The Use of EpiFix® Allograft Implantation to Treat Chronic Diabetic Foot Ulcers in Refractory and Non-Refractory Patients: A Retrospective Case Study Review of Five Patients in a VA Setting

Guy J. Werkhoven, DPM, Eric W. Affeldt, DPM, Gregory T. Rifleman, DPM

Minneapolis Veterans Administration Medical Center

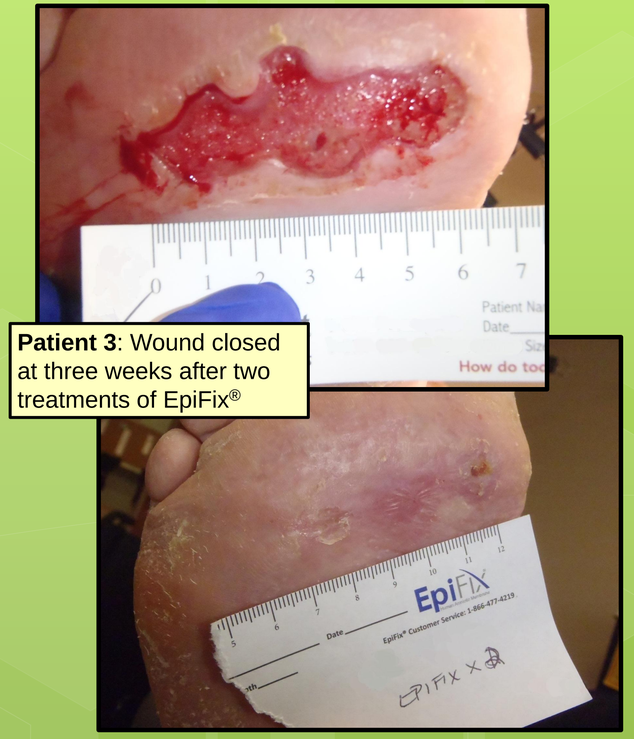
Background

- At Desert Foot 2010, a VA center algorithm for chronic diabetic foot ulcer treatment was developed by Kimmel and colleagues.
- Previous advanced therapy models included living skin substitutes, i.e., Dermagraft®, Apligraf®, and Regranex®.
- Long-term use of living skin substitutes demonstrates a clinical and economic burden in refractory patients within the VA system.
- Amniotic membrane allografts such as EpiFix® have shown promise in treating chronic soft tissue injuries and chronic wounds.
- EpiFix® is an amniotic membrane allograft for utilization in soft tissue regeneration and chronic wound treatment.

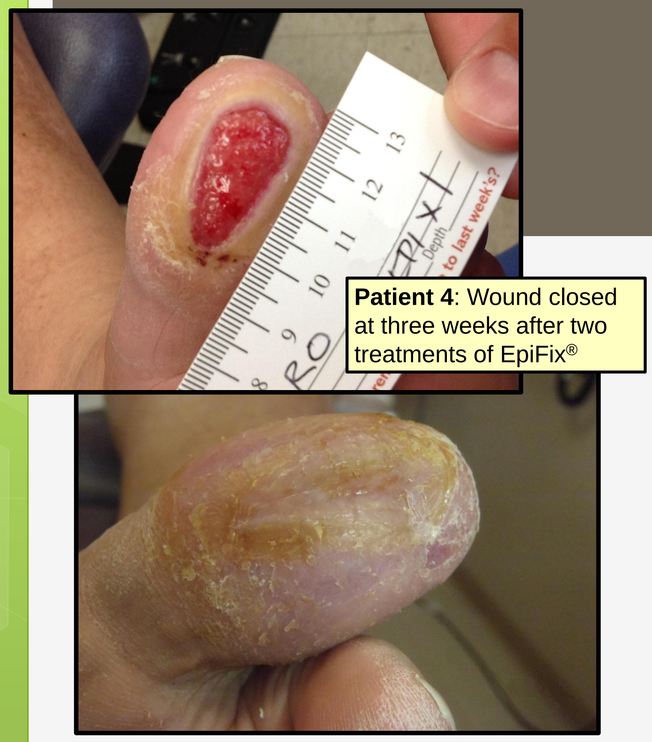
Methods

- Chart review of five patients was conducted to look at historical treatment effect as well as wound closure with EpiFix® allograft.
- Treatment history was assessed to determine refractory versus non-refractory patients.
- Refractory patients were those that failed to achieve complete closure by week eight after treatment with living skin substitutes.
- All patients assessed were diabetic with chronic diabetic foot ulcers or wounds and received the following:
  - EpiFix® bi-weekly
  - Weekly dressing change and bi-weekly sharp debridement
  - Standard topical dressings in adjunct to EpiFix®
  - Assessment of total wound area to determine rate of closure based on complete epithelialization of prior wound bed
- Cost comparisons were made using FSS pricing and assuming equal efficacy

Results

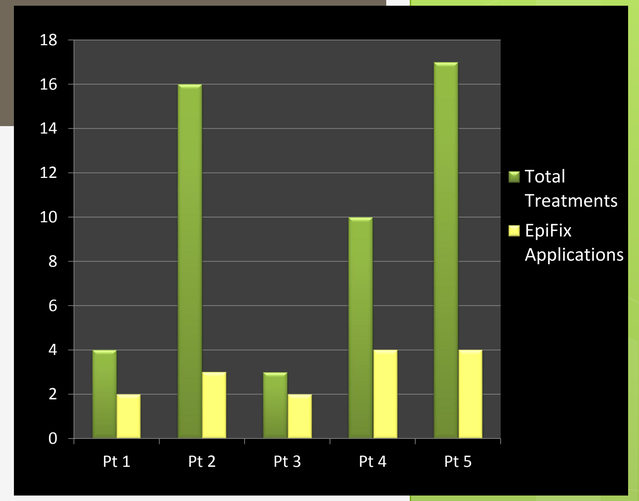


Patient 3: Wound closed at three weeks after two treatments of EpiFix®



Patient 4: Wound closed at three weeks after two treatments of EpiFix®

Comparison of Number of Treatments Required Prior to Wound Healing Between Approved Skin Substitutes and EpiFix®



EpiFix® applications comprised 30% of all advanced treatments for chronic wounds in these patients and effected a total projected savings of $25,639.

Findings

- All five patients achieved complete closure after treatment with EpiFix®.
- All patients were diagnosed with chronic diabetic ulcers as determined by lack of 50% closure after 4 weeks of standard treatment
- Three out of five cases failed to close after utilization of Dermagraft® prior to treatment intervention with EpiFix®.
- Two of five cases had received greater than ten Dermagraft® treatments prior to treatment intervention with EpiFix®.
- No patient required more than four EpiFix® treatments to achieve complete closure.
- Two patients achieved complete closure after two EpiFix® treatments.
- Total combined cost to treat five EpiFix® patients was $12,500 (average per patient price per closure with EpiFix® was $2,448).
- No treatment related side effects were observed in EpiFix® treated patients.

Conclusions

- Retrospectively, EpiFix® was an effective treatment to achieve complete closure of both refractory and non refractory chronic wounds.
- EpiFix® treatment closed all chronic wounds in a rapid fashion regardless of chronicity.
- No secondary side effects were observed in patients treated with EpiFix®.
- Assuming equivalent closure rates, if patients continued treatment with Dermagraft®, the Minneapolis VA would have spent 300% more ($38,094) than with EpiFix® ($12,455). This is a considerable cost savings over alternative advanced therapy.
- Expansion of viable options to treat chronic diabetic foot ulcers in VA settings should be considered.