



Dual-Plane Breast Augmentation for Minimal Ptosis Pseudoptosis (the “In-Between” Patient)

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Abstract

Background: Dual-plane breast augmentation (DPBA) can be an effective technique for treating patients with ptotic breasts who fall somewhere in between the traditional requirements for breast augmentation versus a more extensive augmentation-mastopexy.

Objectives: The author outlines indications for DPBA, describes the technique, and presents outcomes data from patients receiving gel or saline implants in an effort to clarify the advantages of DPBA compared with breast augmentation with or without mastopexy.

Methods: This 8-year retrospective comparative study reviewed the results of saline implants placed with a DPBA technique in a single surgeon's practice during the final 4 years of the FDA moratorium (phase 1) compared with both gel and saline implants placed during the 4 years after the moratorium was lifted (phase 2). Patients were consecutive. The entire patient cohort ($n = 1999$ for primary BA; 3998 implants) was assessed for outcomes.

Results: Of the entire cohort, 24.2% were followed for over 1 year; 23.5% of the 256 DPBA patients were followed for over 1 year. Mean (SD) age was 33.6 (8.7) years. The difference in revision rates between BA versus DPBA was 4.6% (95% confidence interval [CI], 0.7–8.5).

Conclusions: The DPBA approach is most likely suited for patients with minimal ptosis who fall into a “gray area” between normal anatomy (treated with a traditional BA) and frank ptosis (which would require mastopexy). Knowledge of this approach will allow surgeons to more effectively treat patients who present with unique “in-between” anatomy not addressed by ordinary BA and avoid more extensive mastopexy scars.

Level of Evidence: 3

Keywords

breast surgery, gel implants, breast augmentation, mammary ptosis, dual plane, breast implants, augmentation mastopexy

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Breast augmentation is no longer considered a routine procedure.^{1–7} Selecting the proper approach requires detailed analysis of tissue cover, implant style, shape, position of the breast, position of the nipple-areola complex (NAC), and ptosis. Glandular ptosis or pseudoptosis refers to the condition in which a percentage of the gland falls below the inframammary fold (IMF). If pseudoptosis is minimal, these patients may be treated with a traditional breast augmentation (BA) procedure. Frank ptosis refers to an NAC located below center on the mound at the IMF or lower; patients with frank ptosis have traditionally been treated with mastopexy. Patients who fall in between these 2 categories—in other words, they have minimal ptosis—represent a unique challenge when they present for BA. In fact, the author's typical patient with minimal ptosis has consulted 2 to 4 surgeons prior to presentation, and she is often confused by conflicting clinical opinions and surgical recommendations. The patient often recognizes that she has minimal ptosis but is generally adamant against additional breast scars.

Dual-plane breast augmentation (DPBA) can be a useful surgical approach for patients with minimal or glandular ptosis because DPBA enhances the tissue draping interplay between the gland and the implant. With this

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technique, the implant is placed in the partial submuscular pocket customary for BA, but the technique also adds retromammary dissection release of the caudal edge of the pectoralis major muscle (PMM) parallel to the ribs. Releasing the retromammary attachments to the PMM liberates the NAC to rise slightly, rather than forcing the NAC even further inferiorly from a high-riding implant as well as allowing better parenchymal draping.

The hypothesis of this article is that some patients can avoid a mastopexy procedure by undergoing DPBA instead. Clinically, it is necessary to establish which patients are best served by augmentation alone, by DPBA, or by augmentation mastopexy. Studies and discussions have delineated the indications, technique, and risks.⁸⁻¹⁰ Among these, an original article from the United States on *primary* DPBA has not been published for more than 10 years; the last original study on DPBA was published in 2001 (and later reprinted in a 2006 supplement), well before the US Food and Drug Administration's (FDA) silicone gel implant moratorium was lifted on November 17, 2006.¹¹ Several modifications and secondary procedures have been described.¹²⁻¹⁵ Therefore, the plastic surgery literature could benefit from a study comparing newer gel implants with saline implants. To meet these needs, the author conducted a chart review covering 8 years of patient experience comparing saline implants placed with a DPBA technique during the final 4 years of the moratorium (phase 1) to both gel and saline implants placed during the 4 years after the moratorium was lifted (phase 2).

METHODS

Phase 1 of this study (January 1, 2003, to December 31, 2006) was a retrospective chart review of 1003 cosmetic saline BA patients who presented to the author's clinic. Phase 2 was a retrospective chart review of 996 gel and saline cosmetic BA patients treated by the author between January 1, 2007, and December 3, 2010. The patients were consecutive. This study was approved by the Institutional Review Board of the University of Minnesota, Minneapolis, Minnesota (Study #1111M07181).

The author performed 1003 cosmetic BA procedures exclusively with saline implants (2006 implants) during phase 1 and 996 (1992 implants) cosmetic BA procedures during phase 2, for a total of 1999 primary BA patients over 8 years (3998 implants). The entire group was assessed for outcomes and revisions for (1) deflation, (2) malposition, (3) size change, (4) change saline to silicone, (5) capsular contracture (CC), (6) explant, (7) hematoma, (8) mastopexy, (9) lipotransfer (visible wrinkling), (10) partial closure (skin separation), (11) infection, (12) explant with breast reduction, and (13) insertion of secondary implant. Outcomes for gel versus saline implants were compared during phase 2. On the basis of the author's prior surgical outcomes (use of gel from 1983-1992), the patients in phase 2 were told that an equivalent visual result would be obtained with either device, saline or silicone. A standardized checklist was used by all clinic

personnel to ensure that the same preoperative discussion took place with each patient, including the pros and cons of saline versus gel. Patients were allowed to try on and palpate both gel and saline implants. The patient ultimately made the final decision on which device she preferred. The choice of implant type is treated as an "explanatory (*independent*) variable" in this study. Preoperative and postoperative measurements, patient age, date of surgery, and implant size/type/manufacturer were also recorded. All implants placed throughout the study were smooth, round, medium or high profile from a single manufacturer (Allergan, Inc, Irvine, California).

Preoperative Analysis

The management algorithm for the DPBA candidate was used as a decision-making tree (Figure 1). Patients found to have the mid-range criteria on the algorithm, including (1) pseudoptosis, $\leq 15\%$ of the glandular tissue below the IMF; (2) a center-point of the NAC at or above the IMF; (3) a constricted lower pole (NAC-IMF < 5 cm); or (4) a tight IMF, were felt to be reasonable candidates for DPBA. Assessments were made from these measurements to determine which patients would be served best by (1) straight-forward breast augmentation, (2) DPBA, or (3) mastopexy. Specifically, DPBA patients must realize that they may require a mastopexy in the future.

With the patient standing, a large, colored index card was placed in each IMF to meticulously ascertain whether any breast tissue (or the NAC) passed below the horizontal plane of the card (ie, below the IMF). The exact center of the gland was noted, and the difference between the actual NAC position and the center of the gland was measured to determine whether the patient had a low-set NAC compared with center. The ideal DPBA candidate would have an NAC trajectory that points straight anteriorly. In patients whose NAC points downward, the DPBA outcome may be more limited.

Anthropometric measurements were recorded on a clinic chart worksheet. These measures included the distance from the IMF and NAC to the umbilicus, the distance from the NAC to the IMF under stretch, breast width, the distance from the sternal notch to the NAC, breast height, and NAC-to-NAC distance. During this final measurement, any difference in NAC height between sides was evaluated and explained to the patient while she looked in a full-length mirror. The fact that NAC height differences would not be corrected by DPBA was emphasized to the patient. Care was taken to compensate for a size difference when formulating the surgical plan, especially if saline implants were chosen. Any difference in size between breasts was ascertained with the patient in 3 different positions: standing, forward leaning, and supine. Each patient was also asked whether she noticed any size difference when wearing a bra. More ptotic breasts required additional attention to detail in sizing because size differences were potentially more difficult to calculate since the

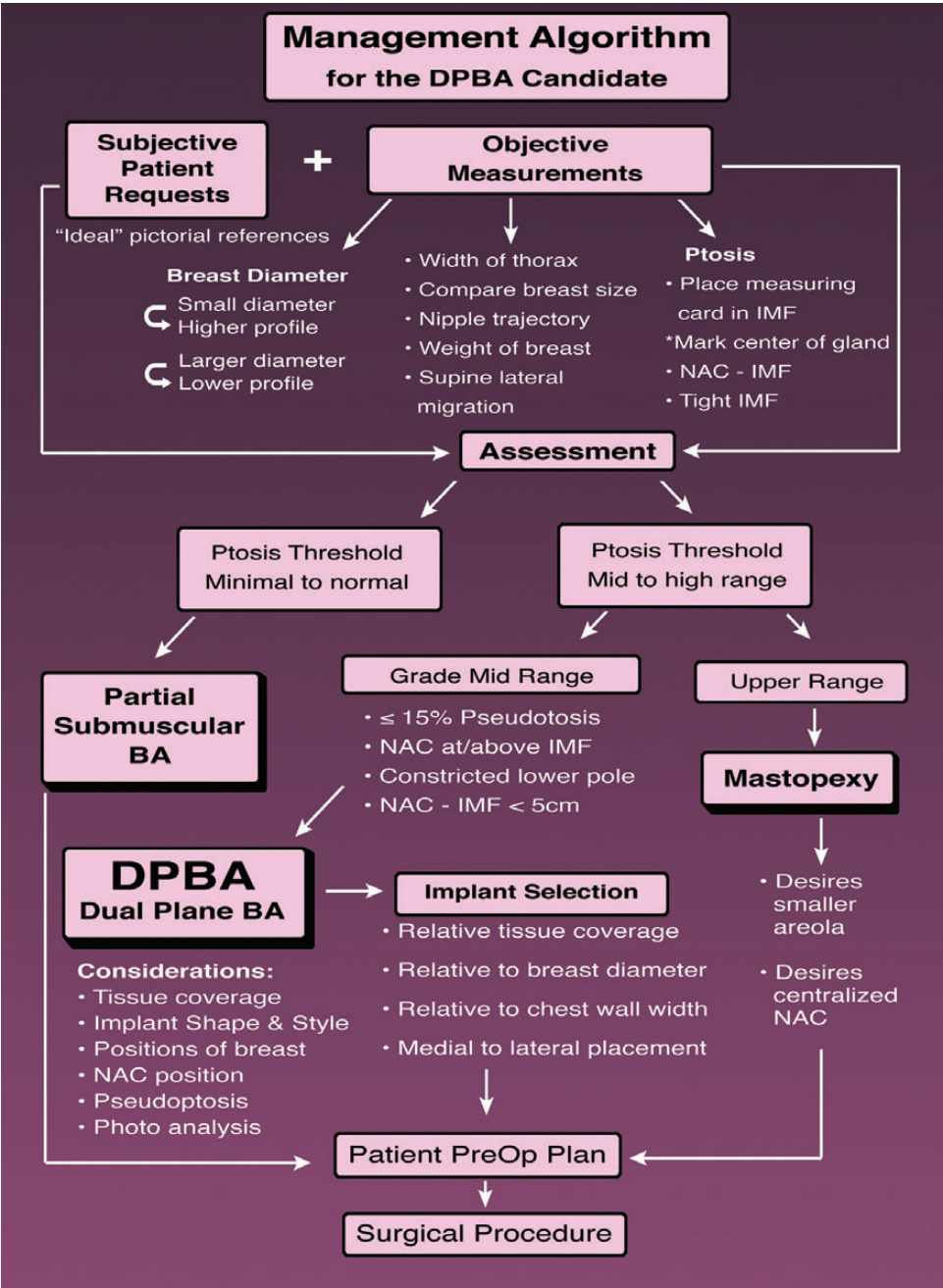


Figure 1. Decision-making algorithm for dual-plane breast augmentation based on the “SOAP” (subjective-objective-assessment-plan) method for medical charting. BA, breast augmentation; DPBA, dual-plane breast augmentation; IMF, inframammary fold; NAC, nipple-areola complex.

tissue mound is more mobile. Patient photos were then printed and analyzed for size differences. If the size difference was appreciable between each breast but similar to the manufactured sizes of prefilled gel implants, gel implants were placed to achieve adequate volume symmetry in a patient opting for gel. If saline implants were chosen, volume adjustments were made during surgery to compensate for a discrepancy between sides.

Noncandidates

The decision between a DPBA and a mastopexy procedure is perhaps the hardest one in this “in-between” group of patients. Two questions are key: First, does the patient want the NAC in the center of the breast mound? Second, does she want her areola to be smaller? Generally, only some type of mastopexy will produce these results. The

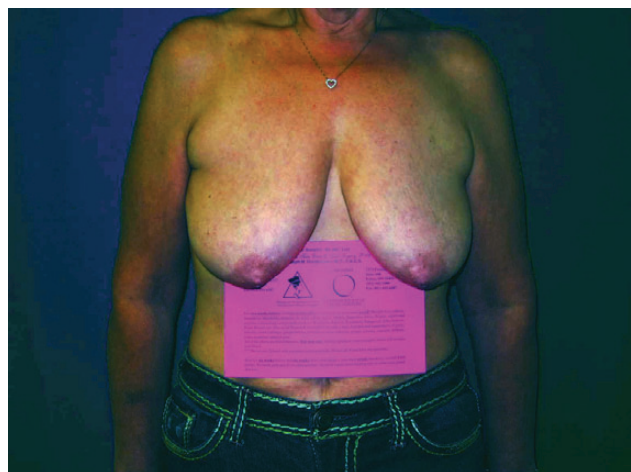


Figure 2. This 54-year-old woman demonstrates 3 contraindications to dual-plane breast augmentation because (1) her nipple-areola complex is 2 cm below the inframammary fold, which is (2) pointing almost straight downward, and (3) her breasts are heavy.

management algorithm for the DPBA candidate was used as a decision-making tree for noncandidates as well (Figure 1). Patients found to be better or worse than the mid-range criteria on the algorithm were excluded and underwent straightforward augmentation or augmentation mastopexy. Patients were directly involved in the decision-making process.

The general weight of the breast had to be assessed because DPBA will not easily mobilize the NAC on a heavier mound as easily as a less weighty gland, nor will DPBA lift a down-pointing NAC from below the IMF (Figure 2). Patients were examined in a supine position during the consultation. While standing at the patient's feet, the surgeon looked cephalad. If the gland(s) fell far laterally, this indicated a marked amount of excess skin

that would limit a pleasing outcome from the DPBA (Figure 3). These patients are examples of noncandidates for DPBA. The excess skin envelope will not conform sufficiently to the implant. Skin reduction would be required. These patients should be considered for a mastopexy, which removes some inferior pole skin.

A tuberous breast deformity is technically not a contraindication to DPBA per se. That said, patients with a tuberous breast deformity are at increased risk for a postoperative double fold, visible tight crease, low NAC, large areola, and uncorrected asymmetry. The patients shown in Figures 4 and 5 have a type II tuberous breast deformity (proposed by Grolleau et al¹⁶), putting them at higher risk for a residual tight crease postoperatively; they are not good candidates for DPBA. However, both patients were opposed to having mastopexy incisions and instead underwent DPBA. They both developed a double fold requiring postoperative molding with a bra (which will be discussed under the section detailing postoperative care), and both demonstrated residual asymmetry with enlarged areolae. Patients with a tuberous breast deformity need to be educated about the likelihood of a suboptimal result if they opt for a DPBA. The surgeon should establish excellent rapport preoperatively with these questionable DPBA candidates.

Implant Sizing

Implant size must be commensurate with assessments of tissue cover, breast diameter, and chest wall width.³ Base diameter of the implant is the most important measurement compared with breast diameter. Implant size selection has been an issue of much discussion in the literature.¹⁷⁻²⁰ The author employed a wide variety of methods, but the final implant size was always established preoperatively. Great care was taken to be certain that the final implant size equated to the patients' dimensions and tissues. In determining the final size selection, the author always placed the highest priority on preoperative

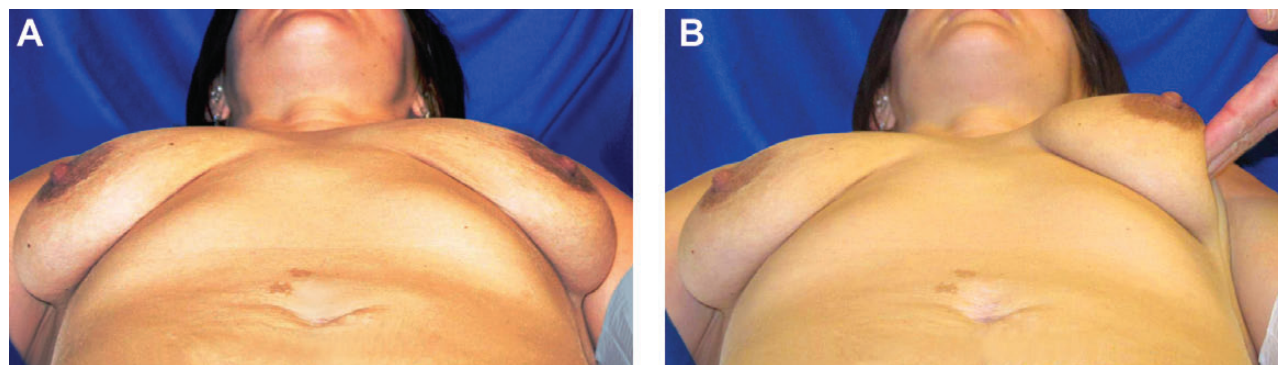


Figure 3. (A) This 34-year-old woman is a noncandidate for dual-plane breast augmentation (DPBA) because her breasts fall far laterally in the supine position. She requires a mastopexy. (B) The desired breast position would be more toward the midline, as demonstrated, for her to be a candidate for DPBA.



Figure 4. Tuberous breast deformity patients are often noncandidates for dual-plane breast augmentation (DPBA). (A) This 33-year-old woman with tuberous breast deformity is 5'4" tall and 149 pounds, with a preoperative size 36B. (B) Six months after DPBA, she was a 34C/D after receiving moderate-profile 390-cc saline implants. Dual-plane breast augmentation fell short in correcting her preoperative asymmetries and enlarged areolae.

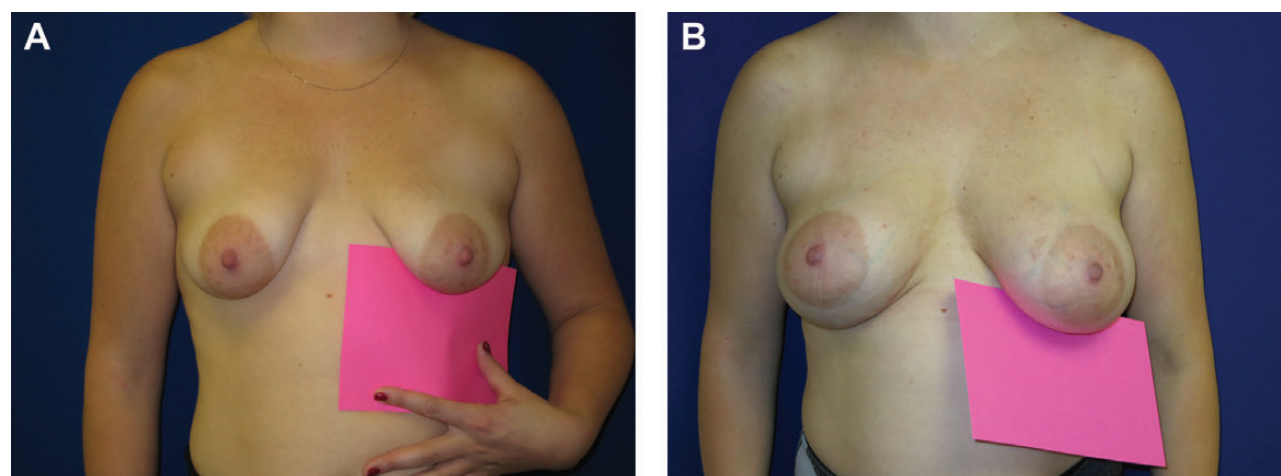


Figure 5. (A) This 26-year-old woman, who is 5'6" tall and 135 pounds, presented with a preoperative cup size of 34B. Her left nipple-areola complex (NAC) was at the level of the inframammary fold (IMF; note pink card as a reference point). (B) Eight months after dual-plane breast augmentation, the patient was a 36D after receiving moderate-profile 390-cc implants. She had residual asymmetries. The left NAC has migrated well above the IMF. Dual-plane breast augmentation merely augmented these tuberous, ptotic breasts without improving the breast appearance. Essentially, this would not be an acceptable result for many patients or plastic surgeons, but in fact many patients merely desire breast augmentation without improving breast symmetry or appearance and want to avoid the scars of a mastopexy.

measurements and potential tissue cover. Then, the patients' verbal requests were factored into the analysis.

During consultation, patient photos were obtained, transferred instantaneously to the computer with an Eye-Fi card (Eye-Fi, Mountainview, California), printed, and analyzed. Each patient tried multiple gel sizers with a bra, under a thin T-shirt. The profile of the implant was secondary, whereas the implant diameter vis-à-vis the diameter of the breasts was primary. A gel sizer placed in a bra preoperatively does not have the same surrounding forces placed on it as a surgical pocket, so approximately 30 to 50 cc was added to the final volume to account for flattening of the implant in the partial submuscular pocket.

Once the procedure was scheduled, the patient was given an instruction card admonishing against blood thinners and nicotine in the perioperative period. Strict, reliable methods of birth control were discussed, and all patients signed a legal release regarding potential pregnancy. Patients were instructed to wash with 4% chlorhexidine gluconate soap for a total of 3 preoperative showers at least 1 hour apart the evening before and the morning of surgery, scrubbing the torso to lower the number of skin contaminants.

Dual-Plane Surgical Technique

Preoperatively and with a chaperone present, the patient's chest was marked with the entire surgical plan and implant sizes. The surgeon reviewed the "ideal" photos brought by the patient during the preoperative consultation as well as the drawings of the surgical plan. These images were hung in the operating room for reference during the procedure.

The surgeon began the procedure with 4 pair of powder-free gloves: first a half-size larger, worn under the normal size, both of which were worn under 2 additional pair that were a full size larger than normal. As the case proceeded, 1 outer pair was removed, such that only an unused pair of gloves touched each implant as it was inserted. Only the surgeon handled the implants. Each patient received 1 dose of intravenous (IV) cefuroxime 1.5 g (GlaxoSmithKline, Research Triangle Park, North Carolina) during the hour prior to surgery because of its exquisite coverage of *Staphylococcus epidermidis*. The patient was put under general anesthesia. After a sterile paint with tinted Chloraprep (2% chlorhexidine gluconate + isopropyl alcohol; CareFusion, Leawood, Kansas) was applied, the patient was covered with sterile draping. Tegaderm (3M Health Care, St Paul, Minnesota) was also applied to each NAC during the last year of this study, to sequester any bacteria-laden nipple discharge that might have been expressed during the breast procedure (Figure 6).

If a periareolar approach was selected, a zigzag incision was made.²¹ An endoscopic axillary approach has been described in the literature,⁸ including recent reports in which a portion of pectoralis was excised.^{22,23} The author made an inframammary incision 3 cm long for saline or

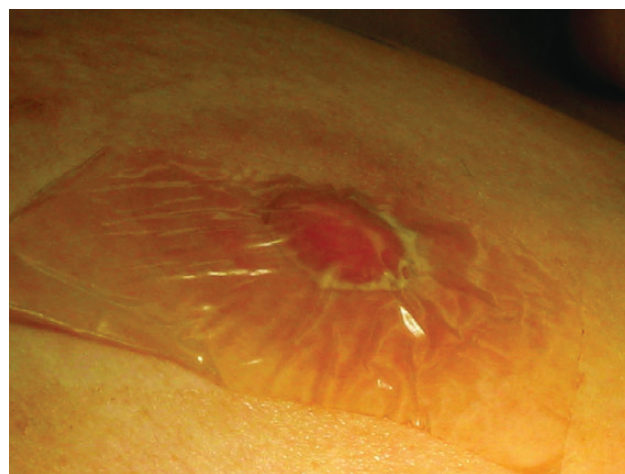


Figure 6. Tegaderm "nipple-shield" sequesters any bacteria-laden nipple discharge that may be expressed during a breast procedure.

4 to 6 cm for gel, depending on implant size and the patient's skin elasticity. Two planes were dissected for a combination of pocket locations (Figure 7). The subpectoral dissection was accomplished first. Dissection was carried down to the underlying pectoralis fascia. In some cases, the PMM attached slightly above the IMF. If the PMM contracted from the Bovie (Conmed Cautery System 2450; Conmed, Utica, New York), the breast bounced, indicating that dissection was heading in the correct direction. If the rectus muscle contracted, dissection was then angled more superiorly. If the local area around the incision contracted, the surgeon recognized that this was potentially a result of intercostal muscle contraction. To avoid penetrating between the ribs, dissection was cautiously redirected superiorly, remaining over the surface of the adjacent rib, because the PMM could have inserted cephalad to the current plane of dissection. Upward traction on the cephalic edge of the incision elevates the PMM off the ribcage. The intercostal muscles *do not* elevate.

Dissection remained superficial to the periosteum and perichondrium to minimize the patient's postoperative pain and discomfort. To develop the pocket, electrocautery was applied in coagulation mode for prospective hemostasis. The pectoralis muscle was *not* released along the medial sternal border. Once the medial pocket was established, the PMM was separated from the pectoralis minor muscle. Dissection advanced from superior-medial to inferior in the lateral pocket to better delineate the fusion area between the 2 pectoralis muscles. The serratus fascia was not elevated. The lateral border of the PMM was not elevated unless necessary to accommodate the implant. Care was taken not to overdissect laterally.

Once dissection of the partial subpectoral space was complete, dissection proceeded in the more superficial subglandular plane (retromammary plane). The retromammary plane was dissected to the level of the inferior

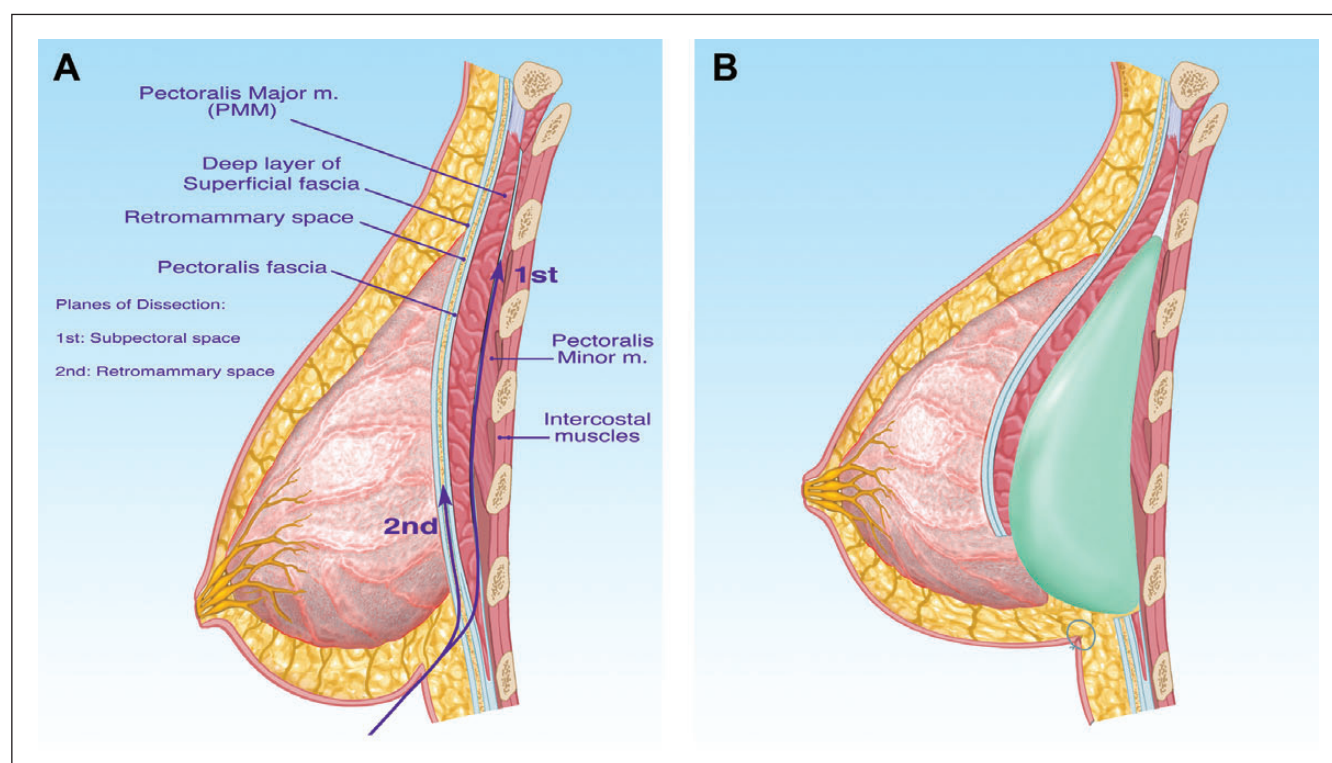


Figure 7. (A) Two planes are dissected for a combination of pocket locations. Once dissection of the partial subpectoral space is complete, dissection proceeds in the more superficial subglandular plane (retromammary plane) enhancing the tissue-draping interplay between the gland and implant. (B) This figure illustrates the crux of dual-plane breast augmentation. Release of the retromammary plane allows the caudal edge of the pectoralis muscle to migrate superiorly, causing the inferior-anterior edge of the implant to now adequately abut against the posterior surface of the breast parenchyma, supporting the gland and nipple-areola complex up and forward.

edge of the areola (6 o'clock) for minor ptosis or tight folds, but if attachments were loose or the conditions were more severe, dissection was carried to the superior edge of the areola (12 o'clock). Care was taken not to release the muscle too cephalad in the retromammary plane. The breast was moved up and down to determine whether adequate release had been obtained. Space was allowed so that the implant would maximally contact the parenchyma and project anteriorly without muscle restriction.

Once both planes were dissected, the medial inferior edge of the PMM was divided parallel to a rib, 1 cm above the IMF level (Figure 8). The dissection extended across the medial inferior portion of the muscle to the lateral edge of the sternum but did not extend superiorly along the sternal border. Finally, judicious release of the inferior pocket with blunt finger dissection was done on a case-by-case basis by stretching and sparing (not transecting) the IMF ligament and dermal attachments to lower the IMF. Following this type of dissection, the implant had pectoral coverage superiorly, as well as pectoral/fascial coverage laterally, and was exposed to the overlying parenchyma inferiorly down to the inframammary fold, as in Figure 7B.

Once dissection of the pocket was accomplished, air was drawn into the pocket by gently elevating the gland off the ribs with a finger or dissector. The incision was

pinched closed with the opposite hand. In this way, the outline of the pocket perimeter was delineated, obviating the need for a sizer (Figure 9). Following the "air-sizer" maneuver, any pocket irregularities were modified as necessary. The pocket was copiously irrigated with Adams pancidal triple antibiotic solution (bacitracin 50 000 units [Xgen Pharmaceuticals, New York, New York]; cefazolin 1 g [Sandoz, Inc, Princeton, New Jersey]; gentamicin 80 mg [APP Pharmaceuticals, Schaumburg, Illinois]), which also provided coverage for methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-resistant *S. epidermidis* (MRSE).²⁴⁻²⁷

The "no-touch" technique was maintained by removing the outer pair of 4 pair of gloves at this juncture. The implant container was opened by the assistant, and the Adams antibiotic solution was poured over the implant. Sensorcaine 0.25% with epinephrine 1:200 000 (APP Pharmaceuticals) was instilled into the pocket immediately prior to implant placement. The implants were then placed into each dual-plane pocket. It is possible to unintentionally insert the implant into the retromammary space, so care was taken to utilize a long enough retractor to elevate below the pectoralis muscle.

A Richardson general surgery retractor (#BT479R; Aesculap, Inc, Center Valley, Pennsylvania) was used for

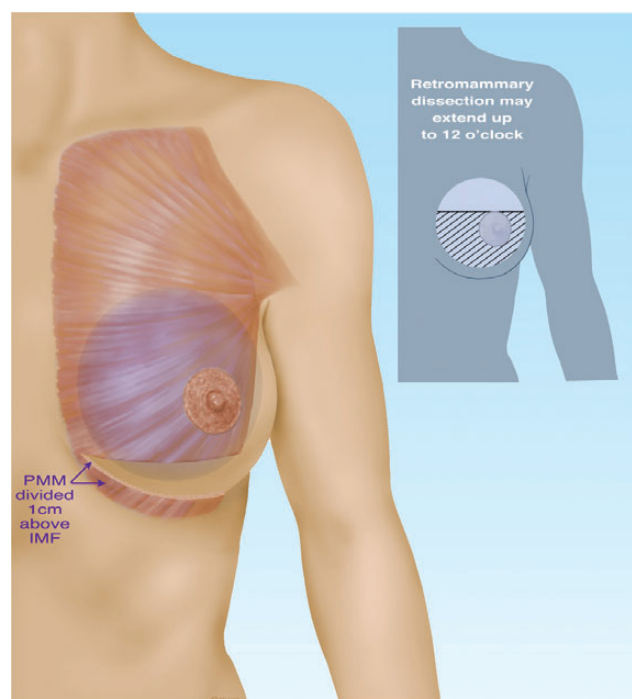


Figure 8. The medial inferior edge of the pectoralis major muscle is divided parallel to the ribs, 1 cm above the inframammary fold. The implant will have pectoral coverage superiorly, as well as pectoral fascial coverage laterally, and be exposed to the overlying parenchyma inferiorly down to the inframammary fold. (Inset) An intraoperative judgment is made whether to carry the retromammary dissection superior to the 6-o'clock nipple-areola complex level or even higher, to the 12-o'clock level. IMF, inframammary fold; PMM, pectoralis major muscle.

gel implant insertion because its 4-cm width accommodates a gel implant. Gentle upward traction was placed on the retractor as the gel implant was being inserted. Once a seal had been established at the incision/mouth of the pocket by the gel implant, the retractor was lifted quickly and forcefully to facilitate insertion with negative pressure. Often, a suction sound was audible if this maneuver was done correctly. If saline implants were placed, a closed fill system was employed.

Minor adjustments were made as necessary once the implant was placed. Care was taken to ensure that the muscle was pulled down over the implant. If the pocket was reentered for hemostasis or further adjustment, fingers or instruments were immersed in the triple antibiotic solution before reentering the pocket. The position of the implant was meticulously assessed from multiple angles in both supine and sitting positions. To stand at the foot of the bed and on each side provided helpful angles for the surgeon, while the anesthesiologist looked from above the drape, focusing on the 12-o'clock position. All patients were placed in a full 90-degree sitting position for the final assessment. Contour irregularities and lack of symmetry became more obvious from a position that simulated the pull of gravity. The "ideal" photos the patient had chosen preoperatively were used as a reference for implant position (medial vs lateral, inferior vs superior). Finally, the surgeon held a towel tightly across the NAC with the patient in the sitting position (Figure 10). This "evening gown" test was useful to compare upper pole asymmetries.

The incision was closed with a running 2-0 Vicryl suture (Ethicon, Inc, New Brunswick, New Jersey) and the dermis was everted with interrupted and running subcuticular 3-0 Monocryl sutures (Ethicon, Inc). Mastisol liquid

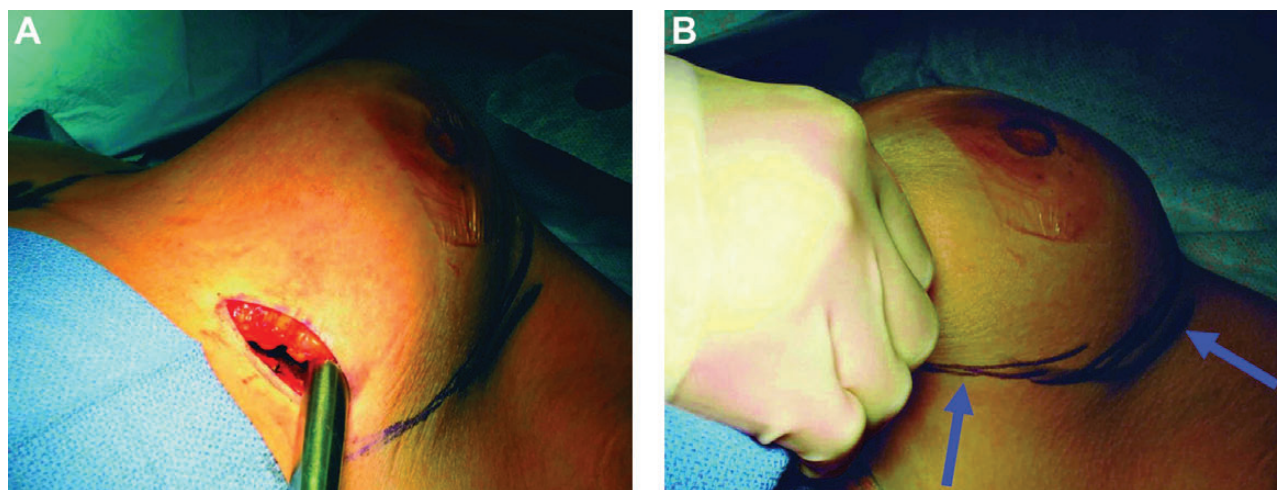


Figure 9. (A) Once dissection of the pocket is accomplished, air can be drawn into the pocket by gently elevating the gland off of the ribs. (B) The incision is pinched closed, demonstrating the pocket perimeter. Following the "air-sizer" maneuver, any pocket irregularities are modified.

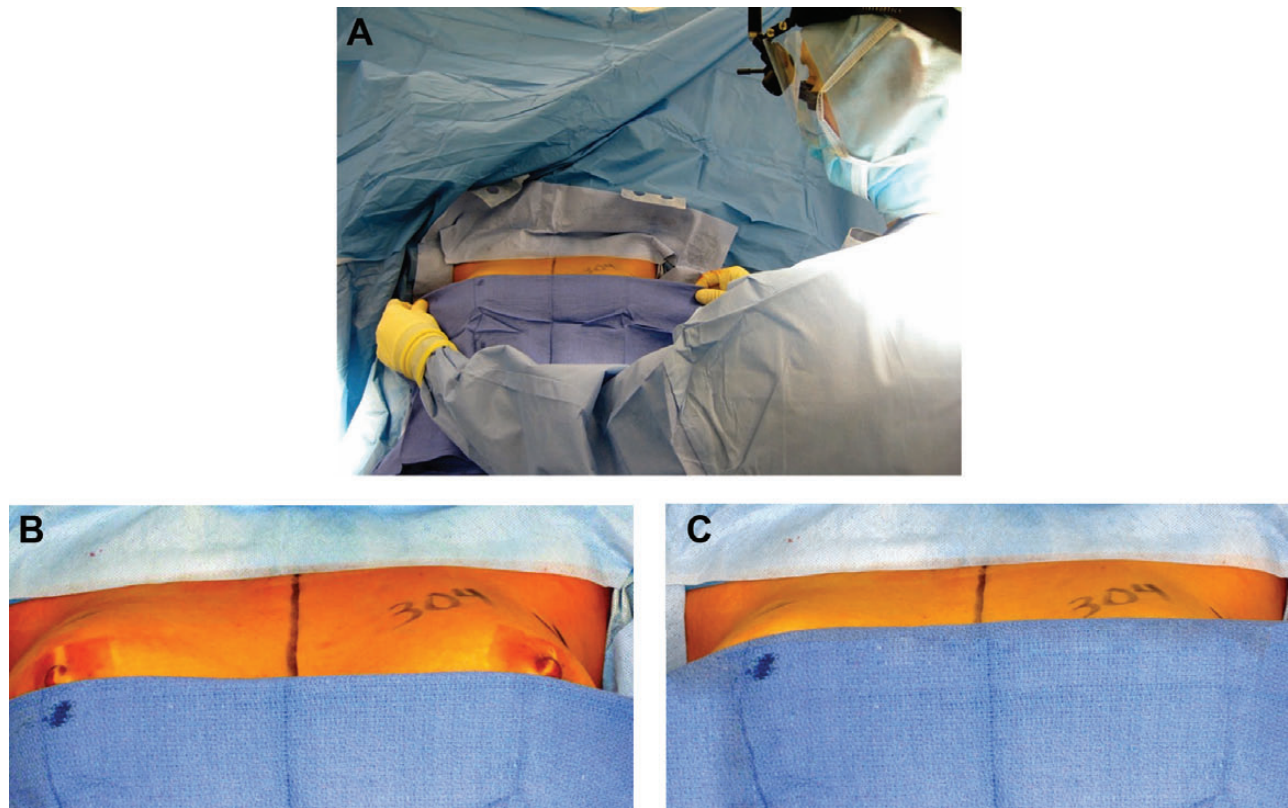


Figure 10. (A, B, C) A towel is held tightly across the nipple-areola complex while the patient is in the full 90-degree sitting position. This “evening gown” test is useful to compare upper pole asymmetries.

adhesive (Ferndale Lab, Ferndale, Michigan) was placed on the incision and allowed to dry, and Steri-Strips (3-M, St Paul, Minnesota) were applied. Patients were discharged with only these adhesive skin closure tapes over their incisions. No bra or dressings were applied routinely. Occasionally, a superior pole breast wrap (Clear Point Medical, Champlain, New York) was applied intraoperatively (or even postoperatively) in selected patients if the implants were found to be riding high. A video of the surgical procedure is available at www.aestheticsurgery-journal.com. You may also use any smartphone to scan the code on the first page of this article to be taken directly to the video on www.YouTube.com.

Postoperative Care

Double Fold

Some patients who preoperatively had an NAC at the IMF level developed problems with postoperative double folds secondary to a tight crease. A tight crease may maintain its contour and resist expansion by the underlying implant, causing flattening along its original length. Patients who presented postoperatively with a double fold were instructed to wear a “cutout” bra (Figure 11). To create this bra, the patient brought in a standard, inexpensive underwire bra.

The lower half of the cup, from immediately above the underwire up to the NAC level, was cut away with a scissors. Patients were instructed to wear the “cutout” bra 7 days a week, 24 hours a day, for the first postoperative month (except when they were bathing or showering). The “cutout” bra invariably expanded the tight IMF because the wire compressed the new IMF and allowed the original fold to relax more superiorly. With this method, the author has found that most taut tissue will succumb to the implant forces and efface over 1 to 3 months.

Multiple steps from prior publications were followed to provide quicker patient recovery.²⁸⁻³⁰ In an effort to avoid CC, patients were instructed, as noted above, to begin raising their arms over their heads and to perform manual displacement exercises hours after surgery. Patients were instructed to massage their implants in all directions except downward, to avoid tension on the incision. Regardless of the preferred CC prevention routine, patients were encouraged to continue with the exercises for years, rather than weeks or months.³¹ If a patient presented with a unilateral firm breast at any time during the postoperative period, she was started on a protocol that included exercises, massage, high-dose vitamin E (2000 U/d),³² and nonsteroidal anti-inflammatory medication. A printed protocol was provided to each patient to aid in her compliance and understanding of individual responsibility. If a

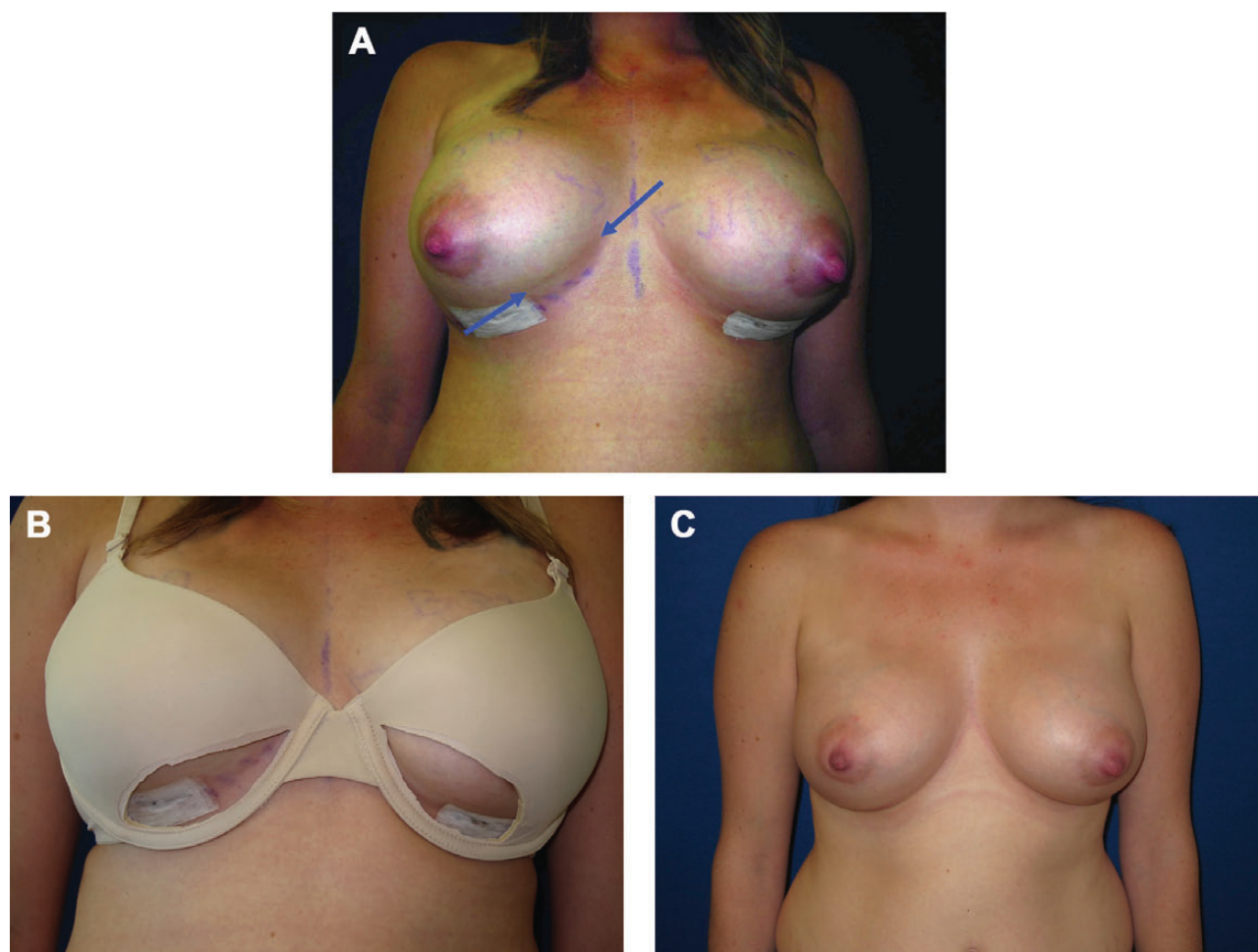


Figure 11. (A) This 24-year-old woman had a double fold, which can be produced from a tight crease present preoperatively. The tight fold may maintain its contour and resist expansion by the underlying implant, causing flattening along its original length. Arrows point to each end of the tight fold. (B) Patients with a double fold are placed in an underwire “cutout” bra. (C) Seven weeks postoperatively, the patient demonstrates effacement of the double fold.

CC was diagnosed, a 90-day treatment protocol of montelukast (Singulair; Merck & Co, West Point, Pennsylvania) was initiated with the option to repeat it once for a total duration of 6 months (although this is an off-label usage). Montelukast is not available in generic formulation, may be expensive, and may not be covered by insurance. The out-of-pocket cost to the patient was approximately \$400 for a 3-month supply, which may be prohibitive.³³⁻³⁸

Photographic analysis was used to define a positive outcome. All patients had 5 standardized preoperative and postoperative photographs, including frontal, side, and oblique views. The surgeon analyzed the photos preoperatively with the patient for asymmetries and ptosis. In turn, all postoperative photos were analyzed and compared with the preoperative photos by 2 third parties (the clinic registered nurse [RN] and the aesthetician) and by the surgeon. Postoperative photos were reviewed personally with all patients in the clinic by the RN and surgeon and given directly to each patient upon request.

RESULTS

One hundred eighteen patients (11.8% of phase 1 cohort) underwent DPBA in the first phase of the study and 138 (13.9% of phase 2 cohort) underwent DPBA in the second phase, for a total of 256 overall (12.8%). Clinical results of 5 patients with combinations of ptosis, glandular ptosis, constricted lower pole, and tight IMF can be seen in Figures 12 through 14. Additional patient images are available in an online-only appendix at www.aestheticsurgeryjournal.com.

Duration of Follow-up

Duration of follow-up was calculated overall and by implant type for all patients. About a quarter of patients—24.2% of the entire cohort of 1999 patients ($n = 3998$ implants) and 23.4% of the 256 DPBA patients—were followed for 1 year or more. Also, 25.9% of the 1554

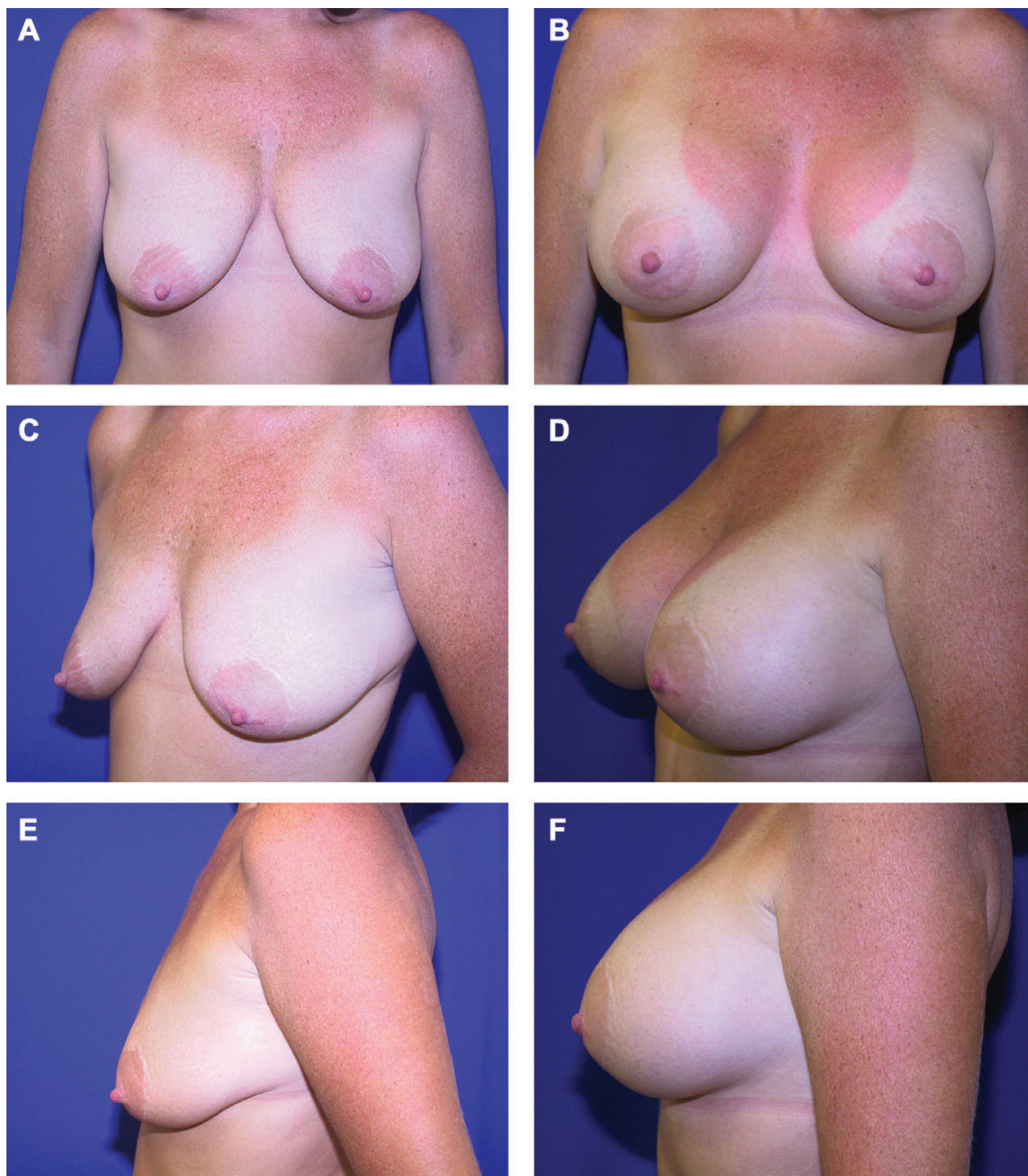


Figure 12. (A, C, E) This 47-year-old woman presented with ptosis and a very low-set nipple-areola complex. She was 5'4" and 130 pounds, with a preoperative size of 34B. (B, D, F) One year after bilateral dual-plane breast augmentation (DPBA) with a 450-cc implant on the left and a 450-cc implant on the right. The patient's postoperative cup size was 34C. Postoperatively, more breast tissue is visible throughout the inferior pole because the DPBA releases the inferior pole tissue, allowing it to rise up like a pendulum.

saline implant patients (n = 3108 saline implants) and 18.2% of the 445 silicone gel patients (n = 890 silicone

implants) were followed for 1 year or more, and 28.0% of the saline DPBA patients (n = 186) and 11.4% of the sili-

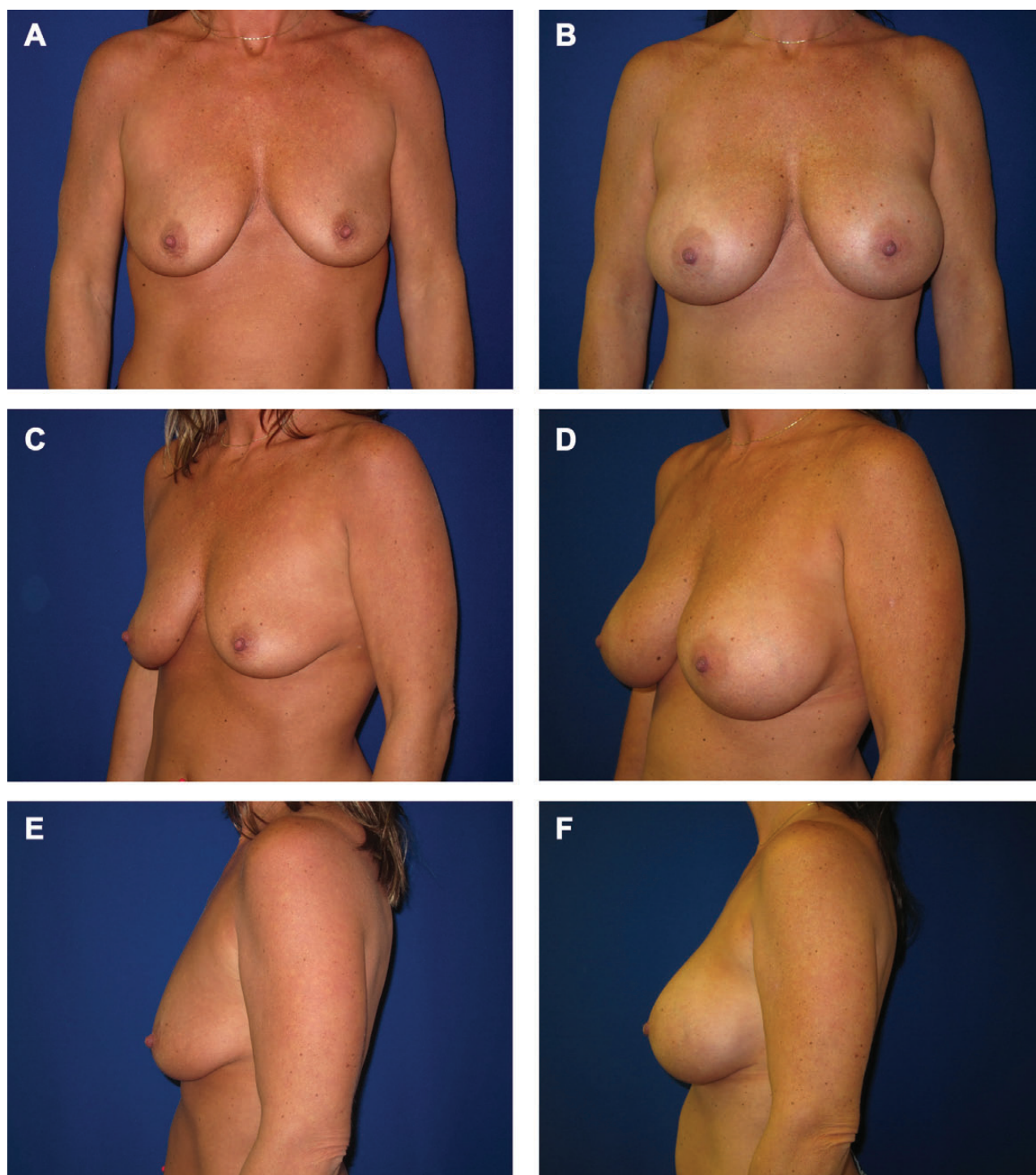


Figure 13. (A, C, E) This 39-year-old woman presented with pseudoptosis. She was 5'5" and 135 pounds, with a preoperative cup size of 38B. (B, D, F) Sixteen months after bilateral inframammary dual-plane breast augmentation with a 480-cc implant on the left and a 455-cc implant on the right. The patient's postoperative size was 38D. Postoperatively, on lateral view, more breast tissue was visible between the inframammary fold (IMF) and the nipple-areola complex. The IMF is lower after augmentation (see the distance from the IMF to anterior elbow crease on the oblique and lateral views).

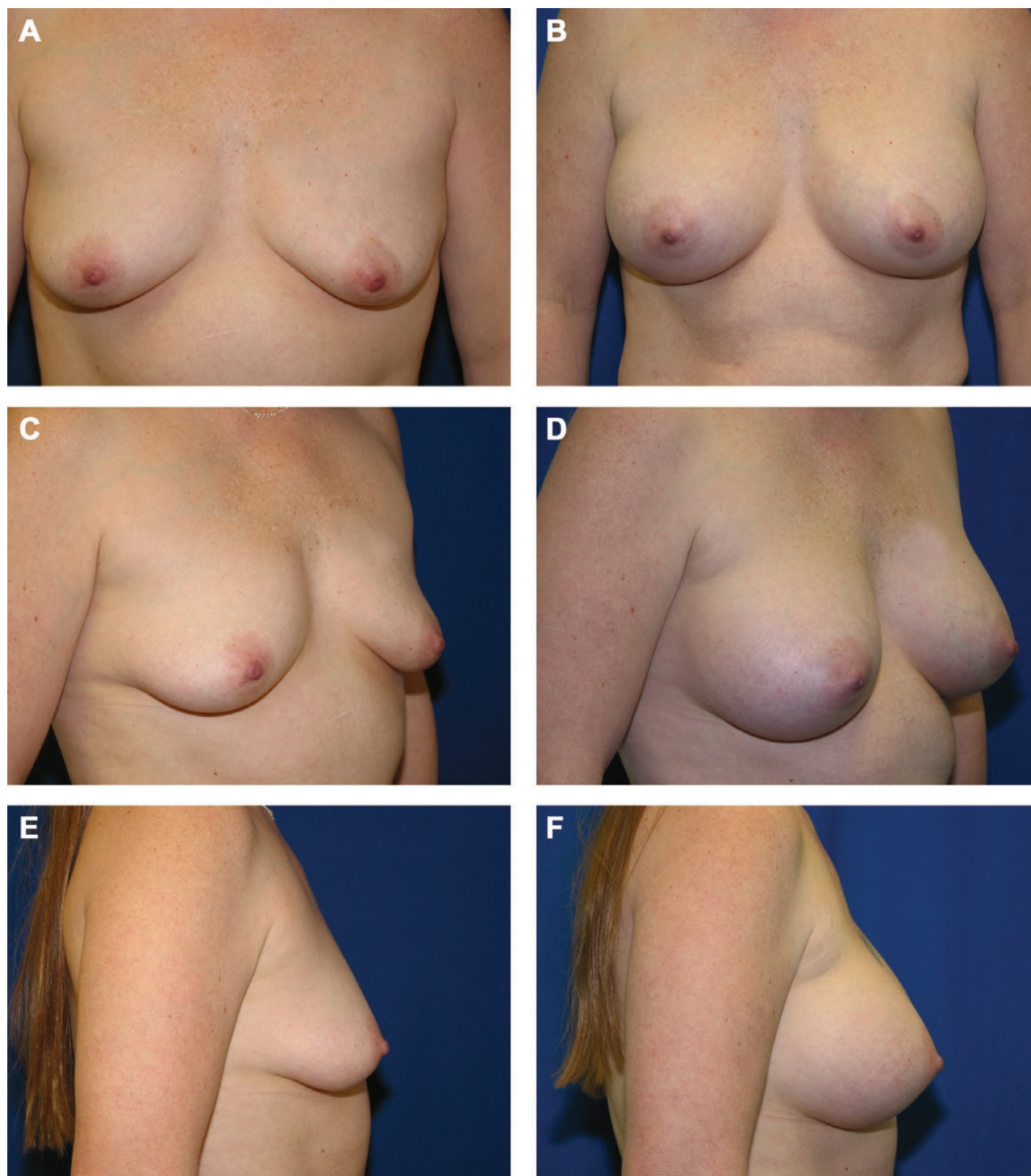


Figure 14. (A, C, E) This 40-year-old woman presented with a tight, irregular, asymmetric inframammary fold (IMF) with a low-set nipple-areola complex (NAC). She was 5'4" and weighed 140 pounds, with a preoperative cup size of 36B. (B, D, F) Two years after bilateral inframammary dual-plane breast augmentation with a 390-cc implant on the left and a 390-cc implant on the right. The patient's postoperative size was 38D. The IMF is lower after augmentation (see the distance from the IMF to anterior elbow crease on the oblique and lateral views). Postoperatively on the frontal view, more breast tissue is visible between the inferior visual border and the elevated NAC.

cone gel DPBA patients ($n = 70$) were followed for 1 year or more. The smaller percentage of follow-up for the gel subset is because the phase 2 four-year study of gel and saline implants closed more recently than the phase 1 eight-year study, which included only saline implants. Most of the 22 patients in the entire cohort and the 3 DPBA patients who did not return for follow-up lived out of state, and these women were followed with phone calls during the first months postoperatively. Of the 1999 patients in the overall cohort, 1003 (50.2%) were in phase 1 and 996 (49.8%) were in phase 2, which is a remarkably consistent number for each phase. Of the entire cohort ($N = 1999$), DPBA accounted for 11.8% of patients in phase 1 and 13.9% in phase 2. Of the 256 DPBA patients, 118 (46.1%) were in phase 1 and 138 (53.9%) were in phase 2. Once the FDA moratorium was lifted and phase 2 began, it took a while for silicone to be accepted by our patients. Of the 996 patients in phase 2, 551 (55.3%) received saline implants and 445 (44.7%) received silicone. The number of DPBA per calendar year varied from 23 to 49. All patients were advised to follow up annually with our office for implant examinations for the rest of their lives.

Demographics

The mean (SD) age of all patients was 33.6 (8.7) years (range, 18-69 years). The median age was 32.9 years. The mean (SD) age of DPBA patients was 36.4 (8.5) years (range, 20-65 years). The median age was 35.4 years.

Implant Characteristics

All patients received 2 implants initially. The mean (SD) implant size in all patients was 350.3 (61.2) cc (range, 120-800 cc). Mean (SD) implant size in DPBA patients was 353.2 (64.7) cc (range, 150-575 cc). All implants placed throughout the study were smooth, round, medium or high profile from a single manufacturer (Allergan, Inc).

Revisions and Untoward Events

There is an implicit assumption in the following results that phase 1 saline and phase 2 saline are combinable, which would make sense because the same manufacturer's saline implant models and the surgical equipment and techniques were similar enough over the 2 phases of saline experience. Since the data from all saline implants were assumed to be combinable, the comparison of saline versus silicone was not confined to phase 2. However, phase 1 patients, all of whom received saline implants, had a longer period of observation during which an untoward event could occur, whereas patients who received silicone implants had, on average, shorter follow-up time. Therefore, revision rates were normalized by patient years of follow-up. That is, the number of events per patient

year of observation was used to assess relative risk to level the playing field when comparing saline and silicone.

Overall, 1868 patients had no revisions and 131 patients (6.6%) had at least 1 revision. Of the 131 total revisions, 109 patients had 1 revision, 21 had 2 revisions, and 1 had 3 revisions. Of the 256 DPBA patients, 229 had no revisions, 27 (10.5%) had at least 1 revision, and 3 had 2 revisions. No DPBA patient had 3 revisional procedures. Of the 1743 patients with non-DPBA surgery, 104 (6.0%) had at least 1 revision. The difference in revision rates between types of surgery was 4.6% (confidence interval [CI], 0.7-8.5). In patients receiving saline implants, the non-DBPA and DBPA revision rates were 6.9% and 11.3%, respectively. In patients receiving silicone implants, these rates were 2.4% and 8.6%, respectively. The pattern is also similar over time. In phase 1, the non-DBPA and DBPA revision rates were 8.9% and 14.4%, respectively. In phase 2, they were 2.9% and 7.2%, respectively.

Saline implants required more revisions in the overall cohort and in the DPBA group than silicone gel implants. Of the 1554 patients with saline implants, 116 (7.5%) had at least 1 revision. Of the 445 patients with silicone implants, 15 (3.4%) had at least 1 revisional procedure. Of the 186 DPBA patients with saline implants, 21 (11.3%) had at least 1 revision. Of the 70 DPBA patients with silicone implants, 6 (8.6%) had at least 1 revision. These data could yield an unfair comparison because the saline cohort had longer follow-up times than did the silicone patients and therefore had more time for events to occur. Therefore, summarization by patient year of follow-up helps to adjust for differences in follow-up time. The revision rates for any kind of secondary procedure were 9.4 revisions per 100 patient years (CI, 7.9-11.1) for saline patients versus 7.1 (CI, 4.0-11.7) for silicone. The difference is 2.3 (CI, -2.0 to 6.7). With DPBA patients, there were more events in the silicone cohort at 23.5 per 100 patient years (CI, 8.6-51.1) than in the saline cohort at 11.7 (CI, 7.5-17.5) (Figure 15). The difference is -11.8 revisions per 100 patient years (CI, -26.6 to 3.1).

Thirteen types of revisions were discovered. The types of revisions are listed in order of frequency for the overall cohort and DPBA cohort (Tables 1 and 2). Deflation tops the lists in both cohorts. No deflations were discovered in gel implants. There were some minor variations between the 2 cohorts. The complications or untoward events are analyzed in detail below.

Implant Failure

Deflation was the most common reason for implant-related revisions in the entire cohort, with 57 ruptured implants in 1999 patients (2.9% of patients) and 3998 implants (1.4% of implants) (Tables 1 and 2). Note that 10 patients experienced 2 deflations. Deflation was also the most common reason for implant-related revision in the DPBA cohort, with 6 ruptured implants in 256 patients (2.3% of patients) and 512 implants (1.2% of implants) (Table 2). All deflations were discovered in saline implants, and all were removed and replaced. Analysis of the

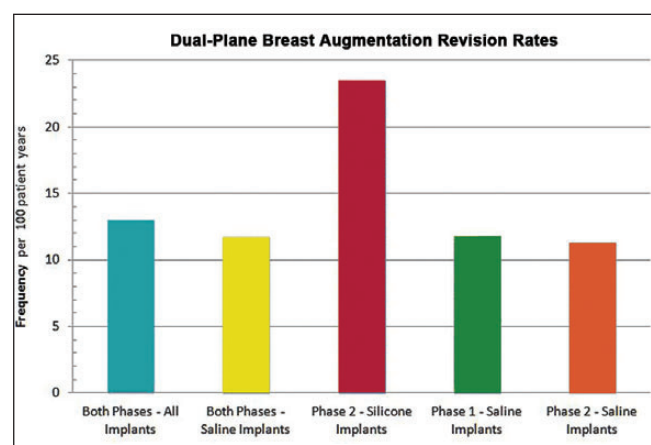


Figure 15. For dual-plane breast augmentation in this study, there were more revisions in the silicone gel cohort, 23.5 per 100 patient years (confidence interval [CI], 8.6-51.1), than in the saline cohort, 11.7 (CI, 7.5-17.5). Much of this difference is from malposition revisions of gel devices. The difference is -11.8 thrombospondin instances per 100 patient years (CI, -26.6 to 3.1). Therefore, this difference is not significant to the 95% confidence interval because the CI is both above and below zero (ie, the CI crosses zero). When one looks at the data, it is clear that saline implants required more revisions (7.5%) compared with gel (3.4%). The primary reason for revision in both cohorts was saline implant deflation.

frequency of deflation per 100 patient years showed saline to be 5.3 in phase 1 and 4.7 in phase 2, versus 0 for silicone gel. Analysis of the DPBA group showed this same trend, with phase 1 as 7.1 deflations per 100 patient years

versus zero for silicone in DPBA phase 2 patients (Tables 3 and 4). No leaks were discovered in gel implants (phase 2), although no formal screening process was required. Patients were informed of the FDA recommendations and criteria regarding postoperative magnetic resonance imaging (MRI) screening. Patients were advised to undergo routine breast exams and mammograms by their primary care provider. One gel implant patient (1/445) elected to have a postoperative MRI to conform to current FDA surveillance recommendations. During the MRI examination, a deflation was detected. The patient decided to undergo surgical intervention, but at the time of surgery, the implant was actually discovered to be intact, causing unnecessary expense, time lost from work, surgeon time lost, and exposure to general anesthesia. In sum, all ruptures occurred in the saline group (57/1554 patients or 3.7%); 10 patients in the entire cohort and 3 patients in the DPBA cohort experienced more than 1 deflation (not exceeding 2).

Malposition

Malposition was the second most common untoward event in the overall cohort, occurring in 26 patients (twice in 1 patient) (26/1999 or 1.3%). There were 26 patients with exactly 1 malposition and 1 patient with 2 malpositions, for a total of 27 patients with at least 1 event. Malposition was the fourth most common untoward event in the DPBA cohort, occurring in 5 patients (5/256 or 1.9%; Tables 5 and 6). Malposition was defined as any movement in any direction of the breast implant outside the original pocket. All malpositions appeared to be inferior in the standing position, but in the supine position, it was discovered they were all inferolateral as well.

Table 1. Event Type in the Entire Cohort (N = 1999), Number of Patients With 0, 1, or 2 Listed by Decreasing Frequency

Cohort	Type of Secondary Procedure	No. of Patients With No Event	No. of Patients With 1 Event	No. of Patients With 2 Events
All	Saline deflation/gel leak	1932	57	10
All	Malposition	1972	26	1
All	Size change	1975	24	0
All	Change saline to silicone	1980	19	0
All	Capsule	1985	13	1
All	Explant	1991	8	0
All	Hematoma	1994	4	1
All	Mastopexy	1995	4	0
All	Lipotransfer	1997	2	0
All	Partial closure	1997	2	0
All	Infection	1998	1	0
All	Explant with reduction	1998	1	0
All	Insert secondary implant	1998	1	0

Table 2. Event Type in the Dual-Plane Breast Augmentation (DPBA) Cohort (n = 256), Patients With 0, 1, or 2 Listed by Decreasing Frequency

Cohort	Type of Secondary Procedure	No. of Patients With No Event	No. of Patients With 1 Event	No. of Patients With 2 Events
DPBA	Saline deflation/gel leak	247	6	3
DPBA	Size change	248	8	0
DPBA	Capsule	250	6	0
DPBA	Malposition	251	5	0
DPBA	Change saline to silicone	251	5	0
DPBA	Mastopexy	253	3	0
DPBA	Hematoma	254	2	0
DPBA	Explant with reduction	255	1	0
DPBA	Explant	255	1	0
DPBA	Partial closure	255	1	0
DPBA	Lipotransfer	256	0	0
DPBA	Infection	256	0	0
DPBA	Insert secondary implant	256	0	0

Table 3. Incidence and Frequency of Saline Deflation or Gel Leak in Entire Cohort

Phase	Implant Type	Sample Size	No. of Patients With at Least 1 Event	Incidence, %	No. of Events	Frequency, %	Patient Years of Follow-up	Frequency (per 100 Patient Years)	95% Confidence Intervals	
									Lower	Upper
Both	Both	1999	67	3.4	77	3.9	1691	4.6		
Both	Saline	1554	67	4.3	77	5.0	1478	5.2	4.1	6.5
	Silicone	445	0	0.0	0	0.0	212	0.0	0.0	1.7
	Saline	1003	58	5.8	67	6.7	1268	5.3		
	Saline	551	9	1.6	10	1.8	211	4.7		

The difference in deflation rates between saline and silicone is 5.2 events per 100 patient years (95% confidence interval, 2.1-8.3). The bold zeros in Table 3 show the distinction between gel rupture and saline deflations in the entire cohort. No gel implant was found to be ruptured in the entire cohort, contrasted to saline implants where 77 implants ruptured. The primary reason for revision in both cohorts was saline implant deflation.

Table 4. Incidence and Frequency of Saline Deflation or Gel Leak in Dual-Plane Breast Augmentation Cohort

Phase	Implant Type	Sample Size	No. of Patients With at Least 1 Event	Incidence, %	No. of Events	Frequency, %	Patient Years of Follow-up	Frequency (per 100 Patient Years)	95% Confidence Intervals	
									Lower	Upper
Both	Both	256	9	3.5	12	4.7	230	5.2		
Both	Saline	186	9	4.8	12	6.5	205	5.9	3.0	10.2
2	Silicone	70	0	0.0	0	0.0	26	0.0	0.0	14.4
1	Saline	118	9	7.6	12	10.2	169	7.1		
2	Saline	68	0	0.0	0	0.0	35	0.0		

The difference in deflation/leak rates between saline and silicone is 5.9 events per 100 patient years (confidence interval, -3.5 to 15.3). The confidence intervals for the individual rates and for the difference are wider than in the case of all patients, because the number of events is smaller and the information therefore less precise. Zero leaks were discovered in gel implants (phase 2).

Table 5. Incidence and Frequency of Malposition in Entire Cohort

Phase	Implant Type	Sample Size	No. of Patients With at Least 1 Event	Incidence, %	No. of Events	Frequency, %	Patient Years of Follow-up	Frequency (per 100 Patient Years)
Both	Both	1999	27	1.4	28	1.4	1691	1.7
Both	Saline	1554	20	1.3	21	1.4	1478	1.4
2	Silicone	445	7	1.6	7	1.6	212	3.3
1	Saline	1003	17	1.7	17	1.7	1268	1.3
2	Saline	551	3	0.5	4	0.7	211	1.9

Table 6. Incidence and Frequency of Malposition in Dual-Plane Breast Augmentation Cohort

Phase	Implant Type	Sample Size	No. of Patients With at Least 1 Event	Incidence, %	Number of Events	Frequency, %	Patient Years of Follow-up	Frequency (per 100 Patient Years)
Both	Both	256	5	2.0	5	2.0	230	2.2
Both	Saline	186	3	1.6	3	1.6	205	1.5
2	Silicone	70	2	2.9	2	2.9	26	7.8
1	Saline	118	1	0.8	1	0.8	169	0.6
2	Saline	68	2	2.9	2	2.9	35	5.7

Many DPBA candidates present with inherently lax tissue, which can lead to postoperative malposition. The tissues frequently cannot withstand the muscular and gravitational forces of the implant. This is the purpose of preoperative supine assessment, because marked lateral migration of the breast would disqualify the patient from DPBA and propel her toward a mastopexy. Malposition was handled in the following manner. The previous inframammary (IM) incision was opened, the expanded area of the pocket was freshened with electrocautery by excising a crescent of capsule, contralateral capsulotomy was carried out when necessary, and capsulorrhaphy was achieved with interrupted 0-Ethibond sutures (Ethicon, Inc). The patients were then placed in the full 90-degree sitting position, and further meticulous adjustments were made to achieve symmetry. For revision of high-riding implants, the previous IM incision was opened, the inferior pocket was released, and the anterior lining was removed from the inferior pole (NAC-IMF) to allow the implant to drop into alignment with the contralateral IMF.

Size Change

Size change was the third most common event in the overall cohort (26 patients or 1.2%) and the second most common event in the DPBA cohort (8 patients or 3.1%) (Tables 7 and 8). The percentages of saline-implant patients who desired a size change—1.4% in the overall population and 3.7% in the DPBA subset (Tables 7 and 8)—appeared to be

at least twice those of silicone-implant patients, which were 0.7% overall and 1.4% in DPBA. However, there was greater opportunity for patients with saline implants to seek a change because as a group they were followed longer than silicone-implant patients. When the incidence of size change is normalized by follow-up time, the 2 types of implants have more similar rates; in the overall population, the rates are the same (1.4 events per 100 patient years). It is clear that more problems occurred with saline because saline implant deflations were self-diagnosed by the patients, but the author does not know whether any silicone implants were ruptured. Zero leaks were discovered in gel implants (phase 2). Women with saline implants who had a size change generally did so long after their initial surgery, even many years afterwards. Some patients had a size change as their primary reason for a revision, whereas other patients had an unrelated untoward event as the inciting primary reason (Tables 1 and 2). Women with gel implants who had a size change (and there were only 3 such patients) seemed to do so sooner after surgery. The same observation holds in the subset of DPBA patients. Patients signed the printed decision management algorithm on size change as part of the preoperative consultation.¹

Change Saline to Silicone

Conversion to gel was the fourth most common event in the overall cohort; 19 patients (1%) requested conversion. Conversion to gel was the fifth most common event in the DPBA cohort, occurring in 5 patients (2.0%). A saline

Table 7. Incidence and Frequency of Size Change in Entire Cohort

Phase	Implant Type	Sample Size	No. of Patients With at Least 1 Event	Incidence, %	No. of Events	Frequency, %	Patient Years of Follow-up	Frequency (per 100 Patient Years)
Both	Both	1999	24	1.2	24	1.2	1691	1.4
Both	Saline	1554	21	1.4	21	1.4	1478	1.4
2	Silicone	445	3	0.7	3	0.7	212	1.4
1	Saline	1003	17	1.7	17	1.7	1268	1.3
2	Saline	551	4	0.7	4	0.7	211	1.9

Table 8. Incidence and Frequency of Size Change in Dual-Plane Breast Augmentation Cohort

Phase	Implant Type	Sample Size	No. of Patients With at Least 1 Event	Incidence, %	No. of Events	Frequency, %	Patient Years of Follow-up	Frequency (per 100 Patient Years)
Both	Both	256	8	3.1	8	3.1	230	3.5
Both	Saline	186	7	3.8	7	3.8	205	3.4
2	Silicone	70	1	1.4	1	1.4	26	3.9
1	Saline	118	5	4.2	5	4.2	169	3.0
2	Saline	68	2	2.9	2	2.9	35	5.7

implant deflation was the most common inciting factor, and the second factor was the availability of gel implants after November 2006. No conversions from silicone to saline occurred.

Capsular Contracture

Capsular contracture was the fifth most common cause for revision in the overall cohort, with 14 patients electing to have surgery (0.7%, or 0.33% of all implants). One patient had a second surgery for recurrent CC. In the DPBA group, the revision rate for CC was third, with 6 capsules (2.3%). The overall CC rate was 0.9 per 100 patient years. Analysis of the frequency of CC in saline implants per 100 patient years showed saline in phase 1 to be 0.6 versus 0.9 in phase 2, and 0.7 for both, contrasted to 2.4 for silicone. Gel implants had a higher incidence of thrombospondin compared with saline for CC. Capsular contracture was treated by capsulectomy and implant exchange and the firm breast protocol described in the Methods section. All 20 operated patients had Baker 3 and 4 capsules. For the group of patients who developed non-surgical Baker 1 and 2 capsules (0.2% of both the overall cohort and the DPBA group), the author adhered to the protocol described in the Methods section for a patient who presented with a unilateral firm breast.

Explant

Eight patients in the overall cohort requested explantation (0.04%), citing that they were at a different place in their lives and no longer felt the need for implants. One patient in the DPBA cohort (0.04%) also requested explantation. One patient in the overall cohort requested explantation with breast reduction, citing that her breasts had increased in size since her initial surgery.

Hematoma

Hematoma occurred in 4 patients (0.02%) from the entire cohort, and 2 of these 4 were from the DPBA cohort. In the DPBA group, 1 hematoma occurred 10 days postoperatively when the patient, an anesthetist, reached with 1 arm to move an obese patient and immediately developed massive swelling on the same side. The second hematoma occurred spontaneously 5 days postoperatively.

Mastopexy

The goal of DPBA is to avoid mastopexy in selected patients. Therefore, this metric is perhaps the most significant measure of DPBA. Four patients of the entire

cohort ultimately underwent a mastopexy as a secondary procedure. Time to mastopexy was 95, 335, 844, and 2329 days, respectively. Three of the 4 were in the DPBA group (3/256 or 1.2%). All of these DPBA patients were “in-between” candidates for a mastopexy preoperatively. Overall, 98.8% of patients avoided more extensive incisions on their breasts as of their last follow-up visit.

Other Events

Other, less common events included 2 skin dehiscences (1 in each cohort), which were closed under local anesthesia. Two lipotransfer procedures for visible irregularities were performed in the entire cohort (none in the DPBA group). One infection occurred (none in the DPBA cohort) in a patient who had a long history of recurrent right breast mastitis and was a heavy smoker. She underwent a prolonged tattoo procedure (4.5 hours) at 51 days postoperatively. She developed a high temperature and right breast mastitis 4 days after the tattoo procedure. Subsequently, she developed an implant infection, ultimately necessitating implant removal. This is the second such occurrence the author has observed from a tattoo procedure done in the early postoperative period. Patients are now counseled to avoid tattoo procedures for 3 months postoperatively.

Striae

Two DPBA patients from the overall cohort presented with postoperative striae. Their photos were taken, transferred instantaneously to the computer with an Eye-Fi card, and analyzed with the patient physically present. In both patients, the same striae were evident preoperatively, so DPBA did not appear to produce new striae in these 2 cases. The patients seemed reassured.³⁹⁻⁴³

DISCUSSION

Current US literature is devoid of clinical studies of patients who received gel implants during primary DPBA. As such, this is the first chart review to evaluate the new FDA-cleared generation of gel implants placed with this technique. The strength of this retrospective chart review lies in its ability to (1) demonstrate that DPBA can be performed successfully with both gel and saline implants; (2) document certain refinements in patient selection and technique, which can maximize the positive outcomes of a DPBA technique; (3) and establish indications and contraindications for DPBA. In a case comparison study, there should be at least as many controls as there are actual treated participants to achieve a valid comparison. This DPBA study demonstrates this balance; during phase 2, 70 patients received (140) gel implants and 67 patients received (134) saline implants. The 2007 to 2010 cohorts both have a median implant age of 2 years, so the next

2 years will be very telling in terms of their relative reliability. The author's longer term phase 1 follow-up data actually surpass the FDA Summary Data of Breast Implant Clinical Trials, since 12.09% of our phase 1 saline patients were followed up at 3 years, compared with only 9.6% for Mentor.⁴⁴

These numbers compare favorably with a prior DPBA study in which Tebbetts⁸ reported a 1.3% CC rate (vs 2.3% with DPBA), 0.4% hematoma rate (vs 0.8% DPBA), and 0% infection rate (also 0% with DPBA). Huang et al⁴⁵ recently reported a 20-year total cohort series of axillary BA demonstrating a 1.9% CC rate (vs 0.7% in the total cohort), a 0.12% hematoma rate (vs 0.02% in the total cohort), a 2.97% malposition rate (vs 1.3% in the total cohort), a 2.5% size change rate (vs 1.2% in the total cohort), a 0% infection rate (vs 0.005% in the total cohort), and a 1.8% rupture rate of implants overall (vs 1.4% of implants in the total cohort but with a shorter follow-up), which also compares with the author's data. Their average implant size was 438.5 ± 51.5 cc (range, 270-630 cc) compared with an average implant size of 352.9 ± 65.9 cc (range, 150-575 cc) in this 8-year DPBA series.

In the author's review, the difference in revision rates between the non-DPBA cohort and DPBA was 4.6% (CI, 0.7-8.5). Of the 1743 patients with non-DPBA surgery, 104 (6.0%) had at least 1 revision. Of the 256 DPBA patients, 27 (10.5%) had at least 1 revision (Table 7). The incidence of revision for DPBA is higher than for BA patients with normal anatomy. A confidence interval around an event rate or a difference between 2 event rates provides a range of values that would likely (ie, with 95% confidence) capture the true population event rate or difference in population event rates. Because confidence limits are reported on the same scale of measurement as the event rate, they are often more interpretable to readers than a *P* value. However, in addition, the confidence interval can be used to assess statistical significance. If the 95% confidence interval around a difference in rates contains zero, it can be interpreted to mean that the difference between the 2 rates is not statistically significant at the traditional .05 level. Regarding differences between saline and silicone, there was a greater rate of revision in the DPBA silicone cohort at 23.5 per 100 patient years (CI, 8.6-51.1) than in the saline DPBA cohort at 11.7 per 100 patient years (CI, 7.5-17.5). The difference (saline rate minus silicone rate) is -11.8 revisions per 100 patient years (CI, -26.6 to 3.1). Since this confidence interval includes zero, the difference in revision rates between silicone and saline among DPBA patients was not statistically significant. Because all implants in phase 1 were saline, whereas implants in phase 2 included both saline and silicone, the author did not compare the 2 phases. An “apples-to-apples” comparison includes the saline devices implanted in phase 1 (11.8 revisions per 100 patient years in DPBA patients) versus saline implanted in phase 2 (11.3 per 100 patient years in DPBA patients). The difference (phase 2 minus phase 1) is only -0.5 revisions per 100 patient years, which is clinically insignificant.

Advantages of DBPA

Compared with single-pocket augmentation, the dual-plane approach allows the surgeon to better adjust the implant vis-à-vis the breast tissue relationship, offering increased benefits with fewer trade-offs. Many breast augmentation patients with “in-between” anatomy consult multiple surgeons and can become confused by opposing surgical recommendations. The dual-plane approach may allow these selected patients to avoid more extensive mastopexy incisions. It is a valuable technique for patients with (1) pseudoptosis, or $\leq 15\%$ of the glandular tissue below the IMF; (2) a center-point of the NAC at or above the IMF; (3) a constricted lower pole (NAC-IMF < 5 cm); or (4) a tight IMF.

Contraindications and Considerations

In this study, DPBA was selected as the surgical method of choice for a given patient only after she had been evaluated thoroughly, with stringent indications in mind. Dual-plane breast augmentation was *not* performed as a routine procedure for primary breast augmentation. If all breast parenchyma was located above the IMF, with tight attachments to the underlying PMM and NAC to IMF of approximately 5 cm, the patient was disqualified from DPBA. Rather, DPBA was reserved only for *selected* patients in this series, instead of being utilized in patients with normal-appearing anatomy. Again, exclusion criteria to DPBA were patients with weighty breasts and those with an NAC trajectory pointing downward or lateral migrating breast mound(s) in the supine position.

It is also essential to discuss the expected postoperative outcomes of this procedure thoroughly with patients, particularly the fact that they may require a mastopexy in the future. Even if the surgical plan is for DPBA, the surgeon should thoroughly establish informed consent for augmentation-mastopexy, so patients understand their options. The trade-off with a DPBA procedure is less scarring, versus more maximal elevation of the NAC with a mastopexy. Dual-plane breast augmentation does not levitate the gland or fashion a high, tight contour. The procedure does not centralize the NAC on the mound or decrease the NAC diameter, nor will DPBA equalize a horizontally disparate NAC.

Clinical Suggestions

Medial release of the pectoralis muscle along the sternal attachments was assiduously avoided in DBPA procedures. Prior to the start of this study, the author overzealously released the muscle both medially and in the retromammary plane, above the level of the NAC, in several initial patients. This extreme release, both from the sternum and from the overlying breast, allowed the caudal edge of the PMM to migrate too far superiorly. In some patients, this resulted in a tight band of muscle that was evident across the breast,

especially upon animation (a so-called window shade phenomenon).⁴⁶ As a result, the author is now more conservative in his retromammary release. Other surgeons have also suggested placing tacking sutures along the inferior edge of the pectoralis muscle to avoid “window-shading.”⁴⁷

A constricted lower pole (ie, in patients with a short NAC-to-IMF distance and a tight crease) must be released significantly and sculpted to render a pleasing visual border along the IMF. At the same time, great care must be exercised to avoid release of the inframammary ligament, to limit “bottoming out” of the implant. Following conservative Bovie (Conmed Cautery System 2450; Conmed) release of the inferior pole, the IMF is stretched gently with finger dissection to further position the implant accurately.

Great care is also taken to adjust the implants intraoperatively. The patient should be painstakingly evaluated in the supine position not only from above (by the anesthesiologist) but also from below and laterally (by other team members in the operating suite). The patient should then be placed in a full 90-degree sitting position, straightened on the table as necessary, and further evaluated. Microadjustments with gentle finger dissection are then made to achieve a pleasing result. The abutting of the implant against the posterior surface of the breast parenchyma acts like a pendulum, which elevates the NAC as the parenchyma swings superior and anterior.

Limitations

Several opportunities exist for further study of DPBA patients. Accurate follow-up times were assessed and calculated meticulously in this study. The initial DPBA cohort has a theoretical 8-year follow-up time, but unless the patients have actually been assessed for up to 8 years, these outcome calculations are not as helpful. Any patient needing a reoperation who had moved out of state was referred to a colleague. It is also possible that a patient received a reoperation elsewhere without contacting us. Furthermore, the follow-up time in phase 2 patients was shorter, so longer follow-up is necessary to assess the overall rates of complications (especially for the gel cohort and for deflations) and recurrence of ptosis for patients who received a DPBA approach. Deflation rates for the saline implants in this study will undoubtedly rise over time. It is fortuitous that nearly equal numbers of patients selected each type of implant.

In this study, no formal assessment of patient satisfaction was done. Quantitative satisfaction evaluation could have provided an opportunity for corroboration of the conclusions drawn from the analysis of reoperation rates and photographic analysis. Although many patients were measured preoperatively (from sternal notch to NAC and NAC and IMF to umbilicus), not every patient was measured for these points postoperatively. Certainly, there is inherent variability when these measurements are taken manually. Better documentation with standardized photographs and a horizontal line overlay would help establish

that the NAC does elevate from DPBA. Standardized (computerized) imaging would decrease this error, but this method was not employed by the author until after the conclusion of this particular study.

Another limitation of the retrospective portion of this study is the lack of MRI follow-up of gel patients. At the time of this study, MRI was the best available means of monitoring gel rupture and was, in fact, recommended as the gold standard of surveillance by the FDA.⁴⁸ At the author's institution, bilateral breast MRI costs \$2200. Despite patient education and informed consent about the FDA recommendations, only 1 gel implant patient elected to undergo a postoperative MRI with out-of-pocket expense. The MRI detected a rupture but, as stated earlier, the implant was actually intact upon surgical exploration. The only MRI performed in this series prompted an unnecessary procedure, anesthetic exposure, expense, time off from work for the patient, and poor use of the surgeon's time. Gray⁴⁹ reported a similar experience with false-positive results in 5 patients (repeating the author's MRI accuracy rate of zero). Pooled summary measures, recently reported in a large series, of sensitivity (true positives) and specificity (true negatives) for implant MRI have been reported as 87% and 89.9%, respectively.⁵⁰ Among lower prevalence populations, Cher et al⁵¹ reported in a meta-analysis that the positive predictive value appeared to be insufficient to warrant MRI use as a screening tool. The summary sensitivity was 78% and the summary specificity was 91%. As a further downside, the authors highlighted that the majority of the published studies examined only symptomatic patients. Once observer variability between radiologists is factored into the equation, overall accuracy may drop even lower. The authors concluded many of the MRI and ultrasound diagnostic accuracy studies examining silicone breast implant ruptures are methodologically flawed. Therefore, patients and surgeons need a more accurate, cost-effective means of diagnosis. An extensive study of the new generation of high-resolution ultrasound coupled with MRI has recently been published and shows excellent results demonstrating 100% accuracy. High-resolution ultrasound is a notable clinical advancement and will undoubtedly help us as practitioners to solve this dilemma for our breast augmentation patients, regardless of surgical approach, implant type, or higher cross-linked gels.⁵²

CONCLUSIONS

Dual-plane breast augmentation is best suited for patients with minimal ptosis who are in the "gray area" between normal anatomy and frank ptosis. Phase 1 (January 2003 through December 2006) involved a retrospective chart review of 1003 cosmetic BA patients who received saline implants exclusively, with a variety of techniques. Phase 2 was a retrospective review and comparative study of 996 gel and saline cosmetic BA patients treated between January 2007 and December 2010. Two hundred fifty-six DPBA procedures were studied, and the outcomes of gel versus saline

were compared. The data from this 8-year retrospective, comparative review support the fact that for a select group of patients with mild to moderate ptosis and proper informed consent, DPBA is a technique that will provide acceptable aesthetic results with low reoperation rates in patients who refuse external mastopexy scars and who will accept preexisting areolar asymmetries and large areolae. Dual-plane breast augmentation allows selected patients who may present after consulting multiple surgeons and receiving disparate recommendations to avoid more extensive mastopexy incisions. Therefore, this approach can provide surgeons and patients with an alternative technique for achieving satisfactory augmentation outcomes.

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