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ORIGINAL ARTICLE BREAST SURGERY

Transition from Round to Shaped Implants in Immediate Breast Reconstruction: Our Preferred Approach and Clinical Outcomes

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Abstract

Background Smooth, round, silicone implants predominate device-based breast reconstruction in the USA; despite their prevalence, complications can include bottoming out, superior contour deformity, rippling, and/or lateral malposition. This complication profile increases the need for revision surgery and subsequent patient dissatisfaction. With the resurgence of shaped, textured, silicone implants in the USA, we report the senior author's success with these devices and outline a strategy to optimize outcomes in breast reconstruction surgery.

Methods A retrospective chart review was conducted on a prospectively collected IRB-approved database of nipple-sparing mastectomies (NSMs) with immediate breast reconstruction with smooth, round, silicone implants (Group A) in 2011 in comparison to textured, shaped, silicone implants (Group B) in 2012. Changes in operative technique were highlighted and extrapolated. Outcomes were reviewed.

Results In Group A, 128 NSMs were performed in 76 patients. In Group B, 109 NSMs were performed in 59 patients. Thirteen percent of patients in Group A had direct to implant reconstruction as compared with 21% in Group B. Patients with textured, shaped implants were more likely to have acellular dermal matrix (61 vs 34%, $p < 0.0001$) than those with smooth, round implants. Patients who had smooth, round implants were more likely to have postoperative nipple malposition (18 vs 0%, $p < 0.0001$,) and rippling (29 vs 0%, $p < 0.0001$.) Patients with textured, shaped implants had fewer operative revision reconstructions as compared with those with smooth, round implants (36.71 vs 12.8%, $p < 0.0001$) Based on these results, our technique has evolved and has eight key technical modifications.

Conclusion With a few adaptations in surgical technique, the transition to textured, shaped, silicone devices for breast reconstruction can be seamless with superior breast contour and reduced complications/revision rates.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Breast reconstruction · Nipple-sparing mastectomy · Shaped implants · Round implants

Introduction

Smooth, round, silicone implants predominate device-based breast reconstruction in the USA. According to statistics provided by the ASPS website, in 2012 alone, ASPS members performed more than 91,000 breast reconstructions [1]. Of these, approximately 70% were performed with silicone implants; the vast majority of which it can be assumed were smooth and round [1]. Despite their prevalence, complications including bottoming out, superior contour deformity, rippling, and/or lateral malposition have been attributed to

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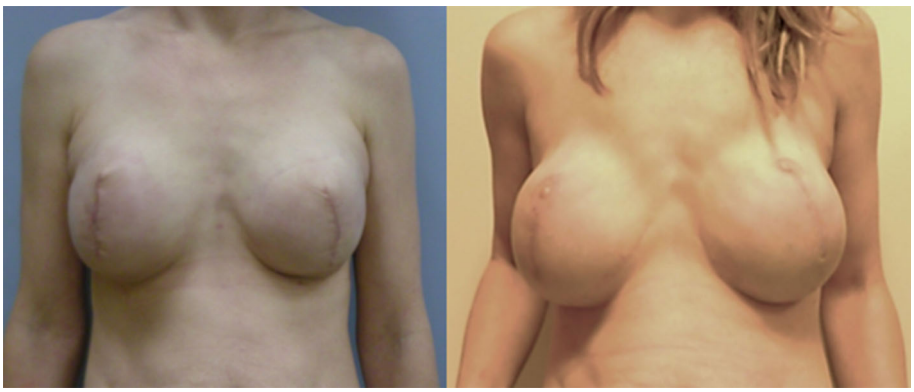

Fig. 1 A 38-year-old female with smooth, round, high-profile, silicone implant reconstruction, 3 months (*right*) and 24 months (*left*) postoperatively

the use of smooth, round, silicone implants in breast reconstruction (Fig. 1) [2–6]. With the recent FDA approval of several textured, shaped devices, plastic surgeons now have another option to consider when choosing a breast implant [7–9].

Textured, highly cohesive, shaped implants have been developed to address many of the issues associated with the use of smooth, round implants in breast reconstruction [7–9]. These so-called fifth generation implants are most notable for a highly cross-linked internal silicone gel that allows them to be form stable and have an increased distribution of gel in the caudal aspect of the implant that gives them a more anatomic contour. Finally, while both smooth and textured shells are available, many surgeons, who are familiar with these implants, choose the textured, silicone shell; this imprinting adds variability to the direction of tissue ingrowth on the implant surface and prevents postoperative implant movement.

Taken together, these properties allow the highly cohesive implants to maintain their anatomic shape in vivo, regardless of the position or orientation of the patient's breast [10]. In contrast to smooth, round, silicone implants, the shaped devices allow for adjustments in not only implant width and projection, but also implant height [3, 7–9]. In effect, the shaped implants permit a more precise titration of the final reconstructed breast dimensions [3, 7–9].

Although highly cohesive, shaped devices have been available in Europe since 1993, the first FDA approved shaped implant was only made available in the USA in March of 2012 [7]. Consequently, there is a relative lack of experience with these implants for breast reconstruction in the USA, and practical guidelines on the technical aspects of using these implants and the expected outcomes are still lacking in the literature [11]. Since 2012, the senior author (M.T.) has been incorporating shaped devices into her breast reconstruction practice. In the appropriately selected patient, these implants provide an excellent option for breast reconstruction following nipple-sparing mastectomy. At this juncture, we felt it appropriate to review our experience and highlight changes in our technique that have led to a successful transition from our prior use of smooth, round, silicone implants. In addition, this study compares our use of shaped implants to our prior use of smooth, round implants in breast reconstruction following nipple-sparing mastectomy, thereby illustrating areas where this switch has led to improved outcomes and reduced complications.

Methods

Study Population

A retrospective chart review was conducted on a prospectively collected, IRB-approved database of women who had undergone NSM with either single-stage or two-stage implant-based reconstruction by a single plastic surgeon at a tertiary-care academic medical center between 2011 and 2012. Both therapeutic and prophylactic NSM patients were included in the database. No patient was excluded from the database because of demographic factors, risk factors, oncologic burden, or postoperative results. Patients were subdivided by those who had smooth, round, silicone implant reconstruction (Group A) in 2011 in comparison to textured, shaped, silicone implant reconstruction (Group B) in 2012. Candidacy for NSM has been described in our earlier works [12]. Candidacy for reconstruction with anatomic implants was chiefly related to patient preference as well as the judgment of the senior author but was also limited by the range of available implant sizes at the time of this study. In Group A, 128 NSMs were performed in 76 patients. In Group B, 109 NSMs were performed in 59 patients.

Surgical Technique

All mastectomies and reconstructions were performed using the same "subdermal" technique outlined by the senior author in previous works [13]. For a single-stage

reconstruction, a permanent implant was placed in a sub-muscular pocket. If the coverage was not sufficient, then a strip of acellular dermal matrix (ADM) was placed inferiorly as a sling for implant coverage. Single-stage reconstruction was reserved at the discretion of the senior author for patients with small volume implants, optimal tissue quality, and minimal clinical or demographic comorbidities.

For two-stage reconstruction, a tissue expander (TE) was placed, in standard fashion, in a sub-muscular pocket and fully covered by the pectoralis major and serratus muscles. Base width, rather than desired cup size, dictated the size of the expander. In cases of poor muscle coverage, ADM was placed at the discretion of the senior author. Most patients underwent between two and three expansions prior to exchange. Permanent implants were available from various manufacturers; size and shape were selected by the esthetic desires of the patient and the clinical judgment of the senior author.

Patients were examined postoperatively at intervals of 2 weeks, 1 month, 2 months, 6 months, and yearly. Outcomes were recorded.

Outcome Variables

Demographic and medical variables were analyzed to identify risks factors associated with poor outcomes following NSM and immediate breast reconstruction with either smooth, round, silicone implants or textured, shaped, silicone implants. Demographic factors included patient age, body mass index (BMI), smoking status, and diabetes. Recorded preoperative variables included sternal notch to nipple distance, breast base width, breast volume resected, prior chest wall or breast radiation therapy, and prior ipsilateral lumpectomy. Intra-operative variables included use of a single-stage reconstruction, use of a peri-areolar mastectomy incision with lateral extension versus an inframammary mastectomy incision, implant size, use of ADM, and unilateral reconstruction. Postoperative variables included nipple–areola complex (NAC) ischemia, NAC malposition, implant rippling, implant show, implant loss, revision reconstruction, and capsular contracture.

Statistical Analysis

For all continuous variables, an unpaired Student test was utilized and both probability values and 95% confidence intervals were reported. For all binary outcomes, a Chi-squared test was utilized and probability values were reported. Statistical significance was defined as a probability value <0.05.

Results

Patient Demographics

The average age of patients was 46.7 years (range 25–71 years) for the round subset (Group A) versus 50.4 years (range 26–77 years) for the shaped subset (Group B) ($p = 0.010$). The average BMI was 21.8 (range 16.7–32.1) for Group A versus 21.6 (range 16.3–34.7) for Group B ($p = 0.66$). Group A included 1.6% of patients who described themselves as current or former smokers compared to 0% in Group B ($p = 0.19$). Prior radiation therapy was recorded in 12% of Group A patients and in 13% of those in Group B ($p = 0.816$). Average sternal notch to nipple distance was 22.4 cm (range 17.5–29.5 cm) in Group A and 22.2 cm (range 18.5–32.0) in Group B ($p = 0.71$). The average breast base width was 14.2 cm (range 11.0–19.0 cm) in Group A and 13.7 cm (range 10.0–19.0 cm) in Group B ($p = 0.015$). The patient demographics are summarized in Table 1.

Intra-operative Findings

Average final implant volume was 497 cc (range 180–800 cc) for Group A and 383 cc (range 170–650 cc) for Group B ($p < 0.0001$). Thirteen percent of Group A patients received a single-stage reconstruction compared to 21% in Group B ($p = 0.099$). Acellular dermal matrix was used in 34% of Group A and 61% of Group B ($p < 0.0001$). The intra-operative details are summarized in Table 2.

Postoperative Results

Postoperative NAC malposition occurred in 18% of Group A and 0% of Group B ($p < 0.0001$). Two percent of Group A experienced postoperative NAC ischemia and 4% of Group B ($p = 0.362$). Postoperative capsular contracture was reported in 23% of Group A and 9% of Group B ($p = 0.0039$). Twenty-nine percent of Group A had postoperative rippling and 0% of Group B ($p < 0.0001$). Postoperative implant show occurred in 2% of Group A and 4% of Group B ($p = 0.362$). Revision reconstruction was performed in 36.7% of Group A and 12.8% of Group B ($p < 0.0001$). Implant loss was recorded in 0.7% of Group A and 3% of Group B ($p = 0.179$). The postoperative results are summarized in Table 3.

Surgical Pearls

After reviewing the outcomes and surgical technique between the transitions from round to shaped implants, the senior author identified eight intra-operative surgical pearls

Table 1 Patient demographics

	Smooth round implants $n = 128$	Textured shaped implants $n = 109$	p value
Mean age, years	46.7	50.4	0.010*
Range	(25–71)	(26–77)	
Mean BMI, kg/m^2	21.8	21.6	0.66
Range	(16.7–32.1)	(16.3–34.7)	
Smoking status			0.19
Smoker	2 (1.56%)	0 (0.0%)	
Non-smoker	126 (98.44%)	109 (100.0%)	
Diabetes mellitus			1.0
Yes	0 (0.0%)	0 (0.0%)	
No	128 (100.0%)	109 (100.0%)	
History of prior lumpectomy			0.1684
Yes	37 (28.91%)	23 (21.10%)	
No	91 (71.09%)	86 (78.90%)	
History of chest radiation			0.816
Yes	15 (12.0%)	14 (13.0%)	
No	113 (88.0%)	95 (87.0%)	
Sternal notch–nipple distance	22.4 cm	22.2 cm	0.71
Range	17.5–29.5 cm	18.5–32.0 cm	
Base width	14.2 cm	13.7 cm	0.015*
Range	11.0–19.0 cm	10.0–19.0 cm	

BMI Body mass index

* Denotes statistical significance

Table 2 Intra-operative findings

	Smooth round implants $n = 128$	Textured shaped implants $n = 109$	p value
Implant volume, average	497 cc	383 cc	<0.0001*
Range	(180–800 cc)	(170–650 cc)	
Single-stage operation			0.099
Yes	16 (13.0%)	23 (21.0%)	
No	112 (87.0%)	86 (79.0%)	
ADM			<0.0001*
Yes	44 (34.0%)	66 (61.0%)	
No	84 (66.0%)	43 (39.0%)	

ADM Acellular dermal matrix

* Denotes statistical significance

to optimize results. Modifications in operative technique with textured shaped implants include: (1) precise pocked dissection for device placement, (2) selection of narrow TE, (3) liberal use of ADM to control the inframammary fold (IMF), (4) filling of TE to eliminate folding of device intra-operatively, (5) postoperative under-expansion of TE to avoid permanent implant malposition, (6) selection of permanent implant based on width, height, and projection rather than volume, (7) use of entire length of mastectomy incision for exchange, and (8) avoiding aggressive capsulorrhaphy/capsulotomy.

Discussion

While smooth, round, silicone implants have traditionally been used for breast reconstruction, issues such as bottoming out, superior contour deformity, rippling, and/or

Table 3 Postoperative results

	Smooth round implants $n = 128$	Textured shaped implants $n = 109$*	p value
Cellulitis			0.1870
Yes	1 (0.78%)	2 (1.83%)	
No	127 (99%)	107 (98%)	
Seroma			0.3344
Yes	2 (1.56%)	0 (0%)	
No	125 (98.5%)	109 (100%)	
NAC malposition			<0.0001*
Yes	23 (18%)	0 (0.0%)	
No	105 (82%)	109 (100%)	
Nipple ischemia			0.362
Yes	3 (2%)	4 (4%)	
No	125 (98%)	105 (96%)	
Capsular contracture			0.0039*
Yes	29 (23%)	10 (9%)	
No	99 (77%)	99 (91%)	
Rippling			<0.0001*
Yes	37 (29%)	0 (0.0%)	
No	91 (71%)	109 (100%)	
Implants show			0.362
Yes	2 (2%)	4 (4%)	
No	126 (98%)	105 (96%)	
Fat Transfer			0.713
Yes	20 (15.6%)	8 (7.33%)	
No	108 (84.4%)	101 (92.67%)	
Revision reconstruction			<0.0001*
Yes	47 (36.7%)	14 (12.8%)	
No	81 (63.3%)	95 (87.2%)	
Implant loss			0.179
Yes	1 (0.7%)	3 (3%)	
No	127 (99.3%)	106 (97%)	

NAC Nipple–areola complex

* Denotes statistical significance

lateral malposition can undermine the esthetic outcome. These complications can increase the need for revision surgeries, which can increase the overall failure rate as well as patient dissatisfaction. [5] The recent approval of anatomic textured silicone implants by the Food and Drug Administration has given surgeons another tool to use in the quest to improve the outcomes of breast reconstruction surgery [7–9]. With a switch from smooth, round, silicone implants to textured, shaped implants has come a realization that some modifications in technique are necessary to maximize cosmetic outcomes.

In general, these modifications represent a change in the goals of the traditional two-stage reconstructive processes. Namely, when using smooth, round, silicone implants, the goals of reconstruction were to create as large of a space and as much skin elasticity in the breast pocket as possible to allow the smooth implant to assume a more ptotic natural appearance [14–16]. Conversely, the ultimate goal, when using shaped implants for reconstruction, is to create a breast pocket that accurately fits the form of the already anatomically shaped implant, and thereafter, limits postoperative changes in implant position. This fundamental change in the reconstructive process is warranted, in part, because of the highly cohesive nature of the anatomic implants, which allows more consistent control of the subsequent postoperative breast shape [7–9].

Eight technical modifications were found to be useful in the transition from smooth, round to textured, silicone implants (Table 4). Of note, all patients in this series underwent nipple-sparring mastectomy followed by immediate breast reconstruction (single-stage or two-stage reconstruction). Modifications 1 and 2 reflect the importance of creating a precise pocket. Detailed pocket dissection particularly in the cranial and caudal direction will limit subsequent expansion in unnecessary directions, while placement of a narrow tissue expander limits subsequent lateralization of the anatomic implant, while facilitating expansion in the lower pole where it is needed most. This point is less critical when using a round implant, because subsequent rotation of the implant within an oversized pocket does not markedly change the shape of the breast mound.

Modification 3 involves the liberal use of ADM to control the IMF position. As indicated by our prior studies, control of the IMF is a key factor in preventing nipple malposition after NSM [2]. Particularly with heavier, form-stable implants, we found that liberal use of ADM, when muscle coverage was not adequate, allowed for more reliable control of the IMF position. Control of the IMF ensures that the final nipple position will be centered over the form-stable implant; in addition, superior displacement of the IMF may lead to superior displacement of the implant and increased implant show. Of note, with a shaped device, once the skin has been re-draped over the implant, the NAC, now central on the new breast mound, may be superior to the most projecting portion of the implant, much like an augmentation patient [17]. In addition, given the increased weight of an anatomic implant compared to a round implant of the same volume, we felt that this modification was also a key factor in preventing bottoming out. While ADMs were used in all patients who had direct to implant reconstruction, as greater experience was gained with the use of anatomic implants, the need for the tissue expander to shape the pocket became less apparent, and as a result, a larger number of direct to implant reconstructions were performed.

Modifications 4 and 5 represent changes made during intra-operative and postoperative expansion. To take full advantage of the preserved skin envelope following NSM, the TE, whenever possible, should be judiciously filled at the time of initial placement. In addition to preventing contracture of the preserved skin envelope, early expansion also aids in centering the nipple. In our approach, the tissue expanders were initially filled to about 50% of their final desired volume. Since the breast pocket is largely established with the initial fill, thereafter over-expansion is to be avoided as this can lead to a pocket that is too large for the anatomic implant, increasing the chances of malrotation, malposition, and asymmetry. Indeed, when comparing the techniques utilized for the two groups, we found that routine over-expansion encouraged implant malposition in the setting of anatomic implant use.

Modifications 6, 7, and 8 were principles employed during placement of the final implant, whether this followed an expansion period, or occurred immediately following the NSM. When selecting a shaped implant, the pocket dimensions, rather than volume, guided the ultimate implant size. This is an important consideration in achieving the ultimate goal of having an implant that precisely fills your pocket. Use of the entire length of the mastectomy incision for exchange reflects the difficulty with placing the anatomic implant within the pocket. They must be placed accurately, as they are hard to move when in the pocket and after placement they are likely to maintain whatever position they are initially placed in. In this instance, accurate placement is more significant than the ultimate length of the scar, which typically heals with minimal hypertrophy, particularly when placed in an IMF position. Finally, we found that aggressive capsulorrhaphy or capsulotomy at the time of the exchange can increase the risk of nipple malposition, rippling, and implant rotation. In most cases, capsulotomy is limited to medial to encourage cleavage and capsulorrhaphy is limited to lateral to prevent implant lateralization.

When we compared our postoperative results of breast reconstruction using smooth, silicone implants, to a demographically similar group of patients who underwent immediate breast reconstruction with textured, shaped implants, we saw an overall decrease in postoperative complications and an improvement in clinical outcomes

Table 4 Technical modifications

(1) Precise pocked dissection for device placement	(2) Selection of narrow TE
(3) Liberal use of ADM to control IMF	(4) Filling of TE to eliminate folding of device intra-operatively
(5) Postoperative under-expansion of TE to avoid permanent implant malposition	(6) Selection of permanent implant based on width, height, and projection rather than volume
(7) Use of entire length of mastectomy incision for exchange	(8) Avoiding aggressive capsulorrhaphy/capsulotomy

TE Tissue expander, *ADM* acellular dermal matrix, *IMF* inframammary fold

(Figs. 2, 3). Of note, there were no differences in major risk factors between the two groups except that patients receiving textured, shaped implants (Group B) were slightly older and had slightly smaller base widths (Table 1). When we examined our results, we found that there was a statistically significant decrease in NAC malposition, capsular contracture, and postoperative rippling in Group B. Consequently, we saw a statistically significant decrease in the need for revision reconstruction in Group B, which we believe is a direct result of the improved cosmetic outcomes. These outcomes mirror results from Sientra's (Santa Barbara, Ca) 7- to 9-year follow-up trials which involved a broader patient cohort that included primary and secondary breast reconstructions as well as augmentation and revision augmentation patients [7, 18, 19]. Additionally, these findings mirror the results found in other studies, which compared the effect of smooth, round silicone implants to textured, anatomic implants on outcomes following breast augmentation [5, 20–22]. In these studies, the authors also demonstrated that an increase in poor cosmetic outcomes leads to an increase in revision surgeries.

The potential bias of a retrospective review of a single surgeon's experience and the relatively small sample sizes of the two groups are obvious limitations to this study. It should be noted that Group B, the shaped implant group, had a statistically significant higher proportion of patients in whom ADM was used as part of their reconstruction, which may be a confounding aspect of the data. Conversely, recently published data indicate that the incorporation of acellular dermal matrix itself may reduce the frequency of malposition, rippling, and need for revision [23]. In a similar fashion, we have internally noted that the liberal use of acellular dermal matrix controls the inframammary fold and defines the boundaries of the device pocket; as such, our surgical approach has evolved over time and we now predominantly use acellular dermal matrix with most device-based breast reconstructions independent of implant type. Furthermore, we recognize that the average body mass index (BMI) of our patients was significantly lower than seen in prior reports, which could have also contributed to our lower overall complication rates [24–26]. It should be noted that only one malrotation was observed during this study. As not all patients underwent a second procedure or additional imaging to screen for malrotation, this value was not included in the comparative analysis. Finally, we also note that the difference in follow-up time between the two groups (2 years for Group A vs 1 year for Group B) may have been a confounding factor in the lower rate of observed capsular contracture seen with anatomic implants. Despite these limitations, however, we believe that the esthetic results

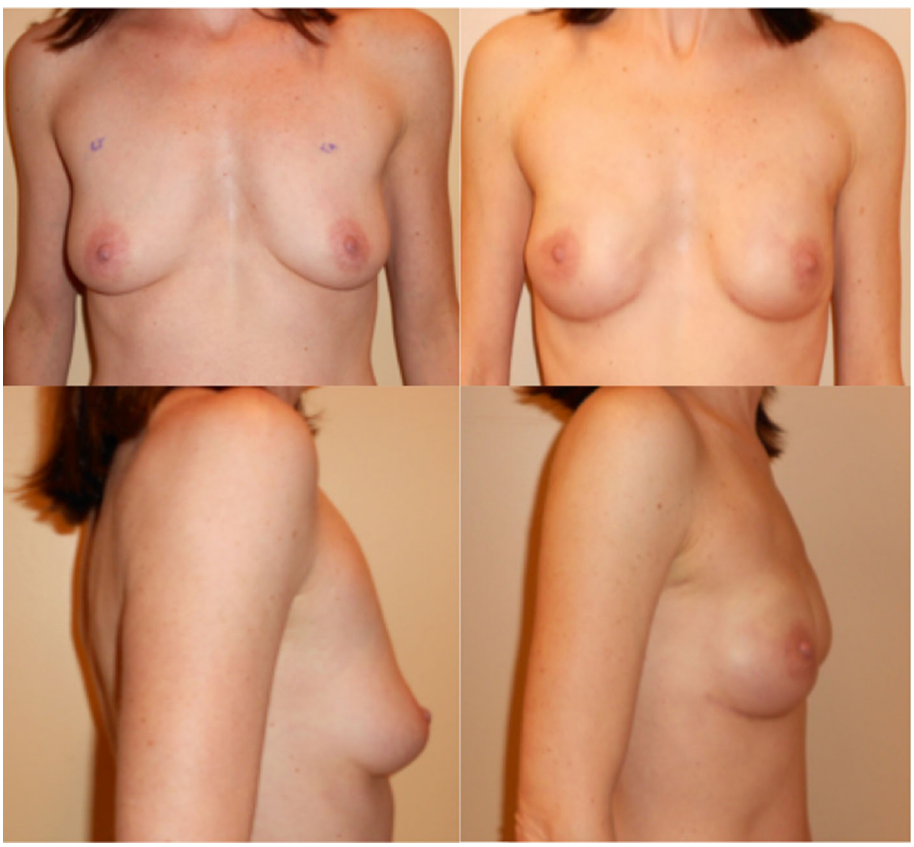

Fig. 2 A 42-year-old female with two-stage anatomic implant reconstruction with Sientra 20646-210MP implants: preoperative (*right*) and 18 months postoperatively (*left*); the reconstruction was staged with Allergan 133 SX-11 tissue expanders

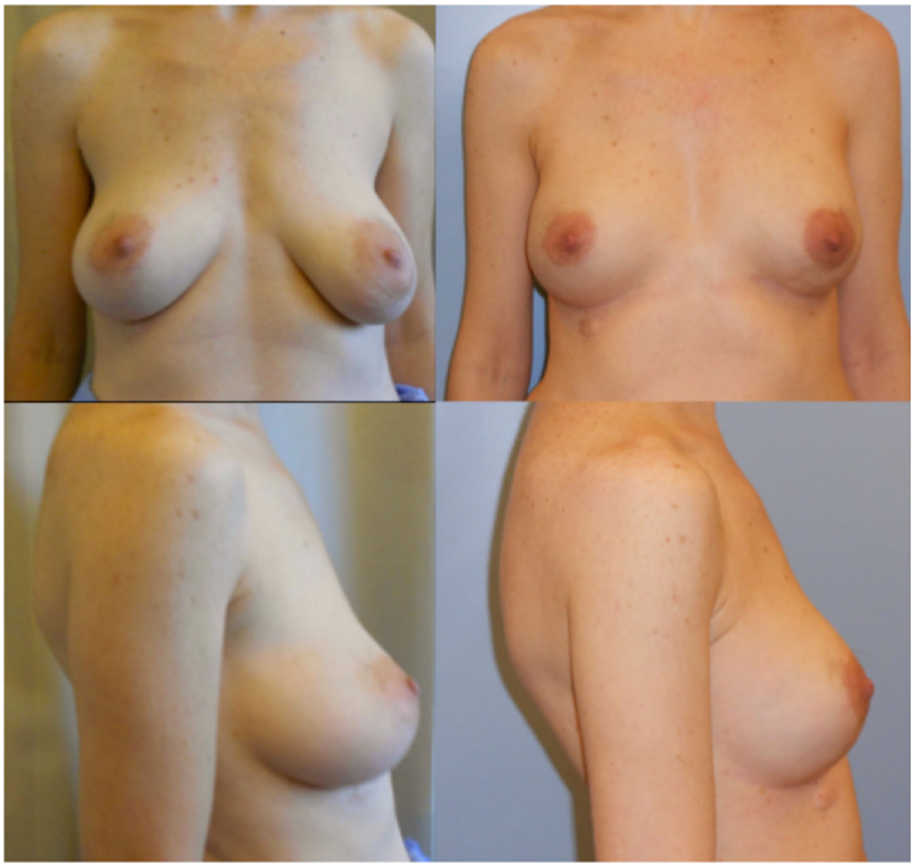

Fig. 3 A 48-year-old female with single-stage anatomic implant reconstruction with Allomax and Sientra 20646-320 RB implants: preoperative (*right*) and 20 months postoperatively (*left*)

and presented surgical modifications are valuable for any surgeon considering the use of anatomic, textured silicone implants for breast reconstruction. Similarly, we recognize that these principles are also readily applied to the patient undergoing breast augmentation who has thin overlying soft tissue coverage.

Conclusion

The incorporation of textured, shaped silicone implants for breast reconstruction into a surgeon's practice can result in esthetically pleasing breast contour, with a lower rate of revision surgery and a diminished complication profile. With a few minor modifications, the transition to the use of textured, shaped silicone implants can successfully be made. The eight surgical modifications presented in this article have easily reproducible and have esthetically acceptable outcomes using textured, shaped implants for breast reconstruction.

Compliance with Ethical Standards

Ethical Standards We declare that this article was composed with the highest ethical standards and that the Institutional Review Board of Weill Medical College (New York, New York) approved all study procedures in accordance with state and federal guidelines.

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