PROMOGRAN™
MATRIX WOUND DRESSING

STUDY TYPE: MULTICENTER, RANDOMIZED, CONTROLLED PROSPECTIVE OPEN-LABEL COMPARATIVE STUDY (LEVEL II)

The Healing Properties of PROMOGRAN™ Matrix Wound Dressing in Venous Leg Ulcers

Vin F, Teot L, Meaume S. J Wound Care 2002;11(9):335-341.

STUDY PURPOSE

The purpose of this study was to compare the healing properties of collagen/oxidized regenerated cellulose dressings (C/ORC, **PROMOGRAN**™ Matrix Wound Dressing, Systagenix Wound Management, Limited, an Acelity Company, Gargrave, UK), non-adherent dressing (ADAPTIC™ Non-Adhering Dressing, Systagenix Wound Management, Limited, an Acelity Company, Gargrave, UK), gauze dressings, and compression therapy (BIFLEX® 16+ Compression Band, Thuasne, France) with a non-adherent dressing (ADAPTIC™ Dressing) with gauze and compression therapy (BIFLEX® 16+ Compression Band) in the treatment of chronic venous leg ulcers.

METHODS

- Patient population
  - Patients with venous leg ulcers present for ≥30 days, free of infection, confirmed venous etiology, and an ankle brachial pressure index of ≥0.8 were included.
  - Wound size was required to be between 2 and 10cm.
  - If the patient had multiple wounds, the largest ulcer ≥3cm away from any other ulcers was the trial ulcer.
  - Patients were randomized into the treatment group with C/ORC dressing (n=37) or the control group with non-adherent dressing plus gauze and a short-stress compression (n=36).
- Treatment
  - The wounds were cleaned with warm sterile saline and the surrounding tissues dried prior to dressing application.
  - The C/ORC dressing was cut to fit the wound followed by application of the non-adherent dressing, gauze, and compression bandages.
  - The control group wounds received a non-adherent dressing followed by gauze and compression bandages.
  - Dressing changes occurred at least twice a week or more, depending on wound conditions.
  - Wound tracings and color photographs were taken after each dressing removal and sent to two blinded investigators for evaluation.
  - Wound healing and patient reported pain during dressing removal were assessed at each dressing change.
- Follow-up
  - Patients were followed for a maximum of 12 weeks.

RESULTS

- Twenty-nine patients completed the 12 week follow-up visits (26 patients were evaluated at 12 weeks; 3 were evaluated at 11 weeks).
- Significantly more patients in the non-adherent dressing group switched to another dressing than the C/ORC dressing group (22.2% versus 5.4%, p=0.035).
- Of the 26 patients that were evaluated at 12 weeks, similar number of wounds healed between the two groups (control group, n=11; C/ORC group, n=15; p=0.373).
- Wound surface area decreased significantly more in patients treated with C/ORC dressings (control group: 36.5 ± 11.4%; C/ORC group: 54.4 ±10.9%; p<0.001).
- No severe local adverse events were reported in either group; however, poor dressing tolerability was noted as the reason to switch to another dressing in 5 control patients and 3 C/ORC patients.

DISCUSSION

- C/ORC dressings trended toward faster healing rates and better clinical outcomes than the non-adherent control dressing.
- C/ORC dressings promoted a significant reduction in wound surface area compared to the non-adherent control dressing.
- The authors acknowledge the potential for bias due to the open-label nature of the study. However, the authors tried to circumvent this bias by having blinded evaluators assess the wound tracings and photographic data for wound healing assessment.

CONCLUSION

The authors conclude that the data indicates better healing rates in patients with venous leg ulcers who received C/ORC dressings compared to patients who received the non-adherent control dressings; however, further studies are needed.

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