

# PROMOGRAN<sup>®</sup>

## LEVEL ONE - RCT STUDY

A randomized controlled trial of PROMOGRAN<sup>®</sup> (a collagen/oxidised 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

- A RCT in diabetic foot ulcers comparing effect of **PROMOGRAN<sup>®</sup>** with control therapy in 276 patients
- After 12 weeks of treatment, 51 (37%) **PROMOGRAN<sup>®</sup>** 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<sup>®</sup>** treated wounds healed compared with 33% of controls (**p=0.056**)
- Patients and investigators expressed a strong preference for **PROMOGRAN<sup>®</sup>** 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<sup>®</sup>** compared to standard therapy (saline-moistened gauze).

### METHODS

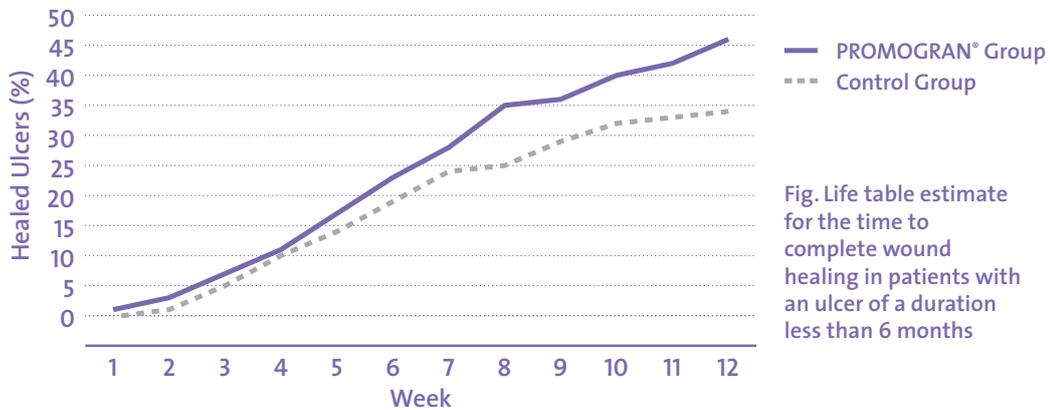
Randomised, prospective, controlled, multicenter clinical trial in diabetic foot ulcers

- 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 Randomised to received either **PROMOGRAN<sup>®</sup>** (n=138) or moistened gauze (n=138) and a secondary dressing
- Main outcome measure was complete healing of the study ulcer

## RESULTS

After 12 weeks of treatment 51 (37%) **PROMOGRAN**<sup>®</sup> 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**<sup>®</sup> group compared to 29/89 (32.6%) in the control group, (p=0.056).



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

Fewer patients in the **PROMOGRAN**<sup>®</sup> group than in the control group had suspected infection reported at any time (17 vs 26, p=0.14).

The patients' rating of **PROMOGRAN**<sup>®</sup> 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**<sup>®</sup> compared to control (9.3 +/- 0.1 vs. 7.4 +/- 0.2, p<0.05).

## CONCLUSIONS

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