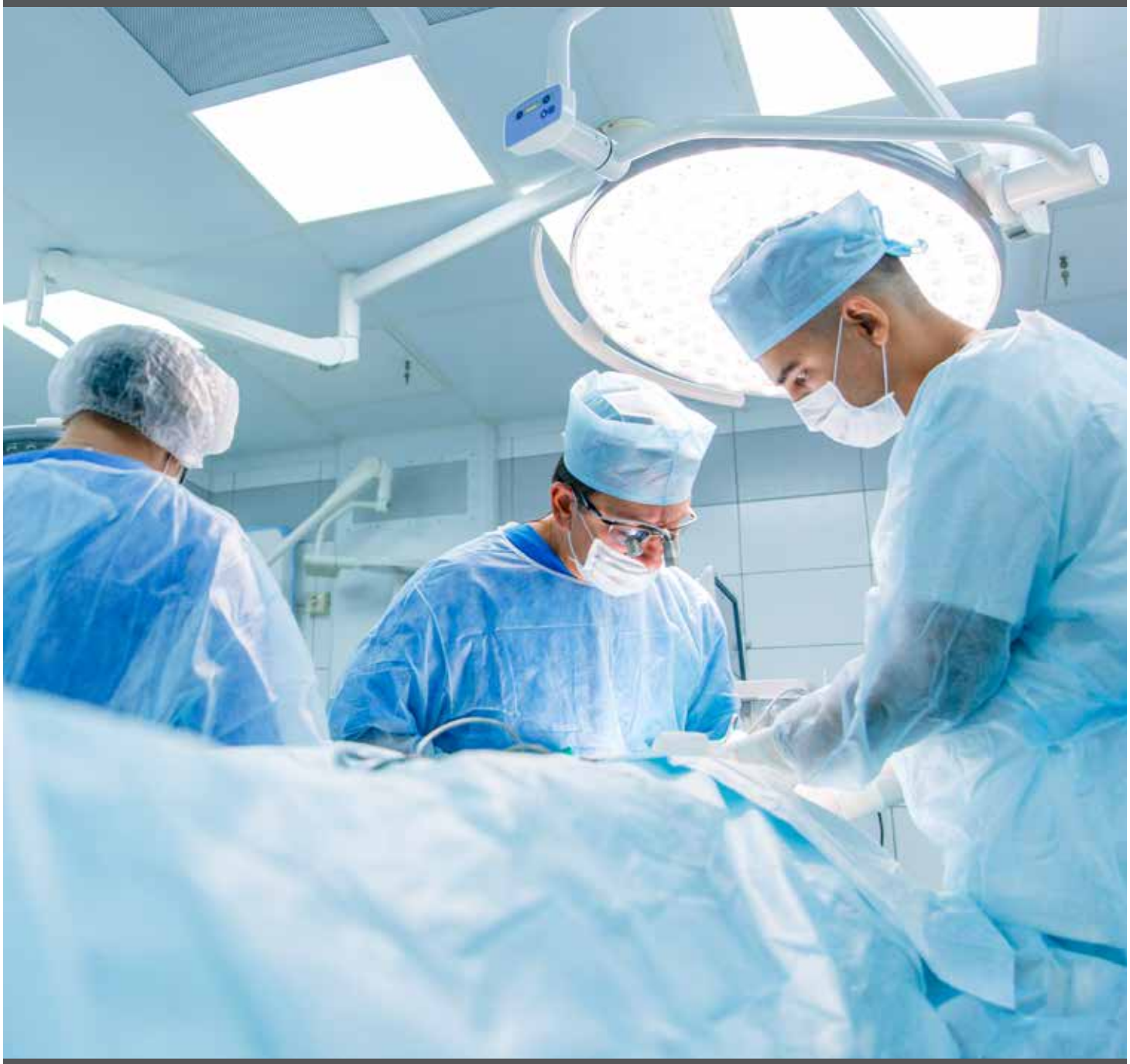
Myriad™

Soft Tissue Matrix

Application Notes and Clinical Evidence Guide 2019



Unlocking regenerative healing for every*body*

AROA

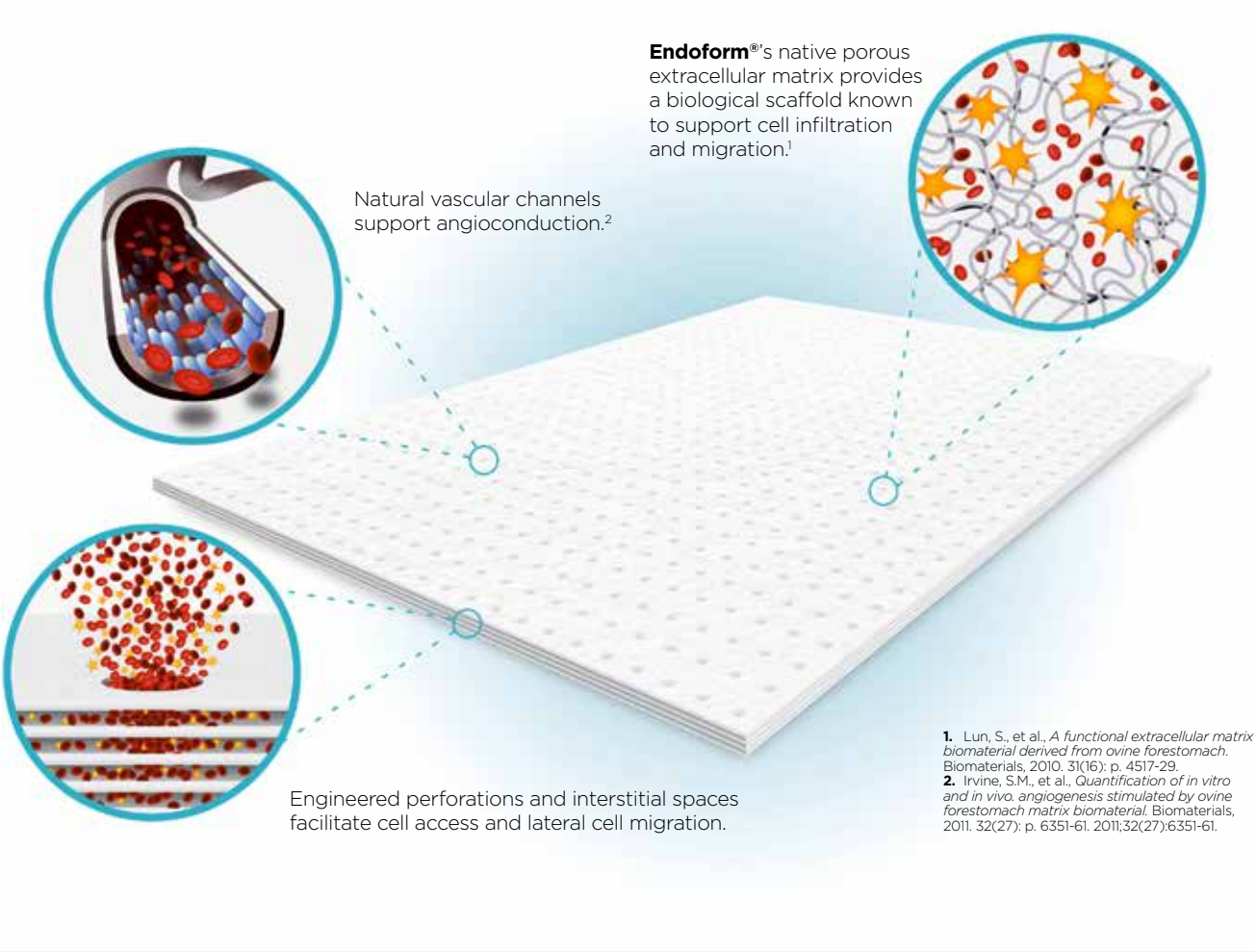
Myriad™

Contents

General Information

Myriad™

Engineered extracellular matrix for soft tissue repair, reinforcement and complex wounds.



1. Lun, S., et al., *A functional extracellular matrix biomaterial derived from ovine forestomach.* Biomaterials, 2010. 31(16): p. 4517-29.
2. Irvine, S.M., et al., *Quantification of in vitro and in vivo. angiogenesis stimulated by ovine forestomach matrix biomaterial.* Biomaterials, 2011. 32(27): p. 6351-61. 2011;32(27):6351-61.

- Natural structure and engineered architecture enables rapid cell access
- **Myriad**™ absorbs blood components and cells to facilitate the tissue building process
- Delivers biology known to support healing
- Delicate processing ensures native tissue structure, biological function and reduced inflammation
- Natural vascular channels facilitate angioconduction
- Versatile soft tissue matrix
- Designed to support surgical mastery
- **Endoform**® ECM – trusted technology in soft tissue repair
- Simplifies inventory management

Myriad™

Application Notes

Always read the **Myriad™ Instructions For Use**. Prescription use only. The following guidelines should not supersede professional or institutional guidelines. These guidelines have been developed based on good surgical technique and the experience of plastic and general surgeons using **Myriad™**. They are intended to be a quick reference to important information on the use of **Myriad™** and as a supplement to the device Instructions For Use and institutional protocols. For additional information contact your Sales Representative at **1-877-627-6224**, or **email customerservice@aroabio.com**

Primary Dressing

Once the **Myriad™** device is placed in the tissue deficit, and in order to protect the device during integration of the tissue and subsequent remodeling, consider using a non-adherent dressing (e.g. petrolatum impregnated or silicon) over **Myriad™**.

Moisture Retention and Management

Wound healing and soft tissue repair is improved in a moist environment. Always ensure **Myriad™** is fully rehydrated prior to use in either implant or dermal repair procedures. Where moisture retention is a potential concern, consider using an alginate-based dressing placed over the non-adherent dressing, or a hydrogel. Consider using **Hydrofera™ Blue Ready** or **Hydrofera™ Blue Ready Border** for antibacterial protection.

Tissue Contact

Once applied to the tissue deficit, **Myriad™** may be secured with light compression so as to ensure contact with the underlying tissues. Repair of deep dermal deficits, for example following tumor resections, may benefit from the use of a bolster dressing (e.g. cotton wool, gauze) (Figure 1) to ensure contact between **Myriad™** and the underlying tissues.

Figure 1.

Preparation of the Site

Do not apply **Myriad™** in the presence of uncontrolled clinical infection, acute inflammation, excessive exudate, or uncontrolled bleeding.

Ideally the tissue deficit will have healthy and well vascularized tissue to optimize the incorporation of **Myriad™**.

Where exposed calvarium is present and denuded of the vascularized periosteum, a bone burr may be used to expose the vascular diploe. **Myriad™** can then be placed on the bleeding calvarium.

Best success with exposed tendon will be seen where an intact vascularized peritenon is present.

Application Notes

Placement and Integration

Myriad™ will absorb blood and blood components once placed in contact with the tissue deficit (Figure 2).

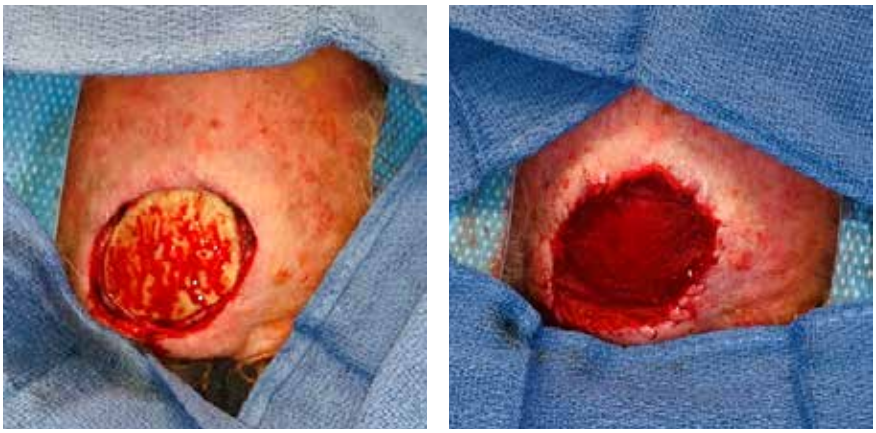


Figure 2.

The rate of incorporation of cells into **Myriad™** will be dependent on the patient and site of the tissue deficit. Typically, granulation tissue will bud through the device in 7-14 days (Figure 3).

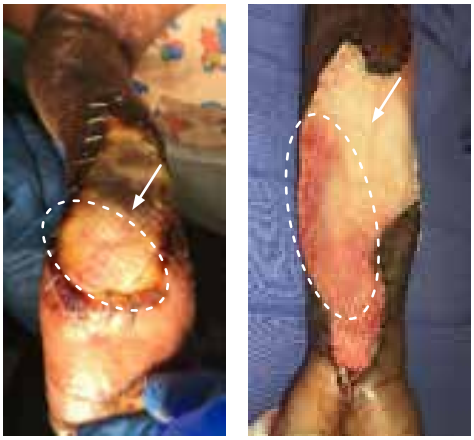


Figure 3.

Over time the extent of granulation tissue will increase as **Myriad™** becomes fully integrated. During dressing changes, the surface of **Myriad™** may be gently debrided to remove any non-adherent material. However, care should be taken not to remove any areas that have yet to be incorporated, as identified by a white-cream appearance (Figure 4)(arrow).

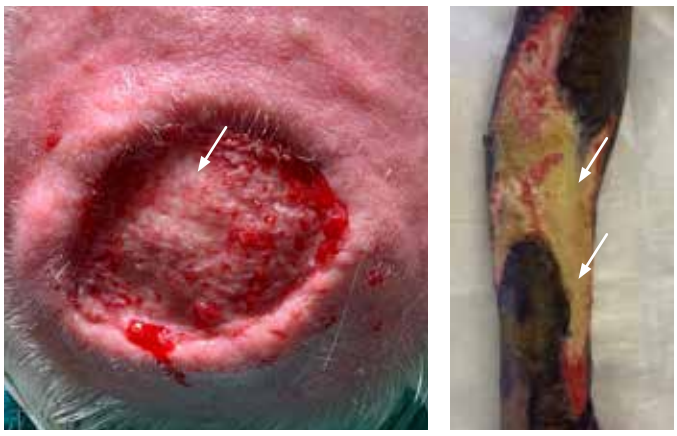


Figure 4.

Myriad™

Clinical Evidence

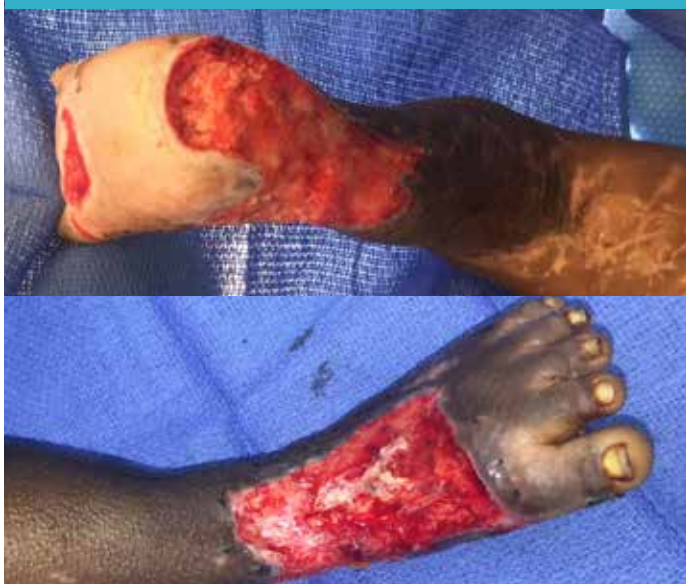
Case Study 1: Surgical Site Dehiscence Following Orthopedic Implants

Type: Exposed bone/tendon
Mechanism of Injury: Surgical site dehiscence
Patient: Female, 3 year old

Case Description:
Three year old female with multiple pterygium syndrome had undergone orthopedic procedure resulting in surgical dehiscence at the implant site. The resulting full thickness deficit, with exposed bone and tendon, had become infected.

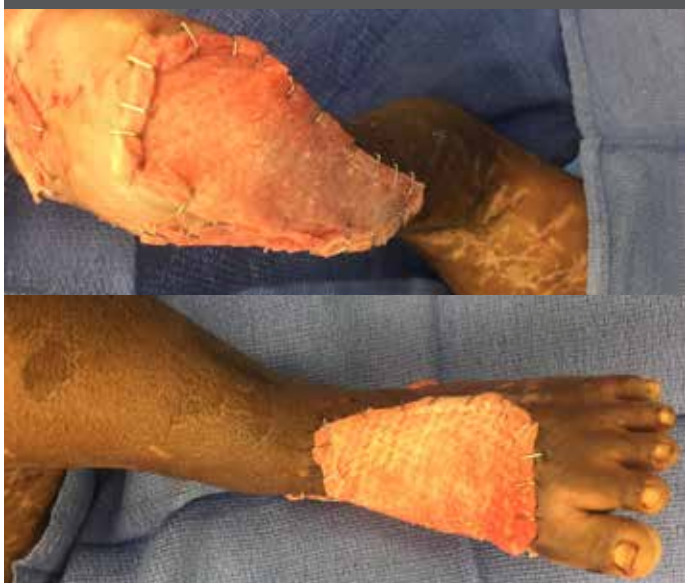
The underlying infection had been addressed and previous surgical interventions had unsuccessfully utilized a bilayer wound matrix in order to rebuild the soft tissue.

Case Study 1



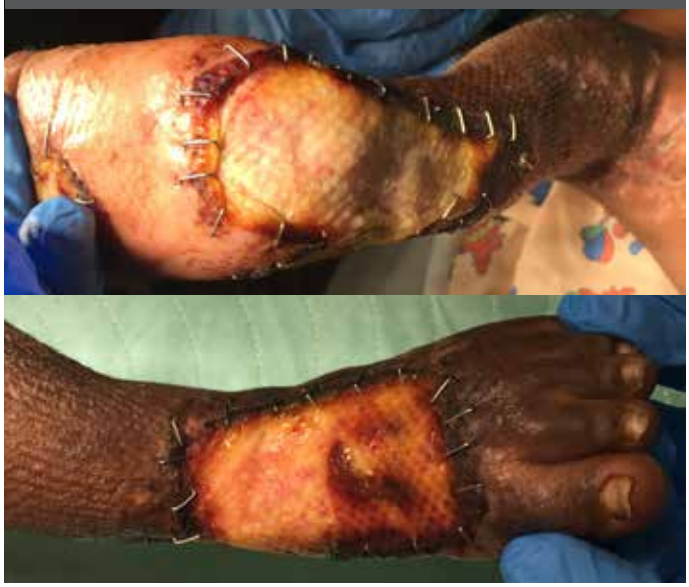
Abigail E. Chaffin, MD, FACS, CWSP, FAPWCA
Associate Professor of Surgery, Program Director, Medical Director – Tulane University / Ochsrer Clinic Plastic Surgery Residency Program. Chaffin, A. E., A. M. Aballay, G. A. Bohn, P. M. Glat, M. N. Desvigne and B. C. H. May (2019). Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series. 41st Annual Boswick Burn & Wound Symposium, Wailea Beach, Maui, HI.

Procedure



Soft tissue deficit was debrided. **Myriad™** 'Thick' placed and stapled to the wound margins. Covered with a non-adherent and a silver alginate dressing to retain moisture. Padding wrap and splint were used to immobilize the site.

Week 1



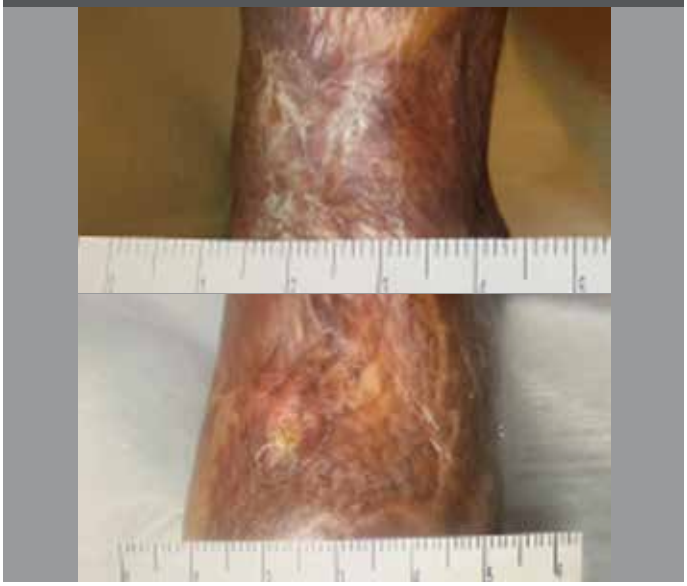
Granulation tissue was seen budding through the device as **Myriad™** became incorporated into the tissue deficit. Residual **Myriad™** was gently debrided from the granulation bed, then a split thickness skin graft placed.

Clinical Evidence

Week 2

100% Graft take one week post split thickness grafting.

3 Month Long-term Followup



Fully epithelialized, and the repaired tissue had good elasticity. There was equivalent range of movement to pre-operative status.

Myriad™

Clinical Evidence

Case Study 2: Complex Forearm Reconstruction With Negative Pressure Wound Therapy (NPWT)

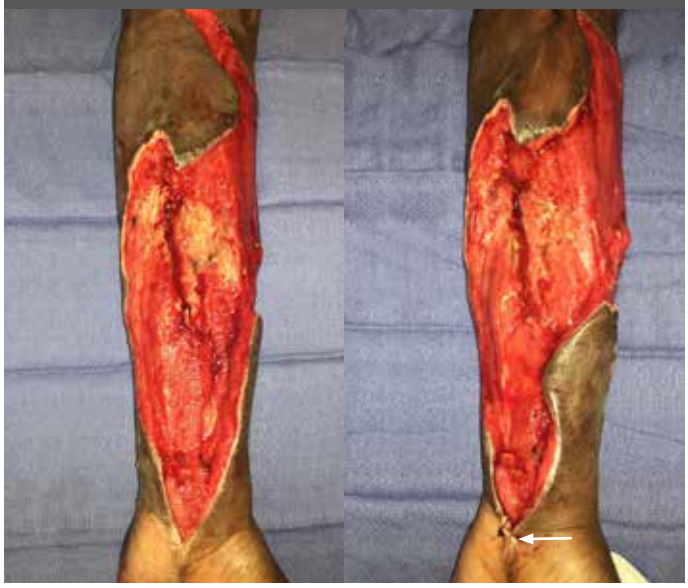
Type: Exposed vital structures
Mechanism of Injury: Compression injury
Patient: Female, 25 year old

Case Description:
Twenty-five year old with uncontrolled diabetes sustained compression injury to the forearm with diabetic ketoacidosis. On admission, the patient underwent fasciotomies and multiple necrotic muscle and soft tissue debridements resulting in very thin coverage of the radial and ulnar arteries.

Case Study 2

Abigail E. Chaffin, MD, FACS, CWSP, FAPWCA
Associate Professor of Surgery, Program Director, Medical Director – Tulane University / Ochsrer Clinic Plastic Surgery Residency Program. Chaffin, A. E., A. M. Aballay, G. A. Bohn, P. M. Glat, M. N. Desvigne and B. C. H. May (2019). Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series. 41st Annual Boswick Burn & Wound Symposium, Wailea Beach, Maui, HI.

Procedure



Sharp debridement and a partial complex closure at the antecubital fossa and wrist (arrow).

Procedure

Myriad™ 'Thick' trimmed to size and seamed together using 4-0 chromic catgut to fit the irregular deficit. Perimeter was stapled to the skin edges. **Myriad™** was covered with a non-adherent dressing, then a layer of NPWT sponge. Lower pressure (75 mmHg continuous) used due to the exposed radial and ulnar artery.

Clinical Evidence

Week 1

Granulation tissue was visible budding through the **Myriad™**. Continued with NPWT with twice weekly dressing changes.

Week 2

New islands of granulation tissue appeared throughout the **Myriad™** as integration continued. Hydrogel applied to assist with moisture retention, non-adherent dressing applied, then NPWT continued.

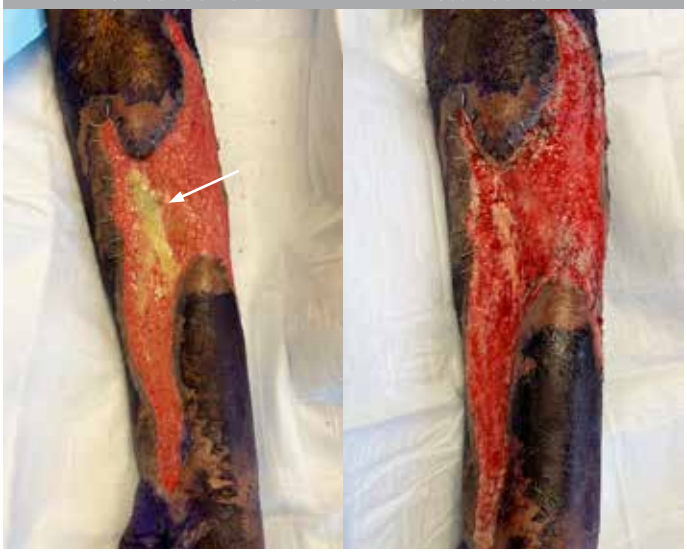
Week 3

Pre Debridement | Post Debridement

Abundance of granulation tissue forming in the deficit. Light curette debridement, then a silver nonadherent contact layer placed over the graft followed by elastic bandage wraps. Silver alginate dressing applied to the hand and finger. Hypergranulation tissue at the wound edges was treated with silver nitrate. Overall a significant improvement in the deficit with the neodermis thickening.

Week 4

Pre Debridement | Post Debridement



A small amount of **Myriad™** was remaining over the mid volar forearm (arrow), covering the radial and ulnar vessels. Insufficient granulation tissue over the arteries to enable split thickness skin grafting in this area. Curette debridement and the dressing regime continued.

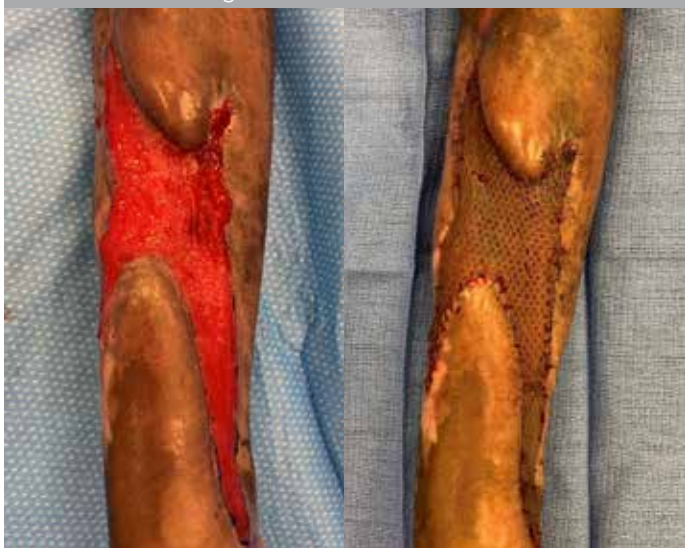
Continued

Myriad™

Clinical Evidence

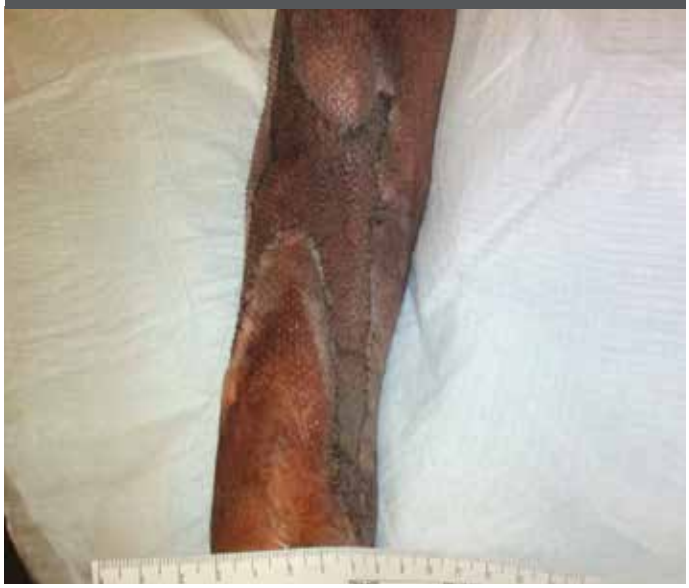
Week 6

Pre Grafting | Graft Placed



Robust granulation bed had formed enabling placement of a split thickness skin graft.

Week 7



One week following placement of the split thickness skin graft and 100% graft take.

Clinical Evidence

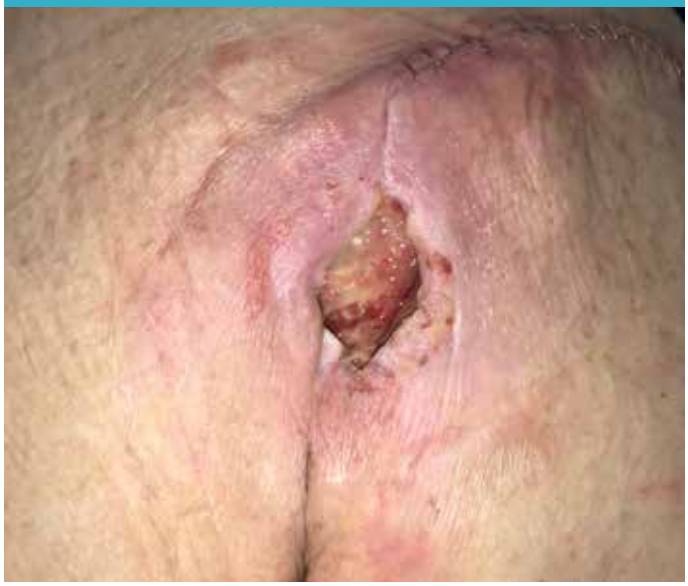
Case Study 3: Surgical Closure Of Chronic Wound

Type: Non-healing pressure ulcer
Mechanism of Injury: Pressure ulcer
Patient: Female, 73 year old

Case Description:
73 Year old female non-ambulatory with a pressure ulcer secondary to Parkinson's disease. Patient had undergone initial surgical excision and flap advancement that had subsequently dehisced.

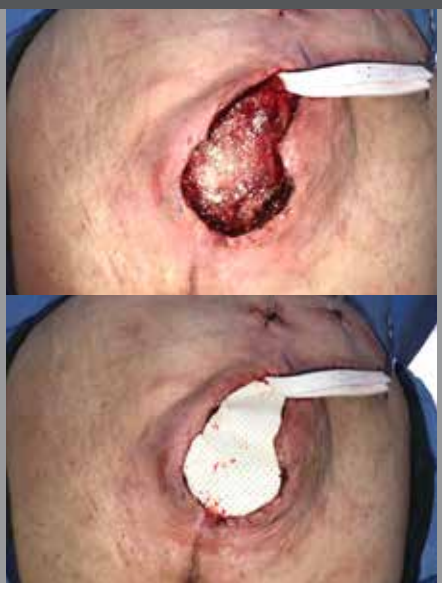
Due to the quality of the underlying tissue, **Myriad™** was implanted to stabilize the sub-cutaneous tissue, prior to a flap advancement and closure.

Case Study 3



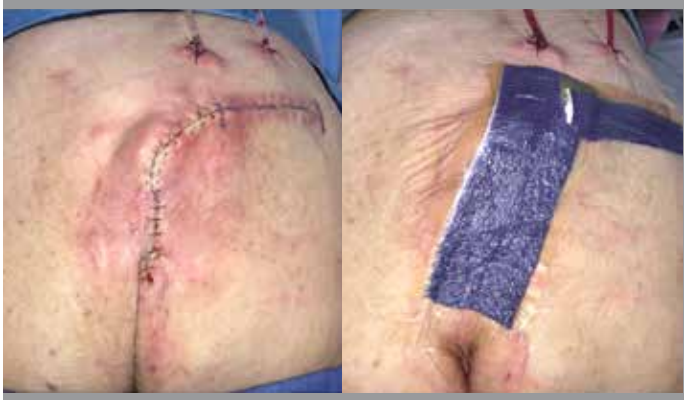
Michael N. Desvigne, MD, FACS, CWS, FACCWS
Valley Wound Care Specialists, Arrowhead Hospital, Glendale, Arizona. Chaffin, A. E., A. M. Aballay, G. A. Bohn, P. M. Glat, M. N. Desvigne and B. C. H. May (2019). Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series. 41st Annual Boswick Burn & Wound Symposium, Wailea Beach, Maui, HI.

Procedure



Surgical excision of the ulcer with partial ostectomy (top). **Myriad™** 'Thick' cut to shape then placed into the deficit (bottom).

Procedure



Flap advancement to cover the **Myriad™** and close (left). Incisional NPWT placed over the incision (right).

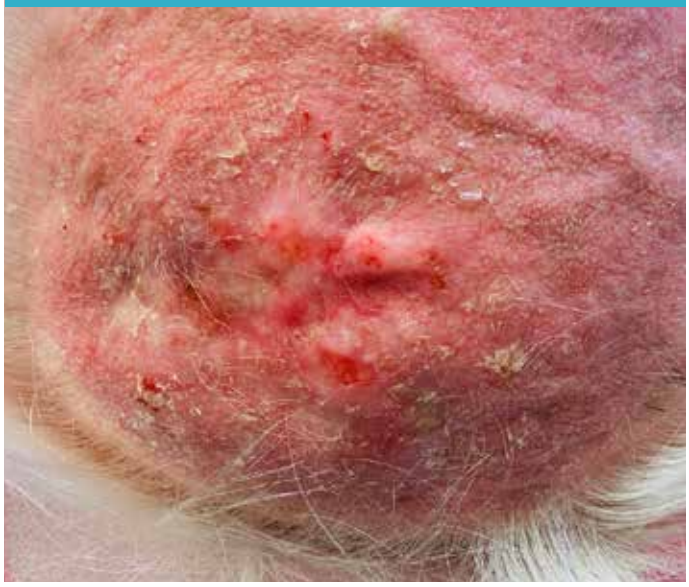
Clinical Evidence

Case Study 4:
Scalp Resection - Non-healing Wound

Type: Non-healing wound
Mechanism of Injury: Previous scalp tumors
Patient: Male, 85 year old

Case Description:
85 Year old male with numerous previous scalp tumors. A non-healing wound had been present on the scalp vertex for approximately 2 years after excision of a squamous cell carcinoma via Moh's. Several applications of amnion had been unsuccessful. MRI showed outer table calvarial osteomyelitis. Patient had history of MRSA and *Staphylococcus Lugedensis* osteomyelitis.

Case Study 4



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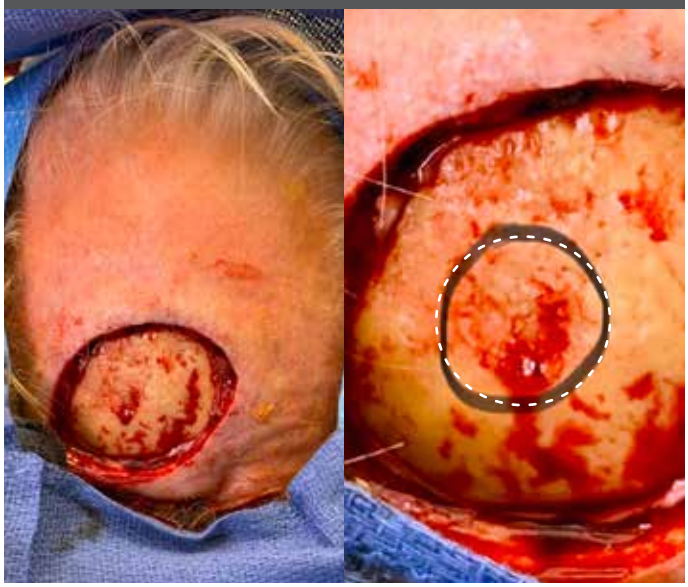
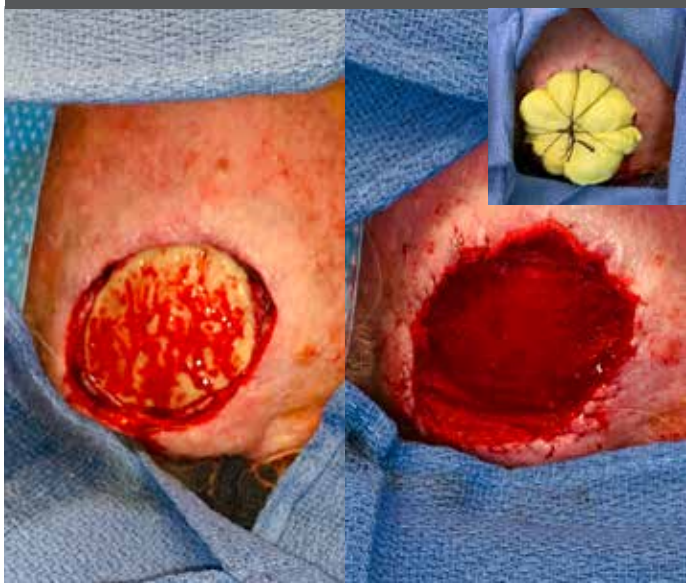
Procedure



Excised the abnormal scalp region to expose an area of irregular central calvarial bone consistent with osteomyelitis (dotted line). Both soft and hard tissues were sent for culture and pathology. Debrided the outer calvarial table with a pineapple burr to achieve punctate bleeding. Total deficit was 7x6.5cm, with no intact calvarium.

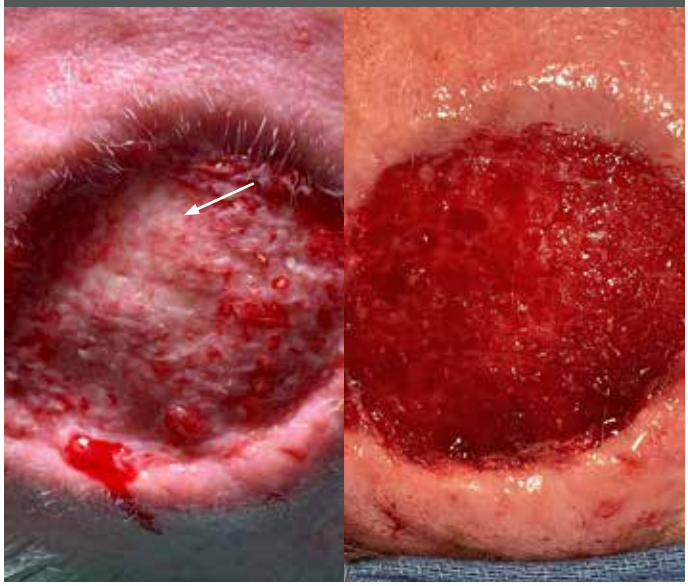
Procedure



Placed **Myriad™** 'Thin', and sutured to the wound margins with 4-0 chromic suture. Applied a nonadherent dressing, mineral oil and a cotton ball bolster, secured with silk sutures to apply compression (right insert).

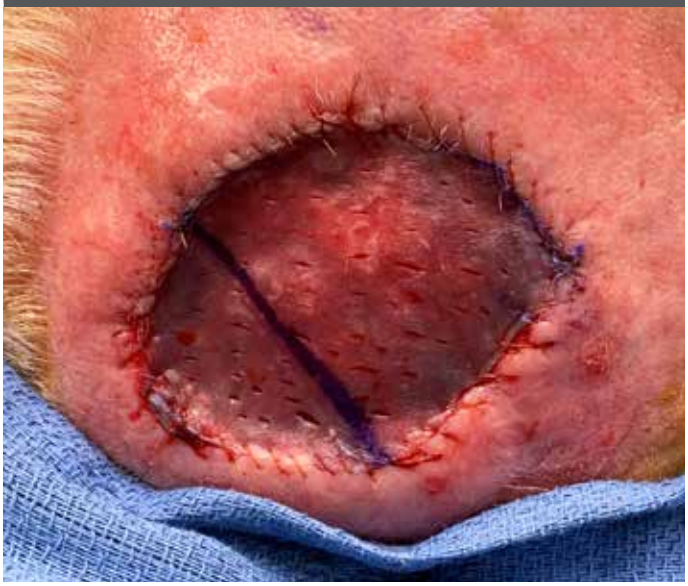
Clinical Evidence

Week 2



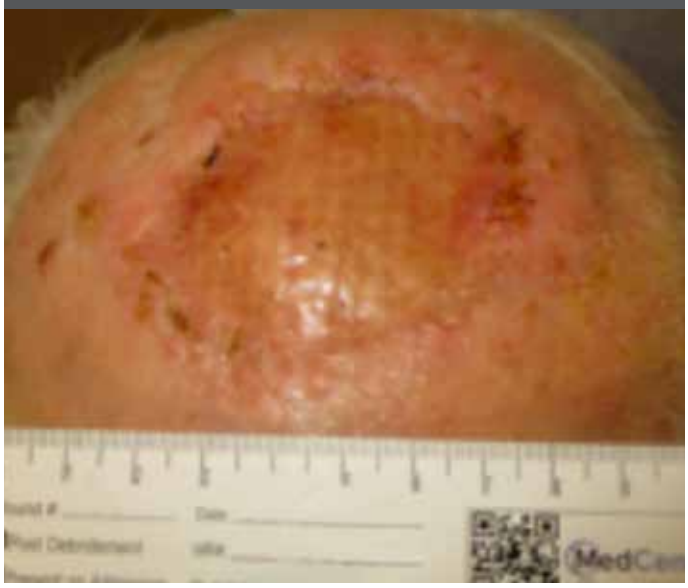
The outer layer of **Myriad™** (arrow) was gently debrided to reveal that the deeper inner layers of **Myriad™** were fully integrated and granulated.

Week 4



Split thickness skin graft placed.

Week 7



100% Graft take and fully epithelialized 3 weeks post split thickness grafting and 7 weeks post **Myriad™** placement.

Myriad™

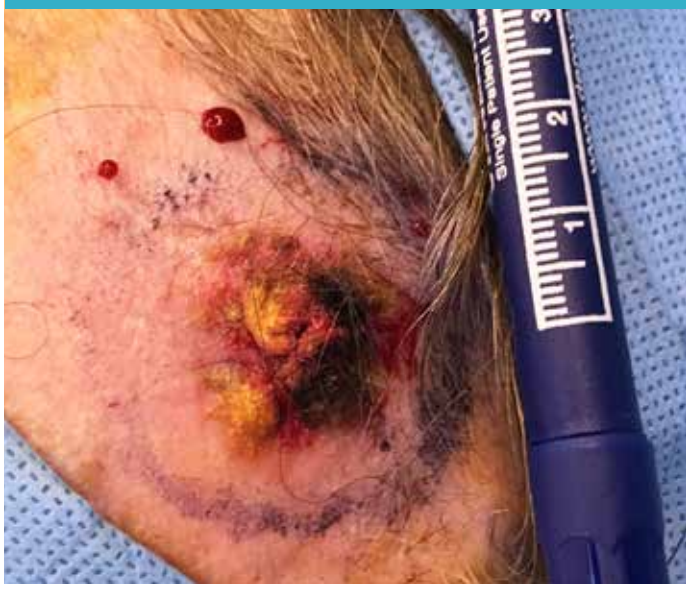
Clinical Evidence

Case Study 5:
Scalp Tumour Resection

Type: Exposed bone
Mechanism of Injury: Squamous cell carcinoma
Patient: Female, 98 year old

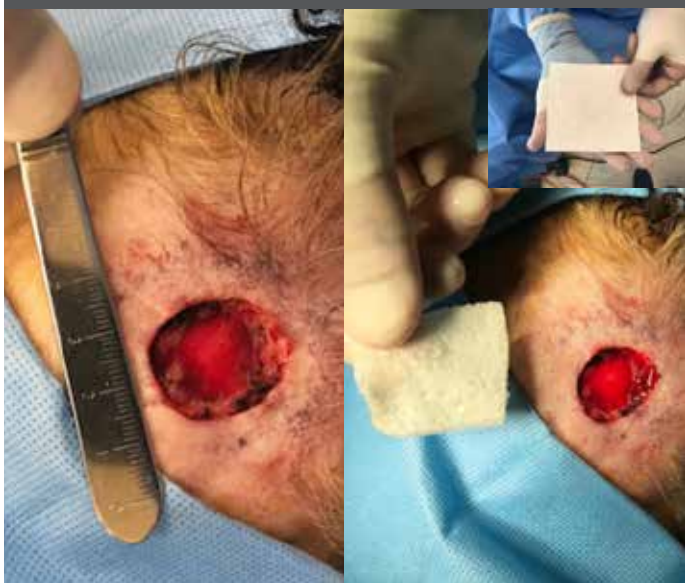
Case Description:
98 Year old female with a squamous cell carcinoma in-situ (Bowens Disease) at the forehead, measuring approximately 1.5 x 1.5 cm.

Case Study 5



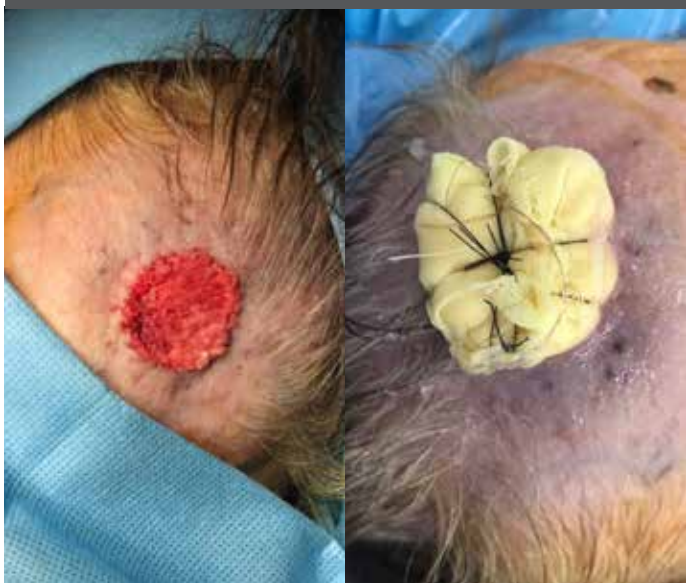
Gregory Bohn, MD
St. Joseph Hospital, Tawas, Michigan, 295 Maple St STE 200 Tawas City, Michigan 48763-9352. Chaffin, A. E., A. M. Aballay, G. A. Bohn, P. M. Glat, M. N. Desvigne and B. C. H. May (2019). Multi-Centre Clinical Evaluation of a Cell Conductive Extracellular Matrix Surgical Mesh in Plastics and Reconstructive Surgery – A Case Series. 41st Annual Boswick Burn & Wound Symposium, Wailea Beach, Maui, HI.

Procedure



Full thickness scalp resection down to periosteum leaving a deficit of 2.1 cm x 2.7 cm.

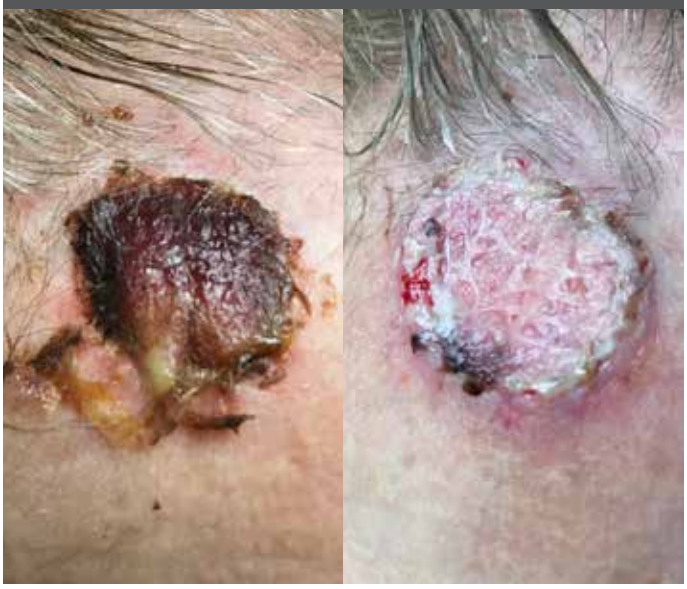
Procedure



Myriad™ 'Thick' cut to size, rehydrated and placed in the deficit and sutured to the peripheral tissue (left). Covered with a bolster dressing to provide compression (right).

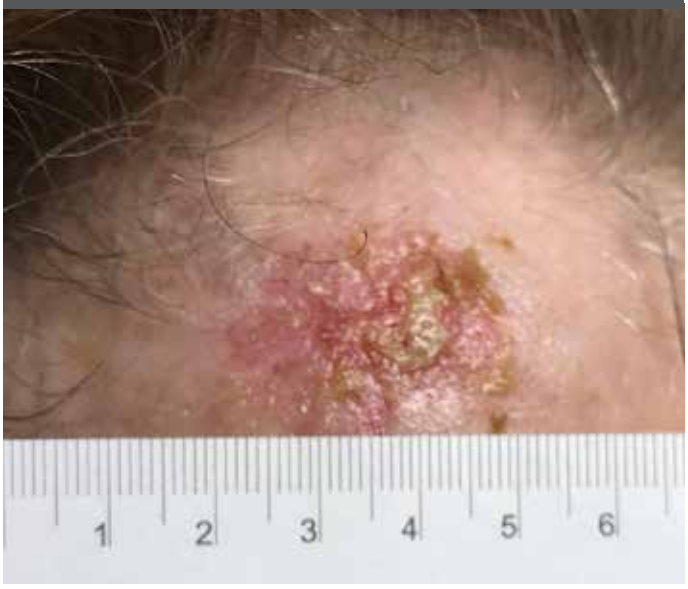
Clinical Evidence

Week 2



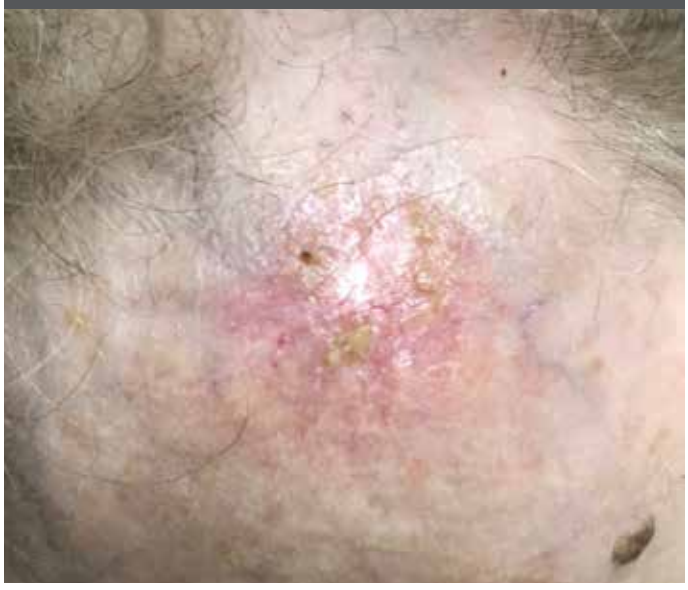
Bolster dressing removed and the area was gently irrigated with saline. **Myriad™** was visible and clearly integrated and vascularizing.

Week 6



The area was completely filled with well vascularized tissue and approximately 80 % epithelialized.

Week 8



The deficit was completely healed, maturing, and did not require further treatment.

Myriad™

Soft Tissue Matrix

Simplifies inventory management

- **Dermal repair**
- **Implantable soft tissue repair**
- **Complex wounds**
- **Impaired healing**
- **Cost savings**
- **Long shelf life**
- **No specialized storage requirements**
- **Flexible SKU range**
- **Terminally sterilized**
- **Reduced viral and TSE transmission risk**
- **Wide cultural and religious acceptance**
- **No human tissue tracking requirements**
- **Less than 5 minutes preparation time**

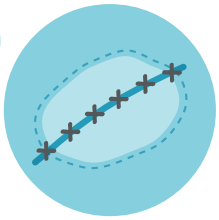
Ordering information

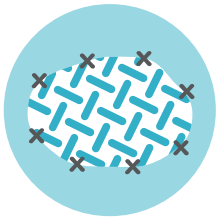
Myriad™ – Thin (~1.0 mm)		
Stock no.	**Product Size (L x W)**	**Quantity/Box**
SR03LG0505US	5 x 5 cm	1
SR03LG1010US	10 x 10 cm	1
SR03LG1020US	10 x 20 cm	1
Myriad™ – Thick (~1.5 mm)		
Stock no.	**Product Size (L x W)**	**Quantity/Box**
SR05LG0505US	5 x 5 cm	1
SR05LG1010US	10 x 10 cm	1
SR05LG1020US	10 x 20 cm	1

Usage:

Read the entire **Instructions for Use** supplied with the product.

Implantation





Dermal Repair

RX Only.

For product questions, sampling needs, or detailed clinical questions concerning our products in the US, please call 1-877-627-6224 or email customerservice@aroabio.com

AROA

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