Negative-pressure wound therapy for hospitalised patients: a paradigm shift

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Background: Negative-pressure wound therapy (NPWT) is widely available, but due to the high cost of the treatment, it is not used to its full potential. Worldwide, wound care providers are trying to facilitate a more practical and cost-effective way of providing this essential therapy. Thus far, none of the low-cost solutions could solve the "tethered to the bed" problem of the wall suction technique. We designed a tubing (Woundprep®) that works with Luer connectors, which is well known by nursing staff. The connectors allow the patient or medical staff to easily and electively disconnect and reconnect the tubing for bathroom breaks, special investigations, or daily linen changes. We aimed to determine if NPWT can be provided with Woundprep® safely and practically in the hospital setting.

Method: A prospective observational study was undertaken that included 16 patients who required NPWT in the hospital. Data was collected prospectively regarding adverse events, pain level, interval of dressing changes, elective disconnection periods, and pressure settings. The tubing pressure was measured daily by a digital manometer in mmHg.

Results: No serious adverse events were recorded. No active bleeding occurred, even though 15 of the 16 patients received low-molecular-weight heparin (LMWH) thromboprophylaxis. No wound sepsis occurred whilst on NPWT with Woundprep®, and the average pain level was 2 out of 10 during treatment. The median interval of dressing changes was 72 hours (range 42–120 hours). The average pressure measured by the digital manometer was slightly higher (7%) than the regulator setting (112.5 vs. 121 mmHg). All patients actively participated in their wounds being connected or disconnected.

Conclusion: NPWT with wall suction and Woundprep® tubing is safe and practical in the hospital setting when standard guidelines are followed. This clinical study may stimulate further work on developing a protocol advising on NPWT in hospitalised patients.

Keywords: negative-pressure wound therapy, wall suction

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Introduction

Negative-pressure wound therapy (NPWT) is widely available, but due to the high cost of the treatment, it is not used to its full potential. Worldwide, wound care providers are trying to facilitate a more practical and cost-effective way of providing this essential therapy.[1-3] Thus far, none of the low-cost solutions could solve the "tethered to the bed" problem of the wall suction technique.[4-6] One disconnectable solution was published, but the tubing did not automatically seal off.[7] We designed a tubing (Woundprep®) that works with Luer connectors, which is well known to nursing staff. The connectors allow the patient or medical staff to easily and electively disconnect and reconnect the tubing for bathroom breaks, special investigations, or daily linen changes.

Patients referred for reconstruction to a plastic surgeon are usually temporarily immobilised by their injuries or wounds. NPWT is an essential treatment for large and complex wounds, whether acute or chronic.[8] Most hospital beds have an adjacent connection point for suction, referred to here as wall suction. The pressure is adjusted on the available regulator in mmHg at the wall suction connection. Whenever the tubing is disconnected electively, the Luer connector automatically seals off the opening of the tubing and keeps the wound hygienic. The suction end of the tubing is sealed off manually (with a supplied and reusable cap). This study aimed to assess the safety and ease of use of the new tubing set to provide NPWT to patients immobilised by their injuries or wounds.

Materials and methods

A prospective observational study was undertaken on patients referred for reconstruction to the Plastic Surgery Department at Netcare Montana Hospital, Pretoria, South Africa, from April 2023 to August 2024. Patients who met the inclusion and exclusion criteria were invited to participate (Table I).

All patients referred for reconstruction to plastic surgery were invited to participate and given ample time to read the patient information leaflet before signing informed consent. An independent clinical monitor (ClinResearch CC) was involved throughout the trial. Data were

Table I: Inclusion and exclusion criteria

Inclusion	Exclusion
Age 18 years or older	Age < 18 years
Haemoglobin > 8 g/dl	Haemoglobin < 8 g/dl
Indication for NPWT	Active bleeding of wounds
Decreased mobility for at least three days	Patient mobility is normal
Informed consent signed	Exposed viscera
	Wound clinically infected
	High risk of bleeding (e.g. treatment dose with LMWH or warfarin therapy)

LMWH – low-molecular-weight heparin, NPWT – negative-pressure wound therapy

collected prospectively on adverse events, pain level, dressing change intervals, elective disconnection periods, and the pressure settings noted. In addition, the pressure of the tubing was measured daily by a digital manometer in mmHg.

An aseptic technique was used with dressing changes in the theatre or the ward. The cleaning solution throughout was chlorhexidine in water. All wounds were debrided in the theatre without using a tourniquet, and good haemostasis was achieved before placing any dressings. During the first procedure, the surgeon would send deep wound biopsies of tissue not in contact with the atmosphere (and not from the wound surface) for microscopy, culture and sensitivity (MCS). This biopsy result was used for directed antibiotic therapy before and during flap reconstruction.

Woundprep® tubing was placed onto another primary dressing, and the patient was not in direct contact with it. The primary dressings used directly in contact with the wound were polyvinyl alcohol foam (Coldex®, Mondomed, Belgium), polyurethane foam (Ligasano®, Ligamed, Germany), or antibacterial cotton gauze (Kerlix®, Covidien, USA) applied according to international guidelines.[9,10] Hydrocolloid dressings (Eakin®, Eakin Healthcare, Ireland, or Comfeel®, Coloplast, Hungary) were applied on the periwound skin of all patients to improve the airtight seal and prevent maceration. A non-adherent layer dressing was applied onto skin-grafted wounds, topped with the Kerlix® gauze. The Woundprep® tubing was then sealed off with a sterile film dressing (Tegaderm®, 3M, Germany) and the Luer connectors connected to each other and to the suction source to activate NPWT.

The pressure was set to 100, 120, or 125 mmHg. The actual pressure was measured daily during ward rounds and noted for comparison with the setting on the regulator. The pain level was documented according to the visual Universal Pain Assessment Tool.[11] The patients were observed for bleeding from the NPWT tubing, and their vital signs were recorded on an online software system. The amount of fluid removed by the NPWT dressing was measured with a syringe and recorded daily. The intervals of dressing changes were documented, as well as the daily elective disconnection and reconnection times.

The primary outcome objectives were to record adverse events, device failure, dressing intervals, linen hygiene, and fluid removal. The secondary objectives were to measure the negative pressure applied and the period of elective disconnection.

Photographs and short videos were taken in all cases, mostly of the wound. Measures were taken to ensure that patients would not be identifiable by this material.

Results

A total of 16 patients were included with various wound types. A summary of patient details is presented in Table II. Examples of wounds

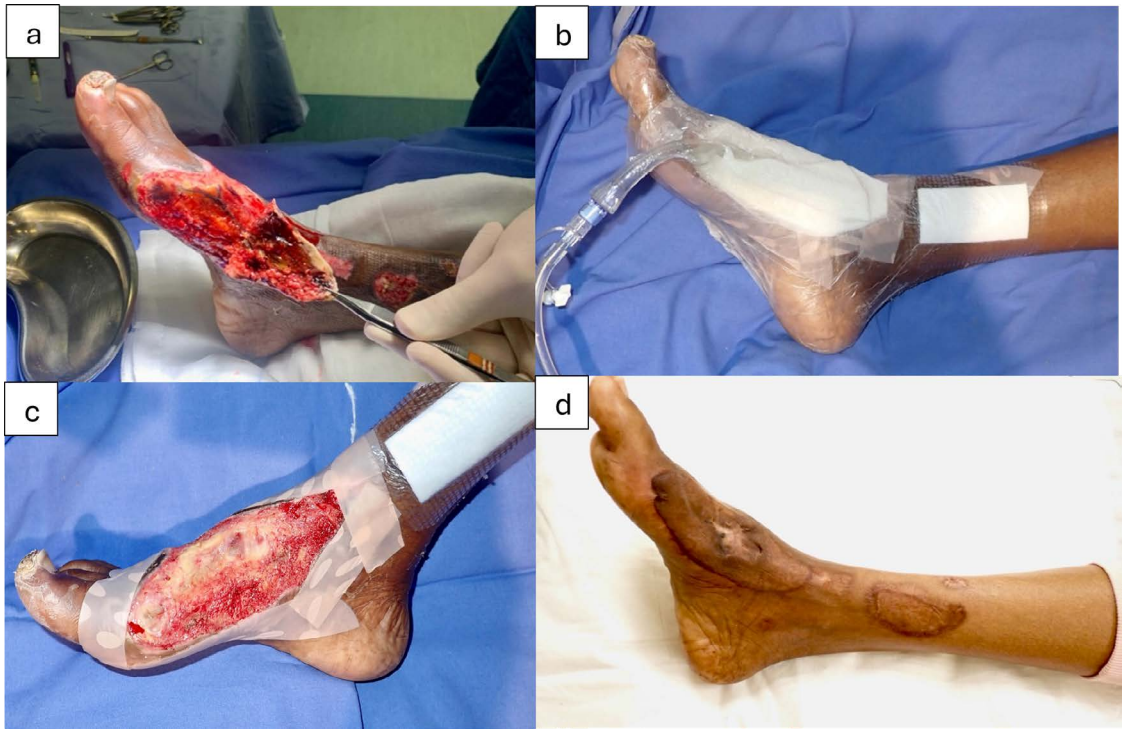

Figure 1: Fourth-degree burn in a 54-year-old female following exposure to a heated beanbag
a – wound excision, b – Woundprep® (NPWT), c – wound bed is prepared for a dermal skin substitute and skin grafted four weeks later, d – result at six-month follow-up, patient can now walk with a normal gait

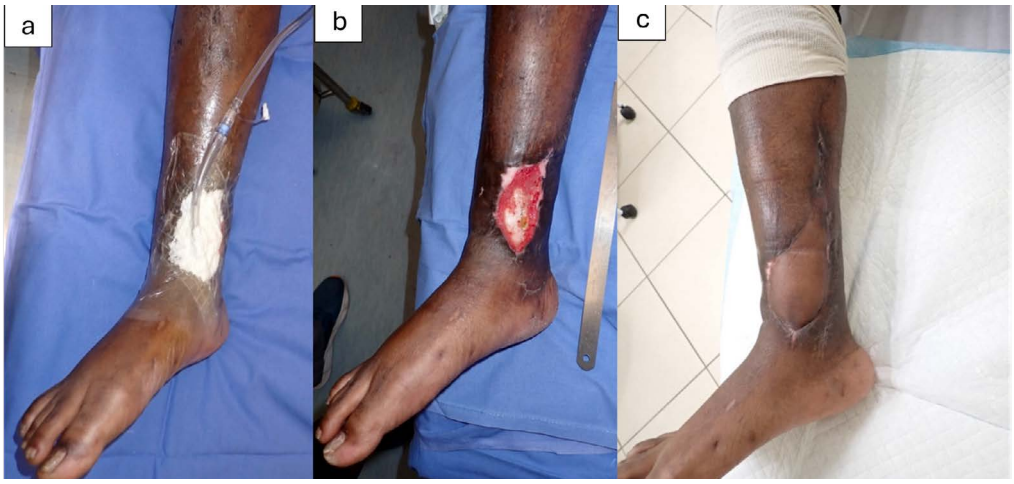

Figure 2: A 37-year-old male suffered an open tibia fracture 11 years before and now presented with an osteomyelitis wound on the right leg distal tibia
a – Woundprep® (NPWT) after debridement by an orthopaedic surgeon, b – wound bed is prepared and radial forearm free flap performed, c – result nine months later with no sinus wound, patient is walking without pain

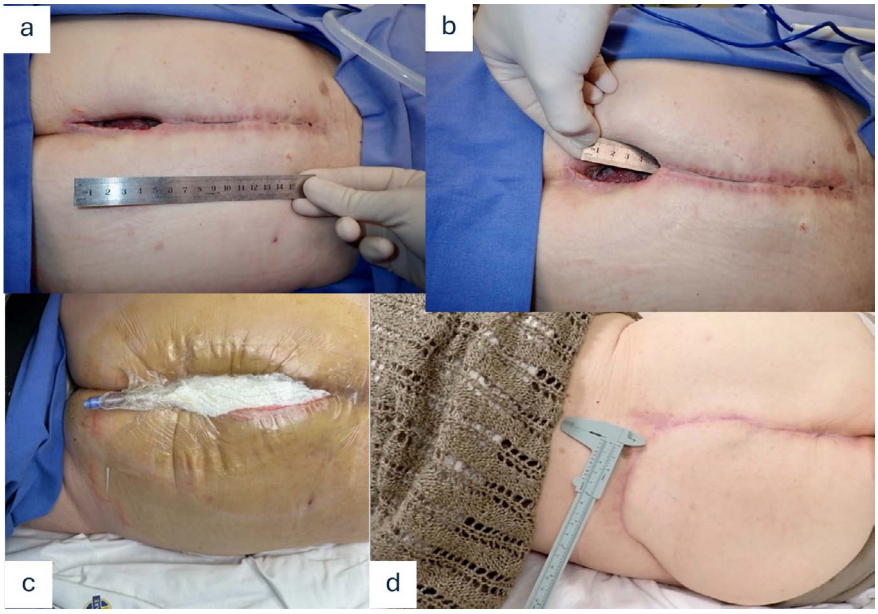

Figure 3: An 81-year-old female with a massive cavity wound after resection of plasmacytoma of the sacrum four weeks before
a – first wound debridement in theatre, b – cavity illustrated with a sterile ruler, c – NPWT with wall suction by Woundprep® for eight days, then gluteal myocutaneous rotation flap, d – six-month follow-up shows stable reconstruction and no pain

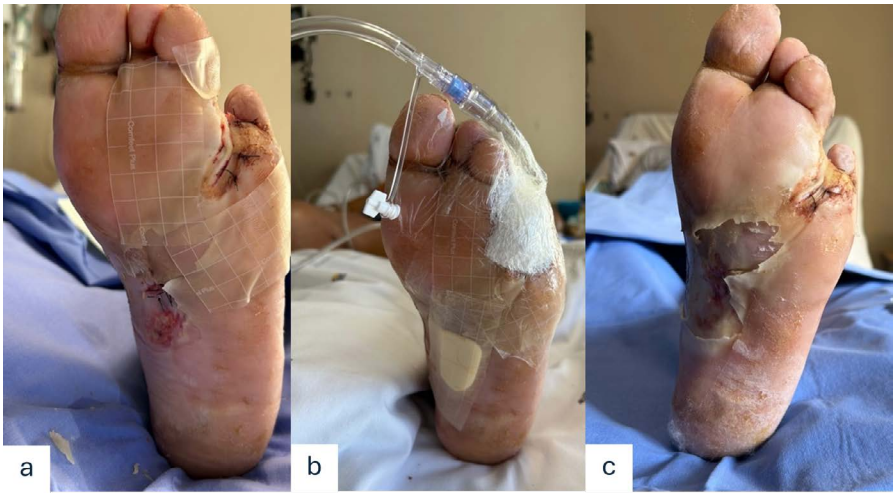

Figure 4: A 55-year-old male with dry gangrene on the fourth toe, diabetes mellitus
a – hydrocolloid dressings on the periwound skin, b – Woundprep® (NPWT) on ray amputation wound, c – wound dry and ready for outpatient wound care on day seven postoperatively

Table II: Summary of patient characteristics

Patient no.	Age (years)	Diagnosis	BMI	Wound size (cm^3)
1	66	Venous leg ulcer for four years	49	352
2	76	Leg skin necrosis (haematoma)	34	312
3	62	Crush injury (left foot)	30	42
4	—	Patient withdrew consent	—	—
5	35	Open tibia fracture (right distal leg)	28	40
6	33	Chronic ulcer on left leg	33	9.9
7	54	Fourth-degree burn (right foot)	18.5	75
8	89	Basal cell carcinoma (right leg)	27	16
9	40	Right leg skin necrosis (soft tissue infection)	18	80
10	71	Skin necrosis (left thigh, ischaemic)	20.5	84
11	68	Chronic wound, osteomyelitis (right distal tibia)	26	54
12	54	Open fracture (left distal tibia)	30	40.5
13	37	Chronic wound, osteomyelitis (right distal tibia)	28	45
14	40	Chronic wound (left lateral ankle)	32	42
15	81	Cavity wound sacrum (extirpative surgery)	23	2 520
16	55	Dry gangrene (fourth toe), diabetes mellitus	26	18
17	70	Venous leg ulcer for two years	46	315

BMI – body mass index

treated are shown in Figures 1 to 4. Patients' ages ranged from 33 to 89 years (average 59 years). Of the 16 patients, 15 had a wound on the lower limb and were on LMWH thromboprophylaxis. A total of 131 days of NPWT by Woundprep® was recorded during this study for an average of eight days of NPWT per patient.

There were no serious adverse events, wound infections, bleeding requiring blood transfusion, or an unplanned return to theatre. There were no device-related failures. Fluid leakage onto linen was recorded on two of the 131 days, and in both instances, nursing staff fixed the leakage by placing additional transparent film dressings. The average pain recorded during the treatment on the trial was 2/10 (range 0–6).

The wall suction pressure (measured daily) ranged from -93 to -143 mmHg, with an average of -121 mmHg. This pressure was 7% higher ($p = 0.002$) than the regulator's setting values, which were -100, -120, or -125 mmHg (average -112.5 mmHg). The intervals ranged from 42 to 120 hours, with a median interval of 72 hours (3 days) between dressing changes. Tubing was disconnected electively two to three times per day, and the total daily period averaged 33 minutes. All patients (16 of 16) actively participated in their wounds being connected or disconnected.

Five of the 16 patients (31%) required a period of NPWT using a mobile device. Wall suction NPWT was used for 11 of the 16 (69%) who were discharged home with conventional wound dressings without needing any mobile device NPWT.

Within 10 weeks, 14 of 16 patients (88%) healed completely. One patient was diagnosed with a non-healable ischaemic wound and, after three days of NPWT, was referred for hyperbaric oxygen therapy at another hospital. One other patient was still being followed up at the time of writing.

Discussion

NPWT is an essential wound-healing tool recommended as first-line therapy for various large or complex wounds. Other recent papers have suggested the combination of NPWT with a multidisciplinary team approach, and we strongly advocate this to be included in hospital protocols.[9,12] In this prospective case series, the team included at least a plastic surgeon, physician, registered nurse specialised in wound care, physiotherapist, and general nursing staff. The low rate of adverse events provides evidence that NPWT by wall suction can be provided safely by such a team in other hospitals with the same level of care.

The measurements of the negative pressures delivered during treatment confirmed that the pressure was stable. The measured pressures averaged only slightly higher (7%) than the regulator's pressure setting. Due to this finding, we suggest a pressure setting of -100 mmHg for wall suction. If lower suction is required, we suggest using a pressure regulator that limits the negative pressure to -70 mmHg, or a digital screen pressure regulator.

Both acute and chronic wounds were included in this study. They were treated with the same surgical approach, consisting of wound debridement in the theatre, NPWT by Woundprep® for a few days whilst awaiting biopsy results, and then reconstruction by a graft or a flap. In most cases, the debridement in the theatre implied surgical excision of the wound. This approach to large or difficult wounds is similar to current published treatment protocols by other plastic surgeons.[13]

The easy connectability enabled patients to use the bathroom on their own. This clinical study showed that all patients were able to achieve this. At the time of disconnection, the Luer connector seals off the tubing, thereby decreasing the chances of wound contamination via fluid running back into the tubing. Moreover, the patient and staff were educated to notify the treating surgeon immediately if there was blood

in the tubing or any fluid leakage onto the linen. By involving patients and nursing staff with NPWT, they can act as the alarm for bleeding, leakage, or any sudden changes.

Of the 16 patients in our study, 15 were on LMWH thromboprophylaxis, yet there was no episode of bleeding. Also, three of the patients included were on chronic aspirin therapy. We planned for careful haemostasis in this subgroup by not placing the NPWT immediately after the debridement. First, we spent time intraoperatively achieving meticulous haemostasis with a combination of limb elevation, adrenaline and saline swabs, compression, diathermy, and placing skin grafts. We especially did not use a tourniquet during the debridement. This is crucial to implement in future protocols for hospital patients since many surgeons often use a tourniquet, which may result in patients developing active bleeding after being sent to the ward.

All 16 patients received nutritional supplementation with multivitamins and protein shakes. All patients' pain levels were determined with a visual pain scale, and pain was well controlled at a level of 2/10. The pain protocol started preoperatively by prescribing a combination of analgesics, as well as relieving their anxiety by talking to patients and addressing their concerns. A buprenorphine patch in combination with paracetamol was used for most of our patients, and a tramadol injection was reserved for breakthrough pain. If used, nonsteroidal anti-inflammatory drugs were only prescribed once a day and not at a maximum dose. As soon as patients mobilised for more than 60 minutes per day without assistance, we regarded them as mobile, and they were considered for outpatient wound care.

Fluid leakage onto linen was reported twice, and in both cases, staff solved the problem by placing additional film dressings. One of the reasons for the leakage was the wound location on the posterior surface of the patient's body, resulting in the seal being lost when dressing edges got disrupted. The seal of a posterior wound is more susceptible to sheering forces when the patient is still in bed. This is another reason to use a hydrocolloid dressing on the periwound skin, as it makes the seal tighter and less likely to get wet.

We used 0.5% chlorhexidine in water for cleaning purposes and advocate against using iodine-containing cleaning solutions whenever NPWT is planned. The reason is that a powdery film forms on the skin surface when the iodine-based solutions dry, making it impossible for film dressings to stick to the skin.

All patients who proceeded with the successful reconstruction of their extremity wounds in our prospective series had palpable foot pulses, and we remind wound care providers to check pulses in the limbs with such wounds routinely. If unsure, we suggest using an arterial Doppler and the opinion of a vascular surgeon. This study did not compare the costs of the Woundprep® tubing (for providing NPWT in-hospital) with that of a mobile device. Future cost comparisons should be made in immobilised patients admitted to the hospital, not in the outpatient setting. The cost of Woundprep® is predicted to be significantly lower than that of mobile devices.

Patients who need NPWT sometimes require the instillation of fluids or antibiotics into the wound.[14,15] In future iterations, irrigation is possible because the design of Woundprep® allows for two sets of tubing to be connected to the same wound. Thus, sterile fluids can be run via an intravenous infusion pump (IVAC® pump) at a predetermined rate into the wound, which can then be suctioned out on the other side.

The method of action of NPWT concerns the removal of wound fluids. Lowering the bacterial load and decreasing the amount of pro-inflammatory cytokines are major factors that underlie the mechanism of improving the wound's proliferative phase or granulation tissue formation.[16,17] Analysis of the fluids removed from the wound can now be done by connecting a syringe to the Luer connector and removing wound fluids from a sterile, controlled environment to determine levels of inflammatory markers. Gathering this data on the wound exudate and relating it to the phase of wound healing may provide insight into the timing of planned reconstructions or grafts. Our study documented the amount of wound fluid removed with NPWT and highlighted the need to measure and analyse the wound fluids.

Conclusion

NPWT with wall suction and Woundprep® tubing is safe and practical in the hospital setting when following standard guidelines. This clinical study may stimulate further work on developing a protocol advising on NPWT in hospitalised patients.

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Conflict of interest

EC Eksteen owns shares in the intellectual property of the tubing design.

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Ethical approval

Pharma-Ethics Independent Research Ethics Committee (ref: 220424682).

Statistical analysis

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