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Breast

Prepectoral 2-stage Breast Reconstruction with Carbon Dioxide Tissue Expansion

Franca S. Kraenzlin, MD
Halley Darrach, BS
Karan Chopra, MD
Gedge D. Rosson, MD
Kristen P. Broderick, MD
Justin M. Sacks, MD, MBA

Background: Roughly 80% of patients undergoing mastectomy in the United States opt for reconstruction with implants. The introduction of acellular dermal matrices has allowed for placement of breast prostheses in the prepectoral plane, while a new carbon dioxide tissue expander (TE) (AeroForm) allows for needle-free, patient-controlled expansion. These 2 novel technologies have ushered in a new patient-centered era of breast reconstruction, with the possibility of reducing patient morbidity for the first time in decades. We hypothesize that AeroForm expanders placed in the prepectoral plane reduce time to second-stage reconstruction, reduce the number of clinic visits, and have lower complications than traditional saline TEs.

Methods: This is a retrospective review of all patients undergoing breast mastectomy and TE placement in the prepectoral plane over a 21-month period (169 patients, 267 breasts), comparing AeroForm expanders to TEs.

Results: The AeroForm group (n = 57) had a shorter period to second-stage reconstruction than the TE group (n = 210) (135.4 versus 181.7 days; $P = 0.01$) and required fewer clinic visits (5.1 versus 6.9; $P < 0.01$). Partial thickness (25.6% versus 12.3%, $P = 0.03$) and full thickness (8.7% versus 0.0%, $P = 0.02$) necrosis were more common in the saline cohort. The rates of infection, hematoma, and seroma requiring drainage were not statistically significant between the 2 groups.

Conclusions: Two-staged breast reconstruction with the use of AeroForm expanders in the prepectoral space marks progress in improving care for breast cancer patients by demonstrating a reduction in some adverse events, the number of clinic visits, and the time to second-stage reconstruction. *(Plast Reconstr Surg Glob Open 2020;8:e2850; doi: 10.1097/GOX.0000000000002850; Published online 27 May 2020.)*

INTRODUCTION

Roughly 80% of patients undergoing mastectomy in the United States opt for reconstruction using breast implants.[1] Although direct-to-implant reconstruction is gaining popularity, a 2-stage tissue expander (TE)-to-implant procedure remains, by far, the most common technique for reconstruction.[2] Since the early 1980s, placement of the TE, and thus the final implant, in the subpectoral plane was the preferred surgical technique.[3–5] Subpectoral implant placement was thought to offer increased tissue coverage to prevent extrusion, minimize implant-related complications such as capsular contracture, and yield a more natural upper pole slope compared to subcutaneous reconstructions.[6,7] However, the introduction of acellular dermal matrices (ADM) has recently allowed surgeons to place breast prostheses in the prepectoral plane, avoiding painful disruption of the pectoralis major muscle, which can produce animation deformities and result in a lateralized appearance of the reconstructed breasts.[8–11] A second recent innovation has addressed the technology behind tissue expansion. Expanders traditionally expand the skin via serial percutaneous injections of normal saline into the TE port using sterile technique in a clinic setting. This modality of tissue expansion has notable shortcomings such as patient discomfort associated with repeated percutaneous needle-sticks, disruption of daily life, the possibility of introducing bacteria into the implant pocket during fills, consumption of scarce physician and clinic resources, and the risk of inadvertent expander rupture.[12]

However, a novel technology using carbon dioxide (CO_2)–based TEs (AeroForm Tissue Expander; AirXpanders,

From the Department of Plastic and Reconstructive Surgery, Johns Hopkins University, Baltimore, Md.

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Inc., San Jose, Calif.) allows gradual, needle-free expansion via a hand-held remote controller. The controller wirelessly allows a patient-initiated release of 10 cc of CO_2 gas per dose. Multiple redundant safety mechanisms allow for a maximum of 3 patient-initiated expansions per day. The expander is programmed to release gas from an internal reservoir up to the labeled volume of the expander.[12] Moreover, additional volume expansions can be administered by the surgeon using a master key. Our institution has combined the use of these 2 innovative approaches to breast reconstruction, and in this report, we review our experience with prepectoral breast reconstruction using the AeroForm TE in comparison to traditional saline TEs.

METHODS

Study Design/Sample

This was an institutional review board—approved retrospective study of consecutive patients over a 21-month period (October 2016 to June 2018) at Johns Hopkins University (Baltimore, Md.). Subjects consisted of consecutive adult (>18 years) woman patients who underwent mastectomy and either immediate or delayed breast reconstruction with AeroForm or saline TEs. Saline expanders were anatomically shaped, were textured, and had integrated ports. All patients had at least 12 months of follow-up or were followed until second stage reconstruction. Five board-certified general surgeons performed the mastectomies, while 6 board-certified plastic surgeons performed the TE placements. AeroForm was approved by the Food and Drug Administration in December 2016[13] and the first breast reconstruction using AeroForm was performed in June 2017. One attending performed TE placement with AeroForm 78.8% of the time once the device was available, making the determination based on breast base width and patient preference. The other surgeons made their device decisions based on patient preference, device availability, comfort with the device, and breast base width.

Study Variables

The use of the AeroForm TE was the main predictor variable of interest. Potential predictor variables that were considered as possibly influencing complication rates following reconstruction were recorded. These included age, obesity (ie, body mass index ≥30 kg/m^2), diabetes, adjuvant chemotherapy and radiation, neoadjuvant chemotherapy, and current smoking status (defined as active cigarette use within the 4 weeks preceding surgery).

Intraoperative fill volumes were included in the analysis; however, there are notable caveats. AeroForm expanders have a known displacement volume (400 cc expander – 160 cc displacement volume; 600 cc expander – 190 cc; 800 cc expander – 240 cc) (Personal communication with AeroForm representative regarding AeroForm starting volumes; June 18, 2019). Traditional expanders have varying displacement volumes, with one study estimating that displacement volumes ranged from a minimum of approximately 65 ml in 250 ml fill volume expanders to a maximum of 112.8 ml in the largest 800 ml fill volume expander.[14] AeroForm OR fill volumes were measured by known displacement volume plus any CO_2 released from the canister. Traditional TE volumes were measured by removing all air from the TE and then measuring the saline or air filled. The displacement volume was not incorporated into the operating room (OR) fill volume for traditional TEs. The amount of and fluid type used in the intraoperative fill was based on attending assessment of mastectomy flap perfusion and breast size. Additionally, AeroForm has a heavier weight than traditional expanders; the small device weighs 150 g, the medium is 165 g, and the large weighs 190 g.[15] However, with the addition of saline, a traditional expander quickly weighs more than the AeroForm device.

Outcomes

Primary outcomes recorded consisted of postoperative complications including complete and partial mastectomy flap necrosis, cellulitis, infections, readmission rates, hematoma, simple seroma, seroma requiring drainage, extrusion, loss of communication with the device (AeroForm), and rupture of the device (saline).

Details relating to expansion such as the number of clinic visits and total days from the date of TE placement to second-stage reconstruction (successful conversion to an implant or autologous flap) were collected.

Infection was defined as the presence of breast cellulitis, physician documentation of the presence of infection, return to the operating room (RTOR) for debridement of an infection, culture-positive seroma, or positive culture during any RTOR. Necrosis was defined based on clinical examination only, with partial necrosis defined as epidermolysis or necrosis without exposure of underlying muscle, ADM, or implant, while full-thickness necrosis was defined as necrosis with exposure of underlying structures.

Statistical Analysis

Data statistics was performed using Excel (Microsoft Corporation, Redmond, Wash.) and STATA (StataCorp, College Station, Tex.). Descriptive statistics including χ^2/Fisher exact tests, two-tailed *t* tests, and multivariate regression were used as appropriate for the data. A value of $P < 0.05$ was considered statistically significant.

RESULTS

This study consisted of 169 patients with 267 breast reconstructions. Of the 267 breast reconstructions, 57 (21.3%) used AeroForm TEs and 210 (78.7%) used traditional saline tissue expansion. The 2 groups were well matched (Table 1) with respect to demographics, obesity, diabetes, age, American Society of Anesthesiologists, prior radiation status, and smoking history. Patient follow-up period was until completion of second-stage reconstruction, to reconstructive failure, or for a minimum of 1 year. AeroForm patients had an average follow-up period of 165.8 days (range: 40–644 days). TE patients had an average follow-up period of 246.7 days (range: 18–871 days).

Table 1. Demographics by Patient

	AeroForm	Saline	*P*
Patients	37	132	—
Breasts	57	210	—
Age (mean), y	48.5	48.9	0.85
Obese, %	21.1	20.0	0.86
Mastectomy weight, g	559.1	532.2	0.55
Average ASA score	1.9	2.1	0.06
Diabetes, %	0.0	6.2	0.05
Current smoker,* %	5.4	6.1	0.88
Nipple-sparing mastectomy, %	45.9	59.1	0.15
Adjuvant radiation, %	3.6	12.3	0.06
Post-mastectomy chemotherapy, %	29.1	17.9	0.07
Acellular dermal matrix, %	100.0	100.0	—

*Current smoker defined as active nicotine use in the last 4 weeks before surgery.
ASA, American Society of Anesthesiologists.

All patients in both groups had immediate 2-stage prepectoral prosthetic breast reconstruction. The mastectomy was nipple sparing in 45.9% of patients in the AeroForm group versus 59.1% in the saline TE group ($P = 0.15$).

At the time of data analysis, reconstruction was successfully completed in 91.9% (n = 34) and 82.6% (n = 109) of participants in the AeroForm and saline groups, respectively ($P = 0.27$). There were 3 reconstructive failures in the AeroFrom group (5.5%) and 13 in the TE cohort (6.1%) ($P = 0.85$). There were no instances of loss of communication with the device, unexpected expansions, rotation of the device, or rupture in the AeroForm group. The AeroForm group had a statistically significant shorter period to second-stage reconstruction than the traditional saline expander group (135.4 versus 181.7 days; $P = 0.01$) (Table 2). The AeroForm cohort also required fewer mean clinic number of visits (5.1 versus 6.9; $P < 0.01$).

Table 2. Postoperative Statistics by Patient

	AeroForm	Saline	*P*
Patients	37	132	—
Breasts	57	210	—
Time to drain removal, d	24.3	21.8	0.08
Readmission, %	10.8	18.2	0.24
No. Clinic visits	5.1	6.9	<0.01
Time to reconstruction, d	135.4	181.7	0.01
Second-stage reconstruction performed (by patient), %	91.9	82.6	0.27

Table 3. Postoperative Complications by Breast

	AeroForm, n (%)	Saline, n (%)	*P*
Patients	37	132	—
Breasts	57	210	—
Adverse events* n (%)	16 (43.2%)	79 (59.8%)	0.07
Hematoma	2 (3.5%)	2 (1.0%)	0.16
Necrosis	7 (12.3%)	71 (33.8%)	<0.01
Partial thickness necrosis	7 (12.3%)	53 (25.2%)	0.03
Full thickness necrosis	0 (0.0%)	18 (8.6%)	0.02
Drainage for seroma	5 (8.8%)	40 (19.0%)	0.07
Cellulitis	4 (7.0%)	17 (8.1%)	0.79
Infection	4 (7.0%)	27 (12.9%)	0.22
RTOR			
RTOR for infection	4 (7.0%)	15 (7.1%)	0.97
RTOR for necrosis debridement	1 (1.8%)	17 (8.1%)	0.09

*Adverse events were defined as the number of patients experiencing at least 1 postoperative adverse event (hematoma, seroma, necrosis, infection).

Table 4. Multivariate Logistic Regression Comparing Traditional Tissue Expanders to AeroForm

	Odds Ratio	*P*	CI Low	CI High
β_0	0.08	0.17	0.00	2.96
Necrosis	0.28	**0.04**	0.08	0.94
ASA score	0.26	**0.02**	0.08	0.79
Vac dressing	9.58	**0.00**	3.31	27.72
Age	1.03	0.22	0.98	1.07
Average mastectomy flap weight	1.00	0.79	1.00	1.00
BMI	1.08	0.23	0.95	1.23
Diabetes	1.00	—	—	—
Alloderm	1.00	—	—	—
Adjuvant radiation	0.48	0.46	0.07	3.41
Current smoker	0.78	0.86	0.05	11.99
NSM	0.75	0.58	0.26	2.13
Hematoma	2.91	0.40	0.24	35.54
Seroma requiring drainage	0.52	0.29	0.16	1.75
Infection	1.12	0.84	0.36	3.54
Dehiscence	1.42	0.78	0.13	16.00

Area under the receiver operating characteristic curve = 0.733.
Bold text indicates the significant *P* values.
ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; NSM, nipple-sparing mastectomy.

The overall incidence of at least 1 adverse event was higher for patients in the saline group (59.8 % versus 43.2%, $P = 0.07$) (Table 3). Partial thickness necrosis was more common in the saline cohort (25.6% versus 12.3%, $P = 0.03$). The AeroForm cohort did not see any patients suffer from full thickness necrosis (0.0% versus 8.7%, $P = 0.02$) unlike traditional TEs. Mastectomy skin flap necrosis requiring a return to operating room was not statistically different between the groups (8.1% versus 1.8%, $P = 0.09$). A multivariate analysis indicated that the AeroForm group had a lower odds of suffering from necrosis postoperatively (odds ratio, 0.28; $P = 0.04$) (Table 4).

Table 5. Necrosis and Intraoperative Fill Volume Stratified by Intraoperative Fill Fluid

	Total Number	Average Intraoperative Fill, cc or ml	*P*	Necrosis n, %	*P*
AeroForm	57	199.8	<0.01	7, 12.3%	0.02
Saline fill	32	137.3		13, 40.6%	
Air fill	125	173.6		37, 29.6%	
No OR fill	57	0		21, 36.8%	

In the traditional TE cohort, patients received either no intraoperative fill, intraoperative fill with air, or intraoperative fill with saline (Table 5). The AeroForm device had lower necrosis rates (12.3%) than TEs receiving no intraoperative fill (36.8%), TEs receiving saline (40.6%), and TEs receiving air (29.6%) for intraoperative fills ($P = 0.02$).

In this sample, breast infection occurred more commonly in the saline cohort (12.9% versus 7.0%, $P = 0.22$), but the results did not reach statistical significance. A statistical power analysis was performed for sample size estimation comparing infection rate to TE type. The effect size in this study was 0.17 and considered to be small using Cohen's (1988) criteria. With an $\alpha = 0.05$ and power = 0.80, the projected sample size needed with this effect size is approximately N = 1120. Other complications such as hematoma formation, seroma drainage, and cellulitis

development were all higher in the saline cohort but did not meet statistical significance in this sample.

DISCUSSION

This study reports on the combined use of a novel breast expander technology (AeroForm) with prepectoral placement with total ADM coverage. We evaluated the time to expansion, number of clinic visits, and rate of complications in patients receiving AeroForm expanders and compared them with patients receiving saline expanders. Since the CO_2-filled AeroForm expander required no percutaneous needle-sticks, an overall lower rate of infection was expected in these patients. Because the device allows at-home expansion without required visitation to the surgeon's office, we hypothesized that quicker time to second-stage reconstruction and fewer clinic visits were expected in the AeroForm group.

In addition to fewer overall adverse events in the AeroForm cohort, there was notably fewer reconstructions suffering from tissue necrosis. Necrosis is multifactorial and results from a combination of patient and operative factors. However, our data suggest that perioperative factors may also play an important role. We believe that there are 3 key reasons the AeroForm patients had lower rates of necrosis: gradual fills, distribution of expander weight, and low expander weight. The ability to gradually expand 10 cc's at a time, 3 times a day, avoids the need for bolus fills during the immediate intraoperative period and postoperative clinic visits. We hypothesize that the more gradual fills avoid sudden ischemic insults to the labile mastectomy skin flaps associated with bolus fills that cause significant sudden volume changes. In fact, Table 5 supports this theory most clearly, with AeroForm having lower rates of necrosis than traditional TEs that received no intraoperative fill or intraoperative fills of air or saline. Over the study period, many of the surgeons switched to filling traditional TEs with air to avoid the weight associated with saline. However, this does not obviate the need for subsequent bolus fills in the postoperative setting. These results point toward a likely protective effect of gradual fills on a labile mastectomy flap.

Moreover, a previous study has determined that the incidence of mastectomy skin necrosis correlates with increasing intraoperative fill volumes and mastectomy weight.[16] While the weight of normal saline in a traditional TE increases dramatically throughout the expansion process, the weight of the air-filled expander remains constant despite increasing volume. The AeroForm device is produced in 3 sizes (small, medium, and large), the largest weighing a mere 190 g. In this study, we did observe higher rates of mastectomy flap necrosis in individuals receiving saline fills compared to AeroForm and air fills.

Finally, the AeroForm CO_2 cartridge, accounting for the majority of the expander weight, is centered in the expander and therefore also centered under the area where the majority of the excess skin is present. We believe this weight distribution can also be protective of the mastectomy flap when compared with traditional expanders whose weight distribution will typically fall at the inframammary fold due to gravity.

Mastectomy skin flap necrosis or infection can be a devastating setback for both patients and surgeons in the progress of breast reconstruction. Our sample demonstrated that the use of AeroForm was not associated with a statistically significant difference in infection rates (7.0% versus 12.9%, $P = 0.22$). While we expected infection rates to be lower in the AeroForm group, a power analysis indicated that a larger cohort of patients are needed to make a determination. Both partial and full thickness necrosis were statistically less likely in the AeroForm group; however, at the current sample numbers, this difference did not correlate to RTOR for necrosis debridement. These complications often necessitate the removal of the TE and delay second-stage reconstruction. More importantly, these complications frequently delay adjuvant therapies, increase cost, increase patient discomfort, require additional operative procedures, and negatively influence the ultimate esthetics of the final reconstruction. Larger studies are needed to determine if this CO_2 expansion system truly has the ability to reduce the incidence of these 2 common complications.

The ability to expand gradually at home may explain the quicker time to implant exchange and final reconstruction in the AeroForm group (135.4 days versus 181.7 days, $P = 0.01$), despite also requiring fewer clinic visits by the AeroForm patients (5.1 visits versus 6.9 visits, $P < 0.01$). A patient is able to expand up to 30 cc per day (10 cc at a time, 3 times per day), allowing for up to 210 cc of expansion per week, a volume larger than the typical weekly bolus saline fills. Notably, at the time of this study, our group had not created a separate postoperative pathway for AeroForm groups, and patients were instructed to expand at their own convenience and comfort. An even greater difference may be observed if patients are placed on a formal expansion regimen. This combination of AeroForm TEs in the prepectoral space may allow surgeons to consistently achieve implant exchange before any need for post-mastectomy radiation therapy, thereby avoiding the need to operate on a previously irradiated field. However, previous studies looking at the optimal sequence of implant exchange and post-mastectomy radiation in subpectoral patients found that radiation to a permanent implant can minimize reconstructive failure at the tradeoff to aesthetic results and higher rates of capsular contracture.[17] Optimal timing and sequence needs to be established for prepectoral patients along with further studies analyzing the effects of radiation as a result of the AeroForm expander.

Prepectoral breast reconstruction with AeroForm TEs marks significant progress in the care of women undergoing breast reconstruction following mastectomy. Our data suggest that AeroForm allows for quicker expansion with lower risk of flap compromise and a reduction in clinic visits. The benefits not studied, but presumed from a needless expansion system, include less discomfort during expansion and less burden on the physicians and patients due to fewer required clinic visitations during the fill process (Fig. 1).

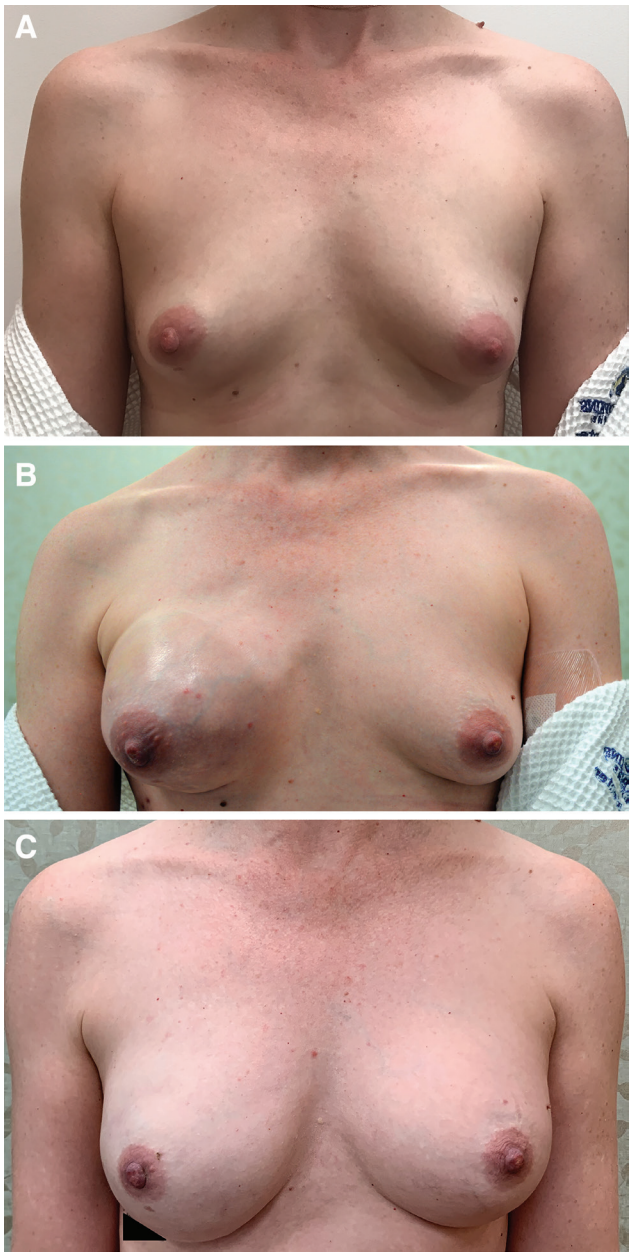

Fig. 1. Patient undergoing breast reconstruction using AeroForm expanders. A, Preoperative photograph. B, Full breast expansion status post right-sided nipple-sparing mastectomy with right-sided AeroForm placement. C, Second-stage reconstruction completed with right-sided silicone implant and fat grafting and left-sided balancing augmentation with silicone implant.

On July 16, 2019, AirXpanders indicated that it would cease operations and file for bankruptcy. Currently, the AeroForm product is not available to patients. We continue to believe in the benefits of this product and anticipate that its patents will be sold.

One potential drawback of the AeroForm device include the inability to remove air from the expander, allowing for the possibility of overfilling the device. However, each expansion is only 10 cc, and it is unlikely to lead to the theoretical complication of ischemic necrosis of the mastectomy flaps. Moreover, radiation protocols do need adjustment to account for the presence of air inside the expander. Studies have demonstrated that radiation therapy does not damage or affect the functionality of the AeroForm TE.[18] Several studies have documented the dosimetric effect of the metallic port found in traditional saline expanders[19–21]; however, the AeroForm expander is relatively new, and published dosimetry studies are limited.[22] Moni et al[23] found that the presence of CO_2 gas and the metallic reservoir did not lead to clinically relevant alterations in radiation dose distribution. Multiple centers in Australia and the United States have successfully established modified radiation treatment planning protocols to adjust for irradiation of the AeroForm device with acceptable dose distribution, but concern remains about the effect on long-term outcomes.

Another potential concern is the inability to deflate the expander for radiation therapy. In the case of AeroForm expanders, one proposed strategy is to delay expansion of the contralateral, noncancer side until a decision is made regarding the need for irradiation. This allows for the standard tangent beam of irradiation for cross table radiation therapy and avoids the potential for incidental irradiation of a healthy breast. At our institution, the radiation oncologists expect second-stage reconstruction or removal of the AeroForm expander before initiation of radiation therapy. Additionally, as our community begins to understand more about breast implant–associated anaplastic large cell lymphoma, it is important to note that the AeroForm expander is a textured expander. In this study, all TEs (saline and AeroForm) were textured.

Finally, there were a number of limitations in our study, specifically in reference to the retrospective nature and sample size. Although adverse events, such as hematoma, drainage of seroma, infection, and RTOR for necrosis debridement all had clinically meaningful lower incidences in the AeroForm group, the sample size did not support significance in this study. Further, larger studies should be completed to understand if true differences between adverse events exist.

CONCLUSIONS

Two-staged breast reconstruction with the use of CO_2-based tissue expansion in the prepectoral space marks progress in improving care for breast cancer patients by demonstrating a reduction in some adverse events, reducing the number of clinic visits required of patients, and shortening the time to second-stage reconstruction. Further studies are required to confirm the potential benefits suggested in the present study. This patient-centric modality of breast reconstruction may prove increasingly attractive in this era of healthcare marked by an increased emphasis on patient-reported outcomes, patient satisfaction, and reducing overall costs to the healthcare system.

Franca S. Kraenzlin, MD
Department of Plastic and Reconstructive Surgery
Johns Hopkins University
Baltimore, MD
E-mail: Fkraenz1@jhmi.edu

PATIENT CONSENT STATEMENT

The patient provided written consent for the use of her images.

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