+ Evidence in focus
Publication summary

Smith+Nephew

Likelihood of new or recurrent diabetic foot ulcers (DFUs) was significantly reduced after application of GRAFIX◊ Membrane compared with other cellular- and tissue-based products in an analysis of Medicare claims

DaVanzo J, Hartzman A, Surfield C, Dobson A. Cryopreserved placental membrane allograft reduces the likelihood of developing a new or recurring foot ulcer and all-cause mortality in diabetic patients, when compared to other cellular- and tissue-based products. *Adv Wound Care*. 2022 Apr 25. [Epub ahead of print]

Available at: Advances in Wound Care

Key points

After treatment with GRAFIX Cryopreserved Placental Membrane, compared with other cellular- and tissue-based products:

Significant reduction in likelihood of a new or recurrent DFU (all time points; p<0.05)

Favorable indirect effect on average mortality rate at 1 year*

Lower occurrences of cellulitis/abscess of the foot and toe (versus other cellular products; most time points)

Overview

- A Medicare claims-based observational study comparing effectiveness of GRAFIX Membrane with other cellular- and tissue-based products (cellular and acellular) in an outpatient setting
- Any new or recurrent DFUs, mortality and DFU-related infections were assessed at 30, 90, 180 and 365 days after completing treatment
- Data from 7,869 Medicare beneficiaries, with confirmed DFUs who were treated for 90 days and had at least one Medicare outpatient claim, were included (2013 to 2017):
  - GRAFIX Membrane, n=786
  - Another cellular product, n=4,546
  - An acellular product, n=2,537

Results

- At all time points, the likelihood of a new or recurrent DFU was significantly reduced after treatment with GRAFIX Membrane compared with the other cellular or acellular products (Figure; p<0.05)
  - Relative reductions ranged from 36.7% after 30 days (other cellular products) to 58.5% after 365 days (acellular products)
- At day 365, average mortality rate was lower with GRAFIX Membrane (12.3%) than with other cellular (17.7%) or acellular products (18.1%)*
- For GRAFIX Membrane compared with other cellular products, there were significant reductions (p<0.05) in occurrences of:
  - Cellulitis/abscess of the foot at 30, 90, 180 and 365 days
  - Cellulitis/abscess of the toe at 180 and 365 days
- There were no significant differences between groups in occurrences of gangrene, osteomyelitis or paronychia

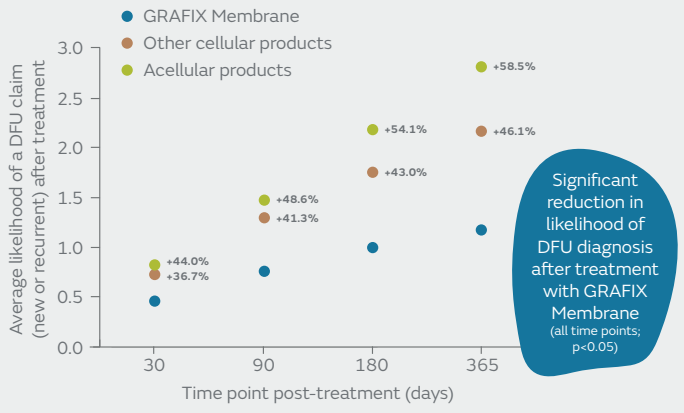

Figure. Average likelihood of a DFU diagnosis with GRAFIX Membrane, other cellular products or acellular products (differences are reported as relative percentage increases with other products vs GRAFIX Membrane)

Conclusions

After completion of treatment, the likelihood of a claim for a new or recurrent DFU was significantly reduced with GRAFIX Membrane versus other cellular and acellular products used in outpatient settings (relative reductions ranged from 36.7% to 58.5%, depending on comparator and time point).

*GRAFIX Membrane cannot save lives and instead may have an indirect effect on mortality

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.

Study sponsored by Smith & Nephew Consolidated Inc.
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