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REVIEW ARTICLE

Is colloidal oat an effective emollient ingredient for the prevention and treatment of atopic dermatitis in infants?

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ABSTRACT

Background: Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by barrier dysfunction and immune dysregulation, often leading to increased allergen penetration, sensitization, and secondary infections. Colloidal oat emollients are widely used in adult AD management, but their role in pediatric AD treatment, prevention, and allergy modulation remains under investigation.

Methods: A comprehensive literature review evaluated clinical and preclinical studies on colloidal oat-containing emollients in pediatric AD treatment and prevention. Studies assessing skin barrier function, immune modulation, AD prevention, food allergy risk, and healthcare utilization were included.

Results: Colloidal oat emollients improved skin hydration, reduced transepidermal water loss (TEWL), and supported barrier repair, leading to fewer AD flares and reduced reliance on steroid treatments. Studies suggest that early, consistent use of advanced emollient formulations may lower AD incidence in high-risk infants and reduce food sensitization rates. Real-world data indicate that patients using colloidal oat emollients have fewer clinic visits and lower overall healthcare costs. Concerns about oat sensitization remain unsubstantiated in most studies.

Conclusion: Colloidal oat emollients are effective, well-tolerated, and cost-efficient for pediatric AD management. Their barrier-restorative and anti-inflammatory properties may reduce AD and allergy risk. Future research should focus on head-to-head emollient comparisons to optimize treatment strategies.

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Introduction

A healthy skin barrier protects the body from environmental insults and regulates moisture levels through a coordinated network of cellular and molecular components. The outermost layer of the epidermis, the stratum corneum, consists of tightly packed corneocytes embedded in a lipid matrix composed of ceramides, cholesterol, and free fatty acids (1). This 'brick-and-mortar' structure is crucial for reducing transepidermal water loss (TEWL) to maintain skin hydration (1,2).

Filaggrin is a key structural protein that aggregates keratin filaments and later breaks down into peptides, amino acids, and key natural moisturizing factors (NMFs) components, including trans-urocanic acid and pyrrolidone carboxylic acid (3,4). NMFs help retain water in the stratum corneum, maintain an acidic pH, and support enzymatic activity in keratinocytes, which enhance skin softness and flexibility while preventing dry skin and itching (5,6). Filaggrin and NMFs are crucial to the skin's barrier function, protecting against environmental insults, allergens, and microbial invasion by maintaining an acidic, high-salt, dry, and aerobic surface environment. The skin barrier is also supported by sebum and intercellular lipids that complement NMFs in preserving skin moisture and resilience (7–9). Additionally, NMF components such as urea regulate genes involved with skin hydration, differentiation, and lipid metabolism (10). By acting as humectants, NMFs attract water into the corneocytes causing them to swell, which prevents gaps from forming between them (11). This produces a resilient skin barrier that prevents the penetration of irritants and allergens (Figure 1) (12).

Changes in the filaggrin gene can reduce NMF levels, leading to dehydration, barrier defects, and increased susceptibility to environmental insults (13–15). Deficiencies in NMFs are associated with skin conditions including psoriasis, atopic dermatitis (AD), and ichthyosis vulgaris (16). AD in particular is an inflammatory skin condition triggered by the penetration of irritants and allergens that interact with the immune system following the breakdown of the skin barrier and is increasingly common in infants (17,18). AD is the initiating step in the march toward progressive allergy, potentially progressing

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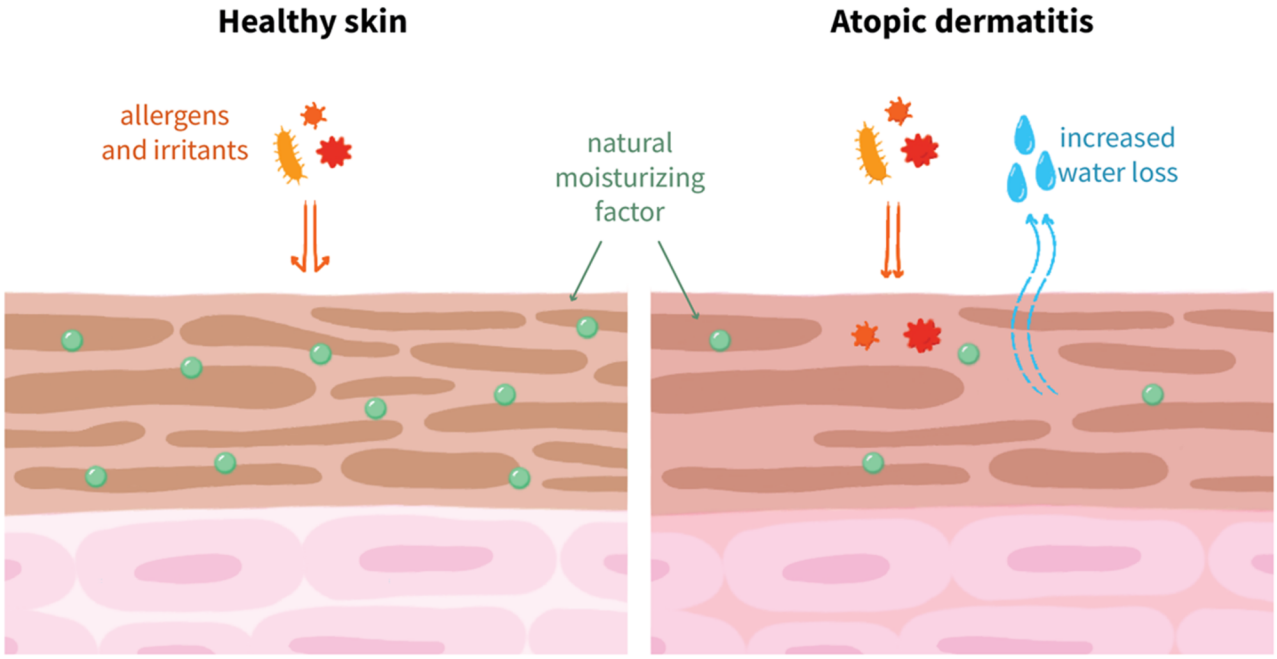

Figure 1. Comparing healthy skin barrier and compromised skin barrier in AD. In healthy skin, the stratum corneum remains intact, with tightly packed corneocytes embedded in a structured lipid matrix. NMFs and intercellular lipids maintain hydration and prevent TEWL. The skin's slightly acidic pH (4.5–5.5) supports enzymatic activity and inhibits the colonization of pathogenic bacteria. In AD, the skin barrier is disrupted, leading to increased TEWL, dehydration, and impaired lipid composition. Gaps between corneocytes allow penetration of allergens, irritants, and microbes, triggering immune activation. Elevated skin pH (~7.3–7.4 in lesional areas) enhances protease activity, leading to further barrier degradation.

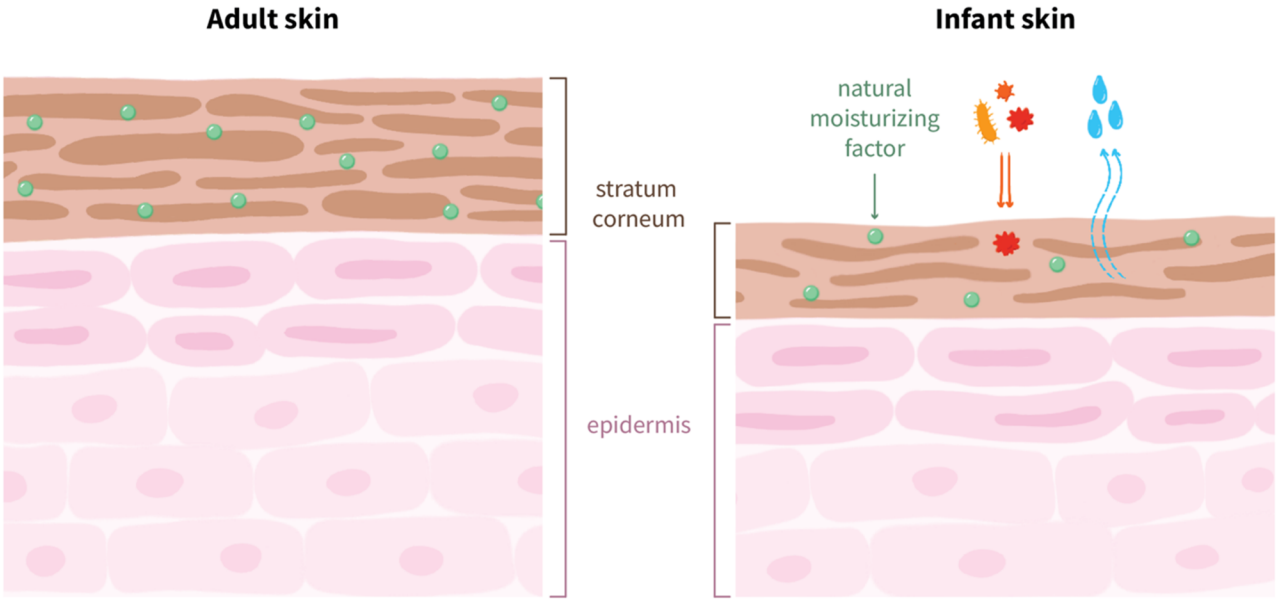

Figure 2. Key structural and physiological differences between infant and adult skin. Adult skin has a fully developed barrier, optimal pH (~4.5–5.5), and well-regulated NMFs, providing enhanced hydration, resilience, and immune defense. Infant skin has a thinner stratum corneum, lower NMF levels, higher TEWL, and a higher initial pH (~6.0–7.0), which gradually acidifies. These differences contribute to the increased susceptibility to irritation and infection of infant skin and highlight the need for early skin barrier protection.

to immunoglobulin E (IgE)-mediated food allergies, asthma, and allergic rhinitis that can persist into adulthood (19).

Why does the majority of AD begin in infancy?

The preponderance of evidence demonstrates that infant skin differs from adult skin (Figure 2), contributing to its vulnerability in AD (20). Healthy infants born at full-term have an immature skin barrier that continues to develop throughout the first year of life. The stratum corneum in infants is up to three-times thinner compared to adults, leading to a more immature barrier function and increased TEWL in the first year of life (20,21).

A study comparing 61 neonates and 34 adults revealed differences in the protein composition of infant skin, including

progressive changes in filaggrin and antimicrobial proteins (22). NMFs in neonates were found to be lower than in adults, yet as infants aged for 2-3 months, their NMF levels became higher than adults (22). These changes in NMF levels were deemed essential for skin protection and infant survival.

Newborn infant skin is normally coated with a waxy mixture of water, cells, and lipids known as the vernix caseosa (Figure 3), which forms a protective chemical barrier before and shortly after birth (23). This sophisticated, natural emollient acts as a physical barrier to skin water loss and possesses antimicrobial and anti-inflammatory activities. The mildly alkaline vernix caseosa contributes to the initially neutral pH of newborn skin, particularly in premature babies, making them more susceptible to infections (23,24). Over the first few weeks to months after birth, skin pH gradually acidifies to form what is known as the acid mantle (typically ranging from 4.5 to 5.5) (25,26). Maintaining a slightly acidic pH is essential for inhibiting both the growth of pathogenic bacteria and excessive activity of proteases like kallikreins (KLK5 and KLK7) which are more active at neutral pH (27,28).

In AD, the skin surface pH increases to more alkaline levels (e.g., 7.3-7.4 in lesional sites), triggering protease activation, excessive corneodesmosome degradation, reduced stratum corneum integrity, and compromised barrier cohesion (29–32). The elevated skin pH also facilitates *S. aureus* colonization, a key pathogen in AD pathogenesis (33). A study comparing the skin microbiota of healthy infants (mean age, 12 months) and healthy adults (mean age, 32 years) found significant differences in microbial composition, abundance, and diversity (34,35). Skin microbiome and immunity are intimately linked, particularly in neonates whose immature cellular immune system relies on innate immunity to defend against infection (23,36). Cells from both the innate and adaptive immune system are present in the stratum corneum in late gestation and after birth; however, fewer numbers of mature immune cell types are present compared to adult skin (37). Strategies to support skin acidification in infants, such as avoiding alkaline cleansers and using pH-balanced emollients, may help restore the acid mantle, suppress pathogenic bacterial growth, and strengthen the skin barrier.

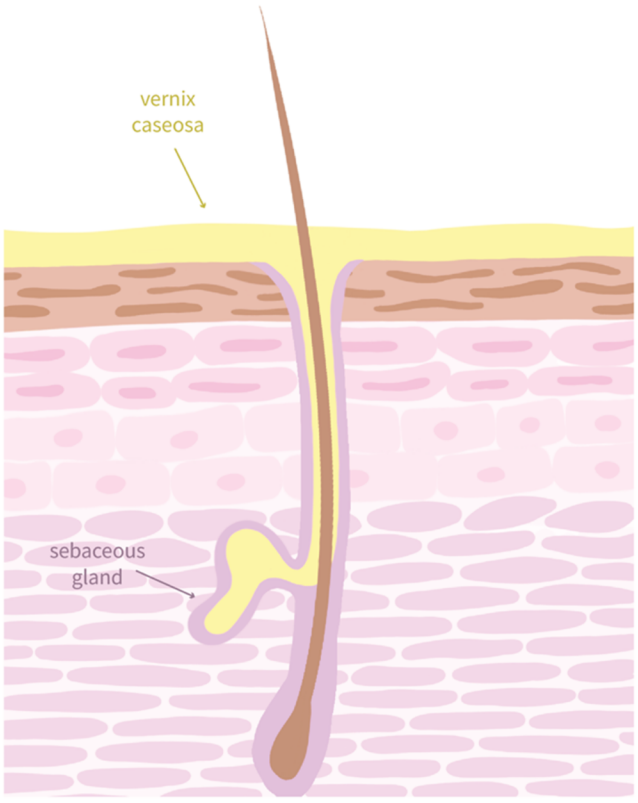

Figure 3. The vernix caseosa initially forms as a protective biofilm, providing hydration and barrier support in the amniotic environment. At birth, it reduces TEWL, acts as a natural emollient, and supports skin barrier maturation and antimicrobial defense.

Restoring the skin barrier with emollients

As skin barrier breakdown is the first event in the development of mild-moderate AD, restoring the skin barrier with emollients is a foundational therapy (38). However, more effective emollient options for the prevention and treatment of AD remain an unmet need (39).

Emollient formulations are built by combining ingredients that confer certain desired properties to a product (40). Emollients vary in composition and mechanism of action in preserving skin barrier function (Figure 4), resulting in different physiological effects on the skin barrier in adults (41,42). While simple emollients typically contain a single molecule type, complex emollients include a vehicle plus active, non-prescription substances that may help repair the skin barrier or reduce inflammation (43).

Understanding the roles of individual ingredients in skin protection as well as the complexity of the formulation are necessary to formulate an effective emollient product (44). The selection of ingredients determines skin barrier repair, skin feel, moisturization capacity, and stability of the formulation. Ingredients may have multiple biological mechanisms of action as well as interactions with other ingredients. The complexity involved in formulating an effective emollient also depends on the relative proportions of ingredients, which contributes to the safety, efficacy, and cosmetic acceptability of a formulation. Small changes in the composition of emollients may have a significant impact on the overall effect of the emollient on the skin barrier. Overall, there are four levels of emollient formulations that result in different physiochemical properties:

1. *Simple occlusive*: Forms a protective layer to prevent TEWL. Occlusive ingredients, such as petrolatum, rest on the surface of skin but do not repair the underlying skin structure or enhance the skin's natural barrier function (Figure 4A). The simplest emollients only contain occlusive ingredients (such as petrolatum), emulsifiers, and water (45,46).
2. *Simple occlusive plus humectants*: Induces or has similar effects as NMFs composed of amino acids, salts, and other humectants that bind and hold water to maintain skin hydration (Figure 4B) (22,47).
3. *Simple occlusive, plus humectants plus physiological lipids*: Adds or promotes the production of natural lipids in skin such as ceramides, fatty acids, and cholesterol to restore the extracellular lipid matrix, strengthening skin barrier function (Figure 4C) (42).
4. *Simple occlusive, plus humectants, plus physiological lipids, plus pH-buffering ingredients*: Exhibits pH buffering capacity to maintain skin pH at optimal 5.5 after emollient application to skin (Figure 4D) (48).

Emollients can promote healthy changes in the skin microbiome, improving barrier function and reducing pro-inflammatory cytokines in damaged skin (49). Some formulations, such as Delta-5 oil containing sciadonic acid, provide anti-inflammatory

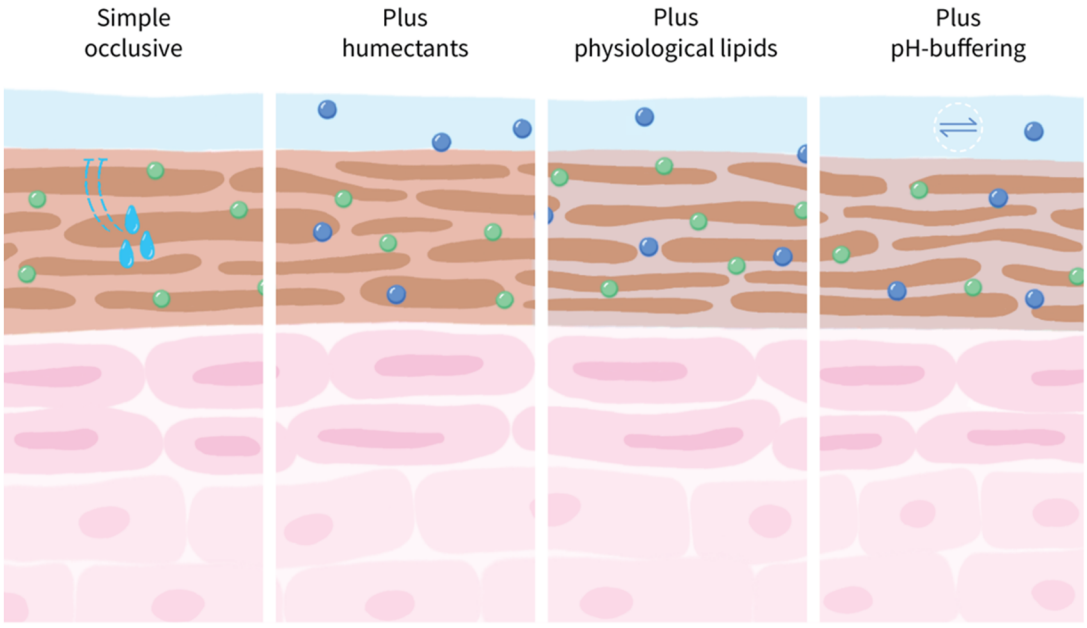

Figure 4. Four levels of emollient formulations resulting in different physiochemical properties. Simple occlusive formulations (light blue) create an artificial barrier to reduce TEWL but do not actively repair the skin. Occlusive formulations with added humectants (dark blue circles) enhance hydration by attracting water to the stratum corneum, mimicking the effects of NMFs (green circles). Formulations incorporating physiological lipids (light blue between cells), such as ceramides and fatty acids, help restore the extracellular lipid matrix, improving barrier function. The most advanced formulations include occlusives, humectants, physiological lipids, and pH-buffering agents to maintain an optimal skin pH (~5.5), further supporting barrier repair and skin microbiome health.

benefits without the side effects associated with steroidal treatments (50).

Emulsification of emollient cream formulations

Emulsifiers are crucial for blending and stabilizing water-soluble and fatty components in cream formulations (51). However, they can disrupt the skin barrier by solubilizing the lipid lamellae (52). Harsh emulsifiers like sodium lauryl sulfate cause greater barrier damage than gentler glycosylated surfactants and are most harmful when not counterbalanced by ingredients like humectants or physiological lipids (53,54). This effect is most pronounced in level-one emollient formulations that lack humectants or physiological lipids, which help mitigate emulsifier-induced barrier disruption (52).

Emulsifiers are essential to produce a cream formulation, however, nonionic ones like PEG-20 ethers, can affect the content of lipids in the stratum corneum. This disruption can weaken the skin's structural integrity and barrier function (55). The balance of the emollient formulation – between occlusives, emulsifiers, and other components like humectants and ceramides – determines its interaction with the skin barrier and lipid lamellae (56). Additionally, emulsifier type and concentration influence the viscosity, permeability, and stability of emulsions, impacting drug release and skin adsorption (57).

Safety of emollient formulations

Emollients generally have a favorable safety profile, with most ingredients deemed nonirritating and suitable for sensitive newborn skin (58). A review of studies across age groups, including neonates, infants, children and adults with AD, highlighted the benefits and safety of emollients across age (59). In newborns, the ratio of skin surface area to body weight is approximately 2.3 times higher than in adults (60). Combined with a thinner stratum corneum, this can lead to increased absorption of substances applied to infant skin; therefore, careful selection of skincare products is advised to minimize exposure to potentially harmful ingredients (61).

Over-moisturization may trap heat and moisture, promoting bacterial growth and inflammation of hair follicles (62). To minimize the risk of skin infections, emollient formulations should be adapted to the climate, with lighter formulations preferred in hot, humid conditions to prevent excessive occlusion, and richer formulations for colder, drier climates to maintain skin barrier integrity. Additionally, emollients can make skin slippery after application, posing a potential slipping risk if deposited in baths, showers, or on hard flooring. Using non-slip mats can help prevent slipping (63).

Colloidal oat as an effective emollient ingredient

Colloidal oat, alone or as an emollient ingredient, has been used as a skin treatment for thousands of years (64). Derived from the grinding and processing of whole oat grain (*Avena sativa*), colloidal oat powder is rich in biochemical compounds that contribute to skin health through multiple mechanisms (65,66). Colloidal oat forms an occlusive barrier on the skin that promotes moisture retention and reinforces the skin barrier (66). Additionally, colloidal oat stimulates the production of lactic acid, a key humectant component of NMF, which helps maintain skin hydration (67). By promoting skin pH balance, colloidal oat supports the skin's acid mantle – a critical defense against pathogens and environmental stressors (68). Colloidal oat has also been shown to increase the expression of skin barrier biomarkers, including genes that encode proteins involved in keratinocyte differentiation, lipid production, and tight junction formation, which collectively strengthen the skin's structural integrity (69).

Clinical studies demonstrate colloidal oat's efficacy in managing conditions characterized by impaired skin barrier function, such as

AD and other eczematous disorders. In a 14-day study of patients (mean age, 34 years) with mild-to-moderate AD, treatment with a colloidal oat emollient was linked to lower prevalence of *Staphylococcus* species on the skin and improved microbial diversity, which are characteristic of healthy skin (70). In contrast, a moisturizer lacking oat lacked these microbial improvements (70). An *in vitro* study further demonstrated that 1% colloidal oat increased the growth rate and metabolism of *S. epidermidis* (beneficial bacteria) versus *S. aureus* (AD-associated pathogen), highlighting its role in modulating skin microbiota (67). However, its impact on infant or pediatric microbiota remains unexplored, highlighting an important area for future research.

The biochemical profile of colloidal oat underpins its multifunctional benefits. Molecules such as complex carbohydrates, proteins, fiber, and β glycans are present in colloidal oat and contribute anti-inflammatory and antihistaminic properties to emollients (71). Among the bioactive components of colloidal oat, avenanthramides have been demonstrated in preclinical studies to have antioxidant, anti-inflammatory, and antipruritic properties (71,72). The ability of avenanthramides to neutralize free radicals and reduce oxidative stress further positions colloidal oat as a valuable ingredient in formulations designed for sensitive and irritated skin (73). A study in healthy female patients (mean age, 44.5 years) with bilateral mild-to-moderate itch and moderate-to-severe dry skin on their lower legs found that treatment with a colloidal oat emollient significantly improved skin dryness, scaling, roughness, and itch intensity (71).

While colloidal oat satisfies many criteria for an effective emollient ingredient – hydration, barrier repair, microbiome modulation, and anti-inflammatory effects – successful formulation requires ingredient compatibility, stability, and delivery systems. Balancing these factors ensures both efficacy and safety, making emollient formulation both a science and an art.

Safety of oat as an emollient ingredient

Colloidal oatmeal has a strong safety profile and is approved by the FDA (U.S. Food and Drug Administration) and Health Canada as an over the counter (OTC) skin protectant ingredient (66,74). Oat-containing emollients have been safely used in infants and young children with AD, with some products deemed suitable for use from birth (59,75). In a study of infants under 12 months with moderate-to-severe AD, oat extract-containing emollients were used alongside corticosteroids without safety concerns (76). Oat-based emollients have also been linked to fewer flares and reduced use of topical corticosteroids in children with moderate AD (77). While colloidal oatmeal is generally safe and well-tolerated, healthcare providers should be aware of the potential for rare sensitization or allergic reactions, particularly in patients with AD or a compromised skin barrier.

Methods

A comprehensive literature search was conducted to identify clinical and preclinical studies evaluating the use of oat-derived ingredients in dermatology, with a specific focus on their role in the prevention and treatment of atopic dermatitis in infants. Studies were included if they investigated the efficacy and safety of oat-based emollients, including potential sensitization, in clinical dermatology settings or examined the mechanisms of action of oat-derived ingredients in skin barrier function, inflammation modulation, or other relevant dermatological processes.

Clinical trials of emollients containing oats

Clinical studies confirm that colloidal oat emollients align with its ingredient physiochemical properties, demonstrating efficacy in dermatological applications. A randomized, double-blind, controlled study of 30 women (aged 18 to 70) with moderate-to-severe xerosis and mild-to-moderate pruritus evaluated the efficacy of a colloidal oatmeal moisturizing lotion compared to its vehicle lotion. After 21 days, the active lotion reduced scaling and dryness more than the vehicle ($p = 0.03$ and $p = 0.004$, respectively) and provided greater itch relief, with patients rating it more effective in reducing itch intensity, duration, and frequency. Skin hydration remained significantly higher for the active lotion at both 21 days and after a 1-week regression ($p < 0.05$). These findings indicate that colloidal oatmeal lotion is significantly more effective than its vehicle in relieving both dryness and itchiness associated with xerosis (78). Another study found that twice-daily use of colloidal oatmeal cream and cleanser significantly improved symptoms and severity of eczema in adults after 4 weeks (59).

Clinical, preclinical, and real-world data confirm the efficacy and safety of colloidal oat emollients applied to adult skin to moisturize or treat AD (59,65,70,79–85). Supported by evidence obtained largely from studies in adult populations, colloidal oat emollients claim to provide temporary skin protection and relief from symptoms caused by eczema according to the United States Food and Drug Administration's Over-the-Counter Skin Protectant monograph published in 2003 (86). The claim is *only allowed with respect to colloidal oat* among all other OTC emollient active ingredients.

Investigations of colloidal oat in clinical trials including pediatric patients with AD

Several controlled clinical trials have evaluated the efficacy and safety of colloidal oat emollients in pediatric patients with AD, highlighting their role in symptom relief and steroid-free AD management.

Two controlled clinical studies investigated the efficacy and tolerability of OTC colloidal oat emollients as treatment for pediatric AD (87). Both studies each enrolled infants and children (3 months to 12 years of age) with a history of atopic skin disease and active AD. The two investigational products were comprised of colloidal oatmeal, licochalcone, ceramide 3, and castor oil. In the first study, skin moisturizing emollient was applied twice daily on the skin of 64 children. After two weeks of therapy, skin hydration significantly improved, and itching, burning/stinging, erythema, and tactile roughness decreased compared to baseline. The second study, which focused on flare treatment in 29 children, found that applying the emollient to active lesions and surrounding skin improved skin hydration and symptoms of AD (including pruritis, erythema, and lichenification) compared to baseline. The emollients were well tolerated in both studies, with only two mild, transient adverse effects (rash and eczema). It was deemed unclear as to whether these findings were treatment related.

The ability of colloidal oat emollients to prevent AD flares was demonstrated in a randomized trial involving 45 children (mean age, 3.5 years) (88). The same colloidal oat emollients as in the previously mentioned Weber study were used in this investigation of steroid-free nonprescription therapies for treatment of pediatric AD (88). The study was conducted in three phases: a washout phase in which only cleanser was applied, a maintenance phase in which subjects received either a cleanser plus emollient (emollient group) or cleanser only (control group) for six months or until flare

occurred, and a 4-week treatment phase for subjects who flared. After six months, the emollient group had a significantly lower rate of flare compared to the control group (21% vs 65%) in addition to exhibiting a prolonged median time to flare (>180 vs 28 days). Overall, flare risk was reduced by 44% with colloidal oat emollient application, and tolerability was rated as good or excellent, with only one subject in the control group experiencing worsening eczema. Authors concluded that emollients and flare treatments containing 1% colloidal oat were safe and effective steroid-free OTC options for maintaining skin hydration, supporting barrier function, and reducing the frequency and severity of flares.

In another clinical study, pediatric patients with AD and xerosis were treated with a daily cleansing product and an emollient cream containing colloidal oatmeal and avenanthramides. The colloidal oatmeal-based products significantly improved epidermal thickness, skin dryness, itching, and cracking after one month of use (89).

To further investigate colloidal oat safety and efficacy for treatment of mild-to-moderate AD in a pediatric setting, a 1% colloidal oat OTC emollient was compared with a ceramide-based steroid-free prescription skin barrier cream (EpiCeram™) in a randomized clinical study (90). The study enrolled 90 patients (6 months to 18 years of age), and the median ages in the groups randomized to OTC or prescription cream were seven years vs 10 years, respectively. The primary endpoint was change from baseline in Eczema Area and Severity Index (EASI) at week 3 evaluated as age-specific percentage of affected area in four body regions. Reductions in EASI score were not significantly different between the two treatment groups in the intent-to-treat (−1.94 OTC and −2.11 prescription, $p = 0.508$) or per-protocol analyses (−1.74 OTC and −1.88 prescription, $p = 0.627$). Adverse event rates were low, with only two cases of mild rash and itching reported in the OTC treatment group that resolved within one day. The OTC colloidal oat emollient provided comparably efficacy and safety to a prescription emollient for the treatment of pediatric AD.

A *post hoc* analysis from the same study focused on a subgroup of 49 Black or African American pediatric patients (91). This analysis was prompted by reported characteristically higher AD presentation in this ethnic group. As baseline demographics were balanced between treatment arms in the overall study population, patients in the subgroup analysis were comparably represented in each study arm. Mean changes from baseline in EASI scores at week three among Black or African American patients were −2.4 and −2.1 for the colloidal oat cream and prescription medication (EpiCeram™), respectively, which were consistent with results from the overall study population. The safety profile for this subgroup was comparable to the total population demonstrating no signal for colloidal oat sensitivity, while also providing a cost-effective alternative for families with an average price of $0.02/g for Aveeno®.

The large-scale COMET study further investigated the efficacy of a colloidal oat emollient in a pediatric population by comparing the change in score and correlations between five different measures of eczema severity, including the EASI score (92). The study enrolled 197 children (12.8 to 21.7 months of age) with AD who were randomized to four different eczema emollient treatments (Aveeno® lotion, Diprobase™ cream, Doublebase™ gel, and Hydromol™ ointment). Scores, based on outcome measures used to evaluate treatment efficacy, improved over time after each emollient application, including the colloidal oat emollient. The greatest improvement in eczema severity occurred at week four after emollient application. Overall, the colloidal oat emollient trended with the lowest EASI score among the emollients tested.

Data from the COMET trial was further analyzed to determine the validity of a tool to measure user satisfaction among four different emollients (93). The Emollient Satisfaction Questionnaire (ESQ) was completed by 99% of parents after 12 weeks of emollient application to their children (<5 years of age) with an AD diagnosis. Scaled satisfaction was rated from low (0) to high (4) across a range of parameters including effectiveness and acceptability. Results of the analysis supported the validity of the ESQ. Moreover, total emollient satisfaction scores across multiple parameters were highest in the colloidal oat-containing emollient group (Aveeno® lotion), with significant differences observed between Aveeno® lotion and Hydromol™ ointment ($p = 0.001$) and for Aveeno® lotion and Diprobase™ cream ($p < 0.03$). These findings highlight the improved cosmetic acceptability of lotions versus heavier creams and ointments.

Additional evidence supporting the benefits of colloidal oat in pediatric AD treatment comes from a study performed in Italy, which evaluated a colloidal oat emollient cream containing, avenanthramides, shea butter, and oat oil in two age categories (infants under the age of three months; children over 12 years of age) (89). Among the 30 enrolled patients, eight had AD, 17 were afflicted with xerosis, and five patients had both conditions. After four weeks of using the cream and body wash, patients showed significant improvements in skin dryness, itching, and cracking ($p < 0.05$) along with a significant reduction of epidermal thickness ($p < 0.05$).

Clinical trials of emollients for the prevention of AD in pediatric patients

While colloidal oat emollients have demonstrated efficacy in treating pediatric AD, *preventing* AD before onset is crucial to reduce the disease burden, particularly in infants identified as high-risk for AD. Several groups postulated that emollients could be used in babies from birth to prevent the development of AD (12). A recent review of studies investigating emollient prevention of AD in infants concluded that emollients are not all the same, noting that some emollients provide skin-barrier strengthening properties while others increase skin permeability to irritants (45). These findings are consistent among several other systematic reviews and meta-analyses of clinical trials investigating the efficacy of emollients in preventing AD in infants (45,56,94–98). Many factors differed across these clinical trials, including study designs, patient populations, type of emollient formulation, and levels of parental compliance with the regimen for their infants, which likely contributed to the discrepant AD prevention results reported (43). Although no direct head-to-head comparisons of emollients in AD prevention exist, emerging patterns suggest certain emollient formulations may be more effective for AD prevention. Table 1 summarizes the findings from 12 studies (10 randomized controlled trials and two pilot studies) that investigated AD prevention in pediatric patients.

The associated risk for an infant to develop AD, such as family history, seems to play a role in the efficacy of AD prevention with emollients. A study in Japan investigated an emollient containing ceramides, cholesterol, and free fatty acids, among other interventions, applied 2-3 times daily from birth through the first six months of life (99). Among infants at baseline risk for developing AD (i.e., no family history of AD), there was no demonstrated benefit of emollient application based on the cumulative incidence at

Table 1. Summary of clinical studies investigating emollient use in prevention of AD in infants categorized by baseline (i.e., no family history of AD) and high-risk (i.e., those with family history of AD) population.

Clinical Studies Investigating Emollient Use in Prevention of AD in Infants								
Risk Level	Study	Study Population	GRADE Level of Evidence[a]	Study Objective	Emollient Ingredients	Design and Administration	Resulting Incidence of AD	Conclusion
Infants at **Baseline Risk**[b] for AD	Dissanayake (2019)[1]	549 infants in Japan	Low	Identify emollients and synbiotics effective in preventing AD	Locobase™ REPAIR Cream (Daiichi Sankyo, Japan) emollient with ceramide, cholesterol, free fatty acids	Randomized to (1) skin care + synbiotics, (2) synbiotics only, (3) skincare only, or (4) no intervention for 6 months of treatment; emollient applied 2-3X daily, initiated at birth, mainly to face	Observed cumulative incidence of AD at 1 year of age: 30.9% in group 1, 32.1% in group 2, 38.6% in group 3, and 25.6% in group 4 ($p > 0.1$)	No demonstrated benefit of intervention in AD prevention for children up to 1 year of age at baseline risk
	Skjerven (2020) PREVENT ADALL Study[2]	2397 newborns in Norway/ Sweden	Low	Investigate whether regular application of skin emollients prevents AD	Ceridal (GlaxoSmithKline Consumer Healthcare, Philadelphia, PA, USA) emollient with petrolatum, micro-crystalline wax (cera microcristillina) and cyclopentasiloxane	Randomly assigned to (1) bath additives/facial cream initiated at week 2, at least 4 days/week; (2) early complementary feeding of peanut, cow's milk, wheat, and egg; (3) combined skin/ complementary feeding group; or (4) no intervention up to 12 months	Observed incidence of AD at 1 year of age: 11% in group 1, 9% in group 2, 5% in group 3, and 8% in group 4 (3.1% risk difference; 95% CI −0.3 to 6.5)	No demonstrated benefit of emollient in AD prevention for infants up to 1 year of age at baseline risk
Infants at **High Risk**[c] for AD	Pilot Study Simpson (2010)[3]	22 neonates at high risk for developing AD	Low	Determine the feasibility of skin barrier protection with emollient application as a novel AD prevention strategy	Cetaphil™ (Galderma Laboratories, Fort Worth, TX, USA) petrolatum-based emollient barrier cream	Emollient application at least 1X daily initiated at birth up to 2 years; no control group	Observed incidence of AD at 1 year of age: 15.0%	Observed trends suggest a protective effect of daily emollient use in high-risk infants for the first year of life when compared with historical controls
	Pilot Study Horimukai (2014)[4]	188 high-risk neonates in Japan	Moderate	Investigate whether daily moisturizer prevents development of AD and allergic sensitization	2e [Douhet] emulsion (Shiseido, Tokyo, Japan) type emollient	Randomized to (1) daily emollient and petroleum jelly application or (2) petroleum jelly only, initiated within 1 week of birth, for 32 weeks	Observed incidence of AD/eczema at 32 weeks of age: 32% in the emollient group, 47% in the control group ($p = 0.12$)	Emollient use significantly reduced the risk of AD/ eczema in high-risk infants for the first 32 weeks of life
	Pilot study for PEBBLES (2018)[5]	80 infants at risk for AD from Australia	High	Investigate the effect of 2x daily application of emollient on incidence of AD	EpiCeram (PuraCap Pharmaceutical LLC, Bridgewater, NJ, USA) ceramide-dominant emollient for the intervention, and other emollients permitted in the control group	Randomized to (1) 2X daily application all over body, initiated within 3 weeks of birth, for first 6 months of life or (2) other emollients	Observed incidence of AD at 12 months of age: 5.3% in the intervention emollient group, 16.2% in the control group ($p = 0.15$)	Observed trends suggest a reduced incidence of AD in high-risk infants with 2X daily emollient use for the first 6 months of life

(*Continued*)

Table 1. Continued.

Clinical Studies Investigating Emollient Use in Prevention of AD in Infants								
Risk Level	Study	Study Population	GRADE Level of Evidence[a]	Study Objective	Emollient Ingredients	Design and Administration	Resulting Incidence of AD	Conclusion
	McClanahan (2019)[6]	100 high-risk infants in Oregon, US	Moderate	Determine whether full body application of an emollient reduces AD incidence after 1 year	Cetaphil™ Restoraderm™ moisturizer (Galderma, Baie d'Urfé, Montreal, Canada) with shea butter, pseudoceramide-5, and two filaggrin breakdown products (arginine and sodium pyrrolidone carboxylic acid)	Randomized to (1) daily emollient application all over body, initiated within 3 weeks of birth, or (2) control group, which applied emollient as needed for dryness (under enrolled)	Observed incidence of AD at 12 months of age: 13.2% in the emollient group, 25.0% in the control group ($p = 0.204$) Observed incidence of AD at 24 months of age: 19.4% in the emollient group, 31.0% in the control group ($p = 0.296$)	Observed trends suggest a protective effect of daily emollient use in high-risk infants for the first 2 years of life
	PEBBLES Study Protocol (2019)[7]	760 infants with a family history of allergic disease (high-risk) in Melbourne, Australia	High	Determine if application of an emollient 2x per day reduced AD risk	EpiCeram (PuraCap Pharmaceutical LLC, Bridgewater, NJ, USA) ceramide-dominant emollient for the intervention, and other emollients permitted in the control group	Randomized to (1) 2X daily application all over body, initiated within 3 weeks of birth, for first 6 months of life or (2) other emollients	Pending (ongoing)	Pending (ongoing)
	Thitthiwong (2020)[8]	52 high-risk infants in Thailand	High	Determine whether enhancing skin barrier reduces incidence of AD	Hospital-formulated emollient with white petrolatum stearyl alcohol, propylene glycol, and glycerin	Randomized to (1) emollient application at least 1X daily, initiated within 10 weeks of birth, after bath up to 9 months, or (2) no emollient in control group	Observed incidence of AD at 9 months of age: 0% in the intervention group, 14% in the control group ($p < 0.05$)	Emollient use significantly reduced incidence of AD in high-risk infants
	BEEP Study Chalmers (2020)[9]	1394 high-risk newborns in the UK	Low	Investigate whether daily emollient application in first year of life prevents AD	Choice of two different commercial emollients: (A) Diprobase™ Gel (Dermal Laboratories, Herts, UK), a petroleum and paraffin-based emollient, or (B) Doublebase™ Cream (Bayer, Berks, UK), a paraffin-based emollient plus humectant glycerol	Randomly assigned to (1) whole body application of emollient 1X daily, starting max of 21 days after birth, up to 2 years or (2) no emollient	Observed cumulative incidence of AD at 2 years of age: 23% in the emollient group, 25% in the control group ($p = 0.61$)	No demonstrated benefit of emollient in AD prevention for children at high risk

(*Continued*)

Table 1. Continued.

Clinical Studies Investigating Emollient Use in Prevention of AD in Infants								
Risk Level	Study	Study Population	GRADE Level of Evidence[a]	Study Objective	Emollient Ingredients	Design and Administration	Resulting Incidence of AD	Conclusion
	Techasatian (2022)[10]	154 high-risk infants in Thailand	High	Test hypothesis that emollients used during infancy can prevent AD in high-risk neonates	Choice of five different commercial emollients: (A) Ezerra™ lotion (HOE Pharmaceuticals Sdn. Bhd., Selangor, Malaysia), (B) Eucerin™ Omega Plus Extra Soothing (Beiersdorf Co., Ltd., Bangkok, Thailand), (C) Eucerin™ Omega Soothing lotion (Beiersdorf Co., Ltd., Bangkok, Thailand), (D) Physiogel A.I. restoring lipid balm (Stiefel Co., Ltd., Bangkok, Thailand) and (E) LyL™ Hydrating moisturizer (Cosmaprof Co., Ltd., Bangkok, Thailand)	Randomly assigned to (1) emollient application 1X daily, initiated within first 3 weeks of birth, over entire infant body for up to 6 months or (2) control group	Observed cumulative incidence of AD at 6 months of age: 21.62% in the emollient group, 54.17% in the control group ($p < 0.001$)	Emollient use which emollients please restate comparison products significantly reduced cumulative incidence and severity of AD in high-risk infants for the first 6 months of life
	STOP AD Study (2022)[11]	321 high-risk neonates in Cork, Ireland	High	Investigate whether daily emollient use from birth to 2 months can reduce the incidence of AD in high-risk infants	AVEENO® Dermexa Fast & Long Lasting Balm (Johnson & Johnson Santé Beauté France, JJSBF) emollient with oat ingredients, fatty acids, and glycerin	Randomized to (1) 2X daily emollient application or (2) standard routine skin care for the first 8 weeks of life	Observed cumulative incidence of AD at 12 months of age: 32.8% in the emollient group, 46.4% in the control group ($p = 0.036$)	Daily specialized emollient use for the first 8 weeks of life significantly reduced the risk of AD in the first year of life in high-risk infants
	Kottner J (2023)[12]	150 neonates at enhanced risk for developing AD in Berlin, Germany	Low	Investigate the effectiveness of a standardized skin care regimen for infants on AD development in infants with atopic predisposition	HiPP Babysanft Pflegemilch (HiPP GmbH & Co. Vertrieb KG) emulsion containing 21% lipid content, glycerin, and other ingredients	Randomized to (1) intervention group or (2) no predetermined or standardized skin care regimen, started no later than 14 days after birth	Observed cumulative incidence of AD at 12 months of age: 10.6% in the emulsion group, 10.6% in the control group ($p = 0.999$)	No demonstrated benefit of emulsion in AD prevention for children at high risk

[a]The certainty of evidence for each study was assessed using the GRADE approach. The highest quality rating is for randomized trial evidence. Five factors may decrease the quality level of evidence: limitations in the design and implementation of available studies, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results (wide confidence intervals), and high probability of publication bias.
[b]No family history of AD.
[c]Those with family history of AD.
AD, atopic dermatitis; GRADE, Grading of Recommendations Assessment, Development and Evaluation.
1. (99); 2. (100); 3. (101); 4. (102); 5. (103); 6. (104); 7. (105); 8. (106); 9. (63); 10. (107); 11. (75); 12. (95).

one year of age (46/120; 38.6% vs 30/117; 25.6%). Another study of infants at baseline risk in Norway and Sweden showed similar results with the use of an emollient intervention (emollient with petrolatum, micro-crystalline wax, and cyclopentasiloxane) applied at least four days per week beginning at two weeks through the first year of life (100). In this study, 11% of patients in the emollient group exhibited AD at one year compared to 8% of patients in the control group. These findings suggest that neither bosic nor sophisticated emollient formulations prevent AD in infants who are not at elevated risk.

In contrast, studies in high-risk infants (i.e., those with family history of AD) have shown more promising results for AD prevention, although emollient formulation appears to be a key determinant of efficacy. For example, Chalmers et al. demonstrated no clinical benefit of simple occlusive emollient application (Diprobase™ and Doublebase™) in the prevention of AD for infants at high risk in the Barrier Enhancement for Eczema Prevention (BEEP) trial (63). On the other hand, with the use of sophisticated emollient formulations, protective effects and reduced incidence of AD ranging from 0 to 32% have been observed in the first year of life (Table 1), indicating that sophisticated emollients may be more effective in AD prevention than simple occlusive emollients for high-risk infants.

One such trial, STOP-AD, found that the use of a colloidal oat, fatty acid, and glycerin-containing emollient from birth to two months of age reduced the emergence of AD in high-risk infants after 12 months (75). In this single-center, two-armed, investigator-blinded, randomized control trial, 321 infants were randomized within four days of birth to either twice-daily emollient application or to standard routine skin care (which did not specify bathing frequency or regular emollient use). Baseline characteristics were balanced between the two groups, and data from control group participants using emollient for four or more days per week were not used. The proportion of parents reporting daily emollient application at 8 weeks in the intervention group was 87%. Most notably, the primary outcome of cumulative AD incidence at 12 months was significantly lower in the colloidal oat emollient group compared to the control group (32.8% vs 46%; $p = 0.036$). Additionally, the skin infection rate was comparable between treatment groups. The STOP-AD study concluded that early and consistent use of a colloidal oat emollient in high-risk infants up to two months can reduce the incidence of AD within the first year of life, supporting the role of complex emollients in skin barrier protection and allergy prevention.

Despite promising results from STOP-AD and similar studies, others using basic emollient formulations have not supported a protective effect of emollient use in high-risk infants (summarized in Table 1). Researchers, including Ní Chaoimh et al. have suggested that future studies should examine the use of more complex emollient formulations for AD prevention. Understanding the mechanisms behind the observed protective effects would be beneficial in addition to performing head-to-head emollient comparisons to identify which sophisticated emollient offer the most benefit in AD prophylaxis.

The effect of emollients on the development of food allergy

The compromised skin barrier in patients with AD allows allergens to penetrate more easily, leading to sensitization (108). This phenomenon is supported by the 'dual allergen exposure hypothesis,' which suggests that non-ingestion exposure, particularly through inflamed skin, combined with a lack of oral exposure increases the risk of allergic sensitization (19). A recent meta-analysis found that nearly half (49.8%) of children with AD exhibited IgE sensitization to at least one food allergen, and 31.4% had an IgE-mediated food allergy (109). Additionally, a systematic review identified AD as a strong predictor of food sensitization by three months, with an odds ratio of 6.18 (110).

The Enquiring About Tolerance (EAT) trial revealed a significant dose-response relationship between frequent moisturizer use at three months and the risk of developing food allergies, with each additional weekly moisturization increasing the risk by 20%. This association was consistent in infants with and without visible eczema, with adjusted odds ratios of 1.20 and 1.18, respectively. Among 1,161 participants, 74 cases of food allergy were identified, with higher prevalence in infants with visible eczema (16.9%) compared to those without (3.0%). Increased moisturization also correlated with higher rates of sensitization, as evidenced by positive skin prick tests and specific IgE levels, even in infants without eczema. These findings suggest that frequent moisturization may influence food allergy and sensitization risk (111,112).

The EAT trial identified olive oil as the emollient most strongly associated with food allergy risk (111). Olive oil has been previously shown to damage the skin barrier in patients with and without AD due to its high oleic acid content which acts as a skin penetration enhancer by disrupting the stratum corneum (113). After olive oil, Diprobase™ and Doublebase™ were linked to the next highest risk of inducing food allergy in the EAT trial (111). This is consistent with findings from the BEEP trial which reported that the use of Diprobase™ or Doublebase™ from birth increased the risk of egg allergy in children compared to no treatment (63). As mentioned previously, emollient formulations often include emulsifiers to solubilize lipids, but these emulsifiers can be damaging to the skin barrier. The use of basic simple occlusive emollients such as Diprobase™ may damage the skin barrier because its formulation does not contain ingredients to counteract the damaging effects of emulsifiers.

The tape strip TEWL method has been employed to evaluate the effects of olive oil, coconut oil, and Diprobase™ on skin barrier integrity in comparison to untreated skin in adults (114). This study demonstrated that all three emollients compromised the skin barrier compared to the untreated control. Furthermore, these emollients enhanced the atopy patch test reaction to house dust mite, providing additional evidence of their detrimental impact on skin barrier function and their potential to facilitate allergen penetration.

Unlike basic emollients, sophisticated emollient formulations used in AD prevention trials do not increase food allergy risk and may even reduce it. The addition of emollient ingredients like humectants, oats, and ceramides has reparative effects which blunt the negative effect of emulsifiers on skin barrier function. The PEBBLES (Prevention of Eczema By a Barrier Lipid Equilibrium Strategy) pilot study found that using a ceramide-containing complex emollient for six months reduced both AD and food sensitization at 12 months in infants. Infants treated at least five days per week showed 0% food sensitization compared to 19% in controls (103). Similarly, the STOP-AD study reported low and comparable rates of food sensitization between the colloidal oat emollient and control groups; however, the authors noted that the trial was not powered to detect differences in rates of food allergy (75).

Studies investigating oat sensitization in pediatric patients

Sensitivity or allergy to oat is uncommon, with most reported cases linked to immune system reactions to avenin, a protein

found in oats (115). Individuals with gluten sensitivity or celiac disease may also react to oats, often due to cross-contamination with gluten-containing grains during processing (116).

A pivotal study by Pigatto et al. evaluated allergic reactions to topical oat and rice colloidal grain suspensions in normal and atopic children with and without previous exposure (117). In this double-blind, randomized patch study, colloidal grain suspensions were applied to skin of children between the ages of six months and two years, an age group commonly associated with AD. This study was prompted by a previously observed case of allergic reaction to oat in a patient in this age group (118). Among 65 enrolled patients, 43 were atopic and 22 were healthy. No cases of urticaria were observed after the first 15 min of open patch testing, and no allergic reactions occurred. Additionally, radioallergosorbent tests (RAST) were performed to assess IgE antibody reactivity to grain extracts. Among the 55 patients tested, eight atopic children showed a positive response to one or more test substances (oat, rye, barley, triticum, wheat, and corn); however, none had corresponding patch test responses. The authors concluded there was no evidence of sensitization to topical colloidal grains in the group studied. This study remains a cornerstone in discussions about oat sensitization and highlights the general safety of topical oat formulations in young children.

Subsequent studies have further investigated the relevance of associated or predisposing factors of colloidal oat sensitization in children suffering from AD. A study conducted more than a decade after the study by Pigatto et al. focused on the association between allergic reactions to food that manifest as skin, gastrointestinal, and respiratory disorders in pediatric populations (119). This study included 154 children with AD between six months and 18 years of age. Allergic skin prick tests (SPT) and patch tests against a broad array of twenty-five different food allergens were performed on enrolled children to identify food products that cause allergy, including oat, wheat, buckwheat, barley, rye, and soy. Oat had the lowest percentage of positive SPT reactions (2.7%) among the tested potential allergens, while soy registered the highest percentage at 40%. After one year of dietary therapy, allergic reactions to oat dropped to negligible levels in tested children. Overall, across a broad array of potential food allergens in a pediatric population, oat was among the least sensitizing.

Comparable results were reported in another study investigating common sensitization patterns to food through epicutaneous skin testing and food allergy rates in 365 children (one to 18 years of age) (120). Thirty-four children (9.3%) in the study had food allergy as detected by SPT, though the false-positive rate for epicutaneous skin testing is notably high for determining food allergies compared to the gold standard of oral challenge testing. Among tested foods, allergy to oat occurred in 11 children (3%), compared with milk in 33 children (9%), egg in 25 (6.9%), peanuts in 18 (4.9%), pork in 16 (4.4%), fish and soybeans each in 15 (4.1%), and chicken in 12 (3.3%).

Results from one study by Boussault et al. diverged from these findings, reporting higher oat sensitization rates in children with AD with 14.6% showing positive atopy patch tests (APT) and 19.2% positive skin prick tests to oat proteins. The risk of sensitization suggests caution in using oat-based products in infants with AD, as 32% of oat cream users had oat-positive APT compared to 0% in non-users (121); however, few pediatric studies have been dedicated to investigating colloidal oat use, especially those ≤2 years of age. This study received attention based on its claim that emollients that contain oat may be a risk factor for AD in children (121). The objective of this study was to measure the prevalence of oat sensitization in an exclusively pediatric population with AD. Skin reactions to 1%, 3%, and 5% oat *pollen* were measured by three different methods including SPT, APT, and repeated open application test (ROAT). Overall reactivity was found in 98 (33%) of 302 children with AD. SPT and APT resulted in 58 (19.2%) and 44 (14.6%) children having a positive test, respectively. Four children (1.5%) were both APT and SPT positive. Only 25 of the total 302 children had ROAT performed with an oat-based emollient, and only seven children had a presumed positive test.

Results from the Boussault study predicted a level of skin reactivity to oat pollen in pediatric patients with AD that is not seen clinically in the pediatric setting (82,117,119,120,122). Attempts to explain this discrepancy have noted the Boussault study used oat pollen as a test allergen, which is unlikely to contain the same oat proteins as colloidal oat and is therefore a dubious predictor of allergy to colloidal oat (123). Critics of the Boussault study also contend that since the study did not report results from all three different pollen concentrations used, the clinical correlation of allergic reactivity and APT result is uncertain (123). In addition, the APT is neither routinely used nor considered to be of clinical significance in the United States. A systematic review concluded the APT is unreliable when used to evaluate children with AD, including those with delayed onset of symptoms after exposure or ingestion (124). The Consensus-based 2018 European guidelines for treatment of AD also state that the food APT is not recommended for standardized routine use (125). Moreover, ROAT with an oat-based emollient were performed in the study on already sensitized children and were conducted in an unsupervised manner (122,123). The strikingly high reactivity to oat pollen from the Boussault study has not been replicated by any other study and contrasts with systematically obtained real-world data from pediatric populations.

While isolated studies have suggested an elevated risk of oat sensitization in children with AD, the majority of evidence supports the safety and low allergenic potential of colloidal oat, particularly in topical formulations. Continued research with robust methodologies is essential to address remaining uncertainties and ensure evidence-based recommendations for pediatric skin care.

Reducing the burden of disease with colloidal oat emollient treatment

The burden of AD extends beyond physical symptoms, affecting quality of life and leading to increased healthcare utilization (126,127). A real-world retrospective study of 45,218 patients found that the use of colloidal oat treatments reduced societal healthcare costs in the overall population, the majority of which were treated with a colloidal oat emollient for AD (128). For subgroup analyses, patients in the study were matched according to age, sex, and disease-related factors and divided into two groups: emollient ($n = 7486$) and non-emollient user ($n = 7846$). Although half of the patients in the emollient group were under 10 years of age, cost results were reported as a mixed population of children and adults. Patients treated with emollients for AD had significantly lower costs, including fewer clinic visits and fewer prescriptions for topical corticosteroids or anti-microbials compared to matched patients not treated with emollients. A sub analysis found that patients who began colloidal oat emollient treatment soon after AD diagnosis had a lower risk of needing topical corticosteroids or antibiotics compared to those who never use a colloidal oat emollient treatment or initiated treatment later. The findings suggest that early integration of emollients, particularly those containing colloidal oat, into AD treatment regimens can enhance disease management while also being cost-efficient.

Discussion and conclusions

This review highlights the critical role of skin barrier restoration in managing AD, particularly in infants at heightened risk. Emollients are fundamental to this process, with colloidal oat emerging as a standout ingredient due to its proven efficacy, safety, and additional benefits. Its anti-inflammatory properties, ability to enhance hydration, and support for skin barrier function make it a valuable component of AD management.

While evidence on AD prevention in infants at baseline risk remains inconsistent, studies in high-risk populations suggest that complex emollient formulations containing colloidal oat can reduce AD incidence when used from birth. For instance, the STOP-AD trial demonstrated that early and consistent application of a colloidal oat emollient significantly reduced AD development in high-risk infants, in addition to preventing the development of food allergies and minimizing sensitization in pediatric patients. These findings underscore the multifaceted advantages of colloidal oat formulations, which provide hydration, reduce TEWL, and maintain an optimal skin pH, collectively strengthening the skin's defenses.

Concerns about oat sensitization, raised by isolated studies like the Boussault study, are not supported by the broader body of evidence. Most research confirms the safety and low allergenic potential of colloidal oat, with discrepancies often attributable to methodological limitations – such as the use of oat pollen instead of colloidal oat in sensitization studies. Additional pediatric-focused studies are necessary to establish a more robust evidence base and reinforce consumer and physician confidence in oat-based products. As the understanding of skin barrier function and its role in allergic diseases continues to evolve, research should prioritize optimizing emollient formulations tailored to diverse populations. This includes investigating the molecular mechanisms of action, long-term effects on AD progression, and head-to-head comparisons of different emollient ingredients and formulations. Such studies will provide clearer insights into the best treatment windows, ingredient profiles, and formulation characteristics needed to maximize the clinical benefits of emollients.

Colloidal oat emollients represent a cost-effective and safe therapeutic option for managing pediatric skin conditions, including AD. Their ability to restore the skin barrier, reduce inflammation, and promote a healthy microbiome positions them as essential components of modern dermatological care. Moreover, their potential to prevent AD and associated allergic conditions, such as food allergies, underscores their broader value in improving health outcomes and quality of life for affected individuals. Future research should aim to establish comprehensive guidelines for the use of emollients in both treatment and prevention, ultimately reducing the burden of AD and enhancing the well-being of pediatric patients and their families.

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Disclaimer

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