

# Rapid Improvement and Protective Effects of an Almond Oil-Based Ointment for Diaper Dermatitis

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## ABSTRACT

**Introduction and Objectives:** Newborns and babies are at risk of developing diaper dermatitis due to constant occlusion and exposure to irritants such as urine and feces. The aim of this study was to evaluate the clinical effectiveness of an almond oil-based ointment on diaper dermatitis in infants.

**Material and Methods:** A multicenter open-label trial of 60 infants (1-36 months) with a known history of recurrent diaper dermatitis was performed. The infants were clear at the time of enrollment. Inclusion criteria was a minimum of 3 episodes of rashes in the diaper area in the four weeks prior to enrollment. The almond oil-based ointment was used daily after each diaper change over 28 days, and data was recorded by the users (persons who applied the product) with daily report logs for the study duration including presence of diaper dermatitis, severity, as well as reports of teething and/or diarrhea. During each visit, a clinical evaluation was performed by an assessor (dermatologist or pediatrician) recording the degree of erythema, skin dryness, skin roughness to the touch, and skin suppleness using a scoring scale from 0 (null) to 9 (very severe). The users also performed an evaluation on product effectiveness and cosmetic qualities.

**Results:** Clinical evaluations showed no erythema, a significant decrease ( $P < 0.01$ ) in skin dryness, roughness, and a significant increase ( $P < 0.01$ ) in skin suppleness after 28 days of product application compared to initial state. During the course of the study, 90% of the subjects showed a decrease in frequency or total absence of diaper dermatitis. One-hundred percent of users rated the product to have a pleasant texture, a good protective effect, spreads easily, and does not irritate the skin. The scent was judged as pleasant by 95%, and for 75% of those applying the product, the texture was described as non-oily.

**Conclusions:** For newborns and infants regularly developing diaper dermatitis, the almond oil-based ointment appears to confer a protective effect from future episodes of diaper dermatitis, improves dryness and suppleness of skin, and is cosmetically acceptable by the users.

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## INTRODUCTION

Diaper dermatitis (DD) is a term used by clinicians to describe a wide range of inflammatory processes that occur in the diaper area.<sup>1</sup> DD is probably the most common cutaneous disorder in infancy and early childhood and is thought to account for nearly 20% of childhood dermatology visits and in up to 25% of children.<sup>1,2,3</sup>

There are a number of causes of DD including candida infections, allergic reactions, seborrheic dermatitis, bacterial infections, and rarer conditions such as zinc deficiency and Langerhans cell histiocytosis, but the most common cause by far is irritant dermatitis, fueled by contact with urine and feces.<sup>4</sup>

The Berg model of diaper dermatitis outlines the pathophysiology of irritant contact dermatitis in the diaper area and consists of the following contributing factors:

1. Increased moisture in the diaper area created by the occlusive effect of the diaper combined with the presence of feces and urine

2. Maceration of the skin and disruption of the skin barrier due to friction within the skin folds in the area
3. pH imbalance from the proteases and lipases found within feces as well as with bathing products
4. This elevated (more basic) pH results in abnormal skin flora, which in turn makes the skin more susceptible to infection by bacteria and fungus.<sup>5</sup>

Barrier creams, ointments, and pastes are often the first line treatments for DD and attempt to provide a water-repellent emollient or protective ointment to the skin.<sup>6</sup> The rationale for using a barrier cream or paste in the treatment or prevention of diaper dermatitis is that a thick occlusive cream or paste will help protect the skin from the increased moisture in the environment and thus support epidermal barrier function. While diaper care procedures aim to support skin barrier function, little is known about the effect of diaper creams on skin barrier function in infants. A study in 2014 investigated the skin barrier

function of diapered and non-diapered skin areas affected by DD in healthy infants and found that areas with DD had higher TEWL and skin pH than unaffected skin areas. Moreover, infants treated with diaper cream had lower TEWL and, interestingly, lower stratum corneum hydration, which may demonstrate protection against maceration.<sup>7</sup>

The aim of this study was to evaluate the clinical effectiveness and cosmetic acceptability of an almond oil- and soybean oil-based ointment on DD in children with recurrent irritant diaper dermatitis.

Almond oil has been used for its numerous health and beauty benefits since ancient times, with many traditions utilizing almond oil to treat dry skin conditions such as psoriasis and eczema, improve skin complexion, and promote soft healthy skin.<sup>8</sup> Almond oil remains sought-after for its rich concentration of oleic and linoleic essential fatty acids, and is used in the cosmetic industry for its penetrating, moisturizing, and restructuring properties.

Almond oil is a non-toxic, non-irritating, nonsensitizing and non-comedogenic, readily emulsifiable ester, which possesses some of the following properties and attributes:

- Imparts a dry lubricating feel in the presence of large amounts of mineral oil or petrolatum
- Superior solubiliser of lipophilic cosmetic raw materials
- High positive spreading coefficient
- Wetting agent and auxiliary suspending agent for water insoluble powdered products
- Stable to hydrolysis within a wide pH range of about 2–12.

There is theoretical concern for allergic potential as it is derived from a tree nut, however, only 1 known case of IgE sensitization is reported.<sup>9</sup>

Glycine Soja Oil (Soybean Oil) is derived from the seeds of the soya plant *Glycine max*. Soy extracts can be found in many cosmetic products, as numerous biologically active compounds have been identified in soybean.<sup>10</sup> Lipids, lecthins, and phytosterols enhance the skin barrier, while isoflavones impart an antioxidant effect.<sup>11</sup> In vitro studies have shown that soybean extracts stimulate collagen synthesis, initiate the elastin repair process, inhibit melanosome transfer, and have antioxidant/anti-inflammatory action; these properties reflected in the clinical benefits of topical soy formulations: anti-inflammatory, moisturizing, photorejuvenation/photoprotection, amelioration of fine lines, and skin lightening/brightening.<sup>10</sup>

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## METHODS

This was a multicenter open-label trial of 60 infants and children (1 to 36 months) with a known history of recurrent mild-to-moderate diaper dermatitis. The investigator group comprised 8 dermatologists and 2 pediatricians.

Inclusion criteria was a minimum of 3 episodes of rashes in the diaper area in the four weeks prior to enrollment but subjects were clear at the time of enrollment. The almond oil-based ointment was used daily after each diaper change over 28 days, and data was recorded by the users (person who applied the product) with daily report logs for the study duration including presence of diaper dermatitis, severity, as well as reports of teething and/or diarrhea. During each visit, a clinical evaluation was performed by an assessor (dermatologist or pediatrician) recording the degree of erythema, skin dryness, skin roughness to the touch, and skin suppleness using a scoring scale from 0 (null) to 9 (very severe). The users also performed an evaluation on product effectiveness and cosmetic qualities.

## RESULTS

All 60 subjects completed the study. Fifty-three percent were female and forty-seven percent were male. The subjects' age ranged from 33 days to 3 years with an average of 11.1 months. The average number of diaper dermatitis episodes was 4.1 and the average duration for the study was 30 days. An average of 6.3 applications of the ointment per day was recorded (Table 1).

Clinical evaluations showed no erythema, a significant decrease ( $P<0.01$ ) in skin dryness, roughness, and a significant increase ( $P<0.01$ ) in skin suppleness after 28 days of product

TABLE 1.

Inclusion Environment Context (60 subjects)			
4 Weeks Prior to Inclusion in the Study	No	+/- SD	Avg No of Applications
Diaper changes per 24 hours	1856	3 - 12	7
Diaper rashes during prior 4 weeks	2561	1 - 14	4.1
Diaper dashes total duration (in days)	3527		4.5
Diaper rashes average intensity	0.596		1.5
Subjects' Distribution by Intensity	Population		Population %
Light	32		53%
Moderate	25		42%
Important	3		5%

TABLE 2.

## Average Clinical Scoring (60 subjects; Comparison with initial state)

Diaper Dermatitis	Visit 1, Day 0 (Avg)	Visit 2, Day 28 (Avg)	Deviation Day 0	Significance
Erythema	0	0	0	N/A
Skin Dryness	2.2	0.6	-1.6	$P<0.01$
Skin Roughness to Touch	2	0	-1.6	$P<0.01$

application compared to initial state. During the course of the study, 90% of the subjects showed a decrease in frequency or total absence of diaper dermatitis (Table 2 and Figure 1).

The product was well-tolerated with no adverse effects reported during the study.

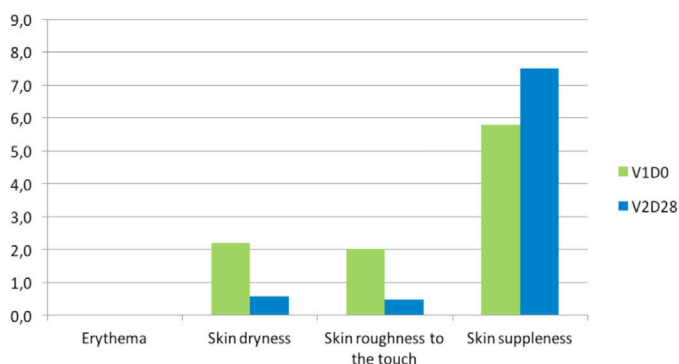
The statistical analysis used the Wilcoxon's test for paired series, for the intragroup evaluations comparison: the statistical treatment consists in determining if there is a significant difference between the individual data collected for the different evaluation times.

### Wilcoxon's Test (two paired samples)

The Wilcoxon's test is a non parametric test allowing the comparison between two paired samples, in this case between the initial report at day 0 and the final report after day 28 (Table 3).

The secondary endpoint was cosmetic acceptability and user perception of the product. One-hundred percent of users rated the product to have a pleasant texture, a good protective effect, spreads easily and does not irritate the skin. The scent was judged as pleasant (95%), and for 75% of those applying, the product texture was described as non-oily. Ease of use was notable for 100% of respondents reporting that "the product acts gently", while 93% of respondents reported "the product ensures a daily protection against the diaper rash" (Table 4).

**FIGURE 1.** Graph of average clinical scoring evolutions in comparison with the initial state (60 subjects).



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The analysis of the daily report logs concerns the occurrence of diaper rash episodes with an intensity scoring, and the reporting of teething or diarrhea. The results show, each week, a steady decrease of the number of teething (from 109 to 57), of diarrhea (from 23 to 5), and of diaper rash episodes (from 68 to 18). Similarly, concerning the declared diaper rash intensity, the average decreases from 0.6 to 0.1. Furthermore, the subjects' distribution by intensity level shows an increase of the population in the weakest level (null intensity: from 52% to 88% of the subjects) and a decrease of the population in the moderate level (from 12% to 3%). These results support the evidence of the product's protective effect.

An analysis of the preventive effect on the diaper rashes has also been carried out by comparison of the initial data "without product application" (ie, 4-week period prior to inclusion) with the final data "with product application" (after the 4-week application period). The results show a decrease of the cumulative number of episodes, observed on the 60 subjects sample (from 248 to 83), a decrease of the episode frequency (from 4.1 to 1.4), and a decrease of the average diaper rash intensity (from 1.5 to 0.7).

The statistical comparison of the final state compared with the initial state confirms these performances were trending toward significance with a significant difference ( $P<1\%$ ) in favor of the product.

TABLE 3.

## Perception Rates for Cosmetic Qualities (60 subjects)

Quotations	Favorable	Unfavorable	Undecided
The product has a pleasant texture	100%	0%	0%
The product has a pleasant scent	95%	5%	0%
The product has a good covering power	100%	0%	0%
The product does not irritate the skin	100%	0%	0%

### DISCUSSION

The purpose of this multicenter open-label trial was to determine frequency and severity of diaper rash and the effectiveness and cosmetic acceptability of an almond oil-based topical product.

**TABLE 4.****Analysis of Diaper Rashes Occurred (60 subjects)**

During the 4 Prior Weeks (preventative care)	Visit 1, Day 0 (without application)	Visit 2, Day 28 (with application)
Cumulated Number of Episodes for The 60 subjects sample	248	83
Episodes frequency	4.1	1.4
Diaper rash intensity	1.5	0.7
Subjects Distribution by Intensity Level		
Null	0 (0%)	21 (35%)
Light	32 (53%)	32 (53%)
Moderate	25 (42%)	6 (10%)
Important	3 (5%)	0 (0%)
Missing data	0 (0%)	1 (2%)

Compared to the initial state of the infants DD, the results indicated that the almond oil-based topical product was effective.

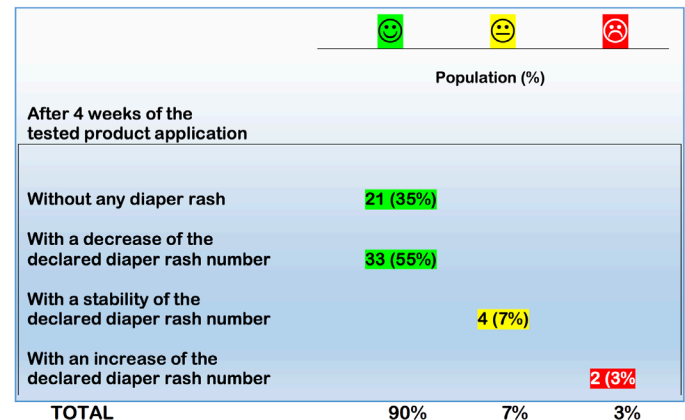
There are many types of barrier preparations available for both the prevention and treatment of DD. These may contain petroleum jelly, zinc oxide, dimethicone, and/or other occlusants and protectants. Some studies have shown that certain preparations are effective in treating DD,<sup>12</sup> while others have not found an effect of diaper creams on the frequency or severity of DD.<sup>13</sup>

## CONCLUSION

Newborns and infants frequently develop dermatitis in the diaper region and this likely reflects an impaired skin barrier in this area.<sup>14</sup> Supportive measures have been shown to restore the skin barrier, decreasing transepidermal water loss,<sup>7</sup> but literature reviews fail to identify a superior preparation for this task.<sup>15</sup>

In the present study, the almond oil-based ointment appeared to confer a protective effect against future episodes of diaper dermatitis, with 90% of the subjects showing a decrease in frequency or total absence of diaper dermatitis after using the ointment. In addition to this important finding, the significant decrease ( $P<0.01$ ) in skin dryness and roughness, as well as the significant increase ( $P<0.01$ ) in suppleness of skin, bolster the notion that barrier repair and maintenance are at play.

Correspondingly, the users also evaluated the product effectiveness according to 5 items. The results show that 100% of the users estimate that the product leaves the skin soft and hydrated. Ninety-eight percent also report that product efficiently protects the baby's bottom, and ninety-seven percent reported that the product leaves the skin more supple.

**FIGURE 2.** Subject distribution according to the evolution of the declared diaper rash number at day 28 (60 subjects).

The cosmetic aspects were judged and found that 100% of the users felt that the product does not irritate the skin, that its texture is pleasant, and that it was able to coat the skin well. The scent was judged as pleasant by 95% of users, while 75% reported that the product texture was not oily.

In sum, 97% of the users judged the product as overall satisfactory and 88% indicated they would purchase it.

The assessors have also evaluated the product. The obtained results show that for all the examined cases, both dermatologists and pediatricians felt that the product respects the skin hydration. Ninety-five percent of assessors reported that the product reduces diaper rash intensity and frequency.

Overall, these results support the efficacy of the diaper ointment for mild to moderate DD, making it a suitable choice for protective care against DD, in particular for children with a predilection to frequent dermatitis in the diaper area.

## DISCLOSURES

Dr. Lio has served as a consultant/advisor and speaker for Valeant, Regeneron/Sanofi, and Pierre Fabre. He has served as a consultant/advisor for Anacor, AO Biome, Exeltis, Galderma, Johnson & Johnson, Theraplex, and Mission, and has received an honorarium for his work on this supplement sponsored by Galderma.

## REFERENCES

1. Wolf R. et al., Diaper Dermatitis. *Clin Dermatol.* 2000;18:657-660.
2. Klunk C, et al. An update on diaper dermatitis. *Clin Dermatol.* 2014;32:477-487.
3. Ward DB, Fleischer AB Jr, Feldman SR et al. Characterization of diaper dermatitis in the United States. *Arch Pediatr Adolesc Med.* 2000; 154:943-946.
4. Coughlin CC, Eichenfield LF, Frieden IJ. Diaper dermatitis: clinical characteristics and differential diagnosis. *Pediatr Dermatol.* 2014; 31 (Suppl 1):19-24. doi: 10.1111/pde.12500.
5. Berg RW. Etiology and pathophysiology of diaper dermatitis. *Adv Dermatol.* 1998; 3:75-98.

6. Humphrey S, Bergman JN, Au S. Practical management strategies for diaper dermatitis. *Skin Therapy Lett.* 2006;11:1-6.
7. Garcia Bartels N, Lünemann L, Stroux A, Kottner J, et al. Effect of diaper cream and wet wipes on skin barrier properties in infants: a prospective randomized controlled trial. *Pediatr Dermatol.* 2014; 31:683-691.
8. Ahmad Z. The uses and properties of almond oil. *Complement Ther Clin Pract.* 2010;16:10-12.
9. Guillet G, Guillet MH. Percutaneous sensitization to almond oil in infancy and study of ointments in 27 children with food allergy. *Allerg Immunol (Paris).* 2000; 32:309-311.
10. Leyden J, et al. Natural options for the management of hyperpigmentation. *JEADV.* 2011; 25:1140-1145.
11. Bowe W, et al. Cosmetic Benefits of Natural Ingredients. *J Drugs Dermatol.* 2014; 13:1021-1025.
12. Rowe J, Mc Call E, Kent B. Clinical effectiveness of barrier preparations in the prevention and treatment of nappy dermatitis in infants and preschool children of nappy age. *Int J Evid Based Healthc.* 2008; 6:3-23.
13. Ersoy-Evans S, Akinci H, Doğan S, Atakan N. Diaper Dermatitis: A Review of 63 Children. *Pediatr Dermatol.* 2016; 33:332-336.
14. Visscher MO, Chatterjee R, Munson KA et al. Changes in diapered and nondiapered infant skin over the first month of life. *Pediatr Dermatol.* 2000; 17:45-51.
15. Blume-Peytavi U, Hauser M, Lünemann L, et al. Prevention of diaper dermatitis in infants—a literature review. *Pediatr Dermatol.* 2014; 31:413-429.

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