The Impact of Device Innovation on Clinical Outcomes in Expander-based Breast Reconstruction

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Background: Staged expander-based breast reconstruction represents the most common reconstructive modality in the United States. The introduction of a novel tissue expander with an integrated drain (Sientra AlloX2) holds promise to further improve clinical outcomes.

Methods: Patients who underwent immediate expander-based pre-pectoral breast reconstruction were identified. Two cohorts were created, that is, patients who underwent placement of a conventional tissue expander [133MX (Allergan)] (Group 1) versus AlloX2 (Sientra) (Group 2). The study endpoint was successful completion of expansion with the objective being to investigate differences in outcome following expander placement.

Results: Fifty-eight patients underwent 99 breast reconstructions [Group 1: N = 24 (40 breasts) versus Group 2: N = 34 (59 breast)]. No differences were noted for age ($P = 0.586$), BMI ($P = 0.109$), history of radiation ($P = 0.377$), adjuvant radiotherapy ($P = 1.00$), and overall complication rate ($P = 0.141$). A significantly longer time to drain removal was noted in Group 1 ($P < 0.001$). All patients with postoperative infection in Group 1 required surgical treatment versus successful washout of the peri-prosthetic space via the AlloX2 drain port in 3 of 5 patients in Group 2 ($P = 0.196$). Furthermore, both cases of seroma in Group 1 required image-guided drainage versus in-office drainage via the AlloX2 drain port in 1 patient in Group 2 ($P = 0.333$).

Conclusion: The unique feature of the AlloX2 provides surgeons easy access to the peri-prosthetic space without altering any of the other characteristics of a tissue expander. This resulted in a reduced time to drain removal and facilitated management of postoperative seroma and infection. *(Plast Reconstr Surg Glob Open 2019;7:e2524; doi: 10.1097/GOX.0000000000002524; Published online 24 December 2019.)*

INTRODUCTION

Breast reconstruction has been demonstrated to have a favorable impact on patient satisfaction.[1] It is, therefore, not surprising that a significant increase in the number of breast reconstructions has been noted, as evidenced by a 29% increase since 2000.[2] Importantly, this trend is predominantly driven by an increase in implant-based breast reconstruction.[3,4] In the United States, implant-based reconstruction remains the most common reconstructive modality following mastectomy in the United States.[5]

Over the past 4 decades, we have witnessed tremendous technical and technological innovations in breast reconstruction which have resulted in superior clinical outcomes with reduced patient morbidity. To this point, reducing patient morbidity is as critical as achieving the goals of breast reconstruction, which is best described by the acronym "5S," ie reconstruction of breasts of adequate size, shape, symmetry, softness, and sensation.[6,7] In autologous reconstruction, the quest to minimize patient morbidity is best illustrated by the transition from pedicled transversus rectus abdominis musculocutaneous to free perforator-based flaps.[8–11] A similar evolution towards minimally invasive approaches in implant-based reconstruction has been seen with a trend away from sub-muscular and towards pectoral reconstructions. Importantly, the introduction of acellular dermal matrices (ADM) coupled with innovative

technologies, eg indocyanine-green fluorescence angiography, has enabled plastic surgeons to offer pre-pectoral reconstruction in a safe manner with reproducible results.

While some authors report of pre-pectoral implant placement without the use of mesh, the majority of surgeons today use ADM when performing pre-pectoral reconstruction.[12–14] However, the latter has been reported to be associated with an increased risk of postoperative complications, notably a significant increase in the rate of seroma formation.[15,16] Importantly, seroma formation can be the "Achilles' heel" of pre-pectoral reconstruction as it prevents incorporation of the ADM and predisposes to secondary infection.[16]

A common approach to preventing seroma formation is prolonged drain placement. Sbitany et al,[17] for example, routinely leave drains in place for a minimum of 3 weeks. However, in light of the associated patient discomfort, modalities that permit a reduction in drain duration are desirable. A recent innovation in tissue expander technology holds promise for addressing this issue. The Sientra AlloX2 tissue expander has an integrated drain which allows access to the periprosthetic space, thus, permitting fluid aspiration even after drain removal[18] (Fig. 1).

The objective of the present study was to determine the value of this novel device in comparison with a traditional tissue expander. We hypothesized that utilization of the AlloX2 tissue expander would be associated with a reduction in time to drain removal.

METHODS

Sample Selection

Institutional review board approval was obtained before conducting the study. A prospectively maintained database was generated for patients who underwent
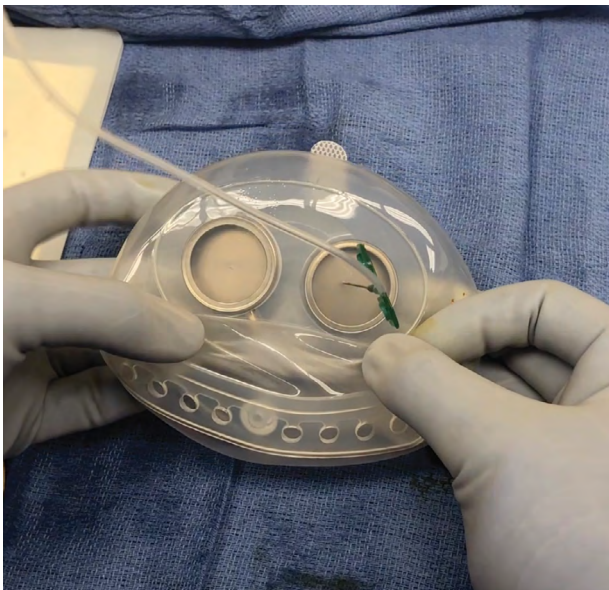

Fig. 1. Sientra AlloX2 tissue expander with a butterfly needle inserted in the injection port. Note, the drain along the lower border of the device, thus, permitting access to the most dependent portion of the expander pocket.

immediate expander-based pre-pectoral breast reconstruction. All reconstructions were performed by the lead author (A.M.). Only patients who underwent staged expander-based reconstruction were included in the study. Two cohorts were created, that is, patients who underwent placement of a conventional tissue expander [133MX (Allergan)] (Group 1) versus tissue expander with integrated drain [AlloX2 (Sientra)] (Group 2). ADM was used in all patients for complete tissue expander coverage. The ADM used was a $16 \times 20\,cm^2$ sheet of either AlloDerm (Allergan) or DermACELL (Stryker). Perioperative antibiotics were discontinued upon discharge on postoperative day 1. The criterion for drain removal was an output of <20 mL/24 hours over 2 consecutive days. Patients undergoing direct-to-implant reconstruction were excluded.

The study endpoint was defined as successful completion of expansion with the ability to proceed to the second reconstructive stage. The objective of this study was to investigate differences in clinical outcomes following tissue expander placement.

Parameters of Interest

Clinical variables collected included age (in years), body mass index (BMI; in kg/m²), race, history of radiation, adjuvant radiation, type of mastectomy (ie nipple-sparing mastectomy versus skin-sparing mastectomy), intraoperative tissue expander fill (in mL), final tissue expander fill volume (in mL), time to drain removal (in days), interval between first and second stage (in months), and type of second stage procedure (expander-implant exchange versus delayed-immediate free tissue transfer versus delayed-immediate hybrid reconstruction).

Statistical Analysis

All statistical analyses were performed on the R statistical package (v3.6.0). A P-value of <0.05 was considered statistically significant. Continuous data were described with means and SDs of the mean when parametric and with frequency and percentage when nonparametric. Descriptive analyses were conducted using two-way T-tests for continuous variables. A Kaplan–Meier curve was constructed based on time to drain removal and compared between groups using a log rank test.

RESULTS

A total of 58 patients who underwent 99 breast reconstructions were included in the study. Twenty-four patients with a mean age of 53.4 years (±12.3) who underwent 40 breast reconstructions (Group 1) were compared with 34 patients with a mean age of 51.7 (±11.2) who underwent 59 breast reconstructions (Group 2). No differences were noted for age [Group 1 (mean): 53.4 ± 12.3 years versus Group 2 (mean): 51.7 ± 11.2 years; P = 0.586] and BMI [Group 1 (mean)] 27.1 ± 7.0 kg/m² versus Group 2: 24.5 ± 3.9 kg/m²; P = 0.109] (Table 1). The majority of patients in either group were White [N = 17 (70.8%) and N = 26 (76.5%) in Group 1 and 2, respectively] followed by Hispanics in Group 1 [N = 4 (16.7%)] and Asians [N = 6 (17.6%)] in Group 2. No difference was noted with respect to history of radiation

Table 1. Patient Demographics

	Group 1 (n = 24)	Group 2 (n = 34)	P
Age (y)	53.42 ± 12.30	51.65 ± 11.22	0.586
BMI (kg/m²)	27.12 ± 6.96	24.48 ± 3.94	0.109
Race			
White	17 (70.8%)	26 (76.5%)	0.763
Asian	2 (8.3%)	6 (17.6%)	0.449
African American	1 (4.2%)	0 (0.0%)	0.414
Hispanic	4 (16.7%)	2 (5.9%)	0.220
Cancer	23 (95.8%)	32 (94.1%)	1.000
History of XRT	5 (20.8%)	4 (11.8%)	0.467
Bilateral mastectomy	16 (66.7%)	25 (73.5%)	0.785
Nipple sparing	17 (70.8%)	24 (70.6%)	1.000
Adjuvant XRT	5 (20.8%)	7 (20.6%)	1.000

No statistically significant differences between study groups.

Table 2. Fill Volumes, Time to Drain Removal, and Time to Stage 2 Reconstruction

	Group 1 (n = 24)	Group 2 (n = 34)	P
Intraoperative fill (mL)	160.42 ± 98.93	166.18 ± 95.27	0.829
Final fill (mL)	413.70 ± 125.17	285.15 ± 137.14	0.001
Time to drain removal (days)	23.46 ± 2.60	15.12 ± 3.89	<0.001
Time to Stage 2 (mos.)	5.61 ± 2.53	5.91 ± 1.86	0.638

[Group 1: N = 5 (20.8%) versus Group 2: N = 4 (11.8%), $P = 0.377$]. Cancer was the indication for surgery in almost all patients [Group 1: N = 23 (95.8%) versus Group 2: 32 (94.1%), $P = 0.77$], with the majority of patients undergoing bilateral [Group 1: N = 16 (66.7%) versus Group 2: N = 25 (73.5%), $P = 0.585$] nipple-sparing mastectomy [Group 1: N = 17 (70.8%) versus Group 2: N = 24 (70.6%), $P = 0.984$]. Reconstruction was performed with AlloDerm in the majority of patients [Group 1: N = 19 (79.2%) versus Group 2: N = 30 (88.2%), $P = 0.377$]. DermACELL was used in the remaining reconstructions. Five (20.8%) and 7 (20.6%) patients underwent adjuvant radiotherapy in Group 1 and 2, respectively ($P = 0.982$) (Table 1).

Intraoperative expander fill volumes were similar in both groups [Group 1 (mean): 160.4 ± 98.9 mL versus Group 2: 166.2 ± 95.3 mL; $P = 0.829$]. A significantly higher final fill volume, however, was noted in Group 1 (413.70 ± 125.17 mL versus 285.15 ± 137.14; $P = 0.001$). Importantly, a significantly longer time to drain removal was noted in Group 1 (mean: 23.5 ± 2.6 days versus 15.1 days ± 3.8 days; $P < 0.001$) (Table 2; Fig. 2). No differences were noted regarding time interval between stage 1 and stage 2 (Group 1: 5.61 ±2.53 versus Group 2: 5.91 ± 1.86 months; $P = 0.638$) (Table 2).

An overall complication rate of 41.7% and 23.5% was noted in Group 1 and 2, respectively ($P = 0.141$). Table 3 displays the respective postoperative complications without any significant difference being present between study groups. An important observation, however, was related to the management of infection and seroma between the study groups. While all 3 patients who developed postoperative infection in Group 1 required surgical treatment, 3 of 5 patients were successfully managed (salvaged) in Group 2 by using the AlloX2 drain port to washout the periprosthetic space with betadine as previously reported ($P = 0.196$).[19] Furthermore, both patients with postoperative clinically detectable seroma in Group 1 required
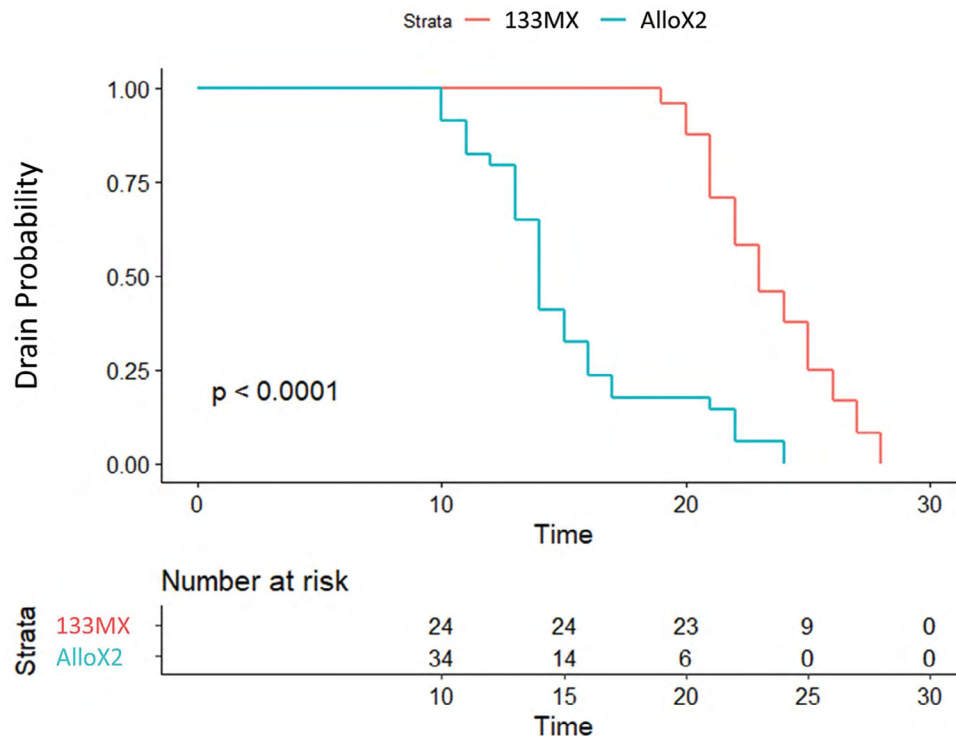

Fig. 2. Time to drain removal. A significant decrease in time to drain removal noted with the AlloX2 device (P <0.0001).

Table 3. Postoperative Complications

	Group 1 (n = 24)	%	Group 2 (n = 34)	%	P
Infection	3	12.5	5	14.7	1
Implant exchange	2	66.7	1	20.0	0.464
Implant removal	1	33.3	1	20.0	1
Nonoperative salvage	0	0.0	3	60.0	0.196
Seroma	2	8.3	1	2.9	0.563
Image-guided drainage	2	100.0	0	0.0	0.333
Mx skin necrosis	5	20.8	4	11.8	0.467
NAC necrosis	1	4.2	1	2.9	1
Overall	10	41.7	8	23.5	0.141

Note that some patients developed more than one complication.

image-guided drainage versus in-office seroma drainage via the AlloX2 drain port in 1 patient in Group 2 (*P* = 0.333) (Table 3).

The reconstructive modalities used at the second stage included expander-implant exchange [Group 1: N = 13 (54.2%) versus Group 2: N = 27 (79.4%), *P* = 0.041], delayed-immediate free abdominal flap transfer [Group 1: N = 5 (20.8%) versus Group 2: N = 3 (8.8%), *P* = 0.255], delayed-immediate hybrid reconstruction, ie free abdominal flap transfer with simultaneous implant placement [Group 1: N = 5 (20.8%) versus Group 2: N = 3 (8.8%), *P* = 0.255], and delayed free abdominal flap following expander loss in one patient (Group 2) (Table 4). Of note, 1 patient in Group 1 did not undergo reconstruction after tissue expander removal secondary to infection.

DISCUSSION

Implant-based breast reconstruction continues to be the most common reconstructive modality following mastectomy. However, it is important to acknowledge the substantial heterogeneity that exists within this reconstructive group. The variations in surgical approach are quite remarkable and include differences in timing (staged versus direct-to-implant), plane of implant placement (total sub-muscular versus sub-pectoral versus pre-pectoral), type of ADM, and even whether ADM is used at all.[20–22]

Pre-pectoral breast reconstruction has become increasingly popular due to its numerous advantages, including decreased postoperative pain, shortened recovery time, effective prevention of animation deformity, and greater control of breast shape and form to name a few.[13,23–26] Initial concerns regarding the safety of this approach could not be substantiated in clinical studies. In fact, a recent head-to-head comparative analysis of matched patients who underwent pre- versus sub-pectoral reconstruction confirmed the safety of pre-pectoral reconstruction.[14]

Despite these favorable outcomes, it is important to acknowledge that pre-pectoral reconstruction mandates a more restrictive postoperative protocol as it pertains to management of complications. For example, small areas of mastectomy skin necrosis require expeditious excision and closure, whereas in cases of sub-muscular device placement a more expectant approach may be justified. Similarly, postoperative seroma formation has different implications in the context of pre- versus sub-muscular reconstruction.

The association of a higher postoperative seroma rates with ADM has been reported by numerous authors.[15,16] Chun et al[16] further hypothesized that seromas are a risk factor for secondary infections. To address this, longer periods of drainage, more restrictive criteria for drain removal, and modifications in drain position have been recommended.[16] It has also been suggested that "careful patient selection, choice of tissue expander/implant volume, and postoperative management are warranted to optimize overall reconstructive outcome."[16] In light of newer technological innovations in expander design, one should also consider choice of expander design in this equation. While the AlloX2 is not believed to reduce the incidence of seroma formation and the authors caution against overstating the benefits of the device,[27] it certainly facilitates management thereof, and as a result, reduces the untoward sequelae of seroma.

Our observations have some practical implications. While the rate of postoperative seroma formation compares favorably with the literature,[28] the ability to drain seroma fluid without image guidance in the office is a major advantage. Certainly, an integrated drain is not mandatory for successful in-office seroma drainage and techniques for successful execution have been reported.[29] However, these techniques fail to successfully access the most dependent portion of the expander pocket. Placement of the integrated drain of the AlloX2 device along the inframammary fold elegantly solves this problem, thus, ensuring successful aspiration of periprosthetic fluid.

Interestingly, the impact of the AlloX2 was more profound in the management of postoperative infections.

Table 4. Stage 2 Reconstructive Modalities

	Group 1 (n = 24)	%	Group 2 (n = 34)	%	P
Expander-implant exchange	13	54.2	27	79.4	0.041
Delayed-immediate free flap	5	20.8	3	8.8	0.255
Delayed-immediate hybrid reconstruction	5	20.8	3	8.8	0.255
Delayed free flap (s/p expander loss)	0	0.0	1	2.9	1
No stage 2 = failed reconstruction	1	4.2	0	0.0	0.414

While all patients in Group 1 required surgical treatment, this was only necessary in 2 of 5 patients in Group 2, thus, corroborating our previous report.[19] The ability to perform bedside washouts of the periprosthetic space provides surgeons the ability to treat early infections without the need for surgical intervention. This changes conventional management of postoperative surgical site infection following expander placement as we can now depart from the practice of temporary observation following initiation of antibiotic therapy but rather can offer a more aggressive regimen, that is, initiation of antibiotic therapy with washout of the periprosthetic space, without the morbidity associated with surgical intervention. Furthermore, the ability to reliably obtain periprosthetic fluid samples for culture expedites identification of a target for antibiotic therapy, thereby minimizing the duration of empiric antibiotic therapy.

Both, the ability to drain seromas as well as to washout the periprosthetic space in cases of early infection at the point-of-contact potentially obviates the need for surgical intervention, thereby reducing cost. While the issue of cost was not a focus of this investigation, it is easily conceivable that foregoing image-guided drainage or surgical intervention in the operating room will be associated with a marked cost reduction.

Existing differences in total expander fill volume with higher final volumes in Group 1 (P =0.001) are explained by the lead author's practice to underfill the expander in preparation of expander-implant exchange, whereas expanders are overfilled in preparation for autologous or hybrid reconstruction. Hence, the significantly higher rate of expander-implant exchange in Group 2 (79.4% versus 54.2%, P =0.041) is not surprising.

Limitations of the present study include the small number of patients, thus, likely being underpowered to detect significant differences in postoperative complication rate.

While the benefits of the AlloX2 as it pertains to facilitating seroma management and treatment of infection has been demonstrated,[19,27,30] larger prospective studies are warranted to substantiate the benefit of this practice.

The unique feature of the AlloX2 provides surgeons easy access to the peri-prosthetic space without altering any of the other characteristics of a tissue expander. While one does not plan to experience a postoperative complication, a valid question in light of the availability of the AlloX2 is why one would forego utilizing a device that facilitates treatment thereof.

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