

A PURE HYPOCHLOROUS ACID (pHA) PRESERVED CLEANSER DOES NOT NEED TO BE RINSED FROM WOUNDS POST APPLICATION: WHAT IS THE CHEMISTRY BEHIND THAT OBSERVATION?

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A commonly used cleanser utilizes pure Hypochlorous Acid (pHA) as an antimicrobial preservative for safe use and storage and consists of a hypotonic saline solution with 300 ppm of hypochlorous acid (HOCl) when manufactured, with a shelf life of 18 months. Hypochlorous acid is a rapid broad-spectrum biocide (1) with an important physiological role in homeostasis and disease. For example, it is present as the primary antimicrobial within the phagosomes of immune cells which eliminate microbes that enter tissue.

Experiments demonstrate that hypochlorous acid solution at concentrations up to 1200 ppm is non-toxic to cells, and in fact its presence at physiological concentrations (approximately 300 ppm) may stimulate proliferation of fibroblasts and keratinocytes (1, 2). In an important clinical study, the direct comparison of ultrasound irrigation with hypochlorous acid versus saline for wound debridement/cleansing demonstrated significantly reduced bacterial count in the wound bed with the hypochlorous acid-based cleanser compared to saline. The use of the hypochlorous acid-based cleanser also showed statistically significant higher success in definitive primary wound closure (3) procedures post cleansing. Other clinical studies in invasive procedures show the benefit from the use of hypochlorous acid preserved solutions (4). It is worth asking whether applications of such specialized cleansers require a post rinse with water or saline.

Topical solutions that are specifically used for removal of germs from wounds are often described as antiseptics, though most of them are more correctly defined in a regulatory sense as wound devices, in the form of solutions that contain antimicrobial preservatives to allow safe use and storage of the product (5).

Several important guidelines do recommend the use of such cleansers, as opposed to soap/water/saline for regular use. Clinicians prefer to use these specialized cleansers in the management of wounds that show signs of infection, contain slough/necrotic tissue, or are visibly contaminated with debris, in particular fecal material usually associated with sacral pressure ulcers (6) or abdominal wounds.

Examples of wound cleansers containing antimicrobial preservatives are presented in Table 1. Depending on the nature of the chemical ingredients in these cleansers, an additional step of rinsing with normal saline is recommended for some of these products. While for others, it is not required, and this has implications in saving time and resources over the long course of wound healing. Experimental results from preliminary work on tissue dissipation of hypochlorous acid from a commonly used cleanser that contains HOCl is presented.

METHOD

Commercially bought lean porcine flesh was used as a wound model in our study. We created a “wound” or a hole in the tissue measuring 5 X 5 cm, then poured into it excess amount (10 ml allowing it overflow above the hole) of the pHA based cleanser (280 ppm HOCl at source. We then used a HOCl measurement strip (an Active Free Chlorine or AFC strip) to determine whether HOCl dissipates in -situ post application by exposing the testing strips within 5 seconds intervals to the cleanser applied surface.

RESULTS

We observed significant drop in HOCl ppm numbers within first 5 seconds of solution exposure, (Figure 1 shows the rapid reduction of AFC over time in our experiment). Essentially, no AFC could be determined after 30 seconds. This supports previous literature on the work done with HOCl in general, but this is the first experiment that is described with the commercial HOCl containing product.

DISCUSSION

The requirement to rinse with saline/water post the usage of some antimicrobially preserved cleansers is likely driven by the consequences of the antimicrobial ingredients if left the wound. Some antimicrobial preservative ingredients, for example, if not rinsed away post use, cause

- (1) Irritation or stinging
- (2) Prolonged (residual) antimicrobial preservative ingredient presence in the wound bed, likely resulting in cytotoxicity
- (3) An undesirable pH shift in the wound bed from the desired mildly acidic pH to, a highly acidic or highly alkaline pH. We know that the desirable pH range for a wound is around 3-6 (7, 8), therefore for example, use of Dakin's solution (pH above 9), or indeed any solution containing hypochlorite, can cause the wound pH to potentially drift, transiently or over time, to a level that necessitates time consuming rinsing to bring the wound back to a more reasonable lower pH.

In contrast to some other long lasting and “sticky to tissue” and reportedly cytotoxic antimicrobial ingredients (such as PHMB, iodine, or chlorhexidine) whose bioclearance pathways from tissue is not well understood, hypochlorous acid based formulations appear to achieve the goals of rapid germ removal from the wound bed (a 5-10 minutes soak seems to suffice in wounds that contain biofilms), without any cytotoxicity, or any observed lingering issues seen when the wounds are not rinsed post cleansing.

There are reasons based in published chemistry on the subject of hypochlorous acid that explain our reported findings with an actual commercial product that contain this antimicrobial preservative. Specifically, rapid reactions of oxidation, or protein chlorination with the hypochlorous acid results in quick dissipation/biodegradation of the molecule in the wound post introduction as an ingredient in a cleanser. Other published work in this area discusses the fate of hypochlorous acid in tissue, and we did not need to repeat those experiments in our model. In essence, use of a hypochlorous acid based cleanser on the wound leaves only residual hypotonic saline on the treated surface as the hypochlorous acid dissipates in the presence of tissue and other organic matter within a matter of seconds (Fig. 1).

Additionally, no discoloration or denaturation of protein has been observed in the presence of excess amount of HOCl solution (Fig 2). The biggest difference in wash dressings containing hypochlorous acid in comparison to the other solutions is in its safety profile and the absence of rinse recommendation is in line with this generally safe nature of the product as evidenced by numerous published clinical studies that report no adverse events. It helps that hypochlorous acid is a naturally occurring antimicrobial in human physiology.

Some rinsing requirements are related to the strength of the cleansing solution used. For the commonly used full strength Dakin's solution application, a final rinse with saline is required, however, in case of diluted product no rinse with saline seems to be necessary but should still be done due to an abundance of caution, as even 5 ppm of the hypochlorite has been found to be cytotoxic.

We prove both via a description of the background and literature on the subject, and on the basis of simple experimentation that products based on the pHA technology, does not need rinsing. More research is needed to augment these findings.

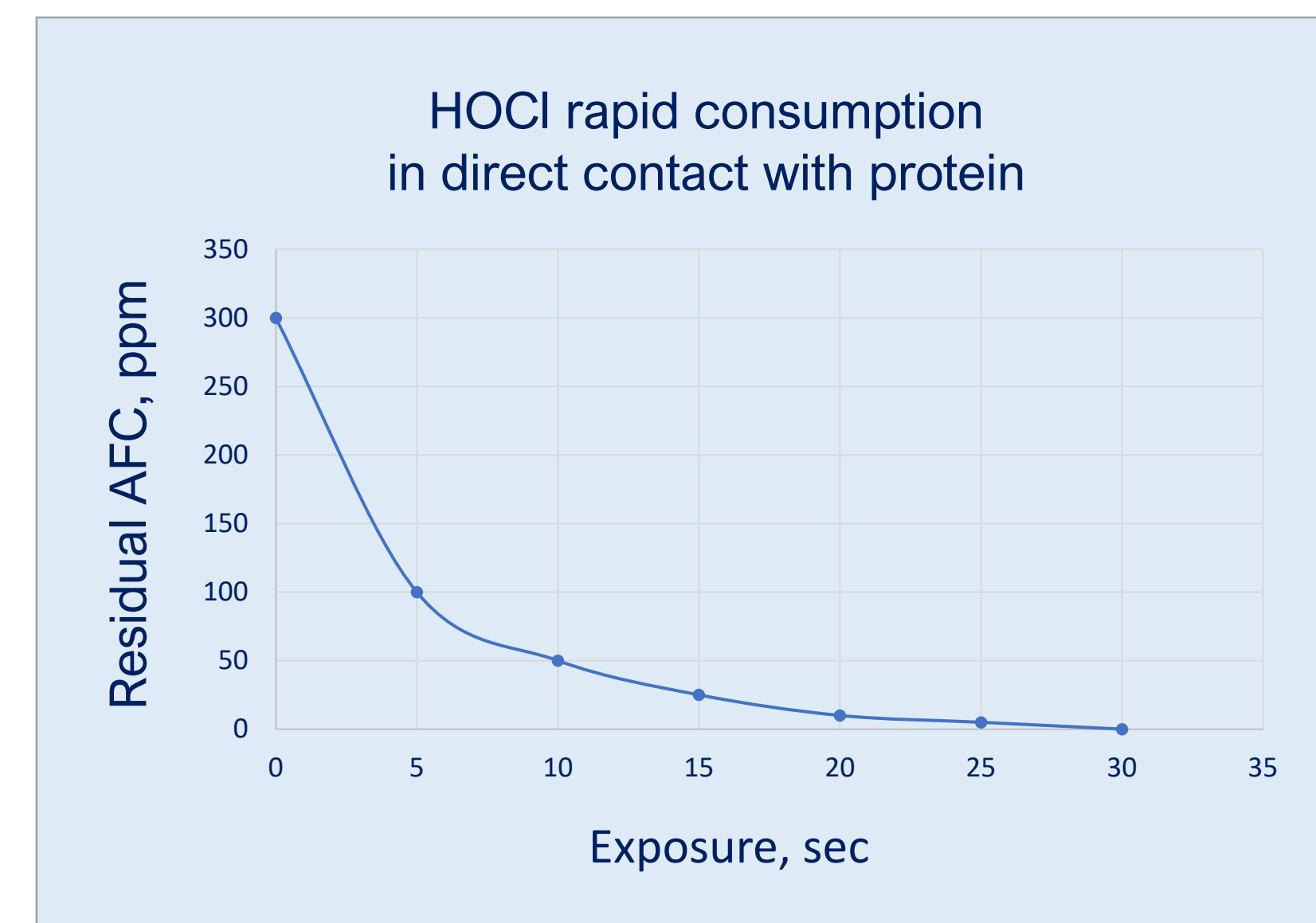
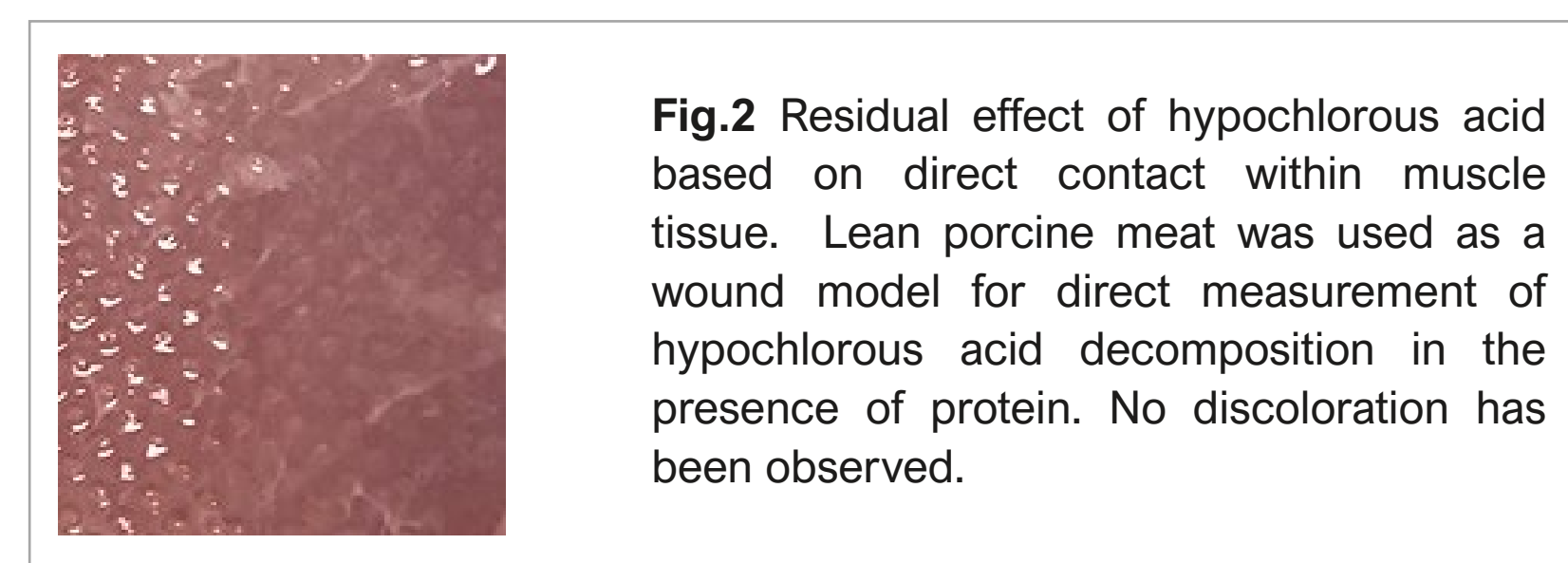


Fig 1 Direct measurement of HOCl degradation in contact with protein based on lean pork meat wound model.



WASH SOLUTION	ANTIMICROBIAL PRESERVATIVES	INDICATION LIMITATIONS	REQUIREMENT FOR RINSING
Bactisure (9)	Ethanol and Acetic acid	Not indicated for use during dressing changes or for use by soaking the product into dressings. Not recommended for pediatric	Immediate rinse with an equal amount of normal saline
Prontosan (10)	PHMB	Not recommended for patients with known allergy to betaine and PHMB; Not recommended on the eyes, central nervous system or meninges or on hyaline cartilage surgery	No rinse recommended after Prontosan application. Product can be applied by cleansing with product saturated gauze
Irrisept (119)	CHG	Not recommended if patient is allergic to chlorhexidine gluconate. Keep away from eyes and ear canals.	Rinse with normal saline for irrigation is required after approximately one minute of Irrisept application.
Surgiphor (12)	PVP-I (povidone – iodine)	May cause a temp irritation and burning sensation on exposed skin; Allergic reactions, such as rash and irritation. Risk of anaphylaxis in case of severe iodine allergy. Note for use with neonates	Rinse with normal saline is required
Dakin's (13, 14)	Sodium Hypochlorite Buffered to pH 10	Cytotoxic @ 0.5% or 5000 ppm - Full Strength Cytotoxic @ 0.25% or 2500 ppm - Half Strength Cytotoxic @ 0.125 % or 1250 ppm - Quarter Strength (14)	Never apply diluted bleach directly to the skin without buffering it first (15)
Vashe (1,3,5,15)	Hypochlorous acid	Not recommended for patient with known allergy to hypochlorous acid	No rinse recommended. Can be applied with product saturated gauze

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