The Use of MicroLyte®Ag Bioresorbable Wound Matrix as a Surgical Implant to Prevent Postoperative Surgical Site Infection

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Introduction

- Surgical site infections (SSI) make up 20-30% of all hospital-acquired infections and 38% of all post-operative complications[1]
- 160,000 to 300,000 SSIs per year in the United States[2,3]
- SSIs require 7-11 additional days in the hospital[4]
- $10 billion impact annually in US[2]

Existing Approaches

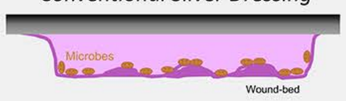
- Prophylactic oral and topical antibiotic use
  - Limited efficacy on resistance strains
  - Limited longevity in the surgical site

The MicroLyte® Approach

MicroLyte® is a polymeric Microfilm Drug-Delivery Platform

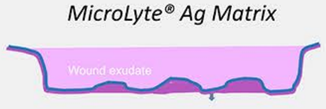
- The thin-film form factor (20-30 µm) provides intimate contact with the tissue surface
- Well-controlled loading of therapeutic bioactives
- **MicroLyte® Ag Matrix** contains a low dose of ionic and metallic silver for antimicrobial effect with far less residual toxicity

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

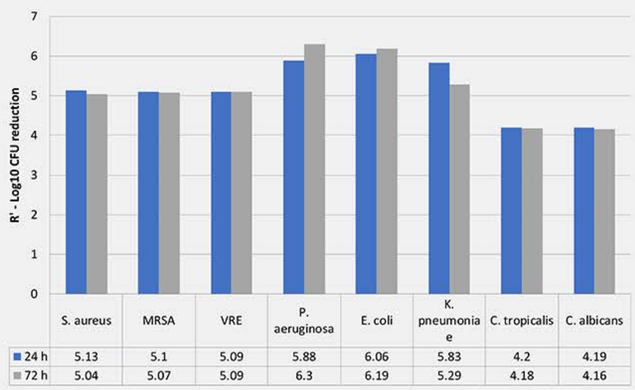
- *Antimicrobial*: Provides active silver in the wound bed for up to 3 days
- *Resorbs in 3-7 days*: Never needs to be removed from the wound bed; currently being evaluated as an implantable
- *Fully Synthetic*: no risk of disease transmission; long shelf life
- *Tissue Repair*: provides a template for cells to grow onto[5]

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



	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

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

Previous Clinical Successes with MicroLyte® Ag Matrix

MicroLyte® Ag Matrix has been successful in stimulating closure in stalled wounds[6]

- 32 patients, wounds stalled for an average of 40 weeks
- Over 12 weeks, 91% (29/32) of wounds had improved with an average wound closure of 73%, and 12 wounds had an average closure >90%

MicroLyte® Ag Matrix has been used to prevent infection in at-risk surgical patients[7]

- 15 diabetic patients with history of MRSA
- **MicroLyte® Ag Matrix** placed on fascia when surgical wound was closed
- No incidence of infection observed at 3-5 day post-op evaluation

MicroLyte® Ag Matrix Indications

- Partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second-degree burns abrasions and lacerations, donor sites and surgical wounds
- May be used over debrided and grafted partial thickness wounds

References

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3. Magill SS, et al. *New England Journal of Medicine*. 2014;370(13):1198-208.
4. Ban KA, et al. *Journal of the American College of Surgeons*. 2017;224(1):59-74.
5. Agarwal, A., et al. Biomaterials. 2010; 31:680–690
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Conflict Statement: Dr. Michael Schurr has a financial interest in Imbed Biosciences, manufacturer of MicroLyte® Ag Matrix.

Case Report: MRSA-Infected Biceps Tendon

Patient

- 33-year-old woman with a medical history including poorly controlled insulin-dependent diabetes, ongoing tobacco abuse, and recurrent necrotizing soft tissue infections
- Presented in December 2017 for a left arm abscess
- Required multiple debridement procedures and she was ultimately left with a chronic left arm wound with exposed bicep tendon.
- Failed split-thickness skin graft placement in January of 2018
- Surgery, NPWT, and IV Abx all failed to stimulate closure of wound

Procedure (March 2018)

- Infected site was surgically debrided and the presence of MRSA infection on the biceps tendon was confirmed
- **MicroLyte® Ag** was applied to the exposed tendon (Panel A) and patient underwent Z-plasty closure (Panel B)
- No oral or topical antibiotics were administered

Outcome

- By Day 4, there was no sign of infection (Panel C) and by Day 14, the wound was well healed and sutures were taken out (Panel D)
- The wound remained healed and patient regained range of motion in her left elbow

Summary

*Faster and more complete closure of a chronically infected wound was achieved by subcutaneous implantation of **MicroLyte® Ag Matrix** than was achievable with other failed therapies.* This patient had multiple risk factors for postoperative surgical site infection including poor glycemic control, polymicrobial infection, and ongoing tobacco abuse. **MicroLyte® Ag Matrix** implanted at the time of surgery was well tolerated and associated with a positive outcome.