# Activated Carbon Cloth Dressing Heals Majority of Chronic, Full-Thickness Lower Extremity Diabetic or Venous Wounds within Four Weeks and Achieves Greater than 50% Area Reduction at Four Weeks in Remaining Wounds

## Preliminary Results of a Randomized Pilot Study


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## INTRODUCTION

Healing chronic lower extremity wounds is an ongoing challenge to clinicians. Due to the tremendous social and economic impacts of wounds on our society, the pursuit continues for effective novel therapeutic approaches for healing chronic wounds.

One emerging modality is a novel activated carbon cloth dressing (Zorflex®, Chemviron Carbon Cloth Carbon, Tyne and Wear, United Kingdom; a division of Calgon Carbon Corporation, Pittsburgh, PA) (Figure 1). This low-adherent, 100% pure activated carbon cloth dressing highly conforms to body contours and maintains contact with the wound surface.[8] The dressing may be used either dry or moistened with sterilized water over dry or discharing, partial and full thickness wounds.[8]

Wound healing was assessed as part of a randomized, prospective study evaluating this particular activated carbon cloth dressing versus a non-antimicrobial foam dressing in chronic, full-thickness diabetic or venous wounds of the lower extremity or foot. A preliminary analysis of the first nine patients enrolled in the trial is presented.

## MATERIALS AND METHODS

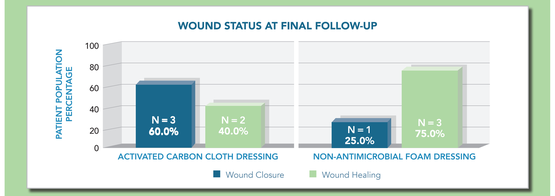
- A randomized, prospective pilot clinical trial is being conducted at two sites by a single investigator to evaluate possible effects of this activated carbon cloth dressing on the total bacterial load and biofilm in a wound bed in wounds of the lower extremity and foot.
  - The study design was approved by an institutional review board and all patients signed an informed consent form (ClinicalTrial.gov Registration Identifier: NCT03461783).
  - Twenty-four subjects will be randomized with equal probability to one of two study groups (12 subjects per group), designated as the experimental and control groups.
    - Subjects in the experimental group will be treated using an activated carbon cloth dressing (Zorflex®) for wet wounds or with saline and the activated carbon cloth dressing for dry wounds (Figure 1).
    - Subjects in the control group will be treated using a non-antimicrobial foam dressing, with or without hydrogel, depending on the moisture level of the wound.
    - Compression dressings were used, if needed, for edema management.
  - Subjects must have full-thickness lower extremity diabetic or venous wounds that are not yet extending to the bone or tendon, not currently being treated with antimicrobial products, and that have been present for at least 4 weeks, but no longer than one year.
  - No antimicrobial products or treatments will be utilized in either group for the duration of the study.
  - Dressings will be changed three times per week, unless otherwise documented by the investigator.
  - Wound photographs and measurements will be obtained using the eKare inSight™ 3D wound imaging system (eKare, Inc., Fairfax, VA).
  - Subjects will be followed for four weeks or time to complete wound closure, whichever occurs first.
- Wound Healing Parameters
  - Subjects who healed or who completed the 4-week follow-up period by April 6, 2018, were included in this preliminary analysis.
  - Wound closure, defined as 100% epithelization, was recorded by the investigator or clinical staff.
  - For wounds that were not healed at the 4-week final follow-up evaluation, wound size measurements taken at screening and final follow-up evaluations were used to calculate percentage area reduction (PAR) using the following equation:
    Wound Area Reduction (%) = $[(A_{Initial} - A_{Final})/A_{Initial}] / 100$

## STATISTICAL ANALYSIS

- Descriptive statistics were used to summarize all study variables.
- Student's t-test was employed to analyze continuous variables that were normally distributed. Mann-Whitney Rank Sum Test was used to analyze continuous variables that were not normally distributed. Chi-Square and Fisher's Exact Test were used to determine statistical differences between categorical variables. Differences were considered statistically significant when the p-value was less than 0.05 with a power of at least 0.8.
- Statistical analysis was performed using SigmaPlot™ (version 13.0, Systat Software, Inc., San Jose, CA).

**FIGURE 1** Activated carbon cloth dressing (Zorflex®, Chemviron Carbon Cloth Carbon, West Midlands, United Kingdom; a division of Calgon Carbon Corporation, Pittsburgh, PA) (**A**) evaluated in this study. This low-adherent, 100% pure activated carbon cloth dressing (**B**) highly conforms to body contours to maintain contact with the wound surface. It may be used either dry or moistened with sterilized water over dry or discharing, partial and full thickness wounds.


**FIGURE 2** Wound status at final follow-up evaluation for the activated carbon cloth and non-antimicrobial foam dressing groups.




## RESULTS

**Patient Demographics**

- Four (80.0%) females and one (20.0%) male were enrolled in the activated carbon cloth dressing group. Three (75.0%) males and one (25.0%) female were enrolled into the non-antimicrobial foam dressing group.
- The mean patient age for the activated carbon cloth and non-antimicrobial foam dressing groups were 68.0 years (median = 63.9; SD = 11.9; range, 54.0 – 85.8 years) and 62.9 years (median = 65.3; SD = 9.0; range, 50.4–70.8 years), respectively.
- All patients in both groups had body mass indices greater than 30 and, therefore, were considered obese.
- The majority of patients were diabetic and neuropathic (Table 1).
- No statistically significant differences in patient demographics were calculated between study groups.

**Wound History**

- Wound age, wound type, wound location, and baseline wound area for the activated carbon cloth and non-antimicrobial foam dressing groups are summarized in Table 2.
- There were no statistically significant differences in wound history parameters between study groups.

**Wounds Healed within 4 Weeks**

- Three (60.0%) of the five wounds in the activated carbon cloth dressing group healed by the 4-week final follow-up evaluation, compared to one (25.0%) of the four wounds in the non-antimicrobial foam dressing group that healed (Figure 2).
- The difference in wound healing between the activated carbon cloth and non-antimicrobial foam dressing groups was not statistically significant.
- A case report of a venous wound treated with the activated carbon cloth dressing that healed within the 4-week final follow-up evaluation despite complex confounding comorbidities is presented in Figure 3.

**Wounds Not Healed at 4-Week Final Follow-up Evaluation**

- Two (40.0%) of the five wounds in the activated carbon cloth dressing group were not healed at the 4-week final follow-up evaluation, compared to three (75.0%) of the five wounds in the non-antimicrobial foam dressing group that did not heal (Figure 2).
- Baseline and final follow-up wound area measurements, as well as PAR, are summarized in Table 3.
  - The differences in mean wound area and mean PAR between the activated carbon cloth and non-antimicrobial foam dressing groups were not statistically significant.
- Photographs and corresponding PAR calculations for the five wounds not healed at the 4-week final follow-up evaluation are compared between study groups in Figure 4.
  - One (50.0%) of the two non-healed wounds in the activated carbon cloth dressing group had a PAR greater than 50% at 4 weeks.
  - Two (66.7%) of the three non-healed wounds in the non-antimicrobial foam dressing group had a PAR greater than 50% at 4 weeks.

**Adverse Events**

- No adverse events, including infection, occurred in either study group.

## DISCUSSION

Prior studies have reported favorable results with the use of this activated carbon cloth dressing as a dressing for wound management.[5,6,12] In a case series involving four patients with recalcitrant venous leg ulcers that were prone to recurrent infection, a reduction in clinical signs of infection, such as exudate and pain levels, and an improvement in wound bed appearance were observed after seven days of treatment with the activated carbon cloth dressing.[4] Another case series demonstrated a reduction in odor control and progression of healing with the use of this dressing in chronic lower extremity and foot wounds.[3] A wound closure rate of 90.7% after five weeks of treatment with the activated cloth dressing was reported in a retrospective study of 18 chronic wounds.[12]

The current clinical trial evaluating this particular activated carbon cloth dressing versus a non-antimicrobial foam dressing in chronic, full-thickness diabetic or venous wounds of the lower extremity or foot is the first randomized, prospective study performed with this product to date. This preliminary analysis was conducted on the first nine patients enrolled in the clinical trial. By the 4-week final follow-up evaluation, three (60.0%) of the five patients treated with the activated carbon cloth dressing healed, compared with one (25.0%) of the four patients in the non-antimicrobial foam dressing group (Figure 2).

Percent area reduction within four weeks of 20% to 40% in venous leg ulcers and at least 50% in diabetic foot ulcers have been proposed as predictors of complete healing by 12 weeks.[2,4,9,11] In this preliminary analysis, one (50.0%) of the two wounds in the activated carbon cloth dressing group and two (66.7%) of the three wounds in the non-antimicrobial foam dressing group that were not healed at the 4-week final follow-up evaluation had a PAR greater than 50% (Figure 4).

## CONCLUSION

- Using healing rates within four weeks, along with the healing prediction guidelines described above:
  - In the activated carbon cloth dressing group four (80.0%) of the five wounds healed or are predicted to heal by 12 weeks.
  - In the non-antimicrobial foam dressing group, three (75.0%) of the four wounds healed or are predicted to heal by 12 weeks.
- The small sample size for this preliminary analysis may be influencing the lack of statistical significance in the healing trends between study groups.
- Completion of the full clinical trial is needed before final interpretations may be made.
- Based on these preliminary results, the activated carbon cloth dressing is performing at least as well as a high-performing standard-of-care control dressing in terms of safety and efficacy in healing chronic wounds of the foot and lower extremity in a patient population with high incidences of obesity, diabetes, and neuropathy.
- Future study will focus on procuring additional clinical data, as well as examining possible mechanisms by which this activated carbon cloth dressing is successfully healing chronic wounds.

**FIGURE 3** Sequential comparison of wound closure from baseline presentation to full closure within the 4-week follow-up evaluation period for a patient whose wound was treated with the activated carbon cloth dressing. The 54-year-old female was considered obese based on body mass index and had a wide range of concomitant conditions, including cardiovascular conditions, chronic obstructive pulmonary disease, lymphedema, and complex regional pain syndrome. Upon presentation, the venous wound on her lower extremity measured 6.6 $cm^2$ and had been present for 4.1 weeks. Despite the complexity of this case, full closure was achieved at 3.6 weeks.

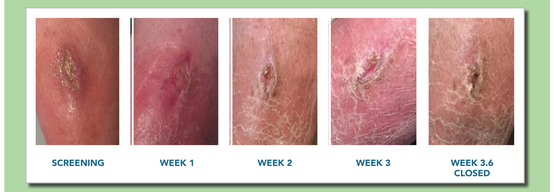



**FIGURE 4** Photographs obtained at the 4-week final follow-up evaluation for wounds that were not healed in both study groups. The two (40.0%) wounds in the activated carbon cloth dressing group (**A** & **B**) that still were healing are compared with the three (75.0%) wounds in the non-antimicrobial foam dressing group (**C**, **D** & **E**) that were healing. Percent area reduction (PAR) of over 50% was achieved within four weeks in one (50.0%) of the two wounds not healed in the activated carbon cloth dressing group and in two (66.7%) of the three wounds not healed in the non-antimicrobial foam dressing group.

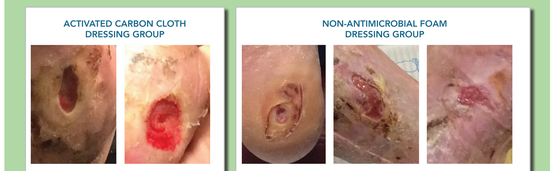



**TABLE 1**

Patient concomitant conditions for the activated carbon cloth and non-antimicrobial foam dressing groups.

| CONCOMITANT CONDITION | ACTIVATED CARBON CLOTH DRESSING GROUP N = 5 | NON-ANTIMICROBIAL FOAM DRESSING GROUP N = 4 |
|---|---|---|
| Diabetes | 4 (80.0%) | 3 (75.0%) |
| Neuropathy | 4 (80.0%) | 3 (75.0%) |
| Peripheral Vascular Disease & Assoc. Conditions | 3 (60.0%) | 0 (0.0%) |
| Lymphedema | 2 (40.0%) | 0 (0.0%) |
| Cardiovascular Conditions | 2 (40.0%) | 3 (75.0%) |
| Chronic Obstructive Pulmonary Disease | 1 (20.0%) | 0 (0.0%) |
| Complex Regional Pain Syndrome | 1 (20.0%) | 0 (0.0%) |

**TABLE 2**

Summary of wound history parameters for the activated carbon cloth and non-antimicrobial foam dressing groups.

| WOUND HISTORY PARAMETER | ACTIVATED CARBON CLOTH DRESSING GROUP N = 5 | NON-ANTIMICROBIAL FOAM DRESSING GROUP N = 4 |
|---|---|---|
| **Wound Age (weeks)** | | |
| Mean ± SD* | 10.9 ± 14.2 | 5.4 ± 1.9 |
| Median | 4.1 | 4.7 |
| Range (min–max) | 4.0 – 36.2 | 4.0 – 8.1 |
| **Wound Type** | | |
| Diabetic | 3 (60.0%) | 2 (50.0%) |
| Venous | 2 (40.0%) | 1 (25.0%) |
| Diabetic/Venous Mix | 0 (0.0%) | 1 (25.0%) |
| **Wound Location** | | |
| Foot, Non-Heel | 3 (60.0%) | 0 (0.0%) |
| Heel | 0 (0.0%) | 1 (25.0%) |
| Ankle | 0 (0.0%) | 1 (25.0%) |
| Lower Extremity | 2 (40.0%) | 2 (50.0%) |
| **Baseline Wound Area ($cm^2$)** | | |
| Mean ± SD* | 2.7 ± 2.2 | 12.7 ± 12.5 |
| Median | 1.9 | 13.2 |
| Range (min–max) | 1.6 – 6.6 | 0.56 – 24.0 |

*SD = Standard Deviation

**TABLE 3**

Baseline and 4-week final follow-up wound area measurements, as well as percent area reduction, for the wounds not healed at the final follow-up evaluation for the activated carbon cloth and non-antimicrobial foam dressing groups.

| STUDY GROUP | WOUND AREA ($cm^2$) Baseline | WOUND AREA ($cm^2$) Final Follow-up | PAR[b] (%) |
|---|---|---|---|
| **Activated Carbon Cloth Dressing** | N = 2 | N = 2 | N = 2 |
| Mean ± SD* | 1.7 ± 0.26 | 1.1 ± 1.3 | 44.0 ± 66.6 |
| Median | 1.7 | 1.1 | 44.0 |
| Range (min–max) | 1.6 – 1.9 | 0.14 – 2.0 | -3.1 – 91.0 |
| **Non-Antimicrobial Foam Dressing** | N = 3 | N = 3 | N = 3 |
| Mean ± SD* | 9.3 ± 12.8 | 1.2 ± 0.71 | 61.9 ± 28.9 |
| Median | 3.4 | 1.4 | 57.1 |
| Range (min–max) | 0.56 – 24.0 | 0.36 – 1.7 | 35.7 – 92.9 |

*SD = Standard Deviation [b]PAR = Percent Area Reduction

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