Long-term Follow-up in Restoring Soft Tissue Deficits with A Novel Human Adipose Allograft Matrix* Matthew Regulski, DPM FFPM RCPS (Glasgow) Wound Care Institute of Ocean County

INTRODUCTION

Lower extremity wounds affect up to 13% of the population with increasing prevalence due to factors such as smoking, diabetes, and hypertension.[1] Unfortunately, after the wound is healed, re-ulceration is common, with approximately 40% recurrent ulcers within 1 year. [2] A novel adipose allograft matrix (AAM) can help support endogenous fat pad restoration and its natural cushioning ability over high pressure points and/or bony prominence. [2] This case study presents three long-term cases treated with AAM that did not re-ulcer, which has allowed patients to continue with their daily activities.

METHODS

We present 3 cases with underlying co-morbidities and soft tissue deficits on the lower extremities. All the patients had gone through previous treatments such as debridement and rotational flap closure without any resolution. AAM was injected subcutaneously in all 3 cases to fill in soft tissue defects and provide a cushion support to the wound bed. Patients were fitted for custom molded diabetic shoes and monitored post-treatment.

RESULTS

All 3 patients did not re-ulcer after AAM application, with long-term follow-up so far at 1 year 9 months up to 3 years. No adverse events were observed throughout this study. Routine monitoring of the patients, inspection of their feet and overall wound management was diligently continued.

CONCLUSION

These cases demonstrate that AAM can support the fat pad and cushioning ability in soft tissue defects and some re-ulceration prevention long-term. This ultimately allows patients to continue their daily activities.

REFERENCES

- [1] Star, Ava. "Differentiating lower extremity wounds: arterial, venous, neurotrophic." Seminars in Interventional Radiology. Vol. 35. No. 05. Thieme Medical Publishers, 2018.
- [2] Shahin TB, et al. Tissue Augmentation with Allograft Adipose Matrix For the Diabetic Foot in Remission. Plast Reconstr Surg Glob Open. 2017. Oct 23;5 (10):e1555.

*Leneva® (MTF Biologics, Edison, NJ)

CASE 1

60 year old male with history of neuropathy

Initial Examination/Wound History: Patient presented with diabetic ulcer at met 5. Wound was present for 6 weeks prior to clinical evaluation. Previous treatment included Blastx, Collagen, Drawtex, CAM walking boot. Treatment: 3cc AAM injected to fill in soft tissue defect and provide protective padding. Offloaded in CAM walking

Outcome: One injection of AAM was used to support soft tissue deficit over met 5. Wound closed in 2 weeks and offloading was continued. Wound remained closed at 1 year 9 months later.







(1 year 5 months later)

CASE 2

52 year old diabetic male with history of cardiovascular disease, myocardial infarction, long history of recurrent diabetic foot ulcers & left foot TMA

Initial Examination/Wound History: Patient presented with Wagner grade 1 right 5th ray ulcer that had been open for 4 weeks from rubbing in his shoe. Wound measured 1cm x 1cm x 0.2cm. Previous treatment included sharp debridement, biofilm gel, & bordered foam.

Patient was scheduled for surgery for wound excision and surgical reconstruction of digital deformity. Treatment: 3cc injection of AAM to peri-wound subcutaneous tissue to fill in soft tissue defect and provide pro-

tective padding. Wound was covered with biofilm gel and a bordered foam. Patient was fitted for a custom molded diabetic shoe.

Outcome: One injection of AAM was used. Wound healed in 6 weeks and remained healed at 3.5 months post treatment. Patient didn't require surgery and was able to return to work as a construction worker.





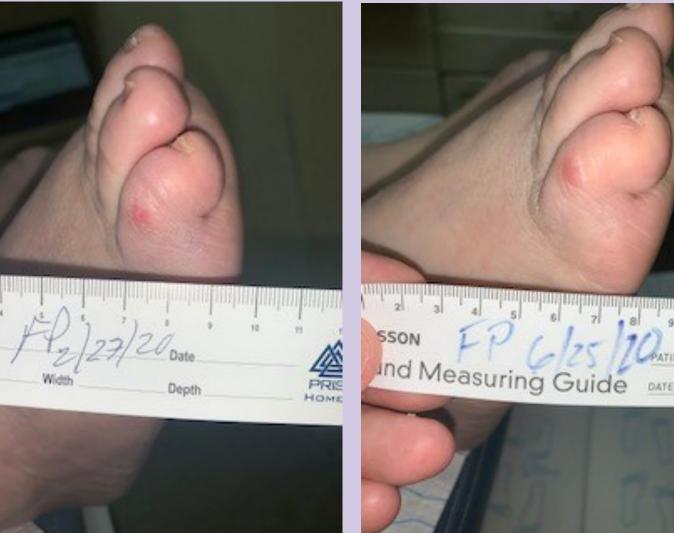




Figure 2A: 05/07/19 (Day 0)

Figure 2B: 06/13/19 (Day 41) - Wound

Figure 2C: 02/20/20 (Day 23)

Figure 2D: 06/25/20

Figure 2E: 06/07/22 (3 years later) - Wound re-

CASE 3

60 year old male with history of progressive neuropathy of unknown etiology

Initial Examination/Wound History: Previous history included multiple open wounds as a result of progressive neuropathy. Patient has undergone past wound excision with surgical reconstruction and a rotational flap for wound closure. The patient presented with pre-ulcerative callous formation and because of operative history is at continual risk of tissue breakdown.

Treatment: Injection of 5cc AAM to fill in soft tissue defect and provided protective padding. CAM walker was used for off loading after the injection. Patient was fitted for a custom molded diabetic shoe.



Figure 3A: 06/18/19 (Day 0) - Injection of



Figure 3B: 07/02/19 (Day 15)



Outcome: One injection of AAM was used. The patients pre-ulcerative lesions and tissue was improved in 2 weeks. Patient remained closed at 6 weeks.

Figure 3C: 03/24/20





Figure 3E: 07/28/20 (1 year 1 month later)





Figure 3G: 06/03/22 (3 years later)

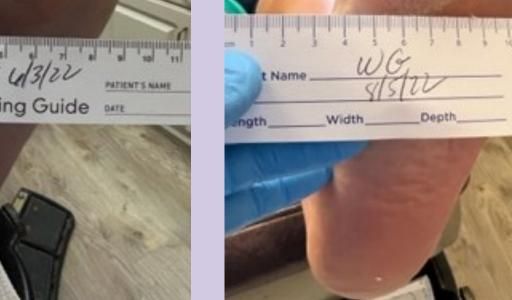


Figure 3H: 8/05/22 (3 years 2 months later)