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A Prospective, Controlled, Randomised, Clinical Study of Negative Pressure Device Without Foam or Gauze for Skin and Soft Tissue Defects

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ABSTRACT

All common negative pressure wound therapy (NPWT) systems include a filler material usually foam or gauze at the wound/device interface. The filler material distributes the negative pressure evenly to all parts of the wound. The foam or gauze may fragment contributing to foreign material being retained in the wound, becoming colonised with bacteria over time, and painful dressing changes. To mitigate these, negative aspects, an impermeable embossed single-layer NPWT membrane dressing has been developed. The dressing has been coined Negative Pressure—Platform Wound Device (NP-PWD) and a foam or gauze is not required to deliver negative pressure. Rather, the pressure is permeated via the spaces between the embossed pyramids and the wrinkles in the membrane. The purpose of this study was to compare the NP-PWD to the standard of care (SOC) NPWT system in the treatment of skin and soft tissue defects. This was a prospective, randomised, controlled clinical trial. The wounds were treated with the NP-PWD or SOC NPWT system. The randomised treatment was applied for 2 days to up to 9 days after the initial application. Follow-up data were collected at each dressing change/removal and included photographs, and assessments for wound healing, infection, and adverse events. In total 24 subjects (12 NP-PWD and 12 SOC) completed the study. The NP-PWD was easy to use and fast to apply and the patients tolerated it well. The transparency of the NP-PWD allowed the provider to see the wound without removing the dressing which is an improvement over traditional NPWT. In terms of wound healing, inflammation, pain, and infection, no differences were observed between the NP-PWD and the SOC NPWT system. The NP-PWD is a simplified, single component NPWT system eliminating the use of the filler material that commonly causes challenges during treatment.

1 | Introduction

Open complex wounds are a significant healthcare burden. They are injuries that are difficult to heal due to extensive skin loss, aggressive infection, or impaired tissue viability and are commonly associated with systemic diseases such as diabetes and vascular disorders [1]. The principles of management of complex wounds involve continuous wound assessment, antimicrobial therapy, and surgical therapy to prepare the wound bed for closure strategies. In today's practice, negative pressure wound therapy (NPWT) is commonly used as a tool for appropriate wound bed preparation that is critical to the success of healing a wound [2]. Since its commercial introduction in the 1990s, NPWT has become the gold standard in the management of wounds with various etiologies and numerous studies over the years have demonstrated its efficacy [3–5].

Summary

- Conventional NPWT systems include a filler material usually foam or gauze at the wound/device interface.
- The NP-PWD is a simplified, single-component NPWT system without foam or gauze.
- The NP-PWD was compared to the SOC NPWT system in the treatment of skin and soft tissue defects.
- This prospective, randomised, controlled clinical trial of 24 subjects demonstrated that the NP-PWD was easy to use, fast to apply, and tolerable by the patients.
- No differences were observed between the NP-PWD and the SOC NPWT system in wound healing, inflammation, pain, or infection.

The NPWT promotes wound healing via four primary mechanisms: Macro- and micro-deformation of the wound, drainage of fluids and by creation of moist wound environment [6]. Once negative pressure is activated it stimulates macro-mechanical stressors that start pulling the wound edges together, thus increasing wound contraction. Simultaneously, the negative pressure stimulates micro-mechanical stressors increasing angiogenesis and granulation tissue formation. The applied suction also removes wound exudate that decreases edema and increases wound perfusion by releasing the pressure caused by the accumulation of fluid around blood vessels [7]. In addition, the suction removes pathogens and inflammatory mediators and cytokines that might delay healing. Finally, the NPWT stabilises the wound by creating a healing promoting moist wound environment [8, 9].

The SOC NPWT systems consist of several parts including an interface dressing, adhesive film dressing, drainage tubing, and a vacuum pump. During application, the interface dressing, foam or gauze, is placed directly on the wound and sealed with an adhesive film dressing. A drainage tube is connected superficially to the foam or gauze with additional adhesive film and connects the interface dressing to a vacuum pump that provides suction leading to negative pressure at the wound site [3, 10].

The purpose of the foam—or gauze—made interface dressings is to fill the void caused by the injury and distribute negative pressure evenly over the wound bed. In addition, they absorb exudate and create a moist wound environment. However, the interface dressing is also associated with several challenges in the NPWT [11]. Especially, tissue ingrowth into the interface dressing has been a persistent problem causing additional trauma, bleeding, and significant pain and discomfort to patients during dressing changes. The dense or thick foam/gauze increases the required pump capacity which can also cause patient discomfort or even ischemia in wounds with compromised vascularity. Furthermore, the foam or gauze may fragment and become colonised with bacteria over time [12, 13].

To mitigate these negative aspects, a novel NPWT system without the interface dressing has been developed. The Negative Pressure Platform Wound Device or NP-PWD consists of an impermeable single layer membrane dressing that is attached to the perimeter of the wound with an integral adhesive. The underside of the membrane is connected to a suction pump and once suction is activated and the desired negative pressure is achieved, the membrane is pulled into contact with the entire surface area of the wound. The surface of the membrane is comprised of three dimensional shapes that in the provided devices resemble pyramids. The tips of the pyramids are in direct contact with the entire wound and surface which provide a structure for micro-mechanical forces, the space between the pyramids provides primary distribution channels for negative pressure and folds in redundant membrane create channels for secondary distribution (Figure 1).

Previous porcine studies comparing foam-containing dressings to the NP-PWD have found them generally equivalent in terms of wound surface area and depth reduction as well as neovascularisation, granulation tissue development, and inflammatory changes [14]. The purpose of this clinical study was to evaluate the feasibility of the NP-PWD compared to standard of care (SOC), foam interface dressing containing NPWT system, in the management of skin and soft tissue defects. The treatments were evaluated through assessment of healing time, feasibility of application, inflammation, infection, patient comfort (pain), and adverse events.

2 | Materials and Methods

This study adhered to the CONSORT (Consolidated Standards of Reporting Trials) throughout the design, execution, and reporting of this randomised controlled trial. The CONSORT checklist was used to ensure transparency, reproducibility, and thorough reporting of study methodology and results [15].

2.1 | Patient Selection

This study was approved by the Advarra Institutional Review Board (IRB No. Pro00071928) and registered at clinicaltrials.gov (No. NCT06552481). All procedures were performed in accordance with the relevant guidelines and regulations of the centre, and all patients enrolled in the study gave written informed consent prior to enrollment. Twenty-eight patients, 18 years of age or older, who were requiring treatment for open skin and soft tissue defects at a hospital within the Baptist Health System in San Antonio, TX, were recruited for participation in this study. The inclusion and exclusion criteria for patient participation are presented in Table 1.

2.2 | Treatments and Study Design

Following consent, the participants were randomised, using a computer-generated randomisation schedule, to receive either the study treatment or SOC. The study NPWT system, Negative Pressure Platform Wound Device (NP-PWD) (Applied Tissue Technologies LLC, Hingham, MA), is a sterile transparent single component NPWT dressing made of polyurethane. Three types of PWDs were utilised in the study: (1) Circular shape NP-PWD (⌀ 3.0″), (2) Oblong shape NP-PWD (1″ × 3″), and (3) Oblong Shape NP-PWD (3″ × 5″) (Figure 2A). The NP-PWD was connected to a small single-use AA battery-operated pump

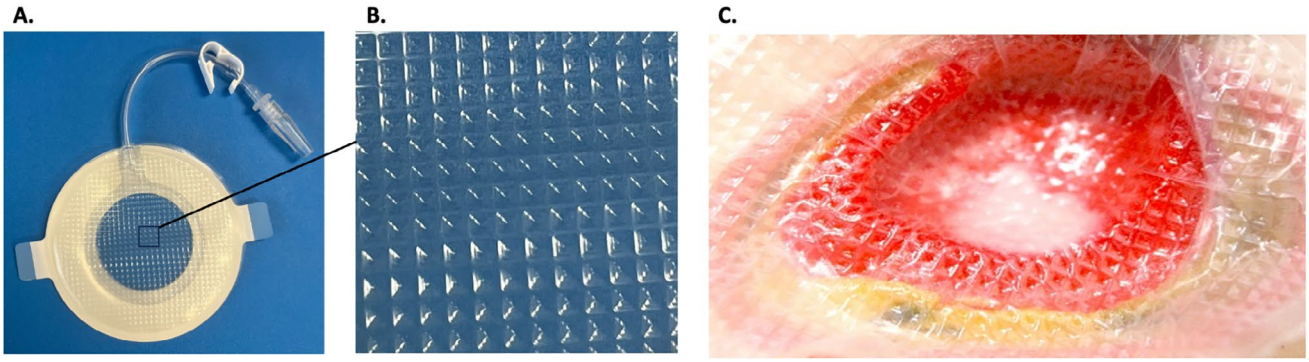


FIGURE 1 | (A) The Negative Pressure Platform Wound Device (NP-PWD) consists of an impermeable, transparent single layer membrane that is attached to the perimeter of the wound with an integral adhesive. The membrane is connected to a suction pump with tubing built-in tubing. (B) The superstructure of the membrane comprises embossed pyramids that are in direct contact with the wound. The pyramids provide a pattern for micro-mechanical forces and the space between the pyramids provides primary distribution channels for negative pressure and folds in redundant membranes create channels for secondary distribution of negative pressure. (C) Once suction is activated and the desired negative pressure is achieved, the membrane is pulled into contact with the entire surface area of the wound eliminating the use of foam or gauze.

TABLE 1 | Exclusion and inclusion criteria.

Inclusion criteria	Exclusion criteria
All subjects enrolled must meet all the following criteria: • Patients 18 years of age or older of either gender • Have an open skin or soft tissue defect requiring treatment	Subjects who meet any of the following criteria will be excluded from the study: • Active malignant disease at the study site • Any concomitant medications or co-morbidities that, in the opinion of the investigator, may interfere with device use • On any investigational drug(s) or therapeutic device(s) to the study site in the last 30 days or any previous enrollment in this study • Pregnant at enrollment

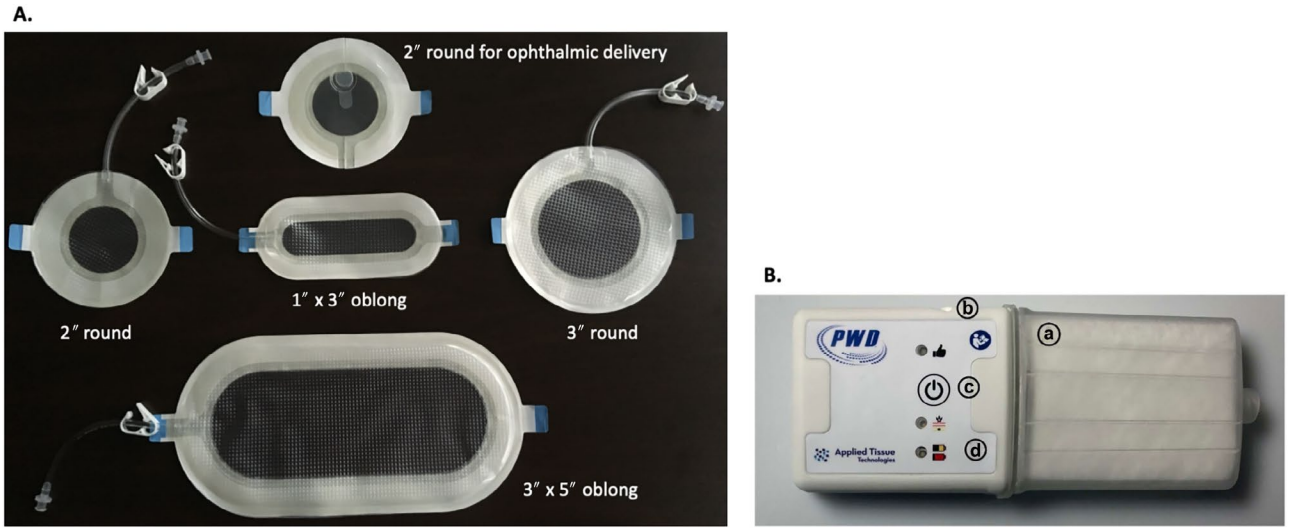


FIGURE 2 | (A) Examples of NP-PWD sizes. In the present study, circular-shaped (4.0″ adhesive base diameter, and a maximum of 2.0″ wound opening), and oblong shaped (5.5″ adhesive base external length, and a maximum of 4.0″ wound opening overall length) NP-PWDs were utilised. PWD is tooled for large-scale manufacturing (GMP) and is compliant with ISO 13485:2016. (B) The NP-PWD uses a small (smartphone-size), single-use, AA battery-operated, electric motor-driven diaphragm pump (Applied Tissue Technologies LLC). It delivers continuous negative pressure at −80 mmHg and is programmed in such a way that it can be operated for a preset device runtime (7 days) after the batteries have been inserted. It contains a disposable exudate canister (50 mL) with an internal bacterial filter and absorbent fleece. (a) Exudate canister; (b) Canister locking lever; (c) On/Off button; (d) Display foil with Status-LEDs.

(Applied Tissue Technologies LLC) and continuous negative pressure was applied at −80 mmHg (Figure 2B). The V.A.C. Granufoam Dressing together with V.A.C. Ulta Therapy Unit was used as the SOC NPWT system. The corded SOC suction pump was connected to a power source and programmed to deliver continuous negative pressure at −125 mmHg (3 M, Saint

Paul, MN). Both NPWT systems were operated based on their instructions for use (IFU).

Prior to the initial application, wound evaluations, and photography were completed to include assessment of infection with deep wound swabs. The wound dressings were assessed for the need for change every 2–3 days and changed if clinically indicated (following each device's IFU). Subjects were followed for up to 9 days post-initial application. At minimum for a subject to be considered complete, the randomised treatment was applied for 2 days after initial application. Therefore, the wounds were divided into three groups based on the duration of treatment: 2–3 day group, 5–6 day group, and 7–9 day group. Follow-up data were collected at each dressing change/removal of the NP-PWD or SOC. The data collected included indications for dressing change, dressing change process, photographs, and assessments of wound healing, infection, and adverse events.

2.3 | Assessments

2.3.1 | Wound Healing

Wound examinations were completed at each visit. Silhouette Star (Aranz Medical Ltd., New Zealand) imaging system was used to capture macroscopic images before, during, and after initiation of the treatment. Wound closure was measured using Silhouette Connect software (Aranz Medical Ltd). Wound healing was assessed based on the examination and the images.

2.3.2 | Pain Assessment

Pain was measured on day 0 before the start of the treatment, during dressing changes, and at final dressing removal. The 0 to 10 analog pain scale was used where a score of 0 means no pain, and 10 means the worst pain you have ever known [16].

2.3.3 | Macroscopical Assessments of Wound Inflammatory Characteristics

Clinical evaluations of the wound inflammatory characteristics including erythema, swelling, warmth, discharge, and odour were performed by nonblinded research nurses at baseline and follow-up for each subject. If any of these characteristics were present, the wound was given a score of 1, if not it was given a 0.

2.3.4 | Bacteriological Analysis of Wound Swabs

Wound culture swabs were taken using the Levine technique prior to the initial dressing application on day 0 (baseline) and at the final dressing removal (final visit) for qualitative bacteriological analysis [17]. The samples were scored for bacterial growth for each bacterial species found in the swab according to the following scale: 0 = No growth, 1 = Very light growth, 2 = Light growth, 3 = Moderate growth, and 4 = Heavy growth.

2.3.5 | Usability and Adverse Events

The study NPWT system was assessed for usability over the course of the study and the wounds were evaluated for any adverse events at every dressing change/removal throughout the study duration by the wound care providers and research nurses.

2.3.6 | Statistical Analysis

Data analyses were done using GraphPad Prism 10.0 software (Graph Pad Software Inc., La Jolla, CA). A comparison of the different groups was performed using a student's *t*-test and values $p < 0.05$ were considered statistically significant. All data are presented as mean ± standard error of the mean (SEM).

3 | Results

3.1 | Patient Demographics

The randomised treatment had to be continued for at least 2 days after the initial application for a subject to be considered complete. In total 28 subjects were enrolled and 24 subjects (86%) (12 NP-PWD and 12 SOC) completed the study. Ten patients were treated for 2–3 days, 7 for 5–6 days, and 7 for 7–9 days. The two randomised groups were similar in terms of demographic characteristics and comorbidities. The majority of patients were female (67%), and the median age was 57 at the time of enrollment. Furthermore, 50%, 38%, and 12% of the enrolled subjects were White, Hispanic, and African American, respectively. The most common mechanism of injury was infection (42%). Patient demographics are presented in Table 2.

3.2 | Wound Healing

Wound healing was studied macroscopically by obtaining digital photographs of the wounds during the study period. Ten wounds were skin-grafted, and no significant differences in wound closure were observed between the two treatments in the 14 non-grafted wounds.

3.3 | Pain

Pain was measured using the 0 to 10 pain scale. The average baseline pain scores on day 0 for NP-PWD and SOC wounds were 4.4 and 4.4, respectively. The average pain scores on days 2–3, 5–6, and 7–9 were 3.7 and 5.2, 4.4 and 6.3, and 3.5 and 3.8, for the wounds treated with the NP-PWD and SOC, respectively. No statistically significant differences in pain were observed between the two groups (Figure 3A).

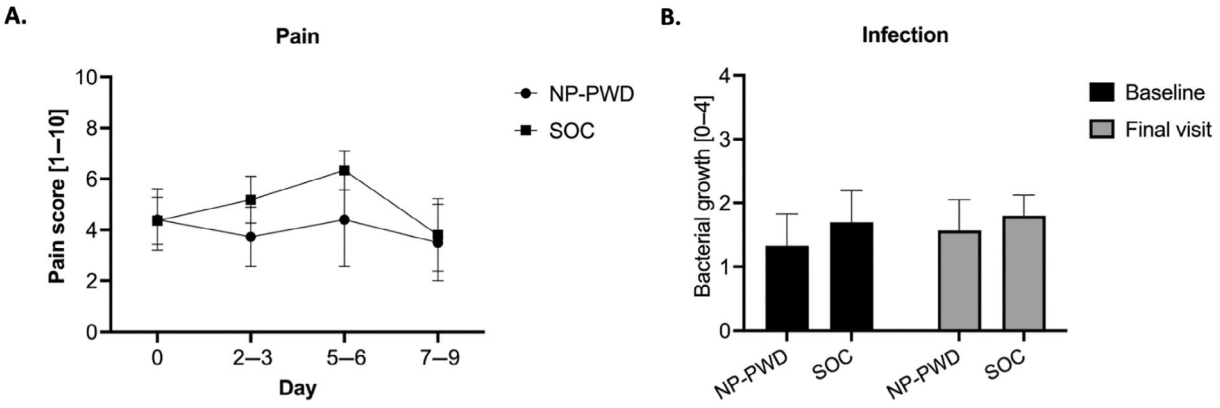
3.4 | Bacteriological Analysis

The average bacterial growth scores at baseline for the NP-PWD and the SOC wounds were 1.3 ± 0.5 and 1.7 ± 0.5, respectively. At the final visit, the average growth score for the NP-PWD-treated

TABLE 2 | Patient demographics.

Subject	Age	Gender	Ethnicity	Treatment	Skin graft	MOI	Location	Size (cm)	DOT (d)
1	68	F	Caucasian	NP-PWD	No	Infection	Right lower leg	6.8×3.5	2–3
2	46	M	Hispanic	NP-PWD	Yes	Abscess/infection	Right achilles	5×3.5	2–3
3	46	M	Hispanic	NP-PWD	Yes	Achilles tear, abscess infection	Right achilles	7.2×2.8	2–3
4	85	F	Caucasian	NP-PWD	Yes	Lymphedema and calcinosis cutis	Right lower leg	2.3×3	2–3
5	49	F	Hispanic	NP-PWD	No	Hidradenitis surgical removal	Right axilla	11×14.5	2–3
6	52	F	Caucasian	SOC	No	Pressure	Coccyx	3×0.5×0.5	2–3
7	51	F	Black	SOC	No	Diabetic foot ulcer	Left foot	26×7	2–3
8	64	M	Hispanic	SOC	Yes	Hidradenitis suppurativa	Left buttock	21×11.5	2–3
9	55	F	Caucasian	SOC	Yes	Hardwear infection	Right lower leg	7.5×3	2–3
10	59	F	Caucasian	SOC	Yes	Infected surgical wound	Abdominal wound	9.5×5×1.5	2–3
11	46	M	Hispanic	NP-PWD	No	Abscess/infection	Right achilles tendon	5×3.5	5–6
12	53	F	Hispanic	NP-PWD	No	Surgical incision infected	Back	16×4×4	5–6
13	55	F	Caucasian	NP-PWD	Yes	Hardware infection	Right lower leg	6.5×3	5–6
14	77	F	Caucasian	NP-PWD	No	Pressure	Left Ischium	5×5.5×4.2	5–6
15	52	F	Caucasian	SOC	No	Abscess	Right buttock	3.5×3×1.2	5–6
16	77	M	Black	SOC	No	Pressure	Sacrum	5.5×10.5×2	5–6
17	38	M	Caucasian	SOC	No	Surgical removal of seroma pocket	Right thigh	16×8×1.5	5–6
18	67	M	Caucasian	NP-PWD	Yes	Mohs surgery area	Left lower Leg	26.7×7.6	7–9
19	49	F	Hispanic	NP-PWD	Yes	Dehisced surgical wound	Right axilla	7.5×6	7–9
20	75	M	Caucasian	NP-PWD	No	Pressure	Right hip	3×3×2	7–9
21	53	F	Hispanic	SOC	No	Infected surgical incision	Back	16.4×3.5×4	7–9
22	55	F	Caucasian	SOC	No	Hardware infection	Right lower leg	6×3	7–9
23	27	F	Black	SOC	No	Picc line infection	Right upper arm	10×8	7–9
24	74	F	Hispanic	SOC	Yes	Radiation	Right lower leg	5.3×2.2	7–9

Abbreviations: DOT, duration of treatment; MOI, mechanism of injury.



C.

Inflammation

	Day 2–3		Day 5–6		Day 7–9	
	NP-PWD	SOC	NP-PWD	SOC	NP-PWD	SOC
Discharge	3/12	5/11	3/6	1/7	1/3	0/4
Erythema	2/12	0/11	0/6	1/7	0/3	0/4
Local Warmth	0/12	0/11	0/6	0/7	0/3	0/4
Odor	1/12	1/11	0/6	1/7	0/3	0/4
Swelling	2/12	1/11	0/6	0/7	0/3	1/4

FIGURE 3 | (A) The graph demonstrates the pain score progression from baseline to days 7–9 for both NP-PWD and SOC. No statistically significant differences in pain were observed between the two groups. (B) The bacterial growth scores for both groups before (average baseline score) and after (average final visit score). No significant differences between the treatment groups were observed. (C) The table describes how many wounds at different time points showed clinical signs of erythema, swelling, warmth, discharge, or odour.

wounds was 1.6 ± 0.5 and 1.8 ± 0.3 for the SOC-treated wounds. The bacterial growth scores for both groups before (average baseline score) and after (average final visit score) treatment are shown in Figure 3B. No significant differences between the treatment groups were observed.

3.5 | Wound Inflammatory Characteristics

The wounds were assessed for different inflammatory characteristics (erythema, swelling, warmth, discharge, or odour) before, during, and after the treatment. On day 0, before the start of the treatment 42% and 33% of the NP-PWD and SOC wounds, respectively, showed signs of inflammation in terms of erythema, swelling, warmth, discharge, or odour. At 2–3 days after treatment, 25% and 27% of the NP-PWD and SOC-treated wounds, respectively, had signs of inflammation. By days 5–6 and 7–9, 50% and 29%, and 33% and 25% of the NP-PWD and SOC wounds, respectively showed signs of inflammation. The results demonstrated that neither of the treatments significantly improved the inflammatory status of the wounds during the study period. Individual assessments for each parameter are shown in the Figure 3C.

3.6 | Usability and Adverse Events

One of the objectives of this study was to evaluate the usability of the NP-PWD in the management of different skin and soft tissue injuries. Being a single-component dressing, the NP-PWD was easy and fast to apply. The transparency of the polyurethane film allowed the provider to see the wound bed, skin graft, or biomaterial without removing the dressing. The battery run pump was also uncomplicated to use and the patients were able to operate it at home and change batteries. Simple battery changes, small size, and lightweight make the NP-PWD system very portable.

Some challenges were also noted. The NP-PWD system was limited to certain shapes or sizes of wounds. Since the system was not plugged into a power source the pump required frequent battery changes. It was also observed that, in a few cases, the adhesive of the dressing lost its integrity over time, resulting in leaks and loss of suction.

3.7 | Example Cases

3.7.1 | Subject 13

A 55-year-old Caucasian female with a hardware infection in her lower right leg, received wound management with the NP-PWD dressing for a duration of 5 days following the placement of Integra over an open ankle wound. The dressing demonstrated adequate drainage, maintained a proper seal, and preserved suction. Consequently, the dressing was retained and monitored daily and removed prior to the patient's discharge on the fifth day (Table 2, Figure 4A).

3.7.2 | Subject 14

A 77-year-old Caucasian female presented with a 4 cm deep pressure wound on the ischium. The NP-PWD dressing was applied in the operating room following debridement, accompanied by a pressure dressing to promote haemostasis

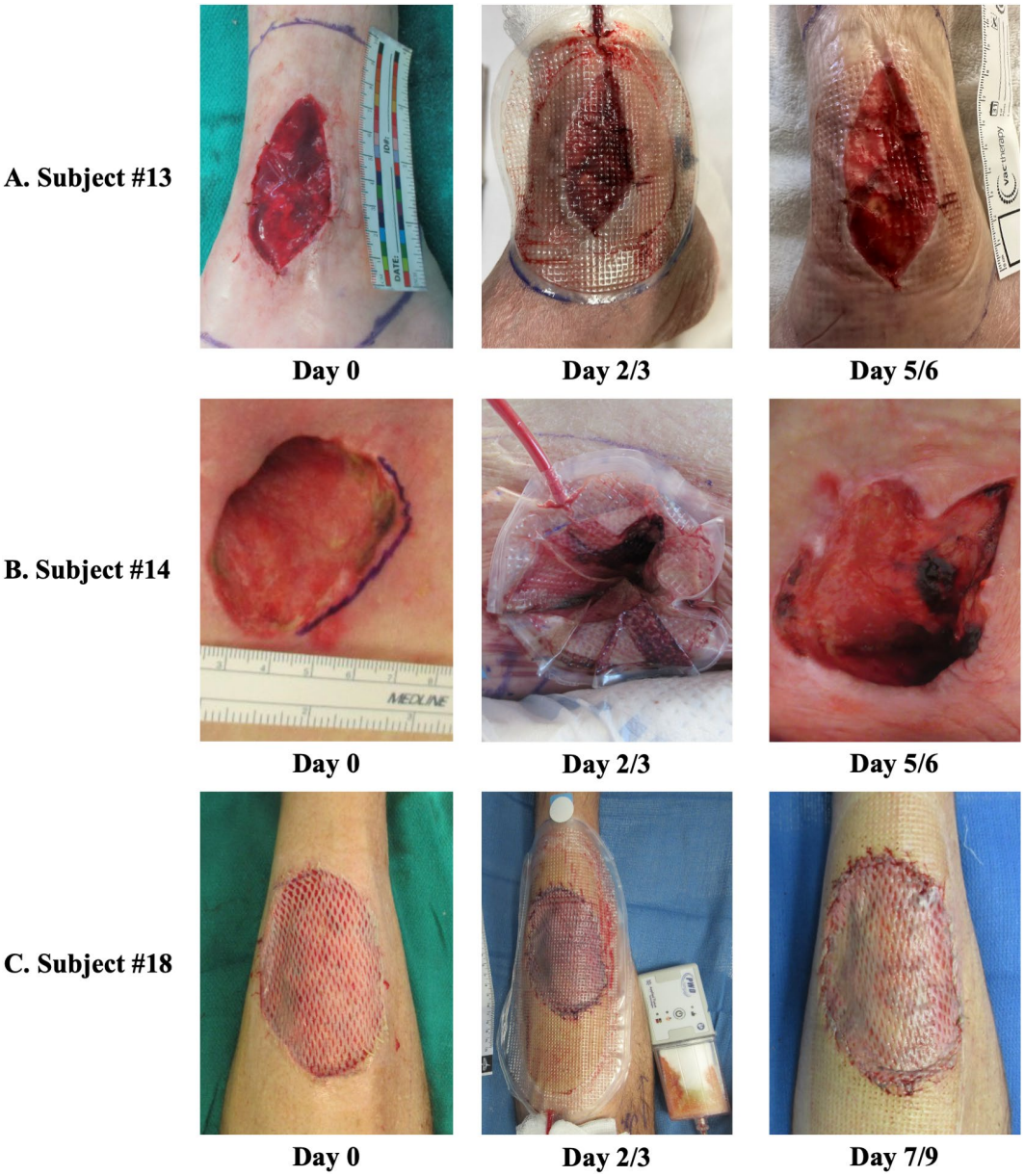


FIGURE 4 | Example cases of three NP-PWD treated wounds. (A) Subject 13, (B) Subject 14, and (C) Subject 18.

for 24 h. Upon removal of the pressure dressing on day 1, it was observed that excess blood had accumulated beneath the dressing and the canister was full; however, the dressing maintained an adequate seal. After replacing the canister, the residual blood was effectively drained, and the dressing continued to provide proper seal and suction. On days 2 and 3, canister changes were necessary, though no additional blood accumulation was observed beneath the dressing. On day 5, given the patient's impending transfer to a long-term acute care facility, the NP-PWD dressing was removed (Table 2, Figure 4B).

3.7.3 | Subject 18

A 67-year-old Caucasian male was equipped with the NP-PWD dressing for a period of 7 days, following a skin graft to the shin subsequent to Mohs surgery. Upon discharge, the patient was sent home with the NP-PWD dressing and associated pump still in place. During the home recovery period, the patient independently performed two battery replacements and one canister change. The patient expressed satisfaction with the system's user-friendliness and its facilitation of wound assessment while the dressing remained in situ (Table 2, Figure 4C).

4 | Discussion

The primary objective of this clinical study was to determine the usability and feasibility of the NP-PWD system in comparison to SoC NPWT device. Besides usability, the effects on wound healing, inflammation, pain and infection were studied. The study demonstrated that the NP-PWD was easy-to-use and fast to apply. It can be left in place for up to 7 days, thus reducing the number of dressing changes in comparison to SOC systems that commonly need to be replaced every 2–3 days. In addition,

transparency of the dressing enabled monitoring of the wound without dressing removal. The results support the conclusions from the previously conducted clinical case series in which the NP-PWD was used to treat closed surgical incisions. The study included 10 incisions and reported similarly to the present study that the NP-PWD was easy to use and the patients tolerated it well. In addition, it was shown that all the incision were intact without evidence of inflammation or infection after 2 weeks of follow-up [18].

In terms of wound healing, inflammation, pain, and infection, no differences were observed between the NP-PWD and the V.A.C. Granufoam Dressing. However, there was a trend showing that the NP-PWD decreased pain in comparison to the SOC system. These results confirmed the findings from a preclinical porcine study comparing the NP-PWD to different commercially available interface dressing NPWT systems in the treatment of excisional full-thickness wounds and both open and closed incisions. Similar to the present study, it was indicated that the NPWT systems, with foam, with gauze, or the NP-PWD without any of the two and just an embossed membrane performed equally in general [14].

One of the benefits of the NP-PWD is that due to the lack of foam or gauze, it can function at a lower negative pressure, thus reducing discomfort and other potential side effects caused by the administration of high negative pressure. Conventional devices usually operate at a negative pressure level of −125 mmHg, whereas, in the present study, the NP-PWD was used at −80 mmHg [19]. In preclinical studies, it has been shown that the NP-PWD is effective even at the level of −50 mmHg [20, 21]. In a porcine study, the NP-PWD was used at negative pressure levels of −80 mmHg and − 50 mmHg to treat full-thickness burns before and after debridement The study demonstrated that, at both negative pressure levels, the NP-PWD efficiently promoted tissue regeneration, decreased burn wound progression, inflammation and bacterial in comparison to controls and no differences between the −50 mmHg and − 80 mmHg were observed [21].

The NP-PWD is a versatile dressing that can also be utilised in wound care without negative pressure. It can be adapted to enclose any size wound over any contour of the body. Prototypes of devices for arms, legs and face have been made. Once the injured area is enclosed with the impermeable polyurethane membrane of the NP-PWD, a moist environment is formed under the dressing and over the injured area. Therefore, the NP-PWD can also be utilised and is FDA cleared to be used as a moist film dressing or a delivery platform for topical therapeutics [22]. In experimental wounds, the device has been used as a platform to deliver very high concentrations of topical antibiotics in the treatment of infected full-thickness skin wounds and burns. These studies have demonstrated that the NP-PWD is efficient at delivering topical antimicrobials and reducing bacterial counts without systemic toxicity [23–28]. In a recent randomised controlled clinical trial with 45 patients, the same circular and oblong shaped NP-PWDs used in the present study, were utilised to deliver gentamicin cream. The combination of the NP-PWD and gentamicin cream was compared to SOC treatments in the management of infected skin wounds and the results demonstrated that delivery of topical gentamicin via the NP-PWD was safe and effective at reducing bacterial load in the wound. In addition, clinical assessment for infection found the NP-PWD to be comparable to the current SOC treatment options [29].

The moist wound environment created by the NP-PWD also provides optimal conditions for skin grafting. Thus, the NP-PWD has been used to cover wounds and burns grafted with split-thickness skin grafts or minced skin grafts [30–32]. In preclinical studies, up to 500-fold expansion of autologous skin to re-epithelialize a skin wound has been achieved when minced skin pieces have been transplanted and covered with the NP-PWD [32]. In addition to skin and soft tissue injuries, the NP-PWD is also FDA cleared to be used to treat eye injuries. Preclinical studies utilising a guinea pig model have shown that use of the NP-PWD was safe on the ocular surface and surrounding tissues and allowed for the delivery of specific volumes and concentrations of therapeutics to the surface of the eye and surrounding periocular tissues through the creation of a watertight seal [33–36].

In conclusion, the Negative Pressure Platform Wound Device or NP-PWD, is an innovative therapy which uses a patented dressing to promote healing by creating a vacuum at the wound surface without the use of an interface dressing. The device promotes granulation of the skin, forming new connective tissue and blood vessels, removes or inhibits microbial and infectious agents, as well as pulls wound edges together for closure. The NP-PWD is FDA cleared as a NPWT dressing with its proprietary pump. In addition, it has been approved as a dressing and delivery platform for non-exudating to minimally exuding wounds, pressure sores, lacerations/ abrasions, partial and full thickness wounds, surgical incisions, second degree burns, donor sites, IV sites, autologous skin graft transplants, on orbital rim to facilitate treating exposure keratopathy and ocular wounds. In the present randomised, controlled, clinical trial with 24 patients, the NP-PWD was compared to SOC NPWT systems in the treatment of skin and soft tissue injuries. The study concluded that the NP-PWD was easy and fast to apply due to its bandage-like application. It was shown that no significant differences in terms of wound closure, pain, inflammation, or infection were found between the NP-PWD and the conventional NPWT system. However, this study has some limitations such as a relatively small sample and wound size as well as short follow up time. Therefore, larger clinical trials are needed to confirm these findings.

Acknowledgements

The authors have nothing to report.

Conflicts of Interest

Dr. Eriksson is the founder and chief medical officer and Mr. Broomhead is the chief executive officer of Applied Tissue Technologies LLC (ATT) which manufactures the NP-PWD. They have not participated in the evaluation or recording of the results or the formulation of the conclusions or summary. All the other authors have no conflict of interest to declare in relation to the content of this article. This study was conducted under a protocol reviewed and approved by the Advarra Institutional Review Board (IRB No. Pro00071928) and in accordance with the approved protocol. The views expressed in this article are those of the authors and do not reflect the official policy or position of the U.S. Army Medical Department, Department of the Army, DOD, or the U.S. Government.

Data Availability Statement

The data that support the findings of this study are available from the corresponding authors upon reasonable request.

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