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Breast implant surface texture impacts host tissue response

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ABSTRACT

Background: Surface texture of a breast implant influences tissue response and ultimately device performance. Characterizing differences among available surface textures is important for predicting and optimizing performance.

Methods: Scanning electron microscopy (SEM) and X-ray computed tomography (CT)-imaging were used to characterize the topography and surface area of 12 unique breast implant surface textures from seven different manufacturers. Samples of these surface textures were implanted in rats, and tissue response was analyzed histologically. In separate experiments, the force required to separate host tissue from the implant surface texture was used as a measure of tissue adherence.

Results: SEM imaging of the top and cross section of the implant shells showed that the textures differed qualitatively in evenness of the surface, presence of pores, size and openness of the pores, and the depth of texturing. X-ray CT imaging reflected these differences, with the texture surface area of the anterior of the shells ranging from 85 to 551 mm^2, which was 8–602% greater than that of a flat surface. General similarities based on the physical structure of the surfaces were noted among groups of textures. In the rat models, with increasing surface texture complexity, there was increased capsule disorganization, tissue ingrowth, and tissue adherence.

Conclusions: Surface area and topography of breast implant textures are important factors contributing to tissue ingrowth and adherence. Based on surface area characteristics and measurements, it is possible to group the textures into four classifications: smooth/nanotexture (80–100 mm^2), microtexture (100–200 mm^2), macrotexture (200–300 mm^2), and macrotexture-plus ($>$ 300 mm^2).

1. Introduction

Breast implants are widely used for cosmetic augmentation and post-mastectomy breast reconstruction. Many types of breast implants are available that differ across a range of physical characteristics, such as shape, size, gel material, and surface texture (Atlan et al., 2016; Maxwell et al., 2014) and also differ in the chemical composition of implant components, such as the elastomer shell (Kappel et al., 2014). Selecting the appropriate implant among the many options depends on personal preferences of the physician and patient, and the desired aesthetic outcome. However, the physical characteristics of an implant may influence clinical performance and should be considered during the selection process. This is particularly true for implant surface texture, which plays a key role in shaping breast tissue response (Harvey et al., 2013).

Following implantation, the host tissue recognizes the breast implant device as a foreign body and initiates an immune response that can result in formation of a collagen fiber capsule around the implant (Efanov et al., 2017; Sheikh et al., 2015). Capsule formation is a normal tissue response but can become problematic when the capsule contracts around the implant, making the breast hard and deformed, a complication known as capsular contracture (Hakelius and Ohlsen, 1992). It is thought that collagen fiber alignment plays a key role in capsular contracture, and that disruption of such fiber alignment may lead to reductions in the incidence and severity of capsular contracture (Bui et al., 2015). The surface texture of the breast implant can impact capsule formation, specifically the organization of the capsule's collagen fibers and adherence of the tissue to the device (Barr et al., 2009; Harvey et al., 2013; Valencia-Lazcano et al., 2013). A smooth silicone implant leads to formation of a nonadherent dense capsule with highly aligned and organized collagen fibers (Brohim et al., 1992; Danino et al., 2018). However, when a device with a textured surface is implanted, tissue ingrowth into the texture surface can disrupt the alignment of the surrounding capsule, which has been associated with lower

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rates of clinically significant capsular contracture and malposition compared with smooth surface implants (Barnsley et al., 2006; Brohim et al., 1992; Clugston et al., 1994; Derby and Codner, 2015; Hakelius and Ohlsen, 1992, 1997; Headon et al., 2015). Deeper and more complex textures promote increased tissue ingrowth (Brohim et al., 1992; Danino et al., 2001; Minami et al., 2006). As a result, the force required to break the interface between the capsule and implant is greater than less complex textures, which may reduce the risk of device rotation (del Rosario et al., 1995; Maxwell et al., 2014). Greater tissue ingrowth has also been correlated with reduced synovial-like metaplasia in human breast capsules due to the reduction in movement between the implant and surrounding stroma (Yeoh et al., 1996).

Breast implant manufacturers continue to develop new implant surface textures using varying methodologies in an effort to stabilize the implant in the pocket through increased coefficient of friction or enhanced integration of the device with breast tissue (Derby and Codner, 2015; Harvey et al., 2013). Herein, we describe the use of scanning electron microscopy (SEM) and X-ray computed tomography (CT) imaging to characterize the topography and surface area of 12 unique breast implant surface textures from 7 different manufacturers and evaluate how surface texture influences capsule formation and tissue adherence in rats.

2. Materials and methods

2.1. Breast implants

The surface texture of shells from 12 different breast implant devices were evaluated (Table 1). Each of these implants are silicone coated except for Polytech Microthane, which is polyurethane coated to create an irregular sponge-like surface. The processes for creating surface texture on the silicone implants differ across manufacturers. For example, the Microcell, Biocell, Nagotex, and Cristalline textures are created using different lost-salt techniques, in which a layer of fine granular salt is applied to the silicone shell before curing, and then removed by rinsing with water after curing. The lost-salt technique used to prepare Allergan Biocell was designed to produce overhangs at the opening of the pores to promote greater tissue adherence. In comparison, the Mentor Siltex texture is generated by a pressure imprint-stamping technique, and the Sientra True texture is produced by an undisclosed technique that does not involve use of salt or pressure stamping (Barr et al., 2017; Chao et al., 2016; Maxwell and Gabriel, 2017).

2.2. Breast implant surface imaging

SEM was used to image the surface of the breast implant textures using a single shell per implant type (Atlan et al., 2016; Barr et al., 2017). One 10-mm diameter disk was cut from the anterior of the shell of each breast implant device and used to capture a top and cross-sectional view of the surface texture. Samples were secured to a specimen mount with carbon adhesive, sputter coated with gold at 25 mA for 2 min, and imaged with a Hitachi S-3400N Tungsten Filament Scanning Electron Microscope using an electron beam accelerating voltage of 5 kV and aperture of 0. Images were captured at 40× and 100× magnification for the top view and 40× magnification for the cross section.

In a separate experiment designed to explore additional methods of pore characterization, SEM images were taken of 2 similar pore textures of different surface areas (i.e., Allergan Microcell and Allergan Biocell) to quantify pore density, pore opening area, surface openness, and texture depth. Details of the methods used in this experiment can be found in the Supplementary material.

X-ray CT was used to determine the surface area of the breast implant textures. Eight 10-mm diameter disks were cut from the shell of each breast implant device, four from the anterior and four from the posterior of the shell. The entire geometry of each disk was acquired by taking a series of 2-dimensional X-ray images (slices) while the implant disk was concentrically rotated 360° in the X-ray beam. These slices containing information about the implant disk's position (with 15 µm voxel resolution) and density (gray scale) were used as the basis for digital 3-dimensional reconstruction of the sample's volume data (Fig. 1a) (ASTM International, 2011; Landis and Keane, 2010). All internal and external surfaces of the implant sample were extracted from this CT volume data. The spatial precision of the CT projection data was checked by a certified CT test standard (ruby bar with a length of 4.0432 ± 0.0020 mm; GE Sensing & Inspection Technologies, GmbH, Wunstorf, Germany).

A vertical cross section of the X-ray CT image was used to measure the thickness of the non-textured area, which was defined as the location starting from the bottom of the disk to the flat area near the top of the disk or the lowest point of any protrusions present on the surface (Fig. 1b). The thickness of the non-textured area was measured in three areas of the cross section and averaged. The average thickness of the non-textured area was used to calculate the surface area of the non-textured area (sides and bottom of disk) according to the formula for the area of a cylinder based on the assumption that the bottom of the disk was a flat surface. The resulting surface area of the non-textured surface was subtracted from the total surface area of the disk (obtained using CT software) to produce a surface area measurement for the textured surface (top of disk) (Fig. 1c). The surface area of the textured surface was calculated in terms of mm^2 as well as the percentage higher than that of a flat surface. The textured surface of the disk can be seen as the top circle of a cylinder; therefore, the surface area of a flat surface texture would be the surface area of a circle with a 5 mm radius (i.e., 79 mm^2).

2.3. Capsule formation

The protocols used in the animal studies were approved by the Institutional Animal Care and Use Committee. This study is conducted in compliance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals, and Allergan, plc standard operating procedures. Capsule formation following subcutaneous implantation of disks cut from the shells of the different breast implants was evaluated in male Sprague -Dawley rats (Charles River Laboratories; Wilmington, MA). A total of six 30-mm disks (3 each from the anterior and posterior of the implant shell) were evaluated for each implant surface texture. The implantation scheme comprises three disks per rat in one of four locations along the torso (right cranial, right caudal, left cranial, and left caudal). The disks were implanted under anesthesia with 4% isoflurane in 2 L/min oxygen, with the textured surface of the disk facing the muscle. Six weeks later, the disk and surrounding tissue were explanted, and the tissue in contact with the textured surface of the disk was excised. Tissue samples were fixed in 10% neutral-buffered formalin, then processed and embedded in paraffin. Sections were cut at

Table 1
Manufacturer and surface texture of breast implant devices.

Manufacturer	Implant type
Allergan plc (Dublin, Ireland)	Smooth texture
	Microcell texture
	Biocell texture
Eurosilicone S.A.S. (Apt, France)	Cristalline texture
Mentor (Irvine, CA, USA)	Siltex texture
Motiva/Establishment Labs (Alajuela, Costa Rica)	SilkSurface texture
	VelvetSurface texture
Nagor (Glasgow, Scotland)	Nagotex texture
Polytech Health & Aesthetics (Dieburg, Germany)	MESMOsensitive texture
	POLYtxt texture
	Microthane texture
Sientra (Santa Barbara, CA, USA)	True texture