✚ Evidence in focus

Publication summary: Ananian CE, et al. *Wound Repair Regen* (2018)*

Smith+Nephew

Using GRAFIX PRIME◇ Cryopreserved Placental Membrane, significantly more patients with diabetic foot ulcers (DFUs) ≤5cm² achieved complete wound closure with reductions in estimated mean costs, compared with Dermagraft®

✚ Plus points

Number of patients achieving **complete DFU closure** with GRAFIX PRIME Membrane and Dermagraft were similar (non-inferior)

>50% relative increase in DFUs ≤5cm² achieving complete closure with GRAFIX PRIME Membrane versus Dermagraft (p=0.0118)

$4,122 **estimated mean cost savings** per person in DFUs ≤5cm² with GRAFIX PRIME Membrane versus Dermagraft (p<0.0001)

Overview

- Prospective, randomized, single-blind, 9-week, head-to-head study at seven centers in the USA in patients with chronic DFUs (duration, 4–52 weeks; size, 1–15cm²)
- Patients received either GRAFIX PRIME Membrane (n=38) or Dermagraft (Organogenesis, Canton, MA, USA; n=37) weekly for up to eight applications or until complete wound closure, whichever was first
  - Standard care was wound cleaning and debridement with off-loading for plantar DFUs
- More patients in the GRAFIX PRIME Membrane group had plantar wounds and wounds of longer duration, and fewer had lateral wounds, compared with the Dermagraft group (all p<0.05)
  - No significant difference in wound size (p=0.732)
- Of the total population (N=75), 62 patients completed the study (per protocol population) and were included in the non-inferiority, clinical outcomes and cost analyses

Results

- Patients achieving complete wound closure (primary endpoint) was similar (non-inferior) for GRAFIX PRIME Membrane and Dermagraft (Figure)
- For GRAFIX PRIME Membrane compared with Dermagraft there were no significant differences in:
  - Wound area reduction ≥50%
  - Number of product applications
  - Mean percentage wound area reduction
- For GRAFIX PRIME Membrane compared with Dermagraft in DFUs ≤5cm²:
  - Significantly more patients achieved complete wound closure at the end of treatment (p=0.0118; Figure)
  - Mean per-patient product costs were significantly reduced

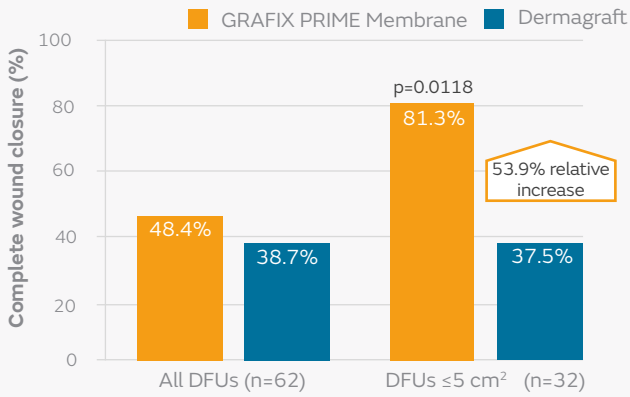

Figure. Complete wound closure (%) at the end of treatment in all wounds and wounds ≤5cm² treated with GRAFIX PRIME Membrane and Dermagraft

Conclusions

Clinical outcomes were similar (non-inferior) with GRAFIX PRIME Membrane and Dermagraft for DFUs of all sizes. For DFUs ≤5cm², significantly more patients achieved complete wound closure with GRAFIX PRIME Membrane with significant reductions in mean estimated costs compared with Dermagraft.

Citation

*Ananian CE, Dhillon YS, Van Gils CC, *et al.* A multicenter, randomized, single-blind trial comparing the efficacy of viable cryopreserved placental membrane to human fibroblast-derived dermal substitute for the treatment of chronic diabetic foot ulcers. *Wound Repair Regen*. 2018;26(3):274–283.
Available from: Wound Repair and Regeneration

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.