Celularity Case Studies

BIOVANCE®

Plantar hallux ulcers

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"Patient recovery time afforded return to an extra-depth shoe upon closure and return to accustomed lifestyle."

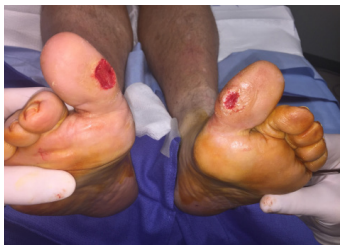
Patient Background

Male | Age: 57

Type 2 diabetes mellitus (DM) with polyneuropathy, hypertension (HTN), acid reflux, hypercholesterolemia, kidney stones, edema

PRESENTATION

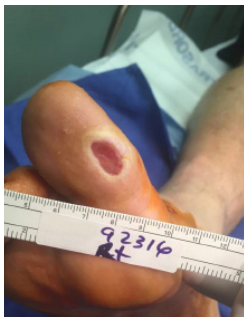
Background:	Diabetic plantar hallux ulcer greater than 1 year
Initial treatment:	Bilateral feet
Findings:	Sharp debridement; offloading RWC (non-adherent); collagenase 1 month; switched to Therabond dressing with silver hydrogel once granular
Pre-op x-rays:	Weekly debridement of devitalized necrotic tissue, enzymatic debridement. Offload in removable walking case and surgical shoe

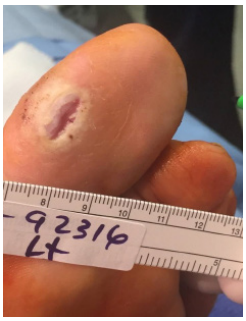


BIOVANCE application 1

TREATMENT STRATEGY

- Type of intervention: Wound care
- Procedure:
  - Prepare wound bed with high-powered saline debridement tool to remove devitalized tissue and epibolized edges
  - Human Amniotic Membrane Allograft Application: Apply BIOVANCE every 4-6 weeks, or when signs of stalling of epithelial migration occurred, until closure obtained
- Additional care: Continued protection with dimethicone cream and covered with silver antimicrobial fabric dressing (Therabond 3-D)



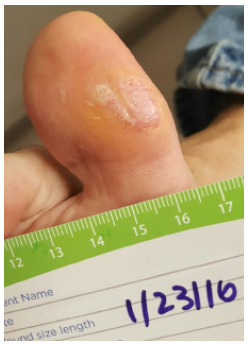


POST-OP

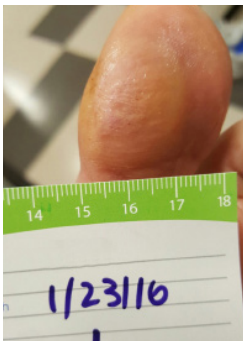
- Minor maceration of edges; tissue remained viable with minimal scarring
- 5 total BIOVANCE applications (2 to the right and 3 to the left)
- Time to closure: Full mature closure noted within 4.5 months and immature closure noted within 3.5 months
- Patient required consistent instruction and discussion of goals for outcome and importance of diabetes control and offloading

Additional comments

- Human dehydrated amniotic membrane allograft appeared to promote steady progress toward healing/closure
- No major safety concerns were observed



Mature closure presented 1 month after decision to stop BIOVANCE (2 applications to right)



3 applications to the left

(BIOVANCE Safety Information)

INDICATIONS FOR USE

BIOVANCE is an allograft intended for use as a biological membrane covering that provides the extracellular matrix while supporting the repair of damaged tissue. As a barrier membrane, BIOVANCE is intended to protect the underlying tissue and preserve tissue plane boundaries with minimized adhesion or fibrotic scarring. Indications include, but are not limited to, surgical covering, wrap or barrier, application to partial- and full-thickness, acute and chronic wounds (such as, traumatic and complex wounds, burns, surgical and Mohs surgery sites; and diabetic, venous, arterial, pressure and other ulcers), including wounds with exposed tendon, muscle, bone or other vital structures.

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

BIOVANCE is contraindicated in patients with a known hyper-sensitivity to BIOVANCE. If a patient has an adverse reaction related to the use of BIOVANCE, immediately discontinue its use. BIOVANCE should not be used on clinically infected wounds.

The pouch contents are sterile if the pouch is unopened and undamaged. Do not use if package seal is broken. Discard material if mishandling has caused possible damage or contamination. Do not resterilize.

BIOVANCE must be used prior to the expiration date on the product pouch. BIOVANCE should not be used together with a collagenase product on the wound.

Please refer to the BIOVANCE 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.biovance.net

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