Device-Specific Findings of Imprinted-Texture Breast Implants: Characteristics, Risks, and Benefits

Roger N. Wixtrom, PhD, DABT; Vikram Garadi, MS, PE; John Leopold, MS; and John W. Canady, MD

Aesthetic Surgery Journal
2019, 1–7

DOI: 10.1093/asj/sjz155
www.aestheticsurgeryjournal.com
OXFORD UNIVERSITY PRESS

Abstract

Background: The relative risks and benefits of various textured breast implants are the focus of considerable discussion. Studies have suggested different risk-benefit profiles for different implant surface topographies.

Objectives: The study aim was to provide device-specific, quantitative information on Mentor's imprinted Siltex Textured breast implants with respect to textured surface characteristics and ISO 14607 classification, risk of breast implant–associated anaplastic large cell lymphoma (BIA-ALCL), and risk-reduction benefits relative to smooth implants.

Methods: Surface metrology was performed. Data for smooth and Siltex implants from the prospective MemoryGel Core Study were evaluated by Kaplan-Meier analysis for the most frequently occurring postoperative complications in augmentation and reconstruction leading to subsequent reoperation.

Results: The overall average surface roughness for Siltex MemoryGel and MemoryShape implants was 29.5 and 36.1 μm, respectively. A statistically significantly lower rate of reoperation in patients with Siltex compared with smooth devices over 10 years was observed for both capsular contracture in subglandular primary augmentation patients (2.02% vs 19.84%) and for asymmetry in primary reconstruction patients (3.88% vs 11.1%).

Conclusions: Surface analysis demonstrated that Siltex implants fall within the ISO 14607 category of "microtexture" breast implants. These devices exhibited a rare risk of BIA-ALCL (0.0012%) based on the most extensive data available. Relative to smooth implants, these Siltex devices provided risk-reduction benefits for the most common reason of reoperation in patients who underwent primary augmentation (capsular contracture) or primary reconstruction (asymmetry) in the Core Study. These findings provide valuable risk-benefit information for surgeons and their patients.

Level of Evidence: 2

Editorial Decision date: May 15, 2019; online publish-ahead-of-print May 23, 2019.

There has long been discussion and debate internationally regarding the relative benefits of textured and smooth breast implants. More recently, the relative risks of textured versus smooth implants have been explored. Views diverge markedly, perhaps most strongly illustrated by the marked geographic differences in device usage: ≥80% of surgeons in Europe, Latin America, and Asia primarily use textured implants, whereas ≥85% of surgeons in the United States primarily, or even exclusively, use smooth implants.[1] The general risks and benefits of textured breast implants, relative to smooth, were recently reviewed by Calobrace et al[2] with a focus on the risk of breast implant–associated anaplastic large

Dr Wixtrom is a toxicologist in Springfield, VA. Dr Garadi is a Principal Engineer and Dr Canady is Integrated Leader, Medical, Clinical and Preclinical, Mentor Worldwide, LLC, Irvine, CA. Mr Leopold is a Senior Biostatistician, DePuy Synthes, JNJ Medical Devices, Warsaw, IN.

Corresponding Author:
Dr Roger N. Wixtrom, 8473 Rippled Creek Court, Springfield, VA 22153, USA.
E-mail: rwixtrom@lscisolutions.com

cell lymphoma (BIA-ALCL),[3] as well as the clinical benefits of reduced capsular contracture for textured compared with smooth implants when placed in the subglandular plane[4-6] and reduced implant displacement/malposition. Other potential benefits of textured relative to smooth implants include reduced stretch in the lower pole of the breast over time and frictional resistance resulting in reduced device rotation.[2]

Textured-surface silicone breast implants, including Mentor's Siltex imprinted implants (Mentor Worldwide LLC, Irvine, CA) and Allergan's Biocell salt-loss devices (Allergan, Irvine, CA), were first introduced in the late 1980s, more than a decade after the first documented use of polyurethane textured breast implants.[7-9] Since then, other surface textures have been introduced, including different types of salt-loss textured implants, a gas expansion type used on Silimed (Rio de Janeiro, Brazil), Sientra (Santa Barbara, CA), and Polytech (Dieburg, Germany) silicone gel–filled breast implants, and other less frequently used alternatives. The various textured surfaces can differ notably in their surface topography and associated clinical performance, including risk of BIA-ALCL,[10] which has been shown in some instances to differ by more than an order of magnitude.[11,12]

These observations have spurred efforts to better understand the risks and benefits of specific types of breast implants and the underlying basis for such differences. With respect to the relative clinical benefits offered by textured breast implants, it has been suggested that a reduction in the rate of certain complications, and more importantly subsequent reoperations, might provide risk-reduction benefits to offset the slightly increased risk of BIA-ALCL, given the inherent risk of secondary procedures—cited by Calobrace et al as a 1:50,000 mortality risk for aesthetic surgery operations (which does, however, include procedures other than breast implant surgery).[2,13] To date, the authors are unaware of any published quantitative analysis of such potential risk reduction due to lowered relative incidence of reoperations for specific types of textured compared with smooth breast implants.

Another effort to differentiate between and better understand the risk-benefit profiles of breast implants has been the recent introduction of various breast implant surface classification systems. Several parameters can be measured or calculated to categorize breast implant surface textures, including roughness,[14] surface area,[15] or a combination of multiple characteristics.[16,17] The International Organization for Standardization (ISO) has specified requirements for nonactive surgical mammary implants in ISO 14607:2018, delineating 3 categories based on the value of average surface roughness (smooth, < 10 µm; microtexture, 10-50 µm; macrotexture, > 50 µm) and providing guidance on how to assess the physical surface characteristics. Recent reports about which currently marketed breast implants fall within each of these ISO categories has been inconsistent.

The purpose of this article is to provide new, detailed, quantitative information on specific characteristics (ISO surface categorization), risks (BIA-ALCL), and benefits (reduction in reoperation incidence for the single leading reason for reoperation in patients who have undergone augmentation or reconstruction) of imprinted Siltex textured breast implants in order to more fully inform current risk-benefit discussions, in light of BIA-ALCL.

METHODS

ISO Surface Characterization

The physical surface characteristics of Mentor's imprinted Siltex textured breast implants were analyzed based on the surface analysis description detailed within ISO 14607:2018. All measurements and surface analyses were outsourced to an independent metrology laboratory that is part of Eurofins Scientific (Sunnyvale, CA), one of the largest analytical testing services providers worldwide. Surface metrology was performed on 2 styles of Mentor Siltex textured breast implants: MemoryShape Tall High Breast Implants (hereinafter referred to as Shaped Siltex) and MemoryGel Siltex Round Breast Implants (hereinafter referred to as Round Siltex). For both styles of Siltex implants, coupons were cut from the base, anterior, and radius locations of 3 devices.

The coupons were all individually bagged, labeled with a unique identifier, and sent to the same Eurofins Scientific laboratory for testing. Optical profilometry images were collected with a Bruker Contour GT-X8 optical profilometer (Bruker Corporation, Tucson, AZ). The profilometer underwent internal, automatic calibration during each measurement. Performance of the instrument was tested weekly with a National Institute of Standards and Technology traceable step-height standard. Image processing procedures involving a Gaussian regression filter (short-wavelength cutoff, 0.008 mm; long-wavelength cutoff, 0.8 mm) and data restoration were employed. Surface variables were calculated in accordance with ISO 25178-2:2012. The surface analyses were expressed in height parameters, spatial parameters, hybrid parameters, and functional parameters. Additional details on the methodology can be found in the Appendix.

Prospective Clinical Trial and Evaluation of Complications and Subsequent Reoperations

The MemoryGel Core Study (clinicaltrials.gov identifier NCT00753922) is a prospective, multicenter, nonrandomized, open-label clinical trial designed to assess the long-term safety and efficacy of Mentor smooth and Siltex Textured round silicone gel–filled breast implants in primary augmentation, primary reconstruction, and revision patients. A separate examination comparing complications and reoperations

for smooth and Siltex Textured implants was included in the original analysis plan of the study. Details of the study (conducted from September 2000 to June 2012) have been provided previously, including the complete study design, inclusion criteria, and patient demographic data.[18] Briefly, females at least 18 years of age were enrolled if they were a candidate for breast augmentation for postlactational mammary involution or general breast enlargement; breast reconstruction for cancer, trauma, surgical loss of breast, or congenital deformity; or revision surgery of a previous augmentation or reconstruction with saline-filled or silicone-filled implants. Patients were excluded if they were pregnant, had nursed a child within 3 months of study enrollment, had been implanted with any silicone implant other than breast implants, had a confirmed diagnosis of rheumatic disease, were a reconstruction patient who had a current condition that could compromise or complicate wound healing, were an augmentation patient with a diagnosis of active cancer of any type, had an infection or abscess anywhere in the body, demonstrated tissue characteristics that are clinically incompatible with implants, possessed any condition that may constitute unwarranted surgical risk, had an anatomic or physiologic abnormality that could lead to significant postoperative adverse events, demonstrated characteristics that are unrealistic/unreasonable with the risks involved with the surgical procedure, had a premalignant breast disease without a subcutaneous mastectomy, had an untreated or inappropriately treated breast malignancy without mastectomy, or had implanted metal or metal devices, a history of claustrophobia, or other condition that would prohibit a magnetic resonance imaging scan. The study protocol received institutional review board (IRB) approval (IRBco, Buena Park, CA and institutional IRBs, a full list of which is provided in the Appendix), all patients provided informed consent before study enrollment, and the study was conducted in compliance with the principles of the International Conference on Harmonization. Kaplan-Meier estimates and corresponding 95% confidence intervals were compared between smooth and Siltex Textured implants for postoperative complications and subsequent reoperations over 10 years. Analysis was focused on the single leading reasons for reoperation for each cohort identified in this clinical study: capsular contracture (primary augmentation) and asymmetry (primary reconstruction). Comparison of the Kaplan-Meier cumulative risk curves was performed through the use of the log-rank test.

RESULTS

ISO Surface Characterization

The surface roughness results are provided in Table 1, which includes a summary of the average surface roughness for each device along with the overall average surface roughness per style. Overall average surface roughness for Siltex Round and Siltex Shaped implants were 29.5 µm (95% CI: 26.8, 32.3 µm) and 36.1 µm (95% CI: 33.0, 39.3 µm), respectively.

Table 1. Summary of Surface Roughness Results for Siltex Textured

	Device	Coupons/ sample	Average surface roughness (µm)[a]	Overall average surface roughness (µm, 95% CI)
Siltex Shaped	A	15	37.5	36.1 (33.0, 39.3)
	B	5	31.6	
	C	5	36.5	
Siltex Round	D	5	30.5	29.5 (26.8, 32.3)
	E	5	28.2	
	F	5	29.8	

[a]This represents the average of surface roughness measured for all coupons excised from that device.

Table 2. Patient Demographics, Implant Surface/Placement, and Follow-Up

Characteristic	Primary augmentation	Primary reconstruction
No. of women	552	251
Mean age (year)	34 (range, 18-65)	45 (range, 18-79)
Race (%)		
Caucasian	87.5	92.0
Asian	3.1	1.2
African American	2.0	2.8
Other	7.4	4.0
Implant surface (%)		
Smooth	69.6	40.3
Siltex Textured	30.4	59.7
Placement (%)		
Subglandular	33.8	10.2[b]
Submuscular/subpectoral	66.3	87.3
Follow-up (%)	57[a]	73[a]

[a]Equivalent to 94.6% and 96.9%, respectively, follow-up of the prior year's patients each year for 10 years. [b]Congenital deformity patients are included within the indication of primary reconstruction and may undergo subglandular implant placement.

Core Clinical Study Findings

Patient demographics, implant usage, and follow-up for primary augmentation and primary reconstruction patients are summarized in Table 2. Further study details and findings beyond those detailed below are provided at clinicaltrials.gov (study identifier NCT00753922).

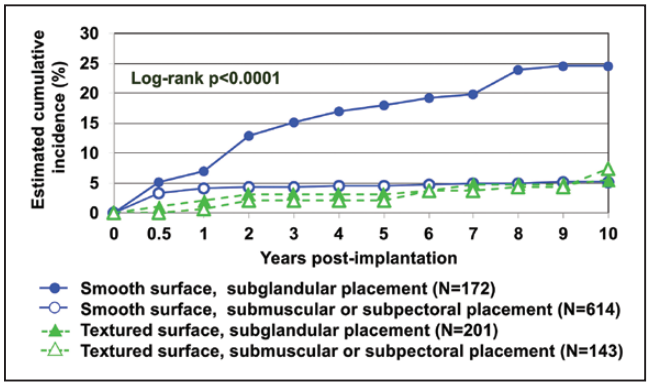

Figure 1. Kaplan-Meier estimated cumulative risk of capsular contracture (Baker III/IV) over 10 years in primary augmentation patients in the MemoryGel Core Study (implant-level analysis).

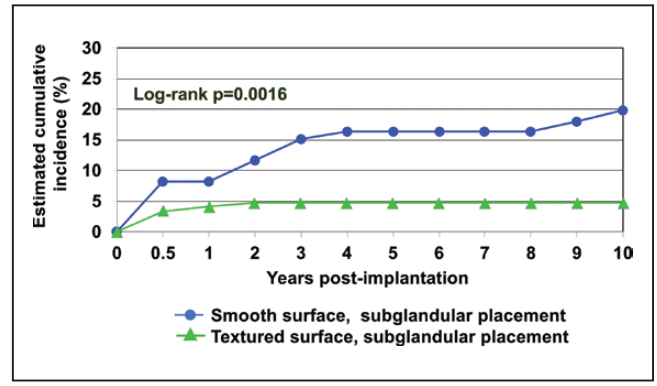

Figure 2. Kaplan-Meier estimated cumulative risk of capsular contracture (Baker III/IV) with reoperation over 10 years in subglandular primary augmentation patients in the MemoryGel Core Study.

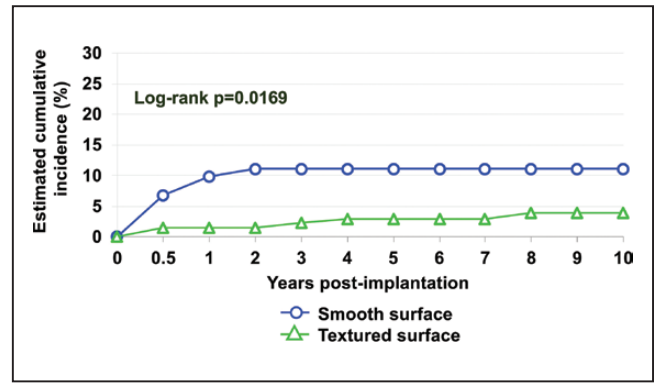

Figure 3. Kaplan-Meier estimated cumulative risk of asymmetry with reoperation over 10 years in primary reconstruction patients in the MemoryGel Core Study.

Capsular Contracture Incidence: Smooth vs Siltex Textured (by Device Placement)

The Kaplan-Meier estimated cumulative risk of capsular contracture (Baker III/IV) over 10 years in primary augmentation implants in the MemoryGel Core Study is presented in Figure 1. The data are presented separately by surface and device placement. The findings demonstrate a statistically significant 5-fold reduction in capsular contracture in patients with Siltex Textured compared with smooth implants placed in the subglandular plane.

Reoperation Rates: Smooth vs Siltex Textured

In primary augmentation patients in the MemoryGel Core Study with capsular contracture (III/IV), a comparison of the estimated cumulative incidence of reoperation over 10 years between those with subglandular Siltex Textured vs subglandular smooth devices demonstrated a statistically significantly (P = 0.0016) lower incidence rate for such reoperation for patients with Siltex Textured vs smooth devices (4.21%; 95% CI: 1.60%, 10.85% vs 19.84%; 95% CI: 12.52%, 30.63%). These reoperation results are presented in Figure 2. Similarly, in primary reconstruction patients (any device placement) with asymmetry, a comparison of the estimated cumulative incidence of reoperation over 10 years demonstrated a statistically significantly (P = 0.0169) lower incidence of reoperation for those with textured (3.88%; 95% CI: 1.63%, 9.13%) vs smooth devices (11.10%; 95% CI: 6.29%, 19.19%). These reoperation results are presented in Figure 3.

BIA-ALCL Incidence

No cases of BIA-ALCL were diagnosed among patients in the MemoryGel Core Study.

DISCUSSION

Categorization of Breast Implant Textured Surfaces

To date, there have been no confirmed cases of BIA-ALCL in patients who have received only smooth breast implants.[19] In the most recent update of a study covering all of Australia and New Zealand, the incidence of BIA-ALCL in patients with imprinted Siltex Textured breast implants was identified as 1 case in 86,029 implants.[12] Given that this rate was an order of magnitude lower than for other types of textured implants included in the study, there have been extensive efforts to better understand the basis for this observed difference. Although the precise etiology of BIA-ALCL remains unknown, and seems likely to be multifactorial,[20] some have suggested that BIA-ALCL risk can be stratified merely based on various proposed surface texture classification systems. However, given the uncertain etiology, by far the most reliable information currently available on BIA-ALCL risk are the long-term data

available for specific implants, rather than any imputed risk assigned to the various yet to be clinically validated classification systems, which combine implants with and without such long-term outcome information.

One attempt to meaningfully group and classify breast implant textured surfaces is the surface roughness classification system designated in Annex H of ISO 14607:2018 (smooth, < 10 µm; microtexture, 10-50 µm; macrotexture, > 50 µm). The results from this study demonstrate that Siltex Round and Siltex Shaped implants are considered "microtexture" because their average surface roughnesses were 36.1 µm (95% CI: 33.0, 39.3 µm) and 29.5 µm (95% CI: 26.8, 32.3 µm), respectively, based on the 3 devices per style tested. This is the same designation that has previously been associated with these devices in the medical literature.[21-23]

Medically relevant classification of breast implant surface texture remains elusive. One factor contributing to this confusion is the use of the same terms (eg, microtexture and macrotexture) in multiple contexts within various proposed classification systems without a uniform definition.[14,15] Consistency with previously established usage of these terms in the medical literature is lacking and there is no long-term clinical validation demonstrating that devices within a particular category have comparable risks for BIA-ALCL. Further adding to the confusion is variation in the surface measurements themselves. Depending on the method used to calculate certain parameters, such as 3-dimensional surface area, significant differences have been reported. For example, one study reported that Biocell Textured implants had a textured area/surface area ratio of 27.9,[11] whereas a second study reported this value to be 18.49.[14] These same studies reported differences for Siltex Textured implants as well (12.4 vs 15.00, respectively), but no difference for smooth implants (1.0 vs 1.01, respectively).

Another proposed classification system was recently announced by the French health authority, ANSM (Agence nationale de sécurité du medicament et des produits de santé). It conducted a study to identify physical parameters that could be used to characterize the surface texture of breast implants in an attempt to standardize the designations currently used by manufacturers.[24] Breast implants of varying surface textures from 9 manufacturers were studied. All analyses were conducted in accordance with Annex A of ISO 14607:2009 (note Annex A from the 2009 version provides guidance regarding testing of surface characteristics which was moved to Annex H in the 2018 version). The supplier designation was then compared with the classification resulting from the ANSM analysis. All designations of "smooth" and "macrotexture" from the manufacturers agreed with the ANSM classification; however, of the 6 designated "microtexture" by their manufacturers, 4 were classified as "macrotexture" by the ANSM. Further adoption of breast implant surface texture classification systems that are focused on BIA-ALCL risk should await clear elucidation of the etiology of the disease, as well as clinical validation of similar or equivalent risk across all devices within a given category.

Specific Risk Reduction Benefits of Imprinted Texture

A 10-year, double-blind, randomized, controlled clinical trial conducted by Collis et al[4] in the United Kingdom evaluated 53 patients who were randomly assigned to receive either Mentor MemoryGel smooth (n = 26) or Siltex Textured (n = 27) subglandular silicone breast implants. These investigators reported a significantly lower incidence of capsular contracture among patients with Siltex implants at both 3 and 10 years postimplantation ($P = 0.001$). Similar findings were observed in the MemoryGel Core Study (Figure 1), with a statistically significant 5-fold reduction in capsular contracture in patients with Siltex Textured vs smooth implants placed in the subglandular plane ($P < 0.0001$). No significant difference was observed, however, between smooth and Siltex Textured implants with submuscular/subpectoral placement. This has led some to suggest that the use of submuscular placement could reduce the incidence of capsular contracture without any need for texture. It is important to note, however, that following the trend of increasing prepectoral placement in breast reconstruction,[25] there is an emerging resurgence in the use of subglandular placement for breast augmentation (based on podium statements at recent national society meetings), in part owing to the reductions in pain that have been associated with such device placement. The survey by Heidekrueger et al[1] cited in the introduction found that 50.4% of plastic surgeons responding from Latin America favored the subglandular plane as the pocket location, although much lower usage of this location was noted in other geographic regions. Another well-recognized benefit of subglandular placement is the avoidance of animation deformity sometimes observed with devices placed in submuscular/subpectoral locations.

Although these specific risk-reduction benefits involving reoperations have not, to our knowledge, previously been calculated, the capsular contracture reoperation findings are consistent with previous studies that have demonstrated a reduced incidence of capsular contracture for smooth compared with Siltex Textured breast implants in the subglandular plane.[4-6] To our knowledge, it is not currently understood what the "minimal effective dose" of texturing is (ie, what degree of surface topography or roughness may be required). As there are no head-to-head, long-term, prospective studies of the different texturing types, and the core studies of the different manufacturers cannot be directly compared, a precise answer is

not available. It is interesting to note, however, that within each of 3 core studies of round implants, there have been notable reductions of capsular contracture for the specific texture type vs smooth, specifically in subglandular breast augmentation; the imprinted-style texture addressed in this report demonstrated a 4.5-fold reduction ($P < 0.0001$) (Figure 1), the gas expansion texture showed a 3.4-fold reduction,[26] whereas the salt-loss texture exhibited a 1.8-fold reduction.[27] All show a similar trend for reduction of capsular contracture in the subglandular plane. With respect to reduced asymmetry and subsequent reoperations in breast reconstruction patients, from the time of their first introduction,[28] a key intended benefit of textured surface breast implants has been to assist in maintaining the positioning of the implant.

The relative reduction in capsular contracture and subsequent reoperations in primary augmentation patients in the MemoryGel Core Study (Figure 2), and the similar reduction in asymmetry and subsequent reoperations in primary reconstruction patients in the same study (Figure 3), as compared with results with smooth implants, provides clinically meaningful risk-reduction benefits as these 2 complications represented the leading reason for reoperations in those cohorts over the 10-year study period.

In addition to the previously cited 1:50,000 (0.002%) mortality risk for aesthetic surgery operations, further and more specific mortality risk estimates can be derived from retrospective mortality data for a 5-year period starting in 2012 from the American Association for Accreditation of Ambulatory Surgical Facilities database, as analyzed by Bucknor et al.[29] Based in part on these findings, which were reported separately by primary surgical procedure, including breast surgery, an estimated mortality rate for outpatient cosmetic breast surgery alone is approximately 1 in 72,000 procedures (0.0014%), whereas for outpatient cosmetic breast surgery performed alone or in combination with abdominoplasty, the estimated rate is approximately 1:24,000 (0.0042%) (details of the derivation of this estimated rate are provided in the Appendix). Considering these estimates, the data reviewed in this report provide evidence that Siltex Texture reduces the risk of reoperations subsequent to capsular contracture and asymmetry, which, at least in part, offsets the rare risk of BIA-ALCL observed with these specific devices.

Study Limitations

Although the present study has many strengths, limitations included the open-label nature of the clinical study and the lower than desired follow-up rate to optimally minimize potential bias. The underlying clinical data for this report are also from a study conducted in 2000 to 2012. As with any long-term study, 10 years in this case, surgical techniques continue to evolve and improve over time, and might affect the study outcomes for patients currently receiving these devices. Another limitation of the study is that direct comparisons with other textures were not possible as this study only included Mentor smooth and Siltex Textured breast implants.

CONCLUSIONS

Detailed quantitative information specific to imprinted-style Siltex Textured breast implants indicate that: (1) these devices fall within the ISO 14607 category of "microtexture" breast implants; (2) the risk of BIA-ALCL is rare with these specific textured devices; and (3) relative to smooth implants, these devices provide risk-reduction benefits for the leading reasons for reoperation in primary augmentation and primary reconstruction patients in the pivotal 10-year prospective, multicenter clinical trial. It is hoped that such findings will further inform surgeon and patient discussions of the overall risk-benefit profile associated with specific implant types, and spur further similar analyses of other textured device options.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr Wixtrom is a consultant for Mentor Worldwide, LLC (Irvine, CA). Drs Garadi, Leopold, and Canady are employees of Mentor Worldwide, LLC.

Funding

This study was sponsored by Mentor Worldwide, LLC; specifically, laboratory services were outsourced to Eurofins Scientific, and the complete costs of the prospective core clinical study were also covered.

REFERENCES

1. Heidekrueger PI, Sinno S, Hidalgo DA, Colombo M, Broer PN. Current trends in breast augmentation: an international analysis. *Aesthet Surg J.* 2018;38(2):133-148.
2. Calobrace MB, Schwartz MR, Zeidler KR, Pittman TA, Cohen R, Stevens WG. Long-term safety of textured and smooth breast implants. *Aesthet Surg J.* 2017;38(1):38-48.
3. Clemens MW, Brody GS, Mahabir RC, Miranda RN. How to diagnose and treat breast implant-associated anaplastic large cell lymphoma. *Plast Reconstr Surg.* 2018;141(4):586e-599e.
4. Collis N, Coleman D, Foo IT, Sharpe DT. Ten-year review of a prospective randomized controlled trial of textured versus smooth subglandular silicone gel breast implants. *Plast Reconstr Surg.* 2000;106(4):786-791.
5. Hammond D, Handel N, Canady J, Wixtrom RN. Impact of surgical approach, together with placement and breast

implant texturing, on capsular contracture: an analysis of 10-year prospective multicenter data. *Plast Reconstr Surg.* 2014;134(4S-1):90-91.
6. Wixtrom R, Canady J, Hammond D, Handel N. Round gel breast implants: interactive effects of texturing and device placement in 8-year prospective clinical results. Paper presented at *The Aesthetic Meeting*, San Francisco, CA, 2014. https://asaps.confex.com/asaps/2014/webprogram/Paper6395.html
7. Gabriel A, Maxwell GP. The evolution of breast implants. *Clin Plast Surg.* 2015;42(4):399-404.
8. Mohebali K, Wixtrom RN. Breast implant engineering and performance. *Plast Reconstr Surg.* 2018;142(4S The Science of Breast Implants):6S-11S.
9. Ashley FL. A new type of breast prosthesis. Preliminary report. *Plast Reconstr Surg.* 1970;45(5):421-424.
10. Doren EL, Pierpont YN, Shivers SC, Berger LH. Comparison of Allergan, Mentor, and Sientra contoured cohesive gel breast implants: a single surgeon's 10-year experience. *Plast Reconstr Surg.* 2015;136(5):957-966.
11. Loch-Wilkinson A, Beath KJ, Knight RJW, et al. Breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand: high-surface-area textured implants are associated with increased risk. *Plast Reconstr Surg.* 2017;140(4):645-654.
12. Magnusson M, Beath K, Cooter R, et al. The epidemiology of breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants. *Plast Reconstr Surg.* 2019;143(5):1285-1292.
13. Keyes GR, Singer R, Iverson RE, et al. Mortality in outpatient surgery. *Plast Reconstr Surg.* 2008;122(1):245-250; discussion 251.
14. Barr S, Hill EW, Bayat A. Functional biocompatibility testing of silicone breast implants and a novel classification system based on surface roughness. *J Mech Behav Biomed Mater.* 2017;75:75-81.
15. 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.
16. Valencia-Lazcano AA, Alonso-Rasgado T, Bayat A. Characterisation of breast implant surfaces and correlation with fibroblast adhesion. *J Mech Behav Biomed Mater.* 2013;21:133-148.
17. Jones P, Mempin M, Hu H, et al. The functional influence of breast implant outer shell morphology on bacterial attachment and growth. *Plast Reconstr Surg.* 2018;142(4):837-849.
18. Cunningham B. The mentor study on contour profile gel silicone MemoryGel breast implants. *Plast Reconstr Surg.* 2007;120(7 Suppl 1):33S-39S.
19. Collett DJ, Rakhorst H, Lennox P, Magnusson M, Cooter R, Deva AK. Current risk estimate of breast implant-associated anaplastic large cell lymphoma in textured breast implants. *Plast Reconstr Surg.* 2019;143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):30S-40S.
20. Rastogi P, Riordan E, Moon D, Deva AK. Theories of etiopathogenesis of breast implant-associated anaplastic large cell lymphoma. *Plast Reconstr Surg.* 2019;143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):23S-29S.
21. Adams WP Jr, Culbertson EJ, Deva AK, et al. Macrotextured breast implants with defined steps to minimize bacterial contamination around the device: experience in 42,000 implants. *Plast Reconstr Surg.* 2017;140(3):427-431.
22. Derby BM, Codner MA. Textured silicone breast implant use in primary augmentation: core data update and review. *Plast Reconstr Surg.* 2015;135(1):113-124.
23. Maxwell GP, Scheflan M, Spear S, Nava MB, Hedén P. Benefits and limitations of macrotextured breast implants and consensus recommendations for optimizing their effectiveness. *Aesthet Surg J.* 2014;34(6):876-881.
24. Rebiere B, Petit E, Cot D. *Définition d'une gamme de texturation pour les implants mammaires—Rapport.* Montpellier, France: Insitut Européen des Membranes; 2016.
25. Glasberg SB. The economics of prepectoral breast reconstruction. *Plast Reconstr Surg.* 2017;140(6S Prepectoral Breast Reconstruction):49S-52S.
26. Calobrace MB, Stevens WG, Capizzi PJ, Cohen R, Godinez T, Beckstrand M. Risk factor analysis for capsular contracture: a 10-year Sientra study using round, smooth, and textured implants for breast augmentation. *Plast Reconstr Surg.* 2018;141(4S Sientra Shaped and Round Cohesive Gel Implants):20S-28S.
27. Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: core study results at 10 years. *Plast Reconstr Surg.* 2014;133(6):1354-1361.
28. Ashley FL. Further studies on the natural-Y breast prosthesis. *Plast Reconstr Surg.* 1972;49(4):414-419.
29. Bucknor A, Egeler SA, Chen AD, et al. National mortality rates after outpatient cosmetic surgery and low rates of perioperative deep vein thrombosis screening and prophylaxis. *Plast Reconstr Surg.* 2018;142(1):90-98.