# The Process of Breast Augmentation: Four Sequential Steps for Optimizing Outcomes for Patients

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**Background:** Breast augmentation has been an integral part of plastic surgeons' practices for over 40 years. Although devices have evolved, patient outcomes are still not ideal, as documented in multiple premarket approval clinical trials. Unlike many other areas of surgery, the practice of breast augmentation has suffered from the lack of a defined process for patient management. The purpose of this study was to clinically define and evaluate the process of breast augmentation and analyze patient outcomes using these practices compared with existing premarket approval trial data.
**Methods:** Three hundred consecutive primary breast augmentations from 2001 to 2005 were followed prospectively. Each patient underwent a defined process of breast augmentation including structured patient education and informed consent; tissue-based preoperative planning consultation; refined surgical technique; and structured postoperative instructions, management, and follow-up.
**Results:** The mean follow-up was 2.1 years. The most common complications were rippling and palpability, soft-tissue stretch, and hypersensitivity. The overall reoperation rate was 3.7 percent for the entire group and 4.7 percent and 2.9 percent for saline and form-stable cohesive gel implants, respectively.
**Conclusions:** Optimizing patient outcomes in breast augmentation requires defining the overall process to allow for enhanced patient outcomes. This is the first report that defines and integrates the entire process comprehensively that is validated by outcomes data. This process is transferable to other surgeons and, using this algorithm, patient outcomes in this study were superior to premarket approval clinical trial data. In summary, approaching this procedure with a global process produces superior patient outcomes in breast augmentation. (*Plast. Reconstr. Surg.* 122: 1892, 2008.)

A process is defined as a group of practices that are completed successively to reach a goal. For 45 years, breast augmentation has been thought of as an isolated surgical procedure; however, well-documented elevated reoperation rates of 15 to 24 percent over 6 years in successive premarket approval studies have resulted in a critical analysis of this procedure.[1,2] Factors that impact outcomes have been identified and practice recommendations have been established.

This analysis has resulted in a redefinition of this procedure to a much broader process beyond the actual surgical placement of the implant. Essential components include comprehensive patient education that enhances informed consent, tissue-based preoperative planning, refined surgi-

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cal technique and rapid recovery, and a strictly defined postoperative management plan. Previous reports have defined individual key areas, and these principles have been integrated, refined, and customized into a comprehensive process that encompasses every key surgeon-staff-patient action point. Although each component may exist individually, the combination of these steps in succession has resulted in enhanced outcomes for patients far better than any one component practiced in isolation. In recent years, as key components of this process have been elucidated, it has been demonstrated that the process is transferable and reproducible.[3–5] The purpose of this study was to clinically define and evaluate the process of breast augmentation and to prospectively analyze patient outcomes using these practices compared with existing premarket approval trial data.

## PATIENTS AND METHODS

All patients were treated by a single surgeon's practice. Patients were followed prospectively from 2001 to 2006. A subgroup of the patients were followed in a U.S. Food and Drug Administration–approved clinical trial with clinical research organization oversight. The four primary subprocesses used for patient care were structured patient education, tissue-based clinical analysis, refined surgical technique, and defined postoperative regimen (Fig. 1).

### Patient Education and Informed Consent

All patients underwent a patient education and informed consent process using a multimodality approach. Initial contact included verbal information and a web-based introduction to the practice philosophy of breast augmentation. Once the decision for consultation was made, a specific patient education consultation was performed to answer specific issues about breast augmentation. After 2002, a specific set of breast augmentation education and informed consent documents (**see Documents, Supplemental Digital Content 1, *http://links.lww.com/A568***) was customized based on previous publications in this *Journal*.[6] Patients were required to complete the documents before their education consultation that was performed either over the phone or in person, lasting on average 45 to 60 minutes, and performed by a patient education specialist. During the education consultation, all concepts, issues, and limitations were addressed directly and covered with the patient, ultimately having the patient assume responsibility for the final decisions (Fig. 2).

### Tissue-Based Clinical Analysis and Planning

The surgeon consultation was performed only after successful completion of the education consultation. The average surgeon consultation time was 30 minutes. The two primary goals of the surgeon consultation were to objectively evaluate the patient's breast and to ensure that the patient's goals (previously defined in writing during the education consultation) were reasonable based on their breast dimensions and tissue. The tissue-based evaluation was based on previously published techniques.[3] The basics of the High Five process allow the surgeon to preoperatively make the five critical decisions that determine outcomes for a breast augmentation:

1. Pocket plane.
2. Implant size (based on predicted tissue-based optimal fill volume of the breast).
3. Implant type.
4. Inframammary fold position.
5. Incision.

The implant size and type were based on two key factors: breast width and breast type (skin envelope compliance and preoperative fill). The ra-


**Fig. 1.** The process of breast augmentation.

**Patient Concerns**

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**Additional Questions for Dr. Adams**

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**Have you had any type of Plastic Surgery before?**
☐ **Are you happy with your results?**
☐ **My role in your care**
☐ **Our commitment to patient education**
☐ **What we'll talk about today**
☐ **Have you read the information we provided you?**
☐ **Clinical evaluation sheet medical history and patient preferences**
☐ **Brief history of augmentation**
☐ **Alternatives versus a single approach**
☐ **Do implants cause disease? The research and sources**
☐ **Breast implants and breast cancer**
☐ **Breast implants and mammography**
All implants interfere with mammograms
☐ **Breast implant technology**
☐ Constantly changing alternatives- current alternatives
☐ Limitations of implants- no implant is without tradeoffs
☐ **Summarizing the alternatives**
☐ Incision alternatives- inframammary, axillary, periareolar
☐ Implant pocket locations- retromammary, retropectoral, dual plane, totally submuscular
☐ Current implant choices (all saline)- smooth round, textured round, textured shaped or anatomic- types and manufacturers
☐ Fitting the procedure and implant to your tissues to minimize long-term risks and compromises
☐ **Determining the best size**
☐ If you could just pick a size, what would it be?
☐ Which is more important, size or problems long-term?
☐ Common misconceptions
☐ How implant size affects your tissues- now and later
☐ Bra cup sizing-we can't guarantee cup size
☐ Balancing your breast with your figure
☐ Measuring your breast, understanding your tissues
☐ Concentrating on shape, fill, dimensions
☐ Photos and planning the operation
☐ **The operation- what's it like**
☐ Day surgery routine
☐ The facility and facility personnel
☐ Anesthesia
Safety of anesthesia, misconceptions, risks
Local versus general anesthesia
Our anesthesia personnel
☐ **During surgery**
☐ What will occur, expected time frame
☐ **After surgery**
☐ Waking in recovery, then to stepdown with caregiver
☐ **Detailed instructions will be given to you**
Tells you and your caregiver what to expect and do
What we do simplifies your instructions
☐ **Recovery and activity**
☐ Importance of resuming normal activity
☐ What we do and what we need you to do
☐ No bandages, bras, straps, drains or special

☐ **Risks of augmentation**
☐ This is a totally elective operation with risks and uncontrollable factors
☐ Bleeding
☐ Infection
☐ Sensation compromise
☐ Capsular contracture
☐ Unsatisfactory aesthetic results or scarring
☐ Interference with cancer detection
☐ Complications may require additional surgery, longer recovery, additional costs
☐ Reviewed risks on consent forms & documents
☐ **Capsular contracture and breast firmness**
☐ What is it?
☐ How a capsule forms
☐ Controlling the capsule
☐ How often does it occur?
☐ Correcting the hard breast
☐ **Factors that the surgeon cannot completely predict or control**
☐ Capsular contracture
☐ Different degrees, if severe, requires reoperation
☐ Surgeon alone makes final decisions re: reoperation
☐ All costs are patient's responsibility, no insurance
☐ Tissue stretch problems- increase with implant size
☐ Stretch allowing implant shift downward or outward
☐ Stretch allowing implant rotation
☐ Traction rippling
☐ Your request for a different size implant after surgery
☐ **All costs for any surgery relating to factors the surgeon cannot predict or control are the patient's responsibility (surgeon fees, facility fees, anesthesia, lab, time off work)- includes capsular contracture, stretch deformities, implant size changes.**
☐ **Importance of communicating with us**
We want to do what you want
You must be honest with us at all times
The surgeon cannot read your mind
☐ **What you can expect from Dr. Adams**
Type of care. Written materials. Photos. The operation. Your care.
☐ **Dr. Adams' Qualifications**
Surgical training, board certification, professional affiliations, scientific publications, other.
☐ **Patient has read all information material provided (Yes/No) _____Pt. Initial.**
☐ **Discussed any significant other's involvement, gave patient copy of Will There Be Anyone Else Involved.**
☐ **Written information provided patient was discussed in detail with patient, answered patient's questions to patient's satisfaction.**
☐ **All informed consent documents discussed in detail with patient, answered patient's questions.**

**_____Pt. Initial _____Pt. Educator Initial**

**Fig. 2.** Patient educator consultation checklist for patients. (Adopted from Tebbetts, J. B. An approach that integrates patient education and informed consent in breast augmentation. *Plast. Reconstr. Surg.* 110: 971, 2002.)

tionale for selecting the individualized implant was reviewed with the patient and anyone else participating in the decision-making process.

The patient's breast photographs were also reviewed with the patient and a photograph-analysis sheet (Fig. 3) was completed and initialed by the patient. Patient asymmetries were identified (size and shape) and discussed, and the reality that the postoperative breast will not "match," realistic expectations for cleavage based on current intermammary distance, rationale for recommended pocket plane, and likelihood of implant palpability, particularly in the inferior and lateral parts of the breast, were all addressed directly with the patient by the surgeon while viewing the photographs.

### Refined Surgical Technique

The surgical plan was developed preoperatively following the surgeon consultation. All operations were performed under general anesthesia with short-acting full muscle paralysis, and patients were premedicated with a single dose of 400 mg of Celebrex (Pfizer, New York, N.Y.). The new inframammary fold incision was planned and executed as previously described.[3] Implant pockets were created under direct vision with no blunt

**Patient:** «Person_First_Name» «Person_Last_Name»

**Date:** _____

❒ L/R breast larger- breasts will **never match!!!**
❒ L/R nipple-areola higher on chest- will not be totally corrected
❒ L/R fold beneath breast higher on chest- will not be totally corrected
❒ Nipple position on the breast mounds is different on the two sides and cannot be totally corrected
❒ Gap between breasts can only be narrowed somewhat- a gap of at least _____cm. will likely remain
❒ Chest wall asymmetries exist that cannot be corrected and will affect breast shape
❒ The position of the entire breast on the chest wall will not change. If one fold beneath the breast is lower than the other, it will also be lower after your augmentation.
❒ The basic shape and configuration of the breasts will be similar to their current appearance and not change drastically, but will be larger
❒ Thinner tissue inferior and lateral can result in implant palpability

❒ Other: _____

❒ Other: _____

❒ Other: _____

❒ Other: _____

Patient Please Initial below to document your understanding and acceptance of the above.

_____ Dr. Adams has reviewed my patient images with me in detail. I have seen, understand, and accept each of the factors listed above that will not change or may be only partially improved following my augmentation. I totally understand and accept that my breasts or components of my breasts will never match on the two sides, and that perfection is not an option, only improvement in the size of my breasts.

**Fig. 3.** Patient image analysis factors unlikely to change or be totally corrected after breast augmentation.

dissection using techniques to minimize tissue trauma.[7–9] The same surgical principles were applied to all implant types, including smooth, round, and textured anatomical implants. Pocket preparation included the use of triple antibiotic irrigation and other techniques to minimize contamination of the implant, including glove change and wiping the skin before implant placement.[8] Sizers were not found to be necessary in [297 of 300 (99 percent)] of cases, and the implant selection was determined during the preoperative consultation before the operative day. Incision closure was performed in three layers using a deep absorbable suture (3-0 Vicryl; Ethicon, Inc., Somerville, N.J.) for closure of the superficial fascia of the breast, a deep subdermal suture (4-0 polydioxanone), and subcuticular skin closure (4-0 Monocryl; Ethicon).

### Postoperative Regimen

All patients were given detailed defined postoperative instructions (Table 1). These were reinforced before the day of surgery and on the day of surgery, and verification of compliance was completed after the patient returned home. Patient outcomes, complications, and recovery were assessed and analyzed.

## RESULTS

A total of 300 primary augmentation patients were followed prospectively between 2001 and 2006. Two subcohorts were also analyzed: (1) 128 consecutive patients undergoing saline primary breast augmentation from 2001 to 2006; and (2) 172 consecutive patients undergoing primary breast augmentation in U.S. Food and Drug Administration premarket approval clinical trials from 2002 to 2006 with standard clinical research oversight monitoring.

Patient demographics are listed in Table 2. The mean age for the main cohort and subcohorts was 36 years. The average implant size was 289 cc for the entire cohort and 302 cc and 276 cc for the saline and form-stable cohesive gel subcohorts, respectively.

Details regarding the implant type and pocket plane are listed in Tables 3 and 4 . The majority of all implants were in the dual-plane pocket. Ninety-eight percent of implants were placed by means of the inframammary fold incision.

Follow-up, patient outcomes and reoperations, and complications are listed in Table 5. The mean follow-up was 2.1 years (range, 9 months to 6 years) for the entire cohort. Mean follow-up for saline and form-stable cohesive gel implants was 1.7 years (range, 9 months to 6 years) and 2.3 years (range, 1 to 5 years), respectively. The reoperation rates were 3.7 percent for the entire cohort and 4.7 percent and 2.9 percent, respectively, for the saline and form-stable gel implant subcohorts. The reasons for reoperation are listed in Table 6. Ninety-

**Table 1. Postoperative Regimen**

| | |
|---|---|
| Wound care | Band-Aid gel strip placed intraoperatively and left for 3 wk and then changed every week for 3–4 mo |
| Bra | Not required; no "push-up" bra for 6 wk |
| Activity | 2-hr nap on arrival home, then out of bed into hot shower for 20 min and get dressed; do not lie in bed; prescribed arm raises completed 5 times every hour while awake for the next 5 days |
| Exercise | Commence aerobic activity at 2 wk<br>Nonchest weights at 4 wk<br>Chest/sit-ups at 6 wk |

**Table 2. Patient and Implant Demographics**

| | All Patients, 2000–2006 | Saline | FS Gel PMA |
|---|---|---|---|
| Age (yr) | | | |
| Mean | 36 | 36 | 36 |
| Range | 20–64 | 20–56 | 21–64 |
| Volume (cc) | | | |
| Average | 289 | 302 | 276 |
| Range | 150–560 | 150–560 | 180–395 |

*FS, form-stable; PMA, premarket approval study.

**Table 3. Pocket Plane**

| Pocket Plane | All ($n$ = 299) | Saline ($n$ = 128) | FS Gel ($n$ = 172) |
|---|---|---|---|
| DP1 | 245 | 104 | 141 |
| DP2 | 43 | 23 | 20 |
| DP3 | 8 | | 8 |
| RP | 2 | 1 | 1 |
| SG | 1 | | 1 |

FS, form-stable; DP, dual-plane; RP, retropectoral; SG, subglandular.

**Table 4. Implant Types**

| | No. |
|---|---|
| Saline | 128 |
| Smooth | |
| Round | 111 |
| Textured | |
| Round | 1 |
| 468 | 16 |
| Total | 128 |
| FS gel | 172 |
| CPG 321 | 135 |
| 410 FM | 28 |
| 410 FF | 5 |
| 410 MM | 4 |
| Total | 172 |

FS, form-stable; CPG, Contour Profile Gel.

**Table 5. Complications, Mean Follow-Up, and Reoperation**

| | All ($n$ = 299) | | Saline ($n$ = 128) | | FS Gel ($n$ = 171) | | CPG ($n$ = 135) | | 410 ($n$ = 37) | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Complications** | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** |
| Capsular contracture | 3 | 1.00 | 2 | 1.56 | 1 | 0.58 | 1 | 0.74 | 0 | 0.00 |
| Soft-tissue stretch | 8 | 2.68 | 7 | 5.47 | 1 | 0.58 | 1 | 0.74 | 0 | 0.00 |
| Infection | 3 | 1.00 | 2 | 1.56 | 1 | 0.58 | 1 | 0.74 | 0 | 0.00 |
| Hematoma | 2 | 0.67 | 1 | 0.78 | 1 | 0.58 | 1 | 0.74 | 0 | 0.00 |
| Rotation | 3 | 1.00 | 2 | 0.78 | 1 | 0.58 | 0 | 0.00 | 1 | 2.70 |
| Deflation | 2 | 0.67 | 2 | 1.56 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| Rippling/palpability | 18 | 6.02 | 4 | 3.13 | 15 | 8.77 | 14 | 10.37 | 1 | 2.70 |
| Hyperpigmentation | 4 | 1.34 | 1 | 0.78 | 3 | 1.75 | 3 | 2.22 | 0 | 0.00 |
| Stretch marks | 1 | 0.33 | 1 | 0.78 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| Asymmetry | 1 | 0.33 | 1 | 0.78 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| Delayed wound healing | 1 | 0.33 | 1 | 0.78 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| HT scar | 3 | 1.00 | 1 | 0.78 | 2 | 1.17 | 2 | 1.48 | 0 | 0.00 |
| Hypersensitivity/neuropathic pain | 6 | 2.01 | 0 | 0.00 | 6 | 3.51 | 6 | 4.44 | 0 | 0.00 |
| Lower pole deformity | 1 | 0.33 | 0 | 0.00 | 1 | 0.58 | 0 | 0.00 | 1 | 2.70 |
| Mean follow-up | 2.1 yr | | 1.71 yr | | 2.3 yr | | 2.5 yr | | 1.7 yr | |
| Reoperation rate | | 3.7 | | 4.70 | | 2.90 | | 3.70 | | 0.00 |

*FS, form-stable; CPG, Contour Profile Gel Implant; 410, Style 410 Implant; HT, hypertrophic.

**Table 6. Reason for Reoperation**

| | All ($n$ = 300) | | Saline ($n$ = 128) | | FS Gel ($n$ = 172) | | CPG ($n$ = 135) | | 410 ($n$ = 37) | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Reason for Reoperation** | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** |
| Capsular contracture | 1 | 9.09 | 1 | 16.67 | 0 | 0.00 | 0 | 0 | 0 | 0.00 |
| Delayed hematoma (5 wk postoperatively) | 1 | 9.09 | | 0.00 | 1 | 20.00 | 1 | 20.00 | 0 | 0.00 |
| Negative exploration hematoma acute | 1 | 9.09 | | 0.00 | 1 | 20.00 | 1 | 20.00 | 0 | 0.00 |
| Infection/seroma | 1 | 9.09 | | 0.00 | 1 | 20.00 | 1 | 20.00 | 0 | 0.00 |
| Size exchange | 0 | 0.00 | | 0.00 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| Patient request removal | 1 | 9.09 | | 0.00 | 1 | 20.00 | 1 | 20.00 | 0 | 0.00 |
| Deflation | 2 | 18.18 | 2 | 33.33 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| Rotation | 1 | 9.09 | 1 | 16.67 | | | | | | |
| Soft-tissue stretch | 3 | 27.27 | 2 | 33.33 | 1 | 20.00 | 1 | 20.00 | 0 | 0.00 |
| Total | 11 | 100.00 | 6 | 100.00 | 5 | 100.00 | 5 | 100.00 | 0 | |

*FS, form-stable; CPG, Contour Profile Gel Implant; 410, Style 410 Implant.

seven percent of patients were able to return to normal activities of daily living (e.g., raise arms above head, drive car, wash, shop, eat, and dry hair) within 24 hours.

## DISCUSSION

The belief that breast augmentation is a simple procedure encompassing little more than placing an implant in a pocket is a misconception, and advances in this procedure have been significant over the past 10 years; however, controlled clinical trials have demonstrated that reoperations continue to be significant (15 to 24 percent at 3 years) for this elective procedure.[1,2] This procedure is much more complex than typically perceived, and the concept of the process of breast augmentation emphasizes the equal if not larger importance of the "nonsurgical" part of the process (e.g., education, tissue-based planning, and postoperative care compared with the surgical procedure itself).

The educational component cannot be overemphasized, as this remains the most critical yet often neglected part of the process. The key components of the educational subprocess are (1) to educate the patient on the practice philosophy and have the patient assume mutual responsibility that the implant will be selected based on her chosen preferences and in accordance with her breast dimensions and tissue or alternative methods recognizing the tradeoffs; and (2) by means of direct doctor-patient interaction to review the patient's own photographs and point out key aspects that should be addressed preoperatively, including 100 percent asymmetry in all patients and limitation in correcting these asymmetries, reasons for implant palpability, and the likelihood of inferior and lateral pole deformity. The image analysis sheet (Fig. 3) is an extremely powerful yet simple tool that is part of the educational process and the surgeon planning consultation.

The tissue-based preoperative planning allows the surgeon to get on base and prevents the patient from striking out on her first try. The High Five process is one of two published and peer-reviewed tissue-based systems in the literature and provides the simplest way to determine optimal fill volume for any given breast.[3] Patients often come to the office wanting to look like a certain centerfold or bathing suit model or be a certain bra cup size, but through the educational process and tissue-based planning it is made very clear that it is "about their tissues." Interestingly, the High Five process allows the surgeon to adjust the volume based on patient request, and in a separate publication, this author has found a significant increase of complications when volume is added above the High Five–recommended volume, particularly in high-risk patients [narrow (breast width $<11.5$), tight envelope (skin stretch $<2$)].[10]

Also cogent is the artist versus the engineer issue, and who should pick the breast implant size: the patient or the doctor. No doubt, much of plastic surgery is both art and science; however, art in itself is truly unstructured and without definable boundaries. The thought that instituting a process-oriented approach will obstruct the "skills of the artist" is a misconception. Realistically, the process will only serve to enhance one's artistic qualities, as it defines the limits that the artistic only approach cannot clearly elucidate.

Formerly, the surgical technique was often the only part of a breast augmentation that many surgeons considered. Surgical advances have currently not only enhanced the actual surgical procedure but clearly defined the importance of the educational and tissue-based planning portions of the process, as these allow the surgeon to make nearly every decision before entering the operating room. This not only allows the surgeon to make better decisions than have historically been made in the operating room (particularly implant size) but also allows the surgical procedure to proceed as efficiently as possible. The concept of a very precise, atraumatic dissection with prospective hemostasis (identifying and controlling vessels and perforators under direct vision before they bleed) allows for both breast pockets to be typically dissected in a total time of typically less that 10 minutes. This not only immensely reduces the amount of tissue trauma but reduces intraoperative narcotics, additional paralytics, and the need for reversing agents, all of which slow postoperative recovery.[9] Although the use of appropriate breast pocket irrigation has been widely accepted,[8,11,12] surgeons often ignore other potential points of periprosthetic contamination, including handling implants without clean gloves and contact of the implant with the outside of the thermoform container or other surgical site components. These practices do not fit with this refined surgical process and should be avoided to minimize complications, including capsular contracture and reoperation.

The last benefit of this refined surgical process is recovery, the second best indicator of the quality of the procedure delivered (with reoperation rate being the first). This report and others have documented full return to normal activities within 24 hours using this process.[9,13,14] In this series, 97 percent of patients (291 of 300) returned to full normal activities of daily living, including washing and drying hair, getting dressed, picking up children younger than 3 years, driving a car, and other similar activities. All aerobic activities that increase heart above 100 beats per minute were restricted for 2 weeks.

Surgeons, patients, and medical personnel are often skeptical about the feasibility of 24-hour, fast track recovery. The process is often modified but, as discussed earlier, a process only functions if it is completed in proper order and procedure. Other adjuncts to the process such as injectables, drains, pain pumps, straps, special bras, narcotics, and limitation of arm movements all detract from the goal of speeding recovery.

On reviewing the data of this study, it is interesting that the reoperation rates were low for all cohorts compared with all premarket approval studies. Also, the lowest reoperation rates were reported for the most stringent studies, with clinical research oversight. The issue of size exchange has also been of interest. There were no patients who underwent reoperation in either cohort for size exchange. It has been suggested that the rate of actual size exchange is dependent on the tendency of the surgeon to respond to a patient's request for size change. This opinion does not take into account the theme of this article on the true power of "the process" of breast augmentation. Size exchange requests within the first 2 postoperative years that result in reoperations for size or style exchange indicate a failure of the surgeon and staff with the patient education and tissue-based planning parts of the process. A patient who has decided to select her implant based on her individual optimal fill volume and what will be safest for her tissues understands the limitations, and these patients remain well educated postoperatively and generally do not request size exchange procedures. This does not mean that these

patients do not go through the normal human psychological acclimatization of "getting accustomed to their new breast size" and "forgetting how they were preoperatively," which is normal human nature, and approximately 20 percent of patients may make a comment to our staff regarding size postoperatively, but they are reminded of the reasons why the size implant was chosen and shown their side-by-side preoperative and postoperative photographs, which usually results in them reaffirming their initial decision (documented in writing) about implant size selection.

Although not the focus in this article, other differences in these data are consistent with other reports, with a trend for less capsular contracture in the form-stable gel implants and more soft-tissue stretch in saline implants.[15,16] There was more rippling and palpability in the form-stable implants compared with the saline implants in this study and there was more rippling and palpability in the Contour Profile Gel implant than in the 410, which is consistent with other reports and likely attributable to the increased form stability of the 410.[17] Retrospectively, this is not visible rippling but implant edge palpability, generally an innocuous finding that resulted in no further surgical revision, and future studies on form-stable implants should separate these criteria to avoid confusion. The diagnosis in this study was made only if the patient complained about palpability. Nevertheless, excellent overall outcomes were obtained with all implant types using this process-oriented approach.

Also cogent is that surgeons and manufacturers often like to talk in terms of results with specific implants; however, in the end, it is *not* about the implant but rather the process, as this is the most significant benefit to patients. Advances in implants in the future will enhance the process but never replace it. The process determines the patient experience, reoperation rate, and recovery, and the overall quality of the process delivered is directly proportional to the overall success.

Perhaps the most significant factor is that the process is transferable. This author was inspired by his mentor, John Tebbetts, to take basic principles and refine, customize, and develop them for clinical practice and surgeon education. By means of focused education and a defined curriculum, surgeons can acquire the skill, knowledge, and expertise to deliver the process described in this study. Independent surgeons in different stages of their careers have reported using similar concepts to produce similar patient outcomes. The combination of these reports totals over 2500 primary breast augmentations, with a mean follow-up of 6 years and a reoperation rate of less than 3 percent.[3–5,7–9] The transferability of this process has also been demonstrated routinely in our residency program at the University of Texas Southwestern. Interested residents have been introduced individually to this process and taken through the phases with direct supervision. It is clear with their own developing practices that they are using these concepts to obtain excellent outcomes in patients.

Limitations of this study and comparison include the fact that any comparison between a selected surgeon(s) versus a large premarket approval clinical trial is not totally an "apples to apples" comparison, although the premarket approval trial surgeons are hand picked by the manufacturer based on known expertise with the procedure. Because of stringent follow-up of U.S. Food and Drug Administration clinical trials with clinical research oversight, reoperation rates might be expected to be higher, yet a 5- to 7-fold increase is not explained by this minor factor.

Interestingly, the data in this study would suggest that, in this series, the subcohort of only U.S. Food and Drug Administration premarket approval clinical trial patients is easily comparable and slightly better than the non–premarket approval data. There have also been reports of premarket approval clinical trial series using similar concepts demonstrating a 0 percent reoperation rate at 3 years.[18]

There has also been speculation that the U.S. Food and Drug Administration requirement for reporting of reoperations that included non–device-related issues, such as breast biopsy, falsely elevates the reoperation rates. When correcting for "non–device-related" reoperations (breast biopsy and excisional biopsy), the reoperation rates at 3 years in the core gel studies for the two companies were 14 and 16.5 percent, which would still indicate a 4- to 5-fold decrease in reoperation rates using the process detailed in this study. The reoperation rate in this study was 3.7 percent compared with 15 to 24 percent for the all premarket approval studies performed in the past 10 years. Reoperations remain our most objective measure of how well we are doing with this procedure. The 2-year reoperation rate is most critical because the majority of the reoperations during this period are the ones that are related directly to the surgeon's decisions and technique.

## CONCLUSIONS

Isolated processes in breast augmentation have been reported to improve outcomes[3,6–9]; however, this is the first single-series study to integrate and report a comprehensive methodology to positively impact patient outcomes. Similar to the use of defined processes in successful businesses and industry, implementing a defined process in breast augmentation serves to systematize this procedure and ultimately helps reduce outcomes resulting in reoperation. The economic impact of the process of breast augmentation for patients and surgical practices, although not the focus of this study, is profound not only immediately but over time, as the trend positively impacts the global breast augmentation market. In the end, the biggest "winner" in the process of breast augmentation is the patient . . . as it should be.

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