Study Purpose
• Baseline fluorescence angiography (FA)
• Aggressive debridement with resection of non-viable tissue
• Two layers of FBADM were applied to the wound

Methods
A retrospective study of eleven consecutively treated patients with full-thickness wounds having depth of at least 0.7 cm. The patients were treated with FBADM (PriMatrix; TEI Biosciences Inc) which was hydrated in sterile saline, activated with patient’s blood, and cut to size. FBADM was then layered on the wounds. The FBADM was then hydrated in sterile saline, activated with patient’s blood, cut to size, and a layer was applied to the wound bed. Care was taken to ensure FBADM was in direct contact with the bleeding wound bed (Fig. 3B), which permits cell migration and deposition of growth factors into the microscopic interstices of the fetal collagen scaffold.

Healing Results
• In all wounds, FBADM layers developed into vascularized dermal-like tissue that was re-epithelialized from wound margins.
• Wounds healed to surface with FBADM layers (Fig. 2A) four to eight weeks faster than wounds receiving only two FBADM layers (Fig. 2B).

Fetal Bovine Acellular Dermal Matrix (FBADM)
• FBADM is a natural dermal collagen matrix supporting re-epithelialization.

Multi-Layered FBADM Application Technique
• Multiple layers of FBADM were applied to a steeply debrided wound bed free of necrotic tissue (Fig. 3A). Initially, wounds were treated with ten layers of FBADM regardless of wound depth. Our technique evolved to utilize as many FBADM layers as necessary to fill the wound defect.
• Pressure wound therapy (NPWT) was applied to the FBADM layer to keep the wound bed moist, and a layer was applied to the wound bed.
• Care was taken to ensure FBADM was in direct contact with the bleeding wound bed (Fig. 3B), which permits cell migration and deposition of growth factors into the microscopic interstices of the fetal collagen scaffold.
• Additional FBADM was applied with fenestrations rotated 90 degrees for each layer (Fig. 4; Technique Schematic). Each layer was in direct contact with the previously applied layer to eliminate dead space between FBADM layers and to maintain appropriate moisture balance.

Conclusion
Layered application of FBADM to completely fill the wound volume is a successful treatment approach for complex lower extremity wounds with significant depth. The success of this application technique can be attributed to the ability of FBADM to rapidly develop into vascularized dermal-like tissue that is capable of re-epithelialization.

Multi-Layered FBADM
Application Technique
In order to determine the appropriate number of FBADM layers, we performed a pilot study of eleven consecutively treated patients with full-thickness wounds to determine the appropriate number of FBADM layers.

Case 1. Non-Healing Lower Extremity Wound
• 71 y/o male with type II diabetes and neuropathy developed an ulcer of his left foot over the fifth metatarsal head complicated by an OM infection.
• Abscessive debridement with resection of the distal 5th metatarsal was performed with a skin graft. The patient was treated with NPWT, IV antibiotics, and HBO therapy initiated with limited healing (Fig. 5A).
• Baseline fluorescence angiography (FA) was performed which indicated complete re-epithelialization (Fig. 5B).
• Two layers of FBADM were applied to the wound one week after presentation (Fig. 5D).
• After three weeks, the wound had healed and the patient was discharged (Fig. 5G).

Case 2. Flapped on Lower Extremity Amputation Site
• 59 y/o male presented with a Wagner Grade III DFU of the right foot that was complicated by OM of the right second metatarsal. The patient had a history of type II diabetes and neuropathy.
• Seven weeks prior, the patient had undergone a second toe amputation with resection of distal segmental soft tissue.
• The wound had been closed with a hinged dressing.
• After completing a six week course of antibiotics, the bone infection cleared and a large cortical tissue defect remained (2.5 cm x 2.5 cm x 2.0 cm) with exposed bone and tendon (Fig. 6A).
• The wound was debried (Fig. 6B) and eight layers of FBADM were applied and covered with a non-contact contact layer that was bolstered with a foam dressing.
• Vascularized tissue over the exposed bone and tendon was generated three weeks after FBADM application (Fig. 6C).
• The generated tissue was abraded to initiate bleeding and FBADM was applied a second time as five stacked layers.
• Three weeks after the second application the wound had completely filled with generated tissue (Fig. 6D).
• Seven weeks after the initial FBADM application re-epithelialization was complete. The wound has remained closed post re-epithelialization (Fig. 6E).

Case 3. Non-Healing Surgical Wound
• 41 y/o obese male with a history of type II diabetes and neuropathy presented with a Wagner Grade IV DFU involving most of the dorsal area of the foot. The wound was secondary to an OM infection of a non-healing fifth toe amputation site and was complicated by exposure of bones and tendons (Fig. 7A).
• The patient underwent Hyperbaric Oxygen Therapy (HBOT) and received an arnoidic wound matrix as well as NPWT with limited success.
• After three months, the wound measured 6.2 cm x 6.2 cm x 0.3 cm and multiple tendons remained exposed (Fig. 7B).
• The wound was debrided and two layers of FBADM were applied to the wound.
• Two weeks after the initial FBADM application, the wound had healed significantly (Fig. 7C).
• Two layers of FBADM were again applied at this point and a third application was carried out after four subsequent weeks (Fig. 7D).
• Seven weeks after the initial FBADM application vascularized tissue was generated to cover the exposed tendons and the wound was completely filled.
• The wound is currently being treated with a silver alginate gel as wound re-epithelialization continues to steadily progress (Fig. 7E-F).

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