

# ORIGINAL ARTICLE

# Outcomes of Mastectomy and Immediate Reconstruction Managed with Closed-incision Negative Pressure Therapy Applied Over the Whole Breast

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Background: Incision healing after mastectomy and immediate reconstruction can be supported with closed-incision negative pressure therapy (ciNPT). Studies have reported patients receiving postoperative care with ciNPT after breast surgery exhibited lower rates of dehiscence, infection, necrosis, and seroma, compared with standard dressings. A recent approach to ciNPT involves the application of negative pressure to the incision and a wider area of surrounding tissue. In this retrospective review, we investigated the outcomes of ciNPT using full-coverage dressings over the entire breast after mastectomy and reconstruction. Methods: Patients underwent mastectomies and immediate prepectoral breast reconstruction with an implant or tissue expander. After surgery, patients received oral antibiotics and ciNPT with full-coverage foam dressings at -125 mm Hg. **Results:** All 54 patients (N = 105 incisions) were women, with a mean age of 53.5 years and 29.1 kg per m<sup>2</sup> body mass index. Common comorbidities included prior chemotherapy (31.3%) or radiation (21.6%), hypertension (14.8%), and diabetes (5.6%). Procedures included skin-reducing (34.3%), skin-sparing (7.6%), and nipple-sparing (58.1%) mastectomies. Lymph nodes were removed in 38 (36.2%)incisions. All patients were discharged home with ciNPT on postoperative day (POD) 1, and ciNPT was discontinued on POD 5-7. At POD 30, three patients developed seromas, requiring revision. Of these, one required removal of the left tissue expander. The remaining 102 incisions (97.1%) healed without complication. Conclusions: Among this cohort, the use of ciNPT with full-dressing coverage of the breast incisions and surrounding soft tissue was effective in supporting incisional healing after mastectomy and immediate reconstruction. (Plast Reconstr Surg Glob Open 2024; 12:e5809; doi: 10.1097/GOX.000000000005809; Published online 30 May 2024.)

# **INTRODUCTION**

According to the American Society of Plastic Surgeons, there were 137,808 breast reconstruction procedures in 2020, representing a substantial 75% increase since 2000.<sup>1</sup> Although breast reconstructions with nipple-sparing mastectomy and immediate reconstruction are often preferred for aesthetic reasons, they can pose higher risks of postoperative complication.<sup>2</sup> Surgical site complications,

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Copyright © 2024 The Authors. Published by Wolters Kluwer Health, Inc. on behalf of The American Society of Plastic Surgeons. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. DOI: 10.1097/GOX.00000000005809 such as dehiscence or infection, can negatively impact patient health and satisfaction, in addition to prolonging hospitalization and elevating health-care costs.

The current standards of postoperative care primarily consist of passive therapy, usually dry or moist sterile gauze with a transparent secondary dressing over the closed incision. However, these dressings typically require changing every 1 or 2 days, which can add pain and stress during the recovery process. Additionally, they are generally inadequate barriers to contamination due to their permeability and, as a result, are vulnerable to bacterial infiltration. In contrast, managing the surgical site via closed incision negative pressure therapy (ciNPT) creates an effective seal against external contamination. This is accompanied by application of -125 mm Hg across the incision for 2–7 days, which helps hold the incision edges together and removes moisture from the site. Clinical data have shown that application of ciNPT with foam dressings directly over the

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

closed incision aids in reducing the incidence of seroma and superficial surgical site infections in class I and class II wounds in patients at high risk for postoperative infections. Multiple studies comparing patients treated with ciNPT versus standard dressings have reported reduced complications, including surgical site infections, dehiscence, necrosis, and seroma with ciNPT.<sup>3–5</sup>

A novel ciNPT dressing design that covers the incision and a greater area of surrounding breast tissue has recently become commercially available, allowing for full coverage of the breast after surgery.<sup>6</sup> Closed-incision NPT is therefore applied to the incisions, the nipple–areolar complex, and the surrounding peripheral tissues. In this retrospective observational study, we report our initial experience using ciNPT with full-coverage dressings over the entire reconstructed breast after mastectomy.

#### **METHODS**

The treatment regimen used in this study was consistent with the World Medical Association Declaration of Helsinki. All risks of therapy were explained to patients, and their consent was obtained before treatment initiation. Patients included in the study underwent mastectomy with immediate implant-based breast reconstruction between May 1, 2019 and February 28, 2020, during which incision management with ciNPT with full-coverage dressings was adopted into standard postmastectomy protocol. Before undergoing surgery, the patients were screened for their suitability for immediate breast reconstruction. Each patient was evaluated for the optimal incision type and procedure based on breast size, shape, skin laxity, and other patient characteristics. Patients underwent skinreducing, skin-sparing, or nipple-sparing mastectomy with immediate reconstruction with prepectoral placement of a tissue expander. Incisions were closed with sutures over a single drain per breast, which was removed 7-12 days postoperatively.

The ciNPT dressing kit (3M Prevena Restor BellaForm Dressings; 3M Company; San Antonio, Tex.) consisted of a polyurethane foam dressing with a skin interface layer (embedded with 0.019% ionic silver) that makes contact with the incision and intact skin. There are three different sizes of dressing available  $(21 \times 1 \text{ cm}, 24 \times 22 \text{ cm}, \text{ and } 29 \times 27 \text{ cm})$ , and the dressing size was selected based on the surgical area characteristics, including the incision shape and length and the surface area of the breast. Attached to the outside of the dressing is an adhesive drape, which is used to adhere to the skin and create the vacuum seal. Using aseptic technique, a single piece of ciNPT dressing was centered and applied over each entire breast, including the incisions and the nipple-areolar complex (in the case of nipplesparing mastectomy), ensuring that the adhesive would not contact or cover the surgical incision. The dressing was oriented to eliminate sharp bends or kinks in the tubing. An adhesive drape was attached over the dressing, and the seal was ensured by firmly pressing around the dressing where the adhesive contacted the skin. Negative pressure was applied using a portable device

# **Takeaways**

**Question:** How well does closed-incision negative pressure therapy with a novel full-coverage foam dressing support healing after mastectomy with immediate device-based reconstruction?

**Findings:** In a 54-patient cohort with 105 breast incisions, the 30-day complication rate was 2.9%. In three cases, seromas formed, requiring returns to the operating room, and an expander was removed in one of these cases. Of the 61 nipple-sparing mastectomies, only one developed postoperative complication.

**Meaning:** Closed-incision negative pressure with foam dressings covering the full breast was effective in managing breast incisions after mastectomy with immediate reconstruction.

(3M Prevena Plus 125 Therapy Unit; 3M Company) at -125 mm Hg for 5–7 days.

Patient demographics, operative data, and outcomes were collected retrospectively with informed patient consent. Descriptive statistics were performed using SAS (SAS Institute; Cary, N.C.).

#### RESULTS

The 54 patients included in the study were all women, ranging in age between 27 and 80 years (mean age: 53.5 years). The average body mass index was 29.1 kg per m<sup>2</sup> (range:  $17-50 \text{ kg/m}^2$ ). Thirty-three patients were obese. Patient comorbidities are shown in Table 1.

The patients underwent skin-reducing (34.3%), skinsparing (7.6%), or nipple-sparing (58.1%) mastectomy with immediate reconstruction (Table 2). The average

#### **Table 1. Patient Comorbidities**

Comorbidity	N = 54 Patients
BRCA positive	3 (5.6%)
Chemotherapy	19 (37.3%)
Diabetes	3 (5.6%)
Hypertension	8 (14.8%)
Prior breast surgery	0 (0%)
Radiation	11 (20.4%)
Smoker	0 (0%)
Obesity	33 (61.1%)
Class 1 $(30-35 \text{ kg/m}^3)$	18 (33.3%)
Class 2 $(35-40 \text{ kg/m}^3)$	7 (13.0%)
Class 3 (>40 kg/m <sup>3</sup> )	8 (14.8%)

BRCA, breast cancer gene.

#### **Table 2. Surgical Techniques**

Туре	N = 105 Breasts
Mastectomy	
Nipple sparing	61 (58.1%)
Skin sparing	8 (7.6%)
Skin reducing	36 (34.3%)
Lymph nodes removed	38 (36.2%)

Table 3. Thirty-day Postoperative Complications

Complication	N = 105 Breasts
Any complication	3 (2.9%)
Surgical site incision	0 (0%)
Dehiscence	0 (0%)
Necrosis	0 (0%)
Seroma	3 (2.9%)
Hematoma	0 (0%)
Expander exposure	0 (0%)
Return to OR	3 (2.9%)
Expander removed	1 (1.0%)
OP an anotic a second	

OR, operating room.



Fig. 1. Breast appearance premastectomy.

weight of breast tissue removed was 590g (range: 121–1521g). Axillary lymph nodes were removed in 36.2% of procedures. The median and maximum number of lymph nodes removed were 3 and 25 lymph nodes, respectively. Of the total 54 patients, 51 (94.4%) underwent bilateral mastectomies.

Patients received ciNPT with full-coverage dressings and were discharged on postoperative day 1. Therapy continued for 5–7 days, and upon completion, the patients returned to the clinic for dressing removal and assessment of the incision. Upon follow-up on postoperative day 30, 102 (97.1%) incisions were healed without complication. There were no incidents of dehiscence, surgical site infection, or necrosis. Three patients developed seromas, requiring revision (Table 3). Of these, one required removal of the left tissue expander.

# **CASE STUDIES**

#### Case 1

A 41-year-old female patient presented to the surgical clinic requiring bilateral mastectomy for breast cancer (Fig. 1). She had no notable medical history. The patient underwent a bilateral nipple-sparing mastectomy with reconstruction with tissue expanders and acellular dermal matrix, resulting in an inframammary



Fig. 2. Application of ciNPT with full-coverage foam dressings post mastectomy.



**Fig. 3.** Appearance on postoperative day 7, immediately after removal of ciNPT dressings.

incision on each breast. Closed-incision NPT was initiated using two full-coverage dressings that covered each inframammary incision and the entirety of each breast (Fig. 2). Negative pressure was applied at -125 mm Hg. The patient was discharged home the day after surgery. On postoperative day 7, ciNPT was discontinued, and there were no signs of complication (Fig. 3). Upon follow-up 1 year after surgery, the tissue expanders had been successfully exchanged for 445-mL implants (Fig. 4). The incision was fully closed, and there was no incidence of surgical site infection, seroma, or any other complication.

# Case 2

A 59-year-old woman presented with an invasive ductal carcinoma of the right breast (Fig. 5). Her comorbidities included hypertension and obesity (BMI  $37 \text{ kg/m}^2$ ), and her A1c was 5.6%. She underwent neoadjuvant chemotherapy, then bilateral skin-sparing mastectomy with



Fig. 4. Appearance 1 year post mastectomy, after exchange to silicone implants. Results are viewed from the right (A), center (B), and left (C).



Fig. 5. Breast appearance premastectomy.



**Fig. 6.** Application of ciNPT with full-coverage foam dressings post mastectomy.

immediate reconstruction with tissue expanders and acellular dermal matrix. In the OR, drains were placed on each side, and ciNPT full-coverage dressings were placed over the incisions (Fig. 6). After discharge, negative pressure was applied at -125 mm Hg for 7 days. When the patient returned for dressing removal, there were no



**Fig. 7.** Appearance after 7 days of ciNPT, immediately after removal of dressings.

complications (Fig. 7). Six weeks after reconstruction, the patient began radiation therapy. Four months after the conclusion of radiation therapy, the expanders were exchanged for 560-mL implants (Fig. 8). Upon follow-up 3 years postreconstruction, the incisions were well-healed, and there were no signs of any complications.

# **DISCUSSION**

Closed incision NPT is a postoperative technique that can support incision healing, especially in the case of patients at risk for complications. By providing a seal over the incision, ciNPT creates a closed environment separating the incision from external contamination. In contrast, gauze dressings provide little protection against infectious agents; bacteria can readily pass through dry gauze layers, and exudate collection within dressing layers can exacerbate bacterial colonization.<sup>7</sup> Closed incision NPT also constantly removes exudate away from the incision, while applying gentle negative pressure across the incision edges and the surrounding tissues.

Studies examining the use of ciNPT directly over breast incisions have shown positive outcomes among patients receiving ciNPT over standard care. In a study



Fig. 8. Appearance 9 months post mastectomy, after exchange to silicone implants. Results are viewed from the right (A), center (B), and left (C).

of 665 closed breast incisions receiving ciNPT or adhesive strips, we previously reported that the ciNPT group experienced significantly fewer incidences of infection, dehiscence, necrosis, and seroma formation, and fewer required a return to the OR (8.5% versus 15.9% any complication).<sup>3</sup> As a result, we incorporated the use of linear ciNPT dressings into our standard postmastectomy protocol. This change was additionally supported by a 51-patient study by Muller-Sloof et al,<sup>5</sup> which observed fewer dehiscences among patients undergoing autologous breast reconstruction with ciNPT versus adhesive strips. Ferrando et al<sup>4</sup> also reported that high-risk patients receiving ciNPT after oncological breast surgery experienced lower rates of skin necrosis and overall complications compared with those with standard care (4% versus 45%). In comparison, there was a 2.9% overall complication rate among our patient cohort managed with ciNPT with full-coverage dressings.

In this retrospective study, we examined the outcomes of patients receiving ciNPT with a novel, fullcoverage dressing after mastectomy with immediate reconstruction. The technique of applying ciNPT over the incision and a wider area of surrounding soft tissue has been reportedly beneficial over abdominal<sup>8</sup> and hand<sup>9</sup> incisions. As we previously used ciNPT to manage mastectomy incisions, we quickly adopted the new full-coverage dressings for all patients undergoing immediate breast reconstruction. In our experience, the dressings were easy to place for all incision types, securely covering and supporting the entire breast without the need for cutting or shaping the dressing. As with all negative pressure dressings, care was taken to avoid placing the adhesive drape across fragile skin and areas with creasing or pinching, and barrier film or occlusive dressing was used to protect these areas, if necessary. In this patient population, a strong majority recovered without incident, with three patients requiring additional care. These three patients all had body mass indices greater than 35 kg per m<sup>2</sup>, which is consistent with studies showing that obesity is a risk factor for incision healing complications.<sup>10,11</sup>

In our clinic, use of ciNPT has been an important tool for improving postoperative care for patients undergoing mastectomy. Mastectomy with immediate reconstruction is typically preferred over delayed reconstruction due to perceived benefits of improved body image and selfesteem in the immediate postoperative recovery period.<sup>12</sup> However, immediate reconstruction can come with increased risks of complication, highlighting the need for proactive incision management.<sup>2</sup> Another factor to take into consideration is the preservation of the nipple-areolar complex, which improves the aesthetic outcome in the immediate postoperative period. Previously, we published data on 331 mastectomies with reconstruction that were managed with ciNPT, in which 132 (39.6%) were nipple-sparing mastectomies (NSM).<sup>3</sup> Compared with that cohort, we were able to increase the percentage of immediate reconstructions after NSM (58.1%), while reducing the number of drains from two to one. Among our NSM procedures, only one (1.6%) showed complications. In comparison, a systematic review of 12,358 procedures found that overall complication rate after NSM was 22%, and the nipple necrosis rate was 5.9%.<sup>13</sup> Although nipple necrosis is an early complication, there was no evidence of total or partial nipple necrosis among any of the patients in this study.

Immediate breast reconstructions typically have higher rates of seroma than delayed reconstruction.<sup>14</sup> A metaanalysis of 51 studies of prosthetic breast reconstructions reported a pooled seroma incidence of 5.4%.<sup>15</sup> In this study, seroma rates were 2.9% among patients managed with full-coverage ciNPT after immediate breast reconstructions with expanders or implants. This is consistent with previous studies reporting low (0%–1.8%) seroma rates for breast surgical incisions managed with linear ciNPT dressings.<sup>3–5,16</sup>

This study is limited in that is a retrospective review without a direct comparison group; therefore, we cannot draw conclusions about potential advantages the fullcoverage approach may have over linear ciNPT dressings. Additionally, the patients in this study may differ from the general population in a way that lowers their risk of postoperative complications (eg, none of the patients were smokers). However, it should be noted that all patients undergoing immediate breast reconstruction during the study period received the new dressings, and none were excluded from this study, limiting selection bias. The follow-up period was 30 days, which is sufficient to document early complications such as skin necrosis, but may overlook late-emerging complications. Long-term follow-up may reveal additional effects of this novel dressing on the recovery process. Further studies comparing breast incision healing outcomes to ciNPT with standard of care and other ciNPT dressings are needed.

In conclusion, we found that ciNPT with full-coverage dressing was safe for use with mastectomy and immediate reconstruction, supporting a low complication rate even among patients undergoing mastectomy preserving the nipple–areolar complex. The new dressing design presents a convenient negative pressure approach to managing both the incision and a broader area of peri-incisional soft tissue.

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#### DISCLOSURES

Dr. Gabriel is a consultant of 3M Company (San Antonio, Tex.) and a consultant for Allergan. Dr. Chan has nothing to disclose.

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