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A 1% Colloidal Oat Balm was More Effective than a Standard Lotion in Protecting and Moisturizing the Skin Barrier in an *Ex Vivo* and Clinical Model

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Introduction & Objectives

The *stratum corneum* of infant skin is thinner and loses moisture quicker than adult skin, while the pH buffering capacity of the skin is still developing[3]. If their moisture barrier is not maintained, an infant's skin can become vulnerable to external allergens penetrating the *stratum corneum*, which can increase the risk of sensitization and subsequent development of atopic disease. One way of fortifying and strengthening the skin barrier is by using an appropriate moisturizing emollient. Moisturizers come in many different forms with various benefits and ingredients. Past research has shown a thick, emollient rich balm with colloidal oat helps hydrate the skin barrier. Few studies have evaluated whether this formulation can fortify the skin barrier by forming a protective barrier on baby's skin to help seal in moisture and reduce allergen penetration. A 1% colloidal oat balm (COB) was hypothesized to show superior efficacy compared to a standard lotion (SL) in improving skin parameters including pH, hydration, barrier function, and visual dryness in two different study designs.

Materials & Methods

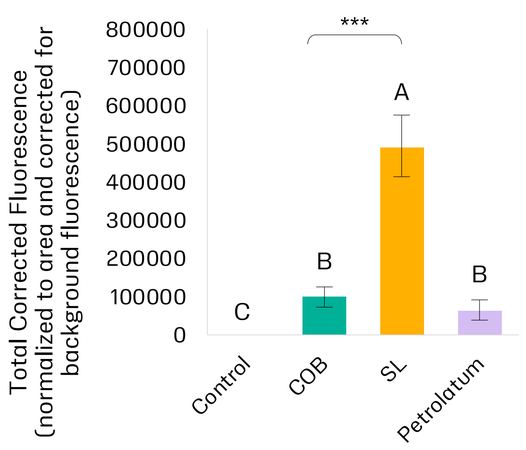
In Study A, an *ex vivo* model with adult skin (age 40) that underwent tape stripping to mimic infant skin evaluated a COB, a SL, and petrolatum for efficacy in preventing penetration of soy peptide (SP) and house dust mite allergen (HDM).

Study B was a 48-hour moisturization clinical study conducted on females with dry skin (n=58, ages 18-65 years old) to compare the efficacy of the COB to the SL and a cream. Instrumental measurements of skin capacitance, conductance (hydration), trans-epidermal water loss (TEWL), and clinical grading evaluations of visual dryness and tactile surface roughness were assessed over the course of 48 hours after a single application of product.

Results

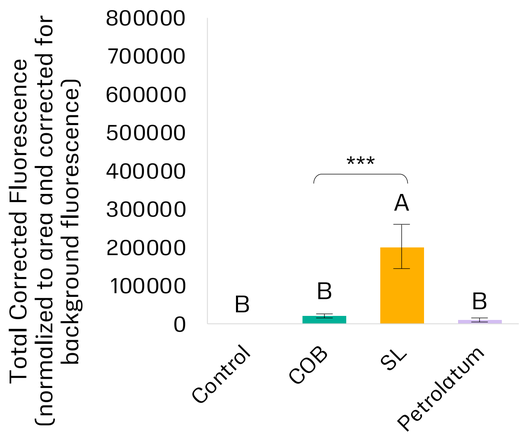
The SL allowed a statistically significantly greater amount of SP ($p<0.05$) (Fig. 1) and HDM ($p<0.001$) (Fig. 2) to penetrate the stratum corneum compared to the COB. When analyzing skin samples treated without the SP or HDM, the COB exhibited the most substantial reduction in skin surface pH, compared to the SL (Fig. 3).

Figure 1. Skin Penetration of 1% Tagged Soy Peptide



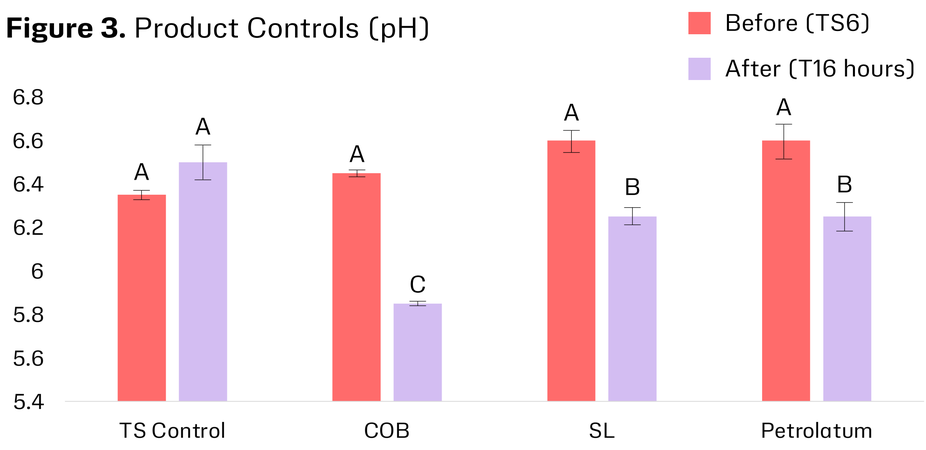
Total corrected fluorescence calculated from fluorescence microscopy images of skin samples treated for 16 hours with COB, SL and Petrolatum containing 1% of tagged soy peptides compared to untreated skin sample ontrol) after 16 hours of incubation in Franz diffusion cells. Total intensity normalized to the area and corrected for any background fluorescence using formula TCF = Integrated density - (area of ROI x Mean Background Intensity), where the values were obtained from ImageJ analysis of each fluorescence image. The bar graph is representative of mean TCF from 6 images ‡ SEM. One-way ANOVA statistical analyses with Tukey's Post hoc test were conducted using GraphPad PRISM; treatments not connected by the same letter are statistically different ($p<0.001$)

Figure 2. Skin Penetration of 0.1% Tagged Der p2 HDM Allergen



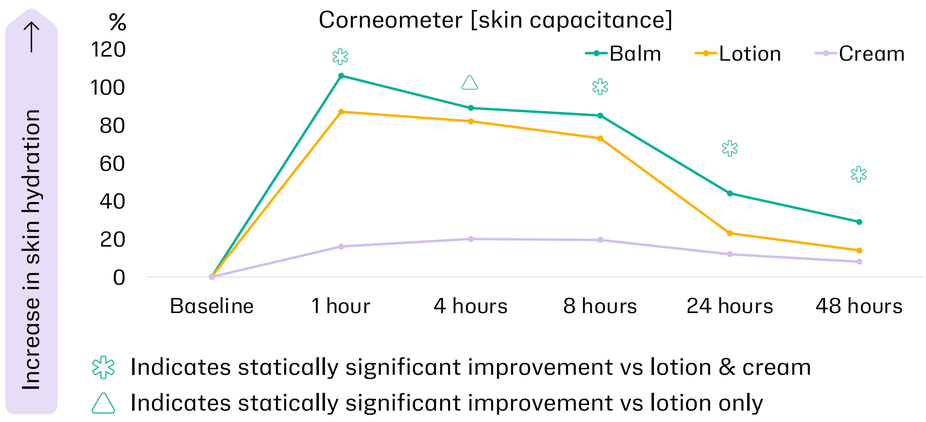
Total corrected fluorescence calculated from fluorescence microscopy images of skin samples treated for 16 hours with COB, SL and Petrolatum containing 0.1% of tagged der p2 allergen compared to untreated skin sample (control) after 16 hours of incubation in Franz diffusion cells. Total intensity normalized to the area and corrected for any background fluorescence using formula TCF = Integrated density - (area of ROI x Mean Background Intensity), where the values were obtained from ImageJ analysis of each fluorescence image. The bar graph is representative of mean TCF from 6 images ‡ SEM. One-way ANOVA statistical analyses with Tukey's Post hoc test were conducted using GraphPad PRISM; treatments not connected by the same letter are statistically different

Figure 3. Product Controls (pH)



pH measurement at the skin surface obtained before treatment (T0) and after incubation with treatment for 16 hours (T16) with no SP or HDM

Figure 4. Percent (%) increase in skin hydration through corneometer measurements compared to baseline



There was a statistically significant improvement in skin hydration for all formulations; however, the COB showed the greatest improvement (Fig. 4). When compared to the SL and cream, the COB had statically significant improvement in moisturization of 4x more and up to 2x more moisturizing respectively (Fig. 5).

All formulas showed statistically significant improvement in trans-epidermal water loss with the COB having a greater improvement compared to the SL. This indicated the COB had better and long-lasting improvement in skin barrier function. The COB also had statistically significant improvement in visual dryness when compared to the SL at 1 hour and in surface roughness, respectively. This confirms the COB formula acts as a protective layer fortifying the skin barrier by reducing trans-epidermal water loss and minimizes dry-skin related symptoms such as visual dryness and surface roughness.

Figure 5. Mean change in moisturization from baseline of the lotion compared to the balm at 1, 4, 8, 24, and 48 hours.

Timepoint	Balm	Lotion	Balm vs Lotion (x times more moisturizing)
1 hr	31.9	4.5	7x
4 hr	27.0	5.6	5x
8 hr	25.8	5.6	5x
24 hr	13.2	3.6	4x
48 hr	8.8	2.0	5x

Conclusion

The findings of both studies demonstrate novel multifunction benefits of a 1% colloidal oat balm (COB), especially when compared to a standard lotion (SL), resulting in an elevated class of complex emollients for newborns and infants.

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