# HPA lanolin and its ability to protect the nipple when breastfeeding: Evidence from a novel clinical model of breastfeeding

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# Background

The causes of nipple trauma during breastfeeding are complex and varied, and it is difficult to generate conclusive data on efficacy of any treatment due to confounding factors inherent in the study population.

# Objectives

- 1. Establish a reproducible and robust model to mimic the damage to skin which is often experienced during breastfeeding.
- 2. Assess the effect of HPA (Highly Purified Anhydrous) lanolin\* on compromised skin.
- 3. Investigate the benefit of pre-treating skin with HPA lanolin prior to the onset of skin damage.

## Method

- 30 participants had experimentally induced skin damage on their inner forearms. Tape stripping was used to reduce barrier function by 20%, and a repeat moisture insult was administered 3 times per day to simulate the impact of a moisture challenge during repeated breastfeeding.
- Four separate test sites were treated as shown in Fig. 1, with two sites (A and B) being treated with the test product HPA lanolin 3 times per day.
- Clinical assessments of erythema and scaling were measured, along with instrumental measures of erythema, skin moisturisation and skin barrier function at eight time points (day -7, day 0 pre & post damage, day 1 - 4 and finally on day 7).

each test site

# Results

### A model of wet repeat insult skin damage

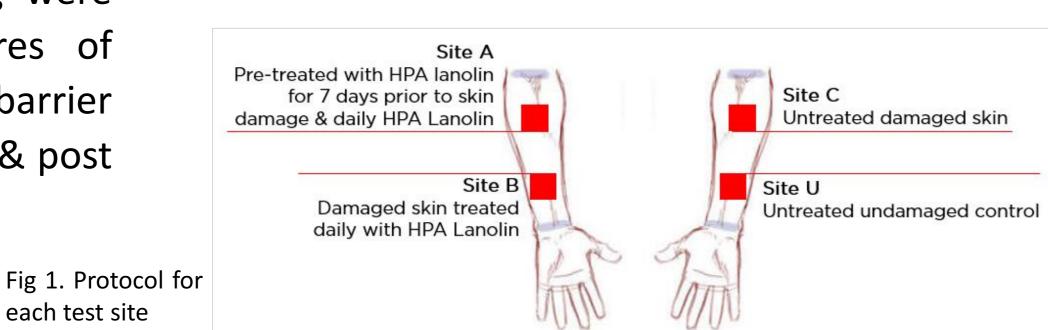
All three instrumental measures of skin biophysical properties (erythema, transepidermal water loss and moisturization) were significantly impacted by the damage protocol, evidenced by the clinical observations; Code C site (damaged, untreated) showed a grade 2 erythema and the highest cumulative erythema and scaling scores.

#### **HPA Lanolin and skin barrier function**

Barrier damage, induced by the repeat insult model, was significantly higher on areas not pre-treated characterized lanolin; by increased transepidermal water loss (TEWL) measurements (Fig 2). At day 7, there was no statistically significant difference between site B and the control site Uindicating that the damaged skin treated daily with had similar barrier function to the undamaged control site.

#### **HPA Lanolin and skin moisturization**

Moisturization levels increased for site A from day -7 to day 0, whereas levels at site C decreased during this time (Fig. 3). Analysis of the differences at both sites indicated these changes were statistically significant (p = 0.001). Moisturization levels numerically higher site A, demonstrating that pre-treatment with HPA lanolin reduced the impact that skin damage has on moisturization levels.

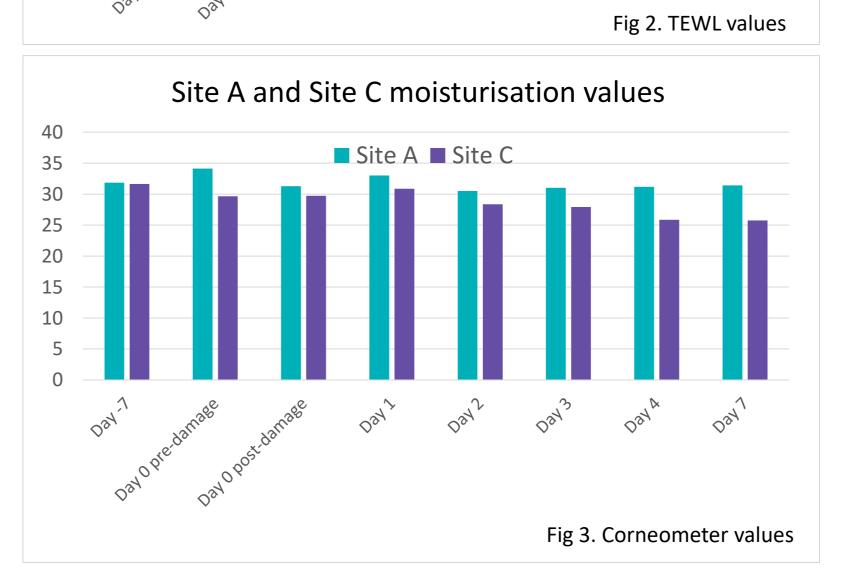


## Discussion

All skin bio-measurements showed changes consistent with low level skin damage. The degree of damage induced was intended to be moderate, and mimic the cumulative damage that is likely to occur through the mechanical and moisture driven challenges that breast skin experiences upon repeated feeding. It should be noted that while the forearm was considered to be acceptably representative, the skin of the nipple has some differences to normal epidermis which should be considered when interpreting the results.

Pre-treatment with HPA lanolin for 7 days was found to significantly increase moisturization of the skin, and maintain this moisturization following induced skin damage, compared to the untreated site. Sites pre-treated with HPA lanolin also maintained equivalent barrier function to the control site upon exposure to repeat insult.

This data indicates that HPA lanolin can provide benefits to the skin both before and during induced skin damage. When applied to skin, HPA lanolin forms an occlusive layer, protecting the skin from further damage and positively impacting the local skin environment. These properties, combined the fact its purity means it does not need to be removed prior to nursing, make it a valuable tool to support a mother's breastfeeding journey.



TEWL values from day -7 to day 7

Site A Site B Site C Site U

# Conclusion

We present here a novel clinical model which reliably simulates the repeat insult, moisture challenges and friction of the breastfeeding infant in a reproducible and clinically relevant way. The model was used to demonstrate that use of HPA Lanolin before and during a period of repeated skin insult protected the skin. As such, HPA lanolin may be clinically useful for nursing mothers to prepare the skin prior to breastfeeding and for continued use during the breastfeeding period to improve breastfeeding experience.

\*Lanolin Nipple Cream, Lansinoh Laboratories