Use of a uniquely adherent silver film (Microlyte® Ag Matrix) to promote healing of recalcitrant diabetic neuropathic ulcers

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Problem/Rationale

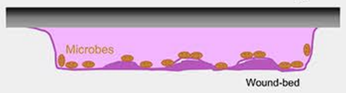
Antimicrobial dressings and matrices are vital to managing inhibitory bioburden resulting in stalled wounds. Though increasingly, higher levels of silver are being used to achieve greater antimicrobial activity, and the excessive levels of silver result in staining of the wound and can inhibit re-epithelialization due to tissue toxicity.

The MicroLyte® Approach

MicroLyte® is a polymeric microfilm Drug-Delivery Platform

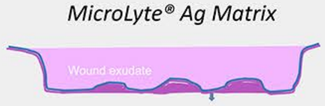
- The thin-film form factor (20-30 µm) provides intimate contact with the tissue surface
- Well-controlled loading of therapeutic bioactives
- Maintains moist wound microenvironment
- **MicroLyte® Ag Matrix** contains a low dose of ionic and metallic silver for antimicrobial effect with far less residual toxicity

Conventional Silver Dressing



Needs **~100 µg/cm² Ag^+** to kill microbes on wound bed

MicroLyte® Ag Matrix



Needs **~1 µg/cm² Ag^+** to kill microbes on wound bed

Key Characteristics of MicroLyte® Ag Matrix

- *Antimicrobial*: Provides active silver (ionic and metallic) in the wound bed for 3 days
- *Resorbs in 3-7 days*: Never needs to be removed from the wound bed and is appropriate for management of chronic and surgical wounds
- *Fully Synthetic*: no animal-products; no risk of disease transmission; long shelf life
- *Tissue Repair*: provides a template for cells to grow onto

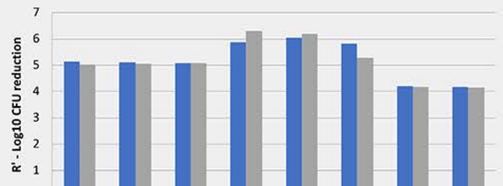
Mode of Action

Wound fluid absorption → **Maintains moist wound environment** → **Contours to microtexture of wound** → **Active agents effective at lower concentrations**

Reduced tissue toxicity and irritation → **Provides a template for cells to grow onto** → **Improved wound healing**

Antimicrobial Performance of MicroLyte® Ag Matrix

MicroLyte® Ag Matrix provides a 4- to 6-log reduction in a variety of bacteria and yeast, including MRSA and VRE.



	S. aureus	MRSA	VRE	P. aeruginosa	E. coli	K. pneumoniae	C. tropicalis	C. albicans
24 h	5.13	5.1	5.09	5.88	6.06	5.83	4.2	4.19
72 h	5.04	5.07	5.09	6.3	6.19	5.29	4.18	4.16

Methods

Two cases of recalcitrant diabetic neuropathic ulcers were evaluated with bioburden felt to be the primary inhibitory cause. Using standard of care treatment for each case with **MicroLyte® Ag Matrix as the primary wound treatment**, complete healing was accomplished rapidly. No untoward effects were identified during the treatments.

Case 1: Right Lateral Foot Ulcer

Patient

- 78-year-old female
- Long history of venous hypertension and leg ulcers as well as moderate Peripheral Arterial Disease treated successfully for venous ulcers
- Developed an open area of her right lateral foot due to trauma

Wound and Treatment

- 7/22/19: Initially 0.1cm x 0.1cm x < 0.1cm with minimal serous drainage. Sheet hydrogel applied with 4-layer venous compression
- 7/29/2019: Increased to 3.1cm x 2.8cm x 0.1 with exquisite pain; **MicroLyte® Ag Matrix** was applied along with 4 layer compression and changed 2x/week
- 8/5/2019: Wound size was 1.6cm x 1.0cm x < 0.1cm
- 8/19/2019: Completely healed; no pain; placed in compression hose (knee high, closed toe, 15-20mmHg)

Outcome

- Healed completely within 20 days of treatment with **MicroLyte® Ag Matrix**

8/5/2019

8/19/2019

Case 2: Neuropathic DFU in Heavy Smoker

Patient

- 71-year-old male, Type 2 DM, very noncompliant
- Smokes 2 ppd of cigarettes and also refuses to wear his diabetic shoes with inserts
- Has already lost the toes on right foot and continues to wear regular shoes

Wound and Treatment

- 5/31/19: Presented with long standing ulcer right 4 met plantar with eschar. Eschar removed exposing heavy callus with crack in callus causing the bleeding and eschar. X-rays showed no osteomyelitis
- 6/10/19: Thick callus identified and debrided. **MicroLyte® Ag Matrix** and TCC applied
- 6/17/2019: Ulcer measured 1.0cm x 0.2 x <0.1cm; red with minimal serous drainage; **MicroLyte® Ag Matrix** and TCC reapplied
- 6/24/19: TCC removed; ulcer healed

Outcome

- **MicroLyte® Ag Matrix** achieved healing on a timeline remarkably short for a noncompliant, diabetic, smoker

6/10/19

6/17/19

6/17/19

6/24/19

Total Contact Casts courtesy of MMedUSA, Mebane, NC

Results and Conclusions

Treatment of inhibitory bioburden with promotion of healing occurred using the **MicroLyte® Ag Matrix** in two recalcitrant wounds. The antimicrobial properties of the MicroLyte® Ag Matrix in conjunction with its unique configuration and adherent properties strongly demonstrate efficacy in recalcitrant wounds in which the configuration or other wound characteristics may make other antimicrobial dressings less efficacious. We present two cases of recalcitrant wounds in which presence of bioburden precluded healing. Both responded very well to this unique silver matrix and healing was accomplished.