**PROMOGRAN®**

**LEVEL ONE - RCT STUDY**

The healing properties of PROMOGRAN® in venous leg ulcers

Vin, F., Teot, L., Meaume, S., J. Wound Care, 2002, 11(9), 335-41

**KEY POINTS**

- A RCT in venous leg ulcers comparing effect of PROMOGRAN® used in combination with compression to control (non-adherent plus compression) in 73 patients
- Study demonstrates that PROMOGRAN® may accelerate healing in venous leg ulcers
- A highly significant difference was observed in relation to reduction in wound area with PROMOGRAN® having a superior effect ($p<0.0001$)
- When wounds were characterized as healing and improving, a 20% difference in favour of PROMOGRAN® was observed ($p=0.0797$)

**STUDY OBJECTIVE**

To evaluate the healing properties of PROMOGRAN®, in the treatment of venous leg ulcers, when used in combination with compression therapy.

**METHODS**

Randomised, prospective, controlled, open-label, multicenter clinical trial in venous leg ulcers

- 73 patients were enrolled, at 14 centers in France, and followed for 12 weeks
- Patients were randomised to receive either PROMOGRAN® (37 patients) or ADAPTIC® (36 patients);
  - both groups had the primary dressing covered with gauze pads and compression bandages (Biflex)
- Target wound size had to be between 2cm and 10cm in any one dimension
- Dressings were changed twice weekly
RESULTS

Complete healing data at 12 weeks demonstrated greater healing in the PROMOGRAN\textsuperscript{®} group. Healing rates for patients who remained with dressing allocated throughout the 12-week period were 41\% for PROMOGRAN\textsuperscript{®} and 31\% for control groups respectively.

Significantly more patients switched dressings in the control group than in the PROMOGRAN\textsuperscript{®} group (22.2\% vs 5.4\%, \(p=0.035\)).

A significant decrease in wound area was measured over the 12-week period in the PROMOGRAN\textsuperscript{®} group compared to control (\(p<0.0001\)); average decrease in wound size for PROMOGRAN\textsuperscript{®} treated wounds was 54.4\%, (median value 82.4\%) compared to 36.5\% for control (median value 44.6\%).

In the PROMOGRAN\textsuperscript{®} group 23/37 (62\%; 49\% healed) of wounds had either healed or showed a improvement of >50\% reduction in wound size as compared to only 15/36 (42\%; 33\% healed) patients in the control group.

CONCLUSIONS

This study strongly indicates that patients with a VLU who receive PROMOGRAN\textsuperscript{®} therapy have better healing rates than those given current standard of care, when used with compression.