

## Introduction

Every year more than 6.5 million patients in the U.S. are treated for chronic wound infections. Infected chronic wounds do not progress through the normal healing process and can take years to heal, making the treatment physically, emotionally and financially demanding for patients and caregivers alike.

Chronic wounds have a burden of bacteria living deep in the wound bed that is not cleared by, or rapidly returns after, surgical debridement resulting in the failure of the therapy.<sup>1</sup> This underlines the need for novel therapies capable of clearing persistent infections from wounds.

MicroLyte™ Ag is a 20 µm thick dissolvable wound dressing that conforms intimately to the micro-contours of a wound-bed and provides antimicrobial barrier to infection for up to 3 days. MicroLyte™ Ag is FDA 510(k) cleared (K153756) for Rx and OTC use.

Here, we report the 30 day interim results from first 20 patients in an ongoing prospective IRB-approved clinical study at Mission Health Wound Center, Asheville, NC evaluating MicroLyte™ Ag dressing in chronic wounds, led by Dr. David Humphrey, MD.

## MicroLyte™ Ag Wound Dressing

MicroLyte™ Ag is a sterile, single use polyvinyl alcohol hydrogel sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with max. of 0.1 mg/sq. inch., compared to 10 mg/sq. inch. in Acticoat (Smith & Nephew).



In published literature, Microfilm dressings with silver were shown to expedite closure of full-thickness splinted wounds in mice that were inoculated with 2x10<sup>5</sup> CFU of *S. aureus* on day zero after surgery. One set of inoculated wounds were covered Microfilms, and all wounds were subsequently covered with a collagen dressing (Biobrane®, Smith & Nephew).<sup>2,3</sup>

## In-vitro Antimicrobial Efficacy

MicroLyte™ Ag wound dressing kills 5 Log<sub>10</sub> CFU of clinically relevant microbes within 24 h and maintain antimicrobial activity of the dressing up to 3 days, as summarized below.<sup>4</sup>

MICROBIAL STRAIN	STRAIN CLASSIFICATION	R- Log <sub>10</sub> reduction (Day 1)	R'- Log <sub>10</sub> reduction (Day 3)
Staphylococcus aureus	Gram Positive	> 5.17	> 5.17
Staphylococcus aureus Methicillin Resistant (MRSA)	Gram Positive	> 5.11	> 5.11
Enterococcus faecalis Vancomycin Resistant (VRE)	Gram Positive	> 5.12	> 5.12
Pseudomonas aeruginosa	Gram Negative	> 5.05	> 5.05
Escherichia coli	Gram Negative	> 5.53	> 5.53
Klebsiella pneumoniae	Gram Negative	> 5.55	> 5.55
Candida tropicalis	Yeast	> 5.16	> 5.16
Candida albicans	Yeast	> 5.16	> 5.16

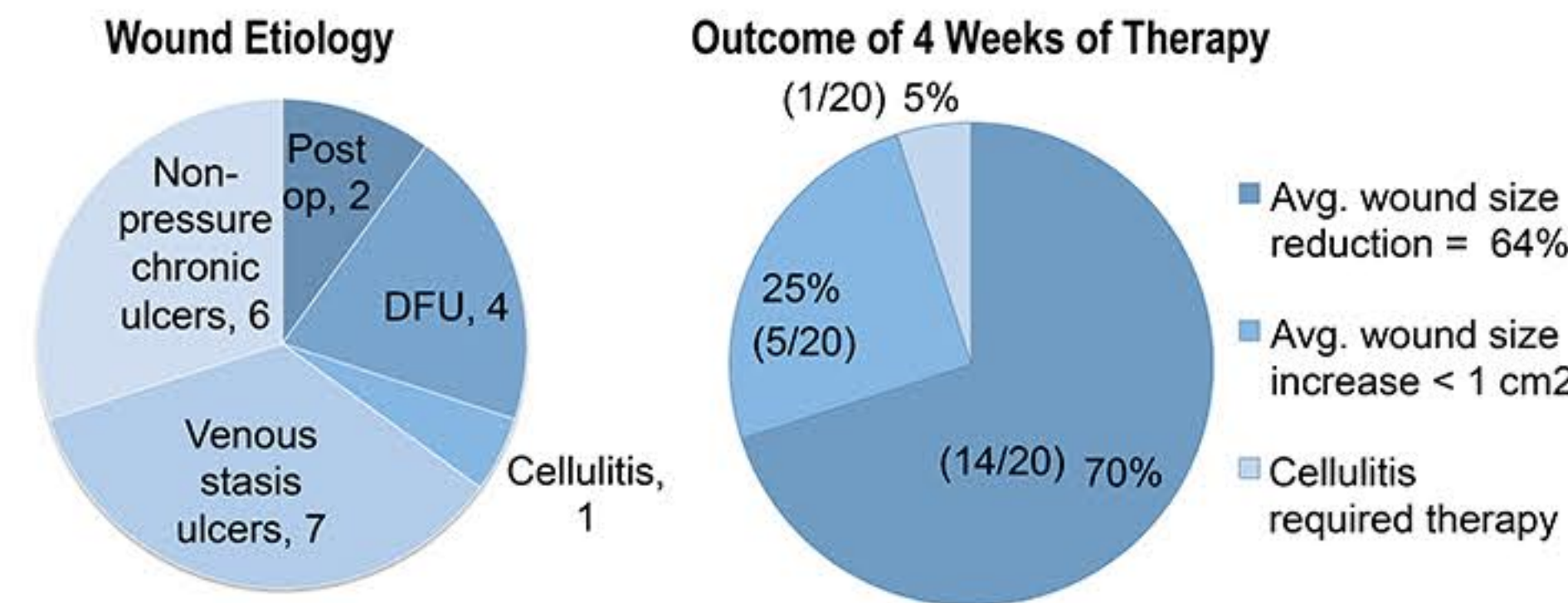
## Acknowledgement

Imbed Biosciences Inc. provided MicroLyte™ Ag wound dressings for this IRB-approved clinical study. Study was funded by internal research grants at Mission Hospitals. MJS possess financial interests in the company.

## References

1. Kirketerp-Moller *et al.*, Journal of Clinical Microbiology, 46(8), 2008.
2. Guthrie, Agarwal, *et al.*, Annals of Surgery, 256(2), 2012.
3. Herron, Agarwal, *et al.*, Advanced Healthcare Materials, 3(6), 2014.
4. Data provided by Imbed Biosciences Inc.

## Results



- Wounds were present for an average of 145 days (range 32 to 360 days) prior to treatment with MicroLyte™ Ag wound dressing.
- 14/20 (70%) of wounds improved with an average of 64% reduction in wound size within the first 4 weeks of therapy with MicroLyte™ Ag wound dressing.
- 5/20 (25%) of wounds had an average increase in size of <1.0 cm<sup>2</sup>.
- One patient (5%) with venous stasis ulcer had wound size increase from 38 cm<sup>2</sup> to 80 cm<sup>2</sup>. This patient had surrounding cellulitis that required antibiotic therapy.

## Conclusions

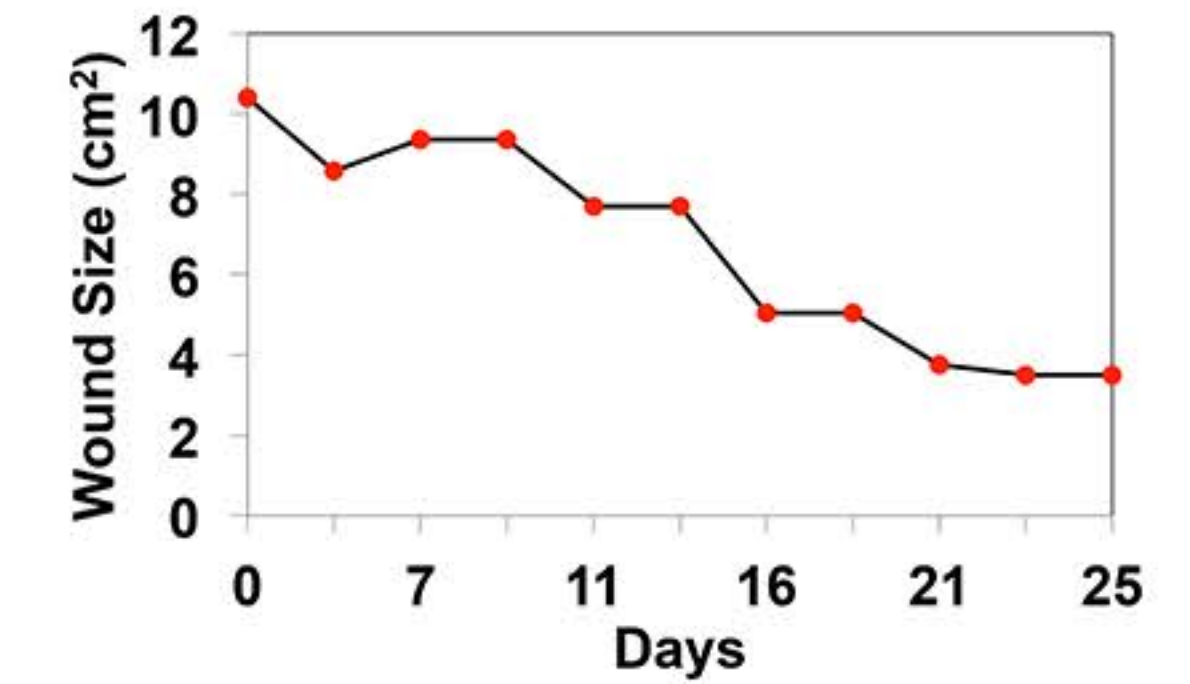
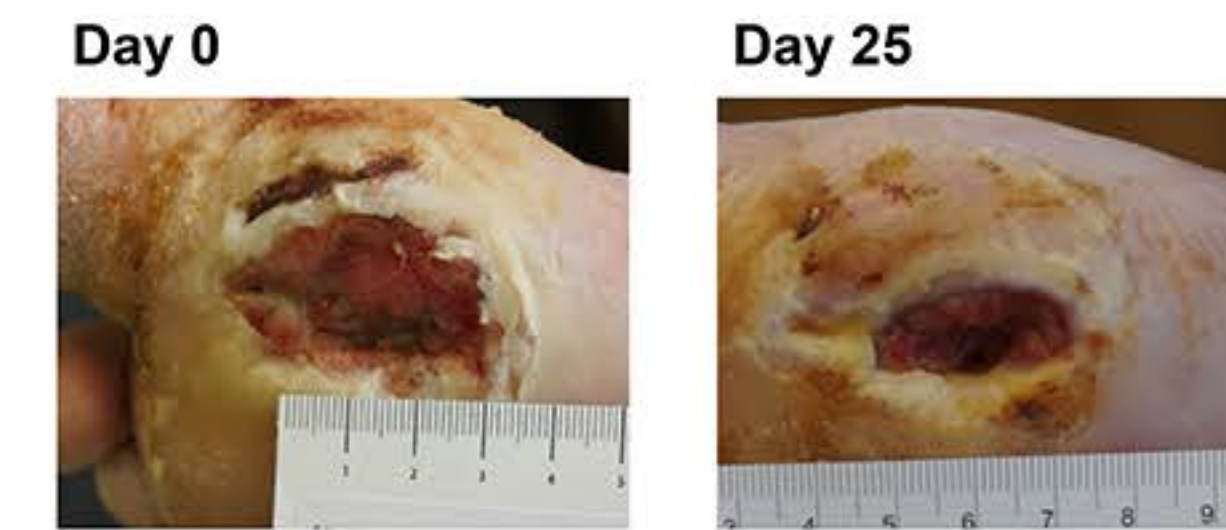
- MicroLyte™ Ag wound dressing is a safe and effective wound dressing in patients with chronic wounds.
- MicroLyte™ Ag wound dressing can be used in conjunction with a variety of wound management techniques including pressure wraps, total contact casts, and negative pressure wound therapy.
- Surface bacterial control of longstanding chronic wounds facilitates the healing process.

## Feedback from Clinical Investigator

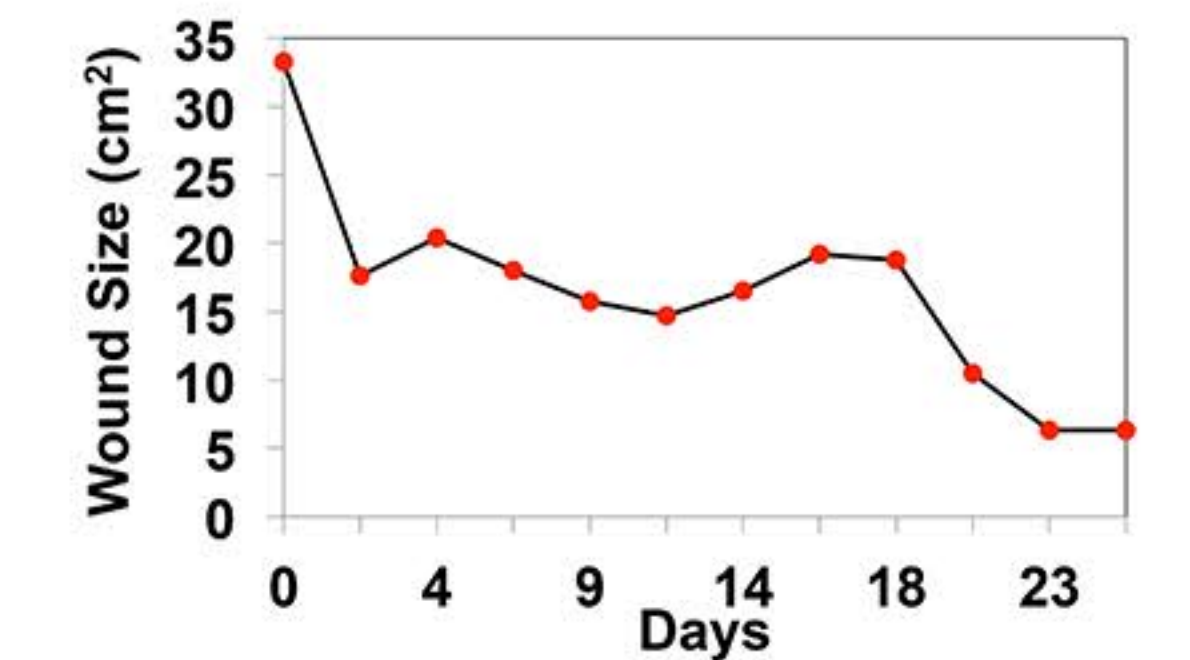
- I was surprised at the improvement in wounds/ulcers that did not appear to have any bacterial burden clinically.
- Very simple to use, though a learning curve for use into tracts/tunnels as the product adheres quickly when in contact to moisture. Note, gloves must be dry!
- The patient with the pilonidal cyst showed improvement with MicroLyte™ Ag (3x per week) used along with NPWT, faster than would have achieved with NPWT alone.
- It works well in diabetic foot ulcers under total contact cast.

## Representative Clinical Examples

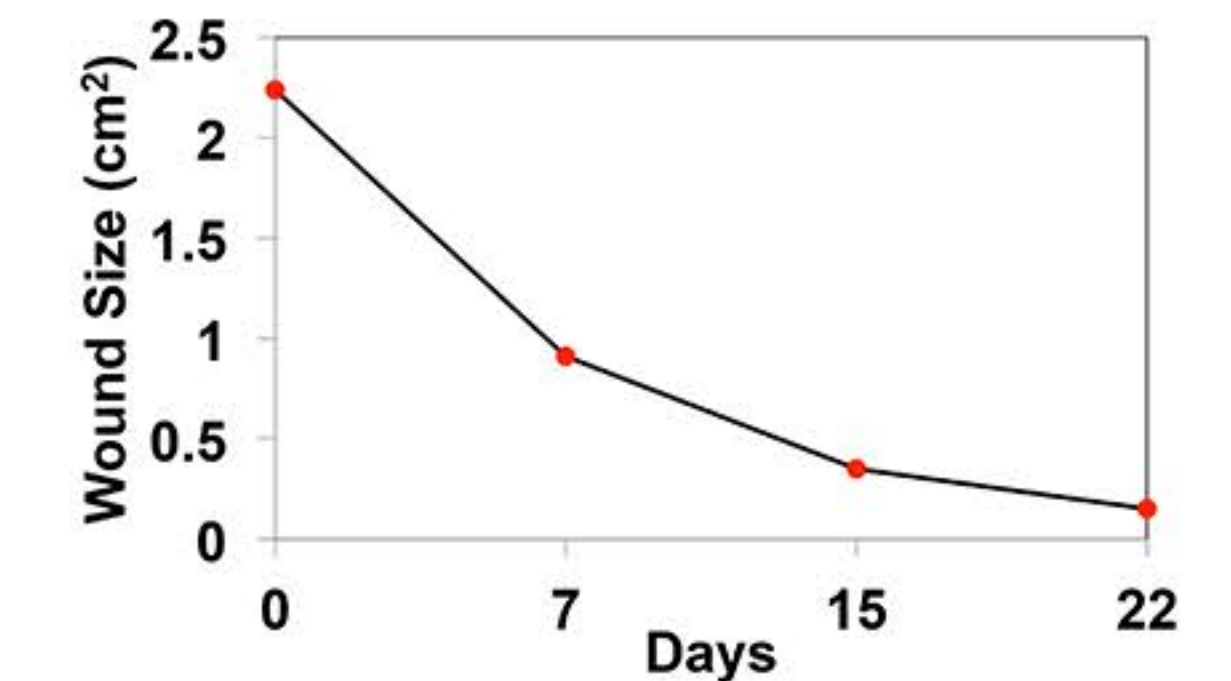
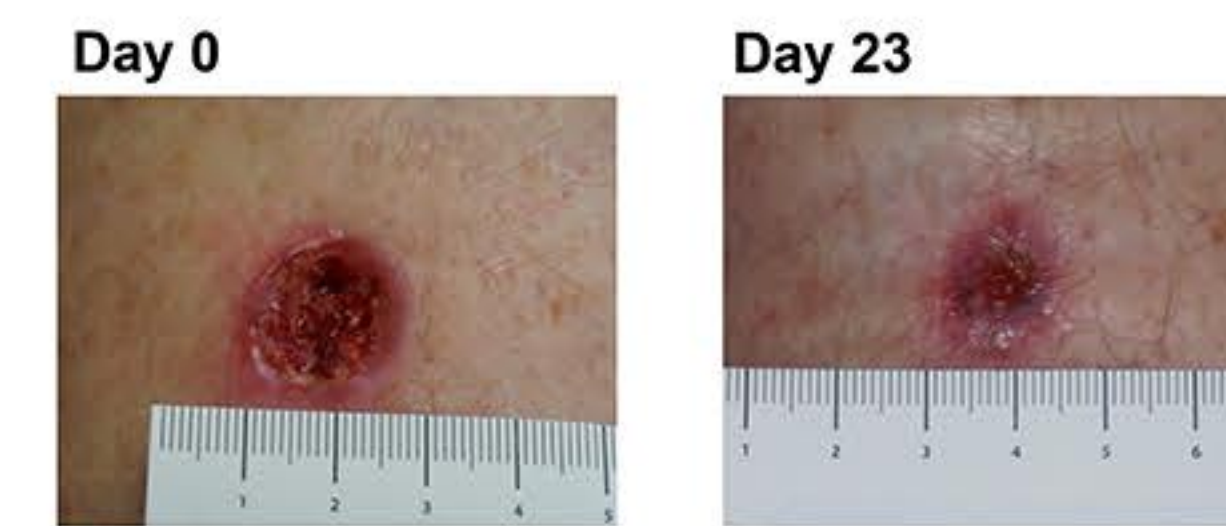
Chronic diabetic foot ulcer (non-healing for 211 days) on a 68 year old male patient. MicroLyte™ Ag applied 2-3x every week. >66% closure within 4 weeks



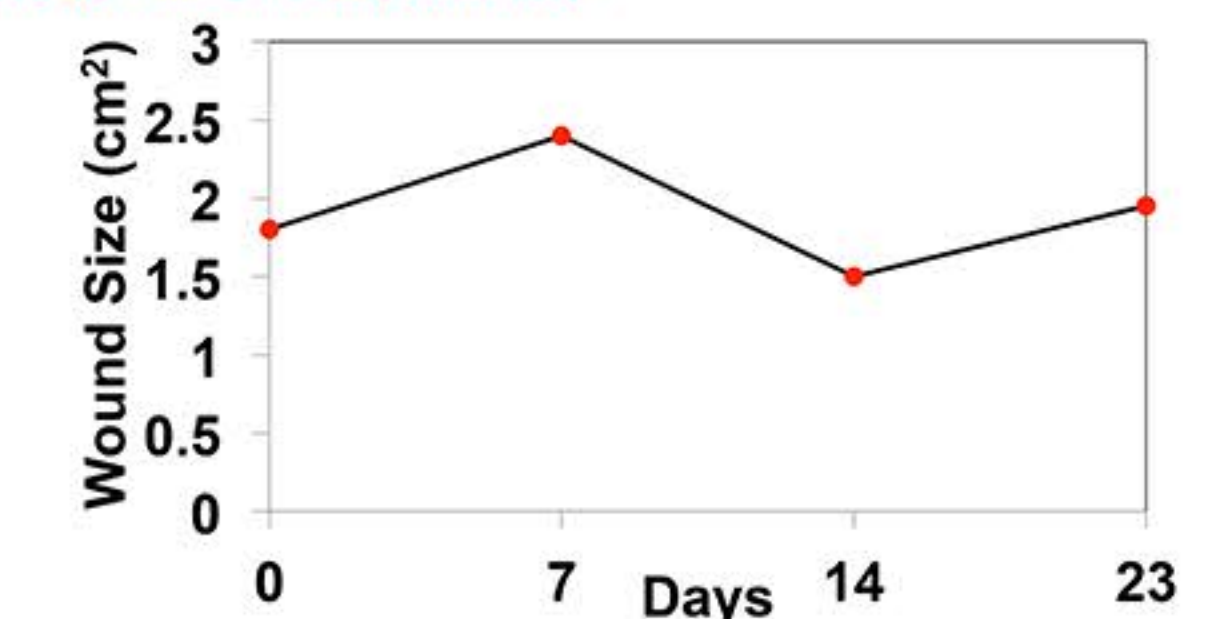
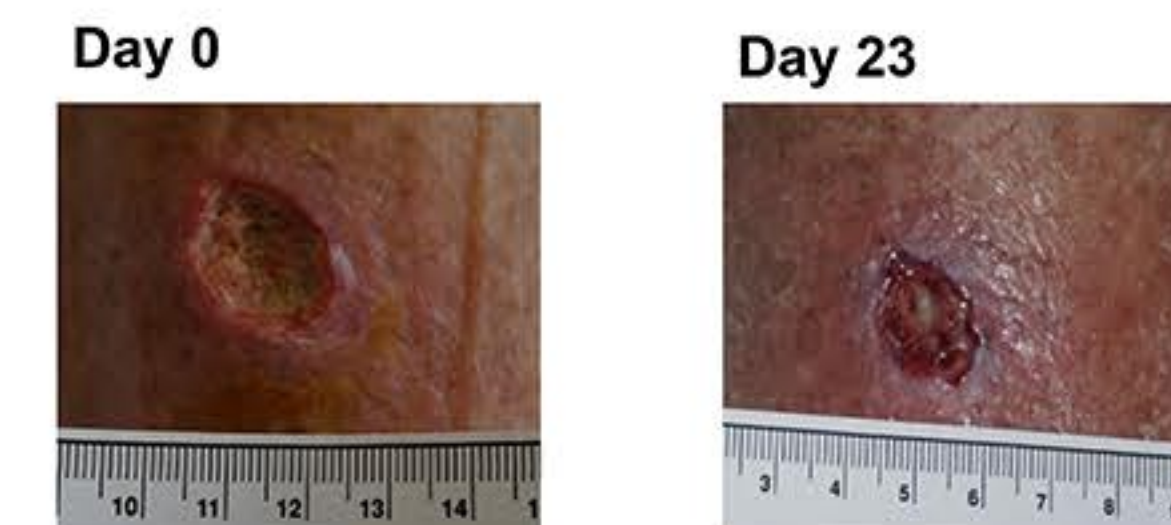
Post-op Pilonidal Cyst (non-healing for 37 days) on a 22 year old female patient. MicroLyte™ Ag applied 2-3 times per week with negative pressure wound therapy. >81% closure within 4 weeks.



Chronic non-pressure ulcer (non-healing for 44 days) on a 74 year old male patient. MicroLyte™ Ag applied once every week. >90% closure within 3 weeks.



Nonpressure Chronic Ulcer (non-healing for 73 days) on a 77 year old female patient. MicroLyte™ Ag applied once every week. Reduction in wound depth and inflammation, and improvement in new granulation tissue formation.



Venous Stasis Ulcer (non-healing for 360 days) on 58-year-old female. MicroLyte™ Ag applied once per week. >70% closure within 3 weeks.

