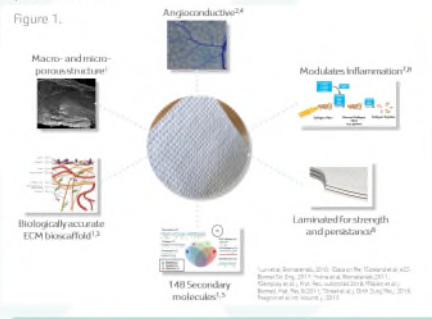


Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series

¹Abigail E. Chaffin, MD, FACS, CWSP, FAPWCA; ²Ariel M. Aballay, MD ³Gregory A. Bohn, MD; ⁴Paul M. Glat, MD; ⁵Micheal N. Desvigne, MD, FACS; ⁶Barnaby C. H. May, PhD

¹Department of Surgery, Tulane University School of Medicine, New Orleans, LA; ²Department of Surgery, West Penn Burn Center, Allegheny Health Network, Pittsburgh, PA; ³St Joseph Hospital, Tawas, IL; ⁴Drexel University College of Medicine, St. Christopher's Hospital for Children, Philadelphia, PA; ⁵Western Regional Medical Center, Scottsdale, AZ; ⁶Aroa Biosurgery Limited, New Zealand

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® Surface (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

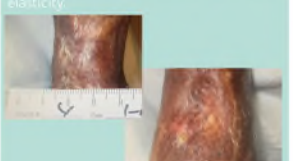
Patient: 3 y/o, ♀. Surgical dehiscence following orthopaedic implants. Exposed bone and tendon. Failed collagen/CS[†] graft.
Pre-op:



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



1 Week: granulation tissue budding. Debridement, STSG applied



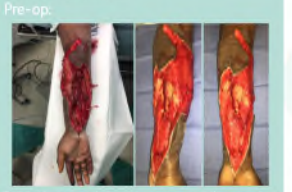
2 Week: 100% graft take



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: granulation tissue budding. Debridement, STSG applied



6 Week: fully granulated. 12/1000[†] STSG placed.



9 Week: 100% epithelialization

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.

Surgical Closure of Chronic Dehiscid Wound – Flap Stabilization and Topical

Patient: 26 yo, ♀. Nonhealing surgical wound following ORIF left ankle.
Pre-op:



Procedure: Surgical excision of the ulcer with partial osteotomy. Placement of OFM PRS 'Thick'.



Flap advancement to cover OFM PRS. Non-adherent and incisional NPWT.



1 Week: infection and dehiscence. OFM PRS applied the wound bed.



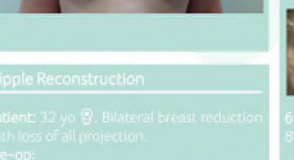
2 Week: OFM PRS applied, with non-adherent and antibacterial foam.

Nipple Reconstruction

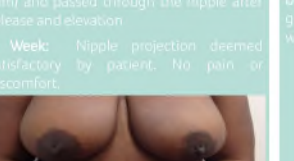
Patient: 56 yo, ♀. Previous (1 year) bilateral breast reconstruction.
Pre-op:



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.



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.

Tumor Resection

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.