

Clinical Evaluation of an Extracellular Matrix Surgical Graft for Reconstructive Surgery over Exposed Bone or Tendon

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INTRODUCTION

Full-thickness skin defects with exposed bone and tendon tissue usually require extensive soft tissue reconstruction to replace the damaged extracellular matrix (ECM). Such wounds do not often heal without intervention and failure to close can lead to chronicity, infection and even amputation. ECM biomaterials can be used for soft tissue reconstruction to provide support and to aid the regeneration of missing or damaged tissue. The ECM 'ovine forestomach matrix' (OFM), modulates inflammation, stimulates blood vessel formation, promotes scaffold infill and undergoes complete remodeling [1]. For plastic and reconstructive surgery (PRS), OFM layers have been laminated without using 'non-natural' components (e.g. crosslinking agents or synthetic polymers) into OFM PRS grafts[#], thereby preserving the structure and biology of single-layer OFM. This study was undertaken to evaluate the performance of the OFM PRS graft when used for full thickness defects with exposed bone and/or tendon.

METHODS

All wounds were debrided during the initial consultation and then as needed during the study. OFM PRS grafts of different thicknesses labelled 'Thin' or 'Thick' (~1 mm and 2 mm thick respectively) were used. Materials were cut to size as needed, and rehydrated with saline prior to application. Wounds were imaged and assessed frequently, and a split thickness skin graft (STSG) was applied as required.

RESULTS

The OFM PRS graft was easy to apply, conformed well to exposed tissues and rapidly vascularized leading to well-formed granulation tissue. Where the OFM PRS graft was used to cover exposed bone and tendon tissue, the regenerated neo-dermis began formation within seven days, with a robust blood supply. Participants reported no pain or adverse events and were satisfied with their surgical outcomes. This set of clinical cases provides preliminary insights into the performance of the OFM PRS graft for exposed bone and tendon cases.

REFERENCES AND DISCLOSURES

Product was provided by Aroa Biosurgery Limited (New Zealand); #Myriad (Aroa Biosurgery Limited, New Zealand); [#]Integra® Bilayer (Integra)

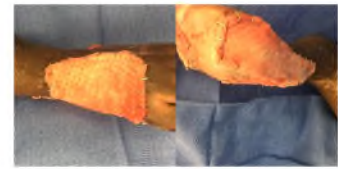
1. Lun, S., et al., A functional extracellular matrix biomaterial derived from ovine forestomach. Biomaterials, 2010, 31(16): p. 4517-29.

CASE 1: Dermal Reconstruction – Pediatric Surgical Dehiscence

Patient History: 3 Year old female with surgical dehiscence following orthopaedic implants. Exposed bone and tendon. Failed collagen/CS* graft.



Procedure: Defect debrided. OFM PRS 'Thick' applied and stapled. Non-adherent/silver alginate and cast/splint.



1 Week: Granulation tissue budding. Gentle debridement, then a STSG applied.



2 Week : 100% Graft take.

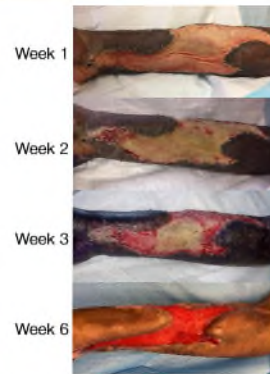


CASE 2: Complex Dermal Reconstruction

Patient History: 25 Year old diabetic female with compression injury with DKA. Fasciotomies, multiple necrotic muscle and soft tissue debridements. Thin coverage over radial and ulnar arteries. Patient refused below elbow amputation.



Procedure: Debridement and partial complex closure at the antecubital fossa and wrist OFM PRS 'Thick' shaped, joined (4-0 chromic catgut) and stapled. Non-adherent dressing + NPWT (75 mmHg, continuous).



6 Week : Fully granulated. 12/1000" STSG placed. **9 Week :** 100% Epithelialization

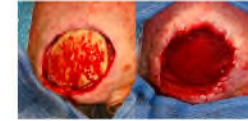


CASE 3 Tumor Excision

Patient History: 85 Year old male with numerous prior scalp skin cancers, with non healing wound on the scalp vertex for 2 years after Mohs dermatologist excision of a scalp squamous cell carcinoma. MRI showing outer table calvarial osteomyelitis.



Procedure: Excised total abnormal scalp region. Debrided outer table with pineapple burr to punctuate bleeding. Total defect 7 x 6.5 cm, calvarium not intact. Applied 10 x 10 cm 'Thin', sutured to edges with 40 Chromic suture.



2 Week: Outer layer gently removed via traction. Inner layers fully granulated. No infection.



4 Week: STSG placed.



7 Week: 100% epithelialized.

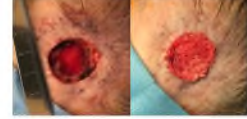


CASE 4: Tumor Excision

Patient History: 98 Year old female with Bowenoid scumous cell carcinoma (~1.5 x 1.5 cm) in-situ.



Procedure: Full thickness scalp resection down to periosteum, 2.1 cm x 2.7 cm. OFM PRS 'Thick', cut and placed on the periosteum. Bolster dressing applied.



2 Week: Removal of the bolster. OFM PRS graft was visible and becoming vascularized and integrated.



6 Week: Deficit is completely filled and 80% re-epithelialized.



8 Week: Deficit maturing. No additional grafting required. Patient very satisfied with cosmetic outcome.

