

# A Single Arm Pilot Study Evaluating Wound Closure with the Application of a Unique Biodegradable Synthetic Matrix in the Treatment of Non-healing Diabetic Foot Ulcers.

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**Intro:** Diabetic Foot Ulcers (DFUs) are a major burden on healthcare systems and on patients. They require continuous long-term care, multiple treatments, frequent visits, and there are a myriad of different treatment modalities, all varying in results and efficacy. The desired result is achieving and maintaining complete closure of the wound to prevent any further complications. To treat these non-healing complicated and multifactorial wounds, a novel bilayer biodegradable synthetic matrix (BBSM) has been created to serve as a temporizing matrix. It is uniquely designed with an open pore microarchitecture to provide a foundation for new organized tissue formation, along with a temporizing sealing membrane that is removed during the healing process.

**Objectives:** This study was designed to evaluate the efficacy of BBSM with the primary endpoint being the percentage of patients achieving complete closure within 12 weeks.

**Methods:** An open-label prospective pilot study was conducted on 10 patients with DFUs. The indications for the application of BBSM were a present Wagner Grade 1 DFU labeled as the index ulcer. If more than one ulcer was present, only the largest was treated with BBSM. The ulcer had to be present and non-healing for more than 4 weeks and less than 1 year, and range in size from 1.0 cm<sup>2</sup> to 25 cm<sup>2</sup>. Adequate circulation to the affected foot was required, with a non-infected wound. Additionally, the subject had to have satisfactory control of their diabetes as measured by HgA1c and proper offloading for at least 14 days prior to enrollment.

## Results:

- All 10 patients remained as active participants of the study for its entire duration.
- Complete closure of the index ulcer was achieved in 7 out of 10 patients (70%) within 12 weeks or less.
- The mean time to closure was 6.25 weeks with the fastest healing at 2 weeks.
- All healed wounds remained closed upon study confirmation closure assessment visit post 2 weeks later.

## Conclusion:

This novel technology (BBSM) proved to be effective in the treatment of DFUs. The high rate of wound closure, ability to quickly achieve full closure, and ease of use make it an effective treatment modality for non-healing DFUs.

Although 3 of the 10 patients did not achieve full closure at 12-weeks, the marked improvement was clinically significant. The temporizing ability of the matrix facilitates the dressing change process and can potentially decrease the frequency of visits.

Further studies with level-one evidence should be conducted to confirm these initial findings. Additional studies may be performed to investigate recidivism rates post closure with BBSM.

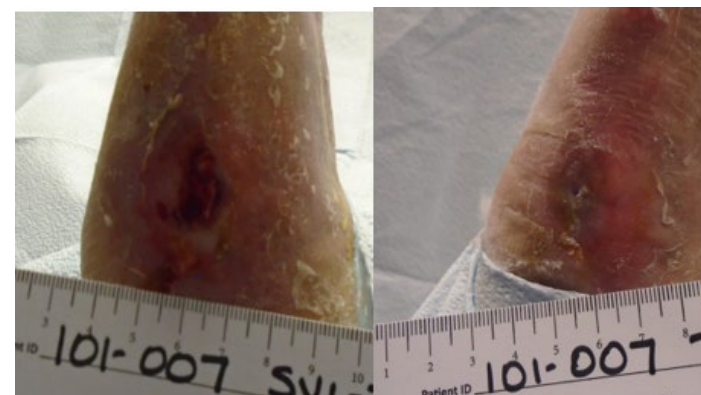


Figure 1. A- 80-year-old, male, Caucasian patient with a BMI of 33.1 initiated the study with a 2 cm<sup>2</sup> Wagner Grade 1 plantar diabetic foot ulcer that had been present for 5 weeks. B- Full closure achieved with BTM at 6 weeks.



Figure 2. A- 48-year-old patient with a 3 cm<sup>2</sup> diabetic foot ulcer that has been present for 24 weeks. B- Complete closure achieved at week 3 post BBSM application.