



# **ORIGINAL ARTICLE**

Breast

# Implant-based Breast Reconstruction Salvage with Negative Pressure Wound Therapy with Instillation: An Evaluation of Outcomes

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**Background:** Implant infection is problematic in breast reconstruction. Traditionally, infected tissue expanders (TE)/implants are removed for several months before replacement, resulting in breast reconstruction delay. Salvage involving device removal, negative pressure wound therapy with instillation and dwell (NPWTi-d) placement, and early staged TE/implant replacement within a few days has been described. The purpose of this study was to compare outcomes of the NPWTi-d salvage pathway with traditional implant removal.

**Methods:** A retrospective review was performed on patients who underwent implant-based reconstruction and developed TE/implant infection/exposure requiring removal. Patients were divided into two groups. Group 1 had TE/implant removal, NPWTi-d placement, and TE/implant replacement 1–4 days later. Group 2 (control) underwent standard TE/implant removal and no NPWTi-d. Reinfection after TE/implant salvage, TE/implant-free days, and time to final reconstruction were assessed.

**Results:** The study included 47 patients (76 TE/implants) in group 1 (13 patients, 16 TE/implants) and group 2 (34 patients, 60 TE/implants). The success rate (no surgical-site infection within 90 days) of implant salvage was 81.3% in group 1. No group 1 patients abandoned completing reconstruction after TE/implant loss versus 38.2% (13 of 34) in group 2 (P = 0.0094). Mean implant-free days was  $2.5 \pm 1.2$  in group 1 versus  $134.6 \pm 78.5$  in group 2 (P = 0.0001). The interval to final implant-based reconstruction was  $69.0 \pm 69.7$  days in group 1 versus  $225.6 \pm 93.6$  days in group 2 (P = 0.0001).

Conclusions: A breast implant salvage pathway with infected device removal, NPWTi-d placement, and early TE/implant replacement was successful in 81.3%. Patients experienced 132 less implant-free days and faster time to final reconstruction. (Plast Reconstr Surg Glob Open 2024; 12:e6116; doi: 10.1097/GOX.0000000000000116; Published online 3 September 2024.)

#### INTRODUCTION

Infection in implant-based breast reconstruction is problematic. Infection in breast reconstruction occurs in up to 22% of patients.<sup>1-7</sup> Patients who experience surgical-site infection (SSI) of their tissue expanders (TEs) or implants often require unplanned office visits and hospital readmission.<sup>8,9</sup> Patients who have an infected TE or

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implant are three times more likely to undergo unplanned reoperations and have higher psychosocial distress, which contribute to worsened postoperative morbidity.<sup>10,11</sup>

Traditionally, infected TEs or implants are removed for several months to allow for clearance for resolution of the infection, clearance of biofilm, and wound maturation before replacement with either an implant or TE. <sup>12-14</sup> This results in a delay of breast reconstruction and a prolonged period of potential asymmetry with no TE or implant on the affected side. <sup>1</sup> After infected device removal, the breast skin pocket may contract and require reexpansion. <sup>15</sup> Hospital-associated costs exceed over \$12,000 when attempting this reconstruction pathway on patients who have previous implant infection. <sup>9</sup> An alternative strategy to manage an infected TE or implant includes conversion to an autologous-based breast reconstruction with or

Disclosure statements are at the end of this article, following the correspondence information.

without implant placement.<sup>10,16,17</sup> However, there is no one consensus as to which reconstruction strategy is preferred following infection of a TE or implant in this patient population. Recently, application of negative pressure wound therapy with instillation and dwell (NPWTi-d) has been used to salvage TEs or breast implants at the time of device removal.<sup>18</sup>

The purpose of this study is a comparative assessment of outcomes in traditional removal of infected implants with a salvage pathway comprising device removal, placement of NPWTi-d, and early staged replacement of a TE or implant within a few days.

#### **METHODS**

Approval for this study was obtained from the institutional review board at Indiana University School of Medicine. A single-center retrospective review was performed for breast cancer patients who underwent implant-based breast reconstruction following mastectomy (2018–2024). Patients who had infection or exposure of a TE or implant requiring removal of the device and minimum 90-day follow-up to assess for SSI and postoperative complications were included in the study.

Patients were divided into two groups. Group 1 (NPWTi-d) was managed with implant removal and placement of NPWTi-d in the breast pocket until clinical improvement, followed by repeat washout and replacement of a TE or implant. Group 2 (control) underwent traditional TE or implant removal and no NPWTi-d, with the intention of leaving the device out for a prolonged

### **Takeaways**

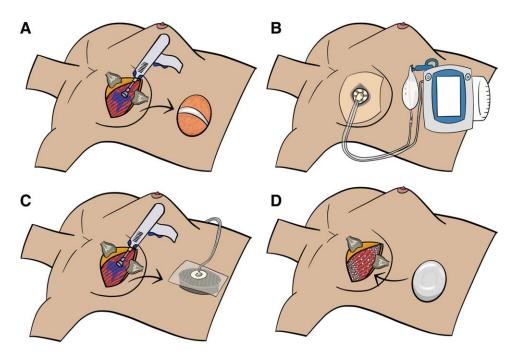
**Question:** How do outcomes of a salvage pathway using negative pressure wound therapy with instillation and dwell, and early staged replacement of a tissue expander/implant compare to traditional removal of infected implants?

**Findings:** Implant salvage success rate was 81.3%. No abandonment of completing reconstruction occurred after salvage versus 38.2% in the control group. Mean implant-free days was  $2.5\pm1.2$  (salvage group) versus  $134.6\pm78.5$  (control group; P=0.0001).

**Meaning:** Patients experienced a salvage rate of 81% and faster time to final reconstruction by 156 days in the salvage pathway compared with the control group managed with standard device removal.

period of weeks to months. Demographic information, medical comorbidities, mastectomy incision type (skinsparing or nipple-sparing), implant plane (prepectoral or subpectoral), and breast cancer treatment were obtained. Outcome variables included postoperative infection resulting in TE/implant loss or hospitalization for intravenous antibiotics, type of breast prosthetic used during salvage, reinfection rate after TE/implant salvage, time interval of being TE/implant free following device removal, and time to final reconstruction. The mean follow-up time was recorded.

The salvage pathway for patients in group 1 involved a two-staged operative approach (Fig. 1). In the first



**Fig. 1.** Application of NPWTi-d for breast implant salvage. Salvage occurs in a two-stage approach. In the first stage, patients undergo removal of the infected tissue expander or breast implant, irrigation of the breast pocket, and debridement of the infected breast capsule (A). An NPWTi-d device is placed and remains until clinical improvement 1–4 days later (B). The second stage included repeat washout (C) and replacement of a TE or implant with absorbable calcium-sulfate antibiotic beads (D).

Table 1. Baseline Characteristics of Patients Who Had Complications after Tissue Expander/Implant Placement for Breast Reconstruction

|                                 | Group 1 (NPWTi-d)<br>(n = 13, 16 TE/Implants) | Group 2 (Control)<br>(n = 34, 60 TE/Implants) | P      |
|---------------------------------|---|---|--------|
| Average age (y)                 | $44.2 \pm 9.3$                                | $50.7 \pm 12.1$                               | 0.0956 |
| Body mass index (kg/m²)         | $33.5 \pm 7.0$                                | $31.6 \pm 6.2$                                | 0.5022 |
| Diabetes                        | 1 (5.9%)                                      | 2 (5.9%)                                      | 1      |
| Current smoker                  | 1 (5.9%)                                      | 4 (11.8%)                                     | 1      |
| Nipple-sparing mastectomy       | 5 (38.4%)                                     | 19 (55.9%)                                    | 0.3412 |
| Skin-sparing mastectomy         | 8 (61.5%)                                     | 15 (44.1%)                                    | 0.3412 |
| Prepectoral                     | 12 (92.3%)                                    | 32 (94.1%)                                    | 1      |
| Subpectoral                     | 1 (7.7%)                                      | 2 (5.9%)                                      | 1      |
| Bilateral                       | 10 (76.9%)                                    | 26 (76.5%)                                    | 1      |
| Acellular dermal matrix or mesh | 12 (92.3%)                                    | 34 (100%)                                     | 0.2766 |
| Unilateral                      | 2 (15.4%)                                     | 8 (23.51.2%)                                  | 1      |
| Neoadjuvant chemotherapy        | 5 (38.5%)                                     | 9 (26.5%)                                     | 0.4861 |
| Adjuvant chemotherapy           | 3 (23.1%)                                     | 10 (29.4%)                                    | 1      |
| Adjuvant radiation              | 4 (30.8%)                                     | 8 (23.5%)                                     | 0.7129 |
| Prior radiation                 | 0 (0%)  | 2 (5.9%)                                      | 1      |

stage, patients underwent removal of the infected TE or implant, extensive debridement of the breast pocket with capsulectomy, complete removal of mesh if present, pulsatile jet lavage with oxychlorosene, and placement of NPWTi-d using oxychlorosene instillation and dwell. 19,20 If the TE or implant was prepectoral and the skin was thin, the anterior capsulectomy was performed with hydrosurgical debridement (Versajet, Smith+Nephew Inc., Fort Worth, Tex.). The patient remained inpatient with the NPWTi-d and broad-spectrum intravenous antibiotics for 1–4 days. Return to the operating room for the second stage of the operation was dependent on clinical improvement (eg, resolving breast erythema, leukocytosis). A second-stage operation was performed comprising removal of the NPWTi-d, repeat washout, and replacement of a TE or implant. Typically, absorbable calciumsulfate antibiotic beads (Stimulan, Biocomposites Ltd, United Kingdom) containing vancomycin 1 g and gentamicin 240 mg are placed at this time.<sup>21</sup> Patients received between 7 and 14 days of oral antibiotics taken postoperatively following the second-stage operation based on culture and sensitivities and attending physician preference.22,23

In the traditional pathway (group 2), patients had removal of the infected TE or implant without NPWTi-d, and the breast pocket was allowed to heal for several months before final implant-based reconstruction or tissue expander placement was attempted. Timing of breast reconstruction following infected TE or implant removal was based on surgeon preference and patient preference, but a minimum of 3 months was allowed before replacement of an implant if staphylococcus or pseudomonas was present. Breast reconstruction salvage using NPWTi-d was performed by two plastic surgeons, whereas the traditional pathway was performed by all four plastic surgeons in this study. Perfusion of mastectomy skin flaps were typically evaluated based on clinical examination following mastectomy, although near infrared laser angiography was used selectively occasionally for direct to implant if perfusion was unclear clinically. A

drain was placed in all patients for postoperative seroma prevention. Drain management included follow-up in the outpatient office and was removed when fluid output was less than 30 mL daily.

All statistical analyses were performed using IBM SPSS Statistics, version 29 (IBM Corporation; Armonk, N.Y.). Categorical variables were analyzed using Fisher exact test. Continuous variables were compared using independent-samples t tests. Two-tailed values of P less than 0.05 were considered statistically significant.

# **RESULTS**

There were 47 patients (76 TE/implants) included in the study. Group 1 included 13 patients (16 TE/ implants), and group 2 had 34 patients (60 TE/ implants; Table 1). The average age in group 1 was  $44.2 \pm 9.3$  years compared with  $50.7 \pm 12.1$  years in group 2 (P = 0.0956). The mean body mass index in group 1 was  $33.5 \pm 7.0$  kg per m<sup>2</sup> compared with  $31.6 \pm 6.2$  kg per  $m^2$  in group 2 (P = 0.5022). There were no differences in the presence of diabetes or active smoking between both groups (P = 1). Mastectomy incision type (skin-sparing or nipple-sparing incision), implant plane (prepectoral or subpectoral placement), and usage of acellular dermal matrix or mesh did not differ between groups (P = 0.2766). The average initial fill of TEs in group 1 was  $291.7 \pm 146.1 \,\mathrm{mL}$  compared with  $246.2 \pm 154.8 \,\mathrm{mL}$  (P = 0.381). Neoadjuvant chemotherapy was given to 38.5% (5 of 13) of group 1 patients compared with 26.5% (9 of 34) of group 2 (P = 0.4816). There were 30.8% (4 of 13) of group 1 who received adjuvant radiation compared with 23.5% (8 of 34) of group 2 patients (P = 0.7129). Adjuvant radiation was administered to patients after developing a TE or implant infection.

Skin necrosis was present in 53.8% (7 of 13) of group 1 compared with 58.8% (20/34) of group 2 patients (P = 1). Infection without skin necrosis occurred 46.2% (6 of 13) in group 1 compared with 41.2% (14 of 34) in group 2 (P = 1; Table 2). The average time interval of

Table 2. Outcomes of Patients Who Had Complications after Tissue Expander/Implant Placement for Breast Reconstruction

| Variables                        | Group 1 (NPWTi-d)<br>(n = 13, 16 TE/Implants) | Group 2 (Control)<br>(n = 34, 60 TE/Implants) | P       |
|----------------------------------|---|---|---------|
| Skin necrosis                    | 7 (53.8%)                                     | 20 (58.8%)                                    | 1       |
| Implant infection                | 6 (46.2%)                                     | 14 (41.2%)                                    | 1       |
| Reinfection rate (90 d)          | 3/16 (18.8%)                                  | 2/60 (3.3%)                                   | 0.0598  |
| Type of prosthetic after salvage |   |   |         |
| TE to TE                         | 8/16 (50%)                                    | 6/60 (20%)                                    | 0.001*  |
| TE to implant                    | 2/16 (12.5%)                                  | 5/60 (8.3%)                                   | 0.6336  |
| TE to no TE/implant              | 0/16 (0%)                                     | 23/60 (38.3%)                                 | 0.0018* |
| Implant to implant               | 6/16 (37.5%)                                  | 0/60 (0%)                                     | _       |
| Type of final reconstruction     |   |   |         |
| Implant                          | 12 (92.3%)                                    | 11 (32.4%)                                    | 0.0003  |
| DIEP                             | 1 (7.7%)                                      | 10 (29.4%)                                    | 0.1467  |
| Flat closure                     | 0 (0%)  | 13 (38.2%)                                    | 0.0094  |
| Time implant-free (d)            | 2.5 ± 1.2 d                                   | 134.6 ± 78.5 d                                | 0.0001* |
| Time to final reconstruction     | 69.0 ± 69.7 d                                 | 225.6 ± 93.6 d                                | 0.0001* |
| Mean follow-up time              | 324.5 d<br>(range 105–637 d)                  | 486.8 d<br>(range 131–931 d)                  | _       |

<sup>\*</sup>A P value of less than 0.05 is considered statistically significant.

TE/implant-free days after salvage was  $2.5 \pm 1.2$  days in group 1 compared with  $134.6 \pm 78.5$  days in group 2 (P = 0.0001).

There were 92.3% (12 of 13) of group 1 patients who had implants as the final reconstruction (six patients TE to implant, six patients direct-to-implant during NPWTi-d operation) compared with 32.4% (11 of 34) of group 2 patients (P = 0.0003). There was one (7.7%) group 1 patient who underwent a deep inferior epigastric artery perforator (DIEP) flap for the final reconstruction compared with 29.4% (10 of 34) of group 2 (P = 0.1467). There were no patients (0 of 13) in group 1 who declined further reconstruction following TE/implant loss compared with 38.2% (13 of 34) of group 2 patients (P = 0.0094). There were 53.8% (7 of 13) of group 1 patients who received absorbable antibiotic beads.<sup>21</sup> Among group 1 patients who had a reinfection, 15.4% (2 of 13) received absorbable antibiotic beads during TE or implant replacement during the second-stage operation.

The success rate of TE or implant reconstruction salvage, defined as no SSI or prosthetic removal within 90 days, was 81.3% (13 of 16 implants) in group 1. The time interval to final implant-based breast reconstruction was  $69.0 \pm 69.7$  days in group 1 compared with  $225.6 \pm 93.6$  days in group 2 (P = 0.0001). The mean follow-up time was 324.5 days (range 105–637 days) in group 1 and 486.8 days (range 131–931 days) in group 2.

### **DISCUSSION**

Infection in implant-based breast reconstruction is challenging. Traditional device removal results in a delay of final implant-based breast reconstruction by several months.<sup>1</sup> Mastectomy skin flap necrosis can lead to secondary implant infection or partial wound dehiscence, ultimately requiring implant explantation.<sup>24,25</sup> Modifiable patient-associated risk factors include optimizing body mass index and cessation of smoking.<sup>13</sup> Provider-related factors to reduce infection include irrigation of the breast

pocket with various antibiotic solutions or delivery of biodegradable antibiotic-coated calcium-sulfate beads, a "no-touch" technique for implant placement, and drain placement. Pl. 21,26-33 Extended oral antibiotics has not been shown to decrease infection. Attempts to salvage the breast pocket after infected device removal has been described by placement of NPWTi-d. R. 20,35-44 Although reports have described the success of NPWTi-d at implant reconstruction salvage by over 80%, time to final implant-based reconstruction has not been well-elucidated in breast cancer patients. R. 355-40

In our study, the breast reconstruction salvage pathway was successful in 81% of breast cancer patients who underwent removal of the infected device, NPWTi-d placement, and early replacement of the TE/implant. Oxychlorosene solution, a derivative of hypochlorous acid, was chosen for instillation and dwell, as previous studies have shown similar rates of 90-day SSI (11.7% versus 11.2%) when compared with traditionally used triple antibiotic solution. 19,20,45 We prefer oxychlorosene as it is readily available at our institution and inexpensive. 19,20 However, aggressive initial debridement/washout and replacement of the implant after waiting for clinical improvement is likely the most critical aspect of success. Equivocal results can likely be achieved with other irrigation solutions if the debridement is extensive. The success rate of breast implant salvage in this study is consistent with similar studies between 83% and 94%. 18,35-39 Patients who received NPWTi-d experienced a shorter time of being implant-free by 132 days compared with patients who had traditional device removal. Our study shows that, similar to Antognoli et al, more than 1-4 days is not required to salvage a TE or implant after infection.<sup>18</sup> The mean implant-free interval in our study was 2.5 days, which was fewer than 4.4-12 days reported from other retrospective studies that evaluated the use of NPWTi-d to manage TE/implant infection. 18,35-40 This minimizes the psychosocial morbidity of a prolonged period of asymmetry and lack of reconstruction on one side.

Breast cancer patients who received NPWTi-d in our study had faster time to final implant-based reconstruction by 156 days compared with those in the traditional pathway. Three retrospective studies evaluated the use of NPWT for implant salvage and reported success rates between 83% and 94%, but did not evaluate time to final reconstruction. <sup>18,37,39</sup> Application of NPWTi-d may be useful to maximize salvage of the affected breast envelope and accommodate faster final reconstruction using implants compared with the traditional pathway.

The rate of DIEP flap for final reconstruction occurred in 7.7% (1 of 13) of patients who received NPWTi-d and was lower than 29.4% (10 of 34) of patients who underwent traditional device removal, although this was not statistically significant in our study. In patients who undergo adjuvant radiation, a tissue expander that is not salvaged before radiation results in a deficiency of skin from contracture requiring conversion to an autologous flap with or without an implant for reconstruction. <sup>16,46</sup> The breast skin envelope may be preserved before adjuvant radiation for final implant-based reconstruction in patients who undergo NPWTi-d during TE salvage.

Patients who underwent the breast implant salvage pathway were less likely to abandon completing breast reconstruction. We found that among patients who underwent the traditional pathway, 38.2% chose to forgo further reconstruction and had an aesthetic flat closure. A retrospective study using a nation claims-based dataset found that patients were 2.92 times more likely to abandon reconstruction and had an abandonment rate of 20.7% following implant removal for infection. 10 Other retrospective studies that evaluated abandonment of reconstruction reported rates between 26% and 57%, which is consistent with the abandonment rate of 38.2% in our study. 16,47-49 In addition to faster time to final reconstruction, use of NPWTi-d may provide an opportunity to complete reconstruction for patients who may otherwise decline due to the extensive emotional and financial burden faced following implant infection.

Limitations of this study includes being retrospective and underpowered by its small sample size. The infection rate at our institution between 2013 and 2018 was 11.5% in a previous study, whereas only 3.4% of TE or implants required removal.<sup>19</sup> Although our study evaluated the role of NPWTi-d for breast reconstruction salvage in patients with TE/implant infection, an alternative technique for breast prosthetic salvage may include early washout alone, without NPWTi-d, and subsequent TE/implant placement when NPWTi-d may not be available. Our group typically has waited a minimum of 3 months before replacement of the implant or TE if Staphylococcus or Pseudomonas grew on culture. If no encapsulated organisms were present and the patient was not on adjuvant chemotherapy or receiving radiation, consideration would be given to earlier replacement of an implant a few weeks later. We would consider these patients high risk for reinfection and place antibiotic beads during replacement of the TE or implant.21 A retrospective study of 43 patients compared early infected breast pocket washout within 72 hours of hospitalization with immediate TE/implant replacement to a delayed

intervention group.  $^{50}$  There were 50% (5 of 10) of patients in the delayed intervention group (washout, prosthetic explanation) who received immediate TE/implant placement, but this study did not find a statistical difference in implant retention (88% versus 60%) at 3 months postoperatively, and both groups were hospitalized for at least 4 days. 50 In the control group, timing of reconstruction occurred based on surgeon preference and patient availability, which may have affected when patients received an implant or reconstruction using a DIEP flap. A DIEP flap can probably safely be performed earlier than replacement of an implant following implant infection. Another limitation of this study is that patients in the control group did not receive antibiotic beads compared with the group who received NPWTi-d. There are confounders that can only truly be neutralized by a randomized, prospective study. However, this study provides data for attempting to minimize implant-free duration after an infection and an impetus for the need for a randomized, prospective study. Although not statistically significant, the reinfection rate of group 1 patients who received NPWTi-d was 18.8% (3 of 16) compared with 3.3% (2 of 60) in the control group. Though this study is underpowered, accrual of patients who experienced TE or implant loss from infection to perform a well-powered study may be long delayed, but may further elucidate reinfection rate of 18.8% in the NPWTi-d group compared with the traditional approach and the impact of using absorbable antibiotic beads. We counsel patients that the NPWTi-d salvage pathway is higher risk for reinfection. Patients may choose to have a "lower risk" removal of the implant or "higher risk" NPWTi-d in attempt to minimize implant-free duration. We believe thorough counseling is necessary with shared decision-making if patients value potentially minimizing the implant-free duration at the cost of higher risk for reinfection.

# **CONCLUSIONS**

An implant-based breast reconstruction salvage pathway with removal of the infected device, NPWTi-d placement, and early replacement of the TE/implant was successful in 81%. Breast cancer patients experienced fewer implant-free days by 132 days and faster time to final reconstruction by 156 days compared with the control group managed with standard device removal. Patients who underwent this salvage pathway were less likely to abandon completing breast reconstruction. Further studies that evaluate the cost-effectiveness of this salvage approach may elucidate its utility in management of an infected TE or implant compared with traditional device removal.

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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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