Publication summary: Lavery LA, et al. Int Wound J (2014)*

SmithNephew

Significantly more patients with chronic diabetic foot ulcers (DFUs) achieved complete wound closure in a shorter time with GRAFIX^o Cryopreserved Placental Membrane than with standard care

+ Plus points



with GRAFIX Membrane versus standard care (62.0 vs 21.3%; p=0.0001) 0_0 27.5 days

Faster complete wound closure with GRAFIX Membrane versus standard care (42.0 vs 69.5 days; p=0.019) 67.8%

Probability of
complete wound closure
with addition of GRAFIX Membrane
to standard care in the
open-label phase

Overview

- Prospective, multicenter, randomized, single-blinded study
- Patients with DFUs (duration 4–52 weeks) received once weekly GRAFIX Membrane (n=50) or standard care of off-loading and non-adherent dressings (n=47) for up to 84 days
- All wounds were appropriately cleaned and surgically debrided at each weekly visit
- Patients receiving standard care whose wounds had not closed by the end of the blinded treatment phase were able to receive GRAFIX Membrane in an open-label treatment phase (84 days)

Results

- GRAFIX Membrane use significantly increased the number of DFUs that achieved complete closure compared with standard care (p=0.0001; Figure)
 - DFUs remained closed at 12-week follow-up in 82.1% of patients with GRAFIX Membrane and 70.0% of patients with standard care
- Median time to complete wound closure was significantly faster with GRAFIX Membrane versus standard care (42.0 vs 69.5 days; p=0.019)
- Complete wound closure was achieved with 50% fewer study visits with GRAFIX Membrane than with standard care (6 vs 12 visits; p<0.001)
- For patients who had failed to heal with standard care alone and added GRAFIX Membrane (n=26), the probability of DFU closure was 67.8% with a mean closure time of 42 days

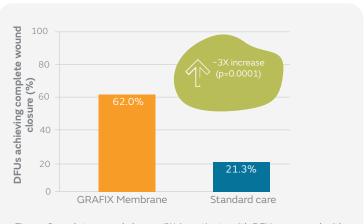


Figure. Complete wound closure (%) in patients with DFUs managed with GRAFIX Membrane and standard care

Conclusions

Significantly more patients with chronic DFUs achieved complete wound closure in a shorter time using GRAFIX Membrane compared with standard care.

Citation

*Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of GRAFIX° for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. *Int Wound J.* 2014;11(5):554–560.

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