Celularity Case Studies

Interfyl®

High-risk diabetic neuropathic foot with soft tissue loss and void/irregular anatomical space in need of tissue structure support

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"Growth flexor tendon remained viable and functional. Tissue remained viable with minimal scarring."

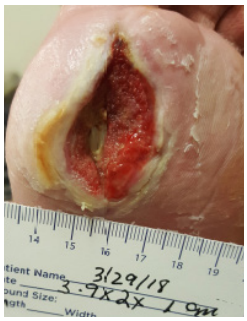
Patient Background

Male | Age: 54

Type 2 diabetes mellitus (DM) with polyneuropathy

PRESENTATION

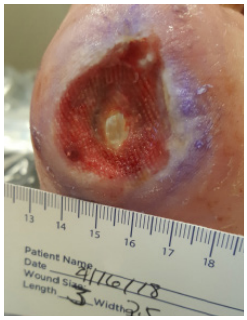
Background:	Diabetic neuropathic plantar foot ulcer sustained over 1 year
Initial treatment:	Conservative: hydrogel, collagen, foam bandage. No offloading Surgical: partial sesamoidectomy with wide excisional wound debridement and closure
Findings:	Vascular studies showing adequate perfusion. Cultures negative
Pre-op x-rays:	Showed hypertrophic sesamoid. Negative for osteomyelitis



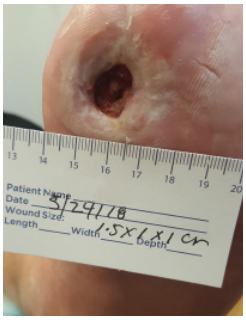
Prior to Interfyl implant

TREATMENT STRATEGY

- Pre-surgical treatment:
  - Prepare wound bed with UltraMIST. NPWT to control drainage
- Surgical intervention:
  - Prepare and debride wound bed with high-powered saline debridement tool to remove devitalized tissue and epibolized edges
  - Flowable Interfyl human connective tissue matrix application
  - Application of BIOVANCE as biological barrier



3 days post-Interfyl #1 flowable below and around flexor tendon space



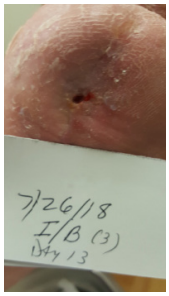
41 days post-Interfyl #1 flowable below and around flexor tendon space. Prior to Interfyl #2

POST-OP

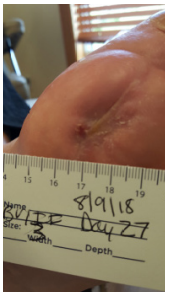
- Patient required consistent reminders of post-op instructions and importance of offloading and diabetes control
- Full mature closure at 122 days and 3 implantations using flowable Interfyl

Additional comments

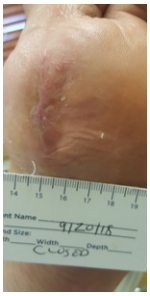
- Growth flexor tendon remained viable and functional. Tissue remained viable with minimal scarring
- No major safety concerns were observed



104 days post-Interfyl #1 flowable below and around flexor tendon space. 13 days after Interfyl #3



122 days post-Interfyl #1 flowable below and around flexor tendon space. 27 days after Interfyl #3



(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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