Celularity Case Studies

BIOVANCE®

Removal of failed hardware with excisional tissue transfer closure

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

"Use of BIOVANCE implant in a high-risk surgical incision reduced the extent of incision dehiscence. Tissue was viable with minimal scarring."

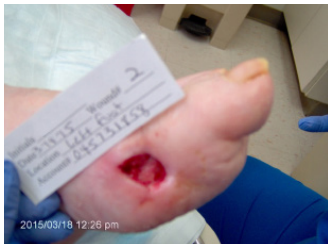
Patient Background

Female | Age: 75

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

PRESENTATION

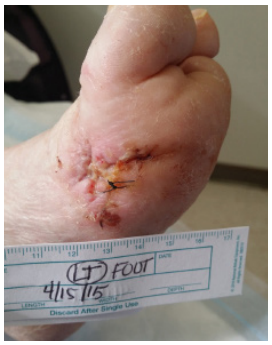
Background:	Diabetic neuropathic chronic foot ulcer greater than 1 year
Initial treatment:	Medial 1st metatarsal LT foot
Findings:	Did not show findings of granulation and necrotic tissue
Pre-op x-rays:	• Antibiotic ointment • Autolytic and sharp debridement



Ulcer pre-op

TREATMENT STRATEGY

- Procedure:
  - Removal of failed hardware
  - Remove scar tissue around ulcer site
- BIOVANCE allograft membrane at each level during layered closure (capsule, subcutaneous/subcuticular)
- Offload with surgical shoe



Day 12 post-op

POST-OP

- Decreased local incision/wound inflammation
- At day 33 (Figure 1) – immature epithelial migration (immature closure), stable base
- At day 47 (Figure 2) – full closure and minimal scarring
- Patient returned to extra-depth shoe within 6 weeks with continued stability at incision site
- No complications with viable tissue and minimal scarring

Additional comments

- Use of BIOVANCE implant in high-risk surgical incision reduced extent of incision dehiscence
- No major safety concerns were observed

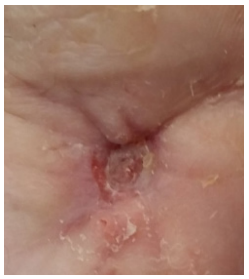


Figure 1. Ulcer post-op day 33. Magnified at 250%

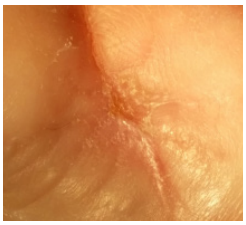


Figure 2. Ulcer post-op day 47. Magnified at 250%

(BIOVANCE Safety Information)

INDICATIONS FOR USE

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CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

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Plantar hallux ulcers

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

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

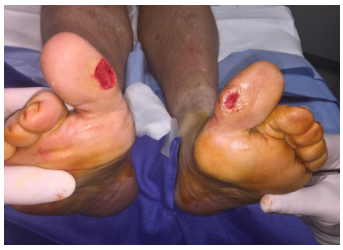
Patient Background

Male | Age: 57

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

PRESENTATION

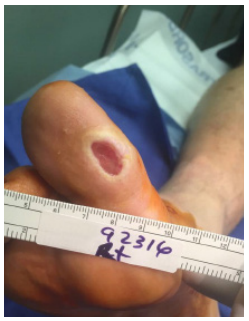
Background:	Diabetic plantar hallux ulcer greater than 1 year
Initial treatment:	Bilateral feet
Findings:	Sharp debridement; offloading RWC (non-adherent); collagenase 1 month; switched to Therabond dressing with silver hydrogel once granular
Pre-op x-rays:	Weekly debridement of devitalized necrotic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

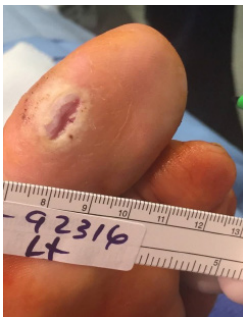


BIOVANCE application 1

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)



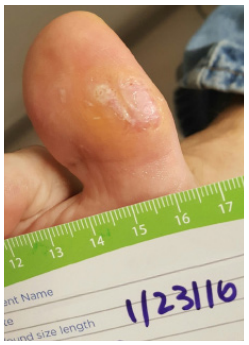


POST-OP

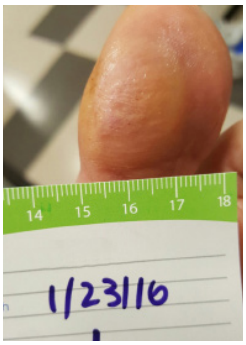
- Minor maceration of edges; tissue remained viable with minimal scarring
- 5 total BIOVANCE applications (2 to the right and 3 to the left)
- Time to closure: Full mature closure noted within 4.5 months and immature closure noted within 3.5 months
- Patient required consistent instruction and discussion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

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Celularity Case Studies

BIOVANCE®

Chronic 4th interspace wound treatment with BIOVANCE

CHRISTOPHER CORWIN, DPM, MS, FACFAS - JOHNS CREEK, GA

"BIOVANCE used to augment wound healing and also to reduce likelihood of recurrent ulceration through regenerative healing"

Patient Background

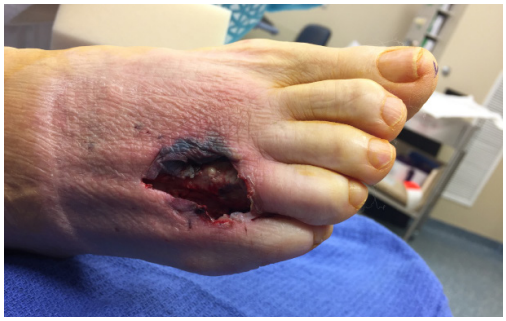
Female | Age: 65

Lupus

Chronic 4th interspace wound

PRESENTATION

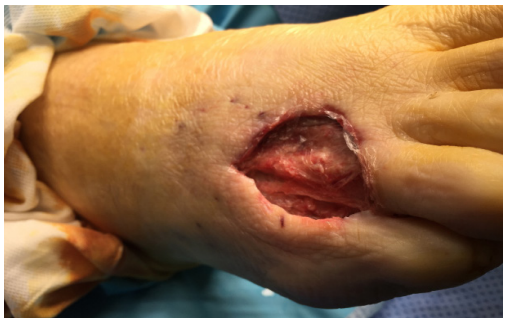
Background:	Patient with history of lupus presented with a chronic 4th interspace wound. Flareup of the wound was noted in the same area over the previous year.
Initial Treatment:	• Incision & Drainage (I & D) with packing for 48 hours • IV antibiotics
Findings/Studies:	• No osteomyelitis
Supportive Treatment:	• Applied negative pressure wound therapy (NPWT) at 75 mm Hg • Patient discontinued use of NPWT after 10 days • Patient placed in surgical shoe for offloading



Female with chronic 4th interspace wound

TREATMENT STRATEGY

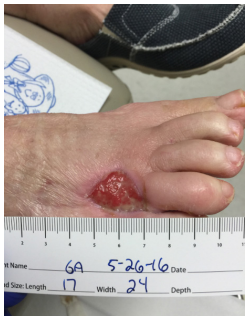
- Debrided non-viable tissue and administered IV antibiotics to manage infection
- Used BIOVANCE and NPWT to get wound closure and to fill the defect that had been a chronic problem for over a year in the 4th interspace
- Patient to use surgical shoe with non-adherent dressing and gauze
- Wound was monitored every 2 weeks for size



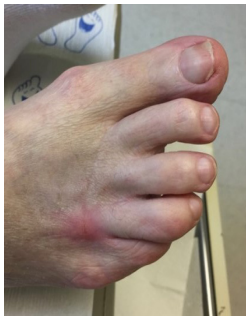
Post I&D with BIOVANCE application

TREATMENT OUTCOMES COMMENTS

- After initial application of BIOVANCE, wound did not stall, it improved every week
- Did not need a re-application of BIOVANCE
- Wound progressed to full healing in 77 days
- Good mobility of skin at the wound level which should translate to less likelihood of future recurrent ulceration
- No major safety concerns were observed



Post-Op approx. 1 month


Post-Op approx. 2.5 months

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