# Early-stage Management of Complex Lower Extremity Wounds Using Negative Pressure Wound Therapy With Instillation and a Reticulated Open Cell Foam With Through Holes

Windy Cole, DPM, FACFAS



**ABSTRACT**

**Introduction.** Treatment modalities that overcome stalled wound healing in lower extremity wounds are crucial for reducing lower limb amputations, which have a 5-year mortality rate of an astounding 70%. Recent non-comparative studies have shown negative pressure wound therapy with instillation and dwell time (NPWTi-d) using a dressing comprised of reticulated open cell foam with through holes (ROCF-CC) provides favorable clinical outcomes for various wound types, including complex lower extremity wounds. **Objective.** The objective of this study is to compare NPWTi-d using ROCF-CC dressings (treatment group) with advanced wound dressings (control group) in patients with chronic lower extremity wounds and known systemic risk factors for delayed healing. **Materials and Methods.** A retrospective assessment was performed for 10 patients with complex lower extremity wounds that underwent an initial debridement and then were treated with either advanced wound dressings (control group; n = 5) or NPWTi-d using ROCF-CC dressings (treatment group; n = 5). Advanced wound dressings were applied to wounds and changed 1 to 3 times per week. Negative pressure wound therapy with instillation and dwell time was applied by instilling normal saline onto wounds, with a dwell time of 20 minutes, followed by continuous negative pressure (-125 mm Hg) for 2 hours. The ROCF-CC dressings were changed every 2 to 3 days. **Results.** Patients in the treatment group had significantly fewer wound complications ($P$ = .024) and underwent significantly fewer surgical debridements ($P$ = .004) when compared with patients in the control group. All wounds in the treatment group healed without complication, whereas only 2 of the 5 wounds in the control group healed. Demographics and comorbidities were similar between groups. **Conclusions.** These data further support the use of NPWTi-d with ROCF-CC to help manage complex wounds of the lower limb.

**KEY WORDS**

lower extremity wounds, negative pressure wound therapy with instillation and dwell time, NPWTi-d, wound complications, debridement, wound cleansing

**INDEX**

*Wounds* 2020;32(6):159–163. Epub 2020 March 31

Impaired healing of chronic wounds has an estimated economic impact of more than $25 billion annually in the United States,[1,2] and chronic wounds of the lower extremities have been estimated to represent 30% to 40% of all wounds.[2] Failure to adequately heal complex wounds of the lower extremity can result in lower limb amputation, and 5-year mortality rates of up to 70% have been reported for patients undergoing lower limb amputations.[3,4] In fact, the 5-year mortality rate for persons with lower limb amputations is reported to be higher than all but 4 cancer types (ie, pancreatic, hepatobiliary, esophageal, and lung).[5] Therefore, treatment modalities that overcome stalled wound healing in lower extremity wounds, along with management of any underlying disease states (eg, peripheral vascular disease, uncontrolled diabetes mellitus), can profoundly impact patient quality of life and the economy.

Wound healing can be impaired by both systemic factors (eg, advanced age, diseases such as diabetes, obesity, and malnutrition) and local factors, including the presence of microorganisms, slough, and nonviable tissue in the wound bed.[6,7] In fact, slough, or nonviable tissue, is a prominent feature of chronic wounds, including many lower limb wounds, and needs to be removed for proper wound healing to occur.[7] The removal of slough generally occurs through debridement (eg, surgical or mechanical); however, debridements or repeated debridements are

**Table 1.** Patient demographics, comorbidities, and wound etiologies

| | CONTROL (n=5) | TREATMENT (n=5) | *P* VALUE |
|---|---|---|---|
| **Age (y)** | | | |
| Mean±SD | 69.2±14.1 | 70.4±10.2 | .871 |
| Median (range) | 66 (56–88) | 73 (54–79) | |
| **Sex** | | | |
| Female | 3 | 1 | |
| Male | 2 | 4 | |
| **Comorbidities (patient no.)** | | | |
| 1 | NIDDM; PVD | Atrial fibrillation | |
| 2 | PVD | PVD | |
| 3 | NIDDM | NIDDM | |
| 4 | NIDDM | IDDM | |
| 5 | PVD | Atrial fibrillation; necrotic ulcer | |
| **Wound type/etiology (patient no.)** | | | |
| 1 | DFU (heel) | Hematoma (calf) | |
| 2 | VLU (ankle) | VLU (lower leg) | |
| 3 | DFU with gangrene of foot | PU (heel) | |
| 4 | DFU (heel) | PU (lower leg) | |
| 5 | Trauma wound (anterior lower leg) | DFU (heel) | |

y: year; SD: standard deviation; NIDDM: non-insulin-dependent diabetes; PVD: peripheral vascular disease; IDDM: insulin-dependent diabetes; DFU: diabetic foot ulcer; VLU: venous leg ulcer; PU: pressure ulcer

not possible in all patients due to patient discomfort.[7]

More recently, negative pressure wound therapy with instillation and dwell time (NPWTi-d) using a reticulated open cell foam with through holes (ROCF-CC) has been developed to assist with wound cleansing by removing thick exudate such as slough and infectious material in patients when debridement is not possible or appropriate.[8] Negative pressure wound therapy with instillation and dwell time using a ROCF-CC dressing has been reported to provide favorable clinical outcomes for large, complex wounds and chronic lower extremity wounds.[8-10] This study compared NPWTi-d using ROCF-CC dressings (treatment group) with advanced wound dressings (control group) in patients with chronic lower extremity wounds and known systemic risk factors for delayed healing.

## MATERIALS AND METHODS

### Study design

A retrospective assessment of 10 patients (N = 10) with complex lower extremity wounds treated with either advanced wound dressings (control group; n = 5) or NPWTi-d using ROCF-CC dressings (treatment group; n = 5) was performed by a single podiatrist between June 2015 and October 2017 at a university hospital in the general area of Cleveland, Ohio. The control group was comprised of patients with chronic lower extremity wounds that were treated before NPWTi-d became available at the current facility, whereas the treatment group included those treated after NPWTi-d became available. Demographic information, wound types, the number of surgical debridements, the number of complications related to wound therapy, and final outcomes were collected for each patient. All data were collected in accordance with the institutional review board guidelines of the hospital.

### Treatment regimen

Patients in both groups underwent an initial surgical debridement of the wound. For patients in the control group, advanced wound dressings (eg, alginate or collagen dressings) were applied to wounds and changed 1 to 3 times per week in accordance with the manufacturers' instructions. Patients in the treatment group had normal saline instilled into the chronic wounds (V.A.C. VERAFLO Therapy; 3M+KCI) with a dwell time of 20 minutes, followed by continuous negative pressure (-125 mm Hg) for 2 hours. The ROCF-CC dressings (V.A.C. VERAFLO CLEANSE CHOICE Dressing; 3M+KCI) were changed every 2 to 3 days.

### Statistical analysis

Statistical analyses were performed using SAS 9.4 (SAS Institute Inc). Continuous variables were presented as the mean ± standard deviation as well as median and range. Data were tested for normality using a Shapiro-Wilk test, and a Wilcoxon rank-sum test was used to analyze differences in the number of debridements and number of complications between groups. Results were considered statistically significant at $P \leq .05$.

## RESULTS

Records were assessed for the 10 patients in this study, which consisted of 4 women and 6 men. The control group included 3 women and 2 men, while the treatment group included 1 woman and 4 men (**Table 1**). The mean age of patients in the control group was 69.2 ± 14.1 years, and the mean age of patients in the treatment group was 70.4 ± 10.2 years; there was no statistical significance when comparing the groups ($P = .871$; **Table 1**). Patient comorbidities included non-insulin-dependent diabetes mellitus, peripheral vascular disease, and atrial fibrillation; wound types included diabetic foot ulcers (n = 4), venous leg ulcers (n = 2), pressure ulcers (n = 2), a trauma wound (n = 1), and a wound resulting from a hematoma (n = 1) (**Table 1**).

Patients in the control group underwent a mean of 7.00 ± 10.1 debridements, whereas patients in the treatment group underwent a mean of 1.00 ± 0.00 debridement ($P$ = .004; **Table 2**). The mean number of complications unrelated to treatment for patients in the control group was 0.800 ± 0.447, and the patients in the treatment group experienced no complications ($P$ = .024; **Table 2**). Complications for patients in the control group included continued infection, toe or transmetatarsal amputation, and a chronic wound that remained open for more than 2 years (**Table 2**). In the control group, only 2 of the 5 wounds healed; 1 patient ultimately underwent a below-the-knee amputation, and another was lost to follow-up after 2 years (**Table 3**). Once adequate granulation tissue formation had occurred (>90% of wound bed) and wound depth was less than 0.3 cm, patients were transitioned from NPWTi-d to other advanced wound therapies. All wounds in the treatment group were closed within 1.5 to 5 months without requiring hospital readmission or operating room return (**Table 3**).

Representative cases of the control and treatment groups are shown in **Figures 1** and **2**, respectively.

**Table 2.** Number of debridements and wound complications

| PROCEDURE/ ASSESSMENT | CONTROL (n=5) | TREATMENT (n=5) | *P* VALUE |
|---|---|---|---|
| **No. of debridements** | | | |
| Mean±SD | 7.00±10.1 | 1.00±0.00 | .004 |
| Median (range) | 3 (2–25) | 1 (1–1) | |
| **No. of complications** | | | |
| Mean±SD | .800±.447 | 0.00±0.00 | .024 |
| Median (range) | 1 (0–1) | 0 | |
| **Type of complication (patient no.)** | | | |
| 1 | Continued infection | N/A | |
| 2 | Return for surgery (x2) | | |
| 3 | Toe amputation, TMA, skin graft | | |
| 4 | Wound open for >2 y | | |
| 5 | None | | |

SD: standard deviation; N/A: not applicable; TMA: transmetatarsal amputation; y: year

**Table 3.** Final outcomes

| ASSESSMENT | CONTROL (n=5) | TREATMENT (n=5) |
|---|---|---|
| **Final outcome (patient no.)** | | |
| 1 | BKA | Healed |
| 2 | Healed after 4 mos | Healed |
| 3 | Healed after 8 mos | Healed |
| 4 | Lost to follow-up | Healed |
| 5 | Remains unhealed | Healed |

BKA: below-the-knee amputation; mos: month

## DISCUSSION

Negative pressure wound therapy with instillation and dwell time is a recent technological advancement to negative pressure wound therapy (NPWT) that includes the periodic instillation of a topical solution into the wound bed.[11] Several published noncomparative case series and studies have shown the application of NPWTi-d using ROCF-CC dressing on complex wounds of the lower extremity can provide favorable clinical outcomes.[8-10,12-15] The current study, to the best author's knowledge, is original in that it compares NPWTi-d using ROCF-CC with other advanced wound dressings typically used on chronic lower extremity wounds. Overall, these data further support the use of NPWTi-d with ROCF-CC to help manage complex wounds of the lower limb.

A difference between the 2 groups in the current study was the lower number of wound complications for patients treated with NPWTi-d using ROCF-CC (**Table 2**). Reported in 2 previous studies,[12,16] NPWTi-d helped reduce bioburden in infected wounds. Goss et al,[12] in a prospective pilot study, reported a mean absolute reduction in bacteria of 10.6 x $10^6$/g of tissue after 7 days of NPWTi-d. Yang et al,[16] in a prospective, randomized study performing serial wound biopsies, reported a 48% reduction in quantitative biofilm-protected bacteria after using NPWTi-d for 7 days. However, both of these studies[12,16] instilled 0.125% sodium hypochlorite solution into the wound beds, whereas the present study instilled normal saline. Other confounding variables, including systemic variables unrelated to the wound type or treatment type, could also have impacted the number of complications in the control group. Still, future studies on whether performing NPWTi-d with saline can affect bacterial bioburden in a wound and whether a reduction can affect wound complications would be beneficial to this patient population.

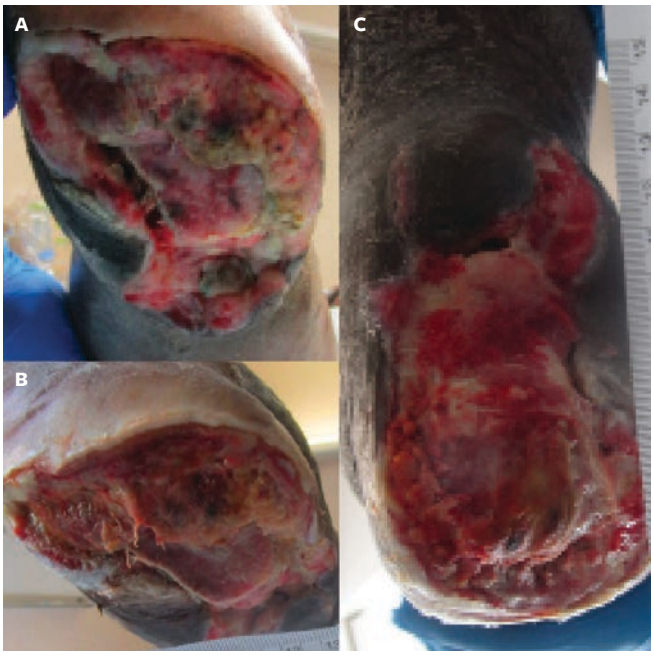


**Figure 1.** A representative case from the control group: diabetic foot ulcer of the heel. (A) Posterior heel ulcer at presentation; (B) ulcer after application of advanced wound dressings for 7 days; and (C) ulcer after 4 weeks of treatments with advanced wound dressings.

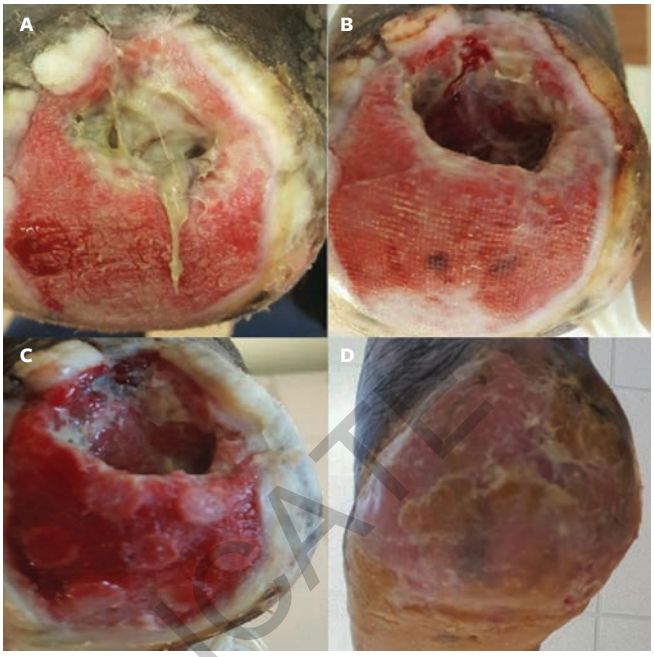


**Figure 2.** A representative case from the treatment group: pressure ulcer of the posterior plantar heel. (A) Posterior plantar heel ulcer at presentation; (B) ulcer after surgical debridement on the day of presentation; (C) ulcer after NPWTi-d using an ROCF-CC dressing for 4 days; and (D) complete healing at 3-month follow-up.

Another major difference between groups in this current study was the lower number of required surgical debridements for patients treated with NPWTi-d using ROCF-CC (**Table 2**). This difference can likely be explained by the ability of NPWTi-d using ROCF-CC dressings to assist with wound cleansing. Téot et al[8] showed that after an average of 1 to 3 ROCF-CC dressing applications (3–9 days), the percent wound surface area with black nonviable tissue was reduced to less than or equal to 10% in 18 of 21 wounds (ie, pressure ulcers, burn wounds, and necrotic wounds after skin incision) and that fibrinous slough was reduced to less than or equal to 10% in 12 of 21 wounds. In the current study, the 5 patients in the treatment group had a reduction in wound exudate and devitalized tissue in complex wounds upon changing ROCF-CC dressings, although the percent change was not quantitatively measured as part of this study. Nonetheless, these data have important cost-saving implications; a Healthcare Cost and Utilization Statistical Brief[17] from the Agency for Healthcare Research and Quality lists debridement of wounds, infections, or burns as both the 17th most frequent (160 400) and the 19th costliest ($1.7 billion) operating room procedure in the United States in 2014.

## LIMITATIONS

This study was limited concerning several aspects of the methodology. First, the cases represent the experience of a single podiatrist at a single institution over a relatively short period of time (about 2.5 years). In addition, the study included a small sample size and was a retrospective study with the potential for selection bias and other known disadvantages, although the author selected consecutive patients who had most recently received therapy within the allotted time frame in an attempt to mitigate some of the selection bias.

Based on these limitations, the results of this study may not be generalizable to other health care providers. However, the the vastly different patient outcomes seen between groups was substantial, and the data suggest the need for larger, more well-controlled studies to compare NPWTi-d with ROCF-CC to other wound care modalities for complex lower extremity wounds.

## CONCLUSIONS

The data from the current study may further support the use of NPWTi-d with ROCF-CC to help manage complex wounds of the lower limb. Further studies are necessary to compare NPWTi-d with ROCF-CC to other wound care modalities, including NPWT, for chronic lower extremity wounds.

### ACKNOWLEDGMENTS

Note: The author would like to thank John D. Short, PhD (3M+KCI, San Antonio, TX) for providing support in manuscript preparation.

Affiliation: Kent State University College of Podiatric Medicine Wound Care, Independence, OH

Correspondence: Windy Cole, DPM, FACFAS, Adjunct Professor and Director of Wound Care Research, Kent State University College of Podiatric Medicine Wound Care, 6000 Rockside Woods Boulevard, Independence, OH 44242-0001; drwec@yahoo.com

Disclosure: Dr. Cole serves as a consultant for 3M+KCI (San Antonio, TX).

## REFERENCES


1. Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. *Wound Repair Regen*. 2009;17(6):763–771.
2. Fife CE, Carter MJ, Walker D, Thomson B. Wound care outcomes and associated cost among patients treated in US outpatient wound centers: data from the US Wound Registry. *Wounds*. 2012;24(1):10–17.
3. Gök Ü, Selek Ö, Selek A, Güdük A, Güner MÇ. Survival evaluation of the patients with diabetic major lower-extremity amputations. *Musculoskeletal Surg*. 2016;100(2):145–148.
4. Feinglass J, Pearce WH, Martin GJ, et al. Postoperative and late survival outcomes after major amputation: findings from the Department of Veterans Affairs National Surgical Quality Improvement Program. *Surgery*. 2001;130(1):21–29.
5. Star A. Differentiating lower extremity wounds: arterial, venous, neurotrophic. *Semin-intervent Radiol*. 2018;35(5):399–405.
6. Guo S, DiPietro LA. Factors affecting wound healing. *J Dent Res*. 2010;89(3):219–229.
7. Percival SL, Suleman L. Slough and biofilm: removal of barriers to wound healing by desloughing. *J Wound Care*. 2015;24(11):498, 500–503, 506–510.
8. Téot L, Boissiere F, Fluieraru S. Novel foam dressing using negative pressure wound therapy with instillation to remove thick exudate. *Int Wound J*. 2017;14(5):842–848.
9. Fernandez L, Ellman C, Jackson P. Initial experience using a novel reticulated open cell foam dressing with through holes during negative pressure wound therapy with instillation for management of pressure ulcers. *J Trauma Treat*. 2017;6(5):410.
10. Blalock L. Use of negative pressure wound therapy with instillation and a novel reticulated open-cell foam dressing with through holes at a level 2 trauma center. *Wounds*. 2019;31(2):55–58.
11. Kim PJ, Attinger CE, Steinberg JS, Evans KK. Negative pressure wound therapy with instillation: past, present, and future. *Surg Technol Int*. 2015;26:51–56.
12. Goss SG, Schwartz JA, Facchin F, Avdagic E, Gendics C, Lantis JC 2nd. Negative pressure wound therapy with instillation (NPWTi) better reduces post-debridement bioburden in chronically infected lower extremity wounds than NPWT alone. *J Am Coll Clin Wound Spec*. 2014;4(4):74–80.
13. Cole WE. Use of multiple adjunctive negative pressure wound therapy modalities to manage diabetic lower-extremity wounds. *Eplasty*. 2016;16:e34.
14. Livingstone JP, Hasegawa IG, Murray P. Utilizing negative pressure wound therapy with instillation and dwell time for extensive necrotizing fasciitis of the lower extremity: a case report. *Cureus*. 2018;10(10):e3483.
15. McElroy E, Lemay S, Reider K, Behnam AB. A case review of wound bed preparation in an infected venous leg ulcer utilizing novel reticulated open cell foam dressing with through holes during negative pressure wound therapy with instillation. *Cureus*. 2018;10(10):e3504.
16. Yang C, Goss SG, Alcantara S, Schultz G, Lantis Ii JC. Effect of negative pressure wound therapy with instillation on bioburden in chronically infected wounds. *Wounds*. 2017;29(8):240–246.
17. McDermott KW, Freeman WJ, Elixhauser A. *Overview of Operating Room Procedures During Inpatient Stays in U.S. Hospitals, 2014. HCUP Statistical Brief # 233*. Rockville, MD: Agency for Healthcare Research and Quality; 2017. HCUP Statistical Brief # 233.