The Use of Absorbable Polyvinyl/Polymeric Microfilm Matrix with Silver in the Treatment of Venous Ulcers: A Pilot Study

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Problem/Rationale

The treatment of chronic venous ulcers continues to be a difficult clinical problem. Appropriate compression therapy is the gold standard for treatment of these ulcers, but managing the multiple issues with the wound bed remains a treatment challenge. A new absorbable polyvinyl/polymeric matrix with silver has been introduced in an attempt to improve healing in patients with venous ulcers. This product is composed of an ultrathin matrix and both ionic and metallic silver which provide local antimicrobial activity for at least 3 days. Because of its thickness of only 20 microns, it easily conforms to the wound bed and maintains a moist wound environment conducive to new blood vessel formation, granulation tissue development, and cell growth. Since it is bioresorbable, there is no need to remove it from the wound bed making wound dressing changes easy and painless. To evaluate the effect of this unique product on patients with venous ulcers, we treated 10 patients with the product combined with short-stretch compression bandaging for 4 weeks to evaluate the effect on wound healing.

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

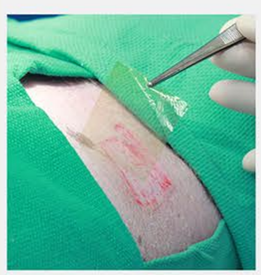
Conventional Silver Dressing

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

MicroLyte® Ag Matrix

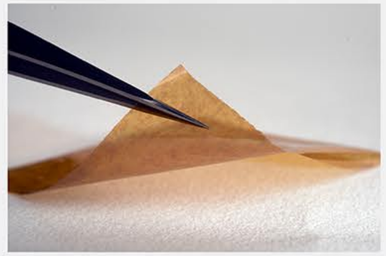
Needs **~1 µg/cm² Ag^+** to kill microbes on wound bed

Key Characteristics of MicroLyte® Ag Matrix

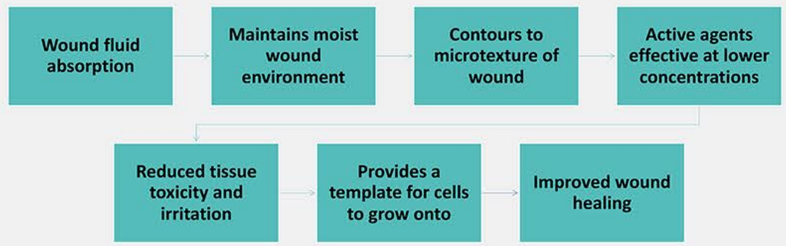


- *Antimicrobial*: Provides active silver (ionic and metallic) in the wound bed for 3 days
- *Resorbs in 3-7 days*: Never needs to be removed from the wound bed and is appropriate for management of chronic and surgical wounds
- *Fully Synthetic*: no animal-products; no risk of disease transmission; long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

MicroLyte® Ag Matrix

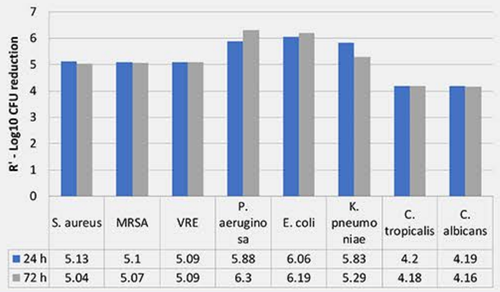


Mode of Action



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

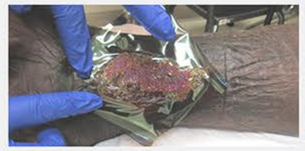
The patient group included 6 men and 4 women with an average age of 63 years (range 41-78 years). All patients had venous ulcers present for more than 6 months, and all ulcers were slow to respond to conventional therapy. The ulcers ranged from 4cm² to 28 cm² with an average of 11.2 cm². After obtaining appropriate informed consent, each ulcer was cleaned with saline and was covered with **Microlyte Ag** and a non-adherent dressing (Adaptic (Systagenix)). Standard short-stretch compression bandages (Coban II (3M)) were applied. Each patient was seen on a weekly basis. Reapplication of the **Microlyte Ag** was done based on the wound bed condition and the degree of healing. Compression bandages were changed each week.

Results

At the end of the 4-week evaluation period, 9 of the patients had shown a significant improvement healing with an average of 48% closure (range from 25% to 100%). One patient had a 50% increase in ulcer size over the same time which could not be explained. There were an average of 2.4 **Microlyte Ag** applications per patient with a range of 1 to 3. The patient with the largest ulcer (28 cm²) healed after 16 weeks of **MicroLyte Ag** therapy. No patient developed a clinical wound infection. All patients were happy with the reduction of pain at the dressing changes.

Venous Ulcer

Applying MicroLyte Ag



MicroLyte Ag Contours into All Areas of Wound Bed

MicroLyte Ag Conforming to Wound Bed

Excess MicroLyte Ag Folded Over into Wound Bed

Ulcer Healed with MicroLyte Ag and Compression

Conclusions

We have treated 10 patients with venous ulcers using this dressing in combination with short-stretch compression bandages and have seen improved healing of all but one patient's ulcer. Patient acceptance and satisfaction with this technique has been universally excellent especially with the reduction in wound pain with dressing changes. Based on these preliminary results, we recommend further evaluation and use of this new, novel product for the treatment of venous ulcers.