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Outcomes of Negative Pressure Wound Therapy on Immediate Breast Reconstruction after Mastectomy

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Background: Immediate expander/implant-based breast reconstruction after mastectomy has become more sought after by patients. Although many patients choose this technique due to good aesthetic outcomes, lack of donor site morbidity, and shorter procedure times, it is not without complications. The most reported complications include seroma, infection, hematoma, mastectomy flap necrosis, wound dehiscence, and implant exposure, with an overall complication rate as high as 45%. Closed incision negative pressure therapy (ciNPT) has shown value in wound healing and reducing complications; however, the current literature is inconclusive. We aimed to examine if ciNPT improves outcomes for patients receiving this implant-based reconstruction.

Methods: This is a retrospective single-institution study evaluating the ciNPT device, 3M Prevena Restor BellaForm, on breast reconstruction patients. The study was performed between July 1, 2019 and October 30, 2020, with 125 patients (232 breasts). Seventy-seven patients (142 breasts) did not receive the ciNPT dressing, and 48 patients (90 breasts) received the ciNPT dressing. Primary outcomes were categorized by major or minor complications. Age, BMI, and final drain removal were summarized using medians and quartiles, and were compared with nonparametric Mann-Whitney test. Categorical variables were compared using chi-square or Fisher exact test.

Results: There was a statistically significant reduction in major complications in the ciNPT group versus the standard dressing group ($P = 0.0247$). Drain removal time was higher in the ciNPT group.

Conclusion: Our study shows that ciNPT may help reduce major complication rates in implant-based breast reconstruction patients. *(Plast Reconstr Surg Glob Open 2023; 11:e5130; doi: 10.1097/GOX.0000000000005130; Published online 1 August 2023.)*

INTRODUCTION

The popularity among women requesting immediate breast reconstruction surgery after mastectomy has slowly risen annually over the past decade. In 2020, 137,808 women underwent breast reconstruction surgery in the United States.[1] This was a 1% increase from 2019, but an overall 75% increase from 2000.[1] Although other options are available to women pursuing breast reconstruction after mastectomy, the most selected technique remains expander/implant-based reconstruction, with more than 70% of mastectomy patients undergoing this type of reconstruction worldwide.[2–4] With expander/implant-based reconstruction, the use of acellular dermal matrices (ADM) has revolutionized breast reconstructions since being introduced over two decades ago by providing more precise control of implant placement, allowing larger volume expansions, and decreasing the risk of capsular contracture.[5,6] In addition, ADM provides additional soft tissue coverage of an existing implant or tissue expander, which has been attributed to its good cosmetic outcome and comparable complications.[7–9] Therefore, it can be understood why so many choose implant-based reconstruction after mastectomy due to the satisfactory aesthetic outcomes, lack of donor site morbidity, increase in bilateral mastectomies versus unilateral mastectomies, and shorter procedure times.[10,11]

Despite being the most common procedure for this demographic, it is not without complications. The most

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commonly reported early complications related to tissue expander/implant-based reconstructions are seroma, infection, hematoma, mastectomy skin flap necrosis, wound dehiscence, implant exposure, and implant deflation.[12,13] Complication incidence rates upward of 45% have been reported.[13] As a result, these complication rates can lead to medical and oncologic management delays and often lead to poor aesthetic outcomes. Many patient and provider-specific variables must be considered as key risk factors when evaluating complication rates, including body-mass-index (BMI), tobacco use, comorbidities, neoadjuvant/adjuvant therapies, and surgical technique.[5,12,14]

Postoperative incision and wound management are vital components in the overall success and healing of postmastectomy expander/implant-based reconstruction. Closed-incision negative pressure therapy (ciNPT) is a technique that creates favorable biomechanical forces to promote healing in surgical and nonsurgical wounds.[15] However, inconsistencies remain in the literature regarding the efficacy of ciNPT in wound management. Some studies demonstrate that ciNPT devices aid in healing while also diminishing complications.[3,4,16] However, other studies do not demonstrate a difference in complications with ciNPT.[17,18] There are also different types of ciNPT on the market. At our institution, we recently implemented the use of 3M Prevena Restor BellaForm, which was specifically designed for breast patients. Our aim was to compare the complication rates for patients undergoing immediate expander or implant-based reconstruction using standard-of-care dressings versus ciNPT. We hypothesize that the use of ciNPT will decrease complication rates.

PATIENT AND METHODS

This study is a retrospective, single-institution study performed between July 1, 2019 and Oct 30, 2020 at the University of Nebraska Medical Center/Nebraska Medicine, examining all mastectomy patients who underwent immediate expander or implant-based breast reconstruction. All mastectomies and reconstructions were performed in the hospital. Mastectomy techniques included nipple-sparing, skin-sparing oblique, and skin-sparing wise-pattern. Skin flap quality was determined by physical assessment, and if questionable, fluorescence imaging was used. Reconstruction techniques included both prepectoral and subpectoral planes. Our breast surgeons preferred to place two 15-french drains for each breast.

Institutional review board approval was granted for this medical chart review. The 3M Prevena Restor BellaForm was introduced in Sep 2019. Abstracted data included demographics (age, BMI, race, tobacco history, medical history, type of cancer, neoadjuvant, and adjuvant chemoradiation); and operative characteristics (implant location, implant type, use of ADM, laterality, and incision type) (Table 1).

Primary outcomes evaluated between the control (standard dressings) and experimental (ciNPT) groups were major and minor complications. The dressings within the control group were Xeroform with Tegaderm along the incisions. Major complications were defined as complications that required an intervention (ie, procedure or operative intervention, admission to the hospital for intravenous antibiotics). Minor complications were defined as complications that were observed, treated with oral antibiotics and local wound care. Both major and minor groups involved complications related to seromas, hematomas, infections, and skin/nipple necrosis. Secondary outcomes evaluated included time to drain removal. The criteria for drain removal in both groups was less than 30 mL of fluid for two days in a row.

PC SAS version 9.4 was used for all statistical analyses. Age, BMI, and final drain removal were summarized using medians and quartiles and were compared between groups (ciNPT versus no ciNPT) with a nonparametric Mann-Whitney test. Categorical variables were compared between groups using chi-square or Fisher exact test. The statistical significance level was set at $\alpha = 0.05$.

Takeaways

Question: Does closed-incision negative pressure therapy (ciNPT) reduce major and minor complication outcomes versus standard dressings for patients undergoing implant/expander-based reconstruction after mastectomy?

Findings: There was a statistically significant reduction in major complications in the ciNPT group versus the standard dressing group.

Meaning: ciNPT may help reduce major complication rates in implant-based breast reconstruction patients.

Table 1. Patient Demographics

Variable	No ciNPT (n = 77), n (%)	ciNPT (n = 48), n (%)	*P*
Age	43	46.5	0.1909
BMI	26.94	25.65	0.2060
White	66 (86)	47 (98)	0.0284*
Current tobacco	4 (5)	2 (4)	0.7948
Hypertension	12 (16)	6 (13)	0.6377
Diabetes	2 (3)	2 (4)	0.6377
Cancer laterality			0.5153
No cancer	21 (27)	8 (17)	
Right	26 34)	21 (44)	
Left	26 (34)	17 (35)	
Bilateral	4 (5)	2 (4)	
Cancer receptors			
ER+	40 (71)	37 (95)	0.0041*
PR+	33 (61)	31 (79)	0.0591
HER+	8 (19)	8 (21)	0.8686
Neoadjuvant chemo	22 (33)	11 (29)	0.6435
History of radiation	6 (9)	0 (0)	0.0835
Adjuvant chemo	24 (36)	11 (31)	0.5549
Adjuvant radiation	18 (27)	8 (22)	0.6435

Note: Continuous variables were compared with nonparametric Mann-Whitney test. Categorical variables were compared using chi-square or Fisher exact test.
*Statistically significant, $P < 0.05$.

RESULTS

A total of 125 patients (232 breasts) were included in the study; 77 patients (142 breasts) did not receive the ciNPT dressing, and 48 patients (90 breasts) did receive the ciNPT dressing. The overall mean age was 43 for the control group and 46.5 for the ciNPT group ($P = 0.19$). Except for race, and estrogen receptor positivity, the two groups were similar in all other aspects of general descriptive characteristics (Table 1). The majority of the patients in the ciNPT group were White (98% versus 86%, $P = 0.02$) and had more estrogen receptor-positive cancers (95% versus 71%, $P = 0.004$). The majority of operative characteristics examined were similar between the two groups, except for the use of ADM. Patients who received the ciNPT underwent more ADM-based reconstruction (100% versus 88%, $P = 0.0126$) (Table 2).

Overall major complication rates were significantly higher in the standard dressing group compared with the ciNPT group (15% versus 14%, $P = 0.0247$) (Table 3). Among the major complications, seven patients were in the standard dressing group, and two in the ciNPT group required explantation. There was no statistical difference between the two groups' minor complications. When looking at variables associated with complication rates, current tobacco use was more likely associated with major complications (12% versus 2%, $P = 0.0291$). There was no difference in complication rates between prepectorally and subpectorally placed implants in the standard or ciNPT group. Time to drain removal was significantly longer in the ciNPT group versus the no ciNPT group (17 days versus 15 days, $P = 0.003$).

Table 3. Overall Complications

Variable	No ciNPT (n = 142), n (%)	ciNPT (n = 90), n (%)	*P*
Major complications	22 (15)	13 (14)	0.0247*
Seroma	1	3	0.1338
Hematoma	5	1	0.3771
Infection	5	0	0.1335
Wounds	1	4	0.0524
Mastectomy necrosis	9	3	0.2919
Nipple necrosis	1	2	0.5412
Minor complications	13 (9)	6 (6.7)	0.9009
Seroma	2	0	
Hematoma	3	1	
Infection	3	1	
Wounds	5	4	

Continuous variables were compared with nonparametric Mann-Whitney test. Categorical variables were compared using chi-square or Fisher exact test.
*Statistically significant, $P < 0.05$.

DISCUSSION

Breast reconstruction continues to play an important role with benefits to psychosocial well-being in breast cancer patients requiring mastectomies.[19] As complication rates have been reported as high as 50% in expander/implant-based reconstruction,[13] ways to reduce complication rates continue to be a subject of interest. The ciNPT device has been demonstrated to be beneficial in infection, seroma, hematoma, and re-operation rates in different surgical specialties for abdominal, sternal, groin, and lower extremity incisions.[18] Its use has also been extrapolated to breast surgery, with recent results demonstrating a significant reduction in overall complications, surgical site infection, wound dehiscence, necrosis, seromas, and re-operation rates using the customizable Prevena dressing.[2] A recent pilot study examined the use of the BellaForm device with prepectoral direct-to-implant reconstruction, demonstrating lower complication rates in seromas, skin necrosis, and total drain volumes with no complications with hematoma, dehiscence, or infection.[20] Other studies have demonstrated no significant difference in wound complications after mastectomies.[17]

The ciNPT device used specifically in our study was the 3M Prevena Restor BellaForm (KCI, an Acelity Company, San Antonio, Tex.). This specific device was FDA approved in 2019 and was designed to be more adaptable for usage with breast surgery, as it encompasses the entire breast footprint. In addition, it provided negative pressure beyond the incision. As noted by other institutions, this may allow better perfusion to the nipple-areolar complex and skin flap with the contouring of the device to the whole breast.[20,21]

This study demonstrated a statistically significant difference between major complication rates favoring the usage of ciNPT. There was no statistical significance when further breaking down the major complications into their subcategories, but this was likely because the sample size was not large enough to capture the differences. However, there were more occurrences of mastectomy skin flap necrosis, infection, and hematoma complications in the standard dressing group. These complications often lead to detrimental outcomes in the reconstruction process. A statistically significant difference was not demonstrated in the minor complication rates between the two groups, and this may be because our patient population had minimal risk factors known to affect wound healing. For example,

Table 2. Operative Demographics

Variable	No ciNPT, n = 77 n (%)	ciNPT, n = 48 n (%)	*P*
Mastectomy incision			0.0679
Nipple sparing	42 (55)	27 (56)	
Skin-sparing oblique	13 (17)	2 (4)	
Skin-sparing wise	21 (28)	19 (40)	
Implant position			0.3315
Prepectoral	50 (65)	27 (56)	
Subpectoral	27 (35)	21 (44)	
Implant type			0.4945
Tissue expander	50 (65)	34 (71)	
Implant	27 (35)	14 (29)	
Acellular dermal matrix	68 (88)	48 (100)	0.0126*
Mastectomy weight (g) (IQR)	634 (388–1073)	658 (406–1048)	0.7157
Mastectomy weight (g) (IQR)	373 (212–587)	357 (224–601)	0.9366

Continuous variables were compared with nonparametric Mann-Whitney test. Categorical variables were compared using chi-square or Fisher exact test.
*Statistically significant, $P < 0.05$.

our sample had lower BMIs and minimal preoperative comorbidities. To no surprise, patients who were current smokers during the time of surgery in our study developed more major complication rates than those who were former or never smokers. Smoking has been demonstrated to attenuate the inflammatory and proliferative healing response,[22] leading to more wound healing problems.

Interestingly, the time to drain removal was longer in the ciNPT group, which was 2 days longer than the no ciNPT group. Although this did not exceed the recommended limit for drain duration of 3 weeks, a positive correlation has been observed between drain duration and infection.[23] Furthermore, this finding contradicts what has been demonstrated previously in that ciNPT can reduce drain duration.[2] BellaForm is unique in enveloping both the incision and the surrounding chest area. It is intended to remain in use for an extended period of up to 14 days rather than the standard 7 days, which could be one of the reasons why drain removal took longer in the ciNPT group in this study. In addition, all our patients in the ciNPT group received acellular dermal matrix (ADM) as part of their reconstruction process, and it has been demonstrated that the use of ADM can increase seroma rates, which may have led to the prolonged drain usage time in our study.[24]

From our experience with this device, generally, patients tolerated it well for 14 days. If removed early, it was because of device malfunctions or skin reaction to the adhesive. As with other ciNPT devices, patients could not shower or get the device wet. Application of the device did require a learning curve among plastic surgeons, namely, ensuring that the sponges within the device were separated and not touching, as this tended to cause malfunctions. Patients who received the device were given the contact information of our Prevena representative, and if this representative could not answer the patient's concerns, they were escalated to us. However, we seldom received calls or concerns to the office. We characterize our overall patient and provider experience as positive with this device. In terms of cost, the device did cost more than its incisional-only counterpart. However, it was the sole ciNPT device used at our institution by the plastic breast surgeons during the study duration. Therefore, insurance coverage was not an issue for these patients for the duration of the study. A future avenue of research would be to compare the outcomes of the BellaForm system, the application of negative pressure beyond the incision, to devices solely ciNPT; a study of this nature would help better ascertain the value of this new ciNPT device.

There are important limitations to this study. This is a retrospective study, incurring design limitations, and it cannot be used to conclude causal relationships. Another limitation to this study was the sample size. Increasing the sample size may have further detected differences in the different complication subcategories and potentially shed light on the importance of other factors within breast surgery, such as tobacco use, technique, and ADM use. There was also limited racial diversity in our sample. Minorities have been shown to have higher postsurgical complications after breast surgery.[25] Besides a racial diversity limitation, our sample consisted of nonobese patients with BMIs less than 30. Patients with higher BMIs have been shown to have higher postsurgical complications.[26] Future studies using this specific ciNPT device for higher-risk populations should be explored.

CONCLUSIONS

Our results demonstrate that ciNPT (Prevena Restor BellaFrom) may help reduce the major complication rate for patients undergoing immediate implant/expander-based breast reconstruction compared with standard-of-care dressings.

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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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