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Simplified Negative Pressure Wound Therapy Device for Application in Low-Resource Settings

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Abstract

Negative pressure wound therapy (NPWT) provides proven wound healing benefits and is often a desirable wound treatment. Unfortunately, NPWT devices are not widely available in low-resource settings (LRSs). In order to overcome identified NPWT barriers, a simplified NPWT (sNPWT) system was designed and iteratively improved during field-based testing. The sNPWT technology, our device design iterations, and the design-based results of our field tests are described. The sNPWT system includes a bellows hand pump, an occlusive drape, and a tube with tube connectors, connecting the drape to the pump. The most critical property of a sNPWT system is that it must be airtight. The details of the design iterations needed to achieve an occlusive system are explained. During the design process, the sNPWT system was tested during the earthquake relief in Haiti. This testing found that a liquid sealant was necessary to seal the drape to the peri-wound skin. A study conducted in Rwanda verified that a liquid latex sealant was safe to use and that the tube connector must be connected to the drape with an airtight method during the manufacturing process. This work has shown that sNPWT is feasible in LRSs. Since the completion of the clinical testing, the design has been further evolved and the developers are working with contract manufactures to produce the final design and preparing for regulatory approval applications.

Keywords

negative pressure wound therapy; wound healing; low-resource settings; wounds and injuries; mechanical

Introduction

Negative pressure wound therapy (NPWT) is the application of a controlled vacuum to a wound cavity. It has been clinically demonstrated to speed the healing time of open wounds by a factor of two or more and to aid in complete recovery with less scar tissue.¹⁻³ In the field setting, NPWT allows for early wound management with wound stability during patient transport. In the clinical setting, its healing benefits promote active healing. Commercial NPWT devices have been available on the market since 1995, and today, there are over 35 different devices available. These devices are typically based on the same engineering principles and are limited by high cost, high electrical power requirement, training needed for their complex computer interfaces, and lack of portability. With these limitations, currently devices are not widely available in low-income communities (LICs) and low-resource settings (LRSs).

In order to create a NPWT device applicable for use in LICs and LRSs, we identified key functional requirements for a simplified NPWT (sNPWT) device: easy-to-use, inexpensive, portable, and mechanically powered. We further identified air leaks into the supposedly occlusive, electrical NPWT dressing systems as the key barrier to realizing these additional functional requirements.^{4, 5} To that end, devices have recently been described, which aim to eliminate air leaks into the system and provide mechanical therapy.^{6, 7} However, these devices have not overcome many barriers and remain limited in their use.

The device described herein, called the *Wound-Pump*, was developed to be a reliable, broadly-applicable, airtight, sNPWT system. The key component is a true airtight dressing, which is applicable to most wound types and body contours. This true occlusive dressing is attached to a mechanical bellows pump with a plastic tube; all connections are airtight. The bellows serves as both the vacuum source and the wound exudate receptacle, minimizing the number of components, complexity, and cost.⁴ As a result, our mechanical system satisfies all sNPWT and general NPWT functional requirements.⁸

The Wound-Pump

Pump

As specified by the FDA, the NPWT vacuum source functional requirement is the ability to deliver a pre-set vacuum pressure to the wound bed.⁸ Therefore, the pump embodiment must have a deterministic behavior. Potential sNPWT pump embodiments were researched and narrowed down to two hand pumps: a plastic bellows pump and a plastic bulb pump, such as a Jackson-Pratt drain.⁵ Both of these are easy-to-use, inexpensive, portable and mechanically powered. However, the vacuum delivered by the bulb pump is highly variable and cannot be easily determined in real time without sensors. The pressure is largely

dependent on how the user squeezes the bulb,⁵ which causes a very inconsistent vacuum application that is not desirable for NPWT.

The second option, a plastic bellows often seen used as a toilet plunger, was proven to have a deterministic behavior for simple, hand-powered operation. A plastic bellows pump behaves like a linear spring^{4, 5} and the compression length of the bellows directly determines the vacuum pressure applied by the pump. At full compression, the pump applies maximum vacuum pressure, which degrades linearly to zero as the pump expands. The user has to simply compress the bellows by-hand to activate vacuum pressure. A pre-set vacuum pressure to the wound can be delivered by compressing the bellows to the desired length. The pressure can be monitored throughout therapy by measuring the length of the bellows and converting it to its corresponding pressure. If there is no air leak into the system, the pump will expand over time with the collection of exudate; therefore, a drop in vacuum pressure is purely determined by the rate of exudate removal from the wound. Between dressing changes, the pump must be monitored, exudate emptied and bellows recompressed, as needed, in order to stay within a predetermined pressure range.

The bellows pump design also plays a significant role in patient safety. Patient exsanguination has previously been reported due to ruptured blood vessels during NPWT.⁹ This exsanguination is preventable with the bellows pump design, where the pump also serves as the exudate collection container. As blood fills the system, the pump physically expands, serving as an instant, visible alarm. Since the bellows has a limited internal volume, vacuum will stop after the bellows is fully expanded. Ideally, for sNPWT design, the internal fluid collection volume capacity should be limited to a safe amount of blood volume to remove from a patient.⁴ If necessary, pump expansion limiting components can be used to limit the expansion length of the pump.⁵ With its expansion characteristics and limited, closed volume, safety from exsanguination is inherently built into the bellows pump design.

Dressing

sNPWT dressings consist of three main components: (1) porous, non-adhesive packing material used to fill the wound cavity (e.g., sterilized sponge or gauze); (2) transparent occlusive cover placed over the porous dressing and adhered to the skin with a true occlusive seal; and (3) airtight connection mechanism to connect the dressing to the vacuum pump (i.e., typically tube connectors and tube). These dressing components are identical to NPWT dressings, other than the transparent cover must be truly occlusive for sNPWT, eliminating all air leaks. In general, NPWT dressings allow over 1 L/min of air to leak into the system, which is not feasible for a hand pump system.⁴ All three components are disposables, which are changed during each wound dressing change.

Porous Packing Material—The porous wound-packing material is the interface material between the vacuum source and the wound bed. Exudate flows from the wound bed through the packing material and tube to the collection container. Open-cell polyurethane foam is the most common material used in NPWT systems. Studies have shown that the design of the packing material influences the wound healing rate, focusing on the pore size in foam.¹⁰

There have also been adverse events associated with foam dressings, including many of the 12 deaths and 174 injuries reported to the FDA from 2007 to 2011. These events were mostly due to the ingrowth of tissue into the pores of the foam, which caused tissue to tear and/or pieces of foam to be left in the wound cavity upon dressing removal.¹¹ Gauze dressings have shown positive results in NPWT,^{2, 12} but have not been studied to the same degree as foams.¹³ In addition, sterile gauze is inexpensive and readily available in most wound care settings, including those in LICs and LRSs. Therefore, gauze is the Wound-Pump packing material.

Occlusive Cover—The key component of the Wound-Pump is our occlusive drape that adheres to the skin in an airtight fashion (Figure 1). It consists of a thin carrier that is coated with skin contact adhesive. This drape provides a protective cover over the wound cavity and gauze packing material and remains airtight for its entire dressing period, which we targeted to be three days. This is a difficult property to achieve, as: (1) any wrinkles in the skin or drape are potential air leak paths into the system, (2) the surface of the skin inherently has wrinkles and hairs; and (3) when applying a planar drape to the contours of the body, wrinkles in the drape are often unavoidable, due to a geometry mismatch. In order to overcome these challenges, we developed a liquid sealant component, based on results from the lab and our work in Haiti (discussed below). We adhered the drape to the peri-wound skin and then, sealed the edges of the drape to the skin using three, thin coats of liquid latex sealant. Successful, occlusive properties for sNPWT can be achieved with this sealant method, when combined with a drape capable of long-term wear.¹⁴ A phase 1 study in Rwanda (further discussed below) verified this sealant method in the clinical setting, as the drape was further refined. Material and thickness of the drape component (both carrier and adhesive) were iterated in real time based on adhesion performance, including the ability to accommodate for different skin types and large body movements. This was to increase its wear time for all wound sizes and locations. Iterations of the drape component are described in Zurovcik 2012.

Connection Mechanism—The tube connection method to the drape is also critical in achieving an airtight seal.^{5, 14} During the Wound-Pump phase 1 study in Rwanda, two tube attachment methods were explored: (1) not manufactured in an occlusive fashion to the drape prior to dressing application (Dressing Design A) and (2) manufactured with an occlusive attachment method to the drape (Dressing Design B).¹⁴ For Dressing Design A, the tube connector was sealed by the user with liquid latex sealant after the drape application. Dressing Design B sealed the tube connector with the liquid latex sealant during the manufacturing process, and therefore, only the edges of the drape were sealed after its application.

For both Dressing Design groups, the tube connector design varied, as detailed in Zurovcik 2012. It was iterated in real time based on performance metrics, targeting: airtight connection, ease of application, fluid transport, and patient comfort. The original tube connector design (n = 10 dressings) for the phase 1 study is included in Dressing Design A. It sealed the tube using only the adhesive drape and liquid latex sealant. Its performance proved that a tube connector component is necessary to achieve repeatable, occlusive

performance.¹⁴ Therefore, a custom component was designed (Figure 1) that was iterated in shape, size, and tube end effects during the phase 1 study. In this embodiment, the tube was attached to a flexible flange in an airtight manner during the manufacturing process. Then, the flange was subsequently attached to the drape using variable attachment designs within the two, different Dressing Design A and B groups.

Clinical Applications

The iterative Wound-Pump dressing design was driven by the results of field applications in Haiti and in Rwanda. Table 1 outlines the design flow of the dressing to overcome air leaks.

Earthquake Relief Effort—The earthquake on January 12th, 2010 in Haiti resulted in an epidemic of acute wounds. A team of four clinicians was deployed to assist with wound care at Hôpital de l'Université d'état d'Haiti in Port-au-Prince and brought several Wound-Pump devices with them, since the lack of electricity hindered the use of donated electrical NPWT devices. The Wound-Pump system consisted of the bellows pump and the first iteration of our occlusive medical drape. The liquid latex sealant component was not used, and the tube was manufactured with an occlusive attachment to the center of the drape.¹⁴ Sterilized gauze available on-site was used for the wound packing material. With a strict screening process, therapy was applied to five patients.

As the mission in Haiti was purely humanitarian, only general results are reported. The Wound-Pump treated wounds were clean and granulating during the two week deployment.⁴ The limited application of the Wound-Pump verified that an additional liquid sealant was necessary. An occlusive seal was possible to achieve without the sealant; however, it had limited application to a small subset of wounds and was not always repeatable between dressing changes.

Phase I Study—The phase 1 study was a prospective single-arm investigation of the biomechanical parameters and adverse events associated with the Wound-Pump system in a LRS.¹⁵ The study took place at two hospitals in Rwanda: Rwinkwavu Hospital and University Teaching Hospital-Kigali (CHUK). In this study, liquid latex sealant was used to seal the edges of the drape to the periwound skin. Two tubing attachment methods, as described above were explored. Sterilized gauze available on-site was used for the wound packing material. Forty-two wounds on 37 patients were treated in this study.¹⁵

Seventy-one dressings were analyzed for occlusive performance. The average time to occlusive failure was 22.2 hours (sd 27.0, range 0 to 72 hours): Dressing Design B (31.7 hours, sd 30.2, n = 37) and Dressing Design A (11.8 hours, sd 18.6, n = 34) ($p = 0.003$).¹⁵ Further analysis verified that the large standard deviations are expected due to high variability in the data. This is due to many factors, including variation of the dressing designs in each group and variety of treated wound locations and sizes.¹⁵ Despite this variability, these data results helped to drive the design path; Dressing Design B outperformed Design A, which proved that the tube connector must be connected to the dressing in an airtight fashion during the manufacturing process.

Dressing Design B was analyzed further by wound location: the Wound-Pump system remained occlusive for more than two days on easy-to-dress wounds (52.7 hours, sd 29.3, n = 11) and for one day on more difficult to dress wounds (medium: 33.0 hours, sd 36.4, n = 4 and hard: 20.9 hours, sd 24.7, n = 22) ($p = 0.029$).¹⁵ This indicated that further dressing iterations were necessary to account for increased body contours. In addition, no serious adverse events were encountered,¹⁵ which verified the Wound-Pump safety in the clinic and LRSs.

Conclusions

sNPWT provides a feasible and safe NPWT solution in LICs and LRSs, including disaster relief environments. In these settings, two main benefits are: 1) clinicians can treat more patients, as the sNPWT dressings need to be changed approximately every three days versus one to two times per day for standard wet-to-dry dressings; and 2) wounds may close faster in an environment where infection risk is extremely high.¹⁶ Since the completion of the clinical study in Rwanda, the Wound-Pump dressing has been further evolved and is currently undergoing contract manufacturing for future clinical trials, commercialization, and regulatory approvals.

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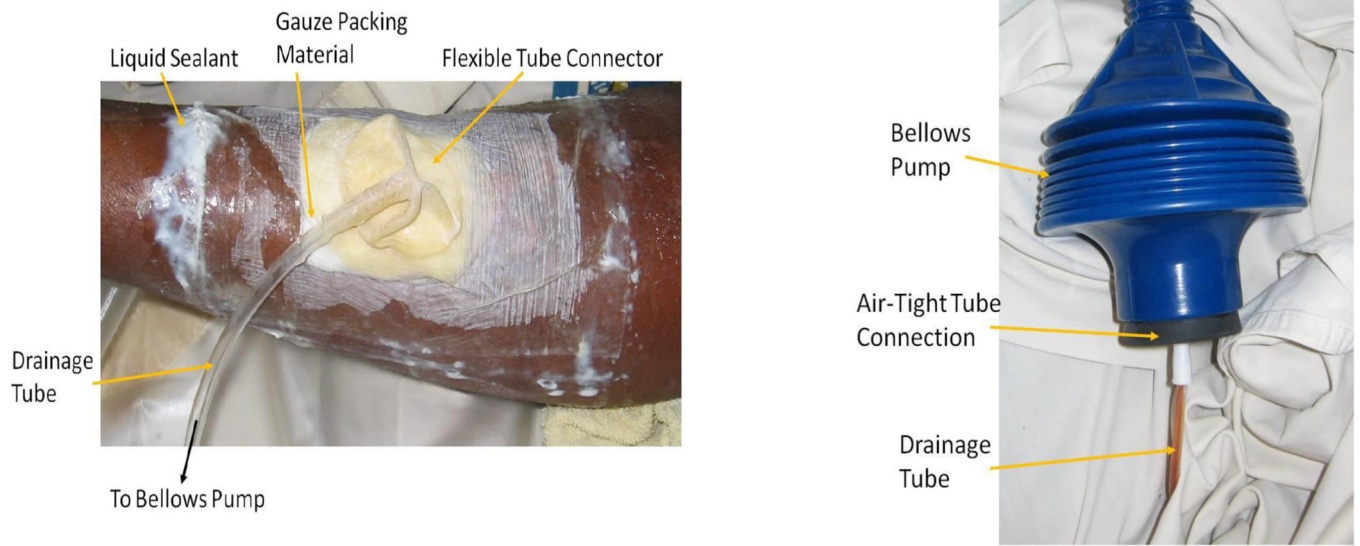


Figure 1.

Left: The Wound-Pump dressing utilizes an occlusive adhesive drape that is sealed with a liquid sealant border over the gauze packing material to the peri-wound skin. The drainage tube is connected to the drape with a flexible tube connector, which is manufactured with an air-tight process.

Right: The drainage tube is connected to the bellows pump with airtight connectors. The bellows pump also serves as the exudate collection container.

Table 1

Design flow of the Wound-Pump dressing between studies.

Study	Dressing Characteristic				Liquid Latex Sealant (used for all dressings)
	T-Joining Embodiment (Zuroveik 2012)		Custom Tube Connector		
	Occlusive Tube Connection during Manufacture	Non-Occlusive Tube Connection during Manufacture (Dressing Design A)	Occlusive Tube Connection during Manufacture (Dressing Design B)	Non-Occlusive Tube Connection during Manufacture (Dressing Design A)	
Earthquake Relief Effort (Haiti)					
Phase 1 Clinical Study (Rwanda)					
Post Phase 1 Study (WiCare, Cambridge, MA)					