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Breast

Two-stage Prosthetic Prepectoral Breast Reconstruction: Comparing Tissue Expansion with Carbon Dioxide and Saline

Karan Chopra, MD
Devinder Singh, MD
Nick Hricz
Kylie Brassard
Virginia Orlov, PA-C
Luther H. Holton III, MD

Background: The AeroForm tissue expander is a carbon dioxide-filled breast tissue expander that allows gradual, needle-free expansion using a hand-held remote controller. This study evaluates 2-stage, prepectoral tissue expander-to-implant breast reconstruction with the carbon-dioxide tissue expanders and compares the outcomes to our recent experience with saline tissue expanders.

Methods: This was a retrospective study of consecutive patients from a single institution. The subjects consisted of women who underwent mastectomy and either immediate or delayed breast reconstruction with AeroForm or saline tissue expanders. Outcomes encompassed postoperative complications including mastectomy flap necrosis, infection requiring readmission and/or intravenous antibiotics, capsular contracture, hematoma, seroma, skin dehiscence, extrusion, premature explant, and loss of communication with the device (AeroForm) or rupture of the device (saline).

Results: This study evaluated 115 patients with 185 breast reconstructions. Of the 185 breast reconstructions, 74 (40%) utilized AeroForm tissue expanders and 111 (60%) utilized traditional saline tissue expanders. Treatment was successful in 100% and 94% in the AeroForm and saline groups, respectively ($P = 0.025$). The incidence of adverse events was greater in the saline group (45.9% versus 32.4%). Surgical-site infection occurred more commonly in the saline group (5.4% versus 0%). Full-thickness skin necrosis occurred at a significantly higher rate in the saline cohort as compared with AeroForm (5.4% versus 0%).

Conclusions: The use of AeroForm tissue expanders offers notable advantages for breast reconstruction. This device when employed in the prepectoral space may be associated with reduced infection rates and decreased utilization of healthcare and patient resources. *(Plast Reconstr Surg Glob Open 2019;7:e2051; doi: 10.1097/GOX.0000000000002051; Published online 25 March 2019.)*

INTRODUCTION

Breast reconstruction rates continue to rise in the United States of America with implant-based reconstruction rising at a higher rate than autologous modalities.[1] Although direct-to-implant reconstruction is gaining popularity, a 2-stage tissue expander-to-implant procedure remains, by far, the most common technique.[2] As the 2-stage technique has evolved since its inception in the early 1980s,[3,4] it became preferable to place the expander and therefore, the final implant in the subpectoral plane rather than in the prepectoral plane.[5] The subpectoral technique was thought to offer increased tissue coverage of the expander/implant, camouflage for capsular contracture, and a more natural upper pole slope compared with subcutaneous reconstructions.[6,7] With the introduction of acellular dermal matrices in the past decade, the pendulum is swinging back to placement of breast prostheses in the prepectoral plane. Acellular dermal matrix coverage and implant placement in the prepectoral plane completely avoids disruption of the pectoralis major muscle, which is often painful, results in animation deformities, and results in a lateralized appearance of the reconstructed breasts.[8–11]

From the Division of Plastic Surgery, Anne Arundel Medical Center, Annapolis, Md.

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Despite multiple refinements, the overall technology behind saline tissue expanders remains quite similar to the concept introduced by Dr. Radovan almost 40 years ago.[12] Traditional saline expanders typically involve the use of serial bolus injections in the office at a weekly or biweekly interval during the postoperative period. Saline tissue expansion has certain disadvantages such as patient discomfort and anxiety associated with repeated percutaneous needlesticks, disruption of work or daily activity, the possibility for introducing bacterial inoculum percutaneously during fills, consumption of office/physician resources as well as the risk of rupture.[13]

The authors adopted the use of the AeroForm tissue expander (AirXpanders, Inc., San Jose, Calif.) to improve the expansion process in a patient centric manner. This device is a carbon dioxide-filled breast tissue expander that allows gradual, needle-free expansion via the patients use of a hand-held remote controller (Fig. 1). The controller communicates wirelessly with the tissue expander to initiate the release of 10-cubic centimeters (cc) of carbon dioxide 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.[14] Importantly, additional volume expansions can be administered by the surgeon using a master key.

Previous results using the AeroForm expander established the efficacy and safety of the device for 2-stage breast reconstruction.[15] All expanders in that prior study were placed in the subpectoral plane.[15] The purpose of this study was to evaluate a single center experience of 2-stage, prepectoral tissue expander-to-implant breast reconstruction with the use of AeroForm carbon-dioxide tissue expanders and compare the outcome data to our recent experience with saline tissue expanders.

METHODS

Study Design/Sample

This was a retrospective study of consecutive patients over a 1-year period from a single institution. Subjects consisted of adult (older than 18 years) female patients who underwent mastectomy and either immediate or delayed breast reconstruction with AeroForm or saline tissue expanders. Saline expanders were textured, anatomic shaped, and with integrated ports. Patients were consecutive, and the decision to place AeroForm versus saline expanders was based on the likelihood of requiring postmastectomy radiation therapy (PMRT). All patients had at least 6 months of follow-up from the time of expander placement. The study was reviewed and approved by the institutional review board for human subject research.

Fig. 1. The AeroForm tissue expander has suture tabs at 3, 6, and 9-o'clock. The battery-operated handheld remote communicates wirelessly with the tissue expander.

Study Variables

The use of the AeroForm tissue expander 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, timing of reconstruction (i.e., immediate or delayed), obesity (i.e., body mass index > 30 kg/m^2), diabetes, hypertension, other significant medical comorbidities (i.e., congestive heart failure, coronary artery disease, renal failure, hypothyroidism, and hyperlipidemia), oncologic history, adjuvant chemotherapy, prior breast surgery, adjuvant radiation therapy, and current smoking status (defined as active cigarette use within the 4 weeks preceding surgery).

Outcomes

Primary outcomes recorded consisted of postoperative complications including complete and partial mastectomy flap necrosis, infection requiring readmission and/or intravenous antibiotics, capsular contracture, hematoma, seroma, skin dehiscence, extrusion, premature explant, and loss of communication with the device (AeroForm) or rupture of device (saline). For the purposes of this study, dehiscence was defined as skin separation without tissue expander exposure while extrusion was defined as dehiscence with exposure of the tissue expander.

Details relating to expansion such as the number of days to achieve the desired size were evaluated, total volume of expansion, and the number of days from the date of tissue expander placement to completion of reconstruction (successful conversion to an implant or autologous flap) were collected as well.

Statistical Analysis

Data analysis using both multivariate and univariate analyses was performed using SPSS (IBM Inc, Aramonk, N.Y.). Chi-square/Fischer's exact tests compared complication rates among different patient demographic and treatment groups. A value of $P < 0.05$ was considered statistically significant.

RESULTS

This study consisted of a total of 115 patients with 185 breast reconstructions. Of the 185 breast reconstructions, 74 (40%) utilized AeroForm tissue expanders and 111 (60%) utilized traditional saline tissue expansion. The 2 groups were well matched (Table 1) with respect to demographics, age, American Society of Anesthesiologists (ASA) score, BMI, prior radiation status, and smoking history. The in-

Table 1. Demographics

Characteristic	AeroForm	Saline	*P*
Patients	47	68	
Breasts	74	111	
Age (mean, y)	49.1±12.6	50.0±10.5	0.787
Ethnicity			
Caucasian	37	54	
African American	9	12	
Asian	1	2	
BMI (kg/m^2)			
Mean ± SD	27±6	27±6	0.647
Average ASA	2	2	0.796
Breast cancer stage			
DCIS	16	29	
1	16	24	
2	11	11	
3	2	4	
4	0	0	
Mastectomy size (g)			
R - mean ± SD	533±561	492±321	0.679
L - mean ± SD	413±221	511±320	0.094
Prior radiation	8	7	0.316
Neoadjuvant chemo	6	18	0.063
Prior smoking	3	3	0.655
Diabetes	1	10	0.011

ASA, American Society of Anesthesiologists (ASA) Score; DCIS, Ductal Carcinoma in Situ.

cidence of diabetes was 9% and 1.5% in the saline versus AeroForm groups, respectively ($P < 0.05$).

All patients in both groups had 2-stage prepectoral prosthetic breast reconstruction. Reconstruction was immediate in 76.5% of patients in the AeroForm group versus 95.5% in the saline tissue expander group (Table 2).

At the time of data analysis, treatment was successful in 100% (n = 52/52 breasts) and 94% (n = 101/107 breasts) in the AeroForm and saline groups, respectively ($P = 0.025$; Table 3). The mean number of days to complete expansion was fewer in the AeroForm group (45±18 versus 87±76; $P < 0.05$; Table 4). The AeroForm cohort also required

Table 2. Procedures

Variable	AeroForm	Saline
Patients	47	68
Breasts	74	111
Mastectomy, n (%)		
Simple	5 (10.6)	5 (7.4)
Nipple-sparing	24 (51)	30 (44.1)
Skin-sparing	8 (17)	10 (14.7)
Skin-reducing	9 (19.1)	22 (32.4)
Modified radical	1 (2.1)	1 (1.5)
Reconstruction, n (%)		
Immediate	36 (76.6)	65 (95.6)
Delayed	11 (23.4)	3 (4.4)
Implant coverage, n (%)		
Alloderm	26 (55.3)	51 (75.0)
Latissimus Dorsi Muscle	3 (6.4)	2 (2.9)
Dermacell	18 (38.3)	15 (22.1)

Table 3. Treatment Success

Outcome	AeroForm	Saline	*P*
Patients	33	66	
Breasts	52	107	
Success	52	102	0.025
Failure	0	5	

Table 4. Days to Complete Expansion

Outcome	AeroForm	Saline	*P*
Breasts	55	107	
Mean no. days ± SD	45±18	87±76	<0.05

Table 5. Days to Complete Reconstruction

Outcome	AeroForm	Saline	*P*
Breasts	52	107	
Mean no. days ± SD	94±49	143±89	<0.05

fewer mean days to completion of reconstruction (94±49 versus 143±89; $P < 0.05$; Table 5).

The incidence of adverse events occurred with greater frequency in the saline group (45.9% versus 32.4%, $P > 0.05$; Table 6). Seroma formation was more common in the saline cohort (9.0% versus 5.4%, $P > 0.05$). SSI occurred more commonly in the saline cohort (5.4% versus 0%, $P < 0.05$). There were more reconstructions in the saline cohort that resulted in dehiscence (5.4% versus 1.4%; $P > 0.05$) and extrusion (2.7% versus 1.3%; $P > 0.05$). Full-thickness skin necrosis occurred at a significantly higher rate in the saline cohort as compared with AeroForm (5.4% versus 0%, $P < 0.05$).

DISCUSSION

This study is the first to report on a novel breast expander technology (AeroForm) while using a newer reconstructive technique (prepectoral placement with total acellular dermal matrix coverage). We evaluated the time to expansion and rate of complications in patients receiving AeroForm expanders and compared them to patients receiving saline expanders. Since the carbon dioxide-filled AeroForm expander required no percutaneous needlesticks, an overall low rate of infection was expected in these patients. Moreover, the device allows at-home expansion without required visitation to the surgeon's office

Table 6. Adverse Events (SSO)

Complication	AeroForm	Saline	*P*
Breasts	74	111	
AEs, n (%)	24 (32.4)	51 (45.9)	0.064
Seroma	4 (5.4)	10 (9.0)	0.345
Hematoma	0 (0)	4 (3.6)	0.045
Postoperative wound infection	0 (0)	6 (5.4)	0.013
Wound dehiscence	1 (1.3)	6 (5.4)	0.112
Extrusion	1 (1.3)	3 (2.7)	0.511
Readmission for IV antibiotics	0 (0)	1 (0.9)	0.321
Temporary loss of communication	1 (1.35)	NA	
Ruptured device	0 (0)	1 (0.9)	
Necrosis, n (%)			
Slight skin	1 (1.3)	0 (0)	0.321
Slight nipple	2 (2.7)	3 (2.7)	1.000
Slight triple point	2 (2.7)	4 (3.6)	0.729
Full skin	0 (0)	6 (5.4)	<0.05
Major nipple	1 (1.3)	1 (0.9)	0.787
Full triple point	0 (0)	1 (0.9)	0.320

Surgical Site Occurrences (SSO); Not Applicable (NA)

and therefore quicker time to final volume was expected in this same study cohort.

The rate of overall complications was lower in the AeroForm cohort compared with the saline group (32.4% versus 46.0%). Moreover, there was a statistically significant difference in infections (0% versus 5.4%) and readmissions for intravenous antibiotics (n = 0 versus 1), which favored the AeroForm group. Some of this may be explained by a difference in comorbidities in the 2 groups such as an increased incidence of diabetes in the saline cohort. Although tissue expander infections are multifactorial and implicate many operative and perioperative factors, our data suggest that multiple percutaneous needlesticks for filling saline tissue expanders may be a contributing factor to the difference in infections observed in this study and the overall high rates of saline tissue expander infections reported in prior studies.

There was a notable difference in dehiscence in the AeroForm versus saline group (1.4% versus 5.4%; $P > 0.05$) and extrusion (1.35% versus 2.70%; $P > 0.05$) also favoring AeroForm expanders. This may be related to the sudden boluses of saline causing a profound volume change when undergoing traditional saline expansion as opposed to more gradual (yet faster) increase in volume using the AeroForm expander. Bolus injections can lead to increased pressure on the mastectomy flap with an unfavorable cascade of events further augmented by increased weight of saline on the skin flaps as opposed to the weight of the air expander, which remains constant despite increasing volume.

The ability for the patient to expand safely at home has many advantages for patients in our practice.[16] First, the ability for the patient to expand up to 30 cc per day (10 cc at a time, 3 times per day) allows for up to 210 cc of expansion per week. Our practice is to avoid overfilling the expander during the time of surgery and in fact leaving the AeroForm expander relatively unfilled allows mastectomy skin flaps time to recover from the stress of surgery without undue vascular stress. This may explain our difference in full-thickness necrosis, which occurred more commonly in the saline cohort, which we tend to overfill at the time of tissue expander placement. Despite the initial "underfilling," the AeroForm patients were fully expanded and exchanged in less time than the saline group. This difference was observed despite not placing patients on a formal expansion regimen. With the combination of this device and prepectoral technique, the patient can reasonably achieve implant exchange before any need for PMRT.

In the present work, 23.4% of the patients in AeroForm cohort underwent delayed reconstruction. The AeroForm expander shell is anatomically shaped and designed to allow for anisotropic expansion favoring the lower pole. In our experience, this has been a powerful choice for delayed patients where the mastectomy skin flaps have undergone significant scarring and retraction (Fig. 2). In our experience, Aeroform allows for focused lower pole expansion (Fig. 3).

The use of AeroForm tissue expanders in the prepectoral space represents a new era of patient-centric breast reconstruction following mastectomy. The clinical benefits that we have noted include the ability to expand gradually in less time, elimination of the risk of iatrogenic introduction of bacteria into the implant pocket, elimination of the chance for iatrogenic rupture during needlesticks, and the ability to expand at their own rate depending on the patients level of comfort expansion. The benefits from a patient care perspective include less burden on the patient for clinic visitation and decreased utilization of healthcare resources during the fill process. Moreover, this expands the ability for breast centers to care for more patients since the time scheduled for expansions is eliminated and patients who live farther away require fewer visits for expansion.

The potential drawbacks include the inability to remove air from the expander, a relatively larger initial size as compared with saline expanders and the need for radiation oncologists to adjust their protocols to account for the presence of air instead of saline inside the expander. Standard PMRT has been shown not to affect the functionality of the AeroForm tissue expander.[17] Several studies have documented the dosimetric effect of the metallic port found in traditional saline expanders[18–20]; however, the AeroForm expander is relatively new and published dosimetry studies are limited.[21] Moni et al.[22] found that the presence of CO^2 gas and a metallic reservoir did not lead to clinically relevant alterations in dose distribution. Management of adjuvant radiation therapy with this device in place requires modification of standard treatment planning protocols designed to irradiate traditional expanders filled with saline. This has been successfully implemented at multiple centers in Australia and the United States with acceptable dose distribution but concern remains about the effect on long-term outcomes. This has implications in the clinical scenario when neoadjuvant chemotherapy patients need to proceed to radiation quickly after mastectomy and before final implant exchange. Longer term studies are required to evaluate the safety and efficacy of radiation in these patients.

The inability to deflate the expander for radiation is another concern similar to the clinical scenario faced after direct-to-implant breast reconstruction with highly projecting cohesive gel implants. These modern permanent breast implants cannot be taped to the side of the patient like a large native breast. In the case of AeroForm expanders, our current preference is to delay expansion of the contralateral, noncancer side until a decision is made regarding the need for irradiation. This avoids the need for adjusting the tangent beam of irradiation for cross table radiation therapy. The presence of a projecting contralateral breast leads to the potential for incidental irradiation of a healthy breast and increased dose to thoracic organs such as the heart and lungs. This is especially relevant when treating left-sided cancers.

Our preference is to radiate the final implant in these patients, which is achievable due to the ability to rapidly expand and exchange the AeroForm expander before treatment. Although radiation negatively impacts the reconstruction regardless of the timing, we have been able to achieve a satisfactory aesthetic result with this practice.

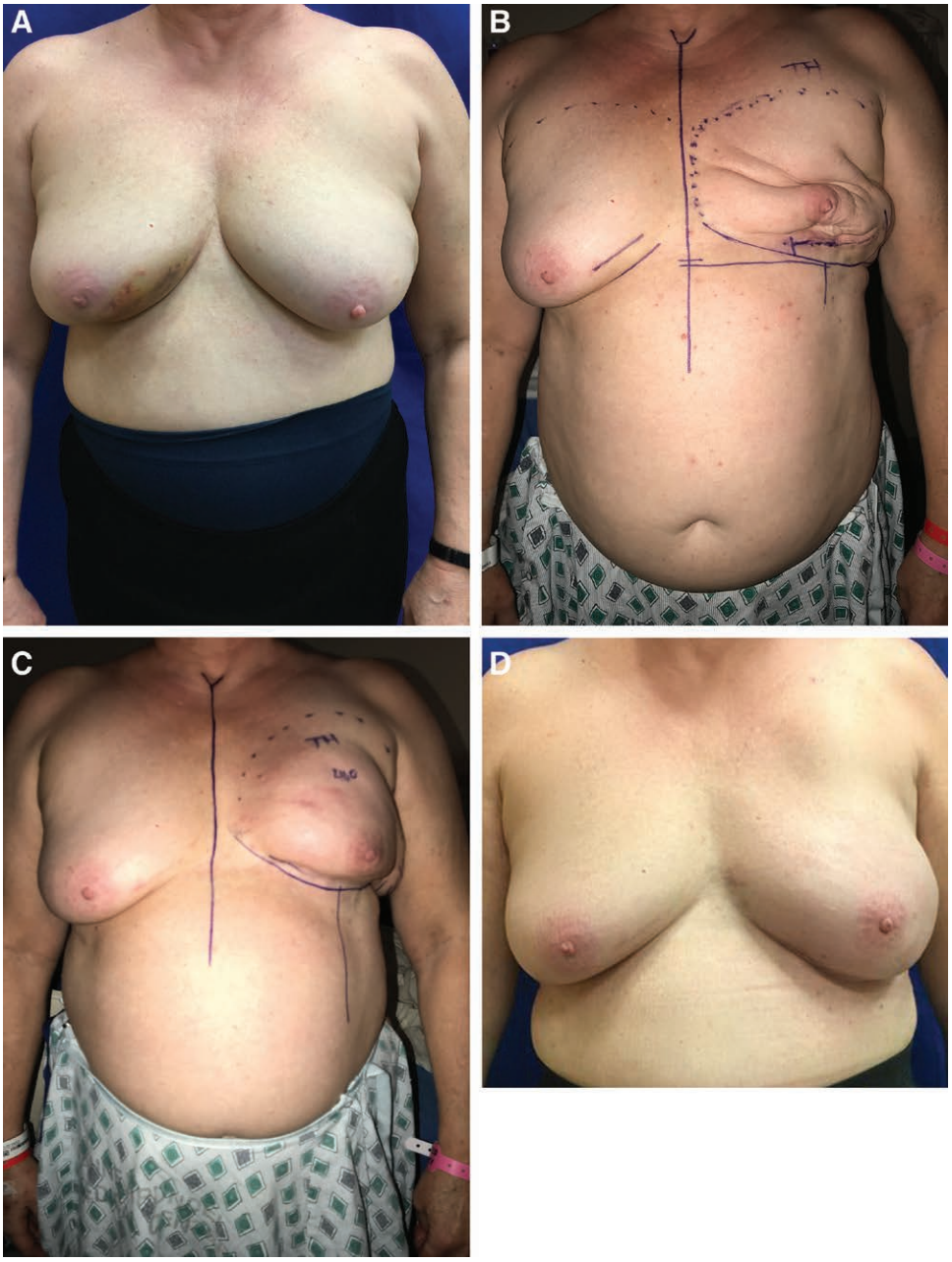

Fig. 2. This is a 64-year-old woman who presented with breast ptosis and a diagnosis of left breast cancer (A). She underwent left nipple-sparing mastectomy for breast cancer. At the time of mastectomy, intraoperative indocyanine green angiography revealed a dense area of poor perfusion. Reconstruction was deferred and the mastectomy incision was closed primarily and dressed with a closed-incision negative pressure therapy dressing (B). The patient received delayed left breast reconstruction with placement of a prepectoral AeroForm tissue expander and acellular dermal matrix (C). Patient shown 3 months after removal of AeroForm tissue expander and exchange for permanent silicone breast implant (D).

CONCLUSIONS

The use of AeroForm tissue expanders offers notable advantages over saline expanders for breast reconstruction. This device, when employed in the prepectoral space, may be associated with reduced infection rates and decreased utilization of healthcare and patient resources. These devices may allow for rapid reconstruction before postmastectomy radiation and obviate the need for open surgery to an irradiated breast. We anticipate a follow-up study to report on these patient's long-term outcomes. Further studies are required to optimize the radiation oncology protocols to adjust for a gas-filled expander versus normal saline for patients who require radiation during the expansion phase of reconstruction.

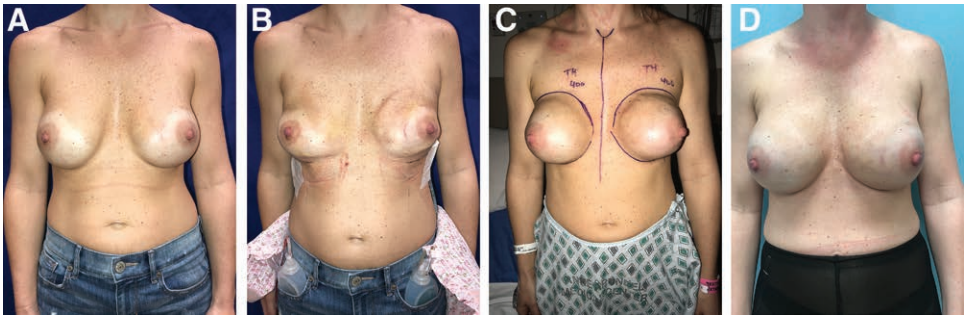

Fig. 3. This patient had a history of prior dual plane saline breast augmentation and a nipple sparing mastectomy (Figure 3A). She underwent bilateral nipple sparing mastectomy and intraoperative indocyanine green angiography demonstrated well vascularized mastectomy skin flaps. The pectoralis major muscle was readvanced and prepectoral breast reconstruction with Aeroform was performed. Shown at early expansion (Figure 3B). Patient tolerated expansion well (Figure 3C) and is shown after removal of AeroForm tissue expander and exchange for permanent silicone breast (Figure 3D).

Luther (Tripp) Holton III, MD
Division of Plastic Surgery
Anne Arundel Medical Center
Annapolis, MD
E-mail: lholton@aahs.org

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