Clinical Effectiveness of Ovine Forestomach Matrix Graft in Complex Lower Limb Reconstruction and Limb Salvage

[1]M. Mark Melin (MD, FACS, RPVI, FACCWS); [2]Richard Kaufman (DPM, CWSP); [3]James E. Geiger, Jr. (DPM, CWSP); [4]Igor Zilberman (DPM); [4]Nooshin Zolfaghari (DPM, CWSP); [5]Howie Que (DPM); [5]James Longobardi (DPM); [6]William Dutch, Jr (DPM); [7]Joseph Skurka (DPM); [8]Brandon Bosque (DPM, CWSP); [8]Shane Dowling (MS-PAS, CWS), [8]Barnaby C. H. May (PhD)

INTRODUCTION

Chronic lower extremity defects may lead to major amputations and have severe consequences on patient quality of life, and ultimately, mortality[1]. There are several pathways to surgical closure of these defects with robust coverage of any exposed vital structures (i.e. bone, tendon, arteries) or volumetric fill often being the initial goal. Ovine forestomach matrix scaffold (OFM) technology has been developed as a robust planar sheet or particulate form which can be utilized in volumetric, contaminated wounds to rapidly build tissue and provide cover to exposed structures with viable granulation, ultimately shortening the time to definitive closure. The OFM graft format is indicated for dermal regeneration and implant procedures.

METHODS

A total of 50 case records were evaluated (n=50) across seven (7) healthcare centers across the United States. Case records were reviewed to identify; patient co-morbidities, defect etiology (e.g. NSTI, DFU, burn, etc.), defect size, presence of exposed structures, CDC contamination score, Wagner score, OFM graft usage, time to 100% granulation tissue, STSG usage, overall time to heal and any post-operative complications. Patient demographics, baseline wound characteristics and healing outcomes were analyzed with descriptive statistics.

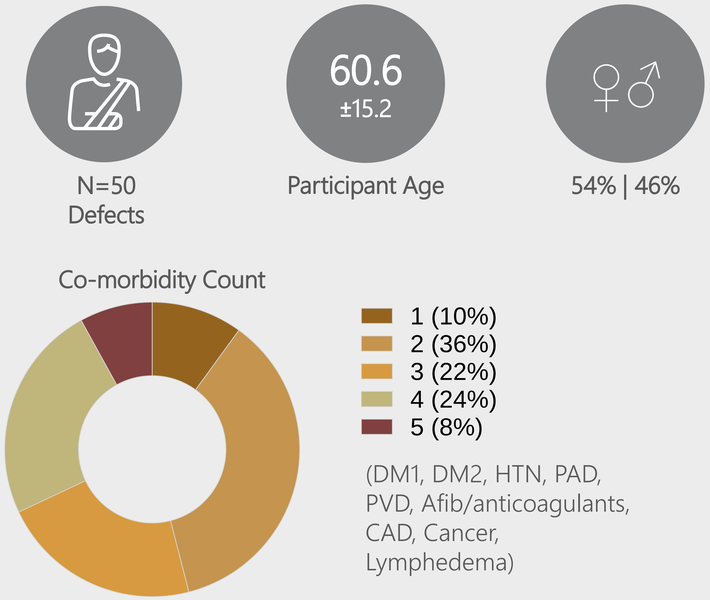
REFERENCES AND DISCLOSURES

ϕMyriad Matrix™ and Myriad Morcells™ (Aroa Biosurgery Limited, New Zealand). [1] Meshkin DH, Zolper EG, Chang K, Bryant M, Bekeny JC, Evans KK, Attinger CE, Fan KL. Long-term Mortality After Nontraumatic Major Lower Extremity Amputation: A Systematic Review and Meta-analysis. J Foot Ankle Surg. 2021 May-Jun;60(3):567-576. . [2]. Flood, M. S., B. Weeks, K. O. Anaeme, H. Aguirre, K. B. Hobizal, S. E. Jiongco, R. J. Klein, A. Lemoi, R. Rafols and A. S. Landsman (2020). "Treatment of Deep Full-thickness Wounds Containing Exposed Muscle, Tendon, and/or Bone Using a Bioactive Human Skin Allograft: A Large Cohort Case Series." Wounds 32(6): 164-173.

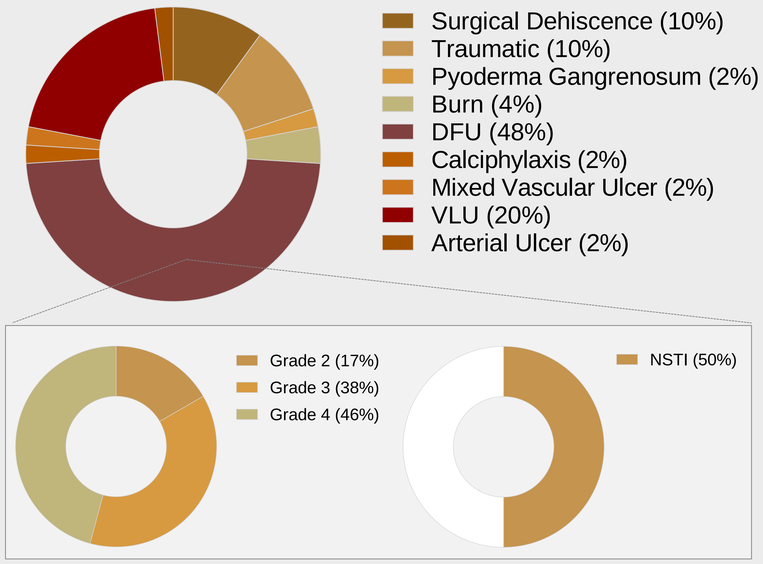
AFFILIATIONS

[1]M Health- Fairview, Edina, MN, USA; [2]Piedmont Atlanta Hospital, Atlanta, GA, USA; [3]Northwestern Medicine , Palos Health, Palos Heights, IL, [4]South Florida Lower Extremity Center, Davie, FL, USA [5]Sharp Chula Vista Medical Center, San Diego, CA, USA ; [6]CNY Foot Surgery, East Syracuse, NY USA ; [7]Ephraim McDowell Regional Medical Center, Danville, KY USA [8]Aroa Biosurgery Limited, Auckland, New Zealand

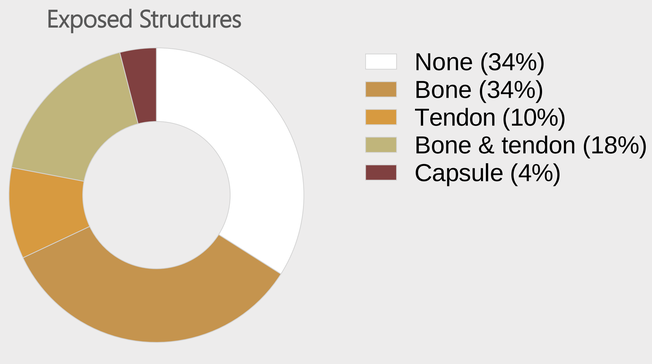
Study Participants



Defect Type



Defect Baseline



84.2 ±106.0 — Mean Defect Area (cm2)

60.0 ±152.5 — Defect Age (weeks)

54% — Confirmed Osteomyelitis

100% — CDC Grade IV

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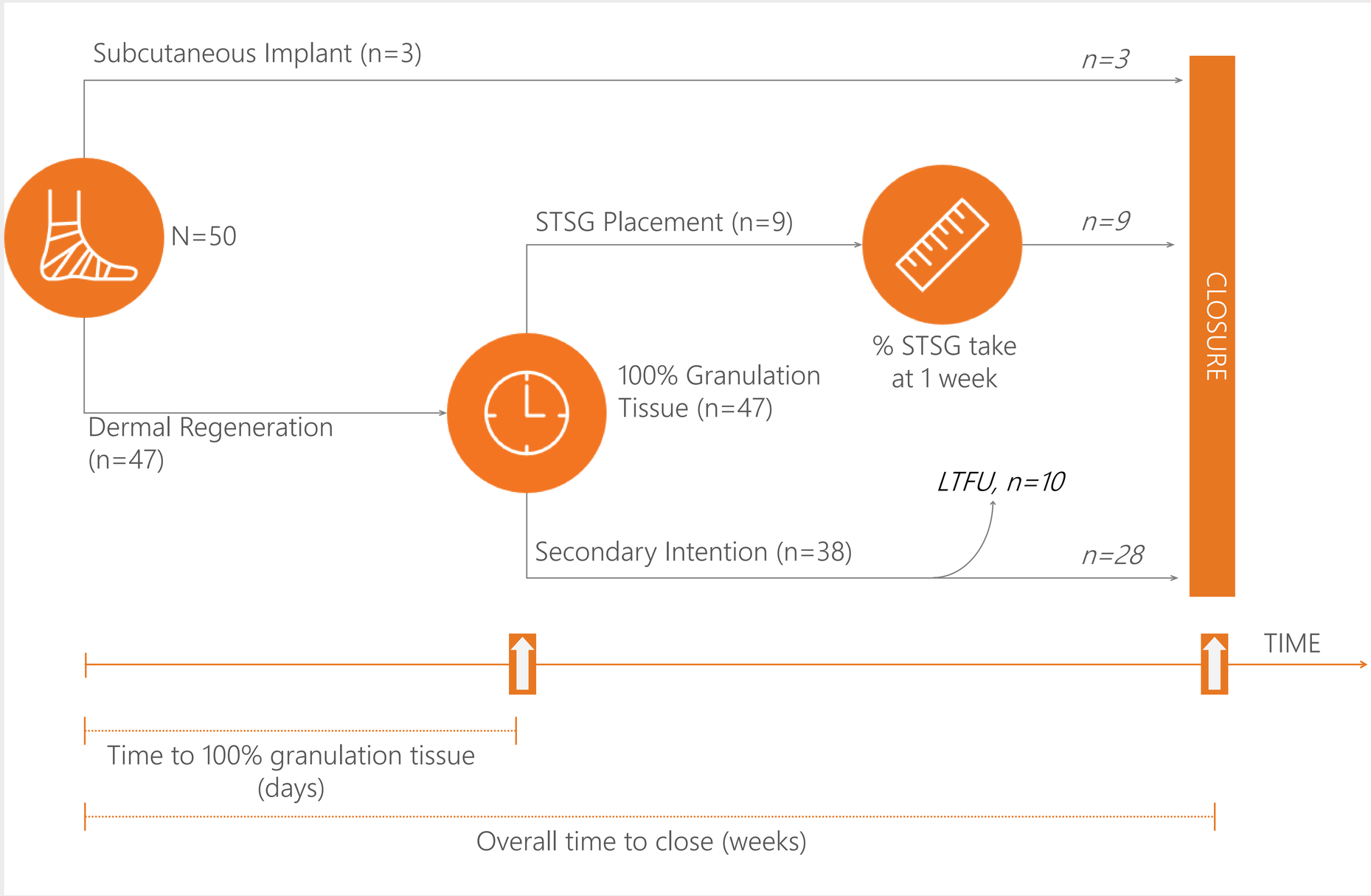
SURGICAL PATHWAY AND STUDY MEASURES



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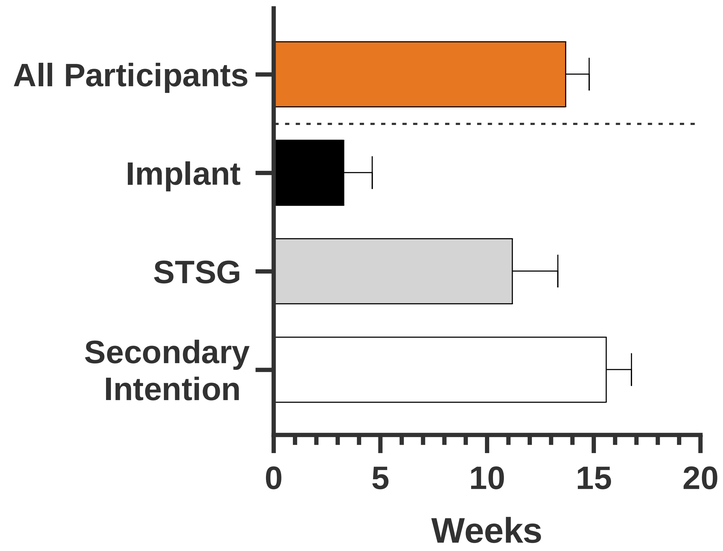
STUDY OUTCOMES

26.0
±22.2
Days

Mean Time to 100% Granulation Tissue



Mean Overall Time to Close (weeks)

1.0
±0.1

Mean OFM Applications

74.6%
±18.0%

Mean % STSG Take – 1 Week

36%

NPWT Usage

4.2
±2.5

Mean NPWT Usage (weeks)

0

Complications

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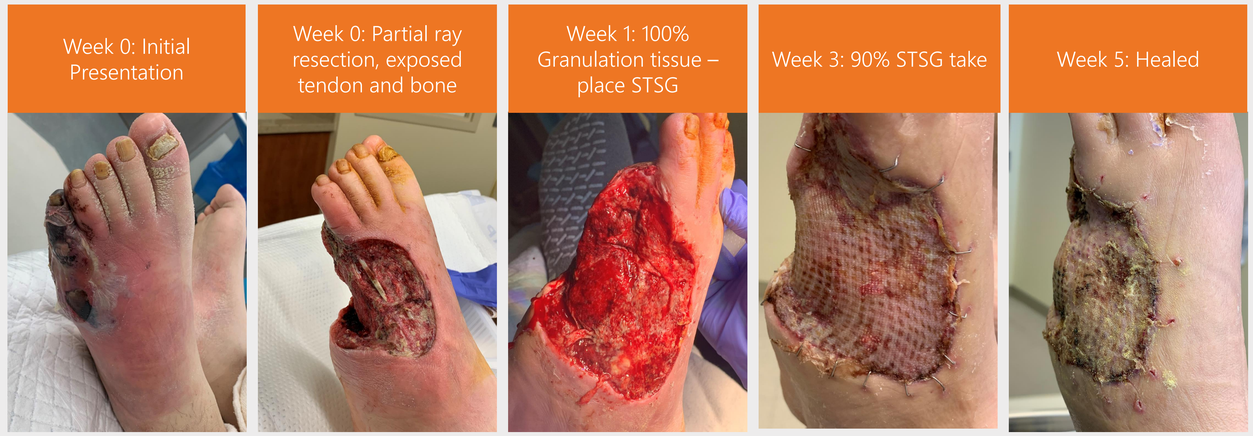
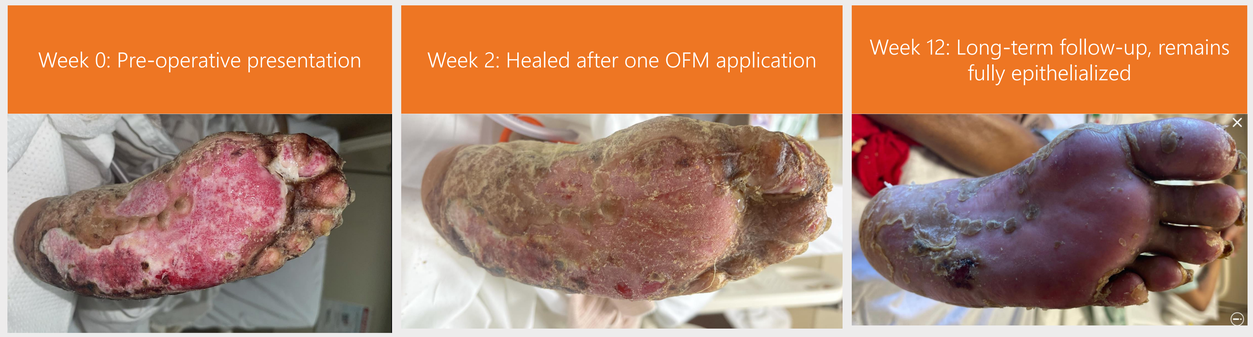
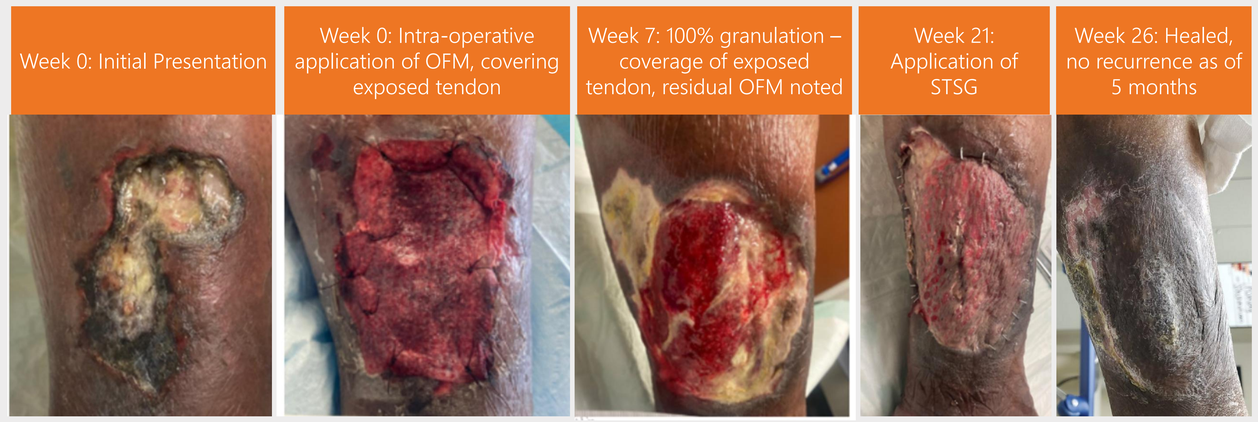
Example Case #1: Staged procedure with STSG. 28-year-old male diabetic - Wagner 4, necrotizing infection.



Example Case #2: Dermal regeneration. 39-year-old female diabetic - deep partial-thickness burn.



Example Case #3: Dermal regeneration. 62-year-old female diabetic, PAD - Pyoderma Gangrenosum.



CONCLUSIONS

- OFM graft was effective soft tissue regeneration of lower extremity defects in complex patients
- Tolerates a contaminated field – no reported infections
- Single application was effective in filling volumetric defects and covering exposed structures.
- No complications observed.