Use of Synthetic Hybrid-Scale Fiber Matrix to Augment Lower Extremity Limb Salvage Procedures

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Introduction

Delayed healing of foot ulcers can often lead to lower extremity amputation. Life expectancy after a lower extremity amputation is typically around 3 years [1]. New therapies are needed to aid in the ulcer healing process and augment limb salvage procedures. A synthetic hybrid-scale fiber matrix, with a structure similar to native human extracellular matrix [2], is gaining popularity in the treatment of chronic ulcers and surgical wounds. This present case series investigates the use of the synthetic hybrid-scale fiber matrix in limb salvage procedures.

Methods

A retrospective study of three patients with nonhealing diabetic foot ulcers was conducted. Each patient underwent percutaneous elevating lesser metatarsal osteotomy surgery with excisional ulcer debridement. Two patients also had a gastrocnemius recession performed with the elevating osteotomies for surgical offloading of their nonhealing wound sites. At the time of surgery, patients received only one application of the synthetic hybrid-scale fiber matrix to the ulcer site for augmentation of their limb-salvage procedures. Ulcer re-epithelialization was monitored at follow up visits.

Results

Three male patients with diabetes mellitus type II were included in the present study. Two patients underwent elevating 5th metatarsal osteotomy procedures, and one underwent an elevating 3rd metatarsal osteotomy procedure. Two patients also had a gastrocnemius recession performed. All three ulcers underwent excisional debridement at the time of surgery, and the synthetic hybrid-scale fiber matrix was applied to the wound bed. The average starting ulcer size was 2.9cm^2 and had an average depth of 0.2cm. Each patient received one application of the synthetic hybrid-scale fiber matrix and all ulcers fully re-epithelialized in an average of 27 days. No complications were identified.

Conclusion

Complete ulcer re-epithelialization was observed in all three cases treated with the synthetic hybrid-scale fiber matrix. The positive results seen in this pilot case series demonstrate the efficacy of the synthetic hybrid-scale fiber matrix in the augmentation of wound salvage procedures.

References

1. Beyaz S, Güler ÜÖ, Bağır GŞ. Factors affecting lifespan following below-knee amputation in diabetic patients. *Acta Orthop Traumatol Turc*. 2017;51(5):393-397. doi:10.1016/j.aott.2017.07.001

2. MacEwan MR, MacEwan S, Kovacs TR, Batts J. What makes the optimal wound healing material? A review of current science and introduction of a synthetic nanofabricated wound care scaffold. *Cureus*. 2017 Oct 2;9(10):e1736. doi: 10.7759/cureus.1736.

Disclosures: BPA is a consultant for Acera Surgical

Case 1

- 78 y/o male type 2 diabetic w/ history of left foot recurrent nonhealing plantar diabetic forefoot ulceration; has failed standard local wound cares (topical medihoney, aquacel), offloading (immobilization boot, sx shoe with accommodation, activity reduction), serial wound debridement.
- History of left foot 2nd digit amputation, ankle soft tissue equinus contracture, and lesser digital hammertoe deformities
- History of right foot transmetatarsal amputation May 2013
- PMHx significant for: DM2, peripheral polyneuropathy, CAD, COPD, hx of colon cancer, HTN, Lyme disease, obesity, hyperlipidemia, and psoriatic arthritis.

Example of synthetic nanofiber wound matrix utilized to augment surgical offloading of nonhealing diabetic foot ulceration

4/27/2022 – Ulcer measures 1.5 x 1.2 cm with 0.1 cm depth (preop clinic appointment)

Left foot - 4/27/2022 | Hx TMA right foot

5/10/2022 – Ulcer measures 1.9 x 1.6 cm with 0 cm depth (after surgical debridement on day of surgery)

5/18/2022 – Wound matrix intact to wound bed, no measurements taken

6/01/2022 – Wound fully healed/epithelialized

Left foot weightbearing dorsal plantar radiograph – 5/10/2022 | Left foot weightbearing dorsal plantar radiograph – 6/30/2022 | Left foot weightbearing lateral oblique radiograph – 6/30/2022

- Patient underwent surgery on 5/10/2022 for the following procedures:
- Left foot percutaneous elevating osteotomy third metatarsal
- Left lower extremity gastrocnemius recession (Strayer type)
- Left foot excisional wound debridement with application synthetic nanofiber wound matrix

Left foot - 6/30/2022 | Left foot - 8/1/2022

Postop visit 1 on 5/18/2022
Postoperative multilayer compression dressing changed, sutures left intact to incision sites and overlying non-adherent gauze/synthetic wound matrix.

Postop visit 2 on 6/1/2022
Plantar diabetic forefoot ulceration noted to be fully healed/epithelialized; sutures removed from incision sites; patient permitted return to showering/bathing, will apply a daily moisturizer to previous incision/wound sites, continue immobilization in offloading surgical boot, permitted heel-only partial weightbearing status.

Postop visit 3 on 6/30/2022
Plantar diabetic forefoot ulceration remains fully healed. Recommended to continue daily moisturizer, full weightbearing activity as tolerated with use of offloading surgical boot for two additional weeks, and then transition into extra-depth diabetic shoegear with multi-density custom orthotic.

Postop visit 4 on 8/1/2022
Previous plantar diabetic foot ulcer remains fully healed, with no new or recurrent wounds. Patient permitted to continue full weightbearing status as tolerated in his extra-depth diabetic shoegear with multi-density custom orthotic.

Case 2

- 56 y/o male type 2 diabetic with history of nonhealing recurrent plantar fifth metatarsal head diabetic foot ulceration
- Underwent surgery on 3/23/2021 for:
  - Left foot minimum incision elevating osteotomy fifth metatarsal.
  - Left foot excisional debridement plantar fifth metatarsal head diabetic foot ulcer with application of synthetic nanofiber wound matrix.
  - After debridement wound measured 1.0 cm x 0.7 cm with 0.4 cm depth.

Postop Follow-up 1 (3/29/2022)
Left foot and ankle compression dressing changed, non-adherent gauze and wound matrix left intact, continue partial weightbearing in offloading surgical shoe.

Postop Follow-up 2 (4/7/2022)
Sutures removed in total to left foot, wound noted to be fully epithelialized with pencil eraser sized eschar over wound base. Continue partial weightbearing in offloading surgical shoe.

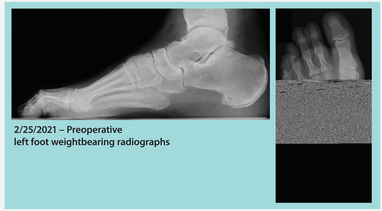
Postop Follow-up 3 (4/21/2022)
Left plantar forefoot ulcer remains fully healed, patient permitted to transition back to regular supportive shoegear, continue with daily moisturizer to healed wound area, weightbearing activity as tolerated.

Postop Follow-up 4 (5/24/2022)
Left plantar forefoot remains fully healed without new or recurrent ulceration. Continue daily moisturizer, weightbearing activity as tolerated in supportive shoegear.

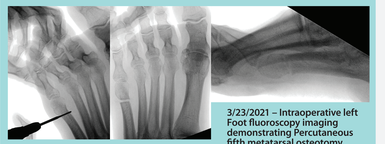
Postop Follow-up 5 (8/23/2022)
Left plantar forefoot remains fully healed without new or recurrent ulceration. Continue daily moisturizer, weightbearing activity as tolerated in supportive shoegear.

Preop clinical photos left foot

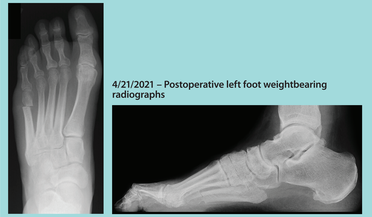
1/27/2022 | 1/27/2022 1.4 cm x 1.2 cm, Depth 0.3 cm | 2/25/2022 1.0 x 0.5 cm, Depth 0.5 cm | 3/17/2022 Wound measures 0.7 cm x 0.3 cm, depth 0.3 cm



2/25/2021 – Preoperative left foot weightbearing radiographs



3/23/2021 – Intraoperative left Foot fluoroscopy imaging demonstrating Percutaneous fifth metatarsal osteotomy



4/21/2021 – Postoperative left foot weightbearing radiographs

3/23/2022 (1.0 cm x 0.7 cm, Depth 0.4 cm) | 3/23/2022 | 4/7/2022 Remaining synthetic wound matrix intact (no measurements recorded) | 4/7/2022

4/21/2022 Complete healing noted to wound site | 5/24/2022 Remains healed | 7/7/2022 Remains healed

Case 3

- 46 y/o male type 2 diabetic presented on 3/26/2020 for infected recurrent plantar lateral fifth metatarsal head diabetic foot ulceration.
- History of left foot 4th and 5th digit amputation.
- Initial treatment consisted of wound debridement, oral antibiotics, offloading, and local wound cares. Due to recurrent nature of ulceration, patient opted to pursue surgical offloading of recurrent wound site.
- Underwent surgery on 8/11/2020 for:
  - Left foot minimum incision elevating osteotomy fifth metatarsal.
  - Left foot excisional debridement plantar fifth metatarsal head diabetic foot ulcer with application of synthetic nanofiber wound matrix.
  - Left gastrocnemius recession (Strayer type).
  - After debridement wound measured 2.5 cm x 2.5 cm with 0.2 cm depth.

Postop Follow-up 1 (8/19/2020)
Left lower extremity compression dressing changed, wound matrix left intact, continue non-weightbearing status.

Postop Follow-up 2 (8/26/2020)
Sutures removed in total to left lower extremity, patient recommended to do once daily betadine impregnated gauze dressing change to remaining wound site after daily hygiene. Continue non-weightbearing status.

Postop Follow-up 3 (9/9/2020)
Left plantar forefoot ulcer fully healed, patient instructed to continue application of daily moisturizer, non-weightbearing status for additional 2 weeks.

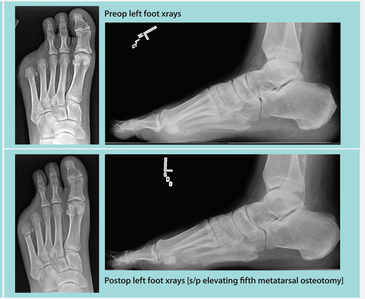
Postop Follow-up 4 (9/24/2020)
Left plantar forefoot remains fully healed without new or recurrent ulceration. Continue daily moisturizer, transition to partial weightbearing activity as tolerated in offloading surgical boot.

Postop Follow-up 5 (10/8/2020)
Left plantar forefoot remains fully healed without new or recurrent ulceration. Continue daily moisturizer, weightbearing activity as tolerated in supportive shoegear.

Left foot infected recurrent diabetic foot ulcer – 3/26/2020

Surgery 8/11/2020 Left foot ulcer debridement w/ application Restrata, MIS elevating 5th metatarsal osteotomy, Strayer gastrocnemius recession
On 8/11/2020 wound measured 2.5 x 2.5 cm with 0.2 cm depth after debridement

Left foot DFU – 8/5/2020
1.2 cm x 0.9 cm, Depth 0.2 cm



Preop left foot xrays

Postop left foot xrays [s/p elevating fifth metatarsal osteotomy]

Postop left foot xrays [s/p elevating fifth metatarsal osteotomy]

Left foot – 8/19/2020
[synthetic wound matrix intact, no measurements taken]

Left foot – 8/26/2020
[0.9 cm x 0.6 cm with 0.0 cm depth]

Left foot healed - 9/9/2020

Left foot remains healed – 9/24/2020

3/17/2021 - Final left foot weightbearing radiographs howing healed elevated fifth metatarsal osteotomy