COLLAGEN/ORC

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

STUDY OBJECTIVE
To evaluate the healing properties of Collagen/ORC, 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 Collagen/ORC (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

*Vin, F. et al. The healing properties of PROMOCLEAN® in venous leg ulcers. J Wound Care, 2002, 11(9), 335-41
RESULTS

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

Significantly more patients switched dressings in the control group than in the Collagen/ORC group (22.2% vs 5.4%, p=0.035).

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

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