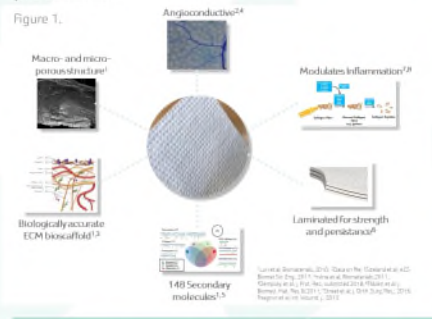


Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series

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Multi-laminate ovine forestomach matrix (OFM) PRS mesh[#] is indicated for both implant applications and dermal regeneration, and is a biologically accurate scaffold for soft tissue repair. The non-crosslinked extracellular matrix biomaterial is rapidly infiltrated, vascularized and remodeled (Fig. 1). A multi-centre evaluation of the OFM PRS mesh was initiated to evaluate the performance of the device in a range of PRS procedures.



- OFM PRS mesh was used for deep partial burns, complex dermal reconstruction, surgical repair of chronic wounds, tumor excision, and cosmetic procedures (n=16 cases total)
- The mesh handled well, conformed easily to the underlying soft tissues and could be shaped to the deficit
- Sutures, staples and NPWT were compatible with the mesh
- Blood and blood components were wicked into the porous structure once placed in the deficit.
- Granulation tissue and a robust blood supply formed within seven days.
- Where patients received a STSG, graft take was excellent (90-100%).
- Participants reported no pain or adverse events and were satisfied with their surgical outcomes

[#]Endoform[®] Myriad (Aroa Biosurgery Limited, New Zealand); [†]Integra Bilayer (Integra); [‡]Hydrofera Blue (Hydrofera LLC). Financial support provided by Aroa Biosurgery Limited (New Zealand); BCHM is a shareholder in Aroa Biosurgery Limited

Dermal Reconstruction – Pediatric Surgical Dehiscence

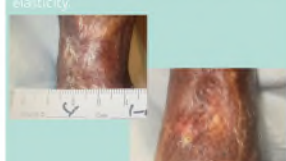
Patient: 3 y/o, ♀. Surgical dehiscence following orthopaedic implants. Exposed bone and tendon. Failed collagen/CS[†] graft.
Pre-op:



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



1 Week: granulation tissue budding. Debridement, STSG applied



2 Week: 100% graft take



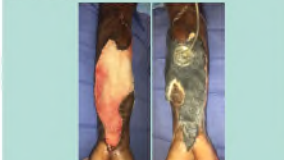
12 Week: Equivalent movement to pre-op status. Regenerated dermis had good elasticity.

Complex Dermal Reconstruction

Patient: 25 yo, ♂, diabetic. Compression injury with DNA. Fasciotomies, multiple necrotic muscle and soft tissue debridements. Thin coverage over radial and ulnar arteries. Patient refused below elbow amputation.
Pre-op:



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).



1-6 Week:



6 Week: fully granulated. 127/1000[†] STSG placed.
9 Week: 100% epithelialization



3 Week: no evidence of incisional dehiscence or wound recurrence.

Flap Stabilization – Surgical Closure of Chronic Dehiscid Wound

Patient: 53 yo, ♂. Previous surgical removal of lap-band resulting in 5 m/o dehiscid surgical wound.
Pre-op:



Procedure: Surgical incision at the margins, through the sub-cutaneous adipose tissue and down to the fascia. OFM PRS "Thick" – trimmed to size, and placed onto the fascia. Two additional devices placed on top of the first.



Flap advancement to cover surface. Drain placed and site managed with incisional NPWT.



1 Week: drain and NPWT removed. Good apposition of the cutaneous tissues. No redness or swelling.



3 Week: no evidence of incisional dehiscence or wound recurrence.

Tumor Excision

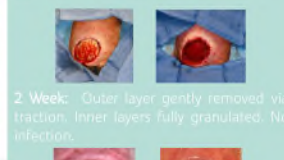
Patient: 85 yo, ♂. Numerous prior scalp skin cancers, with non healing wound on the scalp vertex for 2 years after Mohs dermatologist excision of a scalp squamous cell carcinoma. MRI showing outer table calvarial osteomyelitis.
Pre-op:



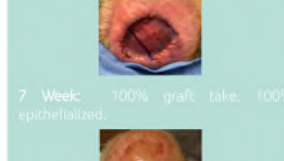
Procedure: Excised total abnormal scalp region. Debrided outer table with pineapple burr to punctuate bleeding. Total defect 7x6.5cm. calvarium not intact.



Applied 10x10cm "Thin", sutured to edges with 4-0 Chromic suture



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



4 Week: STSG placed.



7 Week: 100% graft take. 100% epithelialized.

Nipple Reconstruction

Patient: 56 yo, ♀. Previous (1 year) bilateral breast reconstruction.
Pre-op:



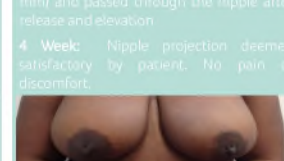
Procedure: OFM PRS "Thin" fashioned into a cylindrical form and placed sub-cutaneous to create projection. Flap advancement to cover the implant.



8 Week: Nipple projection deemed satisfactory by patient. No pain or discomfort.



Patient: 32 yo, ♀. Bilateral breast reduction with loss of all projection.
Pre-op:



4 Week: Nipple projection deemed satisfactory by patient. No pain or discomfort.



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

Tumor Excision

Patient: 98 yo, ♀. Bowenoid. Squamous Cell Carcinoma (1.5 x 1.5 cm) in-situ.
Pre-op:



Procedure: Full thickness scalp resection down to periosteum. 2.3 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 mesh 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.



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