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Breast

The Effect of Early Cultures and Dual-port Expanders on Two-stage, Prepectoral Breast Reconstruction: The 25/25 Study

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Background: Two-stage tissue expander to implant surgery remains the predominant technique for breast reconstruction. Unfortunately, there is a high incidence of reconstruction failure which portends a financial and emotional burden. Most failures are related to postmastectomy skin flap necrosis and infection. Recently, a dual-port tissue expander was introduced to the market, and the authors hypothesize that early cultures from the peri-implant fluid will guide antibiotic treatment and decrease reconstruction failure.

Methods: This is a cohort study of 50 consecutive patients treated for breast cancer or genetic susceptibility via a two-stage, prepectoral technique. The first 25 patients (46 breasts) were treated with a variety of tissue expanders, and the subsequent 25 patients (47 breasts) received a dual-port expander. Routine cultures from the drain port were taken from the dual-port group at the second postoperative visit, and cultures were taken in the control group only when signs of infection were present. All other procedures and interventions were similar.

Results: Fifty patients, totaling 93 breasts, completed the study with a mean follow-up of 145 days. There were no statistically significant demographic or pathologic differences between groups. Fifteen tissue expanders were explanted in the control group and five in the dual-port cohort (32.6% versus 10.6%, $P = 0.012$). All bacteria in the control group failures were either methicillin-resistant *Staphylococcus aureus* or *Staphylococcus epidermidis*, whereas failures in the dual-port group varied.

Conclusion: Treatment of routine, early cultures from a dual-port expander led to a statistically significant decrease in tissue expander explantation. *(Plast Reconstr Surg Glob Open 2024; 11:e5507; doi: 10.1097/GOX.0000000000005507; Published online 8 January 2024.)*

INTRODUCTION

Immediate, two-stage tissue expander placement constituted a majority of the 138,000 breast reconstructions performed in the United States in 2022.[1] Reconstruction failure remains one of the most morbid complications and portends a financial and emotional burden to patients and the healthcare industry. A majority of failures are related to postmastectomy skin flap necrosis and infection,[2] and most infections develop between the initial surgery and implant exchange.[3] Rates of tissue expander infection vary between 2% and 28%, and risk factors of preoperative radiation, obesity, and diabetes are well documented.[2,4–8]

A shift in reconstruction has occurred over the past decade with an estimated half of two-stage reconstructions now performed in the prepectoral plane.[9] The benefits of prepectoral reconstruction are less pain, early recovery, minimal hyperanimation deformity and preservation of pectoralis strength.[10,11] However, prepectoral reconstructions are associated with longer drain times and increased seroma rates.[12,13] In addition, prepectoral reconstruction generally utilizes larger pieces of acellular dermal matrix, and the size and cost of the matrix has come under scrutiny. A study by Kong et al determined the volume of dermal matrix correlated directly with increased drain times and complications.[14] No matter the technique, dermal matrices have been associated with an increase in seroma formation,

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infection, and tissue expander failure, although results are controversial.[7,15–17]

Failure in two-stage breast reconstruction is a significant burden to the patient and the healthcare industry. A survey of breast cancer patients that had or had not undergone reconstruction reported significantly higher out-of-pocket costs and financial stress in reconstructed patients.[18] Complications during breast reconstruction add to the burden. Patients undergoing a second attempt after failure have higher complication rates and repeated failures.[19] Failed expander patients are often reconstructed with autologous tissue at additional cost and morbidity.[20] The hospital system and insurance industry share in the hardship. Yan et al calculated an increase in reconstruction costs of 56% for expander infections and 77% for explanted devices.[21]

Interventions to decrease complications in two-stage reconstruction include the use of intraoperative antibiotic beads,[22] improvements in antiseptic lavage,[23] the use of synthetic meshes,[24] and skin flap perfusion imaging. Recently, the Food and Drug Administration approved a dual-port tissue expander for use in breast reconstruction. The device has an internal drain that can be accessed via transcutaneous needle insertion allowing evacuation of serous fluid and aseptic sampling (Fig. 1). The authors hypothesized that the use of a dual-port expander with routine aspirate cultures would guide early antibiotic treatment and decrease reconstruction failure.

METHODS

This is a study of 50 consecutive patients who underwent skin-sparing or nipple-sparing mastectomies followed by immediate two-stage, prepectoral reconstruction. Patients were treated between November 2019 and September 2022 in a safety-net hospital system in Rapid City, South Dakota. Minor complications were defined as those not requiring operative intervention, whereas major complications required a return to the operating room. Infection was defined as a warm, erythematous breast or culture-positive fluid around the device. Reconstruction failure was defined as explantation of the expander without immediate replacement.

Fig. 1. Dual-port tissue expander with the blue magnet centered over the drain port.

Takeaways

Question: Does the treatment of routine, early cultures from a dual-port expander lead to a decrease in rate of infection, tissue expander explantation, skin flap necrosis, or seroma formation?

Findings: In the control group, we noted 15 of 46 tissue expanders requiring removal, and in the dual-port group, we found five of 47 requiring explantation for a *P* value of 0.012.

Meaning: Antibiotic administration of early culture results from a dual-port expander led to a significant decrease in tissue expander breast reconstruction failure.

The first 25 patients (46 breasts) underwent tissue expander-based reconstruction with a variety of dermal matrices and tissue expander manufacturers (control group). The second 25 patients (47 breasts) were prospectively tallied and treated with a variety of dermal matrices and a dual-port AlloX2 device (Sientra, Irvine, Calif.; dual-port group).

Reconstructions were performed with acellular dermal matrix measuring 16 cm × 20 cm. The matrix was hydrated, fenestrated, and then secured around the device using interrupted 2-0 Vicryl suture. The expanders were sutured to the chest wall with 2-0 Vicryl at the suture tabs. All expanders were filled with saline until the pocket was protuberant but not taught under the guidance of indocyanine imaging (Spy, Stryker Corp., Kalamazoo, Mich.). A single 15F drain (Ethicon, Cincinnati, Ohio) was placed in all breast pockets. Patients received preoperative vancomycin (or clindamycin based on allergy) and 7 days of bactrim or doxycycline as oral postoperative antibiotics. Antibiotic choice was guided by the antibiogram at our institution.

Patients were followed up in the clinic on a weekly basis for the first month and during expander fills thereafter. Patients were assessed for skin flap necrosis, poor wound healing, serous fluid accumulation, and signs of local or systemic infection. In the first 25 patients, fluid was aspirated adjacent to the fill port or at reoperation if signs of infection were present. In the dual-port group, routine cultures from the drain port were aspirated at the second week independent of signs of infection. Drains were removed based on the axiom of drainage less than 30 mL/d for successive days.

Postoperative infections were diagnosed by clinical signs of a warm, erythematous breast or by positive cultures from the implant pocket. For the control group, antibiotics were initiated at the first sign of overt infection based on the Viola et al protocol of minocycline, rifampin, and ciprofloxacin.[25] For patients in the dual-port group, antibiotics were initiated if the initial culture was positive. Oral antibiotics were tailored to the specific bacteria and continued for fourteen days. If overt infection presented in this group, the Viola et al protocol was started at that time.

Postoperative radiation therapy was initiated after patients reached final fill volume, and second-stage reconstruction was delayed until radiation fibrosis improved. Adjuvant chemotherapy, when indicated, delayed second-stage reconstruction until white counts were normalized. Patients were followed up for the study up to their second-stage reconstruction or failure.

Information was pooled from clinic notes, operative notes, pathology records, and oncology summaries. Data were queried with Microsoft Excel (Microsoft Corporation, Redmond, Wash.) and statistics analyzed using StatPlus software (AnalystSoft, Alexandria, Va.). A two-tailed Student *t* test set for a type I error of 5% (alpha = 0.05) was used to determine significance between normal data, and a Fisher exact test and chi-square set for a type I error of 5% was used to calculate significance between nominal data.

RESULTS

All 50 patients completed the study from first stage reconstruction to either expander removal or implant exchange with an average follow-up of 145 days (control 146.2 d, dual-port 143.3 d, *P* value = 0.93). Mean patient age was 49.4 years (range, 27–81) with no difference between groups (control 50.3, dual-port 48.6, *P* value = 0.57). The average BMI was 28.0 with similar numbers between cohorts (control 27.8, dual-port 28.2, *P* value = 0.74). Other comorbidities were matched between groups (Table 1).

We found no difference in mastectomy weight, mastectomy type, or cancer stage between groups. More patients underwent postoperative radiation in the dual-port group, but there was a trend toward more chemotherapy treatment in the control group. Only 16.7% of chemotherapy patients went on to failure in each group.

Several dermal matrices were used, with a majority of reconstructions performed with Cortiva (RTI Surgical, Alachua, Fla.) in both groups (73.7% control and 83.8% dual-port group, *P* = 0.62). Alloderm (AbbVie Incorporated, Chicago, Ill.) was used in six breasts in the control and two in the dual-port, and DermaCell (LifeNet Health, Virginia Beach, Va.) in four breasts in each group. Of the failures, 10 of 15 in the control group and three of five in the dual-port cohort were Cortiva reconstructions. There was no correlation between the matrix used and infection or reconstruction failure (*P* = 0.80).

Most patients in the control group were reconstructed with a CPX4 expander (Mentor Corp., Santa Barbara, Calif.), although one patient received a single-port Natrelle device (Allergan Inc., Irvine, Calif.) and another a Dermaspan expander (Surgical Specialty Products, Victor, Mont.). All expanders were textured. These were on average filled to 275.0 mL or 47.2% of their ascribed fill volume. All patients in the dual-port group were reconstructed with a textured AlloX2 expander with an average fill of 165.9 mL or 32.5% of the total volume (*P* value = 0.0019). There was no difference in implant volumes placed at the second stage (control 592.1 mL, dual-port 564.5 mL, *P* value = 0.45), indwelling drain time (21.3 versus 20.7 days), or duration to second-stage surgery (146.2 versus 143.3 days) (Table 2).

Complications were similar in each group. We noted more infections (11 dual-port and eight control groups, *P* = 0.56) and seromas (nine dual-port and six control groups, *P* = 0.36) in the AlloX2 group, but less major infections requiring return to the operating room. There was no difference in rates of mastectomy skin flap necrosis and reoperations (excluding expander removal). When comparing patients, we noted a trend toward reduction in reconstructive failure in the dual-port group (three dual-port and eight control group, *P* = 0.17), but a significant decrease when comparing expanders (five dual-port and 15 control group, *P* = 0.012) (Fig. 2).

All patients in the dual-port group had cultures drawn from the drain port at the second week (range, 12–16 days). Patients in the control group had fluid cultures drawn at the time of symptom presentation at an average of 50.1 days postoperative. Ultimate failure and removal of the expander occurred at an average of 67.4 days with no difference between groups (control 69.3 days, dual-port

Table 1. Patient and Oncology Data

	Control	Dual Port	*P*
Patient demographics			
Age (y)	50.3	48.6	0.57
BMI	27.8	28.2	0.74
Tobacco use	4 (16%)	4 (16%)	1.0
Diabetes	3 (12%)	2 (8.0%)	0.94
Chemotherapy	12 (48%)	6 (24%)	0.14
Radiation	6 (24%)	8 (32%)	0.75
Oncology data			
Mastectomy weight, g	542.7	495.7	0.39
Prophylactic	5 (20%)	3 (12%)	0.45
NSM	6 (24%)	11 (44%)	0.20
Cancer stage			0.67
DCIS	2 (8.0%)	2 (8.0%)	
Stage I	10 (40%)	14 (56%)	
Stage II	5 (20%)	5 (20%)	
Stage III	3 (12%)	1 (4.0%)	

BMI, body mass index; DCIS, ductal carcinoma in situ; NSM, nipple sparing mastectomy.

Table 2. Treatment Summary and Complications

	Control	Dual Port	*P*
Treatment data			
Initial expander fill, mL	275.0	165.9	**0.0019**
Drain time, d	21.3	20.7	0.67
Exchange days, d	146.2	140.3	0.93
Final implant volume, mL	592.1	564.0	0.45
Complications			
Infection	8 (32%)	11 (44%)	0.56
Mastectomy flap necrosis	6 (24%)	5 (20%)	0.74
Seroma	6 (24%)	9 (36%)	0.36
Hematoma	1 (4%)	0 (0.0%)	0.32
Reoperation*	5 (20%)	5 (20%)	1.0
Explantation (patients)	8 (32%)	3 (12%)	0.17
Explantation (expanders)	15 (32.6%)	5 (10.6%)	**0.012**

*Reoperations exclude the removal of devices for failure.
Values in boldface are statistically significant.

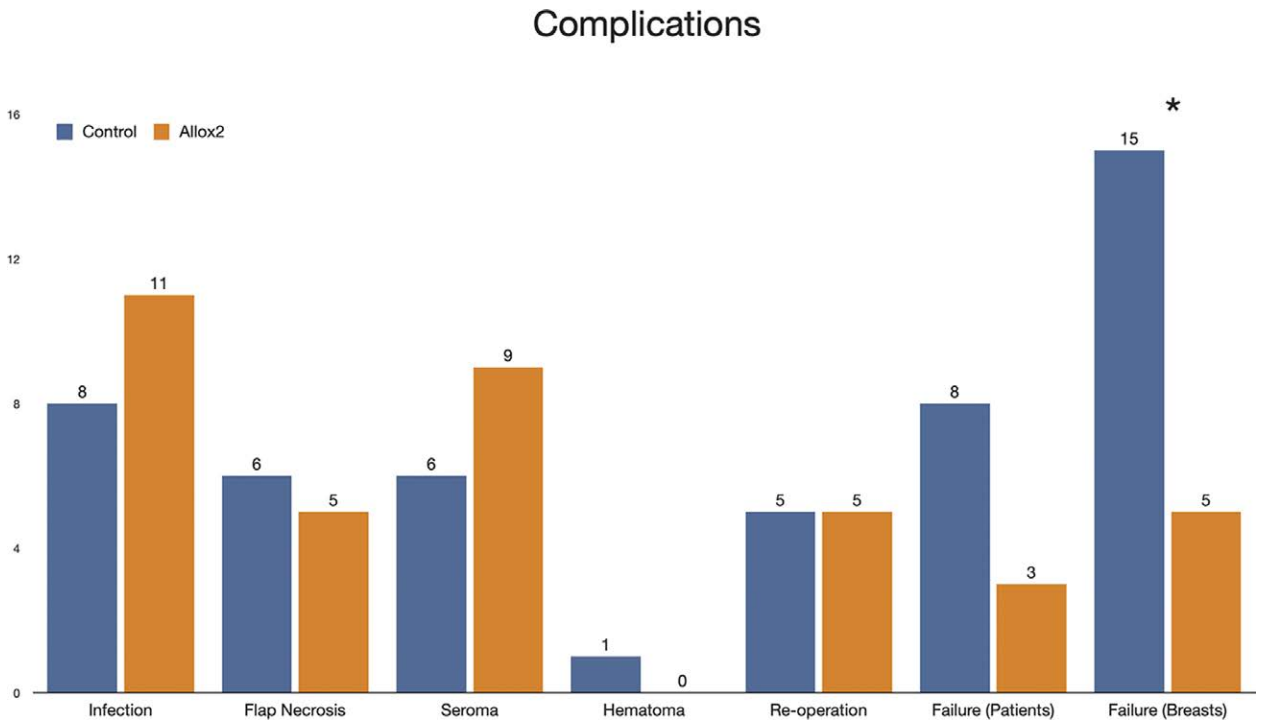

Fig. 2. Complications tallied between the single-port and dual-port groups. *P <0.05.

62.3 days, P value = 0.42). Cultures at the time of presentation or explantation in the control group grew methicillin-resistant *Staphylococcus aureus* (MRSA) in six patients and methicillin-resistant *Staphylococcus epidermidis* (MRSE) in two patients. Reconstruction failures in the dual port grew MRSA, *Pseudomonas aeruginosa*, and *Cutibacterium acnes* (Table 3). Eight patients in the dual-port group had positive cultures that did not progress to reconstruction failure, and a majority of these cultures showed few bacterial colonies (<10).

DISCUSSION

Complications are a common and debilitating problem for patients undergoing immediate, prosthetic based breast reconstruction. The rate of tissue expander infection varies in the literature from 2.0% to 28.0%[2,20,26,27] depending on patient factors, adjuvant treatments, and operative technique. There is the literature supporting increased complications in safety-net hospitals and rural communities attributable to more advanced disease, patient comorbidities, lack of fellowship-trained breast surgeons, and decreased resources.[28–30] The authors noted an unacceptably high 32.0% failure rate and sought change.

Higher intraoperative fill volume is correlated with an increased risk of mastectomy skin flap necrosis and overall complications.[31,32] In this study, the average fill volume in the control group was 275.0 mL, whereas the average in the dual-port group was 165.9 mL. The authors made no concerted effort to change the operative fill between groups, and indocyanine imaging was used in all patients. Of note, the Allox2 device on average has 40 mL more volume than the CPX4 tissue expander (company data), and this accounted for a portion of the lower fill volume. In addition, mastectomy weights were on average 47 g less in the dual-port group. Despite the difference in initial fill, there were similar incidences and severity (SKIN score)[33] of mastectomy skin flap necrosis between cohorts (six versus five patients).

The most common causal agents of tissue expander infections are *S. epidermidis*, *S. aureus,* and Gram-negative rods.[6] *P. aeruginosa* has a 0% to 10% salvage rate in the literature,[25] and Reish et al found a significantly lower salvage rate in patients with MRSA in their review of 1952 breast reconstructions.[26] Viola et al also noted a lower salvage rate in patients with a deep-seated infection versus superficial cellulitis.[25] As a result, most research has turned to prevention of infection rather than treatment, as biofilms are known to be resistant to therapy.[34,35]

Recent articles have described the use of antibiotic carriers within the breast pocket during immediate reconstruction. Kenna et al reported a decrease in tissue

Table 3. Culture Results

Control Failures	Dual-port Failures	Dual-port Nonfailures
MRSA (>50)	MRSA (>50)	*Enterobacter cloacae* (<10)
MRSE (<10)	*Pseudomonas aeruginosa* (<10)	*E. cloacae* (<10)
MRSA (>50)	*Cutibacterium acnes* (<10)	MRSE (<10)
MRSA (>50)		*C. acnes* (<10)
MRSA (>50)		*C. acnes* (<10)
MRSA (>50)		MRSE (<50)
MRSE (>50)		MRSE (<10)
MRSA (>50)		MRSA (<10)

expander loss from 11.9% to 1.5% in 68 patients treated with vancomycin and gentamicin impregnated absorbable beads compared with 67 patients treated with standard triple antibiotic irrigation.[36] Johnstone et al similarly noted a decrease in reconstructive failure from 18% to 6% when patients were implanted with polymethylmethacrylate impregnated with tobramycin and vancomycin.[22] A nonabsorbable product can be problematic in single-stage reconstructions, and the increased cost associated with these products (approximately $1050 at the authors' institution) warrants attention.

Antibiotic lavage has long been a debate in plastic surgery. Betadine was the traditional pocket irrigant of choice, but concerns with the off-label use of 10% Betadine and implant shell integrity caused a shift in practice.[37] Triple antibiotic solution is now the predominant irrigant among plastic surgeons.[38] Studies have shown mixed results in capsular contracture rates with triple antibiotic solution[39] but positive rates of infection prevention, although the heterogeneity of methods is concerning.[40] Chlorhexidine gluconate is a newer pocket irrigant with data supporting decreased overall infections and reconstruction failure in a large trial; however, the authors did note a significant increase in delayed wound healing.[41] Unfortunately, the method of use and dwell times of most pocket irrigations vary by surgeon and often do not meet necessary minimums, causing difficulty in interpreting data.[42–44]

Sampling fluid through the drain port of a dual-port expander is a simple procedure with minimal complications. Fluid was obtainable in all patients, and we experienced no expander deflations. We chose 2 weeks for routine cultures, as our patients were discharged on a one-week course of oral antibiotics, yet another controversial topic.[45–48] The total cost for a body fluid panel which includes Gram stain, aerobic, and anaerobic culture is $11.35 at our institution, considerably less expensive than antibiotic carriers and a 1-L bottle of chlorhexidine gluconate ($1050.00 and $92.82, respectively).

The dual-port tissue expander is new to the market, and there are limited studies comparing the device to single-port expanders. Parmeshwar et al found that use of a dual-port device resulted in a significant decrease in infection from 22.2% to 4.8% ($P = 0.039$) when selecting out prepectoral patients.[49] Conversely, a recent study by Chiang et al found an increase in infections in their dual-port patients; however, there was a significant decrease in the need to return to the operating room for management ($P = 0.01$).[50] Similar to Chiang et al, our study noted an increase in overall infections in the dual-port patients, and we were also able to manage these with fewer returns to the operating room (a decrease in major infections) and overall less expander loss. The discrepancy of infection rates between articles is likely in the definition. Both our study and Chiang et al define infection as overt signs or culture-positive fluid, whereas Parmeshwar et al tallied infections when patients required oral or intravenous antibiotics. In both the previous articles, the incidence of expander loss for major infection was 71.2% and 91.0%; thus, early interventions that prevent a deep-seated infection can prevent ultimate failure.

MRSA and MRSE accounted for nine of the 11 reconstructive failures in this study (81.8%), and all but one showed many bacterial colonies. *S. aureus* is especially virulent with a propensity to form biofilms on implants, and timing to antibiotic treatment is paramount.[34] When sampling early cultures and initiating antibiotics before overt infection, we noted a statistically significant reduction in expander loss. Proactive cultures showed less virulent bacteria with fewer colony counts, and it is postulated that early treatment of circulating bacteria prevented biofilm formation and selection of more aggressive organisms.

Eleven of 25 dual-port patients grew positive cultures (44.0%). Three patients progressed to reconstructive failure on average 62 days after culture, likely due to suppression and not complete eradication of bacteria. Results in the nonfailure, culture-positive patients were three MRSE, two *C. acnes*, two *Enterobacter cloacae*, and one MRSA. All colony counts were rated as few (<10) except one. The presence of *Cutibacterium* and *S. epidermidis* has been positively correlated with the growth of *S. aureus* due to host inflammatory mechanisms and cooperative nutrient harvesting.[51] *C. acnes* is found ubiquitously on the skin and is culture-positive in 14%–41.8% of patients who otherwise have no outward signs of infection following implant-associated surgery.[52] Studies have shown that *C. acnes*, although thought to have low pathogenic potential, causes delayed surgical site infection in the presence of an implant.[53] *C. acnes* also enhances the virulence of other organisms via formation of coproporphyrin III which induces aggregation and formation of biofilms with *S. aureus*.[54] Early detection and management of *C. acnes* species has the potential to prevent late implant failures with coinfection of more aggressive organisms.

This study is limited by the small number of patients, the retrospective nature of the control cohort, and the overall high infection rate in our rural practice. We note a clinically significant decrease (2.5 times) in reconstructive failures in the dual-port group by the patient, although this did not reach statistical significance due to the relatively small sample size (statically significant by breast). The dual-port cohort was also prospectively studied compared with the control group, which may lead to a bias in the technique to actively prevent complications. This could potentially be seen in the lower initial expander fill volume in this group despite the continued use of indocyanine green imaging and intentions not to change any other protocols. The lower fill volume did not lead to a significant decrease in mastectomy skin flap necrosis, but the literature has shown a decrease in total complications with less fill. Finally, the study was initiated because the authors noted a high infection rate in their practice. The reduction in failure may not be as significant in an academic or large, urban center with a lower incidence of complications.

CONCLUSIONS

Antibiotic administration of early culture results from a dual-port expander led to a significant decrease in reconstruction failure. A majority of major infections were

from *Staphylococcus* species, and the bacterial species and colony counts were different in proactive cultures versus retroactive sampling.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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