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Novel low-cost soft-tissue mannequins for medical education

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Abstract

Medical simulators are used to help healthcare practitioners learn and refine skills that can only come with sustained experience and practice. However, many training mannequins currently do not simulate the feel of living tissue with sufficient fidelity. This is a drawback when a diagnosis is made through palpation, as in case of the clinical breast exam (CBE), which is in many resource-limited settings the first and only screening method available. Here we describe a novel method for generating medical simulators which are low-cost and more closely resemble living tissue.

Using commercially available silicone, a breast model was generated. The apparent stiffness was reduced by introducing voids throughout the interior of the model using the lost-wax method. Finite element modeling (FEM) was used to predict the effects of size and distribution of voids on the apparent stiffness of the prototypes. The prototypes generated through this process were evaluated by physicians trained in the CBE.

Our results show that removal of interior volumes produced softer, more pliant and therefore more life-like models when compared to commercially available devices. This was supported by FEM as well as provider assessment of the physical analogues.

We conclude that reducing the apparent stiffness by introducing voids produced simulators which better approximated the mechanical properties of live breast tissue and improved the feel of the simulator. This application of FEM offers an effective tool for low-cost and rapid prototyping, reducing cost and increasing availability in low-resource countries. This approach has the potential to improve medical education by offering a new method for modeling not only breast, but any soft tissue.

Keywords: soft tissue model, breast tissue model, clinical breast exam

Introduction

Existing soft tissue simulators are commonly manufactured with materials such as silicone, gelatin, polyurethane, and epoxy resin matrices (Hench, Jones & Institute of Materials Minerals and Mining., 2005, Silver, 1994). Some of these materials and manufacturing processes are not commonly available in low and middle-income countries (LMICs) (Tran et al., 2012). The materials themselves may be too stiff or uniform in tactile feel, unlike true human tissue, and inserts used to simulate pathology are often only introduced into predefined locations within the mannequin. Gel-based models, using gels encased in plastic covered by a proprietary skin-like material (Salud et al., 2012), may be soft but feel unnatural under shear deformation. Examples of existing products include the Life/form® Advanced Breast Exam Simulator, MammaCare® Learning System Products, the Gaumard® Breast Self Examination Simulator®, and the Limbs & Things® Strap-On Breasts Simulator.

Ultimately, the importance of more realistic models is well documented; better simulators make better-trained practitioners (Kneebone & ApSimon, 2001, McGaghie et al., 2011, Naylor et al., 2009). In regions with limited medical resources, collaborative training for community-based providers and entry-level providers could help address the growing demand for a larger and better trained healthcare workforce(Andreatta, 2017). The purpose of this study is to aid in that process by developing techniques to make soft tissue simulators with more realistic feel.

Breast cancer is the most commonly detected noncutaneous cancer in women in the United States. The National Cancer Institute at the National Institute of Health estimates that more than 260,000 women will have been diagnosed with breast cancer and more than 40,000 deaths will have occurred in 2018 alone (NCI, 2018). Early detection, followed by appropriate treatment, is largely responsible for the improvement in treatment regimens and disease outcome seen in recent decades (Kattlove et al., 1995). However, in low- and middle-income countries (LMICs) access to X-ray mammography and other imaging technologies is limited (Smith et al., 2006). In many cases the clinical breast exam (CBE) is the only option for early detection in resource-limited settings. Failure

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to diagnose cancers early is more common in LMICs; this leads to provider-related delays and more advanced clinical stage at the time of diagnosis (Unger-Saldaña, 2014). While breast palpation is arguably the most important skill to learn, it is only one component of the CBE, which includes patient history, visual observation, and an examination of under arm region (Walker, Hall & Hurst, 1990).

The CBE, a standard screening tool with a sensitivity of 50% and specificity of 82%, remains a valid initial screen prior to pursuing costly alternatives (Croshaw et al., 2011) in countries where such alternative exist. However, medical students often report that the intimacy of the exam and the fear of neglecting a lesion are sources of anxiety and discomfort for both the patient and student (Pugh, Salud & Association for Surgical, 2007). Even experienced physicians and nurse practitioners admit some discomfort and a lack of confidence in their ability to accurately diagnose disease using the CBE (Wiecha & Gann, 1993). Improved training is called for and more realistic simulators are needed to increase the opportunities for deliberate practice and feedback to boost student comfort levels and performance with the exam. Simple elastomer-based mechanical simulators are inherently inexpensive to manufacture and are particularly suited to low-volume rapid fabrication (Alderighi et al., 2018).

Current practice in medical education in the United States and other developed countries is to expose students to the clinical breast exam through paid human subjects and medical mannequins. While paid human subjects provide medical students with real-life examples of breast tissue, it is unclear how common this practice is in LMICs; furthermore these women rarely present with cysts, tumors, or other detectable pathology. Medical mannequins are used because they can be designed to simulate such abnormalities and can significantly reduce student anxiety (Pugh, Salud & Association for Surgical, 2007). The literature also shows encouraging trends in trainee-reported improvement after involvement in simulation experiences in developing countries (Martinerie et al., 2018).

In this paper we describe procedures to design and cast soft tissue simulators with more realistic tactile perception when compared to other simulation models. As a practical demonstration of this novel method for rapid prototyping and controlling the apparent stiffness of materials, we chose to simulate the female breast as a tool for learning the clinical breast exam, but as a general method it may be applicable to other soft tissue medical simulators.

Methods

Figure 1 shows a process chart detailing the fabrication of the simulator.

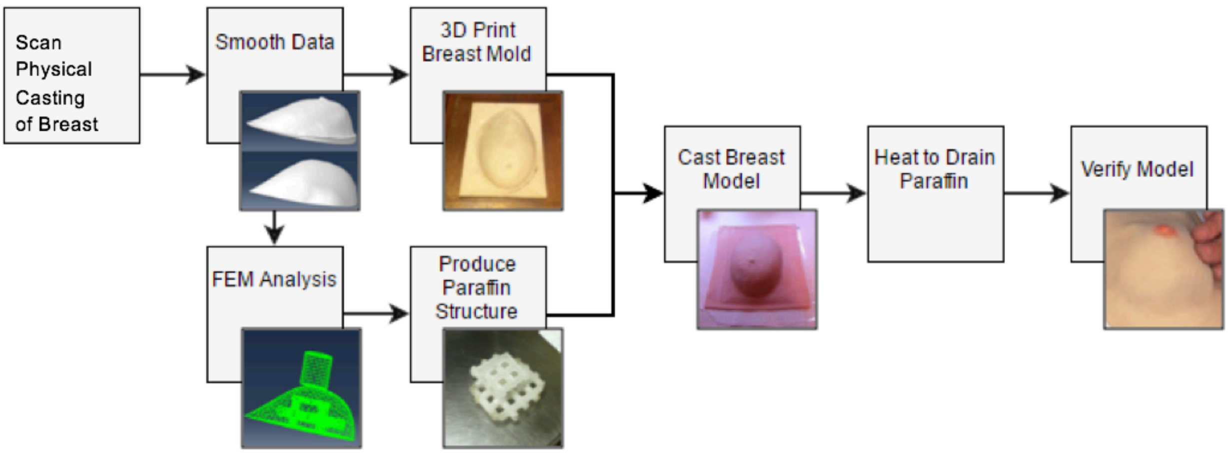

Figure 1. Step-by-step fabrication of a CBE simulator

Creating the Digital Breast Model

Please refer to the Appendix for more detail on the numerical modelling. Briefly, we used a 3D digitizer assembly consisting of a laser scanner paired with Rapidform™ software (3D Systems Geomagic, Morrisville, NC) to construct a coordinate-based representation of the surface geometry of an existing breast simulator (Pugh, Salud & Association for Surgical, 2007). A solid digital breast model was rendered in Solidworks® computer-aided design (CAD) software. Several models were then constructed with identical surface geometry but with differing void configurations where material was "cut out" from the interior of the digital solid. We considered structural integrity, apparent softness, heterogeneity of feel, and ease-of-access to the interior of the model when designing these void configurations. The four digital models ultimately designed were labeled A_D, B_D, C_D, and D_D where subscript "D" denotes that the model is a digital representation. An example of a digital breast model with void geometry is shown in Figure 2.

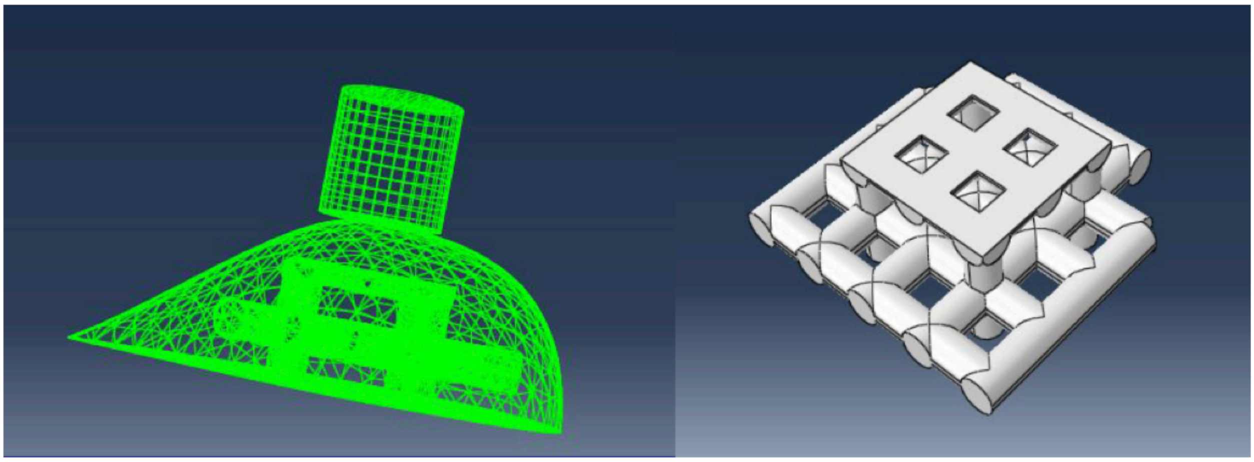

Figure 2. The left panel shows the external wireframe surface of the finite element mesh and rendering of the internal void space of the CBE simulator. The diameter of the cylinders depicted is 8mm. The right panel is a rendering of the void geometry. A large cylindrical rigid indenter is also present in this image

Finite Element Modeling Analysis

Each digital breast model was imported into Abaqus 6.11® and used to represent a substrate for FEM analysis. The goal of analysis was to calculate the substrate's apparent Young's modulus, a common parameter used to measure the material properties of a linearly elastic solid constituent which defines the relationship between a stress (force per unit area) and strain (proportional deformation) for a material. A quasi-static digital simulation was run in which each substrate was compressed with a rigid cylindrical indenter with diameter equal to one-tenth the width of the breast at the base of the grid. The indenter was vertically displaced into the substrate to a depth of 10% of the total thickness of the substrate prior to indentation with the goal of approximating the experience of a finger deforming the surface. The prescribed material parameters of the substrate were chosen to match values for breast tissue, which varies between approximately 3 and 20KPa, as reported in the literature (Samani, Zubovits & Plewes, 2007) and were identical for each substrate, so that only the geometry of the interior void varied. A variation of the Sneddon prediction, a theoretical equation commonly used to assess biopolymer prototypes, was used to calculate the apparent Young's modulus (EA) of the proposed breast model design. The theoretical equation and corresponding dimensions are depicted in Figure 3 (Sneddon, 1965). The mechanical properties of human breasts vary greatly with genetics, weight, age, and other factors. This model represents a single example as a means to describe the process for developing more realistic tactile models.

$$E = \frac{P\,(1 - v^2)}{2 * a * w}$$

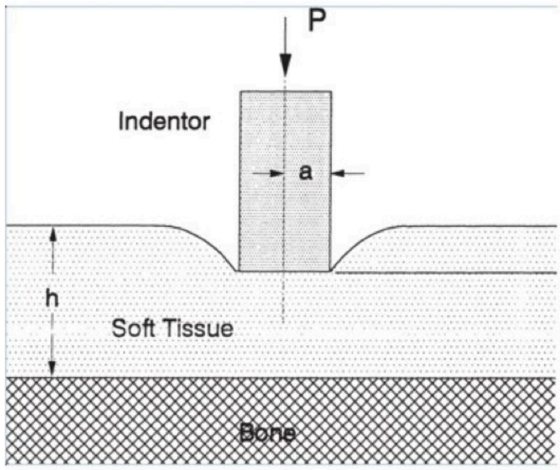

Figure 3. Indentation test and analytical solution (Sneddon, 1965) used to develop predictive FEM for the CBE simulator. E is the Young's modulus, a is the radius of the cylindrical indenter P is the applied force and w is the depth of travel of the indenter

Fabrication of the Physical Model

A 3D printer (ZCorp Zprinter Z450) was used to produce a relatively rigid mold to cast the physical models. The four physical models ultimately fabricated were labeled A_P, B_{P1}, B_{P2}, and C_P where subtext "P" denotes that the model is a physical model. A_P and C_P were the physical representations of digital iterations A_D and C_D, respectively. B_{P1} and B_{P2} both corresponded to digital iteration B_D, but were made with different material compositions.

In the physical mannequin, voids were created in a manner similar to the "lost wax" method of creating a casting. In this process, paraffin is cast in a prescribed geometry and is imbedded in the breast-shaped mold. After the silicone cures around the paraffin framework, the wax-filled silicone mannequin is removed from the mold and gently heated in an oven so that the paraffin drains passively from the model.

A specific mold to create the paraffin structures was machined from a block of aluminum. A grid of hemispherical channels, 1.27cm width and 0.65cm depth separated by 2.54cm (midline-midline) spacing, was milled into a 2.54cm thick aluminum plate. Cylindrical channels were bored through the entire thickness of the aluminum plate at the intersection of the hemispherical channels to create connections or "legs" between the layers. These connections served as channels for the wax to flow out of the model during the final melting step.

After spraying the aluminum mold with Smooth-On Ease Release 200®, liquid paraffin (McMaster Carr, Elmhurst, IL) was poured into the aluminum and allowed to solidify. The top (2x2) layer of the desired paraffin structure was cut from the grid and removed from the aluminum. The bottom layer (5x4 + 1x3) was formed in the same manner, and the two layers were fused with liquid paraffin to create one multi-layered contiguous grid structure to enable drainage pathways from the final cast when heated (figure 2).

Mannequin Casting and Preparation

The bulk material chosen for our final mannequin prototype was Smooth-On EcoFlex® 00-30, a platinum catalyzed silicone elastomer. The material was chosen for its ability to maintain form when cast with wax, low-cost, and its ability to withstand fabrication processes at temperatures needed for the "lost wax" method. The elastic modulus of EcoFlex, with a reported 100% modulus of 68.9 kPa, is far greater than that of adipose tissue, which varies from less than 5 kPa to more than 20 kPa depending on the degree of strain (Andreopoulos & Polyzois, 1994, Zhang, Zheng & Mak, 1997).

The breast mold was sprayed with Smooth-On Ease Release 200. EcoFlex A and B, the components of the silicone elastomer, were mixed in a 1:1 volumetric ratio. Immediately after mixing the two components, Smooth-On Slacker® additive was mixed with the uncured silicone elastomer to further soften the material. The relative volume of EcoFlex A, EcoFlex B, and Slacker additive is referred to as the Slacker ratio. Mannequins A_P, B_{P1}, B_{P2}, and C_P, were composed of 20, 33.3, 27.3, and 23.8 percent Slacker-additive by volume, respectively. The slacker ratios were chosen empirically to soften the material as much as possible without compromising the material's quality. Most notably, the materials produced with higher percentage of Slacker additive by volume had a "doughy" quality. The average cost of materials to produce each physical model was less than US$20 using retail pricing.

Silc-Pig® skin pigment was added in insignificant amounts to the uncured silicone mixture and the solution was mixed for two minutes by hand using a paint stirrer then poured into the breast mold. Mixing was performed by the same person each time to ensure consistency. The paraffin structure was inserted into the solution to the appropriate depth and stabilized, as the paraffin floats in the uncured solution, and the mannequin was allowed to set for five hours before being removed from the breast mold to ensure complete polymerization of EcoFlex, which has a listed cure-time of 4 hours. The cured silicone with embedded paraffin was heated in an oven at 121°C until all paraffin (melting temperature, T_m = 37°C) had melted out of part. To remove the tacky surface finish and achieve a soft texture the part was immersed in a bath of soapy water for no longer than five minutes, dried, and coated with talcum powder.

User Testing

Five Northwestern University Feinberg School of Medicine physicians and nurse practitioners with extensive clinical experience with the CBE evaluated breast mannequins A_P, B_{P1}, B_{P2}, and C_p, as well as another propriety model (Pugh, Salud & Association for Surgical, 2007), hereafter referred to as model D_P, for firmness. Model D_P is composed of a bagged gel covered by a proprietary skin-like material and was used as a comparison to an existing device. Details of the construction and composition of these existing mannequins were not available. Users subjectively assessed firmness on a scale of -5 to 5; -5 being "too soft", 5 being "too firm", and 0 representing firmness of live breast tissue. Users assessed overall realness on a scale of 0 to 5, with 0 labeled "not real at all" and 5 labeled "perfectly imitative of real breast tissue." Sample distributions were assessed for violations in the prerequisite assumptions of homoscedasticity and normality for parametric tests, Levene's and Kolmogorov-Smirnov tests respectively. The appropriate downstream analysis was subsequently selected: Welch's test and Games-Howell post-hoc for violations in homoscedasticity and Mann-Whitney U nonparametric tests for violations of normality. Analyses were performed in Minitab and SPSS 25 (IBM).

Results

Finite Element Modeling

The theoretical Sneddon prediction of E_A is affected by both void configuration and the prescribed Young's modulus as shown in Table 1. The most salient and expected trend predicts a decrease in E_A as a function of increased void volume. Digital models D_D and D_D' which have the same void configuration but differ only in prescribed Young's modulus show that with decreased prescribed Young's modulus, the prediction of E_A is also decreased.

Table 1: FEM prescribed Young's modulus, model name, void volume, reactive force at 10% displacement, and theoretical Sneddon prediction. Note the decrease in theoretical Sneddon value as a function of increased void volume and the decrease in theoretical Sneddon Prediction with the decreased in prescribed modulus

Prescribed Young's modulus (Pa)	Model name	Approximate void volume (mL)	Reactive force at 10% displacement	Theoretical Sneddon prediction (Pa)
20000	A_D	36.19	7.746	17086.17
20000	B_D	64.41	5.661	12487.07
20000	C_D	208.39	4.445	9804.81
20000	D_D	220.63	4.246	9365.85
18000	D_D	220.63	3.821	8428.38

The values presented here represent somewhat arbitrary choices, for there are myriad possible combinations of void volume and void geometry that may give similar results. In the discussion we make the case that this design flexibility is an important feature of the method described.

Mannequin Casting

Table 2 shows the effect of additive on the elastic modulus of the silicone material, as determined by compression tests using Instron 5544 Mechanical testing machines coupled with Bluehill2 software.

Table 2: Silicon:Slacker ratios, percent composition Slacker by volume, and ratio of E_A (experimental model) to E_A (model with 1:1:0 Slacker ratio) as determined by compression tests using Instron 5544 mechanical testing machines coupled with Bluehill2 software

Slacker Ratio EcoFlex1:EcoFlex2:Slacker	Percent by volume	$\frac{E_A(\text{Experimental Model})}{E_A(\text{Model with 1:1:0 Slacker Ratio})}$
1: 1: 0	0%	1
1: 1: :0.5	20%	0.18
1: 1: 0.75	27.3%	0.09
1: 1: 1	33%	0.05

User Testing

The results of user assessments, shown in Table 3, suggest that mannequin C_P, the physical model with greatest void volume, most closely captures the firmness of real breast tissue. Mannequin C was also unanimously chosen as the most realistic simulation overall. Model C_P was statistically superior to all other models in terms of firmness (P=0.001), but overall realness was not statistically superior (P=0.155).

Table 3: Average user firmness and overall ratings for each breast model iteration. Note that mannequin C_P is rated closest to the ideal for both parameters

Model	Firmness	Overall
A_P	1.5	2.6
B_{P1}	-1.3	1.2
B_{P2}	-1	2.2
C_P	-0.8	3.2
D_P	2.4	3

Discussion

The concept of designing voids in CBE training models with specific geometry to reduce E_A of materials has not been explored prior to this study. The optimal model for the CBE simulator was selected based on several criteria. First, the void geometry selected reduced E_A to a value comparable to that of live breast tissue without sacrificing the qualitative feel of the model. Existing models using bagged gels do not feel natural in shear and are often not pliable enough to properly model soft tissue.

Second, our system allows for the easy insertion of materials used to simulate the tactile feel of malignancies, cysts, and other abnormalities commonly detected during the clinical breast exam. The channels of this void geometry allow access for implantation of "lumps" throughout the mannequin. In addition, the silicone material increases the pliability of the entire part and allows for increased accessibility to all void recesses.

Lastly, the irregularity of the void structure chosen reflects the non-homogeneous anatomy of the human breast, a combination of glandular, adipose, and fibrous tissue. This non-homogeneity, which may be manipulated by varying void geometry, is not captured by current CBE training mannequins.

Finite element analysis of the digital breast models confirmed the relationship between void volume and E_A as predicted by the Sneddon model, shown in Table 1. User testing further confirmed the relationship between firmness and void volume. This trend is most apparent in the comparison of Models A_P and C_P. These models had comparable levels of slacker additive but different void volumes. With greater void volume, the apparent firmness of the model was decreased. Models B_{P1} and B_{P2} were characterized by expert users as "doughy" because they were composed of a higher percentage Slacker by volume; these models were therefore rated too soft.

The utility of the CBE as a screening method for early breast cancer for women with average risk for breast cancer has been questioned (Oeffinger et al., 2015), but the case is far from settled in any environment and remains an important practice in at-risk populations. Others argue that the lack of available imaging technologies in LMICs raise questions about these recommendations based on North American and European populations (Gutnik et al., 2016). The CBE is regarded as a useful tool in at-risk women without access to mammography (Gutnik et al., 2016) and for women in LMICs who typically present with more advanced disease than women in developed countries (Dey, 2014). This approach has the potential to improve the quality of medical education in low-resource settings by introducing a new tool for modeling breast tissue and other soft tissues.

Conclusion

Through the novel approach to soft tissue simulation developed in this study, it is possible to reduce the apparent Young's Modulus, E_A, of a solid body through the introduction of voids of specific geometry and to do so at very low cost. This relationship between mannequin stiffness and the volume and distribution of voids may be modeled using finite element methods. By controlling the precise geometry of the voids, it is possible to fabricate models that feel both tissue-like and heterogeneous. The voids also allow for implantation of materials of different stiffness to simulate a myriad of abnormalities within and throughout the mannequin. This approach is not limited to applications in breast modeling, but can be applied to the simulation of any soft tissue.

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Appendix

Geometry of the Breast

We used a 3D digitizer assembly consisting of a Vivid 900™ (Konica Minolta Sensing, INC. Osaka, Japan) laser scanner paired with Rapidform™ software (3D Systems Geomagic, Morrisville, NC) to construct a coordinate-based representation of the surface geometry of an existing proprietary medical simulator5. This representation was smoothed by defining custom fitting options for smoothness using the internal Rapidform Auto Surfacing function and stored as a SolidWorks® (Dassault Systems, Waltham, MA) part file. This file format is compatible with Abaqus® (Dassault Systems, Waltham, MA) finite element modeling (FEM) software. A 3D printer (ZCorp Zprinter Z450), was used to produce the mold used to cast the breast. Several models were considered with identical surface geometry, but differing void configurations. These void configurations were designed to allow for ease-of-access to varying regions of the model, while not interfering with the structural integrity of the device as a whole. A grid approach was chosen for ease of access and intuitive nature of such a design to accommodate placing a desired anomaly within the device. The four digital models ultimately designed and fabricated were labeled AD, BD, CD, and DD where the subtext "D" denotes that the model is digital. These models were tested individually for their respective apparent Young's moduli, a common parameter used to measure the material properties of a linearly elastic solid constituent which defines the relationship between a stress (force per unit area) and strain (proportional deformation) in a material.

Finite Element Modeling Analysis

The surface geometry of the medical mannequin was stored as a SolidWorks part file and was used to produce a digital part representing a solid body of material within the Abaqus software. The material was defined by a Young's Modulus of 20 kPa and Poisson ratio, a description of the relationship between a transverse strain and the resulting axial strain, of 0.49 – parameters chosen to match values for breast tissue reported in the literature referenced in the main body of the paper. The digital part was then used in an Abaqus simulation of a prescribed displacement of a rigid cylindrical indenter acting on a semi-infinite half-space. The calculated reactive force (the normal force imparted on the indenter by the depressed material) was used with the Sneddon solution, a theoretical equation commonly used to assess biopolymer prototypes by describing the normal force on the indenter as a function of indenter radius, indentation depth, and stress/strain profile, to calculate the apparent Young's modulus (EA) of proposed breast model designs.

Abaqus Specifications

The simulated breast was rendered in Solidworks 2011 computer-aided design (CAD) software and imported into Abaqus 6.11. The cylindrical indenter was created within the native Abaqus CAD environment. To create the simulated digital part iterations, the void was designed in SolidWorks, imported into Abaqus, and then used as the template to excise volume within the larger breast CAD part. This resulted in a model with internal cavities. The gross model was defined in accordance with software convention as a "standard" and "explicit" model type, and the breast part was defined and digitally sectioned for computation as an elastic material with a Young's modulus of 20 kPa and an essentially incompressible Poisson ratio of 0.49. The substrate, the breast-shaped digital part in this study, was seeded with an approximate global tetrahedral mesh edge length of 0.016 and with curvature control limited by a maximum deviation factor of 0.1. The minimum size factor of the tetrahedral mesh edge length remained at the default setting. The Encastre boundary condition, which states that all three degrees of freedom for translational and rotational movement are prohibited, ensured the fixation of the breast substrate base. The empirical design can be divided into two distinct steps. First, contact between the indenter and substrate was initiated through infinitesimal displacement of the indenter so that contact was limited, so as to prevent potential chatter-induced convergence failures. The continued displacement of the indenter was then measured to a depth of 10 percent the total thickness of the substrate prior to indentation. All degrees of freedom for the indenter other than the translational displacement in the direction of indentation were defined as zero. The interactions between the contacting bodies were isotropic frictional interactions with tangential frictional coefficients of 0.20 and infinite elastic slip stiffness penalties, a parameter specific to each individual experiment and selected to define the degree of allowable relative motion between the objects during calculations. These settings remained consistent for each digital part iteration studied, meaning the only modified parameter was the geometry of the interior void.