isn't enough, and never will be.

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Abstract

Deep inferior epigastric artery perforator (DIEAP) flap reconstruction surgeries have become a gold standard technique for breast reconstruction surgery. Knowledge of the vascular network of the inferior abdominal wall is crucial for surgery planning. The potential of augmented reality (AR) in this type of surgery is very appealing and is expected to help surgery pre-operative planning. In this work, we propose BREAST Plus as an AR interface that runs on the Microsoft HoloLens headset, which adds relevant and accurate information for marking the location of perforators on top of a patient's tummy skin, right before the surgery takes place. This interface allows surgeons to see beyond the patient's skin. Interface design counted on valuable input from two breast reconstruction surgeons, who provided their needs and requirements to perform skin marking tasks. Since BREAST Plus heavily relies on 3D data registration to anchor data on top of a patient, we also conducted a skin deformation analysis to measure how deviated the computed tomography angiography (CTA) data is from the patient's skin when laid on the surgical bed. A total of 20 data sets were analyzed revealing that skin deformation is not neglectable. The root mean square was 2,447 $\pm$ 1,1 mm, including 30% cases of deformation above 3 mm and 15% above 4 mm. We also conducted a small user study with three breast surgeons in two DIEAP flap surgeries to collect qualitative data on usability, user satisfaction, and preferences. The BREAST Plus interface aided surgeons to visualize relevant information in an immediate and helpful manner. Preliminary results also indicate that Breast Plus can assist surgeons when locating perforators during DIEAP reconstruction surgeries.

Keywords

Augmented Reality; Deep Inferior Epigastric Perforator Flap; Breast Reconstruction; Registration; Skin Deformation; Mesh Alignment

Resumo

As cirurgias de reconstrução mamária com uso de perfurantes da artéria epigástrica inferior profunda (DIEAP) tornaram-se uma escolha de preferência. Para o planeamento da cirurgia, é crucial conhecer a rede vascular da parede inferior do abdomén. O uso de realidade aumentada (RA) neste tipo de procedimentos é muito promissor e espera-se que ajude o planeamento pre-operativo. Neste trabalho, propomos o BREAST Plus como sendo uma interface de RA visualizada a partir do dispositivo HoloLens 2 da Microsoft, adicionando informação relevante, precisa e útil para marcar a localização de perfurantes na pele da barriga da paciente, nos instantes anteriores à cirurgia, permitindo que os cirurgiões vejam além da pele da paciente. O design da interface benificiou da contribuição de 2 cirurgiões de reconstrução mamária, que apresentaram as suas necessidades e exigências. Como o BREAST Plus depende do registo de dados em 3D para ancorar os dados na paciente, realizámos uma análise quanto à deformação da pele para medir o desvio que os dados de angiotomografias computadorizadas (ATC) têm em relação à pele da paciente, quando colocada na cama cirúrgica. Dados de 20 voluntárias revelaram que a deformação da pele não é negligenciável. A raiz quadrada média foi de 2,447 $\pm$ 1,1 mm, incluindo 30% casos acima de 3 mm e 15% acima de 4 mm. Também realizámos um pequeno estudo de utilizadores com 3 especialistas para recolher dados qualitativos sobre usabilidade, satisfação e preferências do participante. A interface ajudou os cirurgiões a visualizar informação relevante de forma imediata e útil. Resultados preliminiares indicam que o BREAST Plus auxilia os cirurgiões a localizarem as perfurantes durante cirurgias de reconstrução mamária usando DIEAPs.

Palavras Chave

Realidade Aumentada; Perfurantes da Artéria Epigástrica Inferior Profunda; Reconstrução Mamária; Ancoragem; Deformação da Pele; Alinhamento de Malhas

Contents

List of Figures

List of Tables

Acronyms

AR Augmented Reality

CTA Computed Tomography with Angiography

CT Computed Tomography

DIEAP Deep Inferior Epigastric Artery Perforator

DUS Doppler Ultrasound

FOV Field of View

ICP Iterative Closest Point

MRI Magnetic Resonance Imaging

MRTK Mixed Reality ToolKit

NASA-TLX NASA Task Load Index

OST Optical See-Through

PLY Polygon File Format

VR Virtual Reality

SUS System Usability Scale

TIN Triangulated Irregular Network

XML Extensible Markup Language

HMD Head-Mounted Display

1

Introduction

Contents

Breast cancer is the most common form of cancer affecting women, resulting in breast deformations in 30 percent of the patients due to the removal of the tumors to avoid their spreading [11]. This can have a deep psychological impact on the well-being of women, so in order to help restore the aesthetic of feminine form, a reconstruction technique with better outcomes is the Deep Inferior Epigastric Artery Perforator (DIEAP) flap [12]. The DIEAP flap reconstruction surgery is a safe and common technique for immediate or delayed breast reconstruction surgery for patients previously submitted for a mastectomy, being considered reliable technique [11]. According to the American Society of Plastic Surgeons, 137,808 breast reconstruction surgeries were performed in 2020, from which 23,324 were performed using the DIEAP flap method [13].

Champalimaud Clinical Center is a state-of-the-art medical, scientific and technological institution, containing several Units specialized in different pathologies. Per year, 35 DIEAP Flaps are done at the Breast Unit. This procedure consists of the harvest of the lower abdomen's excess skin and fat, containing perforator vessels that will preserve the tissue when placed on the breast for reconstruction [14]. Preoperatively, all patients go through a CTA for the surgeons to visualize the perforator vessels whose location is later verified by using a Doppler evaluation intraoperatively. The CTA images are usually represented in two dimensions and have inspired both engineers and doctors to seek ways of transforming that data and facilitating its interpretation as well as the interaction with it, using AR or VR [15]. These tools can be of much interest to surgeons to support preoperative planning and navigation throughout surgery, even if with some limitations.

Technology has already been explored in DIEAP flap surgeries, such as the use of 3D photography, augmented reality headsets, projectors, and mobile-AR to project 3D models into the patient's body, helping the surgeons visualize what is most important, improving their precision and effectiveness [7, 16–18]. However, these projects contain limitations that need to be addressed, such as the calibration and alignment of the 3D models to the patient, the lightning, the registration of the models, the comfort while using the devices, the narrow field of view, and more - either for a preoperative or an intraoperative circumstance.

1.1 Motivation

The DIEAP flap reconstruction surgery is a very complex and delicate procedure, even if performed by a trained surgical team. The procedure consists in transferring excess skin and subcutaneous fat from the abdomen to reconstruct the breast [11]. This tissue has perforator vessels that are carefully dissected along their course - since they go through the muscle - to preserve it and its nerves. The surgeons need to be very cautious during the dissection, so they can be careful when getting closer to the perforators. The most adequate perforators are studied in preoperative planning. The chosen ones need to be perfectly dissected since they will be the main suppliers of the tissue when the reconstruction is done on the breasts. Preoperatively, a CTA is performed, where each perforator is manually identified by the imaging team to support the surgeons mapping the perforators when starting the surgery [5].

A study has reported that the average time of surgery can be 291 minutes - 4.85 hours - for unilateral breast reconstruction and 513 minutes - 8.55 hours - for bilateral breast reconstruction [19]. This is not only exhausting for the surgeons, but it is very overwhelming for the patient's body due to the anesthesia and the reconstruction itself. Decreasing the time expended is an important improvement.

The use of CT scanning on preoperative mapping of the perforators can decrease the operative time by 1 hour and 16 minutes (21%) and save 537€ per patient [20]. Preoperative mapping also allows the selection of the most reliable perforators beforehand.

The preparation of the surgery is an important task since it will determine, to a certain extent, the flow of the surgery and the time it takes. Identifying the course of the perforators is influenced by personal opinions and observations, and such might lead to incoherences between the preoperative study and the surgical findings [5]. Not to mention the time and effort it takes the radiological team to complete the task. Refining the preoperative studying with more intuitive, precise, and possibly autonomous tools, is a major help to the radiological team.

As an interaction paradigm that merges virtual objects in the real-world environment [21], AR empowers surgeons with 'x-ray vision' allowing them to see beyond the patient's skin, in real-time [22–24]. This can be achieved by using AR glasses (such as the Microsoft HoloLens), Mobile-AR, 2D projectors, and other see-through devices. AR navigation systems are capable of projecting three-dimensional models into the patients containing blood vessels, muscles, and other information the surgeons require. The use of this technology can potentially enable surgeons to work hands-free while having access to relevant patient-specific information visualized in an augmented space [25].

AR's current open issue is the registration process, which corresponds to the alignment of the virtual elements with the real world [26]. For the tracking of perforators and anchorage of the 3D models on the patient's body, it is important to have a precise registration process. This can be done, for instance, using markers scanned by the devices. It is also fundamental to use a well-calibrated system that isn't susceptible to relevant deviations when using AR and 3D models on the intraoperative situation [7]. Additionally, it's necessary to consider that the position of the patient while doing the CTA scan is different from the one encountered during surgery. Thus, it's important to study how it can affect the surgery, the data collected, and the data visualized [27].

However, the use of AR headsets in surgery still has several limitations. Its acceptability and improvement are only possible if increasing the exposure and exploration of AR [25, 28]. It is fundamental to evaluate how HMDs can be incorporated into surgical practices, which surgical tasks can benefit from it, and skills the user is excepted to have to perform well. The lack of an automatic registration process is an additional bottleneck to the use of AR in surgical guidance [29]. If the alignment of virtual elements fails, the guiding system is unreliable and can't be used consistently. Moreover, instability is another barrier to the use of devices such as the HoloLens in surgical practice [30–32].

1.2 Problem Statement

Previous research has contemplated augmentations of angio-CT-based perforators during DIEAP flap reconstruction surgeries [7,16–18,23,33,34]. Nonetheless, these approaches were not validated and do not take into account the potential deformation of the patient's lower abdomen due to different positions of image registration between the CTA position and operating table position. The deviation caused by pose transformation has not been quantified before. Due to the absence of previous research on this type of deformation, all works are relying on the assumption that the deformation is irrelevant when projecting the three-dimensional (3D) models on the patients. A study to ascertain the amount of deformation is still lacking.

We will address the conventional task of tracing the perforators and marking their location on the patient's skin in surgery with a ruler, using the information obtained in the CTA scans. This current method is time-consuming and the evaluation of the perforators is a target of subjectivity since there is a lack of graphical and visual elements to help in decision making.

1.3 Scopes and Objectives

The purpose of this work is to explore of the use of augmented reality to improve the planning of the surgery and to mark the perforators on the patient's skin in surgery. Improved preoperative planning and immediate visualization of the perforators location, can lead to speeding up the process with added precision. We intend to create a minimalist interface with the essential information and tools to interact with the 3D model of the patient. With the correct alignment of the 3D model to the patient, the marking of the perforators is expected to be faster and easier.

Since our work heavily relies on 3D data registration to anchor data on top of a patient, we conducted a skin descriptive statistical analysis and statistical inference to measure how deviated the CTA data is from the patient's skin when laid on the surgical bed. The goal of this study is to reveal whether the deformation of the patient's skin from the data acquisition position to the patient's position in surgery, is relevant. If the deformation is above an acceptable value discussed by the surgeons who participate in the study, it should be taken into consideration when performing the fusion of the CTA scan with the surface scan of the patient, for the projection of the models more accurately on the patient's body during surgery.

While doing the research some questions were gathered for further study in this work:

- Is the deformation of the skin between the position of the patient in the CTA scans and the position in the operating table relevant? Can it affect the data, such as the location of the perforators?
- Can the visualization of a 3D model through an AR device (HoloLens 2 by Microsoft) improve surgery planning and reduce surgery time?

These questions will lead us to the following hypotheses:

- If there is skin mesh deformation from the patient's scanning position to the operating table position, there must be an error to consider when building the 3D model. If the deformation is irrelevant, it does not need to be considered since it will not affect the procedure.
- The HoloLens as an AR system allows for better outcomes, resulting in better surgery planning and reduction of surgical time, which improves the efficiency of the procedure.

2

Background

Contents

2.1 Breast Reconstruction using Deep Inferior Epigastric Artery Perforators (DIEAP)s

2.1.1 DIEAP Flap Anatomy

The DIEAP flap used in breast reconstruction surgeries is removed from the lower abdominal. The flap contains skin, fat, and blood vessels - deep inferior epigastric perforators (Fig. 2.1) [35]. The perforators branch from the deep inferior epigastric artery, which approaches the muscle at the lateral edge. The perforators have a short path across the rectus muscle and cross the fascia into the subcutaneous layer. Larger perforators are usually seen 3 to 5 cm near the umbilicus. The breast is vascularized by internal mammary vessels, which are later connected with the flap perforators in the DIEAP flap procedure.

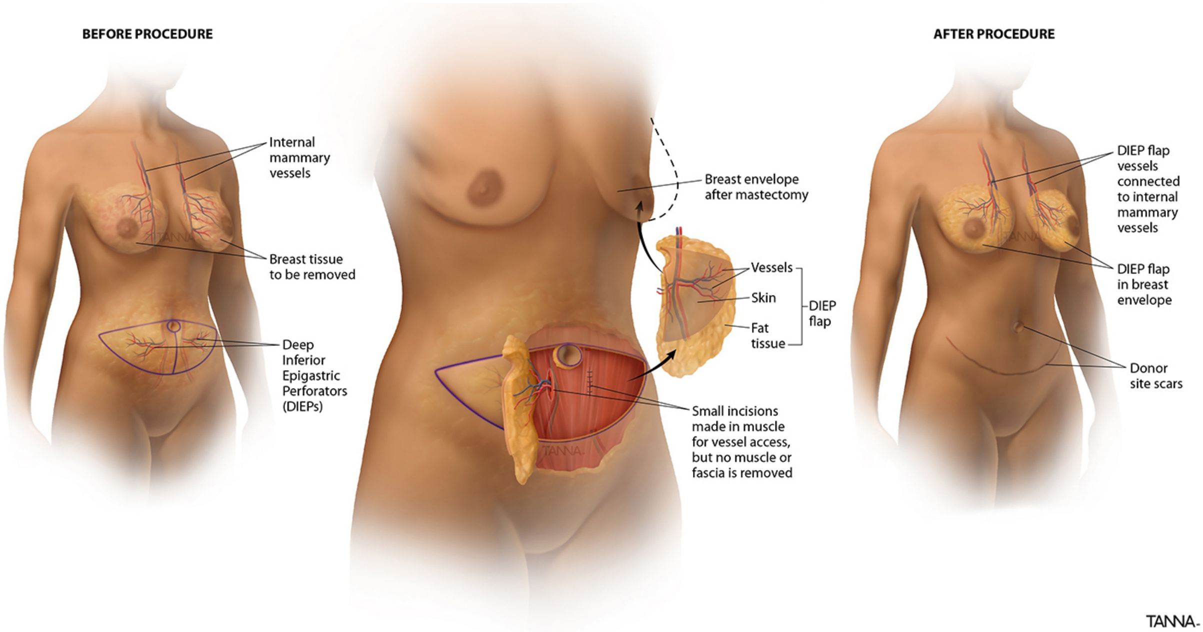

Figure 2.1: DIEAP flap anatomy elements before, during, and after the breast reconstruction procedure [1].

2.1.2 DIEAP Flap Procedure

The DIEAP flap reconstruction surgery is a very complex and delicate procedure, even if performed by a trained surgical team. The procedure consists in transferring excess skin and subcutaneous fat from the abdomen to reconstruct the breast (Fig. 2.2). The perforator vessels contained in the tissue are carefully separated from the rectus muscle along their course to preserve it and its nerves [11]. The surgeons need to be very cautious on the dissection, in order to be careful when they are getting closer to the perforators since some of them will be the suppliers of the tissue when the reconstruction is done on the breasts. When transferring the flap to the breast area, the deep inferior epigastric vessels are connected to the internal mammary vessels or the thoracodorsal vessels on the mastectomy site. For such, it's performed a highly skilled surgical technique named microvascular anastomosis. The flap is then shaped into a new breast, offering the patient a natural and enduring breast, reestablishing their body image with aesthetically pleasing results [12, 14].

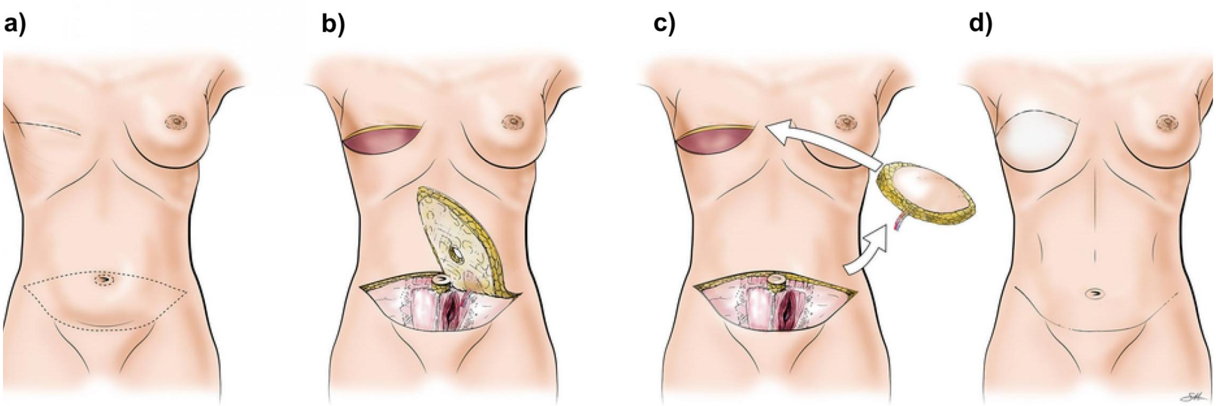

Figure 2.2: DIEAP Flap Procedure [2]. A few moments before surgery the area of the incision is marked (a). In the beginning of surgery, the flap is dissected, and the breast tissue is removed (b). Then, the flap is transferred to the breast (c) and the abdomen and breast are reconstructed (d).

Due to the importance of the perforators, each perforator is manually identified by the imaging team to support the surgeons locate the perforators when starting the surgery [5, 36]. This is done through MRI or CTA, which is performed preoperatively. The radiologists have a demanding task, which is to manually map the perforators, gathering the most relevant information for the surgeons to study. With the extracted information, the surgeons are able to map the perforators in the patient's abdomen at the beginning of surgery using a report with their coordinates, a pen, and a ruler (Fig. 2.3). Besides the perforators' coordinates, the surgeons are also given details of other characteristics collected such as the perforators' caliber, and intramuscular and subcutaneous courses.

2.2 Optical See-Through Augmented Reality

AR has the goal of adding computer-generated information into the real world, offering new solutions to improve the outcomes of surgeries, and allowing surgeons to have a better and real-time visualization of relevant information during surgery which comes from the alignment of both virtual and real objects [21, 22]. AR navigation systems can project three-dimensional models into the patients containing blood vessels, muscles, and whatever information the surgeons desire.

OST HMDs devices have been at the leading edge of research, having yet many limitations to address in order to become part of standard techniques and procedures [37]. The Microsoft HoloLens

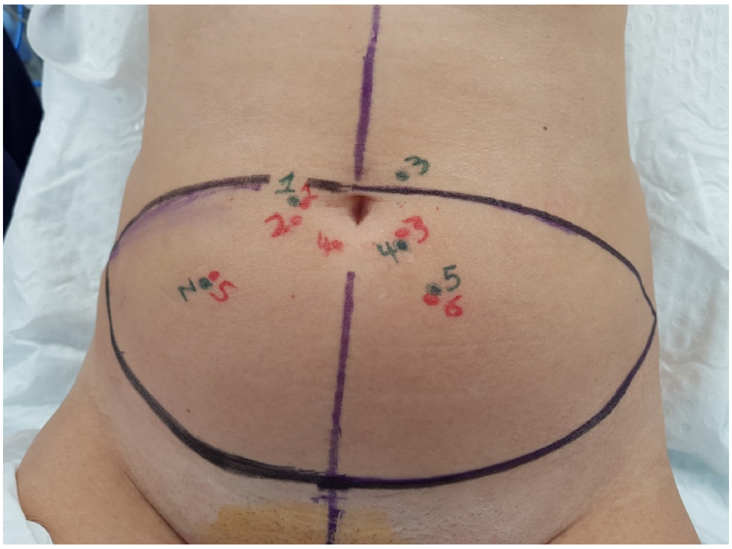

Figure 2.3: Mapping of the perforators' location according to the manual method (green) and an automatic software (red) [3].

are the avant-garde HMD currently. With these semi-transparent displays, it is possible to project three-dimensional virtual objects in the field of view of the user, providing a hands-free work possibility.

The HoloLens 2 is a head-mounted computer that enables the user to have an immersive experience of mixed reality (Fig. 2.4) [4]. They have a FOV of 96.1 degrees and a focal length of 1.08 mm. This headset contains five sensors in its visor: head tracking, eye tracking, depth, inertial measurement unit (IMU), and camera. Some of the HoloLens features include hand tracking, eye tracking, spacial mapping, voice commands, and a larger field of view. It is possible to collaborate with other users in real-time, to develop and solutions for the HoloLens, use third-party apps, among other functionalities.

Even though HMD devices such as the HoloLens have not been designed for surgical tasks, they have shown their potential in the latest research [25, 38]. Currently, the Microsoft HoloLens is the HMD with the most clinical potential due to its access to real-time information without interrupting the surgeon's workflow [39]. This device is considered safe for human functionalities, providing surgeons with information that would normally only be accessed by stopping the procedure and getting physical input. Despite the existence of some limitations, the healthcare industry has been the major investor in research that has been conducted using the HoloLens [40]. Other than being used for medical and surgical purposes, the HoloLens are being currently explored in other areas to solve different kinds of problems such as the design of spaces - including operating rooms. The HoloLens have also been used for civil engineering, education, tourism, etc.

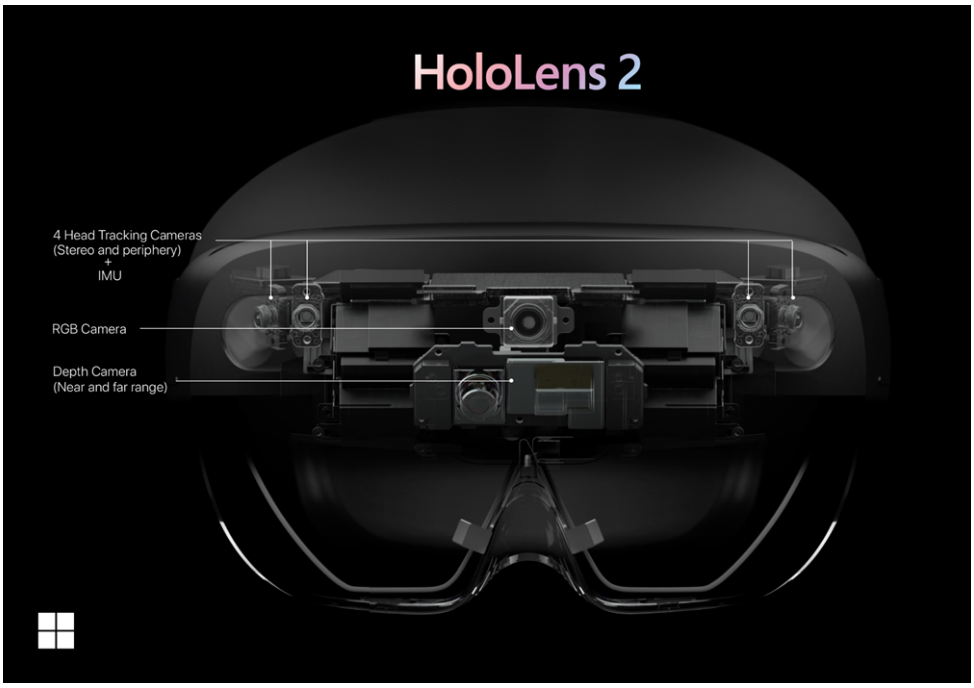

Figure 2.4: Front view of the HoloLens [4].

3

Related Work

Contents

Augmented reality promises to be part of the future of advanced medicine, contributing to more precise and efficient surgical procedures [21]. Several studies and experiments allow this evolution to happen. Thus, they are indispensable to go through when working on new approaches to a common problem.

3.1 Automatic Detection of Deep Inferior Epigastric Perforators

The automatic detection of perforators is not yet achieved with tools other than semi-automatic methodologies relying on computer vision such as the DUS, Angio CT, and the Angie MRI. These methods are used to map perforator branches before surgery to reduce the time spent on the process and its subjectivity [3]. In a pilot study presented by Mavioso et al. after gathering images obtained on an Angio CT, an analysis was performed with a tracking procedure that extracts the course of the perforator with a minimum cost approach to extract both the subcutaneous course and intramuscular course of the perforator. This methodology detected 88 percent of the perforators and reduced the time since there is an immediate detection with little input from the user. However, the algorithm tended to overestimate the caliber of small perforators - larger ones were well measured - and there was a small error on vertical positions, which is not severe since it does not affect the surgery in any way.

A radiologist manually identifies perforators through MRI or CTA, which are very time-consuming methods. Characterizing the 3D course of the perforators is complicated, expensive, and can lead to incoherences between preoperative moments and the actual surgical findings, leading to changes in the intraoperative strategy [5]. Computer-aided detection algorithms might help radiologists consume less time and reach a more accurate and complete description of the perforators. Araújo et al. proposed the use of a semi-automatic extraction of the perforators using a vessel center-line extraction technique. This happens through an accurate and objective extraction of the complete DIEAPs course, followed by tracking the subcutaneous portion of the perforators based on a local gradient field of a vessel-enhanced volume. The A* search algorithm is used to find the optimal and shortest path. Using the A* search algorithm with costs related to a vessel-enhanced volume, the intramuscular course of the perforators is extracted (Fig. 3.1). This is adequate for the tracking of the perforators, to detect where they leave the fascia. The algorithm reached accuracy for most of the volumes in the database while taking very little time to do so. This approach was more capable of neglecting the presence of the muscle when tracking the vessel. On the other hand, perforators that have a long course through the fascia make the tracking method unstable due to the corrupted gradient vectors and it usually stops earlier than it should.

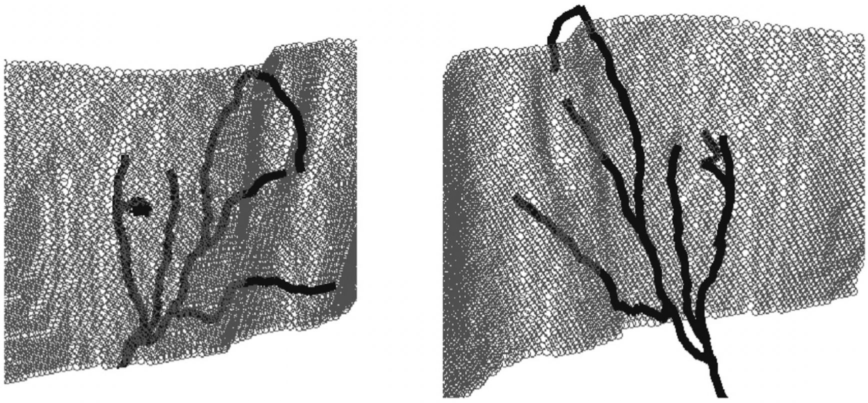

Figure 3.1: 3D representation of the fascia and the extracted vascular network of one hemiabdomen - DIEAP tree [5].

3.2 AR on Preoperative Planning

Mapping the small blood vessels (perforators) is a fundamental step in DIEAP Flap Breast Reconstructions as we know by now. The preoperative study done before the surgery can be upgraded with the projection of a virtual 3D plan based on CTA onto the patient's abdomen. Thus, the doctors are given a more visual and efficient way of locating these perforators, potentially decreasing the time spent on the dissection, its accuracy, and the patient's safety [41]. In this trial, Hummelink et al. conducted a randomized, open, single-center, superiority trial in about 60 adult patients doing DIEAP flap breast reconstructions with a one-week follow-up. The results were positive, since the projection proved to be effective, showing more perforators than the Doppler method. Regarding the procedure itself, the surgery was decreased by 19 minutes - which is a significant amount of time in such a delicate surgery - and the complications were the same for both methods. No registration errors were mentioned in this work.

In another paper regarding preoperative planning, Sato et al. aimed to decrease the surgery time by using computer guidance using ultrasonic images provided before the operation [6]. This was achieved by merging an optical three-dimensional position sensor that provides ultrasonic images. These are carefully measured to build accurate 3D tumor models, which are overlaid and provide live video images of the patient's breasts. This allows the surgeons to visualize the tumor's position with precision, as well as its invasions - which are many times hard or impossible to perceive unless by touching them (Fig. 3.2). The possibility of minimizing the risk of relapses and maximizing the breast's conservation with such a simple system is very thrilling. The only issue was the time it took to obtain the 3D models - 15 minutes or more - including the time it takes to evaluate the reconstructed 3D model with the doubtful areas in which tumors can spread.

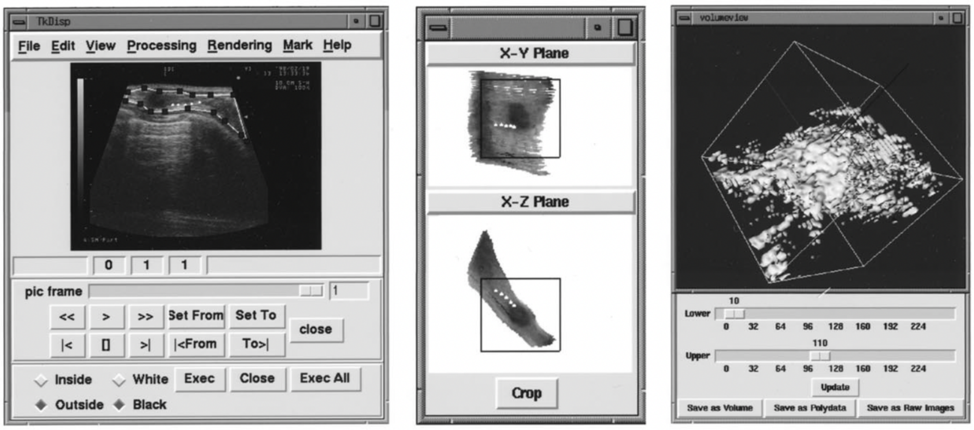

Figure 3.2: Tool for merging ultrasonic images into 3D tumor models [6].

The patient's position from the preoperational mapping to the operating field changes and it needs to consider, in order to reduce time and have good accuracy. Using a practical and small device to do the registration rounding ten minutes - assuming a dataset of twenty scans at most - might help map the information before surgery, with a most accurate expectancy of minimal or major alterations [27]. This can be achieved by building an anatomical complexity model with a skinning model comprised of scalable bones and blend shapes. These are manually designed into a model with the desired information. The result is a surface mesh of the patient reached in a few seconds, whose registration method converges within a few seconds equally. Due to the different positions, the models are challenging to reach and are approximated by blend shapes. However, the model's flexibility and easy regularization lead to consistent results, decreased computational time, and a lower deviation error - despite the use of many scans. Nevertheless, there would be a boost in the results and a time reduction if using validation on a larger population with a Bayesian Regularisation.

Using augmented reality glasses enables surgeons to visualize the perforator vessels of the DIEAP while keeping their hands free for preoperative planning [34]. An AR system that superimposes three-dimensional data collected from CT scans, used on a patient whose skin is marked, can make real-time tracking possible. The glasses contain two projectors and a camera that allow for the restoration of the filmed environment in high definition and with a field of view of 90 degrees. The tracking system of the skin traced allowed us to link the 3D elements to the patient with stability despite the movements, helping on locating the emergency zones of the perforators in a very straightforward way - no need for a remote screen whatsoever. The sensors and quality of the devices allowed us to really have an augmented visualization of the operative field with correction of reflections, color changes, shadow removal, and better lighting. However, in this article, Bosc et al. share their inability to perform any dissection because the quality of the restitution of the operating field through such devices still is insufficient and uncomfortable. In particular, the tracking system is not very stable because of the stroboscopic interaction between the

LED lighting and the video sensor of the glasses. No registration errors were mentioned in this work.

Augmented reality and virtual reality have been explored in many works, in an attempt of figuring out how they can be helpful and how to evolve the area in the best way possible. AR and VR have both been compared in preoperative planning of plastic surgical procedures with the technical accuracy of the procedure, operative time, complications, and costs by using a collection of searches done in *Embase, Medline (Ovid), Web-of-Science, Cochrane, and Google Scholar* databases on October 11, 2019 [42]. VR wasn't exactly well grounded on this study due to a lack of papers, which also impossibilities a comparison between AR and VR. However, the use of AR showed quite better accuracy compared to conventional methods, showing precise results. Regarding DIEAP flaps procedures, AR proved to be more accurate than the Doppler ultrasound, taking less time on surgery to map the perforators and, consequently, dissecting them.

3.3 Potential of Intraoperative 3D Models

When it comes to the intraoperative use of advanced technology such as described so far, much has been investigated and put into practice. Usual medical preoperative procedures to locate breast cancer are often invasive for the patient, time-consuming, and hard for the surgeon's visualization the tumor, requiring image guidance [7]. With this, the urge of using a digital and non-invasive intraoperative localization method using augmented reality has emerged. By using an AR headset such as the Hololens it is possible to visualize the tumor and help guide the surgery. The methodology consists of marking three reference points on the patient's breasts, followed by a 3D surface scan of the skin with the patient in the supine position with the arms at 90 degrees. Then follows the segmentation and volume computation of the MRI tissue portions.

After both of these modalities are overlapped and spatially aligned, including the tumor, they are ready to be uploaded to the Hololens. Then, using the HoloLens, the surgeon will see the tumor projected on the real patient, showing its precise location (Fig. 3.3). It's possible to conclude that AR headsets, used to visualize 3D digital breast models, find their way into a non-invasive method for intraoperative tumor localization. This not only improves the surgeon's abilities, but also the patient's well-being. However, accuracy is not yet perfect, having limitations such as the imaging being acquired in different positions, leading to deformations at the moment of the surgery.

As for using AR glasses for a hand-free 3D intuitive visualization - such as the Microsoft Hololens - its motivation comes as well from the importance of identifying and locating the epigastric arteries and perforators. Normally these are revealed in images and memorized by the surgeon. This can be a barrier to performing at full potential, since using a 2D projector also needs the surgeon to occupy one hand [23]. The process is started with image acquisition and segmentation of the relevant anatomy

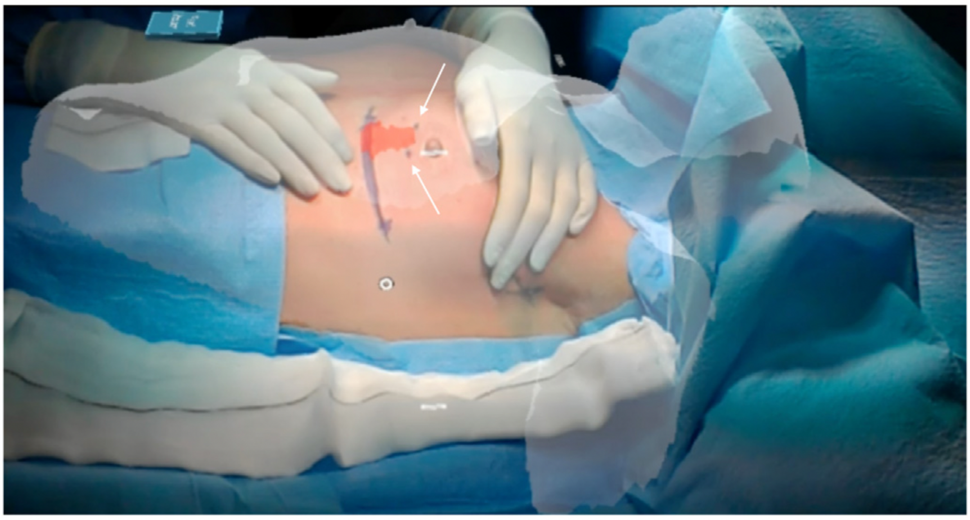

Figure 3.3: Surgeon's point of view when looking at the patient through the Hololens. Overlap between the two carbon tattooing marks (white arrows) and tumor projection with augmented reality (red color) [7]

structures, which are later imported to the Hololens. Then there's real-time tracking of the patient with response markers, followed by the registration and visualization of the patient's holographic anatomy. Real-time tracking using the Hololens allows the anatomy to stay correctly positioned on the patient, even through movements. The 3D holographic AR visualization provides an intuitive and strong perception of anatomy. Anyhow, the workflow of the 3D contents has a depth that might be difficult to estimate due to the real word hand or the fact that the tool does not interact with the content itself.

On the same matter, the following work suggests giving preoperative CTA imaging life for the surgeon to see through the patient's skin without making an incision, guaranteeing accurate identification of perforators [33]. The patient is scanned (CTA scan), followed by segmentation done to limit tissue deformation and facilitate accurate hands-free registration. Then, there is the performance of a model generation to do some refinement, mesh processing (with the help of MeshLab), and the use of the HoloLens App. The registration is executed manually to align the 3D model to the patient's body. The HoloLens have once again proved to be a powerful tool that reduces the anesthetic time as well as improving training and providing remote support. It is more reliable and less time-consuming. However, the presence of a technical assistant is still necessary for the preparation of the preoperative data, its initial application in the operating room, and the approximation of the spatial model position before the surgery starts. Pratt et al. concluded that in the future it would be important to work on automatic registration, volumetric rendering, and instantaneous model alignment, to correct for tissue deformation and measure the impact of the time consumed on surgery.

A hands-free device named VascuLens also experimented on DIEAP flap harvest surgery [17]. The speed and safety of the intramuscular flap dissection are fundamental and the Hololens are both expensive and inconvenient since the surgeons already use headlamps and operative loupes. In this study, the VascuLens are suggested as another simple option that also provides hands-free AR intraoperative guidance, capable of acknowledging the perforator interconnectivity. After mounting the projector above the surgical table, the software is run and the VascuLens generate the image, performs the registration generating the distorted destination projector image, and, projects the perforators´ locations onto the patient. This technique provides guidance to surgeons and keeps them in the loop. Performing the registration in 5 mannequins, the following mean absolute errors were obtained: 3.0 mm, 1.7 mm, 1.7 mm, 4.3 mm, and 1.7 mm. A possible improvement detected would be to brighten the light of the projector and quantify the magnitude of the intraoperative patient movement.

In previous research, we observe the consistent search for a high-fidelity reality-based system that can guide surgeons in surgeries of perforator flap transplantation, which are very difficult procedures. The preoperative image techniques help surgeons gather the most important information. However, there is less guidance during the surgery itself, which is why a system that could overlie a vascular map on surgical places has been put to study a lot as we've seen already [24]. In a new attempt to create a navigation system by mixing both AR and CTA data, the reconstruction of a virtual vascular map is done and projected in the patient using ARToolKit. Markers help with the registration, and after using a tracking display system it is run on an animal model for the system error to be measured. After registration of the 3D model, Jiang et al. obtained an error of 3.474 ± 1.546 mm. AR does provide precise information by displaying the 3D individual anatomical virtual model onto the operative field in real-time, allowing a faster recognition of perforators and consequently a safer dissection. What still needs to be worked on is the update rate of the virtual model which doesn't match with the surgical procedure and the radiation of the CT scan with precision. Moreover, if the perforators have a caliber below 1 mm, they are not detected by CTA and despite the increase in precision, there is quite an invasive registration used by the system.

Use of 3D photography has been used more frequently in pre-operation circumstances than intraoperative ones. The next study goes through three different visualization methods such as screen-based viewing, augmented reality viewing, and 3D printed models, followed by an interview with seven surgeons regarding its usefulness [16]. The process started with the preparation of 3D photography to compute morphological measurements of the specimen. Then, three modalities of visualization provided different representations of these photographs (screen-based viewing, AR and 3D printed models) and were analyzed by the surgeons. The interviews revealed much satisfaction regarding the very fast and practical use of 3D photography since it can reduce time in the operating room leading to fewer expenses. Concerning the HoloLens, it is overall too complex, due to its weight which can bring discomfort and even disturb the surgeons during surgery. Some of the surgeons wanted to see the 3D photograph on the chest wall, being in general a certain limitation when it comes to the incorporation of these technologies in the surgical setting.

Many technological advances have allowed doctors to locate perforators and their routes. However, the use of a smartphone with AR has not been properly explored since it can add information to reality [18]. Pereira et al. of the referred paper have done a study regarding the use of AR for micro-surgical planning with a smartphone (ARM-PS) as a dissection tool with the intention of mapping vessels. The 3D images were provided by CTA data acquisition, imported to a smartphone, and then used an AR app that used the camera of the phone to add those images to reality. This proved to be a non-invasive and accurate method that provides intraoperative findings that correspond correctly with all the ARM-PS drawings for the vessels and lymph nodes' location. The flap harvest surgery time decreased by 20 percent and there were no further problems with using this method.

3.4 Breast and Skin Mesh Registration

The process of skin mesh registration is a fundamental step for precise and accurate tracking of the perforators. To display the hologram of a patient's anatomy correctly through the HoloLens, there needs to be an accurate registration of the model with the abdomen of the patient. In the next study, Wesselius et al. designed a three-dimensional printed, sterilizable, stainless steel pointer with a laser engraved [23]. The HoloLens register the three-dimensional locations of the nevi by tracking the marker on the pointer and using a Procrustes algorithm, the HoloLens calculate how the models should fit over the patient. After the alignment, Wesselius et al. obtained a registration error of 8.8 $\pm$ 6.6 mm.

In the imaging modalities registration process, it is needed a patient-specific 3D digital breast model (phantom model). The model is achieved by gathering breast MRI to perform a 3D surface scan fusion while using one only fiducial marker and three infra-mammary breast surface markers [7]. The MRI is done in the prone and supine position, so the institutional protocol needs to adapt to the change of position of the patient. There are algorithms that simulate this position change, however, this technology can be profited without there being any change on the diagnostic institutional breast MRI registration protocols.

Breast surgeries, such as mastectomies, are increasingly chosen by women in the US. There can be repeated surgeries due to not removing all the tumor's extension. Thus, a mixed-reality system that projects a 3D "hologram" of images from a breast MRI onto the patient using the HoloLens has been proposed. The goal was to reduce the number of repeated surgeries, by accurately identifying the tumor's location during surgical planning [8]. The marking is done with the use of the HoloLens, but first, the surgeon has to align the 3D model to the patient. To perform the registration, ArUco tags are placed with their centers aligned with the centers of the MR-visible fiducial markers.

In this work, there was a small error obtained due to misalignment. To eliminate this error, skin markers that are visible both optically and on MRI could be printed in the ArUco tag shapes or the marker could be a grid pattern used over the skin of the breast using magnetic ink - the grid deforms according to the position of the arm and the deformation is seen in the camera view and MR images (Fig. 3.4 (a)). Another option of registration referred to in the article is to make marker-less breast tracking using a Red Green Blue-Depth (RGBD) camera (Microsoft Kinect V2) that can be used to overlay a breast model obtained from volumetric images onto the patient (Fig. 3.4 (b)). Thus, improving the registration process by deforming the holograms when anchored to the patient ensures accurate tumor location. Anyhow, the results are promising, and the surgeons showed excitement about incorporating mixed reality into their procedures.

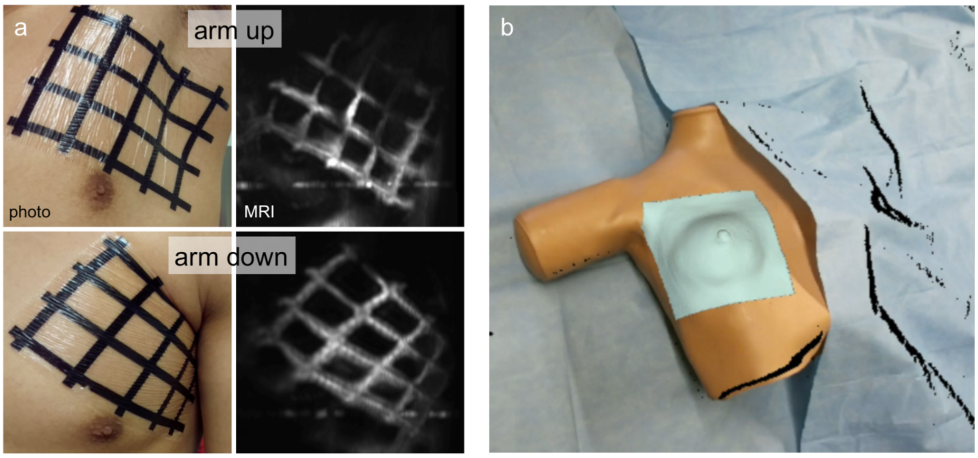

Figure 3.4: The two options of registration. The grid markers (a) and the mark-less model (b) [8].

Technology such as the HoloLens has good display stability for the projection of 3D models. However, there is currently a lack of automatic algorithms that detect a surface and align the model to it. Although there are options for the alignment of the 3D models with the real space using fiducial markers, the manual alignment has been explored and has some advantages [9]. Aligning the model to the surgical field requires reference points, that do not exist unless they are manually indicated. So, the manual alignment explored consisted of initially marking of three points on the body surface, which are then collected using a 3D imaging system. Then, a 3D model is created using these points as a reference (including them). In the moment of alignment (surgical field), three points are marked on the patient's body surface, corresponding to the points of the 3D model, allowing the alignment (Fig. 3.5). The time of alignment was 45.89 seconds and the mean error was 2.98 mm, proving it is a simple and easy method of alignment. The values were not very different from those obtained in other research works. However, further studies are needed to expand the use of HoloLens in the medical field.

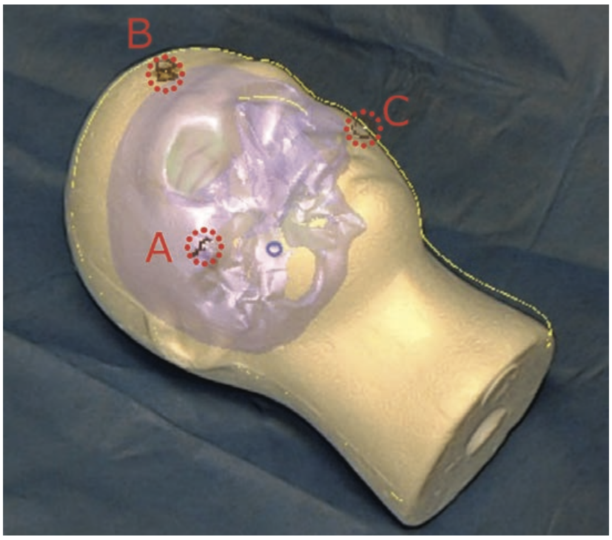

Figure 3.5: Alignment of the 3D model with the phantom, due to the three marks on both [9].

3.5 Discussion

We went through several works and studies regarding mostly DIEAP flap surgeries to understand their complexity (Table. 3.1). The use of AR and automatic detection of perforators have had their contribution to the medical field. Given this, it is important to put together the similarities of the results from these works and figure out where we can improve and add some contribution to what has already been done.

With respect to automatic detection methods to recognize perforators and their paths for DIEAP flap surgeries, a couple of problems were faced. An algorithm explored overestimated the caliber of small perforators, and there was a small error on vertical positions [3]. There was also an issue with tracking the perforators which make a long course through the fascia, making the algorithm stop before it should [5].

In the segment of three-dimensional models, their construction using ultrasound images takes too much time, especially when trying to predict possible areas where tumors can spread [6]. In another article, Bosc et al. were incapable of using the 3D model to perform the dissection of perforators due to it being insufficient and uncomfortable - a particular issue being the instability of the tracking system [34]. Accuracy is also not totally achieved due to the deformation of the skin mesh of the patient from the images being created in a different position from the moment of surgery [7]. There were also surgeons that expected to see 3D photography on the chest wall, but there is not much easiness in integrating these technologies in the surgical setting [16].

As for AR, the depth of the augmented contents might be difficult to estimate [23]. In a few works performed with AR glasses, there have been some limitations, such as the need for the presence of a technical assistant for the preparation and approximation of the data from before the surgery to the surgery itself. It also revealed that the registration, volumetric rendering, and model alignment should also be automatic to avoid errors and decrease time consumed [33]. The use of a 2D projector in one of the works faced a few issues due to insufficient lighting of the projector, along with the need for a magnitude quantification of the intraoperative patient movement [17]. Other work captured another issue concerning the HoloLens: some surgeons found it too complex and uncomfortable to use during surgery [16].

	Purpose				AR					Automatic Algorithms	
	Breast Plastic Surgery (w/ DIEP)	Tumor Removal	Generic Flap Procedures	Study	Intraoperative use of AR Glasses	2D Projection	3D Models	Real-Time Tracking	Smartphone (ARM-PS)	Semi-Automatic Method	A* Search Algorithm
[27]		X					X				
[7]		X			X			X			
[5]	X									X	X
[3]	X									X	
[17]	X					X					
[16]	X				X		X				
[24]			X		X		X				
[6]		X					X				
[42]	X			X	X						
[41]	X						X				
[8]		X				X	X				
[18]	X						X		X		
[23]	X				X		X		X		
[33]	X				X		X		X		
[34]	X				X		X		X		

Table 3.1: Overview of the related work.

Accurate registration of the 3D models using different methods was explored. A study designed a 3D printed, sterilizable, stainless steel pointer with a laser engraved [23]. The nevi marks location is obtained by tracking the marker on the pointer with the Hololens, using a Procrustes algorithm. Another study used one fiducial marker and three infra-mammary markers on the breast surface, detected by the HoloLens [7]. Still using the HoloLens, a study aligned the model using ArUco tags aligned with the MR-visible fiducial markers [8]. A manual method of registration was also explored by using reference points marked on the body surface and the same positioned points on the 3D model created [9]. Manual registration was considered sufficiently fast and accurate [33].

	Registration Process		
	Fiducial Markers	Manual	Marked Nevi
[23]			X
[7]	X		X
[8]	X		
[9]		X	
[33]		X	

Table 3.2: Overview of registration processes on the related work.

In this work, we will address some of these limitations to provide an improvement of AR tools. Previous research, as explored in this work, has led to registration errors in the range of [1.7; 8.8 $\pm$ 6.6] mm. Therefore, we start our work with a study to determine whether the deformation of the patient's skin mesh from the scan position to the surgery position is relevant. Afterward, our focus is to create an improved AR interface, allowing the surgeon to have a flexible interaction with 3D contents, a better visualization of those elements, and consequently a better performance in the preoperative moments of DIEAP flap reconstruction surgeries.

4

Methodology

Contents

4.1 Overview

BREAST Plus is a system created to help surgeons to visualize anatomy elements and better plan surgeries of breast reconstruction using DIEAPs. This system contains an interface of interaction, in which surgeons can not only collect information but also visualize contents in three dimensions and interact with them. This work also contains a study to determine the 3D patient's mesh deformation, in order to ensure the accuracy of the 3D model and the perforants' position, when anchoring it to the patient's body.

To achieve the goals of this work, it was divided into two main phases. The first phase consisted of the 3D patient's mesh deformation study, which required the collection and manipulation of data (Fig. 4.1). The acquired meshes were cleaned using MeshLab by removing irrelevant data points such as arms, scanned dust, or clothing. Each cleaned pair of meshes was then imported to CloudCompare where they were aligned using mesh alignment techniques. Afterward, four statistical outputs were provided for analysis: histogram, mean distance, standard deviation, and root mean square.

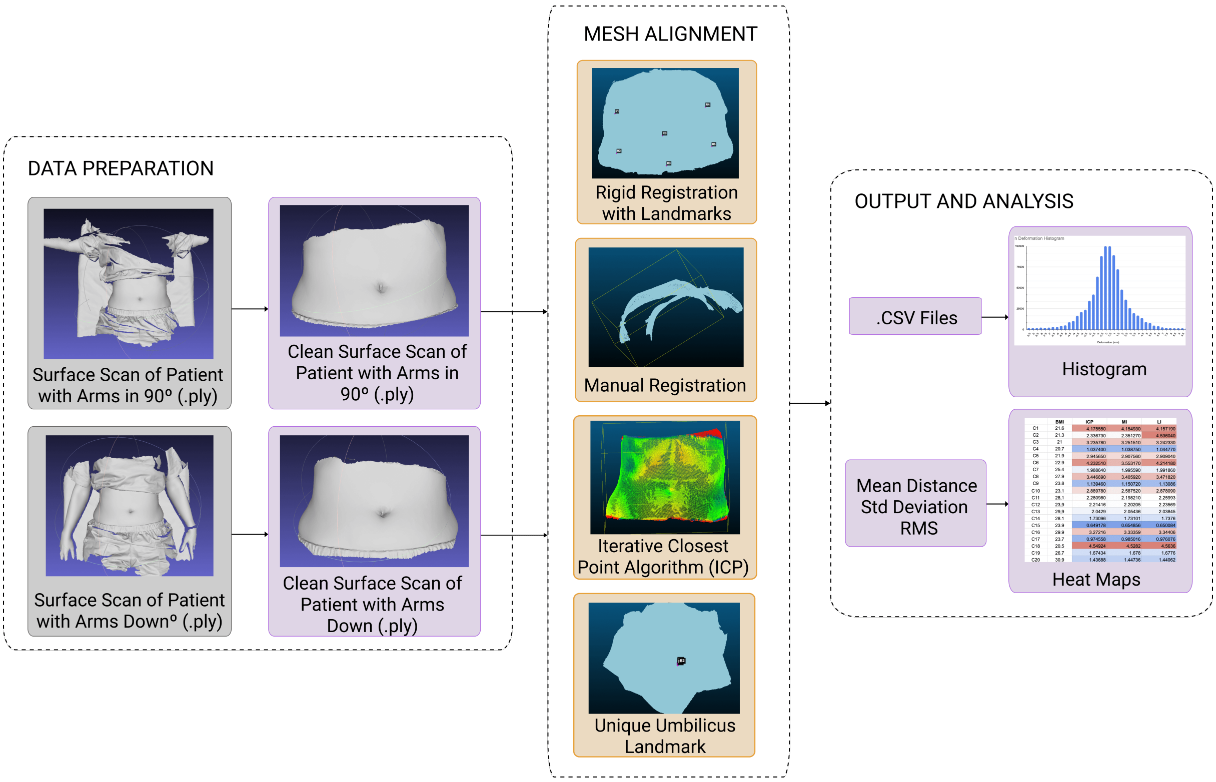

Figure 4.1: Skin deformation analysis pipeline.

Then, started the process of design of the interface of BREAST Plus, which was only possible with observation and co-design sessions. After the co-design sessions, started the phase of construction of the 3D model, which was totally dependent on data gathering. This phase included analysis of a XML file containing data of the patient's anatomical elements and the fusion of those elements with the patient's surface scan. The following phase was the development of the interface (based on the observation and co-design sessions) containing a menu and the 3D model constructed previously (Fig. 4.2). In the final phase, to conclude our work, we performed a user study to evaluate BREAST Plus' interface.

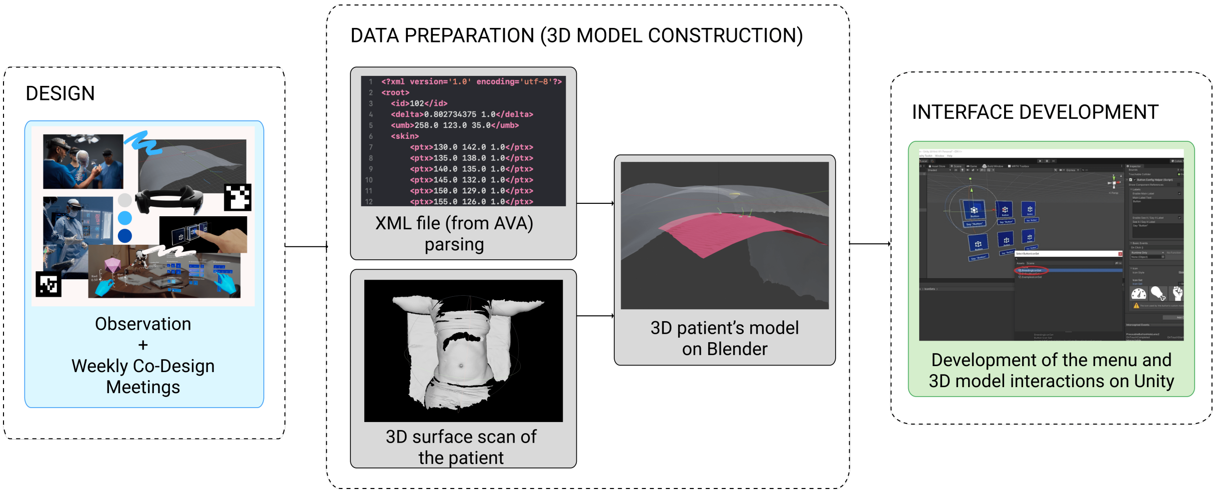

Figure 4.2: Pipeline of the data collection and development of BREAST Plus system.

4.2 Observation & Co-Design Sessions

Observation and co-design are fundamental to creating a system that meets the needs of the experts that are likely to adopt this technology in the future. Observation in loco allowed for initial and relevant brainstorming. Later, co-design sessions were conducted by both designers and non-designers. The goal was to go through a process of iterations as the design gets more refined [43]. The continuous changes in the design were done until the main requirements were developed (Fig. 4.3).

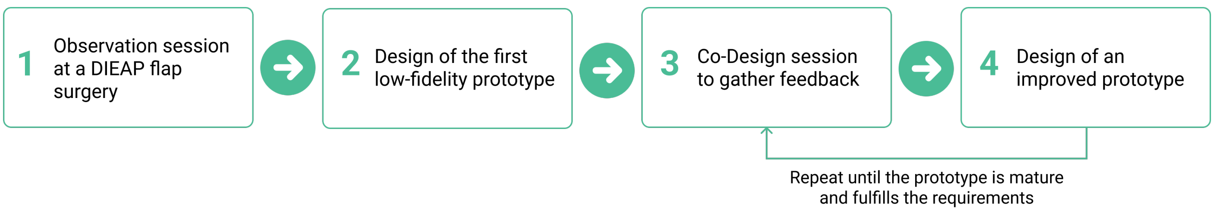

Figure 4.3: Design process: observation sessions and co-design sessions to achieve a final prototype.

4.2.1 Surgical Observation in Loco

Observing the dynamic in the surgical setting prior to designing a suitable augmented space is indispensable. It is the only way, combined with collecting information from the specialists, to meet their needs. The observation session took place during a DIEAP flap breast reconstruction surgery at the Breast Unit - Champalimaud Clinical Center. These sessions had the presence of four surgeons and a nursing team. By observing their workflow, we were able to have a clear view of the process of the planning phase of the surgery and gather very important information. The conventional pipeline used for this surgery starts with the collection of CTA data, which is sent to a radiologist team for analysis. The information collected is then used to create a report. In the planning of the surgery, the surgeons usually resort to the report to learn the characteristics of the perforators, and to make decisions regarding the course of the surgery. Then, the surgeons are also able to gain knowledge of the coordinates of the perforators in relation to the umbilicus and mark them on the patient's abdomen using a ruler and a pen. Despite containing enough information to plan and trace the perforators, the report resorts only to written information and no sort of visual representation of the perforators and their courses. In order to protect the patient's privacy, in this session there was no collection of videos, photos, or audio. However, notes were taken while talking to the surgeons and analyzing the operating room space, to understand how we could improve surgery planning with new tools.

During the observation session, the idea of visualizing all the information of the report in an augmented space was raised. This was the beginning of our work - BREAST Plus - since there proved to be a desire on seeing not only the written information but also a 3D visualization of the perforators and other anatomy elements. An expansion of reality was suggested, in order to add data on the surgical setting - which initial idea consisted of a menu and a 3D model of the patient's anatomy. These elements would be able to provide surgeons information usually seen on a physical report, as well as the possibility to interact with it and consequently be able to mark the perforators on the patient's skin at the beginning of surgery. According to the state-of-art literature, the HoloLens 2 are the HMD with best features for the surgical context [39]. Thus, we decided it would be the most appropriate for the purpose of this study - including the possibility of working hands free, as opposed to tablets or smartphones. The use of technology such as a projector placed on the roof was also not convenient nor appropriate due to the structure of the operating room and placement of the surgical lights.

With such a proposal, our purpose was to help the surgeons visualize the information in three dimensions, reducing subjectivity when analyzing the perforators' characteristics. Simultaneously, it would be possible to reduce time when tracing the perforators.

4.2.2 Co-Design Sessions

To achieve a high-fidelity prototype that met the surgeons' needs, it was established to meet weekly and discuss the changes in the design of the prototype. The informal meetings each week allowed the prototype to grow from low-fidelity to mid-fidelity and finally to high-fidelity prototypes. Along with sketches, some prototypes were developed and the specialists experienced their developed version through the HoloLens for usability feedback. The main goal was to develop an interface that facilitates the manipulation and visualization of the 3D model of the patient's abdominal anatomy, along with being able to have a digital version of the AVA report used in preoperative planning.

The first step was to collect information regarding the information that the surgeons desired to see in the 3D model. Based on that information, the model constructed contains the skin, perforators (including the subcutaneous and intramuscular layers), the names of each perforator, the fascia, and the patient's umbilicus (Fig. 4.4). To provide surgeons the possibility to interact with the model, there would be filters to hide or show the elements of the model. The feedback collected in the meetings was given by four specialists, namely: two breast surgeons, and a senior researcher in computer science engineering.

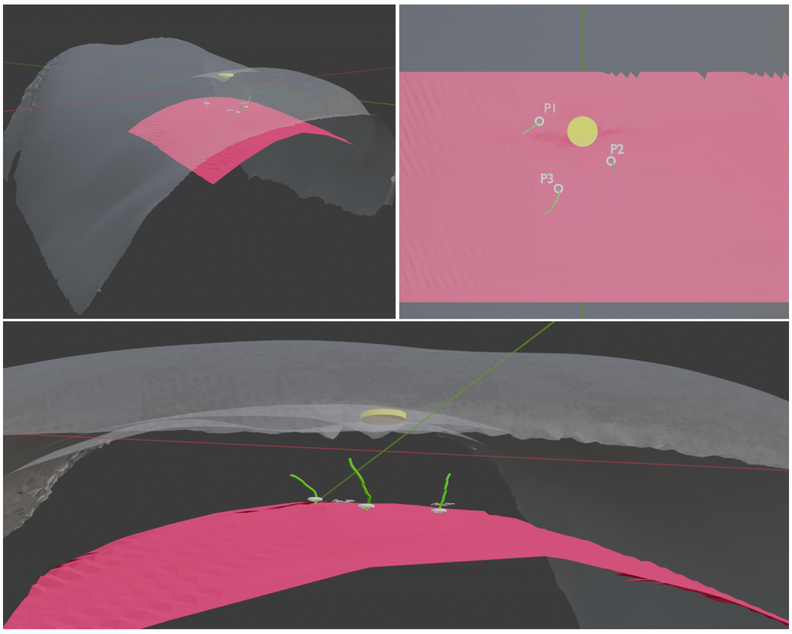

Figure 4.4: 3D Model of the patient's abdomen from three perspectives.

The first menu of filters designed contained filter options solicited by the specialists, such as a selection of the perforators on the right side, the perforators on the left side, the subcutaneous layer, the intramuscular layer, the skin, the fascia, and the perforators with a caliber above or equal to 2 mm or bellow 2 mm (Fig. 4.5). Within the handful of options of interaction that are achievable with the HoloLens, three options were analyzed: a hand menu, a near menu, and a menu possible to grab.

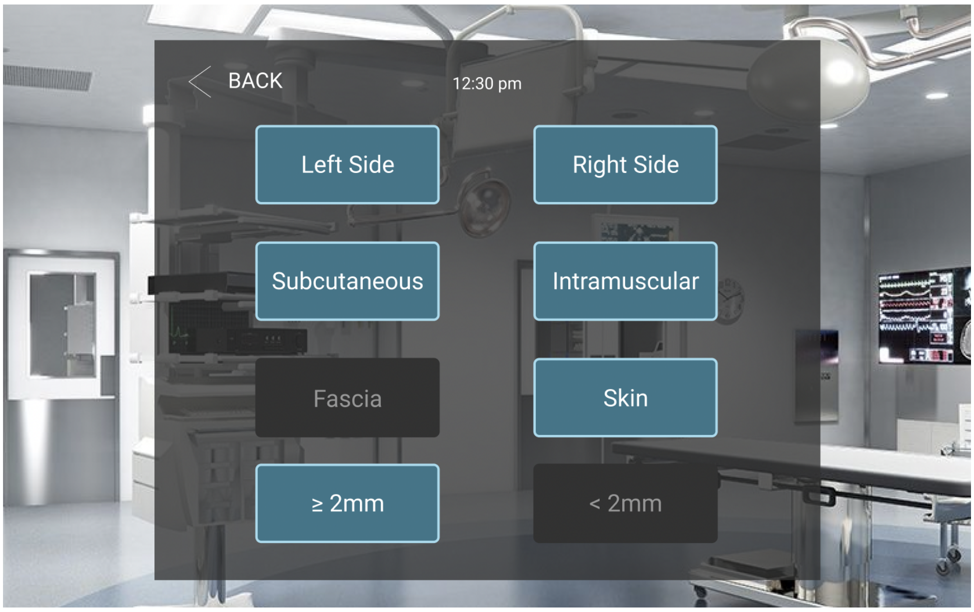

Figure 4.5: First low-fidelity prototype of the filter's menu - to be visualized through the HoloLens.

The first option of interaction presented to the specialists was a hand menu containing filter buttons and a transparency slider to alter the skin's opacity on the model (Fig. 4.6). This option was discarded since it required the hand to be in the field of view of the HoloLens all the time for the menu to be visible, as well as having the inconvenience of occupying a hand that can be of need to the surgeon.

After gathering more feedback from the specialists, we made changes to the design. The new menu design consisted of a menu that would float in front and a little above the field of view of the user. This menu would follow the user and would be available at all times without the need to raise any hand. This menu's content was also modified at the request of the specialists. New tools were added to improve the user's interaction with the model (Fig. 4.7, Fig. 4.8), which consisted of complementary buttons to change the model's position in millimeters for more precision.

An experimental session was planned with the specialists and new feedback was collected regarding the near menu: the menu was still not comfortable enough since the user needed to constantly look up to find it. After brainstorming about the menu and the information it contains, a new menu was then created to fulfill all the requirements. The menu's design had the appearance of a refined AVA report, containing not only the buttons to filter the elements and manipulate the model, but also containing familiar information to the surgeons about the perforators (Fig. 4.9). With the addition of the AVA report's information, the surgeons would be able to have a better transition from using the usual physical report to an augmented reality device with 3D elements. A button for fine-tuning would be included, providing a box around the model for precise manipulation of its position, to complement the manual rough manipulation.

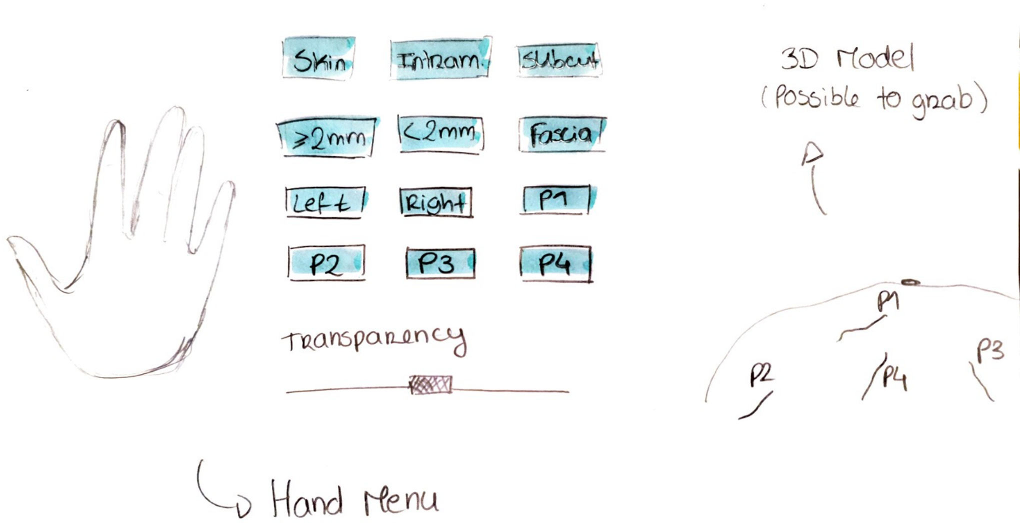

Figure 4.6: Low-fidelity prototype option of the filter's menu that appears next to the palm of the user's hand - to be visualized through the HoloLens.

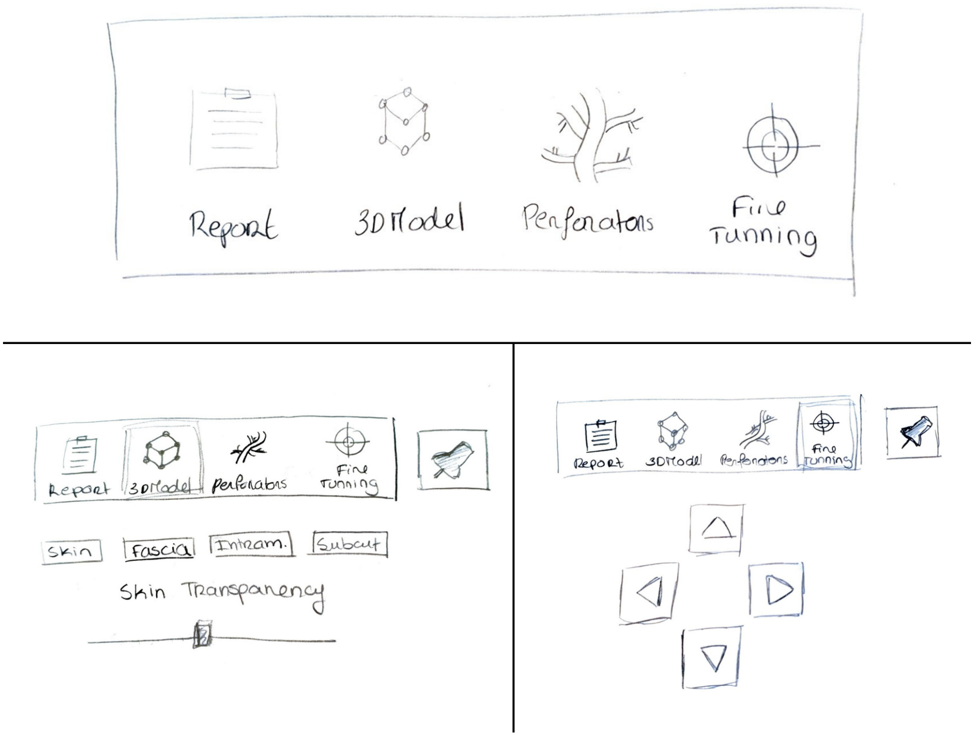

Figure 4.7: Sketches of the near menu that was always in front and above the FOV of the user.

Figure 4.8: Sketch of the POV of the user using the near menu.

Figure 4.9: Sketch of the menu with a report-like appearance (on the left side) and two separate buttons (on the right side) for manipulation of the model's position.

4.3 Data

To perform the 3D skin mesh deformation we had to perform surface scans of the abdominal area of volunteers. The surface scans were acquired using the Go!Scan 3D handheld (CreaformTM[1]), a handheld 3D scanner. As output, we decided to choose the format of PLY to facilitate the alignment between the pairs of meshes and the following computation of distances between their points.

As for the 3D model of BREAST Plus, we used data collected from CTA scans. The CTA scan provided information given as input to the AVA - an automatic system that analyses the CTA scans and gives as output relevant information regarding the perforators [5]. The output is a XML file. This file contains the coordinates for the points of all elements gathered: the skin, fascia, umbilicus, perforators (intramuscular and subcutaneous path), and the caliber of each perforator. By parsing this file and transforming the data into 3D objects, it is possible to export them to Unity and develop the interface. For such, the XML data is parsed to create .OBJ files. Below there is an example of a shortened XML file containing the elements described:

Listing 4.1: Example of a XML file.

```
<?xml version='1.0' encoding='utf-8'?>
<root>
    <id>xxx</id>
    <delta>0.802734375 1.0</delta>
    <umb>258.0 123.0 35.0</umb>
    <skin>
        <ptx>130.0 142.0 1.0</ptx>
        <ptx>135.0 138.0 1.0</ptx>
    </skin>
    <fascia>
        <ptx>160.0 138.0 16.0</ptx>
        <ptx>160.0 138.0 21.0</ptx>
        </fascia>
  <tree>
    <perforator>
        <caliber>2.29</caliber>
        <subcut>
            <ptx>184.87969419594805 124.22546669626499 29.0</ptx>
            <ptx>185.60698436529128 124.5715974958782 29.0</ptx>
```

[1] https://www.creaform3d.com/en/handheld-portable-3d-scanner-goscan-3d

```
            </subcut>
            <intram>
                <ptx>224 158 76</ptx>
                <ptx>224 157 75</ptx>
            </intram>
        </perforator>
    <perforator>
```

4.4 3D Patient's Skin Mesh Deformation

In this study, we perform a descriptive statistical analysis and statistical inference. A descriptive statistic summarizes the data and attributes a description of the samples analyzed [44]. Then, statistical inference allows us to expand and generalize the results of a sample, to a larger population [45].

Twenty volunteers from the medical staff at our Breast Unit were proposed for image acquisition with 3D surface scanning in two different positions. The first position is conducted with the volunteer in the position of the patient during the CTA Scan, in which the arms are down close to the body. The second position is conducted with the volunteer in the position of the patient during surgery with the arms open at 90 degrees (Fig. 4.10).

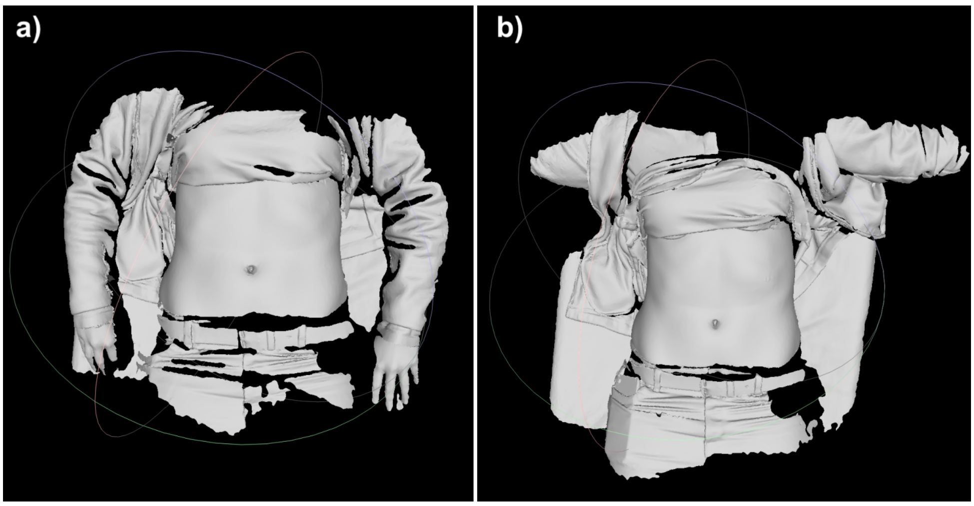

Figure 4.10: Volunteer in the position of the patient during the CTA scan (a) and in the position of the patient during surgery.

The 3D surface scans contain irrelevant points for the study and can negatively affect the results if present while aligning the meshes (Fig. 4.11). Since skin area at abdominal and lower abdominal levels are our focus, every data point outside this area is removed using the MeshLab[2] software. MeshLab contains a tool named “Select Faces in a rectangular region”, which allows the user to select areas on the mesh to remove (Fig. 4.12).

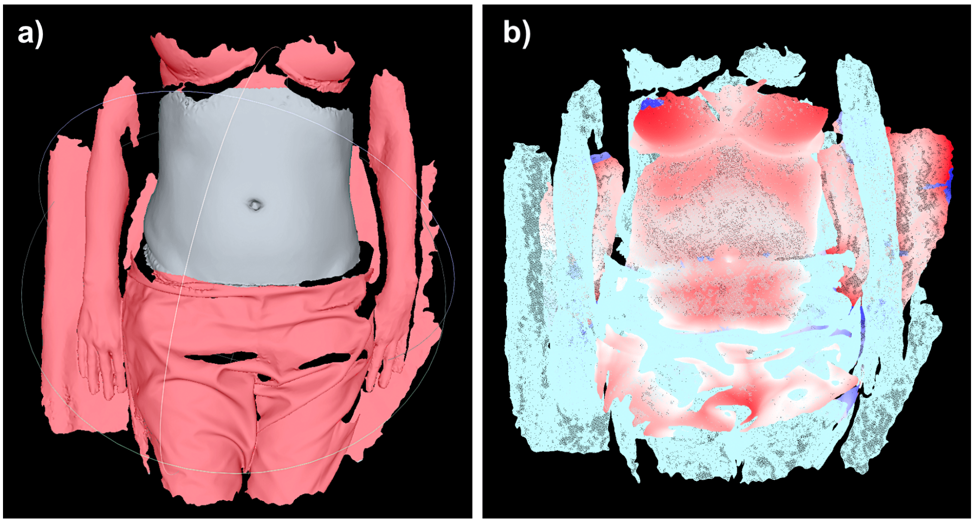

Figure 4.11: Example of a surface scan that captured parts of the body of the patient that are irrelevant to the study (selected in red (a)) and affects the alignment of the meshes negatively (b).

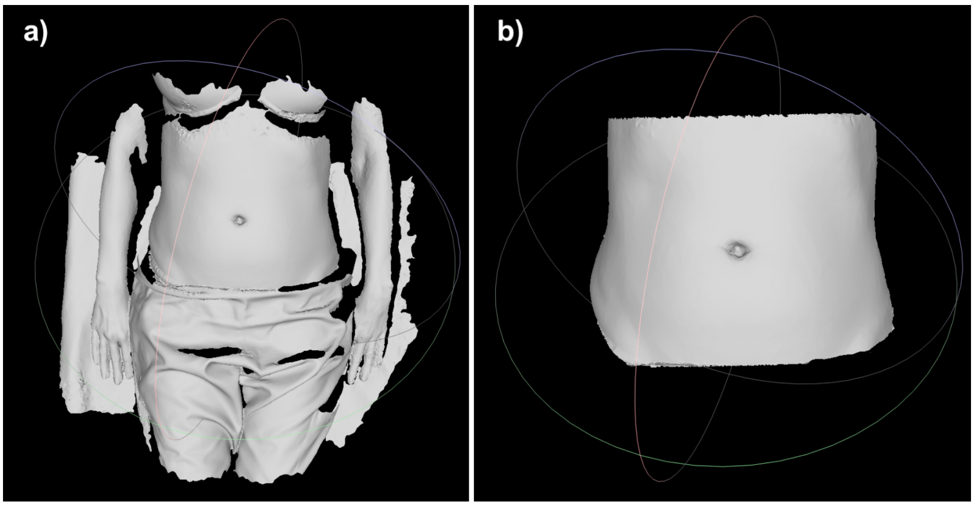

Figure 4.12: Mesh before (a) and after (b) the use of the tool for removing selected areas on MeshLab.

Afterward, the alignment of the meshes and respective acquisition of results is achieved on the CloudCompare[3] software (Fig. 4.13). There are several methods of alignment, and some of them were used to make sure that the methods chosen do not influence the results. Each pair of meshes is aligned using seven different methods which consist of combinations of four distinct types of alignment - ICP,

[2]https://www.meshlab.net
[3]https://www.cloudcompare.org/main.html

manual alignment, and alignment with point pairs - for a more precise evaluation of the deformation.

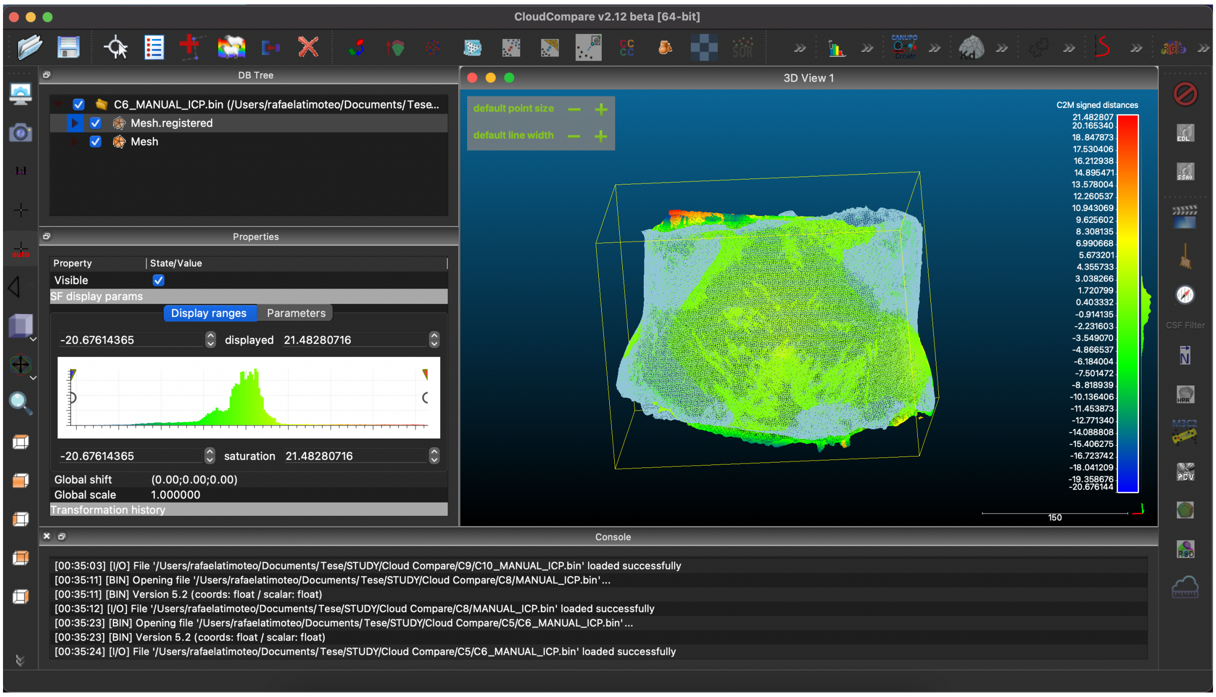

Figure 4.13: CloudCompare Interface

Best alignment methods applied to align each pair of meshes:

- ICP Algorithm [46]: automatic alignment employed to minimize the difference between two similar point clouds that are already registered roughly.

- Manual and ICP: manual alignment using the touchpad to control the position and rotation of the meshes until they look merged, followed by the performance of the ICP algorithm.

- Six Landmarks and ICP: alignment by registration of six landmarks on the abdominal, followed by the performance of the ICP algorithm.

After the alignment is concluded, the distance between the point clouds is automatically calculated with the Cloud-to-Mesh Distance (C2M) algorithm. Each point of one cloud would search for the nearest triangle in the other cloud during computation. After the computation, the compared cloud will possess a color scale representing the distance between the points from it to the reference mesh. Three outputs are returned: mean distance, standard deviation, and root mean square. Additionally, CloudCompare provides a .CSV file containing all points of the computed mesh distributed in intervals of the C2M signed distances to the reference mesh.

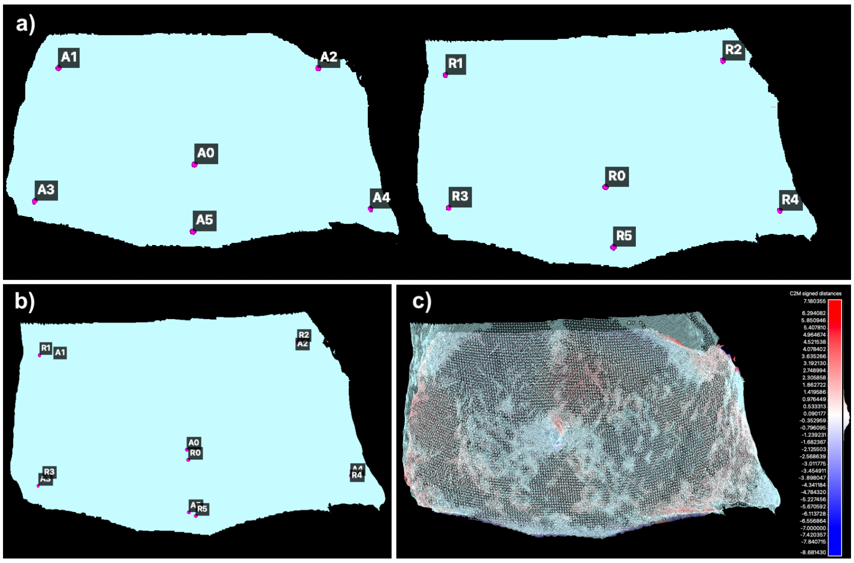

Figure 4.14: Six landmarks plus ICP algorithm: six points were registered on the two meshes (a). These points are used as references for the alignment, which was then followed by the ICP algorithm (b). Color scale of the distances between the meshes after the alignment is done (c).

4.5 3D Model

4.5.1 Parser

The first step in creating the 3D model is the transformation of the input from the XML file into 3D objects. To do so we developed a parser with the Python (version 3.8.9) programming language using the xml.etree.ElementTree module - an efficient API to parse XML data.

The developed parser goes through several sections of the XML file to create separate .OBJ files corresponding to the anatomy element. Each code line inside each section and between tags corresponds to a point of the 3D object. By gathering all these points and creating a Wavefront .OBJ file with them, it is possible to import the 3D object later into 3D software for design purposes. Therefore, the final output will consist of several .OBJ files: the skin, all the intramuscular paths of the perforators (separately), all the subcutaneous paths of the perforators (separately), and the fascia.

4.5.2 Blender

After gathering the separate 3D objects, it is then possible to create the complete 3D model. The analysis and construction of the model were performed using the Blender[4] software (Fig. 4.15). Blender is a free, open-source software for the creation of three-dimensional content, giving us the necessary tools to manipulate the data extracted from the XML file.

[4]https://www.blender.org/

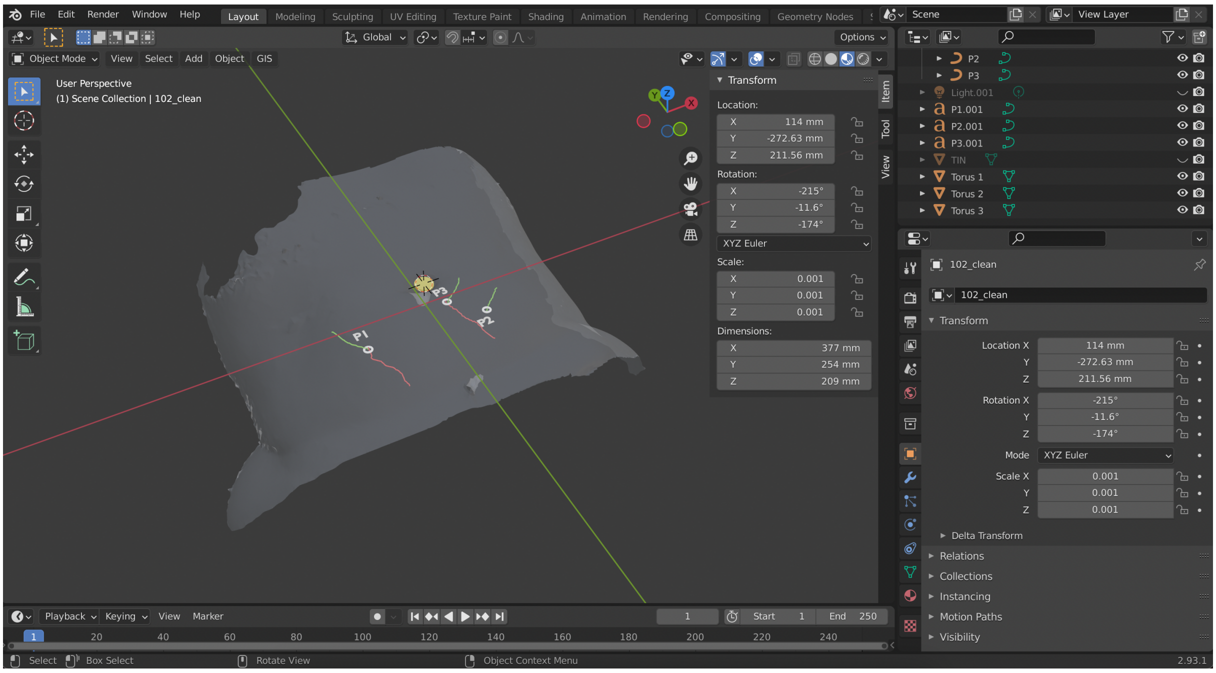

Figure 4.15: Blender's interface while working on the 3D model.

Firstly, the perforators' radius was very thin, so Blender provided tools to increase them. Then, to transform the fascia points into a surface, we used an extension of Blender named "Blender GIS". This extension contains a tool that performs a Delaunay triangulation, which is appropriate to create a 3D surface from points. The type of vector representation of the surface is often called TIN (Fig. 4.16).

The next step is to perform a fusion of the surface scan of the patient with the data collected from the XML file. The surface scan is a fundamental part of the model, since it will be very important for the alignment of the 3D model to the patient in surgery. The fusion is performed manually, using as reference the umbilicus and the skin acquired from the XML file.

4.5.3 Visualization & Data Encoding

After the elements are all put together, the next step was to change the default colors of the .OBJ files into informative colors that would be easily visualized through the HoloLens later on the work (Fig. 4.17).

The final model is composed by:

- Skin;
- Fascia;
- Umbilicus;
- Intramuscular and subcutaneous paths of the perforators;

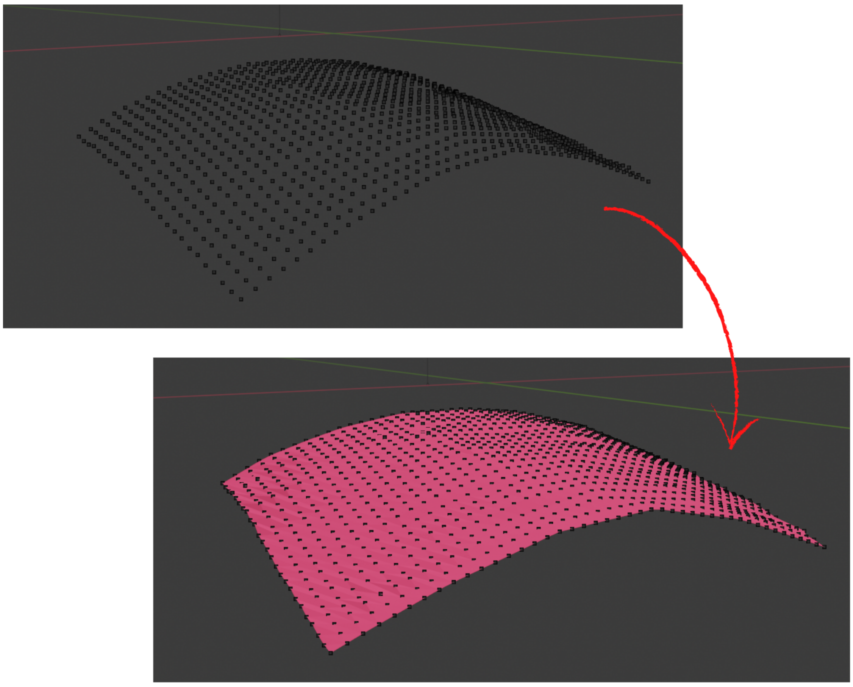

Figure 4.16: Use of the Delaunay Triangulation to create a surface (corresponding to the fascia of the patient) using the points extracted from the XML file.

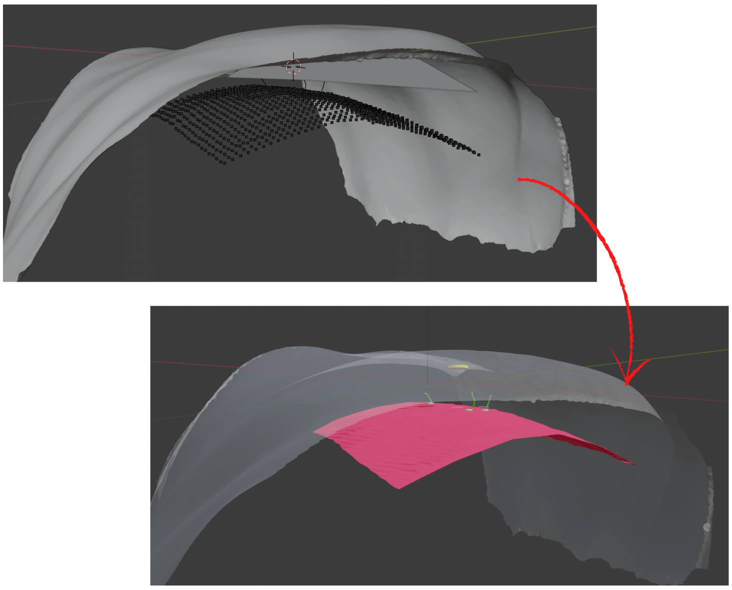

Figure 4.17: Model before and after the manipulation of colors and added visual information.

- Circles of the point in which the perforators cross the fascia (Fig. 4.18);
- Names of the perforators as described in the menu (Fig. 4.18);

Color coding is very important and was discussed in the co-design sessions with the specialists to ensure a good representation of the elements, especially the perforators. For the perforators we decided

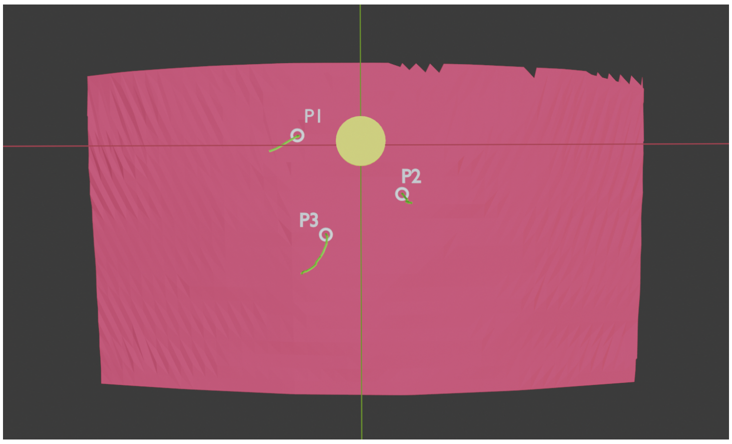

Figure 4.18: View from above, showing the umbilicus, the fascia, the subcutaneous path of the perforators, their names, and the crossing point with the fascia.

there would be three colors of encoding: red would represent the intramuscular path of the perforator, blue would represent the subcutaneous path of perforators with 2mm or less of caliber, and green would represent the subcutaneous path of perforators with more than 2mm of caliber.

When the model was ready, it was exported from Blender as an FBX file, which is a 3D file format that allows the exchange of 3D geometry and animation data. The FBX file was then imported into Unity for the development of an interactive interface.

4.6 BREAST Plus Interface and Interaction Techniques

The interface was developed using Unity (version 2020.3.8f1), the MRTK (version 2.7.3), and Microsoft Visual Studio (version 17.1.1). When building an augmented reality interface, it is important to consider both the visualization and the interaction with the elements [47].

When the BREAST Plus app is opened in the HoloLens, the user can see a panel with a welcoming message with a description of BREAST Plus (Fig. 4.19). For the user to proceed, it is necessary to press the start button, after which the menu (Fig. 4.21) and 3D model will appear in front of the user. Both these elements are not associated with any surface, instead, they are suspended in the air. These elements are always available but never follow the user. Their placement is entirely up to the user. Thus, it is possible to interact with the elements and transport them to where is most convenient.

The interaction techniques chosen are mainly by mid-air inputs involving the hand-tracking features available in the HoloLens 2. These hand movements allow for direct manipulation of the interface (Fig. 4.20). One of the interactions available to perform in the menu (Fig. 4.21) is grabbing using one or both hands, for the change of its scale and position - including rotation (Fig. 4.20 (b)). This way the surgeons can choose where to position the report in the most convenient place in the surgical room. After

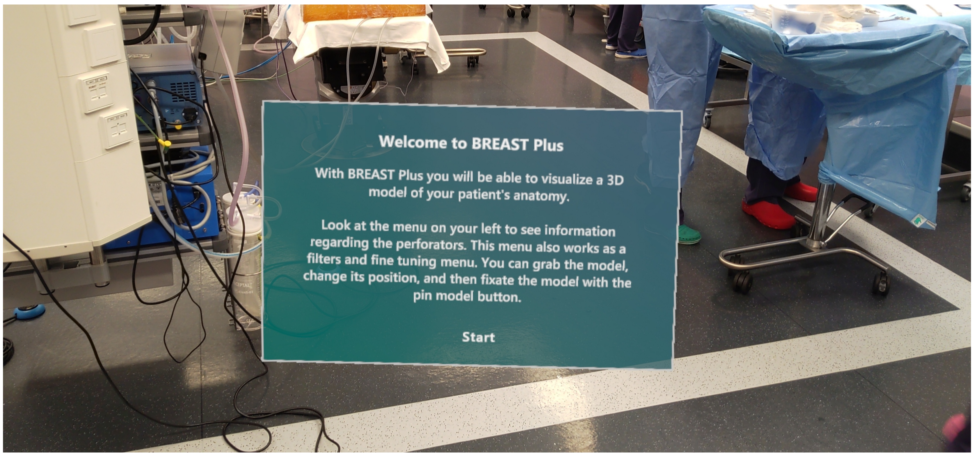

Figure 4.19: Welcoming panel with a brief description of the interface of BREAST Plus.

the menu is correctly positioned, it is possible to pin it so it doesn't react to incidental hand gestures. To press the menu buttons, turning them on and off, the user needs to point their finger at the button and press as if it were a real button (Fig. 4.20 (a)). Besides the buttons, a pinch slider to change the model skin's transparency is available. To interact with the pinch slider the user must perform a pinching hand movement, by closing the index finger and the thumb (Fig. 4.20 (c)).

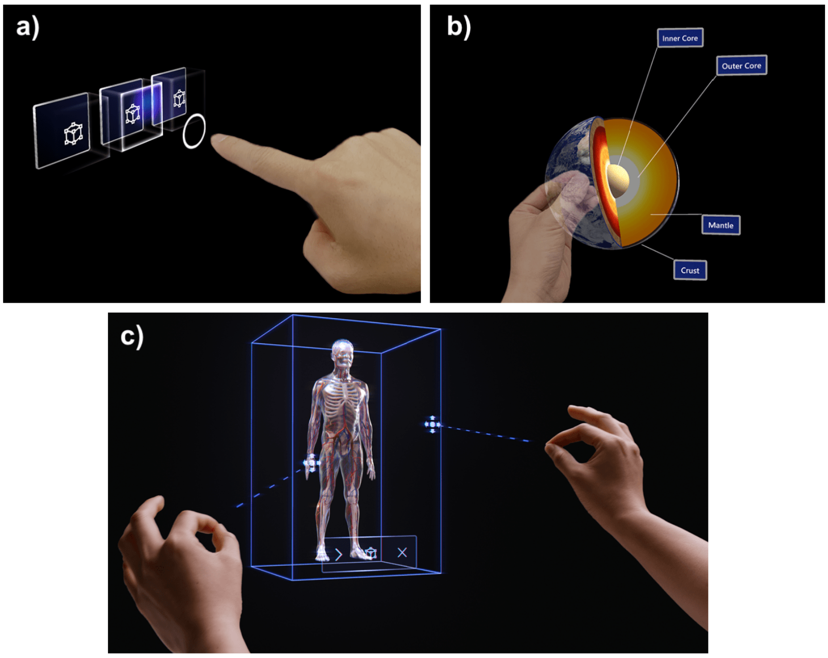

Figure 4.20: Hand gestures captured by the HoloLens used in this system: selecting gesture (a), grabbing gesture (b), and pinching gesture (c).

As for the 3D model, it is possible to grab as well, using one or both hands, only for the change of its position - including rotation. For a better alignment of the model to the patient and consequent calibration, the fine-tuning button on the menu is available. If this button is pressed, a box appears around the model with widgets, which are used to perform more precise transformations - such as translation and rotation on each axis isolated (Fig. 4.22). The interaction technique used in the widgets' case is the pinching hand gesture, as described previously (Fig. 4.20 (c)).

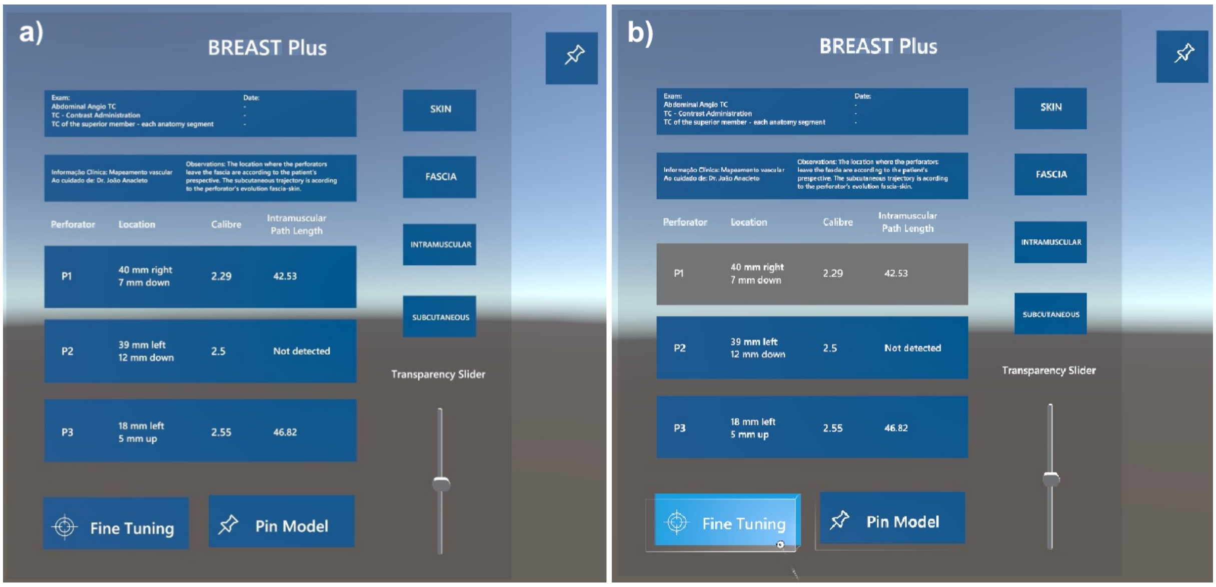

Figure 4.21: (a) Report-like menu for interaction with the 3D model. (b) Example of interaction with the menu: a perforator was hidden (the button's color changes to grey) and the fine-tuning was activated (the button's color changes to light blue).

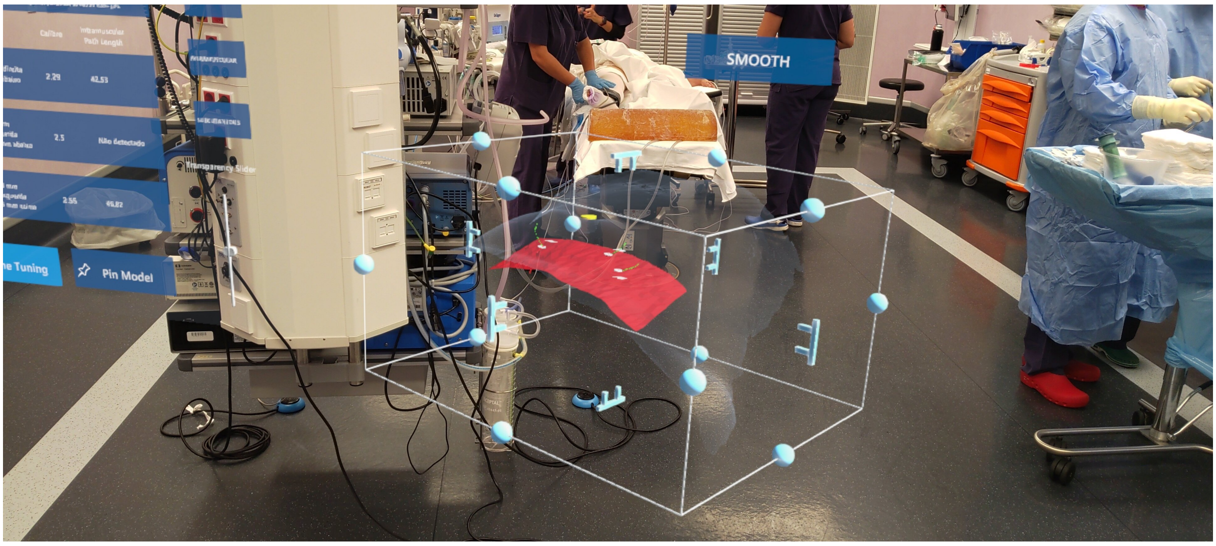

Figure 4.22: View of the fine-tuning box from the HoloLens in the operating room, a few moments before the beginning of a DIEAP flap breast reconstruction surgery.

4.7 User Study

To validate the interface, it is fundamental to experience it in a DIEAP flap reconstruction surgery. Due to the limited number of these surgeries, and added complexity of data collection to prepare the 3D model and interface, only two surgeries were expected for the performance of a qualitative usability study. In this study, performed in the Breast Unit - Champalimaud Clinical Center, three expert plastic surgeons experienced the interface and used it to mark the perforators in the patient's skin. Before the beginning of the experiences, all surgeons were asked to fill out forms for demographic information collection, as well as consent to the collection of data during the experience (Appendix A). Our main focus was the usability of the system. The surgeons were asked to perform a couple of essential tasks, starting with a habituation task to get familiar with the interface. A brief explanation was also given in regard to the gestures recognized by the system to interact with the interface. The habituation task consisted of fundamental steps that prepare the user to perform the principal task.

Then, the surgeons were asked to perform the principal task with the knowledge obtained on the habituation task. The user was now free to use the interface freely and experiment with all tools. When the goal of marking of the perforators is achieved, the experience ends. Due to the lack of more surgeries and experts to perform a quantitative study addressing effectiveness, we did not measure the times of performance.

After the experience, the surgeons were asked to fill out a NASA-TLX and a SUS questionnaire (Appendix A), as well as to answer a small semi-structured interview. Thus, it is possible to estimate the workload of the user, validate the system's usability, and understand the users' level of satisfaction.

The raw NASA-TLX is a multi-dimensional rating scale, in which is estimated a sensitive and well-grounded estimate of workload on a scale of 0 to 100 [48] (Table 4.1). We decided to use the raw NASA-TLX, which doesn't use weights of pair comparisons. The raw NASA-TLX is more simple and has the essential equivalence to the original NASA-TLX, promising greater potential in research settings [49]. The sub-scales consist of six workload-related factors (Table 4.2).

Workload	**Value**
Low	0-6
Medium	10-29
Somewhat high	30-49
High	50-79
Very High	80-100

Table 4.1: NASA-TLX score interpretation.

The SUS is a reliable tool for measuring the usability of a system with ten items on a scale from 1 to 5 (from strongly disagree to strongly agree) [50]. This questionnaire covers the three most important aspects that characterize usability: effectiveness, efficiency, and satisfaction (Table 4.3). The evaluation of usability, as provided by SUS, is extremely related to the context the interface is used and how appropriate it is.

Regarding the use of BREAST Plus interface to complete the task...
Mental demand: How mentally demanding was the task?
Physical demand: How physically demanding was the task?
Temporal demand: How hurried or rushed was the pace of the task?
Performance: How successful were you in accomplishing what you were asked to do?
Effort: How hard did you have to work to accomplish your level of performance?
Frustration: How insecure, discouraged, irritated, stressed, and annoyed were you?

Table 4.2: NASA-TLX questions.

Regarding the use of BREAST Plus interface to complete the task...
I think that I would like to use this system frequently.
I found the system unnecessarily complex.
I thought the system was easy to use.
I think that I would need the support of a technical person to be able to use this system.
I found the various functions in this system were well integrated.
I thought there was too much inconsistency in this system.
I would imagine that most people would learn to use this system very quickly.
I found the system very cumbersome to use.
I felt very confident using the system.
I needed to learn a lot of things before I could get going with this system.

Table 4.3: SUS Questionnaire.

The first step to scoring the SUS is to convert the raw item scores to a scale from 1 to 100. For the odd numbers, the raw score should be subtracted by 1 and for the even numbers, subtract the raw score from 5. Then, the sum is computed and multiplied by 2.5. [51]. The correspondent equations is described below:

$$\begin{aligned} SUS = 2.5(20 + SUM(SUS01, SUS03, SUS05, SUS07, SUS09) - \\ SUM(SUS02, SUS04, SUS06, SUS08, SUS10)) \end{aligned} \tag{4.1}$$

The resulting SUS score can be mapped using an adjective scale as represented in (Fig 4.23) which highly correlates to the SUS scale [10]. Due to "OK" being an ambiguous word, it is considered to suggest a system is acceptable. The adjective rating scale is a useful tool to obtain a subjective label and interpretation for a SUS score.

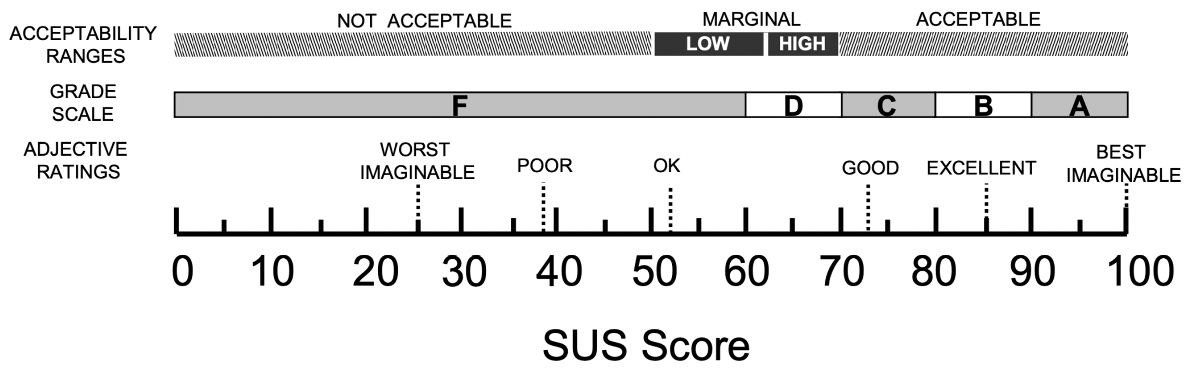

Figure 4.23: SUS score scale with comparison to acceptability scores, school grading scales, and adjective ratings [10].

The last step was to perform a semi-structured interview to collect final feedback regarding the system (Table 4.4). Semi-structured interviews consist of open-ended statements and theoretical questions, which create space for the participant to deliberately expose thoughts and emotions about their experience [52].

Regarding the BREAST Plus system...
In your opinion, the Breast Plus system is additional, not additional, or is it an alternative to the traditional method? Is this method of marking the points preferable to the conventional method?
Does the interface (menu + 3D model) make the data reading more efficient and effective?
What did you like the most (advantages/benefits) about this augmented reality tool during surgery? Why?
What did you like less (disadvantages/limitations) about this augmented reality tool? Why?
What difficulties did you have using this tool? (Calibration, usability, data analysis, etc. . .)
Is there anything you would add or remove from the interface?
Do you find it possible to adopt this kind of technology in surgical practice?
If the answer is yes, how come?
If the answer is no, what barriers do you see?
Considering the tasks you performed, what would you change about this tool to make the process more natural/familiar/intuitive?

Table 4.4: Semi-structured interview.

5

Results & Discussion

Contents

The following section will cover the findings of our studies, based on the methodology planned to gather information.

5.1 Overview

After the acquirement of results from the 3D skin mesh deformation study, we were able to perform a descriptive statistical analysis and statistical inference. This allowed us to comprehend the level of accuracy of the 3D models built with data acquired with the patient in one position - CTA scan - and its display on the patient later in another position - the operating room. Determining the amount of deformation is fundamental for the future high-fidelity display of 3D contents using AR.

Afterward, began the phase of design and development of the BREAST Plus interface. As soon as the system was fully developed, we decided to start the phase of evaluation to understand if BREAST Plus was able to meet the surgeons' needs. The goal was to improve the preoperative planning and the intraoperative moment of visualizing and marking of the perforators in the patient's lower abdomen in DIEAP flap breast reconstruction surgeries.

To conduct an adequate user study, we had the opportunity to have the contribution of three experienced plastic surgeons to experiment with the interface in the preoperative moments of two real surgeries. Before the beginning of the experiences, the participants answered demographic and consent questionnaires. The experience itself consisted of completing several tasks, which help evaluate the usability of the system. We did not measure the error of registration and marking of the perforators, since our main concern was the usability of the interface.

As for gathering feedback from the participants, at the end of the experiences, they were asked to fill out satisfaction questionnaires, as well as to answer a few questions in a semi-structured interview. Although the number of participants was low, we ensure a quality study since it was conducted with the participation of three surgeons whose feedback is the most valuable due to their major experience in the area and interest in the future use of this technology. Two of the participants had already been exposed to the HoloLens technology, while one of them had no experience at all.

5.2 Participants

Twenty female volunteers were submitted for image acquisition with 3D surface scanning in the CTA scan and operating room positions. The volunteers' mean body mass index is 24,312 (range of 20,5 - 30,9). The data collected was used for the 3D Patient's Skin Mesh Deformation study.

Concerning the user study to evaluate BREAST Plus' interface, the evaluation was conducted with the participation of oncoplastic breast surgery experts with 10, 12, and 30 years of experience. The number of reconstruction surgeries that the participants contribute per year is, respectively: 50, between 100 and 150, and more than 200. As for DIEAP flap reconstruction surgeries, all participate in approximately 30 surgeries per year.

Regarding the participants' previous experience with AR: the first and second participants have both had some experience with AR technologies, including the use of HoloLens more than 5 times and 1 to 5 times, respectively. The third participant had no previous experience with augmented reality nor with the HoloLens device, which had only experienced once. The first participant is the only one with experience in the use of AR technologies for preoperative planning of surgeries.

5.3 3D Patient's Skin Mesh Deformation

The best results were achieved using the ICP algorithm (mean distance of 0,033 mm and RMS of 2,423 mm), the combination of manual alignment plus the ICP algorithm (mean distance of 0,04 mm and RMS of 2,363 mm), and the alignment using six landmarks plus the ICP algorithm (mean distance of 0,112 mm and RMS of 2,567 mm). The results for all alignment methods can be found in Appendix B.

For each volunteer, different methods were applied to align the meshes. The different methods and correspondent RMS values obtained were used to create a heatmap (Fig. 5.1). However, there were some particular cases in which the meshes were not aligned correctly, leading to some offset values, such as the results obtained from the C2 volunteer: by using ICP and MI methods of alignment it was obtained the values 2,337 mm and 2,351 mm respectively. However, using the LI method the value escalated to 4,536 mm. It was also possible to observe three cases of deformation in which the values of RMS were above 4 mm (C1, C6, C18) and three cases in which the values of RMS were above 3 mm (C3, C8, C16). This corresponds to 30% and 15% of the results, respectively.

The average of the root square mean obtained, using the three methods described, is 2,447 $\pm$ 1,1 mm (range of 0,649 - 5,046 mm). The standard deviation calculated is 2,886 mm. After the computation of the deformation, .csv files from all patients were gathered and then parsed to create a histogram (Fig. 5.2). The histogram shows a majority of points clustered between the interval of [-5; 5] mm.

5.4 BREAST Plus User Study

5.4.1 Apparatus

The user study was performed in an operating room at the Breast Unit - Champalimaud Clinical Center. The setup consisted of the HoloLens for the main experience, a computer for the participant to answer the questionnaires, and a patient laid down on the operating table.

	BMI	ICP	MI	LI
C1	21.6	4.175550	4.154930	4.157190
C2	21.3	2.336730	2.351270	4.536040
C3	21	3.235780	3.251510	3.242330
C4	20.7	1.037400	1.038750	1.044770
C5	21.9	2.945650	2.907560	2.909040
C6	22.9	4.232510	3.553170	4.214180
C7	25.4	1.988640	1.995590	1.991860
C8	27.9	3.446690	3.405920	3.471820
C9	23.8	1.139460	1.150720	1.13086
C10	23.1	2.889780	2.587520	2.878090
C11	28,1	2.280980	2.198210	2.25993
C12	23,9	2.21416	2.20205	2.23569
C13	29,9	2.0429	2.05436	2.03845
C14	28.1	1.73096	1.73101	1.7376
C15	23.9	0.649178	0.654856	0.650084
C16	29.9	3.27216	3.33359	3.34406
C17	23.7	0.974558	0.985016	0.976076
C18	20.5	4.54924	4.5282	4.5636
C19	26.7	1.67434	1.678	1.6776
C20	30.9	1.43688	1.44736	1.44062

Figure 5.1: Root Square Mean heat map of the results obtained on the 20 meshes using the three best methods of alignment: ICP; manual with ICP (MI); six landmarks with ICP (LI).

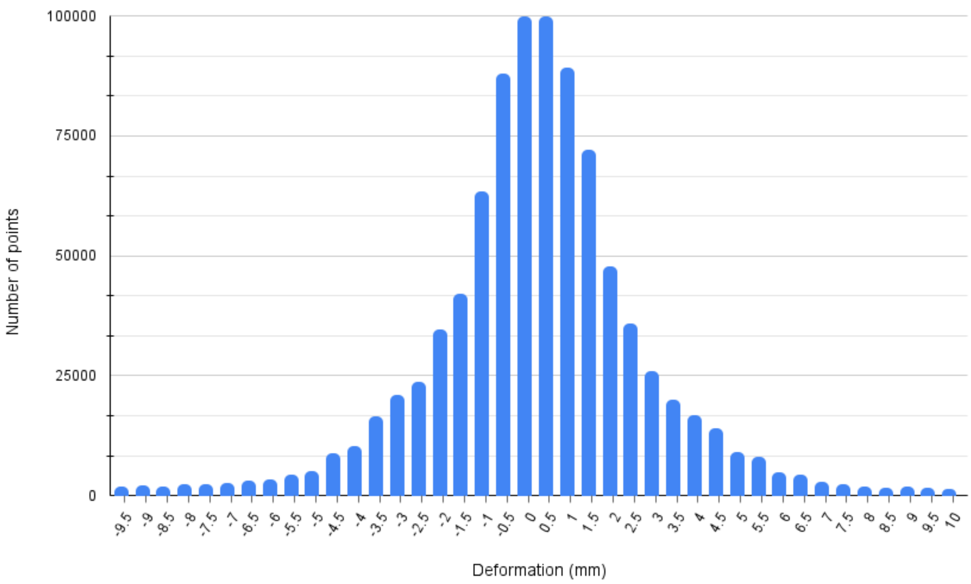

Figure 5.2: Histogram that contains the sum of all points from all volunteers' point clouds (meshes) and their distance from the reference mesh.

5.4.2 Tasks

To ensure the participant becomes acquainted with the essential gestures, contents, and main functionalities of the interface, the experience began with a habituation task. This task consisted of the following steps (not necessarily in the displayed order):

- Grabbing the box and manipulate it with one or both hands;
- Grabbing the menu and changing its placement;
- Filter some of the information displayed using the menu;
- Clicking on the fine-tuning button to manipulate the model using a bounding box;
- Pin the model;

Then, assuming the participant got sufficient knowledge about the main functionalities to benefit from the interface's tools, it was possible to move on to the main task. We did not influence the participants' choices with suggestions of tasks, so the participant could explore the interface freely until the main task was completed. The goal of the main task consisted of anchoring the 3D model to the patient's abdomen and then marking the perforators crossing points with the fascia. The steps that were expected for complete use of the interface, and consequently successful execution of the main task, are the following:

1. Grab the model using one or both hands, to anchor it roughly to the patient;
2. Select the "Fine Tuning" button to manipulate the model through rotation and translation for fine registration, ending the task by deselecting the button for the manipulation box to disappear;
   2.1. While on the "Fine Tuning" mode, the user should select the button "Smooth" for a slower and more precise manipulation of the model;
3. Select the "Pin Model" box to fixate the model;
4. Select the filter buttons, to show or hide anatomic elements of the model;
5. Interact with the transparency slider that corresponds to the opacity of the skin in the model;

5.4.3 Procedure

To execute the BREAST Plus user study we created a protocol to follow (Fig. 5.3). The first step was to explain the context of the study and the goal, as well as to ask the participants to fill out consent and demographic questionnaires.

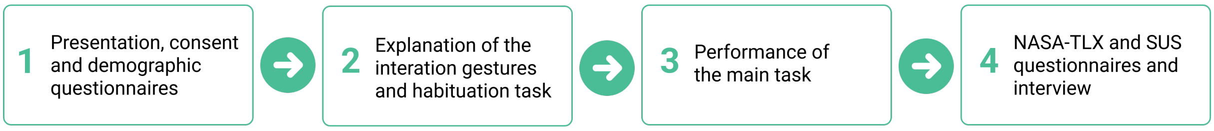

Figure 5.3: Protocol followed on the BREAST Plus user study.

The second step was to give a brief explanation about the gestures needed to interact with the interface and ask the participant to do a habituation task to get familiar with the system. As soon as the habituation task was completed, the participant performed the main task. The main task consisted of visualizing, and registering the 3D model on the patient's abdominal (Fig. 5.4), and marking the perforators. During the performance of the task, observations and comments made by the users while interacting with the system were registered. When the task was fully completed, we asked the participant to answer NASA-TLX and SUS questionnaires, and also to a semi-structured interview. The interviews were only performed a few days after the experience since the surgeons had to start the surgery right after the experience.

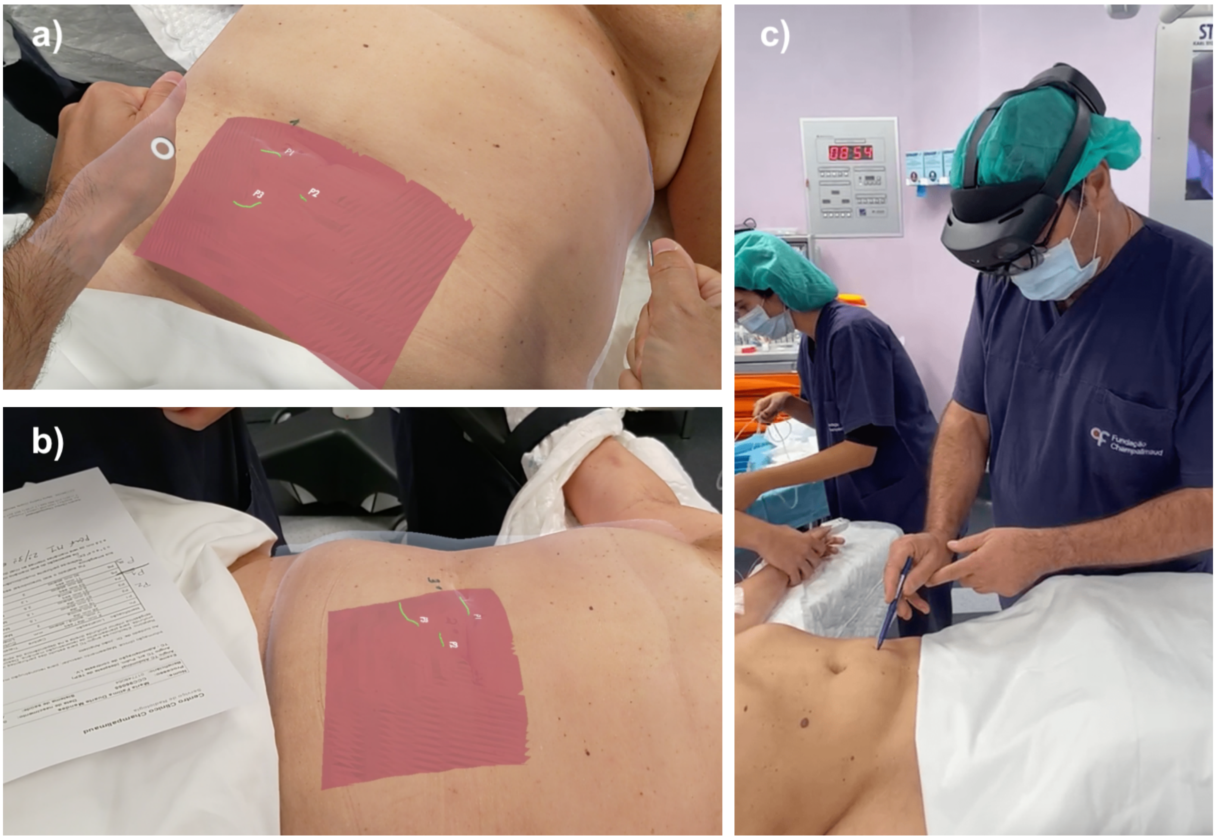

Figure 5.4: Participant grabbing the 3D model (a) to perform the anchorage to the patient's abdomen (b). The participant then marks the perforators on the patient's skin right before the beginning of the surgery (c).

Figure 5.5: Interface of BREAST Plus moments before the beginning of a DIEAP flap reconstruction surgery, through the HoloLens. Menu report on the left side and the patient's model on the right side.

5.4.4 Satisfaction Questionnaires

The SUS questionnaire results for the three participants are represented in Table 5.1. By analyzing the table, we observe a SUS score of 90, 80, and 60, for each participant, respectively.

SUS Questions	P1	P2	P3
I think that I would like to use this system frequently.	5	5	4
I found the system unnecessarily complex.	2	1	2
I thought the system was easy to use.	5	4	3
I think that I would need the support of a technical person to be able to use this system.	2	2	3
I found the various functions in this system were well integrated.	5	5	4
I thought there was too much inconsistency in this system.	1	1	2
I would imagine that most people would learn to use this system very quickly.	3	4	3
I found the system very cumbersome to use.	1	4	3
I felt very confident using the system.	5	4	3
I needed to learn a lot of things before I could get going with this system.	1	2	3
SUS SCORE	90	80	60

Table 5.1: SUS questionnaire results for the 3 participants.

By using the adjective ratings, these values are rated into three adjectives. The SUS score of 90 rates the interface as EXCELLENT. The SUS score of 80 rates the interface as GOOD. The SUS score of 60 rates the interface as OK. It is also possible to see that all participants would like to use this system frequently and that the system was not excessively complex or inconsistent. It is possible to observe that as the previous experience with AR decreases (P1, P2, P3), the scores in the questions regarding easiness and confidence using the interface decrease as well.

The NASA-TLX questionnaire results for the three participants are represented in Table 5.2.

Raw NASA-TLX Questions (1-100)	P1	P2	P3	Average
How mentally demanding was the task?	20	80	40	47
How physically demanding was the task?	20	20	40	27
How hurried or rushed was the pace of the task?	50	40	60	50
How successful were you in accomplishing what you were asked to do?	80	80	70	77
How hard did you have to work to accomplish your level of performance?	70	60	40	57
How insecure, discouraged, irritated, stressed, and annoyed were you?	10	50	30	30

Table 5.2: Raw NASA-TLX questionnaire results for the 3 participants.

Given the score interpretation used for raw NASA-TLX mentioned on the previous chapter, we can observe the average of results from all participants and correspondent attribute interpretations in Table 5.3 .

Workload Factors	Average Score	Score Interpretation
Mental Demand	47	Somewhat High
Physical Demand	27	Medium
Temporal Demand	50	High
Performance	77	High
Effort	57	High
Frustration	30	Somewhat High

Table 5.3: Raw NASA-TLX score interpretation of the results' average.

5.4.5 Semi-Structured Interview

The performance of semi-structured interviews was fundamental to gather relevant feedback to evaluate the BREAST Plus' interface usability. This section is divided in three sub-sections, one for each participant. Although the participants share some opinions, we analysed each separately first.

The first participant had been exposed to AR and to the HoloLens previously. Due to previous experience, the participant didn't have much trouble managing the gestures and the interface features. After experiencing the BREAST Plus interface, the participant reported that it offers an alternative method for marking the perforators. The interface makes data reading more efficient and effective, providing an immediate visualization of the perforators in the patient's abdominal wall. Despite having previous experience, the participant found it slightly hard to use the manual tool to perform the anchorage of model to the patient in the surgical setting. Besides suggesting a future automatic registration and automatic digital anchorage of the radiological data, the participant suggested the possibility to have automatic translations to different languages. Most importantly, if the registration is done automatically in the future, the participant believes this technology can be adopted in the surgical practice.

The second participant had been exposed to AR and to the HoloLens previously. The participant believes BREAST Plus is a preferable alternative method of marking the points since it is much more efficient and effective. The best feature, in the participant's opinion, was the visualization of the perforators' path in a 3D model that is superimposed on the patient's body. It enables surgical planning in a much more natural and quicker way since the surgeons have a visual reference, which is something lacking in the current pipeline. The participant had more difficulty doing a proper anchoring of the model on the patient's body. Plus, the drifting of the model as the operator moves along caused some instability in the visualization of the contents and compromised accuracy. The participant also found the system very touch-sensitive, making the fine-tuning and anchoring harder to perform, compromising usability. Considering that the beginning of surgery is done in a rush, the participant suggested the addition of a preoperative mode and an operating room mode. The preoperative mode would consist of the data from the imagiological report, the perforators' characteristics, and filter options. In the operating room mode, the fine-tuning box would be initially active with bigger handles to make the manipulation easier. Above the box, there could be a button that would open the report as a pop-up in the operating room mode, since it could be necessary to check the report - but it doesn't need to be displayed initially. The participant believes this technology is possible to adopt in the surgical practice if the model's manipulation improves, possibly with the use of better AR tech. The anchoring could be improved eventually with a synchronized fusion of the model with operating room surface scan cameras.

The third participant had less to no previous experience with augmented reality environments. The participant described the BREAST Plus Interface as a valid alternative to the conventional method of marking the perforators. Even if not immediately used on a regular basis, its incorporation in surgical planning is important and has potential as soon as it increases in precision and familiarity to the surgeons. As for the report-like menu and the 3D model, the participant reported that the data reading is more immediate and the elements are easy to visualize. The participant commented that the main advantages of the system are the easy marking of the perforators and the possibility to have a 3D visualization of their characteristics in the surgical space. The limitations found by the participant consisted mainly of the manipulation of the elements of the interface since the gestures were not very intuitive for the first time using the device, even after being explained. The participant believes that there will be a considerable learning curve and need for practice for beginners since the movements are still confusing and the system is very sensitive to incidental gestures. Given the experience, the participant believes it is possible to adopt this technology in the future, but it will be important to decrease the sensitivity of the system in order to have a more precise manipulation of the elements.

5.5 Discussion

5.5.1 3D Patient's Skin Mesh Deformation

The projection of 3D models of registered angio-CT perforators during free flap DIEAP reconstruction in previous research has not considered the errors resulting from a patient's abdominal wall deformation during data acquisition. To the best of our knowledge, this is the first work to perform a descriptive statistical analysis and statistical inference of two different registration positions (arms closed versus arms open) and to quantify target registration errors between both positions. It was possible to confirm that the different methods applied to align the meshes provided consistent results, proving not to have a relevant influence on the values of deformation obtained. This finding is illustrated in the slight color changes in the rows of the heat map presented in the previous section (Fig. 5.1).

Deformation errors may result from data gathering, 3D model reconstruction, and mesh-patient alignment during surgery [53]. Skin mesh deformation can affect the construction of the 3D model, leading to an inaccurate display of the 3D model when anchored to the patient's body. In order to achieve a high-fidelity projection of the 3D model, it is necessary to control the errors that happen in all phases, which consist of the use of different instruments. In order to achieve a high-accuracy projection of the perforators' position, the specialists of the Breast Unit - Champalimaud Foundation established a maximum error of 5 mm on the marking of the perforators. Given the high values obtained in this study such as 30% of the cases of deformation above 3 mm and 15% above 4mm, it is crucial to consider the errors obtained in this study.

Applying the deformation error caused by different data acquisition positions in the reconstruction of 3D models contributes to a more accurate identification of the perforators' location during surgery. The results disclose as relevant the observed deformations to be considered and explored in future research. It is necessary to consider the different positions of the patient when building the models and explore the following errors obtained in the anchoring process using the Microsoft HoloLens.

Nonetheless, this value of deformation can be slightly affected by several factors:

1. In the surface scan's performance, the volunteer's breathing cycles can influence the capture of the mesh. This can lead to distortion in both meshes, which can influence their later alignment;

2. The algorithms used for the alignment of the pairs of meshes can add deformation due to imperfect

alignment, leading to offsetting values that should not be of concern, despite their influence on the final results.

However, the current study has the following limitations:

1. The restricted number of participants has shown interesting and consistent results, however, a larger patient population could dictate more accurate statistics;

2. Further studies concerning the fusion of the CTA imaging transformed into a 3D model with the surface scans are required. From the moment of the CTA scanning to the operating room table some deformations are not being validated in this study, caused by curvatures in the tables in which the patient is laying when data is being acquired, particularly during the CTA scan and later on the operating room;

3. The BMI values used to find a relationship between the results obtained were not conclusive. The range of BMI values is short [20.5; 30.9] and future work should include a bigger sample of patients with a wider range of values to study the correlations between IBM values and the skin's deformation;

4. The landmarks used in the methods of alignment should be previously marked on the surface scans and CTA scans for a more accurate alignment. According to the distance to the umbilicus, these landmarks were chosen on CloudCompare on both meshes. Thus, it showed inaccurate alignment without further adjustments (such as ICP).

5.5.2 BREAST Plus User Study

To validate BREAST Plus' interface, we conducted a user study with three experienced breast surgeons. The participants performed several tasks, answered questionnaires, and an interview, to help us understand whether the interface is helpful and what are its limitations. Receiving feedback from specialists is very valuable since they are the future users of this technology, so their needs must be fulfilled. One of the participants had no experience with HoloLens and AR systems, while the other two participants had already been exposed to these technologies. The feedback from inexperienced and experienced AR participants enriched the feedback. The collected information was overall positive, however, some important limitations were detected.

Regarding the interface's information, the participants gave the following positive feedback:

- The interface contained all the important data the surgeons required;

- The report-like menu was very familiar and made the interaction and manipulation with the 3D model easy and convenient;

- The visualization of the perforators' path in a 3D model overlapped with the patient's body is very relevant and innovative;
- The interface allows an immediate visualization and understanding of the perforators' characteristics.

Despite the completeness of the interface in terms of information, the use of the HoloLens is quite an overwhelming experience for inexperienced users. This will require the users to have previous practice before being able to manage the system fluently. The gestures detected by the HoloLens are one of the main troubles for a beginner since the user might be confused about what gestures to do to perform certain tasks. The HoloLens has a very touch-sensitive system and accidental gestures might lead to reactions of the system that were not desired. The fact that the gestures need to be very clear and precise is a barrier to a completely natural performance, especially for a beginner.

The anchorage of the 3D model to the patient was the more challenging task for all users for the following reasons:

- The manual alignment was not precise enough and required some effort and previous experience;
- In the abdominal area there are few points of reference to perform proper manual alignment unless there were markers. Although the participants used the skin and umbilicus elements as reference for the anchoring, it still lacked precision;
- Considering that the beginning of surgery is done in a rush, we also observed the participants missing out on important tools contained on the interface. One of the participants didn't use the fine-tuning box for positioning the 3D model, which lead to an inaccurate anchorage of the model. Such a situation reflects in the scores obtained in the satisfaction questionnaires specifically on the most inexperienced user, who didn't have the full experience and benefits of the available tools.

Another relevant limitation is the stability of the HoloLens for high-precision procedures. After anchoring the 3D model, a participant noticed that fast head movements and being very close to the 3D model would change the model's position. If the participant looked closely and from different perspectives, the marking points of the perforators would move more than 1 cm. Previous research has proved that the stability of the HoloLens is more precise at low movement speeds and the anchored contents are displayed more accurately at distances of 1.5 and 2.5 m - with an average size error of 6.64% [32]. More research on the same matter has confirmed the inability for a high-accuracy placement of the contents when in close range, reaching values of $\pm$6 mm [30, 31].

The SUS results were positive. The following points contain the main insights we gathered:

- A common desire to use BREAST Plus frequently was expressed by all participants;

- The system is not complex;
- The participants disagreed and were neutral as to the need to learn a lot of things prior to using the system or needing the support of a technical person to use the system;
- Two participants were neutral and one agreed that most people would learn to use this system very quickly;
- The more previous experience with AR the participant had, the easier the system was to use. The same applies to confidence using the system.

As for the raw NASA-TLX results, we could observe the impact of the limitations detected in the interface:

- The mental demand was considered somewhat high and the physical demand was medium. These results were possibly the result of the issues on manually aligning the model, the very touch-sensitivity of the HoloLens, and the inexperience with AR systems;
- The temporal demand was high. We believe the surgeons gave higher values on this workload factor due to the rush they were in - moments right before the start of the surgery are quite stressful;
- The performance was high, which means the overall experience was successful;
- The effort and frustration were high and somewhat high, which is explained by the existent limitations as described above.

Overall, BREAST Plus was considered to have the potential for possible adoption in the future of surgery, as long as the challenges are addressed. The results are very positive, which, to a certain extent, can be explained by the immediate impact of such a new and innovating technology in scene, as well as the closeness of the participants along the design process. Thus, all the participants have shown interest in using these technologies because they believe they can improve surgery planning.

6

Conclusions & Future Work

Contents

6.1 Conclusions

Recently, AR has been considered to assist DIEAP flap procedures for breast reconstruction. AR empowers surgeons with 'x-ray vision' allowing them to see beneath a patient's skin. Our work's purpose was to develop a high-fidelity interface that provides an improved augmented space, that aimed to aid surgeons in preoperative planning of DIEAP flap surgeries, and eventual marking of the perforators. BREAST Plus is an AR interface that runs on the HoloLens 2 and consists of a report-like menu and a 3D model of the patient, containing indispensable information for the appropriate planning of the surgery. To achieve a final prototype that met all essential requirements, we made an observation session in real surgery and planned weekly co-design sessions with the specialists. The observations and feedback collected frequently allowed for several iterations that allowed the interface to reach a mature prototype. Not only we ensured the visualization of quality and accurate content, but also had the possibility to interact with them and filter the information displayed.

A user study conducted with three specialists confirmed that the interface provided immediate visualization of important information, improving surgery planning. However, the manual alignment of the 3D model to the patient's body was the feature with more limitations. By analyzing the semi-structured interview, the SUS and the NASA-TLX results, it was possible to see a common desire to use BREAST Plus frequently. Especially if the limitations are addressed in a near future. Although this experience was performed with a low number of participants, there is a possible relationship between the previous experience with AR technologies and the results. The results of the SUS questionnaire show that the more the participant has experienced AR, the easier it was to use BREAST Plus. The lack of experience with AR could explain the lower confidence while using the system likewise, however, it is also likely its explanation relies on the first-time use of the interface. Overall, the SUS scores, regarding usability, were very positive: 90, 80, and 60. The NASA-TLX scores, regarding workload, were also positive, but reveal a bigger relationship with the limitations of the interface.

Given the high importance of an accurate projection of 3D models on the patients, we performed a 3D skin mesh deformation study. Previous research has worked on space augmentations consisting of angio-CT based perforators during DIEAP flap reconstruction surgeries through AR devices. However, when building 3D models of the patient's anatomy, the deformation of the patient's skin from CTA acquisition and operating table position was not considered when projecting the 3D models on the patients. So, we processed the data sets of 20 volunteers with a 3D rigid registration tool, to perform a descriptive statistical analysis and statistical inference. This work confirmed that the deformation is relevant since it reaches a root mean square of 2,447 $\pm$ 1,1 mm with 30% of the cases above 3 mm and 15% of the cases above 4 mm, allowing us to conclude that the deformation detected should be of concern.

At last, we can conclude that BREAST Plus was a successful and improved AR interface that can be a part of future medicine. To make that future real, some challenges still need to be addressed, and

BREAST Plus has proved that we are getting closer to a high-fidelity use of AR technologies in surgery planning.

6.2 Future Work

Our work provided many positive insights and results that open many questions to be addressed in the future. The first phase of this work consisted of a skin mesh deformation study. According to the results of the study, the deformation is relevant and requires the conduct of more research. The fusion of the CTA imaging transformed into a 3D model with the surface scans requires future research: the curvatures in the tables in which the patient is laying when data is being acquired (during CTA scan) and later at the operating room should be investigated. It is also important to do further research considering the errors in the projection of the final model in the operating table using the Microsoft HoloLens. In the future, studies should also be conducted with more volunteers to study the deformation's correlation with BMI values.

The second phase of this work consisted of the development of an interface containing 3D elements important to the surgeons in DIEAP flap reconstruction surgeries. Given the limitations regarding the number of participants and surgeries to expose the BREAST Plus interface, there are scenarios that still need to be considered, and that could provide more insightful feedback. Therefore, more studies should be performed with more participants (specialists in breast reconstruction) in a higher number of DIEAP flap procedures. As for the 3D model of the patient, we performed a manual fusion of the CTA data with the surface scan of the patient. We suggest further research to improve the fusion. Such can be done by marking reference points on the patient's body before performing the CTA scan and the surface scan.

Standardized use of AR HMD (such as the HoloLens) will require rigorous research with appropriate quantitative evaluation [28]. Furthermore, in this work, we opted for a manual alignment of the 3D model to the patient. We encourage future research to explore automatic registration of the 3D model to the patient's body, possibly using Microsoft Kinect cameras or similar technologies. Users can be exposed to drift as the models seem to dislocate from where they are originally placed, jeopardizing the accuracy of the model's anchorage [30]. To achieve a high-fidelity display of the augmented contents, it is important that their stability is improved and addressed in future research, possibly with the use of Vuforia's SDK (using Vuforia's RGB target recognition) as experienced on previous research [54].

This work was mainly focused on DIEAP flap reconstruction surgeries. However, we believe this technology has the potential to be applied in other medical procedures with due research since the visualization of 3D elements in an augmented space proves to be promising.

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A

User Study Forms

Demographic Profile Form

Dear participant,

We are conducting a study that consists of developing a AR application intended to be used in the operating room during a procedure of DIEAP reconstruction surgery.

All information obtained will be treated confidentially and may not be revealed to anyone, however, it may be used for statistical analysis and for scientific purposes. We commit to keeping the data for 5 years. After this period, all information will be deleted. If you wish, you can request the removal of the data at any time.

Thanks for your collaboration!

1. Gender

   Mark only one oval.

   - Female
   - Male
   - Other

2. Area of medical speciality

   ____

3. Years of experience in the area of speciality

   ____

4. Do you have experience in breast reconstruction surgery?

   Mark only one oval.

   - Yes
   - No

5. If your answer was yes, approximately how many reconstruction surgeries do you participate in per year?

Mark only one oval.

- 50
- 50 - 100
- 100 - 150
- 150 - 200
- > 200

6. Do you have experience in breast reconstruction surgery using DIEAPs?

Mark only one oval.

- Yes
- No

7. If your answer was yes, approximately how many reconstruction surgeries with DIEAPs do you participate in per year?

Mark only one oval.

- 15 - 20
- 20 - 30
- > 30

8. Do you have experience with augmented reality (AR) technologies for preoperative planning of surgeries?

Mark only one oval.

- Yes
- No

9. Have you had any experience in augmented reality (AR) using the HoloLens?

Mark only one oval.

- Yes
- No

10. How many times have you used the HoloLens?

Mark only one oval.

- One time
- 1 - 5 times
- More than 5 times

Informed Consent Form

Dear participant,

We are conducting a study that consists of developing a AR application intended to be used in the operating room during a procedure of DIEAP reconstruction surgery.

For this, we need your contribution!

To participate in this study, you will collaborate in a test, in which you will be present with the prototype of the AR application that is being developed, you will be asked for various tasks and will be recorded of the observations made. At the beginning of the session, you will be asked several demographic questions for inclusion in the study. Throughout the test, several tasks will be proposed and at the end of the session, you will be asked to fill in a satisfaction questionnaire, and a short interview will be conducted. If you permit we will register video, audio, and image recordings throughout the session, so that we can obtain more specific data that will help in the analysis of the results.

All information obtained, including photographs, video and audio, will be treated confidentially and may not be revealed to anyone, however, it may be used for statistical analysis and for scientific purposes.
We commit to keep the data for 5 years. After this period, all information will be deleted. If you wish, you can request the removal of the data at any time. Your authorization to participate in this study is voluntary, and you may, if you wish, deny the consent and abandon the sessions at any time.

To participate in this experiment, we ask you to fill in the consent form present in this questionnaire, agreeing with the sentences written bellow.

Thanks for your collaboration!

Investigator – Rafaela Jorge Timóteo, 5th year of the Master's Degree in Computer Science Engineering, Instituto Superior Técnico
Principal Investigator – Prof. Doutor Daniel Simões Lopes
Supervisors – Prof. Doutor Daniel Simões Lopes, Doutor David Pinto

* Required

1. Name

2. I have read and understood the meaning of this study. I had the opportunity to ask questions, if necessary, and collect the corresponding answers. *

Check all that apply.

- [ ] I agree

3. I understand that the participation in this study is voluntary and that I may withdraw at any time without providing any explanation. I will not be subject to any penalty and the data relating to my experience will be removed and destroyed. *

Check all that apply.

- [ ] I agree

4. I authorize the collection of information during the session in the form of: *

Check all that apply.

- [ ] Audio
- [ ] Video
- [ ] Photography
- [ ] Text
- [ ] None of the above

5. I authorize the use of data collected during the session. *

Check all that apply.

- [ ] I agree

6. I authorize the processing of experimental data within the scope of this project for purposes of analysis, research and dissemination of results in scientific publications or conferences in the project area, by the researchers of this project. *

Check all that apply.

- [ ] I agree

7. I understood that the data collected in this study will be used as mentioned above. *

Check all that apply.

- [ ] I agree

8. I understood that at any time I can have access to my personal data collected in this study, just by contacting the principal researcher of the project, by using the following email: daniel.lopes@inesc-id.pt *

Check all that apply.

- [ ] I agree

9. As described above, I authorize my participation in this study and accept its conditions. *

Check all that apply.

- [ ] I agree

System Usability Scale

	Strongly disagree 1	2	3	4	Strongly agree 5
1. I think that I would like to use this system frequently					
2. I found the system unnecessarily complex					
3. I thought the system was easy to use					
4. I think that I would need the support of a technical person to be able to use this system					
5. I found the various functions in this system were well integrated					
6. I thought there was too much inconsistency in this system					
7. I would imagine that most people would learn to use this system very quickly					
8. I found the system very cumbersome to use					
9. I felt very confident using the system					
10. I needed to learn a lot of things before I could get going with this system					

Figure 8.6

NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

Name	Task	Date

Mental Demand — How mentally demanding was the task?

Very Low — Very High

Physical Demand — How physically demanding was the task?

Very Low — Very High

Temporal Demand — How hurried or rushed was the pace of the task?

Very Low — Very High

Performance — How successful were you in accomplishing what you were asked to do?

Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed wereyou?

Very Low — Very High

B

Skin Deformation Study Table

	IMC	Ouputs (mm)	Manual	ICP	Umbilicus Landmark	Manual + ICP	Umbilicus Landmark + ICP	6 Landmarks	6 Landmarks + ICP
C1	21.6	Mean Distance	-3.309570	-0.202231	4.541880	-0.202543	-0.222927	0.584314	-0.224342
		σ	6.015800	4.533050	11.594400	4.535060	4.533240	6.900140	4.535050
		RMS		4.175550	0.711517	4.154930	4.164140	13.074900	4.157190
C2	21.3	Mean Distance	-0.213484	-0.235168	-0.925364	-0.246978	-0.244932	0.066961	0.608269
		σ	5.531290	2.866600	60.972000	2.879910	2.897520	8.293390	5.932880
		RMS		2.336730	1.638950	2.351270	2.336310	11.9412	4.536040
C3	21	Mean Distance	3.717910	2.025960	6.175680	2.036120	2.050080	2.575220	2.030140
		σ	3.637300	3.323460	14.142700	3.314810	3.289000	3.522630	3.313420
		RMS		3.235780	1.790180	3.251510	3.258670	5.211750	3.242330
C4	20.7	Mean Distance	-1.085600	0.055044	-7.532020	0.057161	0.049851	2.132130	0.041950
		σ	5.102410	1.293220	34.997600	1.292110	1.291120	2.513480	1.296060
		RMS		1.037400	0.670834	1.038750	1.046150	4.929700	1.044770
C5	21.9	Mean Distance	-2.670730	-0.593711	-17.521900	-0.616541	-0.624744	1.518650	-0.621958
		σ	4.710880	3.782000	36.644800	3.779900	3.780970	4.337100	3.777620
		RMS		2.945650	1.134580	2.907560	2.904860	6.531050	2.909040
C6	22.9	Mean Distance	0.364592	-0.317607	-1.317390	0.312591	-0.299670	1.142540	0.255864
		σ	6.805470	5.391410	14.985500	4.528870	5.391750	8.279230	5.405450
		RMS		4.232510	1.043320	3.553170	4.227050	3.805290	4.214180
C7	25.4	Mean Distance	0.791926	0.493977	2.281430	0.490605	0.491421	3.893790	0.465828
		σ	5.526300	2.155450	5.210930	2.158990	2.156870	7.208800	2.157440
		RMS		1.988640	1.794140	1.995590	1.989140	8.356570	1.991860
C8	27.9	Mean Distance	-1.514670	-0.276451	-9.632290	-0.268618	-0.261130	4.484800	-0.256628
		σ	5.633680	4.123980	40.619500	4.124370	4.126280	6.116850	4.126640
		RMS		3.446690	4.292110	3.405920	3.430090	15.041500	3.471820
C9	23.8	Mean Distance	0.074840	0.103745	-4.736480	0.112833	0.105522	0.221586	0.415887
		σ	2.532630	1.353440	12.067700	1.366100	1.357170	4.211900	2.053920
		RMS		1.139460	0.930763	1.150720	1.130860	13.411700	1.9668
C10	23.1	Mean Distance	-1.716950	0.111834	2.020920	-0.350587	0.133099	0.863110	0.101900
		σ	3.989850	3.572710	19.117600	3.505700	3.561320	4.880900	3.568280
		RMS		2.889780	1.542580	2.587520	2.931470	5.991000	2.878090
C11	28,1	Mean Distance	-2.1463	-0.32388	-22.305	-0.344683	-0.330645	-3.59238	-0.365241
		σ	4.230870	2.66587	35.249900	2.678300	2.663770	4.797200	2.663140
		RMS		2.280980	1.2392	2.251560	2.26307	12.1476	2.25993
C12	23,9	Mean Distance	-0.132747	0.226638	2.38416	0.224148	0.226934	-0.863145	0.204427
		σ	3.2862	2.57232	19.3087	2.57543	2.57438	5.18395	2.57468
		RMS		2.21416	0.804738	2.19821	2.18961	6.97361	2.23569
C13	29,9	Mean Distance	0.00421703	0.16506	19.2962	0.176787	0.161271	2.27201	0.163655
		σ	2.686430	2.420550	84.639100	2.423930	2.430090	4.962790	2.433120
		RMS		2.0429	0.569571	2.05436	2.03699	10.4003	2.03845
C14	28.1	Mean Distance	-0.489349	0.0752942	-7.07983	0.0781467	0.0758557	-3.77278	0.0758815
		σ	3.351430	1.682140	24.187100	1.685960	1.685980	3.243670	1.679430
		RMS		1.73096	1.10445	1.73101	1.72457	11.8259	1.7376
C15	23.9	Mean Distance	1.72077	-0.0380929	6.2167	-0.03328	-0.0384299	0.993871	-0.0335857
		σ	2.880130	0.885479	48.073500	0.878324	0.877245	2.428800	0.877714
		RMS		0.649178	0.283211	0.654856	0.652304	8.74196	0.650084
C16	29.9	Mean Distance	-2.73091	-0.419729	-13.0942	-0.409011	-0.414899	1.49727	-0.41324
		σ	6.853880	4.094410	63.657400	4.054570	5.350490	5.350590	4.056810
		RMS		3.27216	1.18792	3.33359	3.33102	6.29382	3.34406
C17	23.7	Mean Distance	-0.432941	0.140343	-0.909767	0.135907	0.170071	-5.82462	0.14004
		σ	3.091580	1.239700	7.756480	1.245890	1.239440	3.425500	1.247440
		RMS		0.974558	1.69308	0.985016	0.981553	12.7829	0.976076
C18	20.5	Mean Distance	-1.47049	0.240622	3.5826	0.199283	0.180792	0.241858	0.207555
		σ	7.909240	5.331400	11.734200	5.316800	5.324860	5.307130	5.309970
		RMS		4.54924	0.280193	4.5282	4.52085	4.56814	4.5636
C19	26.7	Mean Distance	-1.40587	-0.394951	-21.2497	-0.403178	-0.384847	0.99891	-0.388299
		σ	3.765590	1.823370	49.730500	1.822290	1.833890	5.341810	1.831660
		RMS		1.67434	1.58733	1.678	1.67093	13.2948	1.6776
C20	30.9	Mean Distance	0.107465	-0.176557	-2.34394	-0.153653	-0.161026	4.31248	-0.16367
		σ	5.607060	1.690100	40.058300	1.689960	1.689170	3.560120	1.689770
		RMS		1.43688	1.78574	1.44736	1.45514	9.14973	1.44062