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.

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
RESULTS

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

Significantly more patients switched dressings in the control group than in the PROMOGRAN® 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® group compared to control (p<0.0001); average decrease in wound size for PROMOGRAN® treated wounds was 54.4%, (median value 82.4%) compared to 36.5% for control (median value 44.6%).

In the PROMOGRAN® 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® therapy have better healing rates than those given current standard of care, when used with compression.