Plantar Pressure Changes Using a Novel Negative Pressure Wound Therapy Technique

David G. Armstrong, DPM, MSc*†
Kristin Kunze*
Billy R. Martin, DPM*
Heather R. Kimbriel, BS*
Brent P. Nixon, DPM*
Andrew J. M. Boulton, MD‡

This study evaluated changes in pressure imparted to diabetic foot wounds using a novel negative pressure bridging technique coupled with a robust removable cast walker. Ten patients had plantar pressures assessed with and without a bridged negative pressure dressing on the foot. Off-loading was accomplished with a pressure-relief walker. Plantar pressures were recorded using two pressure-measurement systems. The location and value of peak focal pressure (taken from six midgait steps) were recorded at the site of ulceration. Paired analysis revealed a large difference (mean ± SD, 74.6% ± 6.0%) between baseline barefoot pressure and pressure within the pressure-relief walker (mean ± SD, 939.1 ± 195.1 versus 235.7 ± 66.1 kPa). There was a mean ± SD 9.9% ± 5.6% higher pressure in the combination device compared with the pressure-relief walker alone (mean ± SD, 258.0 ± 69.7 versus 235.7 ± 66.1 kPa). This difference was only 2% of the initial barefoot pressure imparted to the wound. A modified negative pressure dressing coupled with a robust removable cast walker may not impart undue additional stress to the plantar aspect of the foot and may allow patients to retain some degree of freedom (and a potentially reduced length of hospital stay) while still allowing for the beneficial effects of negative pressure wound therapy and sufficient off-loading. (J Am Podiatr Med Assoc 94(5): 456-460, 2004)

Reduction of pressure is a critical component of treating wounds on the plantar aspect of the foot. However, people with very deep wounds are generally not medically amenable to standard off-loading modalities. If so-called dead space is not managed appropriately, these deep wounds may be at higher risk for infection, nonhealing, and amputation, unless the patient is subjected to complete nonweightbearing and frequent dressing changes. Negative pressure wound therapy, also known as V.A.C. or Vacuum Ap-
sisted Closure therapy (KCI, Inc, San Antonio, Texas), has proven to be useful in management of complex dead space.1-5 However, it has proven difficult to allow weightbearing on a traditional negative pressure dressing because the tubing often exits at a plantar site (contiguous with the sponge dressing). Bearing weight on this site would increase pressure considerably and would cause a wound with any repetitive stress.

To obviate the previously mentioned problem, one may consider applying the negative pressure dressing using a technique known as “bridging” (Figs. 1–4). This technique was first described by Greer et al6 as a strategy for connecting anatomically distant wounds to a single vacuum unit. However, for this study and for more practical clinical use in the foot, we substantively modified the technique to allow for weightbearing while still using topical negative pressure. This modification involves running contiguous sponges from an area where connected tubing could cause tissue damage to an area that is more conducive to tube connection. In the case of the plantar foot, the sponge is run from the site of plantar ulceration to a dorsal site, where the negative pressure tubing is connected to a portable vacuum unit. The patient may then be placed in a robust off-loading device, such as a removable cast walker, which can be converted into an “instant total-contact cast” (Figs. 1–4).7-9 This treatment could allow a patient to perform many activities of daily living while still receiving the potential benefits of an advanced wound-healing modality.

Although the previously mentioned technique seems to make therapeutic sense, there are no data on whether it increases or decreases potentially damaging pressure on the plantar foot. Therefore, this study was undertaken to evaluate changes in pressure imparted to diabetic foot wounds using a novel negative pressure bridging technique coupled with a robust removable cast walker.

**Methods**

Ten patients undergoing treatment for diabetic foot ulcers were enrolled in this study. The study was approved by the University of Arizona institutional review board. All of the patients had an active, non-infected, nonischemic diabetic foot wound of the plantar forefoot corresponding to University of Texas class I-IIA.10 The diagnosis of diabetes mellitus was verified by each patient’s primary-care physician. Sensory neuropathy was evaluated using a vibratory perception threshold meter (Xilas Medical, Inc, San Antonio, Texas) and the method and criteria de-
scribed by Yuan-Innes et al, Armstrong et al, and Greer et al. These criteria included a vibratory perception threshold greater than 25 V. All of the patients had clinical loss of protective sensation using these criteria.

During the period of dressing change (which takes place every 48 hours with negative pressure wound therapy), patients had their plantar pressures assessed with and without a bridged negative pressure wound dressing on the foot. All of the patients were off-loaded using a DH Pressure Relief Walker (Royce Medical Corp, Camarillo, California), which was converted into an instant total-contact cast using the method described by Armstrong et al. The conversion involved wrapping the removable cast walker with a cohesive bandage after ensuring that all bony prominences were adequately protected. Measurements of plantar pressure were recorded using the F-Scan pressure-measurement system (Tekscan, Boston, Massachusetts). This device is a wafer-thin membrane (0.18 mm) placed between the foot and the pressure-relief walker’s insole using a method previously described by Lavery and coworkers. The system measures pressures at very high resolution (up to 960 sensors at a size of 5 mm²).

To measure absolute peak pressure (without an off-loading device), the HR Mat pressure-assessment system (Tekscan) was used. This system consists of a large in-floor-mounted pressure-sensitive plate measuring 45 × 49 cm and containing approximately 8,352 individual sensor cells. The device captures data at a rate of 60 Hz. Both devices were attached to the same central processing unit and were analyzed using the same proprietary software system (Tekscan). Several practice runs were made to familiarize the patient with the system and to ensure the recording of natural gait for both the HR Mat and F-Scan devices.

The location and value of the largest (peak) focal pressure were recorded at the site of ulceration. This peak pressure was taken from the mean of six recorded midgait steps. The devices were calibrated using a purpose-built air bladder device before each run of measurements for each patient.

Before enrollment, a power analysis was performed. The analysis indicated that using a repeated-measures design of this construct, a difference of 20% in predressing and postdressing application plantar forefoot pressure could be detected with a sample size of ten subjects and approximately four repeated steps with a power of 0.90. We therefore felt confident in using a six-step repeated-measures design per subject. To assess potential differences between predressing and postdressing peak plantar forefoot pressures, a general linear model with pairwise comparisons was used. For all analyses, the α was set at .05.

Figure 4. A negative pressure dressing with removable cast walker (A) was converted into an instant total-contact cast (B) to allow for protected weightbearing. The negative pressure device may be attached to a waist-worn pack or backpack.
Results

Descriptive characteristics of this treatment group included a mean ± SD age of 63.1 ± 13.3 years, a mean ± SD duration of diabetes mellitus of 15.1 ± 3.7 years, and a mean ± SD vibratory perception threshold of 44.0 ± 7.6 V. Eighty percent of the patients were men.

Peak plantar pressures were evaluated over the site of the wound. Using paired analysis, there was, as expected, a large and significant difference (mean ± SD, 74.6% ± 6.0%) between baseline barefoot pressure and pressure within the DH Pressure Relief Walker (mean ± SD, 939.1 ± 195.1 versus 235.7 ± 66.1 kPa; \( P = .0001 \)). There was a more subtle pressure difference between the DH Pressure Relief Walker and the DH–negative pressure combination. In this analysis, there was a mean ± SD 9.9% ± 5.6% higher pressure in the combination device compared with the DH Pressure Relief Walker alone (258.0 ± 69.7 versus 235.7 ± 66.1 kPa; \( P = .0001 \)). These data are illustrated in Figure 5.

Discussion

The results of this study suggest that a modified negative pressure dressing coupled with a robust removable cast walker may not impart undue additional stress to the plantar foot. Use of this combination may allow patients to retain some degree of weight-bearing activity while still allowing for the beneficial effects of negative pressure wound therapy and sufficient off-loading.

Previous work in this area suggests that negative pressure wound therapy is a promising treatment modality that may allow deep, complex wounds to become more superficial and easier to manage. In the present study, there was a mean 9.9% increase in peak pressure at the wound site when adding a bridged negative pressure device. Although this difference is statistically significant, one may question the clinical significance of a mean difference of 22 kPa between the standard and combined modalities. This difference amounts to a mere 2% of the initial mean barefoot pressure imparted to the wound, which could be considered negligible and within the bounds of measurement error. When this fact is combined with the potential therapeutic effect of negative pressure, the risk-benefit ratio may justify use of this combined modality in complex plantar wounds where limited protected walking is important. By allowing limited protected walking, this combined modality may also reduce inpatient length of stay in this high-risk patient population.

References