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Transaxillary Nonendoscopic Subpectoral Augmentation Mammoplasty: A 10-Year Experience With Gel vs Saline in 2000 Patients—With Long-Term Patient Satisfaction Measured by the BREAST-Q

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Abstract

Background: Transaxillary augmentation mammoplasty (TAM) is an option for patients who wish to avoid a visible breast incision from breast augmentation (BA).

Objectives: The authors compared TAM outcome data for gel and saline implants and evaluated patient satisfaction using the BREAST-Q patient-reported outcome measure (BQ).

Methods: In this 10-year retrospective, comparative, and cross-sectional study, the authors reviewed results of saline implants placed with TAM in a surgeon's practice during the final 5 years of the moratorium of the US Food and Drug Administration (phase 1) and compared them with results for gel and saline implants placed with TAM during the 5 years after the moratorium (phase 2). Outcomes were assessed for the entire BA study population (n = 2430 for primary BA; 4860 implants); 670 patients completed and returned the BQ, from which postoperative satisfaction was evaluated.

Results: BQ responses demonstrated a high rate of patient satisfaction, with outcomes comparable to those of other studies. The differences between the median BQ-assessed breast satisfaction and outcome satisfaction scores in the axillary and nonaxillary surgical groups were statistically significant, favoring axillary over nonaxillary. The difference in mean satisfaction scores was marginally significant between the 2 types of implants, favoring silicone gel. The incidence of surgical revision was 7.5% for the entire BA study population and 6.8% for the patients who underwent TAM.

Conclusions: TAM produces long-term patient satisfaction as measured by the BQ. Complication rates are similar to those of other studies. In the present study, patients who underwent TAM and thus had hidden incisions were more satisfied than patients whose incisions were visible.

Level of Evidence: 3

Keywords

breast augmentation, transaxillary, BREAST-Q



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The transaxillary approach is not often discussed with patients preoperatively. In the senior author's experience (J.G.), most patients who undergo breast augmentation (BA) wish to avoid incisions on their breasts. In general, patients have the choice among 3 types of scar patterns: inframammary, periareolar, and axillary. The transaxillary approach is not often discussed with patients preoperatively. The transaxillary approach avoids breast incisions, but if performed without an endoscope, it requires "blind" dissection far away from the incision site. Some surgeons are unfamiliar with and intimidated by transaxillary augmentation mammoplasty (TAM) because positioning the implants can be difficult. Regardless, TAM provides

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another option for patients who wish to avoid breast incisions.

The senior author (J.G.) conducted a chart review to determine (1) whether nonendoscopic subpectoral TAM produces high patient satisfaction, as measured by the BREAST-Q patient-reported outcome measure (BQ)¹⁻⁷; (2) whether the associated complication rates are comparable to those of other studies⁸⁻¹⁴; and (3) if reoperation rates are higher for saline implants (because of deflations) than for silicone gel implants.

To the authors' knowledge, this is the first study to utilize the BQ to assess patient satisfaction and quality of life (QOL) in a long-term study of postoperative BA patients.

METHODS

From January 1, 2002, to December 31, 2011, the senior author conducted a retrospective chart review that represented 10 years of patient experience ($n = 2430$ for primary BA; 4860 implants). He compared outcomes from saline implants placed with different techniques during the final 5 years of the moratorium of the US Food and Drug Administration (phase 1 of the study) with outcomes from both gel and saline implants placed during the 5 years after the moratorium was lifted (phase 2 of the study).^{15,16} The patients were consecutive.

Phase 1 (January 1, 2002-December 31, 2006) comprised 1172 patients who received cosmetic saline implants at several ambulatory surgery centers. Phase 2 (January 1, 2007-December 31, 2011) comprised 1258 patients who received cosmetic gel or saline implants at the same clinics. The patients in both phases accounted for all of the author's patients who underwent primary BA during the study periods.

Patient-reported perspectives (measured with the BQ) were requested from all patients, including those who underwent secondary procedures. If the axillary approach had been documented as at least 1 of the methods of bilateral implant placement, the case was considered axillary.

This study was approved by the Institutional Review Board of the University of Minnesota, Minneapolis, MN (Study No. 1111M07181).

BREAST-Q

Although traditional metrics remain relevant, an evidence-based approach to surgical practice and measuring patient-reported outcomes has become increasingly important.¹⁷ Patient satisfaction was measured with the BQ,¹⁻⁷ a patient-reported outcome measure that assesses patient perceptions of outcomes in breast surgery. This measurement tool has been validated and reliably quantifies satisfaction and QOL. Our study utilized 2 categories from the postoperative

augmentation module of the BQ: patient satisfaction and patient outcomes. All BQ scores ranged from 0 to 100.

A cross-sectional survey was administered to all BA patients retrospectively. An attempt was made to contact the entire 10-year cohort by telephone. Permission to mail the BQ questionnaire was obtained from all 1003 patients who were reachable by telephone. Surveys were completed anonymously. The type of implant and type of procedure were tracked for each questionnaire. The BQ score was calculated using the Q-score program, which converts raw survey scores of 1 through 4 to scores of 0 to 100. Higher scores denote greater satisfaction or better health-related QOL. Follow-up time ranged from 1 to 11 years.

Axillary vs Nonaxillary Incisions

Satisfaction was compared between BA patients who had axillary incisions (TAM; $n = 543$) and those who had visible incisions on the breasts (inframammary, periareolar, or mastopexy; $n = 127$). The BQ scores for breast satisfaction and outcome satisfaction were compared between surgical groups using the median and interquartile range. (The interquartile range is a measure of statistical dispersion of data that are resistant to outliers and is calculated as a range within the 25th and 75th percentiles.) Because the distributions were strongly skewed to the left, the median BQ scores for breast satisfaction and outcome satisfaction were compared between these surgical groups with the 2-sample Wilcoxon signed rank test.

During phase 1 of the study, the senior author (J.G.) performed 1172 cosmetic BA procedures, exclusively with saline implants (2344 implants); during phase 2, he performed 1258 cosmetic BA procedures with gel or saline implants (2516 implants). Thus, the total number of patients who underwent primary BA during the 10-year study period was 2430 (4860 implants). The entire group and the axillary cohort were assessed for the following outcomes and revisions: deflation, size change, malposition, change from saline to silicone gel, capsular contracture (CC), explant, hematoma, subsequent mastopexy, lipotransfer (visible wrinkling), partial closure (skin separation), infection, explant with breast reduction, and insertion of a secondary implant.

Surgical outcomes for gel and saline implants used in phase 2 were compared. Based on the senior author's previous outcomes with gel implants (1983-1992), the patients in phase 2 had been advised preoperatively that the visual result would be equivalent for saline or silicone gel, implants. All clinic personnel followed a standardized checklist to ensure that the same preoperative discussion was held with each patient and included the pros and cons of saline and gel implants. Patients were allowed to "try on" and palpate gel and saline implants and ultimately selected their preferred device. The choice of implant type



Figure 1. This 24-year-old woman demonstrates 3 contraindications to axillary BA because (1) she has 10% to 15% pseudoptosis with breast tissue existing below the IMF (note pink card as a reference point); (2) her NAC, even though it is slightly above the IMF, is set low on the breast mound; and (3) she has a tight IMF. She ultimately had a dual-plane BA to correct these preoperative findings.

is treated as an “explanatory (independent) variable” in this study.

The following information was documented for all patients in the study: preoperative breast measurements, postoperative breast measurements, age, date of surgery, and implant size/type/manufacture.

Preoperative Assessments

Tissue-based planning was provided for all patients. Patients with normal breast anatomy were given the choice of inframammary, periareolar, or axillary incisions. Inclusion criteria for TAM were patients with normal breast anatomy who chose the axillary incision. Exclusion criteria included ptosis, pseudoptosis, or tuberous components; a center-point of the nipple-areola complex (NAC) down to approximately the level of the inframammary fold (IMF); a constricted lower pole (NAC-IMF < 5 cm); or a tight IMF (Figure 1). Assessments were made from these measurements to determine which patients would be best served by straightforward BA, dual-plane BA, or mastopexy.¹⁸

When formulating the surgical plan, the surgeon was careful to compensate for preoperative size differences, especially if saline implants were chosen. Each patient was asked whether she noticed any size difference when wearing a bra. Any difference in size between the 2 breasts was ascertained with the patient in the supine, forward-leaning, and standing positions (Figure 2A-C). Patient photographs were then printed and analyzed for size differences. For patients who selected gel implants, in some cases, the difference in breast size could be addressed by using gel implants of different sizes. If the manufacturer

produces those sizes, then gel implants were often placed in such a manner to achieve adequate volume symmetry. If saline implants were chosen, volume adjustments were made during surgery to compensate for a size discrepancy between the breasts (Figure 3A,B).

Patients who met the inclusion criteria were asked to choose between the 3 incision locations, with the understanding that a scar may be present at that location for the rest of their life. Preoperative measurements and potential tissue cover were the greatest factors for determining selection of implant size. The patient’s personal requests were considered as well.

Once the procedure was scheduled, the patient was given an instruction card that contained important directions such as avoiding 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, taken at least 1 hour apart, starting the evening before surgery and ending the morning of surgery. Patients were advised to scrub the torso to reduce the number of skin contaminants.

TAM Surgical Technique

Two videos (1 for gel, 1 for saline) that include detailed descriptions of the senior author’s technique may be viewed at www.aestheticsurgeryjournal.com or www.surgery.org/videos. A detailed description of the operative technique also is available as a supplementary online text file (at www.aestheticsurgeryjournal.com).

With the TAM approach, it is possible to place large gel implants. An important aspect of TAM is the nonuse of sizers. (Sizers are routinely used by the author in *secondary* breast surgery whether it be TAM or non-TAM.) Once dissection of the pocket was accomplished, air was drawn into the pocket by gently elevating the gland off the ribs with a dissector (Figure 4A-C). The incision was manually pinched closed. Thus, the outline of the pocket perimeter was delineated, obviating the need for a sizer. Following the “air-sizer” maneuver, any pocket irregularities were modified as necessary. Care was taken to adequately stretch the muscle fibers medially.

Postoperative Care for IMF Migration and Double Fold

Occasionally, a shoelace was utilized to “set” the IMF if inferior migration of the implant occurred (Figure 5A-C).⁸ It is important to slightly overcorrect by setting the shoelace 1 to 2 cm higher than the contralateral normal crease, because the reestablished IMF will relax slightly over time. This focal compression allowed manipulation of the IMF

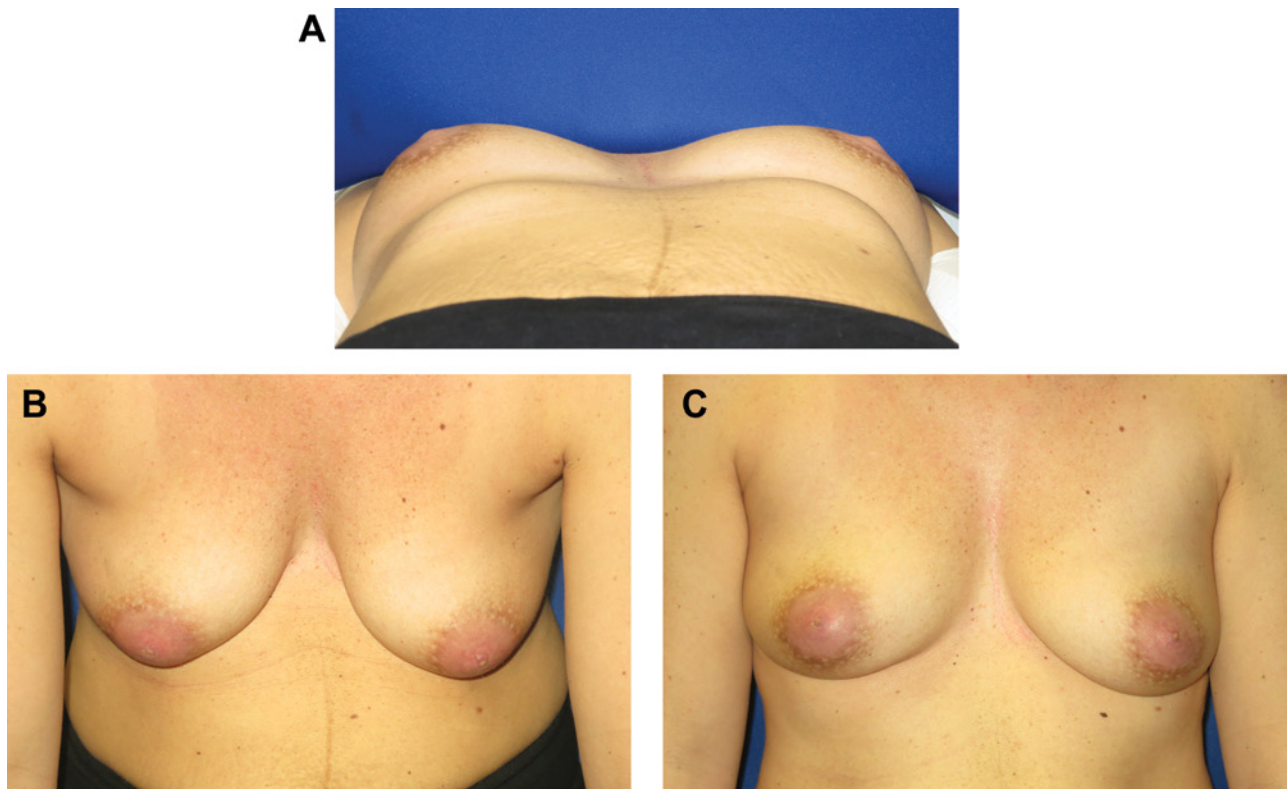


Figure 2. This 36-year-old patient demonstrates a volume difference between her breasts preoperatively. (A) At first glance, while supine, her right breast appears larger, because the right NAC is higher and the medial right breast is steeper in comparison to the left breast. In fact, the base of the left breast is broader than the base of the right breast. (B) These differences are further delineated when the patient leans forward from the standing position. (C) When the patient is standing, it is clear that the left breast is larger.

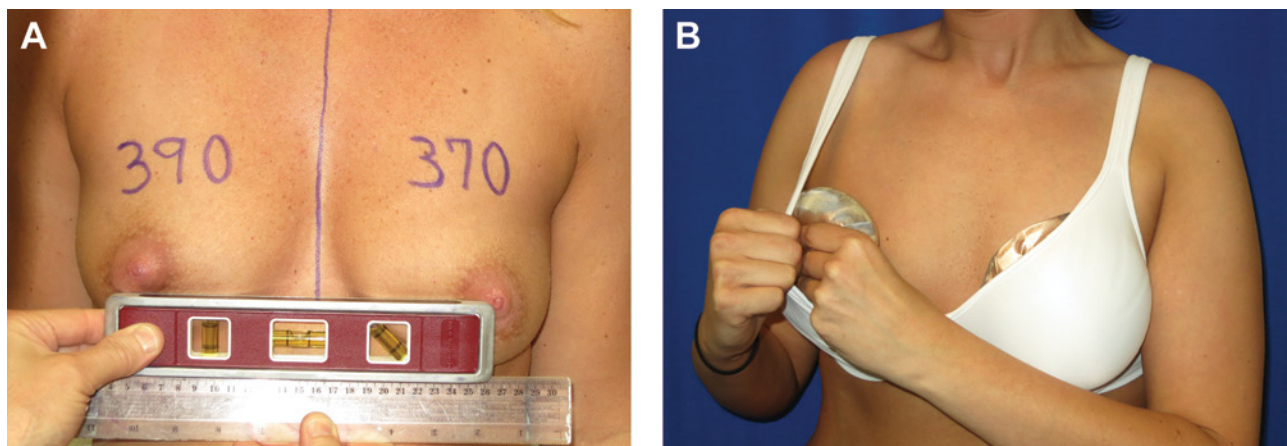


Figure 3. (A) If this same 36-year-old patient (shown in Figure 2) desired placement of saline implants, then asymmetries of the IMF and NAC would be ascertained (note the level and the ruler), and the right implant would ultimately be inflated more than the left. (B) If she chose gel implants, which are prefilled in set increments, then a determination would be made as to whether the difference in breast volume was enough to warrant different-sized gel implants. Her size difference was ascertained from her clinical examination and confirmed by trying on different-sized implants inside a bra. Ultimately, this patient received saline implants placed through an axillary approach, with the final fill-volume of the right implant being 20 cc greater (390 cc) than that of the left implant (370 cc) (Mentor Worldwide LLC, Santa Barbara, CA).

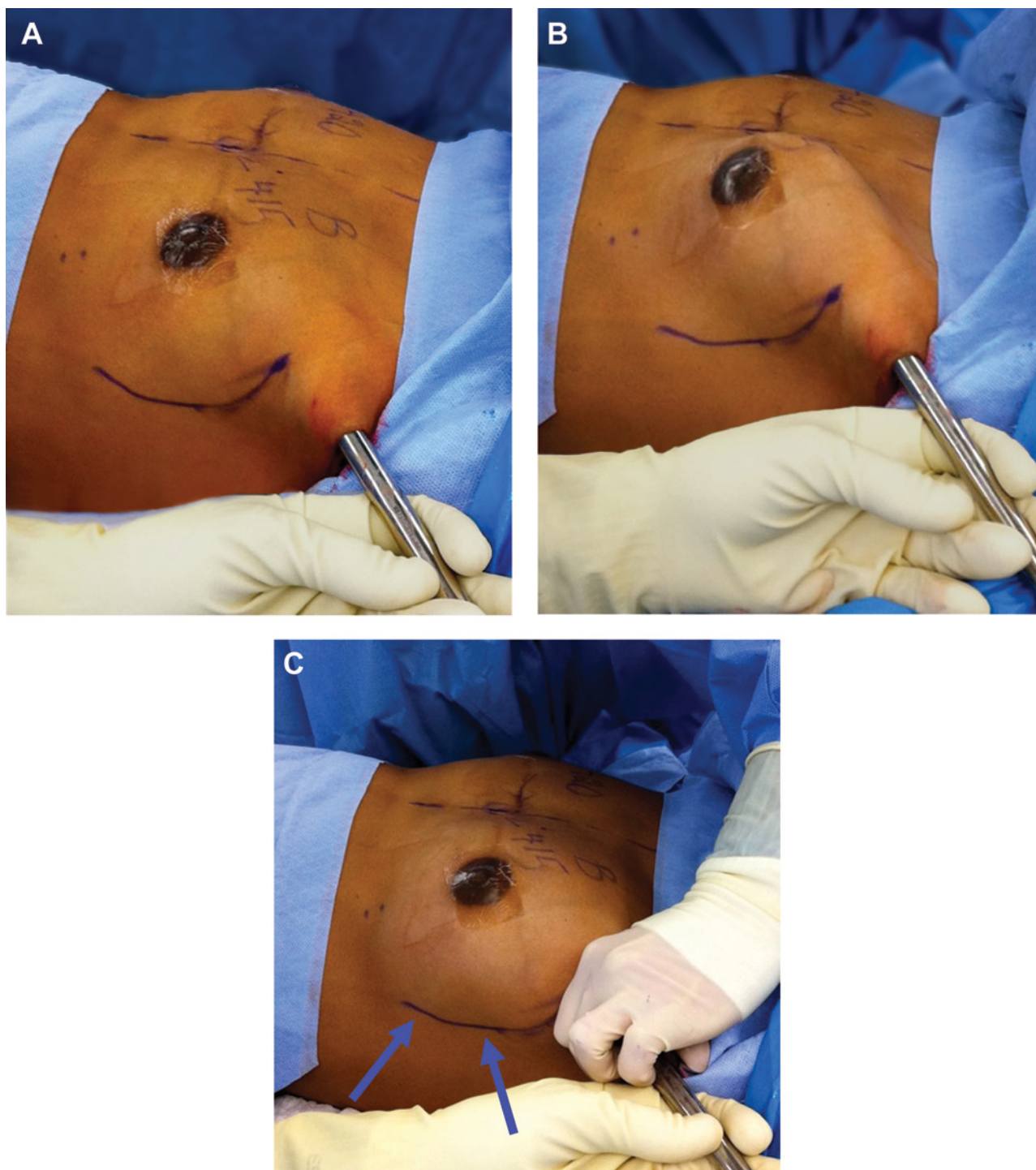


Figure 4. Intraoperative photographs of the “air-sizer” maneuver in this 22-year-old woman. (A) Once dissection of the pocket is accomplished, air can be drawn into the pocket by gently elevating the gland off of the ribs. (B) The incision is pinched closed, demonstrating the pocket perimeter. (C) Following the air-sizer maneuver, any pocket irregularities can be modified. The blue arrows denote 2 small areas of flattening on the lateral perimeter, indicating that additional release is necessary before placement of the implant.

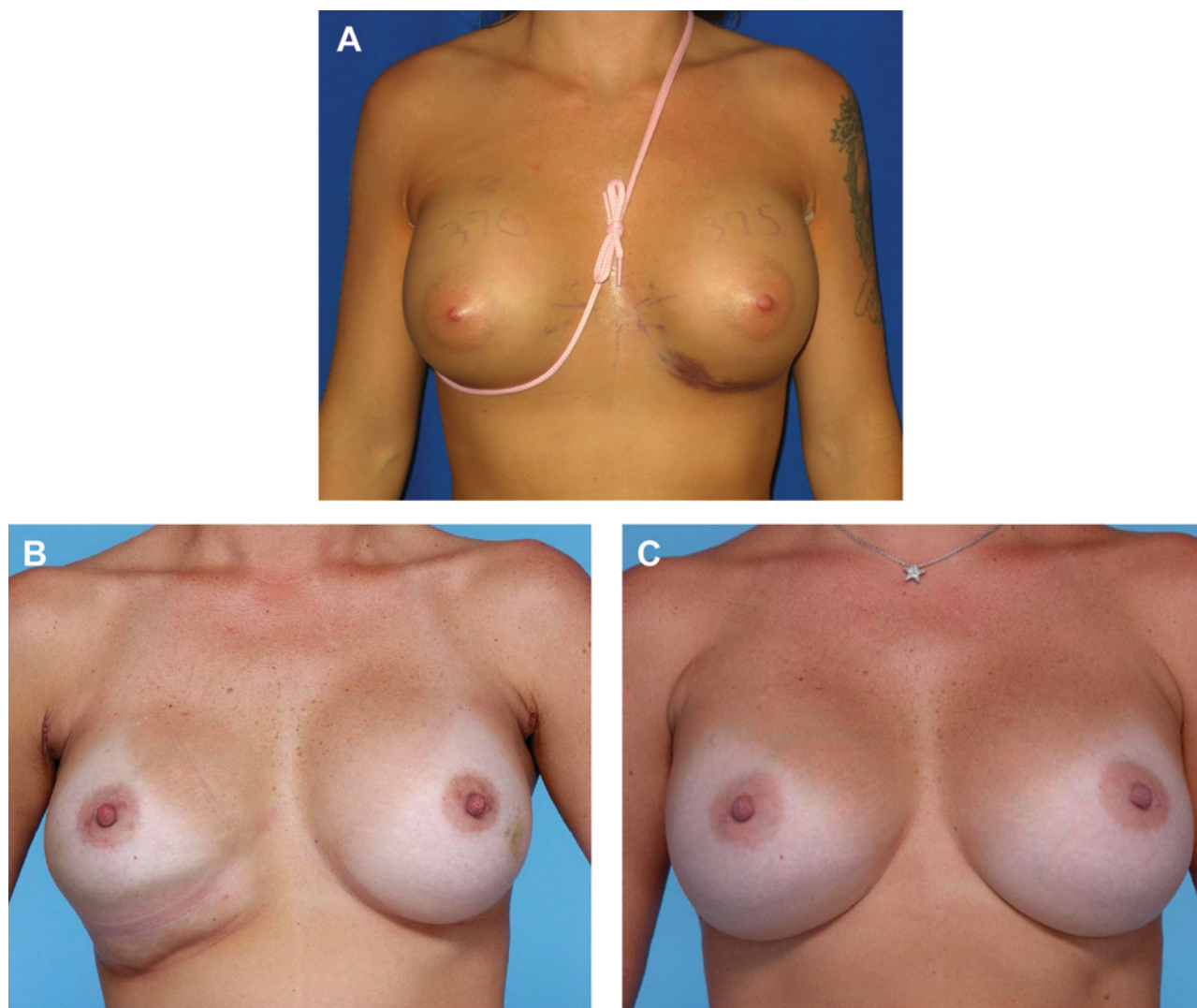


Figure 5. (A) A shoelace tied under the breast of this 30-year-old BA patient helped “set” the IMF to correct early postoperative implant migration or a double fold. (B) Inferior implant migration in this 24-year-old woman occurred 1 week after secondary BA and pretreatment with the shoelace technique. (C) Three months after treatment with the shoelace technique, the right IMF had been corrected. (Pre- and posttreatment photographs courtesy of Dr Daniel Mills, Clinical Assistant Professor, Department of Plastic Surgery, Loma Linda University, Loma Linda, California.)

and sealing of the pocket at the desired location. Patients were instructed to wear the shoelace 7 days a week, 24 hours a day, for the first postoperative month (or longer, if necessary), except when bathing or showering. (Only anecdotal evidence is available to support this practice.) Some patients discontinued wearing the shoelace after they complained of pain and the fact that the shoelace could be visible around the neck.

A deformity that occurred in some patients was a tight crease, which maintained its original tight contour and resisted expansion by the underlying implant, causing flattening along its original length and producing a double fold. A cutout bra was applied to treat the tight crease. If a cutout

bra was recommended, the patient was instructed to bring in a standard, inexpensive underwire bra without gel or padding. The lower half of the cup, from immediately above the underwire up to the NAC level, was cut away with scissors. As with the shoelace, patients were instructed to wear the cutout bra 7 days a week, 24 hours a day, for the first postoperative month (or longer, if necessary), except when bathing or showering. The cutout bra expands the tight IMF because the wire compresses the new IMF and allows 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 during a period of 1 to 3 months. Patient photos outline this method in a prior publication.¹⁸

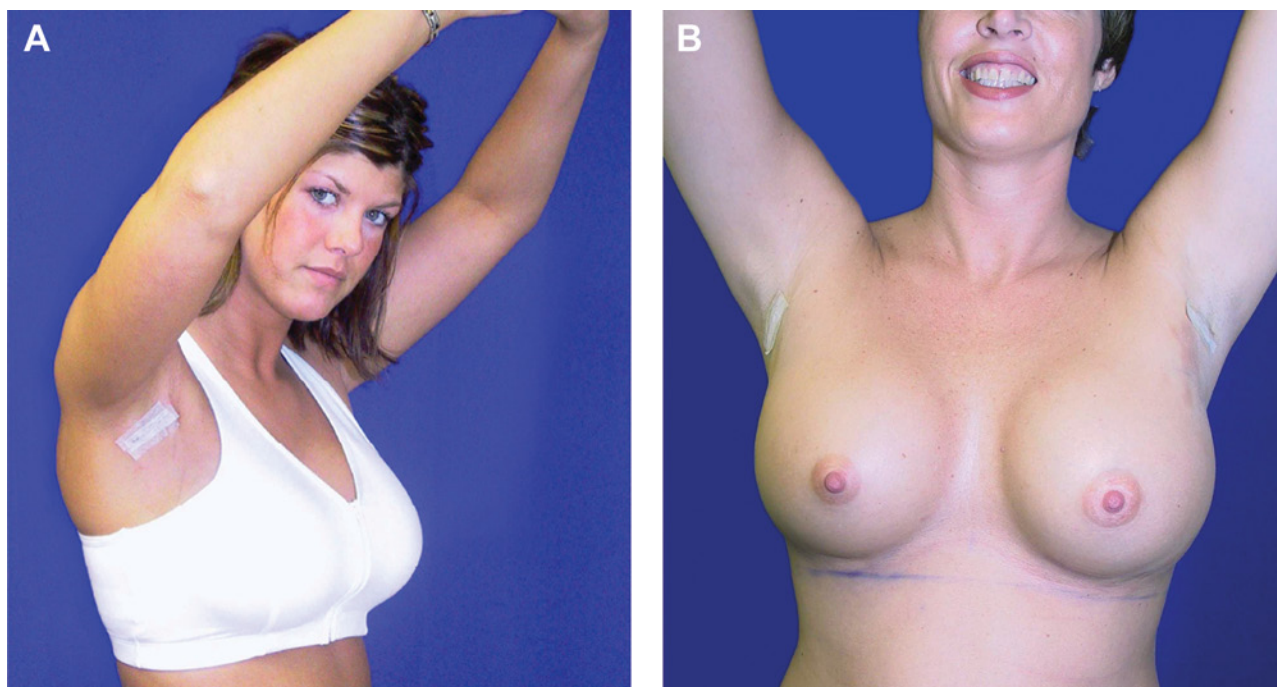


Figure 6. (A) This 21-year-old woman (5'7" tall, 135 pounds) appeared satisfied when seen in the office 24 hours after TAM in which 350-cc saline implants were placed (McGhan/Inamed/Allergan, Irvine, CA). She was pain-free and was not taking medication. To avoid CC and the formation of arm bands, we instruct all patients to begin raising their arms over their heads and performing displacement exercises, starting several hours after surgery. This patient was demonstrating her routine arm exercises ("the wave"). (B) This 33-year-old woman (5'9" tall, 160 pounds) appeared satisfied when seen in the office 24 hours after TAM in which 420-cc saline implants were placed (McGhan/Inamed/Allergan, Irvine, CA). She was pain-free, was not taking medication, and was demonstrating her routine arm exercises ("the wave").

Postoperative Routine: Arm Bands and CC Avoidance

In an effort to avoid tight bands from forming in the upper arms, and as a method of massage to help prevent CC, all patients were instructed to begin raising their arms over their heads and to perform displacement exercises beginning a few hours after surgery (Figure 6A,B). Patients were instructed to lie face down on a hard surface (such as a carpeted floor, or a bread board in bed) for 15 minutes each day. Regardless of the surgeon's preferred massage routine to avoid CC, patients were encouraged to continue these exercises for years, rather than weeks or months.

Evaluations

Clinical photographs and the BQ were used to evaluate outcomes. Five standardized photographs were obtained preoperatively and postoperatively for all patients; frontal, side, and oblique views were included. Preoperatively, the surgeon analyzed the photographs, along with the patient, for asymmetries and ptosis. All postoperative photographs were analyzed and compared with the respective preoperative images by 2 independent evaluators (the clinic

registered nurse and the aesthetician) and by the surgeon. Postoperative photographs were reviewed personally with all patients in the clinic by the registered nurse and the surgeon, and were given to the patient upon request.

RESULTS

Clinical results for 2 patients (1 each for moderate-profile saline and gel implants) are shown in Figures 7 and 8. Overall, 2000 patients underwent TAM (82.3% of the study population): 994 patients in the first phase of the study (84.8% of phase 1 cohort) and 1006 in the second phase (545 with saline implants, 461 with gel implants; 79.9% of phase 2 cohort).

Patient Demographics

The mean age (SD) of all patients ($n = 2430$) was 33.5 (8.6) years (range, 18-69 years; Figure 9). The median age was 32.8 years. The mean age (SD) of the axillary cohort ($n = 2000$) was 32.8 (8.5) years (range, 18-69 years). The median overall age was 32.1 years. The overall interquartile range was 26.9 to 39.0 years, and the interquartile range for the axillary cohort was 26.1 to 37.9 years,

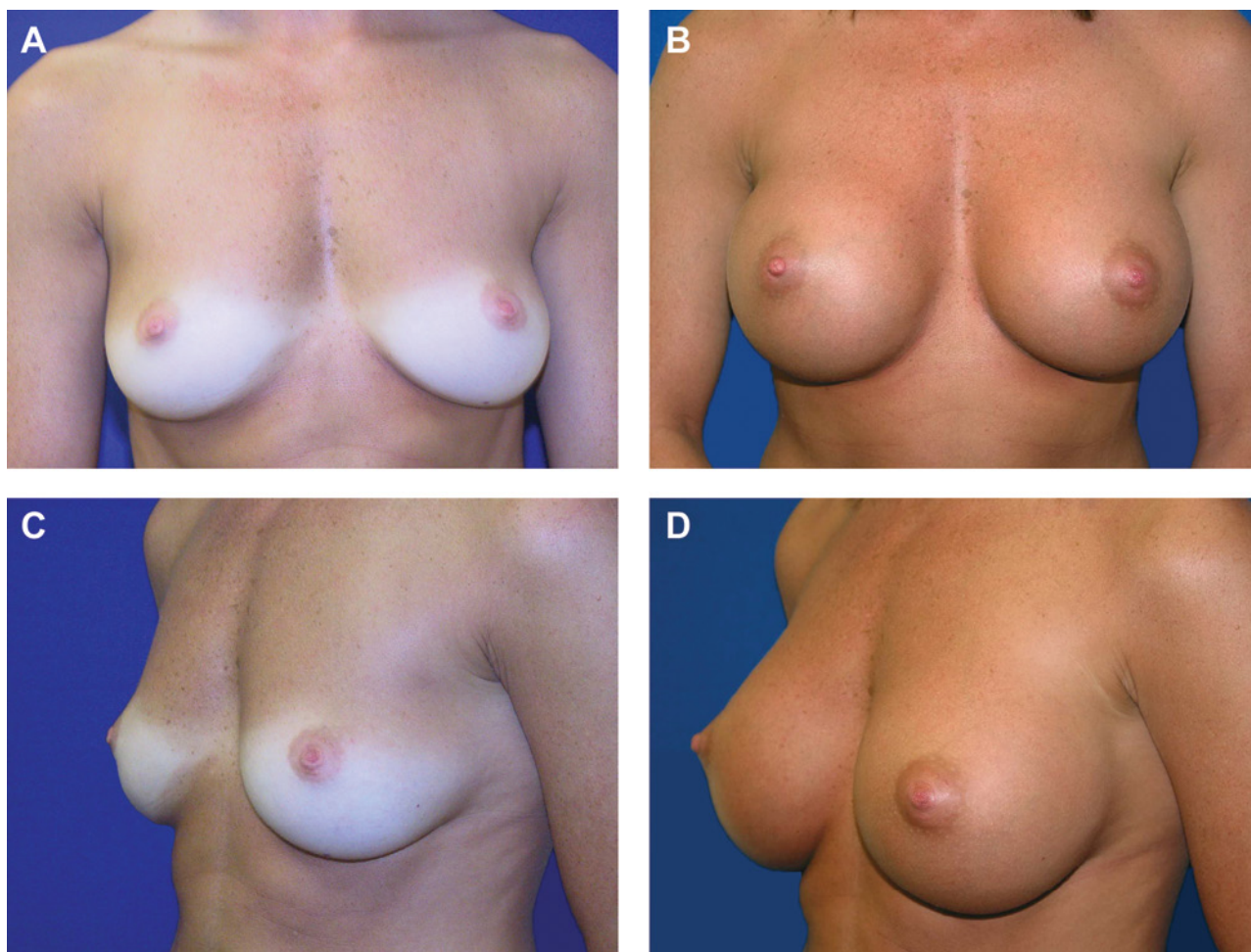


Figure 7. (A, C) This 25-year-old woman presented for BA. She was 5'4" inches tall and weighed 132 pounds. Her presurgical bra size was 34B. (B, D) At 2.5 years after TAM in which 360-cc moderate-profile saline implants (inflated to 390 cc) were placed bilaterally (McGhan/Inamed/Allergan, Irvine, CA). The patient's postsurgical bra size was 34D.

reflecting a slightly younger axillary group. Both cohorts included different ethnicities based on the surgeon's geographical area, but ethnicity was not specifically recorded.

Implant Characteristics

Initially, each patient received 2 implants (1 in each breast). The average implant size (SD) for the entire study population was 354.3 (63.2) cc (range, 150-800 cc; Figure 10). The overall median size was 360 cc. For the axillary cohort, the average implant size (SD) was 354.4 (61.2) cc (range, 180-800 cc) and the median size was 360 cc (same as the overall median size). The interquartile range was 304 to 390 cc for both groups. All implants placed throughout the study were smooth, round, medium- or high-profile devices from McGhan/Inamed/Allergan (Irvine, CA) (98% overall) or from Mentor Worldwide LLC (Santa Barbara, CA) (2%; last 3 months of the study).

BREAST-Q: Measuring Postoperative Outcomes From the Patient Perspective for Breast Satisfaction and Outcome Satisfaction

The BQ cohort ($n = 670$) was analyzed for postoperative breast satisfaction and overall satisfaction with outcomes; follow-up ranged from 1 to 11 years (Table 1). The BQ mean score (standard deviation [SD]) for postoperative breast satisfaction among these patients was 76.0 (16.6) (Table 2). The mean (SD) score for overall outcome satisfaction for these patients was 80.4 (22.4) (Table 3).

Satisfaction: Axillary (TAM) vs Nonaxillary Incisions

The BQ-reported median scores for breast satisfaction and outcome satisfaction differed between the axillary ($n = 543$) and nonaxillary ($n = 127$) groups. For the axillary incision group, median scores were 77.0 and 86.0 for breast

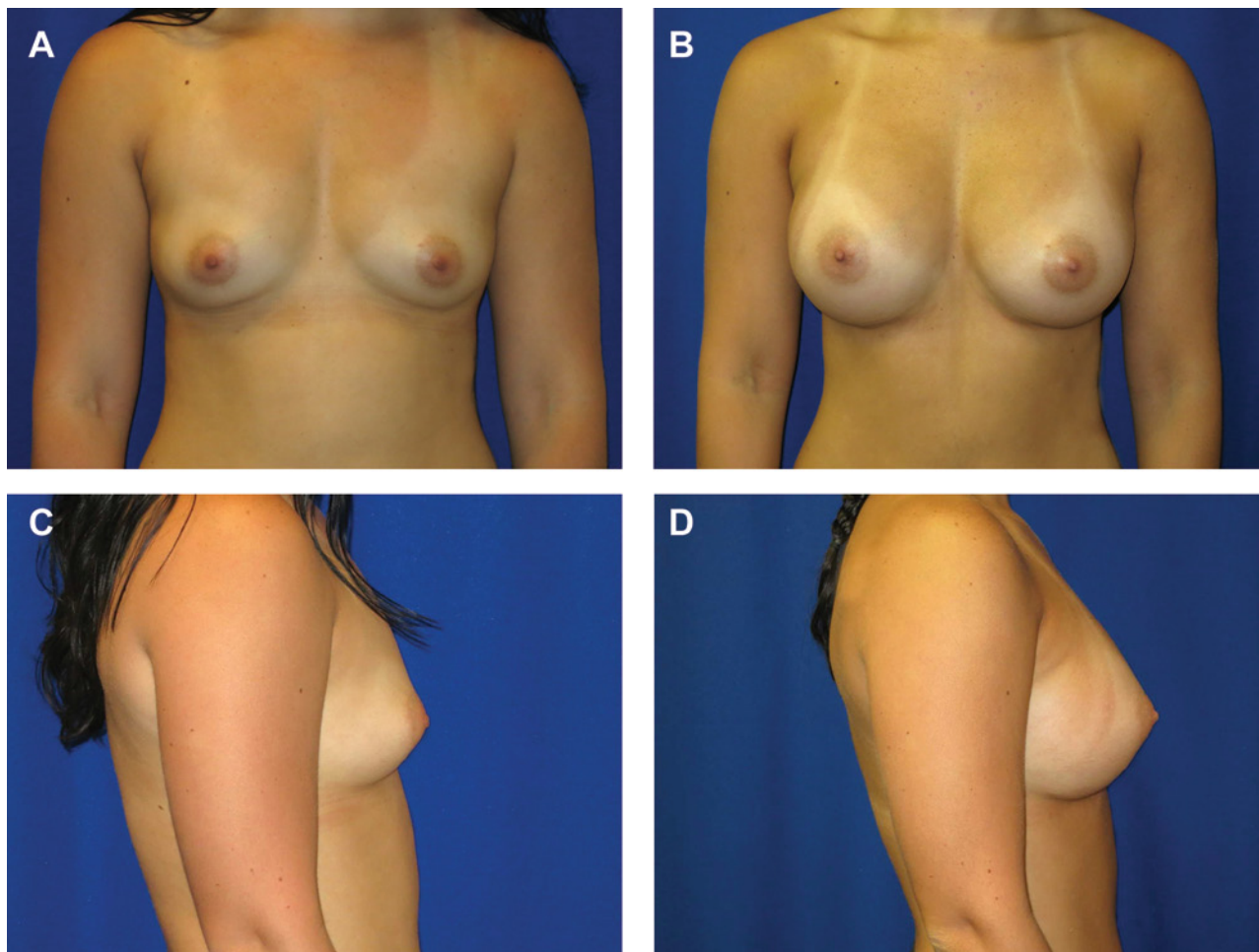


Figure 8. (A, C) This 24-year-old woman presented for BA. She was 5'6" inches tall and weighed 140 pounds. Her presurgical bra size was 34B. (B, D) One year after TAM in which 400-cc moderate-profile silicone gel implants were placed bilaterally (McGhan/Inamed/Allergan, Irvine, CA). The patient's postsurgical bra size was 34D.

satisfaction and outcome satisfaction, respectively. For the nonaxillary incision group, the median scores were 70.0 and 70.0, respectively. The respective interquartile ranges were 23.0 and 30.0 vs 21.0 and 33.0. The differences between the median scores in the axillary and nonaxillary surgical groups for BQ-reported breast satisfaction and outcome satisfaction were statistically significant ($W = 32\,894.5$, $P < .0001$ [Table 4]; $W = 31\,201.5$, $P < .0001$, respectively [Table 5]).

Correlation Between Satisfaction and Outcomes

Correlation analysis was used to describe the linear relationship between breast satisfaction scores and outcome satisfaction scores. The Pearson correlation coefficient for these 2 scores was 0.72, indicating a strong positive linear relationship. Patients with higher breast satisfaction scores also tended to have higher outcome satisfaction scores, as might be expected. The relationship also was strong for each implant type, with correlation coefficients of 0.73 and 0.72 for silicone gel and saline implants, respectively.

Mean satisfaction and outcome scores by year and implant type were calculated (Figures 11-14). Implant satisfaction and satisfaction with outcomes remained stable throughout follow-up.

The difference in mean satisfaction and outcome scores for saline vs silicone gel implants was available for all patients in phase 2 (2007-2011). The combined data from these years were used to test the null hypothesis of no difference in mean score between the 2 implant groups. Results of 2-sample t tests (α level = .05) for mean satisfaction and outcome scores are noted in Tables 6 and 7. There was a marginally significant difference in mean satisfaction scores between the 2 types of implants ($P = .046$); mean scores for patients who received silicone gel implants were slightly higher than mean scores for recipients of saline implants. Although the difference in mean outcome scores was slightly greater than the difference in mean satisfaction scores, it was not statistically significant ($P = .106$).

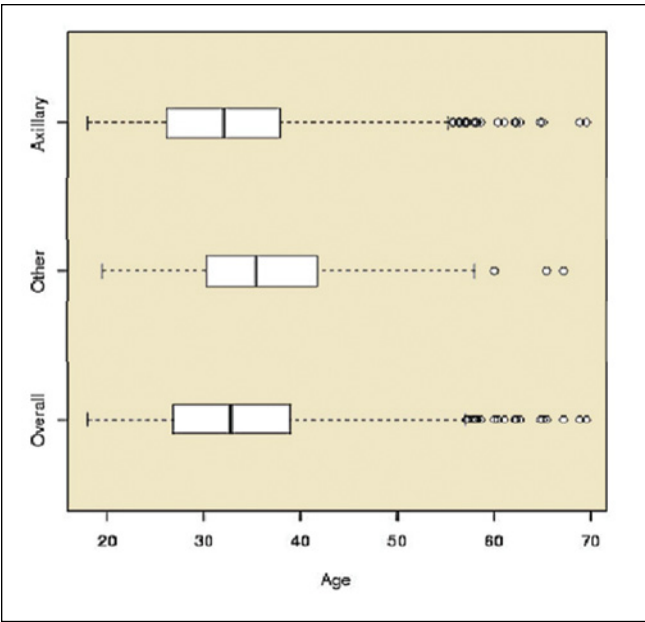


Figure 9. Box plot for patient age. Boxes represent the middle 50% of the age data (years) for each patient cohort. The left edge is the lower quartile and the right edge is the upper quartile; 25% of the observations lie to the left of the box, 25% lie to the right of the box, and 50% are within the limits of the box. The median is represented by the dark line in the center of the box. The “whisker” lines extend to the lowest and highest observation points that are not extreme values or possible outliers (shown as circles). Because the minimum age for BA was 18 years, the lower whisker extends only from 26.88 to 18, or 8.88 units. The upper quartile is 38.97, so that whisker would extend no further than 57.105.

For these evaluations, the *t* test was favored over the *z* score because the *z* score is appropriate only when the population standard deviation (σ) is known. For the present data, the population standard deviation was not known and therefore was estimated from the sample standard deviation (*s*). The *t* test is appropriate because it accounts for the additional variability encountered when the population standard deviation is estimated from sample data.

Representative BQ questions regarding patient satisfaction and outcomes are shown in Tables 8 and 9.

Duration of Follow-Up

Of the entire study population, 23.4% (*n* = 2430) had follow-up of at least 1 year (23.5% of the TAM cohort [*n* = 2000] and 23.0% of the nonaxillary cohort (*n* = 430). The proportion of patients with more than 1 year of follow-up was 34.4% among the phase 1 cohort and 13.1% among the phase 2 cohort. Of the phase 1 participants, 16.6% had at least 3 years of follow-up. Patients who did not return for follow-up were those who lived out of state; however, these patients received follow-up phone calls throughout the first 2 months postoperatively. All patients were

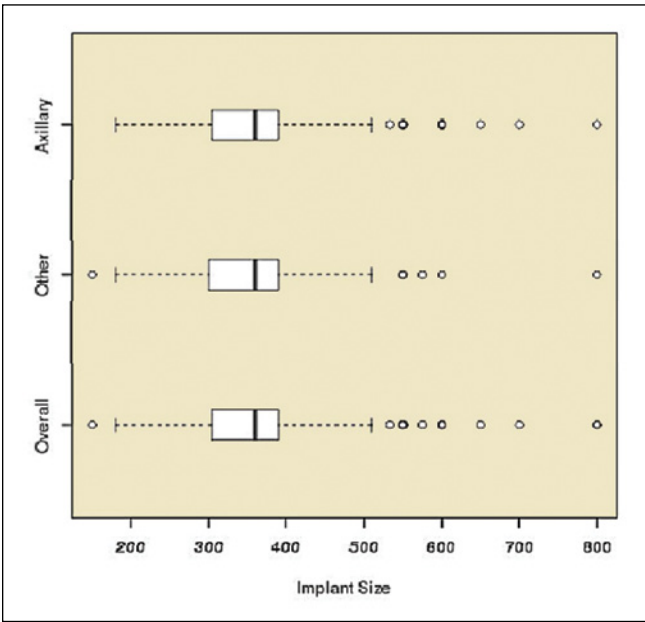


Figure 10. Box plot for implant size. The box in the middle represents the middle 50% of the implant size (cc) data for each patient cohort; that is, the left edge is the lower quartile and the right edge is the upper quartile. Whiskers extend to the lowest and highest observation points that are not extreme values or possible outliers (shown as circles). The median size is indicated by the dark line inside the box.

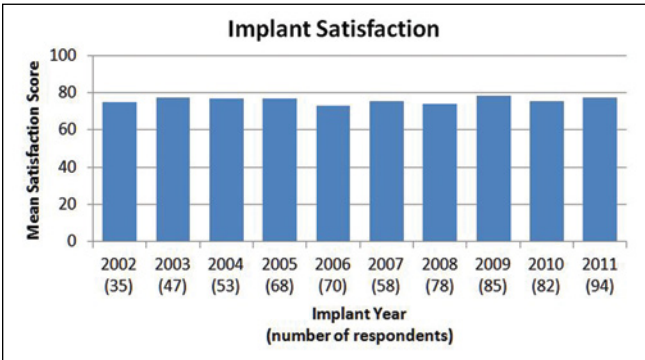


Figure 11. BQ satisfaction scores by year, as reported by BA patients. Each year reflects the mean breast satisfaction score with implants from a total of 670 surveys returned from the 1003 patients who could be contacted postoperatively. The durability and stability of patient breast satisfaction is shown for each year of this 10-year study.

advised to have annual follow-up examinations of their implants at our office, for the rest of their lives.

Revisions and Untoward Events

Overall, 2343 of the 2430 patients did not experience any untoward event. Of the 2000 patients who underwent TAM, 1928 did not require revision surgery. Tables 10 and 11 show the types and incidences of untoward events

Table 1. BREAST-Q Cohort (n = 670) According to Year of Breast Augmentation

Year	No. of Surveys	
	Mailed	Returned ^a
2002	51	35
2003	72	47
2004	82	53
2005	100	68
2006	90	70
2007	96	58
2008	123	78
2009	118	85
2010	130	82
2011	141	94
Total	1003	670 ^b

^aAs of March 29, 2013.^bReturn rate, 67%.

experienced by the entire study population and the axillary cohort, respectively. The incidence of revision was 7.5% overall (180 of 2430; 95% confidence interval [CI]: 6.4, 8.6) and 6.8% for the axillary cohort (136 of 2000); CI: 5.7, 7.7).

Implant Failure

Overall, deflation was the most common reason for implant-related revisions; there were 87 ruptured implants among the 2430 patients (3.6% of all patients; 1.8% of all implants) (Table 12). The incidence rate was identical for the axillary cohort (72 ruptured implants among 2000 patients; 3.6% of patients) (Table 13). With saline implants, rupture is recognized if deflation occurs. However, with gel implants, rupture does not present as deflation, yet it can be assumed if certain clinical changes occur, such as a marked deformity or marked new asymmetry.

DISCUSSION

The BQ mean (SD) score for postoperative satisfaction in the present study (n = 670) was 76.0 (16.6) (Table 2). The higher the score on the scale of 1 to 100, the greater the level of satisfaction. Our BQ satisfaction score compares favorably with that reported by McCarthy et al⁴ (score of 70 [SD 23]) from their study of 41 patients who underwent cosmetic BA,⁴ and with that of the recent study by Coriddi et al² of 59 patients (score of 82.4 [SD 14.3]). In the latter study, the authors used the 2-sample *t* test to compare patient satisfaction between the axillary and nonaxillary surgical groups.

For the sake of brevity, the histograms showing the density of distribution are not included in the present report. However, the 2-sample Wilcoxon test provided an accurate reflection of the data. From our outcomes ($P < .0001$), a

Table 2. BREAST-Q Mean Breast Satisfaction Scores According to Year of Breast Augmentation and Type of Implant^a

Year	All Respondents (n = 670)		Patients			
			With Saline Implants (All Years, n = 479)		With Silicone Gel Implants (2007-2011, n = 191)	
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)
2002	35	74.9 (20.4)	35	74.9 (20.4)	0	NA
2003	47	77.4 (16.6)	47	77.4 (16.6)	0	NA
2004	53	76.6 (15.4)	53	76.6 (15.4)	0	NA
2005	68	76.7 (17.5)	68	76.7 (17.5)	0	NA
2006	70	72.8 (16.5)	70	72.8 (16.5)	0	NA
2007	58	75.2 (16.4)	39	75.3 (15.0)	19	74.9 (19.5)
2008	78	74.0 (17.8)	46	72.7 (18.8)	32	75.9 (16.2)
2009	85	78.5 (16.4)	41	74.9 (18.2)	44	81.9 (13.8)
2010	82	75.4 (16.7)	41	73.1 (16.9)	41	77.7 (16.2)
2011	94	77.5 (14.0)	39	77.9 (12.7)	55	77.2 (15.0)

Abbreviation: NA, not applicable.

^aThe BREAST-Q satisfaction score was calculated for 670 patients who received implants for BA. The score is based on patient responses to 17 items (1 = very dissatisfied, 4 = very satisfied). The item responses were summed and converted into a satisfaction score ranging from 0 to 100. Higher scores indicate greater satisfaction with implant results. The mean (SD) satisfaction score for the 670 respondents was 76.0 (16.6).

Table 3. BREAST-Q Mean Outcome Satisfaction Scores According to Year of Breast Augmentation and Type of Implant^a

Year	Patients					
	All Respondents (n = 669)		With Saline Implants (All Years, n = 478)		With Silicone Gel Implants (2007-2011, n = 191)	
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)
2002	35	78.0 (27.1)	35	78.0 (27.1)	0	NA
2003	47	78.0 (22.5)	47	78.0 (22.5)	0	NA
2004	53	77.1 (22.5)	53	77.1 (22.5)	0	NA
2005	68	81.1 (22.1)	68	81.1 (22.1)	0	NA
2006	69	82.9 (19.3)	69	82.9 (19.3)	0	NA
2007	58	78.3 (23.4)	39	82.9 (20.3)	19	68.9 (26.9)
2008	78	80.6 (23.3)	46	82.6 (25.3)	32	77.8 (20.1)
2009	85	81.7 (23.7)	41	84.6 (22.7)	44	79.1 (24.5)
2010	82	77.8 (24.1)	41	76.0 (27.0)	41	79.6 (21.1)
2011	94	83.8 (18.9)	39	86.5 (15.9)	55	82.0 (20.8)

Abbreviation: NA, not applicable.

^aThe BREAST-Q outcome score was calculated for 669 implant patients. Outcome score was not available for 1 respondent whose BA was performed in 2006. The score is based on patient responses to 8 items related to how the patient feels about the outcome of her surgery (1 = disagree, 3 = definitely agree). The item responses were summed and converted into an outcome score ranging from 0 to 100. Higher scores indicate a more positive perception of the surgery outcome. The mean (SD) outcome score for the 669 respondents was 80.4 (22.4).

Table 4. Wilcoxon Scores (Rank Sums) for Variable BREAST-Q Satisfaction Scores According to Type of Incision^a

Incision Type	No. of Patients	Sum of Scores	Expected Under H_0	SD Under H_0	Mean Score
Axillary	543	191 890.50	182 176.50	1955.83458	353.389503
Other	127	32 894.50	42 608.50	1955.83458	259.011811
Wilcoxon 2-Sample Test					
Statistic	32 894.5000				
Normal approximation					
z	-4.9664				
2-sided $P > z $	<.0001				

Abbreviation: H_0 , null hypothesis.

^aAverage scores were used in the event of a tie; z includes a continuity correction of 0.5.

surgeon could conclude that it would be worthwhile to offer the axillary approach to nonptotic patients whose anatomy is normal, because these patients were more satisfied than those who received the other approaches.

Comparing Mean Satisfaction and Outcome Scores Between Patients With Saline and Silicone Gel Implants

The comparisons of mean satisfaction scores by year, overall and by type of implant (saline vs silicone gel), demonstrate the durability and stability of patient satisfaction

over time (Figures 11 and 12). Each “implant year” reflects that year’s portion of the total number of patients who returned the questionnaire (n = 670) among the 1003 patients who could be contacted postoperatively. The dependent variable was patient satisfaction, and the 2 independent variables were saline and gel implants. The mean (SD) satisfaction score for our 670 patients was 76.0 (16.6) (Table 2). Thus, patient satisfaction with BA remains stable over time.

The comparison by year, both overall and for saline vs silicone gel implants, also shows the long-term durability and stability of patient satisfaction with outcomes (Figures 13 and 14). Each “implant year” reflects the portion of the

Table 5. Wilcoxon Scores (Rank Sums) for Variable BREAST-Q Outcome Satisfaction Scores According to Type of Incision^a

Incision Type	No. of Patients	Sum of Scores	Expected Under H_0	SD Under H_0	MeanScore
Axillary	542	192 913.50	181 570.0	1872.00022	355.928967
Other	127	31 201.50	42 545.0	1872.00022	245.681102
Wilcoxon 2-Sample Test					
Statistic	31 201.5000				
Normal approximation					
z	-6.0593				
2-sided $P > z $	<.0001				

Abbreviation: H_0 , null hypothesis.

^aAverage scores were used in the event of a tie; z includes a continuity correction of 0.5.

Table 6. Mean BREAST-Q Satisfaction Scores According to Type of Implant

Implant Type	No. of Patients (2007-2011)	Mean Satisfaction Score (SEM)	P Value ^a
Saline	206	74.7 (1.2)	
Silicone gel	191	77.9 (1.1)	.046

Abbreviation: SEM, standard error of the mean.

^at test.

total number of patients who provided this information on their questionnaire ($n = 669$ of the 1003 contacted postoperatively). (One of the 670 BQ respondents did not provide an outcome score; therefore, this analysis was based on 669 patients.) Coriddi et al² concluded that patients who were satisfied with their overall outcomes also were satisfied with the appearance of their breasts and, to a lesser extent, had better psychosocial and sexual well-being.² The mean (SD) outcome score for the 669 patients in our series was 80.4 (22.4) (Table 3). As mentioned previously, the relationship also was strong for each implant type, with correlation coefficients of 0.73 and 0.72 for silicone gel and saline implants, respectively.

There was a marginally significant difference in mean satisfaction scores between the 2 implant devices ($P = .046$); scores were slightly higher for patients who received the silicone gel implants (Table 6). The difference between the means was small (3.2 points on the 100-point scale). The small variability of these scores and the relatively large sample size contributed to this being a statistically significant difference. With large sample sizes and small variability (most satisfaction scores were high, so the variability of the satisfaction scores is small), even small differences in means can be statistically significant. Therefore, this very small difference proved statistically significant at the .05 level. More important is the fact that most patients scored their satisfaction and outcomes at a high level, and

Table 7. Mean BREAST-Q Outcome Scores According to Type of Implant

Implant Type	No. of Patients (2007-2011)	Mean Satisfaction Score (SEM)	P Value ^a
Saline	206	82.5 (1.6)	
Silicone gel	191	78.8 (1.6)	.106

Abbreviation: SEM, standard error of the mean.

^at test.

the differences between the 2 implant groups were very small, indicating a high degree of patient satisfaction regardless of implant type.

Mean outcome scores also were similar between the 2 implant groups (a 3.7-point difference on a 100-point scale), yet slightly higher for those who received saline implants (Table 7). Although the difference in mean outcome scores was slightly greater than the difference in mean satisfaction scores between the 2 groups, it was not statistically significant ($P = .106$). This is explained by the larger variability in outcome scores compared with the variability of satisfaction scores. There was no significant difference in outcome scores based on the type of implant.

The follow-up time for patients in phase 1 actually surpasses that of the Food and Drug Administration Summary Data of Breast Implant Clinical Trials; 3-year follow-up was obtained for 16.6% of our phase 1 patients who had saline implants, compared with only 9.6% for the Food and Drug Administration Summary.¹⁹

The revision rate was fairly low in our study. A concern with the nonendoscopic technique is that it may limit the development of an adequate medial pocket and often produce an excessive lateral pocket. To avoid this problem, we took great care to stretch the medial pectoralis muscle fibers and the tendinous attachments. Our revision rate for malposition was 0.9%, and our revision numbers (Tables 11 and 13) compare favorably with those of a previous

Table 8. Representative BREAST-Q Questions and Summary Sample on Patient Satisfaction (n = 670)^a

Questions About Your Breasts and Breast Surgery	Response (%)			
	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
How natural your breasts look?	1	4	19	76
The position of the implants on your chest (too high or low)?	3	5	20	72
How your scars look?	3	6	16	75

^aResponses indicated that >90% of patients were somewhat satisfied or very satisfied.

Table 9. Representative BREAST-Q Questions and Summary Sample on How Patients Felt About the Outcome of Surgery (n = 670)^a

How You Feel About the Outcome of Your Surgery?	Response (%)		
	Disagree	Somewhat Agree	Definitely Agree
Overall the surgery was a good experience	2	10	88
I have no regrets about having the surgery	4	12	84
I am satisfied with the results	5	18	77
Having surgery changed my life for better	6	21	73

^aResponses indicated that >90% of patients agreed or definitely agreed with each statement.

Table 10. Incidence of Untoward Events Among the Entire Study Population (N = 2430)^a

Event	No. of Patients		
	Without Event	With ≥1 Event	%
Saline deflation or gel leak	2343	87	3.6
Size change	2399	31	1.3
Malposition	2401	29	1.2
Change from saline to gel	2408	22	0.9
Capsular contracture	2413	17	0.7
Explant	2418	12	0.5
Hematoma	2421	9	0.4
Mastopexy	2425	5	0.2
Lipotransfer	2428	2	0.1
Explant with reduction	2429	1	0.0
Infection	2429	1	0.0
Partial closure	2429	1	0.0
Insertion of secondary implant	2430	0	0.0

^aEvents are listed in the order of frequency (from most common to least common).

Table 11. Incidence of Untoward Events in the Axillary Cohort (n = 2000)^a

Event	No. of Patients		
	Without Event	With ≥1 Event	%
Saline deflation or gel leak	1928	72	3.6
Size change	1979	21	1.1
Malposition	1982	18	0.9
Change from saline to gel	1985	15	0.8
Capsular contracture	1989	11	0.6
Explant	1991	9	0.5
Hematoma	1993	7	0.4
Infection	1999	1	0.1
Lipotransfer	1999	1	0.1
Mastopexy	1999	1	0.1
Explant with reduction	2000	0	0.0
Insertion of secondary implant	2000	0	0.0
Partial closure	2000	0	0.0

^aEvents are listed in the order of frequency (from most common to least common).

TAM study, by Huang et al,⁸ who reported on a 20-year cohort series of axillary BA. Reasons for revision in their study included: CC, 1.9% (vs 0.7% in our 10-year TAM cohort); hematoma, 0.12% (vs 0.4%); malposition, 2.97%

(vs 1.2%); size change, 2.5% (vs 1.3%); infection, 0% (vs < 1%); and rupture, 1.8% of implants (vs 3.6% of implants [but our follow-up was shorter]). If the patient in our study who experienced infection concurrent with an early

Table 12. Incidence of Saline Deflation or Gel Leak Among the Entire Study Population (N = 2430)^a

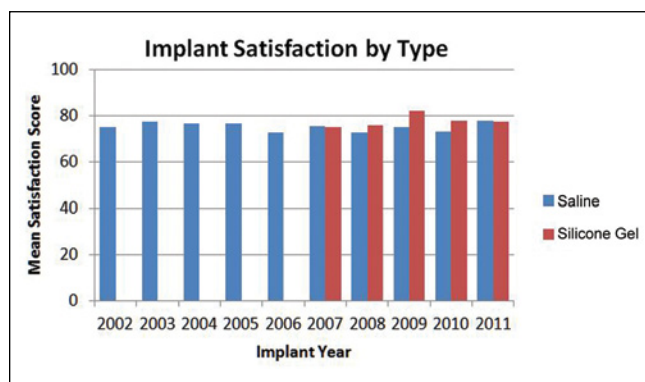
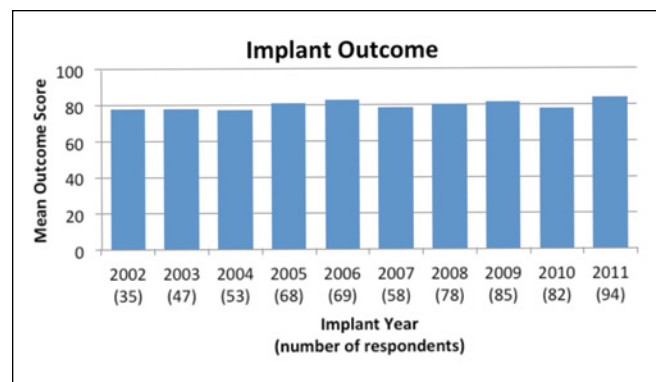
Phase	Implant Type	No. of Patients			Participant Years of Follow-Up	Incidence (Per 100 Years)	95% Confidence Interval	
		Sample Size	With ≥1 Event	Simple Incidence (%)			Lower	Upper
1 + 2	Both	2430	87	3.6	23 929	0.4	0.3	0.4
1 + 2	Saline	1838	87	4.7	20 777	0.4	0.3	0.5
2	Gel	592	0	0.0	3152	0.0	0.0	0.1
2	Saline	666	12	1.8	2809	0.4	0.2	0.7
1	Saline	1172	75	6.4	17 968	0.4	0.3	0.5

^aWith saline implants, deflation serves as confirmation of rupture. A limitation of gel implants is that rupture does not present as deflation; one can only *assume* rupture of a gel implant, based on significant clinical change.

Table 13. Incidence of Saline Deflation or Gel Leak in the Axillary Cohort (n = 2000)^a

Phase	Implant Type	No. of Patients			Participant Years of Follow-Up	Incidence (Per 100 Years)	95% Confidence Interval	
		Sample Size	With ≥1 Event	Simple Incidence (%)			Lower	Upper
1 + 2	Both	2000	72	3.6	19 621	0.4	0.3	0.5
1 + 2	Saline	1539	72	4.7	17 104	0.4	0.3	0.5
2	Gel	461	0	0.0	2517	0.0	0.0	0.1
2	Saline	545	11	2.0	2127	0.5	0.3	0.9
1	Saline	994	61	6.1	14 977	0.4	0.3	0.5

^aWith saline implants, deflation serves as confirmation of rupture. A limitation of gel implants is that rupture does not present as deflation; one can only *assume* rupture of a gel implant, based on significant clinical change.

**Figure 12.** BQ mean breast satisfaction score for each year, according to implant type.**Figure 13.** BQ mean outcome satisfaction score with implants by year, as reported by BA patients.

postoperative tattoo is excluded from the analysis, our rate of infection also would have been zero. The average implant size was 438.5 ± 51.5 cc (range, 270-630 cc) in the study by Huang et al,⁸ and 354.3 ± 63.2 cc (range, 150-800 cc) in our 10-year TAM series.

Bartsich et al²⁰ suggested that the breast harbors significant endogenous bacteria. In their study, quantitative bacterial counts were obtained from intraoperative periareolar, inframammary, and axillary regions of each sampled breast. There was a significant difference in the positive

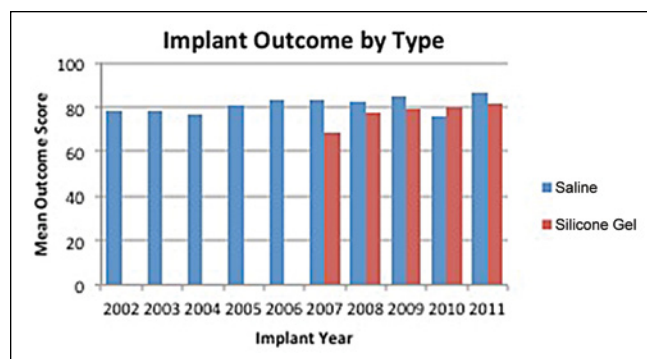


Figure 14. BQ mean outcome score for each year, according to implant type.

culture rate between the 3 sites, with the lowest bacterial counts being in the axillary region and the highest counts being in the periareolar region. The authors suggested that this information could be helpful in selecting an appropriate incision site.

In a recently published, 15-year, long-term study by Stutman et al,¹¹ there was no statistically significant association between incision location (122 patients had axillary incision) and specific complications such as CC, rippling, implant rupture, hematoma, or infection. Jacobson et al²¹ recently reported that the risk of CC was significantly higher with transaxillary incisions than with periareolar or inframammary incisions. However, only 24 transaxillary patients had follow-up, which was of short duration in that study. It is not surprising that the CC rate was higher with TAM, because the implants tend to ride high if the inferior pocket is underdissected. If the implants are tight and riding high postoperatively, an inexperienced examiner could easily mistake these findings for CC. One way to tell the difference between a high-riding implant and CC is to push the implant from side to side. The implant should feel soft if it is high riding. Long-term follow-up is very important because CC may form over time. Release of the inferior pocket will alleviate this “pseudo-capsule.” The senior author of the study by Jacobson et al²¹ agreed that high-riding implants resulting from the transaxillary technique could have been clinically misjudged to be capsules in their small cohort (personal communication, Dr Scott Spear, April 13, 2013). This emphasizes the importance of adequate release of the inferior pocket in TAM. A breast band worn 24 hours a day, 7 days per week, for 1 to 3 months usually corrects high-riding implants.¹⁸ It is noteworthy that 3 hematomas occurred in the study by Jacobson et al,²¹ all in patients who had inframammary (direct visualization) incisions. All 3 required surgical exploration in the operating room.²¹ Even with our nonendoscopic approach, the rate of postoperative hematoma was only 0.4% (7 hematomas among the 2000 TAM-treated

patients). This low rate is attributable to blunt dissection, which disrupts the vessel intima, and to irrigation, which diffuses the clotting factors for hemostasis.

Clinical Suggestions and Considerations

In the present study, TAM was selected only after the patient had been evaluated thoroughly, with stringent indications in mind, and if the patient had chosen this incision. Almost all qualified patients in this series who had normal anatomy selected TAM in order to avoid breast incision. TAM was the routine procedure for primary BA.

Great care must be taken to preserve the lymphatics when dissecting from the axillary fold skin incision to the edge of the pectoralis major muscle and clavipectoral fascia. The issue of lymphatic interruption has been addressed in several publications, and successful mapping and sentinel lymph node biopsy can be performed after TAM.²²⁻²⁴ Clinicians have observed the formation of a fibrous band along the upper arm in up to 15% of patients in large series of axillary BA.^{25,26} These bands reportedly resolved either spontaneously or with massage in all cases, which also has been true in our experience. We suggest routine arm exercises for our patients, not only to help prevent CC but also to prevent or soften the fibrous bands (Figure 6A,B). We believe that these bands may result from clotted superficial veins because they tend to extend distally down to the wrist. In our experience, the bands have always resolved by 3 months postoperatively, with or without massage.

Limitations

Several opportunities exist for further study of the patients who received TAM. Although the initial cohort has a theoretical 10-year follow-up period (and follow-up times were calculated meticulously), unless the patients had actually been assessed for the full 10 years, the outcome calculations may not be completely reliable. Any patient requiring reoperation who had moved out of state, or had been referred to a colleague, could have received the secondary operation elsewhere, without having notified us. The follow-up time for phase 2 patients is shorter because their surgeries were performed later. Longer follow-up is necessary to determine accurate rates of complications (especially for the gel cohort and for deflations). Deflation rates for the saline implants in this study will undoubtedly increase over time. Another limitation of the retrospective nature of this study is the lack of follow-up with magnetic resonance imaging or high-resolution ultrasonography in patients who received gel implants.²⁷

In our study, the BQ was not provided to patients preoperatively. As noted by the authors of a recent comparison

study in which only postoperative patient responses were assessed for shaped cohesive gel vs round cohesive gel implants,²⁸ the BQ has been validated to evaluate only postoperative outcomes. The protocol of Macadam et al²⁸ was similar to that of this study, which compared patient satisfaction and QOL between gel and saline implants. We were able to contact less than half of our study population 11 years later: 1003 (41%) of 2430. Of those contacted, the return rate was 67% (670 of 1003).

Despite these limitations, our BA study is the largest, with the longest follow-up, published to date, and the only study in which patient satisfaction was compared for gel implants vs saline implants. Because the survey of patients extended to 11 years postoperatively, a bias was introduced because not all patients could be contacted. It is possible that the 333 patients who did not return their surveys were dissatisfied, which would yield a positive bias. However, it could also be surmised that dissatisfied patients likely would have returned their surveys as a means to communicate displeasure, which would represent a negative bias.

To date, there is no statistical evidence or data on the success rate of placing a shoelace to form the IMF. Additional study of this procedure is warranted to determine its clinical utility.

CONCLUSIONS

Data from this 10-year, retrospective, comparative review demonstrate that TAM without an endoscope produces long-term patient satisfaction as measured by the BQ. Complication rates were similar to those of other studies. Our findings also show to a statistically significant degree that patient satisfaction is greater after TAM (hidden incision) than after techniques that yield visible incisions. Clearly, the proper choice of BA incision can have a profoundly positive impact on a woman's satisfaction with her breasts and with her surgical outcome, and can substantially improve QOL.

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