FEDERAL UNIVERSITY OF TECHNOLOGY – PARANA

LUCIA REGINA BRANCO

METHOD OF DESIGNING AND MANUFACTURING EXTERNAL PERSONALIZED BREAST PROSTHESES, USING 3D PRINTING AND LOW-COST COMPUTER-AIDED TECHNOLOGIES

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Método de projeto e manufatura de próteses de mama externa personalizadas, usando impressão 3D e tecnologias de baixo custo auxiliadas por computador

Thesis presented as partial requirement to obtain the degree of Doctor in Engineering, of the Post-grade Program in Mechanical Engineering and Materials, focused in Manufacture Engineering, of the Department of Research and Post-grade Curitiba Campus, of the Federal University of Technology - Paraná (UTFPR).
Advisor: Prof Dr. José Aguiomar Foggiatto

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Campus Curitiba

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Trabalho de pesquisa de doutorado apresentado como requisito para obtenção do título de Doutora Em Engenharia Mecânica da Universidade Tecnológica Federal do Paraná (UTFPR). Área de concentração: Engenharia De Manufatura.

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I dedicate this thesis to all those who I met in my life that, for any reason, made blossom the best of my femininity, strengthening it into a loving feeling, a purpose of serving, of helping other women to find this same love for themselves.

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“Follow true love.”
(STEVENS, 2006)

RESUMO

Próteses externas de mama, tecnologias assistivas que buscam auxiliar mulheres mastectomizadas a enfrentarem a assimetria e a lembrança do câncer extirpado, são recursos ignorados pelo Sistema Único de Saúde brasileiro e abordados limitadamente na indústria nacional. Soluções de prateleira são caras para as pacientes que precisam do atendimento dos órgãos públicos e os produtos acessíveis são rudimentares ao ponto de comprometerem a higienização. Ambos são disponibilizados para as pessoas com tamanhos medianos, tão contestados pela Ergonomia, e impõem às usuárias produtos cujos projetos não necessariamente estão fundamentados no conforto. A revisão de literatura demonstrou que existem países em que as próteses externas rudimentares, feitas de alpiste, ainda são tão populares quanto no Brasil, mas que há também recursos personalizados, seguros e de qualidade, para quem pode pagar por eles. Propôs-se como objetivo deste trabalho, desenvolver um método viável economicamente, que viabilize o processo de manufatura de próteses externas de mama personalizadas, usando tecnologias de baixo custo, como a digitalização 3D, CAD, CAM, impressão 3D e moldes, e que ao mesmo tempo possibilite qualidade superior a elas. Oferece-se uma proposta economicamente aplicável por qualquer instituição de apoio a mulheres mastectomizadas. Dentre os resultados, tem-se as perspectivas de vinte mulheres mastectomizadas sobre próteses externas de mama, a avaliação da rotomoldagem para o processo de fabricação das próteses, protocolos de digitalização tridimensional de mulheres mastectomizadas, tratamento de malha tridimensional para diversas compleições de mama. CAM, impressão 3D, pós-processamento de impressão 3D e moldes aplicados à concepção de próteses externas de mama, todos efetivados com equipamentos e *softwares* de baixo custo, e um método economicamente viável para produção de próteses externas de mama, personalizadas ou não, também são apresentados. Tem-se, ainda, a validação do produto "prótese externa de mama", obtido com o método.

Palavras-chave: Impressão 3D; próteses externas de mama personalizadas. tecnologia assistiva; tecnologias tridimensionais; digitalização e modelagem 3D.

ABSTRACT

External breast prostheses, assistive technologies that seek to help mastectomized women face the asymmetry and recall of excised cancer, are resources ignored by the Brazilian Unified Health System and addressed limitedly in the national industry. Shelf solutions are expensive for patients who need the care of public agencies and affordable products are rudimentary to the point of compromising hygiene. Both are made available to people with medium sizes, so challenged by Ergonomics, and impose on users products which designs are not necessarily based on comfort. The literature review showed that there are countries in which rudimentary external prostheses, made of birdseed, are still as popular as in Brazil, but that there are also personalized, safe and quality resources for those who can afford them. The objective of this work was to develop an economically feasible method that enables the manufacturing process of personalized external breast prostheses, of lower initial cost than the prostheses available on the market, using the support of low-cost technologies as 3D scanning, CAD, CAM, 3D printing and casts, and that at the same time allows superior quality to them. It offers an economically feasible proposal by any non-profit institution. Among the results, the perspectives of twenty mastectomized women on external breast prostheses, the evaluation of rotomolding for the manufacturing process of prostheses, three-dimensional scanning protocols of mastectomized women, three-dimensional mesh treatment for various breast complexions. CAM, 3D printing, 3D printing post-processing and casts applied to the design of external breast prostheses, all with low-cost equipment and software, and an economically feasible method for the production of external breast prostheses, personalized or not, are also presented. There is also the validation of the product "external breast prosthesis", obtained with the method.

Keywords: 3D Printing; personalized external breast prostheses; assistive technology; tridimensional techniques; 3D scanning and 3D modelling.

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LIST OF ABBREVIATIONS AND ACRONYMS

AIH	Autorização de Internação Hospitalar (Authorization for Hospitalization)
APP	Application for cell phone
CAT	Comitê de Ajudas Técnicas (Technical Aid Committee)
CT	Computed Tomography
DOM	Document Object Model
ICIDH	International Classification of Impairment, Disability and Handicap
INCA	Instituto Nacional do Câncer José de Alencar (National Cancer Institute)
ITS	Instituto de Tecnologia Social (National Institute of Technology)
MRI	Magnetic Resonance Imaging
NUFER	Núcleo de Manufatura Aditiva e Ferramental (Additive Manufacturing and Tooling Group)
PLA	Polylactic Acid
PVC	Polyvinyl Chloride
SLA	(Stereolithography Apparatus) The first system developed for 3D printing
SNRIPD	Secretariado Nacional para a Reabilitação e Integração das Pessoas com Deficiência, de Portugal (National Secretariat for Rehabilitation and Integration of Disabled People, of Portugal)
STL	(Stereolithography) Derived from the additive manufacturing method called stereolithography, is the file format created by 3D Systems™, used by three-dimensional technologies
SUS	Sistema Único de Saúde (Brazilian Public Health System)
TPU	Thermoplastic polyurethane
TCLE	Free and Informed Consent form
UTFPR	Universidade Tecnológica Federal do Paraná (Federal University of Technology - Paraná)

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1 INTRODUCTION

1.1 Research motivation and background

According to data from the Unified Health System (SUS, the Brazilian Health System), called DATASUS, in December 2019, 689 mastectomy surgeries were performed in Brazil, the removal of the breast due to a malignant tumor (breast cancer). In the same month, the system reports that 138 Hospital Admission Authorizations (AIH) were issued for post-mastectomy breast reconstruction surgeries with prosthesis implantation (ANNEX A). These data indicate that twenty percent of breast reconstruction surgeries were performed after mastectomy, in the cases provided for in law, authorized by the SUS.

In the years between 2008 and 2014, a trend of increase from 15 to 29.3% of reconstructions was pointed out, as mentioned on the website of the Brazilian Society of Mastology (SBM, 2018). Possibly by some concentrated efforts when the legislation that obliges the SUS to pay for the procedure is entered into force (Law No. 12,802/2013). But the trend is clearly reversed to 20%. The other 80% of women who have undergone the mastectomy procedure by the public health service or will join a line that grows up in this proportion, (adding to the thousands left over from previous years), or simply will not apply for breast reconstruction. Despite entering the statistics, some mastectomized women are not candidates for reconstruction surgery, either because they have comorbidities that contraindicate, either because they are afraid of more pain, or for disinterest (GABAY; KARSENTI, 2013).

Breast cancer is the second most frequent in Brazil. For the year 2021, the National Cancer Institute (INCA) estimates the occurrence of 66,280 new cases (INCA [s.d.]). The universe of women who began that year to need an external breast prosthesis should be bigger than 53,000 Brazilians. Some of those women are in a long line, waiting for reconstruction, others do not want it, and still some others do not have clinical conditions to be submitted to such surgery.

Early detection of cancer, which could prevent a mastectomy, depends on mammograms performed even when there are no symptoms (screening mammography). However, the number of mammographs in the country does not meet the needs of the population, sometimes because there are no operators, sometimes because there are no devices, or because they are concentrated in the cities with the highest population density (SBM, [s.d.]).

The examination is uncomfortable and unfortunately there is no more effective substitute. In the medium term, except for the contribution given by the improvement in cancer cure therapies, a decrease in the number of mastectomies in Brazil is not envisaged in the horizon. Pandemics and hospitals blocked with exclusivity for covid patients will probably impact that number.

The search for body symmetry is quite common. Shall that be in cases where patients wait (sometimes years) for reconstruction surgery, or when they are performing their daily activities, having decided that they will not be on the line for that surgery, many mastectomized women resort to external breast prostheses.

In Brazilian stores, external breast prostheses may be found at an approximate initial cost of an equivalent of U$50. In addition to not being accessible to those who, in many cases, no longer had the resources to do a preventive mammography and ended up losing the breast to an advanced stage tumor, they are serial production resources developed by the industry. Shelf items seek to meet different biotypes and different skin tones, in a mass production way. The product offered in the shelves often didn’t consider the needs of those women, they were not part of the project.

The need for research investment to obtain better quality external breast prostheses, combined with lower costs, is greatly emphasized by European research (FITCH *et al.*, 2012a; GALLAGHER *et al.*, 2009; UCOK, 2005), who notice the dissatisfaction of users even in developed countries. If the supply of prostheses in general already has few financial resources dedicated to, breast prostheses, which are under clothing, are more unconsidered yet. However, for a woman mutilated by mastectomy, the lack of symmetry is a constant reminder of cancer, and leaves her with her self-esteem shaken, which affects her recovery (TANNER; ABRAHAM; LLEWELLYN-JONES, 1983).

Several journal articles analyzed the opinions of mastectomized women, and most of them concluded that breast external prostheses need improvement, regardless of the continent where these users were considered. The authors of those articles had contact with women from India (RAMU, *et al.*, 2015), from Ireland (GALAGHER, 2010), from China (LIANG; XU, 2015), from Australia (TANNER; ABRAHAM; LLEWELLYN-JONES, 1983) and from Canada (FITCH *et al.*, 2012), among others. It is not only in Brazil that birdseed prostheses are still widely used (BRANCO; FOGGIATTO, 2017).

Those who detect and publish problems with external breast prostheses, as a rule, are professionals who do not notice them with the intention of promoting, themselves, improvements in those artifacts. Possibly because such researchers do not have the technical conditions to solve them: they are in the area of Nursing, Medicine and Psychology, predominantly. It would be necessary for them to work with a team in the area of Engineering or Design, to develop a solution to the issues they point.

The innovation that this project proposes to develop embraces this multidisciplinary: Engineering and Design professionals, supported by a large specialized hospital and its professionals. It is, therefore, a multidisciplinary scope necessary for the final product, both as the research and the process properly considered.

The processes that give rise to the final product – prostheses – are not always known. Sometimes they are industrial secrets and have in mercantile profit their only purpose. Among the known and disseminated processes there is one, of medium-scale production, which gives rise to models distributed free of charge or at reduced costs, by the associations of mastectomized women: the prostheses of seeds. Cut and sewn in fabric, they are filled with seeds, which, among other characteristics, make them impossible to be used in the sea bath or pool activity.

The research question that this project seeks to answer, therefore, is: How to establish a reproducible method, with support of 3D scanning, CAD, CAM, 3D printing and casting, through which guidelines the manufacture of personalized external breast prostheses is feasible to public health system patients?

1.2 Research opportunity

Studies about external breast prostheses tried to offer options of customization and personalization. Most of them were focused in the process of manufacturing and do not offer a method that could be replicated, except for some with the high costs of proprietary CAD systems or expensive 3D printers. Few of them cared about the chest wall, the area where the breast with tumor was removed from, that not always stays flat. More realistic areola with nipple and Montgomery glands and ptotic breasts were not approached by such methods.

Despite all the advances in research, there is still no manufacturing method for external breast prostheses that provides for an amortization of the initial cost due to pre-existing cast models. A model using low-cost equipment and software, worried with the similarity of a real breast, and feasible to be replicated by non-profit organizations, which could manufacture such prostheses to women who use the public health system. This is the gap that this thesis aims to fulfill.

External breast prostheses, in this thesis, are the consubstantiation of the development of a proposed method to guide the manufacturing process, based on intensive research with users, literature, professionals at the hospitals and institutions and scientific investigation in Mechanical Engineering. The product prosthesis is the result of the conception of such method, which aims the popularization of low-cost technology in assistive technology.

1.3 Hypothesis

It is believed that the capture of three-dimensional images, virtual modeling (CAD), the computational resources of computer aided manufacturing (CAM), casting and 3D printing are appropriate technologies to be used to establish a method to guide the manufacture of personalized external breast prostheses. The quality of such prostheses should be superior to the models available in the country, at the same time having an initial unit cost lower than off-the-shelf prostheses. The hypothesis that drives this thesis is, therefore, that it is feasible to develop a method to lead the manufacture of personalized external breast prostheses to be used by mastectomized women who were not submitted to breast reconstruction.

1.4 Objectives

The thesis project has a general objective, which is based on specific objectives for its achievement.

1.4.1 General Objective

The objective of this project is to develop an economically feasible method to guide the manufacture of personalized external breast prostheses, using the support of three-dimensional scanning, the manipulation of three-dimensional meshes, CAD, CAM, 3D printing and casting, using free or low-cost resources.

1.4.2 Specific objectives

To achieve the objective of the work it will be necessary:

a) Critically evaluate current state-of-the-art in external breast prostheses, nationally and internationally;
b) to identify the anatomical conditions of the body region in which the prosthesis is used, the needs and expectations of the user, their dissatisfactions, the affective aspects of usability of the prosthesis and the conditions to which the external breast prosthesis product is submitted;
c) to develop protocols for three-dimensional image capture, mesh repairing, generation of biomodels and casts;
d) to propose a method to manufacture personalized external prostheses, based on low-cost three-dimensional image capture, CAD, CAM, casts and 3D printing.

1.5 Reasoning

Assistive technology is an area of little approach to science, which recognition dates from the 21st century. People with disabilities only won specific legislation in 2015 (Lei No. 13,146, JULY 6, 2015) and, like every minority portion of the Brazilian population, have difficulty exercising their rights in practice.

External breast prostheses are not yet funded or reimbursed by the Brazilian government, like so many other assistive technology resources. And due to lack of information and availability of resources (such as mammographs and their operators) mastectomy is more frequent the poorer the population. Women who are unable to afford exams are the most punished, first with the tumor, and then with all the painful treatment.

It is also for this reason that seeking a less costly alternative to manufacture a better quality prosthesis than the prostheses of seeds made of becomes a challenge, which probability of solution is greater in a Public University than in a private sector company. Low-cost products, which serve the poor portion of the population, need the support of research done by public institutions, in an attempt to repair part of the government's lack of interest and the emptiness left by private companies.

Thus, this study directs its practical results fundamentally to institutions that have as scope to serve the public that needs assistive technology, but has no way to acquire them by commercial prices, without budget sacrifice. Many women who are victims of breast cancer end up resorting to non-profit organizations or other legal entities that depend on resources from the same source as UTFPR (Federal University of Technology – Paraná). In view of the hypothesis that led this research, the most appropriate place to develop the study, within the institution, was the Additive Manufacturing and Tooling Group (NUFER), a laboratory dedicated to the design of models in additive manufacturing, which has in its faculty with professionals experienced in the area of assistive technology.

To produce a prosthesis for those who can afford out of pocket, already some private companies make, working in a range of values that can go from fifty to three thousand dollars. In the lowest cost range are the models of seed-filled prostheses, and at the top are bespoke prostheses, such as sold in the United States. In order to re-edit the hypothesis of the development of an alternative, with a higher quality than that available in Brazil, with costs lower than those practiced in the North American territory, the author of this study proposed to study a manufacturing process capable of offering an alternative more consistent with the Brazilian reality, without detriment to the quality of the product.

The fundamental pillar of the development of this technology is emotional ergonomics application, an area of Engineering that studies mainly comfort and symmetry. Every mastectomized woman needs respect for these human factors, but it is fundamentally with the women in need of public health system that this project, developed in a public institution, is concerned.

The lack of financial resources already punishes Brazilian women with late diagnosis – that in many cases are responsible for a radical mastectomy – and, later, with the difficulties throughout treatment. This project, then, makes all possible and economically viable efforts in the area of assistive technology, in order to seek processes capable of helping to mitigate the suffering brought by the memory of breast loss.

In addition to social prejudice, present in the life of every woman who feels observed and inferior, due to the asymmetry caused by the removal of one of the breasts, the recall of a poor quality assistive technology plays an important impact on patients' self-esteem. In the search to contribute to the reduction of daily suffering and to provide a better quality of life for mastectomized women who do not perform breast reconstruction, this project finds its greatest reasoning.

1.6 Organization

Five chapters are presented in this thesis.

The first one addresses the importance of the theme in the Brazilian panorama, presents its fundamental concepts, the reasoning of the study, the relevance of developing the method and on which technologies it is based.

The state-of-the-art in the theme of the research is presented in the second chapter. It explains the main characteristics of the external breast prostheses and how they are currently found, worldwide. It then introduces emerging and low-cost technologies – three-dimensional scanning, three-dimensional mesh manipulation, CAM, 3D printing and casting – correlating them with the opportunity they provide in view of the panorama of the lack of an economically feasible method that allows the design of personalized external breast prostheses, with an initial cost lower than those available on the market.

The third chapter describes the materials and methods of research, techniques and procedures adopted to achieve the proposed objectives, and the flow indicated by the proposed method to replicate the designed process. Together with the materials and methods are presented also the results. The choice of not separating the results was made because they are a consequence of the application of the method, and while each part of the prostheses is manufactured, the process is explained and its results are shown.

The validation and discussion of the results compose the fourth chapter.

The fifth chapter brings discussions and suggestions for future studies

“Practice rigorous authenticity.
Surrender the outcome.
Do uncomfortable work.”
(BRODY-WAITE, 2020)

2 EXTERNAL BREAST PROSTHESES

2.1 Assistive technology and external breast prostheses

Until the first decade of the 21st century, the current understanding of Assistive Technology (AT) in Brazil was that it was a field dedicated to a relationship between people with disabilities and artifacts capable of providing them with functionality. The Technical Aid Committee (CAT), the designation for which the AT area was previously known, in December 2007, approved the definition that follows:

> Assistive Technology is an area of knowledge, of interdisciplinary characteristic, that encompasses products, resources, methodologies, strategies, practices and services that aim to promote the functionality, related to activity and participation, of people with impairment, disabilities or reduced mobility, aiming at their autonomy, independence, quality of life and social inclusion (BRASIL, 2007).

This definition is found in the official document published by the Brazilian Federal Government from CAT meetings, in order to disseminate accessibility. This happens because the country became a signatory to the Convention on the Rights of Persons with Disabilities, a treaty of the United Nations (UN), which implied putting on the government's agenda the theme of inclusion in the society of people with disabilities.

Functionality is still predominantly the focus of AT, in Brazil; the term "quality of life" in the legislation, dates from 2007. The classic definitions – those contained in all Brazilian regulations, and, consequently, in national publications – start from the old legal concept, which listed taxingly who was considered a person with disabilities. From this concept derive the ideas of what is covered and what can be funded. Thus, breast prostheses – as well as nose and ear, for example – were classified as "mere" aesthetic, for many years, as if the loss of these parts of the body was just a reflection in the mirror, and not something that deeply affects the person's life.

Except when breast removal implies covering the area of the axillary ganglia, which, due to the length of the procedure, ends up generating some difficulty, pain or excessive swelling in the movement of the ipsilateral arm, a mastectomized woman is not considered deficient, for the legal Brazilian terms. Along the lines of Decree No. 3,298/99, if there was no mobility impairment, i.e., function, there was no disability. A woman from whom the breast was removed would be considered, at most, to have an aesthetic deformity.

Recognizing mastectomy as an impairment would possibly imply new costs for the government, as the supply of prostheses funded by the Unified Health System (SUS) or the exemption of tax for the acquisition of motor vehicles. Other countries – such as Australia (AUSTRALIAN GOVERNMENT, 2019), Canada (GOVERNMENT OF CANADA, 2020), United States (AMERICAN CANCER SOCIETY, [*s. d.*]) and Ireland (KEETON; MCALOON, 2002), for example – include at least some types of external breast prostheses in the list of artifacts covered by the public system. Not by chance, the largest number of publications that assess the importance of self-esteem in recovery also come from those countries, as well as studies that raise the reasons for mastectomized women choosing not to perform breast reconstruction, and research on the quality of available external breast prostheses.

In July 2015, however, the Federal Government approved a legislation that started to be valid in January 2016, which brought a broader focus to the definition that only mentioned functionality. The scope of protection started from the possibility of taking into account a multidisciplinary examination, instead of the restricted list of deficiencies, capable of assessing, in addition to the impediments in the functions, in the structures of the body and the limitation in the performance of activities, socio-environmental, psychological and personal factors and what it called "restriction of participation" (BRASIL, 2015). Since this law, it can be considered that there is a broader concern with the impact of what was previously "mere" aesthetic, and that it does not occur only in the context of appearance, because there are consequences beyond the physical ones, for a woman who has an amputated breast.

There is, notably, a progress in Brazilian legislation, but it is in other world references that one can find better aid for the insertion of breast prosthesis in the list of products encompassed by the term "Assistive Technology". The text of the Brazilian government on the subject (BRASIL, 2009) even mentions a "trilogy" – impairment, disability or disadvantage – defining this as a "deprivation of social participation, in equal rights and conditions" (BRASIL, 2009, p. 15). The approach arises in the light of the definition of ED given by the National Secretariat for the Rehabilitation and Integration of Persons with Disabilities (SNRIPD), Portugal:

> Technical Aid means any product, instrument, strategy, service and practice used by people with disabilities and elderly people, especially produced or generally available to prevent, compensate, relieve or neutralize an impairment, disability or disadvantage and improve the autonomy and quality of life of individuals. (BRASIL, 2009).

Disadvantage, as retro defined, is what attracts looks (first the own regard, and then the others) to everything that is different, asymmetric, out of the ordinary, and intensifies the isolation in society; it is also what an external breast prosthesis seeks to prevent. This definition, which manifests a protection that goes beyond disability, is also supported by the ISO – International Organization for Standardization – for whom external breast prostheses were already considered as Assistive Technology, and in it received the code 06 30 38 (ISO - INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, 2022), within the title: "Technical aid for people with disabilities – Classification and terminology". ISO 9999:2222, that refers to Assistive Technology, is in the seventh edition. The term "assistive products", replaced the term "technical aid" (used in previous editions of the international standard), and classifies each member according to their function, assigning them codes.

Although it presented these international references, the government (BRASIL, 2009) opted, after all, for a restricted protection, and closed its foundation by highlighting a concept of Social Technology, understood as:

> [...] a set of transformative techniques and methodologies, developed and/or applied in interaction with the population and appropriated by them and representing solutions for social inclusion and improvement of living conditions. (BRASIL, 2009, p. 16).

This definition is mentioned here to emphasize the need for AT to be developed from the observation and the user's listening, as highlighted by the text, in continuity:

> [...] the knowledge of the user, their demands and the context in which this technology will be applied, collaborates for this user to appropriate and really enjoy a technology that meets their need and expectation. (BRASIL, 2009, p. 16).

It is at this point that lies the main problem of external breast prostheses (and so many other assistive products): the dissatisfaction of users, both with the artifacts, or with the ways used to present them.

The publications that analyze the non-conformity of these artifacts to the expectations and needs of the users are, as a rule, coming from the areas of Nursing, Plastic Surgery, Oncology and Mastology. It is not under the term "technology" or with the expression "assistive technology" that the searches in the literature point out where the design flaws of these artifacts are. Probably because those who investigate only indicate that there are problems in the product, but cannot, by the area of competence, identify how to fix them.

Repeatedly, as in other areas of AT, when researching prostheses or orthotics, the conclusion of the articles is always due to the need for subjective improvement of artifacts, but without an accurate indication of which parameter, to what extent, needs to be changed. What is commonly observed, along with displeasure, throughout the field of AT, is abandonment: voluntary, represented by the dissatisfaction that can be with one or several parameters of the product, or necessary, that happens when the artifact simply cannot be used, because it hurts, or because, for example, it is not waterproof, as occur with many external breast prostheses (BRANCO; FOGGIATTO, 2018).

In India, where breast cancer is the most common in urban areas and the second most common in rural areas, a group of researchers, using a questionnaire, conducted a telephone survey with 63 women after their third year of cancer treatment (RAMU *et al.*, 2015). They found only 40% of them using some kind of prosthesis. Among the users, 36 in all, six of them wore external prosthesis made of silicone, eight wore a padded cup, twelve of them had cloths or pieces of clothing replacing the breast, and one reported using some other type not described. The concern with self-image was more verified in the group of prosthesis users than in those who did not use any artifact.

The authors pointed out that no study on external breast prosthesis had been done in India, where more than 25% of cancers affecting women are breast cancers. They found out that the most cited causes for the non-use of prostheses were age, lack of motivation and awareness. They also highlighted that 48% of patients are currently under 50 years of age, and that there is an increase in the number of patients aged between 25 and 40 years.

One of the questions that their questionnaire explicitly mentioned was the cost of the prosthesis: "Are you interested in having a good prosthesis, at a reasonable price?", they asked, probably in order to assess whether the price was an impediment to the acquisition of the prosthesis.

With a survival rate of more than five years, which increased from 75% (in the 1970s) to 89% (in 2015), the number of younger women affected by breast cancer in

India also grew, and the intersection of this information with the replies to the previous lead the authors – oncology professionals – to infer that there is a need to develop better prostheses at an affordable price. They do not comment on the range of values that would correspond to "reasonable/affordable price". Again, there is subjectivity guiding the evaluation, but according to Ramu *et al.* (2015), all women accustomed to prostheses reported the need for improvement in comfort, shape, size and cost.

At an international level, there are several patents, but almost nothing about the manufacture of this assistive technology or what guide its design methodology. What is possible is to obtain these approaches indirectly, just as the Indians did: finding out the dissatisfactions, listening to the users.

This is what made a multidisciplinary Irish group, that conducted a study to investigate the supply and fitting of external breast prostheses. They obtained the same answers that in India, but then in a first world country. In Ireland, a first prosthesis is provided, said temporary, one week after mastectomy, and the prosthesis called by the authors of "permanent" is fitted within six to eight weeks after surgery (GALLAGHER, Pamela *et al.*, 2006). Furthermore: it is recommended that it should be replaced every two years, funded by the government medical card, or with some reimbursement for health insurance. And the same is true for the two bras that the woman receives, without charge, on this occasion.

The terminology "temporary", however, is imprecise, given that even the most expensive prostheses have a shelf life, after which they should be replaced, that is, they are also temporary. Gallagher *et al.* (2009) conducted a survey of 527 women with at least 1 year post-surgery, of which 26.4% continued to use the prosthesis called "temporary", and 8% used it more regularly. 43% of respondents indicated that they also wore a bra with a padded cup or something made at home (wool, cotton, rice, shoulder pads or sponge). To the authors, this is an indication that there is a clear dissatisfaction with what is offered as a prosthesis by the system.

Still in the same study, asked for which activity the prosthesis was most relevant, the participant answered “social activities” (some performed outside the home, others at home). They stated that the most limited activities by the prosthesis are sunbathing, buying clothes and swimming. When they specifically asked about dissatisfaction with some item of the external breast prosthesis, weight (24.4%), comfort (17.3%) and movement with the body (14.3%) were among the items highlighted by the authors. They made, however, a more extensive list, which also includes dissatisfaction with:

color (6.8%), shape (11.0%), appearance when in use (10.6%), fit (13.8%), texture (8.9%), temperature (11.2%), durability (8.7%), quality (6.6%) and value by price (13.2%). Satisfaction in general was 11.5%. 43.3% of the women who had to disburse some amount for their prostheses stated that the cost influenced when they had to replace them. Other aspects evaluated by the research dealt with the environment in which these external breast prostheses were provided, the treatment provided by the specialists in the experimentation (they exist in Ireland), the information material and the specific bras.

A novelty that appears in the study of the Irish researches is their indignation with the delay of three weeks in the replacement of prostheses. It should be noted that these are products manufactured in a mass production line.

In a study done exclusively on temporary prostheses it was found that thirty percent of mastectomized women never received a temporary prosthesis, and that in half of the remaining 70% who received it, there was not a professional who was concerned with assisting in the fitting of the temporary prosthesis offered (SIMPSON, 1985, *apud* KEETON; MCALOON, 2002, p. 46)[1].

The research from Ireland is extensive and in-depth, and interviewed, in two other groups, the nurses specialized in breast care and the retailers that commercialize the prostheses. The evaluations extracted from them other significant perceptions, such as the fact that none of them were at stake with the shape, appearance or temperature of the prostheses. These professionals should show the varied models of prostheses available, but according to 25% of the users, the offers were limited. In their conclusions, the researchers highlight that in Ireland people who make prostheses do not have their profession recognized, and that there are no standards of skills and behaviors for those who perform activities related to prosthesis fitting.

In another publication of Gallagher *et al.* (2010), that specifically addressed the focus groups performed with the users of external breast prosthesis, they recorded verbal reports of the evaluations on this assistive technology. There are more detailed the reasons for the dissatisfactions, didactically grouped as "comfort" or "weight". One of the aspects scored was the shape of the external breast prosthesis, uncomfortable when it does not fully cover the new shape of the thorax, leaving hollow spaces between the prosthesis and the skin.

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[1] Simpson, G (1985). Are you being served? Senior Nurse. 2,6,14-16.

A similar survey on the supply and proof of the external breast prosthesis was carried out by a nurse and an oncologist, researchers from the United Kingdom (KEETON; MCALOON, 2002). They state that such experimentation should be between six and eight weeks after mastectomy (silicone model), or immediately after surgery (model called "temporary soft-fill").

In Brazil, Souza (2008) defines the external breast prosthesis as a "viable alternative to safeguard the body image of women", and highlights it "as one of the important coping mechanisms for the preservation or rescue of the female image, as well as being a means of pushing the eyes of society". The analysis of the variables that affect the satisfaction of Brazilian women with external breast prostheses brought very peculiar answers.

Interviewing by telephone 76 women, who underwent mastectomy and who sought the Dom Aquino Corrêa Comprehensive Rehabilitation Center, in Cuiabá (Mato Grosso), to receive an external breast prosthesis, Borghesan *et al.* (2014) inferred a degree of satisfaction of 56.6%. This is the highest tax found in investigations on the subject, in the aspects of weight, heating in the region and displacement of the prosthesis in daily activities.

According to the results obtained by the authors, there was no change in sexual activity, nor in the relationship with the partners of women who suffered breast amputation in the research period (2009 to 2012). In that survey, the models of prostheses found are not mentioned, nor to which, objectively, corresponded those indices. If the prostheses used by Brazilian women are so successful, it would be necessary to measure what mass has this prosthesis that makes the participant feel so comfortable, what relationship it has with the natural breast, as well as from which material used comes the smell that eventually displeases, raised by the research, among other data stated.

A new design in external breast prostheses was analyzed by Kubon et al. (2012): personalized external breast prostheses were offered to mastectomized women, so that they could evaluate their attributes, as well as the experience of tests with professionals in the area, and nineteen of them answered questionnaires about the new assistive technology.

The qualitative methodology allowed analyzing the reports of the participants, enchanted with the prostheses made exclusively for each of them, according to their body shape. It was an air-filled prosthesis, with some risk of deflating on an airplane flight, for example, and which areolar complex did not look so much like the natural, it was reported. Issues such as the difficulty of dressing with some types of bras and the possible slippage in the performance of exercise or swimming were reported. The noise of the prosthesis was also mentioned. In general, participants would recommend the experience and use of the external breast prosthesis to other women in the same situation.

It is common that, in addition to evaluating the appreciation of mastectomized women with external breast prostheses, investigations on this assistive technology indicate the lack of exempt publications that allow to infer which performance parameters effectively are valued by mastectomized women. They do not mention how they have been found out, as well as where the foundations that companies that manufacturers of prostheses take into account in the design of these assistive technologies come from. The explanatory materials produced, as a rule, are made by the prosthesis manufacturers themselves.

Researches point out that it is difficult to overcome breast loss when constantly reminded of the mutilating surgery; several studies are followed along this line that deals with the impact of self-esteem on the recovery/overcoming of cancer, and most of them conclude by the need for improvements in external breast prostheses (CRUZ *et al.*, 2018; TANNER; ABRAHAM; LLEWELLYN-JONES, 1983) (TANNER; ABRAHAM; LLEWELLYN-JONES, 1983).

2.2 External breast prostheses background

Although men and women have, by definition, breasts, and both can develop tumors in the region, it is in female individuals that the diagnostic generates the greatest impact. Because in them the breasts protrude beyond the chest, differently from what usually occurs in them. The anatomical difference, added to the fact that it is also an erogenous zone and is related to the breastfeeding of the descendants, became an aspect that evidences femininity.

Cancerous tumors, when they occur in this area, need to be excised with safety margin. They can take with them, depending on the size that has reached the nodule or according to the amount of them, the volume of the entire affected side, flattening half the breast (when located on only one side), or even all (when bilateral).

Mastectomy is the name of the surgery in which the breast is extracted, and when the full extension of one of them is removed, it is called total or radical mastectomy; if it is possible to keep part of it, mastectomy is said to be conservative, or quadrantectomy, or even setorectomy. The later the diagnosis, the more the disease progresses, and generally the more tissue has to be removed. Nodules with a characteristic of greater aggressiveness may also lead to integral breast loss.

Advances were made in order to preserve as much as possible of the breast region, in the largest number of surgeries (SAKORAFAS; SAFIOLEAS, 2010), since the first technique, elaborated by Pavlos Ioannou (in 1861) and consecrated by the American Halsted (in 1882), was registered (TSOUCALAS *et al.*, 2011). At the same time that the surgical procedure has evolved, the number of cases of breast cancer in Brazil has increased: in 2010, there were 49,240 cases (SBM, 2010); for 2019, INCA projected 59,700 cases (INCA, 2018), which ended up not implying a decrease in the number of women who need to be mastectomized.

There are also advances in the area of diagnostics: devices with more accurate technology are able to report earlier the existence of the tumor. However, whether this effectively provides faster treatment is another issue: better equipment is more expensive and less available in the public health system.

Along the units of the Federation the reality is different. There are regions in which there is simply no mammograph, with any quality whatsoever, or places where the devices are defective, as reported Rede Globo television on Cancer Day (OLIVEIRA *et al.*, 2015). Although not all deaths from breast cancer are due to late diagnosis, it is worth mentioning the research carried out over ten years by the Brazilian Society of Mastology in this topic. It related breast cancer deaths with the Human Development Index (HDI) of each region of the country, and the average was 6.6 deaths for each group of 100,000 people, in the South and Southeast, while in the North and Northeast regions the number is more than double: 14. The researchers analyzed ten-year data and concluded that the reduction in mortality rates was found in the most developed states, and attributed it to the possible reflection of better health care (GONZAGA *et al.*, 2015).

Initiatives such as the Barretos Cancer Hospital, that has eleven vans providing itinerant mammography care and examination in Brazil (CASTRO; MOURA, 2015), are still not enough to cover the deficit in the public system. Even in the capital of the country there is a deficiency in the diagnosis: in September 2016 the Federal

Prosecutor's Office filed a court request to charge an end to the line in the mammography exam at Federal District, in view of the information from the Health Department that there were about four thousand patients waiting for an examination (LUIZ, 2016).

In Brazil, mainly due to late diagnosis, many total mastectomies are still performed. Law 12. 802/2013, in order to protect the self-esteem of those who had to undergo the procedure, determined that immediate reconstruction surgery – that is, in the same surgical act of withdrawal – has its costs covered by the SUS.

The prediction of coverage of that surgery by the SUS existed sixteen years before (Resolution No. 1,483, SEPTEMBER 11, 1997), it was only added that reconstruction should be performed in the same surgical act of mastectomy (or at the time the patient had clinical conditions), both covered by the public health system.

However, it is not any expert who accepts the amounts paid by the Federal Government to perform a reconstruction. Putting together two tables, one that shows how much was paid as medical fees, in July 2020, under the code corresponding to the "reconstructive breast plastic after mastectomy with prosthesis implant" (R$ 5320.76), and another one, which indicates how many of these surgeries were performed (33), in the same period, the amount of R$ 161.23 is obtained, as shown in ANNEX B. What means US$ 29,31 for professional services in each surgery.

Nine professionals were trained in a task force specifically for this purpose, by the agreement of the Brazilian Society of Mastology with the Federal Government, in 2014 (SBM, 2014). Data from that association report that more than 7,000 Brazilians enter the queue for reconstruction each year, mainly because there are not enough doctors to operate, but also, among other factors, because if it is necessary to choose between having two mastectomies and a mastectomy and a reconstruction, the possibility of saving two lives will take priority. Availability of room and equipment enter this weighting.

While waiting for this reconstructive surgery, women resort to external prostheses that, as SUS mentions, only decrease the change in body image, because they are not personalized in their size, nor in their coloring. The concept of prosthesis – which encompasses all artifacts intended to repair a functionality of a non-existent member – is what, minimally, the Brazilian government understands should be used by the patient. In the Consensus Voice, which provides guidance on breast cancer, it is informed that patients should use such artifacts if they are not able to carry out the reconstruction (MINISTÉRIO DA SAÚDE, 2004, p. 18). But it does not consider the free supply of external prosthesis, via SUS, in any model. It is a reality somewhat different from that found in developed countries, in which there is the possibility of covering the costs (or part of them) with a prosthesis and even the cost of the bra that will contain it, as occurs in Ireland (GALLAGHER, Pamela *et al.*, 2009), in Canada (RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC (RAMQ), [s.d.]) and in Australia (CANCER AUSTRALIA, 2021), for instance.

In addition to the huge line of women waiting for breast reconstruction funded by the SUS, there are those who simply do not intend or do not have (yet) clinical indication to do the surgery. Contraindication for immediate reconstruction surgery occurs, as plastic surgery studies indicate (GABAY; KARSENTI, 2013), when there is an obvious risk situation (smoking, obesity, high blood pressure, diabetes, or age over 65 years). It is considered that it is not yet the time when there is, for example, radiotherapy to be done. Among the reasons listed by the research participants that point to causes for the decision not to perform reconstruction definitively, are: fear of a new surgery, fear of more pain, focus on healing (fear of relapse), advanced age, and disinterest.

With regard to the theme of lack of interest, there are several justifications addressed in the literature, especially in the field of Psychology, which point to reasons why a woman does not want – although she has the possibility – to do breast reconstruction, and which relate to the meaning that the breast occupies in her life. Even considering the possible overcoming of the absence of this part of the body, one should keep in mind the eventuality of the declaration masking a real reason, what the researcher needs to respect.

All these women should be presented with the alternative of using an external prosthesis in place of the excised breast, as a way to minimize both visual asymmetry and simulate the sensation of volume. Some mastectomized women will use a shorter-term, more rudimentary resource, to later replace it with an industrial prosthesis; others may remain with the simple artifact throughout their lives, and there are records of those who simply do not use any prosthesis, because they understand that it is trying to mask the disease (POTTS, 2000 *apud* KEETON; MCALOON, 2002)[2], or eventually by caring little for the visual situation, more afraid about the healing.

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[2] POTTS, L. Ideologies of Breast Cancer – Feminist Perspectives. [s.l.]: St. Martin's Press: 2000.

For women who seek a resource to remake body symmetry after a mastectomy, the solutions that are presented have varied between home models and industrialized products, and the most common is that they have a primary focus on breast volume replacement.

Over the years in which breast amputation is recorded, the materials used for breast prostheses varied little: they came from rubber, which was already known for aesthetic purposes, as a seduction strategy, as translated in their drawings *La Vie Parisienne* (MARCELIN, 1881) and seventy years later latex continued to be suggested, according to the Patent US 2543499A (KAUSCH, 1951); with the difference that it is done for the specific purpose of application after surgical removal of the breast. In the following decade, the same author obtained protection for a patent for external breast prosthesis with resilient plastic foam and a resilient yielding backing material, according to patent registration US3067431A (1962).

Despite early technical evolution, still in the 21st century many of the artifacts used and currently marketed (or offered free of charge) impress by the precariousness. In the context of artifacts made in the homes of users are fillings with various cloths, old socks, foams and grains such as bird seeds or millet (TANNER; ABRAHAM; LLEWELLYN-JONES, 1983).

Variations of those are used on almost all continents, starting with Oceania, as they report, and also found in Ireland (GALLAGHER, Pamela *et al.*, 2009), in India, as shown in the Figure 1 (RAMU *et al.*, 2015), and in Brazil (BRANCO; FOGGIATTO, 2018).

Ramu *et al.* (2015) describe that 29.6% of the women interviewed use padded cups as an external prosthesis, while 44.4% use cotton clothing and fabrics as a material to re-put on cotton, which the author refers to as "things made at home".

Between home and industrial manufacturing there are some models produced by charitable associations. Generally they bring together volunteers (victimized or not by breast cancer), that work in a serial production process, based on a pattern designed on paper and cut into fabric, graduated in the various numerals, and in a filling with bird seeds or with polyethylene or plumb granules. It is possible that another variant is in this conception, which are the first models received by the users, still in hospitals, soon after the mastectomy. There are several mentions of their existence, made of sponge, cotton or foam (FITCH *et al.*, 2012b; LIVINGSTON, 2005; THIJS; WIEL, 2001), or with a lightweight material such as polyester fiber (GALLAGHER, Pamela *et al.*, 2009; KEETON; MCALOON, 2002), without the literature commenting on its origin, only referring to the external prosthesis "of temporary use”.

Figure 1 – Homemade prostheses found in surveys carried out with patients from India

Source: Ramu *et al.* (2015)

It is common to report on the little information and minimal choice that women mastectomized for breast cancer had, even three or six months after surgery, before bringing a definitive model to their homes. In countries of Europe, Australia, the United States and Canada it is investigated how the selections of the models occur. In Brazil, there is not much to choose from. Either women use the prosthesis sewn by associations, or they acquire (in the same associations/ foundations or in stores of orthopedic products) models which size numbers are a novelty in the life of the mastectomized woman (they do not necessarily have correspondence with any item of clothing). Its formats were idealized by the industry, with weights and colors equally imposed by some designer not necessarily based on listening or observation of users, or scientific research data.

The approaches that the literature made, in order to understand the shape, volume, color, mass and movement of the breasts and that, in some way, could have been used in the development of better external breast prostheses guide the next item of this review.

2.3 Attributes of the external prosthesis product

Designing an element that is similar to a part of the human body implies measuring. Breasts have several attributes such as shape, volume, color, weight and movement, which should be verified, in order to determine what requirements to be met, to develop a prosthesis as similar as possible to them. Although later, some item of that similarity can be refuted in the detailing phase of the project, but even to know to what extent and why this should be done.

As already mentioned, many researchers conclude their publications stating that the external prosthesis evaluated, measured a high degree of dissatisfaction, heats up, or is very heavy, but does not inform the precise data of the object evaluated (the prostheses themselves), which could allow replicating their study. Some of those features will be raised in the following topics.

2.3.1 Shape

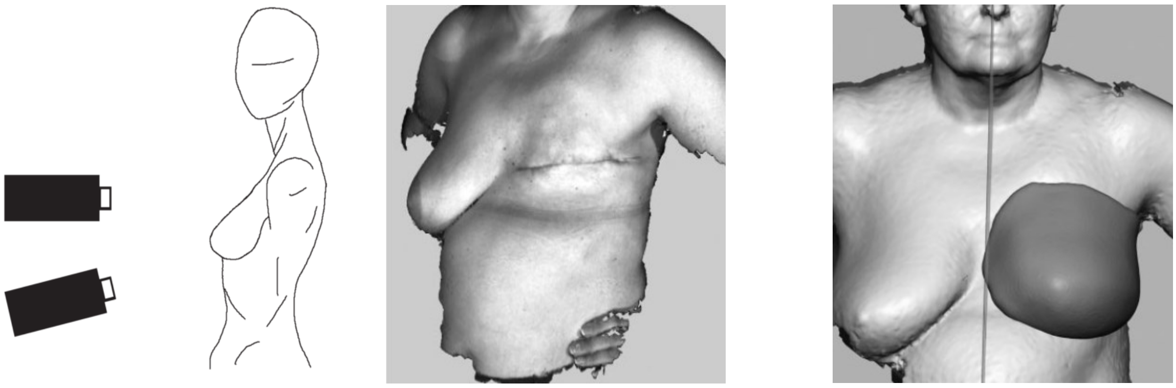
In addition to the common variations between humans, the shape of the breasts eventually varies in the same woman, either by size or by shape, or by the separation that exists between these two skin attachments. The approach to this parameter has evolved mainly with the help of computer resources.

It was in an attempt to predict the shape for an ideal custom bra cups that Wang e Zhang (2007) explored a way to simulate the various breast shapes and created a kind of library of these formats, after capturing real images three-dimensionally. Using free-form-deformation*,* a feature used in virtual modeling and computer animation, they established control points in the mesh generated after scan and, stirring at these points, made the necessary deformations to achieve the shapes they intended. At the end, they planned these shapes to quantify the size of the bra cups.

Eder *et al.* (2011) sought to evaluate the contour of the breast region after implant placement and recorded the area using a portable scanner (Konica Minolta Vivid 910 3-D *laser scanner*™), laser technology, and compared the before and after augmentation mammoplasty, followed over six months. Considering that this type of surgery aims at projection without breast fall, the evaluation allowed good results, but with the high costs of a commercial scanner.

Specifically aiming at the design of a prosthesis, Eggbeer & Evans (2011) used three-dimensional digital image capture of the remaining torso and breast of a unilateral mastectomy (Figure 2a), with a proprietary photogrammetry system (3dMtorso™), as demonstrated in the Figure 2b. They worked on this image using the Geomagic™ software and obtained a cast that not only copied the subsistence shape, but also the part of the skin where the scar was (technically called chest wall), on which the prosthesis generated by them would be placed (Figure 2c). Their technique is demonstrated in the Figure 2.

Figure 2 – The technique by Eggbeer and Evans (2011)



a b c

Caption: a. Positioning to acquire the 3D image
b. Results after 3dMtorso™
c. Results after Geomagic™

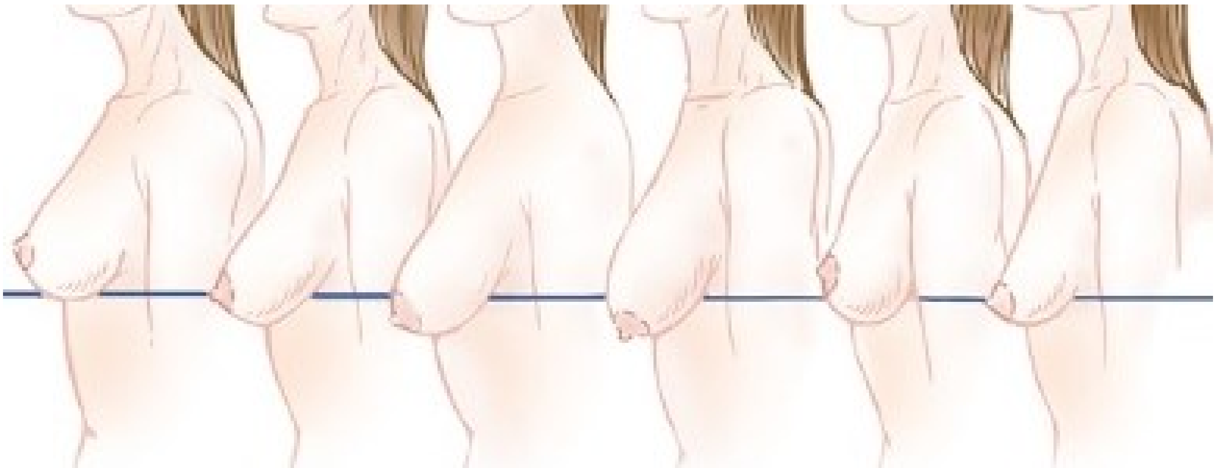
Source: Eggbeer and Evans (2011)

The authors generated images of the breast positioned inside a bra and without it, and chose to make the prosthesis using the image of the participant wearing a bra. They concluded that their prosthesis met their requirements: it was bespoke, weighted 845.0 g, cared about the chest wall and underarm, and had a different profile of the models offered commercially. Their approach discarded the image of the user not wearing a bra. Without the bra, there may be a region of shadow, represented by the fall of the breast over the abdomen.

Breast fall on the abdomen occurs due to sagging, and is technically known as ptosis. It is known that it can be evaluated in some degrees (REGNAULT, 1976), as demonstrated in the Figure 3. As lower the degree, the easier it gets to delimit what exactly is the breast (where it ends and where the abdomen begins).

The challenge of capturing the integral form of the breast with three-dimensional scanning technology is greater, the higher the degree of ptosis, because the breast crease is covered by the breast, and there will be, in that lower area, a shadow zone. By analyzing the mesh, there will then be an opening, which will need to be repaired.

Figure 3 – Graphical representation of ptosis degrees



a b c d e f

Caption: a. Normal
b. Degree – Light sagging
c. Degree 2 – Moderate sagging
d. Degree 3 – Significant sagging
e. Pseudoptosis – Sagging of the lower part of the breast
f. Poor distribution of the parenchyma - Unusual shape

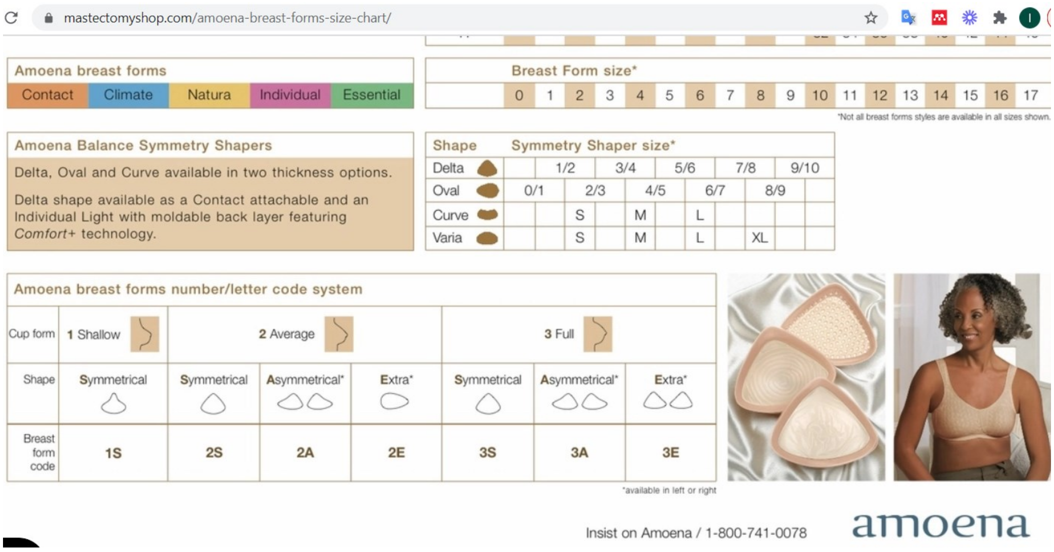
Source: Adapted from REGNAULT (1976)

That is probably why even authors that illustrate their articles with mastectomized women who have ptosis did not contribute to research an alternative able to approach those shadows. This is the case of the method developed by authors who used proprietary scanners (MONTEJO MAILLO *et al.*, 2020) and silenced about ptosis and contours of chest wall.

To speak in breast shape, for an external prosthesis, is not only to worry about the protrusions, but also with the recesses. Some researchers focus their method on the contour result, but in the case of breast prostheses is fundamental for comfort the shape of the chest wall (including the underarm area), especially because it is a region in which the skin is more delicate and should not suffer friction.

Among the most expensive models of off-the-shelf prostheses, the variety of shapes (in addition to sizes and colors) is also already a concern (or a selling argument). Amoena™ even offers the availability of distinct external prostheses for the left side or to the right side of the body, as shown in Figure 4.

Figure 4 – Encompassing a broader universe of shapes



Source: AMOENA BREAST FORMS SIZE CHART, [s.d.]

2.3.2 Volume

Looking at the study by Veitch *et al.* (2012), illustrated by Figure 5, one can better understand the discussion on the issue of the retro shadow zone mentioned. In the approach of Eggbeer and Evans (2011) the strategy used was to use the scanning obtained with the bra worn. Otherwise, it remains always an area of breast not comprised in the volume.

Veitch *et al.* (2012) used the Archimedes model, in which the patient has her breast submerged in a bucket filled with water and obtains the breast volume measuring the water that overflows (Figure 5a), to compare to the mathematical-geometric model that they created.

Using a body scanner, the image was acquired (Figure 5b), and combined with a work of correcting the geometry (Figure 5c). This allowed to include in quantification an area that hardly dissociates itself from the region – the upper part of the abdomen

– considering that the participant of the research is a woman whose breast has dropped volume (and also pronounced abdomen).

Figure 5 – Measurement by Archimedes technique and comparative calculation, made on three-dimensional image

a b c

Caption: a. positioning for water displacement
b. three-dimensional scanning
c. geometry calculations

Source: VEITCH *et al.* (2012)

Both in the more conventional method, which uses water displacement (Archimedes model) and in the most evolved technique, in which three-dimensional scanning is used, the results inform a volume very close to the real one.

It was evidenced that one of the biggest drawbacks of Archimedes' model – which is considered the gold standard – is the evident discomfort, either by positioning or by the research contact – participant or by the situation itself. But it is undoubtedly a less costly method than the use of commercial scanners.

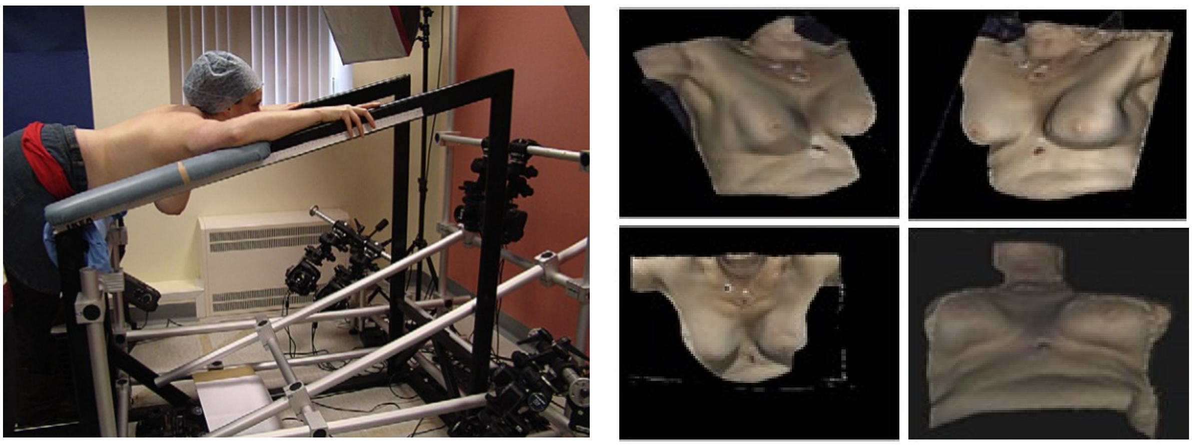
The discomfort was even the subject of an adaptation of Archimedes' model, developed by two surgeons from Istanbul, Tezel and Numanog (1999), for use in breast measurement. Instead of submerging the breast, they proposed subtracting the overflowing amount of an initial volume (previously measured, inserted in a plastic bag), when that package was conformed to the breast.

Another advantage that this type of three-dimensional scanning has, is the possibility of including, if desired, the area closest to the armpit, but as this was not the specific case of the example mentioned in the article, the calculation did not take it into account. It is an important region, when talking about external breast prosthesis, because a mastectomy eventually affects axillary ganglia, which can cause depressions in the musculature, protrusions on the skin, and therefore change the anatomy in that region.

Another obstacle to the use of submersion to measure breast volume is that raised by Henseler *et al.* (2011): it is difficult to measure someone always in the same way, submerging exactly to the same point, stopping at the same place of the chest wall, which ends up implying different results with each record. This is what they found when they made six sequential comparisons of each of their volunteers. These authors used a lower cost system than the work of Veitch *et al.* (2012), and also based on three-dimensional images. Instead of *the body scanner* they set up a system with four tripods, each with two digital photography cameras, and with them they simultaneously captured four pairs of images that were later assembled and generated a three-dimensional surface. Henseler *et al.* (2011) concluded by the reliability of size evaluation made with stereophotogrammetry, but not for indication of volume measurements.

In a later publication, Henseler *et al.* (2012) show the system with the volunteer positioned (Figure 6a), as well as brings the three-dimensional images generated (Figure 6b), which shows that they cannot be used for shape acquisition either, given the angle of capture, considering that the breast is shifted to an unusual position.

Figure 6 – Breast imaging system by stereophotogrammetry



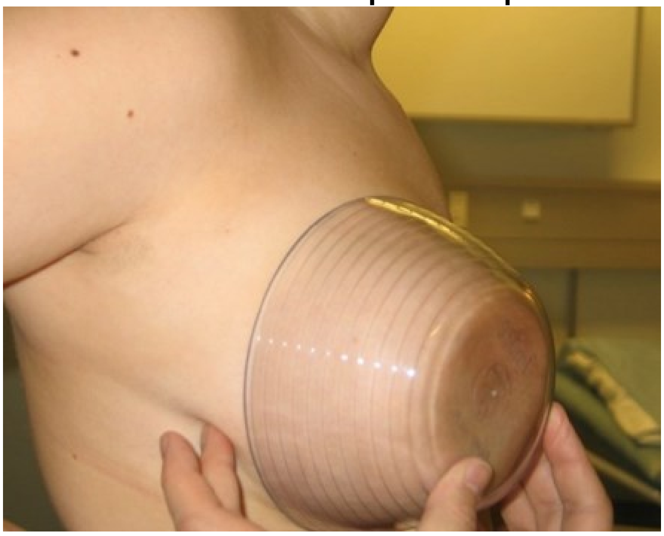
a b

Caption: a. the system, in operation
b. the resulting images

Source: HENSELER *et al.* (2012)

Another publication that evidences the bias of methodologies to measure breast volume when it is bulky and has some fall is that of Ikander *et al.* (2014), who used transparent cups of different sizes to assign in which range would be the breast volume of the patient in question (Figure 7).

Figure 7 – Breast measurement technique, illustrated here with one of eleven different sizes of plastic cups



Source: Ikander *et al.* (2014)

Although more rudimentary than studies using three-dimensional scanning, the image used by the authors' artifact (from the glass containing the breast) points out, again, that the volume they tried to measure encompasses a content despised both in the result sought by Tezel e Numanog (1999), and in the measurement made by Zha *et al.* (2005). These last authors sought a method of measuring the breast without contact, on a mannequin with breast representation (without any projection on the abdomen).

The cup, however, depending on how much skin and musculature is in the breast, may be left with certain regions without filling, which makes this volume evaluation not as accurate either.

If the goal is to use a simpler and cheaper artifact, the Grossman-Roudner disc is more reliable than the plastic cups used by Ikander *et al.* (2014), although, in its original design, the device is also not able to contemplate all volumes. There is, however, the proposal to Kayar *et al.* (2011), which is to follow the same methodology and develop a few more disks. Similar to what was done with the cup, the breast is surrounded with a disc designed in transparent, colorless acetate, with marks that identify the volume, depending on the circumference found from the generation of a conical surface. As the discs are opened, they are that conform to the breast, and not the other way around, as with the cup.

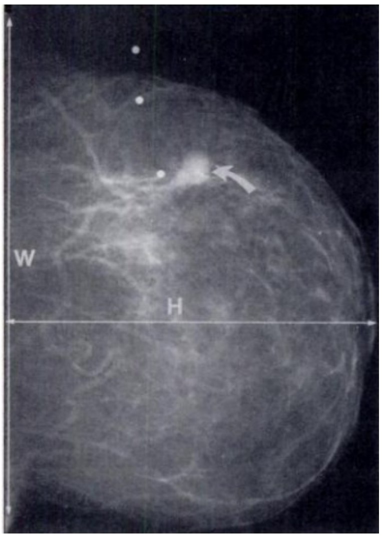
Techniques for measuring breast volume are most commonly used in the field of medicine, in order to determine, for example, which implant will result in the choice of the doctor, at the time of performing a reconstruction with implantation of prosthesis under the skin, or to perform a mammoplasty.

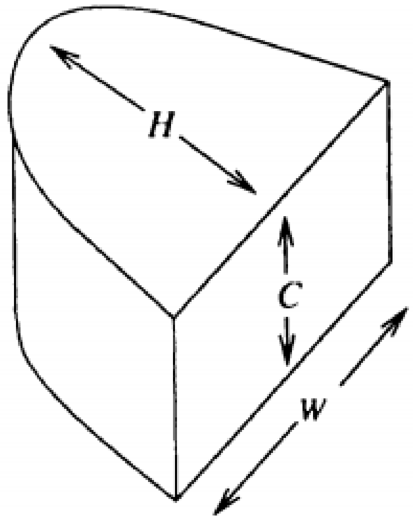
The search for precision in this area derives from the degree of aesthetic requirement of patients who pay for elective surgery, or from the fact that surgeries that reduce breast size are not always covered by public health system. Only patients whose condition of need is proven to the public system – due to excessive weight overload in the spine or by asymmetry, for instance may not pay for it. Indirectly, they end up allowing to inform the volume of the breast for any other circumstance or interest, and therefore it can be of benefit to those who want to infer which volume has the remaining breast, with which the prosthesis should supposedly coincide.

Other suggested techniques to obtain this measurement start from the film of an examination – mammography – to, approaching the recorded form to the image of a geometric solid and applying algebraic formulas or computerized algorithms, predicting breast volume. Kalbhen *et al.* (1999) established differences between six different methods, which vary not only by the chosen three-dimensional shape – circular cone or elliptical half cylinder, among others – but also by the calculation developed. One aspect that fundamentally differentiates this way of measuring the breast volume from those previously presented is that the authors present a kind of "real proof" of the account, using undeniable means: the measurement of the specimen. For a doctor this option is facilitated, since immediately to breast removal, in the operating room, it can have the actual volume, and then compare it with any other method. To ensure greater impartiality, those who measured mammography did not know the value measured in the physical breast, removed in the mastectomy, and the values were then confronted.

Kalbhen *et al.* (1999) highlight that there is the possibility of obtaining this value from other tests, such as magnetic resonance imaging and computed tomography, but this means more radiation and higher costs. Thus, they concluded that the adoption of the formula that indicates that the breast volume can be better approximated using a semielliptical base prism. Among the two options that there were for the application of the tracing, suggested as more direct and linear two measures taken in the craniocaudal projection (instead of the medium-lateral oblique), as shown by the Figure 8, added to the compression measurement (informed by the equipment).

Figure 8 – Transposition of mammography image to solid, for application of the formula V= π/4 x (w x h x c)





Source: KALBHEN *et al.* (1999)

Kayar *et al.* (2011), using this same way of investigation, mammography and the specimen compared the measurements obtained with that of three other methods: Grossmann-Roudner discs, anthropometric measurement, and molding. Although they used the same formula from the previous study, on the same geometric solid (for the mammography design), when they evaluated the specimen, they made the measurement prior to mastectomy, with the breast still in the patient's body. Based on a modified water displacement model, Tezel e Numanoglu (2000 *apud* KAYAR *et al.*, 2011)[3], measured the water contained in a plastic casing, and only that package touched the body of the research participant – who is almost seated, unlike the Tezel e Numanoglu (2000), where she would lie down. Despite these differences in

[3] TEZEL E, NUMANOGLU, A. Practical do-it yourself device for accurate volume measurement of breast. Plast Reconstr Surg. 2000; 105:1019–23.

procedure, the authors also concluded by the higher accuracy of mammography to determine breast volume.

Fung *et al.* (2010) also reinforced the acceptance of mammography as an instrument for determining breast volume, however establishing a reasoning about the projection of an elliptical cone. Later, Maitra, Nag e Bandyopadhyay (2012), also concluded by using mammography as a valid method for calculating breast volume. Arguing that the image engraved on the acetate plate generates two halves of an elliptical paraboloid, the authors established a computer program capable of automating the calculation of this solid. From the measurements of axes drawn on mammography, according to them, it is possible to define, for each set of values, the corresponding volume. The conclusions of the Fung *et al.* (2010), e Maitra, Nag e Bandyopadhyay (2012), however, did not allow the accurateness of the results to be evaluated, since there was no real evidence.

Chae *et al.* (2014) studied the possibility of calculating breast volume accurately, using the feature of images from computed tomography (CT) or magnetic resonance imaging (MRI). They aimed to better plan breast reconstruction surgery, which is why they developed what they called a tactile model, that is, a three-dimensional impression of the body contour of the region, as evaluated by them.

The researchers criticize the method of obtaining volume via *three-dimensional scanner* because, according to them, there is no way to know where the abdomen ends and the breast begins, with accuracy. It is true that the volume has a better chance of accuracy with CT or MRI. However, in addition to the submission of the patient in recovery from cancer to radiation, the image of the breast is impaired by the position in which the capture occurred, which deforms its contour.

They positioned the patients lying down, tilting at 45 degrees (without specifying in which direction), to ensure the action of gravity, they said. The authors also mention the procedure for calculating the form via reconstruction of tomographic images exported to a software, Osirix™, which license costs US$ 699,00, and later for Magics™, by Materialise™, that allows for this comparison. The research proposal was not tested in patients.

It is necessary to highlight that, in a comparison of breast measurements made via magnetic resonance imaging and three-dimensional scanning, they found substantial differences between the two measurements. They credit them to the fact that in the position in which the MRI is made, the patient ends up having included, in the result of the account, an axillary volume that migrates next to the breast, but does not belong to her (KOCH *et al.*, 2011).

It is possible to conclude that the only methods able to inform the shape and also the volume, with precision, are those that use plaster replica and the ones based in 3D scanning.

2.3.3 Color

There are pigmented external breast prostheses on the market, and they share the shelves with colorless products. When a model is presented in color, the most common is that it looks like the “skin” tone of light dolls, and as is happens in toys, there are rarely nuances of dark skin.

One of the largest American manufacturers of American foreign prosthesis was also (and previously, in 1976) the creator of Barbie™ dolls, to which tone this paragraph makes mention. Ruth Handler was for many years the CEO of Mattel Corporation™, as stated on the website of the company Nearly Me™ (NEARLY ME, [s.d.]). The Caucasian tone attributed for long years to the toy, is also the tone of its shelf prostheses, probably not by coincidence. However, the company has updated itself. Released a more inclusive version of the doll in 2020. The new line also includes a vitiligo model, as demonstrated by the Figure 9.

Figure 9 – Mattel™ evolves its main product

Source: (HUFFPOST BRASIL PARENTING, [s.d.])

It is already the first evolution of the product presented in 2019, which gained mention of Time magazine as one of the best inventions of 2019 (LINGEMAN, 2020).

Although the purpose of this company is the profit or preservation of the image by serving afro-consumption and other minorities – in what differs substantially from this study – the company demonstrates that it understood that contemplating different shades of skin is a matter of respect for those who buy their toys. While it seems clear that assistive technology products should deserve the same consideration, for industry it is not always an aspect taken into account.

Worrying about variant skin shades, however, is not a constant even in other product areas with greater visibility. This is the case, for example, of the underwear industry, which annually diversifies the offerings of products called "skin color", as a rule contemplating few or no black skin tones, as mentioned by an activist responsible for a blog of these pieces (A RANGE OF SKINTONES, [s.d.]). She analyzed a product line from the UK, which in that decade decided to invest in producing bras and panties in colors that approach the skin color of black women.

Christian Louboutin also realized this gap and in 2016 updated a collection that was highlighted by the range of variations in the tone "skin" they attributed to his shoes and sneakers (NEWS - CHRISTIAN LOUBOUTIN ONLINE, [s.d.]). Launched in 2013, with five colors, it won two more, specifically with the need to serve an audience usually outside the standard dictated by the production line, as seen in the Figure 10.

Figure 10 – The luxury industry in search of the opportunity to meet the diversity of skin tones

Source: NEWS - CHRISTIAN LOUBOUTIN ONLINE, [s.d.]

Focusing on the manufacture of "skin color" products, Pantone™ has developed a catalogue with varying shades (Pantone SkinTone™ Guide), organizing them, numbering them and disposing of them in strips with a hole of 20.0 mm in diameter, which aims to facilitate a comparison with the physical model.

In a previously cited essay, the researchers added, to the silicone elastomer, a pigment called "Cosmesil color base", in order to achieve the color desired by them (EGGBEER; EVANS, 2011). This is, as far as the research for the present study was done, the most complete concern with breast prosthesis personalization, capable of taking into account an absolutely individualized characteristic – the skin color of each individual – which is an important factor in the self-esteem of those who generally do not find similar respect even in the most popular or large-scale products.

It seems, therefore, a basic issue that when manufacturing an artifact to simulate breast volume should take into account its coloration, still considering that for most of the time it is hidden under clothes. It is a concern has only been seen in the personalized prostheses.

2.3.4 Weight

It is believed that external breast prostheses should simulate the mass of the remaining breast when the mastectomy was unilateral. The current justification is, in most cases, that it would provide postural balance, avoiding problems in the spine or in any other part of the body that depends on the biomechanical equation established by a so-called symmetry. The literature on this effect is still conflicting.

Healey (2003) points out that when they had the mastectomy, many women reached the age of sixty. It is in this age group that most cases of breast cancer occur, say professionals in the area (BUZAID; MALUF, 2015), and it is also when degenerations resulting from the natural wear and tear of the body already occur.

It is known that at this point in life the reflexes of social behaviors, such as the use of high heels, overload of the shoulders with heavy bags or children, pregnancies or simply the positioning of cross-legs, often arise. Thus, the author argues, it is possible that this statement about the need for prosthesis in function of posture is a false belief, an expression that she titled her article in 2003.

At that time, there were no studies that effectively concluded the need for symmetrisation due to the weight lost in the breast. Another point raised by her is that the publications about prostheses were all from the manufacturers themselves. In the year following the date of publication of her article she herself constituted a company, *The New Attitude Custom Prosthesis,* in which she commercializes, among other products, personalized breast prostheses, conceived within a concept of "art" (ANAPLASTOLOGY, [s.d.]).

Perhaps simply claim that weight recomposing is important, as Adriaenssens *et al.* (2011) do, is premature, without further investigations.

The research by Gallagher *et al.* (2009), mentioned previously, evaluated, in addition to several other questions, the perception of users of external breast prosthesis in relation to two aspects that possibly had to do with the weight of the artifact. At that time of the questionnaire, the authors were evaluating the importance that women related to the use of the prosthesis, and the lower rates were attributed to balance (73.6%) and posture (80.3%). Although many thought that there was some influence, weight was not the determinant for the use of the prosthesis; however, it is one of the most influential parameters for dissatisfaction with this assistive technology: 118 of the 527 respondents (24.4%) demonstrated disappointment with this characteristic. Unfortunately, the study did not infer exhaustively whether the weight was perceived as little or as excessive, nor its relationship with the breast weight of each participant.

Evaluating two groups of women who had breast ablation, Ciesla and Polom (2010) made considerations about posture differences in patients who had immediate breast reconstruction after radical mastectomy and those who were only mastectomized. They analyzed a group composed of 38 women, and found that an artifact implanted in the same surgical act of amputation (a skin expander in which serum is injected in order to reach the volume previously occupied by the breast, called Becker-25™) can ensure the maintenance of posture, significantly altered in women who did not receive the implant.

In their study participants were evaluated before surgery and then every six months, for two years by coronal, sagittal and transverse plane checks. The women who received the artifact had alteration scans in only one of the planes, but the further the time of surgery, the more the changes decreased, which seems to indicate that the body is accustomed to the condition imposed. The authors analyzed the iliac line (C7-S1), shoulder deviation, body angle (given by the lower line of the scapula), inclination and rotation of the pelvis and depth difference of the lower edge of the scapula (rotation).

Hojan *et al.* (2014) investigated the asymmetry caused by the absence of one of the breasts. They divided two groups of women submitted to breast removal surgery by age group and concluded that the gait parameter of mastectomized women aged between 37 and 54 years, when they did not have a prosthesis, was significantly different from that found in the control group (not submitted to surgery). In the group of women between 55 and 70 years old, however, the authors did not find big differences.

In another study, Hojan *et al.* (2016) investigated whether the posture of mastectomized women undergoes alteration, depending on the use or not of external prosthesis. Using electromyography, they recorded muscle activities of 51 women aged between 35 and 70 years, and concluded that it does not make much sense to recommend the use of the prosthesis equal weight to that of the amputated breast, in terms of maintaining posture. The protocol provided for simulations without prosthesis, with prosthesis of 10.0g, with prosthesis which weight was 50% of the breast removed in surgery, and with prosthesis of equal weight to that of the amputated breast. The muscle chosen by the researchers was the spine erector, based on a study on the effects of the use of backpacks by children.

In known external breast prostheses there are many ways to achieve the weight idealized by the manufacturer. Those who produce them entirely in a single density of silicone can increase or decrease the quantity of the product, but therefore change the volume and weight. Among those that fill the prostheses with tissue fibers, plumb granules, polyethylene and millet granules, greater or lesser amount of this filling can be placed, however, eventually changing the volume. On the other hand, those who manufacture differently wrapper and content can mess with the content, without varying volume, depending on how they conceive the outside. Although this equation allows changes, it is important to look at compositions which weight implies that the prosthesis falls from the bra, as a warning Livingston (2005), which lists among the most common materials for content: water, silicone, glycerin and latex.

The issue of prosthesis mass impacts not only the perception that the user has of carrying an object outside his body, autonomous, of more than half a kilogram, in some cases. It greatly affects the possibility of keeping this piece in place. Because if the breast that is attached to the body has a mass of 500.0 g, its ligaments support it. But still, over the years, they also lose part of their capacity to sustain, causing ptosis. On the other hand, the prosthesis, it has nothing to keep it connected to the body, which is why keeping an object of half a kilogram tied to the body is challenging.

It seems to be unanimous, however, that the post-surgical period requires a very lightweight resource. An evolution on this topic, analyzed in depth by authors (KEETON; MCALOON, 2002; TANNER; ABRAHAM; LLEWELLYN-JONES, 1983), can be seen in the silicone form developed by Air'Avanti™ (Figure 11).

Figure 11 – Post-surgical state-of-the-art assistive technology

Source: PROTHÈSE MAMMAIRE EXTERNE TRANSITOIRE ET POST-OPÉRATOIRE - AIR'AVANTI, [*s. d.*]

2.3.5 Movement

There are breasts with big volume that have no sagging, and there are small breasts that have already gone through biological processes that have given them leftover skin. To take this equation into account in the offer, manufacturers of industrial external breast prostheses would need to work with diversified silicone densities. This actually happens, but it does not mean that the same company has different standards, at the choice of the woman. A user who can afford a silicone prosthesis, if she effectively wants a product that has a similar consistency to that of the remaining breast, should go to the stores that sell different brands of prostheses and check them, by itself. Other options are visits to associations and discussions with others who are or have been users of the product.

Due to the lack of an instrument or way of measuring, only the visual examination can identify whether or not the movement of the artifact resembles that of the natural breast of each woman, in a given stage of life. Among the few objective relationships that can be established, it is highlighted that the previously mentioned changes in volume and amount of material inside the prosthesis imply changes in movement. This is because material variation or quantity of it implies different behavior in the final product.

The movement of the external breast prosthesis, in itself considered, is not an item much addressed in the literature, and one of the reasons is because it is assumed that the gel material has the closest consistency to the breast. This presumption, however, may obscure the study and development of new materials, as emphasized by Healey (2003), who does a survey on a series of false beliefs about external breast prostheses.

2.3.6 Sensory perceptions

There are other performance parameters that may influence a choice of external breast prosthesis, but with greater difficulty in quantifying or measuring. They are related to the material with which it is manufactured, or by the body's reaction to such component and were highlighted from the others for their subjectivity content. Within the range raised by the literature are noises, smells, texture, consistency, color, temperature and heat. Some responses to these problems were outlined by the industry, others have not. Some studies record what they found as a solution for each dissatisfaction (CRUZ *et al.*, 2018; FITCH *et al.*, 2012a; KEETON; MCALOON, 2002; THIJS; WIEL, 2001).

In order to avoid the issue of body temperature and irritation in touch, for example, some manufacturers have developed a tissue casing to wrap the prosthesis, which is not mentioned in the literature. It is a product sewn into two halves, in which interior fits the silicone prosthesis (like a pocket), before placing it inside the cup of a bra. Thus, the tissue fulfills the function of minimizing friction between skin and silicone, replacing this contact with a better known sensation of the body, supposedly less subject to cause allergy. Usually containing polyamide, the casing does not exactly have the comfort of a 100% cotton fabric. In some cases, it accompanies the prosthesis and can be washed. This gives the possibility of hygiene more frequently.

Reports of external breast prosthesis users complaining about the movement of the artifact occur differently from the subsistent breast were recorded, and eventually in an unnatural sense (when slippage occurs out of the bra, for example) (BORGHESAN *et al.*, 2014; CLARKSON *et al.*, 2011; FITCH *et al.*, 2012b; GALLAGHER, Pamela *et al.*, 2009; HEALEY, 2003).

The most conventional way of maintaining the prosthesis next to the body is inside the cup of the bra, where usually an extra tissue is placed, such as a pocket, that contains it. But not all women have this type of bra, and it would be necessary to add them manually in each of the pieces they acquired, since it is not a line product, in the companies that manufacture most Brazilian underwear. There are, however, companies that are dedicated to making bras for mastectomized women, including manufacturing units with lining only in the right cup, separately from the units with lining in the left cup. Of course, they are different production schedules, with additional costs. That work is also performed, handcrafted, by some associations, who buy off-the-shelf bras and make, one by one, the adaptations of the fabric pockets to the bra cups.

The prosthesis industry presented a response to this difficulty: adhesives and magnets. Although they arose with the intention of solving the equation between body movement and mobility of the external breast prosthesis, they are not unanimous.

The preference for adhesive or conventional prostheses was studied by authors, who concluded that adopting the adhesive model depends on the ease of application and low skin irritation (THIJS; WIEL, 2001). The acceptance of the prosthesis as a part of the body, according to the researchers, is more present in women who prefer adhesive prostheses. The model evaluated by them wears a velcro strap that can be kept up to seven days in place, and dispenses with the use bra set. This indicates that there should be, on the back of the velcro, a patch that remains in contact with the skin. Three disadvantages of this tape are its high cost, a possible irritation of the tissue and the possibility of detaching from the skin.

Nevertheless, the final results indicated that 59.3% of the participants preferred adhesive prostheses, and 40.7% of conventional prostheses. The scientists hypothesized that among those who prefer the adhesive model would be the youngest, but no relationship with age was confirmed.

2.3.7 Areolar complex

Another characteristic that the literature deals with little concern is the areolar complex, which is not always contemplated in external prostheses. Breast reconstruction surgery includes the volume and shape of the contralateral breast, but the areola and nipple would have to be done with another tissue, coming from another part of the body, and are not – until now – routinely performing in the same act of post-mastectomy restorative plastic surgeries.

The absence of the nipple is the most frequent reason for the dissatisfaction of patients undergoing reconstruction, according to mastologist José Roberto Piato. Together with other physicians, he developed a safe technique to assess whether it is possible to preserve the region (UOL NOTÍCIAS, [s.d.]).

Clarkson *et al.* (2011) proposed an alternative of less complexity than a new reconstruction: an adhesive areolar complex, to be glued on the reconstructed breast. The authors point out that these stickers have existed since 1970, but as shelf items. They then proposed to develop such a custom adhesive, in silicone, using, as a model, the contralateral. Despite evaluating an 85% rate of satisfaction with appearance, the authors found that only 34% of women wore the patches most of the time. Among the participants, 59% still wore the adhesive up to six years after its availability. The facial prosthesis outpatient clinic of the University of Vale do Paraíba also produces this personalized kind of nipple adhesive prostheses, highlighting that they avoid more painful procedures, such as grafts or tattoos. Free of charge, they are prepared by hand, with anaplastology techniques (FELIX, 2016).

2.4 To replicate the human body

Reproducing a part of the human body requires a focus on fidelity. Mainly in shape, but eventually of color, texture, volume, mass, movement and/or responsiveness, characteristics also applicable to external breast prostheses, as already seen throughout the literature review. The greater the sophistication of a prosthesis, the greater the number of elements it needs to meet; thus, the generation of the model, as reliable as possible, also requires more of the process and all the inputs involved in it.

In order to manufacture assistive technologies that can provide a higher quality of life to those who need these resources, there are processes that have been approved by use or tradition, and others that are under examination by researchers around the world, as shown thereafter.

2.4.1 Manual technologies

Anaplastologists traditionally seek to acquire human geometry using low-cost materials such as plaster and alginate. The plaster is considered as the material of excellence in cast making, because it is easy to use, malleable, widely available, has thin granules (which allows it to reproduce details), has a remarkable mechanical strength (13 N/mm^2), moderate weight and excellent rendering of light and shadow. Even when considering its volumetric expansion of 0.2% at the time of preparation (exothermic reaction), the reaction is temporary and the physical phenomenon is fully reversed, when it stiffens (DIGITAL SCULPTURE PROJECT, [s.d.]).

However, there is technology evolving in this area, with the respective increase in costs.

Because they also have their use applicable to the arts – especially cinema – the inputs in this area received dedication from the industry, so that they could have their characteristics improved. The plaster, for example, with its fragility, gave space to the silicone rubber (RAMOS, 2011). Alginate, for years used in the reproduction of human dentition, despite its low dimensional stability, evolved into compounds of greater durability.

Both gypsum and alginate continue to be widely used, at least in Brazilian laboratories. Not only because they meet the basic need – fidelity to the model – but because their cost is low (approximately U$0.50, the kg of the plaster, and U$3.0, the kg of alginate).

Such materials usually require hand contact with the body part to be reproduced, eventually require some dirt in the environment and in the individual whose form is intended to copy.

Although materials have evolved, the process itself has not changed much: there is a need to prepare a material in two parts, the mixture is dwelled over the region of the body that is intended to copy, it requires a hardening time (curing, polymerization or drying, depending on the nature of the component) and later, in some cases, it is also necessary a post-processing (MIDGLEY, 1982).

It is noteworthy that these are models that can be lost, as occurs with the breaking of the plaster, for example, or contraction, in the case of alginate.

Plaster is still very used for making areolas, a region that is not recomposed, when a woman undergoes a breast reconstruction. The areolar complex may be copied with alginate, and later replicated in plaster, so that inside of it could be conceived an areola in pigmented silicone rubber, to be temporary glued over a reconstructed breast.

Tattooing is also a complementary technique to reconstruction surgery, which is adopted by some patients in order to return the aspect of the darker area of the breast, and eventually to simulate the three-dimensionality of Montgomery tubers and nipple.

2.4.2 Technologies dependent on industrial processes

Some anaplastologists start from silicone rubber casts to design external breast prostheses, without the possibility of integral customization of the product and, therefore, requiring a standard cast. The prosthesis will be integral or partial (as the breast has been removed by radical or conservative mastectomy) and composed of another silicone rubber (which does not stick to the silicone mold due to the use of releasing agent), usually pigmented in the color of the patient, and subsequently receives the application of a nipple (this, designed by manual technique).

Industrialized external breast prostheses, commercialized in Brazil, seem to obey some basic manufacturing models. The surveys contained here are mainly derived from the study of patents, analyzing only the records that contain the manufacturing method in its description.

The design present in the cheapest products derives from one of the first records, authored by an American (KAUSCH, Walter O, 1951). It provides for a more rigid outside, made of a material such as latex, and an inner part, which would consist of a more flexible product.

That part that the author calls a shell is conceived with the cast being dipped in a container containing liquid latex, and brought to the surface to dry. The author does not explain how this cast is made. Later, it receives a cover, which is what will come in contact with the chest wall.

The model described in this patent of Kausch (1951) estipulates that that cover would be vulcanized, keeping air inside the workpiece. He then suggested that some process take the air out, replacing it entirely with a liquid or fluid substance. The reasons for this are basically two: to avoid eventual noise of the liquid moving in the prosthesis, and because, according to him: "The liquid in the artificial breast confers the desired weight of a natural breast. In the case of amputees, enough fluid is used to make the artificial breast become as heavy as a real breast, therefore balancing the two breasts" (KAUSCH, 1951, p. 2).

It is perhaps from that Kausch project (1951) that derives the thought that the prosthesis, even being external, has to have the same weight as a breast. Its mass is usually not known by the person who will buy the product, with little or no instruction on external prostheses.

Unless by weighting the specimen removed in a surgery (and supposing that it is equal to the contralateral), it is not possible to infer the weight of the remaining breast.

Kausch (1962) registered another industrial process of making that same bark, previously composed of latex diving. This time, however, he developed a process that allowed the assistive technology to be kept hollow. Starting from a rotomolding process, it could house both the remaining part of the breast from a quadrantectomy, or a skin-preserving mastectomy, as well as radical or total mastectomy.

Again, the author does not disclose how the "breast-shaped" cast is generated. The process to which it is submitted, however, is well known, and can be defined thus:

> Rotomolding is characterized by the placement of a quantity of polymer in a cast divided into parts, subsequential closure of this cast, followed by the simultaneous application of rotation on two axes and application of heat. The resin is deposited on the walls of the cast, where it forms a dense, unified layer. When the densification is completed, the cast is moved to a cooling station while the rotation continues. When the demolding temperature is reached, the part is removed from the cast. (OGILA *et al.*, 2017, p. 1).

Rotomolding is a method still based on empiricism, as highlighted by Aressy (2013). His work focused solely on the cooling stage of the artifact produced by this technique, but in fact, any of the phases considered academically lacks approaches that establish times, amount of material, process speeds.

Among the studies carried out, no processes were found involving something similar to rotational molding on two axes, carried out expressly with low-cost casts. Although videos are found on the Internet, tests with academic rigor were not found.

The process, however, could be the one adopted in several external prostheses off-the-shelf, in which there is an industrial secret. Two other patents are cited below that, although not of external breast prostheses, enrich the literature on the subject by the peculiarities addressed, of the rotomolding method. Both worked with polyurethane final product and have as a result artifacts that present a striking feature of the rotomolding process: a hollow artifact inside.

The process draws attention to a very old conception that meets one of the users' complaints: the excessive mass of prostheses. Sometimes filled with bird seeds, sometimes filled with silicone rubber (among other substances), the possibility of being hollow presents a new universe of possibilities for external breast prostheses. It is, however, a shelf product design, the cost of which needs to be amortized by mass production, since it requires conventional casts and the entire rotomolding mechanism to generate the final product.

Rushe (2004) describes a process for the manufacture of hollow polyurethane articles, formed by rotational molding process, and also of the products that result from the cure that occurred in this process.

When describing his invention, the author explains that he has discovered that if non-polymerized polyurethane compound articles contain the appropriate reagents, they can be generated by what he calls rotational modeling. The term "appropriate" suggests changes in viscosity and gravity, for example, to achieve that, by centrifugal force, the compound evenly covers the inside of the cast (RUSCHE, 2004).

The author comments on the possibility of putting additives, such as those that protect against ultraviolet light and cites, at that moment, some agent that protects against bacteria, which can be interesting in the case of prostheses. Dyes are also often used.

It is also approached the possibility of added catalysts, to facilitate the reaction at room temperature. It also explains that the cast can be made of any known material and cites as examples: fiberglass, wood, metal and plastic. It also adds the need for the use of releasing agents.

Rusche (2004), when commenting on the rotation process (which according to whom it would preferably be executed on two axes), mentions that it is known in the literature a calculation that determines the reason for the rotations, which are made in trial and error. He explains that the number of rotations on each axis varies depending on each product that will be molded, knowing, however, that the ratio between the rotations should not be unitary, nor should the second rate be multiple of the first, unless the object to be generated is perfectly spherical. That is, the rotation rate will also vary depending on the shape and size of the final object.

The heating of the mixture between resin and filler component is mentioned. Rushe (2004) explains that warming up this combination is just enough to improve your ability to slide.

Another patent that contains information relevant to the rotomolding method is the cold rotational molding process (VARNER; JOHNSON, 2011). This process started from the design of a mannequin to record the process. Just like the articles described by Rusche (2004), it deals with products equally hollow, formed and designed by a polymer blend, coated by polyurethane foam.

Among the advantages listed by the author are the greater solidity of structure (they can withstand an impact of up to 55 J), the speed of manufacture, the resistance to deformation under temperature (they support up to 85º Celsius) and the lightness of the final product.

Another process described by Varner and Johnson (2011) has one step for the production of a stiffer shell (polymer) and another for the deposition of the foam layer; they occur at sequential moments, and this takes advantage of the still sticky state of the former to adhere to it and form protection. Both parties accept pigments and paints.

The authors recall that it is common to happen in the valleys of the cast a greater thickness of material, and in the apexes, a smaller thickness. In the case of the mannequin, the fingers, also due to the little internal space, end up being more fragile. What determines the completion time of each step is the healing of the material and the slower the reaction, the longer the period in which the components will remain rotating.

In conventional processes, a mannequin needs to be left inside the cast until complete healing, and in the process developed by these authors the piece can be removed in eighteen minutes; this is because the foam lining the outer shell retains any possible deformation to which the external polymer would be subjected.

The mannequin obtained by Varner and Johnson (2011) supported standing, without needing a structure, unlike what happens with those already known in the market. Prostheses made specifically with this rotomolding technique have not been found in the national market.

Another process of conception of external breast prosthesis, which ends up generating a more elaborate and more expensive product, is what intends to contemplate the accommodation of the chest wall, by choosing a softer material, which conforms to the scars and the new body contour given by mastectomy, with the depressions and reliefs of the chest wall.

Several products are suitable for this purpose, one them a recent patent (WOLLNICK; HALLEY, 2015). The authors highlight the existence of external prostheses that, personalized, seek to accommodate the chest wall scar using its negative, but inform that they are of high cost. The product they developed, then, intends to make this accommodation by pressing the prosthesis against the chest, but using a thin and resistant layer of a fluid, in the part that gets directly in contact with the skin.

The product includes at least three layers that are sealed together to make up the front and rear chambers of the prosthesis. This sealing would be responsible for the safety that prevents leakage of the contents of the artifact. A first layer of silicone rubber covers the front chamber and is cured "in breast shape". A fill made with a silicone mass is then placed in the rear chamber. This layer of the back is that contains the fluid that conforms, supposedly without hurting, to the new relief of the chest of the mastectomized woman.

As in several prosthesis models, one of the concerns of inventors is that something pointed reaches the casing that contains the fluid, that fills the external prosthesis. This, in addition to permanently damaging the product, would expose the user to a shaming situation.

Another drawback of the massive prosthesis is that the mass of the fluid requires an external agent – usually a bra – to contain it. Finally, there is still doubt as to the need, usefulness and benefit of the external prosthesis to have the same mass of the remaining breast.

Also in this topic, it is necessary to add that the field research found a model of external breast prosthesis designed in silicone rubber, and filled with polyurethane foam, which manufacturing process is unknown. It is known that it is personalized and it is presented its budget, which is included in ANNEX C. It was brought to the research because it was the best quality product found, and it will be taken as gold standard, in terms of personalized external breast prosthesis.

2.4.3 Digital technologies

Researchers from various areas of knowledge have been interested in sophisticated resources to capture body image, with many advantages over more traditional features, such as clean work and without the need for close contact with the person who serves as a model.

Another gain of the technology is the possibility of further manipulation of the generated model, maintaining a copy of the original model, avoiding rework and the risk of data loss.

It also represents a positive evolution the possibility of objective analysis and measurement of data capable of being quantified in software. They do not depend on the judgment of human eyes, as infers a group of authors who studied the aesthetic results of breast conservative surgery in mannequins and women who had undergone ablation of part of the breast (OLIVEIRA *et al.*, 2011).

Software is, therefore, fundamental, both in the process of capturing the three-dimensional image, as in the manipulation of images, as well as in the printing of biomodels and casts. They exist in free and paid versions.

Despite possible difficulties encountered in the learning process of free software, it is undeniable the importance of operating the process – whether in mesh modeling, image capture or cast generation – without cost or without the threat of having them in the future.

This is a risk known by this research. In this decade, Autodesk™, for example, has already made it a reality. Six years ago, the company offered free use of a program with which one could generate three-dimensional images using photographs, which should be sent to their website*,* and then download the ready file. In addition to the ethical issue of sending images of research participants to third parties, the company, after having its software tested and appreciated by several users, began to make it available free of charge only to students and teachers, for educational purposes.

UTFPR makes available, in its laboratories, the use of Solidworks™ software licenses. The cost, for the institution, is certainly not the same as selling to the end user, of at least five thousand dollars.

In terms of preparing the student for professional life, it is undoubtedly a very important resource. However, as emphasized by the coordinator of the chair of distance education at the National University of Brasilia, Tel Amiel, this is not philanthropy. "If they're not earning from software licenses or selling hardware, they are going to win another way. The idea is to train customers early and create a dependency on services," he says (ROMANI, 2019).

Following the idea of Tel Amiel, the use of the expression "free", whenever it appears in in this work, should be understood taking into account that there may be a cost embedded, not always perceived by the client, which may be that of dependence.

It is, therefore, advocated that it is necessary to open a parallel front of knowledge in the institution, which is independent of a resource that is commercially sold so expensive and that many students are unable to use it at home, after they graduate.

When this is not possible, it will be necessary to assess whether the quality of the software is such that it compensates for the investment, what its contribution is and the impact of its cost on the process.

Digital techniques are fundamentally anchored in a tripod composed of three technologies: three-dimensional image capture, mesh manipulation obtained by capture and additive manufacturing, also known as 3D printing.

2.4.3.1 Three-dimensional image capture

To respect the anatomy of each participant, based on their body measurements and forms, is to provide conditions of dignity, of improving the quality of life of a woman who has been mutilated by a mastectomy, in search of saving her own life, after being affected by cancer.

More traditional resources, consecrated by anthropometry, face challenges such as the need to make several measurements, with different operators, to later make an average of the values. They don't always position their equipment in exactly the same place. Finally, they are resources that require contact with the individual who will be measured. Thus, since 1966 techniques that allow three-dimensional measurement with the use of body scanners have been gaining space, with the proposal: to measure the human body without touching it, preserving accuracy (BRAGANÇA, S.; AREZES; CARVALHO, 2015).

Three-dimensional images are an evolution of photographs, which represent an instant in two dimensions. Fundamentally, progress was represented by adding depth to what was already presented with height and width. Adding this data allowed a reliability that the photograph did not have and that, more at the same time, was simulated by photogrammetry, which used the same equipment, but with controlled scenario, with distances and angles previously defined by an operator.

The use of three-dimensional digitization in the exact sciences inaugurated the terminology "reverse engineering". This is a process that aims to recreate existing geometries on the computer (LIOU, 2008), that can be manufactured objects, or organic forms, such as those of plants and humans.

The name "reverse engineering" is still widely used in several publications, but due to the lack of respect with rights of author (very common use of the technology), other terms have gained strength, such as “scanning” and “3D scanning”.

Some of the variations in the characteristics of the different devices for capturing three-dimensional images involve the speed with which this data collection is performed, the possibility of acquiring color, and – most importantly – the resolution of this generated image, usually translated by a polygonal mesh.

Each point identified by the equipment is translated into Cartesian coordinates, located in space, and the higher the resolution of the device, the greater the number of points it is able to scan. Proportionally, the number of polygons formed grows, as also what is called refinement of the polygonal mesh, as higher the resolution of the scanner. Consequently, its files occupy more processing capacity of a computer.

After the device captures the images, they need to be saved (in order to be preserved, repaired and manipulated), and there are several formats available, the best known and universally used being the STL, name that derived from STereoLlithography. It is a format that was developed for 3D Systems™, in 1988 (FOGGIATTO; SILVA, 2017).

There are several software that performs this procedure, many others that perform rendering and allow the manipulation of these files containing the meshes. The first scanners – and many of the most expensive still marketed – have proprietary software, which usually has cost above thousand dollars, and are eventually embedded in the purchase package of the device.

The consolidated solutions in the market for three-dimensional image scanning are costly and typically target companies and industrial applications.

Commercially used three-dimensional scanning equipment costs over $10,000. In addition to being costly, they usually require preparation before each use, as they require the gluing of markers, and have automatic calibration, but still assisted by the operator.

In order to circumvent the cost of commercial programs and also in the intention of verifying the accuracy of the developed systems, academic groups began to invest in the acquisition of three-dimensional images obtained from less costly equipment.

Ahcan *et al.* (2012) sought to obtain breast volume measurement in order to optimize a model to assist in late breast reconstruction surgery, with tissue from the patient herself. A Lakos scanner was used, which operates by triangulation and was developed by the Faculty of Mechanical Engineering of Ljubljana itself, at an approximate cost of between five and seven thousand euros.

Post-mastectomy reconstruction is a surgery which success depends on the experience of the surgeon and his clinical intuition, and the authors then aimed to obtain a way to determine the volume, shape and contour in the breast, objectively.

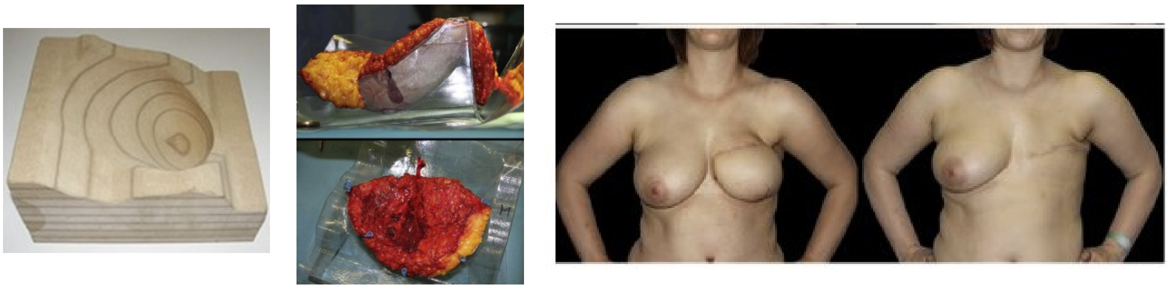
Working with reverse engineering and three-dimensional images, they depart from a replica of the contralateral breast, made of wood (Figure 12a), and evolved into the lightweight cast (Figure 12b), done in vacuum forming (from that first model, machined in wood). In this piece, then, the fabric of the abdomen molded to the breast should be positioned, with the aid of the cast in colorless transparent plastic. It was used as a guide, during surgery time. In Figure 12c, “before and after” of one of the patients in which said reconstruction support was applied.

Not to mention costs, they report, in the methodology, that a customized software was developed to process the data. It is not known whether he would be responsible for manipulating the point cloud, or if it entered a later phase.

Basically, the steps were the capture of healthy breast images, three-dimensional mesh generation, image mirroring, image cutting (obeying the marks made by the surgeon), and positioning the resulting design on a coordinate system.

The cost measured in the study would be six hundred euros per cast in vacuum forming, and the authors estimated that it could fall by half if there was mass production. It happens that this whole process of scanning and working on the polygonal mesh loses its reason for existence, when one imagines serial production of a breast model that is unique. It is a rational thought of Production Engineering, but that does not respect affective aspects of usability and possibly would not have the same positive evaluations, on the part of patients.

Figure 12 – Replica of the breast, for use as a guide of shape and size, in reconstruction surgery



a b c

Caption: a. breast replica, in subtractive manufacture
b. lightweight cast
c. the “before and after” breast reconstruction, in the patient

Source: Adapted from AHCAN *et al.* (2018)

Yang *et al.* (2015) point out some utilities of 3D scanning, such as three-dimensional techniques in breast measurement and monitoring of lipofilling results (which is a reconstruction technique to correct defects after breast oncologic surgeries). They again position as of great value, the use of this equipment to guide surgical decisions and procedures of reconstruction or breast augmentation.

Post-surgical monitoring is useful, they describe, because rarely does the reconstructed breast remain the same as when it is composed, in view of swellings, regeneration, fibrosis, seroma, capsular contracture and implant leakage.

They also comment on the study on breast tissue migration, which is the possibility of evaluating, after surgery, the redistribution of recreated volumes over time. A parameter used by surgeons to perform this definition is to partition the breast at the top and bottom, and use a three-dimensional scanned image that allows virtual manipulation, measurements and analysis not only in two parts, but in all quadrants, as well as locating regions of protrusion or volume insufficiency.

For these and other advantages for predicting expected results, Gladilin[4] (2011 *apud* YANG *et al.*, 2015) surnamed the 3D scanning as "digital fitting room".

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[4] GLADILIN E, GABRIELOVA B, MONTEMURRO P., HEDÉN P. (2011). Customized planning of augmentation mammaplasty with silicone implants using three-dimensional optical body scans and biomechanical modeling of soft tissue outcome. Aesthetic Plast Surg 35:494–501

The output found by Yang *et al.* (2015) for a problem highlighted several times in the literature as one of the major obstacles to the full use of three-dimensional digitization in the breast region – the shadow zone that occurs in breasts with ptosis – was basic anthropometry. They used a ruler to measure the inframammary fold and defined it as a mandatory complement in the procedure.

At the time of that study, several authors had already published other techniques of measurement of breast volume, which could have been discussed by Yang *et al.* (2015). In addition, they infer that there should be no deformation of the skin, and that no pressure should be applied to the capture of the image, which is inevitable, when measuring, with a ruler, a groove that is under the skin.

In fact, it would be more accurate to inform that it is not a question of breast size, but rather of the degree of ptosis that it has. Even low-volume breasts may present a sharp drop that makes it difficult to use scanning, and not every large breast produces a shadow zone, especially in young women who have not become pregnant or breastfed.

The work of Yang *et al.* (2015) was one of the first to mention the volume and difficulty in loading all the equipment that normally make up the scanning system, besides mentioning the defects that occur in the data, in the mesh generated. In fact, the lack of portability compromises not only the dissemination of the use of the resource in research, but also the popularization of technology.

The cost of the equipment that is usually dedicated for this purpose, as well as the difficulty of access to them, are points highlighted by the authors as an obstacle to their application. They are supposed to be referring to handheld or benchtop scanners, not cabin systems, such as the body scanner described by Veitch (2012), addressed previously (2.3.2).

Another criticism made by Yang *et al.* (2015) to three-dimensional scanning equipment concerns the aesthetics represented by pigmentation, acquired surface color and skin quality, items that are not contemplated in this technology, they stated. However, at the time of publication of Yang *et al.* (2015) there were already cheaper sensors that included this function, if, for example, Structure™, by Occipital™.

The authors also make a comparison with the images obtained by computed tomography and magnetic resonance imaging. Regarding the accuracy of measurements, they report that the reproducibility of tomography has deviations lower than 1%, against values between 2% and 9%, of three-dimensional scans. They comment that the gold standard – the Archimedes technique – has accuracy in 80% of cases.

In addition to this issue, Yang *et al.* (2015) comment that three-dimensional scanning is gained by the time in which it is performed, for not subjecting the patient to radiation, because it is a noninvasive procedure and for the results of longitudinal observation.

They conclude favorably to the acquisition of three-dimensional images, and remember the launch of the application 123D Catch™, the year prior to their publication, which could, according to them, bring gains to that methodology.

123D Catch™ ushered in an era of features that brought three-dimensional technology to each user's cell phone of that app. A solution developed by Autodesk™, it started from sequential images that were sent to the company's website and, after some time, were made available for download in some 3Dformats.

In addition to not providing immediate feedback – in order to assess whether image capture had been successful – what happened with the solution, less than two years after the article was published (and after the thousands of free tests sent to the company), it was replaced by a paid version, called ReCap Pro™. Other representatives of this type of software are Trnio™ (SENSING *et al.*, 2017), Meshroom™ (ALICEVISION, [s.d.]) and Qlone™ (QLONE, [s.d.]).

Yang (2015) published a basic approach, covering existing systems for measuring what they called "breast aesthetics", and cited the 123D Catch™ application, which made possible to generate three-dimensional images from two-dimensional images. This author envisioned the usefulness of three-dimensional image capture systems, and also highlighted the critical point that represents the inframammary groove area in the case of breasts with ptosis.

In parallel to these studies that addressed three-dimensional scanning technology in the breast area, some researchers were interested in systems that offered lower costs and greater portability, without sacrificing resolution, or at least proposing a cost-benefit solution that could be negotiable, according to the required accuracy.

Motivation walked alongside a growing impulse: the Maker movement. It advocates valuing customization and democratizing the production of new knowledge. Successors of hackers, who already sought the opening of technologies, Makers practice the freedom to scour hardware and software to understand their operation, without producing damage to others (BOSQUÉ; NOOR; RICARD, 2014). Makers strive for a common well-being, in which all people who want to manufacture have access to the ways and even the productive means of doing so, through the sharing of ideas and, eventually, laboratories (such as FabLabs).

The so-called Makers were already the prosumers (combination of the words producer and consumer), thus described by Alvin Tofler, in The Third Wave (1980). His book provided:

> Someday even the standard sizes may disappear. It may be possible to read a person's measurements on the phone, or point a television camera at us, thus entering data directly into a computer, which in turn will instruct the machine to produce a simple piece of clothing, cut exactly according to the person's dimensions. (TOFLER, 1980, p.189).

One of the hardware makers addressed was Kinect™. Developed by a game manufacturer in 2010, it proposed that users stand in front of the device to perform movements required in games. The scenarios contained in the games and the players' responses to the proposed challenges were simultaneously released as an image on a television monitor.

What that portable sensor did was a three-dimensional reading of the player's body movements, the Makers noted. This is how, by serendipity, the game sensors were discovered as good three-dimensional mesh makers, because their original purpose started from the same principle as three-dimensional images.

Sensors of this category have received accreditation in the scientific community for having fidelity in their records, lower cost than other types of sensors, and for being of simpler and portable use. These features, in addition to the remarkable cost of less than a hundred dollars, popularized the technology (PÖHLMANN *et al.*, 2017). They already come ready for use, do not need to use markers (which are usually adhesives imported from the scanner manufacturer*)* and require only quick calibration (with user-made conferencing), reason for the increasing use of this type of sensor.

Other sensors came, after Kinect™, and they all composed a new crop, in the field of three-dimensional scans, which from then on began to be made with equipment cost around $ 100, and portable.

After Kinect™, came Asus Xtion Pro Live™, Carmine PrimeSense™ and Structure™. The precursors of this application used the device connected to a computer and open-source software*,* such as Reconstructme™. Initially it had free and paid versions, but later its use, as long as it was not for commercial use, was released by the company. Other software *was* emerging, among them: Skanect™, Regard3D™, FabScan Pi™, BQ Ciclop™, MakerScanner 3D™, Atlas3D kit™, all open source or with free version (with fewer features, then).

The Academy began to carry out evaluations of the uses of low-cost sensors, verify their applicability in the field and to compare their functionalities. Authors who write about anthropometry highlight those different types of sensors can be used for different applications. They point out that high-cost equipment is suitable for high-precision anthropometry, and cite devices with Kinect™ technology and accuracy that can be used for other applications(BRAGANÇA, Sara *et al.*, 2018).

Choppin *et al.* (2013), used a system containing three Kinect™ to scan the image of a male mannequin, to which one or two external breast prostheses overlapped. The differences measured were 30.3% in a prosthesis of 400 g, and 33.3%, in a prosthesis of 600 g. They also evaluated the differences obtained for each of the people who made the capture; regarding the system operator, the divergences were 13.9%, in a prosthesis of 400 g and 5.6%, in a prosthesis of 600 g.

The authors' conclusion was favorable to the use of Kinect™ for breast volume measurement, although considering the errors obtained, mainly due to the cost difference between the sensor and commercial scanners. They stressed, however, that it would be necessary to obtain systems that were not dependent on expensive software.

The errors identified, according to them, were minor when the prosthesis was on the table, suggesting that the factor that most interferes in the capture of breast images is the inaccuracy in the definition of which point the breast begins and at which point the chest wall ends.

Henseler *et al.* (2014) evaluated Kinect™ as a skillful tool to measure the region of the breasts three-dimensionally. Although they found a margin of error of 10%, they understood that the system – which was tested in the image capture of nine silicone implants of previously known volumes – has reproducibility and accuracy.

At that time, the authors were measuring implants arranged on a flat table, and used for conference an instrument called Arthur Morris apparatus, which is a transparent tube with volume markings, in which the prosthesis is placed. In some cases, however, the method was not appropriate, because the implant did not fit inside the tube; it exists in another size, but had been made available only in one, and the authors measured internal prostheses of different volumes and shapes. They highlighted the need for some practice to operate Kinect™, as far as the distance it should be from what is scanned.

This is, in fact, an inherent characteristic of the product. Every time a Kinect™ operates at an excessive speed, it signals that it has lost the ability to form the mesh and that the operator should return to the position where this occurred. However, this operation is not always successful and the capture has to begin from zero.

There would be even greater difficulty in controlling two equipment, as in the study of Wheat, Choppin e Goyal (2014), which was intended to compare measurements. The authors used two Kinect™, positioned at an angle of 70^0 to each other, and made a conference of measurements between seventeen points, situating them in a mannequin.

Although they knew that it would be simpler to measure with only one piece of equipment, they chose to use two, justifying that their initial tests did not allow a point cloud formation with only one Kinect™.

The authors considered only the possibility of keeping them static on a tripod and the measurements obtained were subsequently checked with measuring tape and caliper. The differences in measurements found by them had an average of 1.2%, with a maximum of 4.1% and a minimum of 0.0%, which made them conclude by the acceptability of the system.

Henseler *et al.* (2016), who had already used stereophotogrammetry images to acquire three-dimensional images of the breast region, evaluated the same region with Kinect™. Using only one equipment, they captured the images on six women (including one with ptosis), with three different arm positions, each. The software setting determined the distance to be used between the sensor and the human body.

According to the authors, there is a considerable difference between the dynamic results obtained with the different positions of arms, and the displacement between each of the images (of the same patient) that they called fourth dimension image. Distances, however, do not change significantly. The image generated with women having their arms at ninety degrees of the ground was preferred by physicians, in order not to generate shade over the intended area.

Also using only one Kinect™ (Kinect II for XBox One™), Pöhlmann *et al.* (2017) evaluated ten patients before and after breast reconstruction with prosthesis implantation, changing both the position of the sensor and the pose of the study participant.

The authors conducted the study with Kinect™, with the intention of using the results for the best planning of a post-mastectomy breast reconstruction, primarily in the aid of the choice of an implant that did not result in asymmetry, as occurs in one fifth of the patients (which would result in the need for further surgery), as stated.

The protocol of these authors took seven distinct positions for the capture of three-dimensional images and the result obtained by them was not known to surgeons, whose experience was what was usually used to define the size of the implant to be used. Another methodology, which uses the mass of the specimen (as described in the topic 2.3.2 Volume), was used in the comparison made by the professionals who participated in this study with the Kinect™.

The intention of the research was to know if the equipment could be used to determine the most appropriate implant size, and they compared the results obtained with the specimen removed in the mastectomy, as well as with the choice made by the surgeon.

In 61% of the cases the image obtained with the sensor was within a margin of error of 10%, and in 17% of the cases it was less than 30%. Like the previous ones, the authors also reveal the concern of separating what is the final skin fold of the breast from what is chest wall. One of the image captures was made with the sensor in motion, but it was not the one elected for comparisons.

The image of choice featured Kinect™ centered in front of the participant and, according to the description, positioning the arms above the head, with his hands resting on it. Among the participants, there was one whose breast had ptosis; she had the highest breast volume and was where the greatest discrepancy occurred, in the calculation.

They highlighted the importance of breast region and chest wall limits as critical factors for calculating volume measurement accuracy. In their conclusions, the authors were favorable to the use of Kinect™ as a sensor, and pointed out two alternatives for positioning it during imaging: the one with the static equipment, positioned at an angle of 45 degrees, facing the center of the breast, or with the patient at an angle of 45 degrees, relative to the cranio-caudal axis. A custom support for the sensor was suggested, rather than a handle, they said, to avoid uncertainty.

Despite the challenges encountered for the determination of breast volume, the authors were favorable to the use of Kinect™ II for the capture of images and subsequent determination of the volume of the prosthesis to be implanted, mainly due to the speed and low-cost.

The high costs of conventional three-dimensional imaging systems have been highlighted by them. In addition to the amounts between U$20,000 and U$130,000, the need for calibration in each use of conventional equipment were the reasons that led to their decision to choose the Kinect™ (PÖHLMANN *et al.*, 2017).

In October 2017 Microsoft™ announced that it would no longer produce the Kinect™ (REISINGER, 2017). By this time, comparisons of other sensors with those of the Microsoft™ had already been published.

In a metrological evaluation between the Kinect™ and Asus Xtion ™, Gonzalez-Jorge *et al.* (2013) understood that both had similar performance when digitizing geometric solids proposed by them. The sensors were tested in three distinct angles, 45°, 90° and 135°.

The accuracy, according to the authors, is smaller, the greater the distance in which they are operated, and should not be greater than 7.0 m. Its accuracy varied between 5.0 mm and 15.0 mm, with capture made up to 1.0 m away. They have concluded favorably to use both sensors in engineering applications for which extreme precision is not required.

Diaz *et al.* (2015) also compared the Asus Xtion Pro™ and the Microsoft Kinect II™. In general, they evaluated that Kinect II performed better in the evaluated aspects, although it may be influenced by reflections in the corners of objects placed in the scene, deforming them, which is common with time-of-flight *sensors.* They noted that the Asus Xtion Pro™ generates a denser mesh, but they felt that this did not result in better recognition of the object, but rather because it has higher resolution than Kinect II. Researchers were more supportive of using Kinect II™ by the constancy of the results, less error between depth and different colors and a slight difference in their favor, with respect to accuracy. In favor of Kinect™ also counted the possibility of working in an external environment that, according to them, the Asus Xtion Pro™ does not have.

Guidi, Gonizzi e Micoli (2016) made a comparison between Kinect V1, Structure Sensor, ASUS Xtion PRO™ (sensors based on the technology of Primesense™), F200 Creative™ (designed in the projection model of Realsense™) and Kinect V2™. In addition to comparing their performance, they intended to evaluate which device would be best suited for certain applications.

Systematic and random errors were raised by the researchers, in a range of distances of the object between 550mm and 1450mm, and they defined that after 1150mm the results were not reliable. They found the uncertainties similar, among the sensors that work based on Primesense™ technology, going from 2 to 3.9mm in Kinect 1™,1.9 to 2.9mm, in the Asus Xtion™, and from 1.3 to 2.8mm, in Structure™. Worse results (3 to 6.9mm) were attributed to the model based on the Realsense™.

The researchers opined that they all operate sufficiently to capture gestures and understanding of the forms. Despite the inaccuracy of each one, represented by low thermal stability, lack of reliable data and reproducibility, and lack of integration with metrological inspection software – the authors were favorable to uses in which such factors are not important. Some examples given, in which any of them could be used successfully, were: making mockups for design, acquiring shapes and volumes that do not rely on refined details and scanning of human body to estimate clothing size.

Archaeological findings were also the object of analysis of the possibility of measurement with the use of a Structure Sensor™. The measurement accuracy was evaluated in a comparison with photogrammetry. Scientists inferred that the sensor is capable of acquiring the three-dimensional geometry of small findings with millimetric accuracy, but pointed out that minimal details are not always properly recognized by it. Texture reconstruction, provided by the Occipital sensor™, is not accurate they state. Rapid documentation of small archaeological finds is feasible with that sensor, especially if greater accuracy is not a requirement (RAVANELLI *et al.*, 2017).

2.4.3.2 Repairing the meshes obtained by the capture

Files from three-dimensional scanning invariably present holes and other defects in the mesh that represents the object. There are several methods to make the removal of what does not belong to the capture target, and also to repair the defects of the generated mesh, what is called “mesh completion” (SHEFFER; PRAUN; ROSE, 2006) or mesh repairing (PEREZ *et al.*, 2021).

These methods are essential for the scanner or sensor-generated file to be converted into a possible 3D model to be used. At the end of the work, the objective focuses on obtaining a "closed" mesh, the step immediately preceding the design of a biomodel, which is the replica of anatomical structures (D'URSO *et al.*, 1999), which existence is made possible by the conversion of the data contained in three-dimensional medical images into printable files.

As other features were discovered for the sensors, also the software that enables the manipulation of meshes were appearing, and some maintaining the logic that guide the maker movement: open-source and free use. This is the case, for example, with Blender and Meshlab. Meshmixer™, software by Autodesk™, is a software that – at least for now – can be used for free, but its code is restricted to the company.

The evolution of the community that operates open-source software, however, has made the functionalities of these programs resemble the so-called owners, thus making their choice represent less and less a compromise solution.

2.4.3.3 3D Printing

Also known as additive manufacturing (AM), 3D printing it is a constantly developing manufacturing technology, which:

> [...] enables the production of customized structures, from polymers, metals and ceramics, without the need to incorporate casts or machinery, as in conventional manufacturing. [...] It begins with a computer-aided drawing, which creates a virtual structure, from which a subsequent digital process planning is done. Virtual slices and coordinates guide the engines, which in turn control the position at which material deposition must take place. (DESHMUKH *et al.*, 2020, p. 527).

The authors cite that additive manufacturing is also known as layer manufacturing (LM), rapid prototyping (RP), 3D manufacturing (3D fabbing) and Solid Freeform Fabrication.

The way layers are added, and how they bond, is a way to classify the different categories of existing equipment. Currently, according to ISO/ASTM 52900:2021 (ADDITIVE MANUFACTURING — FUNDAMENTALS AND VOCABULARY, [s.d.]), 3D printers are organized into seven categories:

a) Binder jetting (BJT): the material, powdered, forms the layers, which are adhered to by a liquid binder;

b) Directed energy deposition (DED): the material is deposited and, as this occurs, depending on the code sent to the machine, it is melted by thermal energy;
c) Material extrusion (MEX): the material is pushed into a nozzle or hole. Then, it composes the layers, and overlaps them, successively;
d) Material jetting (MJT): the material that makes up the layers is deposited in drops;
e) Powder bed fusion (PBF): the layers are generated by the fusion of a powdered material, melted by thermal energy;
f) Sheet lamination (SHL): the material that forms the layers is on sheets, which are cut and bonded;
g) Vat photopolymerization (VPP): a light-sensitive liquid polymer arranged in a tank is solidified by being illuminated, generating each layer.

The equipment of each of these 3D printing principles generates a physical object, real, from a virtual model, which may have been designed entirely by a modeling program, or imported into it, coming from a three-dimensional scanning process, and then corrected and finalized (CHUA; LEONG; LIM, 2010). Then, the template is sent to a process planning software*,* to generate the code that will be sent to the machine. Such code is what composes the computer aided manufacture (CAM) in the process of AM, as defined by Gibson, Rosen and Stucker (2010): “CAM represents a channel for converting the virtual images developed in CAD into the physical products that we use in our everyday lives” (GIBSON; ROSEN; STUCKER, 2010, p. 20).

The smaller the thickness established by the program for the layers (or slices), the longer the print time and the higher its cost, however the piece will have better quality. The interest in refining the layers exists in the intention of decreasing the stair stepping effect. If this factor is not considered, the finish of the part surface may be compromised, and for this reason there are several software that do process planning, suggesting strategies to minimize that effect (JIN; HE; DU, 2017; PANDEY; REDDY; DHANDE, 2003).

The same software used to carry out process planning is where it is determined a series of settings that are responsible for determining part of the print success and the characteristics of the final product. There must be set how much support will sustain the part, in suspended or very inclined regions. Particularizing to the process by extrusion of material, it is in the process planning software that it is defined the quantity and shape of the part fill, the extrusion temperature, the printing speed, among other parameters.

The construction of the object by additive manufacture by extrusion of material can be made by several materials such as PLA (polylactic acid), ABS (Acrylonitrile Butadiene Styrene) and TPU (Thermoplastic Polyurethane), among others. Some of them will be analyzed in the following topic, applying the literature on 3D printing to breast prosthesis.

2.4.3.4 3D Printing Applied to the manufacture of external breast prostheses

It is when considering that external prostheses depend on a value judgment – which is an evaluation based on the subjectivity of each user – added to contexts of similarity of shape, color and volume, that the external breast prosthesis enters the universe of Engineering.

With all its precisions, its equipment, its measuring instruments and its tools, that field of knowledge is able to develop artifacts that mimic parts of the human body, and has presented results as impressive as it is useful. As each individual has peculiar characteristics, Engineering has allied its three-dimensional modeling tools and additive manufacture also to design customized prostheses.

3D printing by filament-powered printers, due to the reduced cost of the input, has positively impacted the evolution of assistive technology resources (ZUNIGA, 2018). It represents the popularization of additive manufacturing technology, in a practical and accessible application.

The manufacture of prostheses – considered here, homemade or industrial – are either too cheap to achieve quality requirements or are too costly (because they come from expensive inputs), so that the majority of the population that is the victim of a mastectomy can acquire them. Then, the manufacture supported by additive filament manufacture inaugurates the possibility of developing the cast of a custom prosthesis, low-cost and yet good quality.

One of the reasons for the growing importance of 3D printing for the design of prostheses is due to the possibility of 3D modeling generating a biomodel suitable for direct manufacturing by additive manufacturing (GIBSON; ROSEN; STUCKER, 2010).

The author cites the example of a well-known assistive technology, consecrated with a modeling that used to be done conventionally, which can be improved; he describes:

> An example of geometric flexibility is customization of a product. If a product is specifically designed to suit the needs of a unique individual then it can truly be said to be customized. Imagine being able to modify your mobile phone so that it fits snugly into your hand based on the dimensions gathered directly from your hand. Imagine a hearing aid that can fit precisely inside your ear because it was made from an impression of your ear canal […]. Such things are possible using AM because it has the capacity to make one-off parts, directly from digital models that may not only include geometric features but may also include biometric data gathered from a specific individual (GIBSON; ROSEN; STUCKER, 2010, p. 37).

References in the area of three-dimensional printing, the authors thus show the fulfillment of the requirement of geometry – subject to acquisition, modeling and three-dimensional printing – so necessary in an artifact that will have to be embedded in the human body. In the case of the prosthesis, where it is intended to replace a missing part of the individual, it is essential to respect the anatomy, mainly because comfort and symmetry are sought, which is also the case of the external breast prosthesis.

Figure 13 – Personalized prosthesis, with cast made in SLA technology

a b

Caption: a. custom breast mold
b. the cast, closed, receiving manual silicone rubber injection

Source: Eggbeer and Evans (2011)

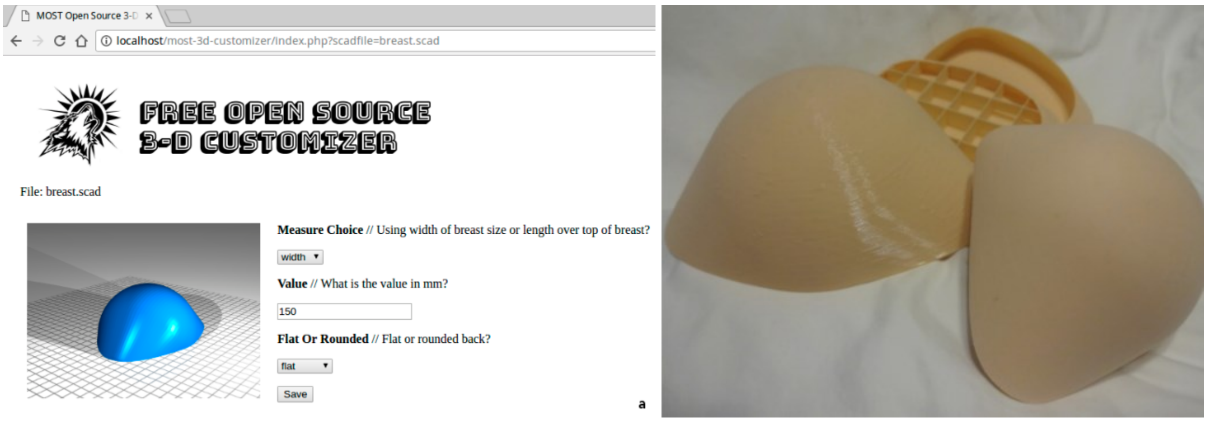
One of the possibilities of using 3D printing in the design process of personalized external breast prostheses was created by Eggbeer and Evans (2011), already described in the subsection 2.3.1 Shape. At that moment it was approached the strategy they used to obtain the shape of the breast, and here it will be shown how they obtained the final product.

The researchers used the mesh obtained by photogrammetry to generate a custom breast cast from a participant in their study, and a 3D Systems™ Corporation SLA 250/50 printer was used to generate it in translucent resin (WaterShed XC resin). The cast is shown in the Figure 13a. Being transparent, it facilitated checking the cast filling, which was made for the manual injection process with silicone, as can be seen in the Figure 13b.

Another attempt to contemplate different breast shapes and provide external prostheses closer to customization is presented on a platform that makes the manufacturing process by additive manufacturing more accessible, the Free Open Source 3D Customizer (NILSIAM; PEARCE, 2017).

One of the examples given was the generation of a partially customized external breast prosthesis. The modeling process becomes is a function performed by the platform, based on an OpenSCAD, hidden to the user, who only wants a result. It is an open source that allows the customization of pre-existing models, free of charge, which was available in user-friendly format, as demonstrated by the application screen, contained in the Figure 14a.

Figure 14 – External breast prosthesis customization



Caption: a. site print screen
b. final product

Source: Pearce (2017)

The focus on the final product shown in the Figure 14b, at the end, presents a view of the prosthesis similar to most off-shelf prostheses; it does not present a highlight of shape, nor color, in the region of the breast areola. The printer technology, which would designate which material to use for printing, would also be at the discretion of the application user.

It is not possible to infer that there is a real accessibility, with regard to the choice of the filling of the prosthesis, which, according to Nilsiam and Pearce (2017), would grant appearance and a sense of naturalness, as well as comfort. This is because filling is a parameter that needs to be changed in process planning software, which is not so simple to operate, for a lay user.

That feeling of comfort to which Nilsiam and Pearce (2017) refers, and which can be called by the technical term of responsiveness, is a response of the product to the pressure exerted by the user. In practice, if the prosthesis was projected to simulate the same response pattern as the subsisting breast, it would need to have an ideal filling, set by and to each user, in addition to a mandatory correlation with the material in which the prosthesis was printed. Easier said than done.

As in three-dimensional scanning technology, additive manufacturing has gained momentum and popularity in the last decade. In 2009, the patent for a printer invented by Steven Scott Crump and owned by Stratasys™ , which operates with fusion and deposition modeling technology, better known by the acronym FDM, fell into the public domain (CRUMP, 1992).

From then on, Makers began to assemble similar equipment, with components cheaper and simpler than those of the company that had the printer registration. It became open source. This has made additive manufacturing that operates by extrusion of material become the cheapest 3D printing system to date (VOLPATO, 2017).

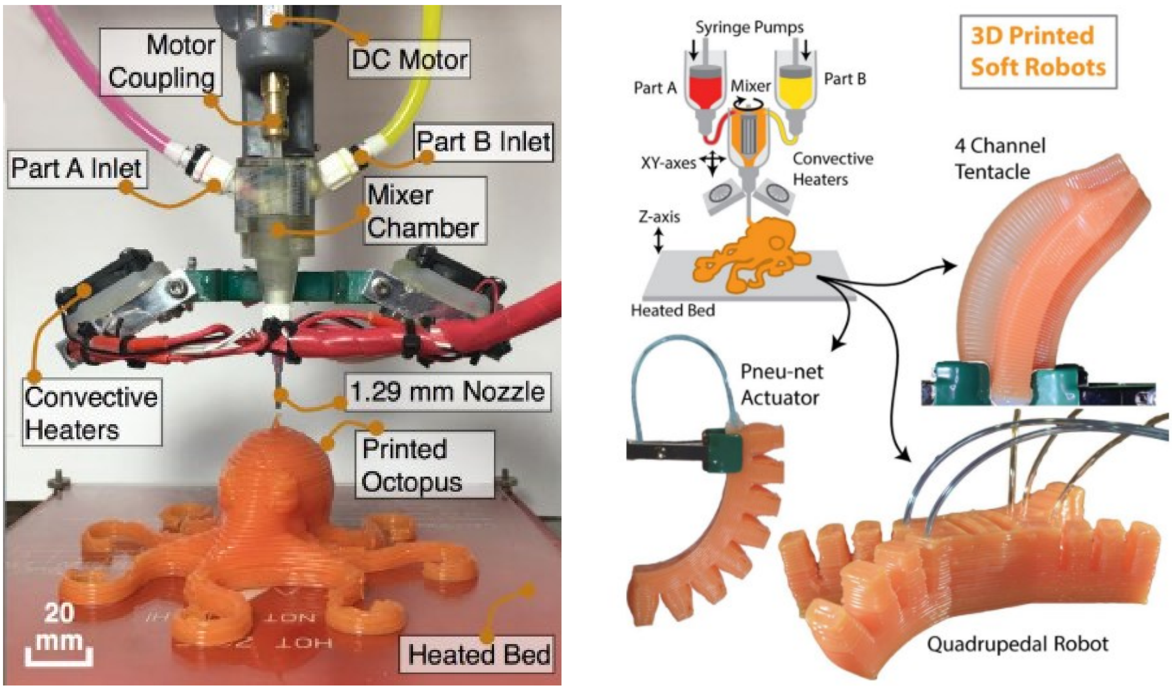
Among the main aspects of the process, which need to be addressed in the design of external breast prostheses, some important choices must be made concerning CAM: the definition of layer thickness, positioning and amount of support. Such definitions will also impact post-processing. All these features must be set in the software of process planning.

A breast prosthesis has an elliptical geometry, in which the characteristic steps of additive manufacturing technology are highlighted. The more the layer needs to make unevenness to find the subsequent one, the more visible the step will be, and the surface quality of the final product will be more compromised.

Another important aspect to be analyzed in the additive manufacturing process concerns the support and base that will be defined for the part. In the case of external breast prostheses, as they are organic forms, the choice may not be so simple (VOLPATO; SILVA, 2017). There is a positioning on the printing table in which the product may require more support for the construction of the part to occur correctly, but it may be the choice according to the aesthetic quality that this orientation of the positioning of the part provides.

Post-processing is also a part of the process that occurs after 3D printing, and that impacts the final result of the model. It can mitigate unwanted characteristics, present as soon as the product is removed from the printer, and can also represent greater time spent, since it is in this part of the process that the support structures that were only useful for supporting the part in the print tray are removed. Printed parts can go through sanding, painting or chemical attack processes to improve their surface quality. The simplest material extrusion printers operate with the same material for the support and the part, only differentiating them by the amount deposited. Removing the supports is a manual task.

Figure 15 – Project for printing robots, directly in silicone rubber



a b

Caption: a. the printer components
b. operation mode and results

Source: adapted from Yirmibesoglu *et al.* (2018)

Printing directly on silicone rubber is still incipient but promising. Yirmibesoglu *et al.* (2018) have developed a customized printer for their use, which is the manufacture of robots in soft and flexible material. They had attempted the TPU (with shore hardness 85A), but concluded that it still did not achieve its purposes, given that it has a material with shore A hardness eight times higher than desired. The system, illustrated in the Figure 15 was developed by them. Its use for purposes that depend on surface finishing, however, remains a challenge, as can be seen in the Figure 15a and in the Figure 15b.

Unkovskiy *et al.* (2018) experienced the application of direct silicone printing to facial prostheses, as can be seen in the Figure 16. The results, in their three finishing stages: no post-processing (Figure 16a), sealed with silicone cover and painted (Figure 16b) and polished with CNC milling machine, sealed with silicone cover and painted (Figure 16c).

Figure 16 – Facial prostheses printed directly on silicone

Caption: a. no post-processing
b. sealed with silicone cover, polished with CNC milling machine and painted
c. sealed with silicone cover and painted

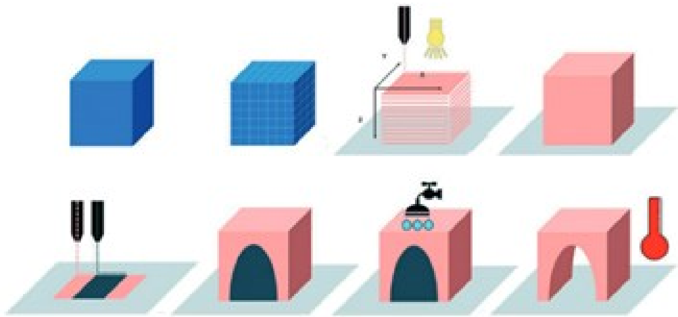
Source: Adapted from Ahcan *et al.* (2018)

In addition to the post-processing done by a CNC milling machine, they had to make a coating for sealing and painting to achieve the user's satisfaction, which required more steps in post-processing, more time and more cost. The process still depends on a human skill not replaced by any machine: labor with delicacy and perception.

The authors used a printer that defines itself as the only one that works with the "drop on demand" system, which means that the printer dumps silicone drops where the software determines, and with each change of direction of the nozzle, a beam of UV light is emitted to cure the silicone already deposited (ACEO®, [s.d.]). In Figure 17 there is a printer operation scheme (Figure 17a) and its head at the time of operation (Figure 17b). The authors do not comment on the printer's working time.

So far, therefore, direct silicone printing needs improvements, or a post-processing that depends on other equipment, such as the CNC milling machine, which requires more cost and a trained operator to make it.

Figure 17 – The ACEO printer™, which prints directly on silicone



a

b

Caption: a. printer's operating scheme
b. the printer head, extruding

Source: adapted from Unkovskiy *et al.* (2018)

2.5 Project Methodology

The proposed method for the manufacture of external breast prosthesis started from the opportunity to research how a Public University could serve non-profit institutions in various places in the country, with a model to meet the need for improvement in a product for mastectomized women. To create the method and prove its viability, it was necessary to develop the assistive product – the prosthesis – which was done according to a design methodology of Engineering, always keeping the focus on the objective of developing a method, applicable by any institution.

Bespoke prostheses are a project that depends, fundamentally, on the existence of a need of users. There are different design methodologies that have been applied for the development of such assistive products. One of them from the area of Design – the GODP (SCHMIDT; MERINO, 2016), and other two, from Engineering – the Methodologies by Pahl *et al.* (2005) and by Rozenfeld *et al.* (2006). Basically, what determines the choice for one of them is in which aspects the systematic is concentrated.

Pahl *et al.* (2005) have established a methodology that divides the project into the phases of: data collection, design requirements, idea generation, preliminary design, detailed design and conceptual design.

There is emphasis to the user, however what is intended is to meet their primary needs, which cannot coincide, when seeking to achieve a gold standard of quality. The authors' focus is on product planning and the methodology ends with product design. The original work (in German) was published in 1996, when 3D printers were not yet popular. In detailing the steps, the authors do not mention prototyping (which can be performed in several phases of the project), nor validation, which are key points in a project that is based on additive manufacturing and which objective is to design an assistive technology.

The validation phase is a return to the user, a step that needs to be respected, as mentioned in the principle contained in the slogan adopted by the American Disabilities Association: “*Nothing about us without us*”. It means that any product or service designed must have the direct participation of someone involved in the category for which it is designed. Listening to the user is, for assistive technology, understand the requirements contained in their testimony, and return to them, so that they will verify if their needs have been met.

In the validation step it is also possible to verify if the user uses the technology developed in the way it was designed, as well as give them the opportunity of the instruction of use, frequent complaint among users of external breast prosthesis (GALLAGHER, Pamela *et al.*, 2009; LIVINGSTON, 2005; MAHON; CASEY, 2003).

The methodology GODP (Project Development Guidance), that came from Design Thinking, devotes greater importance to the creation process, called "ideation". Before it comes a process called "inspiration", in the terms of its authors. Starting with the origin of this term – a "sudden enlightenment", "something that arouses the desire to create” (DICIONÁRIO CALDAS AULETE, [s.d.]) – the theory for the question raised in the present study is considered inappropriate. What underlines the conception of the manufacturing process studied here is a need, a clear lack, that dispenses with a production strategy.

In addition, the methodology is innovative when it has a phase that analyzes the opportunities, justifying that they are usually steps "unconsidered (formally) in all the methodological proposals researched" (SCHMIDT; MERINO, 2016, p. 12). It is necessary to do justice to those who have already registered a methodology contemplating this idea that the authors ignored and put under another denomination.

When writing about products that are designed to serve specific customers, Rozenfeld *et al.* (2006) identify more specific opportunities at a stage they call pre-development. Following an expanded strategy of the methodology arranged by them at the beginning of the work, the authors add this stage and focus where else the project in Engineering needs: in the project activity.

The creation has its space within the planning, for the authors, but it cannot take a time that will not be remunerated if the budget is not accepted. They address a product that will be sold as capital intensive goods, what is not the case of the prostheses. Thus, the Methodology developed by them, when adopted for the design of an assistive product, needs to be adapted, considering that the objective provided for the method developed in this research is not profit, but the fulfillment of a need.

Also, the creation, within the prosthesis genre, is limited, considering that what is intended is to replace a part of the body, that is, there is room to think about cutting-edge materials, for example, but not in innovative forms.

Rozenfeld *et al.* (2006) base their methodology in the model Engineer-to-order (ETO), which design assumes that there are few inputs in stock and also little storage of finished product. It is a production model that includes product engineering, before manufacturing itself.

The initial planning of the project also takes place in that first phase of pre-development, and it needs to at least point out the objective of the project and the activities that will make it possible to make up a commercial proposal.

In the next step is the informational project, during which the needs of users are investigated. It is a phase that only exists when no technical specifications and market information have been provided. Project requirements are defined at this time. The conceptual design, next point, contains the product specifications, which will be detailed in the last design step, among them affective aspects of usability of the prosthesis. There is an express mention of the authors to prototyping and the advances brought by CAD evolution.

Unlike the methodology by Pahl *et al.* (2005), Rozenfeld *et al.* (2006) do not include between conceptual design and detailed a preliminary step, where the design would be better detailed. The authors' choice is based on the evident evolution of design tools, including virtual prototyping, which allow budget calculations to be made already on a geometric model, still in the conceptual phase, which is much more than the outline to which Pahl *et al.* (2005) were used to, when they published their book.

Later is the preparation of production. Which can be a simple event in the case of products "*one of a kind*", that is the case for each prosthesis, since there are few inputs involved in the manufacture.

The delivery of the product (mentioned by them as product launch) follows, and closes what the authors called the development phase, that began in the informational project.

Finalizing their methodology, Rozenfeld *et al.* (2006) point out the phase of monitoring the product and the process, which in this work will be mentioned after the validation of the results. Among the microphases foreseen in the follow-up are vital elements for assistive technology, such as user service, user satisfaction assessment and product discontinuation, which includes the concern of product disposal.

2.6 Considerations about the literature review

Studies published in the last five years are often the best valued by the Academy. Therefore, it is necessary to highlight that there are few studies that are dedicated to the theme of this project, which is why, especially with regard to external breast prostheses, the articles cited are more than five years old. It is believed that the fact that there are few approaches in the issue values even more the novelty of this study.

Having verified the state of the art, the works done by other researchers around the world on the themes "external breast prosthesis", "three-dimensional technologies", "CAD", "CAM" and "casts", it was understood that there are some gaps not yet filled in that universe, and, above all, combining these areas.

Authors who address personalized prostheses (EGGBEER; EVANS, 2011; MONTEJO MAILLO *et al.*, 2020) work with scanners and printers of high cost. Only the first authors searched some similarity of the prosthesis with the region of areola and nipple of the remaining breast.

Those who used casts (EGGBEER; EVANS, 2011), opted for a process still too expensive for Brazilian standards (injection), and those who bypassed the molds (by printing directly in TPU), did not care about the delicate contour of the chest wall, on which the prosthesis will be supported (MONTEJO MAILLO *et al.*, 2020).

Subtractive manufacture could be an option, but still require a previous step, before the cast is achieved (in vacuum forming, for instance), generating a waste.

The published methods for designing external breast prostheses do not describe how 3D scanning can be done and mesh completion is little explained, and such files do not come out perfect. Breast ptosis is not addressed. This is an item that the method proposed by this study will detail, especially because when there is ptosis the treatment of images is more complex. And that represents the majority of cases, since the age group in which mastectomies occur the most is women over 50 years of age (when gravity, pregnancy and weight changes have already acted more).

There was no indication in the literature that the mass of the prosthesis must correspond to that of the remaining breast. Researchers begin to present solutions that provide for lighter prostheses, but do not combine this concern with that of personalization, that takes care of aspects of color and shape, all in the same product. The use of lower cost molds, such as those printed by filament extrusion, is not suggested.

Thus, once a gap has been identified in the Brazilian market, and considering that researches do not propose solutions for countries with low-cost resources, and having in sight that Additive Manufacturing, when applying budget machines, CAD and CAM made with free software, can offer a new way to transpose the challenge, this thesis explores how to get there.

This thesis innovates by presenting a research path in search of an economically feasible method, by which better quality prostheses can be conceived than those found in the Brazilian market. The use of low-cost technologies: 3D scanning with sensors (not professional scanners), CAD and CAM with free or low-cost software, 3D printers that operate with open source and filament extrusion, and molding process are its main features. Respecting the similitude with the remaining breast, as far as the user wishes it. Customization and possibility of replicating the method in various parts of the country are key points of the method conceived in this thesis.

To conceive a customized prosthesis, for the method developed in this thesis, is to embody the freedom of the user in choosing what she wants. It is, in essence, one of the pillars of the application of additive manufacturing to assistive technology – respect for users in projects made for the need of each individual – and the fulfillment of fundamental criteria for affective Design: comfort, affective need, happiness in life (KARWOWSKI, 2005).

The essential requirements, the needs of the users, what they use and know, need to be heard from them. As can be seen, there is little production of literature addressing Brazilian women, in a country there are still many radical mastectomies, predominantly without immediate breast reconstruction. It was decided to go to the field to collect their testimony and this is another novelty presented in this thesis.

With the increasing number of cameras that new smartphones offer, and higher resolution of their images, there may be easier and lower cost, in the short term, that can replace the sensors. The protocol generated for capturing the images in this method, however, will remain important.

It is possible that it is concluded, in the near future, that the direct printing of the customized external breast prosthesis can be done on other softer materials, which will be released, or possibly not in filament, as would be the case of direct extrusion of silicone rubber, as seen in this chapter (YIRMIBESOGLU *et al.* , 2018). Considering the technologies available at the time of the execution of this project, additive manufacture by extrusion of material using PLA filament was chosen for the method described in this thesis, to design the casts that originate the external breast prostheses, personalized or not. It is the most popular and least costly technique in the additive manufacturing process, in 2022.

The methods and processes foreseen for the conception of the manufacturing process of external breast prostheses, personalized, as well as the justification for their choices, are presented in the following chapter.

3 MATERIALS AND METHODS

An exploratory study, this thesis includes a theoretical-practical applied research, based primarily on the available literature on the subject, and, then, on results obtained from data surveys conducted in qualitative interviews which script – a structured questionnaire – found in the APPENDIX A.

Considering that the proposition of a method would only be possible through the manufacture of the product prosthesis, in order to avoid describing the materials and then repeating them all, to explain the methods, they were put together, in this chapter.

3.1 Ethics Committee

The first procedure related to this study took place even before it was accepted by the doctoral program in Mechanical Engineering, and was a basic condition of its existence: the submission of the research project to an Ethics Committee.

The research plan, presented to Plataforma Brasil (the database were all Brazilian researches involving humans must be registered), provided that twenty women submitted to mastectomy of one of the breasts, due to the occurrence of cancerous tumor, would be interviewed at the Erasto Gaertner Hospital. The doctor who supported and signed the indication of the study was head of the Gynecologist and Mastology service of that Hospital. There was also submitted the process to the Ethics Committee, and in its facilities were made the data collection of the participants.

The research project was approved by the Ethics Committee of The Erasto Gaertner Hospital, under registration 57438516.4.0000.0098 of Plataforma Brasil, and the selection of participants was accompanied by the head of breast service of that institution. At the time, Gynecologist and Mastologist MSc. José Clemente Linhares.

The process evaluated by the Ethics Committee will not be detailed, precisely because it occurred before the time of the research, but the documents that allow the understanding of the study are attached in APPENDIXES A, B and C.

The twenty participants of the research were of legal age, capable, all of them patients of the Hospital Erasto Gaertner, submitted to mastectomy of one of the breasts, due to the occurrence of cancerous tumor. The institution gave free use of the places where they were selected, invited, interviewed, measured, had their breasts molded in alginate and digitized three-dimensionally, and also photographed in that region of the body. This stage was held between August and December 2017 in Curitiba.

All files containing the documents (TCLE), mammography films, filming, data and images of the participants, as well as the casts made in plaster, are in the possession of the researcher, as adjusted with the Ethics Committee.

The main results of the analysis of the questionnaires are tabulated, described and analyzed in the following pages.

The questionnaire consisted of one part referring to the external prosthesis and the other, referring to bras. Although bras compose an important operational set, eventually inseparable from the external breast prostheses, they will not be addressed in the thesis.

After the selection via medical records on the day of the patient's consultation, the doctor released the documents, so that the researcher could contact her, within the outpatient clinic. The patient was then invited to participate in the research, that was briefly explained. References to participants will be made using a numbering, assigned in the order in which each of them agreed to be interviewed.

There were refusals, and among all patients scheduled for day care, only two could be interviewed every Monday, due to the availability of place and time of the procedure. The restricted access room was on the lower floor of the outpatient clinic, a quiet place where one could have all the privacy with each of the participants.

The interviews were fully filmed and the participants gave, without charge, to the researcher their rights of image, sound and use of data, as described in the Free and Informed Consent Form (TCLE), contained in APPENDIX B.

After the patient's installation, the researcher again informed that the interview would be all filmed, and then turned on the camera. The approval of the filming authorization was made with the Ethics Committee because it was an interview with emotional content, which could mess with the patients' self-esteem and their intimacy. The proposal, although foreseen in the literature that supported this technique, was unprecedented in that organ, precisely because of the need to safeguard the image rights of the participants. Members of the Committee gave such information, and due to the necessary prudence, clarifications prior to approval were necessary.

More than a transcription, the images of the participants, primary sources of research, are able to transport the researcher to the reality of "social actors", conferring what the authors call an "indicator of reliability and relevance” (BAUER; GASKELL, 2004).

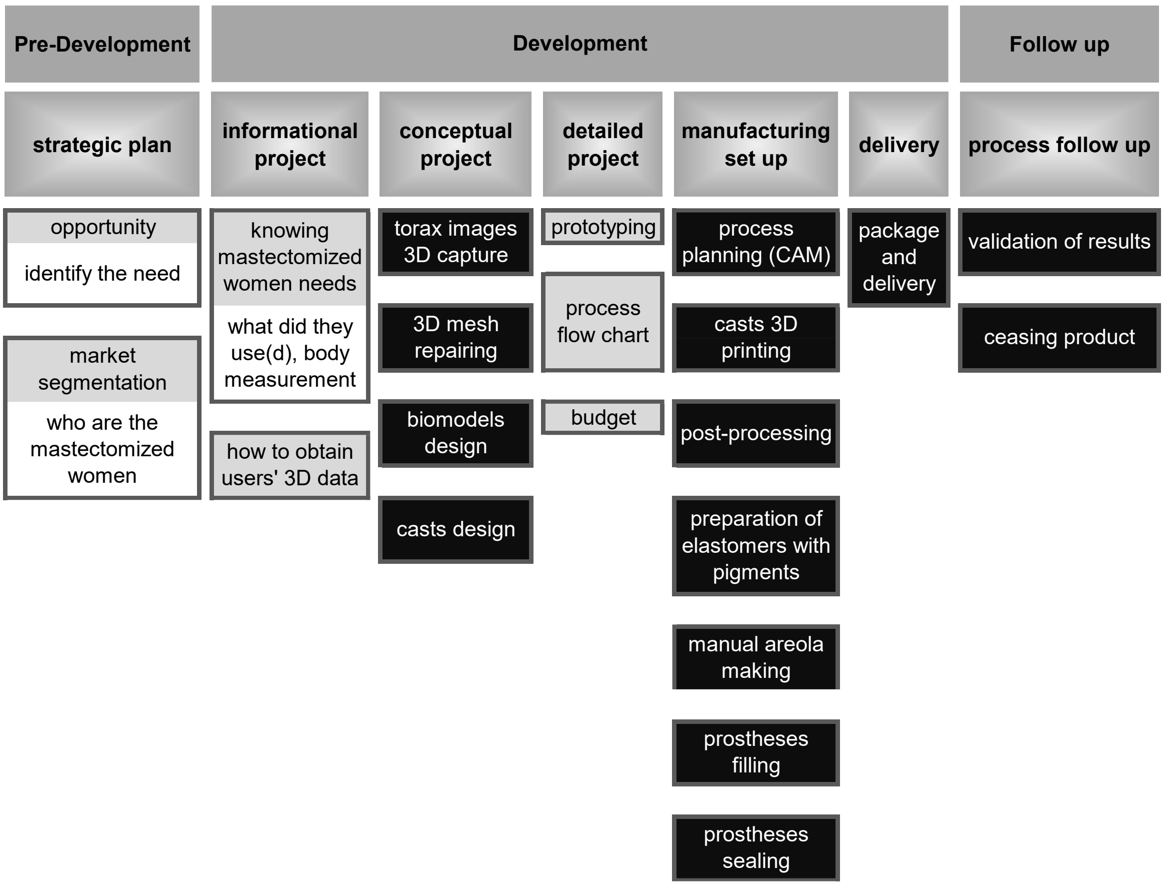
The reading aloud of the full Free and Informed Consent Form (TCLE), with the patient being filmed while listening and accompanying, with a copy in her hands, was also part of the data collection protocol. It aimed the safety of the participant and of the researcher, and also to ensure that even the participants who could be illiterate or of little education had agreed to the terms of the study. This is the document that gives support to all those involved in the process, in case of questioning about any procedure adopted. Written in language of easy understanding, as directed by Plataforma Brazil, the TCLE is set out in APPENDIX B.

3.2 Pre-development

Based on the Rozenfeld methodology for products (2006), the method developed for the design of the personalized external breast prosthesis began through the pre-development stage. To that author, it would be when the segmentation of the market would be sought, identifying where the product would be offered. As this thesis aimed to develop a method, the pre-development was the point to see the mastectomized women and to check what the literature had researched about them, about their needs, about the product “external breast prosthesis” and the methods described to manufacture such products. The research opportunity has already been explained throughout the literature review and the gap of proposed solutions, pointed out in the considerations on that topic.

Still within the pre-development stage, market segmentation was performed. Figure 18 presents the sequence of activities that guided the obtaining of the product which method was developed, as well as highlights, in white letters, which ones will have to be replicated by the institutions that adopt the method.

Figure 18 – Guidelines used to design the method for personalized external breast prostheses manufacture, with 3D scanning, 3D CAD, CAM and 3D printing



Caption: black boxes with white letters contain the steps needed to replicate the method; boxes with black letters indicate all the other steps that composed the investigation to develop the method

Source: The author (2020)

3.3 Informational Project

Part of the development plan, in the definition of Rozenfeld et al. (2006), this is the phase when the users, mastectomized women, had their needs known. At this stage, data were collected on the perception of the users, as well as the added information given by them, capable of adding to what not even the conventional market of prostheses offers. 3D data acquisition challenges were also checked, at this moment.

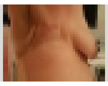
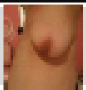
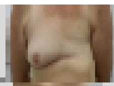
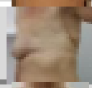
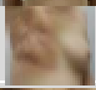
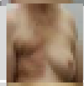
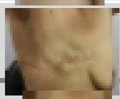
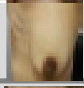
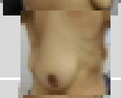
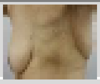
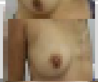
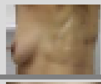
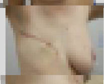
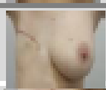
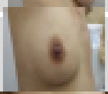
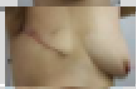
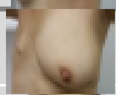
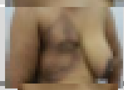
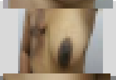
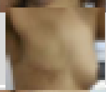
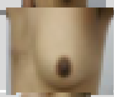
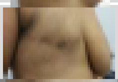
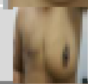
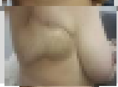
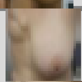
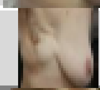
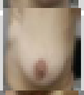
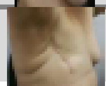
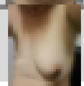
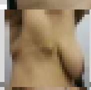
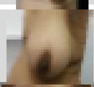
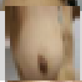
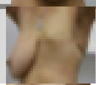
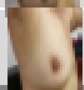
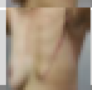
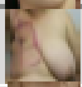
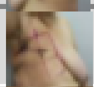
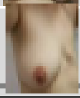
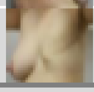
First, the users' perception of existing external breast prostheses, or those they knew, was investigated. For this reason, the research began with the users' approach.

In terms of Sampieri, Collado and Lucio (2013), the voice of the research participants are primary sources of research, and for this reason, they started the work.

The approach can be divided into two parts: one, interview, and the other, taking images and measurements.

Table 1 presents some basic data of the research participants: the name by which they will be referenced in this study, their dates of birth and the identification of the side on which the mastectomy was performed. The age of each of them, and the date on which each of them was submitted to mastectomy (with mention of the time, in months, elapsed since then), took as reference January 2022).

Table 1 – Main information of research participants

participant	birth date	age in 01/28/22	mastectomy in	months passed	right breast	left breast
1	5/14/1961	60	1/31/2017	44		
2	5/3/1955	66	11/11/2005	178		
3	6/14/1959	62	1/24/2017	44		
4	8/21/1971	50	2/22/2016	55		
5	12/17/1939	82	5/25/2006	172		
6	12/20/1967	54	10/1/2015	60		
7	7/8/1982	39	9/5/2016	49		
8	4/8/1977	44	9/5/2016	49		
9	5/24/1970	51	4/25/2017	41		
10	5/23/1977	44	7/27/2017	38		
11	1/3/1978	44	3/20/2017	42		
12	7/25/1977	44	5/3/2017	41		
13	3/15/1970	51	5/13/2017	40		
14	7/27/1949	72	8/12/2008	145		
15	6/26/1950	71	5/26/2015	64		
16	11/7/1955	66	4/4/2004	198		
17	2/14/1949	72	7/7/2017	38		
18	7/29/1965	56	3/16/2017	42		
19	1/10/1963	59	8/4/2017	1449		
20	6/11/1981	40	6/10/2015	1449		

Source: The author (2021)

3.3.1 Analysis of interviews with study participants

Since the preparation of the questionnaire, it was known that dealing with this theme simply with a numerical evaluation would be difficult, and this was the justification for maintaining so many open questions, even if it was more difficult to tabulate. Anyway, the survey contained a quantitative approach, that was further named “parameters of performance”, as published in AHFE 2018 (BRANCO; FOGGIATTO, 2018).

The composition of the questionnaire, as such parameters, came, mainly, from the questions brought in the literature review (EGGBEER; EVANS, 2011; FELIX, 2016; GALLAGHER, P. *et al.*, 2010; GALLAGHER, Pamela *et al.*, 2006, 2009; MAHON; CASEY, 2003), and studies that investigated quality and fitting in external breast prostheses, in depth. Other issues were brought by mastectomized women who inspired this thesis, previously met by the researcher.

The tabulation resulting from the first part of the interview can be visualized in the Table 2. A more detailed approach and its graphical representations will be explored in the following pages.

Table 2 – Participants' answers to the questionnaire of APPENDIX A

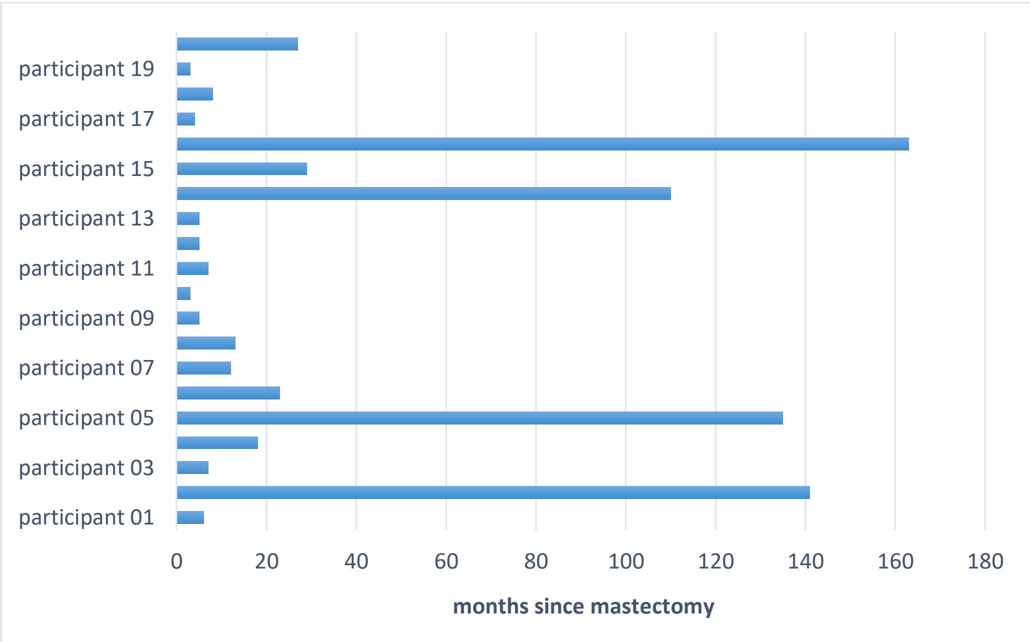
QUESTIONS	PARTICIPANTS																			
	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
model of external breast prostheses, at the interview	nothing	bird seeds ebp	cloth	foam cup	bird seeds ebp	foam cup	knitted knockers	3 piled cups	nothing	nothing	foam cup	socks	silicone EBP	old implant	handmade	cloth	bird seeds ebp	off-the-shelf	nothing	bird seeds ebp
Months passed since mastectomy, until interview	6	141	7	18	135	23	12	13	5	3	7	5	5	110	29	163	4	8	3	27
Knows about SUS reconstruction surgery?	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	M	Y
Who told about it?	DOC	NA	HEG	GYN	3	3	HEG	HEG	NA	HEG	HEG	HEG	HEG	3	HEG	NA	HEG	3	Svicente	3
Will submit to reconstruction surgery?	M	M	W	W	N	M	W	W	NA	M	N	M	W	N	N	N	N	M	M	N
Comorbidity	HBP D O	HBP G	N	HBP	HBP D	N	N	N	N	unknown	N	N	N	HBP D*	HBP	HBP D	HBP D G	HBP D	D	N
Did someone talk about external breast prostheses?	Y	Y	Y	Y	Y	N	Y	N	Y	Y	N	N	N	Y	Y	N	Y	Y	Y	N
Who?	HEG	Colombo	HEG	ASS	HOSP	NA	3	NA	3	HEG	NA	NA	NA	3	HEG	NA	3	HEG	3	NA
When?	POST	POST	POST	POST	6 years	NA	PRE	NA	POST	POST	NA	NA	NA	POST	12 years	NA	POST	POST	POST	NA
Months passed until uthorization to use some artifact	NA	NA	NA	4	NA	NA	3	NA	4	NA	NA	NA	3	5	NA	NA	NA	2	NA	5
Did you use some artifact before authorization?	N	N	Y	Y	Y	Y	N	Y	N	N	Y	Y	N	Y	N	Y	Y	Y	Y	Y
What?	nothing	nothing	cloth	foam cup	cloth	cloth + foam cup	nothing	silicone cup	NA	NA	foam cup	socks	NA	implant	cloth	socks	cloth	bojo	cloth	cloth
Do you know other models of external breast prostheses?	N	N	silicone	Y	N	N	birdseeds	Y	Y	birdseeds	Y	N	Y	Y	N	N	N	N	N	N
Who paid for your first prosthesis?	NA	PAX	NA	PAX	SUS	NA	NA	PAX	PAX	NA	NA	NA	PAX	PAX	PAX	NA	AMMA	boss	NA	PAX
How much did it cost?	NA	100	NA	20	NA	NA	NA	30	15	NA	NA	NA	150	180	30	NA	0	NA	NA	50
Did you substitute it?	NA	1	NA	N	1	NA	N	N	N	NA	NA	NA	N	N	N	NA	N	N	N	N
How many hours do you use your artifact?	NA	16	outdoors	outdoors	24	16	16	24	outdoors	NA	16	outdoors	16	outdoors	outdoors	NA	outdoors	8	outdoors	16
Do you have a relationship partner?	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y
How long in this relationship? (years)	38	35	NA	NA	NA	16	15	12	30	16	20	NA	27	35	NA	NA	30	19	N	13
Did you talk to him about external breast prosthesis?	N	N	NA	NA	NA	N	Y	Y	Y	N	Y	NA	Y	Y	NA	NA	Y	Y	NA	N
Do you feel any limitation, concerning to clothes?	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		N
Did you stop doing some activity?	N	N	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
Do you feel any limitation, concerning movement?	N	N	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N
Activity before mastectomy	sales	housewife	manuf assist	technician	farm worker	housewife	agent	operator	sales	manuf assist	housekeeper	housekeeper	lojista	sales	farm worker	recycling	housewife	cook	cook	sales
right handed/lefty	RH	lefty	RH	RH	RH	RH	RH	RH	RH	RH	RH	RH	RH	RH	L	RH	RH	RH	RH	RH
number of pregnancies	2	3	0	2	11	4	4	1	2	1	3	4	2	2	10	4	1	4	3	1
months of breastfeeding	97	72	0	84	54	32	24	0	48	2	21	72	15	32	264	42	12	44	50	20

CAPTION		
N = does not know	DOC = doctor	G = glaucoma
M = maybe	HEG = Hospital Erasto Gaertner	O = obesity
W = wants	HBP = high blood pressure	PAX = participant
NA = does not apply	D = diabetes	ASS = association
		GIN = gynaecologist

Source: The author (2021)

The research design provided for the approach, after the healing period of the surgery, of women who had undergone unilateral mastectomy due to breast cancer, and who had not undergone reconstruction. The participants needed to be legally capable to consent. Their age ranged from 35 to 77 years, as demonstrated by Chart 1.

Chart 1 – Time elapsed between mastectomy and interview (in months)



Source: The author (2020)

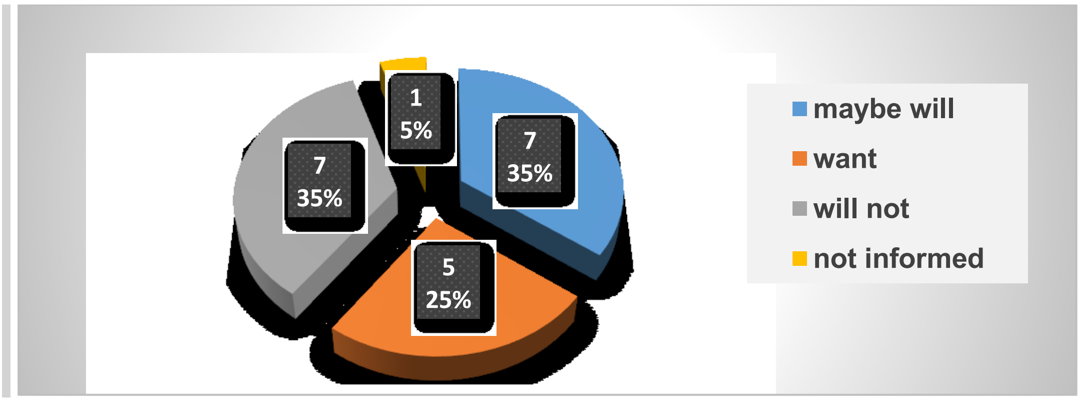
Among the twenty interviewees, there were women who had undergone mastectomy between 5 and 163 months before the interview date. As demonstrated by the distribution expressed in the Chart 1, most of them were concentrated in the first year of the postoperative period.

15% of the participants (3, in all) were not aware that breast reconstruction surgery, after mastectomy, can be performed by the SUS, which may confirm misinformation as one of the factors that contribute to the increase of women in the queues of late reconstruction, since they were not offered the possibility of reconstruction at the time of breast removal.

It is possible that they could not even be submitted to the procedure, considering that 50% of the interviewees have comorbidities such as high blood pressure and/or diabetes. Some did not have any changes before chemotherapy, they reported, but developed diseases after the drug was administered.

Among the participants of this study, 25% stated that they would like to undergo the breast reconstruction procedure, 35% did not know if they intended to join the queue and 35% were sure that they would not apply, as demonstrated by the Chart 2. One of them did not yet have any information on the reconstruction.

Chart 2 – Participants' intention to undergo post-mastectomy reconstruction



Source: The author (2020)

Thus, in principle, the queue of women waiting for breast reconstruction after mastectomy may have gained, in this sample only, 5 more women. Some of them report that they were informed that only after 1 or 2 years of mastectomy that they could undergo reconstruction. It is possible that this information was given according to each case, or not to generate expectation and anxiety, or really due to the impossibility of the vacancy, in that hospital.

It was noted that no previous information was given to these women, on resources to minimize post-mastectomy asymmetry. A single participant knew, by third parties, how to provide her external breast prosthesis, before having her breast removed. The others, 95% of the sample, were only expressly informed about it after surgery. 20% of the participants only had information about external prostheses coming from third parties. Among the patients who received information after having been mastectomized, two patients (participant 05 and participant 15), who learned of some resource respectively six and twelve years after surgery, draw attention.

This misinformation led each of the patients to leave the hospital and spend the first days after surgery without any support for asymmetry, unlike what occurs in countries such as Pakistan (JETHA; LALANI; GUL, 2017), and in European countries, where there are even nurses specializing in post-mastectomy care (GALLAGHER, Pamela *et al.*, 2006).

According to the interviewee responsible for the association of women, maintained in the Erasto Gaertner Hospital itself, they visit each patient who is operated there, before discharge, in order to talk to her. At that moment, they discuss the existence of the external prosthesis they manufacture, in tissue, with bird seeds inside. It is possible, however, that the patient is still under the effect of pain or some medication, or emotionally shaken, and does not pay effective attention in the visit. These would be sufficient reasons for the procedure of instructing to be done prior to surgery, even as a psychological preparation.

The recomendation that some patients supposedly received, in the immediate postoperative period, still in the Erasto Gaertner Hospital, is that they should not put any resources on the chest wall, until three months after surgery. However, even inside the hospital, the head of the breast service does not oppose the use, after one month of surgery, which is the basic healing time. Three months is a guideline given by the representative of the association that assists patients, supposedly determined by an older doctor in the hospital, for which no scientific support was found.

On the contrary, the literature comments on the existence of prostheses in a light model, already in the hospital. As mentioned in the literature review, they are polyurethane foam prostheses (KEETON; MCALOON, 2002). They have an essential purpose of preventing the woman from leaving the hospital already with the evident asymmetry and all the mental impact that this entails. These authors highlight that it is with a foam prosthesis that a mastectomized woman faces, for the first time in this condition, the world outside the hospital.

This event described by the authors is not a reality in Brazil, where most women know the external prostheses already outside the hospital, or inside the hospital, from other patients (at the chemotherapy, for instance). It happens also because the stay in the hospital is no longer than 48 hours. The nursing service of the Erasto Gaertner Hospital reports that, in most cases, with no complications, the patient's stay in the hospital does not exceed 24 hours.

Among those who were using prostheses, 80% paid for them, 10% gained from associations, and 10% gained from third parties.

Among those who had partners (70% of the sample), 36% did not consult them about the prosthesis, which indicates that the decision about the prosthesis tends to be a moment of intimacy that they do not share with their life partners.

For women who were wearing a resource that could be recognized as an external prosthesis, an evaluation of performance parameters related to the model used by them was proposed, in the middle of the questionnaire. The intention of the survey about such parameters was to identify what were the strengths and weaknesses of the artifacts used by them.

This part of the analysis was not fully accomplished, starting with the fact that it could only be done by 50% of the participants. Only ten of the participants were wearing some resource at least resembling a prosthesis. And one of those ten, in regard to ethics, had to be excluded of the process of interview, in this part.

Another point to remark is that what they were using was the only resource known to most of them (that could be even a bunch of socks). At times, it was difficult to extract the "grade" that the participant would give to the appeal, due to the evident shock to the participant. Among the most striking reports obtained during this evaluation, the “participant 2” was highlighted, when asked about the appearance of the prosthesis, when in her hand, she said that she did not even look at it.

Another reason for the inaccuracy of numerical results is due to the fact that the participants do not always associate cause and consequence. By assessing note 10 to the ease of placement of the resource she uses, “participant 4” demonstrated that she does not know the reason for her dissatisfaction with the performance of the product. She actually went to an underwear store and got the form that she worn (a kind of bra cup, made of silicone). It provided the symmetry of the volume, however, "rise" when she worn a top, that is, a tighter outfit. The logic behind this is that the cup, as an unattached element, moves with the top (or with the bra, she told). As the top’s fabric contains elastane, it fits close to the body. But as any elastic, it has the tendency to return to its original contracted state, what means that, gradually, the garment will move (and go up). Normally, that kind of garment is designed to stop in a “barrier” (as the natural underbust volume would be). In not finding any (as she does not have the bust in one of the sides of the body), the top (or the bra) carries, with itself, the cup, towards the shoulder. And, fundamentally, it is precisely because it is very easy to put (parameter to which she assigned another 10), that it is also easy for it to be displaced, to move along with any clothes. It is also a fixation in which the bra could facilitate, but they also do not exist to contemplate body asymmetries.

“Participant 4” assigned a grade 3 only to the shape of the resource, because it hurt when it rose. The final result is that she uses it only when she hangs out, as she explained, to avoid the fact that there may always be someone watching.

The lack of options between the most rudimentary and top-of-the-line ones may also be one of the responsible for the good grades obtained by products that attenuate asymmetry, but have precariousness that should not be acceptable, such as the difficulty of hygiene. It is perceived, more from the analysis of the reports than properly with the numerical evaluation, that the resources found by the participants act as a kind of "lifeline", in order to avoid exactly what “participant 4” described with such property (unknown people’s regard, of curiosity, when she crossed them in the streets).

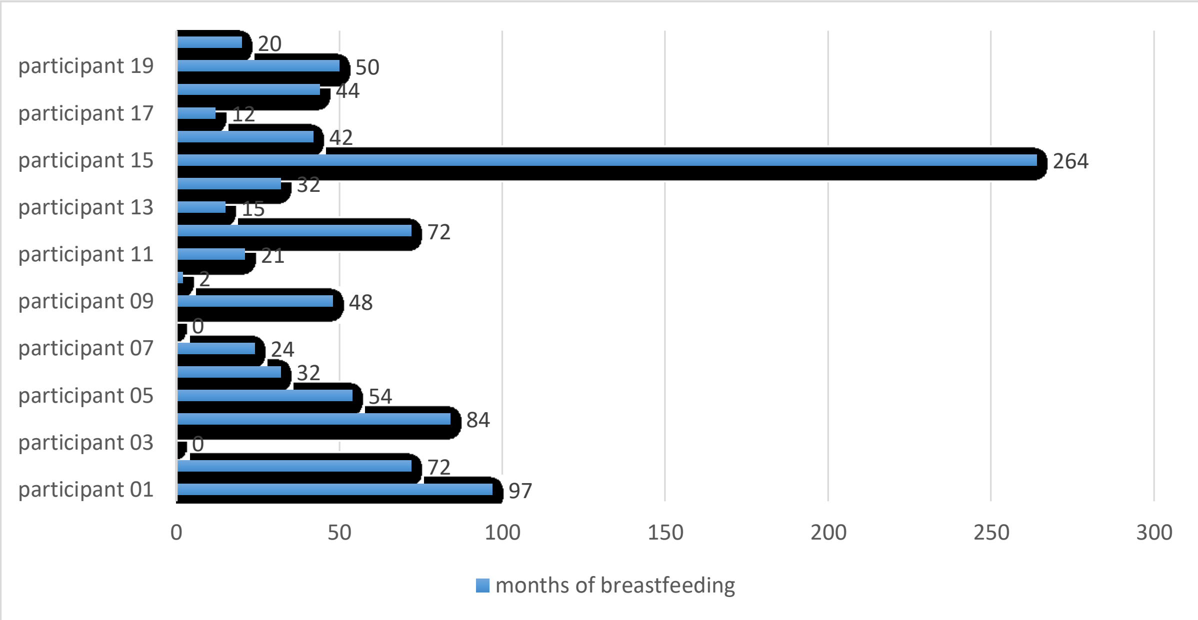
It is interesting to highlight that the interview in which the prosthesis received several maximum scores came from the only participant who was informed about the prosthesis even before the mastectomy surgery. She investigated the contents of the ones she saw and ended up opting, instead of filling with birdseed or rice, "millet seeds", she said. A relative knitted for her the outside, in wool, probably having taken contact with the Knitted Knockers project (KNITTED KNOCKERS HOME | BARBARA DEMOREST, [s.d.]). It is important to keep in mind the emotional character embedded in the resource, but, above all, “participant 07” reported the similarity of the prosthesis with her remaining breast. The person who made the resource was careful to knit it in a tone close to that of the skin of “participant 07”, and asked her to choose a darker shade for the areola region. The participant commented that the volume looked like that of her breast, which conferred more symmetry, as a result.

“Participant 18”, when evaluating the prosthesis she got from her boss, mentioned how much she was touched with the gift, and when she was encouraged to make some statement to the prosthesis, she expressed her love for the gesture of donation. However, even emphasizing her gratitude, she could not be comfortable with the prosthesis that, in his words, "was made in the shape of the breast of a young girl, a little girl". “Participant 18”, who was 52 years old at the time of the interview, had four children and breastfed, in all, for 44 months, what gave her a ptosis around degree 3.

The justification of the question that sought to quantify the time that each participant had breastfed was to demonstrate just one of the reflexes to which a woman's body is subjected, isolating one variable: breastfeeding. The number of months a woman breastfeeds her children often changes the position of the nipple of her breast.

Breastfeeding may not be the only impacting factor to promote breast fall over a woman's abdomen, but the data can provide an overview of the differences between women's breasts ptosis and their correlation with time of breastfeeding. Analyzing the following graph (Chart 3) and checking Table 1, which contains the photographs of the breasts of each of the participants, can give an idea of the correlation.

Chart 3 – Number of months that each participant breastfed



Source: The author (2020)

A woman who breastfed for 264 months – the highest number found in the survey – arguably has her breast with a different complexion from another, that never breastfed. Of course, there is no way an off-the-shelf prosthesis could contemplate these variations.

Together with the skin tone, the shape and mass of each breast make up a set of fundamental characteristics, which justify the need to think about serving mastectomized women with personalized prostheses, that could take into account all these three aspects at the same time. The manufacturing process of an external breast prosthesis needs to include these characteristics as performance parameters to develop the design of a product capable of conferring dignity on mastectomized women. The similarity of the areola and nipple, mentioned by two of the participants, added to what the literature review brought, when mentioning the University that makes areolas for women to glue in their reconstructed breasts (FELIX, 2016).

There is some discussion in the literature about the mass that the prosthesis should contain. This has already been presented in the literature review, and some Brazilian examples will be scored here, given by the participants. “Participant 14” chose to perform the reconstruction in the same surgical act of the mastectomy, but ten days later faced rejection of the prosthesis and had to undergo another procedure, to remove the implant. When she went to look for the association to buy an external prosthesis (five months later), she had the reference of the mass of the prosthesis that had been placed inside her body, of 450.0 g, according to her. And that was how she determined what she wanted as weight on the new prosthesis, now external. At a later moment of the interview, “participant 14” comments on the insecurity of the prosthesis falling from the “pocket” of the special bra, exactly due to the weight, possibly excessive.

“Participant 13” is sure to be dissatisfied with the mass of the prosthesis she uses. She was wearing a prosthesis of the most expensive models sold in Brazil, made entirely of silicone. At the end of the interview, when asked what she would say, if she could say something to the prosthesis, she reported that she would like it to be lighter and that it could have a more appropriate shape. Her prosthesis weighed 700.0 g.

The notion that the mastectomized woman needs to use a resource that simulates, on the mutilated side, the same mass of the remaining breast, does not always come from the patient's perception. “Participant 15”, for example, already had one year past her surgery, when someone told her that she would be crooked if she remained without a prosthesis. “Participant 15” confirmed one of the foundations defended in the literature, that it is difficult to assess that the position of the body has been altered by the lack of mass in the place where the breast is removed.

To make a connection between the displacement of the spine and the removal of the breast can be precipitated: “participant 5” worked in the soil all her life. Using the hoe only in her right hand, would it be possible that she had maintained an upright posture, which allowed her not to have any difference between the sides of her spine? “Participant 15” also wielded the hoe most of his life, before the mastectomy, but is left-handed. No study found evaluated these differences. Would these efforts have contributed to her posture more or less than each of her ten pregnancies?

Although the first data collection of a research on spinal alterations after mastectomy took place shortly before surgery, and a second, a few years later, these inferences about the cause of changes in anatomy (which would supposedly be resolved by prostheses, internal or external) are suspicious. Because the time that follows after surgery is a period of adaptation of functions.

65% (13, in total) of the participants reported the change in physical possibilities, and even work commitment. “Participant 15”, who worked in the swidden, can no longer moan the soil, as he said. “Participant 11”, a maid, can no longer clean, because the surgery has affected the movement of her arm, and “participant 8” could no longer hold her daughter in her lap after the mastectomy. Any human being experiences changes in his body throughout life, but these are some of the examples that show that the body has an abrupt change after that surgery. These changes, which would possibly be blamed on a visible spine bypass on x-ray, cannot be credited solely to the lack of a breast mass. Everything that is new in the body, at some point in life, can influence. So, it becomes very difficult, to any research, to claim that the lack of mass makes a difference.

What is punctuated, above all, is that there is a great difference between the implant – placed under the skin – and an object that is positioned externally to the body, not connected to it. The mass can make a difference as a reflection of the stretch of the elastic of the bra strap, which exists more on one side than on the other, but not necessarily because it returns the mass removed to the body. The external prosthesis does not have this power. As good as it may be, it never becomes part of the body.

Maybe the excess mass in a prosthesis can even be harmful. Asked about the alteration they had in their daily routines after mastectomy, 65% of the participants stated that they suffered limitations. The following activities were cited as hindering: carrying weight, exercising in the gym, performing heavy cleaning, mowing, taking a small child in the arms, mowing in the garden, sleeping over the operated side, washing the back with the arm-operated side, limited range of arm movement, changes in sensitivity and difficulty of grip. Basically, they are effort activities, which can be further aggravated by transporting another half a kilo, exactly on the side of which the breast was extracted and in which they present complaints, also very common in orthopedic offices, for those who are overweight.

As if this reasoning were not enough, there is still an analysis that can be made about the use of external prostheses, expressed by the number of hours that the participant reported making use of them. If she effectively felt the need for a mass symmetry, she would have the external prosthesis (or its equivalent) about 16 hours a day (this number of hours was assigned, during tabulation, whenever the patient stated that she only "took off to sleep" (bra or prosthesis, or both), assuming she had eight hours of daily sleep). However, 45% of them report that they use the prosthesis just to get out of their homes. There are emotional and psychological components that underlie the need to use that resource, which even justify its inclusion as assistive technology, because they mean improvement of self-esteem, provide conditions of similarity (perhaps it is too much to write equality) to people who have become different because they have undergone a mastectomy. Perhaps these reasons are more important than the value commonly attributed to the mass and spinal deviations that the absence of an external prosthesis can cause.

This discussion is one of the most important reasons about the personalization of a prosthesis, conceived with the contribution of additive manufacturing.

What happens with a product designed with the feature of additive manufacturing is that once the prototype is approved, multiple copies can be made from its cast. In addition to spreading out the initial cost, this differential changes the game that forces the woman to undergo an industrial design determination, and transfers to each woman the possibility of deciding whether she wants 200g or 500g in the prosthesis, as she feels comfortable, while testing, or throughout use, or at the time that she shall replace it, in case that her body has not changed.

It was evidenced in 10% of the sample, that patients did not acquire the habit of replacing their prostheses. As it is an object that is hidden, the cost ends up impacting on the decision to substitute it, over time.

In the case of birdseed prostheses, replacement would be important, since the prosthesis tissue can add fungi and mites. No evaluation was found of the seeds over time. In the prostheses made by the Hospital Erasto Gaertner, according to the report of the interviewee responsible for the association that distributes them, an irradiation is made to ensure asepsis. In the others, made by other associations not linked to hospitals, this is unknown.

Two categories were not evaluated and were therefore removed from the tabulation: smell and noise.

As a conclusion of the interviews, it is paramount to say that the richest analysis did not come from grades, but by spontaneous discourse, during the questions, or at the end of the process.

After each interview, the participants were given an opportunity to make free reports, encouraged by the question of what they would say, if they could say something to their prosthesis. The reason for asking open questions are attempts, throughout the interview, to listen to the *verbatim* of the participant in the research. On that issue, specifically, it was to use the most intimate emotional field, in which she could still manifest herself by saying something about the prosthesis that was accompanying her from very close to mutilation, to realize what this product contains or needs to contain.

The expectations, the relationship of the user with the product, their dissatisfactions, everything that is, even spontaneously mentioned, could be used to compose a panorama of the user's needs. Because often the interviewee has no way of dreaming of a concept, when it has never been seen, and only the "translation" of these manifestations (HAUSER; CLAUSING, 1988, *apud* BACK *et al.*, 2008, p. 220) can lead to innovations.

Because mostly working with women in the poorest layer of the population, it would be difficult for them to imagine what really would matter the most in a prosthesis, even more considering that many of them had not seem any other external breast prosthesis, and only knew about such resource at the moment they realized they had that asymmetry. Thus, what was considered by this research to be a guide in the parameters to be achieved was established using the answers described in this subitem, and also what was identified through the literature review. This composed the Table 3:

Table 3 – Parameters to be achieved

LIMITATIONS OF PREVIOUS WORKS	ACTION IN DESIGNING	PARAMETER
shape does not correspond to a woman in hers 50's and beyond	ptosis taken into account	reliability of shape
color does not look like user's skin	registry of skin tones	matching colors
prosthesis slips outside the bra	chest wall included in the prosthesis	personalization of shape
prosthesis is too heavy	search for lighter solutions	satisfaction with weight
high costs	low cost solutions preferred	cost lower than personalized
material does not allow going to the beach or proper hygiene	waterproof materials quoted	waterproof

Source: The author (2021)

3.3.2 Collection of physical data from study participants

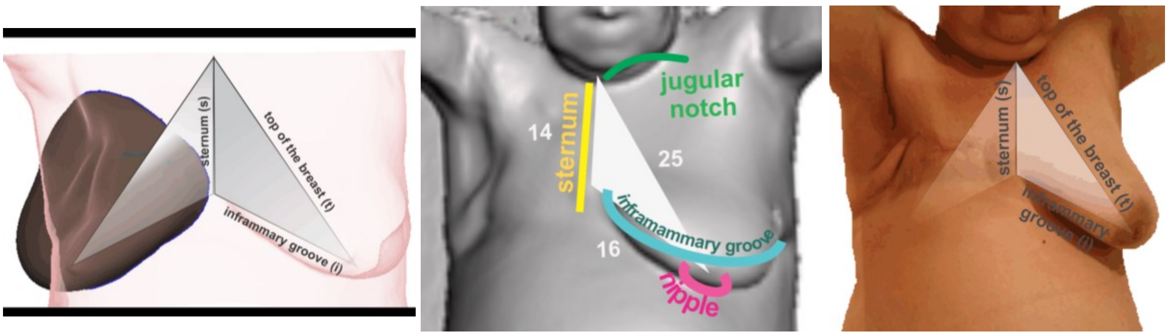
In order to be able to measure the reliability of the three-dimensional resources, physical data of the research participants were collected with traditional methods (using measurement tape and replicated with curved ruler, in the case of the inframammary groove curve) and the similarity of breast color was registered. The data were recorded by the researcher, guided by the form contained in APPENDIX C. Digital photographs of the region of the breast and thorax were also made.

After the interview, the camera was turned off and the participant was asked to remove the top of the clothes, so that the breast region was measured, photographed and digitized.

The measurements taken manually mattered, fundamentally, to the engineering of a more suitable bra, and possibly for future conference with the scanned images, since they were performed with a different system: measuring tape and curved ruler.

To simulate perfect symmetry, the measurements of the triangles of both sides must be equal, considering mirroring from the sternum bone (Figure 19a), from the jugular notch to the point where inframammary groove line begins. One of the sides of the triangle is traced considering the path from the nipple to the jugular notch, passing by the superior part of the breast, and the other, tracing from the inframammary groove extreme until the nipple, passing by the inframammary groove. As a result, this figure may also be indicative of the degree of breast ptosis, as seen in Figure 19c.

Figure 19 – The breast triangle



a b c

Caption: a. the position of the virtual prosthesis, after mirroring the triangle
b. how the breast triangle is composed
c. participant 01 breast triangle, in picture

Source: The author (2021)

On the back of each of the completed forms, finally, the curve of the breast groove was replicated. In addition to corresponding to what would be the wire used in the making of a bra, it is a guide able to confer the curve made in the biomodel, and can contingently be measured in the cast.

The measuring Instrument, called a curved ruler, is a square tube, 100.0 mm on the side, made of flexible, rubberized material. It was handled by the researcher until following as best as possible the design of the inframammary groove of the participant's subsistent breast, while the participant kept the breast away from the abdominal wall, using her hand. After the format conference, the ruler was removed from contact with the skin and overlapped to the sheet, where, with pen, had its design replicated.

As this curve is not originally captured by the sensors (except in the case of a breast with no volume on the abdomen), it is an inspection to be included in the manufacturing process of external breast prostheses.

In addition to the measurements, a scale with several strips of colored paper, called Pantone SkinTone™ Guide, was used to visually measure the tone more similar to that of the skin of the breast and the areola of the participant. That scale is a color library developed by Pantone™, to be a visual reference of human skin tones. The codes contained in it would be a guide to the colors of the prostheses. Its manufacturer does not specify how light may impact, considering that it is a resource used mainly for comparison, and it was used in the regular conditions of fluorescent lamps in the ceiling of the room inside the hospital.

The stripes of the guide have a cut, in one of the borders, to be used to compare, visually, some skin surface and the color shown in the stripe. This is what was made by the researcher, in the moment when all other physical data were collected.

In addition to the measures that were intended for a future study on bras, there were physical data recorded in each of the forms, which are of interest to the process of manufacturing external prostheses. Thus, Table 4 shows these measurements, together with the measured Pantones™, and also a scalene triangle, signaling inframammary groove (i), sternum (s) and top of the bust (t). These designations refer to the dimensions that assist the conference of measurements during the mirroring of the biomodel in the Meshmixer™ software, as seen in the drawing contained in the form, and exposed in the Figure 19a. Meshmixer™ is an Autodesk™ software that was used free of charge, as it had no commercial application. It imports stl files such as those acquired with the low-cost sensors and allow the manipulation of meshes and also measurements.

Table 4 – Pantones and breast triangles

participant	birth date	age in 01/28/2022	mastectomy in	pantone breast	pantone areola	i	s	t	2D images
1	5/14/1961	60	1/31/2017	4Y03SP	1Y11SP	14	16	25	
2	5/3/1955	66	11/11/2005	1R02SP	2Y09SP	25	20	31	
3	6/14/1959	62	1/24/2017	5Y05SP	1Y09SP	13	19	23	
4	8/21/1971	50	2/22/2016	5Y02SP	1R14SP	12	14	24	
5	12/17/1939	82	5/25/2006	4Y0ESP	3Y10SP	13	15	26	
6	12/20/1967	54	10/1/2015	4Y01SP	1Y10SP	11	16	20	
7	7/8/1982	39	9/5/2016	4Y01SP	2R04SP	14	20	23	
8	4/8/1977	44	9/5/2016	1Y01SP	2R08SP	14	17	25	
9	5/24/1970	51	4/25/2017	5Y02SP	2R08SP	13,5	19	24	
10	5/23/1977	44	7/27/2017	5Y08SP	1R14SP	14	23	26	
11	1/3/1978	44	3/20/2017	4Y01SP	1Y14SP	10	18	20	
12	7/25/1977	44	5/3/2017	3Y09	1Y14	12	21	14	
13	3/15/1970	51	5/13/2017	1R03SP	2R05SP	14	26	28	
14	7/27/1949	72	8/12/2008	1R03SP	2R04SP	15	24	27	
15	6/26/1950	71	5/26/2015	5Y01SP	1Y12SP				
16	11/7/1955	66	4/4/2004	3Y08SP	1Y14SP	14	27	30	
17	2/14/1949	72	7/7/2017	5Y01SP	3R10SP	12	22	25	
18	7/29/1965	56	3/16/2017	5Y01SP	4Y05SP	12	19	24	
19	1/10/1963	59	8/4/2017	5Y01SP	3Y08SP	18	26	32	
20	6/11/1981	40	6/10/2015	4Y01SP	4R06SP	12,5	16	21	

Source: The author (2020)

Subsequently, a plastic was offered that protected the entire participant's clothing and a replica of her breast was made in Dencrigel™ alginate (to then be filled in plaster), according to the protocol illustrated in the

Figure 20.

Alginate is a powder, which has been diluted in water, in the proportion of 1:1. It had to be mixed quickly (not more than 20 seconds), already in the application room, and applied immediately (Figure 20d). It is a material usually used by dentists for modeling the dental arch, and has versions that copy the relief in less than one minute. The cheapest the product, the shorter is its handling time.

The modeling done in alginate needs to have its interior filled immediately after drying. This is for two reasons: because it is a material that contracts over time and because it forms a very thin wall, not supported by itself. That is, the alginate cast is unstable and transient; it is fundamental for physical modeling, but only serves for the generation of the negative. To make it stable, to ensure that it did not deform already when removed from the body, some striped bandage strips were used to cover it, pending the time of prey of the alginate. To make it useful, the concave of the breast cast (the negative) was filled with plaster, forming the positive, that corresponded to the shape of the breast.

The plaster powder had to be put in the water, and mixed with a stick. The completion was done in the first minutes after obtaining the model in alginate, right after the participant had left the research room.

Figure 20 – Physical modeling process

Caption:
a. pouring the powder alginate
b. bowl with water
c. jar with water
d. area where alginate was applied
e. jar containing water
f. striped bandage (cut and dipped into the water)
g. area where wet striped bandage was applied
h. removed cast (alginate + dried striped bandage)
i. jar containing water
j. plaster
k. the cast being filled (plaster + water)

Source: The author (2020)

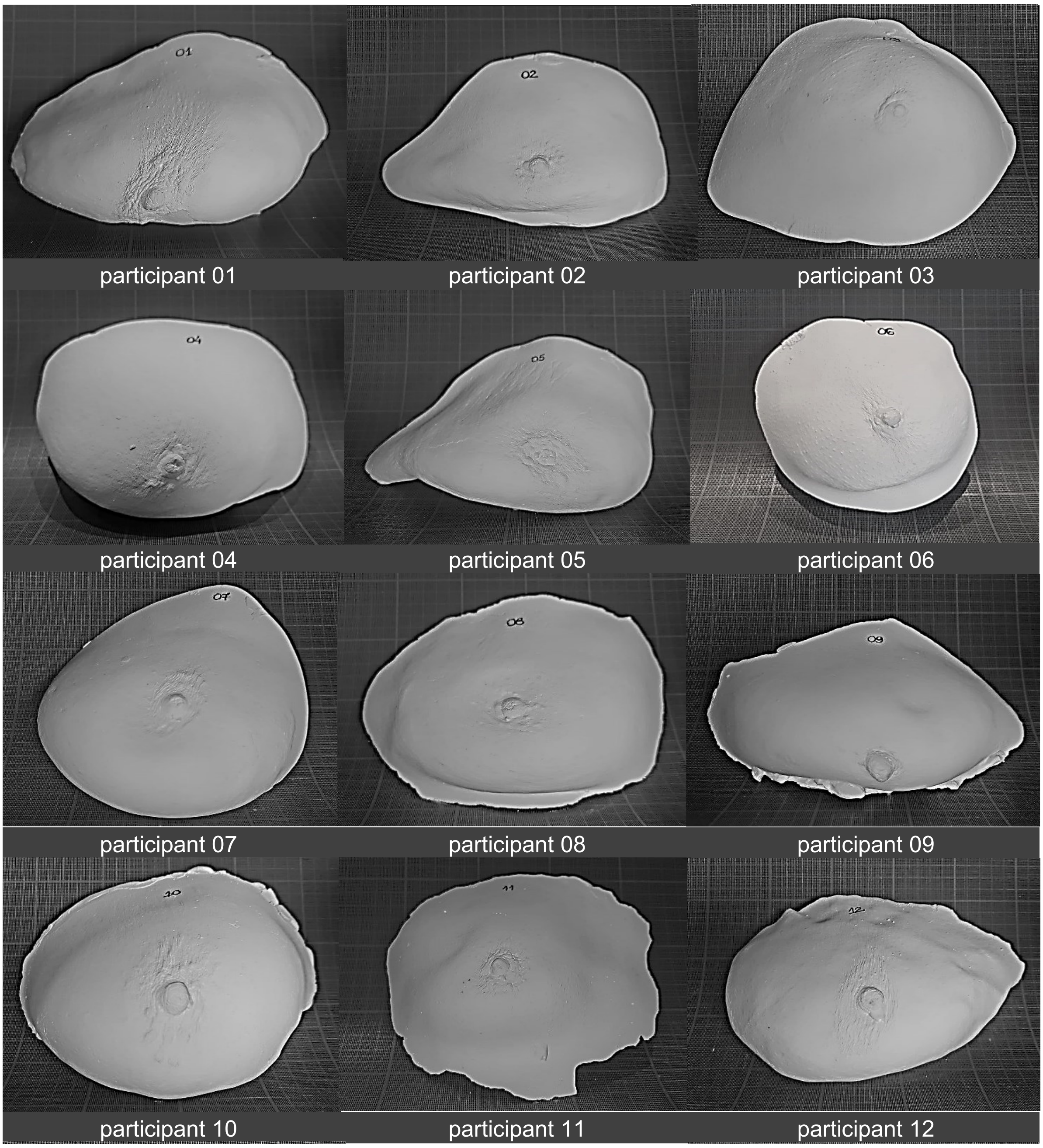
Between the preparation of the alginate mixture, the application of alginate and plaster bandages on the breast, the reaction of alginate, the preparation of the plaster and the filling of the cast with plaster took no more than five minutes. There were cases, however, in which the copy did not come out faithful, considering a deformation caused by the collapse of the alginate, probably by the contact of the breast with a more prominent part of the patient's abdomen. These defects in alginate could be found in two cases (10% of the sample), both when the breast volume was large and the abdomen was prominent.

The plaster models are very reliable in terms of form, as highlighted in the literature review (DIGITAL SCULPTURE PROJECT: ANDREA FELICE, [s.d.]), however, they have the potential disadvantages of the weight of each unit and the fragility in the air. However, they are still unable to delimit the areola region and differentiate it from the rest of the breast. They also do not contemplate the chest wall.

The intention of providing the models in plaster was to verify whether effectively the scales of the three-dimensional captures were consistent with the actual measurement, regardless of contact with the patient. Thus, it could be made a comparison with the plaster model made inside the alginate cast, both still performed in the research room provided by the Erasto Gaertner Hospital.

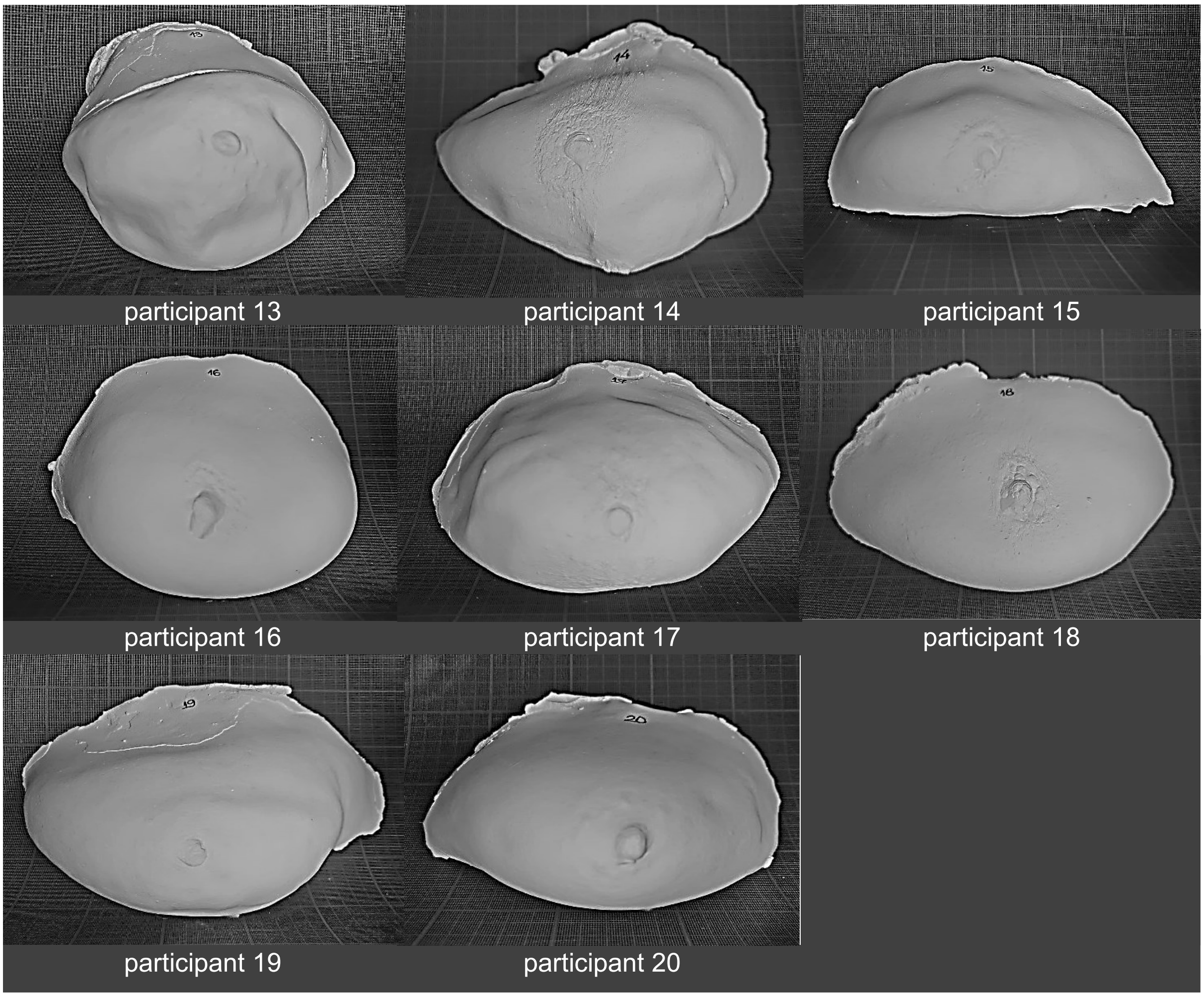
This comparison was carried out and composed the case study published as a book chapter (REGINA; FOGGIATTO, 2021). During the manufacture of the prostheses, the plasters were also used to measure the dimensions of the nipple and breast as a whole, comparing them with the printed cast, as will be seen in subitem 3.5.3 Casts printing, in its Figure 46. Despite some distortions as a function of the point of the body that the alginate reached, it was important to measure the accuracy of the collection of images, to ensure that the method was replicable. The twenty plaster models were photographed and compose Figure 21 and Figure 22. The background of each picture is marked in millimeters; between each of the strongest lines there is a distance of 50.0 mm.

Figure 21 – The plaster models of the breast of participants of this research (01 to 12)



Source: The author (2022)

Figure 22 – The plaster models of the breast of participants of this research (13 to 20)



Source: The author (2022)

It is important to highlight that the plastic measuring tapes used during the collection of physical data, even more than metallic measure tapes, undergo changes in measurement, because they suffer dilation and wear. As the temperature oscillates, so does the material that composes them; in a hot day, one may obtain a smaller measurement; in a cold day, higher numbers. Thus, the measurement conference always bumps into the inaccuracy of manual measurement instruments.

Another problem that occurs with conventional measurement instruments is the fact that their results depend on the point at which the operator positions them, the technique they use and an average, made according to the various measurements made (BRAGANÇA, Sara *et al.*, 2016).

There are also inaccuracies in the calculations made about mammography films, since they are based on images of perfect geometric solids, which do not necessarily correspond to the reality of the breast. They would assist in obtaining the volume in order to facilitate the filling of the prosthesis, but the software that generated the biomodel made such calculation accurately.

Anyway, conventional measurements and mammography films comprised the documents of this research, in order to check what was exposed in the literature (mammograms) and also by practical experience (case of plaster). Added to these files are the two-dimensional (digital) and three-dimensional images of the breast and thorax region, which collections were made in the same event.

3.3.3 Sensors

Several brands and sensor technologies were presented throughout the literature review. The choices, for this study that seeks a low-cost manufacturing process, had to fall on models that met, in addition to this characteristic, the ease of operation, considering that operators can be in any non-profit association in the country, and need to have ease of learning to use the resource. Portability was also an important feature, given the need to collect the images in various locations.

Portable sensors of less than a hundred dollars have come to meet the solutions sought. Thus, the study option was to analyze the solutions of the emerging market for three-dimensional scanning, aiming at low-cost, and possible application of them, in the manufacturing process of personalized external breast prostheses.

Therefore, tests were performed with sensors capable of generating a mesh of acceptable quality for the process of generation of biomodels, and the results of these tests indicated how the images of the study participants would be captured, in order to conceive the external breast prostheses, personalized.

The characteristics of the equipment, its mode of operation, its degree of accuracy, the quality of the meshes that they are able to generate and the programs used for conversion of the digitized points are items that determined on which model fell the choice that guides the manufacturing process.

Two of the low-cost sensors presented in the literature as emerging technologies were chosen. Both were depth sensors. They were chosen primarily for their portability and their cost. Although the sensor most cited in the literature review was Kinect™, it was not evaluated because it had its commercialization discontinued by Microsoft in 2017. The number of studies showing its feasibility to practical applications, though, guided the interest in such low-cost technology (BRAGANÇA, Sara *et al.*, 2018; GONZALEZ-JORGE *et al.*, 2013; HENSELER *et al.*, 2011; LI *et al.*, 2016; WHEAT; CHOPPIN; GOYAL, 2014).

Sensors chosen were the Asus Xtion Pro™, and the Structure Sensor™. Structure Sensor™ operates with Apple™. Asus Xtion Pro™ is open source and its code can be changed by any developer, which has made it popular with Makers, who can communicate with various devices such as computers, mobile phones and tablets. Occipital™ has consistently presented update of the Structure Sensor™, which already had a differential that seemed interesting to the research: the possibility of acquiring the texture. Their main features are listed in the Table 5:

Table 5 – Features of Asus Action PRO™ and Structure™

FEATURES	Asus Xtion Pro™ 	Structure™ 
depth image size (pixels)	VGA 640 x 480 and QVGA 320 x 240	VGA 640 x 480 and QVGA 320 x 240
resolution (pixels)	SXGA 1280 x 1024	1280 x 960
scan distance (mm)	80.0 to 3500.0	400.0 to 3500.0
connection	USB 2.0	USB 2.0 or iPad™ port
size (mm)	180 x 23.0 x 35.0	120.0 x 20.0 x 26.0
mass (g)	200.0	95.0
texture/colors capture	only mesh	texture (plugged into iPad™)
power source	USB	rechargeable battery

Source: The author (2022)

Each of the sensors made the connected capture – via USB cable (in the case of ASUS™), or with the hacker *cable* (provided by Occipital™) – to a Toshiba™ Qosmio™ X875-Q7190 notebook, which configuration has intel core i7™ 3630QM 2.4 Ghz processor, 8GB of RAM and GTX 460 video card of 1.5 GB. A third form of capture came from the same Structure Sensor™, this time connected to an iPad™ 2, as demonstrated in the Figure 23. In this configuration it also generated an image with the texture of the object, using, for this, the camera of the iPad™ 2. Both images – mesh and textured – need to be sent by email for their upload, and the files are sent by e-mail under the extension .skn (which is composed by several .jpg images, among others), to be downloaded, and then they can be stored on a computer.

Their handling was similar: both were connected to the equipment that processes the images and the mesh was controlled via the screen. For the Asus device™ a stand was printed to facilitate the handle, and for Apple, a support for it to be attached to the cover that protected the iPad™. As it was an extra case, the support had to be designed to fit around it.

Figure 23 – The three sets used for 3D scanning

a b c

Caption: a. Asus Xtion PRO™, plugged into the notebook
b. Occipital Structure™, plugged into the notebook
c. Occipital Structure™, plugged into the iPad™

Source: the author (2022)

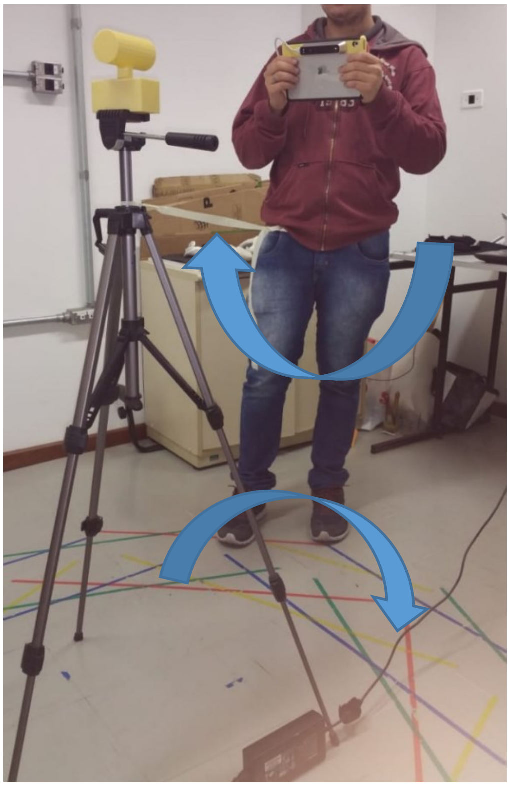
The sensors generated a triangular mesh, and the software of each uses mathematical functions to interpolate the points in a stl file, always calculating three vertices, with a normal vector to the plane formed by them. When the sensor was connected to the iPad™, 3Dscanner™ app (available for free download at the equipment manufacturer's app store) was used, with its standard settings in high quality (and the mesh was a skn file). When connected to the notebook, the Skanect™ 3D software performed this function. The parameters used in both Skanect™ 3D captures were: scene mode configured for 'object', bounding box at 1 m^3, and normal screen aspect ratio.

The cost of a Skanect™ software is US$129. Its choice was also confirmed by the quality of the mesh that it generated, and because it was considered an effective program to reproduce the geometry of parametric objects, according to studies of

Ravanelli, Lastilla e Crespi (2017). The authors point out that it can work with a range of points up to ten times higher than that of its competitors. Its acceptance, in the community of Makers, is for this reason, and also for the simplicity of the commands.

The programs warn when the displacement around the object to be scanned is done at odds, and it was necessary to return to the point where the sensor had lost the continuity of the image. Each capture took around 40 seconds. The models can be exported in stl format, when the software used is Skanect™, and the images generated with the use of iPad™, in skn format, need to be sent by email. They can be imported by Blender™ and Meshmixer™, among others.

Figure 24 – Test with Structure™ sensor connected to the iPad™



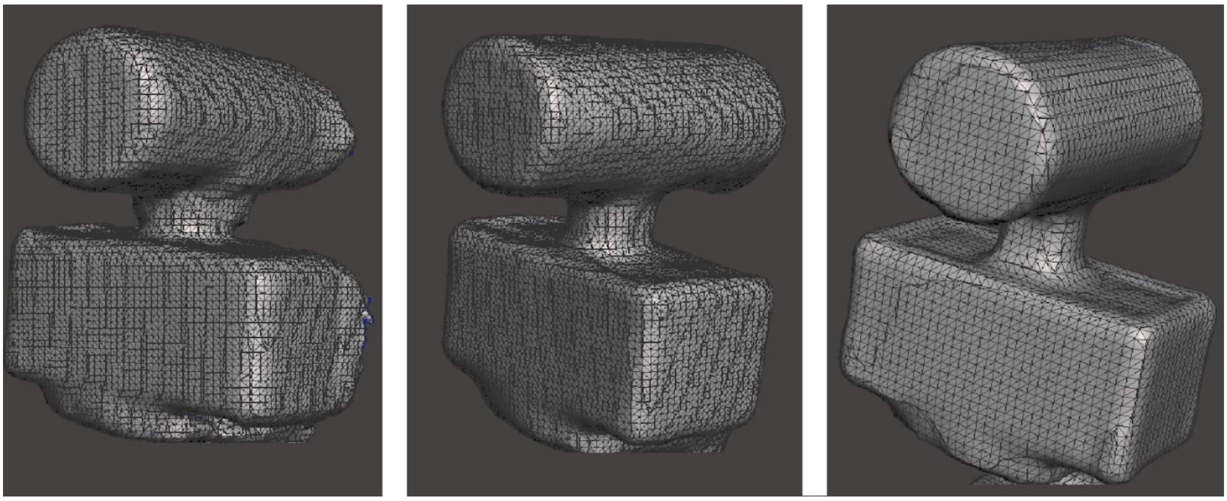
Source: The author (2017)

In order to measure the accuracy and quality of the images generated, a solid printed as reference was digitized and evaluated in the laboratory, using both sensors. Holding each of the sensors, with the determined configuration (sensor + notebook or sensor + iPad™) at a time, an internship moved around the printed solid (mounted on a tripod), until acquired a 360^0 image. His waist was tied to the tripod with a tape, so that he could keep the same distance, and also the ground had marks, to double check that he would move respecting the equidistant circle.

Using the highest number of triangles obtained in a mesh as a reference of 100%, the other two configurations were compared to that amount to inform a percentual, that is shown the Table 6. Using the same logic, the number of apex and the size of the file was also calculated, and are all expressed in the same Table.

The meshes obtained by three-dimensional capture made with the set Asus Xtion PRO™ + Qosmio™ were the best for the results of the research, because they presented better resolution (consequently, also a higher number of triangles), as can be seen in Figure 25:

Figure 25 – Meshes obtained with each of the sensors



42338 triangles	47548 triangles	16586 triangles
a	b	c

Caption: a. Asus Xtion Pro™ mesh, when plugged into the notebook, using Skanect™
b. Structure Sensor™ mesh, when plugged into the notebook, using Skanect™
c. Structure Sensor™ mesh, when plugged into iPad™ 2

Source: The author (2018)

From the generated models, the condition of the meshes was verified, and it was verified that the files scanned with Structure™ connected to the iPad 2™ have lower quality, in addition to a mesh with several errors, while with either of the two sensors, when connected to the computer, it is obtained higher quality, as evidenced in Table 6.

In order to evaluate the accuracy in the measurements made by both sensors, the mesh generated by each of the configuration set was checked with the measurements of the real size of the printed solid (a parallelepiped of 100.0 mm x 50.0 mm, connected to a cylinder of 25.0 mm of diameter). The values of deviation and the percentage errors are exhibited in the Table 7.

Table 6 – Comparative of files generated by Asus Action PRO™ and Structure™

FEATURES	Asus Xtion Pro™ + notebook	Structure™ + notebook	Structure™ + iPad 2™
Amount of triangles	42338 (89,0%)	47548 (100%)	16586 (34,9%)
Amount of apex	21964 (92,3%)	23801 (100%)	8295 (34,9%)
File size	14738 KB (98,5%)	14957 KB (100%)	810 KB (5,4%)

Source: The author (2018)

The data in relation to the Asus Xtion Pro™ are not included in the table, because the scan with it was performed in 180º, only, given its sensitivity to the operator's movement.

Table 7 – Comparative between the solid real geometry and scanned value

MEASUREMENTS	Asus Xtion Pro™ + notebook	Structure™ + notebook	Structure™ + iPad 2™
M1 - 100.0 mm	102,98 +- 0,31	103,02 +- 0,83	102,88 +- 0,32
deviation (%)	2.98	3.02	2.88
M2 - 50.0 mm	51,20 +- 0,50	52,48 +- 0,79	51,45 +- 0,39
deviation (%)	3.76	4.96	2.9
M3 - 50.0 mm		49,34 +- 0,79	49,20 +- 1,03
deviation (%)		-1.32	-1.6
M4 - 100.0 mm		101,80 +- 0,58	100,55 +- 0,23
deviation (%)		1,8	0.55
M5 - 25.0 mm	25,46 +- 0,23	25,07 +- 0,44	25,65 +- 0,27
deviation (%)	1.84	0,29	2.6

Source: The author (2018)

The evaluation concluded that the biggest error was verified using Structure™, when using it connected to the iPad 2™. This configuration was also the poorest in terms of resolution, as it had only 34.9% of the number of triangles in the Structure™ mesh connected to the notebook. It won in smaller file size, as it generated a file that is only 5% of the biggest size; that means a lighter file to manipulate, but impacts quality and precision of the capture.

It was evaluated that depth sensors are generally cheaper than commercial three-dimensional scanners. However, they require post processing, the more laborious the lower the resolution of the image, because they generate some mesh defects, due to the resolution of the equipment and the way the set of points is interpolated by the program. They have accuracy and perform the capture task even faster than the first professional scanners. For some engineering applications that allow margins of error in the millimeter scale, the sensors proved to be useful, as in the purpose of this thesis.

Due to the results of the evaluation, Asus Xtion Pro™, connected to the notebook, was chosen.

3.3.4 Protocol for capturing the three-dimensional images of the research participants

As it was intended to the method for manufacturing customized external breast prostheses to be replicable by any association, there was a need to define and structure each phase of the procedure and all the necessary equipment in the stage of capturing the images of the research participants. That is what is described in this sub-item.

One of the great differentials of the three-dimensional image collection process proposed for the research was to perform it without contact close to the patient. Of course, in a process involving manual conference of measures and modeling with alginate this seemed to make no sense, however, the reason for the existence of these two stages is that of disproof, which also originated a book chapter published by the author of this thesis and her supervisor (REGINA; FOGGIATTO, 2021). For those who perform the method proposed in the thesis, alginate and plaster are expendable step.

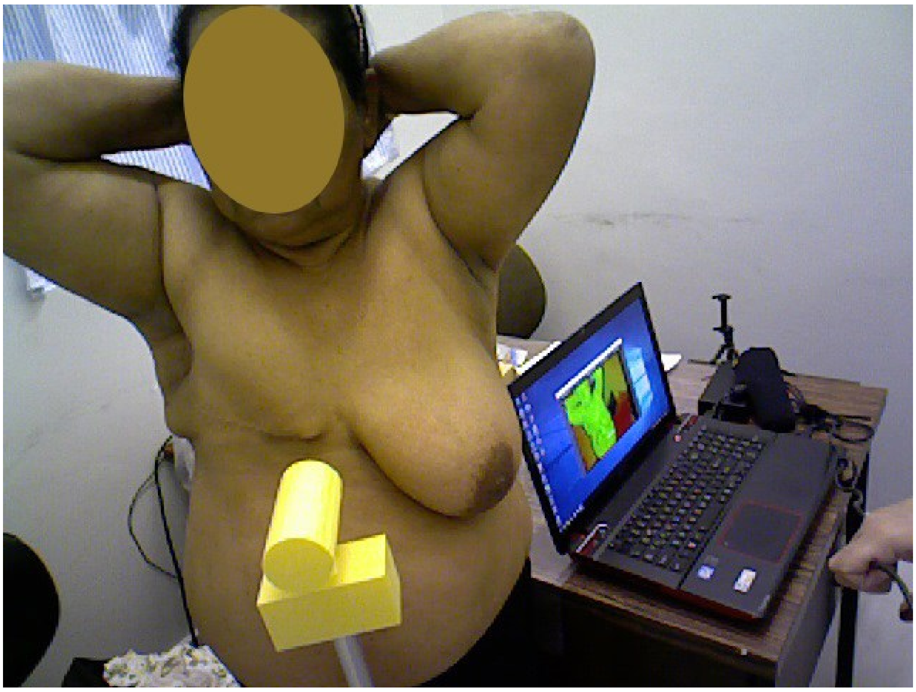
It was defined that the images would be collected following each other, shortly after the interview. The only image that would not be possible to be obtained at that time was that of mammography, since it necessarily needed to be scheduled with hospital technicians. The films of the mammograms, therefore, were withdrawn later. This is another step which importance was to check the data obtained digitally, and as the CAD software operated fairly in the volume calculation, the mammograms are also expendable to those who replicate the method.

From experience obtained with other programs and scanning equipment, it was understood that it would be necessary to keep close to the participant an object, that would serve to measure the fidelity of the size of the images generated, comparing them with the actual size of the object and what was scanned. As in the human body it would be difficult to make such a comparison, an object previously installed in the scene was adopted, to later check its scale in the generated mesh.

For this purpose, the cylinder connected to a parallelepiped 3D printed for the tests was always positioned close to the participant, so that it always had its image captured in the scene.

Participants were instructed to remain immobile during the scanning processes with each of the sets of 3D capture. They had their chests bare, their arms partially raised, and their fingers crossed, over the nape of the neck (Figure 26). To ensure that the collection would have the highest quality possible with each of the sensors, it was redone immediately, each time there was doubt about the integrity of the image (the largest number performed was 4 collections).

Figure 26 – Participant position in the scanning protocol

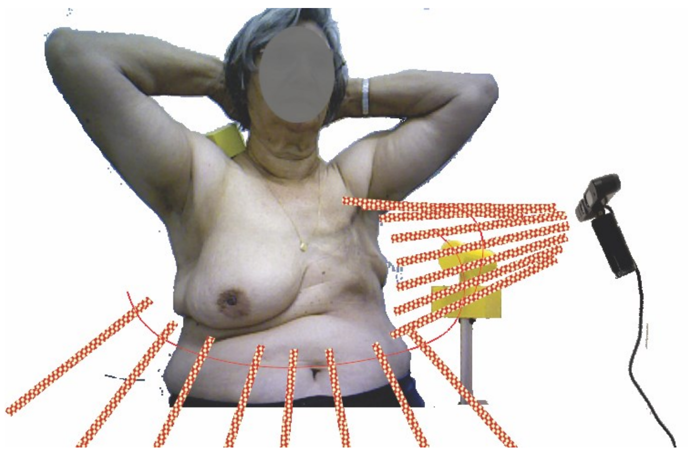


Source: The author (2018)

The position of the chosen arms, among many suggested by the literature (EDER *et al.*, 2011; HENSELER *et al.*, 2016; LEE *et al.*, 2016; LOSKEN *et al.*, 2005; OLIVEIRA *et al.*, 2011; OSMAN *et al.*, 2015; QUIEREGATTO *et al.*, 2014; VEITCH, 2012; WINDER *et al.*, 2014), is primarily due to a question of comfort – because not all patients can raise their arms above the head – and also by an average, which would take place between the position of the arms completely at rest or with the arms above the head.

Each scan was performed by moving the sensor 180 degrees around the front of the patient's chest, in the direction parallel to the ground (between the armpits), and also in curved routes, from the top of the breast to the abdominal area, in order to obtain the image corresponding to the breast and breast groove (Figure 27). These curves respected the distance required by the sensor for capture, signaled on the screen.

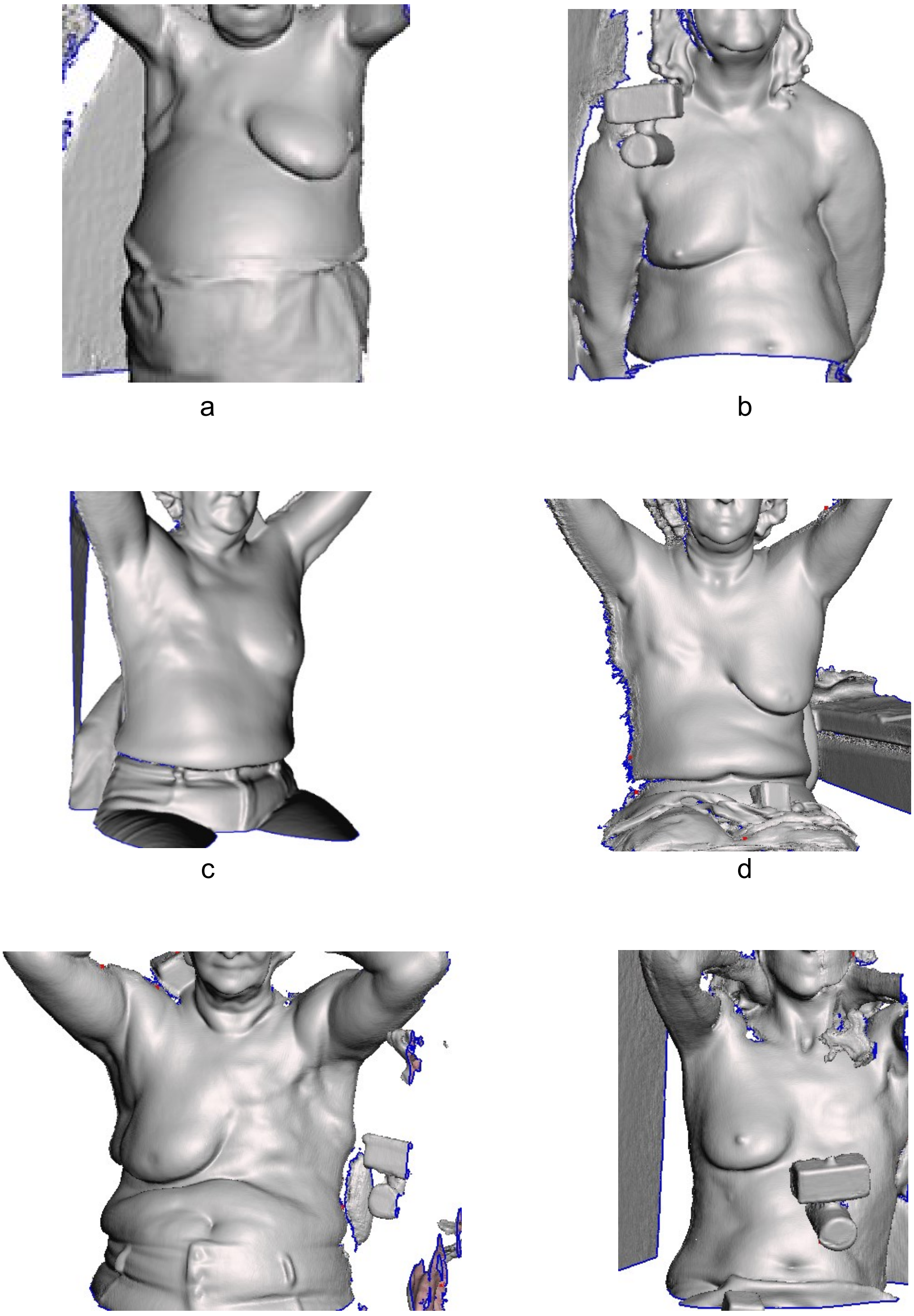
Figure 27 – Positions of scans performed with sensors



Source: The author (2018)

The capture of images of the twenty participants was performed following the same protocol and a print screen of one of the images collected of them composes Figure 28 to Figure 31. They were brought here in the original, except when the object used to measure scale, or the wall, hindered the visualization, when then the noise was previously removed from the digital file.

Figure 28 – 3D Images from "participant 01" to "participant 06"

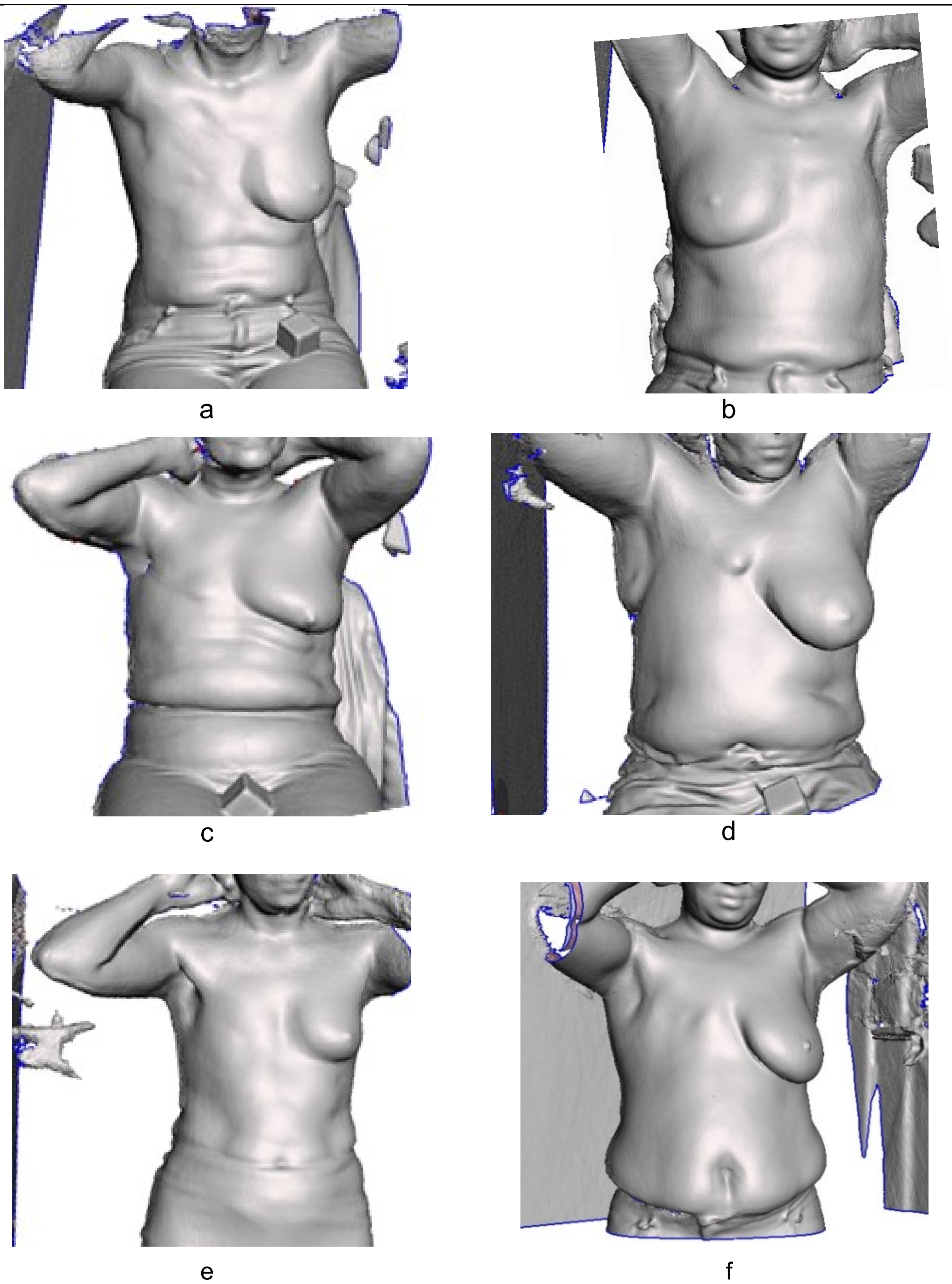


a b c d e f

Caption: a. "participant 01"
b. "participant 02"
c. "participant 03"
d. "participant 04"
e. "participant 05"
f. "participant 06"

Source: The author (2020)

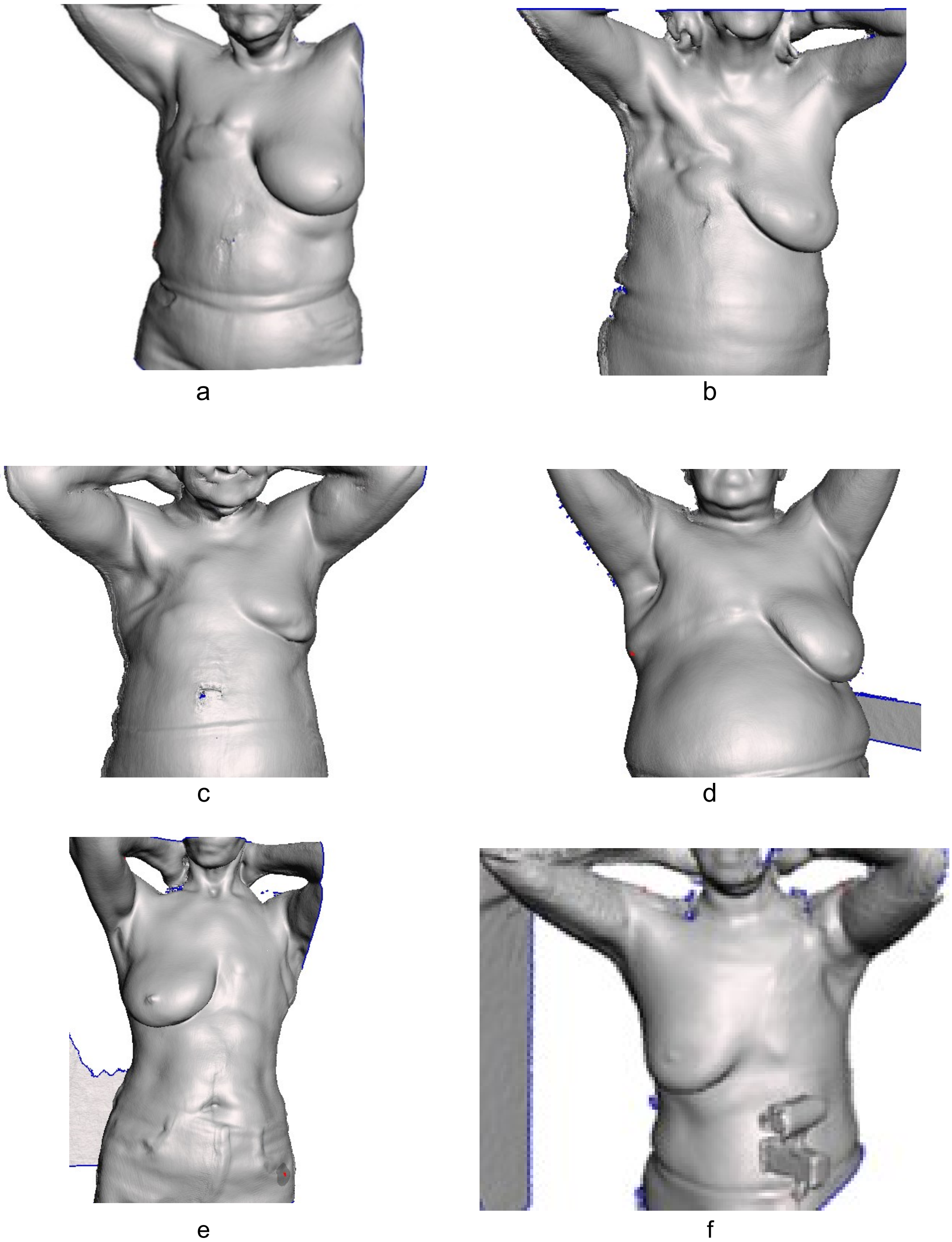
Figure 29 – 3D Images from “participant 07” to “participant 12”



Caption: a. “participant 07”
b. “participant 08”
c. “participant 09”
d. “participant 10”
e. “participant 11”
f. “participant 12”

Source: The author (2020)

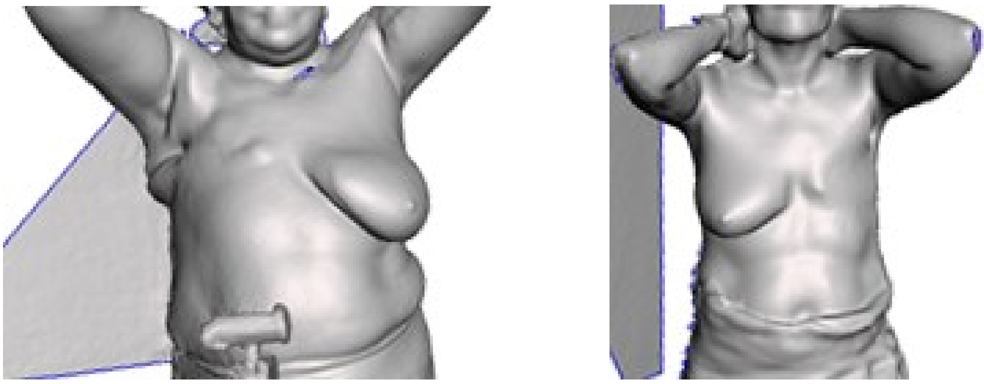
Figure 30 – 3D Images from “participant 13” to “participant 18”



Caption: a. “participant 13”
b. “participant 14”
c. “participant 15”
d. “participant 16”
e. “participant 17”
f. “participant 18”

Source: The author (2020)

Figure 31 – 3D Images from “participant 19” and “participant 20”



a b

Caption: a. “participant 19”
b. “participant 20”

Source: The author (2020)

3.4 Conceptual Project

According to the methodology of Rozenfeld et al. (2006), this was the stage in which product specifications received complementation. Since the data and the needs of the users were already established, it came the moment to collect the physical data of the participants of the research.

The geometry of the breast prosthesis depended on the repairing of the scanned mesh and for this it was necessary to establish a protocol that would allow systematizing this process, as will be seen in the next topic.

3.4.1 3D Mesh Repairing Protocol

Obtained the three-dimensional meshes from the 3D scanning of the study participants, software of free use was used for their repairing. The University had some licenses of others, but they implied costs of thousands of dollars, what would compromise the reproducibility of the method.

As NUFER had some know-how in Meshmixer™ software, this ended up being the first option, and with it were carried out all editions of the stl files. The laboratory had previously tested with different internships some manuals done by former internships there, with tips about the tools of the software, and they all learned easily how to work with the resource.

Considering that these were files with very refined meshes, their processing required intensive work of the PC. In order to avoid computer outage, the first step in importing the data was to modify the original mesh to extinguish regions that were not of interest. Subsequently, the mesh correction process was carried out, with work dedicated to the shadow zones that generated openings, mirroring – considering that it was intended as a result what would be the contralateral breast – and the adequacy of the breast image to the chest wall.

There is, in the process of correction of the mesh, some subjectivity given by the sensitivity and ability of the program operator. Those are meshes with human contours and inaccurate measurements. It is important to highlight that such accuracy, even when it comes to software such as GOM™ (which is a precision software, used by Metrology, capable of assessing distances in digital three-dimensional images), is not absolute. The greatest possible similarity with the real breast was sought. Even because women, with their hormonal oscillations, do not maintain the same body throughout life, or in the course of the same month. And between any parts of the body where there is a contralateral there is a natural asymmetry, which does not interfere with conventional aesthetics.

The biggest challenge in the manipulation of the mesh generated by the sensors is to fix their flaws without changing the body contour, maintaining the curves that the human body has, unique in each woman. Among the failures, the largest was invariably in the region near the breast sulcus, especially in women with higher breast volume, and even more so when she presented a fall over the abdomen (ptosis).

The region of the breast that is in direct contact with the abdomen is impossible to be scanned externally when the woman is vertical. The area near this region often fails whenever the breast causes a shadow zone.

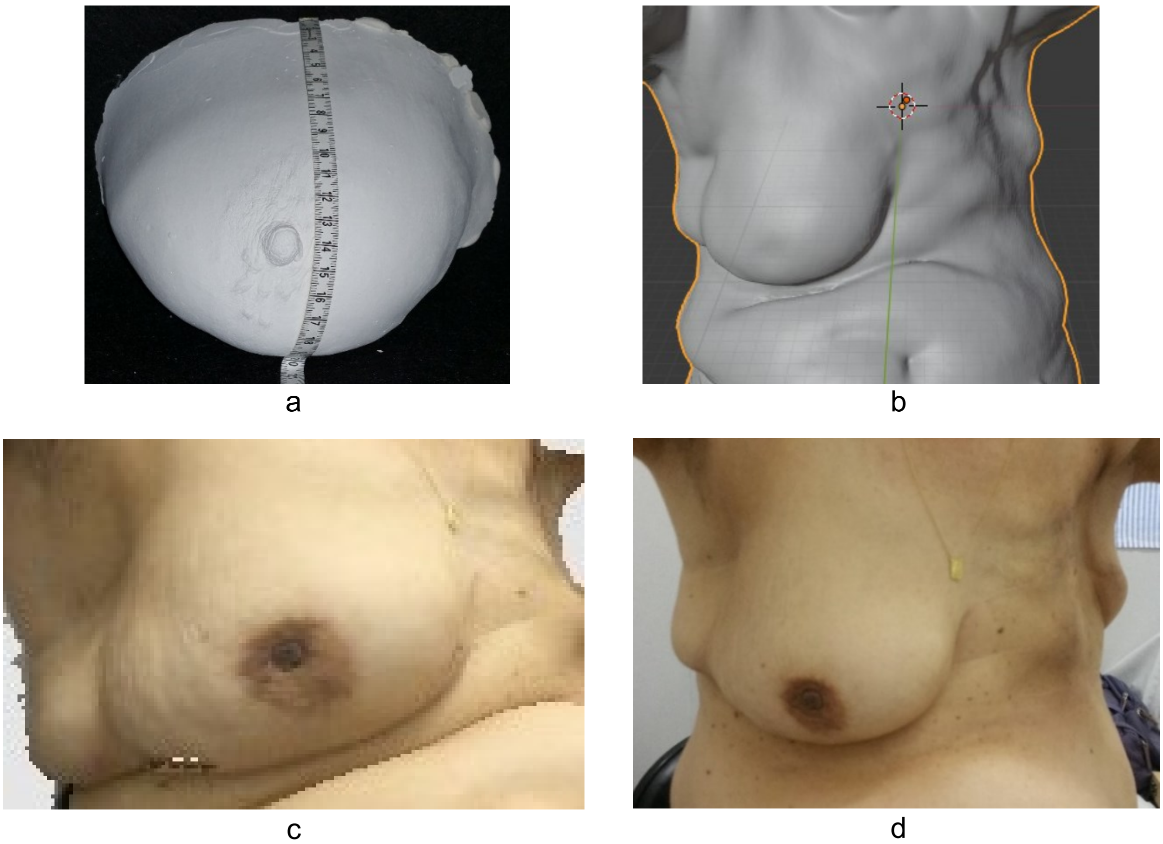
It is noteworthy that the articles found in the literature, when they involve three-dimensional breast imaging, do not present a response to the challenge imposed by ptotic breasts (PÖHLMANN et al., 2017; YANG et al., 2015).

The prosthesis needs to fit into the chest wall, which is an irregular surface, and in addition to the Boolean operation, which subtracts the abdomen from the scanned region as breast, some ability is required in the manipulation of the two surfaces (breast and chest wall), to join them properly.

It was intended to record everything necessary for the correction of meshes, from its capture to, at the end, to generate a protocol that could be multiplied. In view of the volume and practicality, the complete step-by-step and the main commands used in the software, have composed a manual aside, attached in the APPENDIX D.

It was important to guide the images with the textures generated by Structure™. Photographs also helped to arrive at the similarity with the subsistent breast, intended by the study.

Figure 32 – Comparative of the plaster model with the 2D and 3D images



Caption: a. picture of the plaster model
b. image made by Asus Xtion Pro™
c. image made with Structure™
d. digital picture, made with cell phone

Source: The author (2019)

After the work of repairing of three-dimensional meshes, it was possible to verify the result of measurements of the virtual model with the physical measurements of the breast cast in plaster. This model, however, did not count on the region of the chest wall, which only the digitization had, and which was considered by the study as fundamental for the completion of the biomodel, since it is where the prosthesis accommodates to the body, providing comfort.

Figure 32 shows a visual comparison of each of these data collected from one of the participants.

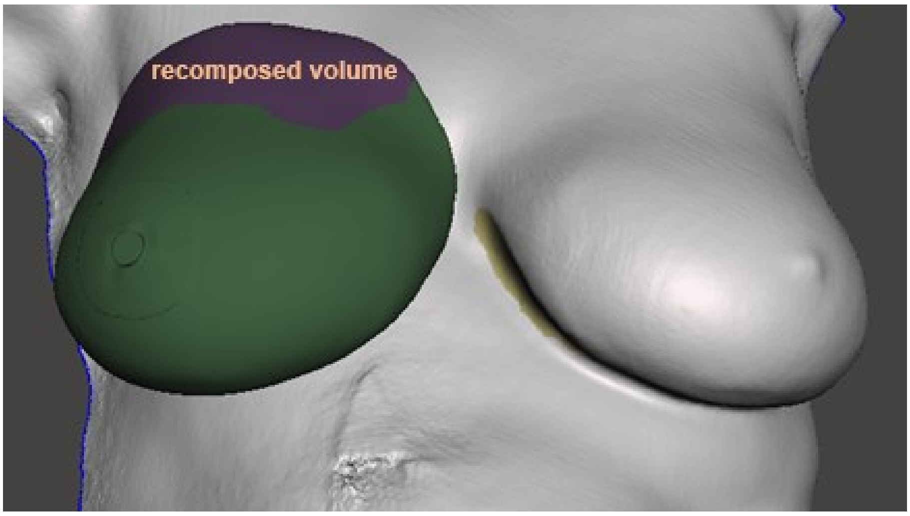
3.4.2 Biomodels protocol

With the mesh that copies the contours of the remaining breast repaired, it has begun the process of generating a biomodel compatible with the relief resulting from mastectomy. The biomodel, for the purposes of this research, is the composition of the breast area subsisting with the region of the chest wall, obtained from scanning.

For this purpose, it was necessary to mirror the file generated by the capture, then already repaired, and position it on the area of the chest wall, using the midline of the sternum region and jugular notch, approximately, as a guide.

In the case of a surgery which objective is to exclude a cancer, the subsisting part often presents depressions and protrusions that need to be "recomposed" by the prosthesis, as illustrated in the purple part, in the Figure 33.

Figure 33 – Mesh manipulation to improve Ergonomy in the model

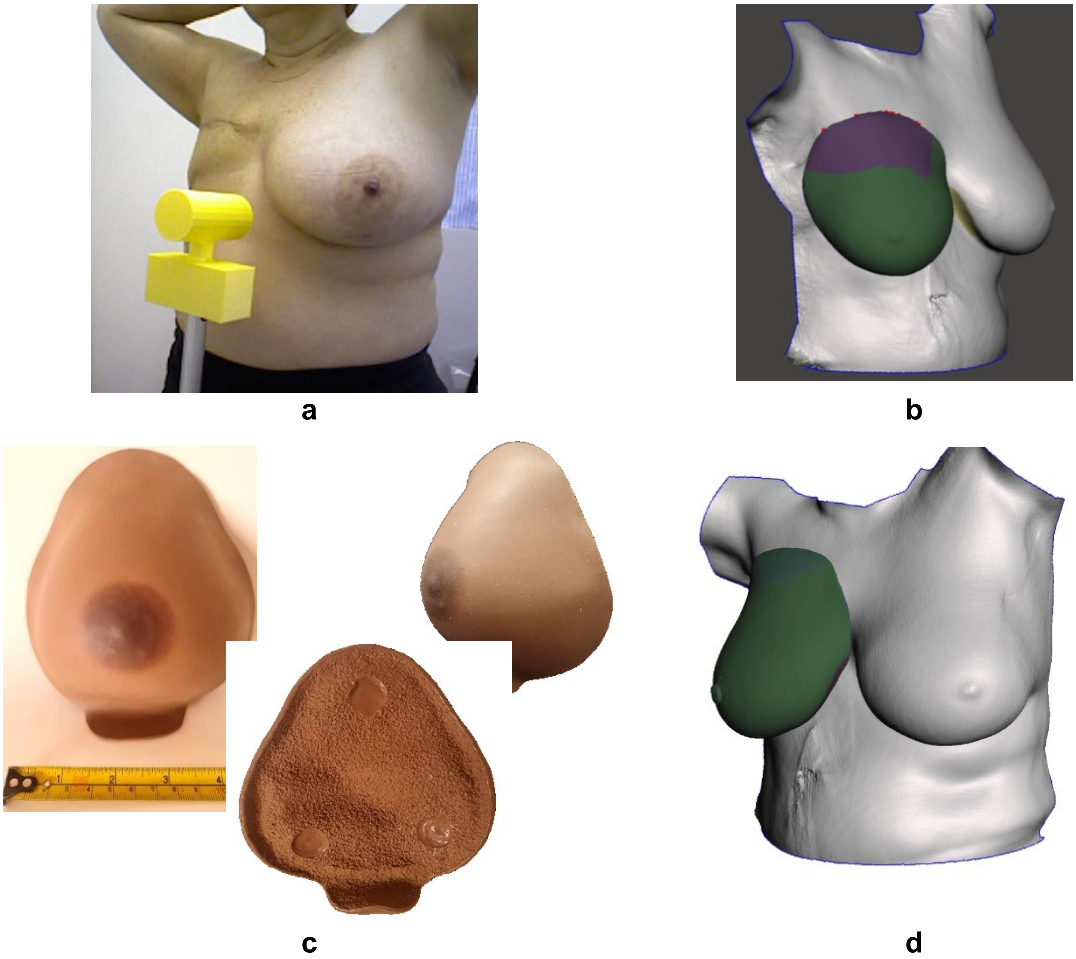


Source: The author (2019)

This is also one of the greatest differentials of bespoke prostheses. They are generated to accompany a new body contour, unique in each patient. The external breast prosthesis purchased in stores presupposes a standard breast, which by nature no longer exists, and is based on a "standard" chest wall and underarm, which also do not exist.

During the execution of the biomodel generation procedure, a fundamental analysis was verified with regard to the areola and nipple.

Figure 34 – Areola and nipple prominence



Caption: a. 3D mesh without the areola relief
b. frame of Structure™ 3D scanning
c. Contourmed™ personalized external breast prosthesis (golden standard, for this thesis)
d. 3D mesh with manipulation to obtain areola and nipple relief

Source: The author (2020)

No biomodel, originally, has an accurate definition of the areola region. This is because the mesh files that gave rise to them do not have that region delimited. The extreme region of the breast, called areola, does not present itself to the sensors as a different area, exactly because there is no new volume or any protrusion – that is what the sensor "reads" – but, in reality, there is a fundamental change, of coloration, as seen in Figure 34a.

Inside the areola there is another volume, larger, which corresponds to the nipple, which the sensor effectively captures, even if not with total precision. There are also Montgomery tubers, generally very small reliefs, and which were also not captured in the sensor images (Figure 34b).

It was possible to obtain with the three-dimensional images most of the shape of the breast and chest wall; however, in the smaller and more detailed region, corresponding to the areola and nipple, the resolution of the equipment does not perfectly meet all the requirements contained in the research criteria. The image generated is effective for identifying the positioning of the nipple, but it cannot show the volume and all the details of the protrusion that it normally has, and that – being different in each woman – provides a distinctive characteristic for the body, as shown in Figure 34a.

Not even the best solution presented in the literature, that used a commercial scanner and an SLA printer to generate the prosthesis injection cast, solved this issue (EGGBEER; EVANS, 2011). Probably because its project core was conceived as an artifact that only remains hidden, inside a bra, as they explain in their method. The intention of the method proposed in this thesis though, is that the user can look her prosthesis, from her perspective or in the mirror, and even without the bra, feel at ease with the prostheses, that has a more familiar image. Considering others regard, but also thyself.

There are also models of external prostheses marketed for two thousand dollars, which use this solution more direct (with discrete change of volume in the region of areola, Montgomery glands and nipple), as noted in the Figure 34c.

The gap, in the literature, of the technical solution for this issue, and the challenge of presenting a proposal of higher quality, led to the search for another alternative.

It was found in a procedure that is considered in the generation of the biomodel file, because it needs to be performed in the manipulation of the mesh, but before closing with it. Starting from the point marked as the protrusion of the nipple, the relief is increased, extruding geometric shapes or using software tools. For a first example, Meshmixer™ and Blender™ were tested. Although both satisfied as a result of mesh, the result obtained with the free Blender software had scaling problems and when printed resulted in a bigger physical model. The original file was the same and the distortion was not caused by the parameters of the printer.

The adoption of these processes together causes the external prosthesis to end up having an additional relief, which does not exist in the natural breast. It is, however, a solution that is closer to the desired customization and symmetry result, with less interference in the final cost of the product. It maintains the replicability of the manufacturing process designed with computational aid, preserving the added artistic.

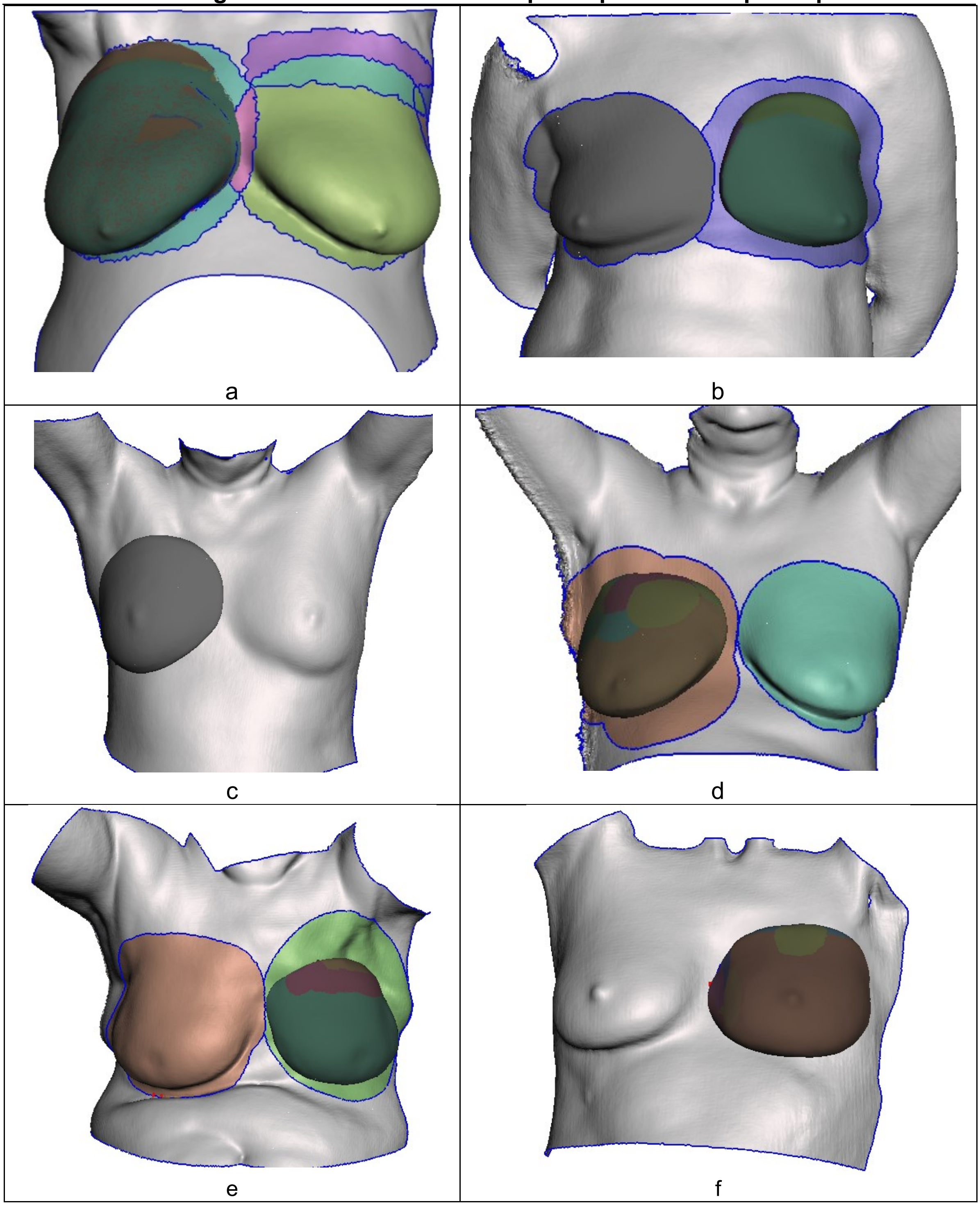
The issue of areola relief also ends up being faced by women who undergo the reconstruction procedure, because it mostly does not include the reconstruction of areola and nipple. Many of the patients later seek a handmade procedure, made by an anaplastologist, which includes marking the region with paint, manual modeling of the areola region with alginate, transformation of this cast into a wax model (which requires some additional work of sculpture), generation of a plaster cast and, later, the generation of the final piece, together with its painting. This piece, then, needs to be glued to the reconstructed breast. The used glue retains it for some time, but not permanently.

The importance of the hospital service that provide those areolas, and also the remarkable area developed in simpler products (KNITTED KNOCKERS HOME | BARBARA DEMOREST, [s.d.]) guided the decision of this research to improve the areola and nipple area.

The fact that the result of the craftsmanship combined with the manufacture via CAD results in a better alternative does not mean that the CAD model cannot be used solely. The biomodels resulting from each of the twenty patients were completed without this manual process. Without loss of the biomodel, the rework that included a level difference of 0.2 mm between the areola, and the rest of the breast was done later. Not doing such a rework would be a plausible solution, but it implies greater attention when laying down the rubber in the areola area, of color usually distinct from the rest of the breast.

Figure 34d, purposely placed in profile, presents the solution generated by this research, done manually in the software, which was to create a relief (non-existent in real life), of 0.2 mm, so that the areola could be filled and highlighted during the process of generating the prosthesis.

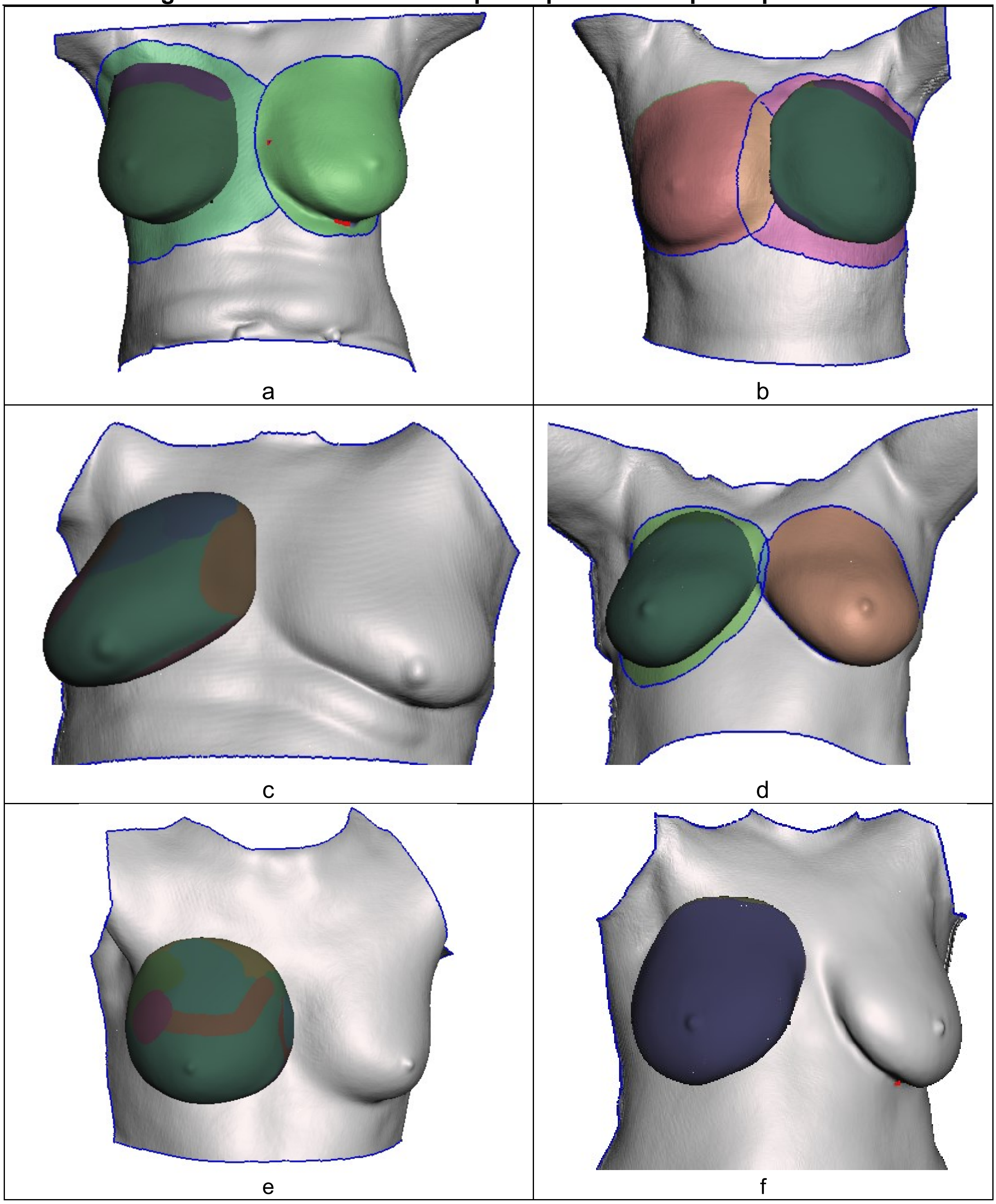
Figure 35 – Biomodels from “participant 01” to “participant 06”



Caption: a. “participant 01”
b. “participant 02”
c. “participant 03”
d. “participant 04”
e. “participant 05”
f. “participant 06”

Source: The author (2020)

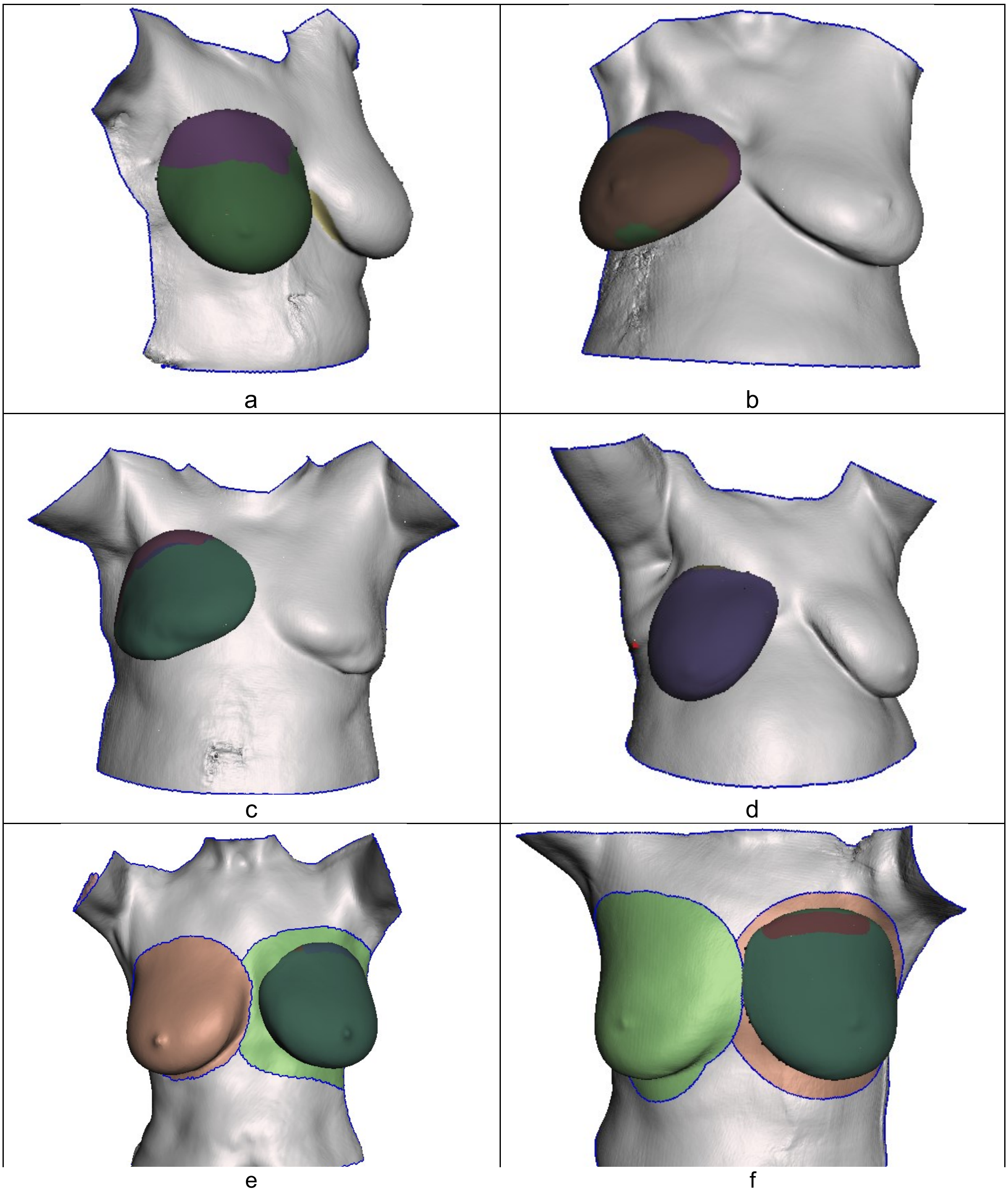
Figure 36 – Biomodels from “participant 07” to “participant 12”



Caption: a. “participant 07”
b. “participant 08”
c. “participant 09”
d. “participant 10”
e. “participant 11”
f. “participant 12”

Source: The author (2020)

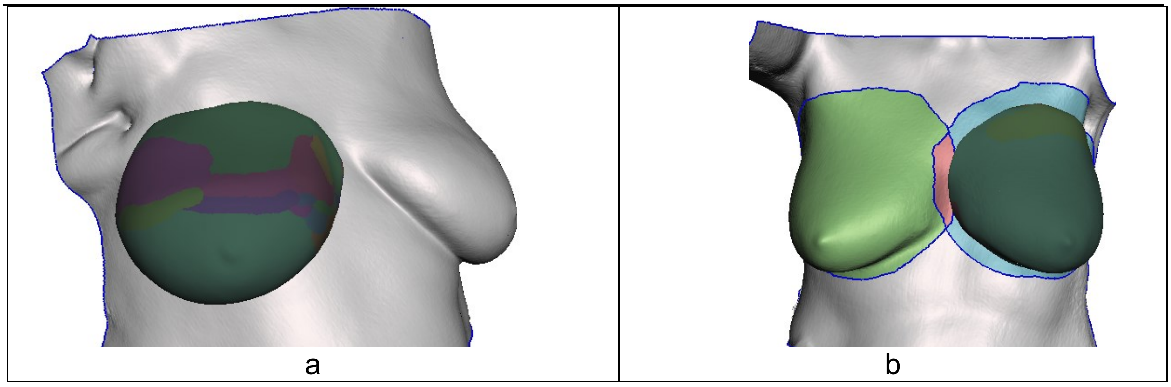
Figure 37 – Biomodels from “participant 13” to “participant 18”



Caption: a. “participant 13”
b. “participant 14”
c. “participant 15”
d. “participant 16”
e. “participant 17”
f. “participant 18”

Source: The author (2020)

Figure 38 – Biomodels of “participant 19” and “participant 20”



Caption: a. “participant 19”
b. “participant 20”

Source: The author (2020)

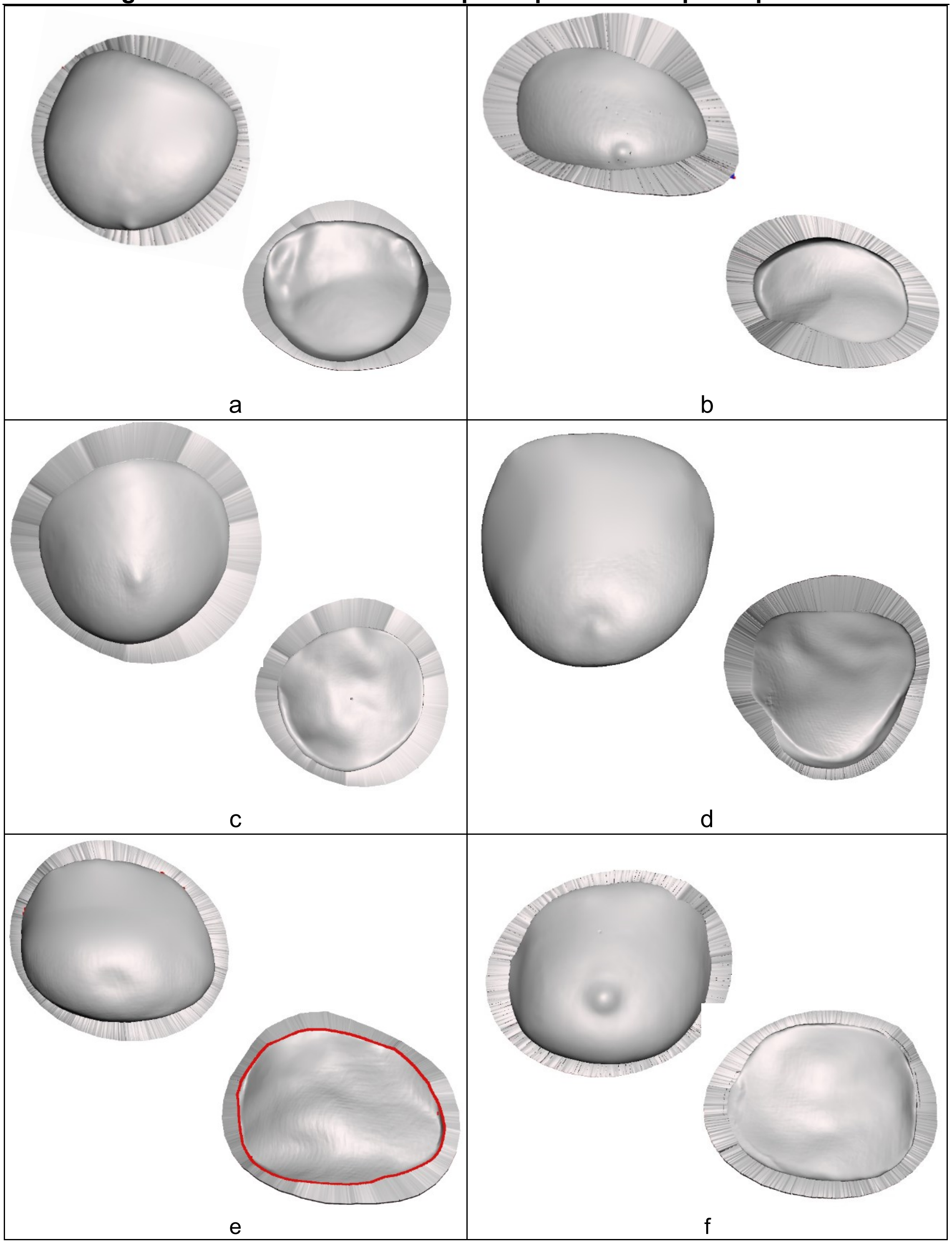
The meshes corrected in this study, therefore, originally have a slight prominence in the nipple area, but not in the areola area, as can be seen in the twenty biomodels generated, which are shown in Figure 35 to Figure 38. For the sake of economy and practicality, no changes were made in those regions, but directly in the cast files. The instruction of the manual resulting from the model conceived in this thesis, however, contemplates the generation of nipple and areola relief already in the stage of mesh manipulation.

Although separated from the mesh correction procedure, the stage of joining the chest wall region occurs immediately in sequence, for operational practicality. Usually after joining the surfaces, it is necessary to insert a thickness in such a way that the solid model is obtained.

The stages of the operational mode are explained in a manual specifically generated to be distributed among non-profit associations, and is included in the thesis as the APPENDIX E. The results of that process of joining are shown in the Figure 39 through Figure 42. They contain images of the templates' virtual files, and are exposed in peers. They correspond, therefore, to one part for the breast (left, top) and another, for the chest wall (right, bottom), which fit perfectly.

For visualization purposes, however, the images were better positioned in order to emphasize an area of greater stress or relief, in order to show their usability, comparing with the images that this study brings.

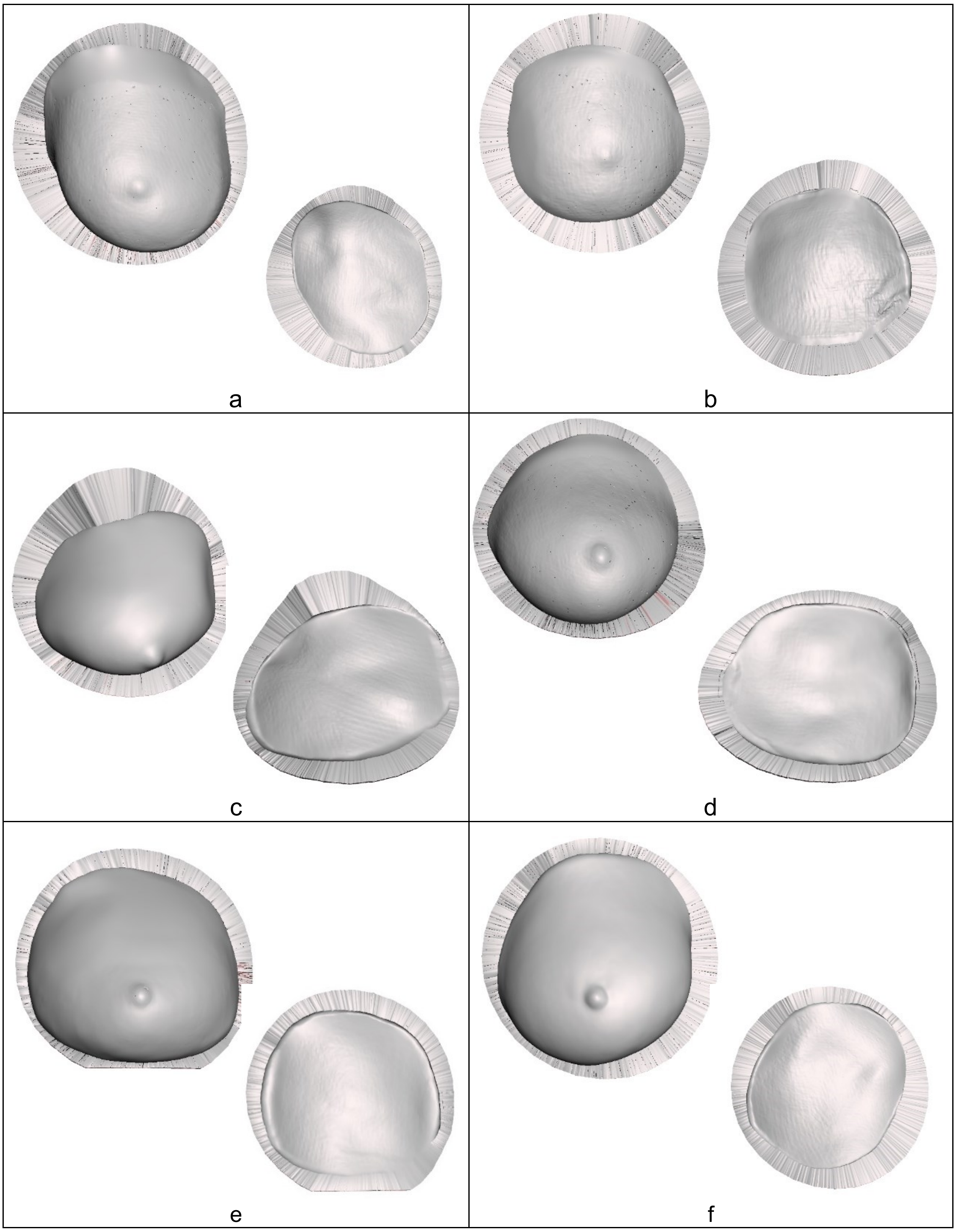
Figure 39 – Virtual casts from “participant 01” to “participant 06”



Caption: a. “participant 01”
b. “participant 02”
c. “participant 03”
d. “participant 04”
e. “participant 05”
f. “participant 06”

Source: The author (2020)

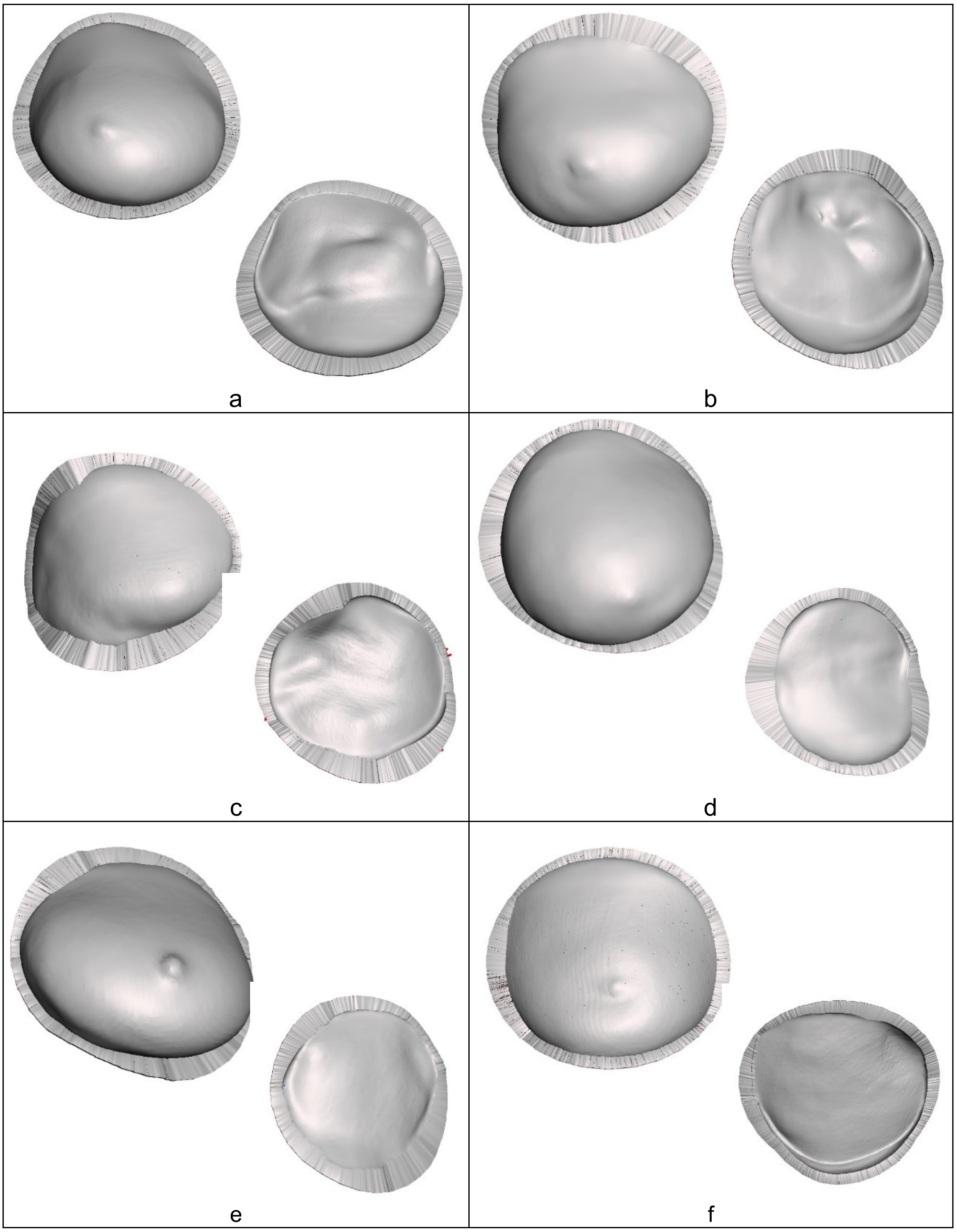
Figure 40 – Virtual casts from “participant 07” to “participant 12”



Caption: a. “participant 07”
b. “participant 08”
c. “particpant 09”
d. “participant 10”
e. “participant 11”
f. “participant 12”

Source: The author (2020)

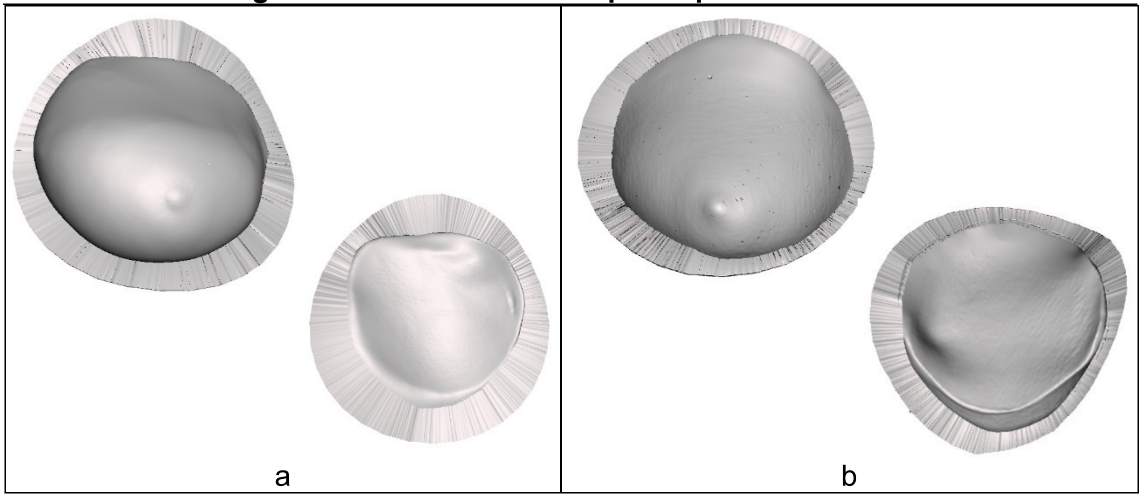
Figure 41 – Virtual casts from “participant 13” to “participant 18”



Caption: a. “participant 13”
b. “participant 14”
c. “participant 15”
d. “participant 16”
e. “participant 17”
f. “participant 18”

Source: The author (2020)

Figure 42 – Virtual casts of participants 19 and 20



Caption: a. “participant 19”
b. “participant 20”

Source: The author (2020)

3.5 Detailed project

Corresponding to the step of Detailed project, inside the Development part of the methodology, at this stage of the project will be presented the choices of materials and methods necessary for the prototyping of the prostheses originated from the method designed. The budget for replicating the method will also compose this phase, together with a flow-chart that resumes the step-by-step of this proposed method.

Ending the Detailed project, the manufacture of the prostheses will be explained in-depth, together with the delivery of such prostheses.

From this point, it was chosen to present the work on five cases, considering that they would be more than enough to prove the concept. Besides, the SARS-CoV-2 (COVID-19) pandemic had just began and it was known that the access to the participants should be avoided. Thus, four breasts with the highest volume were chosen, all with ptosis, and the one with the lowest volume, without ptosis. Conditions as easier access to the participant and ethics parameters were also took into account, to choose which ones would be made.

3.5.1 3D Printers

The choice of printers by the authors cited in the literature review fell on commercial models, which costs exceed ten thousand dollars (CRUZ *et al.*, 2018; EGGBEER; EVANS, 2011; MONTEJO MAILLO *et al.*, 2020), or on models not yet marketed (YIRMIBESOGLU *et al.*, 2018). The option of those authors was not made in the same social and economic reality contemplated in this project. To design a method that aims to be replicated in the whole Brazil, at low-cost resources, it was necessary to resort to machines that operate extruding filament, of open-source technology, because they are the cheapest resource and the most easily found, to date.

The printers used in this work were: 3D Cloner™ DH+, Ender 3 Pro and Ender 5 Pro, property of Additive Manufacturing and Tooling Group (NUFER), e a Makergear™ M2, property of the researcher, all open source. All of them operate by extrusion of material in the form of filament of diameter 1.75 mm, from any manufacturer.

All of them can use both PLA filament and TPU filament for part and support. In the case of TPU, there is a need for platform heating.

Build platform is an item which measurement is crucial. Because the cheapest printers may not be able to contain the cast of a breast prosthesis, which often has dimensions bigger than 150.0 mm. The 3D Cloner™ is a 3D printer that has a tray measuring 210 X 320 mm and was used in tests with PLA, operated with its own software, which accompanies the machine. The Makergear™ M2, is an equipment which tray has 200 mm x 250 mm and was used to print the parts of the "rotomolding" machine (APPENDIX F) and the parts in TPU, operated with the Repetier process planning software. The two Ender machines used Ultimaker Cura™ software, licensed for NUFER.

This is, therefore, a choice made taking into account the low initial cost of the final product, as well as the ease of purchasing inputs for its operation or production.

Materials such as adhesive tape or hair-fixing spray were necessary to assist in fixing the prints in the equipment tray. Spatulas for removal of printed parts make up the list of basic inputs.

3.5.2 3D direct printing of prostheses

It was investigated the possibility of printing directly, on a material suitable to generate a breast prosthesis, from the biomodel file. This was already an idea addressed at a time when Additive Manufacturing was better known as Rapid Prototyping (CHUA; LEONG; LIM, 2010), as described by the authors, when addressing the use of the technique for printing prostheses and implants.

Part of the researchers investigating the design of prostheses mentions the use of printing by extrusion of material, to produce a cast to generate a prosthesis (FANTINI; DE CRESCENZIO; CIOCCA, 2013), while others go from three-dimensional modeling to direct printing (ROCHLITZ; PAMMER; KISS, 2018; TELFER *et al.*, 2012; ZUNIGA, 2018). It is known that the cost of the direct printing process would be the lowest among the alternatives, because it avoids the time and also the costs of printing casts, besides post-processing them. The possible failure in printing and also the step-by-step to generate a cast could also be avoided, if it was possible to print straightforward from the 3D captured file (or still with some manipulation to have a closed and repaired mesh). Thus, verifying whether it was possible to print from the biomodel and directly generate the customized external breast prosthesis was one of the alternatives experienced.

With the stl file of the breast of participant 03, the Repetier software was used as an interface to send the model to the 3D printer Makergear™ model. The printer's build platform was set in 65^0 C. It was necessary to insert the support in the regions of the part with an angle less than 45 degrees, considering that it was a piece of more than 200.0 mm in height.

The first of the tested material options was the TPU (thermoplastic polyurethane), with hardness of 65-70 shore A, Gravaplast brand, to ascertain whether it would generate a suitable part for the application of the project. It is a flexible material, currently marketed in different shore A Hardness.

TPU – thermoplastic polyurethane – is a flexible filament, with a sales cost around 20% higher than PLA. The best characteristic of thermoplastic polymer is its elasticity and the worst – for the application considered – is its results considering stair-step effect.

The TPU was used in three trials, with three different infills. The print parameters allowed the choice of the amount and type of filling and, therefore, the resilience obtained (with the intention of simulating the density of the natural breast).

These tests were performed to verify whether the prosthesis could be printed directly and have enough softness to be used by the participants. The projected result had the characteristics provided by the elasticity of the TPU, added to printing parameters that gave space between the internal filling structures, as if the biomodel was a small air mattress. Table 8 presents the main printing parameters used in the first test:

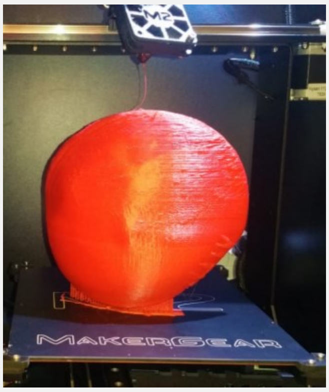
Table 8 – Parameters adopted for direct printing TPU 65-70 shore A

PARAMETER	VALUE	RESULT
Extrusion temperature (ºC)	225	TPU 65-70 GRAVAPLAST
Platform or bed temperature (ºC)	65	
Flow rate/Pulse Width Modulation (%)	100	
Wall thickness (mm)	0.4	
Layer Thickness or Height (mm)	0.2	
Top Solid Layers	4	
Bottom Solid Layers	4	
Outline/Perimeter Shells	5	
Infill (%)	30	
Infill kind	concentric	
Support	base	
Printing Speed (mm/s)	40	

Source: The author (2020)

The printing consumed 142.0 g of filament and took 8 hours in duration. It resulted in a model which external aspect presented evidence of the stair-step effect (characteristic of additive manufacturing) and which resilience was not able to simulate a natural breast, because it was very dense. Therefore, the tests were important to verify the issue of diversified fillers and their impacts on the softness of the prosthesis, if direct printing was the chosen process. Although this is not the chosen option, it was important to know, in practice, the result of the different fillings offered by the various process planning programs, how much can be expected of 3D printing technology operating with TPU. Mimic these results with other materials (vegetable bushing or foam, for example) has become a new challenge.

Table 9 – Parameters adopted for direct printing TPU 65-70 shore A

PARAMETER	VALUE	RESULT
Extrusion temperature (ºC)	225	TPU 65-70 GRAVAPLAST 
Platform or bed temperature (ºC)	65	
Flow rate/Pulse Width Modulation (%)	100	
Wall thickness (mm)	0.4	
Layer Thickness or Height (mm)	0.2	
Top Solid Layers	4	
Bottom Solid Layers	4	
Outline/Perimeter Shells	5	
Infill (%)	20	
Infill kind	linear	
Support	base	
Printing Speed (mm/s)	40	

Source: The author (2020)

As the final result was still that of a very rigid prosthesis, the amount and also the type of filling were changed to verify its influence on what the breast prosthesis density would be. This time, the filling was concentric, and the main parameters used in printing are included in the Table 9. It consumed 149.0 g of filament and took 8 hours.

Table 10 – Parameters adopted for direct printing in TPU, "*fluffy*"

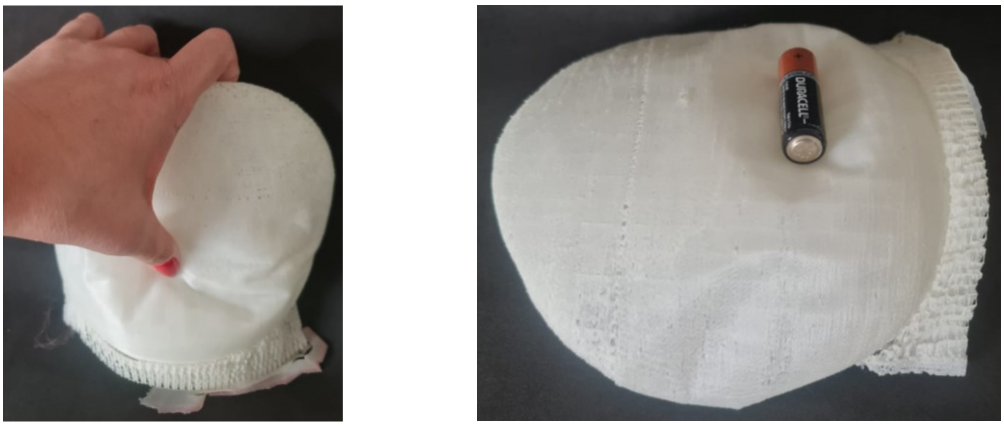
PARAMETER	VALUE	RESULT
Extrusion temperature (ºC)	225	TPU GRAVAPLAST/NINJAFLEX 
Platform or bed temperature (ºC)	65	
Flow rate/Pulse Width Modulation (%)	110	
Wall thickness (mm)	0.4	
Layer Thickness or Height (mm)	0.2	
Top Solid Layers	4	
Bottom Solid Layers	4	
Outline/Perimeter Shells	5	
Infill (%)	20	
Infill kind	linear	
Support	base	
Printing Speed (mm/s)	40	

Source: The author (2020)

The prosthesis of the second trial had a density closer to a real breast. The texture of these two previous results, however, does not resemble the texture of the human skin. And still, because TPU allows the water to enter the prosthesis, it would not be suitable to be better than the prosthesis with seeds, in this aspect. The interest in this analysis became more evident when the flow rate was changed in the print parameters, as illustrated by the Table 10:

At this point it was saw a real possibility of applying direct printing, with a model that could be presented to the user, as a soft alternative (Figure 43a). Probably not as the definitive prosthesis, but as a resource to be used right after the mastectomy surgery, or in the immediate postoperative period, in which the patient still has many restrictions, especially in relation to the need for the healing skin not to be muffled. The direct printed external prosthesis would be a more immediate alternative – partially customized – to existing foam models in Europe. Very smooth and resilient, its response to the weight of an AA battery can be seen in Figure 43b. Still hard to sanitize, though.

Figure 43 – "fluffy" TPU prosthesis, for temporary use



a b

Source: The author (2019)

3.5.3 Casts printing

One of the main reasons for conceiving a three-dimensional model is the perspective of printing it. In the case of this research, unpublished images obtained from mastectomized women were used, and after mesh corrections biomodels were generated. From there, tests were performed in order to verify the possibility of generating personalized external breast prostheses with those files.

Prototyping allowed to verify that breast biomodels or casts of external breast prostheses have volumes that three-dimensional printing takes more than twenty hours, considering the printers that work with extrusion of material used for this thesis.

The variation of time depends, first, on the speed of the equipment printing, the volume of each woman's breast (biomodel's size), and in sequence, the various printing parameters chosen.

It must be kept in mind that the printers operating with filament involved in this study work slowly, and eventually have flaws that can lead to loss of printing. It is also important to remark that there is an initial cost, represented by the manufacture of a cast (detailed in APPENDIX E), and the process considers that this cost is spread out as more units are produced from the same cast.

The same patient should have her external prosthesis replaced in a given time interval. This justifies, therefore, the option for the use of casts: the new unit could then have its manufacture originated from an existing cast, which had been used previously. Generated from the same biomodel of the patient breast, it spreads out the costs – the operational capture and manipulation of the three-dimensional images, and that of the materials used in printing – over the times such cast of the same patient is reused. A discussion about how to keep the parts will be made later in this work.

The printing of the first cast testing was made in a 3D Cloner™ machine, owned by NUFER, took 13 hours and had consumption of 190.0g of material, in the chest wall part, and 175.0 g of material, in the breast part, that took 12 hours and 10 minutes. The parameters of this print are set out in the Table 11 :

Table 11 – Parameters adopted for the printing of the cast in PLA

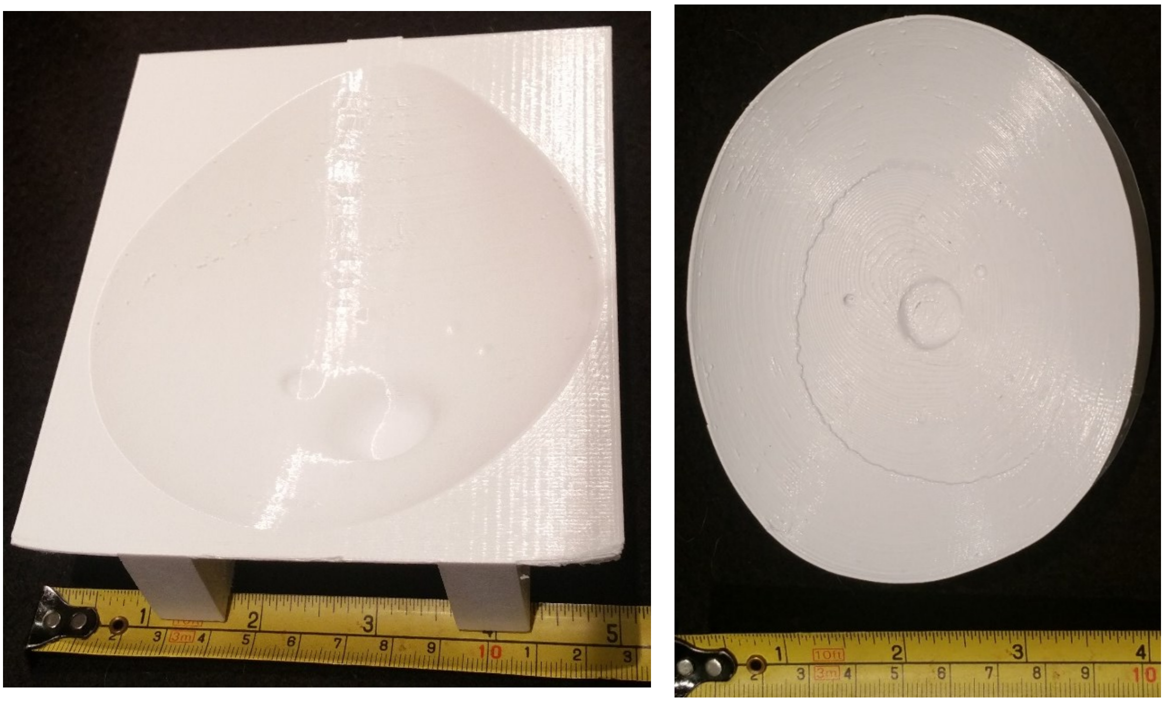
PARAMETER	VALUE	RESULT
Extrusion temperature (ºC)	225	PLA GRAVAPLAST 
Flow rate/Pulse Width Modulation (%)	100	
Wall thickness (mm)	0.4	
Layer Thickness or Height (mm)	0.2	
Top Solid Layers	4	
Bottom Solid Layers	4	
Outline/Perimeter Shells	4	
Infill (%)	15	
Infill kind	linear	
Support	base	
Printing Speed (mm/s)	50	

Source: The author (2020)

Process planning of the file sent for cast printing was done using the free Repetier software and the printer desk was not heated. It was important to add support at angles less than or equal to 45 degrees, considering that it was a piece more than 200.0 mm high. Also, with regard to size, it is noteworthy that biomodel files, in view of the necessary meaning of printing, can exceed the tray size of many printers. Although there is the possibility of rotating the part during process planning, it is an important criterion in choosing a printer.

The orientation of the printing is essential to minimize the stair-step effect – characteristic of 3D printing – in the sense that it would be more evident. This attention was needed because the material inserted in the cast would copy any relief. This effect is all the greater depending on the orientation in which the part is built, as can be seen in the Figure 44, which shows printings of a small area close to the areola. In Figure 44a, the build orientation was made as if the chest was perpendicular to the printing tray, and on the Figure 44b, as if the chest was parallel to the print tray.

Figure 44 – The importance of correct positioning for printing



a b

Caption: a. printing as if the chest was perpendicular to the print tray
b. printing as if the chest was parallel to the print tray

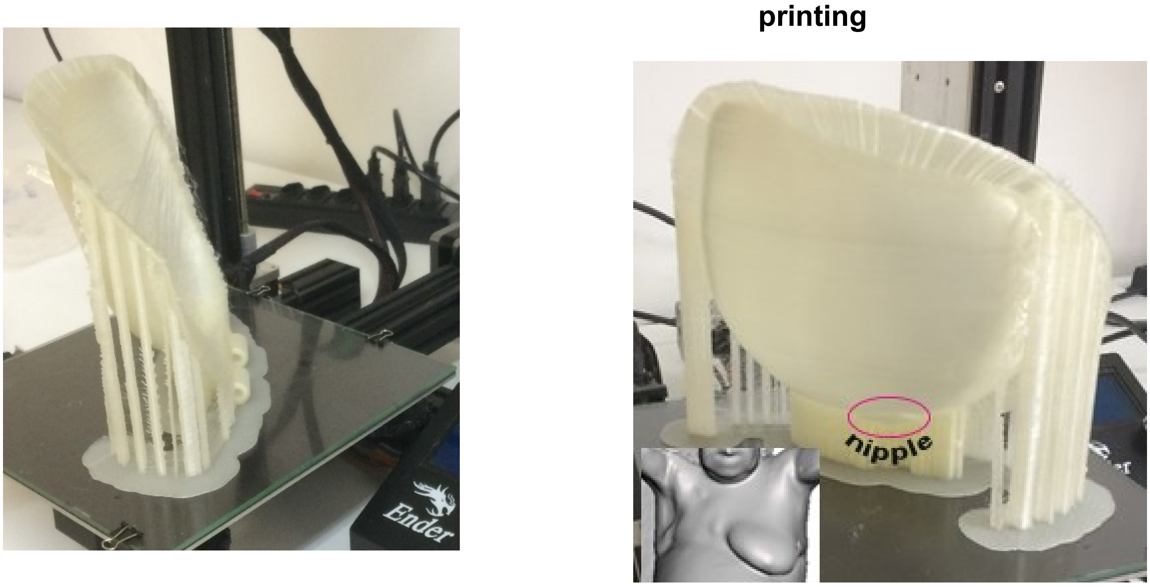
Source: The author (2019)

Although it is known that the reduction of the steps in the printing can be done by abrasion, the more sandpaper is applied, the more it is lost from the original relief and the more time is spent in the post-processing (and in the manufacturing process, therefore). Thus, the attention given to the orientation when printing a cast, is a compromise solution.

Still about the process planning of the printing, a parameter called retraction was checked, because the default generated several thin extruded filaments around the cast, as if the printing was “hairy”. This happened due to the path that printer head is obliged to make when it performs the curves of such a concave shape; then, 6.5mm of retraction must be used (Figure 45a).

There is also a subtlety to be observed in each of the models, considering that some breasts, because of their accentuated degree of ptosis, can end up with the nipple so inclined (Figure 45b), that may imply revising the orientation of the printing.

Figure 45 – Part of the cast correspondent to the breast: ptosis and “hairy” printing



a b

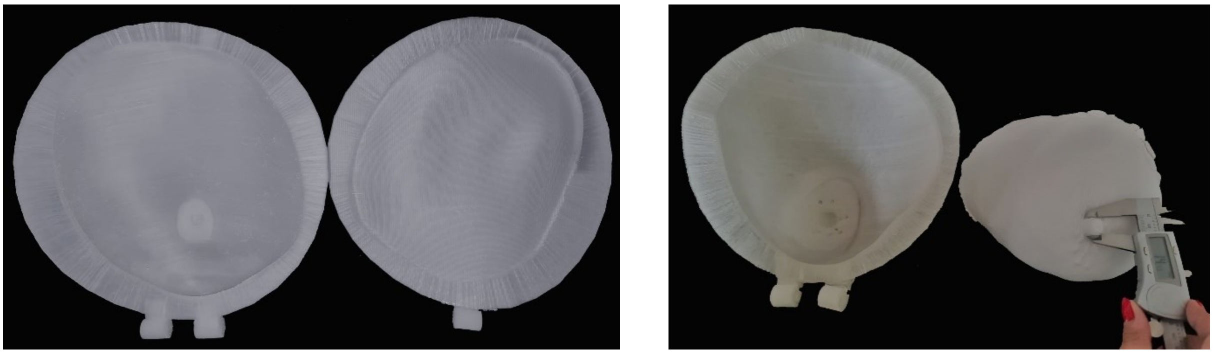
Caption: a. the inclination to minimize time and supports
b. position of the nipple (participant 01)

Source: NUFER (2021)

Obtained by 3D printing as a tool for the manual conception of prostheses, the casts were the most viable alternative found for the application of the method described in this thesis.

The design of the cast predicted a part for the breast region (Figure 46a), and another one to the chest wall area (Figure 46b), that fit and are firmed against each other by screws embedded in passing holes.

Figure 46 – Both parts of the printed cast



a b

Caption: a. printed cast (breast and chest wall)
b. measurement check with the plaster model

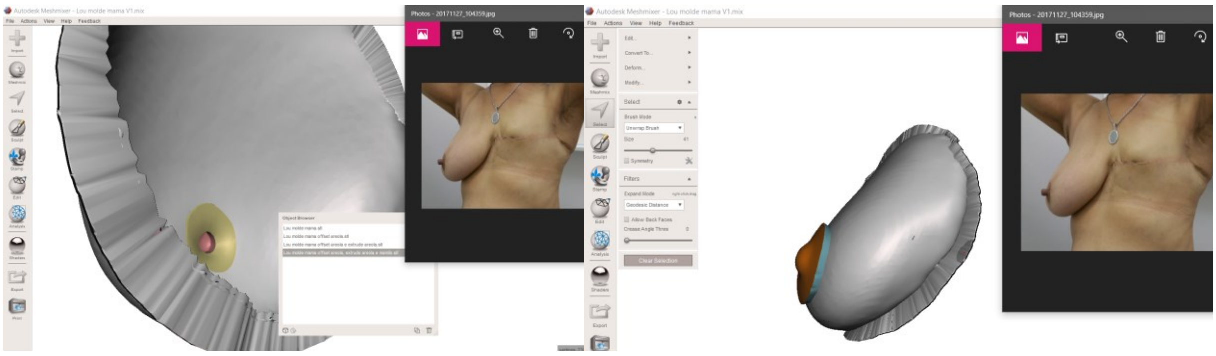
Source: The author (2021)

Alternatively, a system to facilitate the faster coupling of the two parts of the cast has been added to some of the casts, to contribute to accelerate the start of the manufacturing process. It was concluded that it is expendable, as it increases design, printing and cleaning time, if the filling overflows and enters the hinge. Besides, it tends to be more fragile; it broke and had to be repaired, in some models.

The worry about time came also from a trial made with the process of rotomolding. The casts were prepared for the use in that technology, and they were tested in the machine built at NUFER for this use. Although the results obtained with the technic were not satisfying, the tests were documented and all the results related to that technic are in the APPENDIX F.

Considering that the rework already mentioned, in the region of the areolas, had to be done only in one of the parts of the cast (that of the breast), only the files corresponding to those casts undergone modifications. It is evident that the relief of the nipple would exceed the limit first assigned to the thickness of the cast, which is why only that region was thickened in the outside. The result, in virtual modeling, can be verified in the Figure 47.

Figure 47 – Virtual modeling visualization of the areola and nipple



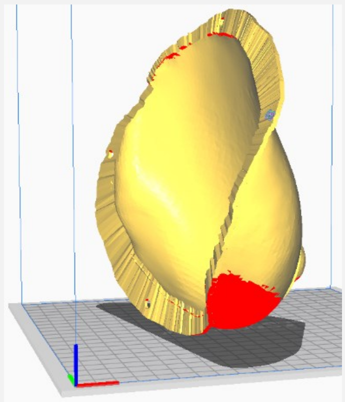
a b

Caption: a. inner part of the cast, corresponding to the breast
b. outside of the cast, with protrusion only in the area of the areola and nipple

Source: The author (2021)

The final definition of parameters for printing all the five casts is presented in Table 12:

Table 12 – Parameters defined in the method, for the 3D printing of the casts

PARAMETER	VALUE	RESULT
Extrusion temperature(ºC)	185	PLA GRAVAPLAST 
Platform or bed temperature (ºC)	60	
Flow rate/Pulse Width Modulation (%)	100	
Wall thickness (mm)	0.8	
Layer Thickness or Height (mm)	0.2	
Top Solid Layers	4	
Bottom Solid Layers	4	
Outline/Perimeter Shells	5	
Infill (%)	50	
Infill kind	grid	
Support	raft	
Printing Speed (mm/s)	45	

Source: The author (2021)

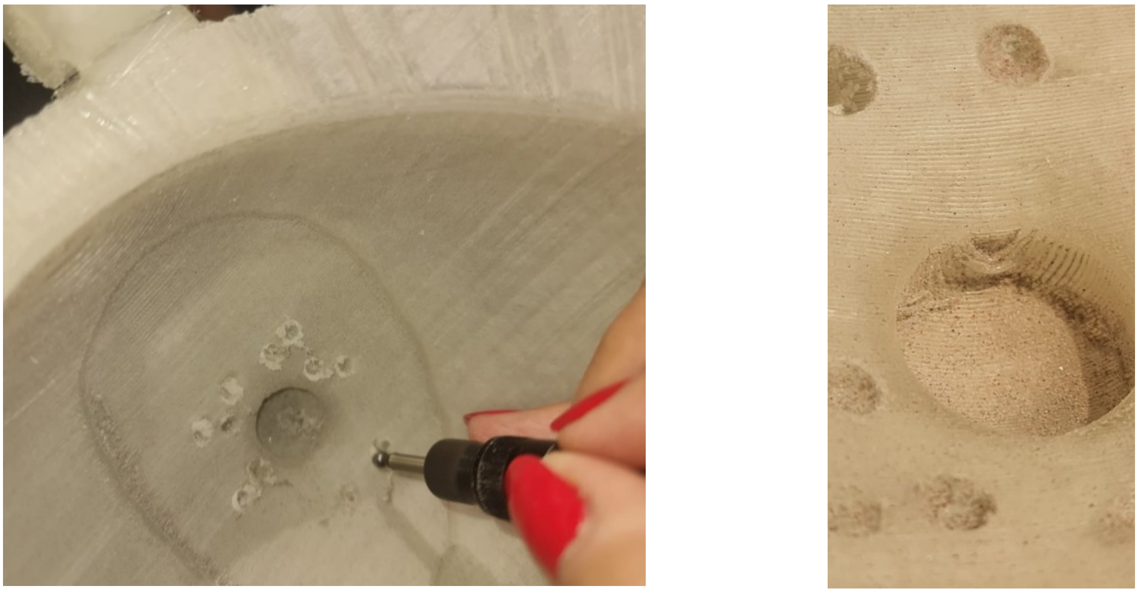
Ultimaker Cura™, the process planning software used for the printings, exhibits the inclination of the part, and the regions where supports will be needed (in red), always respecting the less amount possible of supports inside the cast. The printings were made in Ender 5 Pro and Ender 3 Pro, both properties of NUFER.

3.5.4 3D Printing post-processing

Despite the care taken with the positioning, the inclination still generated supports, required to assure the printing would be successfully braced whenever the inclination of the part had an angle equal or higher than 45 (in relation to the build platform). Removing them was the first step of post-processing.

Although evidencing the negative relief of the nipple and the areola region, the printed cast did not have the Montgomery glands, which often characterize human breasts. It has been tested to do them in the print, but this generates support to be removed from a tiny area, later. Thus, it was decided to make them after the cast was removed from the build platform, using drill ball tip, as illustrated in the Figure 48a.

Figure 48 – Creating the negative relief of Montgomery glands



a b

Caption: a. Montgomery glands handmade design
b. zoom over the irregularities to be sanded

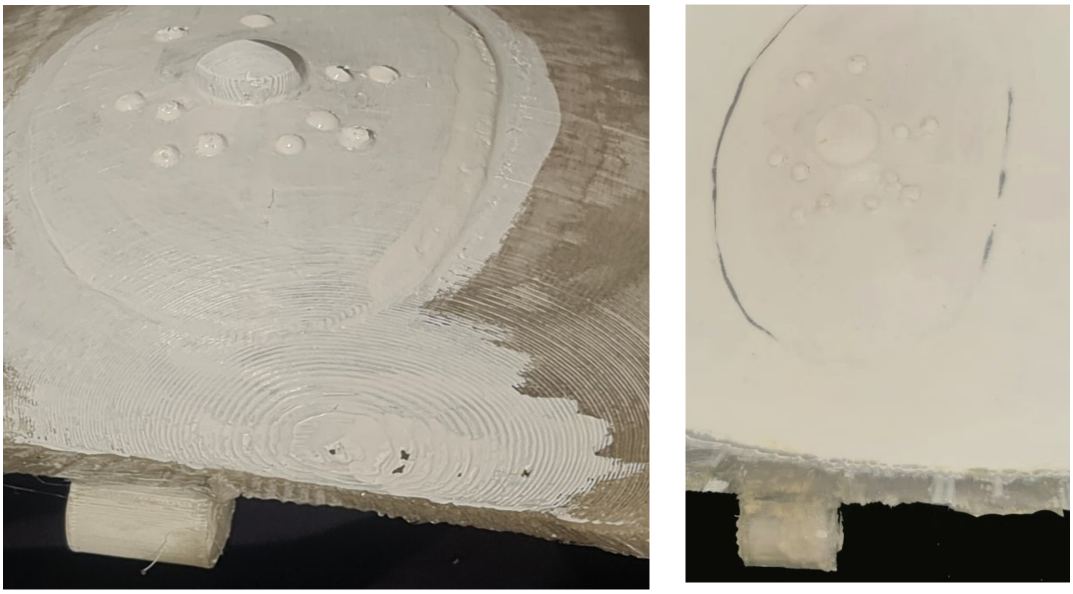
Source: The author (2021)

The inside of the cast, including the nipple region (Figure 48b), required some sanding, with water sandpaper grain 150. The outside and the borders were left as they came out, except the holes of the hinges, which needed to have their support removed with a soldering iron.

It was experienced liquid chloroform, applied with a brush, as some literature (VALERGA *et al.*, 2019) suggested it could reduce the physical aspect of the stair-stepping effect. The results were still far from acceptable, and it required special authorization of Federal Police Department for buying, what makes more difficult to replicate.

After the definition of the relief of the areola and sandcasting, it was applied sealant for plastic 81 Lazzuril™ and primer HS 2K Spectra Lazzuril™. The sealant ensures that the primer adheres to the printing without posterior peeling. Around 20.0 ml of sealant and 20.0 ml of primer were enough for both parts of each cast.

Figure 49 – Post-processing of casts



a b

Caption: **a. the area of the cast where the step effect is more evident (first lay of primer, in process)**
b. same cast, after primer

Source: The author (2021)

The sealant dries in less than two minutes and can be applied with brush. After this time, the primer started to be applied, with roller or with brush (Figure 49a). It needs to be diluted with thinner, and the less thick, the more layers are needed to cover the unevenness. Catalyst can be added, in the mixture, for faster drying. After each layer, the cast was put to dry at least for an hour, and then verified to check if the stair-step effect has disappeared from the surface, that must have become the most regular as possible, similar to what can be seen in the Figure 49b.

Finally, a new abrasion was made, with water sandpaper grain 320.

When the sanding work finished, the cast was cleaned with cloth moistened with water. Once dried, it was ready to give rise to the prosthesis.

The post-processing described here is a step that enables the use of any open printer: even older printers, with worse printing quality, can be used in the application of the method, and although the printed cast might have steeper print steps, the application of the primer is able to give rise to a prosthesis without irregularities, as it is desired.

Although 3 hours may be enough to make the full post-processing, it can be done in less time, according to the practice, and it can also take more time, depending on perfectionism.

3.5.5 Budget

Table 13 – Cost budget of personalized external breast prostheses printing

3D PRINTING COSTS							
participant	PLA breast		PLA chest wall		PLA total (g)	machine hours	cost (US$)
	g	h	g	h			
3	0	34:37:00	0	35:50:00	319,4	70:27:00	6,39
10	0	53:56:00	0	78:32:00	452,2	132:28:00	9,04
13	0	52:14:00	0	39:48:00	279,2	92:02:00	5,58
14	0	30:38:00	0	54:20:00	306,3	84:58:00	6,13
17	0	46:22:00	0	43:30:00	336,9	89:52:00	6,74

Source: The author (2022)

As bespoke products are normally more expensive than off-the-shelf, Rozenfeld et al. (2006) developed their Methodology considering that a budget must be presented to the customer, before the manufacture of the product. Although the product of this thesis is not the prosthesis itself, but the method proposed to its manufacture, the structure will remain respecting the guidelines and sequence proposed in their work.

So, the method proposed in this thesis will include, in this topic, all the budgets for the manufacture of prostheses, for anyone that wish to replicate it.The methodology chosen to estimate costs includes a calculation for each of the prototypes chosen in the sample, and considers the ideal printing scenario, without errors or losses.

It is known that whenever the prototype corresponds to larger breasts, more filament will be demanded. A chest wall cast that has more relief consumes more filament than a plain one. Due to several differences among the casts, it is not possible to trace a proportion, though. The filaments were all bought from the manufacturer and the printing costs are presented in the Table 13.

Post-processing is fundamental for acquiring a regularity of the 3D printed surface. Besides manually made, the amount of each product applied may vary, depending, for instance, on how fast thinner evaporates in a given day. The same brush was used for all the casts and still remain good for more uses. So, in order to have a robust budget, it was decided to assume an average value. A medium based in the total order placed in a regular store, divided by an estimative of the number of units that could be made, using such amount. The total assigned is presented in the Table 14:

Table 14 – Cost budget of personalized external breast prostheses casts post-processing

POST-PROCESSING 3D PRINTING COSTS						
sealer	**primer**	**catalyst**	**thinner**	**brushes**	**sandpaper**	**cost (US$)**
15,87	12,764	6,44	8,33	4,55	11,56	1,49

Source: The author (2022)

The outer part of the prostheses had their outputs acquired in a regular store and also obey a proportion of higher volume of the biomodel, higher amount of silicone rubber. The catalyst used is sold together with the silicone rubber, as a kit. Release agent and pigments are used in a very reduced amount, and for this reason, a same amount was assigned for all the products manufactured. Pigment cost came from a value informed by the manufacturer; release agent, from the same store as silicone rubber. The costs of this step are in the Table 15.

Table 15 – Cost budget of personalized external breast prostheses outer

OUTER COSTS							
participant	breast size (ml)	silicone rubber breast (g)	silicone rubber areola (g)	silicone rubber total (g)	release agent (g)	pigment (g)	cost (US$)
3	484,65	110,0	6,0	116,0	0,05	0,04	2,02
10	950,97	220,0	7,0	227,0	0,05	0,04	3,91
13	1119,57	230,0	6,0	236,0	0,05	0,04	4,06
14	654,60	140,0	5,5	145,5	0,05	0,04	2,52
17	882,66	180,0	4,0	184,0	0,05	0,04	3,18

Source: The author (2022)

When filling is discussed, there is evidence of higher amount of the system polyol + isocyanate needed, the bigger the volume of the biomodel of the breast is. This proportion can be observed in the Table 16. Some difference of temperature in the day of manufacture impact the exothermic reaction of the system. The costs were calculated based in the cost per kilogram, informed by the manufacturer.

Table 16 – Cost budget of personalized external breast prostheses filling

FILLING COSTS					
participant	breast size (mm^3)	poliol (g)	isocianate (g)	PU total	cost (US$)
3	484650	29,1	17,4	46,5	2,75
10	950970	57,1	34,2	91,3	5,39
13	1119570	67,2	40,3	107,5	6,34
14	654599	39,3	23,6	62,8	3,71
17	882661	53,0	24,0	77,0	4,54

Source: The author (2022)

The final calculation of the manufacture of prostheses generated by the method developed in this thesis includes the materials used in cast and support printing, sandpaper and other post-processing inputs, silicone rubber, pigment, release agent. It excludes project time costs, as well as part printing time, from equipment such as 3D printers and sensors. Inputs were all bought in Brazil, in local currency, and to make the conversion it was used the value of one dollar in January 2022, of R$ 5.50.

The estimated reference value per prosthesis varied from US$ 15.21 to US$ 21.97, as demonstrated by the Table 17.

Table 17 – Cost budget of personalized external breast prostheses (totals)

TOTAL COST (US$)						
participant	**printing**	**painting**	**outer**	**PU foam**	**washers**	**cost (US$)**
3	6,39	1,49	2,02	2,75	0,40	13,05
10	9,04	1,49	3,91	5,39	0,40	20,23
13	5,58	1,49	4,06	6,34	0,40	17,88
14	6,13	1,49	2,52	3,71	0,40	14,25
17	6,74	1,49	3,18	4,54	0,40	16,35

Source: The author (2022)

As it was stated along this study, one of the advantages of using 3D printing for external breast prostheses is having the possibility of replicate the product without its main costs, since 3D capture through painting. So, the proof that this hypothesis is true is shown in the Table 18. In this table is highlighted how much each part of the process contributed to the final cost (100%) of the external breast prostheses. Outlined in white letters, costs that would be excluded when the method is applied to obtain other units from the same cast.

Table 18 – Cost budget of personalized external breast prostheses (percentuals)

TOTAL COST (in percentuals)						
participant	**printing**	**painting**	**outer**	**PU foam**	**washers**	**final cost (%)**
3	48,98%	11,40%	15,51%	21,04%	3,07%	100,00%
10	44,71%	7,36%	19,33%	26,62%	1,98%	100,00%
13	31,23%	8,33%	22,73%	35,47%	2,24%	100,00%
14	42,99%	10,46%	17,72%	26,02%	2,81%	100,00%
17	41,22%	9,11%	19,45%	27,77%	2,45%	100,00%

Source: The author (2022)

According to the data, printing added to painting is the part of the process that corresponds to the major costs (between 39,57% and 60,38%, in this sample), aside one of the casts. And these are the fixed costs, that will not exist in a second unit from the same cast. Outer, PU foam and washers (that represent between 39,62% and 60,43 % of the final costs, in dollars, in this sample) would be the only costs when reusing each cast (technically, variable costs).

3.5.6 Logistics

Based on the idea that the fixed costs of a cast can be spread out, when more units are made from the same cast, a first concern is where to keep those casts, in order to make a future utilization possible. They could stay under the guard of the non-profit Associations, where women once searched for the prosthesis and where the process has its start, and it is possible to consider the hypothesis of allowing the patients to keep the casts.

Another concern around the reproducibility of the method is at which point it is, in fact, replicable, given the fact that it needs human resources able to manipulate meshes, and also to operate and eventually repair 3D printers. It is needed to say that close to the hospitals where there are cancer centers, there is a possibility of existence of colleges, and then, students that can handle such tasks.

What sounds more interesting, though, is a solution similar to the strategy adopted by TOM Project (TOM, [*s. d.*]), where community of students are called to help. Since 2022 Brazilian Universities have to propose Extension activities for all the students. Working in 3D meshes, CAM and casts making, could certainly make them learn about the method and to practice the technology that they are taught.

3.6 Produced prostheses

As mentioned before, it was defined that to prove the feasibility of the method developed it was not needed to make as many practical applications as there were participants. This decision was also guided by the fact that 3D printings take a long time and they would be made inside the University, with the equipment kept working during the night, because of the risk of fire. It is a condition, though, specially faced in the University, and with a printer that cannot be stopped and begin again in the next day, at the same point, which is already a feature that new printers have overcame. And still in the parameters of quality in printing that were stated in the beginning.

Then it was stated that it would be enough to attend the extreme conditions found among the participants, during the research: breast with ptosis, users of heavy off-the-shelf prostheses (that possibly could be made lighter with the proposed method), and respect to a challenging (in terms of relief) chest wall shape. Participant 14, for instance, met those conditions and would be enough.

However, as that was a group in cancer remission and the prototyping part of the prostheses was made in the midst of a pandemic, five of the twenty models were selected to have the method applied, in order to contemplate the highest variance found in the research group. The pursuit of similarity, concerning diversified shapes and colors, was a basic premise, in any case.

3.6.1 Outer Material

Silicone rubber was the material chosen to make up the outside of the prosthesis, that would be in contact with the user. It is a material that copies any shape from the cast. That is why the post-processing must be well performed in the printed surface, otherwise the stair-step effect of 3D printing would be also copied.

Although silicone rubber is known by its feature of self-releasing, industrial Vaseline™ was applied to both parts of the cast, with special attention to the nipple and Montgomery glands area, where it was applied with a tiny piece of sponge. A sheet of absorbent paper gently wiped the excess from the cast.

In a first test, the cast had hinges, designed to make faster to fit both parts of it together, considering that after mixing, the silicone rubber has a limited curing time and the filling needs to occur concomitantly. Those hinges received Vaseline™, too, as all the borders. It was concluded, though, that the structure of the hinges was expendable, as it increases design, printing costs and, after the manual filling process, cleaning time, if the filling overflows and enters the hinge.

Silicone rubber is a material commercialized in different hardness and which properties allow the tactile resemblance to human skin. It was known that lower costs would be achieved if there were national suppliers. Project replicability depends on availability, and this alternative also provides more chances for another institution to achieve the same results with this method.

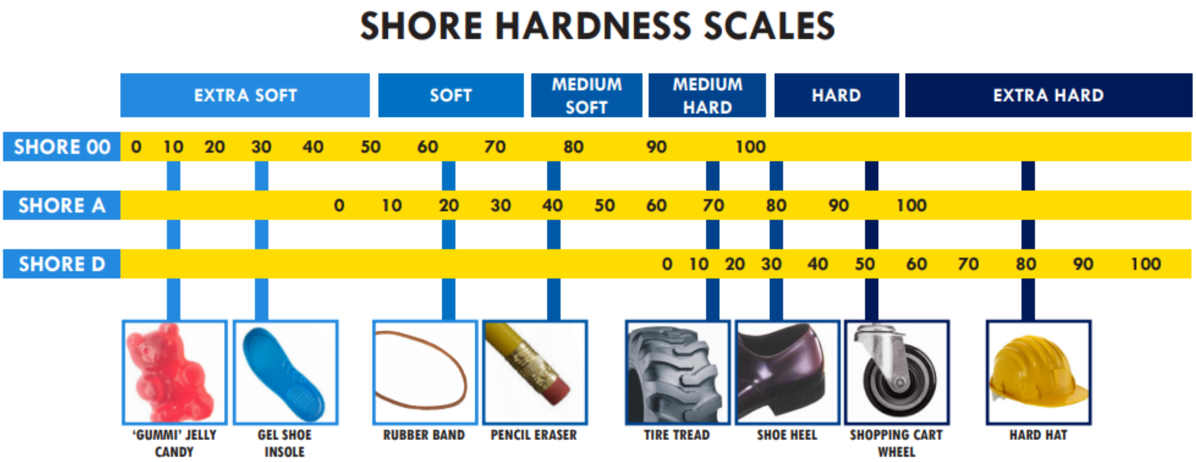
Obeying the definition of the requirement "personalization", adopted by the method, and taking into account what was addressed in the literature about the lack of color diversity in shelf prostheses, it was defined that the manufacturing process includes silicone rubber coloring. This determination is in line with what is found in the commercial prostheses, personalized, which already contemplate the fulfillment of the color criterion closer to that of the breast skin of the mastectomized woman.

Despite all the research, there was no way to measure breast density or skin texture, so that it could be recorded with scientific approach. In the case of texture, some anaplastologists use an industrial indicator, given by the manufacturers of silicone rubber, when there is direct contact with hurt skin.

Such industrial indicator is an improvement sought by the elastomer market, to provide the texture that aims to equate to the skin, comes from one of the components of the silicone: platinum or tin. When the elastomer is based on platinum, its texture tends to be more similar to the human texture, is said to have medical degree and is more expensive than the tin one (at least 500%). Because of this cost, the option in the method of this thesis is the tin based silicone rubber.

There is another feature of the silicone rubber, then well known and measurable, that is formally given by the shore hardness of the material, as can be seen in the Figure 50:

Figure 50 – Shore comparative



Source: (DUROMETER SHORE HARDNESS SCALE, [*s. d.*])

Tensile strength and twisting, commonly referred in the market as tear resistance, were also characteristics taken into account for the choice of rubber hardness. The analysis of the Figure 50, together with the definition of low-cost of design requirements, led to the conclusion that the material to be used by the project would be the one with shore A 15 hardness.

With regard to color, spectrophotometer, one of the options raised by researchers to measure skin tone, was not the target of the method, due to the specificity and increase of the proposal. So, coloring the rubber is a handmade process, based in the comparison with pictures and the Pantone™ Skintone™.

White silicone rubber with *shore* 15 A, was used for the manufacture of the five prostheses made following the method proposed for this thesis. It was the point of departure that would require less amount of pigment to reach sin tones, besides being the cheapest, when compared with transparent and some sold as "skin" tone (case of some platin based ones). The rubber was bought in a dealer that informs that the material comes from Dow Chemical Company™, although the container does not bring any information about the supplier. It only displays the information about the store, "Silicones Curitiba".

As the prosthesis will be in contact only with external skin, it is not a worry that it shall be composed by medical grade input. This was not required by the Ethics Committee that approved the proposal and also the legal worries address medical devices, not assistive technology as the external prosthesis is meant to be.

Asta Química™ pigments were added to the silicone rubber, in order to dye the material in the skin tone of the five participants in the sample. The colors that composed the palette created for this use was composed by: Vermelho ótico 008, amarelo ocre 003, bege pele 007, bege 012, preto 002, branco 002, marrom 010, marrom 300, all of them in the Silpast description.

The process began by separating 5.0 g of silicone rubber and, in another recipient, 0.035 g (3.5%) of its correspondent catalyst. This would compose the areola and the nipple. The selected pigment(s) was (were) added to the silicone rubber with the help of a toothpick, in which tip there was a tiny amount of pigment. The increment of shade was made slowly, as pigments for rubber silicone are strong and reach the color quickly.

When the desired tone was reached, the catalyst was poured into the mix and applied in the areola and nipple, that remained hollow. This was made with the help of a tiny disposable spoon. The cast was held in the hands of the researcher for five minutes, and after that, positioned over a cushion, to assure that the position of the areola remained as parallel as possible to the ground.

The purposely made unevenness in the cast, in the areola region, proved effectivity to prevent the material set in the tone of the areola from going beyond its area (correspondent to the rest of the breast), that usually has a different color. It requires, in any case, a two-stroke operation, that is, it is necessary to the material for the areola to be catalyzed first, and only after stiffening, it is possible to fill the reminiscent breast area, counting new catalyzing time for the material.

One hour later, the areola was already assured not to mix with the next phase, so, the preparation of the amount of silicone rubber determined to the breast and chest wall area could begin. It was specified that the prosthesis is hollow designed (in terms of silicone rubber), that is, it received only one layer of that tin-based elastomer, not exceeding 3.0 mm.

The silicone rubber was weighted and, separated, also the catalyst, in the proportion of 3.0%. A 10% extra, to join the two parts of the cast, was included to the amount of weight of each material, and remained separated, while the casts were covered with the 90% remaining. The quantity of silicone rubber follows a rule based in the area of each prosthesis, and also the density of the used silicone rubber. 100 g of the silicone rubber used for the proposed method represented 120.0 ml, in volume. Accordingly, the constant of 1.33 was adopted to multiply the resultant surfaces. Thus, considering a 3.0 mm of desired thickness, the amount was given by the Equation 1:

$$\textbf{Amount = External area of the biomodel x 3.0 mm x 1.33} \qquad (1)$$

With the silicone rubber separated, the pigments started to be mixed, poured with the tip of a toothpick, to match the most possible the color seen in the screen of the PC (containing the picture of the participant’s remaining breast) and in the Pantone™ Skintone™. There were used as many units of toothpicks as times that it was needed to take more pigment, to keep it pure; each time a toothpick was used, it was trashed right after. When the final color of the rubber silicone was reached, it received the catalyst, then mixed with the help of a stick, for 30 to 60 seconds. Then, the mix was poured, 2/3 first in the part correspondent to the breast, and 1/3 – after the material was totally spread over the breast area cast – in the part dedicated to the chest wall.

Then, it was needed to come back to the concave part of the cast, and spread back again the material that inevitably concentrates in the area of the areola, by gravity. A stick was used to help to scatter back again the material to the other areas of the cast.

Not more than 5 minutes later, 4 washers were distributed along the silicone rubber that recovered the chest wall area, respecting 10.0 mm from the border, and avoiding areas of protrusion (that will conform to the reliefs of the chest wall). This delay respects the time that the main layer needs to stop draining, so that the washers stay in place. The washers were slightly covered by a layer of the remaining silicone rubber.

The washers were used because the method included the possibility of fixation of the prosthesis – externally – to the patient's body, with magnet and adhesives, as occurs in the personalized top-of-the-line commercial prostheses. They are, however, an optional item.

For this application, four metallic washers of 12.0 mm in diameter and thickness of 0.2 mm were placed inside the prosthesis, in the part of the cast that corresponded to the chest wall. It is necessary to wait for the first layer of silicone rubber to catalyze in order to ensure that the washers will not slip or worse, to drown to the external area, defined to touch the chest wall.

Four neodymium magnets were provided for fixation on the skin (with adhesive first aid tape), with 12.0 mm diameter and 3.0 mm in height.

3.6.2 Filling material

Once the outside (which will be in contact with the patient's skin) was generated, the hollow prosthesis received a filler, which allows flexibility in determining the prosthesis' mass. It may be similar to the patient's breast, if she so chooses, but there is no mandatory value to be obeyed.

The literature reports the use of various materials such as tissue fibers, plumb grains, polyethylene pellets and millet granules as solutions for filling the prostheses. In this work, two other materials were tested to fill the external breast prostheses: vegetable *luffa cilindrica* and polyurethane foam.

The polyurethane foam filling solution was verified in the most expensive prosthesis model found during the research, took as gold standard. It promotes precise, integral, lightweight filling, and can have its density controlled. The mannequin described in a mentioned rotomolding patent was also filled with this material, aiming at lightness – a fundamental requirement for this research – as a result (VARNER; JOHNSON, 2011).

The vegetable bushing (*luffa cilindrica*) has been studied as material in the area of green composites, or biocomposites (BERA *et al.*, 2019; CHEN *et al.*, 2017; MOHANTA; ACHARYA, 2016; MOTA, 2016). It is a path of return to the natural and, as the literature emphasizes, it is a material that has attributes such as: lightness, thermal insulation and low-cost.

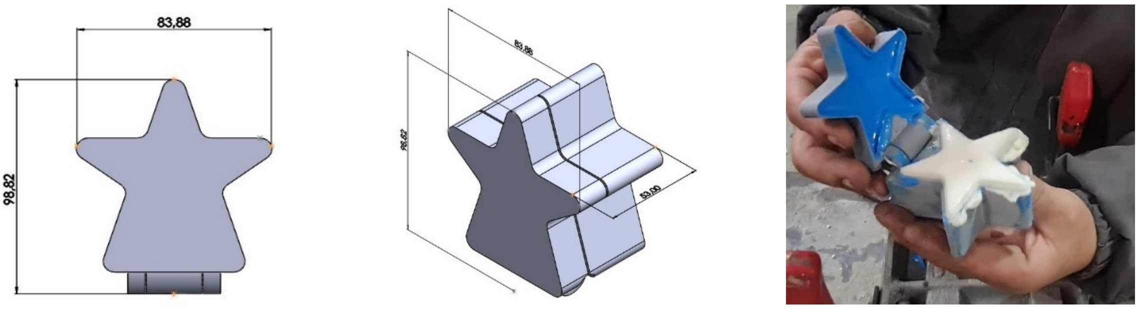
The attribute that simulates breast density was obviously not evaluated in composite studies, but the *luffa cilíndrica* appears as the main material in the patent of a mattress (YOUSHUI, 2015) and an analysis of its resilience, wettability and support performance, also as a mattress filling component (CHEN *et al.*, 2018; LOOFAH MATTRESS - GOOGLE PATENTS, [s.d.]; LU *et al.*, 2019). It plays the role of porous fruit, which natural fiber naturally containing air-filled spaces interests as an alternative material to polyurethane foam, and which resilience can simulate breast density.

In addition to the great availability on national soil, vegetable bushings are compostable in the soil. Thus, also seeking the sustainability bias, it was chosen to test them on the filling of the prostheses. Although they are of lower cost and biodegradability, the delay in the process of making small pieces of it was an obstacle to its use. Mixed with polyurethane foam, it was feasible, however, with excessive increase of time to the process.

A PLA printed cast, with fitting designed for quick closure was used in tests to fill the external prosthesis: first with silicone rubber, which copied the shape, and, on it, polyurethane foam. The cast in which these tests were performed was not that of a breast, but a smaller box, printed in lower quality than the breast file, containing details such as sharp edges, to simulate the difficulty that could be encountered in the actual process (Figure 51b). In Figure 51c, a technician observes the formation of polyurethane foam inside the box.

The chemistry that generates polyurethane foam is an exothermic reaction (in which there is heat and expansion). What limits and determines the end of the reaction is the amount of the mixture made and the space that contains it. So, if the mixture is contained (and compressed) before reaching the proportion planned for it to expand, it will generate a smaller, more compact volume and therefore a denser, less soft foam.

Figure 51 – The part used to simulate the filling



a b c

Caption: a. top view of the box and its hinge
b. measurements of the box (in mm)
c. test over silicone rubber

Source: The author (2019)

The piece with lid simulated the same condition as in a prosthesis, where breast and chest wall make up two parts of a whole. It was assumed that in the real situation the foam would be contained in the projected volume (inside the hollow which walls were silicone rubber), and what would ensure the shape would be a rigid cast, in PLA.

The reaction, in the volume of an external breast prosthesis, does not take more than 1 minute. The two components of the foam – polyol and isocyanate (at 60% of the polyol) – were mixed manually, with the aid of a wood stick, in a cup (both disposable), and after what is called cream time (which is when it begins to expand), the mixture was poured inside the concave part of the cast (corresponding to the breast). The foam was waited until half the cast was reached, to be closed with the corresponding part of the chest wall.

What professionals working with polyurethane foam call "foam collapse" needs that time with the cast opened, and also needs to be done with silicone rubber still in the catalyzing stage, to adhere to its walls.

As the tests were carried out in the company that manufactures foams from liquid components, any desired foam density could, in principle, be placed inside the prosthesis. The result depends on the variation of the components, and also on their specification. Once determined how much softness, strength or density was intended, the technician identified the product that corresponded to this specification, in their product line. There are a few industries in Brazil that sell those components to prepare the polyurethane foam. All the products used for the foam in this study came from Grupo Flexível®, and the amounts used for each of the five prostheses are in the table “filling costs”, of the subsection “3.5.5 Budget”.

Thus, if it is intended to simulate a prosthesis with a density more similar to that of the participant, this is a possible characteristic in the process. Placing more material and compressing it, in the intention of obtaining higher density in the foam, is also possible.

Polyurethane foam was, therefore, the material chosen, for the filling of the prostheses. It was the solution found to confer the possibility of manipulation of the mass of the prosthesis, and one of the greatest differentials of off-the-shelf prostheses currently available in the market.

For the process of filling, it has to be made immediately after the outer part (the silicone rubber) is spread, and still sticking. That is, the material has to be left aside, already weighed, only to be mixed and poured inside. It is the stickiness of the silicone rubber that helps the polyurethane foam to collapse and adhere satisfactorily to the outer material.

Grupo Flexível® supplied the material for the filling, which specification is VSB 2309. The mix was made in the proportion so that for each part of poliol, 60% of isocianate were used. The concave part of the cast is the only one that received the mix, that reacts and is restricted, then, by the part correspondent to the chest wall, that conforms the shape, providing it the limit needed for it to stop expanding.

The amount of poliol followed a rule based in the volume of each prosthesis, in a proportion of 0,006, as in the following equation:

$$\textbf{Amount of poliol = Volume of the biomodel x 0.006} \qquad (2)$$

It is considered a by-product of the model generated in this thesis what was chosen to call a light or transient prosthesis: a polyurethane foam obtained from the same cast printed to conceive the prosthesis, however without any other material around it.

It was made by covering the cast with 0.01 mm PVC transparent film. The result corresponds to the insert mentioned by Eggbeer and Evans (2010), who worked with an injection molding. The conformed foam can be used in the immediate postoperative period, as is done in some developed countries, or, respecting the recommendation of the doctor consulted for this research, when the patient no longer has pain, from the first month after surgery.

For its conception it would be needed the digitization of the region in which the breast was recently excised, evidencing the usefulness of technology without contact with the body.

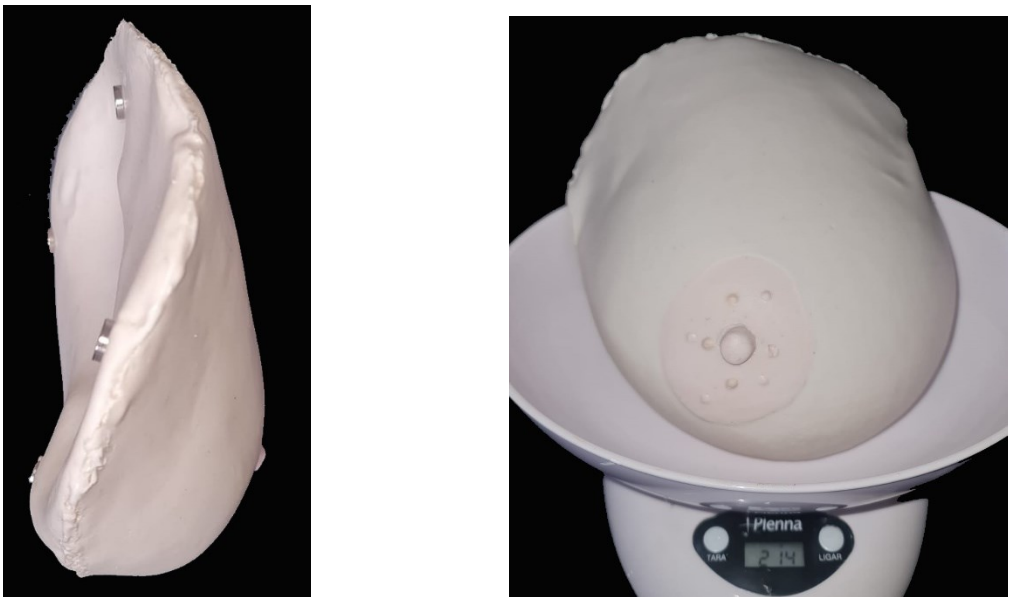
3.6.3 Final touch

After the prosthesis was filled, its two parts were manually joined, with the silicone rubber previously separated for this purpose, in the same color generated for the larger part of the breast.

As it is a long perimeter, the amount was divided in 4 portions, and catalyst was added in a proportion of 4.5% in each part to be applied, subsequentially.

The results satisfied the planned purpose and are demonstrated in the Figure 52.

Figure 52 – External breast prosthesis, personalized for “participant 13”



a　　　　　　　　b

Caption: a. view contemplating the irregularities of the chest wall
b. front view, with mass measurement (214.0 g)

Source: The author (2021)

The prosthesis obtained by this process was the choice made to establish the method proposed in this thesis. It is personalized, parts from capturing images without direct contact with the user's body, uses the equipment with the lowest cost available for these purposes, and is lighter than those found commercially, off-the-shelf. It also allows smoothness and mass manipulation, according to the determination in the prosthesis filling phase.

The method also allows a massive customization, that is, based on some three-dimensional breast files predefined as standard, a production grid can be established, replicating several units from the same cast. It would work as a “library” of external breast prostheses. In this case, the casts achieve their maximum use as a tool, enabling the acquisition by an even greater number of associations. In this case, the costs of digitization are spread over more units, what makes them cost less.

The steps contained in this process were described in detail in a manual, the distribution of which is intended to be non-profit. To ensure that the method and obtaining the prostheses have no costs beyond those inherent to manufacturing, the registration of the method proposed in this thesis will be done in scientific publication and the prosthesis will have its patent requested to the INPI (Instituto Nacional de Propriedade Industrial), on behalf of the Federal Technological University of Paraná.

3.7 Method’s flow chart

The manufacture of external breast prostheses designed by the method developed in this thesis is represented by the flow chart presented in the Figure 53.

Figure 53 – Flow chart for manufacturing personalized external breast prostheses

Source: The author (2022)

4 VALIDATION OF THE PRODUCT GENERATED BY THE METHOD

The most effective way to know if the objectives of this work were achieved was to return to the field, with the process completed, embodied in a personalized external breast prosthesis, which quality was closer to those golden standard personalized presented, and which cost was lower than theirs. Introducing the prosthesis to the user was the core of this phase, the validation. This is what composes the last phase of the Methodology proposed by Rozenfeld et al. (2006), called Follow up.

Although there may be bias in such analysis, there are no anaplastologists dedicated to personalized external breast prostheses in Brazil – as far as this was researched for this study – that could reduce the subjectivity of the results. Literature reviews also composed the evaluation, together with a survey questionnaire.

The delivery of the product, which was intended to be carried out at the Erasto Gaertner Hospital, in the presence of each of the users, became impossible, mainly due to the pandemic, with the risks to access the participants – people with more fragile health – and also by the impediments of work in the University laboratory. The initial plan was to take advantage of the opportunity of a medical consult of the participant at the Hospital, but it was necessary to wait for the researcher to be immunized against SARS Covid, which only occurred in November 2021. At this time, the access to the Hospital's data system had to be requested from the Ethics Committee, which has not yet granted such authorization, and some situations, concerning to the participants, they relocated.

Three of them were found with the breast reconstructed or in process of reconstruction, what was astonishing. One of them, whose evaluation will be shown in this thesis, was found in a new treatment of another cancer, making special diet, with substantial loss of weight (more than 10,0 kg), what certainly modified her body and remaining breast. Another participant was not located and the Hospital does not have any data of her passage there, since 2019. Thus, results validation was impacted.

During the visit to the “participant 13”, who had her breast partially reconstructed during pandemics and is waiting it to be finished, it was possible to have an idea of the performance of product generated by the method, as shown in Figure 54.

Figure 54 – Validation with “participant 13“

a

b

Caption: a. participant’s new chest wall shape
b. frontal view of the prosthesis and natural breast

Source: The author (2021)

Happy with her health and weighting 15,0 kg more, she is waiting for what is called “contralateral breast symmetrisation surgery” (when the natural breast is also submitted to a surgery to make it acquire a new size and/or shape, followed by the reconstructed one). So, the reconstructed breast still does not correspond to the shape of her remaining breast. Anyway, she accepted to place the product developed for her, with the method contained in this thesis, and evidenced that there was some color difference, but the shape seems to respect hers. In fact, even the reconstructed breast, as its skin comes from a donator area of her body, doesn’t have the same tone of her natural breast, so, she did not mind about the tone.

She enjoyed the Montgomery glands reproduction, and she knows that her new (reconstructed) breast will not have them, nor the areola.

Participant 03 was the one who had the lower breast volume (Figure 55a) in the sample. She was submitted to a reconstruction which was performed in the beginning of the year 2020, right before the Covid19 pandemic started. Her reconstruction (Figure 56b) was followed by a new cancer (in the area of reconstruction), which treatment had just finished. She was not satisfied with its results, and did not understand what the surgeon explained that he intended to do later (it was a contralateral breast symmetrisation). Anyway, because she had to be submitted to a new surgery to remove two new tumors from the chest wall, followed by sessions of chemotherapy, she decided that she will not get back to any procedure related to reconstruction.

What should be the validation with participant 03 is shown in the Figure 55c, with the prosthesis put over the reconstructed breast, what obviously cannot exhibit the effectiveness of the assistive technology.

Figure 55 – Validation with “participant 03“

a b c

Caption: a. participant’s chest wall shape when first acquired the 3D image
b. participant’s new chest wall shape (with reconstructed breast)
c. view of the prosthesis over the reconstructed breast

Source: The author (2022)

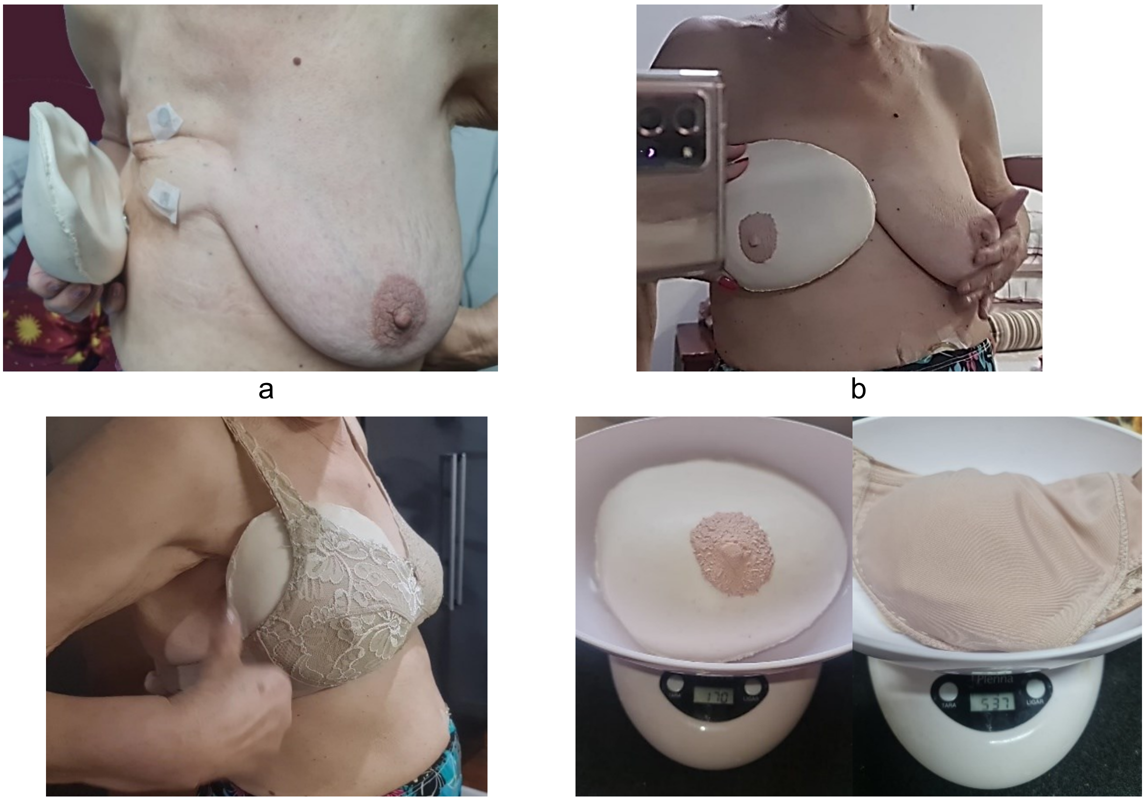
Especially in the case of participant 03 it was realized that there is room for the method to be used to conceive external breast prosthesis even for women who had a lumpectomy (partial removal of the breast) or a reconstruction that did not get to its perfect results, as in her case.

It is needed to remark that the only effective validation was made with a participant that reunited all the challenges to the manufacture: participant 14. Her prostheses presented the highest number of variables in this method: breast ptosis, volume that meant more than 500.0 g in an off-the-shelf prosthesis, multiple unevenness in her chest wall. She had, still, a very special anatomy of her areola (in her remaining breast).

When the surgeon took off her breast, as she intended to have the reconstruction made, they took of the nipple from the ill breast, and replaced it somewhere in the chest wall. Later, she was submitted to a reconstruction and faced a rejection. Then, she was submitted to a new surgery, when the implant was taken off, and part of that nipple remained there, in her chest wall, causing several embossments that a regular off-the-shelf prosthesis could never really accommodate.

With that participant, named “participant 14”, the photos show that the fitting in the chest wall was what was expected by the researcher, as seen in the Figure 56a. The outer and the shape were similar, but certainly with a difference of volume and more accentuated ptosis in the natural breast, as the participant had previously (when booked the visit, in her house) adverted it would happen (Figure 56b). The fitting of the prosthesis of this method, inside the bra of “participant 14” respected the natural contours of her body, as it is shown in the Figure 56c. In the Figure 56d, a comparison between the weight of her conventional prosthesis, an off-the-shelf silicone model inserted in a bra (537.0 g) and the prosthesis conceived by the method of this thesis (170.0 g).

Figure 56 – Validation with “participant 14”



a b c d

Caption: a. the fitting of the prosthesis in the chest wall
b. frontal view of the remaining breast and the prosthesis
c. the prosthesis inside the bra
d. prostheses weight: 170.0 g X 537.0 g

Source: The author (2021)

Assuming a non-padded, wireless bra with 50.0 g, her conventional prosthesis should weight around 487.0 g, what means that the prosthesis manufactured using the method conceived by this thesis weights 35% of that off-the-shelf model.

It is evident a difference between the color of the prostheses, when compared to the color of the skin of the participants, probably the result of a wrong choice of the author of this study, between the Pantone™ and the picture on the screen, and/or the consequence of an illuminant metamerism, that is a phenomenon that may occur when two samples of the same color may be identical, under a certain light, but end up different, under another illuminant.

Matching the colors, far from the patient (with intrinsic tinting), during the process of the choice of pigments to insert in the silicone rubber, “would be too precarious and time consuming” (LEOW *et al.*, 1999), to use the same terms those authors mentioned, when questioning the possibility of using three separate sources of light to thrive in this arena.

The issue with the color could be improved, applying painting over the prostheses already made, always comparing with the participant skin *in situ*, as the anaplastologists make, with extrinsic tinting. Having met the participant treating a new cancer did not leave room for such trials. Besides, the artistic part of the anaplastology requires practice and long training, that this researcher still not have, and probably could not acquire in time to finish this thesis.

Even considering the difference of color, the participant mentioned that comparing to the prosthesis that she was wearing (an explanted prosthesis, in fact), it was much better to view, especially because of the nipple, that she evaluated as much similar to hers.

Another point that has not reached the desired level was the perfection of the shape, what implied a difference between the real ptosis and the prosthetic one. Also dependent of some practice and art, it was an issue to be solved while manipulating the mesh, adding more volume between the chest wall and the abdominal area. She wore the prosthesis under her bra and was happy to see that the contour of the chest wall was fitted and, mainly, that the curvature would make clothes seem much better and similar to the other side (the natural breast).

The researcher left the participant’s house with the intention to come back later, to evaluate her perceptions after some days using the prosthesis, using the same survey form used to evaluate her off-the-shelf prosthesis, but this is never more possible. She had passed away.

Although some inadequacies that may be modified persist, an economically feasible process was reached for the manufacture of customized external breast prostheses, concluding that the hypotheses of this thesis were confirmed.

Long-term assessment, as well as a larger number of participants, will not be possible, given the time required for the completion of this thesis.

4.1 Product and process monitoring

As stated in the Free and Informed Consent Form (TCLE, in Portuguese), the users remain with the researcher's contact data and vice versa. Thus, the monitoring of the performance of the prostheses can be done directly with the research participants and, if necessary, modifications may be implemented in the work.

Deteriorations should also be monitored with a view to compose the manual of the replicable manufacturing process. The disposal of products – casts and prostheses – should be accompanied, considering that they are recyclable (PLA) or reusable (silicone rubber and polyurethane foam cases) materials. Silicone rubber can be put into a new cast, in an application when a bigger amount is needed (to complete, without the need of using a brand-new raw material), and polyurethane foam can be used to make cushioning, compressed and glued with other leftovers.

4.2 Considerations about the applicability of the method

Throughout the development of this method for the manufacture of personalized external prostheses, two institutions of the most populous cities in the state came to UTFPR in search of the external prosthesis. They were: the League for the Action against Cancer (Liga Paranaense de Combate ao Câncer), which is based at The Erasto Gaertner Hospital, but was unaware of this research approved by the Ethics Committee of the entity, and the Cancer Patient Support Center, in Londrina (a city with 580,000 inhabitants).

Neither organisations were aware that customized or personalized prostheses were an option. They only desired a product that could, generically, replace the birdseed prostheses, that they offer to mastectomized women who arrive to their doors.

The two institutions were the target for the implementation of the method conceived in this thesis. Of course, they can only be met by practical application after the patenting of the model by UTFPR, that requires the secret around the method, and, later, its scientific publication.

For the purpose sought by them and all those who have this same emergency need, which is the lowest price, as well as the rapid and massive care of the population, there is an alternative derived from the proposed method, to obtain shelf prostheses, in previously determined standards, already contemplating both colors and shapes closer to the real ones. Without the design of individualized chest wall, but with highlight of areola and nipple, and possibly with magnets for fixation to the body.

The major difference, for the original method, is the suppression of the scanning stage of the woman's chest. The virtual modeling work will be reduced, because it will use a mixture of what is already available, to make up a catalog, from which the templates would be printed.

Then, the greatest cost reduction happens. As a 3D printed tool, the casts allow several uses, spreading out what is the highest cost of the final product. Custom prostheses are more expensive than off-the-shelf. Making multiple prostheses from a mould tool can help to reduce the individual price, but some women will still seek the cheapest option through necessity.

Therefore, the patent will also be requested on the method for obtaining the non-personalized product, off-the-shelf, but mass customized.

“You raise me up, so I can stand on mountains.
You raise me up, to walk on stormy seas.
I am strong, when I am on Your shoulders.
You raise me up to more than I can be.”
(GROBAN, 2003)

5 CONCLUSION AND SUGGESTIONS FOR FUTURE STUDIES

Intersection between 3D Scanning, CAD, CAM, 3D Printing, casting, Assistive Technology and Design, this study used the support of Mechanical Engineering to peer affective aspects of usability for an area in need of resources, for an even more deprived population. With this interdisciplinarity, it was intended to create a method containing an economically feasible manufacturing process that, using technologies that enable customization and low-cost strategies, enables the manufacture external breast prostheses at a state-of-the-art level.

The data collected in the interviews with the participants show the lack not only of assistive technology resources, but also of information on their existence. It was a great research opportunity, which could become a market opportunity and, hopefully, recognition by SUS (Brazilian Health System). For UTFPR, it is also the prospect of returning to society some of the confidence that the population places in Science, Research and Technology. For the researcher, the realization of the professional and personal dream of helping in the healing of the soul and in the support of the femininity so affected of these women who touched her, by presenting to her the prostheses with bird seeds (*Phalaris canariensis* or *Panicum miliaceum*) inside.

The three-dimensional capture of images of the surviving breast of each of the research participants, the treatment of those meshes obtained, the conception of biomodels and casts already generated in a virtual environment show that the intended innovations in the manufacturing process of external breast prostheses are part of a possible and accessible reality, thanks to the application of CAD, CAM, and 3D printing.

Major challenges of this research were obtaining authorization for data collection in real people, respect of the schedule, time and space in the Hospital. The large volume of data generated (and its consequent storage in security and confidentiality) and the volume of information from various areas of knowledge, crossed and analyzed, were also points of worries. Together with that, the learning curve of low-cost and free software operation and the printing time of each of the prototypes, resulted in an unexpected amount of time.

All that impacted the high number of pages of this document. The pandemic cannot be cited as a challenge, but as an obstacle, which eventually altered important plans for the development of the thesis.

The conundrum around the healing or the new diagnosis of tumors in the participants of the study, the changing in their weight or still, a surprising fast track in reconstruction was another challenge in this work. It is possible that what was defined as “the most similar possible” will have to settle within more elastic standards. There are boundaries in what is possible to Engineering to solve, and also personal limitations of skills of this researcher. Considering all that was exposed, the method proposed in this thesis allowed the manufacture of personalized prostheses, lighter, with more respect to the affective aspects of usability, using 3D printing and low-cost resources. Thus, this researcher believes that her objectives were reached.

The contributions, that came as innovations, are:

- an economically feasible proposed method to manufacture external breast prostheses, personalized or not, using low-cost resources;
- a protocol to capture 3D images suitable to manufacture those prostheses, using low-cost sensors;
- a complete description, composing a manual, of mesh repairing, after such captures are made (including ptotic breasts);
- the detailed post-processing of the 3D printed files resulting from the CAD work;
- a whole description of how to conceive (composing a manual) and how to use personalized 3D printed casts to manufacture external breast prostheses;
- the paradigm of the choice of the weight in an external breast prosthesis, discussed and brought to practice in a method using those 3D printed casts, for an even more personalized choice;
- a transparent cost budget about the proposed method and all its origins.

It Is important to mention that institutions that intend to replicate this method will need to have inputs such as a 3D printer, computer with graphic board and a sensor to perform the capture of 3D images. A private space to make such images is imperative. Legal aspects about how and where the data will be kept are also components of the limitations of the replicability of this method.

As suggestions for future studies, the application of automated rotomolding in the manufacturing process announced in this method, the application of new low-cost scanners to the scanning designed in this method, the study of filling materials that may be alternatives to polyurethane foam, improvements in the workmanship of the prostheses, color research (which allows to replicate the various shades of human skin), a development of an application that could make easier for any user to replicate the method and technics for breast bioprinting, that needs to be based on several characteristics described in this method, as well as in the literature referenced in this document.

Any improvement implemented, aimed at the same public, it is expected to be made with the same awareness that guide the design of this method, and that such modifications can be published and used, free of charge, by non-profit organizations. It is a hope that they can enrich (fundamentally) the additions to the manuals and step-by-step, such as those that will be disclosed after the patent application of the external breast prosthesis manufactured by the method conceived by this thesis. Until one can have the discovery of the definitive cure of breast cancer.

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GLOSSARY

Anaplastologist: the person who performs, with manual techniques, the craft (anaplastology) that is dedicated to manufacturing prostheses.

Biomodel: the perfect replica of an anatomical structure, in plastic.

Fitting: value judgment made with the product in the user's body, at the time of proof or experimentation, with the intention of evaluating the conformation, the result of the product when placed next to the body.

Document Object Model or DOM: schema made by a software, which demonstrates how the file is organized, what its elements are, and the hierarchy between them.

GOM: software used for Metrology

Lumpectomy: technique derived from mastectomy, in which only part of the breast is removed.

Radical mastectomy: surgery in which the breast gland, skin (including areola and nipple), lymph nodes of the armpit and pectoral muscles are removed.

Modified radical mastectomy: surgery in which the mammary gland, skin (including areola and nipple) and lymph nodes of the armpit are removed, preserving the pectoralis major muscle.

Total mastectomy: surgery in which the breast gland and skin (including areola and nipple) are removed, with the preservation of the lymph nodes of the armpit and the two pectoral muscles.

Chest wall: region of the thorax from which the breast was removed.

Ptosis: technical term derived from medicine, which designates the stretching of the ligaments that sustain the breast, causing the breast volume to fall over the abdomen, and consequent repositioning of the nipple, which leans towards the ground.

Breast reconstruction: surgery by which the breast volume removed in a mastectomy is recreated, using the patient’s own skin and sometimes an implant.

Late reconstruction: reconstruction not performed immediately after mastectomy.

Shore: hardness measurement unit used for polymers, elastomers and rubbers.

APPENDIX A – Interview with participants research form

name .... mastectomy since .... months/years ..../.......

Do you know about the reconstruction paid by SUS? ( ) no ( ) yes ( ) on the line

Who told you? ....

Option for submitting to reconstruction ....

Comorbidity ( ) no ( ) yes Which? ....

Did someone orient about external breast prosthesis? ( ) no ( ) yes Who? ....

Where? .... When? ....

How long after mastectomy were you authorized to use an external breast prosthesis? .... months

Did you use “something” until then? ( ) no ( ) yes

what? ....

How did you choose your first external breast prosthesis?

....

Were there other options to choose from? ( ) no ( ) yes

Do you know other kinds of prosthesis? ( ) no ( ) yes Which one(s)?

....

Who paid for your first external breast prosthesis? ....

How much did it cost? ....

Did you substitute it? ( ) no ( ) yes

When? .... What kind? .... Why? ....

How many hours you use it, each day? .... In some specific ocasion? ( ) no ( ) yes

From 1 to 10, grade for satisfaction with the actual resource, related to...

performance parameter	1	2	3	4	5	6	7	8	9	10
shape										
color										
size										
weight										
odor										
noise										
texture										
look, underneath clothes										
look, under the bra										
Look, in the hand										
Easy of positioning										
easy of cleaning										

Do you have a partner? ( ) no ( ) yes tempo ....

Did you talk to him about the external breast prosthesis? ( ) no ( ) yes

Do you feel any restriction related to clothes? Did you stop wearing any clothes? ( ) no ( ) yes

Which? ....

Do you feel any restriction in movement? Did you stop doing any activity? ( ) no ( ) yes

What? ....

Activity before mastectomy ....

Right handed / lefty

Number of pregnancies ....

Breastfed for .... meses

If you could say something to your prosthesis ……………………………………………………………….

………………………………………………..

....

How many hours a day did you wear bra, before mastectomy? .... And nowadays? ....

How was its model, before surgery?

unlined spacer padded cup push-up fabric ....

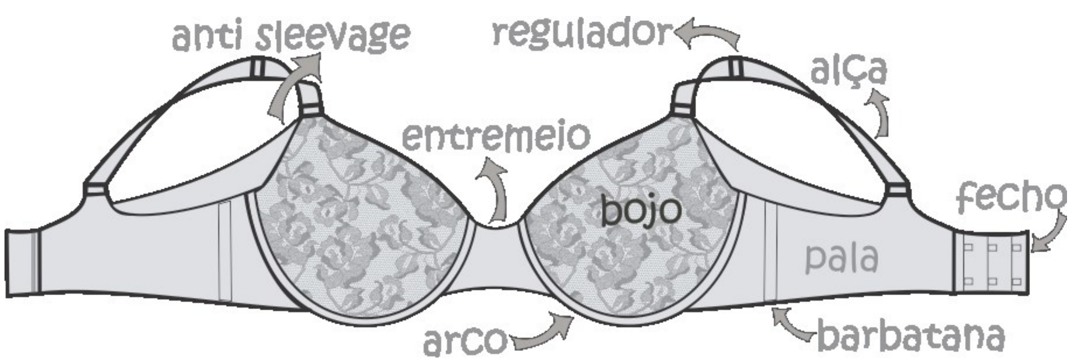
wired wireless

complains about bras already used ....

	brand	size	wire	cup	strap	hook & eye	colors
before					position width	position model	
now					position width	position model	

How did you choose the bra that you wear, nowadays?

………………………………………………… ....



APPENDIX B – Free and Informed Consent form (TCLE)

I, ..., that had surgical indication for the procedure of total breast removal, I agree to participate in the research "Mastectomy without immediate reconstruction: The day after - external prostheses, cups and bras", carried out by the researcher Lucia Regina Branco.

She told me that in the research she intends to make external breast prostheses as similar as possible to the breast that remained, after the surgery of the removal of the one with tumor.

I was informed that the researcher will collect data from my medical records (name, date of surgery) and that she will use imaging tests that I did in the chest region (mammography, CT Scan, MRI). I know she's also going to make images of me from the region, and I agreed to be interviewed in front of the video camera. If any questions cause me discomfort I may not answer and also give up my participation in her study. By signing this term, I agree that she uses these images – audio and video – in academic purposes (classes, congresses, scientific events, lectures or scientific journals), ensuring that they do not identify me, without financial burden to us.

I agree that the researcher follows my consultations and exams, as well as that she proceeds measurements of the region related to the breasts and bra. She also informed me that photographic images and with a sensor, in addition to a modeling made with plaster and alginate, will be made by her, in a private room, in this region.

If I do not feel at ease, whether in the interview or under any circumstances, I know that I can give up participating in the research at any time, without any prejudice to myself and my treatment. I won't have any expense of participating in the research.

The researcher told me that this work of hers should last about two years and that, then, it may be that I myself will not wear a prosthesis or bra made by her, but for the research to happen and in some time these products may exist, some women will probably have to try some models of prostheses and / or bras. If I am one of the guests to try prostheses and / or bras I know that I must inform immediately if any allergy, itching or any uncomfortable feeling occurs to me, and I will go to the doctor if requested. I can also look for the researcher at any time, she gave me a card with the phones on which I can find her, and I must seek the Hospital for any questions about the ethics of research.

Although I know that I cannot expect any immediate result, I was informed that I will have access to the measures, molds, trials of the products, as well as supply of them (if approved), and I agree that the researcher uses everything that has been described here, as long as i do not report data that allow them to know who I am.

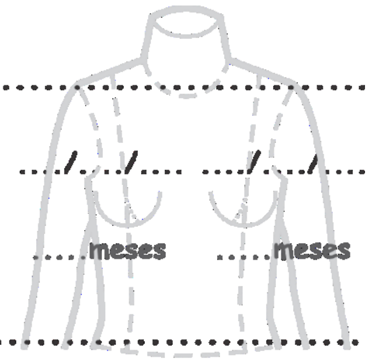
I sign this document in two ways, and one of them stays with me.

Lucia Regina Branco
luciaregina@hotmail.com
41 99996.6969

**Research Ethics Committee of the
Hospital Erasto Gaertner**
R Dr. Ovande do Amaral, 201, Jardim das Americas
41 3361.5271

APPENDIX C – Body data survey form

fotografia



identificação ....

idade ..../..../.... ..../..../....

extração da mama ....meses .....meses

cicatriz ....

simetrização prevista sim ..../.... não

médico ....

local do contato .... data da entrevista ..../..../....

alergias conhecidas ....

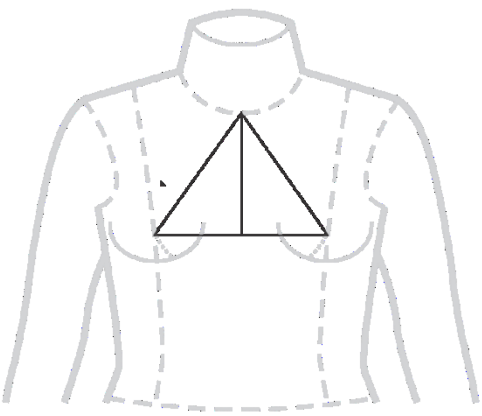
circunferência de tórax........ circunferência de busto......

comprimento de alça .... entremeio........

tonalidade de pele .... (mama) .... (aréola)

marca de pressão do sutiã sobre a pele ....

ajustes manuais ( ) não ( ) sim pontos ....



APPENDIX D – Manual for treatment of 3D mesh for the generation of subsistent breast biomodel, added to the chest wall

Introduction

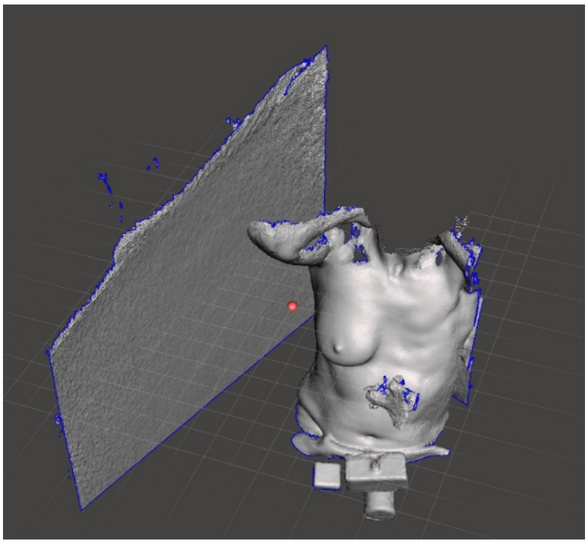
The purpose of this manual is to explain the step-by-step method to obtain a breast biomodel, attached to the chest wall biomodel, which is the part of the body in which the scar left by mastectomy is. Together, they can give rise to an external breast prosthesis, or to the mold of it.

The instructions below are based on a model designed with Autodesk's™ Meshmixer™ software, version 3.5.474, and the images used come from three-dimensional digital capture, which files are saved in stl format.

1. Importing and cleaning the stl file

The scanned torso image needs to be imported into mesh editing software. Usually the file contains parts of the scene in which the scan was made, which do not interest the study, as shown in Figure D 1 They need to be removed because they make it easier to handle the file, which will be smaller.

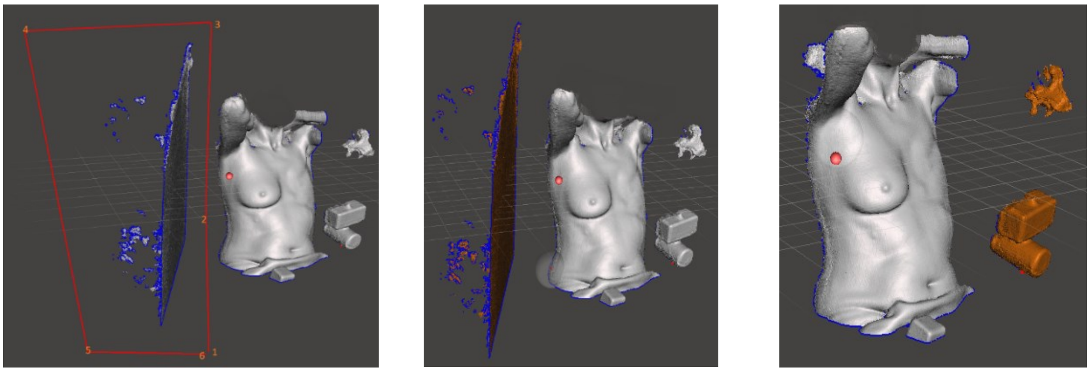
Figure D 1 – Original scan file



Source: The author (2019)

With the file open in Meshmixer™, the S (Select) button is used, and by holding down the left mouse button, a perimeter is drawn around the part to be deleted (Figure D 2a). After checking each selection (part that is marked in orange, with which it will be erased, within the perimeter) – as shown in the Figure D 2b and Figure D 2c – the delete key is used to delete them.

Figure D 2 – Erasing interferences from original scan



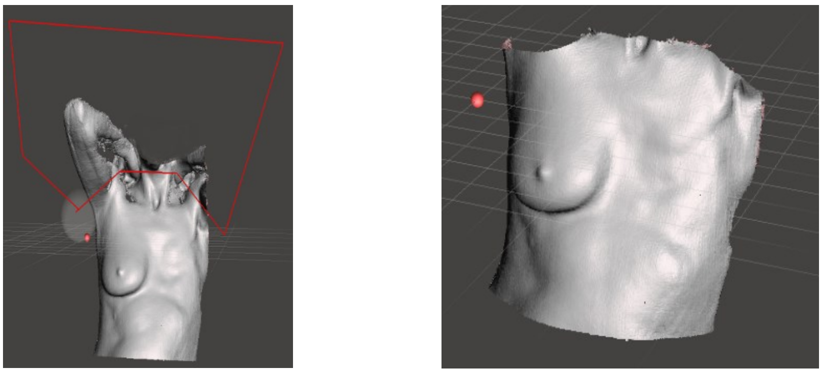
a b c

Caption: a. selecting what needs to be deleted
b. what will be erased in orange
c. other pieces to be cleaned up, in orange

Source: The author (2019)

Then parts of the body mesh will be erased (which have been scanned and will not be used). The selection must be made in the area, as Figure D 3), and deleted, using the Delete key, obtaining results similar to that of Figure D 3.

Figure D 3 – Erasing surplus from what was scanned



a b

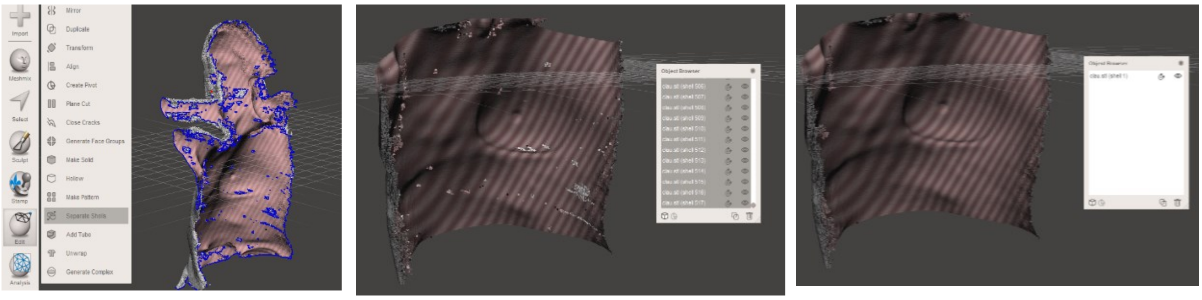
Caption: a. selecting the perimeter to be erased

b. results, after erasing the selected area

Source: The author (2019)

Next, in the Edit menu, select the Separate Shells option, as shown in Figure Figure D 4a. What remained corresponds to the main component that will be worked (Figure D 4b), already a cleaner and lighter model than the original, as in the Figure D 4c.

Figure D 4 – Deleting parts, using the object browser



a b c

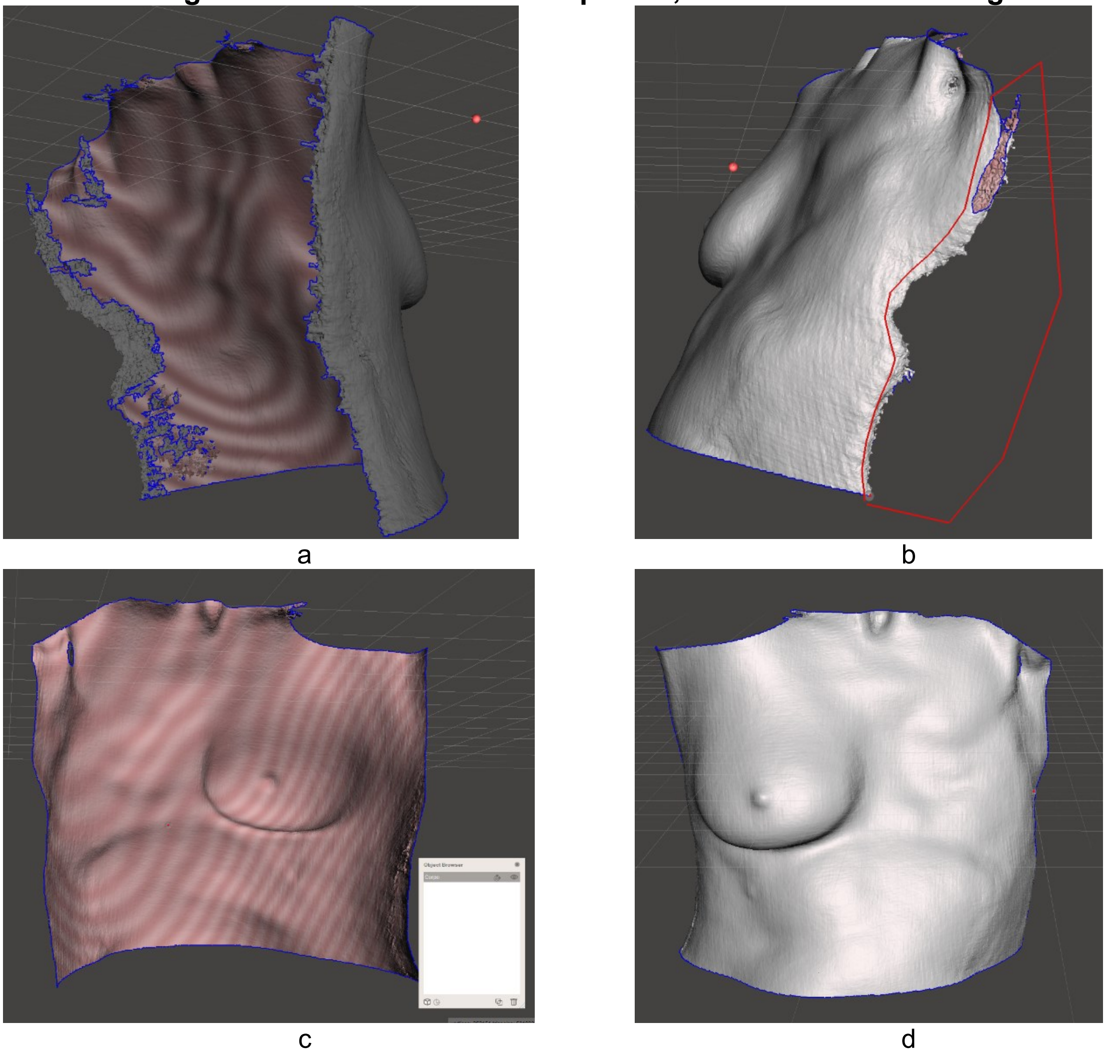
Caption: a. menu Edit, option Separate Shells
b. the separate objects, in the object browser
c. results

Source: The author (2019)

It is possible to rotate the model in the most appropriate position to extract only the face being seen, in another plane.

It follows removing the surplus, at the side edges (Figure D 5a), cleaning the outer most part, which is still part of the body scanning. Select the perimeter of it (Figure D 5b), and using the separate shells option, erase everything that is not necessary for the image, leaving only the first mesh (Figure D 5c). The result is contained in the Figure D 5d.

Figure D 5 – Withdrawal of surpluses, seen from another angle



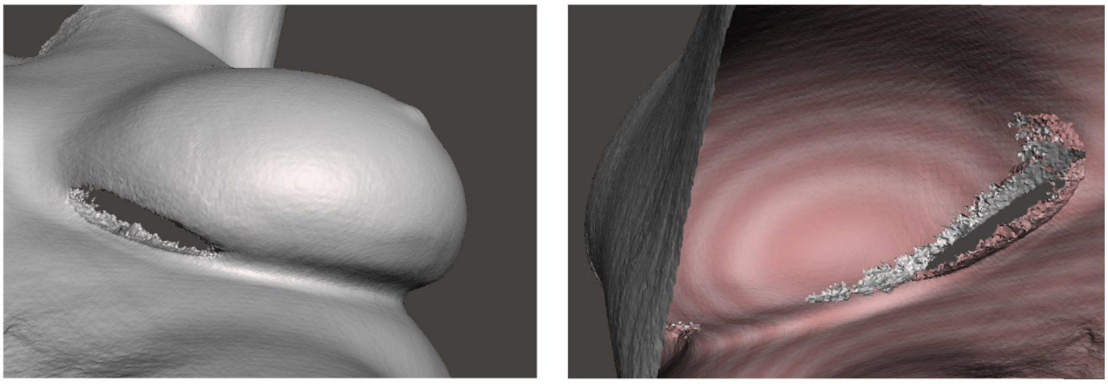
Caption: a. the scanned area, as in the original
b. unwanted perimeter selection
c. use of the command Separate Shells
d. the resulting image

Source: The author (2019)

2. Corrections in case of gap in breast biomodel mesh

Sometimes the volume of the breast casts a shadow over the abdomen, and the capture of the image in the inframammary groove may be compromised, generating regions with flaws, as Figure D 6a and Figure D 6b. Correction of these defects should be done anatomically.

Figure D 6 – Gap(s) in the region of the inframammary groove mesh



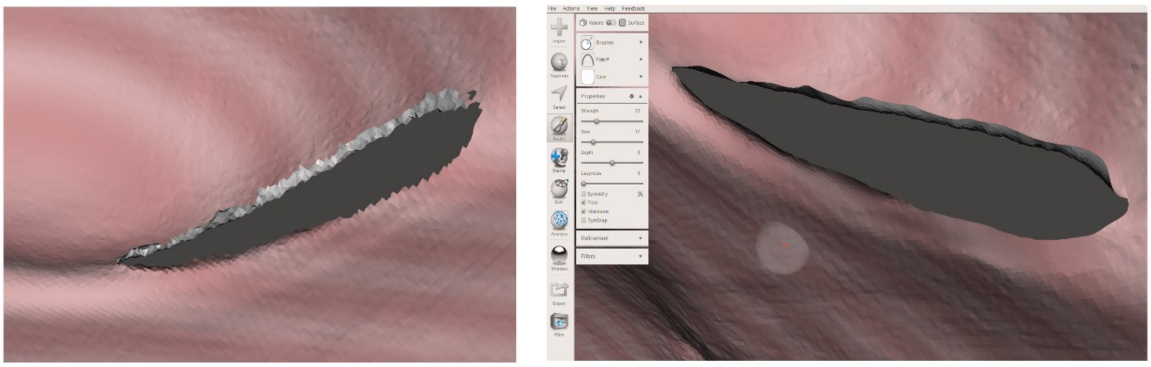
a b

Caption: a. the gap, seen by the external area
b. view of the original capture

Source: The author (2019)

The correction is composed of the cleaning processes of the area, when selecting the inner part with lost triangles, which are erased, followed by smoothing the correction (Figure D 7a). This can be done using the Bubble Smooth brush, taking care not to change the existing curves on the body, as seen in Figure D 7bFigure D 6.

Figure D 7 – Correction of the gap(s) in the inframammary groove mesh



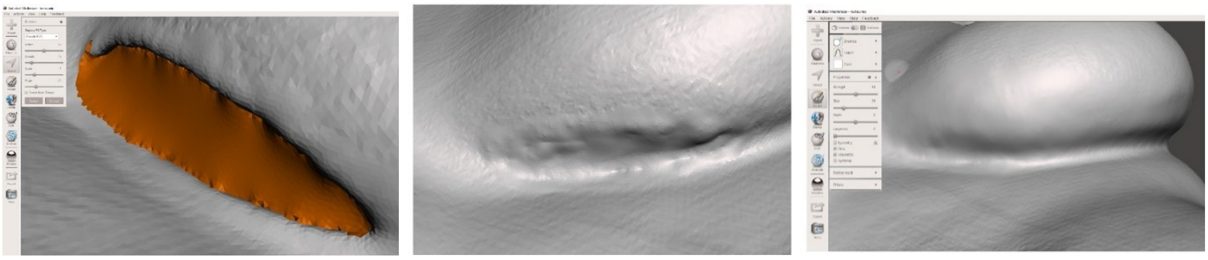
a b

Caption: a. the gap, seen by the internal area
b. Bubble Smooth brush correction

Source: The author (2019)

The edge of the hole is selected (Figure D 8a), and with the Fill function (F key), the gap is closed in the mesh, as demonstrated by the Figure D 8b.

Figure D 8 – Use of brushes for mesh closure



a b c

Caption: a. filling, with the function Fill
b. use of brushes to collect protruding parts of the mesh
c. results

Source: The author (2019)

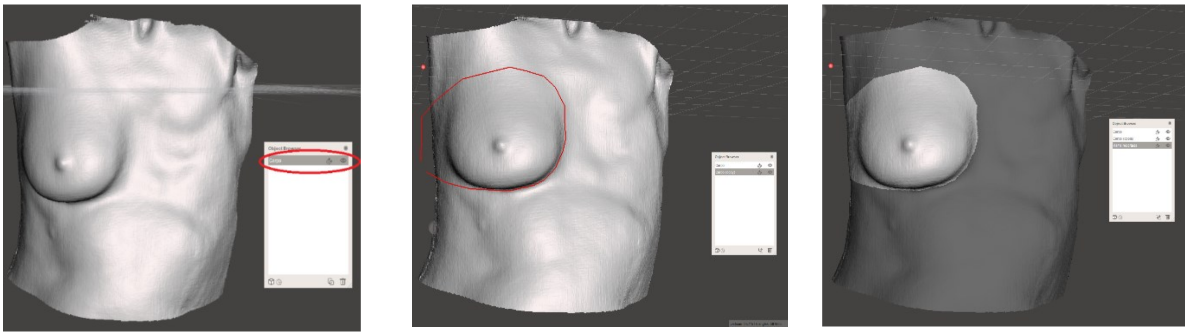
With the geometry closed, the brushes for mesh correction are followed by: Pinch, Inflate, and Spike to pull parts that are indented, Flatten, to rewind, and finally the Bubble Smooth, Shrink Smooth, and Inflate brushes for mesh smoothing, as shows Figure D 8c.

3. Duplication of breast biomodel

Leave the model aligned in relation to the planes, using the Transform command (T), if necessary (Figure D 9a). It enables the translate option, and allows to rotate the image relative to the axes, facilitating the later steps.

Select the Body object in object browser (Figure D 9b) and, by clicking Edit > Duplicate, create a copy of it. With the copy selected, accessing the Select menu, select the part relative to the breast. Holding Y pressed, or opening the Edit > Separate sub-menu, separating the selected part from the rest of the body, as shown in Figure D 9c.

Figure D 9 – Duplication of the breast biomodel



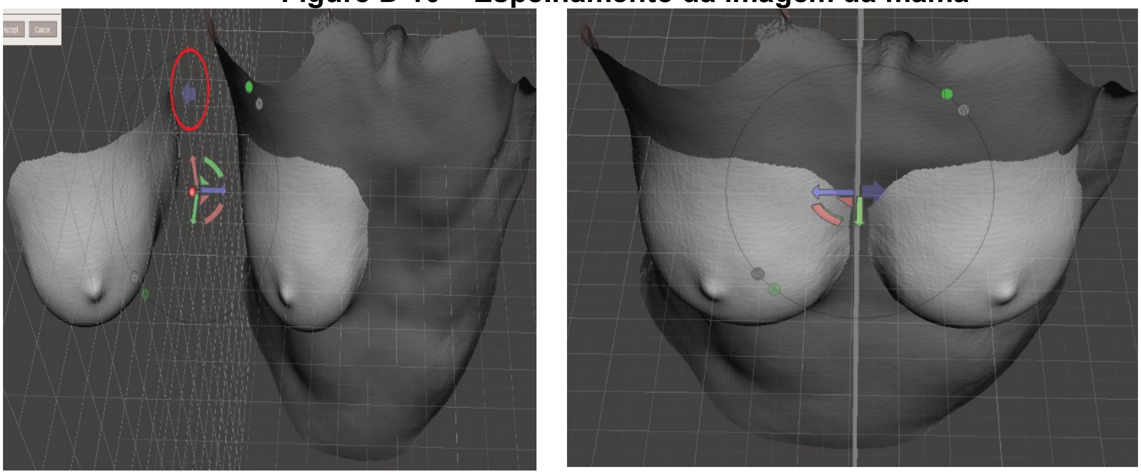
a b c

Caption: a. positioning the model, with the command Transform
b. selecting the breast mesh for duplicating
c. the copy, also indicated in the Object Browser

Source: The author (2019)

Next, mirror the breast, using the Edit menu > Mirror. If the copy is being made to the reverse side, use the blue arrow (which points the direction of the mirror) to flip the side of the copy (Figure D 10). Then move the plane using the grid drive arrows, until the copy no longer has a connection to the breast, as shown in the Figure D 10b.

Figure D 10 – Espelhamento da imagem da mama



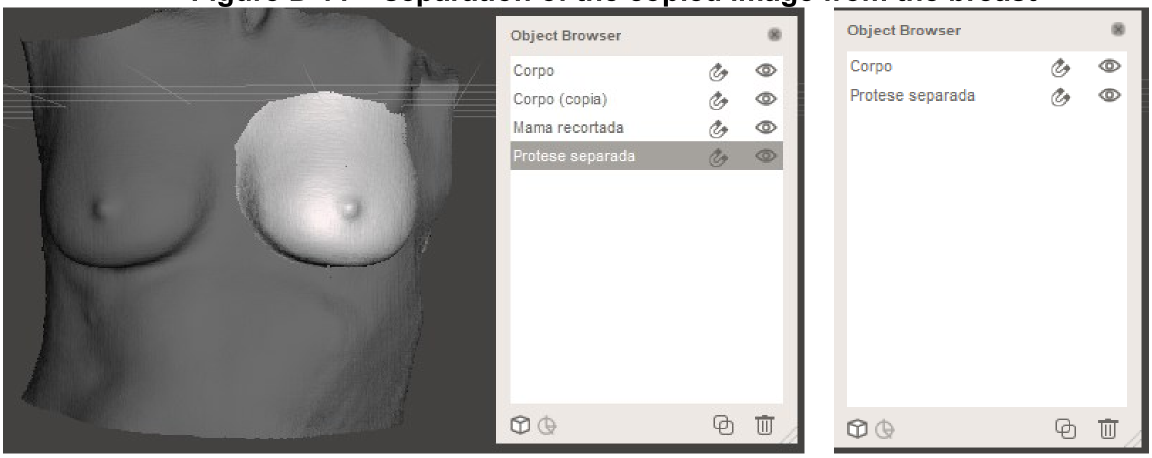
a b

Caption: a. espelhando e reposicionando
b. a cópia, reposicionada

Source: The author (2019)

Then select only the copy created, using the Select menu, and, circling the entire copy, or with a small brush, double-click the middle of the breast image. Use the separate option, to keep the Object Browser as in Figure D 10a. The copy made and the biomodel of the selected breast are erased, leaving only the original file and the biomodel, as in the Figure D 10b.

Figure D 11 – separation of the copied image from the breast



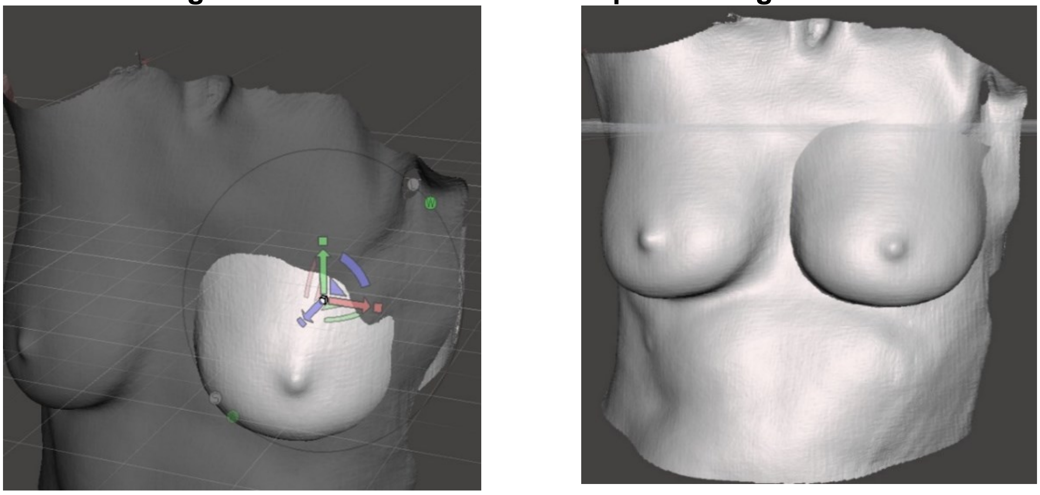
a b

Caption: a. separating copy and original
b. aspect of the Object Browser

Source: The author (2019)

Then selecting the object from the breast biomodel, and using the Edit > Transform menu, rotate and move the duplicate image of the breast on the axes, until it fits, so that it looks symmetrical to the anatomy. The ribs and sternum bone can be used as a reference, as exemplified in Figure D 12a, finalized as shown in the Figure D 12b.

Figure D 12 – Posicionando a cópia da imagem da mama



a b

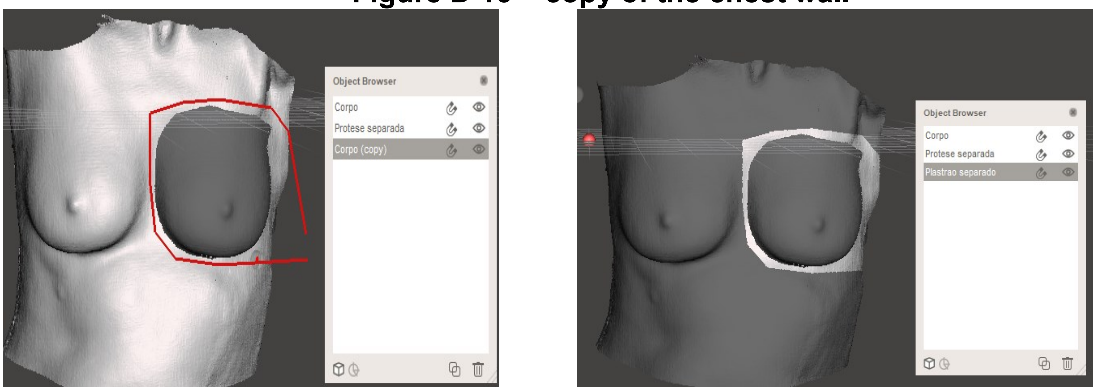
Caption: a. copy fitting
b. use of the plan to get the most symmetrical result

Source: The author (2019)

4. Copy of the chest wall

The chest wall biomodel needs to be copied. A copy of the object relative to the original body is created, which is where the editing will be made. Made the copy, select the part relative to the chest wall, as Figure D 13a. Then, using the Separate option, move the chest wall to a new object, and delete (Delete icon) the copy made from the body, as demonstrated in the Figure D 13b.

Figure D 13 – copy of the chest wall



a b

Caption: a. chest wall image selection
b. erasing the copy of the body image

Source: The author (2019)

5. Correction of breast and chest wall biomodels

The selection of objects is made with some leftover edges, to be used in adjusting the position of the breast to the chest wall. They will now be removed, respecting the anatomy of the curves of the body, using the subsistent breast as a guide, to make the regions as similar as possible.

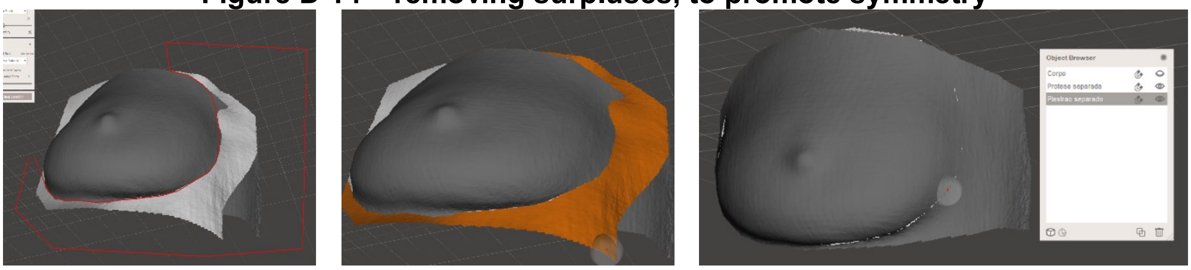
Starting with the chest wall, as demonstrated in the

Figure D 14a and

Figure D 14b, the parts that exceed the breast limit should be deleted, using brushes and lines from the Select menu, until removed the excess that had been left, as shown in the

Figure D 14c. The body object can remain hidden for easy viewing, by selecting the eye icon on the Object Browser.

Figure D 14 – removing surpluses, to promote symmetry



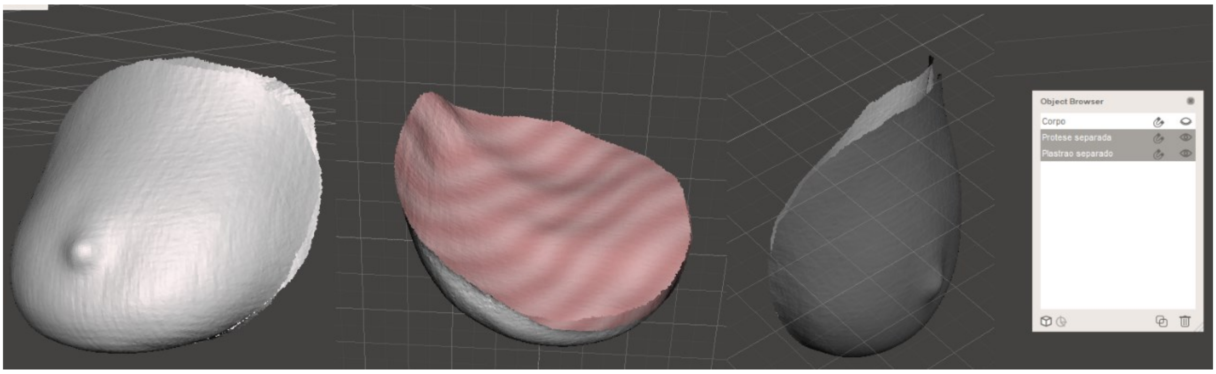
a b c

Caption: a. selection of excedents
b. removal of excedents
c. result of the adequacy of the parties

Source: The author (2019)

Next, the same procedure is performed, selecting the object of the breast biomodel, which will be cut to the limits of the chest wall biomodel, or as close as possible to it, because there are cases in which the breast biomodel is too far away from the chest wall biomodel, because the mastectomy required that a larger region was removed from the chest. At the end there should be an image as exemplified in the Figure D 15.

Figure D 15 – Clipping the excess edges in the chest wall area



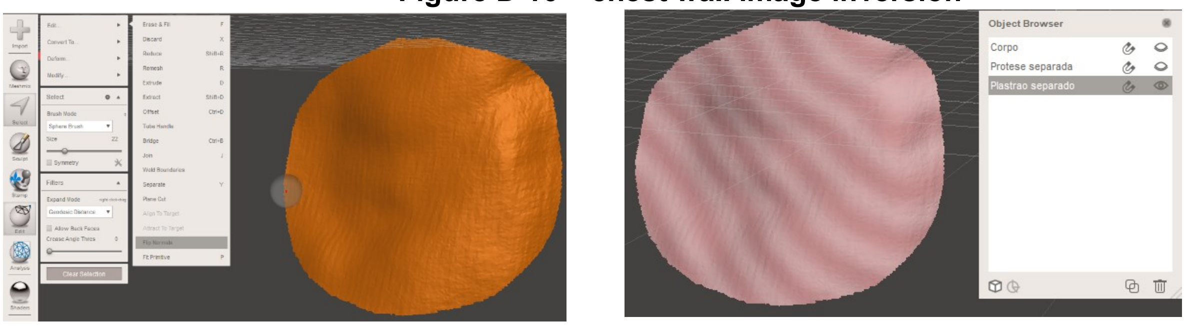
Source: The author (2019)

6. Breast biomodel joining to chest wall biomodel

As verified, the breast cannot always be perfectly fitted to the chest wall, and unevenness and recesses are perceived. In this step will be made the correction, in an anatomical way.

Meshmixer™ always identifies the front and back side of an object. Thus, the first step is to invert the front side of the chest wall by selecting the chest wall object in object browser. Using the Select option, click on each of its vertices, and choose the Flip Normals option, as shown in Figure D 16a. This will correct the right inside of the object, as shown in Figure D 16b, so that a closed solid could be created.

Figure D 16 – chest wall image inversion



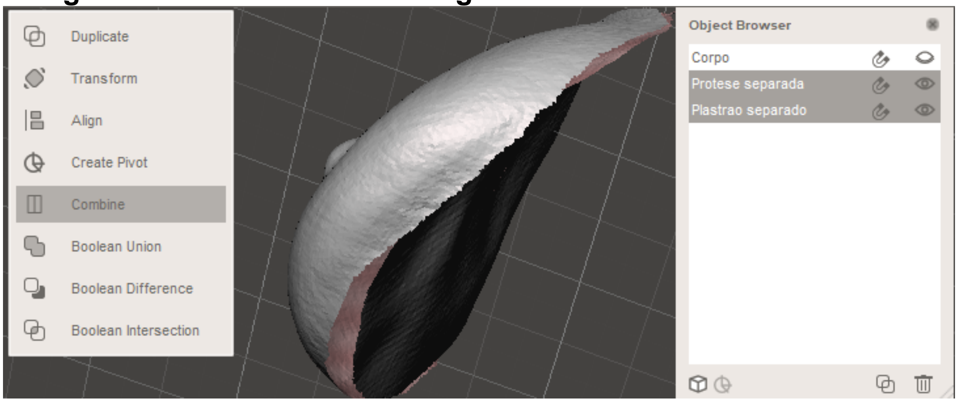
a b

Caption: a. chest wall image selection
b. correct identification of chest wall image

Source: The author (2019)

Checking that the two objects – breast and chest wall – have the edges as similar as possible, select both in the Object Browser, and click the Combine option, as demonstrated in the Figure D 17.

Figure D 17 – union of the images of breast and chest wall



Source: The author (2019)

The next step is to create a closed solid, joining the edges of the two open objects. For better viewing of them, if they are not active, border lines can be viewed with the keyboard shortcut (Ctrl + Shift + B), or in the View > Show Boundaries menu. Start by removing intersections between the two bodies, if any, so that the edges are close, but do not cross each other.

The next step can be performed in several ways, depending on the situation. The more generic form will be explained, but tools like ZipperEdge, sculpt, or Inspector, can work in specific situations.

Select the Bridge function (Ctrl + B) from the Select menu. It generates a mesh between two selected borders. Select some points in the mesh to apply the Bridge command, preferably points where the edges are closest, as exemplified Figure D 18 and Figure D 18.

This process should be carried out around 5 times, per biomodel. It is possible to take as a basis the distance shown between the first "bridge" and the second, as seen Figure D 18. The operation must be done every small span found, so that the bridges allow the closure of them.

In the file used in this tutorial, four bridge operations (Figure D 18) were performed, but the larger the breast biomodel, possibly the more times the command has to be applied.

It is important to save the file before each application of the bridge function, as the program may freeze during its use.

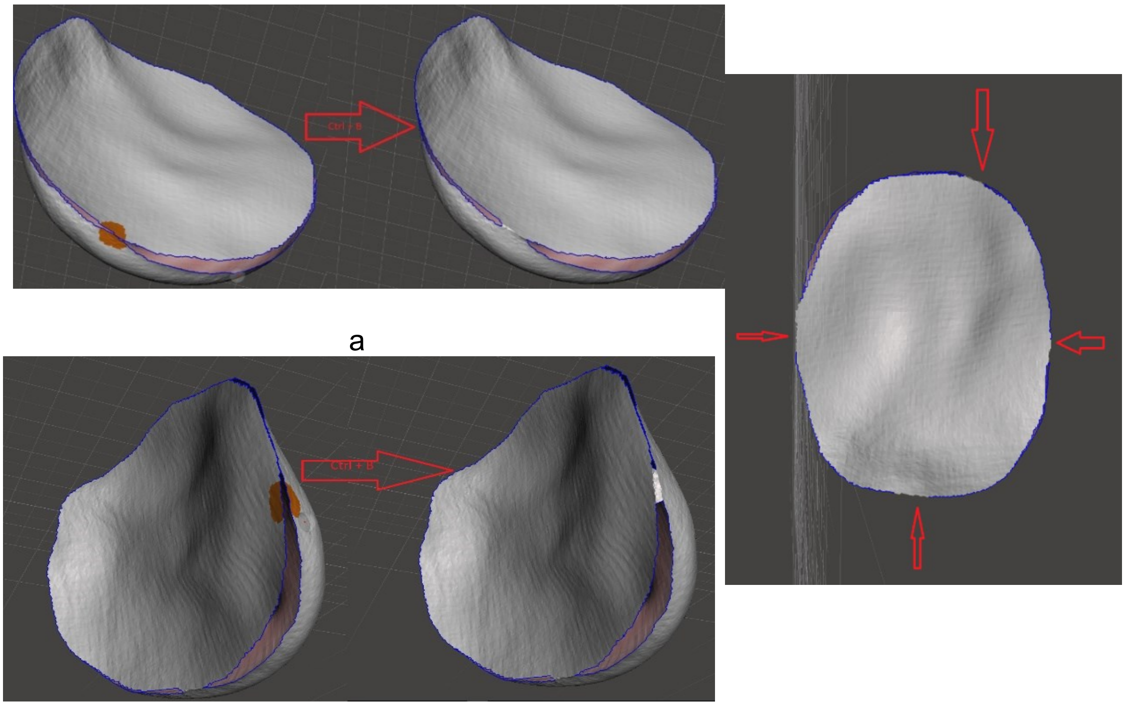
The edges, when joined together, are much simpler to close, and this is done using the Fill function, also present in the Select menu.

To do this, select the border to close. Using the Select Menu, a brush size between 6 and 10 must be chosen to allow to select small vertices of the object. To view or hide the vertices of the image, the "W" shortcut key can be used.

Using the mouse, it is possible to make an approximation of the image, until the border can be viewed clearly. As in Figure D 19a, press a double click in the mouse over the border, selecting the outline of the entire image, as Figure D 19a. Double-click should be made as close to the border as possible, otherwise it will select the entire object.

With the border correctly selected (Figure D 19b), by pressing the F shortcut button or pressing Replace in the selection sub menu, the Fill menu options can be seen. There are several choices from which to select, to help achieve a more faithful geometry to anatomy.

Figure D 18 – Creating a closed solid



a

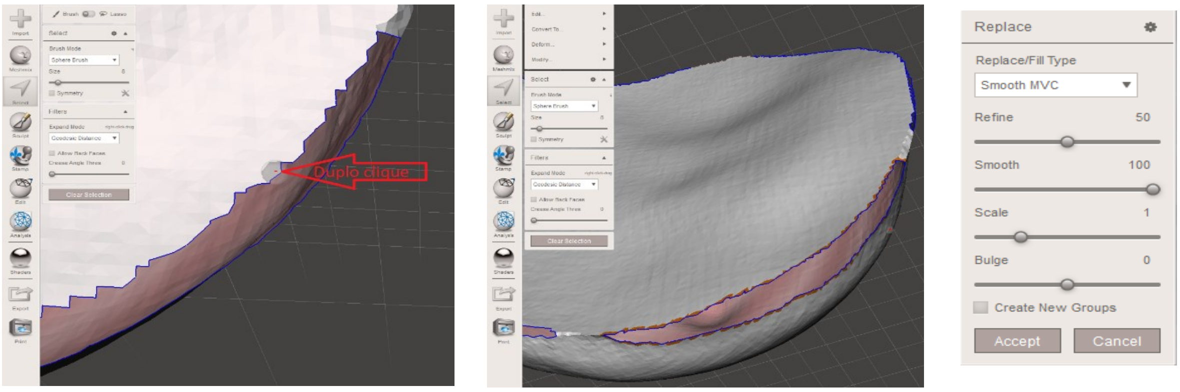
b c

Caption: a. selection of points that need to be joined

b. bridge command in operation
c. result of the union of the parties

Source: The author (2019)

Figure D 19 – Union between the adhering edges



a b c

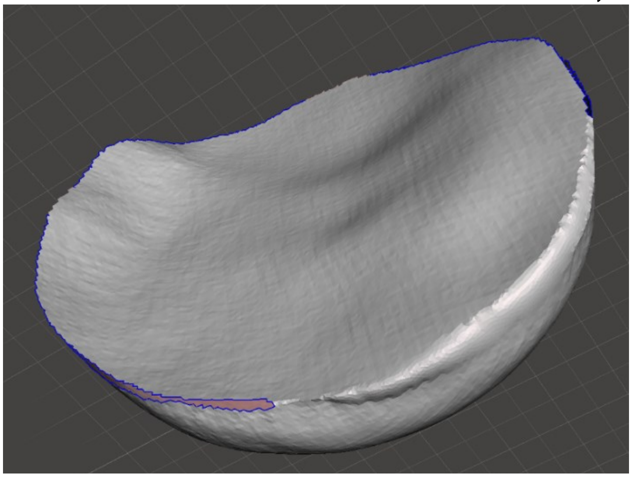
Caption: a. image contour selection
b. the Fill command, in operation
c. menu Fill options

Source: The author (2019)

The options to be modified for anatomy correction are the Scale, which increases or decreases the size of the coverage (increasing or decreasing curvature), and the Bulge option, which makes it more or less flat, depending on the chosen value. It is necessary to test different combinations to arrive at a value that respects the anatomy.

The functions explained should be used until a harmonious result is achieved, as shown in Figure D 20. A higher number of bridges may be needed, to improve the result.

Figure D 20 – Chest wall and breast biomodels, united

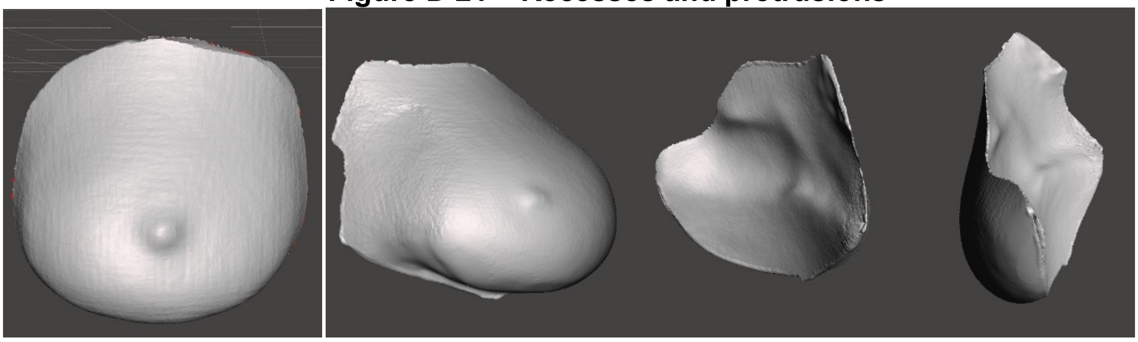


Source: The author (2019)

The procedure should be performed until all edges are closed, as Figure D 21: a breast that found a flatter chest wall, and in Figure D 21, a breast that was added to a chest wall with more recesses and protrusions. There will also be bumps in that junction (the contours of the breast biomodel). They will be smoothed in the next step.

If some red dots appear where the edges of the file, which is now closed, go to the Analysis > Inspector > Auto Repair All menu, to correct the errors.

Figure D 21 – Recesses and protrusions



a b

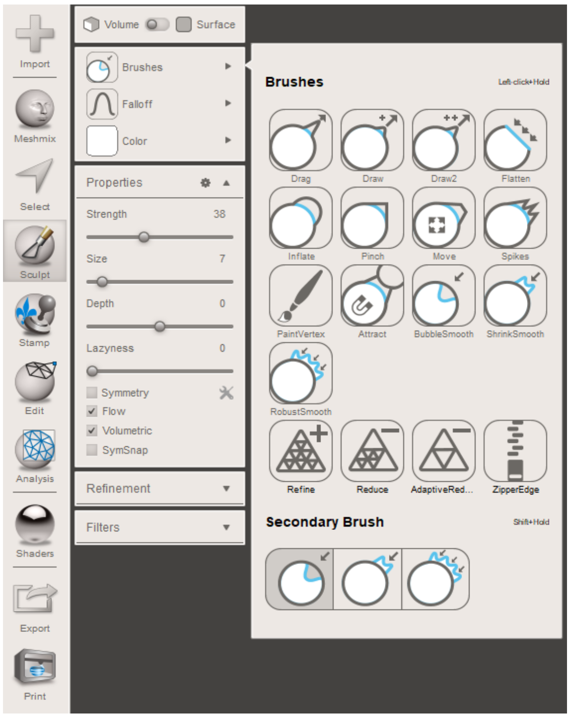
Caption: a. breast that was attached to a chest wall with few irregularities
b. breast that was added to a chest wall with more irregularities

Source: The author (2019)

7. Use of brushes to sculpt and soften the biomodel

The Sculpt menu gives access to several brushes to work with the 3D model. They allow several settings and options, which result in many combinations to perform the work. The main brushes used and their functions will be detailed below, and the others can be understood by testing the brushes with their different parameters, in some 3D model. Figure D 22a exemplifies access to the brushes, as well as their icons, and explains their operation (Figure D 22b).

Figure D 22 – Brush menu



Flatten: Flattens the selected surface

Inflate: Adds material to the mesh, radially

Move: moves part of the mesh

Spikes: creates sharp peaks in the region

BubbleSmooth: smoothes the mesh, decreasing peaks and valleys in triangles, and makes geometry more anatomical

ShrinkSmooth: stronger version of BubbleSmooth

Attract: pull the edges of one mesh, relative to the selected one

ZipperEdge: connect separate edges of a mesh

a b

Caption: a. the brushes menu
b. functions of the most commonly used brushes

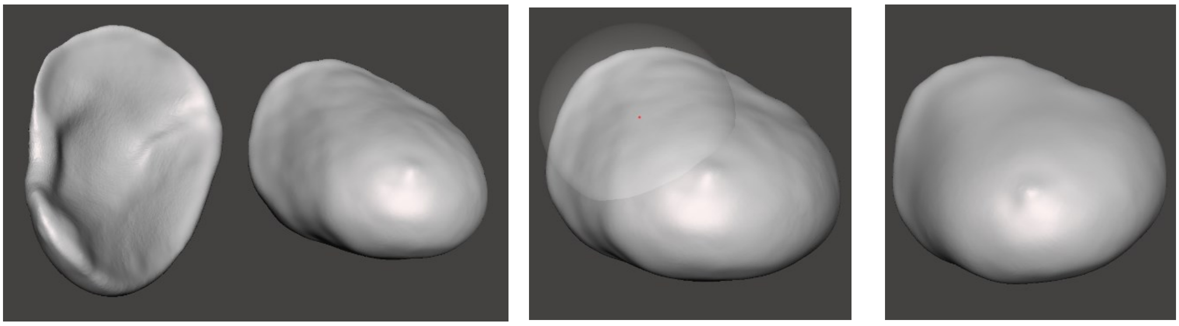
Source: The author (2019)

As an example of using brushes, it follows the application to smooth the edges generated in the process of joining the breast and chest wall biomodels. By selecting the BubbleSmooth brush, with medium strength and size, and applying to the edges of the meshes, it is possible to reach an anatomical geometry, as Figure D 23a, where the partition line generated by the connection disappears.

There are also some bumps left in the breast biomodel mesh (Figure D 23b). They can be smoothed with both the BubbleSmooth brush and shrinksmooth, using a larger area in the brush. The result should be a surface like that seen in Figure D 23c.

The harmony of the resulting geometry can be observed by enabling the visualization of the biomodel meshes together with that of the Figure D 23a.

Figure D 23 – Use of brushes to enhance the surface of the biomodel



a b c

Caption: a. hiding the junction between the biomodels
b. smoothing the shoulders
c. the result

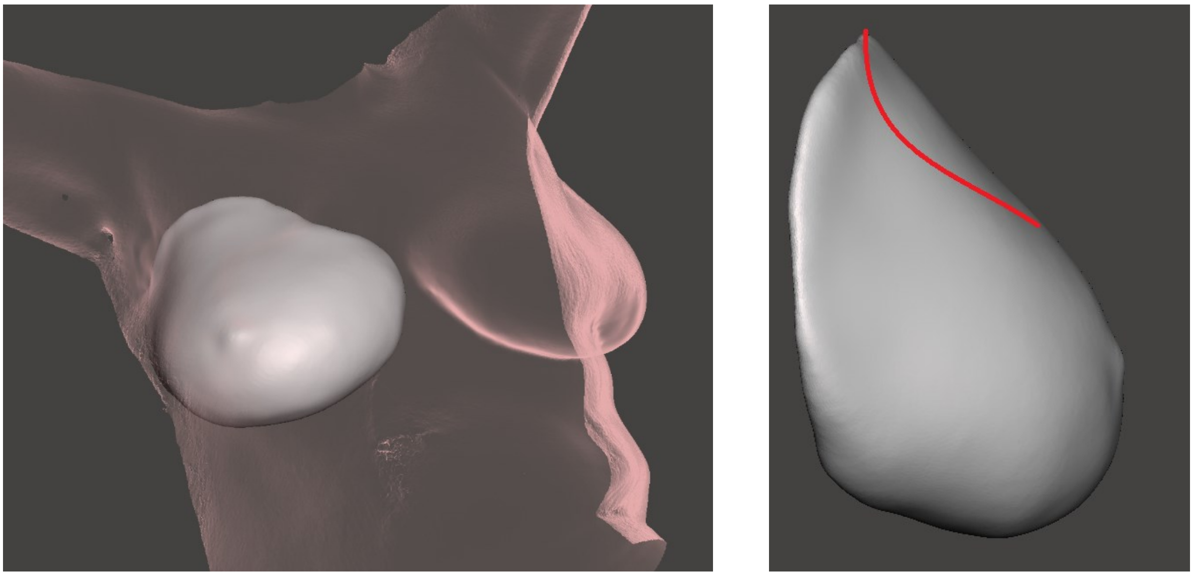
Source: The author (2019)

This process varies greatly, depending on the geometry of each patient, and requires a case-by-case analysis. After the correction and adaptation of the geometry is finished, an analysis can be made with the patient or person responsible for requesting the prosthesis for final verification.

The last step is to export the file. Select only the breast biomodel in the Object Browser and click the File -> Export menu. Selecting the .stl extension, as Figure D 25. The biomodel save process can take several minutes, depending on the complexity of the mesh. Figure D 25 demonstrates the file export process.

As a file exported in the format "STL ASCII Format", it can be opened by Blender software, and in it can be generated the mold for the prosthesis.

Figure D 24 – Biomodel finish



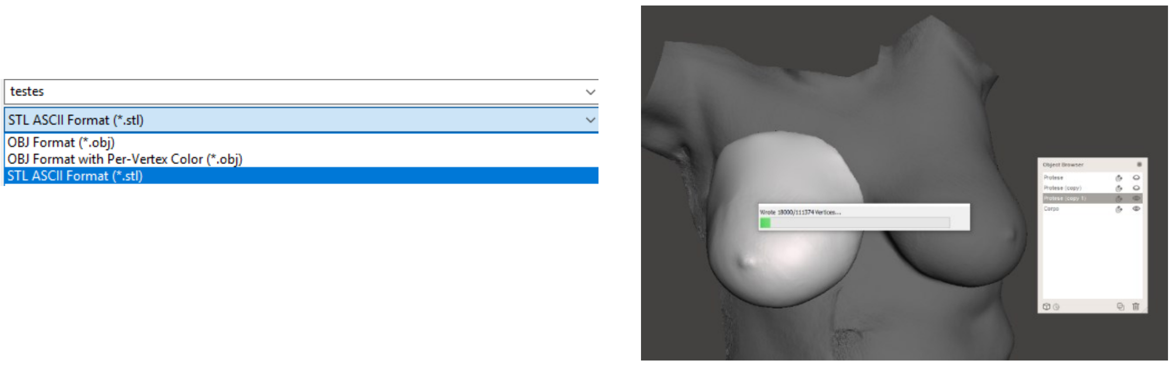
a B

Caption: a. adequacy of the biomodel to the thorax
b. link between biomodel and body

Source: The author (2019)

s.

Figure D 25 – Exporting the biomodel



a b

Caption: a. choice of file export format
b. the file export process
Source: The author (2019)

APPENDIX E – Manual for cast generation for external breast prosthesis, customized, from the breast biomodel

Introduction

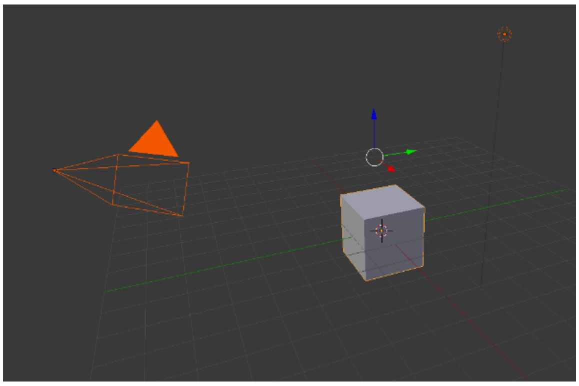
This manual aims to explain the step-by-step method to obtain a breast biomodel mold that was attached to the chest wall biomodel. The objective of this process is to generate a mold that can give rise to an external breast prosthesis.

The instructions below are based on a model designed with Blender software, and the images used come from three-dimensional digital capture, which files are saved in the format stl.

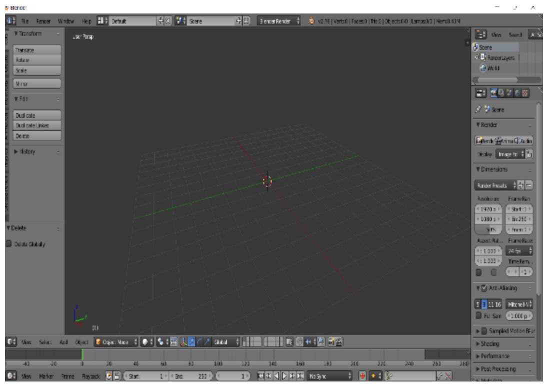
1. Creation of molds, from the biomodel generated

Blender's standard interface, as seen in Figure E 1, comes with some sample items, by default that need to be erased. By pressing the keyboard shortcut A (All) twice, and pressing the Delete key, the scene will be empty, as seen in the Figure E 1b.

Figure E 1 – Cleaning Blender's home screen



a



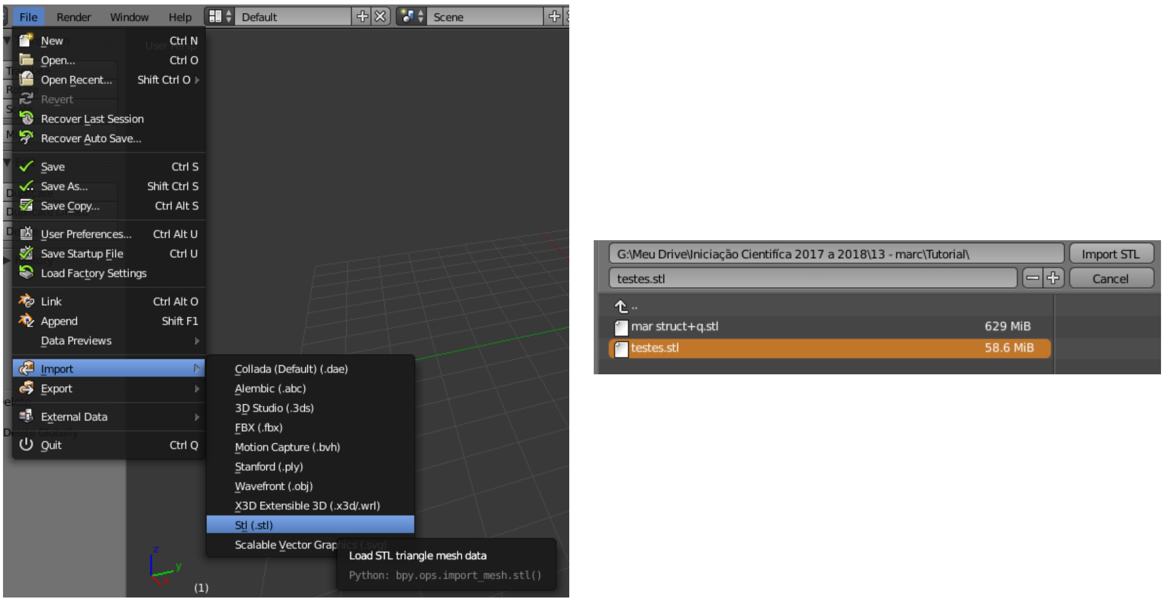
b

Caption: a. Blender's inicial screen
b. ready to work scene

Source: The author (2019)

Then the biomodel saved in Meshmixer in the .stl format must be imported for Blender. This is done by clicking on the File > Import > STL (Figure E 2 a) menu. A check box opens, and where the file is, it must be selected with the mouse. Next, click on "Import Stl", as viewed in the Figure E 2 b.

Figure E 2 – Importing the stl file to Blender



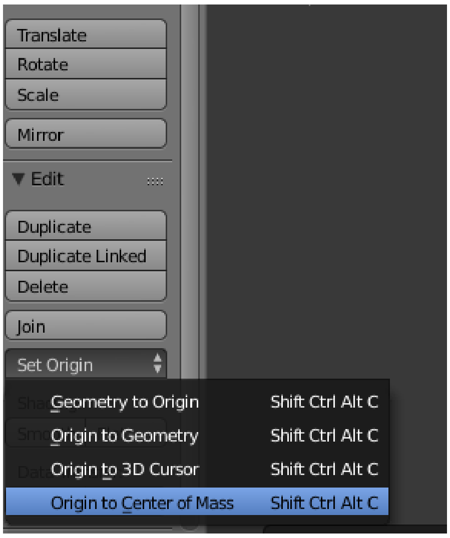
a b

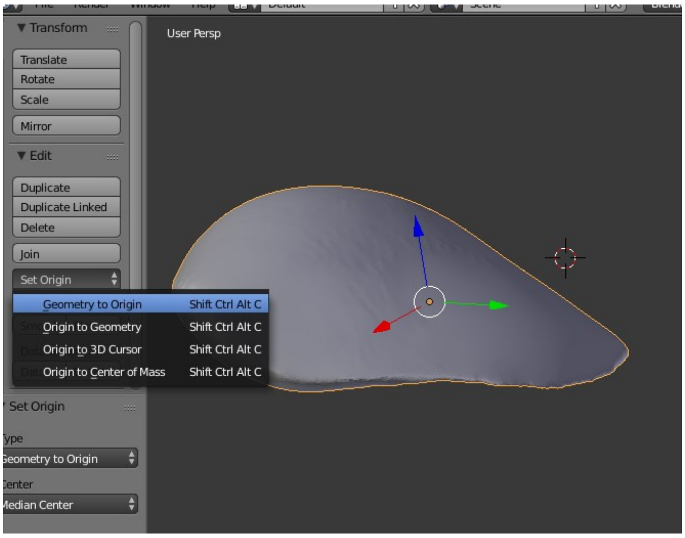
Caption: a. Blender home menu
b. choice of file location

Source: The author (2019)

The next step is to define the position of the biomodel in the "origin" of the program, because sometimes the generated model appears in a random coordinate in space, which can hinder the work of the program. To set the center of mass of the biomodel as origin also facilitates its visualization. By accessing the left side menu, as viewed Figure E 2 , or using the Ctrl+Shift+Alt+C keyboard shortcut, the options for setting the source are displayed. "Origin to Center of Mass" must be selected, and then again in the menu (Figure E 3a), the "Geometry to Origin" option should be chosen. Thus, the model will be fixed in the position called "origin", as demonstrated by the colored axes, in the center of Figure E 3b and Figure E 2 .

Figure E 3 – The best initial positioning





a b

Caption: a. menu where the center of mass of the biomodel is indicated
b. menu where the biomodel is pointed to the origin

Source: The author (2019)

2. Creation of the partition line in the model and division of the parts of the cast

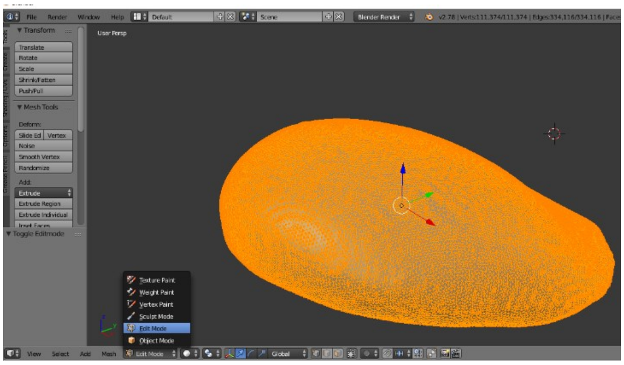
For template creation, the file needs to be divided into two parts. This selection is manual, and must be made in what will be the partition line of the cast, that is, the line that divides the concave part of the convex part. Some commercial (paid) software allows the selection of this line automatically, but not Blender.

Thus, the line will be selected manually, using Blender's Knife feature (Figure E 4 a). Considering that the material to be leaked in the mold will be flexible, it is acceptable to have to stretch a little the prosthesis that will come out of it, at the time of demolding, because it will return to its original size. Therefore, there is greater tolerance in the partition line, and the option is made depending on the biomodel having recesses specific to the anatomy of the body.

By opening the mesh editing menu, called "Edit Mode", in the TAB key shortcut, or in the bottom menu, as viewed Figure E 4 b, it is possible to see the selected mesh.

Figure E 4 – Seleção do biomodelo e da ferramenta para efetuar a separação

a



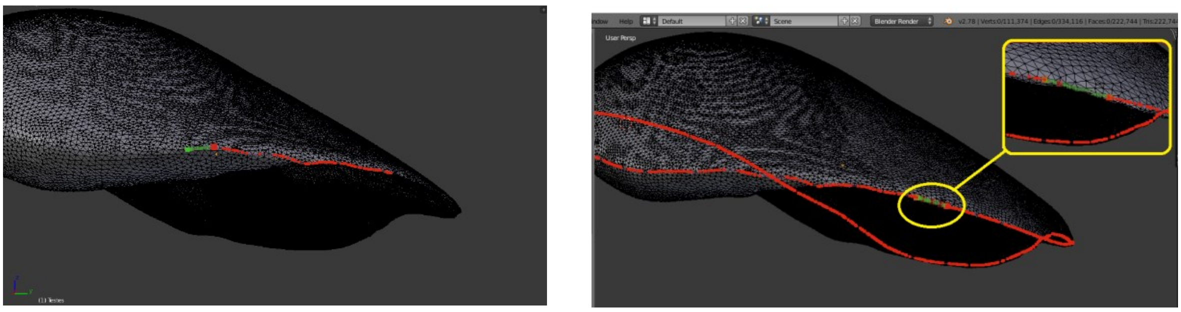
b

Caption: a. location, in the menu, of the tool "Knife"
b. biomodel mesh, selected

Source: The author (2019)

Using the A key, as done earlier, the overall selection of the part is removed to allow the partition line to be made.

Figure E 5 – Partition line selection



a b

Caption: a. generating the partition line, in the biomodel
b. biomodel to the closing point of the mold partition line

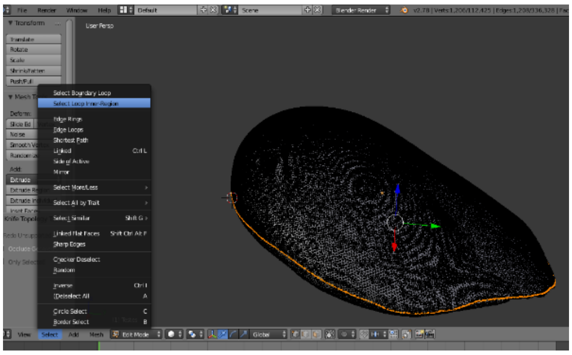
Source: The author (2019)

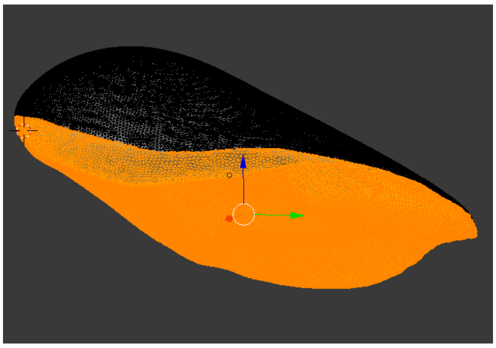
Using the K shortcut key, or the space key and looking for the "Knife" command and selecting "Knife Topology Tool" (Figure E 4 a), the selection is enabled, and allows to click on several points of the mesh (Figure E 5 a), until generating a closed partition line. The last point to be selected must be in the same location as the first, generating the line that can be viewed in the Figure E 5 b.

To verify that the partition line was done correctly, with the partition line selected, it should be applied the Select > Select Loop Inner-Region tool from the bottom menu (Figure E 6a). If the partition line selection has no errors, holes, or intersections, one of the parts of the template is selected Figure E 6b. If this option selects the entire object, the partition line needs to be redone.

Care must be taken not to cut parts in the void, and remember to select the endpoint at the same location where the starting point was selected.

Figure E 6 – Partition line selection





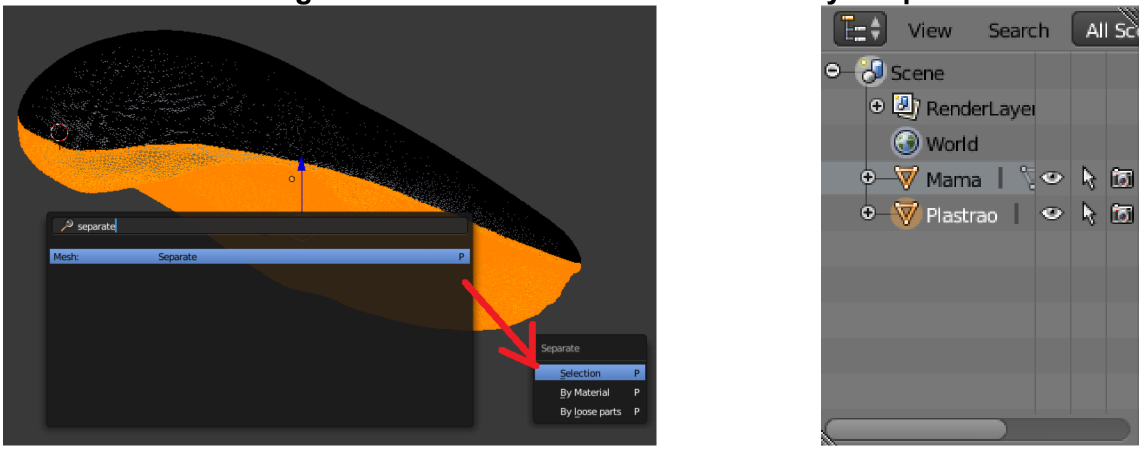
a b

Caption: a. finished partition line, in the biomodel
b. proof that the biomodel generated a partition line

Source: The author (2019)

With one of the selected parts, using the keyboard shortcut (P key), or by pressing the space bar and typing "Separate > Selection", the template will be divided into two models, which can be viewed in the Object Browser, on the upper right side (Figure E 7 a). They can be renamed, to facilitate organization (just double click the left mouse button). To help to view and hide one side of the biomodel, press the eye icon (Figure E 7 b).

Figure E 7 – Division of the biomodel by the partition line



a b

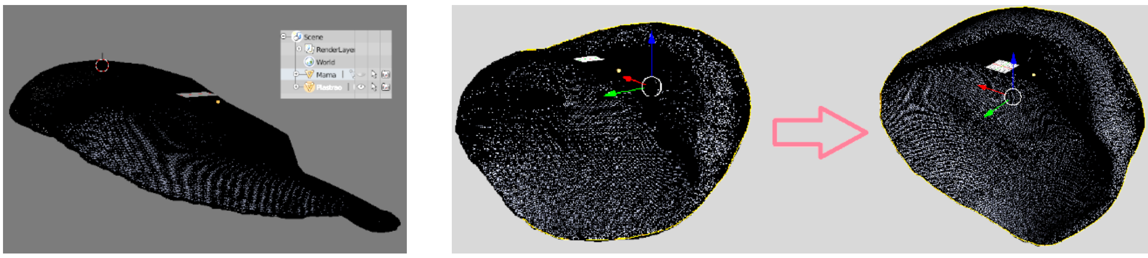
Caption: a. operation of the "Separate > Selection" command
b. Mouse arrow, pointing eye icon

Source: The author (2019)

3. Creation of the side flaps for cast fixation

With one of the parts of the mold selected, as Figure E 7 a (the triangular icon in the menu is left with a yellow backlight), the other part should be hidden. Open edit mode (TAB key), as displayed in Figure E 8 b. In the following example, the chest wall has been selected.

Figure E 8 – Generation of cast tabs



a b

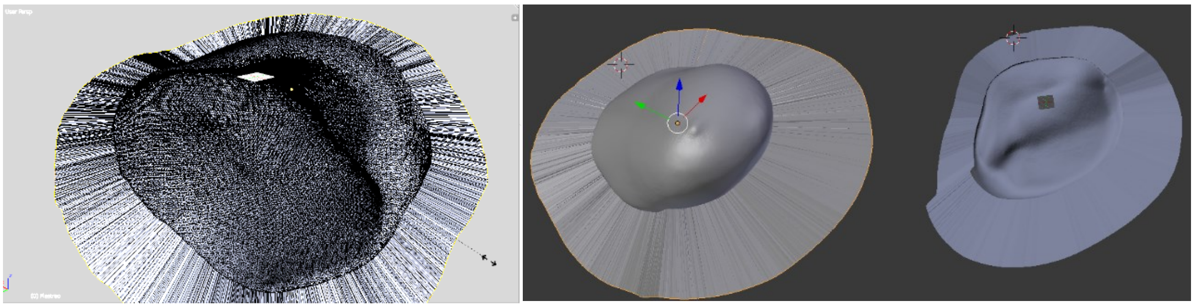
Caption: a. concealment of one of the parts of the biomodel
b. Blender editing mode

Source: The author (2019)

Using the Shift+Alt keys and the right mouse button, the edges of the object must be selected until it ensures a closed line (Figure E 8 b). If any points are forgotten, the object will have noticeable holes when creating the side tabs. If so, it is needed to go back and select the partition line correctly.

With the selected line, using the "S" keyboard shortcut, open the Scale option, and as Figure E 9 a. With the help of the mouse, create a tab with leftover in size, around the image that will be the template, for later adjustments.

Figure E 9 – Creation of the flap around the cast



a b

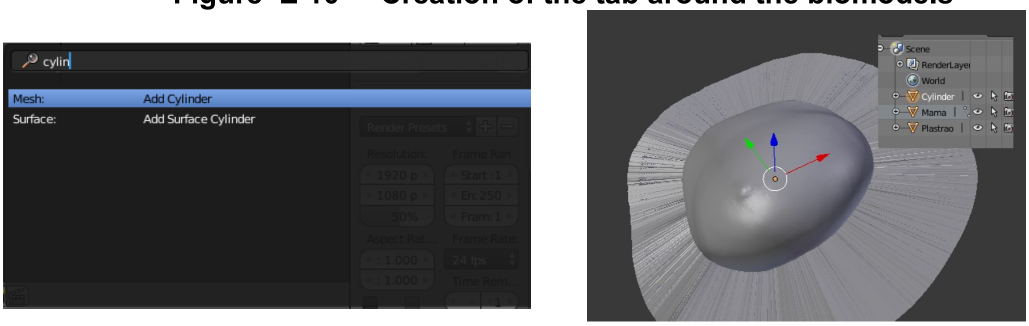
Caption: a. creation of flap around the mold
b. result

Source: The author (2019)

Then, hiding the chest wall image, select the breast image, and perform the same procedure. The result should be similar to that of Figure E 9 b.

The edges created now need to be the same size. For this, the two meshes need to be visible, and a third object will be created in object browser: a cylinder.

Figure E 10 – Creation of the tab around the biomodels



a b

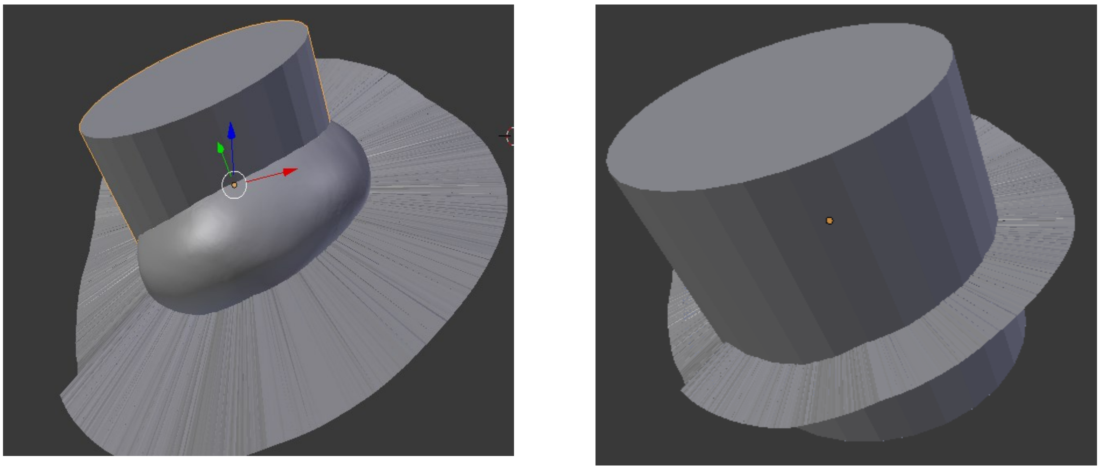
Caption: a. adding the cylinder to the object
b. positioning of the cylinder insert, using the arrows

Source: The author (2019)

Without any object selected (Figure E 10 a), open the command menu and type "Cylinder". Select this created object in the Object Browser, and, using the move arrows, position this cylinder in the center of what the breast mold will be, as visualized in the Figure E 10 b.

Using the Scale and Rotate functions, fit the cylinder so that it covers, hides, entire biomodel, and leaves a volume of material on top, and underneath the biomodel (Figure E 11 a). It will be needed to apply scale and rotation to one of the part planes. This is done by pressing the S and R key to select the option, and then clicking or X, or Y, or Z, to select which plane will be rotated. In the sequence, the part needs to be adjusted to make a uniform edge across the part, as visualized in the Figure E 11 b.

Figure E 11 – Positioning of the cylinder in the biomodel



a b

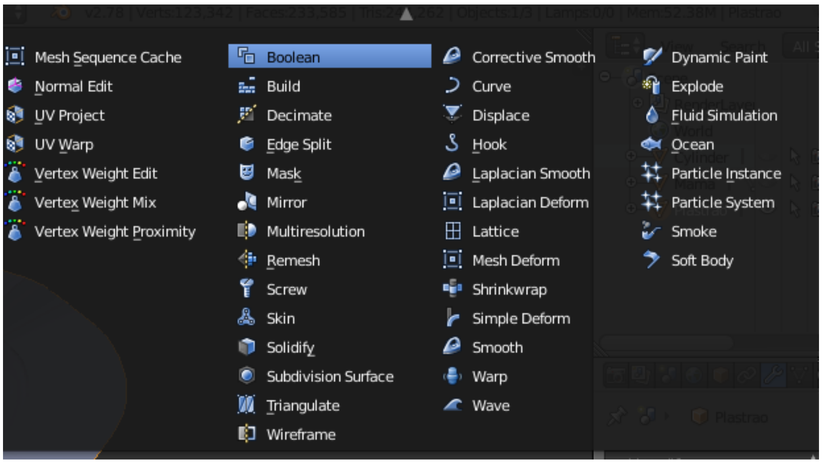
Caption: a. adding the cylinder to the object
b. proper positioning of the cylinder

Source: The author (2019)

Then hide the cylinder, and select one of the parts of the biomodel. In the example below the chest wall was selected, and the breast was hidden, as seen in Figure E 12 a, and then the reverse selection will be made.

By selecting the chest wall, a menu on the left side below the Object Browser can be accessed (Figure E 12 a); the "Modifier" column must be selected (an icon with a fork wrench). Select "Add Modifier > Boolean", as seen in Figure E 12 b.

Figure E 12 – Choosing boolean operation



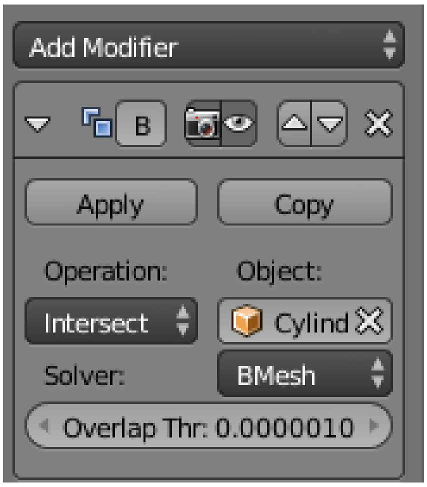
a b

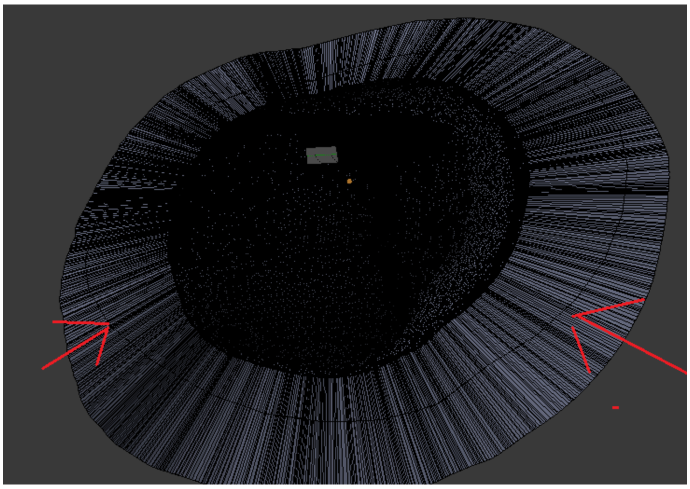
Caption: a. selection of the object on which the operation will be performed
b. selection of the operation that will be performed on the object

Source: The author (2019)

A menu will open (Boolean operations menu). From it, the Intersect option should be chosen, with the Cylinder object, as Figure E 13 a. Opening the chest wall biomodel in edit mode, it is possible to verify that the cylinder line was created in the part (Figure E 13 b).

Figure E 13 – Performing the boolean operation





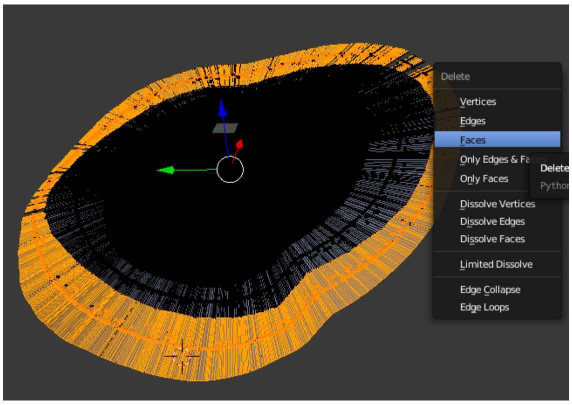
a b

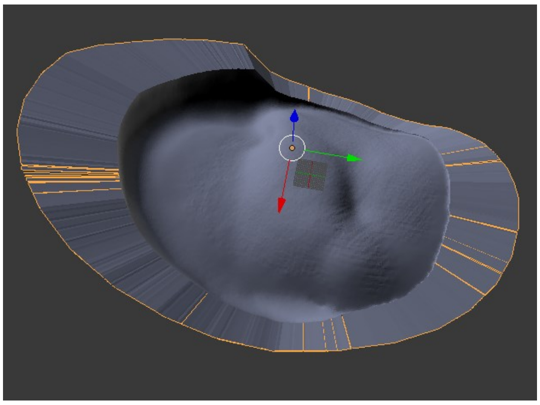
Caption: a. selection, in the Boolean operations menu
b. the operation, already performed

Source: The author (2019)

Using option C, in face selection mode, the outside should be selected and erased, using delete > faces, as seen Figure E 14 a. The result must be similar to what is shown in Figure E 14 b.

Figure E 14 – Chest wall cast edge outside cutout





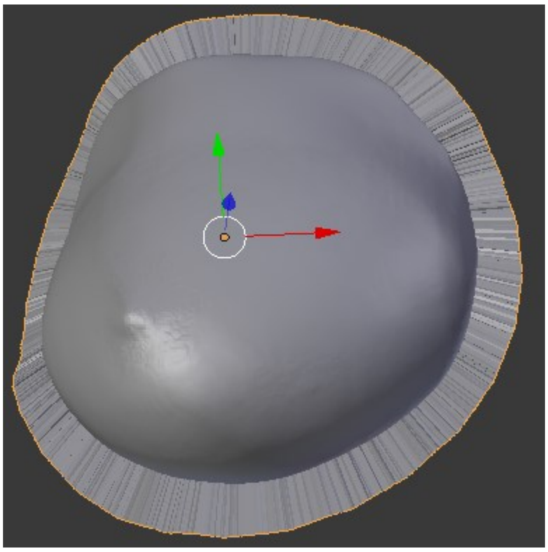
a b

Caption: a. selection from the outside
b. the result

Source: The author (2019)

The same procedure should be performed for the breast part, leaving only the selected part of it visible, applying the Boolean Figure E 13 , and performing the cutouts of Figure E 14 . The final result should be similar to that found in the Figure E 15 .

Figure E 15 – Breast mold edge outside cutout

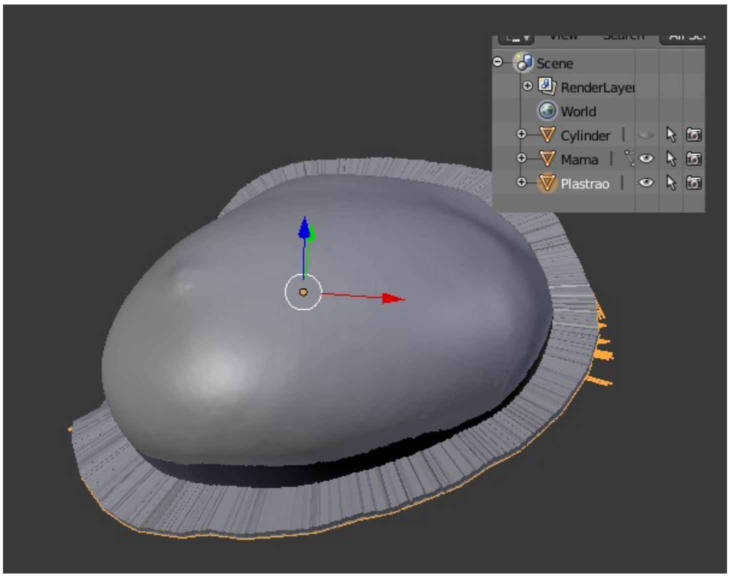


Source: The author (2019)

4. Providing thickness to the final product

After the edge selection steps, it is needed to provide thickness to the surfaces of the casts. Select the chest wall, to enter edit mode, and select the shortcut key A, to select the entire object. Then press the E key to perform the thickening operation, and enter the value (in mm) of the desired thickness, then pressing enter, right after. If the thickness is coming out on the wrong side, type the negative value (-2, for example). The final result can be seen in the Figure E 16 .

Figure E 16 – Adding surface to the breast cast

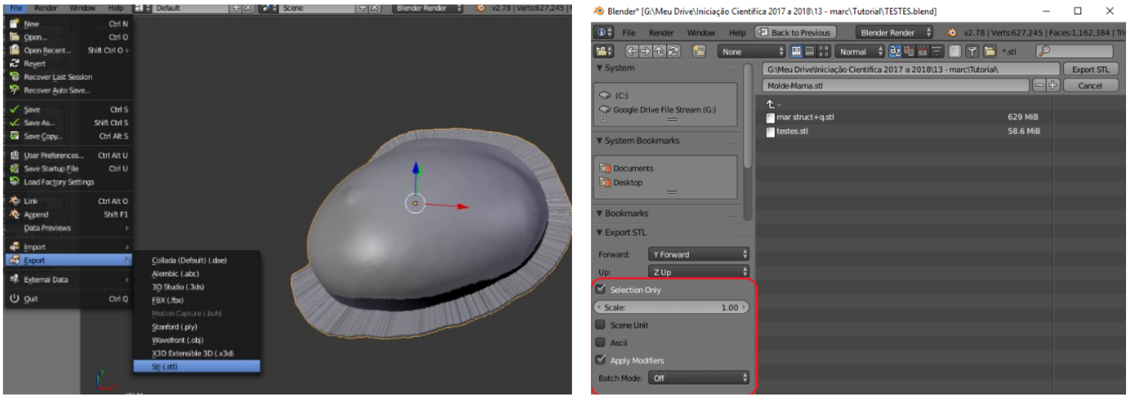


Source: The author (2019)

5. Exporting the final files

To export both sides of the cast, one object at a time must be selected in object browser. Leaving only the chosen one visible, access the menu "File > Export > STL", as seen Figure E 17 a, keeping the export options as defined in the Figure E 17 b.

Figure E 17 – Export of each template file



a b

Caption: a. export commands
b. options to be set

Source: The author (2019)

6. Post processing

Later processing steps, such as corner rounding or correction of null geometries, can be performed in Meshmixer™ or other three-dimensional image editing software, if needed.

APPENDIX F – “Rotomolding” manufacturing

During the literature survey, a patent of breast prosthesis conceived by the rotomolding process was found (KAUSCH, Walter 0., 1962). The process presented itself as a possibility to be analyzed, with adaptations.

As defined in the subsection “2.4.2 Technologies dependent on industrial processes”, rotomolding is an industrial process conceived to generate hollow parts, and this feature is why rotomolding use was considered for this study.

To achieve this model similar to rotomolding, it was necessary to build an equipment, of sufficient size so that a cast of a prosthesis could rotate in the system, and that does not exist in the market. The name “rotomolding” appears in quotation marks, because the concept of rotomolding itself presumes the use of heat in the process, which does not occur in the design of the external breast prosthesis of this research.

Again, following the ETO methodology as recommended by Rozenfeld (2006), the equipment was planned to specifically meet NUFER, at that time representing what would be equivalent to a non-profit association that ordered such product.

As it was intended that any institution could use the sketch to make its own machine, it could not use very costly items or difficulty in acquisition, as defined in the design requirements.

In the informational design, it was established that the size of the machine needed to contain each of the twenty breast casts and this was used to define the necessary printing volume for the machine to be used.

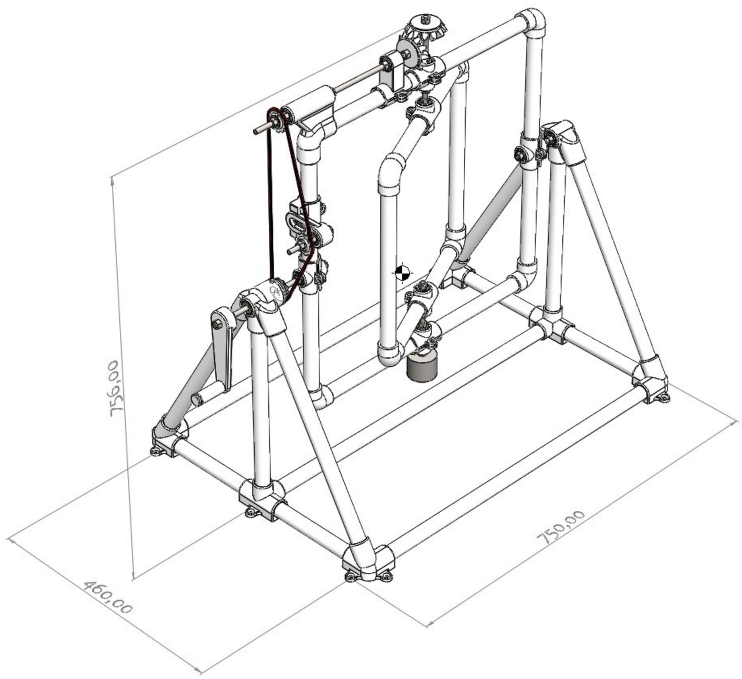
The conceptual design had three-dimensional modeling performed in SolidWorks and calculations on the commercial material (off-the-shelf) required. The detailed design determined the direction of printing of the parts, measurements of the cuts of pvc pipes and how the assembly would be carried out.

Based on models of existing rotomolding machines of larger size, a machinery model was developed, in a PVC structure, which connections are shelf or printed in PLA (Figure F 1). PVC pipes, fittings, chain, bearings, bolts, nuts and shafts were purchased commercially, within the budget equivalent to U$ 40. The highest value corresponded to the PLA roll used to print the non-commercial parts.

The equipment was composed by two frames, connected between them by metallic axis. Their conception was projected so that whenever the external frame made a complete turn, the internal frame performed 1.5 turn, in the perpendicular sense, simultaneously. This intersection of movements proportionate all the walls of the cast to receive the material that will compose the part, and the fact that the cast is always turning in the middle of both axes, avoids the material to accumulate in the center of the mold. The movements of the axes begin by the impulse of a handle, manually operated, in this project adapted from the existing industrials. In order to make the movements of the axes easier, bearings were inserted in connections held by the pvc tubes of each axis. There is also a triangular structure that holds firmly both axes and the handle.

The printing of the components of the "rotomolding" machine was made in PLA of the brand Makergear®. The external breast prosthesis casts were printed in PLA manufactured by the company Gravaplast®, from Joinville.

Figure F 1 – “Rotomolding” machine project



Source: Rodrigo Pulido Arce and Leonardo Brandt (2019)

Casts for the rotomolding system aim to generate a hollow object (RUSCHE, 2004). With a properly designed cast the challenges of the method fall on the amount of material that is intended to have on the cast walls and how this material behaves during the movement of the cast.

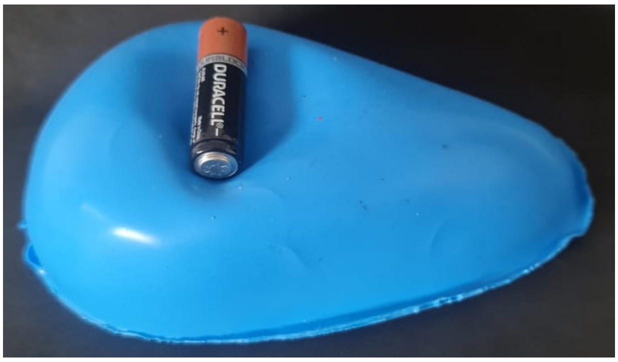
The machine was first tested with a transparent cast because there was a need to control whether the cast would be fully filled. A cast in transparent acetate, of Easter egg, was used, which even keeps similar to the shape of the breast cast. As it was a large form, the researcher closed it not as ovoid, but as an ovoid medium, with an equally transparent acetate, but flat, in order to save material, without compromising the test.

Based on the dimensions of the shape, its volume (39264.91 mm^{3}) was calculated and it was determined that 20% of the total would be used to form the final object layer. Silicone rubber was used for testing. As it operates with a catalyst, it was mixed only when the system was all assembled and fixed to the table, able to receive the cast and be rotated.

There are recommendations for silicone cast rubber to be used in vacuum in order to avoid air bubbles, or with a low viscosity liquid (BJORKE, 1992). However, in the process of "rotomolding", greater fluidity was mandatory, to help the mixture between polymer and curing agent to spread and cover the entire surface of the cast. As it was a double-part cast, a seal was required. Acetate does not require any releasing agent to avoid the silicone rubber not to stick on the cast.

Externally the copy was faithful, and internally there was accumulation of material in a specific region, but the copy of the model, externally, was executed with such perfection that it retains air inside, that is, the final product was fully sealed (Figure F 2).

Figure F 2 – Product resulting from test of the "rotomolding" machine



Source: The author (2019)

The surface that should make up the prosthesis was thinner than the projected, though. This occurred because part of the material placed inside the cast accumulated in a specific area, generating a thicker region. This occurred possibly due to the irregularity of the manual spinning.

The system functioned as conceptualized in the original rotomolding, and according to the designed, filled the cast fully, leaving its interior hollow, validating the equipment developed.

A two-part cast was designed for a second testing in the same equipment. It was made from the breast biomodel file of one of the research participants and with a few steps, a new file was obtained, using the free Blender software.

The choice was testing the smallest breast surface: 54201.1 mm^2. Its surface was multiplied by the aimed thickness of 3.0 mm (resulting 162.603,3), and then multiplied for the factor 1,33, considering that each ml of the silicone rubber results in 1.33 grams.

216.26 grams of silicone rubber were catalyzed for testing in two steps. The first 5.0 g were used manually, for the region and color of the areola, and half an hour later, the rest of the material, in the closest color measured as being from the rest of the skin, was placed inside the cast, to be rotated in the machine.

Even considering the machine, it should be kept in mind that there is a region of the cast – the areola and the nipple – that will have to be performed manually, depending on the different coloring. The silicone rubber needs a time interval to catalyze, and only then it can receive the amount for filling the rest of the breast cast.

In the second test, this time already with the prosthesis cast, some regions were so thin that they seemed to have different color, when in fact they were a transparency generated by the lack of material. It had accumulated in the extreme region of the cast, probably by centrifugal force, similarly to the first test.

The hypothesis is that this occurred because of the irregular turning of the machine, which could have the system operated by a controlled, electronic mechanism, which could be developed on an Arduino plate, which also has low-cost. This, however, depends on a study of movements and electronics, which was not the target of this thesis. It is, however, an alternative tested, but as it was not the one that obtained the best results, it is described as a starting point and suggestion for future studies.

The design of the main equipment – the rotomolding machine – is approved, according to tests carried out in the NUFER laboratory, one of which is registered in Figure F 3. It weighs 4.7 kg and fits in a stroller.

Figure F 3 – The "rotomolding" machine, in operation

Source: The author (2019)

The following estimate exposes the cost of a unit of that equipment, although it was not the chosen as the best option for implementing the method.

Its costs were calculated without considering the costs of design, printing and assembly hours. Improvements, in order to increase the number of shelf connections and reduce printed connections, as well as to automate the operation of the machine, should change this cost reported in Table F 1. Taking into account the price of one dollar, in January 2022, for R$ 5.50, the estimated reference value, per equipment, is $ 70.89.

Table F 1 – Cost budget of the "rotomolding" machine

OUTPUT	COST (U$) package price	COST (U$) total used
pvc pipe 25,0 mm	2,73	3,91
6000,0 mm standard length		8600,00 mm
off-the-shelf pvc connectors	0,13	1,02
different types/medium cost by piece		
threaded standard bar	2,18	9,60
1000,0 mm standard length		
PLA for connectors	20,00	26,00
kg		1,3
gear	0,73	2,18
per piece		3
bearings	0,91	13,64
per piece		15
screws and nuts		14,55
different types/medium cost by piece		
bicycle chain	3,64	20,00
per piece		1
TOTAL		**70,89**

Source: The author (2020)

ANNEX A – DataSUS (december/2019) screens: mastectomies x reconstructions

› PROCEDIMENTOS HOSPITALARES DO SUS - POR LOCAL DE INTERNAÇÃO - BRASIL

AIH aprovadas segundo Região
Procedimento: 0410010057 MASTECTOMIA RADICAL C/ LINFADENECTOMIA, 0410010065 MASTECTOMIA SIMPLES, 0416120024 MASTECTOMIA RADICAL C/ LINFADENECTOMIA AXILAR EM ONCOLOGIA, 0416120032 MASTECTOMIA SIMPLES EM ONCOLOGIA
Período: Dez/2019

Região	AIH aprovadas
TOTAL	689
1 Região Norte	28
2 Região Nordeste	114
3 Região Sudeste	371
4 Região Sul	125
5 Região Centro-Oeste	51

Fonte: Ministério da Saúde - Sistema de Informações Hospitalares do SUS (SIH/SUS)

Notas:

1. Dados referentes aos últimos seis meses, sujeitos a atualização.
2. A partir do processamento de junho de 2012, houve mudança na classificação da natureza e esfera dos estabelecimentos. Com isso, temos que:
   - Até maio de 2012 estas informações estão disponíveis como "Natureza" e "Esfera Administrativa".
   - De junho de 2012 a outubro de 2015, estão disponíveis tanto como "Natureza" e "Esfera Administrativa", como "Natureza Jurídica" e "Esfera Jurídica".
   - A partir de novembro de 2015, estão disponíveis como "Natureza Jurídica" e "Esfera Jurídica".

› PROCEDIMENTOS HOSPITALARES DO SUS - POR LOCAL DE INTERNAÇÃO - BRASIL

AIH aprovadas segundo Região
Procedimento: 0410010090 PLASTICA MAMARIA RECONSTRUTIVA - POS MASTECTOMIA C/ IMPLANTE DE PROTESE
Período: Dez/2019

Região	AIH aprovadas
TOTAL	138
1 Região Norte	1
2 Região Nordeste	19
3 Região Sudeste	90
4 Região Sul	21
5 Região Centro-Oeste	7

Fonte: Ministério da Saúde - Sistema de Informações Hospitalares do SUS (SIH/SUS)

Notas:

1. Dados referentes aos últimos seis meses, sujeitos a atualização.
2. A partir do processamento de junho de 2012, houve mudança na classificação da natureza e esfera dos estabelecimentos. Com isso, temos que:
   - Até maio de 2012 estas informações estão disponíveis como "Natureza" e "Esfera Administrativa".
   - De junho de 2012 a outubro de 2015, estão disponíveis tanto como "Natureza" e "Esfera Administrativa", como "Natureza Jurídica" e "Esfera Jurídica".
   - A partir de novembro de 2015, estão disponíveis como "Natureza Jurídica" e "Esfera Jurídica".

ANNEX B – DATASUS screens, showing the amount paid to doctors' fees

Não seguro | tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/qiuf.def

INFORMAÇÕES DE SAÚDE
AJUDA
DATASUS Tecnologia da Informação a Serviço do SUS
NOTAS TÉCNICAS
DATASUS

PROCEDIMENTOS HOSPITALARES DO SUS - POR LOCAL DE INTERNAÇÃO - BRASIL

Valor serviços profissionais segundo Região
Procedimento: 0410010090 PLASTICA MAMARIA RECONSTRUTIVA - POS MASTECTOMIA C/ IMPLANTE DE PROTESE
Período: Jul/2020

Região	Valor serviços profissionais
TOTAL	**5.320,76**
1 Região Norte	140,02
2 Região Nordeste	1.540,22
3 Região Sudeste	2.100,30
4 Região Sul	1.540,22

Fonte: Ministério da Saúde - Sistema de Informações Hospitalares do SUS (SIH/SUS)

Notas:

1. Dados referentes aos últimos seis meses, sujeitos a atualização.
2. A partir do processamento de junho de 2012, houve mudança na classificação da natureza e esfera dos estabelecimentos. Com isso, temos que:
   - Até maio de 2012 estas informações estão disponíveis como "Natureza" e "Esfera Administrativa".
   - De junho de 2012 a outubro de 2015, estão disponíveis tanto como "Natureza" e "Esfera Administrativa", como "Natureza Jurídica" e "Esfera Jurídica".
   - A partir de novembro de 2015, estão disponíveis como "Natureza Jurídica" e "Esfera Jurídica".

Não seguro | tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/qiuf.def

Ministério da Saúde

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PROCEDIMENTOS HOSPITALARES DO SUS - POR LOCAL DE INTERNAÇÃO - BRASIL

AIH aprovadas segundo Região
Procedimento: 0410010090 PLASTICA MAMARIA RECONSTRUTIVA - POS MASTECTOMIA C/ IMPLANTE DE PROTESE
Período: Jul/2020

Região	AIH aprovadas
TOTAL	**33**
1 Região Norte	1
2 Região Nordeste	11
3 Região Sudeste	12
4 Região Sul	9

Fonte: Ministério da Saúde - Sistema de Informações Hospitalares do SUS (SIH/SUS)

Notas:

1. Dados referentes aos últimos seis meses, sujeitos a atualização.
2. A partir do processamento de junho de 2012, houve mudança na classificação da natureza e esfera dos estabelecimentos. Com isso, temos que:
   - Até maio de 2012 estas informações estão disponíveis como "Natureza" e "Esfera Administrativa".
   - De junho de 2012 a outubro de 2015, estão disponíveis tanto como "Natureza" e "Esfera Administrativa", como "Natureza Jurídica" e "Esfera Jurídica".
   - A partir de novembro de 2015, estão disponíveis como "Natureza Jurídica" e "Esfera Jurídica".

ANNEX C – State-of-the-art prosthesis estimate

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Hello there

Hello Lucia.

I have attached a brochure for you to refer to and if you click on the ContourMed link below, it will take you to our website. Normally, we locate a boutique for you, they would then run the insurance to see if it would be covered. We conduct the scan, within a few days, we have a fit foam that arrives for you to try on and see if there needs to be any adjustments. When the fit foam properly fits and no adjustments need to be made, we would then sign off for the final to be made. Within a few weeks, you will receive your final form. It is a custom, so we do want it perfect, so it may take 3 or 4 visits, sometimes more. It really depends on the individual situation.
Am I correct in saying that you for sure do not have insurance that will cover a custom breast prosthesis? The Custom forms are $3600.
Will you be back in the US any time soon?
Keep in touch.

Jolene Resz
ContourMed Inc.
501-907-0530 (office)
501-907-0533 (fax)
417-846-7697(mobile)
Jolene.r@contourmed.com

Virage ContourMed BREAST FORMS