Celularity Case Studies

Interfyl®

Removal of failed hardware with excisional tissue transfer closure

DONALD E. MRDJENOVICH, DPM, CWS, FACCWS – ALTOONA, PA

"Human connective tissue matrix appeared to promote steady progress toward healing/closure."

Patient Background

Female | Age: 87

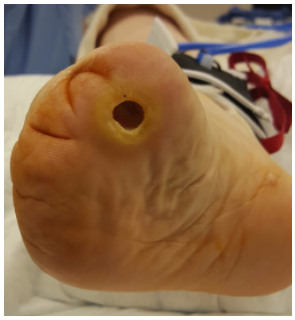
Type 2 diabetes mellitus (DM) with polyneuropathy, hypertension (HTN), rheumatoid arthritis (RA), hypothyroidism, congestive heart failure (CHF), acid reflux, and coronary artery disease (CAD)

PRESENTATION

Background: Failed hardware on left 1st metatarsal medially

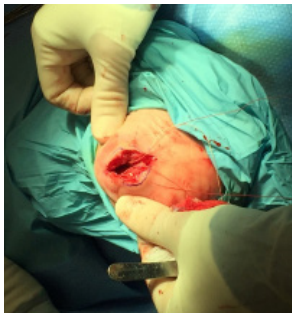
Initial treatment:
- Antibiotic ointment
- Autolytic debridement using silver hydrogel and collagen 3 weeks pre-intervention
- Offload in removable walking cast with customized multidensity insert

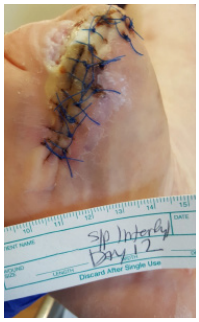
Studies:
- Negative Cx (cultures)
- Vascular status: adequate perfusion
- Diagnostic imaging: possibly osteomyelitis and abscess
- Partially amputated 1st metatarsal with remodeled distal aspect



TREATMENT STRATEGY

- Standard local care to prepare wound bed, decrease bioburden, debridement, offloading, assess perfusion to limbs with noninvasive ventilatory support (NIVS), percutaneous transluminal angioplasty
- Offload in removable walking cast with customized multidensity insert
- Plan excisional debridement ulcer/bone and layered closure using Interfyl flowable to fill void and BIOVANCE. Disposable negative-pressure wound therapy (NPWT) for high-risk incision
- Plan to apply series of dehydrated human amniotic membrane allografts and implant Interfyl as needed every 4 weeks, or when signs of wound-closure stalling occur
- Complications: Post-op complications included wound incision breakdown as a result of ambulatory forces. Tissue remained viable and closed with minimal scarring





POST-OP

- Patient non-compliant to post-op instructions and did not follow up regularly to appointments. Patient also non-adherent to offloading
- Figure 1 – Interfyl application #2, 63 days after initial procedure. Excisional debridement with retention suture. Void filled to within 0.5 cm surface. Granular viable base
- Shallow ulcer with devitalized edge noted – edges debrided in office and Interfyl #3 with nylon retention sutures
- Mature close 9 months (270 days) from initial deep sterile abscess I&S with excisional debridement, layered closure, and implant of flowable Interfyl despite an 8-week period when patient did not follow up
- No major safety concerns were observed

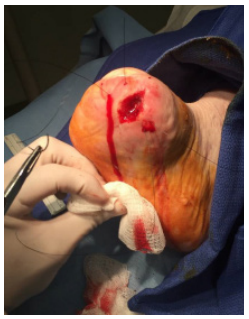


Figure 1. Interfyl #2. 63 days after initial I&D. Excisional debridement with retention closure. Void filled to within 0.5 cm surface. Granular viable base

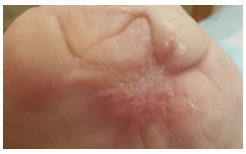


Figure 2. Mature closure. 9 months (270 days) from initial deep sterile abscess I&D with excisional debridement and layered closure and implant of flowable Interfyl

(Interfyl Safety Information)

INDICATIONS FOR USE

(For surgical indications)

Interfyl is intended for use as the replacement or supplementation of damaged or inadequate integumental tissue. Indications include, but are not limited to, treatment of soft tissue voids, correction of soft tissue defects, soft tissue augmentation during repair of dehisced or complicated surgical closures and repair of small surgical defects resulting from either medical or surgical conditions including those with exposed vital structures (bone, tendon, ligament, or nerve).

(For wound indications)

Interfyl is intended for use as the replacement or supplementation of damaged or inadequate integumental tissue. Indications include, but are not limited to: augmentation of deficient/inadequate soft tissue and treatment of deep dermal wounds; surgical wounds; soft tissue voids as a result of tunneling wounds, fistula tracts, or dermal undermining-including those with exposed vital structures (bone, tendon, ligament, or nerve).

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

Interfyl should not be used in clinically infected sites. If a recipient had an adverse reaction related to previous use of Interfyl, do not re-apply.

Do not use Interfyl for intravenous, intra-arterial, intra-ocular, or intrathecal applications.

Interfyl must be used prior to the expiration date on the product pouch. Once opened, Interfyl must be used within two hours or discarded per institutional procedures. The contents are sterile if the vial/syringe (container) is unopened and undamaged. Do not sterilize.

Please refer to the Interfyl Package Insert for complete product information.

For product information, product complaints, or adverse reaction reporting, call 1-844-963-2273.

For more information, please contact Celularity at 1-844-963-2273 or visit www.interfyl.com

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