LANSINOH CLINICAL RESEARCH REPORT

A Novel Clinical Model for Breastfeeding Concludes HPA® Lanolin Protects the Nipple when Breastfeeding

Katie Bourdillon, PhD., Tom McCausland MA, Stephanie Jones MSc. Lansinoh Laboratories, Leeds, UK

Summary

Lanolin's emollient and hydrating properties have provided many generations of breastfeeding mothers soothing relief to sore, cracked nipples. Its emollient and hydrating properties are well evidenced.

This novel research demonstrated that Lansinoh HPA® lanolin replenished the essential lipids of the skin, repairing the skin's natural barrier function, simultaneously moisturizing, protecting and conditioning the skin.

Whilst positioning and attachment are paramount to enable, pain-free effective breastfeeding, mothers may find it helpful to use HPA® lanolin to prepare and protect their nipples, immediately prior to, or during breastfeeding.

INTRODUCTION

The causes of nipple soreness during breastfeeding are complex and varied.

It is difficult to generate conclusive independent research to provide effective solutions due to many different factors related to this study population.

OBJECTIVES

1. To 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 low level skin damage.

METHODS

Thirty healthy participants had experimentally induced skin damage on their inner forearms using the following method:

- Tape Stripping - used to reduce barrier function.
- Repeat moisture insult** administered 3 times per day, from Day 0 to Day 7, to simulate the impact of repeated moisture challenge experienced during regular breastfeeding.

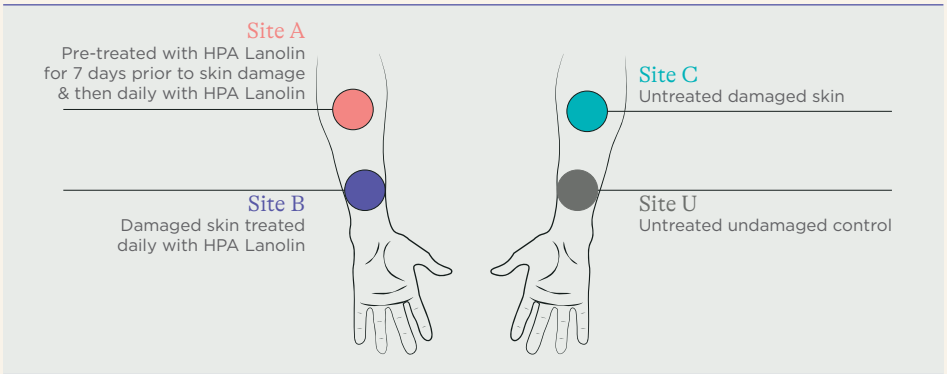

Figure 1. Four separate sites tested.

Four separate test sites were treated as shown in *Fig. 1.*

- **Site A**

  From Day -7 to Day 0, participants applied HPA® lanolin 3 times per day prior to initial skin damage.

  On Day 0, skin damage was induced using tape stripping and moisture insult.

  Moisture insult continued daily from Day 0 to Day 7.

  HPA® lanolin continued to be applied from Day 0 to Day 7.

- **Site B**

  From Day -7 to Day 0, no HPA® lanolin was applied prior to initial skin damage.

  On Day 0, skin damage was induced using tape stripping and moisture insult.

  Moisture insult continued daily from Day 0 to Day 7.

  HPA® lanolin was applied from Day 0 to Day 7.

- **Site C**

  On Day 0, skin damage was induced using tape stripping and moisture insult.

  Moisture insult continued daily from Day 0 to Day 7.

  HPA® lanolin was not applied to the site at any time.

- **Site U**

  As the control site, no skin damage was induced and no lanolin applied.

** Lansinoh HPA® Lanolin, ** (1% aqueous sodium lauryl sulphate solution (SLS solution)*

IMPACT ON SKIN

To determine the impact on skin, assessments of skin irritation, scaling, skin moisturisation and skin barrier function were measured at eight time points:

Day -7, Day 0 - pre & post damage, Day 1-4, Day 7.

RESULTS

A model of wet repeat insult skin damage

Three instrumental measures of skin biophysical properties (skin irritation, Trans-Epidermal Water Loss (TEWL) and moisturization) were significantly impacted by the Sodium Lauryl Sulphate (SLS) damage protocol.

Skin irritation exposed to the SLS protocol was observed in 23 participants (77%). Only one recorded instance of skin irritation was recorded in control site (Site U).

Increased rates of scaling were observed for SLS exposed test sites compared to the control site. This was supported by a significant increase in mean value.

There was a significant increase in trans-epidermal water loss in the SLS treated sites A & B, compared with the control, while skin moisturization levels decreased.

These results suggest the SLS protocol reproducibly induced cumulative damage to the skin.

HPA® LANOLIN PROTECTED SKIN BARRIER FUNCTION

Barrier damage, induced by the repeat insult model, was significantly higher on areas not pre-treated with lanolin (sites C & U); characterized by increased trans epidermal water loss (TEWL) measurements (Fig 2).

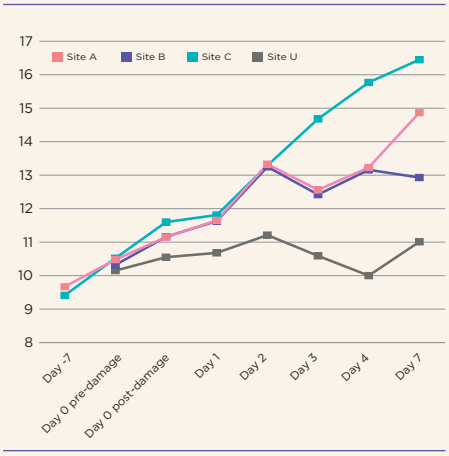

Figure 2. TEWL values from day -7 to day 7

At day 7, there was no statistically significant difference between site B and the control site - indicating that the damaged skin treated daily with lanolin had similar barrier function to the undamaged control site.

HPA® LANOLIN IMPROVED 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).

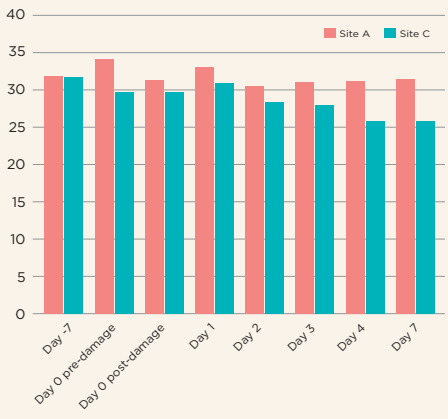

Figure 3. Site A & Site C moisturisation values

Analysis of the differences at both sites indicated these changes were statistically significant ($p = 0.001$).

Moisturization levels remained numerically higher at site A, demonstrating that pre-treatment with HPA® lanolin reduced the impact that skin damage has on moisturization levels.

CONCLUSION

- 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 likely to occur through the mechanical and moisture driven challenges that breast skin experiences upon repeated feeding.
- Pre-treatment with HPA® lanolin for 7 days prior to skin damage increased moisturization of the skin.
- This moisturization was maintained 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.

Source:
Bourdillon K, McCausland T, Jones S. HPA® lanolin and its ability to protect the nipple when breastfeeding: Evidence from a novel clinical model of breastfeeding. Poster presented at Royal College of Obstetricians and Gynaecologists World Congress. 2022 June 13-17: London. UK.

Key Points

Many mothers can experience sore cracked nipples due to the friction and repeated suction from an infant when breastfeeding.

- Keeping sore, cracked nipples moisturized can soothe and protect the skin, enabling mothers to continue to breastfeed while the cause of the nipple soreness is being addressed.
- Using this novel simulated model, the data presented here shows Lansinoh HPA® lanolin replenished the essential lipids of the skin, repairing the skin's natural barrier whilst simultaneously moisturizing, protecting and conditioning the skin.

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