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A Biomimetic Approach for Designing a Full External Breast Prosthesis: Post-Mastectomy

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Abstract: This work presents the design of a new breast prosthesis using the biomimetic technique for cases of complete mastectomy to address the problem of the increasing number of women diagnosed with breast cancer in Mexico who are candidates for a mastectomy. The designed prosthesis considers the morphology of a real breast regarding its internal structure to obtain authentic mobility and feel. In order to accomplish this, a model was obtained in 3D CAD using a coordinate measuring machine (CMM) that can be scalable without losing its qualities, and which can be used in any type of patient; afterwards, a finite element model was developed and a static analysis performed with suggested load cases to evaluate the sensitivity and naturalness of the prosthesis; and finally, a modal analysis was conducted. The results obtained in displacements and in distribution of stress for the load cases assessed are consistent with those of a real breast: there were smooth contours and there was natural mobility in the prosthesis designed by means of the biomimetic technique.

Keywords: breast cancer; biomimetic design; breast prosthesis

1. Introduction

Breast cancer is the accelerated, disorganized, and uncontrolled growth of cells in the mammary gland and it affects the entire population, although it is not significant in the male population [1,2]. In Mexico, breast cancer is one of the main causes of death, according to the records of INEGI for 2016. In women, incidence peaks in the group of 60 to 64 years of age and then drops in the group of 65 and older; the greatest increase was observed in women aged between 25 and 44 years old and between 45 and 49 [3]. For this reason, emphasis has been placed on awareness and on studies focused on this disease due to the importance of early-stage diagnosis and treatment of breast cancer. Unfortunately, this type of cancer is usually detected in advanced stages. The severity of this type of cancer can be classified into 5 stages, depending on the degree of invasion and the patient's likelihood of survival: stage 0, I, II, III and IV. In Mexico, 90% of the cases are detected in stages III and IV, and as stated in 2014 by the National Center of Gender Equality and Reproductive Health (CNEGSR) the patient's probability of survival is from 7 to 36%, where the main option for fighting breast cancer is surgery [4,5]. Surgery consists of extracting the tissue invading the mammary gland and the lymph nodes—"mastectomy". The type of mastectomy depends on the degree of tumor advancement corresponding to the most drastic case, since the patient's mammary gland is removed. Extirpation of the cancerous tissue results in decreased physical and cognitive functioning, together with a lower perception of overall health in the individual. The patient experiences a curvature of the spine and shoulders due to the imbalance caused by the tendency to hide this part of her body. In addition, the person has muscle contractions, discomfort in the neck, back pain, a loss of tissue; her gait also becomes slower and less controlled, and her steps longer [5–9]. Psychologically, patients subjected to a mastectomy can experience a variety of ailments such as depression and anxiety, since the fear of social discrimination is one of the greatest problems after the surgery [10]. The methods of breast reconstruction after a mastectomy help to counteract these ailments. These methods consist of using tissue inserts (generally from different parts of the patient's own body), internal implants (mainly bags with saline materials) or external breast prostheses [11,12]. However, post-mastectomy breast reconstruction methods present a series of conditions that can affect the patient's health.

In the case of reconstruction with a tissue implant, the patient will again need surgery, at the same time as another part of her body will be physically affected and altered; in the case of reconstruction by implants, there is the risk of a rupture of this bag, which contains materials that can cause allergic reactions, anaplastic lymphomas, and heterotopic ossifications [11,13–15].

Nanotechnology is currently also benefiting the development of implants and prostheses [16]. Nanotechnology has the potential to bring enormous changes to the fields of breast surgery. Breast implants with nanofiber coatings to deliver specific anti-cancer drugs are currently under study. In addition, the prostheses can also delivery drugs that help to treat the injury of the surgery and to avoid problems due to excessive heat or ventilation [17].

The use of external prostheses is a safer option, since they do not involve a surgical procedure and can be used by the patient at any time. There are external prostheses available on the local and world markets; nevertheless, their main problem is that they have crude and simple designs that are far from offering the natural performance and realistic sensation of a breast; that is, such prostheses have generic designs that do not match the culture and the size required according to the needs of each patient [7,12,18]. Using a breast prosthesis that is not suitable for the patient with regards to her weight, size, and sensitivity can have an impact on her health, provoking and aggravating physical problems such as muscle pain, hunched shoulders, curvatures, etc. The patient is also affected psychologically when using an unsuitable breast prosthesis, with problems such as insecurity and discomfort in carrying out her daily activities. Therefore, prostheses with better ergonomic designs are required for patients, not only to fulfill the person's esthetical needs (which is the main reason), but also to fulfill the suitable weight, size, and sensitivity requirements [19]. The present document is aimed at the design and analysis of external breast prostheses

As of the commercial and scientific research conducted, the following tendencies stand out regarding the design of breast prosthesis:

- Symmetry and balance.
- Realism and sensitivity, analogous to a real breast.
- Lightness, which helps avoid and alleviate lymphedemas.
- Suitable for maintaining a comfortable environment in the scar region.
- Safe and reliable when carrying out a range of activities.
- Suitable for providing smooth adherence without pressure.
- Reusable and accessible for any person.

Some of the above points can be achieved by designing external prostheses tailored to the size and needs of each patient, naturally benefitting posture and the performance of daily activities (work, family, sports, etc.) [20]. There are diverse scientific and technological advances in the literature that provide computational models and finite element models focused on simulating the mammary gland for preclinical evaluation, prevention, training, diagnostic [21–31] or on analyzing the biomaterials used for implant reconstruction [14,15,32]. In the case of the most advanced computational models of a breast for the simulation of the anatomy is the anthropomorphic software breast phantom. The anthropomorphic software breast phantom simulates the skin, regions of adipose and fibroglandular tissue, and the matrix of Cooper's ligaments and adipose compartments using 3D breast and 2D mammographic imagines [33]. However, the use of finite element breast models in the design process and the analysis of breast prosthesis, considering the internal anatomy of the breast (biomimetics) or the behavior of a prosthesis in a manner similar to a real breast has not been reported. In particular, this work presents the design and the analysis of a breast prosthesis for cases of total mastectomy using computational methods (CAD, FEM) and the biomimetic technique. This last technique considers the morphological and physiological features of a real breast for the design of the external breast prosthesis. It is expected that the prosthesis will perform similarly to the breast regarding structure, symmetry, consistency, contour smoothness, mobility, and a sensation that is realistic to the touch. A prosthesis with such features would contribute significantly to the patient's physical rehabilitation and social integration.

2. Materials and Methods

The methodology proposed in this work covers the development of an external 3D breast prosthesis model based on the breast contour of a medical mannequin. The model was sized in this manner with the objective of having a design base that could be analyzed and evaluated through the finite elements method. Likewise, the 3D model will allow the analysis of the external breast prosthesis to different scales; that is, the prosthesis can be customized for different users while maintaining its properties. There are different techniques for modeling mammary glands: magnetic resonance, RX, infrared imaging, photographs, 3D laser scanning or coordinate measuring machines [20,34,35]. These techniques are supported by novel complex algorithms for computer simulation that allow obtaining computational anthropomorphic models which could feasibly be replicated in 3D print. In this work we sought to apply a simple and accessible technology. Therefore, a coordinate measuring machine was used (CMM) for modeling the breast contour of the prosthesis as shown in Figure 1. The breast is definitely not considered a rigid tissue as it can deform during the measurement process. The magnitude of these deformations is negligible because the contact force of the test tip (probe) is regularly less than 1 mN and can be adjusted according to the desired degree of sensitivity. Some success cases reported in the literature are directed at nanoscale measurement applications [36], ultra-precision applications [37] and applications of non-rigid elements in the automotive industry [38].

To take the measurements on the medical mannequin, concentric circles were traced along the surface of the mannequin's breast, which were distributed uniformly [39]. The measurement time for a single breast with the available coordinate measuring machine took 5 min.

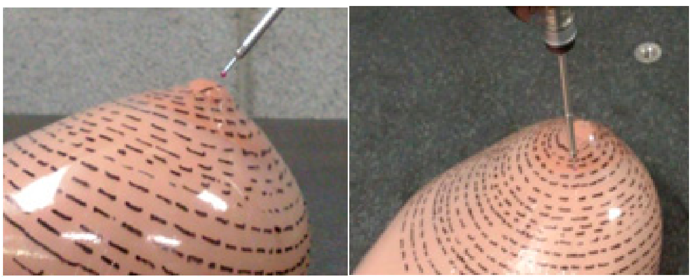

Figure 1. Random measurements on the contour of the mannequin's breast.

With the data obtained regarding the periphery of the circles, a point cloud was generated and contouring of the prosthesis was performed via concentric circles. With this, the skeleton of the external structure of the prosthesis was formed, which also has a protuberance to emulate a nipple (Figure 2).

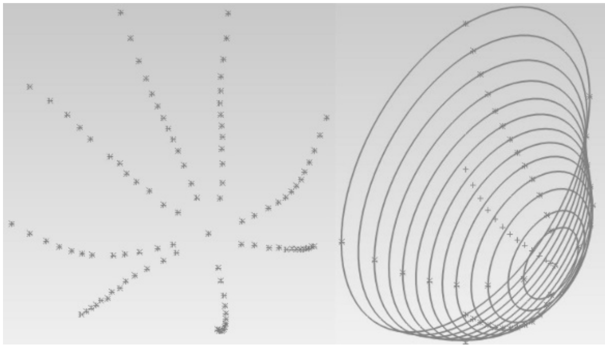

Figure 2. Isometric view of the skeleton for the 3D model.

With respect to affixing the prosthesis, which will be in contact with the wearer's thoracic wall, spheres were added to the back of the 3D model to allow air to circulate between the thoracic wall and the prosthesis. This prevents the increase of temperature in this part of the body and reduces perspiration on the surface where the surgery scar is found, as shown in Figure 3.

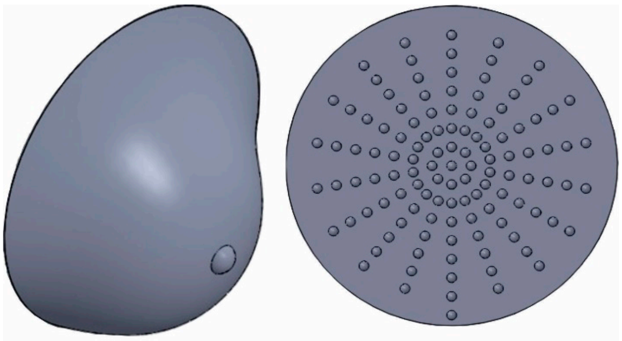

Figure 3. 3D Designed prosthesis model: isometric and back view.

In the inner part of the prosthesis, which is one of the main contributions of this work, an internal biomimetic structure was incorporated (not considered in any prosthesis); that is, it resembles the internal structure of a real breast, since the internal structure directly affects the mechanical behavior of the prosthesis [15]. Biomimetic endeavors to understand how life functions on different levels, imitating the structures and organisms found in nature with the aim of creating new structures, new materials, and new products-based mainly on nature [40–43]. There are different structures in the breast that provide support to the mammary gland. A main structure is the glandular tissue, in which bundles of small bodies known as lobes are found, as will be explained in the following section.

Morphology and Histology of the Female Mammary Gland

The mammary gland is composed of 15 to 20 sections called lobes, which are arranged in the same way as the petals of a daisy. The lobes, lobules, and the bulbs are all connected by thin tubes called ducts, which connect in the nipple, and fat fills the spaces between the lobules and the ducts [44,45]. Figure 4 shows a graphic diagram with the different structures in a real breast [46].

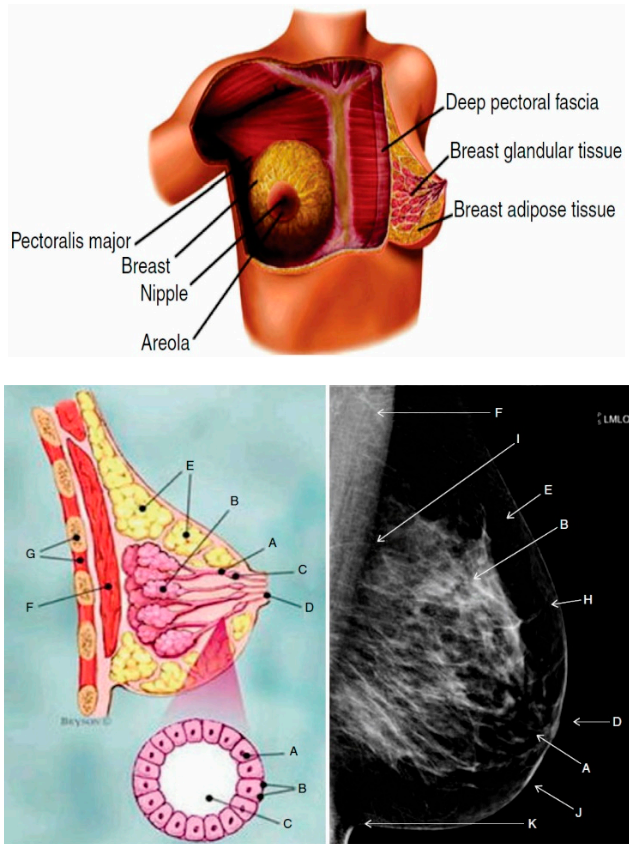

Figure 4. Internal anatomy of the breast: A Lactiferous duct, B Lobules, C Cross section of lactiferous duct, D Nipple and Adipose tissue, F Pectoralis major muscle, G Chest wall, H Cooper's ligaments, I Retromammary space, J skin, K Inframammary fold (Adapted with permission from [44], Copyright Springer Nature, 2018).

This work sought to imitate the lobular arrangement in a real breast; consequently, a structure was proposed that emulates the bundle of lobes found in the internal structure of the breast.

In the internal structure of the prosthesis, several types of 2D geometry were considered according to the manufacturing ability of the prosthesis and the stress distribution property during application of loads on the prosthesis model. The most relevant structures were: (a) Rectangular structure; (b) Rectangular structure with rounded corners and (c) Triangular or lobular structure. The results showed that the triangular structure is the best choice to be used in the prosthesis. Once the type of internal structure has been defined, then the internal structure in the 3D model of the prosthesis is done manually by using CAD in approximately 30 minutes, this time is determined by the designer's experience.

The distribution of lobes in the prosthesis was placed within a circular adjustment with the aim of taking advantage of the qualities of this adjustment with respect to the deformation fields and to the distribution of stress. The circumferential adjustment is used when it is necessary to obtain a uniform distribution of loads or stress in components. The lobular cavities gradually increase in size the closer they are to the back part. This arrangement also has an element of connectivity with the nipple, just as in the real lobular arrangement—following the pattern of the petals of a daisy. Figure 5 shows the complete 3D model; in this image, the placement of the lobular structure and the circular adjustment in the inside of the prosthesis shell can be seen.

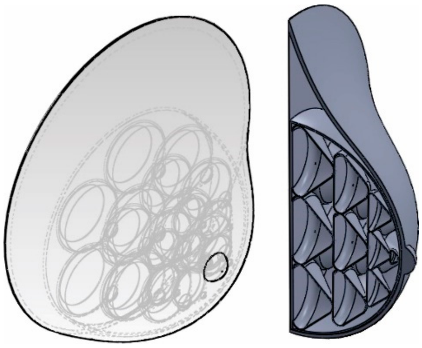

Figure 5. 3D Model of breast prosthesis: isometric cutaway view.

The circumferential adjustment and the design of the internal biomimetic structure based on the real anatomy of a female breast achieve the greatest approximation to the structure and shape of a real breast through the shell or delimiting surface obtained. Consequently, the behavior of the external prosthesis is expected to be similar to that of a real breast.

With respect to the lightness of the prosthesis, the proposed prosthesis (with biomimetic technique) for a patient with a complete mastectomy who used a C cup has an approximate mass of 0.7 kg (6.86 N), which is acceptable considering that she uses a C cup. Undoubtedly, weight is also a determining factor in the dynamic and realistic behavior of the breast. In this sense, the proposed prosthesis improves the mechanical properties of the same due to its internal structure. To verify dimensions, geometry, adjustments, and final finish of the prosthesis, a rapid prototype was built with ABS material. The first prototype of the design is shown in Figure 6 and it was confirmed that the qualities of the prosthesis mean that it can be manufactured simply and economically.

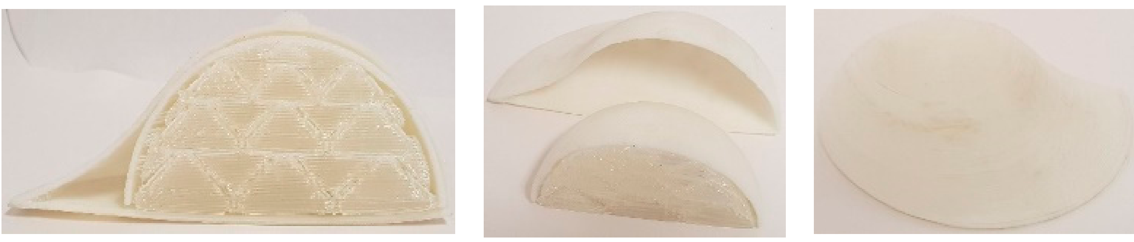

Figure 6. Printed model of the designed biomimetic prosthesis.

The use of 3D printing in the development of functional prototypes is well known, as it is the use of stereolithography printers for additive manufacturing. This type of printer allows the combination of materials that can give specific properties for each working condition. Currently, 3D printing of polymers such as silicone is well placed for rapid test models and small-scale manufacturing (ears, noses, etc.). In the future, there is no doubt that 3D printing of polymers such as silicone will have radical advantages for the breast prosthesis proposal presented in this manuscript, in addition to the possibility of printing a prosthesis specific for each patient. In the case of large-scale manufacturing, it is possible to take advantage of standard silicone-based methods and molding systems.

3. Model FEM: Modeling and Analysis in Finite Element

Different breast models have been developed using finite elements in particular cancer detection studies or in the design of brassieres with different uses. The models are solid volumes without any frills in the inner part. The model developed in this work specifies the inner part of the prosthesis using the biomimetic technique. In the different geometries of the designed breast prosthesis model, three structure types were considered: the outer shell, the internal structure, and the spaces formed by the former two. Figure 7 shows the structure and the interaction of elements considered for the prosthesis model, such as solid elements (skin and tissue) and the fluid zones. Different breast models have been developed using finite elements in particular cancer detection studies or the design of brassieres with different uses. The models are solid volumes without any frills in the inner part. The model developed in this work specifies the inner part of the prosthesis using the biomimetic technique.

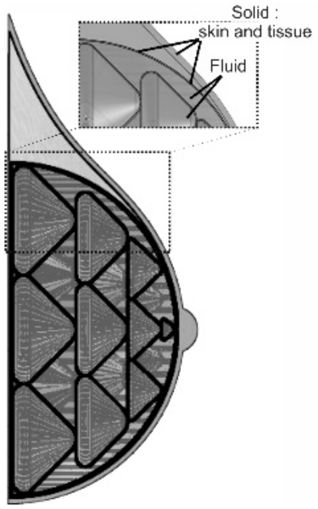

Figure 7. Structure and the interaction of elements considered for the prosthesis model.

In the external structure, 2 mm of thickness with a Young modulus of 10 Kpa, Poisson modulus of 0.4 and damping ratio (ζ) of 0.05 were considered, these properties are very close to those of human skin. For the internal structure, a hyper elastic nonlinear material (Neo-Hookean) was considered with a Young modulus of 15 Kpa, Poisson modulus of 0.4 and damping ratio values (ζ) of 0.06, similar to the properties of glandular tissue. In addition, properties of fatty tissue of 2.5 Kpa, Poisson modulus of 0.499 and damping ratio values (ζ) of 0.06 were considered for the interior [13,15,23,47,48]. These properties can be obtained using medical grade silicone with different configurations spaces (Softgel A-341C—DC 200 silicone); silicone has been widely used for the development of prostheses because it is not toxic, and it is biocompatible with the human body, withstanding common sterilization methods. In addition, this silicone has a hardness between 10 and 90 (degrees Shore A). With this, a 3D finite elements model was developed with 273,965 5-node tetrahedral elements measuring 1.98×10^{-5} m, as shown in Figure 8. The size of the mesh was optimized using diverse mesh criteria until the optimal size was reached.

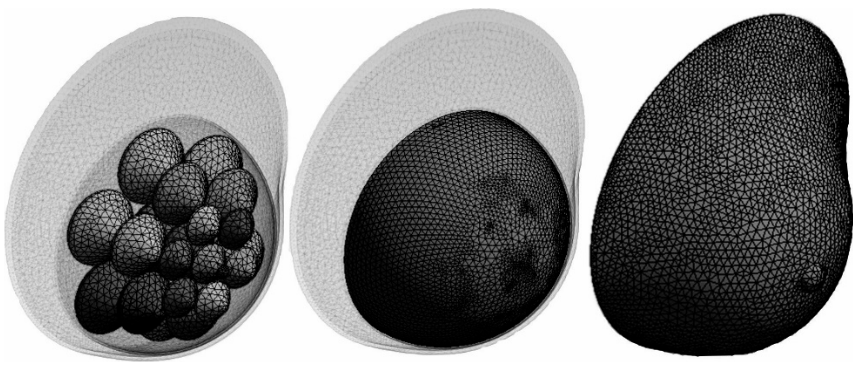

Figure 8. Type and size of mesh for the model.

In the boundary conditions, the back part of the prosthesis was considered, fixed to the patient's thoracic wall, completely fixed, and the other elements free. The model was subjected to different load cases to analyze its behavior and functionality [31,49]. The most common load cases are for postures: standing upright, prone (on all fours) and lying supine. Additionally, new cases are proposed in this work to evaluate the sensitivity and naturalness of the prosthesis, termed inspection or palpation load cases. These cases are shown in Figure 9 below, where the palpation force applied was 5 N.

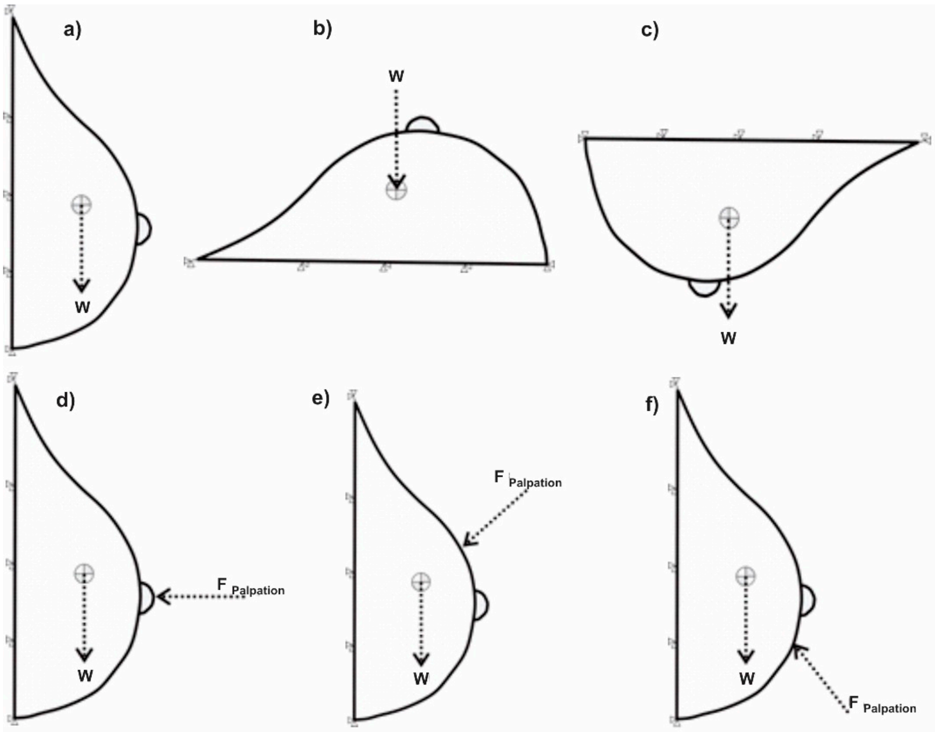

Figure 9. Different load cases proposed to evaluate the finite element model: (**a**) standing person, (**b**) position prone (on all fours), (**c**) lying supine, (**d**) horizontal force applied to the nipple region, (**e**) combines the effects of gravity with a point load in the upper part of the prosthesis and (**f**) combines the effects of gravity with a point load placed in the lower part of the prosthesis.

One of the main aims of this work is to analyze the displacements and the distribution of the stress that can occur in the designed prosthesis in the different load cases proposed. Finally, a static and dynamic (modal) analysis was performed to know the behavior and evaluate the performance of the prosthesis.

4. Results and Discussion

The finite element model breast prosthesis was subjected to the proposed load cases. The first case "a", involves the condition of a standing person, where only the gravity is affected. Figure shows the displacements and stress generated by this condition.

The case for a standing person is one of the most important because it is one of the predominant positions in daily life. Figure 10 shows displacements in the range of 0 to 26 mm, with the greatest magnitude of displacement found in the nipple. Likewise, the distribution of displacements in the prosthesis is symmetrical and with good trajectory; it does not present punctual stress (stress concentration) and its maximum stress is approximately 7 Kpa. The prosthesis does not present defects in its form or contour or on its surface for this load case. The results are consistent with that of the profile of deformation and magnitude of displacement reported by [50,51], similar to the deformation of a real breast under the effects of gravity. Cases "**b**" and "**c**" represent the positions prone (on all fours) and lying supine. These are the most frequent in a person's daily life. Figure 11 shows the results obtained under these load cases for displacements and stress.

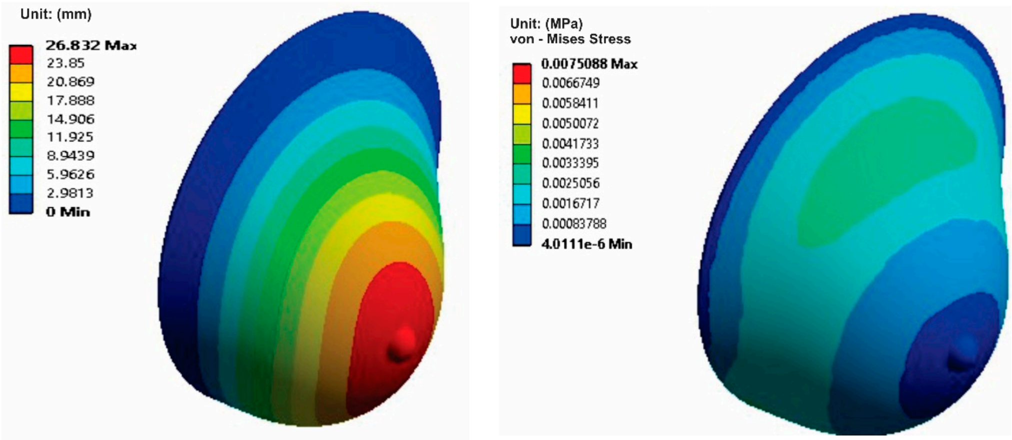

Figure 10. Displacement and Von Mises stress contour plots for case "**a**".

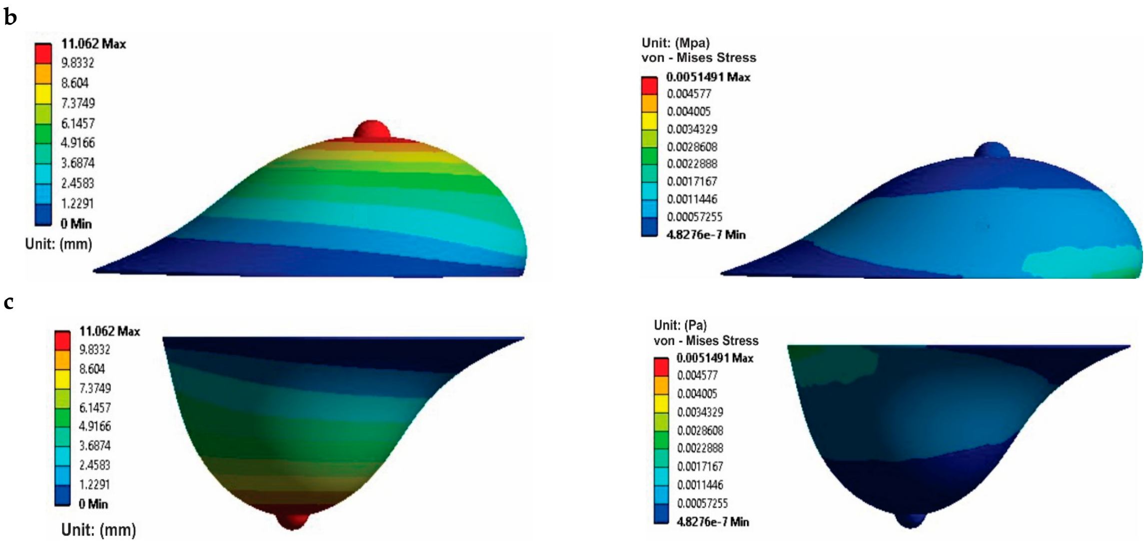

Figure 11. Displacement and Von Mises stress contour plots for case "**b**" and "**c**", respectively.

Maximum displacement of 11 mm and a stress of 4.1 Kpa were obtained for both weight conditions; although the magnitudes are the same, the distribution fields show variations in the interior of the prosthesis. The prosthesis shows a symmetrical contour without any problems and the form agrees with that reported by other works on breasts [21,30,52,53]. Table 1 shows the comparison between the obtained displacements and those reported in the literature. In addition, the prosthesis shows a good distribution of stress.

Table 1. Comparison of obtained displacements with those reported.

Breast Position	Maximum Displacement Obtained (mm)	Maximum Displacement Reported (mm)
Standing	26	27.5 [22], 30 [50], 20 [31]
Prone	11.06	15.6 [53], 24 [27]]
Supine	11.06	11 [44], 14 [24]

It can be observed that the displacement values (in the proposed prosthesis) are within the results reported by similar research. The differences presented in the values are due to the dimensions, materials and conditions of each computational model or experimental model that were used. Load cases "**d**", "**e**" and "**f**" are suggested for this work with the aim of evaluating the sensitivity of the prosthesis; these cases consist of the combined effect of gravity and a palpation force applied in the model. Case "**d**" presents a horizontal force of 5 N applied to the nipple region; the results, seen in Figure 12, demonstrate that the combination of these weights achieves a uniform distribution in the lower part of the prosthesis. This quality in the prosthesis translates into a natural behavior and a good response to touch, preventing undesirable behaviors such as collapses or ruptures of the material and a bad buffering against exerted pressure. The results obtained for weight case "**e**", which combines the effects of gravity with a point load in the upper part of the prosthesis, demonstrating that the shape of the prosthesis is suitable, and the distribution of stress is symmetrical. For the last case, "**f**" combines the effects of gravity with a point load placed in the lower part of the prosthesis. These last three cases (cases "**d**", "**e**" and "**f**"), termed palpation cases, obtained displacements in the range of 12 to 70 mm and magnitudes of stress of 4 Kpa to 31 Kpa making case "**d**" the most critical with the greatest values obtained. The results obtained with respect to the magnitudes of stress are congruent with those reported to case studies of cancer detection or evaluation of brassieres for breasts [54,55].

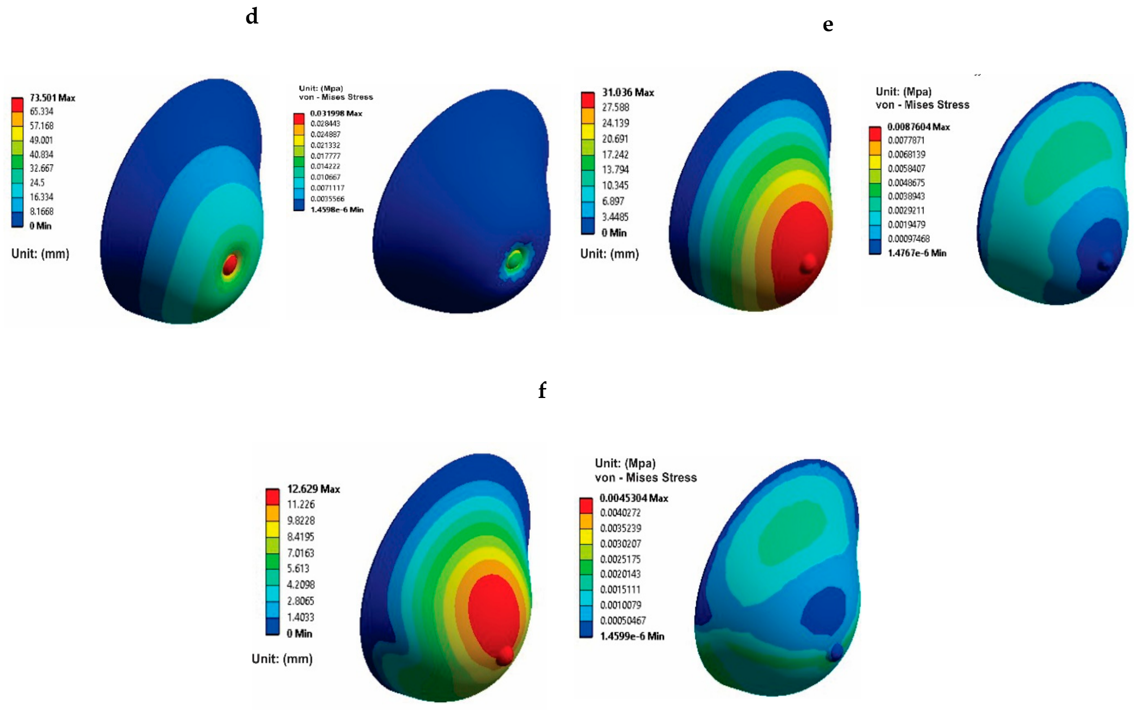

Figure 12. Displacement and Von Mises stress contour plots for case "**d**", "**e**" and "**f**", respectively.

A good distribution of loads is observed in the simulation results obtained from the load cases since the stress are distributed in a greater area, indicating that a movement and a natural response are generated in the prosthesis. On the other hand, the internal structure presents stress along its entire contour, due to the implementation of lower density solid between the spaces (fluid) and the spherical adjustment adapted for this design.

Modal Analysis

Modal analysis depends on the material properties. Unfortunately, only a few studies reporting the mechanical properties of real breast tissue are available in the literature, commonly ignoring tissue damping. However, it is difficult to take a damping value as a standard because the damping of human tissue depends on its location, the work it does and the amount of collagen present in each patient's tissue. The damping directly affects the magnitude of the displacements and in a small proportion, the vibration frequency. It can be observed that the tendency is to consider the breasts as under-damped systems [25,56,57].

With the aim of evaluating the behavior dynamic of the prosthesis model a modal analysis was performed within the frequency range of 0 to 6 Hz. This range was considered because people who walk or run have a frequency of step of 1.5 to 4.5 Hz [25,53]. In the simulation results shown in Figure 13, the prosthesis presented 4 natural frequencies and 4 modal forms.

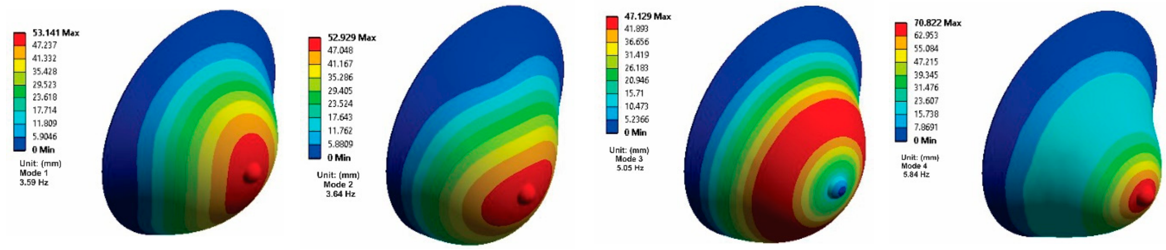

Figure 13. Displacement contour plots for modal analysis.

The first mode shown in Figure 13 represents the displacement generated above and below the prosthesis in resonance to a frequency of 3.59 Hz—predominant for the case of gravity. The other modes of vibration are 3.64, 5.05 and 5.84 Hz, respectively. The movements of the prosthesis in resonance do not manifest strange movements or behaviors beyond the naturalness of the same. Table 2 shows the comparison of the obtained natural frequencies with those reported in the literature.

Table 2. Comparison of the obtained natural frequencies with those reported.

Mode	Frequency Obtained (Hz)	Frequency (Hz) [25]
1	3.59	4.87
2	3.64	4.91
3	5.05	4.99
4	5.84	5.02

The frequency values obtained are very close to the values reported in the literature. Variations to these values may be caused by the properties of the materials used.

5. Discussion

The main hypothesis approached in this work is that the internal biomimetic structure and the circumferential adjustment in the prosthesis would generate a natural behavior in daily activities and realistic to the touch for people who use the prosthesis. The above qualities are not present in any commercial product and in the scientific literature no advancement is reported in this field. For this purpose, a biomimetic model in 3D was developed that includes a lobular configuration in its internal structure and a circumferential adjustment. The model can be scalable for any type of patient. The circumferential adjustments are used to obtain better distributions of stress in some engineering applications. Therefore, a finite element model was generated, which was evaluated with different load cases: standing upright, facing down on all fours, facing up and the cases of palpation proposed, and a modal analysis. The results obtained in terms of displacements and stress are within the results presented in works that use FEM models for cancer diagnosis or detection and for brassiere design. The deformation of the prosthesis contours is symmetrical and smooth; likewise, it does not present irregularities on the surface and has natural deformation patterns, resembling a real breast. The fields of stress indicate that the loads are distributed uniformly due to the contour and prosthesis structure; that is, the loads are not concentrated on a particular point, which means that the person will have the sensation of consistency to the touch without feeling great opposition to the palpation force applied, giving the prosthesis a great feeling of realism and belonging. The biomimetic lobular structure remained stable and without any problems during the evaluation of the prosthesis for the load cases posed. In cases "**b**" and "**c**", the same magnitudes of displacements were obtained, as shown in the cutaway section of the models (Figure 14), where although the magnitude is the same, the distribution within the structure is different.

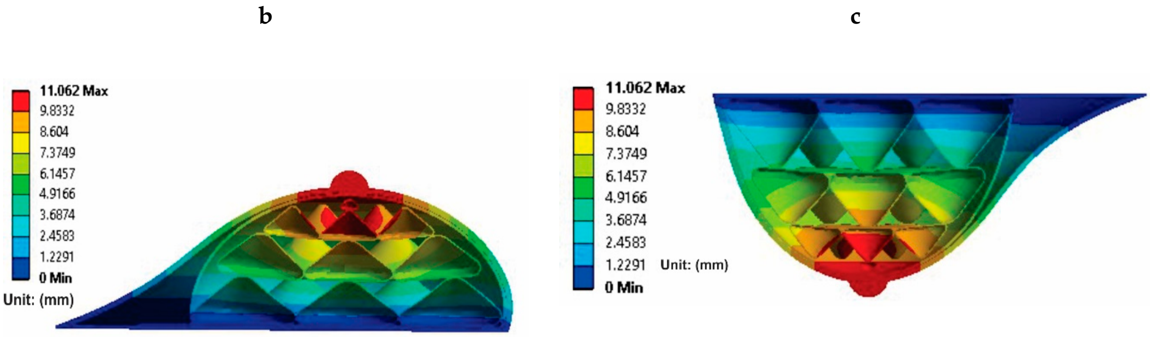

Figure 14. Displacement contour plots (cutaway) for case "**b**" and "**c**", respectively.

The internal biomimetic structure of the prosthesis behaves satisfactorily for the load cases evaluated, as shown in Figure 15. In this figure can be observed at the displacement contour plots for cases "**a**", "**d**", "**e**" and "**f**" that the displacement values are within the results reported by similar research.

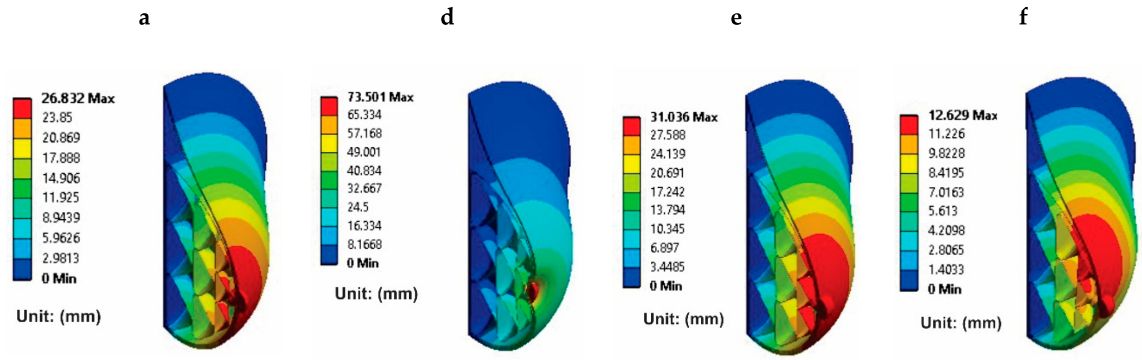

Figure 15. Displacement contour plots for cases "**a**", "**d**", "**e**" and "**f**".

Likewise, in modal analysis, the prosthesis presents the behavior of the internal biomimetic structure, as shown in Figure 16.

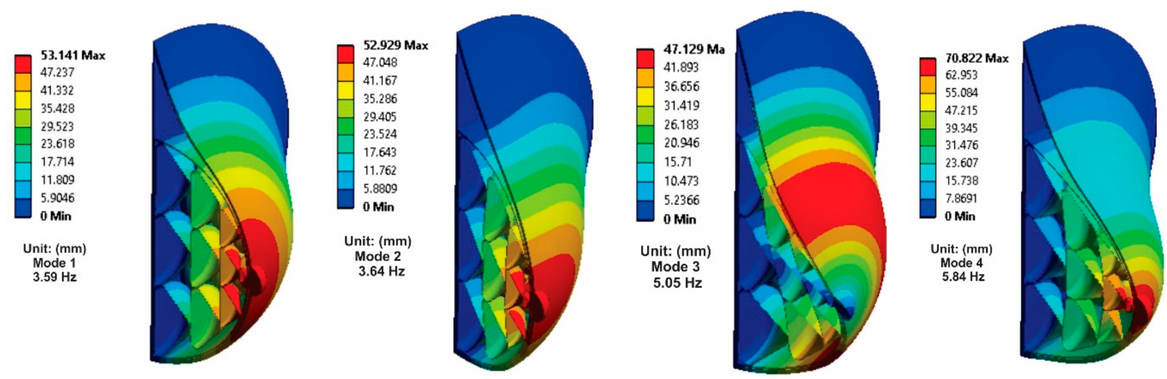

Figure 16. Displacement contour plots for modal analysis.

As can be appreciated in the above figure, in no modal form does the proposed prosthesis present irregularities or bad behavior. These results ensure good functioning when the prosthesis is subjected to dynamic perturbations. The analysis of the results obtained in terms of displacements and stress, lie within the results reported in the literature that use FEM models for cancer diagnosis or detection and for brassiere design. The deformation of the contours of the prosthesis is symmetrical and smooth, as well. There are no irregularities on the surface, and it has natural deformation patterns to resemble a real breast. The fields of stress indicate that the loads are distributed uniformly due to the contour and structure of the prosthesis; that is, the loads are not concentrated on a particular point, which means that to the touch, the person will have the sensation of consistency without feeling much resistance to the palpation force applied, giving the prosthesis a great feeling of realism and belonging. The lobular biomimetic structure remained stable and without any problems during the evaluation of the prosthesis for the load cases posed.

In the future we intend to develop a hybrid system that considers all the components of the design process or the development of a program in the "deep-knowledge and models" philosophy that would help us in measurement, scaling, modeling and manufacturing for prostheses similar to those presented in [58]. This methodology reduces the process input variables and generates results for decision making or manufacturing design plans [59]. Software of this type predicts magnitudes from the measurement—model by involving static and dynamic behavior of the design parts.

6. Conclusions

In this paper, the biomimetic technique was used for the design of a breast prosthesis for cases of complete mastectomy. The prosthesis considers the morphology of the breast for the configuration of its internal structure. This configuration will give the prosthesis the naturalness and behavior of a real breast. Hence, a 3D prosthesis model was built, which can be easily scalable without affecting its functionality and it was assigned silicone-based materials with properties very similar to those of a real breast (fat and glandular tissue). With the model obtained in CAD, a finite element model was developed to perform a static analysis with load cases that simulate the daily activities of a person, analyzing the displacements and the distribution of stress. Finally, a modal analysis was performed in the frequency range of 0 to 6 Hz. The main conclusions obtained from theoretical studies and experimental tests are listed below:

- We successfully biomimetize the internal structures of a real breast to design and analyze a breast prosthesis for cases of complete mastectomy. With the biomimetic technique, a realistic model of the prosthesis can be easily obtained.
- The lobular (biomimetic) geometry used for the design and the spherical adjustment that was adapted to define the internal structure of the prosthesis proposed in this work properly distributes the stress generated by the loads it was subject to. In addition, it can be concluded that the qualities and functioning of the prosthesis designed in this work will allow it to be adapted to different body types, by scaling the model, without affecting its functionality.
- The load cases considered for the prosthesis study do not show irregularities in contour or shape on their surface nor in the internal structure. The displacements and stress found in the prosthesis analysis are within the ranges reported in works related to diagnosis, detection, and evaluation of brassieres.
- Regarding final dimensions, finish, and manufacturability, the model was printed using ABS material. With this, it is possible that the prosthesis can be printed in 3D in an easy and uncomplicated way with the appropriate technology.
- With the dynamic analysis performed in the prosthesis model the fundamental frequencies were obtained. This will prevent reaching conditions of resonance (critical deformations) during use that can affect the natural behavior of the prosthesis or damage its structure. The above ensures that the proposed prosthesis design will not fail and can be used for a variety of activities.

As a conclusion, it can be verified that the prosthesis has realism in mobility and touch.

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