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IDEAS AND INNOVATIONS

Breast

Randomized Controlled Trial to Assess Negative Pressure Wound Therapy versus Standard-of-care Dressings in Breast Surgery: A Pilot Study

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Background: Standard breast reduction dressings such as Prineo are used to cover surgical wounds, in combination with a binder or support bra. The Prevena Restor BellaForm is a negative pressure wound therapy dressing that covers the entirety of the breast mound and is purported to provide further support and reduce swelling. The aim of this study was to compare the Restor to standard-of-care dressings.
Methods: The study was a randomized control trial of women undergoing bilateral breast reduction with one breast being dressed with the Prevena Restor BellaForm dressing and the other having standard of care (Prineo). Outcomes measured were drain outputs, postoperative length of stay, quality of scarring, patient preference for dressings, and adverse events. Follow-up was at 1, 2–6, and 26 weeks.
Results: The results show a reduction in postoperative days 1 and 2 average drain output on the Restor side compared with standard dressings. Patient-reported outcome measures showed less bruising. There was no difference in postoperative length of stay and no difference in appearance of scars at the 26-week follow-up period. One patient required removal of the dressing due to irritation and one patient required assistance with resealing of the vacuum.
Conclusions: We have shown benefits to drain output and comfort using close incisional negative pressure therapy in breast reduction mammaplasty. We plan to continue to investigate close incisional negative pressure therapy in larger comparative trials for other breast procedures including implant-based reconstruction, where a reduction in drain output could be of great benefit to both healing and reduction of infection risk. *(Plast Reconstr Surg Glob Open 2024; 12:e5799; doi: 10.1097/GOX.0000000000005799; Published online 17 July 2024.)*

INTRODUCTION

Close incisional negative pressure wound therapy (ciNPWT) is thought to alleviate tension on the wound, remove fluid, and maintain a sterile wound field to allow improved postoperative healing.[1]

In 2019, the Prevena Restor BellaForm was approved for breast surgery, with a heart-shaped interface providing coverage of the entire breast. This improvement aimed to provide the benefits of ciNPWT and the compression of the breast mound to obliterate dead space and provide support.

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This dressing was used in this randomized control trial to measure differences in outcomes observed in breast reduction mammoplasty (BRM) between the Prevena Restor BellaForm and standard-of-care dressings with 2-octyl cyanoacrylate skin adhesive (Dermabond Prineo Skin Closure System; Johnson and Johnson, Puerto Rico).

METHODS

A prospective randomized trial was undertaken at three centers (by three surgeons) in Sydney, Australia. Ethics approval was obtained from the Macquarie University human research ethics committee. Inclusion criteria included women older than 18 years of age undergoing bilateral breast reduction who were able to provide written consent for trial inclusion. Exclusion criteria included smokers, any previous breast surgery, or patients with known sensitivity or allergy to any of the dressing components.

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

Data collected included demographics, medical history, smoking, body mass index (BMI), and weight of tissue resected from each breast.

For each patient, one breast was randomized to the intervention (Restor dressing) and the other breast to the control, dressed with standard-of-care dressing (Prineo with/without overlying paper tape dressing). All surgeons utilized Wise pattern skin resection with superomedial pedicles.

Application of the Restor involves clear plastic sheets placed in a triangular silhouette around the breast. The Restor dressing is placed over the breast mound and wounds (Fig. 1).

There is a silver impregnated polyester fabric skin interface that prevents direct foam contact with the skin. Drains can be included under clear plastic dressings. A negative pressure of 125 mm Hg is applied and checked for a seal per standard VAC care. A standard compression bra was then applied.

Follow-up time points were 1, 2–6, and 26 weeks. The Restor dressing was left on suction until removal at 1 week to allow for wound review. Data on adverse outcomes, clinical photographs, a clinician evaluation form, and patient-reported outcome measure forms were compiled.

The primary outcome compared was reduction in drainage output. Secondary outcomes included time to drain removal, scar quality, patient comfort, and surgical complications (such as infection, seroma, hematoma, and skin necrosis). Pain and discomfort associated with each dressing was assessed using a questionnaire. Scar quality/cosmesis was assessed subjectively.

RESULTS

A total of 20 patients were enrolled. Average age and BMI of patients was 45 years and 27.67 kg/m^2, respectively. Average weights of resection were 483.3 g on the Restor side versus 488.5 g for the control (no significant difference). Average day 1 postoperative drain outputs were 19 mL on the Restor side and 31.2 mL for controls.

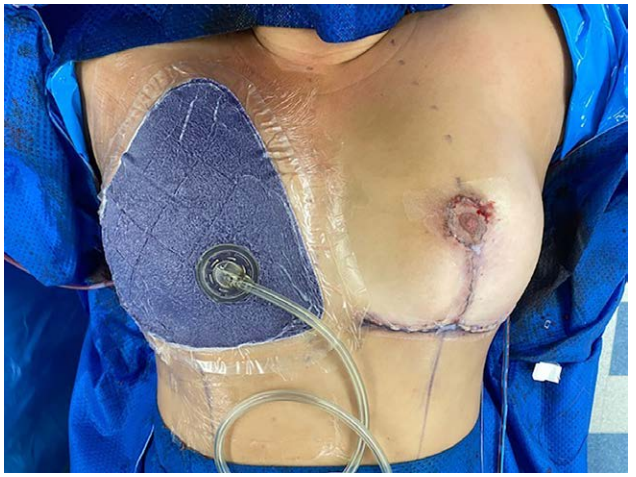

Fig. 1. Prevena dressing in situ covering the breast mound.

Takeaways

Question: Can negative pressure wound therapy provide reduction in drain output, swelling, and bruising, as well as increase patient comfort in the context of breast reduction surgery?

Findings: Our findings show a reduction in drain output and an improvement in feelings of support from the negative pressure dressing. This comes with issues such as reactions to the dressing and difficulty keeping a negative pressure seal.

Meaning: The use of negative pressure compared with standard-of-care dressings in breast reduction is a useful adjunct to improve the patient experience after breast reduction. Further large-scale study is required.

Average day 2 postoperative drain outputs were 30 mL on the Restor side and 44 mL for controls. Four patients had no drains. Fifteen patients were discharged on day 1 postoperative, three on day 2 postoperative, and two on day 3 postoperative.

One patient had the Restor dressing removed on day 1 postoperatively due to irritation and itchiness. One patient attended the emergency department for VAC resealing. Two patients treated with ciNPWT experienced superficial wound dehiscence along the vertical scar (managed with surface dressings).

Variables were analyzed using unpaired *t* tests (Table 1).

Although average drain output was reduced, this did not reach statistical significance.

In comparison questionnaires, of a total possible 40 points, the Prevena and Prineo dressings scored 32.2 and

Table 1. Demographics, Drain Outputs, and Discharge Days

Variables		Significance
Average age, y	45	
Average BMI, kg/m^2	27.7	
Average weights of resection, g		
Restor	483.3	$P = 0.95$
Control	488.5	
No. pts drains out day 1	12	
Average D1 drain outputs, mL		
Restor	19	$P = 0.32$
Control	31.2	
No. pts drain out day 2		
Average D2 drain output, mL		
Restor	30	$P = 0.21$
Control	44.7	
No. pts drain out day 3	1	
Average D3 drain output, mL		
Restor	7	
Control	5	
No. pts without drains	4	
Day of discharge		
1	15	
2	3	
3	2	

Pts, patients.

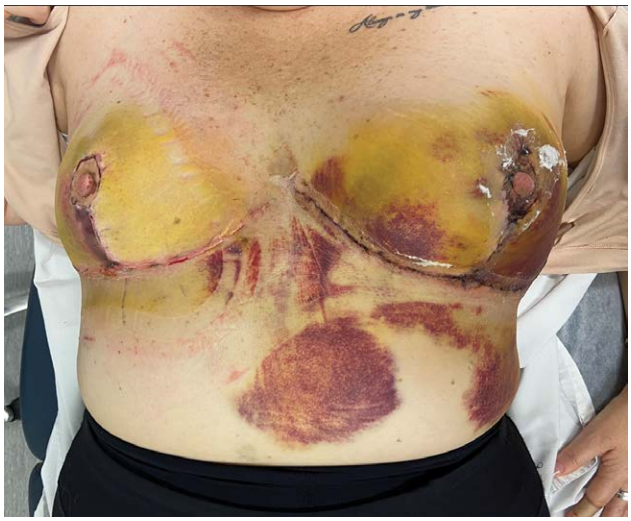

Fig. 2. A patient 1-week postoperatively after a breast reduction (450 g on the left and 500 g on the right) with reduction in bruising and swelling on the right breast, which was dressed with the Prevena dressing. This was still noticeable at the 3-week postoperative mark.

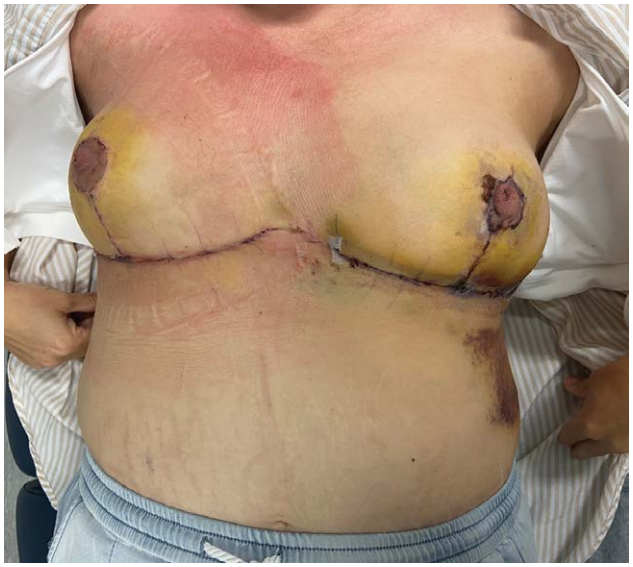

Fig. 3. One week postoperative result after 1100 g reduction bilaterally with significantly reduced swelling and bruising of the right (Prevena) breast compared with the left.

35, respectively (where a higher score indicates the best dressing. This difference was not significant).

Patient feedback included feeling more support, reduced pain, and reduced swelling from the Restor dressing, as well as some reporting anxiety from not being able to see their breast/wounds, itchiness, and irritation.

With regard to scarring, each surgeon individually reviewed postoperative photographs at the 6 month mark, with no obvious differences observed between sides.

Figure 2 shows a patient 1-week postoperatively after a breast reduction (450 g on the left and 500 g on the right) with reduction in bruising and swelling on the right breast, which was dressed with the Prevena dressing. This was still noticeable at the 3-week postoperative mark (Fig. 3).

DISCUSSION

BRM is well described to reduce pain, improve function, and objectively improve health-related quality-of-life scores comparable to the general population.[2] The main complications of the procedure include wound breakdown, seroma, hematoma and poor-quality scarring. Furthermore, ongoing drain output can delay hospital discharge.[3]

Rates of wound dehiscence reported in the literature range from 14% to greater than 25%.[4]

Gabriel et al[5] revealed a highly significant effect in favor of ciNPWT with reduced surgical complication rates; shorter drain usage times; and lower rates of necrosis, infection, and seromas as compared with the recipients of standard dressings such as sterile gauze or absorbent dressings. Ferrando et al[6] also demonstrated that the ciNPWT is well-tolerated, reliable, and an adaptable dressing capable of reducing postsurgical complications and improving scar outcomes. Total drain output, day of drain removal, and adverse events were compared between cohorts with a minimum follow-up of 6 months.[6] Johnson et al[7] showed that application of ciNPWT to breast reduction wounds reduced early wound dehiscence.

The Restor dressing is hypothesized to improve outcomes in the following ways:

1. Coverage of all surgical incisions, reducing tension and promoting increased vascularity.
2. Wide sterile field: reduced risk of contamination and need for dressing changes when the patient is discharged.
3. Reduction of underlying edema and seroma risk through preventing shear forces.

Our results show a reduction in average drain output in the first and second postoperative days. We experienced two superficial wound dehiscence patients with larger volume reductions which healed uneventfully with surface dressings

The main drawback of the Restor relates to the sticky plastic required to maintain a negative pressure seal causing skin irritation/allergy. One patient experienced moderate-to-severe skin reaction and had the therapy removed at day 1 or 2. Clinically, these reactions were blistering skin erythema and pruritus, nonresponsive to oral antihistamines.

The cost of the Prevena Bella system is A$795 compared with Prineo at A$128 per unit, where two units may be required for wound coverage.

CONCLUSIONS

We have shown benefits in drain output and comfort using ciNPWT in BRM. We plan to continue to investigate ciNPWT in larger comparative trials for other breast procedures including implant-based reconstruction.

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DISCLOSURES

KCI (Acelity) provided the dressings used in the study without charge for purposes of scientific examination. The authors have no financial interest to declare in relation to the content of this article.

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