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Advances in Tissue Expander Technology Enable Early Targeted Intervention in Prepectoral Breast Reconstruction

Farrah Liu, MD*
Dominic Henn, MD*†
Kerry Shrefren, NP*
Arash Momeni, MD, FACS*

Background: Seroma and infection are among the most common complications after staged prepectoral implant-based reconstruction. Advances in tissue expander technology permit seroma aspiration via an integrated drain port, thus, holding promise for improving clinical outcomes.

Methods: A prospectively maintained database of patients who had undergone immediate prepectoral breast reconstruction using the Sientra AlloX2 tissue expander was used to determine the rate of postoperative seroma formation, its volume and microbiological spectrum, as well as postoperative complications.

Results: 49 patients (mean age: 49 years, mean body mass index: 24.5 kg/m^2) underwent 79 prepectoral breast reconstructions. Seroma was clinically suspected in 26 reconstructions (32.9%) and was easily aspirated in all cases via the integrated drain port. Importantly, periprosthetic fluid was successfully aspirated in 45 reconstructions (57%) without any clinical evidence for seroma, with aspirated cumulative fluid volumes exceeding 10 cm^3 in 12 reconstructions. Bacterial cultures from aspirated fluid were positive in six patients (12.2%), of whom two developed clinical signs of infection, at which point targeted antibiotic treatment was initiated.

Conclusions: Our study demonstrates that routine office-based aspiration of periprosthetic fluid via the integrated drain port of the AlloX2 tissue expander not only permits successful aspiration of periprosthetic fluid but also allows aspirated fluid to be sent for culture, thus, providing a lead-time advantage for initiation of targeted antibiotic therapy in cases of postoperative surgical site infection. Furthermore, our observations indicate that positive bacterial cultures in the absence of clinical signs of infection do not mandate antibiotic therapy. *(Plast Reconstr Surg Glob Open 2021;9:e3781; doi: 10.1097/GOX.0000000000003781; Published online 19 August 2021.)*

INTRODUCTION

Breast cancer is the most common malignancy in women, with over 250,000 annual diagnoses in the United States.[1] Postmastectomy breast reconstruction has established itself as a critical component in the treatment algorithm of breast cancer patients, as evidenced by an almost 40% increase in the number of breast reconstructions performed in the United States over the past 20 years.[2] The main contributor to this growth has been implant-based reconstruction, which accounts for 80% of all breast reconstructions. Most commonly, implant-based breast reconstruction is performed in a staged approach, which involves the placement of a tissue expander (TE) at the time of mastectomy followed by expander-implant exchange. Recently, the advent of prepectoral breast reconstruction and the introduction of technological innovations, such as novel prosthetic devices, have improved patient outcomes after implant-based breast reconstruction.[3,4]

Challenges with implant-based reconstruction in general, and prepectoral reconstruction in particular, have been related to postoperative seroma formation and infection. In fact, seroma has been identified as a risk factor for infection.[5] The increased incidence of seroma formation has been linked to the use of acellular dermal matrices (ADM). Thus, early recommendations included maintaining drains for at least 3 weeks following prepectoral reconstruction[6]; the advent of novel technology, however, has

*From the *Division of Plastic and Reconstructive Surgery, Stanford University, Stanford, Calif.; and †Department of Hand, Plastic and Reconstructive Surgery, BG Trauma Center Ludwigshafen, University of Heidelberg, Germany.*

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permitted earlier drain removal while permitting access to the periprosthetic space, allowing for aspiration of periprosthetic fluid following drain removal.[7]

While reported rates of postoperative seroma formation vary widely, ranging from 0.2% to 20%,[8–15] the ability to access the periprosthetic space with ease provided an opportunity to investigate the rate of postoperative seroma formation and volume thereof, the microbiological makeup of seroma fluid, and rates of infection.

PATIENTS AND METHODS

Institutional review board approval was obtained before conducting the study. A prospectively maintained database of consecutive patients who had undergone immediate prepectoral expander-based breast reconstruction with ADM was analyzed. The same surgical technique was used in all patients. After determining the desired width of the tissue expander, a 16 × 20 cm sheet of ADM was brought onto the surgical field and placed in a saline bath. Thereafter, the ADM was draped over the deflated TE and trimmed to provide anterior coverage with an inferior cuff—that is, the ADM was draped over the inferior edge of the TE and covered the posterior surface for approximately 2–3 cm.[4] Of note, the suture tabs of the TE were used and secured the TE to the ADM. This is particularly important when using smooth TE to prevent rotation of the device. The TE-ADM construct was then inserted into the breast pocket. After confirming the desired TE position, the ADM was secured to the pectoralis major muscle/chest wall soft tissues with absorbable sutures. All patients included in the study underwent placement of either textured or smooth Sientra AlloX2 TE (Santa Barbara, Calif.). Textured devices were placed in the first eight patients, with all subsequent reconstructions being performed with smooth devices. Surgical drains were placed in the plane between the ADM and the mastectomy skin flaps and removed once the drainage had decreased to less than 20 cm^3 per 24 h over two consecutive days. All reconstructions were performed by a single surgeon (AM). Exclusion criteria included subpectoral (ie, dual plane) and total submuscular TE placement, TE placement in conjunction with latissimus dorsi muscle flap transfer, and delayed reconstructions.

Parameters retrieved included age, body mass index, intraoperative TE fill volume, final TE fill volume, and postoperative complications. Postoperative complications were categorized as minor (those treated outpatient) and major (those requiring inpatient and/or operative care).[16,17]

Data were collected regarding the presence of any clinical suspicion for seroma, the amount of periprosthetic fluid aspirated at the first postoperative clinic visit, as well as the cumulative amount of periprosthetic fluid aspirated postoperatively. The integrated drain port was accessed weekly until expansion was complete. Of note, surgical drains were removed once the above-mentioned criteria were met, even if fluid was successfully aspirated via the TE drain port. All fluid aspirates were sent for gram stain and aerobic and anaerobic culture. Rates of asymptomatic bacterial contamination and postoperative infection were noted and the impact of surface texturing on these rates was investigated.

RESULTS

Demographics

A total of 49 patients with a mean age and body mass index of 49 years (range, 19–71) and 24.5 kg/m^2 (range, 19.4–39.2), respectively, underwent a total of 79 breast reconstructions. Of these patients, 41 underwent 66 breast reconstructions with smooth TE (25 bilateral, 16 unilateral), whereas eight patients underwent 13 reconstructions with textured devices (five bilateral, three unilateral) (Table 1). All TEs were placed in the prepectoral plane. The most commonly used ADM was Alloderm (Allergan, Dublin, Ireland, N = 41 patients), followed by Cortiva (RTI Surgical, Deerfield, Ill.; N = 4 patients), and Dermacell (LifeNet Health, Virginia Beach, Va.; N = 4 patients). Average intraoperative and final TE fill volumes were 200 cm^3 (range, 125–500) and 277 cm^3 (range, 125–700), respectively (Table 2).

Aspirated Fluid Volumes

Postoperatively, seroma was clinically suspected in 26 reconstructions (32.9%). Twenty-one of these had been performed with smooth TE, thus, representing 31.8% of all reconstructions with smooth devices. The remaining five reconstructions with clinical evidence of seroma had been performed with textured TE, thus, representing 38.5% of all reconstructions with textured devices. Notably, all seromas were successfully aspirated in clinic, using the integrated drain port without the need for image-guided intervention.

Importantly, given the practice of routine aspirations via the integrated drain port, periprosthetic fluid was successfully aspirated in 45 reconstructions (57%) without any clinical evidence for seroma, with aspirated cumulative fluid volumes exceeding 10 cm^3 in 12 reconstructions. Notably, the aspirated fluid volume during

Table 1. Patient Demographics

	Mean (Range)
Age (y)	49.0 (19–71)
Body mass index (kg/m^2)	24.5 (19.4–39.2)
	N
Race	
White	37
Asian	5
African American	1
Hispanic	6
Preoperative XRT	2
Adjuvant XRT	11
Neoadjuvant chemotherapy	2
Adjuvant chemotherapy	12
Indication for mastectomy	
Cancer	45
Prophylactic	4
Laterality of mastectomy/reconstruction	
Unilateral	19
Bilateral	30
Mastectomies with axillary lymph node dissection	8

Table 2. Expander-related Information

Type of TE Used (Patients/Breasts)	
Smooth	41 (66)
Textured	8 (13)
	Mean (Range)
Mean intraoperative TE fill volume (cm^3)	200 (125–500)
Final TE fill volume (cm^3)	277 (125–700)
Time to drain removal (d)	14.8 (10–28)
Aspirated fluid volume (initial clinic visit) (per breast), cm^3	
With clinical suspicion for seroma	32 (10–95)
Without clinical suspicion for seroma	2.6 (1–11)
No. aspirations (per breast)	3.1 (1–6)

the first postoperative clinic visit was significantly higher in patients with clinical suspicion for seroma (mean: 32 cm^3, range: 10–95 cm^3) than in patients without clinical evidence of seroma (mean: 2.6 cm^3, range: 1–11 cm^3, $P < 0.0001$, Fig. 1). Furthermore, it is noteworthy that in 20 reconstructions (25.3%), greater than 30 cm^3 was aspirated at the initial clinical visit, despite the presence of two drains. Drains remained in place for a mean of 14.8 days (range, 10–28) (Table 2). The mean cumulative aspirated seroma volume over the course of the postoperative period was 43.4 cm^3 (range, 0–350 cm^3). No significant differences were noted between smooth and textured TEs in regard to volumes aspirated at the first postoperative clinic visit (smooth, 8.5 cm^3 ± 2.36 cm^3 versus textured, 7.69 cm^3 ± 3.49 cm^3; $P = 0.88$) (Fig. 2). Similarly, no differences between devices were noted in regard to cumulative aspirated fluid volumes (23.3 cm^3 ± 5.9 versus 18.9 cm^3 ± 7.5; $P = 0.75$) (Fig. 3).

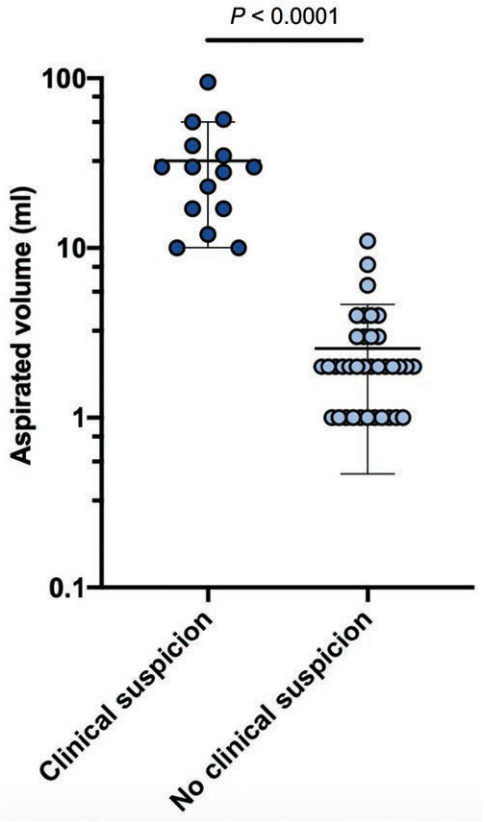

Fig. 1. Aspirated seroma volume at first clinic visit in patients with and without clinical suspicion for seroma (data points = breasts).

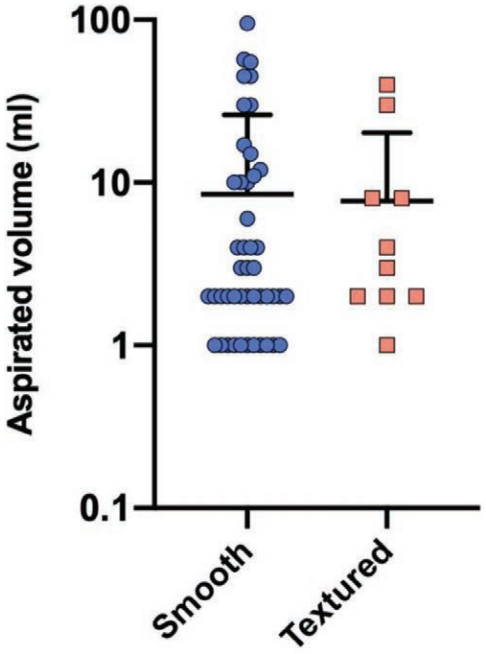

Fig. 2. Aspirated seroma volume at first clinic visit in patients with smooth and textured tissue expanders (data points = breasts).

Postoperative Bacterial Culture Results

Bacterial cultures from aspirated periprosthetic fluid were positive in six patients (12.2%), representing eight reconstructions (10.1%), of which four had been performed with smooth and four with textured TE. Of note,

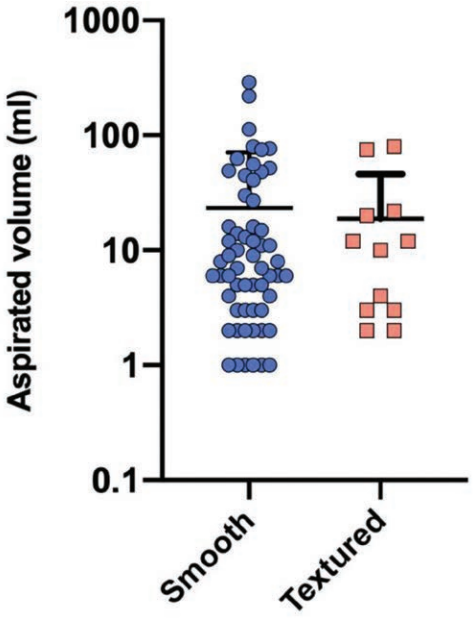

Fig. 3. Cumulative aspirated seroma volume in patients with smooth and textured tissue expanders (data points = breasts).

antibiotic therapy was not administered for positive culture results in the absence of clinical signs of infection. Among patients with positive cultures of fluid aspirates, only two patients developed clinical signs of infection.

One of these patients was a 39-year-old female patient who had undergone bilateral reconstruction with textured devices and was found to have a positive culture result from the left breast aspirate 26 days postoperatively. The identified pathogen was *Actinomyces neuii*. One week later, the patient developed clinical signs and symptoms of left breast surgical site infection. As the pathogen had already been identified, targeted antibiotic therapy with doxycycline was initiated immediately along with bedside washout of the periprosthetic space with dilute betadine. This allowed TE salvage without the need for surgical intervention. The infection resolved with a 10-day course of targeted antibiotic therapy and the patient recovered uneventfully (Table 3). An additional five patients developed postoperative surgical site infection, of whom four patients also had developed mastectomy skin necrosis, thus, necessitating surgical intervention.

DISCUSSION

The increasing popularity of prepectoral reconstruction is paralleled by an increasing interest in the incidence of postoperative seroma formation as well as measures for its prevention and treatment. A review of the literature demonstrates that reported rates of postoperative seroma formation vary widely, likely because the diagnosis is typically made clinically. Although reported rates of postoperative seroma formation range between 0.2% and 20%,[8–15] a much higher rate (ie, 32.9%) of clinically suspected periprosthetic fluid accumulation was noted in the present study. This is perhaps related to a heightened index of suspicion, as determining the rate of postoperative seroma formation was a major objective of this study. Importantly, however, access of the integrated drain of the AlloX2 permitted easy access to the periprosthetic space, which allowed for successful periprosthetic fluid aspiration in 57% of asymptomatic reconstructions, thus, unmasking the true rate of undrained periprosthetic fluid. These observations demonstrate the limited sensitivity of clinical examination in detecting undrained periprosthetic fluid. Office-based access of the drain port, furthermore, mitigates the need for ultrasound-guided procedures and radiology consultations, thus, preventing delays in patient care. The potential impact on clinical care is substantial when considering that more than 30 cm^3 was aspirated at the initial clinic visit in 20 reconstructions (25.3%), despite the presence of two drains. While not the focus of this study, early intervention and fluid aspiration potentially contributed to preventing additional procedures and hospital costs. The value of early intervention in this manner certainly deserves more rigorous clinical investigation.

Bacterial Culture of Drained Fluid

The ability to drain periprosthetic fluid with ease not only permits treatment of postoperative seroma, but also allows aspirated fluid to be sent for culture. While the ability to use the integrated drain of the AlloX2 TE for periprosthetic washouts, and thus, successfully treating select patients with periprosthetic infections without surgical intervention have been previously reported,[7,18,19] the value of having knowledge of the microbiological makeup of the periprosthetic fluid in an asymptomatic patient became evident in a patient who went on to develop surgical site infection. Having knowledge of the presence of *Actinomyces neuii* permitted initiation of targeted antibiotic therapy without delay, thus, avoiding a trial with broad-spectrum antibiotics and permitting salvage of the device without surgical intervention. The advantage of being able to identify the pathogen was also commented on by Fairchild et al, who following early detection and treatment of methicillin-resistant *Staphylococcus aureus* via intravenous and periprosthetic washout with vancomycin were able to salvage the TE without surgical intervention.[19]

Utility of Antibiotic Treatment in Culture-positive Fluid

It is noteworthy that antibiotic therapy was not initiated for positive bacterial cultures in the absence of clinical signs of infection; and indeed, only two of six patients with positive cultures developed infections in this study. This suggests that culture positivity of seroma fluid does not mandate initiation of antibiotic therapy. Given the rise in antibiotic resistance, it is prudent to be diligent about the initiation of antimicrobial therapy.[20] The knowledge of culture results, however, permits initiation of targeted antimicrobial therapy once clinical signs and symptoms of infection do develop, rather than broad-spectrum therapy. In this study, we adhered to this concept and closely observed asymptomatic patients with positive culture findings. The information regarding bacterial culture speciation and sensitivities was readily available, thus, providing a lead-time advantage for targeted antibiotic therapy. Successful implementation of this concept is illustrated in the case of a 39-year-old patient with *Actinomyces neuii* infection.

Table 3. Culture Results and Treatment of Surgical Site Infection

Patient ID	Age	Body Mass Index	Uni- versus Bilateral Reconstruction	Expander Type	Fluid/Seroma Culture Result	Clinical Infection	Surgical Treatment
1	64	29	Unilateral	Textured	*Staphylococcus, coagulase negative*	No	No
2	39	24	Bilateral	Textured	*Actinomyces neuii*	Yes	No
3	54	28	Unilateral	Textured	*Enterobacter cloacae*	No	No
4	42	21	Unilateral	Smooth	*Staphylococcus aureus*	Yes	Washout and TE exchange
5	57	22	Bilateral	Smooth	*Abiotropa spp.*	No	No
6	50	31	Unilateral	Smooth	*Staphylococcus, coagulase negative*	No	No

Clinical Scenarios that Mandate Operative Intervention

It is important to mention that surgical treatment for postoperative complications, including infection, was still necessary in several patients in this study. This highlights that, independent of seroma formation and positive fluid cultures, clinical scenarios exist that mandate surgical intervention. One such scenario is the development of mastectomy skin necrosis following prepectoral device insertion. This represents a shift in management of postoperative complications, as nonoperative treatment of mastectomy skin necrosis, while an option in submuscular reconstruction is not a viable option in prepectoral reconstruction. This is an important characteristic of prepectoral breast reconstruction, which, while being the least invasive modality of implant-based reconstruction, is also the least forgiving in the setting of ischemic complications and delayed wound healing.

Limitations

We concede that the limitations of the present study include its retrospective study design, relatively small number of patients, and inclusion of cases of prepectoral reconstruction only. However, our findings can be regarded as a starting point for more rigorous analysis investigating the value of routine aspiration of periprosthetic fluid and microbiological analysis. Although we may not be able to extrapolate our findings to dual-plane subpectoral or total submuscular breast reconstruction (because it pertains to the rate of postoperative seroma formation or infection), the ability of being able to access the periprosthetic space via the integrated drain port of the AlloX2 TE certainly holds promise to be advantageous in those instances as well. Future studies are certainly warranted to demonstrate the role of such interventions.

Arash Momeni, MD, FACS
Division of Plastic and Reconstructive Surgery
Stanford University School of Medicine
770 Welch Road, Suite 400
Palo Alto, CA 94304
E-mail: amomeni@stanford.edu

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