Evidence-Based Medicine: Breast Augmentation

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ABMS MOC®

Learning Objectives: After reading this article, the participant should be able to: 1. Understand the key decisions in patient evaluation for cosmetic breast augmentation. 2. Cite key decisions in preoperative planning. 3. Discuss the risks and complications, and key patient education points in breast augmentation.
Summary: Breast augmentation remains one of the most popular procedures in plastic surgery. The integral information necessary for proper patient selection, preoperative assessment, and surgical approaches are discussed. Current data regarding long term safety and complications are presented to guide the plastic surgeon to an evidence-based approach to the patient seeking breast enhancement to obtain optimal results. (*Plast. Reconstr. Surg.* 140: 109e, 2017.)

The popularity and patient satisfaction of breast augmentation has remained high, with nearly 280,000 procedures being performed in 2015.[1,2] The past 4 years have ushered in the U.S. Food and Drug Administration approval of a plethora of new devices, from a new generation of saline implants, to highly cohesive form-stable silicone devices.[3] With these approvals, there are also valuable new data to guide the surgeon in both evaluation and surgical technique. The goal of this article is to summarize the current evidence on breast augmentation. Plastic surgeons should strive to combine this data with their own experience and expertise to achieve the safest and highest quality outcomes.

EVIDENCE ON PREOPERATIVE ASSESSMENT

As discussed in the previous MOC article for this topic, few authors describe an objective system for preoperative assessment and planning in breast augmentation. The articles previously quoted from Tebbetts and Adams[4,5] remain an excellent reference. This includes both the five key decisions and three key measurements in preoperative planning and evaluation.

Additional authors have described personal series and techniques with the introduction of shaped implants onto the U.S. market to delineate the additional planning to be used with these devices.[6–11] Key parameters for preoperative planning include the breast and desired base diameter, breast tissue pinch thickness, nipple-to–inframammary fold distance on stretch, and sternal notch–to-nipple distance. Combining these measurements with the now four available implant parameters diameter, height, projection, and volume allows the surgeon to customize breast augmentation in a way not previously possible.

The use of three-dimensional imaging in both patient consultation and surgical planning has been documented to show a high level of accuracy and patient satisfaction.[12] The use of this and other predictive technologies to simulate the patient's postoperative surgical appearance demonstrate improved patient communication and decreased reoperation for size change.[13,14]

Hidalgo and Spector discuss the importance of evaluating chest wall shape (Figs. 1 and 2) and its effect on implant position and projection. This is especially important when considering current form-stable silicone gel devices. In addition, Hidalgo has also demonstrated the effectiveness of using implants in preoperative sizing, and provides an excellent discussion of their personal approach.[15] Bayram et al.[16] further classify breast, chest wall, and vertebral deformities to improve the preoperative evaluation of difficult cases.

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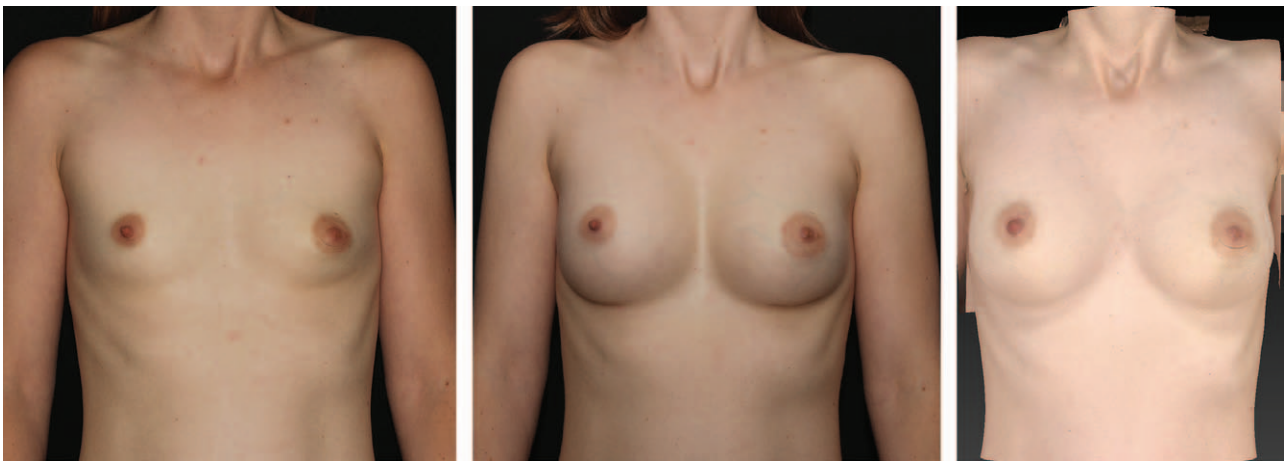


Fig. 1. Patient images demonstrating preoperative, simulated, and actual postoperative results show excellent predictive capability.

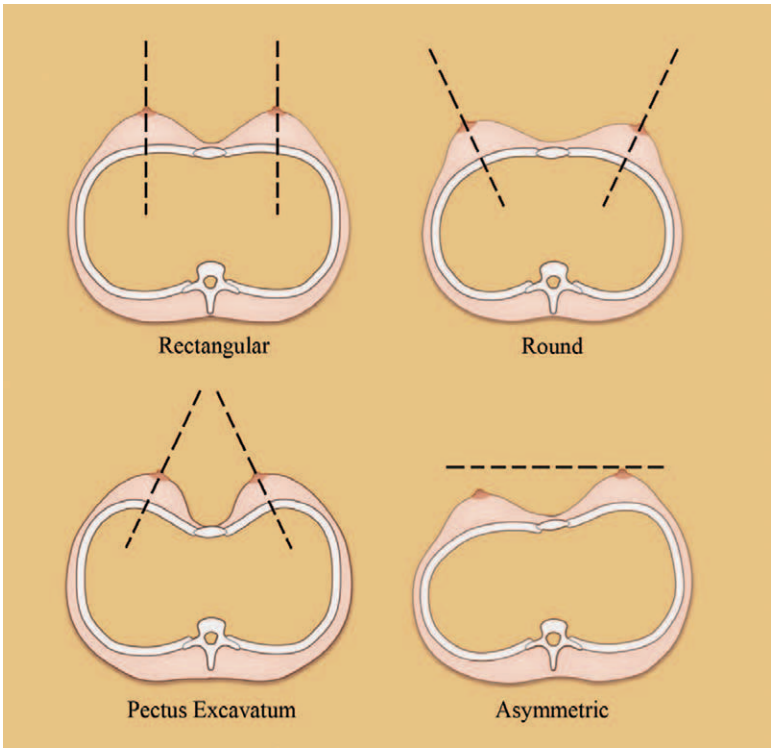
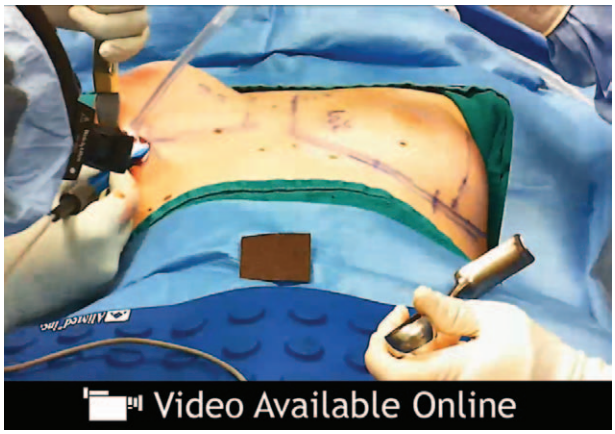


Fig. 2. Chest wall shape can affect the axes of the breasts and their relative projection. (Reprinted with permission from Hidalgo DA, Spector JA. Breast augmentation. *Plast Reconstr Surg*. 2014:133:567e–583e.)

The author's personal technique[7] is to combine the use of three-dimensional imaging data with a commercially available volumetric sizing system to select the patient's best implant. This combination allows the patient to "choose" her desired volume, and then uses the measurements acquired to assess realistic implant parameters. Combining this information with tissue-based planning allows the surgeon to educate, plan, and execute each patient's procedure. (**See Video, Supplemental Digital Content 1**, which displays key technical considerations in breast augmentation. This video is available in the "Related Videos" section of the full-text article on PRSJournal.com or at ***http://links.lww.com/PRS/C207***.)

Patients are first evaluated with the surgeon's three-dimensional imaging system of choice (Fig. 3). The patient uses the volumetric sizing system to "try on" her desired breast size (Fig. 4). In the author's clinical experience, this system has produced a more consistently reproducible result



Video. Supplemental Digital Content 1, which displays key technical considerations in breast augmentation, is available in the "Related Videos" section of the full-text article on PRS-Journal.com or at ***http://links.lww.com/PRS/C207***.

than using implants themselves in a bra. Next, the patient's desired volume and tissue-based measurements are used to select the appropriate implant. Three-dimensional imaging can be used to simulate this result to enhance patient discussion. A key point is that imaging software is designed to create an attractive outcome. Patients should select their size based on sizers and surgeon judgment, not on three-dimensional imaging—it is only confirmatory. Finally, it is the author's preference to allow the patient to share two desired breast photographs. Not as a promised result, but to ensure their selected size corresponds to their expectations. This can be a surprisingly helpful exercise. Readers are encouraged to review the full article for further details.

EVIDENCE ON SURGICAL APPROACH

Incision Location

The benefits and individual surgeon preferences between inframammary, periareolar, and transaxillary incisions have been well documented[9,17] (Table 1).

Previous articles have supported a benefit of the inframammary incision in the reduction of capsular contracture.[18,19] Data from recent publications have continued to support the use of the inframammary approach as statically significant in the prevention of capsular contracture[20,21] (Table 2).

Pocket Location

The benefits of pocket location choices are well established. As originally described by Tebbetts,[22] the use of dual-plane implant placement allows redistribution of the breast tissue overlying the submuscular implant. This is accomplished through the use of the appropriate dual-plane level, with the objective of maintaining maximal muscle coverage while allowing optimal lower pole expansion. To use this technique, the surgeon should dissect a standard submuscular pocket protecting the medial pectoral muscle attachments. Then, the surgeon can selectively release the pectoral muscle fibers in the lower pole of the breast. Calobrace et al.[23] discuss the key features of this technique with an excellent video example of the technique here (Fig. 5).

Recent data support the notion that submuscular position decreases the incidence of capsular contracture.[8,21,24–26] Large prospective studies from all three major U.S. breast implant manufacturers show clear differences between smooth implants placed

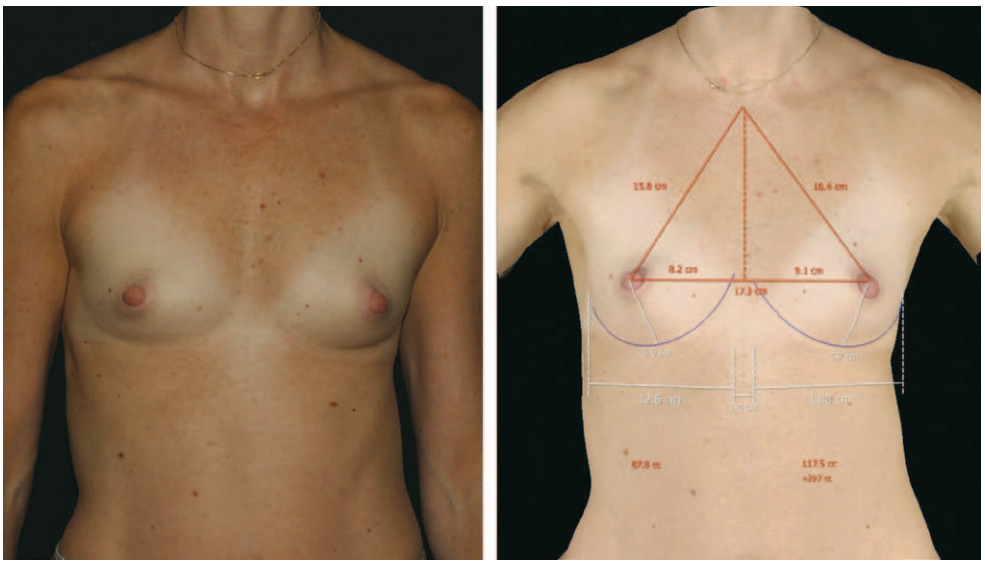


Fig. 3. Preoperative analysis is performed with both clinical measurements and the three-dimensional imaging system.

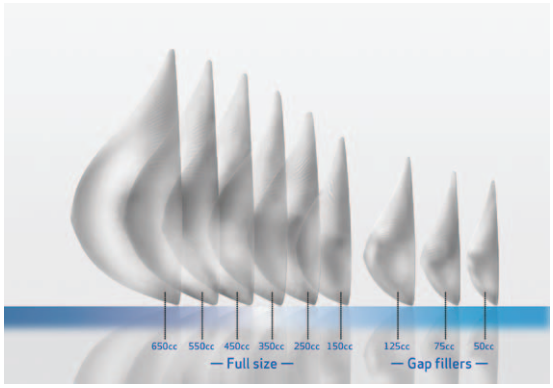


Fig. 4. This commercially available sizing system is the author's preference for patient size selection. Patients use these sizers with a tight-fitting bra to simulate swimsuit or workout appearance; a tight white t-shirt, which appears larger; and a tight black t-shirt, which is slimming.

in the submuscular plane versus subglandular. Two of three studies show a decrease in these locations for textured devices as well. The risks and benefits of each of these options must be considered in patient consultation.

IMPLANT SELECTION

Shaped versus Round Implants

There remains a great deal of controversy as to the indications and benefits for various implant shapes. Although there is no reproducible evidence for the superiority of shaped (nonround) breast implants,[27] there are clearly indications and surgeon preferences that claim benefit. Specific indications for anatomically shaped devices include limited soft-tissue coverage, desire for a full but natural result, breast and chest wall asymmetry, constricted breast type, and short nipple-to–inframammary fold distance.[7,28] The unique shape and gel cohesivity of anatomical devices provide significant benefits to patients in these categories.

Caplin[29] provides an excellent review comparing the indications and outcomes for the use of Mentor MemoryShape breast implants. Of note is the decreased rate of capsular contracture in both augmentation and revision augmentation patients with shaped implants. A statistically significant decrease in implant rupture at 8 years was noted with shaped devices. Patient satisfaction, however, was high with both round and shaped devices.

Textured versus Smooth Implants

The use of textured surface breast implants, both round and anatomically shaped, has increased with the U.S. Food and Drug Administration approval of fifth-generation cohesive gel devices. Surface texturing has been shown as noted above to reduce capsular contracture. In addition, the use of texturing has been advocated to decrease implant malposition and rotation in anatomically shaped devices.[8,20,24,30] Key considerations in the use of texturing include

Table 1. Advantages and Disadvantages of Incisions

Incision	Advantages	Disadvantages
Inframammary	Most control; ability to manipulate/set IMF; least implant effects (trauma and contamination)	Scar not ideal unless planned properly
Periareolar	Good access to breast; scar can be very well disguised usually	Can result in poor scarring; higher capsular contracture rates; contamination in theory; NAC sensitivity more affected
Transaxillary	No scar on breast	Remote from pocket; tends to promote blunt dissection; less controlled pectoralis major release unless endoscopically assisted; dual-plane dissection not possible

IMF, inframammary fold; NAC, nipple-areola complex.

Table 2. Pocket Location Comparison

Plane	Advantages	Disadvantages
Subglandular[31]	Ease of dissection Decreased pain No animation deformity Pendulous breast or mild ptosis	Increased capsular contracture Visibility/palpability Rippling
Subfascial[32]	? Capsule protection = submuscular ? Smoother upper pole shape Avoid animation deformity	Difficult dissection Thin layer inferiorly Unclear data to support
Submuscular	Decreased capsular contracture Improved upper pole aesthetics Better mammography	Animation deformity Prolonged recovery Increased seroma/rotation with texturing
Dual plane	Correction of ptosis Correction of lower pole constriction Correction of mild nipple asymmetry	Increased dissection Exposure of implant to gland

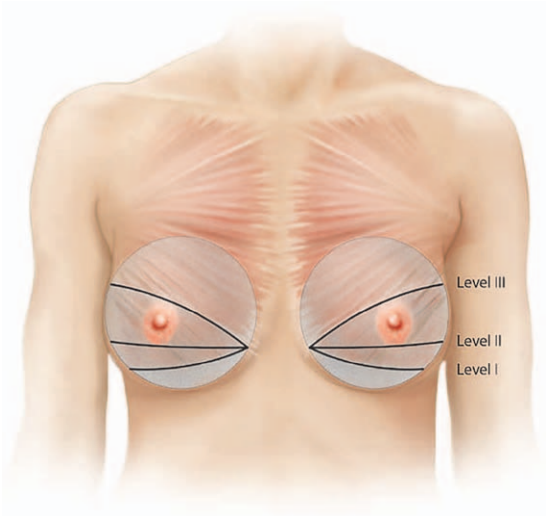


Fig. 5. Levels of dual-plane dissection. Dual-plane level I is used for most augmentations and includes division of the pectoral muscle along the full length of the inframammary fold. Dual-plane level II is used for breasts with a mobile parenchymal/muscle interface with separation of the parenchyma and muscle to the level of the nipple. Dual-plane level III is used for glandular ptotic and constricted lower pole breasts with separation of the parenchyma muscle interface to above the level of the nipple. [Reprinted with permission from Calobrace MB, Kaufman DL, Gordon AE, Reid DL. Evolving practices in augmentation operative technique with Sientra HSC round implants. *Plast Reconstr Surg*. 2014;134(Suppl):57S–67S.]

individual patient characteristics and desires, including soft-tissue coverage (pinch thickness), body shape/type, implant size, and requirement for an anatomically shaped device (Figs. 6 and 7).

PROCEDURE CONSIDERATIONS

Pocket Dissection

The evidence for the benefits of atraumatic dissection of the breast implant pocket are clear regardless of pocket or implant selection. Data have clearly shown that blood within the implant pocket is a source of both inflammation and nutrition for bacterial contamination. In addition, blunt dissection can lead to more painful and prolonged postoperative recovery[10] (Fig. 8).

Pocket Irrigation

Adams et al. have clearly defined the role of antibiotic irrigation of the implant pocket as a primary modality to improve outcomes in breast augmentation.[33] Other authors have demonstrated this using povidone-iodine irrigation as well[34] despite U.S. Food and Drug Administration labeling restrictions.

Oral Antibiotics

There remains no documented evidence that postoperative oral antibiotic use can reduce postoperative complications. Review data have shown no decrease in infection, capsular contracture, or local complications with the use of postoperative antibiotics. This includes both primary and revision augmentation.[35] Recent evidence on biofilm formation may define a clearer role for antibiotics in the prevention of both capsular contracture and breast implant–associated ALCL.[36]

Incision Length

The use of silicone, textured, and now highly cohesive silicone gel implants has led to a requirement for longer incision lengths to allow safe insertion of the devices. A migration toward the inframammary incision has been noted for this reason as well. Incision length in the inframammary incision varies from 4 to 6 cm. It is important to note that a shorter incision carries the risk of both trauma to the skin edge during retraction and dissection,

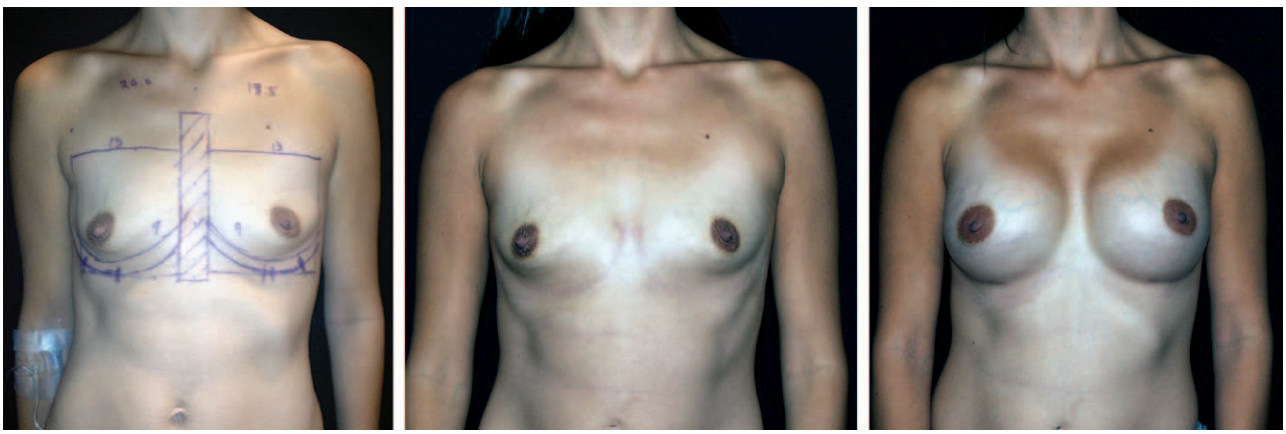


Fig. 6. Short nipple-to–inframammary fold distance with shaped implants. (*Left*) Preoperative markings for augmentation. (*Center*) Preoperative anteroposterior view. (*Right*) Anteroposterior view obtained 6 months after augmentation.

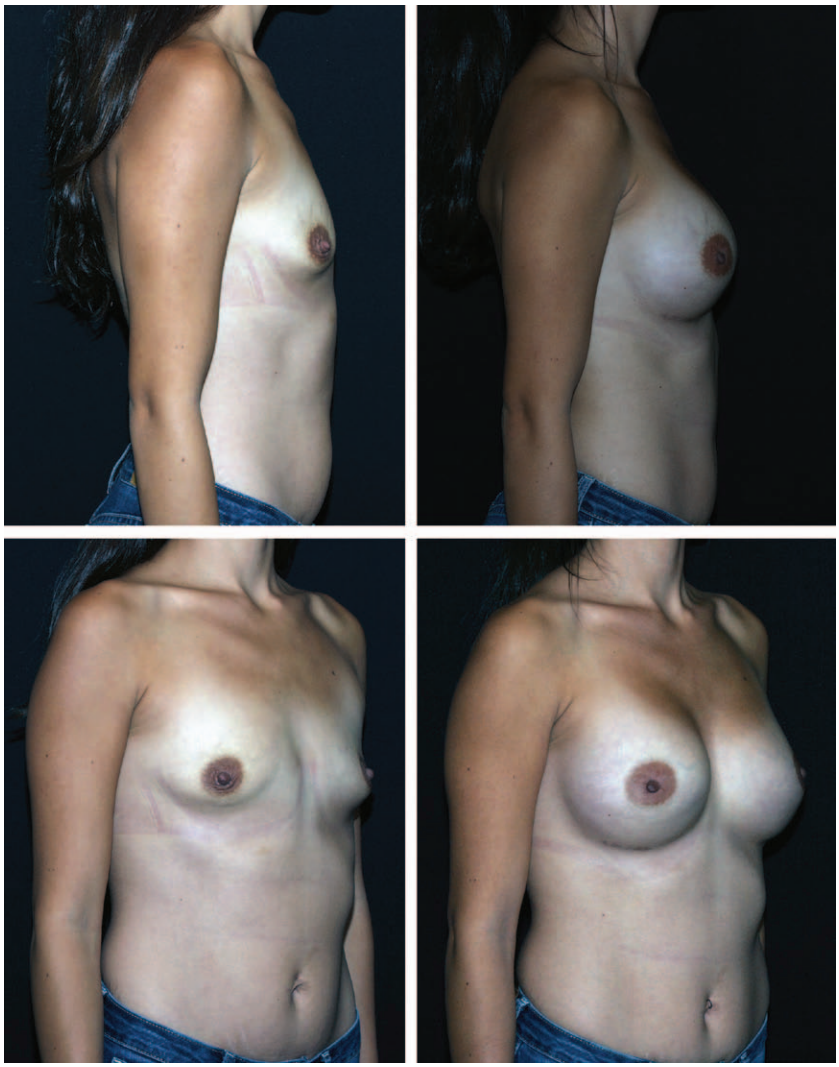


Fig. 7. Images obtained before (*left*) and 6 months after augmentation (*right*).

Fig. 8. Monopolar dissection forceps can be used to sweep or pinch, increasing surgical efficiency. Both hand- and foot-switched models are available.

and damage to the implant during insertion. The use of insertion devices, although helpful, has not been shown to allow decreasing the incision length.

Nipple Shields

The use of protective nipple shields has become a common strategy for preventing bacterial contamination during implant insertion. Wixtrom et al. demonstrated that the nipple ducts present a potential source of contamination during breast surgery.[37] They concluded that meticulous hemostasis, use of nipple shields, and submuscular device placement may contribute to a lower incidence of capsular contracture (Fig. 9).

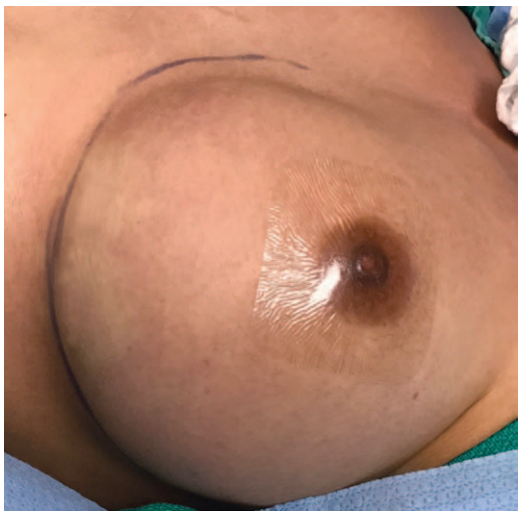


Fig. 9. Nipple shield in place to minimize pocket contamination during dissection and implant insertion.

Insertion Funnel

The "no-touch" technique, glove change, and insertion funnels have all been advocated as means of decreasing the contamination associated with implant insertion. Recent data support the use of the insertion funnel with a decrease in reoperations because of capsular contracture within the first 12 months of primary breast augmentation[38] (Fig. 10).

Capsular Contracture

Although complication rates from breast augmentation have been documented to have decreased,[8,20,24,25] capsular contracture remains one of the most common reasons for reoperation in elective breast implant surgery. The use of a leukotriene antagonist has been purported to decrease the incidence and severity of capsular contractures.[39,40] In a prospective study, Graf et al.[41] showed that the use of montelukast decreased the incidence and severity of capsular contracture.

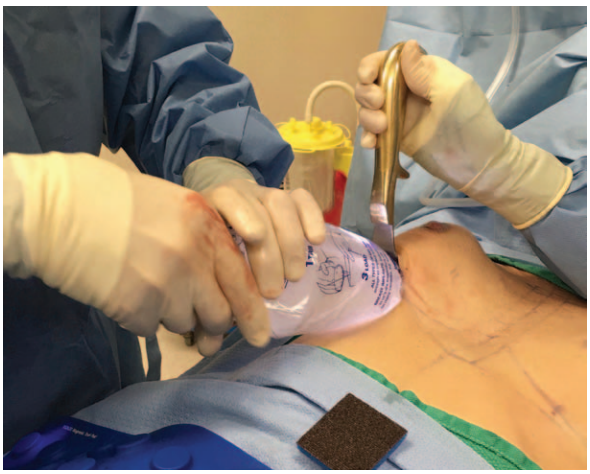


Fig. 10. Insertion funnel.

A recent review of the management of capsular contracture[42] defined how little clinical evidence exists regarding the current treatment gold standard: capsulectomy, site change, and implant exchange. Importantly, there were no controlled trials that met inclusion criteria; however, several key points were noted (Table 4). In addition, the authors caution that assumptions commonly held regarding capsular contracture are often derived from primary augmentation data, and may not apply to revision operations. Finally, the authors present an algorithm for the management of contracture based on these findings.

Use of Acellular Dermal Matrix for Secondary Breast Surgery

In 2012, Spear et al.[43] presented a series of 75 patients using acellular dermal matrix for aesthetic breast implant patients. The majority were revisions for capsular contracture, malposition, rippling, and palpability, with high success and patient satisfaction and low complication rates. Maxwell and Gabriel[44,45] have described their significant series of difficult revision patients using acellular dermal matrix and the neopectoral pocket. In this series, there is also significant success in treating similar indications. Although this treatment regimen is encouraging, the material cost has limited its acceptance in the cosmetic patient.

Double Capsule and Late Seroma

Multiple authors have described the incidence of double capsule and late seroma in the use of textured implants.[46,47] Late seroma is arbitrarily defined as occurring greater than 1 year after implantation. Clinical implications of this phenomenon include breast swelling, infection, implant malposition and rotation, and subsequent need for reoperation.[48] These reviews suggest the potential effect of aggressive texturing as a primary culprit in this phenomenon. Hall-Findlay[49] suggests that a process of friction between the aggressively textured implant and the surrounding tissue may result in the chronic production of fluid; thus, the rates of seroma may be lower in less aggressively textured devices. The 10-year data from the Allergan 410 Study shows a 1.6 percent rate of seroma formation.[25] The 6-year data from the Mentor CPG Study shows a seroma rate less than 1 percent.[50] Seroma formation in the Sientra 9-year data for

Table 3. The Six Misconceptions among Physicians and Patients Regarding Anatomical Implants*

Misconception	Reality
There is little difference in aesthetic outcomes between anatomical and round implants.	This is true in certain cases but certainly false in others. It depends on implant projection and tissue cover.
Anatomical devices create an empty appearing upper pole and/or hanging breasts.	These devices typically create a linear or slightly concave upper pole that aligns with aesthetic ideals. They can also give fullness and indirect lifting through elevation of the NAC and soft tissue.
There is a high risk for rotation with anatomical devices.	The risk of rotation requiring reoperation is low and can be reduced through appropriate surgical technique.
The use of anatomical implants requires an overly complex process for the surgeon (preoperatively, perioperatively, and postoperatively).	Optimal planning and technical principles should be applied with both round and anatomical devices.
Anatomical implants are too firm compared with round devices.	Anatomical implants are relatively firmer than round devices, but (within the breast) the feel is not unnatural and many patients prefer it.
Round implants are always a suitable alternative for anatomical implants.	This is not always the case; for example, in patients with a well-defined IMF and short lower pole.

IMF, inframammary fold; NAC, nipple-areola complex.
*Data from Hedén P, Montemurro P, Adams WP Jr, Germann G, Scheflan M, Maxwell GP. Anatomical and round breast implants: How to select and indications for use. *Plast Reconstr Surg.* 2015;136:263–272.

Table 4. Evidence in Treatment of Capsular Contracture

	Evidence	Discussion
Total vs. partial capsulectomy	Weak	Extent of capsulectomy is poorly reported; recommend only removing parts of capsule that are safe (i.e., not posterior wall in SM plane).
Site change	Good	CC is lower in studies with site change including neopocket.
Implant exchange	Good	CC lower, especially in same plane.
Implant type	Insufficient evidence	No obvious trends between textured, saline, or silicone devices.
Use of ADM	Possible	Studies show a lower recurrence rate, but long-term follow-up data are still needed.

CC, capsular contracture; SM, submuscular; ADM, acellular dermal matrix.

true textured devices was 1.2 percent in all primary augmentation devices. Approximately half of these implants were "true textured" devices; the rest were smooth. Derby and Codner's[30] review of textured implant core data attempted to show differences between manufacturers but study design "limited the extent of seroma results reported." Seroma rates in this study for shaped implants only was 0.2 percent (Fig. 11).

Late Seroma and Anaplastic Large-Cell Lymphoma

Most concerning in the past two decades is the incidence of breast implant–associated anaplastic large-cell lymphoma (ALCL).[51] This entity was first diagnosed and associated with breast implants in 1997, and is almost only associated with a history of textured implants and/or tissue expanders. The most common presentation of these patients is late seroma, with some patients presenting with mass, tumor erosion, or lymph node metastasis. A recent review by Brody[52] reviewed the world literature on this entity. Key points include the following: (1) 173 cases were documented, (2) no cases were found in patients with documented smooth devices only (although this remains controversial, as the data in many cases are incomplete), (3) there may be an associated genetic predisposition as suggested for cutaneous T-cell lymphoma, and (4) the cause is likely multifactorial.

Recent research by Deva et al. showed bacterial biofilm and contamination in breast implant–associated ALCL and nontumor (contracture) implant capsules. The capsules from patients with tumor had significant presence of Gram-negative bacteria (*Ralstonia* species) compared to nontumor capsules (*Staphylococcus* species). In his discussion, Adams[53] explains that these data may support the bacterial induction model, as there are also other types of implant-associated lymphomas. In addition, there is also "a precedent for bacteria-induced lymphoma—specifically a gastric lymphoma associated with Helicobacter pylori (a Gram Negative bacterium similar to Ralstonia and Pseudomonas)." Growing evidence is beginning to support a multifactorial cause, including the factors indicated above: bacterial component, genetic predisposition,[54] and the suggestion that implants with a macro texture surface may more readily trigger this rare disease. As the bacterial component is better understood and characterized, there may be a potential preventative role for certain antibiotics. Because of this potential inflammatory pathway, and prevention of capsular contracture in general, Adams[55] recommends a 14-step plan to minimize pocket contamination.

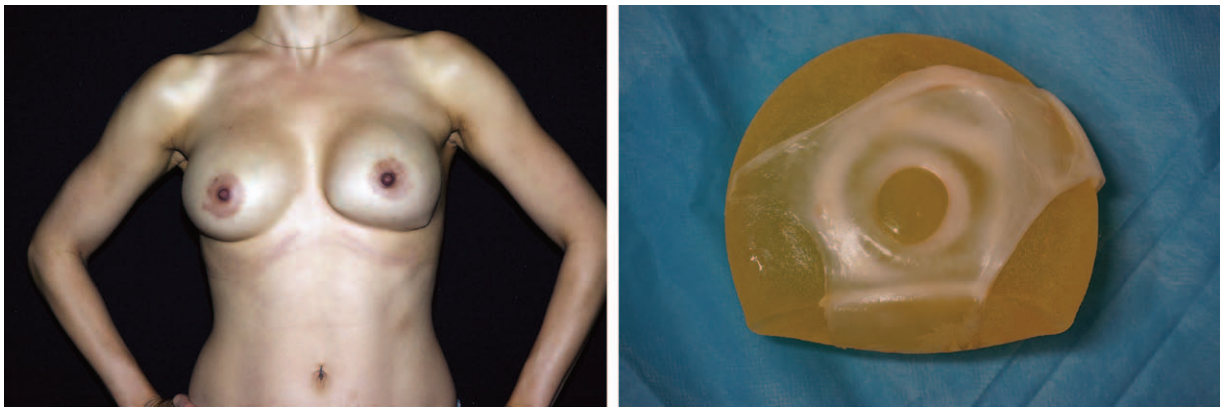


Fig. 11. Late seroma and capsular contracture. (*Left*) This patient had a tight pocket with palpable and visible knuckling. (*Right*) The matching fold in the implant after removal is easily seen along with this partial double capsule.

Although this entity is rare, the burden of proof and treatment remains with the surgeon for early recognition and proper diagnosis, along with appropriate patient education. Most patients present with an enlarged breast and delayed seroma. The key diagnostic maneuver to rule out ALCL in the late seroma is aspiration of the fluid and examination for the presence or absence of the CD30 marker. The American Society of Plastic Surgeons has created a position statement on the appropriate implant specimen and pathology procedures.[56] In addition to U.S. Food and Drug Administration manufacturer-mandated labeling, the American Society of Plastic Surgeons has also added example breast implant–associated ALCL language to downloadable informed consent documents. There has been a significant discussion regarding the inclusion of breast implant–associated ALCL in the standard informed consent process. Clemons et al.[57] recently discussed the merits of this.

Recently, Clemons et al.[58] reviewed 87 cases if breast implant–associated ALCL to determine the optimal treatment regimen. They concluded that "surgical management with complete surgical excision is essential to achieve optimal event-free survival in patients with BI-ALCL." Laurent and colleagues[59] discuss the significant difference between the in situ and invasive presentation of breast implant–associated ALCL in terms of treatment and survival. These data reinforce the need for both close patient follow-up and intervention.

Finally, the American Society of Plastic Surgeons in collaboration with the U.S. Food and Drug Administration has created the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology Registry. The combination of adequate informed consent, appropriate patient education, proper diagnosis and treatment guidelines, and a prospective registry to guide plastic surgeons' future decisions should allow a more accurate understanding of this disease entity.

CONCLUSIONS

The science of breast augmentation has changed dramatically over the past 5 years. Lista and Ahmad[60] noted the lack of systematic processes regarding manufacturer and device data, technique, and decision-making. The introduction of a new generation of textured, shaped, and more cohesive silicone gel implants to the U.S. market has brought not only new devices, but long-term safety data, and more detailed technique approaches to augmentation mammaplasty. In addition, the more accurate awareness of complication rates, breast implant–associated ALCL incidence, and technique options demand a more thorough approach to patient education, surgical planning, and informed consent. Although in its pilot stage, the National Breast Implant Registry should provide additional resources for surgeons to glean best practices and large-scale patient outcome data.

Plastic surgeons should take the opportunity to review these approaches from multiple different authors, and formulate an individual evidence-based approach to breast augmentation. Each surgeon will need to evaluate their own clinical experience and approach to best use these new devices and techniques. Proper awareness and use of the data presented should possibly translate into both improved outcomes and better patient safety and satisfaction.

This article has given the reader an opportunity to review current key components of breast augmentation with implants. Surgeons should

carefully review the references in both the article and the CME questions to further refine their knowledge and skill. As in all aspects of our specialty, the blending of art and science serves to advance the delivery of the best results possible to our patients.

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