COLLAGEN/ORC

LEVEL ONE - RCT STUDY
Randomized comparative trial of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers.


KEY POINTS
- A RCT in neuropathic diabetic foot ulcers comparing Collagen/ORC with standard of care (MWH) in 40 patients
- A significant difference in the number of wounds healed and time to complete healing was found when neuropathic diabetic foot ulcers were treated with Collagen/ORC compared to control treatment (moist wound healing)
- Collagen/ORC also resulted in a greater percentage reduction in wound size compared to control treatment. Wound size assessment included volume, area and ulcer depth

STUDY OBJECTIVE
To evaluate the efficacy of Collagen/ORC in the treatment of neuropathic diabetic foot ulcers.

METHODS
Randomised, prospective, controlled, longitudinal, clinical trial in neuropathic diabetic foot ulcers
- 40 patients were enrolled, and followed for 6 weeks
- Patients were randomised into 2 groups; Collagen/ORC (n=20) and control (n=20; standardized protocol for good wound care). The wounds in both groups were covered with TIELLE®, a moist wound healing dressing
- Wounds were evaluated using the Wagner and Texas classifications prior to the start of the study
- All wounds received decontamination therapy (ACTISORB®) prior to randomisation and wound dressings were changed every 48 hours
RESULTS

Complete healing was achieved in 12/19 (63%) patients receiving Collagen/ORC treatment compared with 3/19 (15%) patients in the control group (p<0.03)

The mean time to achieve healing was 23.3 +/- 9.9 days in the Collagen/ORC group compared with 40.06 +/- 1.15 days in the control group (p<0.01)

The percentage reduction in ulcer size was greater in the Collagen/ORC-treated group as compared to control.

<p>| PERCENTAGE REDUCTION IN ULCER SIZE FOR EACH GROUP |</p>
<table>
<thead>
<tr>
<th>VOLUME</th>
<th>AREA</th>
<th>DEPT</th>
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</thead>
<tbody>
<tr>
<td>Collagen/ORC</td>
<td>83.3 ± 22.1</td>
<td>46.1 ± 27.14</td>
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<tr>
<td>CONTROL</td>
<td>60.8 ± 22.5</td>
<td>26.1 ± 31</td>
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CONCLUSIONS

In this study, the use of Collagen/ORC in patients with neuropathic diabetic foot ulcers demonstrates a superior wound healing response, with an increased number of wounds healed and a shortened time to healing compared to control treatment (p<0.05).