

Use of Bilayer biodegradable synthetic matrix for limb salvage in patients with complex wounds

Said Atway, DPM; Clinical Associate Professor, Department of Orthopaedics-Podiatry, Wexner Medical Center at Ohio State University,
Javier Guirola, MD and Ross Robinson, BS

Intro: Below the knee amputations are known to increase mortality rates on patients. As limb salvage treatment options continue to evolve, these amputations are very common. The desired outcomes of limb salvage are to preserve the limbs and their functionality. A Novel technology, Bilayer biodegradable synthetic matrix (BBSM) has been created to treat patients with complex wounds that would often result in lower limb amputation by functioning as a temporizing matrix. Its unique microarchitecture promotes organized tissue formation while its sealing membrane temporizes the wound.

Objectives: To evaluate the efficacy of BBSM as a treatment option in limb salvage cases.

Methods: This is a retrospective case series that includes two patients with different complex wound etiologies, who needed a limb salvage treatment option and treated with BBSM.

Case 1:
A 30-year-old patient with Factor V Leiden deficiency and dysvascular limb status post open midfoot amputation and chronic wound. There was continued difficulties with healing the wound with instability of the limb and chronic pain. The wound was debrided and BBSM was applied and monitored for 3 weeks until it delaminated.



Figure 1. A – Post midfoot amputation chronic wound with BTM secured on it showing signs of integration. B- Post BBSM delamination, complete closure was achieved through secondary intention.

Case 2:
59-year-old patient with wet gangrenous forefoot with PAD and recent bilateral foot amputation with delayed healing and exposed deep anatomic structures requiring multiple surgical interventions and debridement. BBSM was applied and monitored until it auto delaminated.



Figure 2. (Patient B). A- Gangrenous Forefoot open wound post amputation with exposed anatomical structures. B- BBSM secured and showing signs of integration. C- BBSM auto-delaminated and wound re-epithelialized by week 12.

Results: Patient #1

- Delamination of BBSM occurred after 3 weeks revealing a healthy granular base of tissue.
- Wound was subsequently treated with NPWT to allow for secondary intention healing.
- Due to the progress and wound improvement the decision was made to allow the area to continue to heal by secondary intention without the need for STSG.
- Wound closed at 6 months and has remained closed for 18 months

Results: Patient #2

- Wound after auto-delamination revealed organized tissue over deep exposed structures that went on to achieve complete epithelization at week 12.
- Patient has gone on to complete use of both limbs with return to activity and ambulation despite bilateral foot amputations

Conclusion: While initially designed to provide a temporizing membrane for preparation of the wound for split thickness grafting. BBSM provided a scaffold for complete wound healing by secondary intention in the two cases presented. BBSM has demonstrated to be an effective treatment option in two limb salvage cases by promoting healthy organized tissue formation in complex wounds that may prevent the need for limb loss or need for further surgical intervention in these two cases. Further level 1 studies will need to be performed to confirm these findings, also long term follow ups will be required to assess the preserved limbs.

Disclosures: Javier Guirola is an employee of Polynovo Biomaterials Pty Ltd. Ross Robinson is an employee of Polynovo Biomaterials Pty Ltd.