

A randomized controlled trial of PROMOGRAN™ Matrix (a collagen/oxidized regenerated cellulose dressing) vs. standard treatment in the management of diabetic foot ulcers

Veves, A., Sheehan, P., Pham, H.T. Arch Surg, 2002, 137(7), 822-7.

Key Points

- RCT in diabetic foot ulcers comparing effect of PROMOGRAN™ Matrix with control therapy in 276 patients
- After 12 weeks of treatment, 51 (37%) PROMOGRAN™ Matrix treated wounds had achieved complete wound closure as compared to 39 (28.3%) control patients, ($p=0.12$)
- Increased efficacy in ulcers of less than 6 months duration – 45% PROMOGRAN™ Matrix treated wounds healed compared with 33% of controls ($p=0.056$)
- Patients and investigators expressed a strong preference for PROMOGRAN™ Matrix compared to moistened gauze; greater user preference

Study Objective

To evaluate the healing rates of diabetic foot ulcers during a 12-week period in patients treated with **PROMOGRAN™ Matrix** compared to standard therapy (saline-moistened gauze).

Methods

Randomized, prospective, controlled, multicenter clinical trial in diabetic foot ulcers

- Protocol was designed according to fundamental principles of the expert panel of the American Diabetes Association & approved by FDA prior to initiation
- 276 patients were enrolled, at 11 centers and followed for 12 weeks
- Patients were randomized to received either **PROMOGRAN™ Matrix** (n=138) or moistened gauze (n=138) and a secondary dressing
- Main outcome measure was complete healing of the study ulcer debrided wounds with a necrosis/fibrin cover.

Results

After 12 weeks of treatment 51 (37%) PROMOGRAN™ Matrix treated wounds had achieved complete wound closure as compared to 39 (28.3%) control patients, ($p=0.12$).

In patients with wounds of less than 6 months duration a greater difference in healing was demonstrated; 43/95 (45.3%) patients healed in the PROMOGRAN™ Matrix group compared to 29/89 (32.6%) in the control group, ($p=0.056$).

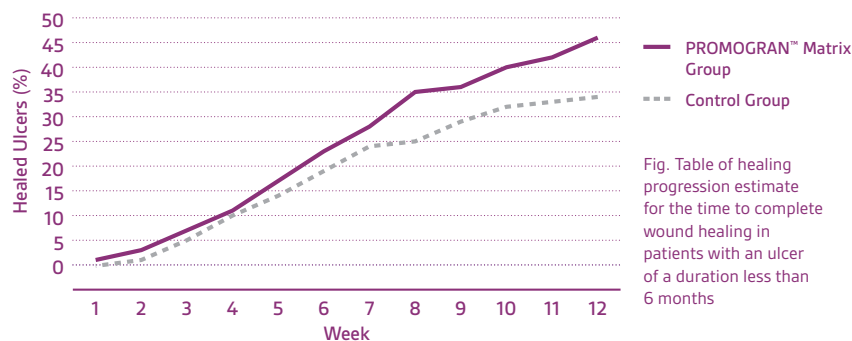


Fig. Table of healing progression estimate for the time to complete wound healing in patients with an ulcer of a duration less than 6 months

A similar number of wounds healed in patients with wounds greater than 6 months duration, in both groups.

Fewer patients in the **PROMOGRAN™ Matrix** group than in the control group had suspected infection reported at any time (17 vs. 26, $p=0.14$).

The patients' rating of **PROMOGRAN™ Matrix** dressing was significantly higher than control (8.6 +/- 0.1 vs. 7.6 +/- 0.2, $p=0.01$).

The clinician rating was also higher for **PROMOGRAN™ Matrix** compared to control (9.3 +/- 0.1 vs. 7.4 +/- 0.2, $p<0.05$).

Conclusion

This study demonstrates that **PROMOGRAN™ Matrix** may be a useful adjunct in the management of diabetic foot ulcers, and in particular for wounds of less than 6 months duration.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

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