INTRODUCTION

According to the American Society of Plastic Surgeons, breast augmentation is the most common cosmetic surgery procedure and has been so every year since 2006. The annual number of breast augmentation procedures increased by 39% in the past decade, from 212,500 procedures performed in 2000 to 296,203 performed in 2010.

Women seek breast augmentation to improve their physical proportions, achieve a more feminine figure, and enhance their self-image and confidence. Candidates for augmentation mammoplasty come from many walks of life and have myriad psychological profiles. After undergoing breast augmentation, women have reported high levels of satisfaction, including enhanced self-image, increased self-esteem, and improved sexual function.

A survey of 455 patients who received silicone implants showed that 99% were satisfied with the outcome 1 month after the procedure and that 95% remained satisfied 6 years later. Survey respondents indicated satisfaction with breast size, shape, and feel and reported sustained improvement in body image but no improvements in health-related quality of life.

The literature is replete with articles on various aspects of breast augmentation. The procedure has not only generated copious academic debate about the technical aspects of creating an aesthetically pleasing breast but its safety has also sparked considerable angst in the political arena. The purposes of this review are as follows:

- Provide the reader with an overview of the history of breast augmentation surgery
- Review and compare various methods of breast augmentation.
- Discuss preoperative examination, patient counseling, and surgical planning
- Evaluate the advantages and disadvantages of various implant types, incision locations, and pocket locations
- Analyze the literature regarding outcomes of surgery, with an emphasis on complications such as capsular contracture, implant rupture, and revision surgery
- Review the controversy regarding silicone gel implants, the United States Food and Drug Administration (FDA) decisions, and the most current data on safety profiles, outcomes, and health-related concerns
Plastic surgeons performing breast augmentation must thoroughly understand all the elements listed above to provide appropriate care to their patients.

HISTORY

The first reported augmentation mammoplasty dates back to 1895, when Czerny\cite{9} transplanted a lipoma to the breast to replace tissue that was removed in resecting an adenoma. Berson\cite{10} attempted fat grafting to the breast in the early 1940s but noticed 30\% to 50\% graft resorption postoperatively and subsequently proposed dermis-fat and dermis-fascia-fat grafts to minimize fat resorption of grafts. In the 1950s, Longacre\cite{11,12} described pedicled dermis-fat flaps based at the inframammary fold (IMF) to augment the breast. In those days, petroleum gel, beeswax, shellac, and epoxy resin were all injected into the breast as soft-tissue fillers.\cite{13} Uchida\cite{14} reported the use of injectable silicone in 1961.

The early methods had universally unsatisfactory results that led to the development of alloplastic materials. Sponges made from polyurethane, Teflon, and polyvinyl alcohol were used as solid-material implants in the 1950s and 1960s\cite{13} but resulted in firmly contracted, immobile breasts without aesthetic appeal.\cite{15,16}

The search for a softer implant material led to the manufacture of dimethylsiloxane (silicone) sponges. Silicone is inert and has unique properties that allow it to be produced as a spray, gel, or solid.\cite{17,18} Silicone has been a component in hairspray, infant formula, beer, antacids, medical grade tubing, and lubricants because of its versatile properties. In 1962, Cronin and Gerow\cite{19} introduced the first sealed silicone gel-filled breast implant. It was teardrop shaped, with a smooth surface, and used Dacron (Invista, New York, NY) patches to help hold it in position.

As reported by Maxwell and Gabriel,\cite{2} the implant was unfortunately associated with a high incidence of capsular contracture, which prompted development of later-generation implants in the 1970s that were round and seamless with a thin smooth shell, creating a more natural look. However, the later-generation implants were associated with an increased risk of silicone “bleed” and shell rupture. Third-generation silicone implants have stronger, bilayer (double-lumen) shells that last longer and reduce the risk of silicone bleed and contracture. Fourth- and fifth-generation implants include those with polyurethane-covered textured surfaces and greater cross-linking (or cohesiveness) of the gel to help it hold its shape.\cite{2}

The inflatable saline-filled implant was first reported by Arion\cite{20} in 1965. It was billed as an alternative implant that could be introduced through smaller incisions than the silicone gel prosthesis. Saline-filled implants were subsequently developed by American manufacturers and marketed for clinical use in the 1970s.\cite{21,22} Original saline implants had high deflation rates. That problem has been addressed in newer generation saline implants by changes to the valves and the process by which the shells are cured.\cite{2}

In 1976, the Medical Device Amendments Act gave the FDA authorization to regulate medical devices.\cite{23} The FDA subsequently classified silicone implants as class III devices and called for submission of pre-market approval applications for these products.\cite{23} Increasing concerns in the 1980s regarding the potential of silicone gel implants to cause autoimmune disorders\cite{24-26} fueled by media speculation and legal actions against manufacturers culminated in the FDA’s issuing a voluntary moratorium on the use of silicone gel implants in 1992.\cite{23} Silicone gel implants were removed from the United States market soon thereafter. Canada’s regulatory agency followed suit, and silicone implants disappeared from the Canadian market as well.

During the time they were banned in North America, silicone gel implants remained available in most other countries and were used extensively across the globe. Breast augmentation was still highly sought in the United States despite health concerns. Saline implants filled the void left by
the absence of silicone implants but were plagued by high deflation rates and uncertain durability. The FDA eventually reapproved silicone gel breast implants and allowed them back on the market in November 2006. Approximately 20 epidemiological studies have found no increased risk of connective tissue disease associated with silicone breast implants. In 2010, silicone implants were used in approximately 51% of breast augmentations, and saline implants were used in approximately 41%. Details of the FDA ban, epidemiological studies, and prospective and post-approval industry studies designed to investigate the safety of silicone implants are reviewed below.

**PREOPERATIVE EVALUATION**

**Morphometric Analysis**

Surgeons should take note of all dimensions of a patient’s breasts, including the breast “footprint” and the shape of the breast on that footprint. Evaluation of the footprint includes noting the location of the upper and lower poles and the medial and lateral borders. The shape of the breast on the footprint includes its volume, projection, and slope. The surgeon must consider how each of these dimensions can and will be affected by the procedure and also must make the patient aware that the breast is likely to hang below the footprint to some degree after the procedure.

It is important to take note of any preoperative asymmetries because they are likely to become more prominent after breast augmentation. Patients often are unaware of mild to moderate differences in thoracic shape, but an attentive surgeon who adapts placement and volume of the implant to the underlying anatomy can improve patient satisfaction rates.

Breast and chest wall asymmetries are inherent in humans and are present in virtually all women. Although this is a recurring theme in the breast augmentation literature, data regarding anterior chest wall and breast asymmetries noted in women seeking breast augmentation are lacking in the literature. The spectrum of asymmetries in this patient population ranges from the subtle almost unrecognizable difference to the severe deformity, Poland syndrome. Discrepancies in the size and position of the nipple-areola complex (NAC), volume of the breast mound, base width, and/or position of the IMF might be present. Chest wall deformities typically involve the manubrium (e.g., pectus excavatum, pectus carinatum, or a prominent costosternal junction). Rib torsion, rib rotation, sunken chest wall, flaring lower costal cartilages, and hypoplasia of the pectoralis major muscle might also be present.

Some studies attempted to apply more objective parameters to breast augmentation. In an extension of the analysis of breast morphology presented by Penn, Westreich measured 22 parameters in 50 women who had what he considered to be “aesthetically perfect breasts” and concluded that the sternal notch-to-nipple and nipple-to-nipple distances determined the proper volume for breast augmentation. These studies suffer from the inherent bias of the author’s selection criteria, which were purely subjective. The notion of a “perfect breast” is a misconception that does not exist in nature, nor can it be achieved surgically.

Brown et al. studied the breast morphometry of 60 women in an attempt to establish a control group to define the “average breast” rather than the “perfect breast.” The women were all content with the shapes of their breasts, had not had any previous breast surgery, and did not desire alteration to their breasts. The authors noted several key landmarks on the breast; horizontal measurements were taken from the midline and vertical measurements were taken from the sternal notch on the midline axis. Although they found a high degree of bilateral asymmetry in all measurements (Table 1), the only statistically significant difference between mean right and left breast measurements was in the most inferior horizontal level of the IMF (55%). Breast projection and areolar diameter were asymmetric in 27% and 28%, respectively. These data confirm
the natural asymmetry that occurs in an average population of women.

Rohrich et al.\(^3\) looked at the incidence of breast and chest wall asymmetries in a breast augmentation population. This was a retrospective review of 100 randomly selected women who underwent primary breast augmentation at their institution. Preoperative photographs were critically evaluated by four independent surgeons to assess breast and chest wall characteristics. The anatomic parameters analyzed were nipple position, size of the NAC, chest wall asymmetries, breast volume, base constriction, and IMF position. The results of the analysis are shown in Table 2.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>% Asymmetric (N = 60)</th>
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<tbody>
<tr>
<td>Nipple location</td>
<td></td>
</tr>
<tr>
<td>Horizontal</td>
<td>32</td>
</tr>
<tr>
<td>Vertical</td>
<td>30</td>
</tr>
<tr>
<td>Inframammary fold location</td>
<td></td>
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<tr>
<td>Horizontal</td>
<td>55</td>
</tr>
<tr>
<td>Vertical</td>
<td>20</td>
</tr>
<tr>
<td>Base of Breast (lowest point of breast)</td>
<td></td>
</tr>
<tr>
<td>Horizontal</td>
<td>32</td>
</tr>
<tr>
<td>Vertical</td>
<td>25</td>
</tr>
<tr>
<td>Breast projection</td>
<td>27</td>
</tr>
<tr>
<td>Areolar diameter</td>
<td>28</td>
</tr>
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</table>

Overall, 88% of women had at least one parameter of asymmetry and 63% had two or more, including asymmetrical position (53%) and size (24%) of the NAC, breast volume (44%), base constriction (29%), IMF position (30%), and chest wall deformity (9%). Their observations confirm the inherent differences among various anatomic components of a woman's breast.\(^3\)

The original studies\(^3\) were distinct in design and objective. Brown et al.\(^3\) prospectively established a control group to serve as a reference range of “normality” that might aid in the planning of reconstructive and aesthetic breast surgery. The control group consisted of a wide age range of patients with a mean age of 38

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years (range, 15–88 years). The authors made direct patient measurements and went on to compare breast morphometry in a small group of patients undergoing breast reduction and breast augmentation with control group measurements. In contrast, the study design used by Rohrich et al. was that of a retrospective review. The authors’ goal was to evaluate the extent of preexisting breast asymmetry in an average patient population seeking breast augmentation (age unspecified). The analysis was conducted from patient photographs rather than direct measurements, and there were no comparison groups. Despite the differences in study objectives and methodology (Table 3), both author groups arrived at similar conclusions regarding female breast morphometry: asymmetry is highly common regarding any feature of the breast and chest wall.

More recent studies have used imaging and other technologies to evaluate asymmetries of the breast or chest wall. Hirsch and Brody used cross-sectional thoracic computed tomography (CT) in 50 female patients. All participants exhibited asymmetries from right to left sides, either in anterior to posterior diameter or angular measurements. Furthermore, the authors noted that there was considerable variability in thoracic shape and that the shape of the anterior chest wall affected breast projection such that a sloped chest wall was associated with lateral projection and a

<table>
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<tr>
<th>Table 2: Asymmetry before Breast Augmentation</th>
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<tr>
<td>Asymmetry</td>
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<tr>
<td>Nipple-areola complex</td>
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<tr>
<td>Size</td>
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<tr>
<td>Chest wall</td>
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<tr>
<td>Pectus excavatum/carinatum or rib flaring</td>
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<tr>
<td>Breast mound</td>
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<tr>
<td>Inframammary fold position</td>
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</table>
flatter wall was associated with anterior projection. Surgeons need to take chest wall contour and asymmetry into account to ensure that the postoperative outcome they describe to the patient will be achievable.

Using four-dimensional photography to confirm manual measurements of 125 patients, Gabriel et al.\(^{35}\) reported significant \((P < 0.05)\) differences between right and left sides in 82% of participants and some degree of soft-tissue and/or chest wall asymmetry in 100% of women. Using a three-dimensional scanning technique to evaluate the breasts of 100 women before augmentation surgery, Liu et al.\(^{36}\) reported that all patients had asymmetry in at least one parameter, 92% had asymmetry in at least two parameters, and 72% had asymmetry in three or more parameters (Table 4). Patients frequently are unaware of the asymmetry until after breast augmentation, at which point they might fault the procedure or the surgeon if they have not been forewarned.\(^{37}\)

<table>
<thead>
<tr>
<th>Study design</th>
<th>Brown et al.(^{32})</th>
<th>Rohrich et al.(^{33})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient evaluation</td>
<td>Direct patient measurements</td>
<td>Subjective photographic assessment</td>
</tr>
<tr>
<td>Mean age of cohort (yr)</td>
<td>38</td>
<td>Not identified</td>
</tr>
<tr>
<td>Number of comparison groups</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Data (% asymmetry in study population)</td>
<td>Nipple-areola location</td>
<td>30–32</td>
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<td></td>
<td>Areola size</td>
<td>28</td>
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<td></td>
<td>Inframammary fold location</td>
<td>20–55</td>
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Three-dimensional optical body scanning and computational modeling might allow for more than just preoperative delineation of asymmetries. By comparing preoperative and postoperative three-dimensional photographs from 14 patients, Tepper et al.\textsuperscript{38} confirmed objective changes in breast morphology. The authors found that breast augmentation significantly increased breast volume by an average of 301.5 mL, internal angle of breast projection by 13.6 degrees, sternal notch to nipple distance by 11 mm, and anterior-posterior projection by 23.3 mm ($P < 0.01$, $P = 0.018$, and $P < 0.01$, respectively). Of note, anterior-posterior projection was approximately 21% less than anticipated based on the implant dimensions.

Gladilin et al.\textsuperscript{39} used three-dimensional technology to provide patients with a photo-realistic appearance of postsurgery breasts. The simulation was shown for different surgical scenarios, including different implant types and different placements in the chest. Comparing the preoperative images with actual postoperative outcomes, the authors found the images to be realistic and accurate, with less than an average 1-mm modeling error for 89% of the breast surface.\textsuperscript{39}

### Clinical Examination

The preoperative clinical examination is of paramount importance to the success of the procedure. Every plastic surgeon must develop an individualized and comprehensive approach to evaluate patients for breast and chest wall asymmetries. The chest wall must be critically evaluated for deformities and irregularities of the

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**Table 4**

<table>
<thead>
<tr>
<th>Preoperative Breast and Chest Wall Asymmetry: Series of 100 Breast Augmentation Cases\textsuperscript{36}</th>
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<tbody>
<tr>
<td>% with Significant Asymmetry</td>
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<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>Nipple level</td>
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<tr>
<td>Nipple-to-midline distance</td>
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<tr>
<td>Inframammary fold level</td>
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<tr>
<td>Breast width</td>
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<tr>
<td>Breast projection</td>
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<tr>
<td>Anterior chest wall projection</td>
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<tr>
<td>Breast volume</td>
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</tbody>
</table>

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rib cage and for hypoplasia of the pectoralis major. The physical characteristics of the breast tissue, base width, and nipple-areola size and position must be documented. The degree of breast ptosis should also be evaluated. Patients with grade II ptosis or greater might benefit from concomitant mastopexy.

Preoperative psychological screening is an important part of evaluating patients’ candidacy for the procedure. If the patient’s history includes psychopathology or if psychopathology is suspected by the plastic surgeon, the patient should be referred for a mental health consultation before the procedure is performed.40

Epidemiological studies41−43 suggest that women who have undergone breast augmentation have a suicide rate that is two to three times that of the general population.40 It is not clear whether the breast augmentation population has higher preoperative rates of mental illness.41 Furthermore, the studies were primarily conducted in Sweden,41,42 which has a high suicide rate in general, and it is not clear whether results are applicable to the United States population.44

It is important to screen for body dysmorphic disorder (BDD)—a preoccupation with an imagined defect in appearance or markedly excessive concern over a slight physical anomaly that leads to distress and functional and/or social impairment.44 BDD affects 6% to 12% of patients undergoing cosmetic plastic surgery. Medical or surgical procedures rarely relieve symptoms of BDD, and patients with this condition are at high risk for suicide. Therefore, patients requesting breast augmentation should undergo professional preoperative screening for BDD.44

**Preoperative Counseling**

The physical examination findings must be candidly discussed with the patient during preoperative counseling. Tebbetts and Tebbetts45 advocated a staged repetitive patient education and informed consent process. All asymmetries must be discussed as part of the informed consent process. Breast augmentation patients must be aware that subtle differences in their breasts before surgery might become exaggerated after surgery. This possibility must be emphasized in the informed consent information. If patients understand the prevalence of their anatomic variances, they will have realistic expectations for the outcome of surgery, which lessens postoperative complaints and leads to higher levels of patient satisfaction after breast augmentation.

A surgeon must delve into a patient’s reasons for requesting breast augmentation and her desired outcome. It is important to address any unrealistic goals and expectations regarding outcomes of the surgery. The patient’s desires must be balanced against the reasonable likelihood of achieving those results. A high level of patient satisfaction can be ensured if the patient’s aesthetic goals are attainable with the surgeon’s skill and experience.

Many patients (and even surgeons) hold the misperception that a convex upper pole is the ideal breast shape, leading patients to seek to add or enhance their cleavage, despite the fact that natural breasts have either a straight or slightly concave upper pole.37 Patients need to understand that this is difficult to achieve. Beyond a certain volume, larger implants will only drop the lower pole and not raise the upper pole.27 Suturing the breast tissue higher on the chest wall does produce long-lasting results.27

Preoperative counseling should include a discussion of potential short- and long-term side effects and complications. It should also include a discussion of what to expect during the postoperative period. Forty-eight women were surveyed regarding their experience with breast surgery (augmentation, reduction, or reconstruction). Most said there was some aspect of the postsurgical experience for which they had not been prepared, including degree, duration, and/or location of pain; itching; degree of swelling; and numbness in or around the breasts that might adversely affect sexual pleasure.46 Many of the women in the survey who had undergone
augmentation also expressed disappointment that their surgeon had failed to communicate the benefits of postoperative massage in improving physical sensation and decreasing scarring. Patients must exhibit an understanding of the risks to provide informed consent. Some women also find it beneficial to see pre- and postoperative photographs with a range of outcomes, including best, typical, and worst outcomes. Other resources that might be of benefit to women before breast augmentation include the contact information of women who have undergone breast augmentation and a list of credible web sites with information regarding the procedure.

As discussed below, recent updates from the FDA also warn that breast implants are not meant for lifelong use. Physicians should clearly convey to patients who are considering breast augmentation that they are likely to eventually require subsequent surgery to remove or replace the implants. Prospective patients should also be informed that breast augmentation might cause cosmetically undesirable and irreversible changes to the breast. The FDA also recommends magnetic resonance imaging (MRI) examinations at 3 years after surgery and then every 2 years thereafter to detect asymptomatic rupture. Patients must also be informed of the cost of MRI and must note that this screening might not be covered by insurance.

**OPERATIVE PLANNING**

**High Five Process**

Tebbetts and Adams advocated a bi-dimensional assessment they referred to as “the high five decision support process.” The process is a quantifiable approach to tissue assessment that uses defined measurements for making decisions. It consists of five key elements to consider when planning breast augmentation, as follows:

1. Optimal soft-tissue coverage and pocket location for the implant: determines risk of visible traction rippling, visible palpable implant edges, and possible excessive stretch or extrusion; plane can be subglandular or submuscular

2. Implant volume (weight): determines the effects of the implant on tissue over time, risks of excessive stretch, excessive thinning, palpability, visible traction rippling, ptosis, and parenchymal atrophy

3. Implant type, size, and dimensions: determines control over distribution of fill within the breast; adequacy of envelope fill; and risks of excessive stretch, thinning, palpability, rippling, ptosis, and parenchymal atrophy

4. Optimal location of the inframammary fold: based on the width of the implant selected; determines the position of the breast on the chest wall, the critical aesthetic relationship between breast width and nipple-to-fold distance, and distribution of fill

5. Incision location: determines the degree of trauma to the adjacent soft tissues, exposure of implant to endogenous bacteria in the breast tissue, surgeon visibility and control, potential injury to adjacent neurovasculature, and potential postoperative morbidity

Measurements are obtained with the patient seated and back straight (Fig. 1). On the basis of these measurements, the surgeon makes the five key choices (Fig. 2). These decisions are discussed with the patient at the time. Tebbetts and Adams reported a reoperation rate of 3% in nearly 2000 patients who underwent the high five method of surgical planning and implant selection and were followed for more than 6 years. The rate compares very favorably with those of manufacturers’ pre-market approval studies of saline implants.
submitted in 2000, in which the average reoperation rates were 17% for size exchange and 9% for adjustments.49,50

Pocket Location

Implants can be placed in the subglandular, subfascial, or submuscular space (Fig. 3).51 Dual-plane pockets that combine subglandular and partial retropectoral pocket location have also been described by Tebbets,52 who has clarified the nomenclature and detailed potential benefits and tradeoffs of some of the pocket locations (Table 5).52−56

Subglandular Space

Early augmentation procedures involved limited blunt dissection in the subglandular plane that created pockets slightly larger than the implant.57–59 It was then realized that the forces of wound contraction further reduce the size of the implant pocket and emphasis was shifted to developing a generous pocket. Some think that subglandular implants restore breast shape more effectively and correct ptosis better than submuscular implants.60 However, there must be adequate soft-tissue coverage when considering a subglandular implant. Tebbets and Adams48 and Tebbets52 recommend a subpectoral pocket for patients with a skin pinch test <2 cm.

Subfascial Space

The subfascial plane is a relatively new implant position that is gaining in popularity. The implant is placed in the superior half (upper pole) of the breast in the subfascial position such that the anterior wall of the pocket consists of pectoral fascia, breast parenchyma, subcutaneous tissue, and skin.54 The integrity of the pectoral fascia can be preserved in some but not all cases with this approach.53 Matching the pocket size to the implant’s height and width and adjusting the skin envelope to the implant size helps prevent movement or rotation of the implant.54 It should be noted that if implant exchange is necessary after subfascial breast augmentation, the surgeon must perform a capsulectomy and use internal sutures to adjust the pocket dimensions to the new implant.54 In a series
of 1000 patients, 99.6% reported satisfaction with subfascial breast augmentation.\textsuperscript{55}

There have been some uncommon (1:500) reports of Mondor’s syndrome occurring after subfascial implantation.\textsuperscript{56} This syndrome consists of superficial thrombophlebitis in the subcutaneous veins of the thoracoabdominal wall, which manifests as a palpable and sometimes visible cord running from the IMF toward the umbilicus. Associated symptoms include tenderness, erythema, pain, pruritus, arthralgia, and sometimes fever. Of three patients with this syndrome in one report,\textsuperscript{56} all were high-performance athletes. The cord resolves spontaneously within 6 months without recurrence, but this can be shortened to approximately 2 weeks with a single dose of 5 mg of betamethasone.\textsuperscript{56}
Submuscular Space

Because most breast augmentation candidates are thin, submuscular implantation has become most popular. Submuscular implantation can be partial retropectoral or total submuscular (complete muscle coverage with pectoralis major and serratus anterior). A partial retropectoral or total submuscular pocket provides the necessary soft-tissue coverage superiorly in a glandular ptotic breast with a thin superior pole but risks a “double bubble” deformity as the parenchyma slides inferiorly off the pectoralis and implant. A constricted lower pole in a thin patient needs additional coverage superiorly, while muscle cover inferiorly restricts expansion of the lower pole. Dempsey and Latham described the first breast augmentation with implantation in the subpectoral plane. The subpectoral plane has many advantages, as follows:

- Lower incidence of capsular contracture
- Blunting of implant edges by the muscle, producing better breast contour
- Less exposure of the prosthesis to bacterial contamination from contact with glandular tissue
- Dissection in a less vascular plane and lower rates of hematoma
- Maximal preservation of nipple sensation

However, subpectoral placement can result in implant malposition, breast asymmetry, abnormal contouring, or undesirable implant movement with chest muscle contraction.

Regnault observed that subpectoral implants tend to shift superiorly and laterally when the muscle origins are not released to the level of the sternum. Scully reported that an intact pectoralis origin is often the reason for lower capsular contracture because of the repeated compressive...
<table>
<thead>
<tr>
<th>Pocket Location</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subglandular</td>
<td>-Increased control of breast shape</td>
<td>-Increased risk of edge visibility or palpability</td>
</tr>
<tr>
<td></td>
<td>-Usually faster postoperative recovery</td>
<td>-Possible increased interference with mammography</td>
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<tr>
<td></td>
<td>-Minimal of no distortion with pectoralis contraction</td>
<td>-Possible increased risk of capsular contracture</td>
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<tr>
<td></td>
<td>-Increased control of inframammary fold position and shape</td>
<td></td>
</tr>
<tr>
<td>Subfascial</td>
<td>-Greater support for superior pole</td>
<td>-Mondor syndrome (rare)</td>
</tr>
<tr>
<td></td>
<td>-More accurate control of breast shape and inframammary fold position</td>
<td>-Need to perform capsulectomy and use internal sutures to adjust pocket dimension if implant exchange subsequently needed</td>
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<td></td>
<td>-More firmness in periareolar area</td>
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<td></td>
<td>-Short recovery time</td>
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<td></td>
<td>-Low incidence of capsular contracture (0.4% Baker III and IV)</td>
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<td></td>
<td>-Reduced risk of rotation of anatomic implants</td>
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<td></td>
<td>-Greater soft-tissue coverage of implant compared with subglandular location</td>
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<tr>
<td></td>
<td>-Less risk of double-bubble, bleeding, implant movement, and postoperative pain compared with submuscular</td>
<td></td>
</tr>
<tr>
<td>Partial retropectoral</td>
<td>-Muscle coverage mandatory if pinch is &gt;2 cm above breast parenchyma</td>
<td>-Lateral implant displacement over time</td>
</tr>
<tr>
<td>(pectoralis origins intact)</td>
<td>-Possibly more accurate mammograms</td>
<td>-Less control of upper medial fill</td>
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<tr>
<td></td>
<td>-Less risk of visible or palpable implant edges</td>
<td>-More postoperative tenderness, longer recovery</td>
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<tr>
<td></td>
<td>-Possible less risk of capsular contracture, especially with silicone gel-filled implants</td>
<td>-Distortion of breast shape with pectoralis contraction</td>
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<td></td>
<td></td>
<td>-Less control of inframammary fold position</td>
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<tr>
<td></td>
<td></td>
<td>-Higher risk of superior implant displacement</td>
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<tr>
<td></td>
<td></td>
<td>-Inframammary fold deepening prolonged</td>
</tr>
<tr>
<td>Pocket Location</td>
<td>Advantages</td>
<td>Disadvantages</td>
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<tr>
<td>-----------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Total submuscular</td>
<td>-Possible increased coverage inferolaterally (clinically insignificant)</td>
<td>-Lateral implant displacement over time</td>
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<tr>
<td></td>
<td></td>
<td>-Less control of upper medial fill</td>
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<tr>
<td></td>
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<td>-More postoperative tenderness, longer recovery</td>
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<td>-Distortion of breast shape with pectoralis contraction</td>
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<td>-Highest risk of superior implant displacement</td>
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<td>-Longer operative time</td>
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<td></td>
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<td>-Longest postoperative recovery and morbidity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Least accurate inframammary fold</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Longest time for inframammary fold depth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Greatest risk of inframammary fold irregularities and inaccuracies</td>
</tr>
<tr>
<td>Dual plane</td>
<td>Compared with subglandular—</td>
<td>-Possible increased risk of implant visibility inferiorly compared with partial</td>
</tr>
<tr>
<td></td>
<td>-Same increased control of lower breast shape</td>
<td>retropectoral location</td>
</tr>
<tr>
<td></td>
<td>-Same recovery time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less risk of edge visibility or palpability with upper pole coverage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less interference with mammography</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less risk of capsular contracture because of less contact with parenchyma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Compared with partial retropectoral—</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Same muscle coverage needed if pinch is &lt;2 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less risk of lateral implant displacement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Better control of upper medial fill</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less postoperative tenderness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Faster recovery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less distortion of breast shape with pectoralis contraction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Less risk of superior implant displacement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Increased control of inframammary fold position and depth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Same possibility for accurate mammograms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Small possibility of less capsular contracture</td>
<td></td>
</tr>
</tbody>
</table>
forces generated by pectoralis contraction. Biggs and Yarish reported a capsular contracture rate of 32% with subglandular implants versus 12% in the subpectoral group.

**Dual-plane Augmentation**

Tebbetts introduced the concept of dual-plane breast augmentation (Fig. 4). He noted that this implant position maximizes the benefits of each pocket location and limits the risks of a single pocket location. Dual-plane augmentation alters the parenchyma–muscle interface to counteract the double-bubble phenomenon. It is important to preserve the muscle origins of the pectoralis major along the sternum to avoid medial visibility of the implant, symmastia, and rippling of the overlying skin.

Mofid and Singh retrospectively reviewed the outcomes of conversion from subglandular to dual-plane position implants during revision breast augmentation surgery. By using AlloDerm (LifeCell, Branchburg, NJ) sutured to the lower edge of the pectoralis major muscle to the chest wall, the authors created a composite pectoralis-AlloDerm pocket for the implant in 10 patients. Those patients were compared with 15 case control patients who underwent pocket conversion with a standard technique of marionette sutures and internal capsulorrhaphy sutures from the lower edge of the pectoralis major muscle to the anterior capsule or breast fascia in the subglandular plane. Complications occurred in 73% of the standard group compared with none of the patients in the AlloDerm group ($P < 0.05$).

**Implant Selection**

Implant–related variables include size, shape, shell texture, filler substance, and final implant volume. No incontrovertible evidence is available to support one choice over another.

Selection of implant size can be a complex process, but evidence shows that patients who undergo preoperative sizing are more satisfied and less interested in size revisions postoperatively. Whereas surgeons must select implant size by cubic centiliters, patients most commonly refer to bra and cup sizes when speaking about breast volume. Bra and cup sizes are highly variable from one manufacturer to the next. Patients’ perceptions of their own cup size are also inaccurate. Regnault et al. found that a 100-mL increase in volume translates into approximately one cup size increase. Various methods have been proposed to predict the appropriate size of an implant for augmentation, including having the patient perform a preoperative trial by wearing the implants in a sports bra. The preoperative decision-making process is as important as any aspect of surgical technique. The resulting form of the augmented breast will be determined by the dynamic interaction over time between the soft-tissue envelope, quality of the breast parenchyma, and dimensions of the breast prosthesis. Large implants (>350 mL) induce adverse changes on the native breast tissue; this soft-tissue atrophy is progressive and must be considered preoperatively. A breast implant will also cause costal cartilage remodeling, leading to a concave chest wall beneath the prosthesis. It is important for patients to understand that they bear responsibility for their final choice of implant.

**Incision Location**

Various locations have been proposed to minimize or hide the incisional scar of surgical breast augmentation. The current choices include periareolar, inframammary, transaxillary, and periumbilical incisions. Surgeons should be skilled in various techniques to accommodate a patient’s anatomy or preference for a specific approach.

The ideal location for the incision offers ample control of the surgical field and least trauma to normal tissue. These criteria must be combined with the desires of an informed patient who is aware of the risks and benefits of each incision. Spear et al. presented an algorithm for
Figure 4. Extent of dissection at the parenchyma-muscle interface (above), the position of the inferior edge of divided pectoralis origins (center), and pectoralis position relative to the implant (below) for types I, II, and III dual-plane augmentation techniques. (Reprinted with permission from Tebbetts.52)
locating the incision in breast augmentation surgery (Fig. 5) that takes into account nipple size, fold position, and need for concurrent procedures. Hidalgo\textsuperscript{60} presented a review of his experience with breast augmentation and discussed how to choose the optimal incision (Table 6).

Periareolar

Some surgeons think that the periareolar approach is the most versatile.\textsuperscript{60,74} The scar generally is well camouflaged, especially when placed along the inferior areolar border.\textsuperscript{75} To facilitate matching the incision edges during skin closure, it can be helpful to make symmetrical marks on opposite sides of the incision site before incising the skin.\textsuperscript{75}

A periareolar incision provides central access to all quadrants of the breast for subglandular and submuscular dissection, proves useful when the IMF needs to be lowered a considerable distance, and is the logical approach when a concurrent mastopexy needs to be performed. A periareolar incision is also indicated for patients with tuberous breasts in whom parenchymal alterations (e.g., scoring of the lower poles or parenchymal excision) are necessary.\textsuperscript{60,74} This incision is additionally useful in secondary procedures that require capsulectomy, implant exchange, or capsulorrhaphy to correct implant malposition.

![Breast augmentation algorithm](Modified from Spear et al.\textsuperscript{74})
### Table 6
**Incision Options**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Axillary</th>
<th>Periareolar</th>
<th>Inframammary</th>
<th>Periumbilical*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant plane</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submuscular</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Subglandular</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Implant type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saline round</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Saline shaped</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Silicone round or shaped</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Preoperative breast volume</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High (&gt;200 g)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Low (&lt;200 g)</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>+</td>
</tr>
<tr>
<td>Preoperative breast base position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Low</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Breast shape</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tubular</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Glandular ptosis</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Ptosis (grades I and II)</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Areolar characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small diameter</td>
<td>+</td>
<td>–</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Light or indistinct</td>
<td>+</td>
<td>–</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Inframammary crease</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>+</td>
</tr>
<tr>
<td>High</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>+</td>
</tr>
<tr>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Secondary procedure</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
</tbody>
</table>

*Included for completeness but generally not recommended.

+, applicable; –, generally not recommended.
The periareolar incision is contraindicated in patients whose areolar diameter is <3 cm or who have lightly pigmented areolae with indistinct margins. It also transects the lactiferous ducts, which can increase the risk of bacterial contamination of the pocket. It might interfere with nipple sensation, considering that superficial nerves are severed. Capsular contracture rates are higher with periareolar incisions (9.5%) than with inframammary incisions (0.6%). Furthermore, despite a usually well-concealed scar, this incision does place a potentially visible scar on top of the breast mound.

Inframammary Incision

The inframammary incision currently is the most common approach to breast augmentation, and it is the simplest and most straightforward. It is suited to patients who have substantial breast volume preoperatively, slight glandular ptosis, or post-partum atrophy. The nipple-to-IMF distance in these patients usually is long enough to prevent IMF displacement after surgery. This incision also allows direct access to the subglandular and submuscular dissection planes; the subpectoral plane is entered without disruption of the breast parenchyma. The length of the incision varies to accommodate implants of all sizes. The scar is generally hidden in the well-developed IMF and usually visible only with the patient lying down. However, Fanous et al. suggested that the scar can be rendered even less noticeable by using a short incision (1.5 cm) and saline implants.

Depending on the implant and tissue characteristics, the IMF might need to be lowered. Tebbetts and Adams and Spear et al. described techniques to estimate the new incision location below the original IMF. It is important to keep the incision off the lower pole of the breast and hidden in the new crease. The inframammary approach is not indicated when the IMF is high or nonexistent, in the constricted breast, or in the tubular breast deformity. Some surgeons think that the IMF incision is less versatile in secondary cases requiring capsulectomy or capsulorraphy of the superior pole. This approach might be associated with a high risk of wound dehiscence or scar widening, considering that the weight of the implant is forced onto the incision by gravity.

Transaxillary

The transaxillary incision is appealing because it avoids a scar on the breast, is usually well concealed under the arm, and offers direct access to the subpectoral plane. The short, transverse incision in the axilla does not violate the breast parenchyma. The transaxillary incision is said to be indicated in very thin patients, those with small parenchymal volume, high breast position on the chest, small areolae, ill-defined IMF, or minimal breast ptosis. Disadvantages are that a second inframammary procedure is frequently required and pigmented or hypertrophic scarring can be visible, especially with sleeveless clothing.

The technique was originally described as a blunt dissection in the subglandular plane, but it was not practical. It is generally known that most surgeons today use the incision to access the subpectoral space. Blunt dissection is not ideal because it is blind and gives rise to concerns over insecure hemostasis, inadequate pocket dissection, and malposition of the implant. Since the advent of endoscopic techniques, sharp dissection under direct visualization with accurate hemostasis and precise muscle release are possible. Howard noted that the incidence of implant malposition decreased from 8.6% to 2% with the use of endoscopy. Tebbetts reviewed his 28-year personal experience with transaxillary augmentations using both blunt (331 patients) and endoscopic (359 patients) techniques. He detailed the relevant anatomy and key surgical steps in a successful endoscopic transaxillary breast augmentation. The Baker grades III and IV capsular contracture rates were 4.2% and 1.3% for blunt and endoscopic dissections, respectively. Problems with the inframammary fold or contour irregularities occurred in 3.6% of the blunt dissection group.
compared with 1.1% of the endoscopic group. Transient lymphadenopathy or lymphatic banding was observed in 10.3% of the blunt group versus 2.2% of the endoscopic group. Implant malposition occurred in 1.8% of the blunt dissection group and 0.2% of the endoscopic group.

The transaxillary approach is not indicated in cases in which parenchymal manipulation is expected, such as for tuberous breasts and ptotic breasts, or when using “anatomic” implants or large silicone gel implants because of potential damage to the prosthesis during insertion. Secondary procedures are essentially impossible via the transaxillary approach. Concerns that transaxillary breast augmentation might interfere with sentinel lymph node integrity have so far proven unfounded.

**Transumbilical**

The transumbilical breast augmentation (TUBA) is another endoscopic approach that keeps the incision off the breast and places it in the umbilicus. A subcutaneous tunnel is carved above the rectus fascia, the dissection is carried superiorly to the subglandular space, and an implant pocket is fashioned hydraulically with the use of expanders. Deflated implants, rolled like a tobacco leaf, are inserted and then filled with saline to 50% more than final volume (to expand the pocket), and then the excess is removed.

The potential for implant malposition and trauma increases with remote-access augmentation, especially with textured and anatomic implants. The transumbilical approach is not approved by the FDA for silicone gel implants. Pound and Pound reviewed the outcomes of 1400 TUBA procedures involving both subglandular and submuscular implant placement. The incidence of deflation was reported to be 1.1%. The contracture rate was 4.2% Baker grade II and <1% Baker grades III and IV. The incidence of hematoma was <1%.

Brennan and Haiavy reviewed a single surgeon’s experience with TUBA in 245 patients followed for 1 year. The authors noted more postoperative firmness with subglandular implants relative to subpectoral implants, which was a negative predictor of patient satisfaction in the study group. The rate of hematoma was 0.4%; umbilical wound infection, 3.2%; implant deflation, 1.2%; tunnel seroma, 2%; asymmetry, 4.1%; and capsular contracture, 3.7%. TUBA is contraindicated in very thin women; in patients who have truncal obesity, <2-cm pinch test on the breast, previous abdominal surgery or hernia; and for secondary breast augmentation. Many surgeons also dislike this approach because of poor access to the implant pocket, inability to create a subpectoral pocket, and need for a second incision if revision or replacement is required.

**COMPLICATIONS**

Bengtson urged cosmetic surgeons to track and then report data on numbers of procedures performed and various outcomes, including complications. He thought that most surgeons tend to overestimate the number of procedures and underestimate the number of complications unless they are specifically tracked and recorded. Options for data tracking include use of a personal database, enrollment in a patient follow-up study supported by breast implant manufacturers, use of modified inventory and tracking software, and use of Internet- or inventory-based tracking programs provided by implant manufacturers. Such tracking and sharing of data and procedures can lead to improved processes for individual surgeons and the cosmetic surgery field as a whole.

**Capsular Contracture**

Capsular contracture is the most common complication associated with breast augmentation. It occurs in up to 30% of cases, and is the primary reason for revisional surgery. Capsular contracture rates are lower with low-bleed silicone implants, textured implants, submuscular placement, non-IMF incisions, and primary augmentation versus
revision or reconstruction. Other factors associated with elevated risk of capsular contracture are years of implantation, small surgical pocket, and thickness of the implant shell. Whether the risk of capsular contracture is greater with silicone than with saline implants is a matter of debate. One meta-analysis reported that capsular contracture rates are 2.25-fold higher with silicone implants, whereas a systematic review of 16 publications could not accept or reject the hypothesis that silicone implants have a higher rate of capsular contracture.

Histological findings show that capsules surrounding breast implants vary in thickness and have three layers:

1. Internal layer adjacent to implant: single or multilayered layer containing macrophages and fibroblasts
2. Middle layer: loosely arranged connective tissue (collagen fibers) and internal vascular supply
3. Outer layer: dense connective tissue with external vascular supply

The etiology of capsular contracture remains unclear. Both hypertrophic scar and infectious hypotheses have been proposed to explain the formation of a hard capsule around the implant in breast augmentation.

Hypertrophic Scar Hypothesis

Although hematomas left in place without drainage have been incriminated in the development of hard capsules in an animal model, microscopic analyses of hard periprosthetic capsules fail to substantiate a hypertrophic scar etiology. Hypertrophic scarring can have hematoma, granuloma, or genetic causes. The occurrence of unilateral capsular contracture after bilateral augmentation negates a humoral mechanism.

The histology of the fibrous capsule around smooth-walled silicone implants is well documented. The membrane consists of a thin inner layer of fibrocytes and histiocytes surrounded by a thick layer of relatively acellular collagen fiber bundles. The outermost layer is composed of loose connective tissue. The middle layer is made up of densely packed collagen bundles lying parallel to each other. Synovial metaplasia has been shown to be present in as many as 50% of implant capsules. Secretory cells contribute proteoglycans and other friction-reducing moieties to the implant lumen.

Myofibroblasts are known to be present on the capsules around breast implants, accumulating largely on the area of the capsule in contact with the implant’s surface and accounting for 7.3% to 50% of capsule thickness.

These contractile cells are thought to contribute to capsular contracture as part of a foreign body reaction initiated by silicone that is either shed by the implant shell or filtered through the walls of an implant.

Prantl et al. attempted to correlate the histological features of capsules with the clinical classification of contracture. Samples of capsular tissue obtained from 24 patients with various degrees of contracture were analyzed for thickness and cellular components. There was a positive correlation between capsular thickness and Baker grade. Greater capsular thickness was also associated with a higher number of silicone particles and silicone-loaded macrophages in the capsule. Despite this and many other studies of the capsular contracture phenomenon, a definitive correlation between the presence of silicone in the capsule, number of fibroblasts, and hardness of the capsule has not been established.

Confounding this hypothesis is delayed capsular contracture developing years after implantation. High levels of peptide growth factors have been identified in advanced contractures that might signify a chronic, low-grade, foreign body reaction around gel implants, prolonging the healing process.

Calcification has also been observed in as
many as 16% of capsules during explantation\textsuperscript{120} and relates to longevity of implantation. Implants in place for 23 to 26 years had a 100% incidence of capsular calcification; implants in place for 11 to 20 years had a 26% incidence of capsular calcification; and implants in place for <10 years had a 0% incidence of calcification.

\textit{Infectious Hypothesis}

Subclinical infections have been incriminated in the development of capsular contracture.\textsuperscript{121-126} Studies in animal models showed increased implant hardness and accelerated capsule formation when implants were contaminated with \textit{Staphylococcus epidermidis} or \textit{Staphylococcus aureus},\textsuperscript{124,125} supporting an immunological reaction in contracted capsules. \textit{Propionibacter}, \textit{Enterobacter}, and \textit{Bacillus} species have also been implicated.\textsuperscript{88}

Burkhardt et al.\textsuperscript{123} cultured pathogens in 30 (71\%) of 42 breast capsules during open capsulotomy for contracture. The dominant organism was \textit{S. epidermidis}, which is also routinely cultured from nipple secretions.\textsuperscript{121-123}

Dobke et al.\textsuperscript{127} reported 81 positive cultures in 150 explanted silicone implants—a 54\% rate overall. When the capsules were contracted, the incidence of positive cultures was 76\%, versus 28\% when they were not clinically contracted. \textit{S. epidermidis} was the predominant organism (in 84\% of cultures).

Virden et al.\textsuperscript{128} suggested that subclinical infection around silicone breast implants is more common than the results of standard laboratory cultures suggest. The authors noticed a slime layer referred to as a \textit{glycocalyx biofilm} on the surface of explanted prostheses. This biofilm is made of extracellular polysaccharides and glycoproteins produced by bacteria. The authors theorized that the bacteria hide within this biofilm and go undetected by routine culture methods. Using special culture media, they found that 56\% of contracted implants and 18\% of non-contracted implants were positive for \textit{S. epidermidis}. In contrast, routine cultures of the entire series were positive in only 5\% of cases. A causal association between subclinical infection, the presence of biofilm, and capsular contracture was also reported by Tamboto et al.\textsuperscript{129} in a porcine model. A four-fold increase in risk of capsular contracture was noted among biofilm-positive specimens.

Del Pozo et al.\textsuperscript{130} used vortexing and sonication to sample biofilm bacteria on the surface of 45 breast implants that had been removed for reasons other than overt infection at the Mayo Clinic. Of 27 implants removed because of significant capsular contracture, nine (33\%) had \geq20 colony-forming units (CFU) of bacteria/10 mL sonicate fluid (considered by the authors to be a significant positive implant culture). In contrast, only one (6\%) of 18 implants removed for reasons other than substantial capsular contracture had such levels of bacteria. Isolated bacteria included \textit{Propionibacterium} species, coagulase-negative staphylococci, and \textit{Corynebacterium} species.

\textit{Classification}

Baker\textsuperscript{114} introduced a clinical classification scheme for grading the severity of capsular contracture that is based on symptoms and physical examination (Table 7).\textsuperscript{114,131}

\textit{Preventing Capsular Contracture}

Several modalities have been proposed to prevent capsular contracture. The modalities range from antibiotics administered in the implant or in the pocket, to administration of systemic medications, to various implant massage techniques.

\textit{Antibiotics—According to Williams,}\textsuperscript{132} Dubin instilled bacitracin foam in the pocket of more than 2000 breast augmentations and reported firm breasts in fewer than 3\% postoperatively. Burkhardt
et al.\textsuperscript{126} reviewed the postoperative course of 124 women with subglandular saline implants to determine the effects of pocket irrigation with antibiotics. Various antibiotics were injected in and around the prostheses, and patients were followed for 24 months. Early (<3 months) contracture was reduced from 29% in the control group to 4.25% in the treatment group. Although the protective effect of antibiotics dissipated after 3 months, the final contracture rate was still lower in the experimental group: 19% versus 41% in the control group at 24 months.

In a later study, Burkhardt and Eades\textsuperscript{133} reported 12% Baker grade III and IV contractures when the implant pockets were irrigated with Betadine (Purdue Pharma, Stamford, CT) and 28% when irrigated with saline. The authors concluded that pocket irrigation with 5% povidone-iodine (50% Betadine) was as effective as other antimicrobial agents in controlling bacterial invasion around the prosthesis. They found no correlation between capsular contracture and hematoma formation, intercurrent infection, breast injury, or displacement exercises.\textsuperscript{125}

Adams et al.\textsuperscript{134} compared the \textit{in vitro} efficacy of various agents in retarding bacterial growth on implants. Dilutions of povidone-iodine and combinations of double antibiotic solutions were tested. The authors concluded that a combination of 10% povidone-iodine, gentamicin 80 mg, and cefazolin 1 g was most effective in controlling common pathogens associated with infection around breast implants.

In 2000, the FDA issued a caution alert regarding Betadine in contact with any breast implant because of potential weakening of the shell.\textsuperscript{135,136} On the basis of unpublished data submitted by the Mentor Corporation (Santa Barbara, CA) showing delamination of the adhesive on the valve patch of saline implants,\textsuperscript{137} which the manufacturer believed was caused by Betadine, the FDA recommended discontinuing pocket irrigation with Betadine. A review of the data showed that 75% of the observed deflations were reported by a single surgeon who used intraluminal injection of Betadine, not pocket irrigation.\textsuperscript{137} No other series to date has confirmed a relationship between Betadine and implant deflation.

In 2007, Wiener\textsuperscript{138} analyzed implant deflation and capsular contracture rates in 1244 women operated on between 1998 and 2005 who received pocket irrigation with Betadine at various dosages and saline implants. The observed deflation rate was 0.24%, and the rate of capsular contracture

<table>
<thead>
<tr>
<th>Baker Grade</th>
<th>Firmness</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No palpable capsule</td>
<td>The augmented breast feels as soft as an unoperated one.</td>
</tr>
<tr>
<td>II</td>
<td>Minimal firmness</td>
<td>The breast is less soft, and the implant can be palpated but not visible.</td>
</tr>
<tr>
<td>III</td>
<td>Moderate firmness</td>
<td>The breast is harder, the implant can be easily palpated, and the implant (or distortion caused by it) can be seen.</td>
</tr>
<tr>
<td>IV</td>
<td>Severe contracture</td>
<td>The breast is hard, tender, painful, and cold. Distortion often is marked.</td>
</tr>
</tbody>
</table>

\textbf{Table 7}  
Baker Classification of Capsular Firmness in Augmented Breasts\textsuperscript{114,131}
classified as Baker grade II or greater ranged from 0.5% to 2.2% in the four groups reviewed. These data suggest that proper use of Betadine irrigation has no effect on the rate of deflation of saline implants and might contribute to a low risk of capsular contracture.

Adams et al.\textsuperscript{138} looked for an alternative antibiotic regimen for breast augmentation after the Betadine ban and found that the following combination was most effective in reducing bacterial concentrations:

- 50,000 units of bacitracin
- 1 g of cefazolin
- 80 mg of gentamicin
- 500 mL of saline

Shah et al.\textsuperscript{139} studied the effect of cephalosporins added to the outer lumen of inflatable prostheses implanted in pockets contaminated with \textit{S. epidermidis}. The authors concluded that intraluminal antibiotics are of value in decreasing capsular contracture, particularly at low levels of bacterial contamination of the implant pocket.

Pfeiffer et al.\textsuperscript{140} performed a retrospective comparison of women who underwent breast augmentation at two time periods: 2000 to 2002, when cephalothin was added to the saline/epinephrine solution used to irrigate the implant pocket and outer lumen of the implants, and 2005 to 2007, when saline-epinephrine solution without antibiotics was used. The frequency of infection was higher in the latter group that did not receive antibiotics (12.8% versus 6.7%; \(P = 0.044\), as was the frequency of seroma (7.6% versus 2.9%; \(P = 0.036\)), but the rate of capsular contracture was not statistically significantly different (8.1% versus 5.9%; \(P = 0.393\)).

Corticosteroids—Two studies in the 1970s assessed the effect of pocket irrigation with Kenalog (Bristol-Myers Squibb, New York, NY)\textsuperscript{141,142} and found favorable results in terms of maintaining capsular softness. Subsequently, thinning of skin flaps, subcutaneous tissue erosion, and implant exposure associated with steroid administration were reported.\textsuperscript{143} The steroid apparently pools in the lower pole of the pocket and can predispose to skin erosion and implant extrusion.\textsuperscript{144} Intraluminal methylprednisolone was reported to diffuse through the shell of implants over 60 days,\textsuperscript{144} although clinically, only five of 100 patients developed capsular contracture. Intraluminal doses (≤20 mg) of methylprednisolone might be beneficial and are associated with few complications.\textsuperscript{145,146} Higher doses are associated with complication rates of 60% to 80%.\textsuperscript{145,146}

The diffusion rate of methylprednisolone through the elastomer envelope of a breast implant is concentration dependent rather than dose related.\textsuperscript{147} As expected, diffusion across the implant shell is slower for double-lumen implants and levels off after 10 months for all types of inflatable implants.\textsuperscript{147} In a study conducted by Morykwas et al.,\textsuperscript{146} the diffusion half-life of methylprednisolone was 20 months. The authors reported that steroids are released from breast prosthesis for a longer time than previously thought, which might explain some of the long-term detrimental effects of steroid use. A multicenter review of 504 women presented by Gutowski et al.\textsuperscript{149} found that although intraluminal antibiotics and steroids confer a protective effect against capsular contracture, they double the risk of implant deflation.

Cyclosporine A—Stark et al.\textsuperscript{150} tested the immunological, T-lymphocyte-induced reaction hypothesis of capsule formation in a rat model. The authors found a significant (\(P < 0.001\)) decrease in capsular thickness when intraluminal cyclosporine A was used. The collagen layer of the capsule in the treatment group was thinner and less organized than that of the control group. The mechanism of action of cyclosporine A is thought to be inhibition of the release of interleukin-1, which is a fibroblast proliferation factor that can be responsible for excessive collagen deposition. Cyclosporine A has not been tested in clinical trials.
Vitamin E—Peters et al.\textsuperscript{151} studied the effects of vitamin E on implant capsules in a rat model and noted delayed development of a periprosthetic capsule. It was suggested that patients ingest vitamin E after augmentation mammoplasty to capitalize on its known anti-inflammatory properties and reduce the rate of capsular hardness. Baker\textsuperscript{152} recommends a regimen of 1000 units of vitamin E administered orally twice a day, beginning 1 week before surgery and for 2 years postoperatively. It is unclear whether the positive results in that series were because of the vitamin E administration or other factors. Despite much study, no definitive evidence indicates that vitamin E prevents or ameliorates capsular contracture.\textsuperscript{153}

Cyclooxygenase-2 (COX-2) Inhibitors—COX-2 is expressed primarily in response to inflammatory stimuli and mediates the production of prostaglandins that support the inflammatory process.\textsuperscript{154} The COX-2 enzyme has been detected in the capsules of silicone implants in animal models,\textsuperscript{154} and researchers hypothesize that COX-2 inhibitors (e.g., celecoxib) might be of benefit in preventing capsular contracture. Many surgeons have prescribed COX-2 inhibitors in an attempt to minimize contracture and anecdotally mention a benefit; however, no published data on the effects of COX-2 inhibitors after breast augmentation in humans are available to date.\textsuperscript{155}

Implant Massage—Implant massage was independently described in the 1970s by Vinnik\textsuperscript{156} and Hoehler\textsuperscript{78} to preserve the dissected volume of the implant pocket. The two authors described forcibly moving the implant within the pocket in a series of “expansion exercises” that are performed every few hours. This frequent movement theoretically keeps the developing capsule from tightening around the implant.

The benefit of implant massage is debated. Many authors advocate its use and report a reduction in capsular contracture rate,\textsuperscript{156–158} whereas others\textsuperscript{159} find no benefit with implant massage initiated at 2 weeks postoperatively. Because a capsule is histologically evident on postoperative day 3,\textsuperscript{99} it could be argued that massage is effective only if it begins very soon after surgery. The clinical evidence for pocket massage is inconclusive, as are animal studies of implant compression and expansion.\textsuperscript{160,161}

Multimodal—Effective management of the implant capsule likely involves a number of measures. Becker and Springer\textsuperscript{162} described a multimodal approach to the breast implant capsule, which over 15 years led to a decrease in contracture rate in their series from 20% to 2%. The specific management components that brought about the improved outcome could not be identified.

Managing Capsular Contracture

Closed Capsulotomy—The goal of closed capsulotomy is to hydraulically tear the scar of the capsule without rupturing the implant.\textsuperscript{157,163} This is accomplished by manually compressing the breast until there is an audible “crack” signifying capsular fracture. One report shows successful return to Baker grade I after closed capsulotomy in most patients,\textsuperscript{131} whereas others describe recurrence of firmness in 31% to 80% after closed capsulotomy.\textsuperscript{61,114,160} Planas et al.\textsuperscript{164} advocated the use of external ultrasound to prevent recurrence of contracture after closed capsulotomy and reported a success rate of 82% in cases treated 12 months after capsulotomy.

Closed capsulotomy is associated with complications such as hematoma, implant rupture, gel migration, dumbbell deformity, and incomplete rupture of the capsule.\textsuperscript{165,166} A combined report of 750 plastic surgeons showed an overall complication rate of 10% after closed manipulation of implants in the treatment of contracture.\textsuperscript{166,167} Extracapsular rupture seems to be associated with a history of closed capsulotomy;\textsuperscript{167} more than 50% of women found to have ruptured implants during
This observation is not surprising considering that the manual force (pounds per square inch) applied during closed capsulotomy almost always exceeds the breaking strength of most implants. In 1999, the Institute of Medicine of the National Academies of Science released its final report after 2 years of investigation of silicone implants. The committee did not recommend closed capsulotomy for the treatment of capsular contracture.

Open Capsulotomy and Capsulectomy—A capsule can be surgically scored in several places, partially stripped, or totally excised. The overall results of open capsulotomy and implant replacement using primarily gel-filled smooth-surfaced implants have been disappointing, with recurrence of contracture in 37% to 89% of patients.

The indications for capsulectomy are ill-defined and not universally accepted. The recommendations presented by Young for post-augmentation prosthesis explantation (Table 8) and capsulectomy (see list below) are the perspective of one surgeon and not a consensus. Young presented the following guidelines for capsulectomy during explantation:

- No replacement of explanted implant or tissue expander
- Exchange for new implant in a different tissue plane
- Exchange for larger volume implant
- Replace smooth implant with textured implant
- Explantation of polyurethane-covered shell
- Capsular contracture (Baker grades III and IV)
- Calcified or thick fibrous capsule
- Infection

Collis and Sharpe found a significantly lower rate of recurrent contracture when implant exchange was combined with total capsulectomy (P < 0.001). It is possible, according to Yu et al., to endoscopically extract and replace encapsulated implants via axillary incision without the need for additional scarring in patients whose implants were originally inserted via transaxillary incision.

Revision with Dual-plane or Submuscular Technique—Spear et al. noted that they prefer to correct capsular contracture by exchanging the implant and converting its position to a dual plane. The authors reviewed their 7-year experience in 85 patients who had a long-standing history of capsular contracture and who were treated by this technique. The original implants had been placed either subglandularly or submuscularly and were either silicone gel- or saline-filled. The original implants were removed, the pocket was converted to a dual-plane configuration, and new implants were inserted. The most frequent (3.5%) complication that occurred was implant malposition requiring reoperation. One year after surgery, only 2% of patients had Baker grade II capsular contracture; the remainder had Baker grade I. These data suggest that established capsular contracture can be effectively treated with implant exchange and conversion to a dual-plane pocket.

Ventura et al. converted subglandular implants with fibrous capsules to submuscular implants. After explantation, the authors performed a partial capsulectomy, leaving the portion of the capsule from the deep plane intact as a “patch.” The capsule was placed in a submuscular pocket, and the patch was sutured to the pectoralis muscle. To avoid flattening, the authors used an electroscalpel to make incisions on the patch in a mesh pattern until they reached the muscle fiber plane. They suggested that this approach promotes adherence of the implant to the muscle, permits future access to the retromuscular space without injuring the muscle, and increases projection of the implant.
Implant Repositioning—Xue and Lee\textsuperscript{176} reported good outcomes with a minimally invasive procedure that left the capsule in situ in 14 patients with Baker grade III or IV capsular contracture. With this procedure, the authors first performed a blunt dissection in all planes around the capsule and then made an incision in the capsule to remove the implant. The implant was then repositioned anterior to the primary capsule, without removing it from the cavity unless there was suspicion of leak or infection. The entire procedure was performed through the original transaxillary or submammary incisions. All 14 patients achieved Baker grade I and were satisfied with results.

Lee et al.\textsuperscript{177} also reported success with a technique that involves repositioning the implant and leaving the capsule in situ. The authors first separated the posterior surface of the pectoralis muscle and the anterior surface of the capsule. After exposing the anterior of the capsule, they made a central incision in the capsule to remove the implant. They irrigated the interior of the capsule with normal saline and Betadine and then sutured the anterior and posterior capsule walls to prevent seroma formation and implant migration. The implant was then repositioned anterior to the capsule. They used this technique in 74 patients (139 breasts), 51 with capsular contracture and 23 with implant malposition. The only complication was hematoma in two patients. Three patients subsequently experienced recurrence of Baker grade III capsular contracture.

Pharmacological Treatments for Capsular Contracture—Several recent investigations have explored pharmacological options for management of capsular contracture. In a rat model, the anti-fibrotic, anti-inflammatory agent pirfenidone reduced capsule thickness, proliferation of fibroblast-like cells, and recruitment of inflammatory cells.\textsuperscript{178} Leukotriene antagonists showed some benefit in a small retrospective study (montelukast; N = 19)\textsuperscript{179} and a larger prospective controlled study (zafirlukast; N = 120).\textsuperscript{180} In an open-label, prospective, controlled pilot study, oral pirfenidone, a wide-spectrum anti-fibrotic drug, eliminated or reduced capsular contracture, even in patients with grade III or IV at baseline.\textsuperscript{181} French researchers found that Flector Tissugel

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Table 8
Guidelines for Explantation and Replacement: Capsulotomy Optional\textsuperscript{171}
(Laboratoires Genévrier, Sophia Antipolis, France)—an adhesive patch that releases the nonsteroidal anti-inflammatory drug diclofenac epolamine—placed over the breast reduced capsular contracture, particularly in women with grade II contracture or with grade III contracture of longer than 10 months’ duration.182 Percutaneous injections of triamcinolone acetonide between implant and capsule produced some relief in the form of reduced discomfort and capsular thickness in a small series of patients with grade IV contracture.183 Large, prospective, randomized trials are needed before any of these therapies can be recommended.

Surgical Complications

Hematoma

Williams141 reported a hematoma rate of 3% in more than 600 breast augmentations. Alderman et al.184 found the incidence of hematoma to be 0.5% and 0.9% in two national databases of 70,749 women who underwent single or combined breast augmentation procedures. Substantial hematomas are associated with wound infection and capsular firmness and should be surgically evacuated.94,121 One study showed that 86% of patients with postoperative hematomas developed capsular contracture.159 Although the majority of hematomas occur during the immediate postoperative period, delayed-onset hematomas have rarely been reported, with some occurring years after breast augmentation or reconstruction.185

Seroma

Periprosthetic seromas usually resorb within 4 or 5 days.186 A persistent seroma should be drained under ultrasound control.187 Excessive use of electrocautery and concentrated antibiotic irrigations intraoperatively have been linked to seroma formation.188,189

Although late seroma is rare (0.1%–1.7%),190–192 it has recently drawn considerable attention because development of spontaneous seroma around the implant has been a common finding in cases of anaplastic large-cell lymphoma (ALCL).193 Late (≥1 year after augmentation) development of seroma should be managed with ultrasound-guided aspiration of fluid with cultures, cell count, and cytological testing,190 including appropriate staining for markers of lymphoma.193 Other causes of late seromas include sliding, shearing, and rubbing motions and a fold in the implant.191,192

Wound Infection

The 2011 FDA safety update194 noted that wound infections occur in up to 5% of breast-implant study participants, making it one of the most common short-term local complications along with hematoma. Two-thirds of infections occur shortly after surgery and usually are caused by skin pathogens such as group A streptococci, S. epidermidis, or S. aureus. However, infections can develop years or even decades after surgery. Long-term infections are more likely to be caused by aerobic gram-negative bacilli.194

It has been common practice to use cephalosporins for perioperative prophylaxis. However, considering the recent increase in methicillin-resistant S. aureus, empiric use of an antibiotic with coverage of methicillin-resistant S. aureus is justifiable.195 A retrospective review of 26 patients with 31 infected breasts from 2001 through 2006 found S. aureus in 21 (68%) of the infected breasts. Of these, 14 (68%) were methicillin resistant.195

Courtiss et al.121 reported a wound infection rate of 2.2% in 899 breast augmentation cases. The infection typically became evident at a mean 12 days postoperatively. Treatment consisted of drainage of the implant pocket and administration of appropriate systemic antibiotics after culture. Sixteen of 29 implants were salvaged with this protocol. The most common pathogen was S. aureus.

Toxic shock syndrome occurring after infection around a breast implant has been reported.196,197 The infecting organism in these
cases was *S. aureus*. Other rare pathogens isolated from implant infections include *Candida albicans*,198 *Curvularia spp.*,199 *Aspergillus niger*,200,201 mycobacteria,202–205 and *Clostridium perfringens*.206

The NAC has to be considered as a legitimate source of bacterial contamination during breast augmentation surgery because the lactiferous ducts connect directly with the skin through the nipple. Positive cultures from the NAC have been obtained in more than 90% of samples.207

**Decreased Nipple Sensation**

The NAC is innervated by a lateral branch of the fourth intercostal nerve with overlapping contributions from the anterior and lateral cutaneous branches of the IIIrd through Vth intercostal nerves.208 The nerves parallel corresponding arteries of the same name. The anterior branches of these neurovascular bundles must be preserved to ensure nipple sensation; this is accomplished by displacing them laterally with blunt dissection.209 The nerve branches are more easily mobilized in the subpectoral plane than in the subglandular plane because they become more fixed as they pass through the deep fascia into the glandular breast tissue and are therefore more likely to be injured during extensive electrocautery or sharp dissection of the lateral breast pocket. Early reviews show an incidence of diminished nipple sensation after breast augmentation averaging approximately 15%.113,208

**Galactorrhea**

Spontaneous lactation is a rare complication of aesthetic breast surgery.210–213 It is thought to be caused by transection or irritation of the thoracic nerves during dissection, triggering impulses that travel via the dorsal nerve roots to the hypothalamus and pituitary to stimulate a rise in prolactin secretion. Prolactin elevation in the presence of falling estrogen and progesterone levels (in a menstrual cycle regulated by birth control pills) can bring about spontaneous lactation 1 to 2 weeks after surgery.

The galactorrhea is effectively treated with bromocriptine to suppress prolactin secretion.214 Intercostal nerve blocks have also been suggested to interrupt the afferent pituitary stimulation.215,216

**Pain**

In a survey of patients from Denmark who had undergone breast augmentation, 44.2% reported pain, which was moderate to severe in 9.5%.217 Patients with pain were less likely to be satisfied with the surgery, and 6.3% of respondents regretted the surgery because of the pain.

Pain after breast augmentation is most often associated with severe capsular contracture. Another possible cause is neurapraxia of the IVth intercostal nerve secondary to the dissection. The discomfort usually resolves spontaneously within 6 months.

Huang218 presented a report of eight patients who after breast augmentation complained of pain specific to the lateral breast mound and subscapular area and who exhibited an unsightly inferolateral bulge. Surgical exploration revealed that the serratus anterior muscle was detached from the rib beyond the posterior axillary line in every case. All patients were relieved of their symptoms after removal of the implants or repair of the defect in the lateral wall of the submuscular pocket.

Randomized prospective controlled trials have reported that pocket irrigation with bupivacaine and ketorolac reduces pain during the first few hours to days after submuscular breast augmentation;219,220 however, results have been mixed regarding whether this practice reduces or increases need for narcotic analgesics during the same time period.219,220

**Symmastia**

Symmastia after breast augmentation is the result of migration across the midline of one or both implants221 from over-dissection of the pocket medially, which is a technical error. Symmastia is avoidable with appropriate preoperative planning, implant selection, and surgical execution.
Spear et al. analyzed a series of 20 patients treated for symmastia and noted that 60% had excessively large (>400 mL) and wide (base width ≥14 cm) implants. The authors listed the following risk factors for symmastia after breast augmentation: 1) excessively large implants; 2) disproportionately wide implants for the patient’s chest wall dimensions; 3) chest wall skeletal deformities (e.g., thoracic hypoplasia, pectus excavatum); and 4) simultaneous mastopexy and augmentation.

The correction of symmastia is very challenging. Some surgeons recommend maintaining the pectoral muscle fascia attachments medially during the augmentation procedure to avoid visible rippling and symmastia later. However, symmastia can develop even when the fascia is intact as long as the medial sternal attachments of the muscle are aggressively released. Spear et al. suggested that symmastia can be corrected in a simple, one-stage procedure by creation of a neosubpectoral pocket between the pectoralis major and the anterior implant capsule wall (Fig. 6).

Other variants of displacement complications include IMF malposition and double-bubble deformities. IMF malposition is affected by fold asymmetries preoperatively; lower pole stretch; implant style, type, and size; and pocket location. Double-bubble deformities can be caused by a mismatch between the implant diameter and the breast base width. They can also occur with IMF malposition coupled with submuscular implants or with subglandular implants in constricted breasts.

**Rippling**

Rippling can occur from underfilling or traction. Underfill rippling occurs in the upper pole of the breast because of folds in the implant shell. Traction rippling occurs when bands of scar tissue form between the implant, capsule, and overlying dermis. It can be avoided by ensuring adequate soft-tissue coverage, precise pocket dissection, and appropriate size of implants. Traction rippling often is associated with textured implants.

**Effects on Lactation and Breast-feeding**

Most women who undergo breast augmentation are in their reproductive years, yet the effect of the surgery on future breast-feeding ability is seldom discussed. Breast milk has nutritional and immunological properties that make it superior to infant formulae. Breast-fed babies have enhanced protection against eczema, otitis media, asthma, diabetes mellitus, and iron-deficiency anemia. Breast-feeding also assists with the infant’s digestion, neural development, and overall growth. Women who undergo breast augmentation are unlikely to produce adequate milk to nourish an infant without supplementation. This condition is called lactation insufficiency. Cruz and Korchin retrospectively compared breast-feeding outcomes between 105 women with saline implants who subsequently gave live birth and 107 small-breasted women of similar age. They found that the control group without implants were more likely to succeed at breast-feeding (88%...
Figure 6. Technique for correction of symmastia. A, Relationship of breast implant and various layers of soft tissue as present preoperatively. B, Neosubpectoral plane is shown located between anterior surface of implant capsule and posterior surfaces of pectoralis major muscle superiorly and breast parenchyma inferiorly. Dissection is performed and neosubpectoral space created with previously described dual-plane technique. C, Implant is shown in neosubpectoral space on top of obliterated old implant space. (Reprinted with permission from Spear et al.)
versus 63%; \(P < 0.05\) and less likely to supplement with formula (27% versus 46%; \(P < 0.05\)). The outcomes were not significantly different between the subgroups of women who had inframammary versus periareolar incisions (\(P > 0.05\)).

Lactation is a complex process mediated by the hormones prolactin and oxytocin. With breast-feeding, the act of an infant suckling the nipple stimulates the production of prolactin, which fills the breast with milk via a process called lactogenesis, in preparation for the next feed. Oxytocin is also released, which triggers milk letdown. Nipple sensation and the afferent limb of the suckling reflex can be substantially altered by breast augmentation surgery, particularly when the periareolar approach is used. The periareolar approach also leads to direct damage of glandular tissue: the severed lactiferous ducts cannot empty properly and eventually atrophy, further decreasing total milk production. Women who have undergone periareolar breast augmentation are five times more likely to experience lactation insufficiency.

Up to 20% of women who have had breast augmentation experience discomfort for 5 years or longer, making breast-feeding uncomfortable. Other identified risk factors for postoperative lactation difficulties are capsular contracture, hematoma, tissue atrophy, infection, and multiple revision operations.

**Rupture**

Ruptures of both saline- and silicone gel-filled implants have been reported. Technical errors are the primary reason for implant failure. Nicking the shell with a needle, forceps, retractor or other instrument or forcing it through too small an incision can weaken the shell or damage the internal gel.

Silicone Implants—The rupture of silicone gel-filled implants is of much greater concern because of the possibility of gel migration outside the breast capsule. Dowden describes degrees of escape of silicone gel from a prosthesis as follows:

A *leak* occurs when a small amount of gel passes through a small detectable hole in the shell. This results in a thin coating of gel around the external surface of the shell.

A *rupture* occurs when there is a major tear and a significant amount of gel migrates out of the shell but is still confined to the capsule.

An *extrusion* is displacement of gel outside the capsule into adjacent tissue.

Silicone implant ruptures are described as *intracapsular* or *extracapsular* based on the integrity of the capsule.

Dragu et al. presented a report of six patients who experienced bilateral rupture of silicone implants after breast augmentation. Five had peripheral cutaneous siliconoma that required surgical excision, and one developed intrapulmonary siliconoma that necessitated a lobectomy with resection of segment 10.

Silicone oil diffusing out of the semipermeable implant envelope is called *silicone bleed* and is considered a normal process of all silicone implants. The amount of oil bleed varies with implant age, brand, and gel characteristics. Some silicone implants from the 1980s contained a fluorinated silicone shell that significantly decreased the amount of gel bleed.

The true prevalence of implant rupture is
unknown but seems to be mainly related to time since implantation. With increasing implant age, the strength and elasticity of the implant shell decrease, although the specific in vivo conditions that cause the weakening remain unknown. Some surgeons think that lipid infiltration of the implant shell is responsible, whereas others hypothesize that swelling of the elastomer shell by silicone fluid is the cause. Surgical trauma during the insertion process can also weaken the implant shell.

Robinson et al. reviewed the records of 300 consecutive patients at the time of implant removal and noted that 63.5% of implants were disrupted. They concluded that most implants lose their integrity between 8 and 14 years after placement. Cohen et al. examined 350 gel implants at the time of open capsulotomy or implant exchange and also noted a rupture rate of 63% among implants that had been in place for longer than 12 years.

Other risk factors for rupture include implant type, degree of contracture, and patients’ habits. The data on implant rupture are very difficult to interpret because there are many variables involved, most notably implant characteristics and generations. The thin-walled, second-generation implants exhibit the highest rate of rupture. Collis and Sharpe reviewed data from 478 explanted prostheses and reported a 33.7% overall rupture rate: 33% for first-generation implants, 65% for second-generation implants, and 9% for third-generation implants. These data suggest that the newer generation, thicker-shelled implants resist rupture better.

Intracapsular ruptures account for 80% to 90% of detected implant ruptures. Although intracapsular ruptures do not pose a danger to the patient, the FDA recommends removal of the implant. Extracapsular rupture and gel migration can lead to silicone granulomas. In the meta-analysis conducted by Marotta et al., the incidence of implant-related complications that required surgical correction was 33% during the first 6 years.

Diagnosis of Rupture—Many ruptured silicone implants are silent and are discovered only at the time of routine mammography (MMG) or implant exchange. MRI, MMG, ultrasonography, and CT can be used to detect ruptured silicone implants. Each method has advantages and disadvantages, as discussed below. When choosing a diagnostic technique for a patient, other considerations include the cost of the test, its availability, the expertise of the radiologist, and potential contraindications or patient limitations.

MRI: The FDA-approved labeling for silicone implants recommends MRI 3 years after breast augmentation surgery and every 2 years thereafter, unless contraindicated. MRI has the highest (>90%) sensitivity for detection of silicone implant rupture. In a direct comparison of MRI, MMG, and ultrasonography, sensitivity was 93%, 68%, and 77%, respectively, and specificity was 73%, 81%, and 69%, respectively.

However, McCarthy et al. have criticized the FDA recommendations for lacking supportive evidence, showing that use of MRI to screen for implant rupture leads to a reduction in morbidity. They recommend “shared decision making” that takes into account the patient’s values and health preferences and the risks and costs of MRI.

MRI evaluation might not be an option for all patients because of its cost or contraindications. Patients who have pacemakers, aneurysm clips, or other metallic foreign bodies and patients who are claustrophobic are not candidates for MRI. Some patients are not candidates because their size or weight precludes MRI.

Accuracy of MRI might be lower in cases of asymptomatic ruptures compared with symptomatic ruptures. MRI can detect both intracapsular and extracapsular ruptures. The entire implant, and especially the tissue in close proximity to the chest wall that can be difficult to appreciate with other imaging techniques, can be visualized in multiple
planes with MRI. The unique frequency of silicone on T1- and T2-weighted imaging makes for excellent images in diagnosing implant rupture, and MRI does not use ionizing radiation.

High-resolution images are optimized with specialized breast coils that suspend the breast and minimize breathing artifacts. The breast coil raises sensitivity in detecting implant rupture to the 95% to 100% range. The most reliable sign of intracapsular rupture is the “linguine sign,” defined as the presence of multiple, curvilinear, low-signal-intensity lines within the silicone gel.

Extracapsular implant rupture is diagnosed when focal areas of high-signal-intensity representing free silicone are seen beyond the capsule and in the surrounding tissue. The linguine sign is also frequently seen in extracapsular rupture and is relatively more common in second-generation implants filled with a less-viscous gel.

Rupture from a silicone implant that has not collapsed is an intracapsular rupture and is defined as a tear of the silicone implant shell without collapse or with only partial collapse of the implant. The teardrop sign will be present when free silicone enters a radial fold in the implant shell (Fig. 7). Ruptures from silicone implants that have not collapsed often result from focal tears that can easily be missed on gross inspection of the implant. Third-generation and newer implants have thicker, more viscous gel and are more likely to produce the teardrop sign when ruptured.

**MMG:** Breast implants can be examined for potential changes during the annual mammogram. With traditional mammographic views, only a limited amount of breast tissue can be visualized: 56% and 75% with subglandular and submuscular implants, respectively. The Eklund displacement views—manually pushing the implant toward the chest while selectively compressing the breast—increase the amount of breast tissue that can be evaluated to 64% and 85%, respectively.

MMG effectively visualizes the breast parenchyma; therefore, any extracapsular silicone can be easily detected. However, it should be noted that MMG does not detect intracapsular ruptures, which account for a majority of ruptures. Mammographic features that are not specific to implant rupture include a measurable dense periprosthetic band or rim of tissue that might correlate with the implant capsule, periprosthetic calcification, asymmetry of implant size or shape, or focal herniation of the implant. Reports of implant rupture from the compressive forces of the MMG technique have been published for both saline- and silicone gel-filled implants.

A study by Nemecek and Young found 62% sensitivity and 82% specificity for mammograms in cases of implant rupture after augmentation. The overall accuracy was 73%. Ruptures were more easily detected in subglandular implants than in those placed beneath the muscle.

**Ultrasonography:** Reports of the effectiveness of ultrasonography in detecting implant failure

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*Figure 7. Rupture of implant shell without complete collapse. Teardrop signs (arrows) indicate silicone within a radial fold and outside implant lumen. (Reprinted with permission from Gorczyca et al.)*
range from 32% to 74% sensitivity.\textsuperscript{261–264,273–276} Operator experience, type of equipment used, and other technical factors possibly account for the spread.\textsuperscript{260} Ultrasonography also requires real-time evaluation for best results and has a steep learning curve.

Ultrasonography is relatively inexpensive compared with MRI and CT, can be used for women who are claustrophobic and for those for whom MRI is contraindicated, and does not involve ionizing radiation. Small amounts of free silicone in breast parenchyma or axillary lymph nodes can be identified with ultrasonography.\textsuperscript{256}

Reliable signs of rupture observed with ultrasonography include hyperechoic or hypoechoic masses, dispersion of the sonographic beam ("snowstorm sign"), and multiple parallel echogenic lines within the implant interior ("stepladder sign").\textsuperscript{251,254,268,274,276–280} The stepladder sign is the most consistent sign of implant rupture.\textsuperscript{260} The parallel echogenic lines represent the collapsed implant membrane floating within the silicone gel and is analogous to the linguine sign on MRI.

Extracapsular rupture is diagnosed when there are focal nodules of free silicone in the breast parenchyma.\textsuperscript{260} In this case, the snowstorm sign stems from increased echogenicity of the breast tissue and loss of normal parenchymal interfaces resulting in dispersion of the ultrasound beam. The nodules represent silicone granulomas.

Ultrasonography is limited in evaluating the posterior wall of the implant and adjacent soft tissue deep to it because of attenuation of the beam by silicone.\textsuperscript{274} Reverberation artifacts can be mistaken for echoes and can result in false positive findings. Ultrasonography sensitivity decreases substantially in the presence of a contracted capsule,\textsuperscript{281} in cases of Baker grade III or IV contracture, CT or MRI is preferable.

Bengtson and Eaves\textsuperscript{282} recently reported encouraging results from phase I, II, and III trials of high-resolution ultrasonography in visualizing and evaluating the integrity of fourth- and fifth-generation silicone gel implants. Phase I \textit{in vitro} and \textit{ex vivo} assessments showed that all high-resolution ultrasonography equipment platforms and most transducer heads evaluated were successful in detecting intact and intentionally damaged shells in various fourth- and fifth-generation implants. The phase II study, which evaluated high-resolution ultrasonography to assess previously diagnosed unilateral implant failure in three patients, found that the method correctly identified implant rupture, consistent with MRI and surgical findings in all patients. The phase III prospective comparison of radiologist-performed high-resolution ultrasonography, surgeon-performed high-resolution ultrasonography, and MRI found that all methods accurately predicted implant status in all 29 breasts imaged, which was confirmed by surgery in symptomatic and asymptomatic patients. A phase IV prospective trial is ongoing to determine the sensitivity and specificity of high-resolution ultrasonography in evaluating current implant designs. Bengtson and Eaves noted that the relative affordability, accessibility, availability, and dynamic real-time visualization provided by HRUS represent important potential advantages over MRI in screening and in future diagnosis of breast implant shell failure.

\textbf{CT:} CT is an alternative diagnostic modality for patients for whom MRI is contraindicated. The radiological findings and diagnostic accuracy of CT in cases of intracapsular rupture are similar to those of MRI\textsuperscript{260} (i.e., collapse of the implant shell creating the classic linguine sign).\textsuperscript{251,254,258,260,283} Extracapsular ruptures can be difficult to appreciate on CT scans because of the poor soft-tissue differentiation of CT imaging; Hounsfield units are similar between silicone and soft tissues.\textsuperscript{260} Nevertheless, most extracapsular ruptures can be identified by the collapsed implant shell. CT uses ionizing radiation, a possible contraindication in young patients.\textsuperscript{260}
EVOLUTION OF SILICONE IMPLANTS

Maxwell and Baker\textsuperscript{284} identified five generations of silicone gel implants on the basis of gel viscosity and properties of the elastomer shell (Table 9). The third generation of implants was developed in the mid-1980s in an attempt to strengthen the shell and minimize the silicone bleed phenomenon.

When a textured surface was added, the resulting implants were fourth-generation devices. Cohesive silicone gel implants are considered fifth-generation devices.

The extent of cross-linking of the silicone polymers during implant manufacture determines the firmness of the silicone gel. A cohesive gel

### Table 9

**Evolution of Silicone Gel-Filled Breast Implants\textsuperscript{284}**

<table>
<thead>
<tr>
<th>Implant Generation</th>
<th>Years</th>
<th>Description</th>
</tr>
</thead>
</table>
| First              | 1962–1970     | - Thick two-piece shell  
                      - Smooth surface with Dacron fixation patches 
                      - Anatomically shaped (teardrop)  
                      - Viscous silicone gel |
| Second             | 1970–1982     | - Thin slightly permeable shell  
                      - Smooth surface (no Dacron patches)  
                      - Round shape  
                      - Less viscous silicone gel |
| Third              | 1982–1992     | - Thick, strong, low-bleed shell  
                      - Smooth and textured surfaces  
                      - Round shape  
                      - More viscous silicone gel |
| Fourth             | 1993–present  | - Thick, strong, low-bleed shell  
                      - Smooth and textured surfaces  
                      - Round shape  
                      - More viscous, cohesive silicone gel  
                      - Refined manufacturing processes |
| Fifth              | 1993–present  | - Thick, strong, low-bleed shell  
                      - Smooth and textured surfaces  
                      - Round and diverse anatomic shapes  
                      - Enhanced cohesive and form-stable silicone gel |
implant is “form-stable,” meaning that cross-linking is to such a degree that the gel—now a semi-solid—maintains its shape and the shell does not fold regardless of what happens to the implant. Implants marketed before 1993 were not cohesive. Cohesive breast implants have been nicknamed “gummy bear breast implants” and are popular in Europe. In the United States, the first cohesive form-stable silicone gel implants received FDA approval in March 2012. Clinical trial data on these implants are reviewed in the following section.

Modern Silicone Implants

The two largest American manufacturers of silicone breast implants are the Mentor Corporation (Santa Barbara, CA) and Allergan (Irvine, CA; formerly Inamed). These companies conducted extensive pre-market approval studies of smooth, textured round, and textured anatomic prostheses, which in large part formed the basis for the FDA’s reinstatement of silicone gel implants for primary breast augmentation in 2006. The results of these studies are summarized below.

Anatomic silicone implants are available in Europe, Brazil, Canada, and, most recently, the United States. Sientra Inc. (Santa Barbara, CA) is the American manufacturer of the cohesive form-stable silicone gel breast implants that were recently granted FDA approval. With the exception of these implants, in the United States, all other anatomic implants currently are available in saline only. Results of the data on the anatomic silicone implants currently in clinical trials are nonetheless provided below for completeness.

Sientra Silicone Gel Implants

Sientra’s form-stable silicone gel implants are available in round or shaped profiles with smooth or textured surfaces and with low, moderate, or high projections. Extensive silicone cross-linking allows these form-stable implants to retain their shape when in the vertical position. Stevens et al. conducted a prospective study of 355 patients who received Sientra’s form-stable silicone gel implants for either augmentation or reconstruction. The overall complication rate was 9.6% per patient or 4.8% per implant. Cosmetic revisions were performed in 7.6% of patients, largely for size change. Capsular contracture occurred in 1.4% of patients and 0.7% of implants and accounted for all implant-related revision operations.

Data from the ongoing, 10-year, open-label, prospective clinical trial required by the FDA as a condition of approval are available through 5 years. Of the 1788 patients enrolled, 1116 had primary augmentation, 363 had revision augmentation, 225 had primary reconstruction, and 84 had revision reconstruction. Approximately one-third of patients undergo serial MRI to assess for silent rupture. The 5-year complication profiles for the primary and revision augmentation groups are shown in Table 10.

The Baker grade III or IV contracture rate was 8.8% for the primary augmentation group and 7.9% for the revision augmentation group. The implant rupture rate was 2.0% for the primary augmentation group and 1.5% for the revision augmentation group. The reoperation rate was 16.6% for primary augmentation and 29.7% for revision augmentation. The most common reasons for reoperation across all groups were implant style or size change (19%), capsular contracture (17.6%), and asymmetry (9.5%).

Allergan Silicone Gel Implants

Allergan’s Round Implants—Allergan’s round silicone gel implants are available in smooth or textured surfaces and in four profiles (moderate, midrange, high, and full). According to the manufacturer, these implants feature a taper-cut patch hole that reduces patch thinning, a 360° barrier shell designed to reduce silicone diffusion, and cross-linked silicone polymer that minimizes creasing and promotes a more cohesive structure in the event the shell is compromised.
Table 10
Complications at 5 Years Based on Kaplan-Meier Analysis of Patients Who Received Sientra Form-Stable Silicone Gel Implants

<table>
<thead>
<tr>
<th>Local Complication</th>
<th>Primary Augmentation (n = 1116)</th>
<th>% (95% CI)</th>
<th>Revision Augmentation (n = 363)</th>
<th>% (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymmetry</td>
<td>1.2 (0.7–2)</td>
<td></td>
<td>2.5 (1.2–4.9)</td>
<td></td>
</tr>
<tr>
<td>Breast mass, cyst, or lump</td>
<td>1.7 (1–2.8)</td>
<td></td>
<td>0.8 (0.2–3.1)</td>
<td></td>
</tr>
<tr>
<td>Breast pain</td>
<td>0.9 (0.4–1.6)</td>
<td></td>
<td>1.6 (0.7–3.8)</td>
<td></td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>8.8 (7.2–10.8)</td>
<td></td>
<td>7.9 (5.4–11.6)</td>
<td></td>
</tr>
<tr>
<td>Hypertrophic or abnormal scarring</td>
<td>0.9 (0.5–1.8)</td>
<td></td>
<td>1.7 (0.7–4)</td>
<td></td>
</tr>
<tr>
<td>Implant extrusion</td>
<td>0.1 (0–0.7)</td>
<td></td>
<td>0.9 (0.3–2.9)</td>
<td></td>
</tr>
<tr>
<td>Implant malposition</td>
<td>1.9 (1.2–2.9)</td>
<td></td>
<td>4.8 (2.8–8)</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>0.8 (0.4–1.6)</td>
<td></td>
<td>1.5 (0.6–3.6)</td>
<td></td>
</tr>
<tr>
<td>Nipple sensation changes</td>
<td>3.4 (2.4–4.7)</td>
<td></td>
<td>2.3 (1.1–4.8)</td>
<td></td>
</tr>
<tr>
<td>Rupture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>2 (1.3–3.2)</td>
<td></td>
<td>1.5 (0.6–3.8)</td>
<td></td>
</tr>
<tr>
<td>MRI cohort only</td>
<td>4.2 (2.6–6.7)</td>
<td></td>
<td>2.8 (0.9–8.4)</td>
<td></td>
</tr>
<tr>
<td>Ptosis</td>
<td>2.6 (1.8–3.9)</td>
<td></td>
<td>3.3 (1.7–6.2)</td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td>0.5 (0.2–1.2)</td>
<td></td>
<td>0.6 (0.2–2.5)</td>
<td></td>
</tr>
<tr>
<td>Seroma or fluid accumulation</td>
<td>0.7 (0.3–1.4)</td>
<td></td>
<td>1.6 (0.7–3.9)</td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td>0.8 (0.4–1.6)</td>
<td></td>
<td>0.3 (0.1–2.4)</td>
<td></td>
</tr>
<tr>
<td>Upper pole fullness</td>
<td>0.1 (0–0.8)</td>
<td></td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Wrinkling or rippling</td>
<td>1 (0.6–1.9)</td>
<td></td>
<td>3 (1.6–5.5)</td>
<td></td>
</tr>
</tbody>
</table>

CI, confidence interval; MRI cohort, those patients who underwent serial magnetic resonance imaging to assess for silent rupture.
Spear et al.\textsuperscript{290} reviewed the 6-year, 715-patient data for round silicone gel implants from the Inamed Silicone Breast Implant U.S. Study Group. Among the women studied, 455 (64\%) had undergone primary breast augmentation and 147 (21\%) had undergone revision augmentation. Approximately one-third of patients are undergoing serial MRI to detect silent rupture. The complication profiles of these cohorts are shown in Table 11.

The Baker grade III or IV capsular contracture rate was 14.8\% in the primary augmentation group and 20.5\% in the revision augmentation group. The implant rupture rate was 5.5\% for primary augmentation and 2.3\% for revision augmentation. The reoperation rate was 28\% for primary and 40.3\% for revision augmentation, and the primary reason for reoperation was capsular contracture.

Allergan’s Anatomic Implants—As noted above, Allergan’s anatomic implants currently are available only outside the United States or in clinical trials. Style 410 is the best studied of Allergan’s anatomic implants. These implants are available in various sizes, have maximal projection in the lower pole, provide lower pole fullness, and have a textured surface. Style 410 implants contain highly cohesive gel and are said to be form-stable, even in the event of a rupture,\textsuperscript{54} but projection does change with body position. Weum et al.\textsuperscript{291} found that in the supine position, dimensions are comparable to those specified by the manufacturer but in the prone position, projection increases by an average of 29.5\%.

Maxwell et al.\textsuperscript{292} recently reported the data on Style 410 obtained from a prospective, nonrandomized, pre-market approval study required by the FDA, which is through the 6th year of the expected 10 years of follow-up. A total of 941 patients have been enrolled, including 492 patients undergoing primary augmentation and 156 patients undergoing revision augmentation. Approximately one-third of the patients underwent serial postoperative MRI evaluations as surveillance for implant rupture. The complication profiles for these cohorts are shown in Table 12.

The Baker grade III or IV contracture rate was 4.6\% for the primary augmentation group and 6.9\% for the revision augmentation group. The implant rupture rate across all cohorts was 6.4\% by patient and 3.8\% by implant. The reoperation rate was 19.4\% for patients who had undergone primary augmentation and 35.1\% for those who had undergone revision augmentation. The primary reason for reoperation was implant style or size change in the primary augmentation group and implant malposition in the revision augmentation group.\textsuperscript{292}

Malposition is typically attributable to rotation of anatomic implants, the risk of which can be increased by large pocket size, the presence of capsular fluid, double capsules, periprosthetic mesh, prosthetic massage, and implantation into the submuscular plane.\textsuperscript{54} Schots et al.\textsuperscript{293} reported a particularly high rate of rotation (8.2\%) with Style 510 implants during a mean follow-up of 21.9 months. Furthermore, Style 153, which was a double-lumen anatomic implant, was removed from the market because of a high rate of rupture (19.1\% with >6 years of follow-up) resulting from a design flaw.\textsuperscript{294}

Hedén et al.\textsuperscript{295} published one of the largest series to date on the outcome of breast augmentation with anatomic cohesive gel implants. Of the total 1676 prostheses implanted, the authors reported a 4.2\% capsular contracture rate, <1\% rotation, and <1\% rupture. A subsequent review of 286 breast augmentations with Style 410, cohesive, fourth-generation implants\textsuperscript{296} showed a 5.6\% capsular contracture rate and 0.3\% incidence of rupture. The mean follow-up duration was 6 years.

\textit{Mentor Silicone Gel Implants}

\textbf{Mentor’s Round Implants}—Mentor’s round silicone implants also come in a choice of smooth or textured surface and three projections (moderate, moderate plus, and high).\textsuperscript{297} According to the
### Table 11
Complications Associated with Primary and Revision Breast Augmentation

<table>
<thead>
<tr>
<th>Complication</th>
<th>Primary Augmentation (n = 455) % (95% CI)</th>
<th>Revision Augmentation (n = 147) % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key risks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation</td>
<td>28 (24−32.5)</td>
<td>40.3 (32.5−49.1)</td>
</tr>
<tr>
<td>Implant removal with replacement</td>
<td>10 (7.4−13.2)</td>
<td>18.6 (12.8−26.5)</td>
</tr>
<tr>
<td>Implant removal without replacement</td>
<td>2.8 (1.6−5)</td>
<td>4.4 (1.9−10.4)</td>
</tr>
<tr>
<td>Implant rupture</td>
<td>5.5 (2.8−10.7)</td>
<td>2.3 (0.3−15.4)</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baker grade III or IV</td>
<td>14.8 (11.7−18.5)</td>
<td>20.5 (14.5−28.6)</td>
</tr>
<tr>
<td><strong>Additional risks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast pain</td>
<td>9.6 (7.2−12.8)</td>
<td>9.6 (5.6−16)</td>
</tr>
<tr>
<td>Swelling</td>
<td>8.3 (6.1−11.3)</td>
<td>7.3 (4−13.2)</td>
</tr>
<tr>
<td>Implant malposition</td>
<td>5.2 (3.5−7.7)</td>
<td>6.2 (3.1−12)</td>
</tr>
<tr>
<td>Hypertrophic or abnormal scarring</td>
<td>3.7 (2.3−6)</td>
<td>6.1 (3.1−11.7)</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>3 (1.8−5.1)</td>
<td>3.7 (1.6−8.7)</td>
</tr>
<tr>
<td>Implant palpability or visibility</td>
<td>1.6 (0.8−3.4)</td>
<td>7.5 (4.1−13.6)</td>
</tr>
<tr>
<td>Wrinkling or rippling</td>
<td>1.2 (0.5−2.9)</td>
<td>3.9 (1.7−9.2)</td>
</tr>
</tbody>
</table>

CI, confidence interval.
* occurring in >5% of study patients.
<table>
<thead>
<tr>
<th>Complication</th>
<th>Augmentation (n = 492) % (95% CI)</th>
<th>Revision Augmentation (n = 156) % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key risks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation</td>
<td>19.4 (16.1–23.4)</td>
<td>35.1 (27.9–43.6)</td>
</tr>
<tr>
<td>Implant removal with replacement</td>
<td>9.6 (7.2–12.8)</td>
<td>20.2 (14.4–28)</td>
</tr>
<tr>
<td>Implant removal without replacement</td>
<td>0.7 (0.2–2.1)</td>
<td>3.6 (1.5–8.5)</td>
</tr>
<tr>
<td>Implant rupture</td>
<td>5 (2.4–10.2)</td>
<td>5 (1.3–18.4)</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baker grade III or IV</td>
<td>4.6 (3–7.1)</td>
<td>6.9 (3.8–12.5)</td>
</tr>
<tr>
<td><strong>Additional risks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast pain</td>
<td>2.7 (1.5–4.7)</td>
<td>2.1 (0.7–6.3)</td>
</tr>
<tr>
<td>Swelling</td>
<td>2.7 (1.5–4.7)</td>
<td>2.8 (1–7.2)</td>
</tr>
<tr>
<td>Implant malposition</td>
<td>2.3 (1.3–4.2)</td>
<td>6.1 (3.2–11.3)</td>
</tr>
<tr>
<td>Infection</td>
<td>1.7 (0.9–3.4)</td>
<td>2.1 (0.7–6.3)</td>
</tr>
<tr>
<td>Seroma or fluid accumulation</td>
<td>1.4 (0.6–3)</td>
<td>2.4 (0.8–7.5)</td>
</tr>
<tr>
<td>Hypertrophic or abnormal scarring</td>
<td>1.1 (0.5–2.7)</td>
<td>2.7 (1–7.1)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1.1 (0.4–2.5)</td>
<td>2 (0.6–6)</td>
</tr>
<tr>
<td>Delayed wound healing</td>
<td>1.1 (0.4–2.6)</td>
<td>1.3 (0.3–5.1)</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>0.8 (0.3–2.2)</td>
<td>5.7 (2.9–11.2)</td>
</tr>
<tr>
<td>Wrinkling or rippling</td>
<td>0.7 (0.2–2)</td>
<td>2.7 (1–7.1)</td>
</tr>
<tr>
<td>Redness</td>
<td>0.7 (0.2–2)</td>
<td>0</td>
</tr>
<tr>
<td>Upper pole fullness</td>
<td>0</td>
<td>1.4 (0.4–5.6)</td>
</tr>
</tbody>
</table>

CI, confidence interval.
manufacturer, features include a cohesive gel formulation that holds together with a natural “give” to resemble natural breast tissue and a set-fill volume that renders results predictable.297

Cunningham and McCue298 reviewed the data from the Mentor Core Study on round silicone gel implants, available for the first 6 years of the 10-year study. Enrolled are 1008 patients, including 552 primary augmentations and 145 revision augmentations. The complication profiles for these cohorts are shown in Table 13. Incidence of rupture is based on a subgroup of 420 patients undergoing regular MRI; however, moving forward, all patients in the study must undergo annual MRI. Primary reasons for reoperation include capsular contracture grades II, III, and IV (33.3%) and size change (14.8%). These were also the most frequent reasons for explantation.

The Baker grade III or IV capsular contracture rate was 8.1% for primary augmentation and 18.9% for revision augmentation. The implant rupture rate was 0.5% for primary augmentation and 7.7% for revision augmentation. The reoperation rate was 15.4% for the primary augmentation group and 28% for the revision augmentation group. The primary reason for reoperation was capsular contracture.

Mentor’s Anatomic Implants—As noted above, Mentor’s anatomic silicone implants are available only outside the United States or in clinical trials. Mentor’s anatomic silicone implant has a more textured surface than that of Mentor’s round implant and a greater degree of cross-linking for a more stable form.54

Cunningham299 reported outcomes obtained with the Mentor textured anatomic gel implants. Data from the first 2 years of the 10-year study

| Table 13 |
| 6-Year Cumulative Incidence of Key Complications Associated with MemoryGel Breast Implants Based on Kaplan-Meier Analysis298 |

<table>
<thead>
<tr>
<th>Key Complications</th>
<th>Primary Augmentation (n = 552) % (95% CI)</th>
<th>Revision Augmentation (n = 145) % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any reoperation</td>
<td>19.4 (16.3–23.1)</td>
<td>34.2 (26.8–40.3)</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>9.8 (7.6–12.7)</td>
<td>22.4 (16.3–30.4)</td>
</tr>
<tr>
<td>Baker grade III or IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explanation without replacement</td>
<td>4 (2.5–6.2)</td>
<td>8.1 (4.6–14.3)</td>
</tr>
<tr>
<td>Explanation with replacement</td>
<td>3.9 (2.5–6)</td>
<td>10 (5.9–16.9)</td>
</tr>
<tr>
<td>Infection</td>
<td>1.6 (0.9–3.1)</td>
<td>1.4 (0.4–5.6)</td>
</tr>
<tr>
<td>Rupture (suspected or confirmed)</td>
<td>1.1 (0.3–4.3)</td>
<td>11.6 (5.4–24.2)</td>
</tr>
</tbody>
</table>

CI, confidence interval.
are currently available for review. A total of 955 patients were enrolled in this study, including 572 who had undergone primary augmentation and 123 who had undergone revision augmentation. Of these, 149 women with primary augmentation and 123 with revision augmentation were randomly assigned to undergo postoperative MRI. The complication profiles for these cohorts are shown in Tables 14 and 15.

Baker grade III or IV capsular contracture was documented in 0.8% of primary augmentation and 5.4% of revision augmentation cases. No implant ruptures occurred in either group. The reoperation rate was 9.4% for primary augmentation and 12.8% for revision augmentation. The primary reason for reoperation was patient request for implant size change in the primary augmentation group and wound dehiscence in the revision augmentation cohort.

Silicone versus Saline Implants

Although silicone implants are back on the market, saline implants remain a reasonable alternative with high rates of patient satisfaction (87.5% at 10 years in one study).300,301 Silicone arguably creates a more natural feel with less palpable or visible rippling, especially in patients with minimal breast tissue. However, saline implants allow for smaller incisions and smaller scars and have a lower risk of rupture or capsular contracture.300 MRI to detect rupture is necessary for silicone but is expensive, and non-reimbursed imaging is not needed for saline implants.300 Saline implants cost approximately half the amount of silicone implants, and revision surgery is less extensive and less expensive for saline implants.300

Regulatory History in Brief

The FDA was granted the authority to regulate breast implants in 1976. Table 16 reviews the regulatory history and the involvement of the FDA since that time.302

During the late 1980s and early 1990s, a number of reports25,303,304 were published about a possible association between silicone gel-filled breast implants and nonspecific autoimmune disease. In the United States, a panel of experts was assembled through the Institute of Medicine of the National Academies of Science to review the available data; a similar process was initiated in the United Kingdom. The resulting analysis found no evidence linking silicone breast implants to systemic disease305 but did note a high frequency of local complications stemming from capsular contracture and implant rupture. In 1992, the FDA called for a voluntary moratorium on the use of silicone gel implants. The implants were removed from the market in the United States and, shortly thereafter, in Canada.

By the end of the decade, the two leading manufacturers of silicone breast implants had begun pre-market approval studies in the United States, which continued through the early 2000s. The data from the pre-market approval studies were subjected to scientific review, and in 2006, the FDA once again approved the use of silicone gel implants for primary breast augmentation. Since then, the FDA has continued to monitor breast implant safety and to require follow-up data from the manufacturers. FDA announcements in 2011 focused on a possible association between breast implants and development of ALCL, a rare form of Hodgkin’s lymphoma, and the fact that breast implants are not permanent.

In August 2011, the FDA held a 2-day meeting with breast implant manufacturers, experts in the field, and others.306 The reintroduction of breast implants to the market in 2006 came with the requirement that the manufacturers conduct six post-approval studies, including following participants from pre-market “core studies” for 10 years, and that each enroll more than 40,000 additional women with silicone implants into “large studies” for 10 years to evaluate long-term safety.194,306 To date, data collection has lagged behind expectations. Allergan has collected preliminary 2-year data for 60.5% of women with silicone and 45.1% with saline implants. Mentor
Table 14
Complications at 2 Years Associated with Primary Breast Augmentation with Mentor Contour Profile Gel Implants

<table>
<thead>
<tr>
<th>Complications</th>
<th>Primary (n = 572)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% (95% CI)</td>
</tr>
<tr>
<td><strong>Key complications</strong></td>
<td></td>
</tr>
<tr>
<td>Reoperation</td>
<td>9.4 (7.2–12.4)</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td></td>
</tr>
<tr>
<td>Baker grade III or IV</td>
<td>0.8 (0.3–2.1)</td>
</tr>
<tr>
<td>Implant removal with replacement with study device</td>
<td>1.2 (0.5–2.6)</td>
</tr>
<tr>
<td>Implant removal without replacement</td>
<td>0.9 (0.4–2.5)</td>
</tr>
<tr>
<td>Infection</td>
<td>0.7 (0.3–1)</td>
</tr>
<tr>
<td>Rupture (MRI cohort)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Additional complications</strong></td>
<td></td>
</tr>
<tr>
<td>Nipple complications†</td>
<td>2.8 (1.7–4.6)</td>
</tr>
<tr>
<td>Scarring, including hypertrophic scarring</td>
<td>2.5 (0.6–2.6)</td>
</tr>
<tr>
<td>Breast sensation changes</td>
<td>1.9 (1–3.5)</td>
</tr>
<tr>
<td>Position dissatisfaction</td>
<td>1.4 (0.7–2.9)</td>
</tr>
<tr>
<td>Breast mass†</td>
<td>1.1 (0.5–2.6)</td>
</tr>
<tr>
<td>Breast pain†</td>
<td>1.1 (0.5–2.5)</td>
</tr>
<tr>
<td>Implant rotation</td>
<td>1.1 (0.4–3)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1 (0.4–2.6)</td>
</tr>
</tbody>
</table>

CI, confidence interval; MRI cohort, those patients who were randomly assigned to undergo postoperative magnetic resonance imaging.

*, occurring in ≥1% of the study patients.
†, Rosenberg Self-Esteem Scale, Medical Outcomes Study 36-Item Short-Form Health Survey, Body Esteem Scale, Tennessee Self-Concept Scale, and Function Living Index-Cancer (for cancer patients only) were used in the assessment.
### Table 15
Complications at 2 Years Associated with Revision Breast Augmentation with Mentor Contour Profile Gel Implants

<table>
<thead>
<tr>
<th>Complications</th>
<th>Revision (n = 123)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complications</strong></td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>Key complications</td>
<td></td>
</tr>
<tr>
<td>Reoperation</td>
<td>12.8 (7.9–20.3)</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td></td>
</tr>
<tr>
<td>Baker grade III or IV</td>
<td>5.4 (2.5–11.6)</td>
</tr>
<tr>
<td>Implant removal with replacement with study device</td>
<td>3.5 (1.3–9)</td>
</tr>
<tr>
<td>Implant removal without replacement</td>
<td>3.4 (1.3–8.7)</td>
</tr>
<tr>
<td>Infection</td>
<td>0.8 (0.1–5.6)</td>
</tr>
<tr>
<td>Rupture (MRI cohort)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Additional complications</strong></td>
<td></td>
</tr>
<tr>
<td>Hematoma</td>
<td>5.4 (2.5–11.6)</td>
</tr>
<tr>
<td>Implant palpability</td>
<td>2.7 (0.9–8)</td>
</tr>
<tr>
<td>Nipple complications</td>
<td>2.7 (0.9–8.1)</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>2.5 (0.8–7.5)</td>
</tr>
<tr>
<td>Implant rotation</td>
<td>2.3 (0.5–9.2)</td>
</tr>
<tr>
<td>Breast sensation changes</td>
<td>1.9 (0.5–7.4)</td>
</tr>
<tr>
<td>Granuloma</td>
<td>1.9 (0.5–7.4)</td>
</tr>
<tr>
<td>Implant movement</td>
<td>1.7 (0.4–6.8)</td>
</tr>
<tr>
<td>Patient dissatisfied with feel of implant</td>
<td>1.7 (0.4–6.6)</td>
</tr>
<tr>
<td>Breast mass</td>
<td>1 (0.1–6.9)</td>
</tr>
</tbody>
</table>

CI, confidence interval; MRI cohort, those patients who were randomly assigned to undergo postoperative magnetic resonance imaging.

*, occurring in ≥1% of the study patients.
has collected 3-year data for 21% and 9.6% of those groups, respectively\textsuperscript{194}—much lower than the goals set by the FDA.\textsuperscript{306,307} To date, this has precluded detection of very rare complications, but at the time of this interim analysis, no evidence of connective tissue disease or reproductive problems has been presented.\textsuperscript{194} A high dropout rate from post-approval studies was attributed to requirements for completion of voluminous paperwork (annual 25-page questionnaires) and costly MRI procedures.\textsuperscript{306,307} Panelists suggested that a national registry of all women who have received breast implants might facilitate data collection and make it easier to identify long-term complications; this option is under consideration by the FDA.\textsuperscript{306,307}

**SILICONE IMPLANT SAFETY**

**Durability**

The FDA has cautioned that implants are not lifetime devices and that the risk of complications (e.g., capsular contracture, implant rupture and deflation, wrinkling, asymmetry, scarring, pain, infection) increases over time.\textsuperscript{47,194} The longer implants remain in place, the more likely it is that they will have to be removed because of complications or unsatisfactory appearance.\textsuperscript{47} Up to 20% of women who have undergone breast augmentation have their implants removed within 8 to 10 years. Removal without replacement of implants can lead to unaesthetic dimpling, puckering, or sagging of the breast.\textsuperscript{47,194}

**The Connective Tissue Disease Controversy**

Several anecdotal reports and case series\textsuperscript{25,26,308–315} have suggested a cause-and-effect relationship between silicone breast implants and various connective tissue diseases, such as progressive systemic sclerosis, scleroderma, rheumatoid arthritis, and lupus erythematosus. The evidence for this supposed link was the sporadic observation that some women with long-term exposure to silicone developed an immunological reaction and symptoms of collagen disorder.\textsuperscript{314,316,317} The hypothesis was bolstered by the finding of elevated blood silicone levels in women with breast implants compared with an age-matched, nonaugmented control group.\textsuperscript{318}

A review of the data indicates several flaws with that argument. Most initial studies of breast implants and connective tissue disorders were conducted in a highly select group of patients who were referred either to rheumatologists because of symptoms or to plastic surgeons for explantation\textsuperscript{319} and are therefore biased to symptomatic patients. Hölmich et al.\textsuperscript{319} searched the published literature and found only five studies\textsuperscript{320–324} in which the patient population was not selected on the basis of clinical course or symptom (Table 17). Only one study\textsuperscript{324} (n = 238) consisted exclusively of women with cosmetic breast implants. In another study\textsuperscript{320} (n = 344), 85% of women had undergone cosmetic breast augmentation. The other three studies\textsuperscript{321–323} involved primarily patients undergoing breast reconstruction.

Any association between silicone implant rupture and connective tissue disease has little scientific basis. Hölmich et al.\textsuperscript{319} proposed that the concept of a “silicone-related disease” has been incorrectly identified by rheumatologists based on a selected group of symptomatic patients who happened to have breast implants. The authors thought that these patients’ nonspecific symptoms were related to capsular contracture or implant rupture and were being misinterpreted as representing those of systemic disease. Elevated plasma level of silicone is a universal finding in women with silicone implants and not an indication of implant leakage.\textsuperscript{325,326} In a 2011 publication, Lipworth et al.\textsuperscript{327} argued that there is no convincing evidence that breast implants increase the risk of connective tissue disorders and that any claims to the contrary “are not supported by the scientific literature but rather are a residual by-product of the unprecedented large-scale product liability litigation in the USA....” Multiple comprehensive reviews and meta-analyses have failed to uncover
### Table 16

**Regulatory History of Breast Implants in the United States**

<table>
<thead>
<tr>
<th>Date</th>
<th>Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1976</td>
<td>Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Breast implants were classified as class II and were reviewed through the pre-market notification [510(k)] process.</td>
</tr>
<tr>
<td>1988</td>
<td>In response to emerging safety concerns, the FDA reclassified breast implants as class III devices (requiring pre-market approval). However, in accordance with the law, breast implants continued to be reviewed through the 510(k) process until the FDA issued a rule calling for submission of PMA.</td>
</tr>
<tr>
<td>April 1991</td>
<td>The FDA issued a final rule calling for submission of PMA for silicone gel-filled breast implants.</td>
</tr>
<tr>
<td>November 1991</td>
<td>The FDA held an Advisory Panel meeting to discuss several PMA for silicone gel-filled breast implants. The panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, but unanimously recommended that the FDA permit the implants to remain on the market.</td>
</tr>
<tr>
<td>January 1992</td>
<td>The FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them, while the FDA reviewed new safety and effectiveness information that had been submitted.</td>
</tr>
<tr>
<td>February 1992</td>
<td>Based on new information, the FDA held a second Panel meeting to reevaluate the safety of silicone gel-filled breast implants. This time, the Panel recommended that silicone gel-filled breast implants be removed from the market pending further evaluation of the new data.</td>
</tr>
<tr>
<td>April 1992</td>
<td>The FDA concluded that none of the PMA submitted for silicone gel-filled breast implants contained sufficient data to support approval. Access to silicone gel-filled breast implants should continue for patients undergoing breast reconstruction and for replacement of existing silicone gel-filled breast implants (revision). Implants used for these indications should be considered to be investigational devices, and women who received them should be followed through adjunct clinical studies.</td>
</tr>
<tr>
<td>July 1992</td>
<td>The FDA approved Mentor’s Adjunct Study protocol for its silicone gel-filled breast implants for patients undergoing reconstruction and revision only.</td>
</tr>
<tr>
<td>March 1998</td>
<td>The FDA approved Allergan’s (formerly Inamed) Adjunct Study protocol for its silicone gel-filled breast implants for patients undergoing reconstruction and revision only.</td>
</tr>
<tr>
<td>June 1998</td>
<td>The FDA approved Allergan’s IDE study (i.e., Core Study) for its silicone gel-filled breast implants for a limited number of patients undergoing augmentation, reconstruction, and revision at a limited number of sites.</td>
</tr>
<tr>
<td>March 2000</td>
<td>The FDA held an Advisory Panel meeting to discuss three saline-filled breast implant PMA. The Panel recommended that the FDA approve two of the PMA but not the third.</td>
</tr>
<tr>
<td>May 2000</td>
<td>The FDA approved the first PMA for saline-filled breast implants from Allergan (formerly McGhan) and for Mentor. These implants were approved for augmentation in women age 18 years and older and for reconstruction in women of any age.</td>
</tr>
<tr>
<td>August 2000</td>
<td>The FDA approved Mentor’s IDE study (i.e., Core Study) for its silicone gel-filled breast implants for a limited number of patients undergoing augmentation, reconstruction, and revision at a limited number of sites.</td>
</tr>
<tr>
<td>Date</td>
<td>Regulation</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>July 2002</td>
<td>The FDA held an Advisory Panel meeting to update the Panel on post-market (after approval) information and data for the two approved saline-filled breast implant PMA.</td>
</tr>
<tr>
<td>December 2002</td>
<td>Allergan submitted a PMA for its silicone gel-filled breast implants.</td>
</tr>
<tr>
<td>October 2003</td>
<td>The FDA held an Advisory Panel meeting to review Allergan's PMA for its silicone gel-filled implants. In a 9 to 6 vote, the Panel recommended approval with conditions, including a minimum age requirement for augmentation.</td>
</tr>
<tr>
<td>December 2003</td>
<td>Mentor submitted a PMA for its silicone gel-filled breast implants.</td>
</tr>
<tr>
<td>April 2005</td>
<td>The FDA held an Advisory Panel meeting to review Allergan's updated PMA and Mentor's PMA. In a 5 to 4 vote, the panel did not recommend approval of Allergan's PMA (because of a concern with one style in the application). In a 7 to 2 vote, the panel recommended approvable with conditions for Mentor's PMA. The Panel recommended that the FDA require conditions, including a minimum age for augmentation and post-approval studies.</td>
</tr>
<tr>
<td>November 2006</td>
<td>The FDA approved Allergan's and Mentor's PMA for silicone gel-filled breast implants. This was the first time silicone gel-filled breast implants were available for augmentation, in addition to reconstruction and revision, since the moratorium was established in 1992. As conditions of approval, each manufacturer was required to conduct six post-approval studies to further characterize the safety and effectiveness of their silicone gel-filled breast implants and to answer scientific questions that the pre-market clinical trials were not designed to answer.</td>
</tr>
<tr>
<td>January 2011</td>
<td>The FDA issued a Safety Communication on anaplastic large cell lymphoma (ALCL) in women with breast implants. Based on a review of the scientific literature, the FDA believes that women with breast implants might have a very small but increased risk of developing this disease in the scar capsule adjacent to the implant.</td>
</tr>
<tr>
<td>June 2011</td>
<td>The FDA issued an Update on the Safety of Silicone Gel-Filled Breast Implants. The update included preliminary results of the post-approval studies that Allergan and Mentor were required to conduct as conditions of their 2006 silicone gel-filled breast implant approval.</td>
</tr>
<tr>
<td>August 2011</td>
<td>The FDA held an Advisory Panel meeting to discuss and receive recommendations on post-marketing issues related to silicone gel-filled breast implants. Also discussed at the meeting were innovative methodological approaches to post-marketing studies regarding silicone gel breast implants and key long-term safety issues associated with silicone gel breast implants in the real-world setting.</td>
</tr>
<tr>
<td>March 2012</td>
<td>The FDA approved Sientra Inc's PMA for a silicone gel-filled breast implant. As a condition of approval, the manufacturer was required to conduct a series of post-approval studies to further characterize the safety and effectiveness of their silicone gel-filled breast implant and to answer scientific questions that the pre-market clinical trial was not designed to answer.</td>
</tr>
</tbody>
</table>

FDA, United States Food and Drug Administration; PMA, pre-market approval applications; IDE, investigational device exemption.
Table 17
Association between Silicone Breast Implant Rupture and Connective Tissue Disease: Published Studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Country</th>
<th>Study Design</th>
<th>Study Population</th>
<th>Rupture Frequency</th>
<th>Main Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown et al.,220</td>
<td>United States</td>
<td>Cohort</td>
<td>N = 344</td>
<td>69% (n = 236) had ruptures</td>
<td>Comparison between women with extracapsular ruptures and combined group of those with intact implants and intracapsular ruptures— Fibromyalgia: OR = 2.8, 95% CI = 1.2–6.3; Raynaud syndrome: OR = 4.2, 95% CI = 1.1–16; other CTD: OR = 2.7, 95% CI = 0.8–8.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>85% received implants for cosmetic augmentation</td>
<td>31% of those (21% of study group, n = 73) had extracapsular ruptures</td>
<td></td>
</tr>
<tr>
<td>Berner et al.,221</td>
<td>Germany</td>
<td>Cross-sectional</td>
<td>N = 32</td>
<td>41% (n = 13) had ruptures</td>
<td>Women with implant rupture compared with those without— No differences among 23 self-reported CTD-related symptoms; numbness/tingling in extremities reported by 44% with intact implants and 85% with ruptured implants (P = 0.02)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100% received implants as reconstruction after breast cancer surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gaubitz et al.,222</td>
<td>Germany</td>
<td>Cohort</td>
<td>N = 90</td>
<td>27% (n = 24) had ruptures</td>
<td>No differences among 14 CTD-related symptoms in women with or without rupture; no differences among 12 CTD-related symptoms in those with silicone in liver; two symptoms over-reported by those with silicone in liver: 1) tingling/numbness of the fingers in 82% with silicone in the liver and 52% without (P = 0.006); 2) photosensitivity in 57% with silicone in the liver and 31% without (P = 0.02)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>53% received implants as reconstruction after breast cancer surgery</td>
<td>54% of those (14% of study group, n = 13) had silicone in the liver shown by nuclear magnetic resonance spectroscopy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>25% received implants for cosmetic augmentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>22% received implants as reconstruction after mastopathia surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contant et al.,223</td>
<td>The Netherlands</td>
<td>Cohort</td>
<td>N = 57</td>
<td>0.5% (n = 3) had signs of rupture 1 yr after reconstruction</td>
<td>No differences in self-reported complaints or rheumatological parameters between women with and without rupture</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100% received implants as immediate reconstruction after mastectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>50% of the mastectomies were prophylactic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hömich et al.,224</td>
<td>Denmark</td>
<td>Cohort</td>
<td>N = 238</td>
<td>39% (n = 92) had ruptures</td>
<td>Ruptured versus intact implants— Risk of defined CTD*: OR = 0.9, 95% CI = 0.1–6.7; risk of undefined CTD†: OR = 1, 95% CI = 0.3–3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100% received implants as cosmetic augmentation</td>
<td>25% of those (10% of study group, n = 23) had extracapsular ruptures</td>
<td>Extracapsular ruptures compared with intact implants— Risk of defined CTD*: OR = 3.8, 95% CI = 0.4–35.1; risk of undefined CTD†: OR = 0.8, 95% CI = 0.1–4.5</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; CTD, connective tissue disease.
*Defined CTD includes Sjögren syndrome, systemic lupus erythematosus, rheumatoid arthritis, scleroderma, dermatomyositis, and polymyositis.
†Undefined CTD includes ill-defined rheumatological symptoms (e.g., fibromyalgia).
any verifiable evidence of an association between silicone gel implants and autoimmune disorders.\textsuperscript{316–334}

The issue continues to be evaluated by experts and the FDA. After conducting a comprehensive review of the literature in 2010, Bassetto et al.\textsuperscript{335} noted that although silicone might not be a direct cause of connective tissue disorders, it might promote a stronger inflammatory response in patients who are generally predisposed to bad scarring or autoimmune diseases. Thus, because long-lasting implants in such patients might cause an increase in fibrosis to the point of capsular contracture, they might also stimulate an antiself response that could lead to the development of autoimmune diseases. This hypothesis is supported by data from Wolfram et al.\textsuperscript{336} who analyzed sera from 143 patients, including 93 women with silicone breast implants and 50 women in a control group, none of whom had symptoms of autoimmune disease. The authors found that women with implants had elevated serum levels of anti-polymer antibodies, procollagen III, and circulating immune complexes compared with women in the control group. Serum levels were highest in women with severe fibrotic reaction (Baker grades III and IV).

Most recently, Lee et al.\textsuperscript{337} conducted a large, prospective, cohort study that included 3950 women with breast implants and 19,897 women without breast implants. The authors found a 60\% higher rate of self-reported connective tissue disorders and a 39\% increase in connective tissue disorders confirmed by medical records of women with breast implants. The study had numerous limitations, including the following:

- Differences in baseline characteristics between the women with implants and the women in the control group; women with implants were leaner, more likely to smoke and to consume more alcohol, more likely to be postmenopausal and using postmenopausal hormones, more active, and more likely to have a history of breast cancer; women in the control group were more likely to have a history of hypertension or high cholesterol
- A low response rate among women eligible for study participation
- A differential response to the screening questionnaire (implants > no implants)
- Poor and differential responses to requests for medical records among women with positive screening questionnaires (implants < no implants)
- Self-report of connective tissue disease, considering that women with implants might have greater awareness of symptoms
- Low overall incidence of connective tissue diseases

A few additional cases of connective tissue disease have been found in the post-approval studies, but based on the data from those cases and a review of the current literature, the FDA concluded in its 2011 Safety Update, “Overall, the current body of evidence does not support an association between silicone gel-filled breast implants and connective tissue disorders.”\textsuperscript{194}

**Platinum Toxicity**

Platinum is a catalyst in the cross-linking reactions of the silicone gel and shell. The FDA has expressed concern regarding whether the platinum would diffuse out of the breast pocket and result in adverse health effects. Wixtrom\textsuperscript{338} reviewed the literature and analyzed the safety profile of platinum regarding silicone gel breast implants.

Platinum exists in different metallic species according to its valence or oxidative state. The common valences of platinum are 0, +2, and +4. The metallic platinum used in electrodes for
medical devices and in coronary stents has a valence of 0. This is the most biocompatible form of platinum, is nonallergenic, and is not associated with neurological disease. The platinum used in chemotherapy drugs (e.g., cisplatin) has a valence of +2 and has the potential for renal toxicity and ototoxicity. The platinum used in the manufacture of silicone breast implants has a valence of 0. Diffusion studies of the current generation of implants by the leading manufacturers indicate minute levels of platinum released under physiological conditions (<0.1%). On the basis of these data, Wixtrom concluded that the platinum in silicone gel implants is nonallergenic, is nontoxic, and does not pose a health risk to patients.

On the other hand, Maharaj questioned the conclusion that platinum in breast implants is in the 0 valance state. Although platinum in the 0 valance state is used as one of the starting materials to produce a catalyst that is then used to make the components of the implant, the final oxidation state of platinum in the implants is unknown. Maharaj noted that the only study that had directly evaluated breast implants for platinum oxidation states found platinum largely in the 2+ or 4+ oxidation states and that all other available reports were from industry or authors who received industry reports.

Silicone and Breast-feeding

Contamination of breast milk with silicone was one of the many concerns raised by the FDA. Mothers with breast implants were warned not to breast-feed their infants because of suspected silicone contamination of breast milk. The alternative source of nutrition would be infant formula, which also contains silicone from the manufacturing process. Semple et al. reviewed the concentration of silicon (a proxy measurement of silicone) in the breast milk and serum of women with older generation (before 1992) silicone implants and compared it with that of the breast milk and serum of nonaugmented breast-feeding women. The silicon concentrations in regular store-bought cow’s milk and in several types of commercially available infant formula were also measured. The authors found that the concentration of silicone in implanted women was not statistically different from that in women without breast implants (P = 0.66). The mean silicone level in cow’s milk and commercially available infant formulae was substantially higher than in breast milk from either group.

Health Outcomes in Offspring

At one time, it was feared that children of breast-augmented women could be exposed to silicone either through transplacental diffusion or by way of breast milk. Published reports suggested that the transfer of silicone or immune complexes in breast milk could cause childhood “rheumatoid symptoms” or “scleroderma-like” abnormal esophageal motility. Case reports described myalgias and neonatal lupus in children born to mothers with silicone breast implants. Kjøller et al. reviewed the literature and identified four epidemiological studies from Scandinavia that compared outcomes of children born to mothers with silicone breast augmentation versus other cosmetic surgery procedures and general population control participants. Scandinavian countries have a long and distinguished history of nationwide record-keeping through hospital, birth, and cancer registries that enables unbiased recording of health outcomes and provides a strong basis for epidemiological studies. The evidence to date does not support an increased risk of health problems—esophageal and rheumatic disorders, congenital malformations, or perinatal mortality—to the offspring of women with silicone breast implants.

Breast Cancer

Questions regarding the potential carcinogenicity of silicone breast implants emerged shortly after the implants became commercially available 30+ years ago. In general, breast cancer rates in the
United States have increased substantially since that time, and as more women underwent breast augmentation procedures, case reports of breast cancer in women with implants began to surface in the literature. In addition, as women’s longevity increased, more breast cancer cases were diagnosed in the higher risk, older age groups, some of whom might have undergone breast augmentation.

The concerns of many women with breast implants focus on the following: 1) presence of cancer in the breast and other anatomic sites, 2) delayed detection of breast cancer, 3) recurrence rate of breast cancer, and 4) length of survival after diagnosis.

**Incidence**

Multiple epidemiological studies conducted since 1992 have shown a lower risk of breast cancer for women who have undergone breast augmentation with silicone implants than is expected in the general population. The findings have been confirmed worldwide. The reasons for the decreased risk of breast cancer in augmented women are still speculative: a population already at low risk, small breast size predisposing against breast cancer, enhanced immune response, tissue compression with decreased blood supply to a potential tumor, and/or lower tissue temperature locally.

**Detection**

Breast implants obscure a proportion of the breast and compress natural breast tissue. Therefore, standard two-view MMG is inadequate and can miss abnormalities in patients who have breast implants. One technique that helps visualize breast tissue on MMG in women with implants is to displace the implant posteriorly against the chest wall, forcing the breast tissue over and anterior to the implant. This technique, however, is not effective and can be painful in women with capsular contracture. Furthermore, displacement views must be conducted in addition to standard views, which doubles the patient’s radiation exposure and increases the workload of the radiographer.

Few data are available on the use of other imaging modalities, such as ultrasonography and MRI, in the diagnosis of breast cancer in women with breast implants. Standard percutaneous breast biopsy can be used for tissue diagnosis, but imaging guidance is recommended to avoid damaging the implant. Recent studies indicate that sentinel lymph node mapping can be successfully performed in women who have undergone breast augmentation or other cosmetic surgery procedures of the breasts.

Despite difficulties with screening, Hoshaw et al., Brinton et al., Pukkala et al., Friis et al., and Deapen found no statistically significant delay in the diagnosis of breast cancer in women with breast implants. In contrast, Xie et al. reviewed data from a cohort of 24,558 Canadian women with breast implants and 15,893 women who had undergone other plastic surgery procedures at the same practices and found that women with breast implants were more likely to have breast cancer diagnosed at an advanced stage \( (P < 0.01) \). However, the authors reported that survival was similar in both groups.

**Recurrence**

A review by Noone of 88 epidemiological studies found no connection between breast implants and breast carcinoma. No increase in the risk of recurrence and no delay in the detection of recurrence were observed in patients who had undergone mastectomy reconstructed with implants. Other works have confirmed these statements.

**Survival**

A statistical comparison of 3953 patients with breast cancer who had not undergone breast augmentation and 129 patients with breast cancer who had undergone augmentation revealed a higher frequency of palpable tumors, slightly higher risk of
invasive tumors, and increased likelihood of axillary lymph node metastasis in augmented patients.\textsuperscript{374} Nevertheless, the stage of disease, mean tumor size, recurrence rate, and breast cancer-specific survival were identical for both groups. Several other investigators have concurred.\textsuperscript{360,373,375}

Hoshaw et al.\textsuperscript{357} summarized the results of these studies as follows: “Researchers have consistently found no persuasive evidence of a causal association between breast implants and any type of cancer…. Women with implants should be reassured… that, compared with women without implants, they are not at increased risk for cancer, are not diagnosed with later-stage breast malignancies, are not at increased risk for breast cancer recurrence, and do not have a decreased length of survival.” In the 2011 safety update,\textsuperscript{194} the FDA concluded that breast implants do not seem to increase risk of breast cancer or impair survival in women with breast cancer.

**ALCL**

In August 2011, the FDA released a statement that women with breast implants might have a very low but increased risk of developing ALCL in the area immediately surrounding the implant.\textsuperscript{376} The FDA is aware of approximately 60 reports of ALCL in women with saline or silicone breast implants worldwide. Considering that there have been only 60 reports among 5 to 10 million women who have received implants worldwide, the absolute risk of ALCL is thought to be small.\textsuperscript{376} One case-controlled study\textsuperscript{377} from The Netherlands estimated that women with silicone breast implants have 18-fold higher odds of developing ALCL than do women without implants; however, incidence is still only an estimated 0.1 to 0.3 cases per 100,000 women with implants. An independent panel of scientists from the RAND Corporation (Santa Monica, CA) agreed that there is a positive association between ALCL and breast implants but

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{schematic_representation_of_effusion_associated_ALCL.png}
\caption{Schematic representation of effusion-associated ALCL. (Modified from Thompson et al.\textsuperscript{383})}
\end{figure}
did not think that it has yet been proven to be a causal association.\textsuperscript{378,379}

Many of the ALCL cases have been described in the medical literature.\textsuperscript{377,380,381} In these cases, ALCL occurred 1 to 30 years after placement of either saline or silicone breast implants.\textsuperscript{377,380,382} Lymphomas were located in the fibrous capsule surrounding the implant\textsuperscript{377} and can be present in tissue or in the effusion fluid between the implant and fibrous capsule (Fig. 8).\textsuperscript{382,383} Some cases of ALCL present with seromas or palpable masses (1−10 cm)\textsuperscript{379,380} and some with just effusion without a mass lesion.\textsuperscript{383} Presenting symptoms include pain, redness, and capsular contracture\textsuperscript{379} and other implant-related breast symptoms.\textsuperscript{380} ALCL associated with breast implants is almost always activin receptor-like kinase 1-negative but seems to have an indolent course, comparable to that of cutaneous rather than systemic ALCL,\textsuperscript{379−383} leading some experts to argue that it should be considered a distinct clinicopathological entity.\textsuperscript{383,384}

Patients suspected of ALCL should be referred to an oncologist for evaluation.\textsuperscript{376} The RAND Corporation called for increased vigilance in detecting ALCL in women who have undergone breast augmentation but noted that if the lymphoma is localized, it does not require chemotherapy or radiation.\textsuperscript{378}

\section*{Other Statistical Associations}

Women with breast implants have been linked with higher than average rates of cancer of the lung and bronchus,\textsuperscript{366,371} cancer of the vulva,\textsuperscript{366,385,386} and suicide.\textsuperscript{373,375} These associations are intriguing but ill-defined and prompted Brinton\textsuperscript{386} to conclude that there is no convincing evidence that breast implants alter the risk of non-breast malignancies. Brinton suggested it is more likely that the observed associations relate more to lifestyle characteristics, such as cigarette smoking and sexual behavior, than to the effects of the implants.

In the 2011 safety update,\textsuperscript{194} the FDA indicated that with the possible exception of ALCL, the cancers seem to be unrelated to the effects of the implants and that no increase in risk has been identified in the post-approval studies to date.

Lipworth and McLaughlin\textsuperscript{387} noted a consistent two- to three-fold increase in the rate of suicide among women with cosmetic breast implants across five epidemiological studies conducted in North America and Europe. Although data on psychiatric history before breast implantation are largely lacking, Lipworth and McLaughlin suggested that a history of serious psychiatric illness before cosmetic breast implant surgery among a subset of these women is the likely explanation for the increased risk.

\section*{NONIMPLANT-BASED BREAST AUGMENTATION}

\subsection*{Autologous Fat Grafting}

Autologous fat grafting for breast augmentation was introduced by Bircoll\textsuperscript{388} in the 1980s. The fat was injected in 5-mL increments for a maximum augmentation of 130 mL.\textsuperscript{388,389} These initial reports spawned a heated discussion within the plastic surgery community regarding the safety of fat grafting to the breast. In 1987, the American Society of Plastic and Reconstructive Surgeons Ad-Hoc Committee on New Procedures condemned the use of autologous fat injection for breast augmentation.\textsuperscript{389} It was thought that much of the injected fat would not survive and that the subsequent necrosis would lead to scarring and calcification that would render screening for breast cancer difficult.\textsuperscript{389}

Advocates of fat grafting argue that calcifications occur after any aesthetic breast surgery such as reduction, augmentation with implants, and liposuction, yet plastic surgeons continue to perform these procedures. Recent studies from Europe showed successful, safe fat transfer to the breast.\textsuperscript{390−400} Coleman and Saboeiro\textsuperscript{400} reported their results in 17 patients followed for a mean 62.2 months. Indications for fat grafting included
micromastia, post-augmentation deformity, secondary deformity after explantation, tuberous breast deformity, Poland syndrome, and deformity after mastectomy and reconstruction. The breast was shaped by layering fat at different levels. The largest portion of fat was infiltrated into the pectoralis major muscle, and the next largest portion into the subpectoral and subglandular spaces; the final shape was obtained with fat grafts to the superficial subcutaneous planes. The total amount of fat used ranged from 50 to 400 mL. Breast volume seemed to stabilize after 4 to 6 months. One patient developed a superficial infection, and two patients were diagnosed with breast cancer revealed by postoperative MMG (in an area not grafted with fat in one patient). The authors proposed that fat grafting for breast augmentation is less traumatic because of the blunt nature of the technique and that it therefore carries less of a risk to ducts, nerves, and vessels.

In another prospective study, Del Vecchio and Bucky first used the BRAVA Breast Enhancement and Shaping System (Bio-mecanica, Inc., Miami, FL) for pre-expansion and then performed “mega-volume” (>300 mL) autologous fat grafting for breast augmentation in 25 patients (46 breasts) from 2007 to 2009. The procedure took approximately 2 hours. After the grafting procedure, patients wore the BRAVA expander device at regular intervals for 2 to 4 weeks. Indications included micromastia, post-explantation deformity, tuberous breast deformity, and Poland syndrome. This procedure resulted in an average two-fold increase in breast volume and soft, natural breasts. No new oil cysts, fat necrosis, or masses were detected by MRI at 6 months postoperatively.

Illouz and Sterodimas reported 25 years of experience with autologous fat transplantation (25–900 mL) to the breast in 820 women. Most had improvements in breast size and/or shape. Complications occurred primarily during the first 6 months and included ecchymosis (n = 76), striae (n = 36), hematomas (n = 12), and infection (n = 5). Thirty-four patients experienced long-term breast asymmetry. Liponecrotic cysts developed in 16.7%.

Retrospective follow-up of 66 patients who underwent autologous fat transplantation at the Shanghai Ninth People’s Hospital in China found that breast contour was significantly improved in 42.4%, improved in 36.4%, and not improved in 21.2% based on physician assessment. Patient reports showed 40.9% were very satisfied, 39.4% were satisfied, and 19.7% were unsatisfied. Eleven patients developed palpable masses that were shown by MMG and other imaging to be liponecrotic cysts with benign calcification.

Two recent studies assessed whether fat transplants affect the accuracy of MMG. Carvajal and Patiño performed bilateral MMG on 20 patients an average of 34.5 months (range, 6 months–7 years) after autologous fat injection for breast augmentation. Common findings included benign bilateral scattered microcalcifications and dispersed radiolucent oil cysts. The authors suggested that anticipation of such findings in patients who have undergone autologous fat injections might allow for imaging follow-up if necessary and reduction in the number of unnecessary biopsies or other evaluations. They also recommended that fat injection for breast augmentation be avoided in patients with a family history of breast cancer.

Veber et al. retrospectively assessed 31 mammograms of women who had undergone fat transplantation for breast augmentation (n = 1), for Poland syndrome (n = 4), for tuberous breast (n = 5), and in combination with mastopexy (n = 21). Radiographic findings included cystic lesions (26%), microcalcifications (16%), architectural distortion (12%), and macrocalcifications (9%). The authors also compared pre- and postoperative mammograms of 20 women and found no significant changes in breast tissue density based on either the international American College of Radiology classification or a personalized rating system (P = 1 and P = 0.91, respectively). They also found no significant difference in pre- versus postoperative American College of Radiology Breast Imaging Reporting and Data System classification (P = 1).
In January 2009, the American Society of Plastic Surgeons issued “guiding principles” regarding fat transfer and fat grafting procedures, including breast augmentation. Later in 2009, the Society published conclusions from their Fat Graft Task Force. The Task Force concluded that fat grafting can be considered for breast augmentation and for correction of defects associated with medical conditions and previous breast surgery. However, the Task Force was unable to make specific recommendations because of insufficient data and lack of standardization of techniques for graft harvesting, preparation, and injection. It was noted that the longevity of the graft is unknown and that changes in body weight can affect graft volume over time.

Regarding safety of the procedure, the Guiding Principles state, “Based on available literature, complication rates associated with fat grafting are not, overall, unduly high. Risks and complications reported in the literature include infection, bleeding, fat embolism and graft volume loss; though, risks and complications of autologous fat grafting are not necessarily limited to these reports. Cases of severe complications and death appear to be extremely rare. Concern regarding the interference of autologous fat grafts with breast cancer detection is not validated by the limited number of studies available on the topic.”

The American Society of Plastic Surgeons Guiding Principles also note, based on expert opinion, that caution is warranted for fat grafting in patients at high risk for breast cancer (e.g., women with breast cancer type 1 or 2 gene mutations and/or personal or familial history of breast cancer). Furthermore, surgeons should have patients provide informed consent, noting that limited scientific evidence is available to verify the safety and efficacy of fat transfer procedures.

External Soft-Tissue Expansion Device
Khouri et al. introduced the BRAVA system of nonsurgical breast augmentation, which consists of an apparatus that applies external negative pressure to the breast mound to try to induce growth. For 10 to 12 hours per day for 10 to 14 consecutive weeks, the patient wears a bra-like vacuum device that applies 20 mmHg of distraction forces to the breast. The expected enlargement is one-half to one cup size, or 75 to 100 mL of breast volume.

Khouri et al. reported a stable increase in breast size of approximately 55% with up to 30 weeks of follow-up. MRI showed that new fibroadipose tissue and breast parenchymal tissue accounted for the volume increase. Women with tight, relatively immobile breasts are not good candidates for this approach. The validity of this technique awaits independent confirmation.

Hyaluronic Acid
Interest has been shown in using hyaluronic acid gel for nonsurgical breast enhancement, and one such product, Macrolane (Q-MED, a Galderma Division, Uppsala, Sweden), has achieved approval in Europe (but not in the United States) for this indication.

Inglefield presented a prospective study of 194 women treated with Macrolane (20–200 mL) for breast enhancement at London Bridge Plastic Surgery in the United Kingdom between November 2007 and August 2009. The product was inserted through asymmetric 3-mm stab incisions below the IMF and was placed into the retromammary space using a blunt 16-gauge cannula and tunneling retrograde technique. Gentle molding achieved the final breast shape, and incisions were closed with dressing and tape, without sutures. This procedure achieved a mean 1.2-cup size increase, and all patients reported some degree of improvement at all time points up to 12 months. Mild to moderate side effects included product migration, lumpiness, scar pigmentation, and breast pain. Major adverse events (8.7%) included infection, capsular contracture, early resorption, and product removal. Six patients experienced early resorption of hyaluronic acid.
(>50% volume loss) within 6 months.

According to the manufacturer, the body gradually breaks down hyaluronic acid, which lasts for up to 12 months, after which repeated injections are required to sustain the effect. The recommended technique involves a single needle pass or multiple needle passes, injecting the product at the upper breast pole or lateral part of the IMF, and using the injected product as a tissue expander.

In a recent article, McCleave raised the following concerns about the product:

- Safety is largely unknown because of limited availability of data.
- Capsular contracture rate seems high (30%).
- MRI shows that large volumes of hyaluronic acid remain after the 12-month period, which could have unknown long-term consequences.

- Long-term effects on breast screening and breast cancer risk are unknown.
- Asymmetry can result from irregularly placed deposits that migrate according to the path of least resistance.

**CONCLUSIONS**

Breast augmentation has become the most common cosmetic surgery performed in the United States. Careful preoperative assessment and sizing are key to minimizing complications and maximizing patient satisfaction. It is also crucial to ensure that patients understand all the potential risks, the recommended postoperative care and follow-up requirements, and the anticipated need for additional surgery to address complications that are likely to arise over time.
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