Celularity Case Studies

Interfyl®

High-risk diabetic neuropathic ulcer with soft tissue loss and void

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"Interfyl provided cell adherence and growth and appeared to promote steady progress toward healing and closure."

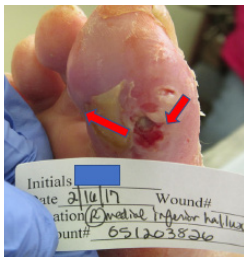
Patient Background

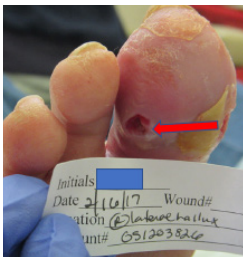
Female | Age: 70

Type 2 diabetes mellitus (DM) with polyneuropathy

PRESENTATION

Background:	Diabetic neuropathic plantar hallux ulcer of the right foot
Initial treatment:	Treated initially with oral Levofloxacin 30 days until cultures negative for bacteria. Local care with silver hydrogel and hydrofiber packing
Findings:	Tunneling ulcer through medial to plantar to lateral hallux. Tendon exposed. Bone palpable but not visible. Loss of subcutaneous fat plantar tuft
Pre-op x-rays:	Negative for fracture or osteomyelitis

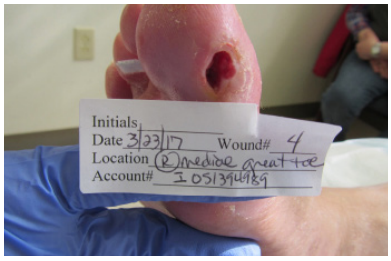




Arrows indicate communication between ulcers. Area of tuft undermined with tissue loss

TREATMENT STRATEGY

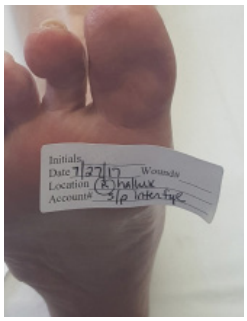
- Human Connective Tissue Matrix application: Interfyl flowable
- Regular (weekly) debridement of devitalized necrotic tissue
- Local standard of care to support wound bed
- Bioburden control using oral antibiotics until 2 negative cultures
- X-rays and assess perfusion to limbs with NIVS
- Offload in removable walking cast
- Prepare and debride wound bed with high-powered saline debridement tool to remove devitalized tissue and any epibolized edges
- Apply flowable Interfyl human connective tissue matrix to fill void and support tissue deficit at plantar hallux
- Cover with dehydrated human amniotic membrane
- Total Interfyl applications: 1 implantation using flowable Interfyl

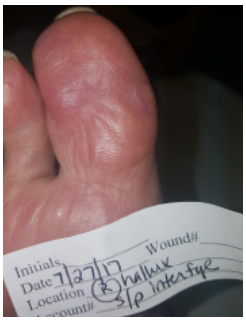


6 weeks: Prepared for Interfyl after obtaining 2 negative cultures and sustaining standard of care with moist wound healing and drainage control

POST-OP

- No post-application complications other than minor maceration of edges. Tissue remained viable with minimal scarring
- Total of 1 implantation using flowable Interfyl. High-risk diabetic neuropathic ulcer with soft tissue loss and void
- Time to full mature closure noted within 2 months and final discharge with full maturity at 4 months
- Patient recovery time afforded return to extra-depth shoe upon closure and return to accustomed lifestyle





4 months post-implant

Additional comments

- Plantar hallux ulcers are very difficult to close traditionally due to propulsion/sheer forces and biomechanical changes to neuropathic foot
- Interfyl provided cell adherence and growth
- Plantar ulcer tissue remained viable with granular tissue and no inflammation
- Interfyl appeared to promote steady progress toward healing/closure and maintained tissue structure support and elasticity
- No major safety concerns were observed

(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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