Intra- and Inter-Shell Roughness Variability of Breast Implant Surfaces

Michael Atlan, MD, PhD; Brian M. Kinney, MD; and Tracy Ann Perry, PhD

Aesthetic Surgery Journal
2020, Vol 40(5) NP324–NP326

DOI: 10.1093/asj/sjz369
www.aestheticsurgeryjournal.com
OXFORD UNIVERSITY PRESS

Editorial Decision date: December 18, 2019; online publish-ahead-of-print March 13, 2020.

We congratulate Wixtrom and colleagues on their quantitative surface characterization of 2 styles of Siltex Textured Mentor Breast Implants (Mentor Worldwide, LLC, Irvine, CA): MemoryGel Siltex Round ("Siltex Round") and MemoryShape Tall High (CPG 332).[1] For each style, shell samples were obtained from the base, anterior, and radius locations of three devices and surface measurements analyzed per the International Organization for Standardization (ISO) classification of breast implant surfaces ISO 14607:2018 Non-active surgical implants—mammary implants—particular requirements. The overall average surface roughness of Siltex Round and CPG 332 implants were 29.5 and 36.1 µm, respectively, which categorizes the devices as "microtextured" by ISO 14607 criteria: smooth less than 10 µm, microtexture 10–50 µm, and macrotexture greater than 50 µm.

Consideration of topographic variability within the shell, as well as across products within a portfolio, is of paramount importance to accurately classify shell surfaces. Atlan et al[2] recently reported significant differences between anterior and posterior surfaces, respectively, for Mentor Siltex (125 vs 143 mm^2; $P = 0.02$), Allergan Biocell (Irvine, CA) (213 vs 248 mm^2; $P < 0.01$), Polytech POLYtxt (Dieburg, Germany) (347 vs 431 mm^2; $P = 0.01$), and Nagor Nagotex (Cumbernauld, UK) (337 vs 278 mm^2; $P < 0.01$) devices. It is critical to note that although Wixtrom et al obtained multiple measurements from distinct areas across the implant, according to ISO 14607, the precise posterior locations of the measurements were not specified. This is important given the visible presence of concentric rings of seemingly different textures on the posterior side of both implant styles (Figure 1).

Wixtrom's work illustrates the relevance of our recent research in which shell surface roughness was measured with qualified methodology, based on ISO 14607 specifications, and more rigorous sampling. Surface roughness was measured on the 2 Mentor implant styles in the Wixtrom study in addition to two Siltex tissue expanders, CPX4 and Becker, to determine if the visible inconsistencies in the Siltex texture (Figure 1) were quantifiable.

Overall average surface roughness values (Table 1) for Siltex Round and CPG 332 implants were 31.39 µm and 46.31 µm, respectively, and for CPX4 and Becker tissue expanders, values were 63.11 µm and 39.08 µm, respectively. According to ISO 14607:2018, the Siltex Round, CPG 332, and Becker tissue expanders were microtextured, whereas the CPX4 tissue expander was macrotextured despite a microtexture designation claimed by the manufacturer.

Perhaps more importantly, there was a great deal of variability in roughness between sampling locations within each implant style. Except for Siltex Round, all implants showed at least one location in the macrotexture range. The radius and

Dr Atlan is a Plastic Surgeon, APHP Hopital Tenon, Université Pierre et Marie Curie Paris VI, Maitre de conférence des Universités Praticien Hospitalier, Paris, France. Dr Kinney is a Plastic Surgeon, Keck School of Medicine, Division of Plastic Surgery, University of Southern California, Beverly Hills, CA. Dr Perry is Vice President of Science and Research, Establishment Labs, Alajuela, Costa Rica.

Corresponding Author:
Dr Michael Atlan, 4 rue de la Chine, 75020 Paris, France.
E-mail: drmichaelatlan@gmail.com; Instagram: @drmichaelatlan

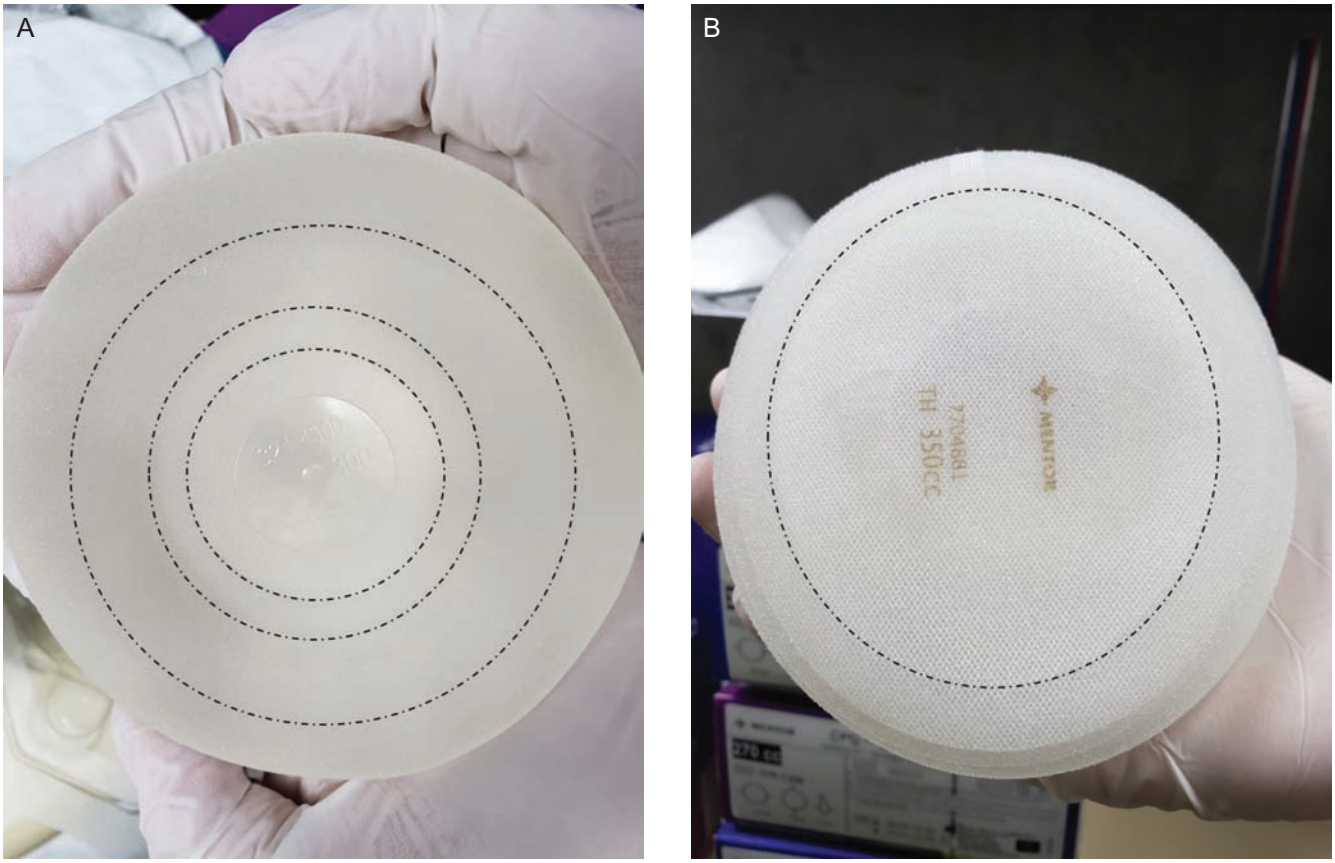

Figure 1. Position of roughness measurements on the posterior of the Mentor Siltex devices, which correlate with the presence of concentric rings of uneven texture. Five measurements were taken from each sampling area on the posterior, anterior, and radius locations of 3 devices. The analysis was performed utilizing a noncontact profilometer µSurf mobile. An internal control implant, Motiva Ergonomix, was also sampled (employing a single posterior sampling location). (A) Four distinct areas on the posterior of the Mentor Siltex Round and CPG 332 implants were sampled. (B) Two distinct areas on the posterior of the Mentor Siltex CPX4 and Becker tissue expanders were sampled.

posterior D locations of the CPG 332 implant were identified as macrotexture (52.05 and 59.37 µm, respectively), as were the radius (63.89 µm), posterior A (68.74 µm), and posterior B (69.87 µm) locations of the CPX4 tissue expander. The posterior B location of the Becker tissue expander was also identified as macrotexture (53.7 µm). The surface roughness of the internal control implant Motiva Ergonomix was 3.18 µm and within range of historical and published data.[3]

Overall, the results identified considerable variation in the average roughness values within each Siltex device tested and between individual family product lines. Recent findings from the Australian regulatory agency Therapeutic Goods Administration's Laboratories, which examined locally approved mammary implants to verify classification of surface roughness according to ISO 14607:2018, further support our findings. The Therapeutic Goods Administration found that whereas smooth envelope implants were consistent in their categorization, discrepancies were identified in the classification of textured implants.[4] We propose that breast implant surfaces with inherent visible variation in physical characteristics must include sufficient representative sampling areas to capture where variability exists. Although speculative, greater surface roughness likely correlates with increased friction, particulate shedding, and inflammation, all which may be risk factors associated with development of breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL).

Currently, there are no data that correlate location of a BIA-ALCL mass to geometry of the implant. Is the mass situated globally "in the capsule," or is there a more precise location that may yield causative information on the nidus for triggering transformation of cells? Without an accurate way to identify the precise location of the cellular event that could trigger a cascade of inflammatory events, variability between "microtexture" and "macrotexture" across the surface of an implant does not seem a shrewd choice for surgeons or their patients with concerns about BIA-ALCL. Likewise, the validity of the methodology and surface classification specified in ISO 14607:2018 may require refinement. The variability in the different versions of the imprinted Siltex texture suggests the need for more consistent and controlled advanced manufacturing

Table 1. Shell Surface Roughness Values for Siltex Implants and the Motiva Ergonomix Implant (Internal Control)

	Siltex round breast implant (n = 15)	CPG 332 breast implant (n = 15)	CPX 4 tissue expander (n = 15)	Becker tissue expander (n = 15)	Motiva Ergonomix breast implant (n = 15)
	Surface roughness, µm average ± SD/median (range)				
Overall roughness	31.39 ± 6.61/33.31 (23.06-45.57)	46.31 ± 9.27/42.27 (34.15-60.11)	63.11 ± 11.80/59.19 (46.24-86.51)	39.08 ± 11.65/37.63 (23.00-65.43)	3.18 ± 0.51/3.02 (2.41-4.12)
Sampling location					
Anterior	29.60 ± 1.35/29.92 (27.43-31.76)	47.47 ± 4.37/47.09 (40.39-55.89)	49.93 ± 4.88/47.26 (44.52-58.82)	36.48 ± 6.55/36.53 (25.71-48.25)	3.29 ± 0.54/3.25 (2.56-4.12)
Radius	36.41 ± 2.48/35.5 (32.58-40.88)	52.05 ± 7.89[a]/49.71 (40.68-64.32)	63.89 ± 5.81[a]/62.68 (57.91-79.47)	40.44 ± 4.58/38.87 (33.69-48.28)	3.22 ± 0.43/3.02 (2.70-3.98)
Posterior A	28.13 ± 6.70/28.59 (20.43-40.20)	41.09 ± 3.30/41.58 (35.18-46.72)	68.74 ± 11.31[a]/71.09 (50.00-83.53)	25.71 ± 4.42/24.79 (19.83-33.16)	N/A
Posterior B	26.54 ± 4.62/25.93 (19.02-34.74)	39.10 ± 3.28/39.23 (34.27-44.51)	69.87 ± 11.45[a]/72.85 (51.17-86.51)	53.70 ± 7.66[a]/52.8 (41.33-65.43)	N/A
Posterior C	27.08 ± 4.06/25.46 (22.66-34.54)	38.77 ± 3.01/39.12 (34.15-44.14)	N/A	N/A	3.02 ± 0.53/2.80 (2.41-3.89)
Posterior D	40.61 ± 3.00/40.3 (34.47-45.57)	59.37 ± 8.31[a]/56.93 (48.69-76.12)	N/A	N/A	N/A

N/A, not applicable. [a]Sampling regions with an average surface roughness > 50 µm.

technologies. Plastic surgeons should be aware that there are at least 3 different types of surface textures ranging from microtexture to macrotexture under the name "Siltex."

Disclosures

Dr Atlan was a product advisory board one-time consultant receiving an honorarium from Establishment Labs for the specific arrangement. Dr Kinney serves as a member of the Establishment Labs Scientific Advisory Board; is an investigator in the Motiva Implants investigational device exemption (IDE) US clinical trial; and has been granted equity awards in Establishment Labs Holdings, Inc. Dr Perry is Vice President of Science and Research, Establishment Labs.

Funding

This study was sponsored by Establishment Labs Holdings, Inc.

REFERENCES

1. Wixtrom RN, Garadi V, Lerpold J, Canady JW. Device-specific findings of imprinted-texture breast implants: characteristics, risks, and benefits. *Aesthet Surg J*. 2020; 40(2):167-173.
2. Atlan M, Nuti G, Wang H, Decker S, Perry T. Breast implant surface texture impacts host tissue response. *J Mech Behav Biomed Mater*. 2018;88:377-385.
3. James GA, Boegli L, Hancock J, Bowersock L, Parker A, Kinney BM. Bacterial adhesion and biofilm formation on textured breast implant shell materials. *Aesthetic Plast Surg*. 2019;43(2):490-497.
4. Australian Government Department of Health, Therapeutic Goods Administration. *Biomaterials and Engineering Laboratory Report: Non-active Mammary Implants*. https://www.tga.gov.au/biomaterials-and-engineering-laboratory-report-non-active-mammary-implants. Published 2019. Accessed December 6, 2019.