Textured Silicone Breast Implant Use in Primary Augmentation: Core Data Update and Review

Brian M. Derby, M.D.
Mark A. Codner, M.D.

Atlanta, Ga.

Summary: Evolution of silicone breast implant design has focused primarily on advances in implant fill, surface texture, and shape. Fifth-generation, shaped, form-stable, silicone breast implants from all three major implant manufacturers are now approved for use by the U.S. Food and Drug Administration in the United States. As part of this approval, the U.S. Food and Drug Administration mandated Core Study follow-up of silicone implants for 10 years after premarket approval. An updated and comprehensive collection of Core data from all three manufacturers is presented in this review. In addition, cause and rates of capsular contracture, seroma, rippling, and malposition are discussed. New concepts such as tissue friction coefficient are discussed that may influence outcome after primary breast augmentation. The theoretical advantages and disadvantages of the various textured surfaces ranging from microtexturing to macrotexturing are presented in relation to breast tissue incorporation. (*Plast. Reconstr. Surg.* 135: 113, 2015.)

Statistics from the American Society of Plastic Surgeons indicate that 290,000 breast augmentations were performed in the United States in 2013.[1] Implant selection for primary augmentation has evolved away from use of smooth round saline implants, toward increasing use of round textured silicone implants and shaped devices. Since shaped devices were approved for use in 2013, surgeons who have been accustomed to smooth round implants are using textured devices often as practice patterns have changed. This article describes the differences between the textured implants and provides a summary of the long-term Core data from manufacturer and clinical studies. The concept of microtexturing and macrotexturing is described in detail with scanning electron microscopy of the different manufacturers' implant surfaces (Fig. 1). Furthermore, the Core data are summarized in a single reference with respect to evidence-based outcome data.

Cronin and Gerow introduced the first silicone breast implant in 1964 (Dow-Corning Corp., Midland, Mich.).[2] The silicone breast implant evolved over subsequent decades (Table 1), yet despite these advances, adverse outcomes such as capsular contracture led to a U.S. Food and Drug Administration moratorium on silicone breast implant use in the United States in 1992, other than for investigational purposes. The moratorium was lifted in 2006, permitting the use of silicone implants for primary breast augmentation.

As a condition of approval, the U.S. Food and Drug Administration mandated follow-up of silicone device performance through Core Studies.[3–9] The goals of the Core Gel Studies are to provide evidence-based results over 10 years from evaluation of patients with silicone breast implants from different manufacturers. Three- to 10-year follow-up is now available from the three major implant manufacturers.

The most common complications following primary breast augmentation include capsular contracture, implant malposition, rippling, and seroma. Because reports of capsular contracture rates range from 2 to 45 percent of patients, there is often lack of clarity in complication rate reporting in the literature.[10–15] The data are also confounded by multiple variables, including cohorts ranging from single-surgeon series to meta-analyses, different techniques incorporating

From Mark Codner MD Plastic Surgery.
Received for publication March 31, 2014; accepted June 18, 2014.

DOI: 10.1097/PRS.0000000000000832

Disclosure: *Dr. Derby has no financial information to disclose. Dr. Codner receives direct, ongoing funding that is used for the purpose of supporting research project expenses; has a consulting relationship with Mentor Corp. (Santa Barbara, Calif.) and Ulthera, Inc. (Mesa, Ariz.); and receives royalties for books published by Quality Medical Publishing and Elsevier.*

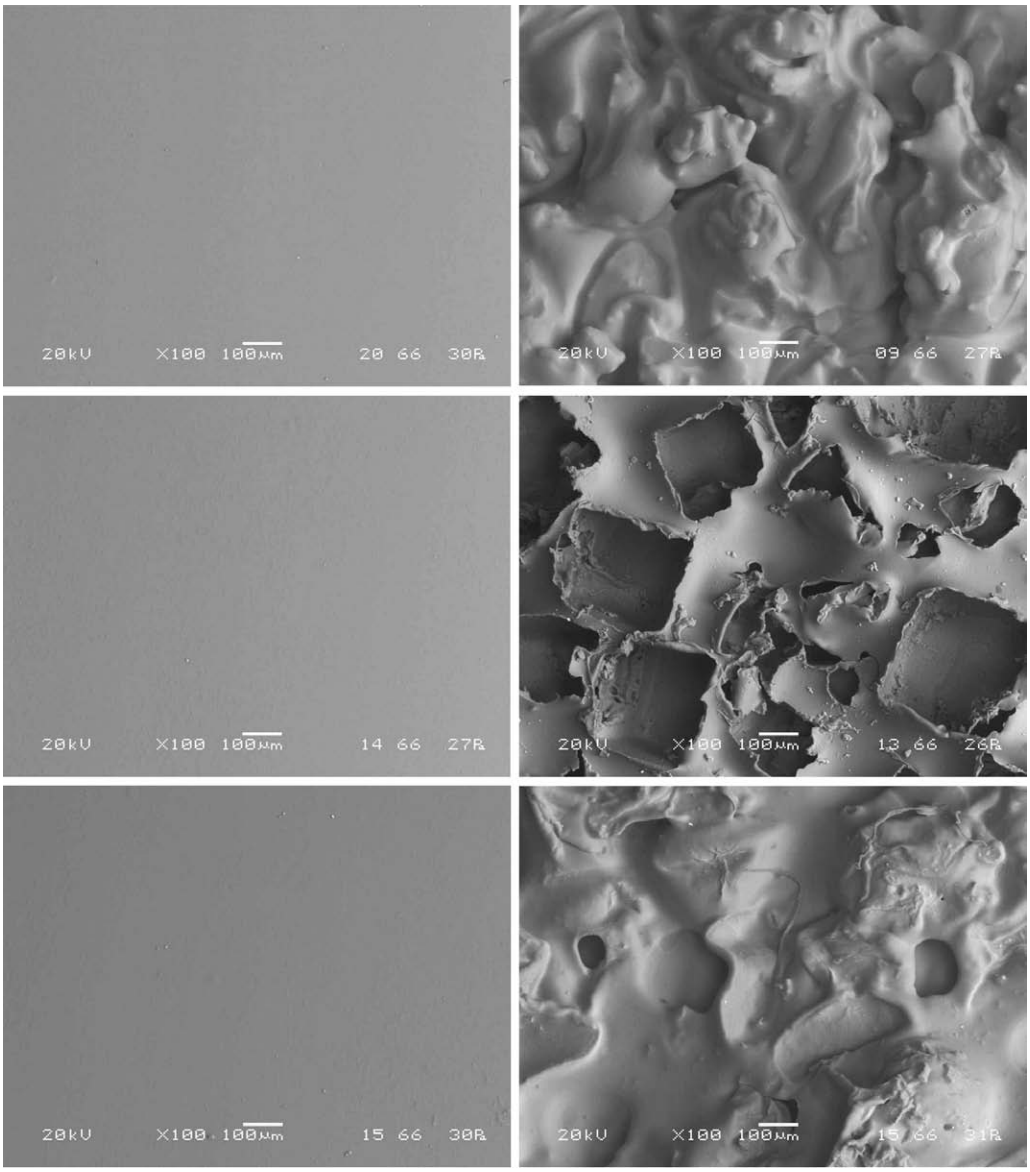


Fig. 1. Scanning electron microscopic images of smooth and textured implant surfaces. Mentor, Allergan, and Sientra smooth implant surfaces are represented by *left, above, center, and below*, respectively (original magnification, × 100). Mentor Siltex, Allergan Biocell, and Sientra TRUE Texture surfaces are represented in *right, above, center, and below*, respectively (original magnification, × 100). (Images provided by Mentor Corp.)

Table 1. Generational Differences in Silicone Breast Implants

Generation	Years	Shell Thickness (mm)	Gel	Internal Barrier Lining	Shaped
First	1963–1972	0.75	Thick	No	No
Second	1972–1980	0.13	Thin	No	No
Third	1981 onward	0.28–0.30	Thick	Yes	No
Fourth	1993 onward	0.5	More cohesive, form-stable	Yes	No
Fifth	1993 onward	0.075–0.75	Highly cohesive, form-stable	Yes	Yes

subglandular versus submuscular placement, and different implant texturing methods from different manufacturers.

To provide more objective evaluation of capsular contracture, Baker and Gylbert et al. developed capsular contracture grading systems[16,17]

(Table 2). Gylbert's Breast Augmentation Classification system is comparable to the Baker scale, but the opinion of the patient is not included.[18] Although the causes of capsular contracture are multifactorial, the leading theory points toward subclinical implant infection with *Staphylococcus epidermidis* from mammary ducts.[19–23] Biofilm formation and blood in the breast pocket, contributing iron as a source of bacterial nutrient, have also been described.[24,25] Results of a higher incidence of capsular contracture with smooth implant surface in the subglandular position have been reproducible in several studies, suggesting that implant physical properties such as surface may also contribute to capsular contracture.[26,27] Textured implants, particularly in the submuscular position, have been associated with the lowest rates of capsular contracture.[28,29]

Current implant textured surfaces use a number of different techniques to create microscopic pores in the surface of silicone implants. Theoretically, this leads to physical disruption of surrounding capsular tissue. The efficacy of surface texturing in reducing capsules may derive from interruption of parallel collagen fiber orientation during capsular formation around a breast implant.[30–33] This has been repeatedly studied in clinical series, randomized controlled trials, Core Gel Studies, and meta-analyses.[26,27,34–42]

Allergan (Allergan, Inc., Irvine, Calif.), Mentor (Mentor Corp., Santa Barbara, Calif.), and Sientra (Sientra, Inc., Santa Barbara, Calif.) have all received approval from the U.S. Food and Drug Administration for clinical use of textured breast implants. Since these companies use markedly different techniques for the formation of their respective textured implant surfaces, the purpose of this article is to summarize these differences and the long-term outcome data reported by the manufacturers and individual clinical studies to provide a single summary of the complication rates.

Table 2. Comparing Baker and Breast Augmentation Classification Grading Systems for Capsular Contracture*

Grade	Baker	BAC
I	Breast feels normal; neither surgeon nor patient with complaint	Breast feels normal to surgeon
II	Minimal contracture; surgeon feels capsule but patient does not	Breast capsule feels slightly thickened to surgeon; none to slight distortion
III	Moderate contracture; surgeon and patient feel capsule	Breast capsule feels firm to hard to surgeon; none to slight distortion
IV	Severe contracture; breast distortion noticeable with naked eye	Breast capsule feels hard to surgeon; severe distortion

BAC, Breast Augmentation Classification.
*Data from Barnsley GP, Sigurdson LJ, Barnsley SE. Textured surface breast implants in the prevention of capsular contracture among breast augmentation patients: A meta-analysis of randomized controlled trials. *Plast Reconstr Surg.* 2006;117:2182–2190.

This article compiles the three major manufacturers' data for capsular contracture, malposition, seroma, and rippling for silicone implants from the Core Studies. Although rippling rates have been reported to be higher in a single surgeon's series of textured implants, this has not been substantiated in studies with higher levels of evidence with multiple surgeons and increased numbers of patients.[12,13] Double capsules and late seromas have also been reported.[43–45] A discussion of manufacturer differences in textured implant surfaces, form-stable implants, and the impact on complications is presented. New concepts, including tissue friction coefficient, that may influence malposition after primary breast augmentation, are also presented.

PATIENTS AND METHODS

A literature search of PubMed and the Cochrane Library was performed to obtain the most updated data from silicone breast implant Core data studies. The following key words were used for the literature search: core, silicone implant, augmentation mammaplasty, capsule, capsular contracture, breast, complication, texture, seroma, and rippling. Authoritative Web sites were also reviewed for Core data retrieval.[46] Data were extracted; entered into a Microsoft (Microsoft Corp., Redmond, Wash.) Excel spreadsheet; and separated for Mentor, Allergan, and Sientra. Bar graph figures were generated to demonstrate Core Study complication rates over a 10-year period following primary breast augmentation with silicone implants. Only verifiable data from each manufacturer were included (Figs. 2 through 7) for a side-by-side trend comparison of different manufacturer Core data.

RESULTS

Table 3 demonstrates Core complication profiles for silicone breast implants from the three major manufacturers. Mentor and Allergan data were recorded separately for round and shaped implant models. These two manufacturers

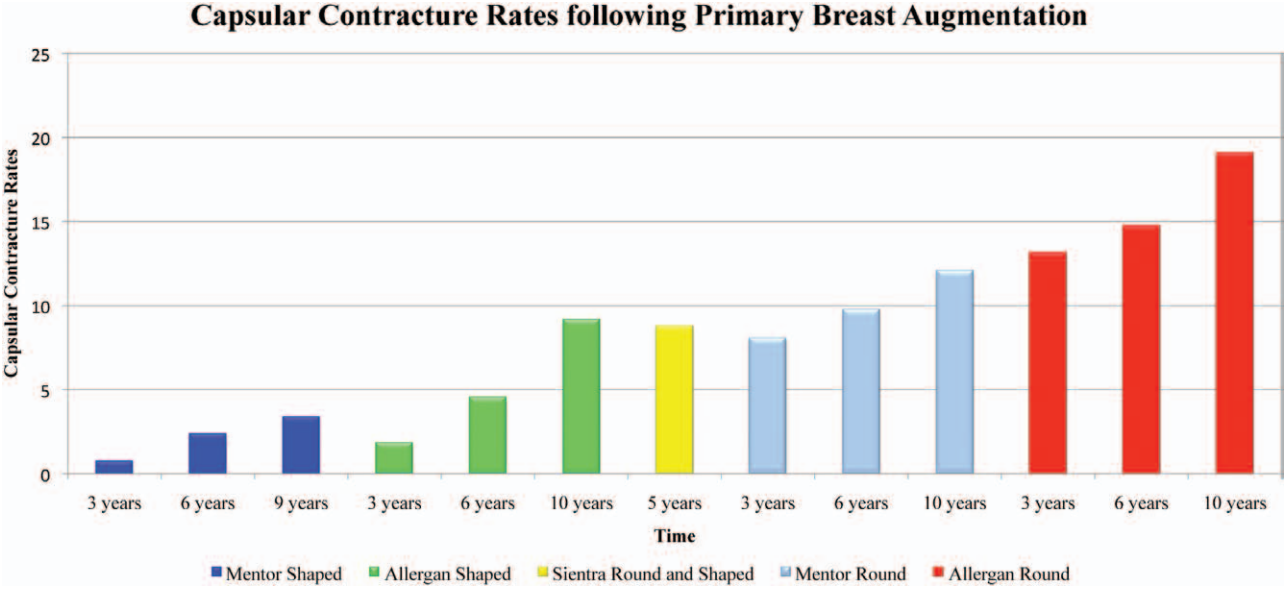


Fig. 2. Primary breast augmentation capsular contracture rates, expressed as percentage of patients, from the three major silicone implant manufacturers.

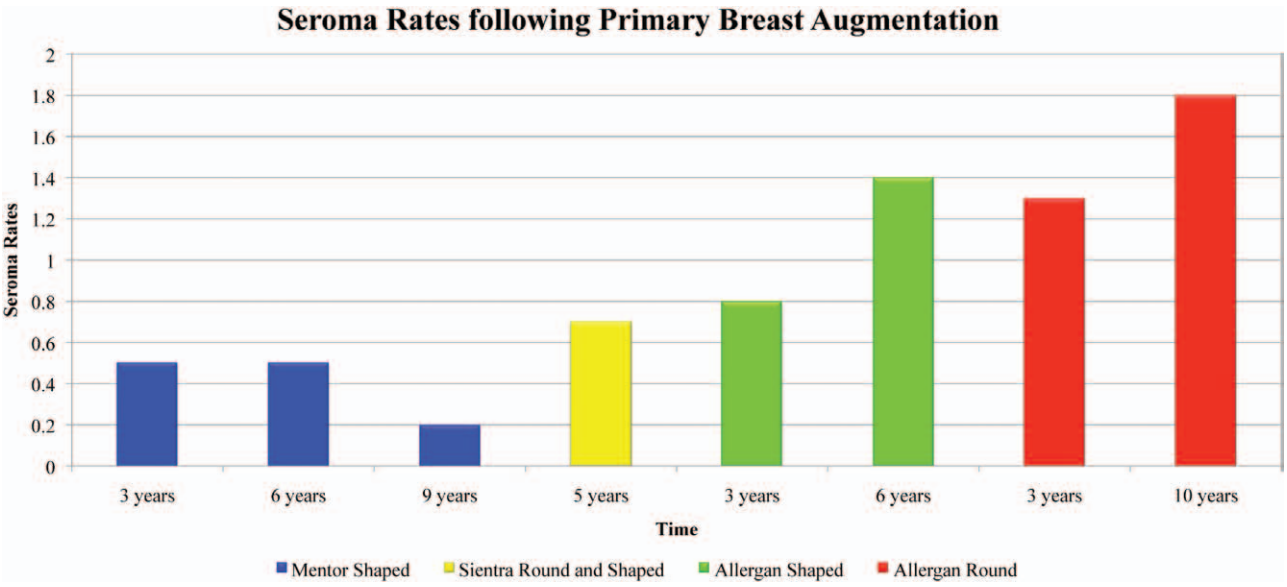


Fig. 3. Primary breast augmentation seroma rates, expressed as percentage of patients, from the three major silicone implant manufacturers.

underwent separate U.S. Food and Drug Administration approval processes for their round and shaped silicone implants. Sientra received U.S. Food and Drug Administration approval for their round and shaped breast implants through a single application process, and therefore their data are combined. Figures 2 through 5 demonstrate key complication rates over a 10-year period following primary breast augmentation. Figure 2 demonstrates an increased trend in capsular contracture rates over time for both round and shaped implants. Because of the reporting differences in the Core data among manufacturers, capsular contracture rates cannot be directly compared. Furthermore, the Core study design also limited the extent of seroma results reported in Figure 3. Figure 4 summarizes the differences in manufacturer-specific rippling rates. Figure 5 demonstrates a tendency toward reduced malposition with the use of textured, shaped Allergan implants compared with round implants by the same manufacturer. This measure of malposition

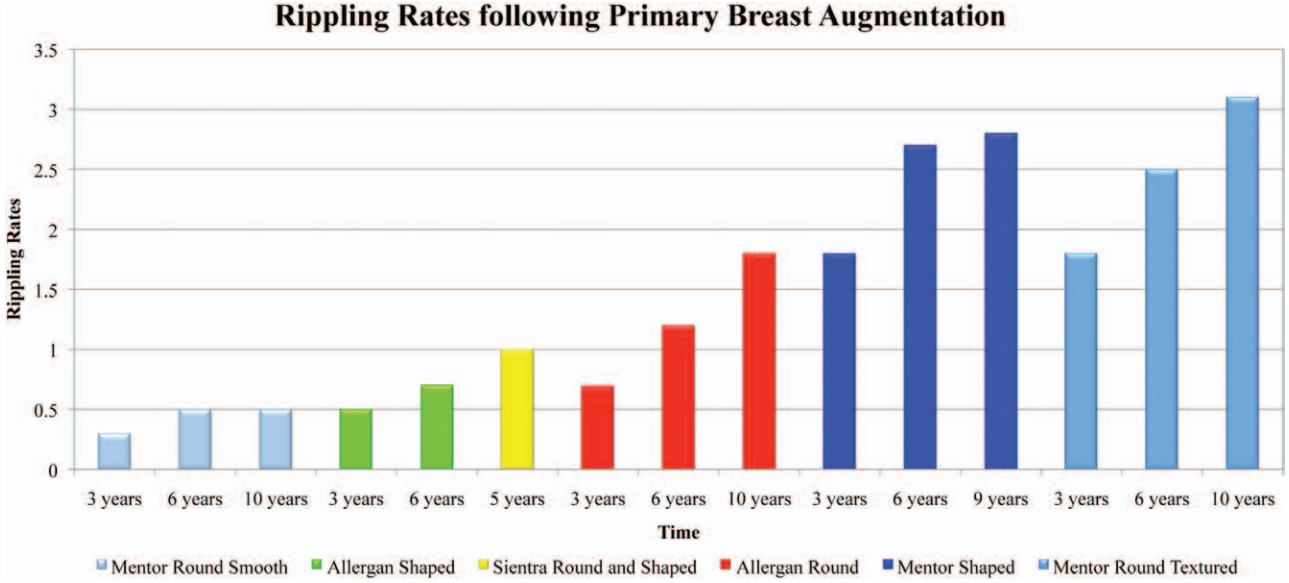


Fig. 4. Primary breast augmentation rippling rates, expressed as percentage of patients, from the three major silicone implant manufacturers.

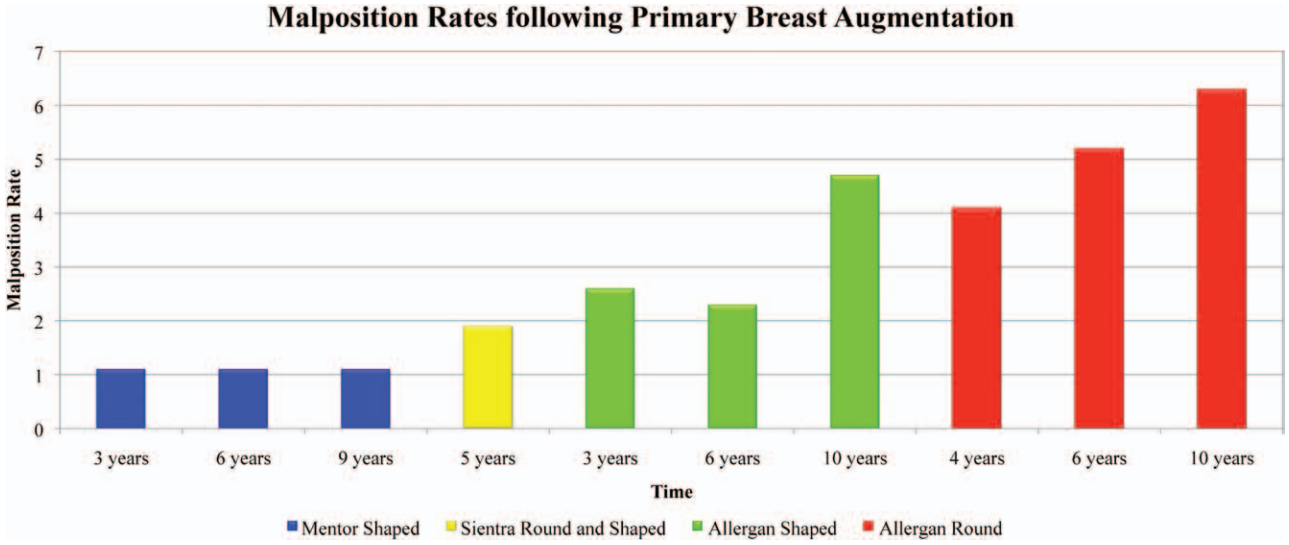


Fig. 5. Primary breast augmentation implant malposition rates, expressed as percentage of patients, from the three major silicone implant manufacturers.

does not include malrotation of shaped devices. Similar trends cannot be studied for Mentor or Sientra either because of a lack of data acquisition in Core studies, or the combined inclusion of smooth, round, and shaped device data in their cohorts. Therefore, statistical comparison between manufacturers was not possible because of the variability in manufacturer-specific Core study design.

DISCUSSION

A summary of the three U.S. manufacturers' Core Studies of complication profiles for silicone implants, up to 10 years following primary breast augmentation, has been provided. Different implant textures were compared using the following complication rates: capsular contracture, malposition, seroma, and rippling. Although direct comparisons cannot be made, this article serves as a source summary of the largest cohort of long-term data. The advantages and disadvantages of manufacturer-specific texturing processes were correlated with the recently described phenomena of double capsules and late seromas. Lastly, the concept of tissue friction coefficient as it relates to breast implant surgery is discussed.

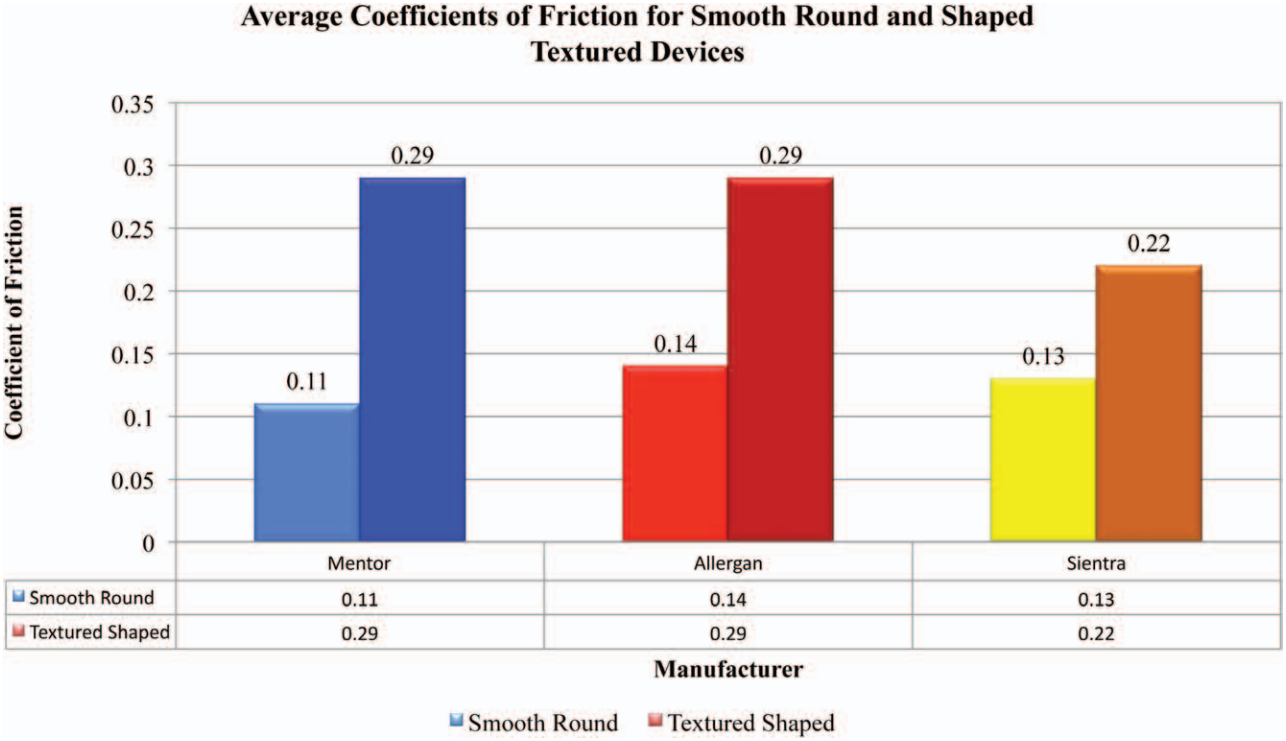


Fig. 6. Average coefficient of friction for Mentor, Allergan, and Sientra smooth and shaped breast implants. (Data from Rowe S. Ethicon AS&T Laboratories Protocol No. CP526. *Determination of Coefficient of Friction for Sientra, Allergan, and Mentor Anatomically Shaped, Gel-Filled Mammary Implants*. October 2013, Santa Barbara, Calif. October 31, 2013.)

Histology of Capsular Contracture

Histologic tissue responses to textured and smooth silicone implant device surfaces contrast with clinical outcomes.[31,47] Textured implants result in thicker and more inflammatory capsular tissue formation than smooth-surfaced implants, yet despite these findings, clinical comparisons suggest reduced capsular contracture rates with textured implant use.[26,27,34,39,40,47]

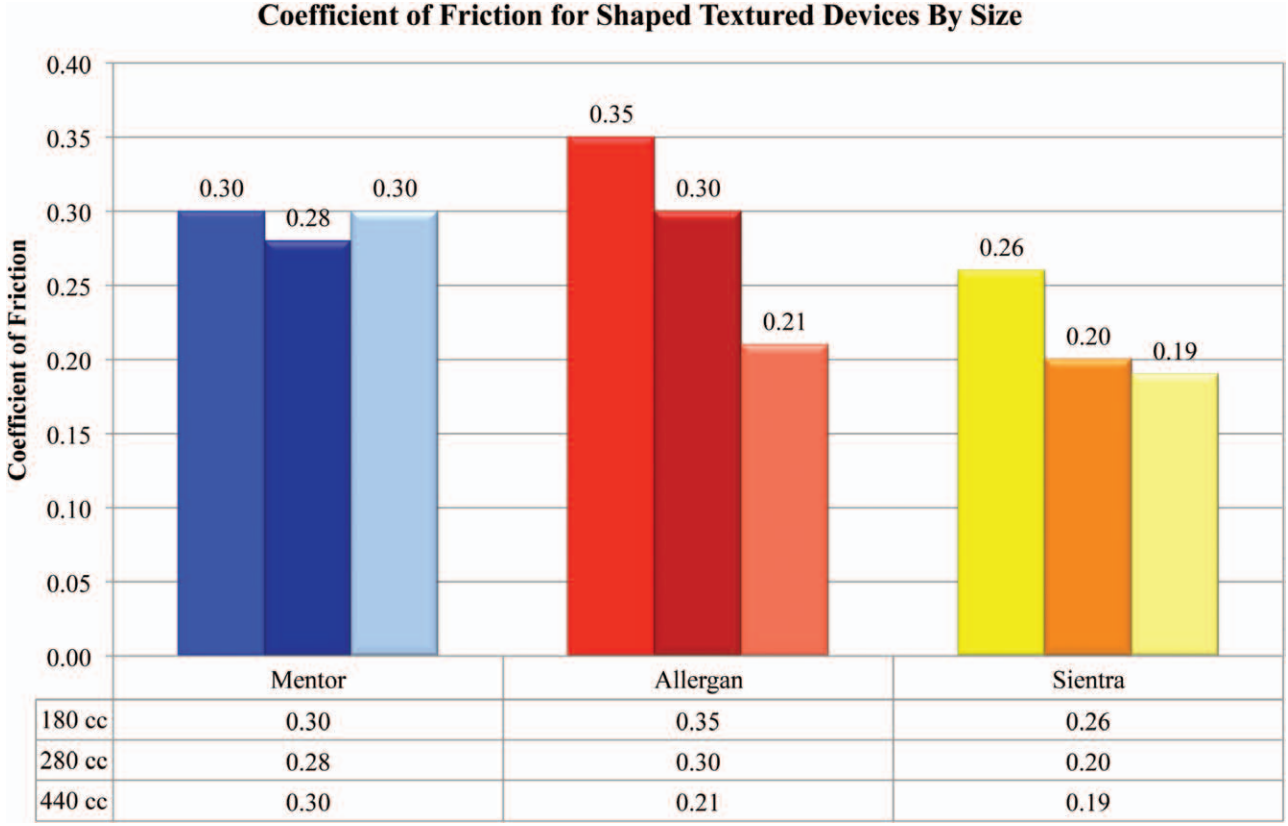
Force vectors around an implant contribute to capsular contracture.[31] Myofibroblasts may contribute to this force production.[30,48] These cell populations peak during the first week of wound healing in breast capsular tissue and have demonstrated responsiveness to agonists and antagonists of smooth muscle contractility.[30] Because the inflammatory mediator leukotriene triggers smooth muscle contraction in bronchioles, use of antileukotriene agents has been reported to reduce progression of early stages of capsular contracture.[49]

In summary, despite histologic findings of thicker and more inflamed capsular tissue around textured implants, textured implants demonstrate reduced capsular contracture rates compared with smooth implants in primary breast augmentation. Capsulotomy has been theorized to be clinically effective because of unloading of myofibroblast tension, resulting in apoptosis and cell death, with improvement in capsular contracture.[50]

Manufacturer-Specific Texturing Processes

Each manufacturer uses a proprietary texturing process, resulting in differences in texture pore density, diameter, depth, and distribution on the implant surface. All implants undergo an initial process of silicone shell manufacture followed by company-specific processes for surface texturing.[51] Allergan uses a "salt-loss technique" for Biocell macrotexturing. Mentor uses negative-contact polyurethane foam imprinting to produce Siltex microtexturing.[31] Sientra claims proprietary confidentiality for their TRUE Texture technique.

Detailed assessment of textured breast implant surface histology has been performed.[52] Biocell pores demonstrate diameters of 600 to 800 μm, with depths of 150 to 200 μm that are distributed irregularly across the implant's surface. Siltex pores are five times smaller, with a 70- to 150-μm diameter and 40- to 100-μm height. Siltex texturing is more evenly distributed over the surface of the implant. Round Siltex breast implants have 100 pores per inch, whereas shaped Siltex implants have 65 pores per inch. Microscopic



	Mentor	Allergan	Sientra
180 cc	0.30	0.35	0.26
280 cc	0.28	0.30	0.20
440 cc	0.30	0.21	0.19

Fig. 7. Average coefficients of friction, according to implant size, for Mentor, Allergan and Sientra shaped breast implants. (Data from Rowe S. Ethicon AS&T Laboratories Protocol No. CP526. *Determination of Coefficient of Friction for Sientra, Allergan, and Mentor Anatomically Shaped, Gel-Filled Mammary Implants*. October 2013, Santa Barbara, Calif. October 31, 2013.)

architectural description of Sientra's TRUE Texture implant surface has not been released by the manufacturer. Figure 1 demonstrates scanning electron microscopic architectural differences between smooth and textured implant surfaces from the three major manufacturers.

Danino et al. were among the first to examine corresponding capsular architecture surrounding textured surface implants. Biocell's 600- to 800-μm diameter surface pores allowed for mirror-image capsular ingrowth, whereas Siltex's 70- to 150-μm diameter surface pore microtexturing resulted in linear fibrosis of corresponding capsular tissue.[52] Microtexturing and macrotexturing parameters are likely to be more formally defined as implant manufacture evolves and the contribution to surgical outcomes of proprietary processes are better appreciated through more rigorous comparative study.

Improved understanding of pore density, depth, and diameter of microtexturing versus macrotexturing may assist in the appropriate selection of breast implants for use in primary breast augmentation. This concept, combined with the suspected multifactorial causes of capsular contracture, is an important component of an evolving pool of evidence-based medicine.[30,31,48,53,54]

Cause of Capsular Contracture and Textured Implants

Subclinical implant infection with *Staphylococcus epidermidis* is a leading cause of capsular contracture.[20,21,23] Bacteria can bind to an implant regardless of smooth or textured surface characteristics.[55] Once exposed to an implant, bacteria may form a biofilm through established stages: reversible attachment, irreversible attachment, growth, differentiation, and dissemination.[56] Several studies name bacterial biofilm as a potential cause of breast implant capsular contracture.[19,25,57] Other causes of contracture that support the multifactorial hypothesis have been considered: silicone versus saline fill,[58] hematoma,[12,59] implant pocket location,[27,28] use of antiseptic irrigation,[20,23,60] incision location,[61,62] and implant surface morphology.[26,27,29,40]

Seven randomized controlled trials evaluating the impact of surface texture on capsular

Table 3. Kaplan-Meier Estimated Cumulative Incidence Rates for Key Complications up to 10 Years after Primary Breast Augmentation for Mentor Implants*

Follow-Up (yr)	Implant Texture	Total No. of Patients	Augmentation Patients	Contracture Rate (III/IV) (%)	Seroma Rate (%)	Rippling Rate (%)	Malposition Rate (%)
3	Smooth and Siltex round	1008	552	8.1	N/A	Smooth, 0.3; textured, 1.8	N/A
6	Smooth and Siltex round	1008	552	9.8	N/A	Smooth, 0.5; textured, 2.5	N/A
10	Smooth and Siltex round	1008	552	12.1%	N/A	Smooth, 0.5; textured, 3.1	
3	Siltex shaped	955	572	0.8	0.5	1.8	1.1
6	Siltex shaped	955	572	2.4	0.5	2.7	1.1
9	Siltex shaped	955	572	3.4	0.2	2.8	1.1

N/A, not available.
*Sources: 10-Year Core Gel Clinical Study Final Report. Santa Barbara, Calif: Mentor Worldwide, LLC; April of 2013; and 9-Year MemoryShape (formerly Contour Profile Gel) Clinical Study Annual Report. Santa Barbara, Calif: Mentor Worldwide, LLC; November of 2013.

Table 4. Kaplan-Meier Estimated Cumulative Incidence Rates for Key Complications up to 10 Years after Primary Breast Augmentation for Allergan Implants*

Follow-Up (yr)	Implant Texture	Total No. of Patients	Augmentation Patients	Contracture Rate (III/IV) (%)	Seroma Rate (%)	Rippling Rate (%)	Malposition Rate (%)
4	Smooth and Biocell round	715	455	13.2	1.3	0.7	4.1
6	Smooth and Biocell round	715	455	14.8	N/A	1.2	5.2
10	Smooth and Biocell round	715	455	19.1	1.8	1.8	6.3
3	Biocell shaped	941	492	1.9	0.8	0.5	2.6
6	Biocell shaped	941	492	4.6	1.4	0.7	2.3
10	Biocell shaped	941	492	9.2	N/A	N/A	4.7

N/A, not available.
*Sources: Health Canada. Summary basis of decision for Natrelle silicone-filled breast implants-smooth and textured shell. September 25, 2012. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/md-im/sbd_smd_2012_natrelleround_61865_60524-eng.php. Accessed February of 2014; Health Canada. Summary basis of decision for NATRELLE highly cohesive silicone-filled breast implants. January 17, 2014. Available at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/md-im/sbd_smd_2013_natrellecohesive_88573-eng.php. Accessed February of 2014; and U.S. Food and Drug Administration summary of safety and effectiveness data for Inamed silicone-filled breast implants. November 17, 2006. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056b.pdf. Accessed March of 2014.

Table 5. Kaplan-Meier Estimated Cumulative Incidence Rates for Key Complications up to 10 Years after Primary Breast Augmentation for Sientra Implants*

Follow-Up	Implant Texture	Total No. of Patients	Augmentation Patients	Contracture Rate (III/IV) (%)	Seroma Rate (%)	Rippling Rate (%)	Malposition Rate (%)
5 yr	Smooth round TRUE Texture round TRUE Texture shaped	1788	1116	8.8	0.7	1.0	1.9

*Source: Stevens WG, Harrington J, Alizadeh K, et al. Five-year follow-up data from the U.S. clinical trial for Sientra's U.S. Food and Drug Administration-approved Silimed brand round and shaped implants with high-strength silicone gel. *Plast Reconstr Surg.* 2012;130:973–981.

contracture are summarized in the meta-analysis by Barnsley et al.[26] Pooled data yielded an odds ratio of 0.19 (95 percent CI, 0.07 to 0.52), supporting capsular contracture reduction associated with surface textured implants. Capsular contracture occurred five times more frequently with smooth surface implants in the subglandular plane. Data for submuscular subgroup analysis were derived from a single, underpowered comparative study.[36] Nonrandomized studies support the claim of reduced capsular contracture when implants are placed in the submuscular position.[6,28,29] The systematic review by Wong et al. included six studies (all included in Barnsley's meta-analysis) demonstrating reduced capsular contracture rates at 1, 3, and 7 years postoperatively with textured devices used in breast augmentation.[27]

Although the former studies focused on review of data collected before 2000, Stevens and colleagues offered a more contemporary analysis.[28] Sientra TRUE Texture implants were used for subglandular and submuscular primary breast

augmentation. The 5-year Kaplan-Meier overall device rate for capsular contracture was 7.6 percent. Textured implants demonstrated the lowest contracture rates: 2.1 percent for submuscular and 4.9 percent for subglandular placement. Smooth-surfaced submuscular and subglandular implants demonstrated less favorable capsular contracture rates of 5.1 and 21.0 percent, respectively. Multivariate analysis revealed that smooth implants and subglandular placement increased the risk of developing capsular contracture by 4.7 and 4.6 times, respectively. Therefore, smooth silicone implants should be avoided in the subglandular position.

Fifth-generation, form-stable, highly cohesive, shaped breast implants have reduced rates of capsular contracture in comparison with earlier generation implants.[4,6–9,63–66] Hypothetically, the highly cohesive gel exerts counterpressure, expanding the surrounding breast tissue, thereby improving shell incorporation and minimizing capsular contracture formation.[8,66] Figure 2 demonstrates potential reduced capsular contracture with shaped implant use compared with round implant use in primary breast augmentation. A more natural feel has been described with shaped implants because the implant, breast, and capsule move and feel like a natural breast.[8,66] This is often in contrast to the feel of smooth-surfaced implants that move separately within the pocket from the breast tissue.

Malposition and Shaped Textured Implants

Textured shaped devices minimize the risk of malrotation within the pocket resulting from friction between the implant and the tissue. The concept of "friction coefficient" mentioned by Bengtson in his report of style 410 Core Study results at 3 years is an important concept, as textured implants have a higher tissue friction coefficient than smooth implants.[8] Friction (f) equals the coefficient of friction (μ) multiplied by force (n) pressing two objects together ($f = \mu N$).[67] The coefficient of friction (μ) is dependent on the materials used (i.e., glass on ice has a low coefficient of friction, and rubber on cement has a high coefficient of friction).[67] Industry-directed study has determined the coefficient of friction for all three major manufacturers' smooth and shaped implant surfaces (Figs. 6 and 7).[68] All manufacturers' textured implants demonstrated statistically greater friction coefficients compared with their smooth surface counterparts. Mentor and Allergan demonstrated statistically significant differences in average coefficients of friction for their textured implant surfaces compared with Sientra's textured surface, but not when compared with each other (Fig. 6). The implant shells of larger Allergan and Sientra shaped implants have reduced coefficients of friction compared with smaller implants from the same manufacturers (Fig. 7). This is likely because of a reduction in pore density over a larger surface area in the larger implants. This size-dependent phenomenon was not demonstrated between smaller and larger Mentor microtextured devices. Considered together, the results from Figures 5 through 7 are suggestive of the relationship between microtexturing, macrotexturing, and the tissue friction coefficient that may reduce the incidence of malposition. Despite comparable coefficients of friction for Mentor and Allergan shaped devices, microtextured devices demonstrated reduced malposition rates compared with macrotextured devices (Fig. 5). Precise pocket development to optimize contact between implant surface and surrounding tissue likely contributes to a reduced risk of implant malposition.

Seromas and Textured Implants

Despite the reduction in capsular contracture that textured devices provide, macrotexturing may be responsible for late seroma formation and double capsules.[43] "Late seroma" is generally believed to occur more than 1 year after surgery.[63] Spear et al. demonstrated late seroma occurrence at a mean of 4.7 years after surgery.[44] Late seromas have drawn recent attention given the ongoing investigation into their possible relationship with anaplastic large-cell lymphoma.[69–71] Hall-Findlay identified a subset of primary breast augmentation patients who developed late seroma formation and double capsules.[43] Fourteen patients with double capsules were identified, all of whom had macrotextured implants. The cause of the problem was suggested to be mechanical, secondary to forceful separation between aggressively textured implants and their capsule. Microtextured surfaces have also been demonstrated to result in seroma but may have received less attention because of lack of literature support regarding microtextured surface seroma formation and symptomatic double capsules.[72] Guidelines for management of late seroma after breast implant placement are available to rule out anaplastic large-cell lymphoma.[45] Both the seroma fluid and capsule tissue should be sent for malignant cytologic and immunohistochemical stains, including CD30 and cytokeratin.[45]

Rippling and Textured Implants

Limited reports suggest that rippling may occur more frequently with the use of textured implants.[12,13] Appropriate patient selection, accounting for adequate soft-tissue coverage through tissue pinch and calculation of body mass index, may minimize this risk. Rippling correlates strongly with body mass index less than 18.5 in primary breast augmentation. Underweight patients demonstrate statistically more frequent rippling with smooth saline implants compared with smooth silicone implants in the subglandular position.[73]

Earlier generation silicone implants have less silicone cross-linking and, therefore, less form-stability. To be truly form-stable, an implant must maintain its shape, regardless of position. An implant's form-stability may affect how well its superior pole maintains shape and avoids rippling when subjected to gravity in the upright position.

Texture-type also seems to correlate with rippling. Handel et al. noted a significant difference in frequency of skin rippling among breast augmentation cohorts with Biocell (10 percent) compared with Siltex (2.2 percent) textured implants.[12] These results complement the understanding that Siltex microtexturing results in a weakly adherent capsule, contrary to the strong adherence and tissue incorporation of Biocell macrotexturing.[43,54] In cases of revision surgery for capsular contracture after Siltex implant use, Malata et al. found capsules lined with synovial-like fluid.[34] The weakly adherent capsule associated with Siltex devices may be secondary to synovial metaplasia. Synovial metaplasia has not been shown to occur with Biocell implants.[74]

STUDY LIMITATIONS

With the exception of rippling rates for Mentor round implants, Allergan and Mentor Core data did not report complication rates separately for each surface subtype. This prevented extraction of round, textured implant–specific complication rates for the majority of complications reported in this review, along with valid statistical comparison of these rates among manufacturers. Only complication rate *trends* were reported in this article. The intention of the article was to offer a consolidated resource referencing 10 years of published Core data. Reported data should be considered in the context of the studies from which they were derived. Manufacturer studies were not set up similarly, and reported results are incomplete, or not specific to textured devices, as shown in Table 3. Future comparative, randomized trials may validate use of one textured implant over another to minimize complications focused on in this review. Other limitations, inherent in a retrospective review of primary breast augmentation outcomes, include the confounding variables of surgical technique, implant location, and differences in manufacturer texturing processes. Furthermore, this study was primarily limited by reviews of single-surgeon series, a limited number of meta-analyses/systematic reviews, and Core manufacturer reports.

CONCLUSIONS

This review article describes the fundamental differences in the microscopic surface textures of silicone breast implants with respect to size, depth, and surface area distribution in addition to the techniques used to manufacture the three different surfaces. A summary of the 10-year Core data is presented for ease of comparison. Although no conclusions can be drawn with respect to direct comparison between groups because of the inherent differences in the design of the Core Gel Studies, the incidences of three large cohorts are presented side-by-side in a single reference demonstrating rates of capsular contracture, seroma, and malposition in the largest series available in the literature. These data, despite the limitations, are very important for beginning to recognize potential differences in outcomes and complications based on microtexturing and macrotexturing.

Furthermore, the concept of a textured implant surface's tissue friction coefficient is presented. The coefficient of friction produced by macrotexturing and microtexturing objectively quantifies the level of adherence between the implant and surrounding breast tissue. The clinical relevance relates to differences in tissue and implant adherence by ingrowth, distinct from the friction produced without tissue ingrowth. Potential advantages include reduction in capsular contracture and rotation. Potential disadvantages include surface fragmentation, rippling, and double capsules.[52] Future implant studies should focus on the clinical outcomes associated with implant surface microtexturing compared with macrotexturing used in breast augmentation.

Mark A. Codner M.D.
Mark Codner MD Plastic Surgery
1800 Howell Mill Road, Suite 140
Atlanta, Ga. 30318
macodner@gmail.com

ACKNOWLEDGMENTS

The authors thank Lynne Ferrell, M.L.S., medical librarian and archivist, Schnepp Library at Memorial Medical Center in Springfield, Illinois, for providing expert assistance in manuscript retrieval for this literature review; and Mentor for their provision of microscopic images for all three manufacturers presented in this review in addition to additional surface texturing and coefficient-of-friction data.

REFERENCES

1. American Society of Plastic Surgeons. 2013 cosmetic plastic surgery statistics. Available at: http://www.plasticsurgery.org/news/plastic-surgery-statistics/2013.html. Accessed March 1, 2014.
2. Cronin TD, Gerow FJ. Augmentation mammaplasty: A new "natural feel" prosthesis. In: *Transactions of the Third International Congress of Plastic Surgery*; October 13–14, 1963; Washington, DC. Amsterdam, The Netherlands: Excerpta Medica Foundation; 1964.
3. Cunningham B. The Mentor Core Study on Silicone MemoryGel Breast Implants. *Plast Reconstr Surg.* 2007;120:19S–29S.
4. Cunningham B. The Mentor Study on Contour Profile Gel Silicone MemoryGel Breast Implants. *Plast Reconstr Surg.* 2007;120(Suppl 1):33S–39S.
5. Cunningham B, McCue J. Safety and effectiveness of Mentor's MemoryGel implants at 6 years. *Aesthetic Plast Surg.* 2009;33:440–444.
6. Hammond DC, Migliori MM, Caplin DA, Garcia ME, Phillips CA. Mentor Contour Profile Gel implants: Clinical outcomes at 6 years. *Plast Reconstr Surg.* 2012;129:1381–1391.
7. Spear SL, Murphy DK, Slicton A, Walker PS; Inamed Silicone Breast Implant U.S. Study Group. Inamed silicone breast implant core study results at 6 years. *Plast Reconstr Surg.* 2007;120(Suppl 1):8S–16S; discussion 17S.
8. Bengtson BP, Van Natta BW, Murphy DK, Slicton A, Maxwell GP; Style 410 U.S. Core Clinical Study Group. Style 410 highly cohesive silicone breast implant core study results at 3 years. *Plast Reconstr Surg.* 2007;120(Suppl 1):40S–48S.
9. Maxwell GP, Van Natta BW, Murphy DK, Slicton A, Bengtson BP. Natrelle style 410 form-stable silicone breast implants: Core study results at 6 years. *Aesthet Surg J.* 2012;32:709–717.
10. Ersek RA. Rate and incidence of capsular contracture: A comparison of smooth and textured silicone double-lumen breast prostheses. *Plast Reconstr Surg.* 1991;87:879–884.
11. Ersek RA, Salisbury AV. Textured surface, nonsilicone gel breast implants: Four years' clinical outcome. *Plast Reconstr Surg.* 1997;100:1729–1739.
12. Handel N, Jensen JA, Black Q, Waisman JR, Silverstein MJ. The fate of breast implants: A critical analysis of complications and outcomes. *Plast Reconstr Surg.* 1995;96:1521–1533.
13. Handel N, Cordray T, Gutierrez J, Jensen JA. A long-term study of outcomes, complications, and patient satisfaction with breast implants. *Plast Reconstr Surg.* 2006;117:757–767.
14. Pollock H. Breast capsular contracture: A retrospective study of textured versus smooth silicone implants. *Plast Reconstr Surg.* 1993;91:404–407.
15. Spear SL, Elmaraghy M, Hess C. Textured-surface saline-filled silicone breast implants for augmentation mammaplasty. *Plast Reconstr Surg.* 2000;105:1542–1552.
16. Baker JL. Augmentation mammaplasty. In: Owsley JQ, Peterson RA, eds. *Symposium on Aesthetic Surgery of the Breast.* St. Louis: Mosby; 1978:256–263.
17. Gylbert L, Asplund O, Jurell G, Olenius M. Results of subglandular breast augmentation using a new classification method: 18-year follow-up. *Scand J Plast Reconstr Surg Hand Surg.* 1989;23:133–136.
18. Hakelius L, Ohlsén L. Tendency to capsular contracture around smooth and textured gel-filled silicone mammary implants: A five-year follow-up. *Plast Reconstr Surg.* 1997;100:1566–1569.
19. Shah Z, Lehman JA Jr, Tan J. Does infection play a role in breast capsular contracture? *Plast Reconstr Surg.* 1981;68:34–42.
20. Burkhardt BR, Dempsey PD, Schnur PL, Tofield JJ. Capsular contracture: A prospective study of the effect of local antibacterial agents. *Plast Reconstr Surg.* 1986;77:919–932.
21. Pajkos A, Deva AK, Vickery K, Cope C, Chang L, Cossart YE. Detection of subclinical infection in significant breast implant capsules. *Plast Reconstr Surg.* 2003;111:1605–1611.
22. Adams WP Jr, Conner WC, Barton FE Jr, Rohrich RJ. Optimizing breast-pocket irrigation: The post-betadine era. *Plast Reconstr Surg.* 2001;107:1596–1601.
23. Adams WP, Rios JL, Smith SJ. Enhancing patient outcomes in aesthetic and reconstructive breast surgery using triple antibiotic breast irrigation: Six-year prospective clinical study. *Plast Reconstr Surg.* 2006;117:46S–52S.
24. Marques M, Brown SA, Cordeiro ND, et al. Effects of fibrin, thrombin, and blood on breast capsule formation in a preclinical model. *Aesthet Surg J.* 2011;31:302–309.
25. Marques M, Brown SA, Cordeiro ND, et al. Effects of coagulase-negative staphylococci and fibrin on breast capsule formation in a rabbit model. *Aesthet Surg J.* 2011;31:420–428.
26. Barnsley GP, Sigurdson LJ, Barnsley SE. Textured surface breast implants in the prevention of capsular contracture among breast augmentation patients: A meta-analysis of randomized controlled trials. *Plast Reconstr Surg.* 2006;117:2182–2190.
27. Wong CH, Samuel M, Tan BK, Song C. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: A systematic review. *Plast Reconstr Surg.* 2006;118:1224–1236.
28. Stevens WG, Nahabedian MY, Calobrace MB, et al. Risk factor analysis for capsular contracture: A 5-year Sientra study analysis using round, smooth, and textured implants for breast augmentation. *Plast Reconstr Surg.* 2013;132:1115–1123.
29. Stevens WG, Harrington J, Alizadeh K, et al. Five-year follow-up data from the U.S. clinical trial for Sientra's U.S. Food and Drug Administration-approved Silimed brand round and shaped implants with high-strength silicone gel. *Plast Reconstr Surg.* 2012;130:973–981.
30. Baker JL Jr, Chandler ML, LeVier RR. Occurrence and activity of myofibroblasts in human capsular tissue surrounding mammary implants. *Plast Reconstr Surg.* 1981;68:905–912.
31. Abramo AC, De Oliveira VR, Ledo-Silva MC, De Oliveira EL. How texture-inducing contraction vectors affect the fibrous capsule shrinkage around breasts implants? *Aesthetic Plast Surg.* 2010;34:555–560.
32. Brohim RM, Foresman PA, Hildebrandt PK, Rodeheaver GT. Early tissue reaction to textured breast implant surfaces. *Ann Plast Surg.* 1992;28:354–362.
33. Taylor SR, Gibbons DF. Effect of surface texture on the soft tissue response to polymer implants. *J Biomed Mater Res.* 1983;17:205–227.
34. Malata CM, Feldberg L, Coleman DJ, Foo IT, Sharpe DT. Textured or smooth implants for breast augmentation? Three year follow-up of a prospective randomised controlled trial. *Br J Plast Surg.* 1997;50:99–105.
35. Tarpila E, Ghassemifar R, Fagrell D, Berggren A. Capsular contracture with textured versus smooth saline-filled implants for breast augmentation: A prospective clinical study. *Plast Reconstr Surg.* 1997;99:1934–1939.

36. Asplund O, Gylbert L, Jurell G, Ward C. Textured or smooth implants for submuscular breast augmentation: A controlled study. *Plast Reconstr Surg.* 1996;97:1200–1206.
37. Burkhardt BR, Demas CP. The effect of Siltex texturing and povidone-iodine irrigation on capsular contracture around saline inflatable breast implants. *Plast Reconstr Surg.* 1994;93:123–128.
38. Burkhardt BR, Eades E. The effect of Biocell texturing and povidone-iodine irrigation on capsular contracture around saline-inflatable breast implants. *Plast Reconstr Surg.* 1995;96:1317–1325.
39. Hakelius L, Ohlsén L. A clinical comparison of the tendency to capsular contracture between smooth and textured gel-filled silicone mammary implants. *Plast Reconstr Surg.* 1992;90:247–254.
40. Coleman DJ, Foo IT, Sharpe DT. Textured or smooth implants for breast augmentation? A prospective controlled trial. *Br J Plast Surg.* 1991;44:444–448.
41. Fagrell D, Berggren A, Tarpila E. Capsular contracture around saline-filled fine textured and smooth mammary implants: A prospective 7.5-year follow-up. *Plast Reconstr Surg.* 2001;108:2108–2112.
42. 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;106:786–791.
43. Hall-Findlay EJ. Breast implant complication review: Double capsules and late seromas. *Plast Reconstr Surg.* 2011;127:56–66.
44. Spear SL, Rottman SJ, Glicksman C, Brown M, Al-Attar A. Late seromas after breast implants: Theory and practice. *Plast Reconstr Surg.* 2012;130:423–435.
45. Bengtson B, Brody GS, Brown MH, et al.; Late Periprosthetic Fluid Collection after Breast Implant Working Group. Managing late periprosthetic fluid collections (seroma) in patients with breast implants: A consensus panel recommendation and review of the literature. *Plast Reconstr Surg.* 2011;128:1–7.
46. U.S. Food and Drug Administration. Post-approval studies. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm. Accessed February 18, 2014.
47. Bern S, Burd A, May JW Jr. The biophysical and histologic properties of capsules formed by smooth and textured silicone implants in the rabbit. *Plast Reconstr Surg.* 1992;89:1037–1042.
48. Barker DE, Schultz SL. The theory of natural capsular contraction around breast implants and how to prevent it. *Aesthetic Plast Surg.* 1980;4:357–361.
49. Cheng HT, Lin FY, Chang SC. The effects of antileukotriene agents on capsular contracture: An evidence-based analysis. *Plast Reconstr Surg.* 2012;129:1018e–1020e.
50. Hwang K, Sim HB, Huan F, Kim DJ. Myofibroblasts and capsular tissue tension in breast capsular contracture. *Aesthetic Plast Surg.* 2010;34:716–721.
51. Barr S, Bayat A. Breast implant surface development: Perspectives on development and manufacture. *Aesthet Surg J.* 2011;31:56–67.
52. Danino AM, Basmacioglu P, Saito S, et al. Comparison of the capsular response to the Biocell RTV and Mentor 1600 Siltex breast implant surface texturing: A scanning electron microscopic study. *Plast Reconstr Surg.* 2001;108:2047–2052.
53. Poeppl N, Schreml S, Lichtenegger F, Lenich A, Eisenmann-Klein M, Prantl L. Does the surface structure of implants have an impact on the formation of a capsular contracture? *Aesthetic Plast Surg.* 2007;31:133–139.
54. McCurdy JA. Relationships between spherical fibrous capsular contracture and mammary prosthesis type: A comparison of smooth and textured implants. *Am J Cosm Surg.* 1990;7:235–238.
55. Jennings DA, Morykwas MJ, Burns WW, Crook ME, Hudson WP, Argenta LC. In vitro adhesion of endogenous skin microorganisms to breast prostheses. *Ann Plast Surg.* 1991;27:216–220.
56. Deva AK, Adams WP Jr, Vickery K. The role of bacterial biofilms in device-associated infection. *Plast Reconstr Surg.* 2013;132:1319–1328.
57. Tamboto H, Vickery K, Deva AK. Subclinical (biofilm) infection causes capsular contracture in a porcine model following augmentation mammaplasty. *Plast Reconstr Surg.* 2010;126:835–842.
58. Schaub TA, Ahmad J, Rohrich RJ. Capsular contracture with breast implants in the cosmetic patient: Saline versus silicone. A systematic review of the literature. *Plast Reconstr Surg.* 2010;126:2140–2149.
59. Bengtson BP. Complications, reoperations, and revisions in breast augmentation. *Clin Plast Surg.* 2009;36:139–156.
60. Wiener TC. The role of betadine irrigation in breast augmentation. *Plast Reconstr Surg.* 2007;119:12–15.
61. Stutman RL, Codner M, Mahoney A, Amei A. Comparison of breast augmentation incisions and common complications. *Aesthetic Plast Surg.* 2012;36:1096–1104.
62. Jacobson JM, Gatti ME, Schaffner AD, Hill LM, Spear SL. Effect of incision choice on outcomes in primary breast augmentation. *Aesthet Surg J.* 2012;32:456–462.
63. Lista F, Tutino R, Khan A, Ahmad J. Subglandular breast augmentation with textured, anatomic, cohesive silicone implants: A review of 440 consecutive patients. *Plast Reconstr Surg.* 2013;132:295–303.
64. Hedén P, Boné B, Murphy DK, Slicton A, Walker PS. Style 410 cohesive silicone breast implants: Safety and effectiveness at 5 to 9 years after implantation. *Plast Reconstr Surg.* 2006;118:1281–1287.
65. Hedén P, Bronz G, Elberg JJ, et al. Long-term safety and effectiveness of style 410 highly cohesive silicone breast implants. *Aesthetic Plast Surg.* 2009;33:430–436.
66. Brown MH, Shenker R, Silver SA. Cohesive silicone gel breast implants in aesthetic and reconstructive breast surgery. *Plast Reconstr Surg.* 2005;116:768–779.
67. The Engineering Toolbox. Friction and coefficients of friction. Available at: http://www.engineeringtoolbox.com/friction-coefficients-d_778.html. Accessed February 6, 2014.
68. Rowe S. Ethicon AS&T Laboratories Protocol No. CP526. *Determination of Coefficient of Friction for Sientra, Allergan, and Mentor Anatomically Shaped, Gel-Filled Mammary Implants.* October 2013, Santa Barbara, Calif.
69. Jewell M, Spear SL, Largent J, Oefelein MG, Adams WP Jr. Anaplastic large T-cell lymphoma and breast implants: A review of the literature. *Plast Reconstr Surg.* 2011;128:651–661.
70. Kim B, Roth C, Chung KC, et al. Anaplastic large cell lymphoma and breast implants: A systematic review. *Plast Reconstr Surg.* 2011;127:2141–2150.
71. Taylor KO, Webster HR, Prince HM. Anaplastic large cell lymphoma and breast implants: Five Australian cases. *Plast Reconstr Surg.* 2012;129:610e–617e.
72. Hall-Findlay EJ. Reply Letters: Breast implant complication review: Double capsules and late seromas. *Plast Reconstr Surg.* 2011;128:818–821.
73. Codner MA, Mejia JD, Locke MB, et al. A 15-year experience with primary breast augmentation. *Plast Reconstr Surg.* 2011;127:1300–1310.
74. del Rosario AD, Bui HX, Petrocine S, et al. True synovial metaplasia of breast implant capsules: A light and electron microscopic study. *Ultrastruct Pathol.* 1995;19:83–93.