

# Final Efficacy and Cost Analysis of a Fish Skin Graft vs Standard of Care in the Management of Chronic Diabetic Foot Ulcers

## PURPOSE

A prospective study evaluating the efficacy, safety and cost benefit of the use of Fish Skin Grafts compared to Collagen Alginate Treatment (CAT) for the of treatment resistant diabetic foot ulcers

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## POPULATION

- 102 ITT patients with treatment resistant diabetic foot ulcers (DFUs) not involving tendon capsule or bone (UT 1A/1C)

## DESIGN

- Prospective, multi-center, randomized, controlled trial to evaluate patient outcomes for the treatment of DFUs

## INTERVENTION

- Patients received two weeks of standard of care (SOC) treatment, consisting of offloading the DFUs with a walker, excluding those achieving greater than 20% wound area reduction after that time
- Patients were randomized to either SOC treatment plus a weekly application of fish skin graft or to collagen alginate wound dressing (CAT) alone

## RESULTS

- The use of fish skin grafts resulted in **1.8x more** DFUs healed within a 12-week period compared to CAT, which was statistically significant ( $p=.0163$ )
- Of the wounds that had not fully healed in 12 weeks, the mean percentage wound area reduction (PAR) was significantly greater with fish skin grafts compared to CAT, **86.3%** for fish skin grafts compared to 64.0% for CAT ( $p=.0282$ )
- Fish skin grafts have annual cost savings of **\$2818** per patient compared to CAT and should be considered as a more efficient and cost-effective solution for treating DFUs than CAT

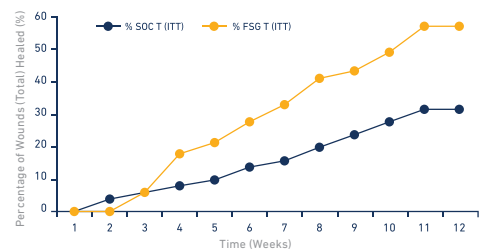


Figure 1. Percentage of total wounds healed by week as intention to treat (ITT). The numbers of healed wounds in the fish skin graft treatment arm gradually increased weekly and was significantly more than SOC group at the end of treatment period of 12 weeks, noting 1.8 times more wound healing ( $p=.0163$ ).



Figure 2. Photographs of representative patients treated with fish skin grafts showing progression of wound healing. Patient 1: A 57-year-old male presented with a foot ulcer (FU) of 2 cm<sup>2</sup> in size that had been present for 7 weeks. After 5 fish skin graft treatments, the wound area decreased over 84%. At the week 7 EOS visit (following the sixth treatment), the ulcer was confirmed to be fully healed. Patient 2: A 71-year-old female presented with a FU of 1 cm<sup>2</sup> in size that had been present for 5 weeks. fish skin graft treatment was applied weekly to the wound area, resulting in a 98% reduction in wound area over 5 weeks. Complete healing was confirmed at the week 6 EOS visit.

**Abbreviations:** CAT, collagen alginate treatment; DFU, diabetic foot ulcer; UT 1A/1C, DFU extending at least through the dermis but not into tendon, muscle, or bone; SOC, standard of care; PAR, percentage wound area reduction; ITT, Intention to treat; EOS, end of study.

## CONCLUSIONS

- Treatment of DFUs with fish skin grafts resulted in significantly more wounds healed and annualized cost savings of \$2818 per patient compared with CAT. In addition, the use of fish skin grafts requires significantly fewer dressing changes and applications.

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