

A Blinded, Randomized Controlled Clinical Trial Evaluating the Effect of Hybrid-Scale Fiber Matrix* in the Treatment of Chronic Diabetic Foot Ulcers

Dr. Khalid Husain, DPM, FASPS, FACCWS, FACFAS

Introduction

Chronic diabetic foot ulcers (DFUs) often experience inadequate healing rates, and alternatives to existing therapies are needed to improve the success of wound healing. Synthetic hybrid-scale fiber matrices promote wound closure with increased neovascularization and reduced inflammation compared to commercially available xenografts [1]. Pilot human clinical trials further demonstrated promising outcomes with 75-85% of DFUs treated with hybrid-scale fiber matrix achieving complete re-epithelialization by 12 weeks [1,2]. The goal of this randomized, controlled, single-blind clinical trial (NCT04918784) was to compare the clinical efficacy of hybrid-scale fiber matrix with standard of care (SOC) in the treatment of chronic DFUs

Methods

Patients with DFUs >4 weeks in duration up to 30cm² were observed during a 2-week run-in period before being randomized to receive either hybrid-scale fiber matrix or SOC applied weekly for up to 12 weeks. Post-application, ulcers were examined weekly for progression, percent area reduction, and quality of tissue healing. The primary outcome measure was the percentage of ulcers achieving complete re-epithelialization at 12 weeks

Results

Forty-eight subjects were enrolled and randomized to treatment with either hybrid-scale fiber matrix or SOC. After the 12-week treatment period, 14 of 19 ulcers (74%) in the hybrid-scale fiber matrix arm demonstrated complete re-epithelialization, compared with 6 of 18 ulcers (33%) in the SOC arm (p=0.014, p< 0.05). Ulcers that healed in the hybrid-scale fiber matrix arm had a mean time to complete closure of 6.6 ± 3 weeks with a mean of 6.9 ± 3.5 applications. The incidence of complete healing in the hybrid-scale fiber matrix arm is statistically superior to that in the SOC arm.

	Synthetic Hybrid-Scale Fiber Matrix	Standard of Care
Complete Closure at 12 weeks (Number of wounds, n, %)	14 (74%)	6 (33%)
Continued wound closure at 2 week follow up (Number of wounds, n, %)	14* (100%)	3* (75%)
Weeks to closure (mean ± SD)	6.6 ± 3	7 ± 2.7
Number of synthetic hybrid-scale fiber matrix over 12 weeks (Mean ± SD)	6.9 ± 3.5	-

*1 standard of care patient did not complete the 2 week follow up visit

	Subjects Enrolled (n=48)
Number of patients who completed 12 weeks of treatment	37
Gender	75% Male 25% Female
Patient age (Mean ± SD)	67 ± 11.5
Ulcer surface area, cm ²	5.6 ± 7.8
Comorbidities	Neuropathy (96%) Hypertension (92%) Dyslipidemia (72%) Previous Ulcers (55%) Cardiovascular Disease (40%) *Other (62%)

*Other comorbidities include peripheral artery disease, renal impairment, chronic obstructive pulmonary disease, and retinopathy



Progressive healing of a diabetic foot ulcer treated with the synthetic hybrid-scale fiber matrix. The wound measured 1.32cm² at week 0, .49cm² at week 3, and was closed by week 11 after 9 applications of the matrix.



Progressive healing of a diabetic foot ulcer treated with the synthetic hybrid-scale fiber matrix. The wound measured 2.24cm² at week 0, 1.8cm² at week 3, and was re-epithelialized by week 6.

Discussion

The present study represents the first randomized controlled trial to evaluate the clinical efficacy of a synthetic skin substitute in the treatment of chronic DFUs and demonstrates the clinical superiority of hybrid-scale fiber matrix to SOC in achieving complete re-epithelialization in refractory ulcers. The rate of complete healing as observed in this study is comparable to other advanced therapies.

*Restrata® Acera Surgical, Inc., St. Louis, Missouri
References: 1. Regulski MJ, MacEwan MR. Implantable nanomedical scaffold facilitates healing of chronic lower extremity wounds. Wounds. 2018 Aug;30(8):E77-E80.
2. Abicht BP, Deitrick GA, MacEwan MR, Jeng L. Evaluation of wound healing of diabetic foot ulcers in a prospective clinical trial using a synthetic hybrid-scale fiber matrix. FASSTRAC. 2022 2(1):100135.