EPIFIX® DEMONSTRATES SUPERIOR HEALING RATES IN DFUs vs. SOC

In a recently published **Level 1 study** examining the efficacy of EpiFix in conjunction with Standard of Care (SOC) for the treatment of diabetic foot ulcers (DFU), it was reported that **EpiFix demonstrates higher healing rates with a superior wound healing trajectory** in a heterogeneous patient population compared to SOC alone (control).

110 Subjects Treated in Intent-to-Treat Group

98 Subjects Treated in Per-Protocol Group

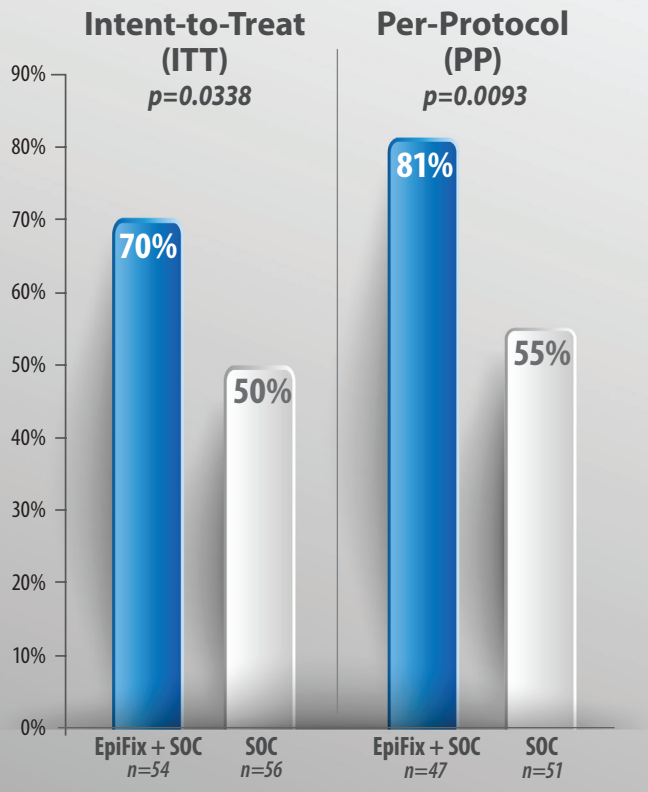
14 Centers

Large Geographical Distribution

12 Weeks

81% Healing Rates

EpiFix Demonstrated Superior Wound Healing at 12 weeks vs. SOC



Level I Evidence:

- Study participants receiving weekly EpiFix with SOC* exhibited superior wound healing compared to treatment with SOC alone.
- EpiFix patients were significantly more likely to completely heal compared to control.
- Cox regression analysis showed **subjects treated with EpiFix were more than twice as likely to heal completely within 12 weeks** as those not receiving EpiFix, after adjusted for covariates such as wound size, wound location, history, etc.
- ITT analysis reduces bias that may occur when factors such as protocol deviation and non-compliance are excluded from the analysis. PP data more closely reflect expected clinical practice outcomes on patients who are compliant with the study protocol.

**SOC = alginate dressings, absorbent non-adhesive hydropolymer secondary dressings, gauze, and an offloading device (cam walker, offloading boot, shoe, or complete contact cast) as indicated.*

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STUDY OVERVIEW

Objective	To determine the safety and effectiveness of EpiFix as compared to control therapy for the treatment of non-healing diabetic foot ulcers (DFUs)
Subjects	110 subjects were enrolled in the Intent-to-Treat Cohort. Subjects randomized 1:1 in treatment arms 98 subjects met the inclusion/exclusion criteria (Per-Protocol Cohort)
Treatment Groups	Treatment: EpiFix plus SOC Control: SOC = sharp debridement, standard wound dressings with alginate dressings, absorbent non-adhesive hydropolymer secondary dressings, gauze, and an offloading device (cam walker, offloading boot, shoe, or complete contact cast) as indicated.
Primary Endpoint	Incidence of complete wound closure assessed over a 12 week period

Results[1]:

- **98 subjects met the inclusion/exclusion criteria (Per-Protocol Cohort):**
  - 47 EpiFix and 51 received SOC
  - The study population in this trial is representative of what clinicians see in normal daily practice
- **Healing Rates at 12 weeks:**
  - EpiFix = 81% of patients who received weekly EpiFix plus SOC had complete healing
  - Standard of Care = 55% of patients who received weekly SOC had complete healing
- **SOC Group Results Observations:**
  - These healing rates are expected when the subjects are treated weekly over a 12 week period with good wound care practices including adequate debridement, offloading and dressings such including alginates, hydropolymer secondary dressings, etc.
  - Patients enrolled into either the EpiFix or SOC arms were treated and evaluated weekly regardless of healing rates. Patients were not exited from the trial early unless it was deemed medically necessary.
- Differing clinical practice patterns and observed dissimilarities in study protocols, debridement techniques, racial distribution, and patient/provider compliance were contributing factors to variances in healing rates from this study compared to previously published studies.

This study confirms findings from previous Level 1 studies that diabetic foot ulcers treated with **EpiFix** have **significantly greater rates of healing**.

EpiFix®

Dehydrated human amnion/chorion membrane allograft

PURION®

EpiFix is processed using the PURION process, a unique approach that provides an easy to use allograft stored at ambient conditions.

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1. Tettelbach W, Cazzell S, Reyzelman AM, Sigal F, Caporusso JM, Agnew PS. A confirmatory study on the efficacy of dehydrated human amnion/chorion membrane dHACM allograft in the management of diabetic foot ulcers: A prospective, multicentre, randomised, controlled study of 110 patients from 14 wound clinics. *Int Wound J.* 2018;1–11.