Reducing Bioburden and Disrupting Hard to Remove Microbial Colonies with The Use of Pure Hypochlorous Acid (pHA)* to Reduce Bioburden in all Plastic Surgical Reconstruction

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BACKGROUND

Surgical reconstruction of chronic wounds using soft tissue flaps is a routine approach to achieve closure. Due to the poor tissue quality, longstanding inflammation, bioburden and impaired blood supply, the success of flap closure is marred by reported complication rates of 25-58%.

Pure Hypochlorous Acid (pHA*) Preserved Cleanser has been studied extensively in its ability to disrupt biofilms. Laboratory studies have shown that hypochlorous acid has the ability to mechanically disrupt 90% of microbial aggregates and colonies after just a short order of exposure

Pure Hypochlorous Acid (pHA*) Preserved Cleanser:
- pH range 3.5-5.5 is conducive to healing
- Average skin pH is 5.5
- Ideally combined with sharp debridement where possible for wounds with mature microbial colonies
- 5-8 min of pHA* solution contact with wound
- Treats 90%-95% of microbial colony organisms
- Interacts with organic matter in wound and dissipates in seconds, no residual toxicity concerns
- Safe to use with skin substitute grafts in same operative setting
- Rapid rate of bacterial removal with pHA* solution is seen (in vitro) [1]
- Chronic wounds and plastic surgical wound reconstructionis complicated by
- Microbial contamination, complex colony formation,pH disturbance from a mildly acidic range
- Basic science research has demonstrated efficacy of pure hypochlorous acid (pHA*) cleanser against microbes and complex colonies, as well as favorable effects on keratinocyte and fibroblast migration
- HOCl is a component of the innate immune response
- Aids pathogen killing via the neutrophil oxidative burst [2]

OBJECTIVE

We hypothesize that pHA Preserved Cleanser that has been utilized for wound cleansing may be beneficial for patients who undergo surgical wound reconstruction.

METHODS

- A retrospective review over a 20- month period
- 95 surgical reconstructive procedures
- 93 of 95 patients received pure Hypochlorous Acid (pHA) based cleanser that has a pH of 3.5 to 5.5, to help reduce the bacterial burden prior to closure.
- The two patients who did not were being treated for localized skin cancers that underwent resection and local flap closure as an outpatient procedure

Demographics:
- 95 patients (57 male 38 female))
- 93 patients: 60 pressure ulcers, 6 lower extremity wounds (venous stasis ulcers), 6 cancer resections, 6 abdominal wall reconstructions, 6 Hidraadenitis and or pilonidal disease, and 5 miscellaneous (autoimmune disease, TMA neuroma, and Morel-Lavallee lesion), and 4 with hardware exposed.
- 2 patients: Facial skin cancer underwent resection with local flap without use of pHA
- 1 Surgeon
- Hospitalist for medical management
- Infections Disease specialist for antibiotic management

RESULTS

- 93 surgical procedures were performed and treated with pHA to assist bacterial burden
- All patients received pHA soak and or irrigation intraoperatively. The HOCl was placed in a sterile container on the operative table. Following excisional debridement and pulse vac irrigation in those cases with significant debris, pHA was poured onto a lap sponge or 4x4 gauze, with the pHA soak intraoperatively for 10 min. We report no postoperative infections in all cases presented here.

Complications: 20%
- Incisional Dehiscence: 15 (13 Pressure ulcers 1 HA, 1 Abdominal wall)
- Seroma: 2
- Partial graft loss: 2
- Post op infection: 0

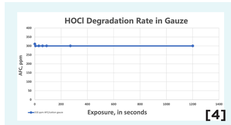
PROVEN EFFICACY ON PLANKTONIC GERMS

Bacteria die 3-6 logs, most with 5 logs minimum, within seconds of HOCl exposure.

Organism	Time to kill	% Reduction
MRSA	15 seconds	99.999%
VRE	15 seconds	99.999%
Escherichia coli	15 seconds	99.999%
Acinetobacter baumannii	15 seconds	99.999%
Bacteroides fragilis	15 seconds	99.999%
Candida albicans	15 seconds	99.999%
Enterobacter aerogenes	15 seconds	99.999%
Enterococcus faecium	15 seconds	99.999%
Haemophilus influenzae	15 seconds	99.999%
Klebsiella oxytoca	15 seconds	99.999%
Klebsiella pneumoniae	15 seconds	99.999%

Organism	Time to kill	% Reduction
Micrococcus luteus	15 seconds	99.999%
Proteus mirabilis	15 seconds	99.999%
Pseudomonas aeruginosa	15 seconds	99.999%
Serratia marcescens	15 seconds	99.999%
Staphylococcus epidermidis	15 seconds	99.999%
Staphylococcus haemolyticus	15 seconds	99.999%
Staphylococcus hominis	15 seconds	99.999%
Staphylococcus saprophyticus	15 seconds	99.999%
Streptococcus pyogenes	15 seconds	99.999%
Staphylococcus aureus	15 seconds	99.995%
C. difficile endospores	15 seconds	99.93%

[3]



[4]

HOCL BEHAVIOR IN GAUZE AND TISSUE

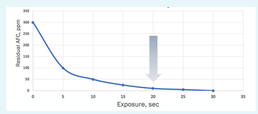
How much HOCl should be poured onto standard 4x4 gauze and packing to achieve maximal effect? HOCl is 100% Stable for 20 mins in Saturated Gauze or Gauze that is dripping with the HOCl cleanser.

IF BACTERIA DIE WITHIN SECONDS, WHY SOAK FOR 5-10 MINUTES? AS THEY MAY BE PRESENT IN MORE DIFFICULT TO ELIMINATE COLONIES

Soaking for 5-10 minutes allows time to kill bacteria in more realistic 3-D conditions, like in a wound, and break down polysaccharides and proteins.

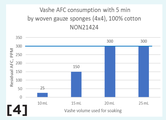
HOCL SAFETY PROFILE IS DUE TO RAPID BIODEGRADATION AT THE WOUND/GAUZE INTERFACE

HOCl is rapidly consumed in direct contact with tissue protein.



THE RIGHT AMOUNT OF HOCL IN 4X4 GAUZE FOR SOAKING 5-8 MINUTES

The ideal amount of HOCl in a 4x4-inch gauze is ~30 ml (or ~1 oz); less than that means losing HOCl concentration in the gauze in 5 min. It is advised to soak gauze "till dripping" to reach this level of HOCl liquid presence in gauze.



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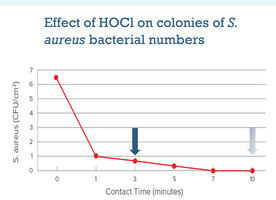
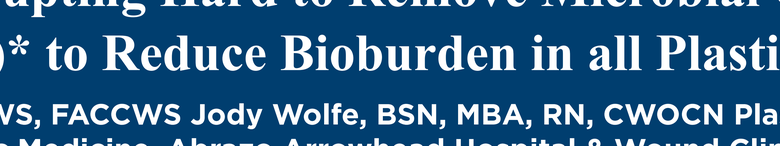


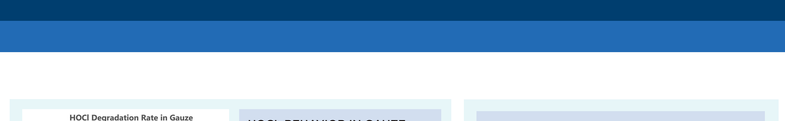
[5]

CASE 1

86 year old female with h/o venous insufficiency followed by local wound physician for venous leg ulcers. Presents for surgical treatment including operative debridement and staged STSG.
Medical history: HTN, Breast cancer, Lupus
Treatment:
- Admitted for staged debridement and control of bioburden with Fluorescence bacterial monitoring
- Initial Imaging with significant bacterial burden
- Received NPWTi-d Therapy with pHA for wound bed preparation for 72 hours
- Intraoperatively, pHA utilized as 10-minute soak
- STSG performed with placement of placental allograft to optimize healing.
- NPWT continued with to recipient site and donor site.



SIGNIFICANT BIOBURDEN ON INITIAL PRESENTATION | DEBRIDEMENT PERFORMED FOLLOWED BY NPW-TI-D, PHA | 72 HOURS FOLLOWING NPWTI-D

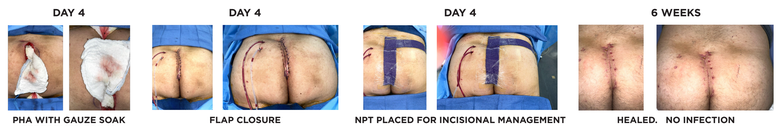


PHA WITH GAUZE SOAK PERFORMED FOR 10 MINUTES PRIOR TO STSG | POST PHA SOAK | STSG PLACEMENT WITH PLACENTAL ALLOGRAFT | 3 WEEKS S/P STSG PLACEMENT. NO INFECTION

CASE 2

24 year old male s/p previous surgery for pilonidal disease, now with recurrent disease.
Medical history: Healthy
Treatment:
- Taken to OR for surgical excision and flap closure
- Intraoperatively, pHA utilized as 10-minute soak
- Placental Allograft placed to optimize healing
- Porcine Allograft used for deep tissue scaffolding
- NPT Therapy initiated for incisional management immediately following closure

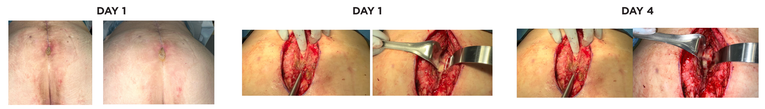
PILONIDAL SINUS TRACT AT PRESENTATION | EXCISION PERFORMED WITH ELLIPTICAL EXCISION | EXCISION TO THE LEVEL OF PERISOSTEUM



PHA WITH GAUZE SOAK PERFORMED FOR 10 MINUTES PRIOR TO CLOSURE | FLAP CLOSURE | NPT PLACED FOR INCISIONAL MANAGEMENT | HEALED. NO INFECTION

CASE 3

74 yo female s/p spine surgery complicated by PE requiring antigoagulation that resulted in hematoma and secondary dehiscence.
Medical history: DVT, PE (On anticoagualants)
Treatment:
- Taken to OR for surgical closure with finding of deep tissue abscess.
- Underwent drainage of abscess and debridements.
- Intraoperatively, pHA utilized as 10-minute soak
- NPWTi-d initiated with pHA
- Returned to OR 72 hours for definitive surgical closure.
- Intraoperatively, pHA utilized as 10-minute soak
- Placental Allograft placed to optimize healing
- NPT initiated for incisional management immediately following closure



PURULENCE ON INITIAL PRESENTATION | PURLENCE INVOLVING DEEP TISSUE | DEBRIDEMENT PERFORMED FOLLOWING DRAINAGE OF ABSCESS

PHA WITH GAUZE SOAK PERFORMED FOR 10 MINUTES FOLLOWED BY NPWTI-D | 72 HOURS FOLLOWING NPWTI-D | PHA WITH GAUZE SOAK PERFORMED FOR 10 MINUTES PRIOR TO CLOSURE

NPT PLACED FOR INCISIONAL MANAGEMENT | HEALED. NO INFECTION

CONCLUSIONS

pHA Preserved Cleanser that has been utilized wound cleansing may be beneficial for patients who undergo surgical wound reconstruction.

pHA utilized intraoperatively as a 5-10-minute soak may help reduce bacterial burden and may reduce the risk of postoperative infection.

pHA seems to be compatible with the use of biological matrices used to promote wound healing such as human dermal matrix and amniotic grafts.

We believe there may be a role for pHA to remove biorburden, necrotic tissue, and associated debris to lead to infection free in patients undergoing surgical wound reconstuction.

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*Pure Hypochlorous Acid Preserved Cleanser
*Vashe Wound Solution, Urgo Medical North America

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