Conquering Chronic Non-Healing Wounds with Pure Hypochlorous Acid

John R. Crew, MD1, Randall Vanilla, RN, MSN1, Thomas Allandale Rocas III, RN, BSN, CWCN1, Dmitri Debabov, PhD2, Surianil Abdul Rani, MSc2, Lu Wang, PhD2, Ramin Najafi, PhD2, and Mark Anderson, PhD2

1 Wound Care Center, Seton Medical Center, 1900 Sullivan Avenue, Daly City, CA 94015
2 NovaBay Pharmaceuticals, Inc. 5980 Horton Street, Suite 550, Emeryville, CA 94608

Abstract

Chronic non-healing wounds are a persistent problem in many settings and are associated with a high incidence of infection, pain, and impaired function. NeutroPhase® is a 510(k) cleared self-preserved preparation of HOCl that has been shown to be effective in treating chronic non-healing wounds. This study explores the use of NeutroPhase® as a key agent in wound care and to address this serious unmet medical need. Pure 0.01% HOCl (NeutroPhase®) has been shown in a well-established chronic granulating wound rat model to be an effective topical antimicrobial and to have a potential application as an antimicrobial wound irrigation. NeutroPhase® is a 510(k) cleared self-preserved preparation of HOCl that has been shown to inactivate P. aeruginosa, E. coli, S. aureus, C. albicans and A. niger in solution. Using Sorbact as the wound mesh dressing in combination with NeutroPhase® as the irrigation solution assists in wound healing. NeutroPhase® is not toxic to living tissue.

Materials & Methods

For the Zone of inhibition assay, 100 µL of the formulations were applied every 15 min and removed before next application. Up to 4 treatments were completed over 1 hr. The clear parts represent "kill zones." A combination of NeutroPhase® (0.011% HOCl) as the irrigation solution and Sorbact® (Algo Medical AB, Åskem, Sweden) as the wound mesh dressing was used to treat patients with chronic non-healing wounds. Before treatment, the wound area was cleansed and the wound was debrided, then the skin was dried. Then Sorbact mesh was sized and placed in the wound. ABlake drain was placed in and on the Sorbact mesh. The adhesive drape was attached and placed over the entire area including the Sorbact mesh. The area around the tubing was sealed with Stomadhesive. The tubing was connected to a 510(k) cleared self-preserved irrigation system, hydrogen peroxide, acetic acid and povidone-iodine that remain in widespread use today. However, used at typical concentrations, these antiseptics can actually impede wound healing. We have more than 30 clinical case studies where we used NeutroPhase® with and without negative pressure wound therapy (NPWT) to assist in wound healing. Common pathogens observed in these chronic wounds include Staphylococcus aureus, S. epidermidis, P. aeruginosa, and Enterobacteriaceae. In our in vitro experiment, we also show that 0.01% pure HOCl is more active than sodium hypochlorite against S. aureus by a zone of inhibition assay. HOCl has been described as being 80-100 times more potent as a germicide than the hypochlorite anion (OCl⁻; high pH). NeutroPhase® is pure 0.01% hypochlorous acid (i.e. >97% relative molar distribution of active chlorine species as HOCl) in a 0.9% saline solution at pH 4.5 and NovaBay has an FDA cleared 510(k) for wound care. Our data show that there is a clear utility of the use of NeutroPhase® as a key agent in wound care and to address this serious unmet medical need.

Introduction

Chronic non-healing wounds have many factors contributing to the impairment of healing such as the presence of foreign bodies, tissue maceration, ischemia, infection, and biofilms. The clinical picture can be further complicated by systemic factors such as diabetes, malnutrition, renal disease, and advanced age. Therefore, chronic non-healing wounds are a clinical problem that for some is a serious unmet medical need. Pure 0.01% HOCl (NeutroPhase®) has been shown in a well-established chronic granulating wound rat model to be an effective topical antimicrobial and to have a potential application as an antimicrobial wound irrigation. NeutroPhase® is a 510(k) cleared self-preserved preparation of HOCl that has been shown to inactivate P. aeruginosa, E. coli, S. aureus, C. albicans and A. niger in solution. Using Sorbact as the wound mesh dressing in combination with NeutroPhase® as the irrigation solution assists in wound healing. NeutroPhase® is not toxic to living tissue.

Results

• The results demonstrate that NeutroPhase® is an important irrigation solution in treatment of chronic non-healing wounds.
• Sorbact helps reduce tissue maceration.
• NeutroPhase® in combination with Sorbact as the wound mesh dressing utilizing negative pressure wound therapy assists in wound healing.
• These case studies show NeutroPhase® in combination with Sorbact® has the potential to be a very effective wound care product for use in managing difficult to heal wounds.

Discussion

Chronic non-healing wounds have many factors contributing to the impairment of healing such as the presence of foreign bodies, tissue maceration, ischemia, infection, pressure and biofilm. The clinical picture can be further complicated by systemic factors such as diabetes, malnutrition, renal disease, and advanced age. Therefore chronic non-healing wounds impact the patient’s mortality and morbidity. Systemically administered antibiotics do not effectively decrease the level of bacteria or the associated biofilm in a chronic granulating wound. Topical antiseptics have a long history of use, such as sodium hypochlorite (Olvan’s solution), hydrogen peroxide, acetic acid and povidone-iodine that remain in widespread use today. However, used at typical concentrations, these antiseptics can actually impede wound healing. We have more than 30 clinical case studies where we used NeutroPhase® with and without negative pressure wound therapy (NPWT) to assist in wound healing. Common pathogens observed in these chronic wounds include Staphylococcus aureus, S. epidermidis, P. aeruginosa, and Enterobacteriaceae. In our in vitro experiment, we also show that 0.01% pure HOCl is more active than sodium hypochlorite against S. aureus by a zone of inhibition assay. HOCl has been described as being 80-100 times more potent as a germicide than the hypochlorite anion (OCl⁻; high pH). NeutroPhase® is pure 0.01% hypochlorous acid (i.e. >97% relative molar distribution of active chlorine species as HOCl) in a 0.9% saline solution at pH 4.5 and NovaBay has an FDA cleared 510(k) for wound care. Our data show that there is a clear utility of the use of NeutroPhase® as a key agent in wound care and to address this serious unmet medical need.

Conclusions

• NeutroPhase® formulation shows greater antimicrobial activity than Microcyn formulation in the Zone of Inhibition assay against S. aureus.
• The results demonstrate that NeutroPhase® is an important irrigation solution in treatment of chronic non-healing wounds.
• Sorbact helps reduce tissue maceration.
• NeutroPhase® in combination with Sorbact as the wound mesh dressing utilizing negative pressure wound therapy assists in wound healing.
• These case studies show NeutroPhase® in combination with Sorbact® has the potential to be a very effective wound care product for use in managing difficult to heal wounds.

References


Data source: NeutroPhase is a 510(k) cleared product for wound cleansing only and we are claiming only antimicrobial activity in solution.