

The Performance of a Negative Pressure Device on Chronic Wounds of the Lower Leg and Foot

A Pilot Study



The Performance of a Negative Pressure Device on Chronic Wounds of the Lower Leg and Foot

A Pilot Study

INVESTIGATORS

Dr. Jeffrey Page
Principal Investigator

Darren Woodruff, BA, BSc
Contributing Investigator

SPONSOR

Kalypto Medical, Inc.
*1250 Northland Drive
Mendota Heights, MN 55120*

SPONSOR REPRESENTATIVE
John Buan, PhD
*Vice-President of Marketing &
Product Development*

Abstract

This was a proof of concept study to investigate the performance of a Negative Pressure Wound Therapy system consisting of a miniaturized pump device and an associated fluid retaining dressing on chronic wounds of the lower leg and foot (for detailed device description, see Appendix A). The study was completed from March to June of 2008.

Six subjects were enrolled with various types of chronic ulcers and were treated with the Negative pressure Wound Therapy system over a 72 hour period, during which there were three visits and two dressing changes. Wounds and the peri-wound skin were monitored for infection, leakage, dermatitis, and maceration, while the dressings were examined for evidence of moisture, adherence to skin, and adherence to the wound. The dressings functioned as designed although they required augmentation on two occasions. The devices maintained the prescribed pressure

and functioned as designed to alert the ease of use of the portable system. The proof of concept was achieved in that the prototypes of both the miniaturized pump device and the fluid retaining dressing functioned as would be expected for a negative pressure wound therapy system. Furthermore, the dressing technology, which changes the wound fluid storage paradigm by eliminating the canister and storing exudates in the dressing, did not, during the 72 hour period of wear, create any adverse effects in the wound bed or macerate or damage the peri-wound skin. Experience with the new system led to several modifications that will further improve the functionality of both the device and the dressing.



NP1000 Dressing, Pump & Tubing

Introduction

Chronic lower extremity ulcerations are challenging to heal and costly in terms of both resources consumed and patient suffering. Among the several advanced technologies currently employed to accelerate chronic wound closure is Negative Pressure Wound Therapy (NPWT). (Argenta) NPWT consist of the application of suction to the wound bed through an intermediary material such as gauze or foam. The wound dressing is sealed with a material such as a transparent film to create the potential for a vacuum. Tubing is used to connect the dressing with a device that creates suction. With existing models, the drainage removed by the suction device is typically stored in a canister contained within the pump. The device is to be used 23 hours of every day. At the time of the initiation of the study, there were three commercially available devices that had been approved by the Federal Drug Administration (FDA) for the application of NPWT.

There are hundreds of articles in the literature regarding different applications for Negative Pressure Wound Therapy. A number of those articles focus on management of lower extremity chronic wounds (Armstrong). The wound care literature documents the efficacy and safety of NPWT as well as a reduction in wound complications with NPWT is employed. However, a consistent concern of caregivers and patients alike is the time-consuming nature of dressing changes and the cumbersome inconvenience of carrying the pumps wherever the patients go. This limits compliance on the part of the patients. The investigators believe that a less costly, more portable, and simpler NPWT system would improve patient mobility, compliance, and outcomes.

The primary objective of this study was to verify and validate the engineering performance of an experimental NPWT system in use on chronic wounds of the human leg and foot. The study device provides negative pressure in the same pressure range as approved devices (40 mmHg to 125 mmHg). The experimental NPWT device was made lighter and smaller through miniaturization, to enhance convenience and increase mobility for the patient. The negative pressure is provided through a new type of wound dressing that serves as a storage reservoir for the drainage. The wound dressing contains an absorbent, hydrophilic synthetic material. All elements of the wound dressing and the pump device are fabricated with materials that are biologically compatible. The dressings are sterilized with an FDA approved and validated process.

Materials and Methods

During this pilot study, the new dressing and associated device were utilized for a total of three days. At the initiation visit the wound and peri-wound tissue were assessed and the wound bed prepared through debridement and cleansing. The study dressing was then applied. The initial dressing was removed after 24 hours to allow for assessment of the wound, the surrounding skin, and the dressing materials. The wound dressing was then reapplied and removed a second time 48 hours later for further assessment. After the third study visit, the patient was returned to his/her treating podiatrist for resumption of the previous wound care regimen.

Device

The device studied was the Kalypto Medical NPD 1000c Negative Pressure Wound Therapy Device. (Figure 1). The device is currently under development as a class II medical product, subject to the 510(k) clearance procedure, product code JCX. Subsequent to this work, the device was cleared for marketing in the US under the FDA 510k process. The Center for Medicare Services (CMS) granted the manufacturer access to the E2402 pump billing code for this system, with the same level of payment as is given to the manufacturers of competing negative pressure systems. It provides negative pressure (in the same pressure range as approved devices) over a wound bed, through a proprietary dressing, in the range of 40 mmHg to 125 mmHg. It is powered by three AA alkaline batteries and the patient has no electrical connection to the device. The accompanying dressing was occlusive in nature (to maintain the negative pressure) and has an absorptive capacity of 50 milliliters. The multi-layer dressing consisted of a non-adherent layer for contact with the wound bed and an absorbent, hydrophilic material. A screen portrays icons to inform the patient and the caregiver of the current dressing pressure, status of battery life, and any loss of the vacuum seal. All elements are fabricated with materials with demonstrated biocompatibility and in many cases are FDA cleared for use as stand-alone products. The dressings are sterilized with an FDA approved and validated process.

Patients

A total of five male and one female subjects were examined in this study. These six subjects met the inclusion criteria which included being between the ages of 18-75, having an ulceration of small to moderate size (1 cm to 5 cm diameter) and of shallow to moderate depth (1 mm to 5 mm depth) on the lower leg, ankle or foot. Adequate circulation in the extremity was also necessary which was demonstrated by a palpable pulse or an ankle/brachial index of 0.7 or higher. The patients also had to be able to attend all study visits and give informed written consent. Patients were excluded if they had an ulceration which was of large size (>5 cm), greater depth (>5 mm), appeared infected (signs of inflammation including erythema, increased drainage, purulent drainage, warmth or edema) or if the patient had inadequate circulation (non-palpable pulses or an ankle/brachial index <0.7) or was unable to adequately offload the chronic wound site.

The type of ulcer varied in the six subjects. Two subjects had venous leg ulcers, one subject presented with an ulcer at the midfoot of a collapsed Charcot foot, one subject presented with an ulcer at the site of a prior first metatarsal resection, one subject presented with an ulcer at the stump of a transmetatarsal amputation and another subject presented with a diabetic plantar ulcer on the great toe. All subjects have written informed consent. The study was approved by the Institutional Review Board of Midwestern University.

Treatment

Prior to the application of the negative pressure wound dressing, an initial history and physical examination were performed to determine study eligibility. If the patient met the inclusion criteria, then the wound was prepared for the negative pressure dressing.

The wound was prepared prior to each application of the negative pressure wound dressing through wound debridement and cleansing. The condition of the peri-wound skin was noted as was the color and degree of granulation tissue in the wound base. The wound was photographed at each study visit just prior to application of the study dressing.

Each subject participated in a series of three study visits with the first and second visit on consecutive days. The time between the second and third visit was 48 hours. At the first visit the subject was fitted with a study dressing and the NPWT study device. (Figure 2) The subject wore it continuously for 24 hours and then returned for the second visit. At the second visit, the wound site and peri-wound skin was examined for injury, maceration and dermatitis. If none was found, then the subject was fitted with a second dressing that was worn continuously for 48 hours. At the third visit, the dressing was removed and the subject resumed standard care for the wound.



Figure 2: Patient Initial Fitting

Measurements

- a. Wound Assessment:** Representative photos were taken prior to, during, and after treatment. Prior to dressing removal, the dressings' physical characteristics were documented, e.g. the ability of the dressings to maintain a seal that prevented leakage and whether the materials adhered to normal skin but not the wound base (re-injury). In addition, after removal of the dressing, the condition of the wound and the peri-wound skin was recorded with special interest in any signs of re-injury of the wound base, injury, dermatitis or maceration of the surrounding skin, and the clinical signs of infection (e.g., erythema, increased or purulent drainage, warmth, edema). (Table 1)
- b. Leakage:** At each dressing change the dressing was examined for any evidence of leakage. This was determined by noting the physical evidence of actual drainage and reports from the patient that the device indicated a leakage condition during the treatment. (Table 1)

Results

1. One subject experienced a slight amount of maceration when the dressing's absorptive capacity was exceeded after two days. No other subject had any change in maceration of the skin surrounding the wound.
2. A small leakage of fluid occurred in one patient (the same patient above whose dressing capacity was exceeded).
3. The dressing was well adhered to the surrounding skin in all cases at the time of removal.
4. The dressing adhered minimally to the wound bed of one ulcer and not at all in the others.
5. There were no incidences of dermatitis caused by a reaction to the adhesive in the dressing.
6. There were no infections.

Table 1: Clinical observations of 6 patients with lower extremity ulcers being treated with a miniaturized NPWT device over 72 hours.

Patient	A (1)			B (2)			C (3)			D (4)			E (5)			F (6)		
	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
Dermatitis*	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	1	1	1
Infection*	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Dressing Moisture [^]	N/A	2	2	N/A	3	4	N/A	2	3	N/A	2	2	N/A	2	3	N/A	2	1
Leakage*	N/A	1	1	N/A	1	2	N/A	1	1	N/A	1	1	N/A	1	1	N/A	1	1
Adherence to skin [#]	N/A	4	4	N/A	4	4	N/A	4	1	N/A	4	4	N/A	4	3	N/A	4	4
Adherence to wound [#]	N/A	1	1	N/A	2	2	N/A	1	1	N/A	1	1	N/A	1	1	N/A	1	1
Maceration*	1	2	2	4	1	3	1	2	1	2	1	1	1	1	1	1	1	1

* Score:

- 1= Absent
- 2= Mild
- 3= Moderate
- 4= Marked
- 5= Extreme

[^] Score:

- 1= Dry
- 2= Slightly moist
- 3= Moderately moist
- 4= Very moist

[#] Score:

- 1= Non-adherent
- 2= Slightly adherent
- 3= Moderately adherent
- 4= Completely adherent

Discussion

The primary goal of this study, that of proving the concept of accomplishing NPWT with a miniaturized device and a dressing that serves as a reservoir, was accomplished. The secondary objective of demonstrating safety of the dressing technology, which is a new concept in negative pressure wound therapy, during this short pilot study was also accomplished. However, this was not designed to be an efficacy study and therapeutic safety cannot be demonstrated without a longer study.

One of the primary concerns with any occlusive dressing is the possibility of an accumulation of fluid that may harm the peri-wound tissue through excessive maceration. No maceration resulted from the dressings in this study. (Figure 3 a & b) In addition, the use of adhesives that secure the dressing and achieve a seal must be such that the dressing functions properly without sticking to the wound bed or adhering too firmly to the peri-wound skin. Removal of the dressing must not cause injury to either the wound bed or the surrounding skin. For this reason, additional contact layers are sometimes employed. A non-adherent, antimicrobial contact layer is built into the study dressing. Furthermore, absorption or removal of wound exudates must be complete enough to prevent bacterial overgrowth or the accumulation of metalloproteases, but allow enough moisture to remain to prevent desiccation and promote of healing. In this pilot study all wounds remained appropriately moist.

All six study subjects related their unsolicited comments about the ease of use of the pump. The pump was lightweight and easy to carry. Many of the subjects slipped it into a pocket with one placing it in her purse. Two of the subjects suggested that a belt holster of some type would increase the convenience. Most of the subjects ran the tubing inside a pant leg, which allows the subjects to conceal the device and protect the tubing. Two had previously used other brands of negative pressure wound therapy devices and expressed a definite preference for the smaller device.

Some challenges were encountered during the study. Some of the challenges included the infrequent loss of negative pressures and delays in establishing the appropriate pressure at the time of a new dressing application. In two cases, subjects stated that they lost pressure while at home and the pump turned on continuously until the subjects augmented their dressings to restore the seal and allow the pump to maintain optimum pressure by infrequent, intermittent adjustments. In a few of the cases, it took several minutes after a fresh dressing was applied for the pressure to reach the optimum level and allow the pump to shut down. Examination of the internal mechanism revealed a kink in some tubing within the housing that when corrected permitted prompt performance.

As a result of the patient and clinician experience in this study, recommendations were made to the engineering team for small improvements to the design of the system, including aspects of application of the dressing and ergonomics of the transport of the pump by the patient. Thus, some of the experiences in this study will be dissimilar to those seen with the use of the more refined final product.

Conclusion

This proof of concept study accomplished the primary objective which was to verify and validate the engineering performance of an experimental NPWT system in the presence of actual chronic wounds of the lower extremity. Positive feedback from the subjects as to the convenience and ease of use of the new system was informative. This smaller device seems to be an improvement over the larger devices currently available. Larger studies will be necessary to evaluate efficacy and safety.



Figure 3a: No maceration



Figure 3b: No maceration

Appendix A: Device Description

The NPD 1000 Negative Pressure Wound Therapy System is a small, portable system comprised of a battery operated electromechanical pump with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to create an environment that promotes wound healing. This is achieved by bringing the wound edges together, reducing edema, promoting granulation tissue formation and perfusion, and by removing wound fluids and infectious material.

The NPD 1000 pump provides negative pressure in two modes, intermittent and continuous, in pressure ranges from -40 mmHg to -125 mmHg. In continuous mode, the pump holds the dressing at the prescribed pressure continuously between dressing changes. In intermittent mode, the pump cycles between the prescribed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. PVC tubing connects the dressing to the pump via a pressure port fitting. The dressing has 3 windows near the pressure port to monitor when the dressing is nearing its exudate capacity.

The NPD1000 dressing is comprised of the following:

- Semi-occlusive outer layer that maintains the negative pressure
- Pressure port with an in-line hydrophobic, anti-bacterial 0.2 µm filter and fitting to which the NPD pump system is attached via tubing
- Hydrogel gasket to seal the wound area
- Super absorbent non-woven polymer matrix to absorb exudates
- Non-stick Silverlon® wound contact layer

References

1. Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. *Ann Plast Surg* 1997;38:563-76.
2. Armstrong DG, Lavery LA, Abu-Rumman P, et al. Outcomes of subatmospheric pressure dressing therapy on wounds of the diabetic foot. *Ostomy Wound Manage* 2002;48(4):64-8.
3. Buttenschoen K, Fleischmann W, Haupt U, Kinzl L, Buttenschoen DC. The influence of vacuum-assisted closure on inflammatory tissue reactions in the postoperative course of ankle fractures. *Foot Ankle Surg* 2001;7:165-73.
4. Clare MP, Fitzgibbons TC, McMullen ST, Stice RC, Hayes DF, Henkel L. Experience with the vacuum assisted closure negative pressure technique in the treatment of non-healing diabetic and dysvascular wounds. *Foot Ankle Int* 2002;23:896-901.
5. DeFranzo AJ, Argenta LC, Marks MW, et al. The use of vacuum-assisted closure therapy for the treatment of lower-extremity wounds with exposed bone. *Plast Reconstr Surg* 2001;108:1184-91.
6. Frykberg RG, Armstrong DG, Giurini J, et al. Diabetic foot disorders: a clinical practice guideline. *J Foot Ankle Surg* 2000;39(5 suppl):S1-S60.
7. Joseph E, Hamori CA, Bergman S, Roaf E, Swann NF, Anastasi GW. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. *Wounds* 2000;12:60-7.
8. Larsson J, Agardh CD, Apelqvist J, Stenstrom A. Long-term prognosis after healed amputation in patients with diabetes. *Clin Orthop* 1998;350:149-58.
9. McCollon SK, Knight CA, Valiulus JP, Cunningham MW, McCullough JM, Farinas LP. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. *Ostomy Wound Manage* 2000;46(8):28-34.
10. Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. *Ann Plast Surg* 1997;38:553-62.
11. Page JC, Newswander B, Schwenke DC, Hansen M, Ferguson J. Retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defects. *J Wound Care* 2004;17:354-364.
12. Philbeck TE Jr, Whittington KT, Millsap MH, et al. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. *Ostomy Wound Manage* 1999;45(11):41-50.
13. Philbeck TE, Schroeder WJ, Whittington KT. Vacuum-assisted closure therapy for diabetic foot ulcers: clinical and cost analyses. *Home Health Care Consultant* 2001;8(3):1-7.
14. Reiber GE, Boyko EJ, Smith DG. Lower extremity foot ulcers and amputations in diabetes. In: Harris MI, Cowie C, Stern MP, editors. *Diabetes in America*, 2nd ed, NIH publication no. 95-1468. Washington, DC: National Institutes of Health; 1995.

