

Anionic Chelation: A New Dynamic in Wound Care



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Introduction/Background

Peripheral arterial related ulcers can frequently be recalcitrant to healing despite using optimal standards of care. Increasingly recognized for their ability to promote chronicity and inflammation, biofilms have received much more attention in standard wound care protocols in recent years. In this case report we herein report on the clinical efficacy of a new anti-biofilm agent (Fentonite® AgFresh® Hydrogel) that uses the body's inherent Fenton reaction combined with polymer micelles containing a unique antimicrobial agent.

Methods/Procedures

This 81 year old woman with a history of Peripheral arterial disease, congestive heart failure, and a prior mitral valve replacement had a wound infection and dehiscence subsequent to a right ankle fusion. Prior to presentation in July 2022 she had already undergone operative debridements, hyperbaric oxygen therapy, dermal skin replacements, and amniotic tissue implants without resolution of her four wounds. She was subsequently switched to the Iron/polymer/ preservative anti-biofilm gel as her only advanced therapy. Wounds were cleaned with application of the hydrogel three times per week.

Results

After three months two wounds completely resolved. Two wounds have reduced 60-70% in size and healthy viable tissue can now be seen over the entire area of each wound. Approximate total cost of office visits and product was \$7800, a fraction of the cost of the prior treatments.

Conclusions

This case report demonstrates the clinical benefits of using this unique non-cytoxic anti-biofilm agent to promote chronic wound healing in a complex patient with peripheral arterial disease post ankle fusion. Notably, a number of prior advanced therapies had been used unsuccessfully in managing these wounds. While having undergone extensive laboratory testing to support its effectiveness, further clinical studies with the chelating hydrogel are warranted to demonstrate its clinical efficacy.

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POSTER 1 OF 2

BACKGROUND

81 year old female patient with multiple chronic non-healing wounds for 6+ years.

PATIENT'S MEDICAL HISTORY

- · Cancer of left breast, stage 1, estrogen receptor positive
- Acute CHF (congestive heart failure) possibly diastolic
- Mitral valve replacement 2014 and 2021

- Neuropathy, toxic (HCC)
- · Osteoarthritis, localized, shoulder, right
- Hyperlipidemia

- Surgery right ankle fusion due to neuropathy
- Right ankle infection
- · 3 Skin grafts lower extremity with later failure of grafts

- · Split thickness graft right lower leg with later failure of grafts
- Congenital lymphedema

- PVD (peripheral vascular disease) (HCC)
- · Atherosclerosis of native artery of both lower extremities with intermittent claudication (HCC)
- · Varicose veins of left lower extremity with ulcer of ankle with fat layer exposed (HCC)

- Thigh shingles
- Bell's palsy

2020

- Open wound of right knee with artificial knee with complication, subsequent encounter
- Popliteal artery stenosis, right (HCC)
- Tibial artery stenosis, right (HCC)

2021

· Mitral valve replacement

- Acute respiratory failure with hypoxemia (HCC)
- Acute on chronic systolic CHF
- Multiple open Wounds in bilateral low ext
- Moderate protein-calorie malnutrition (HCC)
- Hypercholesterolemia
- S/P MVR (mitral valve replacement)
- UTI (urinary tract infection)
- Sepsis (HCC)
- Pacemaker implanted

CASE STUDY

8/28/22

9/29/22

Previous costs and treatments 2016 - July 2022 have included 1. Amniotic Tissue on at least three different occasions

- totaling a cost of over \$200,000.
- Dermal skin used on at least three occasions totaling lat east \$80,000.
- Hyperbaric chamber, Infliximab, Warton's jelly injections true relief treatments over \$120,000.
- Multiple operating room debridements costing over 200,000.
- 5. Weekly office visits over \$200,000

Approximate total: \$800,000.00

There was intermittent improvement between 2016 and the first half of 2022 using the previous treatments noted above. During the previous time of care the wounds continued to fail and increased in size.

New Treatment Protocol

The patient was changed to:

Thermoset Anti-biofilm Cleanse

AgFresh™ Wound Hydrogel 2-part suspension wound dressing

Results After Three Months of Treatment.

- 2. Two wounds have reduced 60-70% in size and healthy viable tissue can now be seen over the entire area of each wound.
- 3. Total product costs to date less than \$300.
- 4. Weekly office visits \$7,500.
- 5. Treatment will continue to full resolution of

remaining wounds. Approximate total: \$7,800.00

8/28/22

9/29/22





11/8/22

2/22/23



INVESTIGATORS

Michael Lavor, MD is Medical Director of Saguaro Wound Care Clinic. He served as Dept. Chairman for General and Vascular Surgery at Tucson Medical Center, and Chief of Surgery and Staff at El Dorado Hospital. He is weutral cetters, and challed to surgery and fellow in the American College of Surgeons. He's past president of the Rocky Mountain Vascular Surgical Society, a Fellow in the Southwestern Surgical Society, a Fellow in the Southwestern Surgical Commander/OKC of a surgical base in Afghanistan, 2012-2013.



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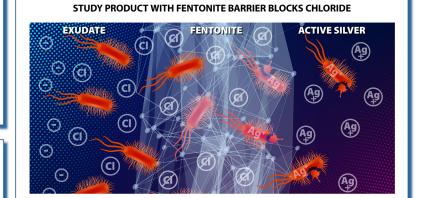
STUDY PRODUCT ANTIMICROBIAL TESTING FOR SELECT PATHOGENS Escherichia coli Streptococcus pyrogens Staphylococcus epidermis Candida albiancs Pseudomonas aeruginosa

AgFresh™ Technology

guarantees that wound care specialists are getting fresh, not aged, silver in every package. The two-compartment sachet separates the water-based hydrogel from the silver-Fentonite[™] proprietary blend. AgFresh[™] delivers fresh silver that is ready to fight infections with the full potency health care experts expect. If it doesn't say AgFresh™ then you may be getting "aged" silver.

Fentonite™

A proprietary blend of minerals and nutrients that cleanse and aid in the antimicrobial effectiveness of silver and other medicants.





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PRODUCT INFORMATION

PART NUMBER	NAME	SIZE	DESCRIPTION	CASE UPC	CARTON UPC	CARTON QTY	CASE QTY
MC601530B	BioRelese®	1oz	Wound and Burn Dressing	614409567851	614409567868	1 EA	24 CARTON
MC601550B	BioRelese®	1.7oz	Wound and Burn Dressing	614409567875	614409567882	1 EA	24 CARTON
MC601650B	BioClense™	1.7oz	Sprayable Wound and Burn Dressing	614409567899	614409567905	1 EA	24 CARTON
MC601670B	BioClense™	3oz	Sprayable Wound and Burn Dressing	614409567912	614409567929	1 EA	24 CARTON
MC603508S	AgFresh®	8mL	Silver Wound and Burn Dressing	614409567936	614409567943	5 EA	5 CARTON
MC603530S	AgFresh®	30mL	Silver Wound and Burn Dressing	614409567950	614409567967	5 EA	5 CARTON