

MiMedx Clinical Evidence Review

Studies	EpiFix® Results
EpiFix DFU RCT Study ¹	Complete wound closure: 92% at 6 weeks (p=.001)
EpiFix DFU RCT - Crossover Study ²	Complete wound closure: 91% in 12 weeks (p=.001)
EpiFix DFU RCT - Long Term Follow Up ³	94% Remained Healed 9-12 months after initial closure
EpiFix DFU RCT - Weekly vs. Biweekly Application of dHACM ⁴	Overall Complete wound closure: 92.5% healing in 12 weeks <i>Mean time to healing:</i> - Weekly applications: 2.4 weeks - Biweekly applications: 4.1 weeks
EpiFix DFU RCT EpiFix vs. Apligraf® vs SOC Study ⁵	Complete wound closure: 85% at 4 weeks, 95% at 6 weeks
EpiFix VLU Surrogate Endpoint Study ⁶	62% of Pts achieved ≥ 40% wound closure at 4 weeks
EpiFix VLU Multicenter RCT ⁷	Complete wound closure: 60% at 12 weeks, 71% at 16 weeks
EpiFix DFU Multicenter RCT ⁸	Complete wound closure: 81% at 12 weeks (Per-Protocol) & 70% at 12 weeks (Intent-to-Treat)
EpiCord DFU Multicenter RCT ⁹	Complete wound closure: 81% at 12 weeks (Per-Protocol) & 70% at 12 weeks (Intent-to-Treat)

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1. Zelen CM, Serena TE, Denozieri G, Fetterolf DE. A prospective randomized comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. *Int Wound J*. 2013 Oct;10(5):502-7.
2. Zelen CM. An evaluation of dehydrated human amniotic membrane allografts in patients with DFUs. *J Wound Care*. 2013 Jul;22(7):347-8, 350-1.
3. Zelen CM, Serena TE, Fetterolf DE. Dehydrated human amnion/chorion membrane allografts in patients with chronic diabetic foot ulcers: a long-term follow-up study. *Wound Medicine*. 2014 Feb;4:1-4.
4. Zelen CM, Serena TE, Snyder RJ. A prospective, randomized comparative study of weekly versus biweekly application of dehydrated human amnion/chorion membrane allograft in the management of diabetic foot ulcers. *Int Wound J*. 2014 Apr;11(2):122-8.
5. Zelen CM, Gould L, Serena, TE, Carter MJ, Keller J, Li WW. A prospective, randomized, controlled, multi-centre comparative effectiveness study of healing using dehydrated human amnion/chorion membrane allograft, bioengineered skin substitute, or standard of care for treatment of chronic diabetic lower extremity ulcers. *Int Wound J*. 2014 Nov 26. doi: 10.1111/iwj.12395.
6. Serena TE, Carter MJ, Le TL, Sabo MJ, DiMarco DT. A multicenter, randomized, controlled clinical trial evaluating the use of dehydrated human amnion/chorion membrane allografts and multilayer compression therapy vs. multilayer compression therapy alone in the treatment of venous leg ulcers. *Wound Repair Regen*. 2014 Nov-Dec;22(6):688-93.
7. Bianchi C, Cazzell S, Vayser D, Reyzelman A, Dosluoglu H, Tovmassian G, and the EpiFix VLU Study Group Farrer D, Taffe E, Loveland L, O'Connor D, Baer M, Dahle S. A Multi-Centre Randomised Controlled Trial Evaluating the Efficacy of Dehydrated Human Amnion/Chorion Membrane (EpiFix) Allograft for the Treatment of Venous Leg Ulcers. *Int Wound J* 2017; doi: 10.1111/iwj.12843.
8. 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.
9. Tettelbach W, Cazzell S, Sigal F, et al. A multicentre prospective randomised controlled comparative parallel study of dehydrated human umbilical cord (EpiCord) allograft for the treatment of diabetic foot ulcers. *Int Wound J*. 2018;1–9. <https://doi.org/10.1111/iwj.13001>.