

Special Topic

Long-Term Safety of Textured and Smooth Breast Implants

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Aesthetic Surgery Journal
2017, 1–11
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DOI: 10.1093/asj/sjx157
www.aestheticsurgeryjournal.com

OXFORD
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Abstract

In this review, the authors provide a 20-year review and comparison of implant options and describe the evolution of breast implant surface textures; compare available implant surfaces; present long-term safety data from the 10-year US-based Core clinical studies; list the key benefits and risks associated with smooth and textured implants; and provide perspectives on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). The authors explore the key benefits and risks associated with all available devices so that optimal and safe patient outcomes can be achieved.

Editorial Decision date: August 7, 2017.

Breast augmentation is one of the most common aesthetic operations performed in the United States. Since 1997, the number of augmentation procedures in the United States has increased by 207%, according to The American Society for Aesthetic Plastic Surgery.¹ During this time, the characteristics and usage of smooth and textured breast implants have changed due to the advances in gel and texture technology, the approval of shaped implants, and the evolution of surgical techniques.

Silicone implants currently available in the United States include fourth- and fifth-generation devices from three manufacturers, Sientra (Santa Barbara, CA), Allergan (Irvine, CA), and Mentor (Irvine, CA).² The current breakdown of breast implant usage in the United States is approximately 87% smooth and 13% textured.³⁻⁵ In contrast, device preferences differ substantially outside the United States, with 90% usage of textured implants in Europe and Australia. The purpose of this article is to describe implant options and stress the importance of maintaining these options to allow surgeons to weigh the risks and benefits of the choices to provide the best individualized outcome for each patient. In this review, the authors will describe

the evolution of breast implant surface textures; compare available implant surfaces; present long-term safety data from the 10-Year US-based Core clinical studies; list the key benefits and risks associated with smooth and textured implants; and provide perspectives on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

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Evolution of Breast Implant Surface Textures

The first silicone gel breast implant was manufactured by Dow Corning Corporation (Midland, MI) in 1962. Silicone breast implants were grandfathered in by the Food and Drug Administration (FDA) based on the overall safety profile of silicone devices used widely in medicine. By 1972, second-generation gel implants became available, which offered a silicone shell, silicone gel, and a polyurethane textured surface (Surgitek [Racine, WI], a subsidiary of Bristol-Myers Squibb [New York, NY]), designed to achieve an improved aesthetic outcome.⁶ The polyurethane-textured surface was designed to reduce the risk of capsular contracture and create a “one breast feel” based on the adherence of this surface type to the surrounding breast tissue. Questions surrounding the safety of polyurethane surface, including concerns about the carcinogenic nature of the breakdown product of polyurethane, 2,4-touluediamine (2,4-TDA), seen in bench studies and the delamination of the polyurethane shell seen clinically. This led to abandoning polyurethane in favor of a new type of textured surface which was developed for third-generation devices. The textured surface was created on the actual silicone polymer shell to mimic the effects of polyurethane on reducing capsular contracture rates.⁷ These nonpolyurethane textured surfaces gained popularity, both on silicone implants around the world and on silicone and saline implants in the United States.

In 1992, the FDA issued a moratorium on all third-generation silicone gel implants and required manufacturers to provide additional safety and effectiveness data. This moratorium fostered the creation of fourth- and fifth-generation silicone gel implants under FDA and subsequently American Society for Testing Methodology guidelines. New parameters for shell thickness and gel cohesivity led to the development of implants with improved quality and a wider variety of surface textures and shapes. These devices are currently available from all implant manufacturers in the United States.²

While the moratorium on silicone breast implants eventually spurred advances in implant technology, it also shifted the US market to saline implants. Textured implants came into disfavor in the United States due to the poor performance of saline textured implants, including high deflation rates, visible wrinkling, and high rates of revision procedures.^{8,9} Therefore, while US plastic surgeons transitioned almost exclusively to using smooth saline implants, the rest of the world continued to favor textured silicone implants. After the FDA moratorium was lifted in 2006, US surgeons naturally gravitated towards smooth-surfaced silicone gel implants for breast surgery, based on their prior experience with smooth saline implants.

Surgeons outside the United States continued to use textured silicone gel implants based on evidence of improved outcomes compared to smooth implants. Recent international data show that the number of breast augmentation cases around the world is nearly three times that of the United States, and almost all implants used outside the United States are textured.¹⁰ Indeed, international data reported over the past two decades support benefits of textured implants, including a protective effect against capsular contracture, predictability of placement, and increased pocket control.^{11,12} Dr. Charles Randquist, a leading breast surgeon practicing in Sweden, has performed more than 6000 breast augmentations over a 20-year period using textured implants. His experience describes superior control over short- and long-term aesthetic results with highly cohesive textured gel implants. Furthermore, he reports low rates of capsular contracture, rupture, rippling, bottoming out, visibility, and reoperation utilizing these implants.¹³

Since the approval of Sientra’s round and shaped implants in 2012, there has been a growing dialogue and understanding of the many benefits of textured implants. The positive attributes of textured implants described by surgeons around the world are substantiated by the results of major clinical trials. Senior author Dr. Grant Stevens’ US experience in the past 15 years includes over 6000 textured devices demonstrating low rates of capsular contracture, malposition, and reoperation.¹⁴⁻¹⁸ US surgeons now have a wealth of data to rely on when evaluating the risks and benefits of smooth and textured silicone breast implants to develop an algorithm for implant selection that can lead to individualized and optimal patient outcomes.

Comparison of Textured Implant Surfaces

The leading theory on the pathogenesis of capsular contracture includes alignment and contraction of fibroblasts within the capsule that forms around a breast implant. The explanation for why smooth implants have a higher rate of capsular contracture is that the fibroblasts within the capsule align to the surface of the implant in a planar arrangement readily allowing for contraction. The rationale behind the manufacturing of textured silicone implants relates to the ability of the irregular surface texture to disrupt this planar arrangement, thereby reducing the risk of capsular contracture. The texture processes used by different manufacturers produce distinct microenvironments, which are capable of influencing cell shape and integration. The strength of adherence of ingrown fibrous tissue to different textured surfaces is dictated by the size of the pores that define each manufacturer’s surface texture.

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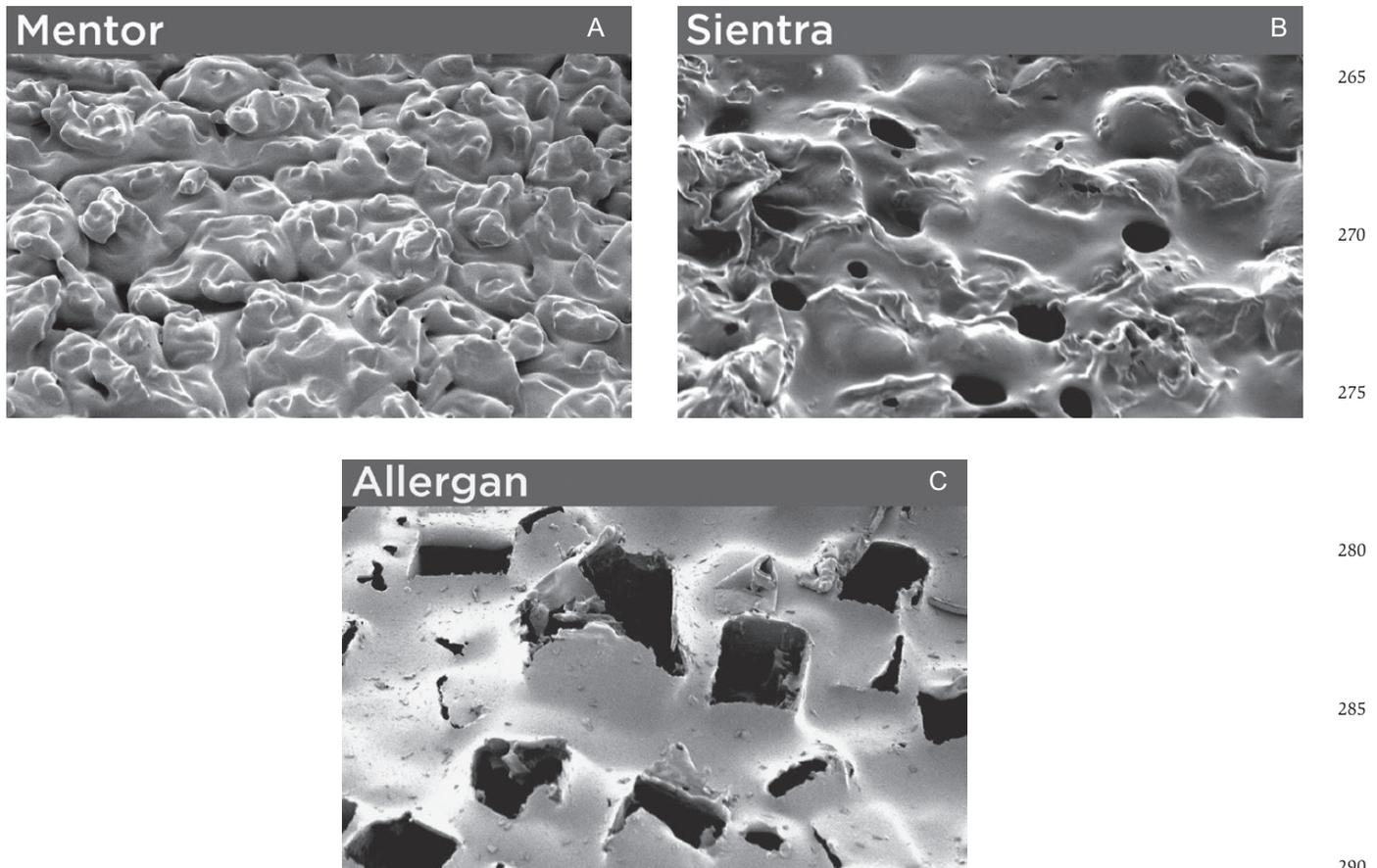


Figure 1. Scanning electron microscopic (SEM) images of (A) Mentor, (B) Sientra, and (C) Allergan textured surfaces at $65\times$ magnification. SEM is the industry standard to characterize the combination of shell surface disruption and pores promoting tissue adherence to the textured shell surface.

Different textures also present different degrees of resistance to movement through friction.¹⁹ The substantial differences between surface textures produced by the three US manufacturers can be seen on scanning electron micrographs (Figure 1).

Although the benefits of textured implants include a reduced risk for capsular contracture and other benefits mentioned above, reports in the literature have spurred discussions regarding complications associated with textured breast implants, such as late seroma, double capsule, and BIA-ALCL.^{4,20} It is important to recognize that the textured surfaces from each of the three US manufacturers performs differently clinically, and many of the benefits and risks associated with textured surfaces are specific to each specific texture. The unique characteristics of the different implants mandate that we consider each textured device on its own merit, and avoid generalizing all textured implants as one in the same. These differences include texture manufacturing technique, degree of adherence to tissue or tissue in-growth, and risk of adverse outcomes.^{21,22} Mentor texture does not exhibit tissue in-growth but does have a high coefficient of friction to limit movement and rotation. Allergan texture is described as macrotecture, it

is the most aggressive and exhibits a high level of tissue in-growth to prevent movement and rotation. Sientra texture is described as a blend of the micro- and macrotecture with minimal to no in-growth seen and a high coefficient of friction (Table 1).

Long-Term Safety Data: The 10-Year US-Based Core Clinical Studies

Following the moratorium in 1992, the FDA required manufacturers to conduct long-term clinical trials to establish the safety and effectiveness of silicone gel breast implants. Because of this mandate, the United States is in the unique position to have five 10-year datasets from FDA-mandated pivotal studies. The Core studies are 10-year, open-label, prospective, multicenter clinical studies for breast augmentation and breast reconstruction indications, using both smooth and textured devices. The key complications in the primary augmentation cohort from the three US implant manufacturers through 10 years are listed in Table 2. Note that the Sientra dataset includes smooth round, textured round, and textured shaped implants²³⁻²⁵ and the Mentor

Table 1. Comparison of Textured Silicone Gel Breast Implant Characteristics^{21,22}

Textured device	Process	Clinical outcomes
Mentor (Irvine, CA)	Negative contact imprinting (stamping) with polyurethane foam.	<ul style="list-style-type: none"> • Least aggressive texture • Lacks adherence; resists movement through friction • Least effective for limiting mobility and providing pocket control • Reduced capsular contracture compared to smooth • Late seromas and double capsules rare
Sientra (Santa Barbara, CA)	Volitization of ammonium carbonate with heat. Does not use sodium chloride rinse, wash, sugar, soak, scrub, or pressure stamping.	<ul style="list-style-type: none"> • Moderately aggressive texture • Resists movement through friction • Adherence is rare • Reduced capsular contracture compared to smooth • Infrequent late seroma • Double capsule rare
Allergan (Irvine, CA)	Calibrated sodium chloride crystals that are rinsed, washed, soaked, and then scrubbed after curing.	<ul style="list-style-type: none"> • Most aggressive texture - macrotexture • High stability and limited implant mobility • Often adheres to surrounding tissue ("Velcro effect") • Can result in pseudo-capsule formation, and higher rates of late seroma and double capsule

Table 2. Risk of Key Complications Following Primary Augmentation Through 10 Years by Patient Kaplan-Meier Risk Estimates*

Complication/event	Sientra 10-year ²⁵ (N=1116)	Mentor 10-year ²⁶ (N=552)	Allergan 10-year ²⁷ (N=455)
Number of implants	2230	1102	908
MRI cohort patients	398	220	158
Rupture (MRI cohort)	8.7%	24.2%	9.3%
Reoperation	24.2%	25.5%	36.1%
Capsular contracture III/IV	12.9%	12.1%	18.9%

*Note: The clinical studies from these manufacturers are not designed to be compared head to head. Each individual product's complication rates are presented.

and Allergan datasets include only smooth and textured round implants. In general, these data demonstrate similar rates of complications between all three manufacturer's devices.^{26,27} Data point outliers include a higher rate of rupture with Mentor implants compared to Allergan and Sientra implants (24.2% Mentor vs 8.7% Sientra and 9.3% Allergan) as well as higher rates of both reoperation and capsular contracture with Allergan implants compared to Mentor and Sientra implants (reoperation: 36.1% Allergan vs 24.2% Sientra and 25.5% Mentor; capsular contracture: 18.9% Allergan vs 12.9% Sientra and 12.1% Mentor, with these differences being statistically significant). An important caveat is that these studies are not meant to be head to head comparisons.

Key Benefits and Risks Associated With Smooth and Textured Implants

It is important to understand the key differences between smooth and textured breast implants as it relates to both risks and benefits of each. Tables 3 and 4 outline the key

benefits and limitations of smooth and textured silicone implants and considerations for patient selection.

Clinical outcomes data from the 10-year Core studies are provided in Tables 5 to 7. These data include a comparison of the smooth vs textured results in the Sientra Core study²⁵ (Table 5), and comparisons of Mentor's and Allergan's round studies to their shaped studies (Tables 6 and 7).²⁶⁻³⁰ In general, reduced rates of complications, including capsular contracture, are seen with textured devices. Although there were a mix of surface textures in the round clinical trials (Mentor and Allergan approximately 60% smooth, 40% textured), considerable decreases in complications were noted in the shaped trials (all textured implants).

Capsular contracture continues to be the leading cause of morbidity and reoperation following breast surgery, with reported incidences as high as 19%.²⁷ Published evidence and expert opinion describe potential risk factors for capsular contracture, including the use of smooth or saline-filled implants, subglandular placement, periareolar incision, and previous radiotherapy to the breast.³¹⁻³⁶ There is published evidence and expert opinion also on strategies to minimize the risk of capsular contracture, for example, Stevens et al reported a lower capsular contracture rate can be achieved with textured implants, submuscular placement, and the use of inframammary incisions.³³ The benefits of textured implants appear to be greatest in reducing capsular contracture when the implant is placed in the subglandular position. An analysis of primary augmentation outcomes from long-term studies using a multivariate analysis revealed similar results.³² The analysis demonstrated significantly reduced relative risk for capsular contracture with submuscular vs subglandular placement and textured vs smooth devices. Other complications, such as malposition and secondary procedures, were reduced

Table 3. Smooth Round Silicone Implants: Benefits, Limitations, and Patient Selection Considerations

Benefits	Limitations	Patient selection
<ul style="list-style-type: none"> • Feel and movement of a natural breast, soft • Implants easily placed and incisions slightly smaller • Newer generation cohesive smooth round implants have less wrinkling due to optimal fill • More forgiving with implant placement and will settle over time • In reconstruction patients, can create a more natural feel and match to a contralateral native breast • In reconstruction patients, can create a more natural shape in radiated tissue due stretch forces from implant movement within the pocket 	<ul style="list-style-type: none"> • Higher rates of capsular contracture, especially when placed above muscle • Greater mobility, often drift to sides (“lateral slip”) and settle to bottom of pocket; can stretch lower pole over time • Reduced control of pocket 	<ul style="list-style-type: none"> • Patients that do not require lowering of the IMF • Patients desiring a natural result but with good upper-pole fullness • Patients with nonsloping chest walls • Patients with thin soft tissue coverage, as smooth implants less likely to wrinkle

IMF, inframammary fold.

Table 4. Textured (Round and Shaped) Silicone Implants: Benefits, Limitations, and Patient Selection Considerations

Benefits	Limitations	Patient selection
<ul style="list-style-type: none"> • Provides frictional resistance to movement and/or adherence to stabilize the pocket position • Stability of texture creates less stretch in the lower pole of the breast over time • Stabilizes implant when lowering IMF and in sloping chest walls • Lower capsular contracture rate, especially in subglandular position • Shaped implants stabilized by texture, minimizing the risk of rotation • In reconstructive patients, shaped implants create a more natural upper pole and reduce the incidence of wrinkling, specifically in prepectoral reconstruction 	<ul style="list-style-type: none"> • May require larger incision • Exact pocket dissection • Requires tissue based planning for predictable results • Potentially higher rate of wrinkling • Higher risk of late seromas and double capsules • Stability of textured implants increases risk of waterfall (snoopy deformity) in heavy or lax breast envelopes • Small but increased association with BIA-ALCL 	<ul style="list-style-type: none"> • Significant benefit seen in revision and in cases with sloping chest walls minimizing implant malposition often seen in these patients • Useful when treating capsular contracture by lowering the risk of recurrence • In augmentation mastopexies, can reduce stretch deformity and recurrent ptosis • When using large implant in patients with poor soft tissue, texture reduces stretch deformity • Shaped implants allow implant selection based on width, volume, projection and height providing optimal results in reconstructions • In reconstructive patients, textured implants may resist deformation of radiation induced capsular contractures

IMF, inframammary fold.

with inframammary compared to periareolar/axillary incision sites and with textured vs smooth devices. Finally, a 2015 meta-analysis of 16 randomized controlled trials and two retrospective studies demonstrated that smooth breast implants were significantly more likely to be associated with capsular contracture, with a relative risk of 3.10 (95% CI, 2.23-4.33) compared to textured implants.³⁶

Perspectives on Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)

Risk for breast implant associated-anaplastic large cell lymphoma is a prominent topic of concern in the plastic surgery community. While it is a rare disease, there is a heightened awareness and concern regarding the correlation of textured implants with the increased risk of developing BIA-ALCL. The World Health Organization (WHO) in 2016 designated BIA-ALCL as a unique ALCL entity.³⁷ Research continues into its possible association with textured breast implants,^{4,38,39} and recent updates by

regulatory agencies in the United States and Australia note an increase in the number of overall reported cases.^{40,41} Countries that have provided statistics on confirmed BIA-ALCL cases, such as the United States, France, and Australia, have reported that macrot textured implants are featured in a majority of reported cases.^{4,39-42} Although the occurrence of BIA-ALCL is rare, regulatory updates in combination with media coverage have drawn concern from both plastic surgeons and patients. The causes of BIA-ALCL are being actively investigated, including the extent to which implant surface may play a role in its development.

Deva et al have published a well-researched hypothesis that bacterial contamination introduced at the time of breast implant surgery may over time lead to a biofilm that triggers an inflammatory and immune system response.⁴³ This response, in conjunction with genetic predisposition, may over time lead to BIA-ALCL.⁴⁴ It has been proposed that implants with a greater surface area allow for a larger bacterial load and therefore a greater risk for lymphocyte stimulation and/or transformation.^{39,44} Some authors have theorized that the immune system might also respond to a component of textured surfaces, and that a rough surface

Table 5. Sientra Core Study Primary Augmentation Kaplan-Meier Risk Estimates for Key Complications Through 10 years, by Surface Type

Sientra Round and Shaped Core Study ²⁵		
Complication/event	Smooth N=644	Textured N=472
Reoperation	24.8%	23.5%
Rupture (MRI cohort)	10.8%	5.9%
Capsular contracture III/IV	16.3%	8.4%
Seroma/fluid accumulation	0.2%	2.5%
Wrinkling/rippling	1.9%	2.1%

Table 6. Mentor Core Round and Shaped Studies Primary Augmentation Kaplan-Meier Risk Estimates for Key Complications Through 10 Years by Surface Type

Mentor Round and Shaped Core Studies		
Complication/event	Mentor round Core study ²⁶ (smooth and textured) N=552	Mentor shaped Core study ²⁷ (textured) N=572
Reoperation	25.5%	23.0%
Rupture (MRI cohort)	24.2%	6.4%
Capsular contracture III/IV	12.1%	3.8%

Table 7. Allergan Round and Shaped Primary Augmentation Kaplan-Meier Risk Estimates for Key Complications Through 10 Years, by Surface Type

Allergan Round and Shaped Core Studies		
Complication/event	Allergan round Core study ²⁷ (smooth and textured) N=455	Allergan shaped Core study ^{28,29} (textured) N=492
Reoperation	36.1%	29.7%
Rupture (MRI cohort)	9.3%	17.7%
Capsular contracture III/IV	18.9%	9.2%
Seroma/fluid accumulation	1.8%	1.6%
Wrinkling/rippling	1.8%	0.9%

integrity. As discussed in Adams et al, the basis of these concerns stemmed from product complaints of implant delamination following intraluminal use of betadine.⁴⁸ Subsequently, Mentor conducted a series of preclinical in vitro studies, and in 2000 a contraindication was added to the manufacturers' labeling. While many surgeons continued to use betadine off -label, many transitioned to using antibiotic only solutions which may not provide adequate Gram-negative coverage (eg, the standard triple antibiotic solution containing Cefazolin, Bacitracin and Gentamycin).^{43,44,49} It is important to implement proper pocket irrigation, such as outlined in the 14 Point Plan,⁴³ to ensure the sufficient coverage against Gram-negative and Gram-positive bacteria

The epidemiology of BIA-ALCL also suggests geographic variation in incidence⁵⁰ as well as genetic variance, such as the absence of cases in Asian patients. Other observations include:

- Clusters of cases by surgeon, with some surgeons having multiple events, possibly representing nosocomial contamination³⁹;
- similar mechanisms of malignancy outside breast implants have been described,⁵⁰ including H. Pylori (Gram-negative) in association with gastric lymphoma, cutaneous infections, and cutaneous lymphomas, and ALCL cases diagnosed in patients with silicone orthopedic devices.

BIA-ALCL most commonly presents as a late occurring fluid collection or as a palpable mass adjacent to the implant.⁵¹ The majority of cases present, on average, eight to ten years following implantation.⁵¹ A full evaluation is recommended when a patient develops a fluid collection more than one year after surgery (most commonly at 8 to 10 years) or a palpable mass adjacent to the implant. The following steps should be taken^{51,52}

- Perform ultrasound scan.
- If fluid is detected, drain and test with CD30 immunohistochemistry and flow cytometry to diagnose BIA-ALCL.⁵¹

could be irritating or abrasive, increasing the risk of an inflammatory response.⁴⁵

One interesting finding is the difference between the types of bacteria found in breast implant capsules from capsular contracture compared to those found in capsules from BIA-ALCL. There is a predominance of Gram-positive bacteria present in capsular contracture cases and a predominance of Gram-negative bacteria present in BIA-ALCL cases. There are likely two pathogenic pathways caused by bacterial biofilm: for Gram-positive bacterial biofilm (eg, *Staphylococcus*), a pathway toward inflammation and fibrosis leading to capsular contracture; and for Gram-negative bacterial biofilm (eg, *Ralstonia picketti*, *pseudomonas*, *breundimonas*), a pathway toward lymphocyte stimulation and/or transformation and eventual lymphoma.⁴⁴

As Gram-negative bacteria and specifically *Ralstonia picketii* is the most commonly implicated type associated with BIA-ALCL, identifying the best methods for reducing these types of bacteria at the time of surgery is key to possible prevention. Betadine (50% or greater concentration) has been noted as one of the only antiseptic agents that is bactericidal against *Ralstonia picketii*.^{46,47} The FDA issued a warning and a recommendation against the contact of betadine as an antiseptic agent with breast implants over concerns about weakening silicone shell surface

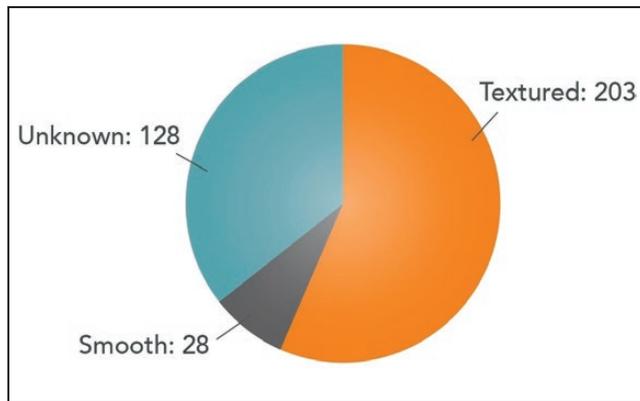


Figure 2. BIA-ALCL reports grouped by implant surface (numbers provided in February 21, 2017 FDA update) (based on cases reported to the MAUDE Database).

- Mammograms are not useful in diagnosing BIA-ALCL.⁵³ In confirmed cases PET scans may be performed to help stage the disease.⁵¹
- It is important to note that most seromas are not BIA-ALCL, but fluid testing can be used to confirm.⁵³

The vast majority of patients who are diagnosed with BIA-ALCL can be cured. Recommendations for treatment include^{53,54}

- Most cases are cured by the removal of the implant and the entire capsule surrounding the implant.
- The majority of patients require no additional treatment.
- Infrequently, patients will need to undergo Brentuximab vedotin, chemotherapy, or radiation therapy when there is extracapsular disease that is unable to be completely excised.⁵¹

The FDA states: “If you have breast implants, there is no need to change your routine medical care and follow-up.”⁴⁰ Expert consensus advises that asymptomatic women without breast changes do not require more than routine follow up. FDA continues to affirm that “BIA-ALCL is a very rare condition.”⁴⁰ Neither the FDA nor any of the plastic surgery societies suggest additional screening or removal of implants for asymptomatic women.^{40,55}

BIA-ALCL: 2017 FDA Update

The FDA issued an update in March 2017 regarding BIA-ALCL that included 359 medical device reports (MDRs) submitted to the Manufacturer and User Facility Device Experience Database (MAUDE).⁴⁰ These MDRs were grouped by implant surface, with a majority associated with textured implants (Figure 2).

A published analysis of the MAUDE database, identified 258 unique cases of BIA-ALCL, of which 70.3% were associated with Allergan devices (both saline and silicone) (Figure 3).³⁸

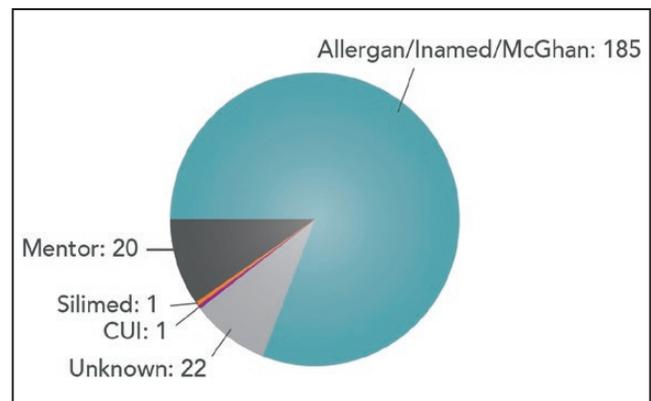


Figure 3. Summary of BIA-ALCL reports submitted to FDA's MAUDE database by manufacturer as of September 10, 2015.

BIA-ALCL: Current Perspective

The highest priority in breast surgery is always the safety and well-being of patients. With recent concerns about BIA-ALCL, it is important to recognize how rare it is. Through 2015, there were 173 confirmed cases of BIA-ALCL.⁵⁶ That same year, 364,000 women underwent breast augmentation and reconstruction with implants. For comparison, here are other incidence rates:

- Risk of breast implant rupture through 10-years is 8.7% (1 in 11.5).²⁵
- Risk of capsular contracture through 10-years is 13.5% (1 in 7.4).²⁵
- Risk of reoperation through 10-years is 31.6% (1 in 3).²⁵
- Average woman's risk of developing breast cancer in her lifetime is 12.5% (1 in 8).⁵⁷
- Risk of developing recurrent breast cancer after mastectomy is 5% to 8% (1 in 12.5-20).⁵⁸
- Risk of death in a car accident in a lifetime is 0.15% (1 in 645).⁵⁹
- Risk of death from complications from a cosmetic procedure is 0.002% (1 in 50,000).⁶⁰
- Risk of developing BIA-ALCL associated with a breast implant is 0.003% (~ 1 in 30,000).⁵⁴
- Risk of developing advanced BIA-ALCL with lymph node metastasis is approximately 0.0004% (~ 1 in 250,000).⁵⁴
- Risk of developing BIA-ALCL and not resolved within 3 years is approximately 0.0002% (~ 1 in 500,000).⁵⁴

A recent article describes the usefulness of micromort, or a person's risk of dying as 1 in a million, when explaining to new patients or those presenting with delayed onset seromas the risk of BIA-ALCL compared to everyday activities.⁶¹ For example, drinking 0.5 L of wine or walking 17 miles increases risk of death by 1 micromort, whereas the risk of death by BIA-ALCL is 0.4 micromorts for a woman having bilateral breast implants.

Table 8. BIA-ALCL Risk Estimates in Australia/New Zealand, Implants per ALCL⁶²

	Biocell	Polyurethane	Siltex
BIA-ALCL risk estimate	1 in 3705	1 in 3894	1 in 60,631

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma.

In Australia and New Zealand, researchers and the Therapeutic Goods Association (TGA) have reported BIA-ALCL rates based on total implant sales and restricted analysis to include patients exposed to a single type of texture only (Table 8).⁶² It is important to note that the TGA data relate to disease incidence only in Australia/New Zealand and may not be applicable to all geographic areas.

Assessing the potential risk, one should review the current count of known cases worldwide. The worldwide occurrence of BIA-ALCL in Silimed (Rio de Janeiro, Brazil) and Sientra textured implants is 1 in 200,000 (Table 9).

Limitations

Various complication rates from each of the three manufacturers were presented in Tables 2, 5, 6, and 7. Comparison of these rates between the manufacturers was limited because each was obtained under different protocols with a mixture of implant types. Regarding this BIA-ALCL review, the general limitation (not unlike most BIA-ALCL accounting endeavors) lies in the reliance on MAUDE and other adverse event reporting systems from outside the United States, both of which contain incomplete, inaccurate, and/or unverified reports. The cases associated with Sientra and Silimed textured devices (reported in this manuscript) were limited to those reported in the MAUDE database, those reported directly to Sientra and those identified via literature searches (similar to the counts for the other manufacturers). Furthermore, BIA-ALCL risk estimates cannot be directly compared across manufacturers, as they are based on known reports in published literature (Tables 8 and 9). As research is ongoing, the authors present the best information available as of the date of this manuscript and will continue to update surgeons as more information becomes available.

CONCLUSION

The evolution of breast implant technology and refinements over time has led to continued improvements in patient outcomes. FDA requirements led to five important 10-year Core studies that have consistently demonstrated

Table 9. Sientra and Silimed Worldwide BIA-ALCL Frequency

	Sientra and Silimed worldwide*
BIA-ALCL risk frequency	1 in 200,000

*Estimate based on review of Silimed's worldwide market share/distribution of textured devices over a 20-year time frame. Sientra and Silimed textured implants are created using an ammonium carbonate volatilization process.

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma.

the long-term safety of silicone gel breast implants. Understandably, the moratorium created a population of surgeons more comfortable with the use of smooth breast implants and a vacuum of experience related to textured devices. The experience of plastic surgeons outside the United States, the availability of shaped implants in the United States, and 10-year core data all provide evidence that textured implants may provide more optimal outcomes in certain types of breast surgeries, both aesthetic and reconstructive. The stability of textured implants in the breast pocket may support better outcomes in patients with chest wall abnormalities, revisional breast cases, poor soft tissue cases including mastopexies, and may reduce risk for capsular contracture in all cases. Texture also provides the pocket control and position stability for shaped implants utilized in appropriate aesthetic or reconstructive cases. Differences in texture between manufacturers are critically important as the performance and associated sequela of each texture are unique. Wrinkling, late seromas, and double capsules have been seen in varying degrees based on texture types. Similarly, it is also true that the very rare incidence of BIA-ALCL correlates with certain texture types. The concern for this rare occurrence has recently overshadowed the ability to have a fair and comprehensive discussion about textured implants.

BIA-ALCL research will continue and current theories and numbers will evolve accordingly. It is clear that we must be good medical practitioners: thoroughly consent patients, uphold surgical best practices, and promote awareness of symptoms and treatment algorithms, as early diagnosis is key to best outcomes.⁵¹ ASAPS, ISAPS, and ASPS recommend educating breast implant patients on the risk of BIA-ALCL and the early detection of symptoms. Surgeons should consider including BIA-ALCL in the list of potential complications on breast implant informed consents.^{55,63} and can include the common presenting symptoms such as delayed seroma, mass, or unexpected changes in breast shape, and to see their physician if these symptoms occur.

It is the authors' hope that we can continue to openly explore all benefits and risks associated with all available devices so that optimal and safe patient outcomes can be achieved.

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

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