Journal of Orthopedics and Orthopedic Surgery

Case Series Open Access

The Prevena Restor Bella.FormTM in the management of lower limb traumatic wounds

Oliver Miles[1]*, Eugenia Koulaeva[2], Sally Ng[1,2]

[1]Department of Plastic and Reconstructive Surgery, Austin Health, Heidelberg, Australia

[2]Department of Plastic and Reconstructive Surgery, Eastern Health, Box Hill, Australia

Article Info

Article Notes
Received: February 28, 2024
Accepted: April 23, 2024

***Correspondence:**
*Dr. Sally Ng, Department of Plastic and Reconstructive Surgery, Austin Health, Heidelberg, Australia; Email: sally.ng@austin.org.au

Keywords
Trauma
Lower limb
Reconstruction
Wound

Abstract

Objectives: The Prevena Restor Bella.Form™ is a novel closed incisional negative pressure wound therapy with a 14 day lifespan and a large contact area. This study aims to demonstrate the utility of the Prevena Restor Bella.Form™ in high risk lower limb traumatic wounds.

Methods: 4 consecutive patients with complex traumatic lower limb wounds were included. The Prevena Restor Bella.Form™ was applied as a primary therapy or an adjunct to soft tissue reconstruction. Wounds were monitored fortnightly, limb circumference measured and patient satisfaction assessed by a questionnaire. All 4 patients healed within 6 weeks of Prevena application.

Results: No cases developed wound complications. Limb oedema, assessed by circumference, decreased in all patients within 2 weeks. All patients were satisfied with the Prevena Restor Bella.Form™ with regards to comfort and mobility.

Conclusions: Prevena Restor Bella.Form™ demonstrated clinical effectiveness in all patients, and was universally well tolerated.

Level of Evidence: IV

Introduction

Between 2020 and 2021, traumatic injuries were responsible for 8.4% of the disease burden and 7.9% of healthcare expenditure ($8.9 billion) in Australia[1]. Lower limb injuries account for 25% of these injuries, representing a significant healthcare burden. Lower limb trauma presents many issues for wound healing, including the tendency to develop limb oedema as well as a vulnerability to vascular disease. Even directly closable wounds from a significant mechanism of injury, or in the setting of diabetes mellitus, is at risk of wound infection, oedema and dehiscence[2,3]. Any mechanism that can aid wound healing thus has great application for lower limb trauma.

Negative pressure wound therapy (NPWT) is one such mechanism, and has demonstrated many benefits, including reducing oedema, creating a sterile barrier, offering continuous negative pressure and reducing tension across a wound line[4]. Utilisation of closed incisional NPWT (ciNPWT) is in its infancy, however via the induction of angiogenesis, maintaining a sterile wound environment and wound oedema reduction, ciNPWT has clinical utility in wounds at high risk of breakdown. Previous studies on ciNPWT have predominantly focused on elective breast, elective abdominal and elective lower limb orthopaedic wounds, thus ciNPWT is now becoming part of routine wound management at some major centres[5-7]. A recent 2019

meeting in the United States of America found an expert panel who recommended the use of ciNPWT in high risk patients and high risk wounds[8]. This meeting neglected some of the highest risk wounds in surgery, those secondary to lower limb trauma. Despite meta-analyses describing the benefits of ciNPWT on wound infections and dehiscence in orthopaedic trauma[9], this treatment modality is potentially under-utilised.

The Prevena Restor Bella.Form™ dressing is a larger ciNPWT with a 0.019% ionic silver impregnated dressing foam, made to surface large contoured wounds, such as in breast surgery and lower limb vascular amputations, and has demonstrated benefits in wound healing in those contexts[10]. The application of the Prevena Restor Bella.Form™ to lower limb wounds has great clinical potential, however is insufficiently studied.

As such, this study hopes to identify the impact of the Prevena Restor Bella.Form™ in a subset of high risk lower limb wounds. We aim to explore the dressing's effect on healing time, the rate of wound complication development, and the quantifiable impact on lower limb oedema in traumatic lower limb wounds.

Methods

This study was a case series of 4 consecutive patients referred to a single plastic surgeon between June and August of 2022 for advice regarding traumatic lower limb wounds. Inclusion criteria included being 18 years old or more, having a lower limb wound sustained from trauma, having capacity to consent to inclusion in the study and having a wound where NPWT was part of the appropriate clinical management. Oedema and lower limb swelling was a key component to the wound complexity in all patients and patients were either not fit for vascularised flap coverage or less invasive surgical reconstructions were preferred. The Prevena Restor Bella.Form™ was then applied, either as a sole therapy or as an adjunct to surgical management at the time of reconstruction with split thickness skin grafts (STSG). All patients were fitted with a loose compressive circumferential wool and crepe bandage from toes to knees. Mobility restrictions were decided on a case-by-case basis. All patients were advised to keep their leg elevated when at rest.

Patients had their limb circumference measured 3cm proximal to the lateral malleolus, 3cm inferior to the fibula head and at a point halfway between these 2 landmarks at the time of Prevena Restor Bella.Form™ application. The Prevena Restor Bella.Form™ has a battery life of 2 weeks, so patients were followed up at 2-week intervals where they had their wounds inspected for signs of infection, dehiscence, discharge and skin integrity. Limb circumference was re-measured to assess degree of oedema at 2- and 4-weeks post application of the Prevena Restor Bella.Form™. The Prevena Restor Bella.Form™ was ceased once the wound was clinically determined to be healed and stable.

Patients had their satisfaction with the device assessed once treatment was completed, consisting of 5 questions (Table 1). These questions were designed to assess impact of the device on daily activities, overall hospital experience, device comfort and mobilisation.

This case series represents a predominantly qualitative study with purely descriptive statistics. No statistical analysis was conducted. The STROBE STATEMENT was used to ensure proper reporting of methods, results and discussion.

Results

Case 1

This 84-year-old female sustained an open tri-malleolar fracture following a fall which required open reduction and internal fixation (ORIF). She had a background of ischaemic heart disease, type 2 diabetes and previous strokes. She was referred with lateral leg incisional flap tip necrosis with threatened exposed underlying metalware at her initial wound review following ORIF (Figure 1). Given she was a poor free flap candidate due to her comorbidities, the decision was made to minimally debride and manage conservatively with the ciNPWT. Following her 2-week wound review which showed incremental improvement, the patient was transferred to a rehabilitation facility. After 6 weeks of Prevena Restor Bella.Form™, secondary intention healing had adequately progressed and she was deemed fully healed and weight baring commenced, in keeping with orthopaedic recommendations and her stable wound.

Table 1: Patient questionnaire responses following treatment course of Prevena Restor Bella.Form™

Feedback				Yes	No
Does the device impact on your daily activities?				-/-	100%
Does the device contribute to the overall satisfaction of your hospital experience				100%	-/-
Comfortability assessment	Poor	Average	Good	Very good	Excellent
Comfortable with range of movement	-/-	-/-	-/-	25%	75%
Comfort of dressing	-/-	-/-	-/-	25%	75%
Ease of mobilisation	-/-	-/-	-/-	25%	75%

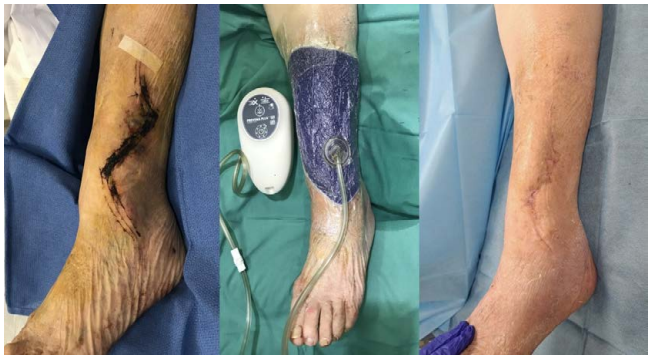

Figure 1: Case 1. Left – lateral leg wound with compromised necrotic flap tip pre-application of Prevena; Central – leg with Prevena in situ; Right – Fully healed wound 6 weeks following initial Prevena application.

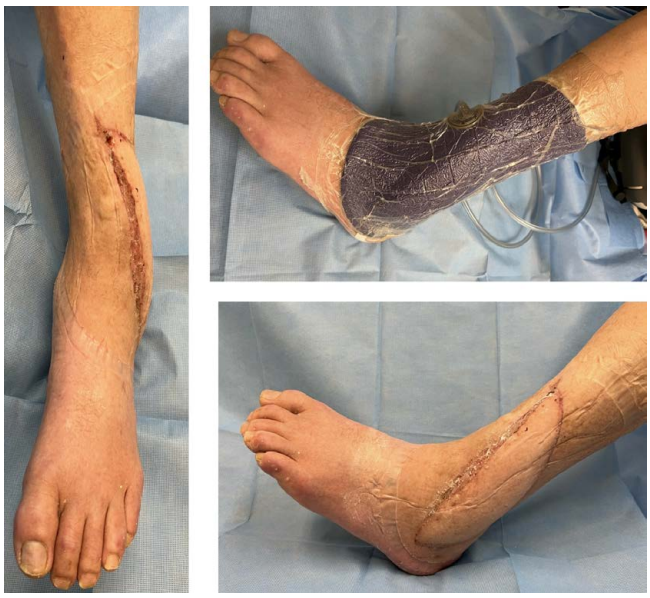

Figure 2: Case 2. Left – dehisced anterolateral thigh flap anterior inset prior to Prevena therapy; Top right – Prevena in situ; Bottom right – following 4 weeks of Prevena therapy.

Case 2

A 64-year-old male was referred with an open distal tibial periprosthetic fracture following a fall. He had a background of a tibial ORIF 10 years prior and obesity. He underwent debridement, removal of metalware, tibial ORIF and an ankle fusion. He had soft tissue loss laterally that was reconstructed with an anterolateral thigh flap. At day 21 there was delayed healing at the distal flap inset, as well as leg and flap oedema and a 5x5mm grade 2 achilles pressure ulcer. Given the wounds were at risk of deterioration, to prevent debridement and need for further reconstruction of exposed metalware, the decision was made to utilise the Prevena Restor Bella.Form™ to manage oedema and encourage wound healing. Following application of the Prevena Restor Bella.Form™ for 4 weeks, all wounds had fully healed with a reduction in oedema (Figure 2).

Case 3

A 39-year-old male with a crush from an excavator sustained midfoot and ankle fractures. He had a history of dorsal foot burns and a previous skin graft 5 years prior. Dorsal foot swelling progressed resulting in an 8x8cm area of dorsal foot skin necrosis over the previous skin graft requiring debridement at the time of ORIF (Figure 3). An artificial dermal matrix (ADM) was applied for coverage over the pre-existing scarred wound bed, and a Prevena Restor Bella.Form™ over the ADM. Following 4 weeks of NPWT, oedema had reduced and the ADM fully integrated. A STSG was applied with an overlying Prevena Restor Bella. Form™. The patient was kept resting in bed, only allowed to ambulate to the toilet and kept in a CAM boot. After 2 weeks the graft had fully taken, and at 4 weeks the wound stable enough to cease NPWT (Figure 4).

Case 4

A 29-year-old female with a background of obesity developed a spontaneous lower limb compartment syndrome requiring fasciotomies and serial debridement of necrotic anterior and lateral compartment musculature.

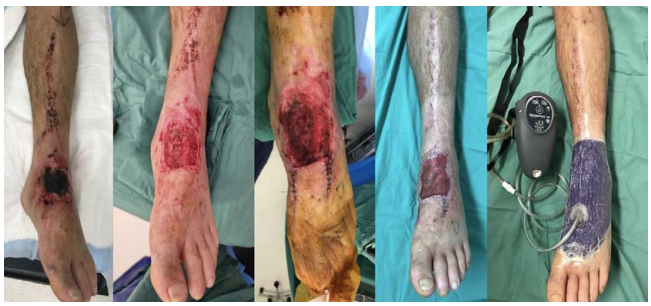

Figure 3: Wound progression in case 3. From left to right: Dorsal foot skin necrosis following crush injury; Skin defect post initial debridement; Skin defect following mid-foot open reduction internal fixation and further debridement; Post application of acellular dermal matrix (ADM); Prevena applied over the ADM.

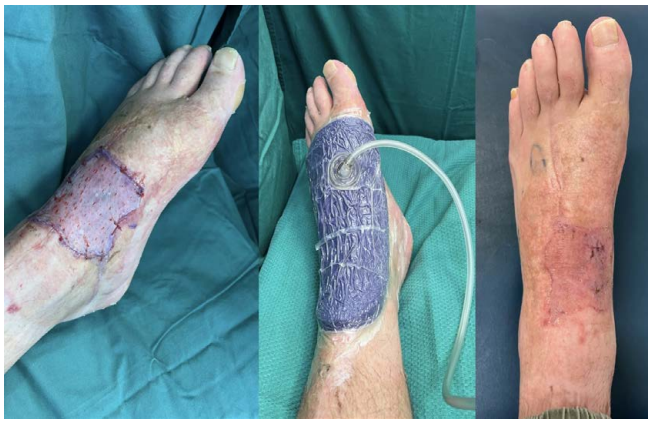

Figure 4: Case 3 wound healing. Left – Application of split thickness skin graft (STSG) following initial Prevena therapy; Centre – Prevena as primary dressing over STSG; Right – 4 weeks post STSG.

Table 2: Leg circumferences in cm prior to Prevena Restor Bella.Form™ application and at 2-week intervals

(cm)	Case 1 – Leg wound			Case 2 – Free flap			Case 3 – Foot STSG			Case 4 – Leg STSG		
	Fibula head	Mid calf	Lateral malleolus	Fibula head	Mid calf	Lateral malleolus	Fibula head	Mid calf	Lateral malleolus	Fibula head	Mid calf	Lateral malleolus
Pre Bella	49	30	28.5	38.5	29.5	30	36.5	34.5	31.5	50	41	26
Week 2	46	29	25	38	28.5	27	35.5	32.5	30	48	38	25
Week 4	46	29	25	38	28.5	27	35.5	32.5	30	48	38	24
STSG= split thickness skin graft												

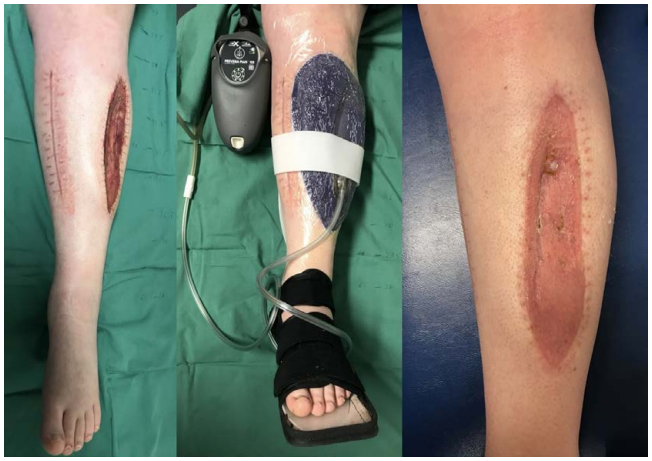

Figure 5: Case 4. Left – Left leg lateral fasciotomy wound pre skin grafting; Centre – Prevena as primary dressing over STSG; Right – 4 weeks post STSG.

The resultant lower limb was grossly oedematous. The lateral fasciotomy wound was not directly closable and given the residual significant contour deformity to her medial leg, an ADM was applied with an overlying Prevena Restor Bella.Form™. After 4 weeks the ADM was reconstructed with a STSG and the Prevena Restor Bella.Form™ applied again. She progressed well at her 2 week wound review and was fully healed at 4 weeks post-operatively (Figure 5).

Survey feedback was 100%. Patients universally were satisfied with the Prevena Restor Bella.Form™ and scored the dressing either 'Very Good' or 'Excellent' with respects to comfort and range of motion (Table 1). All 4 limbs demonstrated a reduction in their limb circumference following Prevena Restor Bella.Form™ application (Table 2).

Discussion

This study aimed to demonstrate the effectiveness of the Prevena Restor Bella.Form™ in treating traumatic lower limb wounds. In our series of 4 patients, the universal experience was of a healed wound within 6 weeks of device application or 4 weeks from the time of reconstruction. All patients had barriers to healing, particularly related to mechanism of injury and underlying comorbidities, yet none progressed in wound breakdown following application of the Prevena Restor Bella.Form™.

Via its size, the Prevena Restor Bella.Form™ is able to create a near circumferential contact area over lower limbs. This enables it to broaden its effect to the entire zone of injury, and sometimes beyond this where dependent oedema accumulates. Limb oedema compromises wound healing, but also worsens post-operative pain and joint stiffness, incredibly important for limb surgery and facilitating earlier access to rehabilitation[11].

Limb circumference reduced in all 4 subjects, with the most profound effect being within the initial 2 weeks of application (Table 2). Although not quantified in the literature, ciNPWT is speculated to decrease oedema by limiting subcutaneous potential space adjacent the zone of injury, and improving venous and lymphatic drainage[11,12]. Limb circumference is a readily accessible and reliable method for measuring limb oedema[13], however it is crude and does not account for changes in muscle mass or soft tissue loss, as is the case in 3 out of 4 patients in our series. Future studies may investigate the impact of NPWT on oedema via modern bioimpedance measures[14]. Comparative studies assessing standard dressings, ciNPWT and the Prevena Restor Bella.Form™ may illuminate the quantifiable impact on limb oedema.

Another key finding was the universally positive experience patients had with the Prevena Restor Bella. Form™, according to the feedback survey (Table 1). All patients were satisfied with the device with respects to daily life, their treatment and report either 'very good' or 'excellent' scores to the questions targeting comfort of the dressing. As previously stated, the dressing is near circumferential, thus is thought to profoundly reduce oedema. This reduction in oedema may result in less stiffness and pain, potentially contributing to the experienced comfort of the Prevena Restor Bella.Form™.

Patients in cases 3 and 4 had previously been treated with the standard vacuum assisted closure (VAC) dressing prior to involvement in this study. Both patients experienced subjectively better comfort with the Prevena Restor Bella. Form™, prompting one to report that the Prevena Restor Bella.Form™ "compared to the standard VAC [was] 100% better". Although short and user friendly, our questionnaire is not validated or standardised. Validated questionnaires may be employed in future studies to quantify the patient experience of the Prevena Restor Bella.Form™. This would aid in comparison of patient experience with the Prevena

Restor Bella.Form™ with other dressings, and should be considered in potential future prospective study design.

Another advantage of the Prevena Restor Bella.Form™ is the 2 week life span of the dressing and its battery. Compared to the standard VAC, the Prevena battery is compact, lighter and not reliant on daily charging, being convenient to the patient and decreasing the regularity of clinic visits for both patients and hospital staff. This also increases the lifespan of the primary dressing applied at surgery to 2 weeks. Although various cost effectiveness studies have not demonstrated a clear cost benefit for the use of ciNPWT[15], it is worth noting that these studies compared NPWT techniques versus standard simple dressings regimens. An internal comparison was made between the 14day Prevena Restor Bella.Form™ dressings and the cost of a standard VAC with a foam change at 1 week, demonstrating a cheaper price of AUD$795 for the Prevena Restor Bella. Form™ versus AUD$808 for the VAC. This is particularly beneficial for traumatic lower limb wounds with soft tissue loss requiring skin grafts where VAC dressings are used to stabilise STSGs, highlighting a potential subgroup of limb wounds where the Prevena Restor Bella.Form™ would be both clinically and economically superior.

This case series demonstrates the successful use of the Prevena Restor Bella.Form™ on traumatic lower limb wounds. Limited by the small sample size and the lack of a control group, this study highlights the need for future larger randomised controlled trials exploring the use of Prevena Restor Bella.Form™, in particular comparing the Prevena Restor Bella.Form™ with commonly used NPWT dressings and attempting to quantify oedema reduction by assessing tissue bioimpedance.

Declarations

The authors have no conflicts of interest to disclose. The authors received no financial support for the research, authorship, and/or publication of this article.

Patients have given informed written consent to the publication of images and/or data.

This study received exemption from full hospital research ethics committee approval via Eastern Health. All patients gave full consent for participation in the study.

References

1. Injury in Australia. Australian Government Department of Health. 2022. Available from: https://www.aihw.gov.au/reports/injury/injury-in-australia
2. Benirschke SK, Kramer PA. Wound healing complications in closed and open calcaneal fractures. Journal of Orthopaedic Trauma. 2004; 18(1): 1-6. doi:10.1097/00005131-200401000-00001
3. Harris AM, Althausen PL, Kellam J, et al. Complications following limb-threatening lower extremity trauma. Journal of Orthopaedic Trauma. 2009; 23(1): 1-6. doi:10.1097/bot.0b013e31818e43dd
4. Sirisena R, Bellot GL, Puhaindran ME. The role of negative-pressure wound therapy in lower-limb reconstruction. Indian Journal of Plastic Surgery. 2019; 52(01): 073-80. doi:10.1055/s-0039-1687922
5. Ferrando PM, Ala A, Bussone R, Bergamasco L, et al. Closed incision negative pressure therapy in oncological breast surgery. Plastic and Reconstructive Surgery - Global Open. 2018; 6(6). doi:10.1097/gox.0000000000001732
6. Wang J, Chapman Z, Cole E, et al. Use of closed incision negative pressure therapy (CINPT) in breast reconstruction abdominal free flap donor sites. Journal of Clinical Medicine. 2021; 10(21): 5176. doi:10.3390/jcm10215176
7. Pachowsky M, Gusinde J, Klein A, et al. Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. International Orthopaedics. 2011; 36(4): 719-22. doi:10.1007/s00264-011-1321-8
8. Silverman RP, Apostolides J, Chatterjee A, et al. The use of closed incision negative pressure therapy for incision and surrounding soft tissue management: Expert panel consensus recommendations. International Wound Journal. 2021; 19(3): 643-55. doi:10.1111/iwj.13662
9. Wang C, Zhang Y, Qu H. Negative pressure wound therapy for closed incisions in orthopedic trauma surgery: A meta-analysis. Journal of Orthopaedic Surgery and Research. 2019; 14(1). doi:10.1186/s13018-019-1488-z
10. West J, Wetherhold J, Schulz S, et al. A novel use of next-generation closed incision negative pressure wound therapy after major limb amputation and amputation revision. Cureus. 2020. doi:10.7759/cureus.10393
11. Lin KC, Li Y-S, Tarng Y-W. Safety and efficacy of prophylactic closed incision negative pressure therapy after acute fracture surgery. Injury. 2020; 51(8): 1805-11. doi:10.1016/j.injury.2020.05.032
12. Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): Hematoma/Seroma and involvement of the lymphatic system. Wound Repair and Regeneration. 2011; 19(5): 588-96. doi:10.1111/j.1524-475x.2011.00714.x
13. Nishimura M, Kato T, Onodera S. Evaluation methods for the measurement of lower leg edema in healthy young adults. Yonago Acta Medica. 2020; 63(4): 294-300. doi:10.33160/yam.2020.11.007
14. King RJ, Clamp JA, Hutchinson JW, et al. Bioelectrical impedance: A new method for measuring post-traumatic swelling. Journal of Orthopaedic Trauma. 2007; 21(7): 462-8. doi:10.1097/bot.0b013e318123e88a
15. Costa ML, Achten J, Knight R, et al. Negative-pressure wound therapy compared with standard dressings following surgical treatment of major trauma to the lower limb: The whist RCT. Health Technology Assessment. 2020; 24(38): 1-86. doi:10.3310/hta24380