

# Toward Drainless Breast Reconstruction: A Pilot Study

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**Background:** Implant-based breast reconstruction with immediate tissue expander placement is the predominant form of breast reconstruction in the United States. Closed-suction drains are frequently employed to minimize seroma accumulation, although they carry the risk of serving as a port of entry for bacteria, posing a concern in the presence of implanted materials such as breast implants or acellular dermal matrix. Introduction of a dual-port tissue expander designed to facilitate the collection and removal of seroma fluid provides a new way of performing breast reconstruction without external drains.

**Methods:** We conducted a pilot study using the AlloX2 dual-port expander on five consecutive patients to demonstrate feasibility of this approach at Cedars-Sinai Medical Center by the two senior authors (E.R. and D.K.).

**Results:** Patients averaged seven clinic visits before they were ready for expander exchange, totaling a mean of 137.5 days. Patients averaged 1.9 clinic visits before output was less than 40cm<sup>3</sup> (1.6 for right breasts and 2.2 for left breasts), with two of the patients never reaching that output. There was one complication; a single patient had unilateral flap necrosis and implant exposure due to excessively large breasts and thin skin flaps, necessitating expander removal and latissimus flap reconstruction. The other four patients underwent successful implant reconstruction.

**Conclusions:** This pilot study demonstrates the feasibility of breast reconstruction without external drains using a dual-port expander with built-in seroma reservoir. From these results, it is apparent that dual-port tissue expanders with built-in seroma reservoir offer a safe and effective way to perform breast reconstruction without drains in appropriately selected patients. A larger prospective cohort will be needed to definitively demonstrate lower infection and reconstructive failure rates. (*Plast Reconstr Surg Glob Open* 2022;10:e4560; doi: [10.1097/GOX.0000000000004560](https://doi.org/10.1097/GOX.0000000000004560); Published online 17 October 2022.)

## INTRODUCTION

With a steady annual increase in breast reconstruction procedures,<sup>1,2</sup> surgeons are always seeking innovative ways to improve outcomes, as measured by decreased complications, lower revision rates, and higher patient satisfaction. Although there are advantages and disadvantages with every approach to breast reconstruction, a common method employed in implant-based breast reconstruction involves two stages: initial placement of a saline-filled tissue expander, which is followed sometime later by replacement with a permanent prosthetic device.<sup>3</sup> This technique is often chosen for its technical simplicity, short operative

time, and reduction in donor site morbidity associated with autologous tissue reconstructions. With any type of breast reconstruction, closed-suction drains are commonly employed to minimize the risk of fluid collection and seromas, and to simultaneously allow for tissue opposition during healing. Despite the benefits of drain use, there is an established association between drains and infection.<sup>3-5</sup> Infections translate to higher rates of explantation and reoperation. Furthermore, surveyed patients report drains as a significant nuisance following breast surgery.<sup>4</sup> Safely performing breast expansion without this potential source of infection and patient dissatisfaction would serve as a significant step toward improving breast reconstruction.

Ziedler et al reported their experience in 40 patients with a new dual-port tissue expander by Sientra, the AlloX2.<sup>6</sup> This innovative expander has an injection zone with two ports: the first for tissue expansion, and a second port that provides access to a sump built into the expander for collection of periprosthetic fluid (Fig. 1). The authors report that at 6 months of follow-up without significant complications, this new expander presented a safe alternative to conventional tissue expanders. However, despite the second “internal drain,” the authors elected to use external

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close-suction drains until fluid evacuation was less than 20 to 30 cm<sup>3</sup> per 48 hours. The innovative design of this expander has been identified by other groups, proving the utility of this device.<sup>7,8</sup> Expanding upon the Ziedler study, Franck et al utilized dual-port expanders, comparing a cohort with and without drains to show the feasibility of the technique, but did not have patient-reported outcomes.<sup>9</sup>

In an effort to demonstrate the feasibility of avoiding drains with this new type of tissue expander, along with an emphasis on patient satisfaction, we conducted a pilot study with five consecutive patients. Each underwent bilateral mastectomies with immediate dual-lumen tissue expander placement and removal of suction drains before discharge from the hospital on postoperative day 1. Our results support the conclusion that the AlloX2 tissue expanders can be used safely without prolonged external drain usage.

## METHODS

Institutional review board and Cancer Institute Protocol Review and Monitoring Committee (PRMC) approval were obtained to recruit five consecutive patients for this study. All nonsmoking women undergoing bilateral mastectomy for cancer or cancer prevention were screened for participation in this study. Patients with BMI less than 30 kg per m<sup>2</sup> who elected for subpectoral-implant-based reconstruction were offered participation. Unilateral mastectomy patients, current smokers, patients with bleeding dyscrasias or clotting disorders, those undergoing complete axillary lymph node dissection, those with BMI greater than 29, those with history of prior breast radiation or expected need for post-mastectomy radiation, and those with stage IV or unresectable disease were excluded. The theoretical risks (namely undrained seromas) and benefits (eg, less

## Takeaways

**Question:** Although external drains serve as a mainstay of prosthetic-based breast reconstruction despite the known associated complications, is breast reconstruction via a dual port expander with built-in seroma evacuation port a feasible alternative to eliminate external drains at discharge?

**Findings:** Drainless breast reconstruction is safe and feasible with dual-port tissue expanders with built-in seroma evacuation ports with high patient satisfaction scores.

**Meaning:** Drainless breast reconstruction should be offered to select patients to reduce the need for external drains, effectively reducing the complications associated with them.

drain-related discomfort, possible lower infection risk) of drainless implant reconstruction were discussed as part of the informed consent process.

Following each mastectomy, a standard subpectoral pocket was developed and an AlloX2 expander of matching base width was sutured to the chest wall using the incorporated suture tabs. Fenestrated acellular dermal matrix (ADM, either Flex HD Pliable, MTF Biologics, Edison, N.J. or AlloDerm, Allergan Inc., Santa Barbara, Calif.) was used in an off-label fashion to envelop the portion of the expander not covered by pectoralis major muscle. The ADM was sutured from the lower lateral edge of the pectoralis major muscle to the chest wall with interrupted absorbable suture. A temporary single drain was placed in each subcutaneous pocket (to gauge the quantity and nature of fluid accumulation for the first 12 hours postoperative). A standard layered absorbable-suture



**Fig. 1.** ALLOX2 dual-port expander. Animation showing aspiration and expansion ports. Images used with permission of Sientra, Inc.

**Table 1. Patient Demographics**

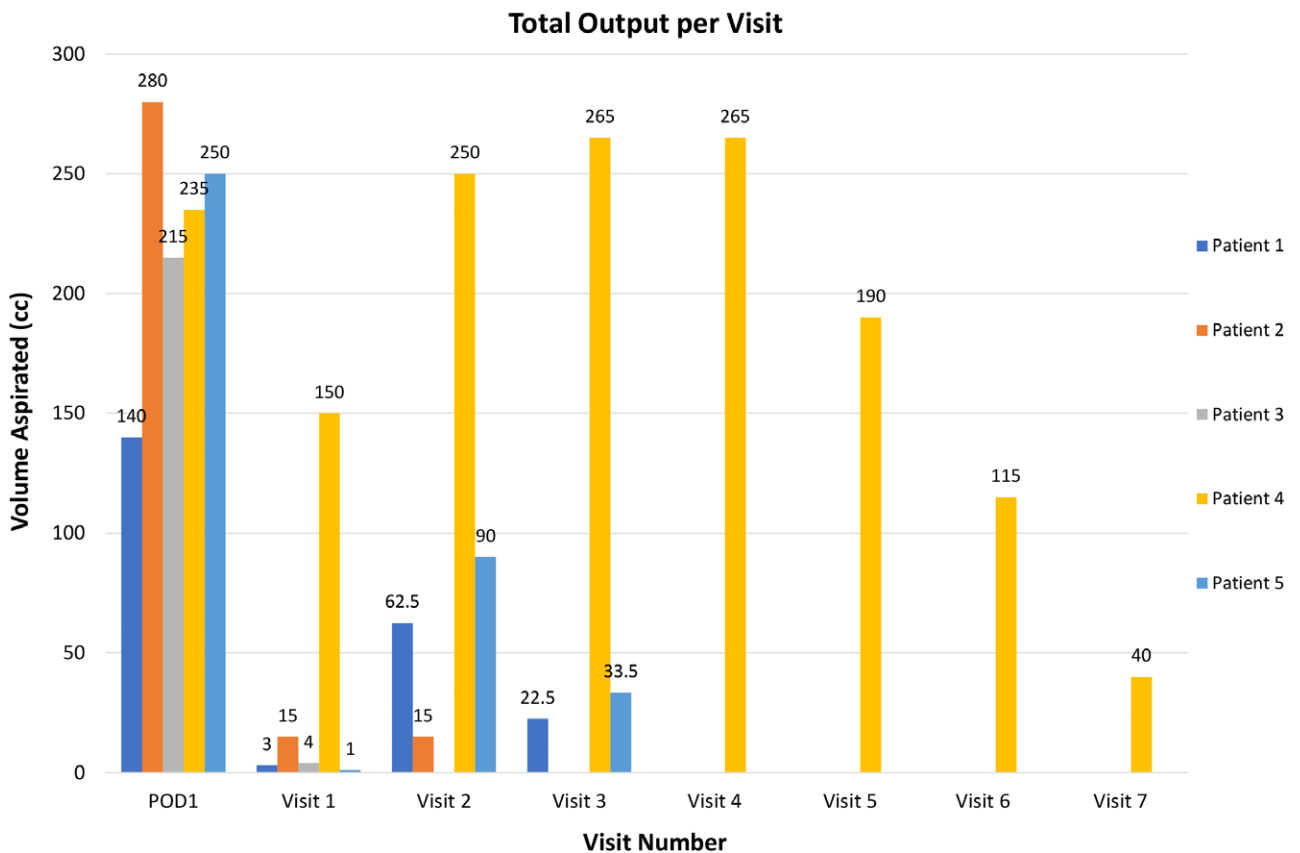
Patient	Age	BMI (kg/m <sup>2</sup> )	Mastectomy Weight (g)		Number of Evacuation Visits	Number of In-clinic Expansions	Final Implant Volume (cm <sup>3</sup> )	Major Complications
			Right	Left				
1	62	21.5	447	440	3	5	R: 445 L: 405	None
2	47	23.5	382	528	2	2	R: 485 L: 485	None
3	55	18.3	154	116	1	4	R: 240 L: 240	None
4	69	23.6	1221	962	7	5	R: 270 L: 540	Mastectomy flap necrosis
5	53	24.9	266	208	2	5	R: 190 L: 220	None
Average	57.2	22.4	494	450.8	3	4.2	-	-

skin closure was performed. The patients were admitted for overnight observation, and the external drain was removed before discharge from the hospital on postoperative day 1. Patients were initially seen twice weekly for aspiration from the seroma port. Once output reached a manageable level (<40 cm<sup>3</sup> per visit), visits became weekly, corresponding with tissue expansion, which started two weeks postoperatively. Seroma port access and tissue expansion were both performed using sterile technique. The special finder magnets provided by the manufacturer allowed the surgeon to locate and access each port unambiguously.

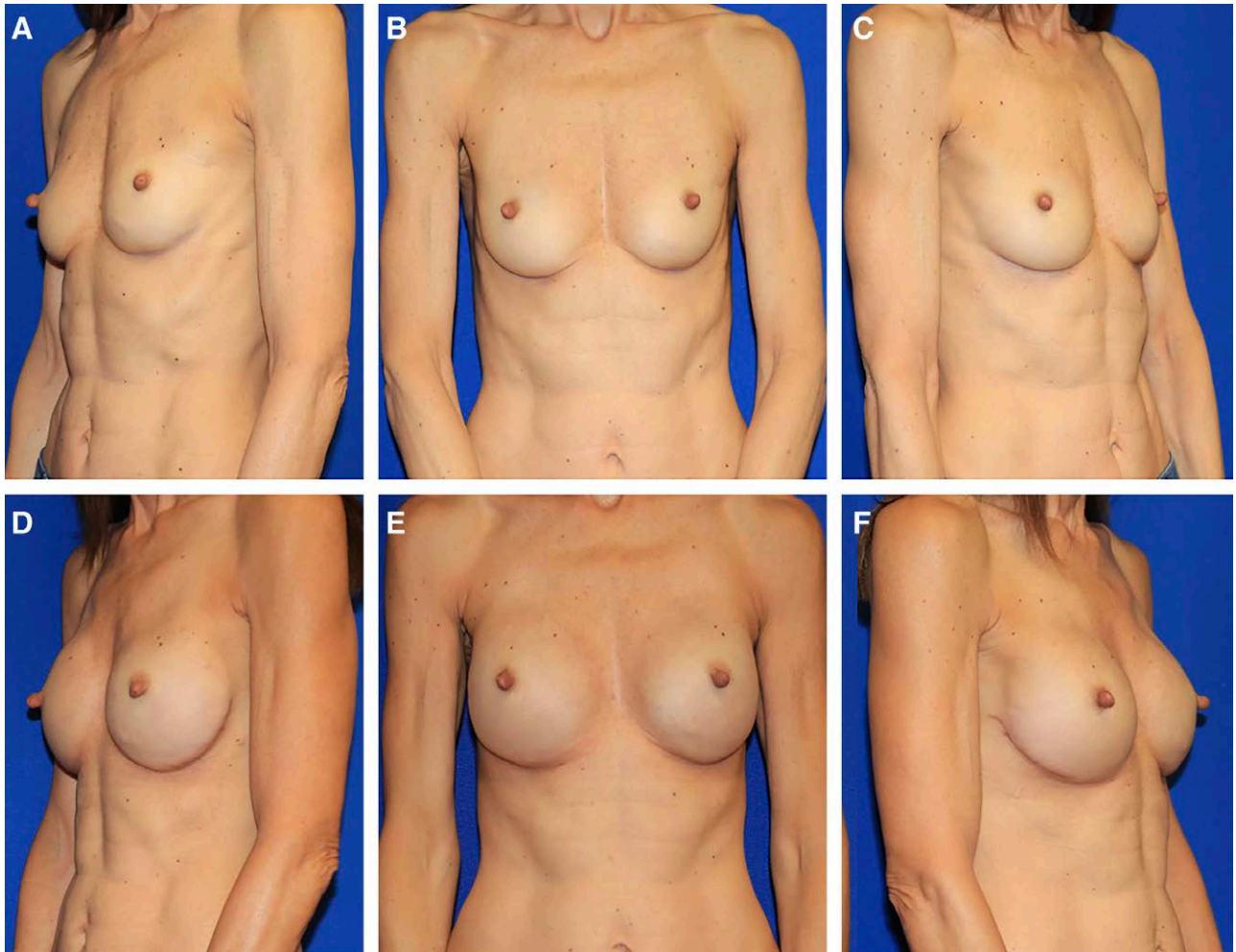
Patients were administered early (before mastectomy) and late (at first visit after expander removal) surveys to assess attitudes about both study participation and overall satisfaction with the reconstruction. Patients were queried regarding satisfaction with their choice of reconstruction, likelihood of recommending drainless expanders, how informed they felt, and how much discomfort they experienced with expansion and fluid removal.

**RESULTS**

Five consecutive patients underwent two-staged breast reconstruction using AlloX2 expanders (Table 1). The



**Fig. 2.** Seroma volume removed per patient per visit. Range of volumes (maximum and minimum) removed per breast shown at the top of each bar.



**Fig. 3.** Patient 3 shown before mastectomy (A-C) and 2 months after replacement of expander with a permanent silicone gel implant (D-F).

average age of participants was 57.2 years (range 47–64), with an average BMI of 22.4 kg/m<sup>2</sup> (range 18.3–24.9). All patients underwent bilateral mastectomies, with three additionally having unilateral axillary sentinel lymph node biopsies. The average breast specimen weight was 472 g (range 208–1221). The average number of clinic encounters until patients reached less than 40 cm<sup>3</sup> of aspirate from each breast was three (range 1–7) (Fig. 2). Four patients underwent second-stage reconstruction with silicone gel implants without incidence (Fig. 3). One patient

developed unilateral mastectomy skin flap necrosis and required latissimus flap reconstruction. Because one of her drainless expanders was removed at the time of skin flap debridement, this patient was withdrawn from the study. All patients have undergone successful second stage reconstruction without other complications.

Responses to these surveys remained consistent during the early and late postoperative periods (Table 2). Importantly, patients felt their discomfort with seroma aspiration was less than expected.

**Table 2. Patient Pre- and Poststudy Survey Results**

Question	Average Prereconstruction Score (Anticipated)	Average Postreconstruction Score
Knowing what I know today, I would definitely choose to have breast reconstruction.	5 (5–5)*	4.25 (3–5)
Knowing what I know today, I would definitely choose to have the type of reconstruction I had.	4.25 (3–5)*	4.5 (3–5)
I would recommend the type of reconstruction procedure that I had to a friend.	4.25 (3–5)*	4.5 (3–5)
I felt that I received sufficient information about my reconstruction options to make an informed choice.	4.75 (3–5)	4.75 (3–5)
The discomfort associated with tissue expansion was:	2.75* (1–5)	3.5 (2–5)
The discomfort associated with seroma aspiration was:	4* (3–5)	5 (5–5)

Data reported as average (with range shown in parentheses). Questions 1 to 4 used a Likert scale from 1 to 5 (1 = strongly disagree, 3 = neither agree nor disagree, and 5 = strongly agree). Questions 5 and 6 used a Likert Scale from 1 to 5 (1 = much more than I expected, 3 = about what I expected, 5 = much less than I expected). Questions marked (\*) reflect expectations, since these were obtained before surgery.

## DISCUSSION

This prospective study of five consecutive patients shows that drainless, two-staged breast reconstruction with the use of dual-port expanders is safe and feasible. Patients in this study averaged three visits before output from the port was less than 40 cm<sup>3</sup> from each breast. One patient experienced mastectomy skin flap necrosis, due at least in part to her very large breast size (the specimens averaged more than 1000 g/breast) and thin skin flaps. Use of expanders or implants in any breast reconstruction larger than 1000 g is fraught with higher risk of complications. Review of the literature supports this assertion. Yalanis et al reported their results on 253 breast reconstructions, in which mastectomy weights of greater than 500 g were associated with a 10 times higher rate of skin necrosis and 18 times higher when the mass of resected tissue was greater than 1000 g.<sup>10</sup> A second study showed that mastectomy specimens greater than 500 gm are significantly associated with all categories of complications, including seroma formation and skin necrosis.<sup>11,12</sup> Consistent with this finding, the affected patient had very high fluid accumulation volumes (Fig. 1). Typically, in our practice, individuals with large breasts are only offered tissue expanders if they are willing to undergo removal of excess skin to reduce the size of the remnant pocket. The failure to screen out larger-breasted patients was one flaw of our study design. Fortunately, the patient withdrawn from the study was able to undergo successful reconstruction with implants after skin reduction and a latissimus flap to correct the irregular envelope on the affected side.

Patient's survey responses captured overall satisfaction with the process. All patients answered that they would choose drainless expansion again based on their experience, and a majority would "strongly" recommend this approach to a friend (n = 4). Patients also felt that the aspiration induced much less discomfort than they anticipated.

Drains are widely used in two-staged breast reconstruction, primarily to prevent seroma formation. A review conducted by the American Society of Plastic Surgeons and Canadian Society of Plastic Surgery on breast reconstruction practices found that all surveyed surgeons placed drains at the time of surgery; 50.3% placed one drain, 48.3% placed two drains, and 1.3% placed more than two drains.<sup>13</sup> Although the pathophysiology of what causes seroma accumulation is not well understood, drains prevent potentially morbid fluid buildup.<sup>5,14-16</sup> In some cases, drains may not be needed due to the body's innate ability to reabsorb excess extracellular fluid, but disrupted vascularity and damaged lymphatics are thought to play a prominent role in the setting of a recent mastectomy, causing leakage and preventing the body from handling the excess fluid.<sup>14</sup> The aim of drain placement is to evacuate excess fluid, promote tissue opposition, and minimize the opportunity for static fluid to become infected. Undrained fluid can also make tissue expansion more challenging due to the induced changes in breast volume and turgor. Furthermore, seromas can cause asymmetry and prevent an accurate estimation of expander volume, which adds uncertainty to permanent implant selection.

Despite the perceived benefits of drains, external suction appliances have been shown to increase various complications in breast reconstruction.<sup>5</sup> The most studied complication is the increased incidence of infection. External drains provide a direct path for skin flora and environmental pathogens to enter the breast pocket where the expander resides. Prostheses are particularly susceptible to surface colonization and implant-associated infection when drains are in contact with those devices.<sup>17</sup> Increased rates of infection lead to significant morbidity, including hospitalization for antibiotic treatment, implant removal, additional reconstructive procedures, and the potential for sepsis.<sup>2,3,18</sup> The ramifications of additional procedures (ie, explantation) to manage more severe infections include delays in reconstruction and adjuvant cancer therapies.<sup>18</sup> Patients report significant hinderances that drains pose during their postoperative course, citing discomfort in carrying out daily activities, the need for additional outpatient clinic visits and sometimes prolonged postoperative hospitalization for pain management.<sup>4</sup>

ADM use has gained popularity in breast reconstruction since its introduction for soft tissue reconstruction, as it provides a simple way to create a form-fitting pocket for implant positioning and coverage, whether prepectoral, subpectoral, or dual plane. Capsular contracture rates have been reported to decrease when ADM is used for prepectoral reconstructions.<sup>19,20</sup> Despite the popularity of ADMs in breast reconstruction, as of this writing, the FDA has not approved any ADM for use specifically in breast implant coverage. Surgeons who use ADM with the device described in this study (either in a subpectoral or prepectoral plane) often advocate for creating more fenestrations in the ADM overlying the openings in the aspiration reservoir to optimize contact with seroma collecting in the dependent portion of the breast and thus prevent fluid buildup (unpublished data).

Notwithstanding the observed and theoretical benefits of ADM use, studies have shown that there are also disadvantages, such as a greater degree of seroma formation. In one study of 415 implant-based reconstructions, Chun et al found that ADM use led to increased rates of seroma and infection compared with reconstructions that did not utilize ADM.<sup>21</sup> There was also a higher rate of native breast skin flap necrosis in the ADM group.

Small pilot studies, by nature, have limitations. Statistical conclusions about equivalence to standard-of-care treatments among a diverse patient population cannot be made. The intent of the authors in this study was to demonstrate that early removal of drains did not lead to an unacceptably high reconstructive failure rate. The single reconstructive failure was demonstrably related to the use of expanders in a large-breasted patient without reducing the skin envelope. Lessons learned in this pilot study have allowed the authors to design a larger randomized control trial (with modified inclusion criteria) in which drain use will be eliminated.

## CONCLUSIONS

We report a prospective pilot study of five patients undergoing bilateral mastectomy and immediate

two-staged reconstruction with a unique seroma-collecting dual-port expander without the use of external drains beyond the period of hospitalization. The results support the use of these devices to achieve expansion without prolonged drain use in select patients. A larger cohort is needed to study how drainless tissue expansion will affect infection, explantation, and reoperation rates.

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