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Dynamic Analysis of a Bio-Inspired External Breast Prosthesis Using Finite Element Analysis

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ABSTRACT
This paper presents the dynamic analysis of a novel bio-inspired external breast prosthesis for cases of complete mastectomy in order to address the problem of the growing number of women diagnosed with breast cancer in Mexico who are candidates for a complete mastectomy. The designed prosthesis takes into account the morphology of a real breast as for its internal structure to obtain authentic mobility and feel. A finite element model was developed and a dynamic analysis was conducted (modal and harmonic) in the frequency range of 0 to 6 Hz. In addition to the previous vibration modes, the following vibration modes were obtained that have not yet been reported in the literature within the frequency range of 6 to 12 Hz. The results obtained in the dynamic analysis are consistent with those of a real breast: there were smooth contours and there was natural mobility in the prosthesis designed. In addition, small deformation displacement magnitudes are present when the prosthesis was under vibration conditions, which does not affect its functionality. This will prevent reaching conditions of resonance (critical deformations) during use that can affect the natural behavior of the prosthesis or damage its structure.

Keywords-Modal analysis, Bio-Inspired design, breast prosthesis

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I. INTRODUCTION

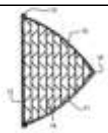
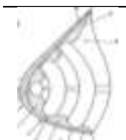
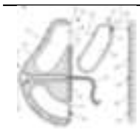
According to the National Institute of Statistics and Geography (INEGI) in 2016, the leading cause of death is breast cancer for women. For this reason, emphasis has been placed on awareness and studies focused in the importance of diagnosis and treatment to early-stage breast cancer [1, 2]. Unfortunately, this type cancer is usually detected in advanced stages. The severity of this type cancer can be classified into 5 stages, according to 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 [3-5]. Surgery consists of extracting the tissue invading the mammary gland and the lymph nodes. The 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 [5-11]. 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 that 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 [12-16]. On the other hand, external prostheses are 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. There are diverse scientific and technological advances in the literature that provide computational models focused on simulating the mammary gland for diagnostic cases

[8,17-29] or analyzing the biomaterials used for implant reconstruction [15,16,30,31]. However, no computational model considers the internal anatomy of the breast or analyzes the behavior of the prosthesis in a manner similar to that of a real breast, that is, during the patient's daily activities. This research aims to evaluate the dynamic behavior of a novel bio-inspired prosthesis similar to a real breast, as no works have been reported in the literature that cover these topics. In particular, this work presents the modal analysis and harmonic response analysis of a breast prosthesis for cases of total mastectomy using the finite element method.

II. METHODOLOGY

The idea of having prostheses similar to a real breast is not new with a market and patent review of external breast prostheses was possible to identify a large number of external breast prosthesis options, much of these prosthesis are solid models with single-piece simple silicone design with different shapes: pear, round, tear-drop with different projections, triangular with different sizes. The commercial prosthesis only consider the shape of the breast with slight bumps while recreation of nipple shape and do not involve any other features. The prosthesis also incorporate a thermoregulatory system that makes it adopt the body temperature of the user. None of the previous prostheses considers the internal structure in the design or focus on realism when using it. In addition to the above, an analysis of available patents was carried out in order to know the design proposals that seek to place prostheses on the market similar in shape, structure and behavior to a real breast. In accordance with the above, it is possible to identify the physical, aesthetic and material characteristics that have been proposed in the designs. The table below shows the patents found:

Table 1. Patents with greater relevance

Patent	Description
	• Shell shape, elastic fabric, outer layer of polyurethane, multiple layers of threads between fabrics forming porous fabric, held at the back with adhesives. Non-commercial [32].
	• Variable tear drop shape with adhesive fastening, low density gel, silicone outer layer, multiple concentric circle-shaped chambers to the nipple. Non-commercial[33].
	• Variable shape depending on the volume, silicone elastic materials on the outside, silicone gel filled inside with lower density silicone gel, air or saline solution. Non-commercial[34].
	• The tear drop shape varies according to the volume; filling is manual or, automatic, silicone in the outer layer and plurality of chambers. Non-commercial [35].

In view of the results found in patents, it is clear that more and more studies and proposals on external breast prostheses are being directed towards designs that resemble the actual structure of a mammary gland. In most of the designs found no one has focused on the behavior and natural response of the breast prosthesis. However, there are no specific proposals that consider the design at the inner part of the prosthesis in order to obtain a better behavior close to that of a real breast. The methodology proposed in this work covers additionally the development of an external 3D breast prosthesis model based on the breast contour of a medical mannequin reported in [36]. The model was taken with the objective of having a design base that could be analyzed through the finite elements method. Figure 1 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.

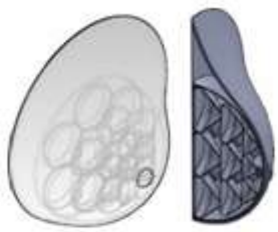


Figure 1. 3D Model of breast prosthesis: isometric cutaway view.

The circumferential adjustment and the design of the internal 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. 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.

III. MODELING AND FINITE ELEMENT ANALYSIS

Different breast models have been developed in finite element for particular cancer detection studies or for the design of brassieres for 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, unlike what is reported in literature. In the different geometries of the designed breast prosthesis model, three structure types were considered: the outer shell (skin and tissue), the internal structure, and the spaces formed by the former two. 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 2.5Kpa , Poisson modulus of 0.499 and damping ratio values (ζ) of 0.06 were considered for the interior [10, 16]. 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 273965 5-node tetrahedral elements measuring 1.98e-5 m, as shown in Fig. 2.

Figure 2. 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. With the model of the prosthesis finished a dynamic analysis was performed to know the behavior and evaluate the performance of the designed prosthesis

Dynamic Analysis of breast

The dynamic behaviour of a vibratory system is directly affected by material properties such as mass, stiffness and damping. Unfortunately, only few studies present the dynamic properties of real breast tissue, in the case of damping few research studies report it or in many cases it is ignored. One of the best papers reporting viscous damping of a breast is [21]. In this work the mean value of viscous damping ratio (ζ) was finally ascertained to be 0.215± 0.013. 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. Under this principle, this does not differ from the arrangements found in the formation of mineral materials currently used to emulate human tissue. In the biological tissue, the order in which collagen molecules adhere gives the final properties of the tissue and therefore the damping. In most breast studies, only internal or hysterical damping caused by material properties is considered, not viscous damping. This same paper compares the fundamental frequencies when considering viscous damping or not. The difference between the frequencies is minimal, not surprisingly, the damping directly affects the magnitude of the displacements and a small measure of vibration frequency. Of course, the behavior of human tissue is non-linear, but for simple cases it is considered linear for small displacements. Other works report damping ratio values (ζ) such as 0.475 ± 0.062 [37], 0.686 [38], 0.19-0.827 [39], for example. It can be observed that the tendency is to consider most breast systems as systems under-damped systems. Only a few works consider the breast system as over damped systems [40]. In the proposed prosthesis, we consider damping ratio values (ζ) of (0.05, 0.06, 0.06) skin, adipose and muscle respectively. The modal analysis was performed in a first stage in the range of 0 to 6 Hz corresponding to modes reported in the literature and in a second stage from 6 to 12 Hz, modes not yet reported and part of the contribution of this work. To perform the harmonic analysis, a steady state sinusoidal load of 5N was applied in a frequency excitation range of 0 to 12 Hz. The main objective of the harmonic analysis is to determine the structure response in the proposed frequency range.

IV. RESULTS AND DISCUSSION

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 [21, 41]. In the simulation results shown in Fig. 3.

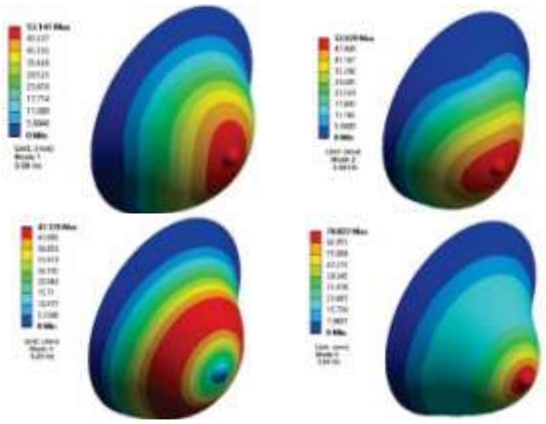


Figure 3. Displacement contour plots for modal analysis

The first mode 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. 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. The response of the structure to the harmonic load it subjected to in the frequency range of 0 to 6 Hz is shown in Fig. 4.

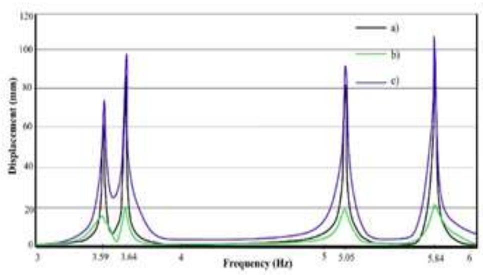


Figure 4. Displacement response at a) , b) and c)

The response peaks are coincident with the natural frequencies found by modal analysis. The observed points were selected as follows: a) middle central line (middle point) , b) posterior central line (Chest wall), and c) anterior central line (Nipple). The peak response in displacement of 5.84Hz was the one that showed the most aggressive behavior with a displacement of 106 mm before the evaluated load condition measured in point c. The other response peaks were also analyzed showing a similar response but with lower displacement values compared to point c, specifically the lowest displacement point were found at the response peak of point b. The design of the prosthesis maintained an adequate behavior during the harmonic analysis, the displacements are considered within the adequate range of the materials used in the prosthesis. Once the harmonic response has been analyzed, it is determined that the internal arrangement of the prosthesis improves the adequate distribution of the loads, this will be reflected in better acceptance and sensitivity in the patient.

In addition to the previous vibration modes, the following vibration modes were obtained that have not yet been reported in the literature within the frequency range of 6 to 12 Hz, are shown in Fig. 5.

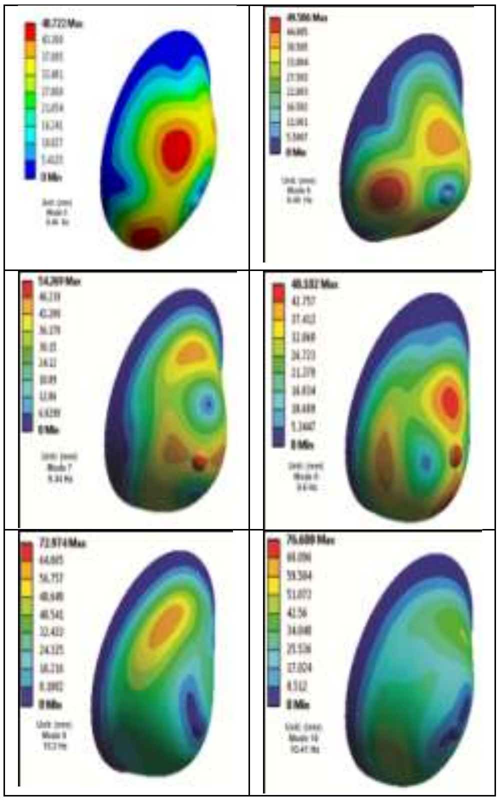


Figure 5. Displacement contour plots for modal analysis

As can be seen in the previous images, there are no irregularities in the contour of the prosthesis and no strange behavior when resonating. The main hypothesis approached in this work is that the internal structure bio-inspired 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.

V. CONCLUSIONS

The lobular geometry (internal structure bio inspired) used for the breast prosthesis 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 dynamic 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 types of activities of daily living in which dynamic loads are present, without affecting its functionality. Likewise, in modal analysis the prosthesis presents 4 vibration modes in 3.59, 3.64, 5.05, and 5.84 Hz. The first mode represents the displacement generated above and below the prosthesis in resonance. The movements of the prosthesis in resonance do not manifest strange movements or behaviors beyond the naturalness of the same.Other modes of vibration in the frequency range of 6 to 12 Hz that have not been reported in the literature were found as a contribution to this work. Vibration modes are found in the following frequencies: 8.46, 8.49, 9.34, 9.6, 10.2 and 10.4 Hz. The vibratory behavior of these modes was adequate within the expected for the designed prosthesis. The harmonic response of the designed prosthesis maintained an adequate behavior, the displacements are considered within the adequate range of the materials used in the prosthesis. The peak response in displacement of 5.84Hz was the one that showed the most aggressive behavior with a displacement of 106 mm before the evaluated load condition measured in point c. The other response peaks showed a similar response but with lower displacement values compared to point c, specifically the lowest displacement point were found at the response peak of point b.As a conclusion, the design evaluated in this work presents an adequate dynamic behavior that gives it possibilities of being a commercial product that meets the needs of patients affected by breast cancer and who were exposed to a complete mastectomy.

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