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Breast

Surface Areas of Textured Breast Implants: Implications for the Biofilm Theory of Capsule Formation

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Background: Increased surface area of mammary implants is suggested as a causative agent for the development of biofilms, which may lead to capsular contraction. The aim of this study was to quantify the surface areas of round implants of different textures and examine how these data can be interpreted with regard to clinical observation.

Methods: Surface areas of textured round breast implants were calculated from previously reported confocal scanning microscopic assessment, and dimensions sourced from 3 breast implant manufacturers (McGhan, Mentor, and Silimed). Statistical comparisons were made between manufacturers for different implant volumes, profiles, and texturing.

Results: There was a difference in surface area between manufacturers for all implant profiles and between manufacturers for equivalent volume implants (F (3, 253) = 2,828.87; $P < 0.001$). Silimed polyurethane implants (mean area = 6.12×10^6 mm^2) was the highest. Natrelle (mean area = 1.2×10^6 mm^2) was the next highest, followed by Siltex (mean area = 4.8×10^5 mm^2). Mentor smooth implants (mean area = 4×10^4 mm^2) had the lowest mean surface area. There were no differences in surface area between the different profiles for Siltex, Silimed polyurethane, and Mentor smooth implants of the same volume.

Conclusions: The increased surface area produced by texturing, although different between manufacturers, seems to provide protection against capsular contraction. Correlation with clinical data indicates that the surface area alone cannot account for these differences. Smooth implants, which have the smallest surface area have the highest incidence of capsular contraction. These data are at odds with the biofilm theory of capsular contraction. *(Plast Reconstr Surg Glob Open 2018;6:e1700; doi: 10.1097/GOX.0000000000001700; Published online 19 March 2018.)*

INTRODUCTION

A recent hypothesis proposes that increased surface area of texturing on a mammary implant increases the likelihood of developing anaplastic large cell lymphoma (ALCL) and capsular contraction via the mechanism of biofilm formation caused by an infectious agent.[1,2] A "threshold" hypothesis proposes that a high level of bacterial contamination is linked to development of ALCL, whereas lower levels are hypothesized to be important in the development of a capsular contraction. It has previously been demonstrated that textured implants retain more bacteria than smooth surfaces[3]; therefore, it would be predicted that highly textured implants would demonstrate a higher incidence of capsular contraction than smoother surfaces.

The analysis of topographical surface areas of 4 different textures demonstrates dramatically different surface areas for a 1 mm^2 of implant surface,[1] yet these differences do not at present seem to translate into implant-specific risk of developing ALCL or capsular contraction.

This article presents the calculated surface areas of textured implants for the manufacturers discussed in the recent study, across different implant profiles and discusses the clinical implications of these differences. As such, it presents a counterargument for the importance of biofilm

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formation in the development of capsular contraction and possibly ALCL.

METHODS

Dimensions of round textured mammary implants of different profiles were obtained from the manufacturers of Biocell (Allergan Sales LLC Irving, CA), Siltex (Mentor Worldwide LLC Santa Barbara, CA) and Silimed polyurethane (Silimed Inc Rio de Janeiro, Brazil.).

Treating each implant as an ellipsoid, the smooth surface area was calculated using the Knud-Thompsen derivation of Klamkin's formula[4] (*vide infra*), where a and b are the radius of the implant and c is the projection, utilizing a value of $P \approx 1.6075$ which yielded a maximum relative error of 1.061%.

$$SA = 4 \cdot \pi \left(\frac{a^p b^p + a^p c^p + b^p c^p}{3} \right)^{\frac{1}{p}}$$

The surface area of the texturing over the implant was calculated from data previously published[1] and applying it to the ellipsoid calculation.

Differences between surface areas of profiles both within manufacturer groups and between manufacturer groups were calculated using separate 4×4 subject's factorial analysis of variance.

RESULTS

The relationship between implant volumes and total surface area of an implant is shown in **Supplemental Digital Content 1** for different manufacturers and implant profiles (**see figure, Supplemental Digital Content 1**, which displays the area of implant texturing for different implant volumes and different manufacturers. (a) Low profile (b) Moderate profile (c) High profile (d) Extra high profile, ***http://links.lww.com/PRSGO/A693***).

Table 1. Descriptive Statistics across Implants of Different Profiles and Surfaces

Implant	Mean Volume (cc)	SD	Mean Surface Area (cm²)	SD	N
Natrelle (Biocell)	427.79	174.68	437.72	123.74	75
Low	516.67	147.72	511.87	96.57	15
Moderate	357.50	149.95	386.73	111.19	22
High	391.25	192.33	402.69	127.61	20
Extra high	471.89	169.59	477.17	119.10	18
Siltex cohesive II	371.98	193.14	386.30	130.80	58
Moderate	360.53	197.43	385.19	136.69	19
Moderate plus	360.53	197.43	369.55	132.20	19
High	393.75	193.12	403.26	128.40	20
Silimed (polyurethane)	324.19	140.50	417.30	120.90	43
Advance LO	281.82	135.96	376.06	118.13	11
Advance MD	305.91	140.14	401.94	122.95	11
Advance HI	333.64	153.09	425.61	129.56	11
Advance XH	380.50	132.23	470.42	108.03	10
Smooth (mentor)	410.05	193.96	402.80	131.63	92
Low	391.92	194.83	409.42	139.99	71
Moderate	422.92	194.06	415.81	131.83	76
Moderate plus	411.36	198.77	408.39	131.65	73
High	416.75	200.70	372.41	125.40	48

Table 1 displays the descriptive statistics for volume and untransformed surface area of textured implants across the range of implant manufacturers and profiles. An initial Pearson correlation indicated strong, positive, significant correlations between volume and surface area for each manufacturer ranging from 0.96 to 0.97, indicating that surface area increased with volume for each manufacturer.

To examine differences in volume and surface area between different profiles, the data were initially split by profile so that a comparison of the volume and surface area of each manufacturer for each of the 4 profiles could be determined (**Supplemental Digital Content 1**). Results indicated a very large significant difference in surface area between the manufacturers for low, (F (3, 67) = 711.26; $P < 0.001$; $\eta^2 = 0.97$); moderate, (F (3, 72) = 678.49; $P < 0.001$; $\eta^2 = 0.97$); high, (F (3, 69) = 664.19; $P < 0.001$; $\eta^2 = 0.97$); and extra high profile implants, (F (3, 45) = 1,293.20; $P < 0.001$; $\eta^2 = 0.98$).

Post hoc comparison between manufacturer types (Table 1) indicated that there was a significant difference between the surface areas between manufacturers (Fig. 1) for equivalent volume implants (F (3, 253) = 2,828.87; $P < 0.001$). Silimed polyurethane implants (mean area = 6,121,770.53 mm²) was higher than all the others, n = 43. Natrelle (mean area = 1,221,234.71 mm²) was the next highest (n = 75), followed by Siltex (mean area = 479,009.01 mm²; n = 58). Mentor smooth implants (mean area = 40,279.61 mm²) had the lowest mean surface area (n = 92).

There were no differences in surface area between the different profiles for the Siltex, Silimed, and Mentor smooth implants of the same volume. However, the Natrelle low profile implants showed a significant difference between profiles (F (3, 71) = 5.04; $P = 0.003$; $\eta^2 = 0.18$). Post hoc tests indicated that Natrelle low profile implants had a significantly larger surface area than moderate ($P = 0.002$) or high-profile implants ($P = 0.005$). Interestingly, extra high-profile implants also had larger surface area than high ($P = 0.039$) or moderate profile implants ($P = 0.016$).

DISCUSSION

The biofilm theory of development of capsular contraction[4] proposes that bacterial contamination on a breast implant surface leads to the developments of a biofilm. In a dose–response fashion, high levels lead to development with ALCL, whereas lower levels produce capsular contraction. The basis of this hypothesis is a porcine model with the techniques of biofilm detection applied to a series of samples taken from capsular contraction patients. It is flawed significantly in its methodology, in that it has neither controls for either the animal or human branch of the study. As such, the lymphocyte proliferation demonstrates cannot be interpreted in the context of a threshold phenomenon, either across species , or in the absence of bacteria.

However, from the biofilm theory of capsular contraction formation, it would be expected that exposure to large areas of texturing to the breast would be more likely to develop significant biofilms compared with smaller areas. The sequelae would therefore be an increased risk of en-

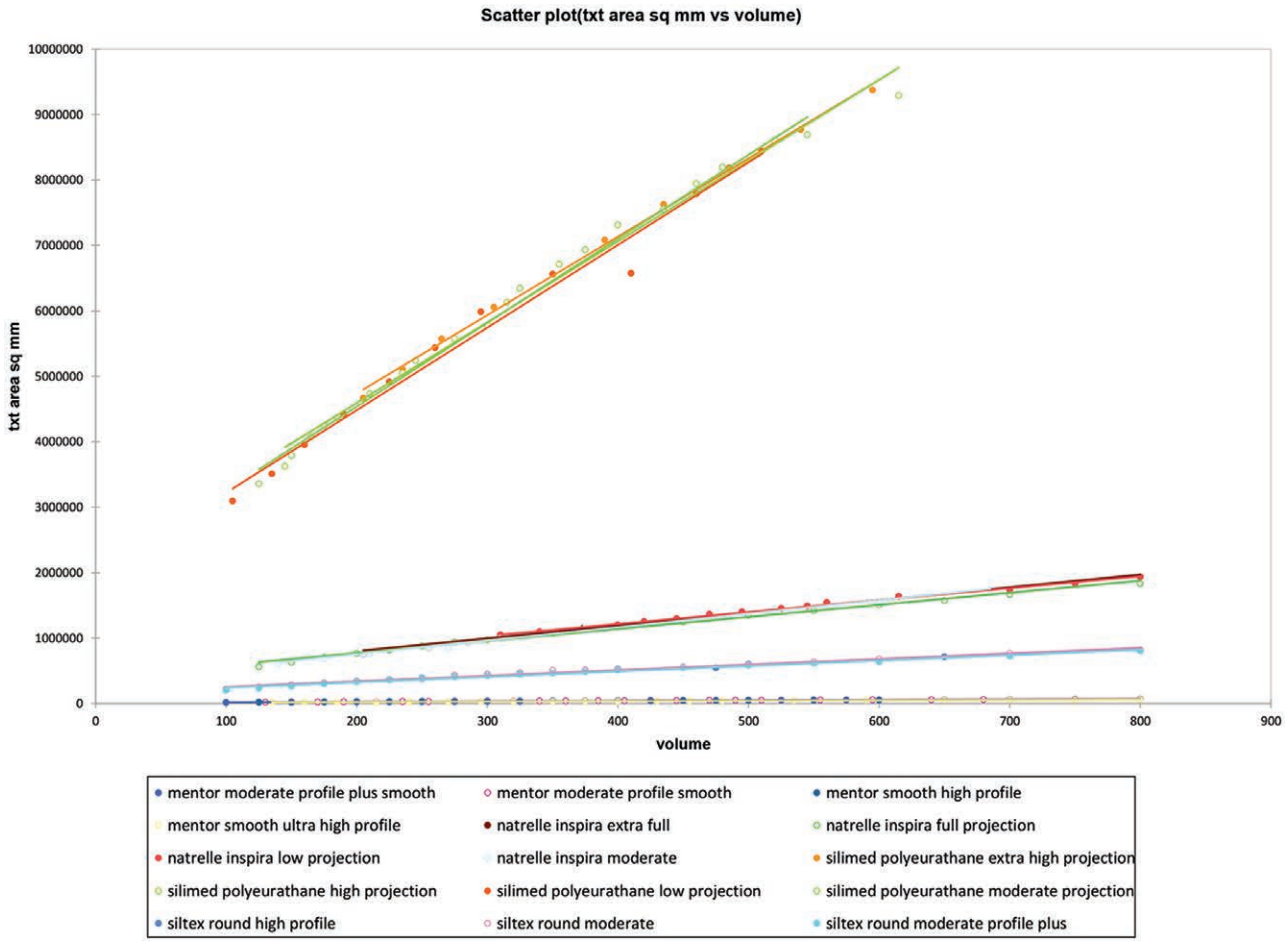

Fig. 1. Area of implant texturing for different implant volumes and different manufacturers.

capsulation through development of biofilms and possibly an increased susceptible to development of ALCL. As such, it would also be expected that larger implants would be more likely to produce capsules (and possibly ALCL) than smaller ones. This article challenges the hypothesis that increased surface area per se is responsible for biofilm formation, and consequently capsular contraction or ALCL.

Although the pore size of a texturing has been proposed as important in the developments of biofilms through bacterial or fibroblast adhesion, the irregularity of surfaces makes this difficult to assess. In particular, scanning electron microscopy (SEM) and confocal microscopic assessment has demonstrated that the pore opening may not be reflective of the surface area, given that some textures produce an overhang, which prevents interaction of the breast tissue with the surface.[5]

It is not clear from either animal studies nor clinical data as to the importance of biofilms in the development of capsular contraction. A porcine model demonstrated no difference in capsule formation between smooth and textured implants, despite having a 72-fold biofilm increase in the textured implants.[6,7] Although it has been proposed that once an implant has an established biofilm, it behaves ostensibly as a smooth implant; this is not supported by clinical data, which consistently show a higher incidence of capsular contraction with smooth implants.[8–10] A number of meta-analyses have shown that textured implants are associated with a lower risk of capsular contracture.[11,12] In a recent Cochrane type review, the incidence of capsular contraction for textured silicone implants in primary cosmetic augments was 2.4–14.8% at 6 years and 18.9% at 10 years.[13] Polyurethane implants had an incidence of 1% at 5 years follow-up.

Similarly, the texture type has not been shown to influence the incidence of capsule formation,[14] despite differences being apparent in the texturing described.[5] This current study demonstrates differences in the surface area exposed for interaction with either breast tissue or biofilm formation between manufacturers, yet it would seem from the clinical data that this bears no correlation with clinical incidence of capsular contraction. With regard to specific manufacturers, the Natrelle Style 410 implant (Biocell textured, McGhan) has reported a capsular contracture rate of 4.8% at 3 years[15] and 4.6–5.6% at 6 years.[16,17] Siltex MemoryGel implants (Mentor LLC) reports a 3-year incidence of capsular contraction of 8.1%[18] with round implants and 2.4% for the shaped product.[19] Although polyurethane-coated implants have the most textured surface, these have the lowest incidence of capsular contracture.[20] A recent risk analysis concluded that smooth implants resulted in increased odds of capsular contracture.[8,9]

Table 2. Surface Areas of Different Implant Textures Per Square Millimeter Described by Different Studies

	Area of Texturing/mm² of Implant Surface (Loch-Wilkinson et al.[1])	Area of Texturing/mm² of Implant Surface (Barr et al.[5])
Biocell	27.7	18.49
Siltex	12.4	15.00
Smooth	1.0	1.01

Interestingly, 2 long-term studies examining complications in higher profile implants have shown that they have a reduced incidence of capsular contraction compared with lower profile and smaller volume equivalents.[8,21] This study might account for the observation, in that it demonstrates no difference between the surface area of different profiles for equivalent volumes of equivalent texture types, implying that the amount of interface is the same for all profiles.

The surface area per square millimeter of implant surfaces described in the recent study by Loch-Wilkinson et al.[1] differs significantly from that described by Barr et al.[5] (Table 2). Reinterpretation of the data from this study utilizing the figures by Barr et al.[5] would indicate that the surface area of Biocell implants is 33.7% less, and that of Siltex is 17.3% more than that described in the article by Loch-Wilkinson et al.[1] The difference between the surface areas of these 2 implant textures, while remaining significantly different, may be less than suggested. It also highlights some of the difficulties with measuring surface roughness on implants.

This study compares the implant surface areas derived from a theoretically calculated surface area with clinically published results for capsular contraction in implants with the same surface type. Although not providing a direct link, the study makes the point that an increased surface area appears to be associated with reduced capsular contraction rates. More importantly, however, it questions the hypothesis by Loch-Wilkinson et al.[1] that increased surface area relates to increased biofilm-mediated problems, namely capsular contraction and possibly ALCL.

A number of methods that might reduce bacterial contamination of an implant have been shown to correlate with a reduced incidence of capsular contraction.[22,23] Although there is an assumption that these measures have reduced the incidence of contamination and therefore biofilm formation, there is no direct evidence that this has occurred. A recent commentary has succinctly drawn together these concerns in relation to the development of ALCL and an infectious etiology.[24] Only 1 study[25] has shown that bacteria are present in the majority of contracted breasts (89.5%) compared with noncontracted breasts (57.9%). This is a very small series of 19 contracted and 8 noncontracted breasts, and the results by no means can be interpreted as conclusive, given that biofilms are notoriously difficult to detect. It might well be that biofilms exist as normal commensals in breast implants and are nonpathological in the majority of cases. The issue therefore becomes why some individuals develop capsules while others do not, and therefore the significance of biofilms in the development of capsules as a whole.

From the proposed biofilm theory for the pathogenesis of ALCL, it is suggested that high surface area textured implants have been linked with increased rates of ALCL due to a larger surface area being available to bacterial contamination, which promotes inflammation that drives the development of ALCL. A lower level of contamination is proposed for the development of capsular contraction. From this, it would be imagined that polyurethane implants would have the greatest incidence of ALCL and capsular contraction by many orders of magnitude. However, at present, there is no evidence for increased risk of developing ALCL with 1 manufacturer compared with another. Similarly, the 3-year incidence of capsular contracture with polyurethane implants is lower than those of textured or smooth implants. It should be pointed out that the comment that ALCL never occurs in smooth implants is not accurate, and a series of 18 cases were highlighted recently.[26] The recent classification by Barr et al.[5] of implant surface may provide an enhanced understanding over and above simple surface area of the interaction between the breast and the implant. Given that fragmentation of silicone in orthopaedic prosthesis has been linked to the development of lymphoma, it may be that "fragmentation" of the surface is more important than the area per se.

CONCLUSIONS

This study describes the relative surface areas of breast implants created by different texturing and examines these data in the context of development of capsular contraction. The increased surface area produced by texturing, although different between manufacturers, seems to provide protection against capsular contraction regardless of the surface area. Smooth implants, which have the smallest surface area yet, have the highest incidence of capsular contraction.

If the biofilm hypothesis for development of capsular contraction and ALCL is valid, the essential paradigm of "why do textured implants, which have an apparent higher incidence of biofilms, have a lower incidence of capsular contraction?" has yet to be answered by solid in vitro research that is support by in vivo and clinical studies.

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