PROMOGRAN PRISMA™ MATRIX

STUDY TYPE: MULTICENTER, RANDOMIZED CONTROLLED TRIAL (LEVEL I)

Randomized controlled trial on collagen/oxidized regenerated cellulose/silver treatment

STUDY PURPOSE

The primary aim of this study was to compare the clinical outcomes of patients with diabetic foot ulcers (DFUs) that were managed with a collagen/oxidized regenerated cellulose/silver (C/ORC/S) matrix or a standard dressing (control). A secondary aim evaluated whether inflammatory protease levels in the wound fluid from responders and nonresponders of both treatment groups could be correlated to clinical outcomes.

METHODS

- Population: A total of 39 patients with DFUs were randomized to either C/ORC/S (n=24) or control treatment (n=15) between 2007 and 2009 at two wound healing centers.

- Treatment
  - Debridement and off-loading were included in the standard treatment protocol for both groups
  - C/ORC/S group: The dressing was prewet prior to applying directly onto the wound bed of wounds with low levels of exudate
  - Control group: Wounds were treated according to standard treatment protocol
  - Dressings were changed at least twice per week (according to the condition of the wound)
  - Wound area measurements and wound fluid samples were taken weekly

- Follow-Up:
  Wound outcomes were followed for 14 weeks

- Primary endpoints:
  - Response to treatment from baseline to week 4 (responders with ≥50% reduction in wound area; non-responders with <50% reduction in wound area) - Wound improvement from baseline to week 14 (≥50% reduction in wound area)
  - Wound healing rates from baseline to week 14 (full epithelialization)

- Secondary endpoint:
  To correlate protease (MMP-1, MMP-9, and elastase) and protease inhibitor (TIMP-1) levels with clinical outcome

KCI
An Acelity Company

Acelity™

RESULTS

There were no significant differences between the two groups with regard to patient demographics or wound characteristics.

- **Compared to the control group, the C/ORC/S group resulted in:**
  - Significantly more wounds with ≥50% reduction in wound area by Week 4 (79% vs. 43%, respectively; p=0.035)

  - Significantly higher proportion of improved wounds with at least 50% reduction in wound area at weeks 4, 8, and 10 (p=0.035, p=0.018, and p=0.046, respectively)

  - A greater proportion of wounds that healed by week 14 (52% vs. 31%, respectively; p>0.05)

  - Significantly fewer patients withdrawing from the study due to infection (0% vs. 31%, respectively; p=0.012)

  - The results of this study suggest that individual protease levels may not be suitable biomarkers of healing status; however, compared to responders, the sum of matrix metalloproteinase-9 and elastase concentration levels was significantly higher in nonresponders at baseline (p=0.0705) and week 4 (p=0.012)

DISCUSSION

- The authors acknowledged that measuring individual inflammatory protease levels may not take into account the biochemical profile of each wound, which resulted in large degrees of variation within the patient population.

- When comparing the healing rate of wounds between the treatment groups, the control group plateaued after 8 weeks, while the C/ORC/S treatment group continued to increase over the 14 week observation period. This finding may suggest that the number of healed wound in the C/ORC/S group may continue to increase beyond 14 weeks.

CONCLUSION

The authors concluded that "collagen/ORC/silver treatment significantly increased healing rates and decreased levels of infection compared with standard therapy".

KCI
An **Acelity** Company

Acelity™