Treatment od Diabetic Foot Ulcers and Post-Opertaive Wound Infections with Copper-Iodine Complex Solution as an Adjunct in Wound Bed Preparation: A Case Series of 5 Patients

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Introduction

Chronic wounds are a health problem and have devastating consequences for patients and contribute costs to healthcare systems, societies, and countries. The majority of chronic wounds are stalled in the inflammatory stage of wound healing due to a multitude of factor. Bioburden, infection, biofilms, poor vascularity, pressure, edema, and nutrition all cause the wound to stop its normal linear healing trajectory and remain in a chronic state. Debridement and irrigation are a gold standard to convert a chronic wound to an acute wound. Utilizing an adjunctive wound irrigation solution can significantly improve outcomes in the wound management process.

Copper-Iodine Complex Solution (CICS) is an FDA 510(k) cleared wound irrigation system. As an antimicrobial preservative in solution, CICS has a proven broad-spectrum antimicrobial activity against bacteria, fungi, yeast, and viruses without inducing resistance. CICS has demonstrated a 1-minute Time-Kill rate at 99.9999%, in vitro, for over 20 microorganisms. Additionally, CICS has demonstrated persistent antimicrobial activity for up to 72 hours.

CICS has been demonstrated to be non-cytotoxic, non-pyrogenic, non-irritating, and non-sensitizing to dermal tissue. CICS is intended for use by healthcare professionals for cleansing, irrigating, moistening, and debriding to remove wound debris from acute and chronic dermal lesions that are partial and full thickness wounds such as 1st and 2nd degree burns, stage I-IV pressure injuries, diabetic ulcers, stasis ulcers, abrasions and minor skin irritations, post-surgical wounds grafted and donor sites, in addition to moistening and lubricating absorbent wound dressings. CICS has been demonstrated to be non-cytotoxic, non-pyrogenic, non-irritating, and non-sensitizing to dermal tissue.

Free iodine (I_2), up to 250 ppm, acting in concert with copper ions, produces a synergistic effect that helps remove contamination within the solution and assists in the cleansing, irrigating, and debridement of wounds. Iodine, as a drug, penetrates the cell wall of microorganisms causing damage of the cell membrane and cell death. Copper binds to cell structures, permeates cell membrane and promotes membrane lipid destruction, leading to cell death. Copper also can disrupt the interface between the biofilm's extracellular polymeric substance (EPS) and allow for disruption of the attachment to the wound bed. Additionally, copper ions support angiogenesis and collagen synthesis in wound healing. This study evaluated its clinical effect on bioburden, odor, and pain control in chronic wounds of varying etiologies.

Materials and Methods

Five patients with full thickness wounds, both diabetic foot and or post-surgical wounds underwent debridement followed by irrigation and dwelling with CICS for primary and solo dressing for wound care. Each patient has their baseline visit and 2 subsequent visits for assessment. Patients or their caregivers changed the dressing once daily with CICS and covered with CICS moistened gauze only, no secondary dressing. At the baseline visit and 2 subsequent visits the following wound bed parameters were identified and recorded:

- Biofluorescent imaging (MolecuLight) pre and post debridement after 10 min CICS dwelling
- Wound dimensions (L x W x D)
- Exudate
- Odor
- Pain
- Granulation tissue
- pH

MolecuLight biofluorescence imaging

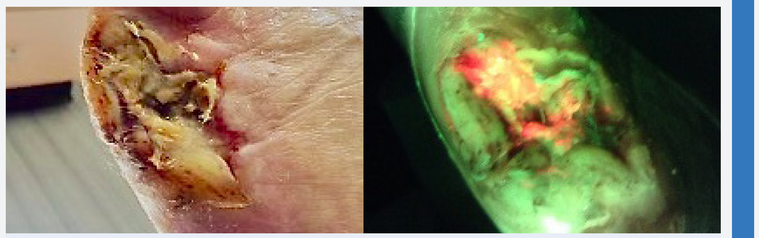
Bacteria is one of the components that could impair a normal wound healing process. If left unregulated could lead to infection at the ulceration and surrounding area. Bacteria at levels below $1x10^4$ CFU/g is classified as contamination or colonization, which interprets bioburden or bacteria that is not causing clinical issues and usually no major antimicrobial dressings are needed. However, if levels are equal or are over $1x10^4$ CFU/g, healing at the ulceration site due to bacteria can be impaired. If left unregulated, local or systemic infection can occur. MolecuLight, a device which is a noncontact fluorescence wound imaging device, is able to detect most bacteria at this critical inhibitory bacterial load (CIBL) or $1x10^4$ CRFU/g. Bacteria over this threshold of $1x10^4$ CFU/g is detected as a red hue or cyan fluorescence.

Results

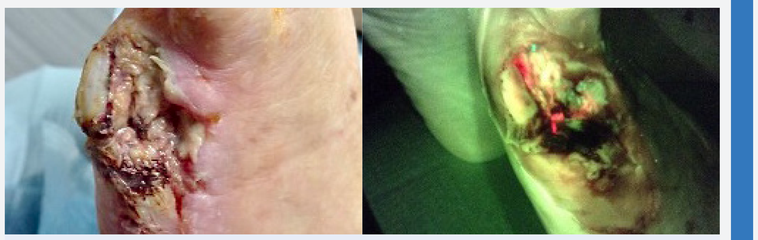
Of the five the 5 patients evaluated in this series (mean age 63 years), two presented with post-surgical wound infections and three with diabetic foot wounds. The group compromised both male and female patients with common comorbidities including diabetes mellitus, hypertension, peripheral neuropathy, and peripheral vascular disease. All of these comorbidities with their current wound bed environment contribute to the consistent inflammatory phase of the wound bed. Across all four patients, the mean wound volume reduction was 54% over a 3-week period. One patient, DFU of the hallux, achieved complete healing. Odor resolved in the wound bed by visit number two in all patients. Pain score was minimal, however, many of the patients presented with sensory neuropathy. Exudate was moderate in 3/5 patients initially and minimal at visit 2 and 3. Granulation tissue, while nonexistent or minimal in all patients at baseline visit, improved markedly by week 2 -3. Biofluorescent imaging was positive in all patients, 2 with Pseudomonas and 3 with other species at baseline, one maintained mild fluorescence at week two and all others were negative through week 3. Wound bed pH was measured with Hanna HI1271 instrument (Woonsocket, RI), pre and post debridement. All patients were noted to have an initial alkaline reading (mean 8.7) and post debridement, values 8.0 – 7.0). Subsequent week 2 and 3 ranged from pre debridement values of 8.0 – 7.2 and post debridement values of 7.3 – 6.4.

Results

Case 1: 68-year-old female with 5th toe amputation resulting in a chronic wound. Medical history is consistent with type 2 diabetes mellitus and hypertension.

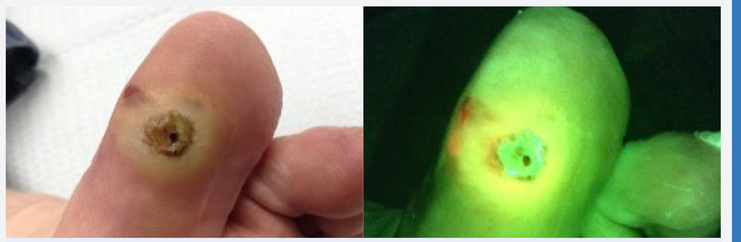


Pre debridement and MolecuLight image: note fluorescent imaging with red indicating >104 CFU/g in the wound bed



Post debridement followed by 10-minute CICS dwelling and MolecuLight image: note significant reduction of the red biofluorescence in the wound bed

Case 2: 56-year-old male with type 2 diabetes mellitus, peripheral neuropathy, and hypertension with ulceration of the hallux.



Pre debridement and MolecuLight image: note subcutaneous abscess and the MolecuLight demonstrating cyan florescence indicating Pseudomonas aeruginosa

Results

Case 2: 56-year-old male with type 2 diabetes mellitus, peripheral neuropathy, and hypertension with ulceration of the hallux.

Post debridement followed by 10-minute CICS dwelling and MolecuLight image: note the absence of cyan fluorescence and minimal red fluorescence remaining.

Conclusion

The utilization of CICS has demonstrated improvement in outcomes in the management of wound bed preparation as a dwelling antimicrobial preservative in solution and as a mechanical irrigant. The biofluorescent imaging has demonstrated significant decrease in bioburden in the wound bed over the three-week assessment. All factors evaluated in this evaluation trended to reset the chronic wound toward a linear, acute wound healing trajectory. CICS was well tolerated, reduced odor, bioburden, alkalinity, and exudate in the wound bed. Additionally, in this 3-week evaluation, increased granulation tissue was clearly noted in the wound bed. CICS represents a safe, effective, and well-tolerated adjunct in the treatment of chronic wound management. Further clinical studies are warranted to evaluate patient care initiatives for optimizing positive outcomes.