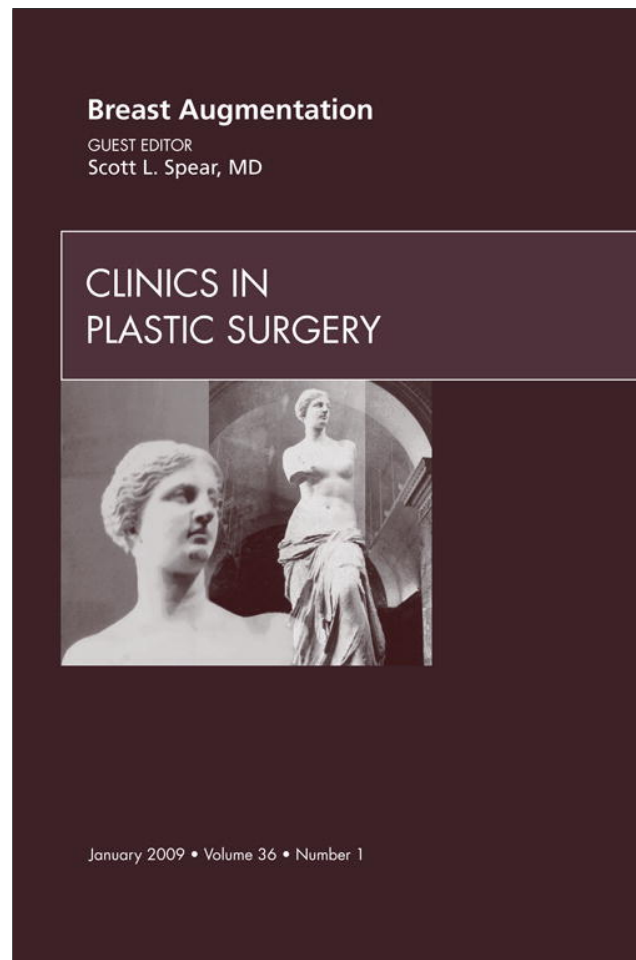


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Complications, Reoperations, and Revisions in Breast Augmentation

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KEYWORDS

- Defining complications
- Most common complications in breast augmentation
- Reoperations and revisions
- Classification systems
- Outcomes and evidence based data in augmentation
- Track and document patient data
- Process of breast augmentation
- Capsular contracture, malposition, recurrent ptosis, and coverage problems
- Current literature and solutions

What is your personal complication rate in breast augmentation surgery? How many of your patient complications undergo surgical revisions and over what time period?

Quite frankly, I believe as plastic surgeons, we do not specifically follow or track our own patients closely enough to know these answers. We should each know where we have been to know where we are heading, and know where we are to know where we are going. Complications and their tracking are very dynamic events. Our postoperative patient's breasts are always changing. However we should each have an idea, for a snapshot in time, an average 3- to 5-year follow-up, what our overall complication rate and surgical revision rates are, and etiology of the revision if known. Anecdotal medicine, at least in the United States, ended during the American Civil War, or the War of Northern Aggression if you grew up below the Mason-Dixon Line.^{1,2} The statement that war changes and advances medicine, particular the field of surgery, has to be one of the greatest understatements of all time. At least in the United States, it was during these dramatic

times of war that true outcomes-based and evidence-based medicine was born. Every interaction between a surgeon and a sick or injured soldier was meticulously documented and recorded, and the foundation for outcomes-based medicine was born.³ Somewhere between 1861 and now, particularly in the field of plastic surgery, some of our critical appraisal of science and data, its application to how we practice plastic surgery—the procedures we perform and devices we use, has been partially lost.

This moment of enlightenment came for me when I enrolled in the McGhan Style 410 Form Stable Cohesive Gel Silicone implant study. This was my first experience with an FDA-based, premarket approval protocol where multiple reviewers and organizations were tracking my patients and data. It forced me to look more critically at my own patient outcomes and complications. The results surprised me! I believe most surgeons will tend to overestimate the number of procedures we perform, and underestimate our complications unless we specifically track and record them. Hopefully, this article will encourage you to begin

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an increased introspective interest and sensitivity to begin this process on your own. If so, then it will have accomplished the most important take-home point. Data collection options include tracking patients with your own individual database, enrolling in one of the patient follow-up studies supported by the breast implant manufacturers (but since not every patient will enroll, additional mechanisms and tracking may be required for complete accuracy), use an implant inventory and tracking software modified for tracking patient complications and revisions, and/or finally, there is an early initiative to reduce complications in breast augmentation by one of the implant companies that may provide a Web- or inventory-based structure to assist with patient data tracking.

The first step is to personally commit to look critically at our own results and begin to follow our patients long term with a method of follow-up that we can integrate into our practices. Then take the next step: for the benefit of all of our patients and colleagues, openly, honestly, and transparently report and present our individual data. Subsequently, to be open to look at other surgeons' methods and data, other ways to do things, and then if they show fewer complications or benefits with acceptable trade-offs, be bold enough to modify or change the way we practice. Because plastic surgery is so dynamic, we should each continue to reevaluate where we are over time. Change is hard and there are many potential obstacles, but even if one of our own patients has an improved outcome or is saved a complication or surgical revision, wouldn't it be worth it? Finally, I believe this is not about globally trying to standardize how things are done or even about establishing "Best Practice" guidelines. It is about looking individually to ourselves and our own practices and to committing to do better. There is a reason why in karate there are no 10th-degree black belts, only 9th. No one can ever be perfect, we can only strive for it. Plastic surgery is no different.

"I am careful not to confuse excellence with perfection. Excellence, I can reach for; perfection is God's business."

—Michael J. Fox

Plastic surgery of the breast is unique in that we are not just looking at patency rates following an anastomosis or patient survival rates with one chemotherapy regime over another. It was interesting that in last month's *Clinics in Plastic Surgery*, Sheila Sprague and Paula McKay defined outcome- and evidence-based plastic surgery as, "...the integration of the best research evidence with

clinical expertise and patient values into clinical decision making. It can be defined as the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients." And they go on to state, "...emphasizing the need to properly evaluate the efficacy of plastic surgical interventions before accepting them as standard surgical practice. It involves the process of systematically finding, appraising, and using research findings as the basis for clinical decisions."⁴ Accordingly, there are very few things in medicine and plastic surgery that are "Absolutes," and there remains a great deal of room for individual approaches.⁵ Plus we are not giving away our artistry. Plastic surgery is *both* an art *and* a science, not *either/or*. DaVinci was an incredible artist but used scientific and data-driven mathematical "Divine Principles" to analyze, paint, and sculpt the human body, right?

In reviewing these next few pages, my hope is that you will not disconnect the outcomes from the patients, or think, "Oh great, another classification system." No method of documenting or reporting is perfect. Presented will be both tabular and algorithmic methods. However, the main goal is for you to take an individual challenge. Not take the complication personally, but to personalize the process, and if you have not already done so, begin to accurately document and record your patient breast augmentation experiences. Not one method will work for each surgeon or practice, but the first step is to truly make the commitment and begin to look individually at our own results. If you are completely honest and transparent, the results may also surprise you.

COMPLICATIONS, REOPERATIONS AND REVISIONS

com·pli·ca·tion (kŏm plĭ-kā'shən) when pertaining to medicine is defined by the online Free Dictionary as:

"A secondary disease, an accident, or a negative reaction occurring during the course of an illness and usually aggravating the illness."

Or, a complication may be a problem that arises following a procedure, treatment, or illness. Complications are more of a global, all-encompassing term and they may range in severity from minor to severe, and may or may not result in additional surgery. Why complications are so difficult to categorize is that they include many factors that are preventable and some that are not. They include factors with known causes and many with unknown or just suspected causality. To further "complicate" things, in plastic surgery, there is an elective component to what we do and certain

subjectiveness. For instance, what one surgeon may deem a significant capsular contracture, another surgeon may not. Also, most of the procedures we perform including breast augmentation, are elective to begin with. No description or evaluation method is perfect, but regardless of the “grey zones,” many complications are definable and many require a medical or surgical intervention. These are the most important, because they are the ones we can potentially impact and change, and they will be the focus of this article. In the past, I have defined “major” complications as those that require a surgical intervention to enhance or correct, and “minor” as one that resolves on its own or without surgical intervention.⁶ This also is not perfect, a pulmonary embolus is obviously a major complication in severity, but may not be operable. However, concerning complications we can potentially prevent or treat, this is a helpful classification.

Next, the term “reoperation” has been thrust upon us and is a commonly used term. It has been described in detail,⁷ but understanding some basics are important. The Food and Drug Administration (FDA), in order to capture as many complications as possible, includes “reoperations” as any additional surgery a patient may have during her involvement in a study. For instance, a scheduled second-stage reconstruction and expander/implant exchange or a nipple reconstruction is considered a *reoperation*. We are all well aware of how we alter our vocabulary to accommodate an insurance, legal, or governmental organization. We do it every day when we do our CPT coding, but we should understand the distinction in the terminology. The term, “revision,” is a more accurate and better term to describe a major complication, or a patient who we are reoperating on who has had the exact or similar prior procedure and had a complication or adverse event that we are enhancing or correcting. A breast augmentation revision patient assumes that she has had a prior breast augmentation. A mastopexy should not be considered a *reoperation* or *revision* unless the patient has had a prior mastopexy, however the FDA and some others would define this as a *reoperation*. It will take some time to work through these semantics, but these terms are important when we discuss or report complications, and I believe “surgical revision” is a more accurate term.

THE PROCESS OF BREAST AUGMENTATION

There are two, and probably more, ways to generally evaluate complications. The most common is to evaluate each complication specifically and

work backward to try to determine if anything could have been done differently to have prevented the problem. Another way is to be more proactive and try to determine if there was a breach in the process of breast augmentation that caused the complication, and then to address or change the *Process* to prevent the problem from occurring in the future. In the past I viewed breast augmentation as an event in time, a surgical procedure. I now look at it as a “process.” This *process* has been defined and may be separated into four segments: (1) patient education and informed consent, (2) tissue-based operative planning, (3) precise surgical technique, and (4) defined post-operative care (**Fig. 1**).⁸

Many postoperative complications may be traced back to a breach in one or more of these specific *process* areas. For instance, a high implant exchange rate for size may be a failure of adequate informed consent and patient education. A high revision rate for malposition of the inframammary fold may be a technical error or too large of an implant base width, and so forth. When going through these complications and your personal complications, it may be very helpful to try to determine if there was a violation in one or more areas of the breast augmentation *process*.

Fig. 2 depicts the most common postoperative complications following breast augmentation in algorithmic format. It has been modified and expanded since its original publication.⁹ In the pre-market approval (PMA) studies and recent studies released by the implant manufactures and further studies reported for saline, silicone gel-filled, and silicone-form stable devices list the most common complications and reasons for revision as capsular contracture, implant malposition, ptosis or sagging of the breast, hematoma, and size change request.

The Process of Breast Augmentation

4 Key Steps to Success in Breast Augmentation

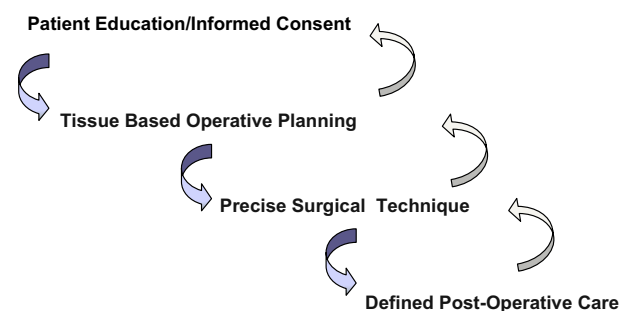


Fig. 1. Breast augmentation is best defined as a series of four main parts or subprocesses versus a specific event or operative procedure. (From Adams W, S8 Course ASAPS, 2005, with permission.)

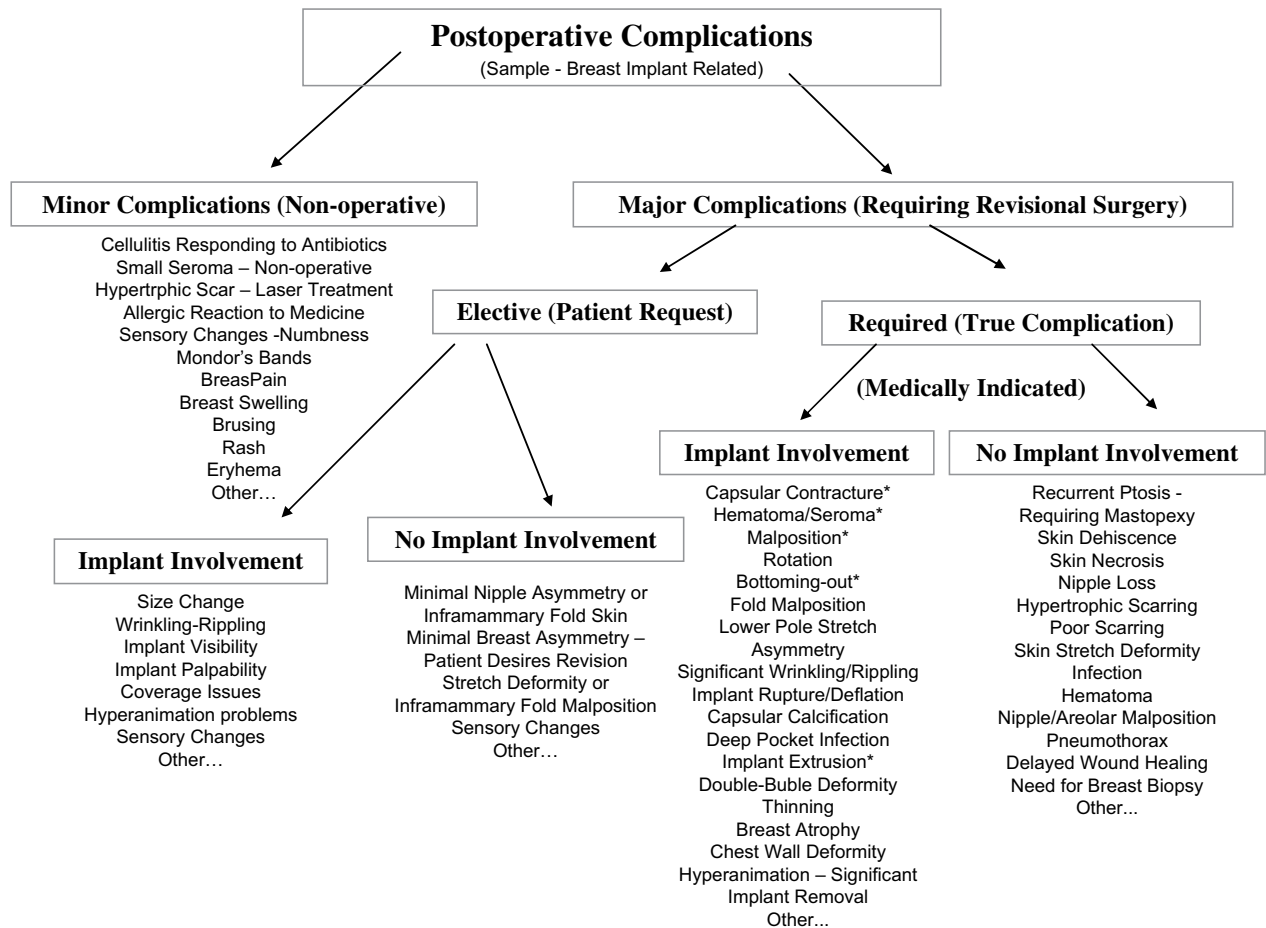


Fig. 2. Algorithmic method of listing breast augmentation complications. The complications are separated into “major” complications that require an operative revision and minor, those that do not. They are further broken down into who is driving the revision, the patient for more of a minimal deformity or the surgeon for a medically indicated problem, and finally whether the complication is implant related or not. (Modified and expanded from Bengtson B. Standardizing revision and reoperation reporting. *Plast Reconstr Surg* 2008;121:1871–2; with permission)

Table 1 shows complications data from the In-amed core data for both augmentation, revision and reconstruction patients.¹⁰ **Tables 2** and **3** show the most common reasons for revisions from the Mentor core data for augmentation and reconstruction cohorts respectively.¹¹

In the Allergan Silicone Primary Augmentation PMA study, capsular contracture rates were 13.2%, and 17.0% in the Revision cohort at 4 years. The Saline PMA data for Allergan showed a 9% capsular contracture rates for primary augmentation and 25% for breast reconstruction at 3 years.¹⁰ Three-year data for Mentor PMA study groups revealed an 8.0% capsular contracture rate in the primary augmentation group and 18.9% in the revision augmentation group at 3 years.¹¹ It is important to note these studies are not side by side comparison of implants and have different designs and follow-up time. In both manufacturers’ data, capsular contracture was the number one complication following breast augmentation and the most common reason for surgical revision.

We will review these common complications following breast augmentation and subsequent need for revision. We will also focus on some techniques, methods, or procedures that may be performed to minimize, reduce, or eliminate these complications, or to change our current process of breast augmentation to maximally impact these complications. **Table 4** lists complications following breast augmentation in tabular format beginning with common patient complaints, symptoms, or clinical descriptions and some current methods for treatment.

SPECIFIC COMPLICATIONS FOLLOWING BREAST AUGMENTATION

Capsular Contracture

Capsular contracture (**Fig. 3**) remains the number one complication and primary reason for revision in breast implant studies ranging from 15% to 30% with up to 50,000 patients treated yearly.^{10–16} The etiology remains somewhat of a mystery but the main implicated factors range from silicone

Table 1
Most common reasons for revisions

Primary Reason	Primary Augmentation (%)	Revision Augmentation (%)	Primary Reconstruction (%)
For reoperation occurring in >8% of reoperations			
Capsular contracture	27.5	18.1	14.5
Implant malposition	14.4	11.7	20.3
Ptosis	12.0	9.6	4.3
Need for biopsy	10.2	8.5	10.1
Hematoma/seroma	6.6	13.8	8.7
Asymmetry	4.2	3.2	17.4
For implant removal (with or without replacement) occurring in >8% of explanations			
Capsular contracture	33.0	22.6	21.2
Patient request for style/size change	20.6	18.9	12.1
Implant malposition	10.3	18.9	27.3
Asymmetry	9.3	1.9	21.2
Suspected rupture	9.3	9.4	6.1

From Spear S, Murphy D, Slicton A. Inamed silicone breast implant core study results at 6 years. *Plast Reconstr Surg* 2007;120:85–165.

Table 2
Most common reasons for revision for the augmentation cohort

Reasons for Reoperation	Primary (%)	Revision (%)
Capsular contracture Baker grade II/III/IV	36.7	39.7
Patient request for style/size change	14.7	12.1
Hematoma/seroma	11.0	8.6
Scarring/hypertrophic scarring	11.0	5.2
Biopsy	5.5	10.3
Asymmetry	4.6	1.7
Ptosis	3.7	1.7
Infection	2.8	1.7
Delayed wound healing	1.8	8.6
Implant malposition	1.8	3.4
Wrinkling	1.8	1.7
Breast pain	0.9	1.7
Implant extrusion	0.9	3.4
Necrosis	0.9	
Suspected rupture	0.9 ^a	
Tear in capsule	0.9	
Total	109	105

^a The device was removed and found to be intact.

From Cunningham B. The mentor core study on silicone memorygel breast implants. *Plast Reconstr Surg* 2007;120:195–295.

Table 3
Most common reasons for revisions for the reconstruction cohort

Reasons for Reoperation	Primary (%)	Revision (%)
Asymmetry	20.3	4.2
Biopsy	13.9	29.2
Capsular contracture Baker grade II/III/IV	12.7	12.5
Implant malposition	11.4	8.3
Patient request for style/size change	11.4	4.2
Infection	5.1	
Scarring/hypertrophic scarring	3.8	
Ptosis	3.8	4.2
Hematoma/seroma	3.8	4.2
Breast cancer	3.8	4.2
Implant extrusion	2.5	4.2
Nipple complications (unplanned)	2.5	4.2
Delayed wound healing	1.3	
Breast pain	1.3	
Implant palpability/visibility	1.3	4.2
Muscle spasm	1.3	12.5
Total	79	24

From Cunningham B. The mentor core study on silicone memorygel breast implants. *Plast Reconstr Surg* 2007;120:195–295.

gel bleed, lack of compressive forces, pocket position, surface characteristics, and external factors such as radiation to the most common factors of bacterial contamination and hematoma/seroma. Methods that have been tried in attempt to minimize capsular formation include intraluminal or pocket steroids, introduction of low-bleed shells and gels, systemic antibiotics, saline-filled or double-lumen implants, underfilling of implants, creating a larger or “mega pocket,” talc-free gloves, implant displacement exercises, avoiding agents that may increase bleeding, submuscular placement, increase heavy surface texturing, and atraumatic techniques that decrease blood and seroma formation. Although many of these factors may influence the occurrence and degree of capsule formation, today most plastic surgeons and researchers would agree that there are two main causal theories of adverse capsule formation resulting in contraction: Bacterial Theory and Hypertrophic Scar Theory.

The Infectious Theory has been championed by many investigators including Burkhardt and colleagues,¹⁷ Adams and colleagues,¹⁸ Weiner,¹⁹ and Pajkos and colleagues.²⁰ *Staphylococcus epidermidis*, *Propionbacter*, *Enterobacter*, *Bacillus*, and other species have been implicated. The theory involves a low-level contamination of a skin bacteria or seeding of an implant following

a transient bacteremia in the implant space, and may involve a biofilm that forms around the implant when present. This has led to the development of various solutions to prevent bacterial contamination in the form of pocket irrigation. The FDA has regulated against the use of Betadine for pocket irrigation based on what appears to have been an anecdotal report in 1998 that Betadine could break down or harm a silicone shell when used intraluminally. This has made its way into the implant product labeling, and in 2000, without specific controlled experimental or clinical data to show that it is truly detrimental, Betadine warnings were put in place including extraluminal use for pocket irrigation. This original isolated report has been refuted by multiple studies and investigators,^{19,21} without any policy changes. There have been attempts to have the FDA review and revisit the science of Betadine and silicone shells, but until that reversal, surgeons will need to continue to use other agents or obtain off-label consent. In the interim, varying antibiotic and antibacterial agents are being used including Vancomycin, Hebiclens, Bacitracin, Cephalosporins particularly Ancef, Gentamicin, and others alone or in isolation are being used. One of the more popular pocket irrigation solutions is the “Adams Solution,” which includes: Bacitracin 50,000 units, Cefazolin 1 gram, and Gentamicin 80 mg in 500 mL of normal

saline for at least a 5-minute contact time without active evacuation, glove changes, and no touch techniques.¹⁸

The Hypertrophic Scar Theory entails a noninfectious material such as blood or seroma collects around an implant and initiates a capsular contracture.^{21–23} Some have identified and implicated a myofibroblastlike cell as being involved.²⁴ In experimental studies as far back as 1975, Cholmondeley and colleagues²⁵ noted that hematoma around an implant increased capsular contraction rates. Clinically, Hipps and colleagues,²⁶ Williams,²⁷ Freeman,²⁸ Handel and colleagues,²² and others have reported an increase in capsular contracture in patients who had seroma or hematomas postoperatively that were not drained. Clinical experience has shown the vast majority of undrained hematomas develop Baker III-IV capsular contractures requiring revision, resulting in a very low threshold to return to operating room for drainage. Concurrently, there are a large number of delayed hematoma reports resulting in capsular contractures. Although less commonly used in primary augmentation, small short-term drains have been advocated by Jewell and others with low reported capsular contracture results.

An extremely interesting and intriguing finding surrounds use of the new Soft Tissue Matrix, or Acellular Dermis, such as Alloderm and Strattice, and its influence on capsular contraction and applications to breast revision cases. For significant contracture to occur, the encapsulation of the implant must be circumferential. Both histologically and clinically there is no attachment of an implant or expander, even heavily textured, to Alloderm or Strattice and also there is no capsule that forms beneath the material (**Fig. 4**). So the question is: Can a clinically significant Baker III-IV capsular contracture form with this material present? How much material is required to prevent the bridging of the capsule across the material? Although only with short-term 6-month follow-up, even for recalcitrant cases, there has been no recurrence when using this tissue. The early results are certainly exciting!

The take-home messages concerning capsular contracture are that because of its unknown etiology, many techniques should be instituted: minimizing bacterial contamination or seeding in the pocket including triple antibiotic irrigation, or meticulous atraumatic cautery dissection with prospective hemostasis under direct vision to minimize blood and fluid formation around an implant. The science would support surgical techniques and methods to decrease hematoma and fluid collection as well as bacterial contamination as ways to effectively reduce capsular contracture rates.

We also tend to be an “either-or” society, when in fact it is more likely that in most cases it may be “both-and.” There are likely multiple factors at play in capsular contracture formation, and these may be different in their degree of involvement from patient to patient. There is minimal downside to practice these techniques except for a slight increase in cost. Specific research into the effects of surface texturing, form-stable devices, antibiotic irrigation, and pocket position as well as problems such as double capsule formation continues; we will also drill down into prior published data looking at these factors, and carry on new research into the etiology of capsular contracture. Until these areas are further defined, we should consider doing all we can to minimize its occurrence or recurrence.

Malposition

Implant malposition (**Fig. 5**) is the second most common complication in most studies and is actually a very broad category that encompasses a wide range of complications including lateral malposition; inframammary fold malposition or lower pole stretch (bottoming out) or a combination of both; and synmastia, which is an extreme form of medial malposition, and may also encompass shaped implant rotation and varying degrees of asymmetry. Most implant malpositions are preventable. The importance and significance of the inframammary fold is gaining a great deal more attention and will be covered in more detail later in this article. Lateral and medial malposition most often result from an overdissection of the lateral breast pocket or over-release of the pectoralis muscle off their sternal attachments. For partial submuscular or dual-plane pocket dissection, the muscle may be released off of the rib attachments but the sternal attachments should be preserved. Patients must understand that cleavage will need to be created with external forces, ie, bras, not surgically. Synmastia can be difficult to correct although it can be successfully done in one stage with a capsular flap, Neopocket techniques with further support using a soft-tissue dermal matrix. Care should be taken not to overdissect the lateral pocket, with fine tuning done under direct vision with cautery dissection incrementally if needed after the implant is in position. Tissue-based planning is also critical to avoid malposition. If an implant size is selected that outweighs the soft tissue support of the breast or if the base width of the implant greatly exceeds the base width of the breast, malpositions and stretch deformities are more likely to occur.

Table 4
Classification of breast augmentation complications and secondary breast deformities

Patient Concern/Complaint	Underlying Etiology	Anatomic Deformity /Diagnosis	Treatment Options*
Malposition problems			
Breasts are different	Present preoperatively? Underestimated	Asymmetry	Multiple various approaches including explanation
Too far out/arm rubs against	Over dissection of pocket, implant size	Lateral malposition	Capsulorrhaphy, capsular flap, soft tissue matrix
Too far in/breasts touching	Release of pectoralis of sternum	Medial malposition/ synmastia	Capsular flap, neopocket/soft tissue matrix, staged
Double bubble/breast coming off implant	Mismatch implant and breast, IMF malposition	Unrecognized constricted breast/double bubble	Plane position change, breast scoring, smaller implant, mastopexy
One breast too low/ bottomed-out	Technical error, unrecognized asymmetry preop	Fold malposition	IMF reconstruction, soft tissue matrix
	Implant too large		
Skin stretched out, nipple too high	Lower pole skin stretch	Lower pole stretch deformity/bottoming out	IMF reconstruction, crescent skin resection
Implant spinning/moving/ wrong shape	Rotation of shaped implant	Shaped implant rotation/ pocket stretch	Exchange to round device, capsular flap-neopocket
Capsular contraction			
Breast too tight	? Etiology unknown	Significant capsular contraction	Capsulotomy
Breast too high	Bacterial theory	Baker III-IV capsule	Capsulectomy
Breast too hard	Hypertrophic scar blood-fluid theory		Antibiotic irrigation
Painful			Implant explanation or exchange
			Change planes
Visible wrinkling/rippling	Thin/poor coverage		Exchange to textural implant
I feel my implants too much	Implant visibility/ palpability		Soft tissue matrix/Acellular Dermis
Soft tissue coverage issues			
Visible wrinkling/rippling	Poor-thin coverage	Wrinkling/rippling	Multiple surgical options
I feel my implants too much	Implant visibility/ palpability	Implant palpability	Pocket change capsular flap, soft tissue matrix

My skin is too thin	Thin tissues/ soft tissue coverage Glandular atrophy	Breast glandular atrophy Overall thinning	Fat grafting, autogenous flap latissimus flap
	Oversized implant Implant style-saline	Soft tissue coverage issues	Capsular/autogenous flap Implant exchange for gel
	Implant factors - underfill - or low fill volume devices Capsular contracture		Implant exchange higher fill volume device Silicone for saline
Breasts are sagging	High-textured implant		Form-stable device
Bad stretchy skin	Poor skin elasticity	Visible wrinkling	Deeper pocket, soft tissue matrix
Recurrent ptosis			
Breasts are sagging	High-textured implant/concurrent capsular contracture	Waterfall/Snoopy deformity	Mastopexy, capsulotomy, capsulectomy smooth round implant, soft tissue matrix
Bad stretchy skin	Poor skin elasticity	Lower pole stretch	IMF or lower pole skin resection
Breasts falling off implants	Implant too large	Recurrent ptosis	Smaller implant if present
	Residual breasts too large	May be form of double-bubble	Mastopexy, breast pilcation
Hematoma/seroma			
My breasts are swollen/ painful	Hematoma	Hematoma	Surgical drainage
Breasts are hard	Seroma	Seroma	Surgical drainage/ Postoperative drain placement
Hyperanimation issues			
Moves too much/ looks weird with motion	Submuscular placement	Hyperanimation with submuscular device	Convert to subglandular
"Great at rest but how about when I do this?"	Inadequate pectoralis release	Intermammary widening	Divide muscle further, soft tissue matrix?

(continued on next page)

Table 4

(continued)

Patient Concern/Complaint	Underlying Etiology	Anatomic Deformity/Diagnosis	Treatment Options*
Extrusion			
My implant is coming out! What's this 'blue' color?	Thin tissue coverage, capsular contracture	"Holy \$#%#@ !!!"	Simple excision and revision? explantation/delayed revision
My skin is too thin	Pressure phenomenon/ infection?	Pending extrusion/exposure	Capsular flap/consider acellular dermis
Infection			
			Local muscle flap Capsulectomy-antibiotic irrigation
			Explantation +/- delayed reaugmentation
Infection	Contamination	Infection	Attempted salvage
	Systemic bacteremia		Explantation +/- delayed reaugmentation
Size change			
My breasts are too small/I'm unhappy	Misread of patient expectations	Elective size change	Improved informed consent/ patient selection
Too big	Disconnect in patient evaluation/ informed consent	Breasts truly disproportionate?	Recommend size change a minimum of 100 mL–150 mL different
Non-implant–related complications			
Hypertrophic scarring			
Thick, ugly, red painful scars	Genetic component/ unknown?	Hypertrophic scarring	Vascular laser/ dilute steroid injection/ silicone sheeting
Bad scars			
	Poor scarring/infection	Skin dehiscence	
	Black, Asian skin types	Sterile suture abscess?	
Nipple malposition			
My nipples are in the wrong spot	Implant malposition	Nipple malposition/lower pole stretch or bottoming out or fold malposition	IMF skin resection
Sticks out of bra/bathing suit	Poor surgical planning		Nipple repositioning
Pneumothorax			
No symptoms	Puncture through pleura only	Air in pleural space	Evacuate air in pleural space intraoperatively

Short of breath	Puncture of lung	Pneumothorax	Chest tube
Sensory changes			
Nipple or breast is numb	Intercostal/lower pole nerve stretch or division	Sensory changes	Avoid division
Skin cellulitis			Tincture of time
Skin is red and hot	Erythema	Cellulitis	Appropriate antibiotics
Mondors bands			
Weird band/string beneath my breast	Occluded veins, superior epigastric vein	Mondors bands	Tincture of time/reassurance
Prolonged bruising			
Black and blue	Blood	Bruising	Tincture of time
Bruising	Hematoma	Hematoma with textured device	Consider evacuation if with form-stable device

* Explanation without implant replacement is always an outpatient and should be considered for recurrent capsular contracture, recurrent malposition, extrusion, or infection.

Inframammary Fold Malposition

The inframammary fold (IMF) is a very unique structure that deserves a great deal of respect. The surgeon must specifically look for fold asymmetry preoperatively, and if present postoperatively determine if it is attributable to lower pole stretch, a lowering of the inframammary fold, or both, because surgical treatment is different. Acland's group in Louisville has done some very interesting histological work looking at the anatomy of the IMF (Fig. 6).²⁹

Clinically, this correlates to what I term the resting versus the true fold (Fig. 7). Each of us performing a Wise pattern reduction, has initially placed an incision directly in the resting IMF with the patient in a sitting or standing position only to see the incision ride up on the breast postoperatively. This is because of the varying position of the fascial slips and where they insert into the skin. These fascial slips originate from a lower position (true fold) on the chest below and insert at a higher position exerting forces onto the skin (resting fold) deeper fascial layers that insert in a lower position on the chest wall.

Tissue-based principles of implant selection have been refined and can very accurately determine the IMF position based on the style, type, and size of the implant selected and the patient's breast characteristics and measurements.³¹⁻³⁵ Based on these principles, the new ideal fold position may be determined and set or the original true fold maintained. For instance, the implant size or style may be chosen as a priority to minimize or eliminate the need for fold position change. Accordingly, in a constricted breast deformity, it is important to know where the fold should actually sit, based on the implant selected.

The internal position of the resting and true fold may vary from patient to patient up to 2 cm. The IMF may be set or resecured with sutures, such as a 2-0 Vicryl. Although there are multiple methods for correction, one variation has recently been described for repositioning a low IMF.³⁶

In your own patients who have had a prior IMF incision, it should be easy to discriminate between stretch of the lower pole of the breast, or bottoming out, and a fold malposition. If the incision remains symmetrical to the contralateral side and there is no additional skin or implant below the incision line, then there is lower pole stretch. If the incision is riding up on the breast then there is a fold malposition. Documenting nipple to fold distances over time is also very helpful. If the lower pole is stretched, then the focus is to reduce the skin envelope. As a generalization, the worst stretch deformities seen for revision are implants

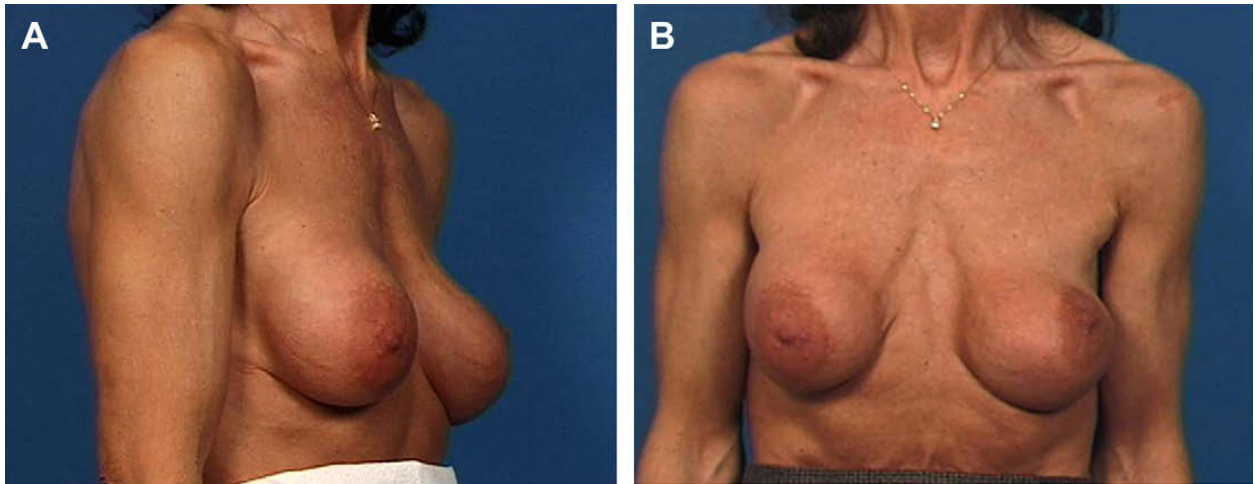


Fig. 3. Lateral (A) and frontal (B) views of a patient with Baker IV capsular contracture. She has 300 cc round silicone devices 26 years ago placed in the subglandular position.

disproportionate to the patients' soft tissues, saline implants more commonly than silicone, and smooth surface implants in the subglandular position. So a larger, greater than 450-mL implant, smooth saline implant in a subglandular pocket is more likely to present with a stretch deformity. The least likely patient for stretch is a highly form stable, heavily textured implant in the partial submuscular or dual plane position with these patients having less than 1 cm stretch at rest and less than 2 cm on stretch with an average 4-year follow-up. If any stretch deformity is present, along with a crescent skin resection in the IMF, exchange for a silicone device, exchange for a smaller device, changing pocket position to submuscular, and/or adding a soft tissue dermal matrix for further support should all be considered.

Double-Bubble Deformity

This malposition variant may result from a mismatch between the implant diameter and the

base width of the breast. Alternatively, it may occur with a submuscular implant and IMF malposition, or more rarely with a subglandular augmentation of a constricted breast. Prevention of this complication is key in avoiding an IMF malposition and choosing an implant that is the same diameter or slightly smaller than the breast diameter. A real set-up for developing this problem is a constricted type breast with a small breast diameter and a high fold. For a constricted breast, scoring is required to allow the breast to unfold and open up over the device, with the patient also requiring a concurrent mastopexy (**Fig. 8**).

Recurrent Breast Ptosis

Recurrent ptosis has been the most common cause for reoperation in my last 500 primary breast augmentation patients using heavily textured devices. Particularly when using full-height implants, they may remain too high on the breast with the breast becoming recurrently ptotic off the device.

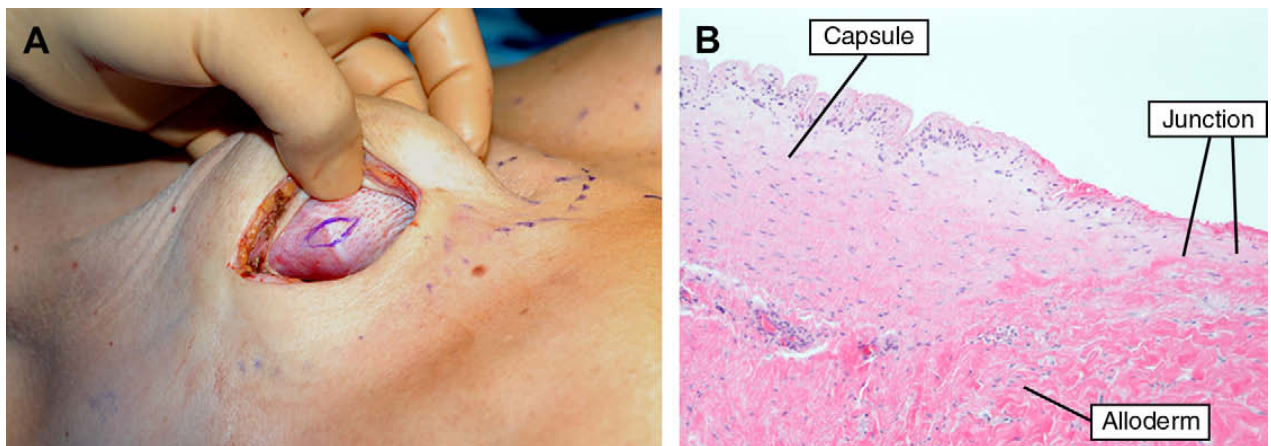


Fig. 4. Both clinically (A) and histologically (B), the junction of the acellular dermis and implant capsule is depicted. Alloderm and Strattice are both nonadherent to an underlying implant with no extension of the capsular layer beneath the matrix material. The impact of this on the development of capsular contracture will be interesting to follow. Is a 0% capsular contraction rate possible?



Fig. 5. Right inframammary fold malposition in a patient with a dual plane augmentation.

This may also be termed as a “Waterfall” or “Snoopy deformity” with the breast cascading off of the implant. After switching to smooth implants when raising the nipple more than 4 cm, and performing a simultaneous vertical to full mastopexy, this problem has not recurred. For patients either with an extremely deflated breast and minimal parenchyma or borderline on whether they will require an implant, staging these patients should also be considered.

Wrinkling and Rippling

Soft tissue coverage remains a top priority in breast augmentation. Until devices have no visible wrinkling, or clinical edge palpability, I typically accept the trade-offs with a dual-plane placement for the added coverage. When using the subglandular

position, patients should have a minimum of 2-cm pinch thickness. However, even with adequate soft tissue coverage, the gland may atrophy over time and lower pole stretch occur. Saline devices, underfilled gel devices, and heavy surface texturing may all increase the occurrence of wrinkling further prioritizing a partial submuscular position. Visible wrinkling is also a common complication following treated capsular contraction and thinning can be extremely difficult to correct. Exchange to a silicone-filled device, changing planes to retropectoral position, and consideration again for a soft tissue matrix may be beneficial. It is a bit early to advocate soft tissue coverage universally with an acellular dermis; however, early experience with this material is very promising. Both a tenting effect on stretch and a thicker material are advantageous. Clinically, prominent wrinkling above the point where a soft tissue matrix stops, but not directly beneath the material, has been evident. The verdict is still out, but this does hold out additional hope and options in treating these very difficult patient problems.

Hyperanimation Deformities

Presentations surrounding distortion with implants in the submuscular position are being increasingly discussed. Actual data on this were recently presented by Spear at the 2008 American Society for Aesthetic Plastic Surgery in San Diego, in which he found approximately 10% of patients had a significant amount of distortion enough to seek surgical solution. He noted that thin, very active

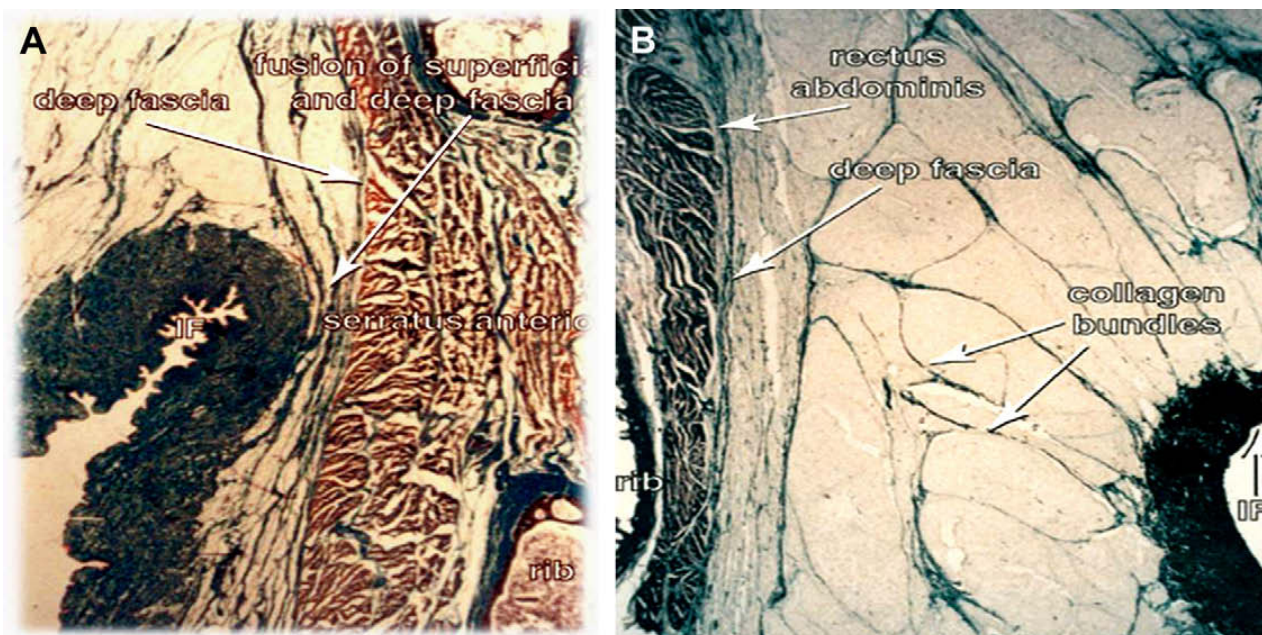


Fig. 6. Histology of the inframammary fold, A and B, show exceptionally well the dynamics of the fascia in this region where the fascial slips extend from the deeper tissues at an upward angle allowing for an implant to potentially rest in a lower position on the chest than the resting fold where the superficial fiber attach to the skin.

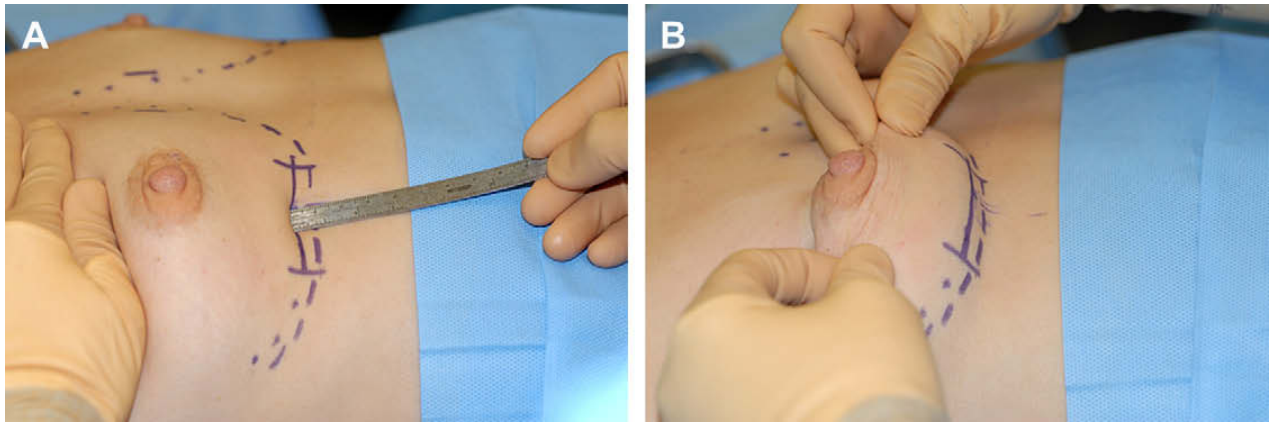


Fig. 7. (A) Clinical view of the marked fold at rest in the standing or sitting position where the superficial fiber creates the fold at rest versus (B) the internal attachment of the fascia slips that attach at a lower position down the chest wall, up to 2 cm lower in some patients.

muscular patients or body builder types were the most common to present with this problem. He also noted that this is also the exact population that benefits from more coverage and placement of an implant in the submuscular position. Absent from these discussions advocating the subglandular position is any patient follow-up, data, or science concerning the trade-offs of increased glandular atrophy, capsular contracture, visible wrinkling and rippling, and increase in distance of the nipple to fold over time with concomitant lower pole stretch and implant malposition and their frequency in subglandular augmentation. Presentations should also include the reporting of data demonstrating the trade-offs of placing these devices in the subglandular position, particularly

implants greater than 400 mL, with nipple to IMF measurements over time. Hyperanimation may also be more of a significant problem in breast revision patients than primary augmentation, and again may be an indication for a soft tissue matrix as a pectoral extension. In primary augmentation with adequate pectoralis release off of the ribs to the sternal margin and a dual plane, the vector is changed from more of an oblique upper pull to a more direct lateral vector with an increase in cleavage and intermammary distance unconcerning to most patients (**Fig. 9**).

Until more actual science is introduced into this discussion, I am afraid that we will continue to see separate subglandular and submuscular camps showing complications and problems from each

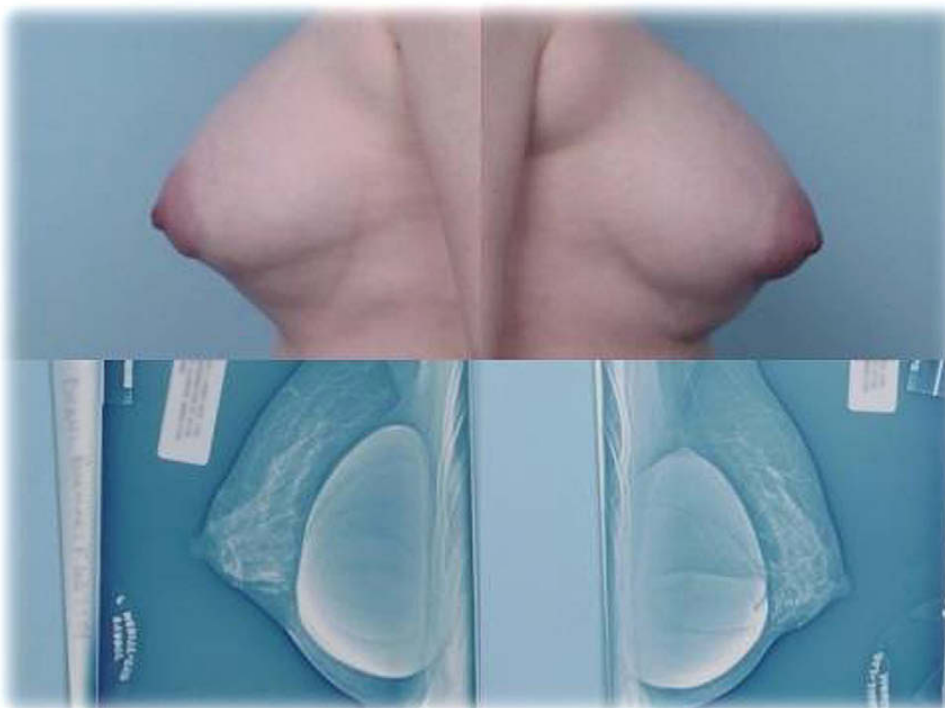


Fig. 8. Double-bubble deformity beautifully depicted on a Xero-mammogram following augmentation of a patient with a constricted breast deformity.

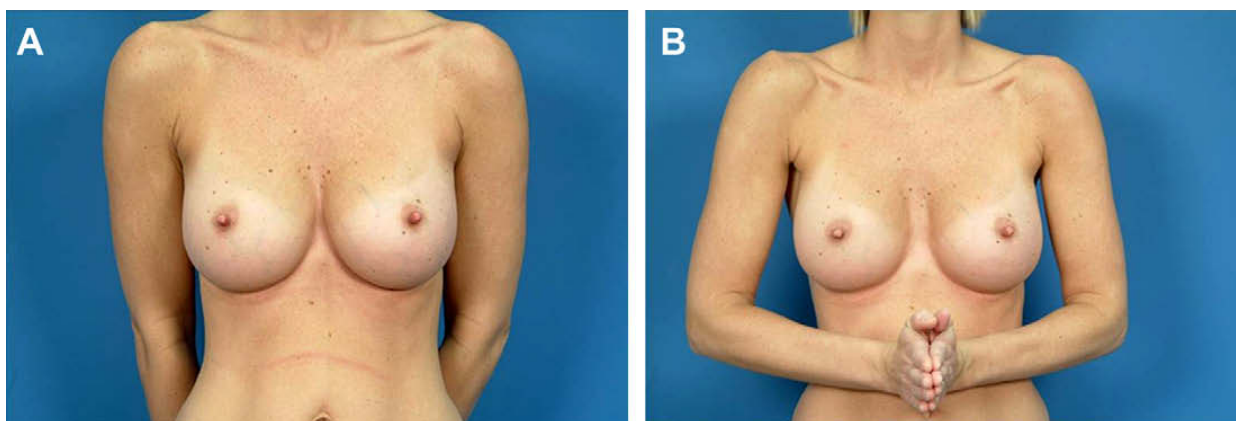


Fig. 9. (A and B) Form-stable implants have been placed in a partial retro-pectoral position with release off the rib insertions and dual-plane release but preservation of the sternal attachments. The vector of pull is changed from oblique to transverse with additional resistance of the animation from the stability of the device resulting in minimal widening of the cleavage and intermammary distance.

approach, with the surgeons left to decide for themselves which trade-offs they believe are most significant. Subfascial breast augmentation and soft tissue matrices have yet to fully weigh in here as well.

Hematoma and Seroma

Hematoma rates have been reported and range from 0.5% to 2.0%. Although some would advocate more of a conservative approach, I believe the risk of capsular contracture and not treating a hematoma far outweigh the risks if left untreated. Conversely, if treated and drained when diagnosed, healing typically proceeds normally. This is a definite instance where a surgical drain should be placed postoperatively. An additional topic that needs addressed is the use of nonsteroidal medications such as Celebrex preoperatively and ibuprofen postoperatively. Motrin is commonly used as the main or only postoperative medication without an increase in hematoma rates. In the *Physicians Desk Reference*, bleeding is not a listed side effect of this nonsteroidal, although associations have been made. One last point, as heavily textured form-stable devices are increasingly used, surgeons should recognize that a hematoma may not appear as an expanding fluid collection, but may expand directly into the tissues going down the flank or back because of the tight pocket. If significant ecchymosis occurs with a heavily textured device, this should be considered and treated like a hematoma.

Size Change

Elective implant size change remains one of the top reasons for breast augmentation revision surgery and makes up 1.5%, or half of my personal

primary breast revisions over the past 7 years. This complication may create a significant and costly revision for the surgeon and the patient, and often represents a failure of the first process of patient education and informed consent. There is a subset of patients who get caught up in the specifics of numbers and sizes of devices. Because of this, it is best to present a range of implants, of approximately 100 mL, to patients based on their specific tissue-based planning assessment that optimizes the fill of her breast. It is also important to emphasize that it will take 100 to 150 mL for her to see a visual difference in her breast and overemphasize that the next breast implant size up or down will have minimal to no visible change! “Even though 300 mL sounds like a lot more than 270 mL, it is 2 tablespoons!” Concurrently, if a patient comes in demanding a specific size or projection, this is a real “red flag.” Showing multiple before and after photographs of patients with similar breasts, potentially trying on sizers, bra stuffing, may be used, but regardless of the method this remains as one of the most difficult aspect of the preoperative process. Truly educating a patient in this area takes time and it is very important that patients understand, are involved in, and sign off on the implants that are selected.

Over the past few years there has been an increased use of photographic imaging, particularly 3-D imaging. This is a very exciting area, but just as in rhinoplasty, until we can deliver what we are simulating, surgeons must do everything in their power not to imply a warranty and use the systems as an educational tool.

Finally, understanding the physical differences between silicone and saline are important. Briefly, silicone weighs less, and is less dense than saline. Try placing a saline implant next to a silicone

device in a saline- or water-filled basin. Silicone floats. Saline implants hover and are isodense. Next, saline implants, because of their increased density and contribution of the weight of the shell, are 7% to 15% heavier. So when replacing a 300-mL saline implant filled to 330 mL, it actually weighs 350 to 360 grams. Weigh it on your scale next time. So you will need to use a silicone device approximately 10% larger just to get back to baseline because silicone implants are prefilled and their final weight includes their surrounding shell. Because of this, along with silicone implants typically being less projecting, and revision patients wanting to be larger, this information is helpful to know what implant sizes to order. This is even more significant in reconstruction with tissue expanders adding up to 80 grams or up to 20% of the overall weight of the final expander. For example, you should be prepared to replace a tissue expander filled with 350 mL with a 420- to 450-mL silicone implant.³⁷

Device-Related Complications

Device-related complications are mainly a manufacturing issue; however, there are a few critical pieces to discuss. Implant rupture and shell failure is implant-style dependent^{10,11,30} with the new form-stable devices having by far and away the lowest shell-failure rates of less than 1%.³¹⁻³⁴ As surgeons, we likely remain the number one reason for implant failure—iatrogenic. The implant may be impacted with the front or back of a needle, grabbed with a forceps, or scraped with a lighted retractor or other instrument, which may initiate the problem. Attempting to place an implant through too small of an incision, particularly a silicone gel, and even more so a form-stable device, may generate damage to the shell or internal gel. A minimum of a 4.0-cm incision for a round device and 5.0-5.5-cm incision for a highly form-stable

device should be used, even longer for implants over 400 mL. Lubricants such as sterile xylocaine or protective sleeves may also be useful to assist with insertion. Evolution and improvement of breast implant devices continues and the future is exciting. By the time of this publication, the form-stable devices will hopefully be FDA approved and the next generation of implants entering trials. Also keep your eye on new detection methods for implant failure in situ such as the new high-resolution ultrasound (**Fig. 10**) to detect implant shell failure.³⁷

Other Nonimplant-Related Complications

Although more common in revisional breast surgery and less frequent in primary augmentation, it is important to mention a few main principles. Always obtain prior operative notes and review your own before any revision, and at the same time do not completely trust everything you read. Have a very healthy respect (in fact, fear is good) of potential skin and nipple loss in prior augmentation mastopexy patients. Consider other incisions, such as inframammary for revision patients, and either stage the mastopexy or perform minimal nipple repositioning de-epithelialization only without undermining. Recognize that new complications following a revisional breast operation are much higher, 5- to 10-fold in prior PMA studies, and care should be taken to avoid creating a new complication while addressing another, i.e., creating a malposition when correcting a capsular contracture. Keep your eye on fat grafting and the future of new tissue matrix substitutes, as they have a great deal of applications by providing additional tissue that further supports and stabilizes repairs and helps to prevent additional malpositions and recurrent capsular contracture.

Unfortunately we do not have the space to cover the less common problems of implant exposure,

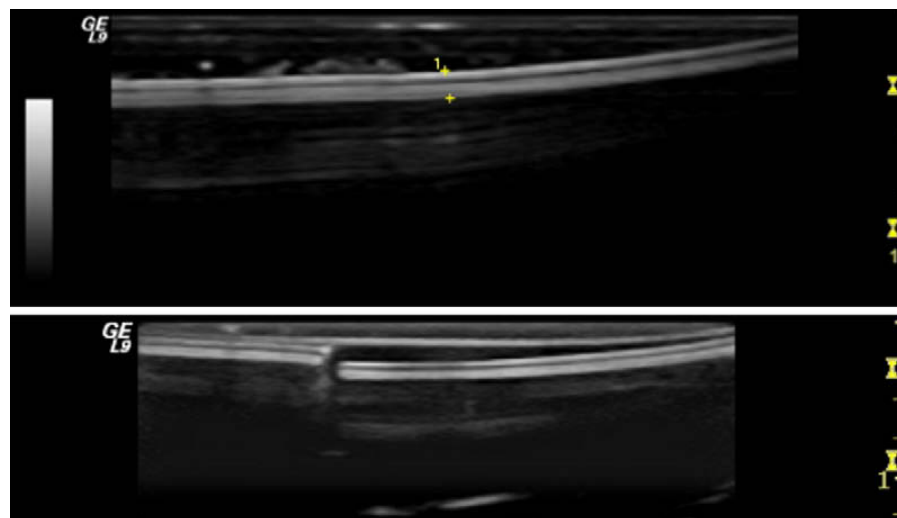


Fig. 10. New high-resolution ultrasound images of an intact and cut “ruptured” smooth silicone Style 15 (Allergan) implant shell visualized with a GE LOGIQ-9 and M12Lprobe.

infection, asymmetry, and others. Even with pocket irrigation, no touch techniques, and parenteral antibiotics, infection may occur. Consideration for placing an Opsite or Tegaderm over the nipple, or using a larger Barrier drape for suspected rupture or to reduce infection should be entertained.^{38,39} Pending or frank implant exposure in the absence of a deep space infection may be salvaged. Capsular flaps may also be beneficial in these instances.^{40–43}

This article has dealt mainly with the description and classification of complications following breast augmentation, presenting literature on their occurrence and some suggestions for avoiding complications. There are some excellent resources on surgical algorithms and solutions to correct or enhance these complications and revisional breast augmentation surgery listed here along with sources focused on prevention of complications.^{35,42–46} Again my hope would be that you will accept the challenge to look back and also move forward to track your personal patient data, openly and honestly share your results and data for the benefit of your colleagues and future breast augmentation patients, and, even though it is difficult, where required, to be open enough to change the way you practice. If only **one patient** is saved a revision or a major complication following breast augmentation, wouldn't it be worth it?

“Clinical Impression is what’s left in your chair when you stand.”

—Les Hovey

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