Computational Design of External Breast Prothesis According to Physical Properties of Elastomeric Materials

Edwin A. Ramírez[1], Iliana Corona[1], Fermín C. Aragón[1,2*], B. Alemón[2], Y. Ramírez[1]

[1] Instituto Tecnológico y de estudios superiores de Occidente, Industrial process department, Guadalajara, Mexico

[2] Tecnológico de Monterrey, school of engineering and science, Guadalajara, Mexico

Fermin.castro@iteso.mx

Abstract

This paper presents a computational design for an external breast prosthesis by means of a finite element analysis (FEA) according to theoretical physical properties of an elastomeric material. The first 3D model design was created using anthropometrics dimensions of a woman and a CAD software. Afterwards the model was analyzed through FEA and computational simulations based on mechanical loads applied to the prosthesis during the daily activities of a woman and on the physical properties of the elastomeric material selected, in this case, the polydimethylsiloxane (PDMS). The performance evaluation of the prosthesis was made following the Mooney-Rivlin mathematical model for elastomers. The 3D design obtained with displacements and distribution of stress due the loads applied, could be prototyped by 3d printing process or a molding process to make an external breast prosthesis that mimics to a real breast.

Key words: External breast prosthesis, Finite element analysis, Mechanical simulation, PDMS, Prosthesis.

1. Introduction

Cancer is a large group of diseases in which any organ or tissue has abnormal cells growing uncontrollably. Those cells go beyond any boundaries and spread by the whole body. Breast cancer is the most frequent type of cancer for women and it alone represents the 15% of all cancer deaths, having a raising tendency in close years [1]. Currently in Mexico breast cancer is the second cause of death in women between 30 and 54 years of age, this is not only because it is a developing country but also because it is rarely diagnosed in its early stage. Only 5% to 10% of cases in the country are detected at an early stage compared to 50% of cases in the United States [2]. Surgery comes as most convenient option to remove cancer in early and last stages, which means to remove a part of the breast or completely. The mastectomy implies physical and psychological changes in the lifestyle of the patient (work and family environment). The removed tissue results in curvature of spine and shoulder, muscle contractions, back pain, and the general decrease of physical and cognitive function [3]. Even though mastectomy is the most effective treatment alternative, it is accompanied by subsequent psychological problems for the woman regarding to her personal acceptance. According to a Latin-American survey, 97% of the patients who underwent a lumpectomy in conjunction with radiotherapy reported feeling attractive after treatment, contrary to the mastectomy where the 78% considered themselves less attractive [4].

As some postoperative alternatives, basically there are two possibilities for the women in order to recover their body equilibrium and to improve confidence in their physical appearance. The first one is

dx.doi.org/10.24254/CNIB.20.64

having a new breast reconstructive surgery and the second is the use of external breast prostheses to avoid the invasive surgical procedure. Both options have not only aesthetic but also anatomical functions as they provide the missing weight and volume according to the body structure. Breast prostheses are generally made of biopolymers and in their most rudimentary forms including seeds and natural materials [5].

There are not so many publications about the improvement of patient's relationship with the breast prosthesis, the most common complaints are excessive sweating caused by the material, lack of naturalness and discomfort [6]. Therefore, a well-conditioned prosthesis is required, and a remarkable feature to achieve this goal is the material. Due to this information gap, research and simulations are considered important for the future implementation of a prosthesis suitable for the body of each woman.

External Breast prosthesis offers a save option to patients who are not willing to risk with reconstruction surgeries or are not qualified for it. This paper presents a computational design for an external breast prosthesis using finite element analysis (FEA) according to theoretical physical property of an elastomeric material. The 3D Model obtained with displacements and distribution of stress due the loads applied, could help to get a printable model or a mold to fabricate an external breast prosthesis that mimics to a real breast.

2. Methodology

The development of the research work was divided into 3 sections, in which the material was characterized in an theoretical way based on the information of the state of the art, an analysis was proposed from the finite element technique for the study of deformations with the experiment raised and the Mooney-Rivlin constants were obtained and configured in the software to run the simulations of the proposed conditions.

2.1 Material Requirements and physical properties

According to Cruz et al "The tactile properties of the prosthesis should also mimic those of skin and flesh to achieve a realistic feel. Skin has a particular softness and pliability when touched, so the material must be soft and with suitable surface elasticity" [7]. Furthermore, the main factors in the design of external breast prostheses are how they feel and act comparatively to natural breasts, weight, and the interaction with scar tissue. The weight of prosthetic breasts is also important because of its effect on balance and posture, and the damage it could cause to the shoulders and back [8] [9]. The most common material used in external prosthetic breasts is a Silicone elastomer, known as polydimethylsiloxane (PDMS), due to its ability to mimic the feel of a natural breast [10].

In order to define the physical properties of the PDMS used for the computational simulation, the formulation recommended by Rajesh considering the hydrosilylation mechanism for its polymerization [11] was selected and shown in Table 1.

Table 1. Polydimethylsiloxane (PDMS) formula [11].

Composite	% (in weight)
PDMS	74.8
Platinum (Pt) catalyst (100ppm)	0.2
Hydride crosslinker	25.0

The physical properties of the PDMS according to Cai et al for the density (ρ) [12] and Nunez et al for viscosity (μ) [13] are shown in Table 2.

Table 2. Physical properties of polydimethylsiloxane (PDMS) [12].

Density ρ (g/ml)	0.965
Viscosity μ (Pa•s)	0.18

The shape of the model in this study was defined by geometrical profiles. In this case, different anthropometric measures were used; then lacking measurements were substituted with assistance of three transversal sections silhouettes outlines. These sections were arranged for matching proportion among them in three orthogonal planes: two with the purpose of defining boundaries and the third one to act as a path joining the first two since it is a requisite of the design program [14]. The profiles completely define the shape of the model, but not its dimensions. Throughout initial values arbitrary designated to generate and define the first contours, ratios and proportions were calculated in relation with new variables from the anthropometric measures. Thus, the added variables become independent and turn the unknown measures into linear equations with the generated ratio as the slope [15]. The CAD design, which is the breast prosthesis CAD, is generated with the previous process, and it is planned to be used in the next simulation. The Figure 1 shows the breast model proposed with some of the applied loads and the fixed surface. This breast model mimics to a real breast and is similar to the 3D models obtained by Pianigiani et al and Cruz et al. [16] [17].

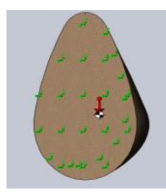

Figure 1. Breast prosthesis CAD design with the applied charges.

2.2 Finite element model

The mechanical response of the breast prosthesis is a main factor for the design process. It is important to know how the prosthesis behaves under certain loads, which are commonly applied by the users, the gravity and breast brassiere compression. The Finite Element Analysis (FEA) is appropriate to simulate the physical behavior of complex engineering systems. The calculations made with FEA make approximations of the material and geometry behavior based on discrete and irregular domains with finite elements.

The model is characterized by linear tetrahedral elements in a nonlinear static analysis, which was solved by the iterative method Newton-Raphson. For the analysis, the prosthesis would be considered as a unique solid with a single uniform material. The surface, commonly put on the patient chest, was considered a fixed geometry to monitor the exposed surface behavior (Figure 1). The loading conditions are diverse due to difference situations where the breast prosthesis could endure load situations. The first case study is considering gravity over the model, but different positions can bring different strains and strengths. The first case is subdivided into three cases regarding gravity: erect, supine, and lateral decubitus positions (as shown in Figure 2).

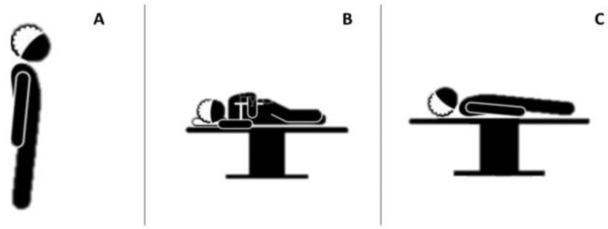

Figure 2. The Finite element model take into consideration three position: (A) erect position, (B) supine decubitus position, and (C) lateral decubitus position.

For the second case, the force generated by a brassiere is added to de gravity in the mentioned positions, thus another three cases are added (Figure 3a). This force is calculated with the Hooke's law as shown in 1 and 2:

$$F = k*l \tag{1}$$

$$k = E*A/L \tag{2}$$

Where *F* is the force aplied by the brassiere over the breast, *k* is the elastic constant, *l* is the breast projection distance, *E* is the elastic modulus of the strap material, *A* is the transversal area of the strap, and *L* is the length of the strap. As last, a mesh is generated for the solid as the one shown in the Figure 3b. The mesh used was a curvature-based model with size elements range of 5 to 25 mm. Consequently, the constant surface with not much relevance for the study uses bigger element sizes that those closer to edges.

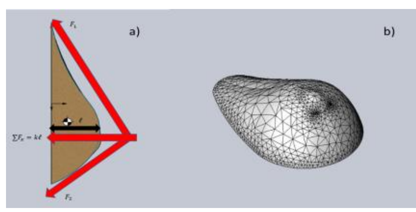

Figure 3. Breast representation in a) force diagram and b) meshed breast prosthesis design.

2.3 Mooney-Rivlin constants

Nonlinear simulation was selected, which covers the cases in where the stiffness depends on the displacements. Therefore, displacements do not vary linearly to the loads applied over a material. To characterize material with this behavior, many theoretical models were developed such as the Birderman model (1958) and the Harth-Smith model (1966), the case study for this work is based on Mooney-Rivlin, Ogden Model. The Mooney-Rivlin model (1940) can be easily applied to cases where the material remains homogenous even after deformations or where this are a function of position. This model allows to calculate stress and twix with very accurate results when comparing to experimental data. The Mooney-Rivlin equation can be presented as in equation 3 where W represents the general strain-energy function, λ is for the magnitude of deformation in its variations stretch-squeeze on the length, width and different planes, and finally C is the elastomer constant that can be calculated out of experimental data.

$$W(\lambda_1, \lambda_2, \lambda_3) = C_1(\lambda_1^2 + \lambda_2^2 + \lambda_3^2 - 3) + C_2(\lambda_1^{-2} + \lambda_2^{-2} + \lambda_3^{-2} - 3) \quad (3)$$

Equation 3 is simplified into its quadratic and derived form as shown in 4.

$$Ww' = 2C_1\lambda_{i-}2C_2\lambda_i^{-3} \quad (4)$$

The material characterization involved for the simulation requires minimum values to run the simulation, which are the physical properties of the polydimethylsiloxane (PDMS) and two constants of Mooney-Rivlin. In the case of the simulation of this research work, the constants C1 and C2 were referred in Table 3 according to the experimental results reported by Nunes et al [13].

Table 3. Constants for the mathematical model by Mooney-Rivlin for polydimethylsiloxane (PDMS) [13].

Constant Mooney-Rivlin	(MPa)
C1	0.06
C2	0.046

3. Results and Discussion

The finite element breast prosthesis model was analyzed in three positions stated with two forces cases: gravity and gravity with brassiere pressure. The Figure 4 shows the stresses and displacements for the first case in the three positions. The Figure 4a shows concentrated stresses along the edge of the fixed surface, which grow as it is closer to the down section. It matches with expectation because the weight upper sections of the breast are supported by the lower ones. The maximum displacement is located at the tip of the breast, which is the farther part and therefore, the one with the most ability to move. The Figure 4b shows a common behavior related to the stress, but it has a uniform stress distribution over the fixed surface, which allows a lower maximum stress.

The higher stress is closer to the nipple due to higher mass amounts concentrated, nevertheless these differences are low compared to the other positions. The displacement in the supine decubitus position is also lower than the one in erect position because of the material stiffness. For the lateral decubitus position, the gravity was set to point the left direction out. The stresses in Figure 4c shows almost symmetrical stress in both sides of the breast; it is rather like the Figure 4a. The difference is such left side is under compression and right side is in tension; particularly, the tension side is slightly bigger. Also, the maximum displacement is still in the nipple area, but it is higher unlike the other positions.

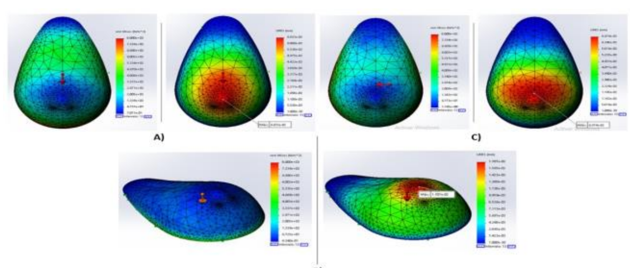

Figure 4. Simulation results for stresses and maximum displacements in the three positions for the first case: A) erect position, B) supine decubitus position and C) lateral decubitus position.

The Figure 5 shows the simulation results with the applied forces from the second case, which are gravity and brassiere pressure. Each figure includes stresses and displacements for the mentioned positions. The Figure 5a shows the results for the erect position; the displacements are in the left side and stresses in the right one. It is shown that the prosthesis behaves comparable to the first case in the same position since essential conditions are similar. Stresses are in the edge of the contact surface and they vary around the farthest surroundings of the nipple. The supine decubitus position is shown in the Figure 5b for the same case two. In left side are displacements, where maximum values are in the tip of the prosthesis because movement freedom like the first case in Figure 4b. Also, stresses are concentrated in same areas, but there is an increase since higher forces are applied over the surface in contact with the brassiere and they share direction with applied gravity.

The last position for the second case is shown in Figure 5c. The figure shows displacements like previous cases, but maximum value is located next to the tip in the direction of the force. Also, the stresses behave as compression and tension shown before, although the applied pressure increases stress concentration in the tension sides. These values are higher since the force caused by pressure go in the same direction that applied gravity.

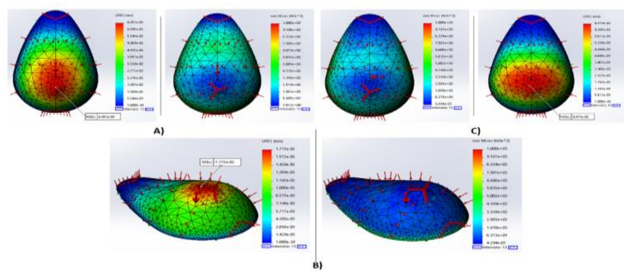

Figure 5. Simulation results for stresses and maximum displacements in the three positions for the second case: A) erect position, B) supine decubitus position and C) lateral decubitus position.

Table 4. Comparison among maximum strains and stresses values in the analyzed cases.

Cases	ε_{max} (mm)	σ_{max} (Pa)
Erect	6.634e-02	489
Supine decubitus	2.214e-03	121.4
Lateral decubitus	6.978e-02	463.5
Erect with brassiere	6.639e-02	600
Supine decubitus with brassiere	1.712e-02	145.5
Lateral decubitus with brassiere	7.011e-02	551.9

The results between the two cases can be compared through the Table **4**, which shows the maximum stress and displacement values in each case for the three positions. Stresses in each position show similar conditions in both cases, but there are increments with the pressure applied over the surface with brassiere contact. Anyway, the stresses are well distributed, therefore the model has no stress concentrations, there is the exception in the edge of the flat surface in contact with the chest patient. Also, displacements in all cases are in low proportions compared to the dimensions of the breast. This results are similar to those obtained by Cruz et al [17] plus in both research works the loads are not concentrated on a particular point and there are no irregularities on the surface so it has natural deformation patterns to resemble a real breast.

4. Conclusion

The computational design proposed in this research work obtained a 3D Model with minimum displacements and minimum concentration of high stresses. The technique and the software used to perform the design taking into account the physical properties of an elastomeric material as the one chosen for to get this 3D model, represent a simple an accessible way to design an External Breast Prosthesis. The considerations to choose the formulation of the elastomeric material were overall the weight and the tactile properties that the patients wanted according to Ya-nan Liang et al [9].

The 3D design obtained could be prototyped by 3d printing process or by molding process to make an external breast prosthesis that mimics to a real breast.

In accordance with the study of finite elements and the results obtained, there is a premise of the behavior of the element with the experimental conditions of stability, however, it is necessary to continue with the experimental validation of the polymer and the manufacture of the first pieces to subject them to physical loads, and in this manner, we can provide more certainty about the results obtained in the computational simulation.

Declaration of conflicts of interest

The authors declare that they have no conflict of interest for this work.

Acknowledgments

To the Jesuit University of Guadalajara for providing us with the knowledge and human capital to carry out this work, to Master in Engineering Fermin Castro for Directing this work with commitment and enthusiasm and with the same importance to Biofemme, a company that cares about Mexican women who suffer from cancer and need the use of external breast prostheses. B. A. acknowledges the Bionic Extreme funds.

References

[1] World Healt Organization, "Cancer," 15 Abril 2020. [Online]. Available: https://www.who.int/cancer/prevention/diagnosis-screening/breast-cancer/en/.

[2] Knaul et al, "Cancer de mama en México: una prioridad apremiante," *Salud Publica de México,* no. 51, pp. s335-s344, 2009.

[3] L. L. Reaby and L. K. Hort, "Postmastectomy attitudes in women who wear external breast prostheses compared to those who have undergone breast reconstructions," *Journal of Behavioral Medicine,* vol. 18, no. 1, pp. 55-67, 1995.

[4] G. Margolis, R. L. Goodman and A. Rubin, "Psychological Effects of Breast-Conserving Cancer Treatment and Mastectomy," *Psychomatics,* vol. 31, no. 1, pp. 33-39, 1990.

[5] L. R. Branco and J. A. Foggiatto, "External Breast Prostheses: Brazilian Performance Parameters," *Advances in Intelligent Systems and Computing* , pp. 498-505, 2017.

[6] S. Roberts, P. Livingston, V. White and A. Gibbs, "External Breast Prosthesis Use," *Cancer Nursing,* vol. 26, no. 3, pp. 179-186, 2003.

[7] R. L. J. Cruz, M. T. Ross, S. K. Powell and M. A. Woodruff, "Advancements in soft-tissue prosthetics part A: the art of imitating life.," *Frontiers in Bioengineering and Biotechnology,* vol. 8, 2020.

[8] E. Rostkowska, M. Bak and W. Samborski, "Body posture in women after mastectomy and its changes as a result of rehabilitation.," *Adv. Med. Sci.,* vol. 51, p. 287–297, 2006.

[9] Y. n. Liang and B. Xu, "Factors influencing utilization and satisfaction with external breast prosthesis in patients with mastectomy: A systematic review.," *International Journal of Nursing Sciences,* Vols. 2(2),, pp. 218-224., 2015.

[10] Q. Chen, S. Liang and G. A. Thouas, "Elastomeric biomaterials for tissue engineering.," *Progress in polymer science,* vol. 38, no. 3-4, pp. 584-671, 2013.

[11] Rajesh et al, "Liquid Silicone Rubber Vulcanizates: Network Structure-Property Relationship and Cure Kinetics," *Polymers and Polymer Composites,* vol. 18, no. 9, pp. 477-488, 2010.

[12] Cai et al, "Soft Poly (dimethylsiloxane) Elastomers from Architecture-Driven Entanglement Free Design," *Advanced Materials,* Vols. 27(35),, pp. 5132-5140, 2015.

[13] L. C. S. Nunes, "Mechanical characterization of hyperelastic polydimethylsiloxane by simple shear test.," *Materials Science and Engineering,* vol. 528, no. 3, pp. 1799-1804., 2011.

[14] T. P. La H. Brown, C. Ringrose, R. E. Hyland, A. A. Cole and T. M. Brotherston, "A method of assessing female breast morphometry and its clinical application," *British Journal of Plastic Surgery,* pp. 355-359, 1999.

[15] B. Longo, A. Farcomeni, G. Ferri and A. Campanale , "The BREAST-V: A Unifying Predictive Formula for Volume Assessment in Small, Medium, and Large Breasts," *Plastic and Reconstructive Surgery Journal,* pp. 132-139, 2013.

[16] S. Pianigiani, L. Ruggiero and B. Innocenti, "An Anthropometric-Based Subject-Specific Finite Element Model of the Human Breast for Predicting Large Deformations," *Frontiers in Bioengineering and Biotechnology,* 2015.

[17] Cruz et al, "A Biomimetic Approach for Designing a Full External Breast Prosthesis: Post-Mastectomy," *Applied Sciences,* pp. 357-373, 2018.