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COLLOIDAL OATMEAL IN ATOPIC DERMATITIS

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Atopic dermatitis (AD), or atopic eczema, is a common chronic, inflammatory and pruritic skin disorder that usually begins in childhood and may continue into adulthood.^{1,2}

It has been estimated that about 10% to 20% of all children suffer from AD, with 65% of them developing the disease during the first year of life and 90% before 5 years of age.³ Furthermore, about 60% of affected children will continue to present some symptoms as adults, although the disease tends to improve significantly with age.³ Atopic dermatitis symptoms and their chronicity inflict a substantial psychological and financial toll on patients as well as their families, often more than type 1 diabetes and other chronic dermatological conditions.^{4,5}

The pathogenesis of AD is multifactorial and derives from an interaction between the patient's own body (skin barrier, genetic background and immune system) and the environment (microbes, allergens, climate and irritants).²

A genetically impaired skin barrier, with loss-of-function mutations in the filaggrin gene, is a key culprit in the development of AD.⁶ The disrupted skin barrier, evidenced by increased transepidermal water loss (TEWL), favors skin penetration of irritants and allergens from the environment, leading to cytokine release, dermal inflammation and itching.^{7,8} These phenomena start a vicious cycle of scratching, additional barrier damage and inflammation, and possible superimposed infection, ultimately producing the typical eczematous lesions of AD with a chronic-relapsing course.⁹

It is important to stress that dry skin (xerosis), barrier abnormalities and decreased content of ceramides, a class of stratum corneum lipids, are found both in lesional and non-lesional skin of AD patients.¹⁰ Thus, moisturizers that soothe pruritus, hydrate, protect and restore the barrier are essential for the correct management of AD and are considered first-line agents in the treatment of the disease, as suggested by several consensus reports on pediatric atopic dermatitis.¹¹⁻¹³ The daily use of moisturizers is also recommended as complementary to prescription medications for enhancement of treatment efficacy and for steroid-sparing effect.¹¹

Colloidal Oatmeal

The use of oat as a topical agent for soothing and cleansing the skin dates back to ancient times. Colloidal oatmeal derives from the whole oat grain and can be considered a "multifunctional" natural emollient containing lipids and

fatty acids, polysaccharides, enzymes, vitamin E, proteins and saponins. It is currently approved as an over-the-counter (OTC) skin protectant drug¹⁴ and is particularly helpful in eczema. Its chemical complexity and compositional simplicity (finely grounded powder) deliver a variety of dermatological benefits: moisturization, barrier protection, anti-inflammatory and anti-irritant activities, as well as soothing, buffering and cleansing actions.¹⁵

The antioxidant effect of colloidal oatmeal is due in particular to the presence of avenanthramides, vitamin E, ferulic acid and other antioxidants.¹⁶⁻¹⁸ Avenanthramides are polyphenolic compounds with potent antioxidant and anti-irritant activities, as well as anti-pruritic effects.¹⁹ Avenanthramides are unique in that they are only found in oats grains. Published data suggest that these polyphenolic compounds demonstrate a broad range of bioactivity in vitro.^{16,19,20} In preclinical models, avenanthramides decreased irritation from contact allergy, reduced itch-induced scratching comparable to that of topical hydrocortisone 1%.¹⁹ The anti-pruritic properties seem to be due to a histamine block.¹⁹

Avenanthramides have therefore been suggested as natural ingredients for the improvement of atopic skin. In a dose-response study, purified avenanthramide fractions were applied to a skin erythema model. Results showed a significant reduction in skin redness 24 hours after application when used at concentrations as low as 1.5 ppm.²¹

In addition to avenanthramide extracts found in oat grains, whole oat kernels can be fractionated to extract oat oil. Whole oat oil is composed of a mixture of lipids, falling into four main lipid classes: triglycerides, diacylglycerol, phospholipids, and free fatty acids, with smaller amounts of sterols, phosphatidylethanolamine, and other compounds. These oat lipids have the potential of reducing transepidermal water loss and restoring the skin permeability barrier.

Various in vivo human studies have shown that avenanthramide-enriched formulations significantly soothe pruritus and improve parameters of atopic skin both in infants/children and adults.²² Past investigations conducted in the United States on babies and children with mild-to-moderate AD showed that a regimen of colloidal oatmeal cream (with avenanthramides, ceramides and panthenol) and colloidal oatmeal-based cleanser significantly improved many parameters of AD from baseline.^{22,23} Specifically, the regimen reduced itching by more than 45% and significantly improved IGA and

EASI scores as early as week 2 of use; Baby/Child Quality of Life Index was also significantly improved.²³

These past studies have shown the effectiveness and safety of colloidal oatmeal in atopic dermatitis in the US population. Additional data has now become available on the safety and efficacy of colloidal oatmeal formulations in other geographical environments.

New Colloidal Oatmeal Studies

A few international studies have recently assessed the efficacy of a soothing colloidal oatmeal-based emollient (containing avenanthramides) in improving the clinical aspect of AD and patients' quality of life (QoL).

An open multicenter study conducted in Portugal, Italy and Greece from November 2010 to May 2011 that evaluated a total of 71 patients was presented in poster form at the 21st EADV Congress in Prague, Czech Republic. They ranged in age from 8 months to 53 years with more than 60% of patients under the age of 6 years. Patients presented with mild-to-moderate eczema and were instructed to continue the use of any topical steroids/immunomodulators that had been started before the trial. Patients applied the colloidal oatmeal-based emollient cream to face, body and eczematous sites twice daily for 12 weeks. Clinical grading of atopic skin parameters was performed by the dermatologist. Patients in the Greek group (N=41) were also tested for skin hydration via corneometry. The corneometer provides a measure of the hydration of the stratum corneum through electrical capacitance. Three successive measurements were taken at the elbow and knee folds under standardized temperature and relative humidity.

The results showed that the emollient significantly improved clinical dryness, scaling, itching and erythema throughout the study and as early as week 4 (first evaluation point), as scored by the dermatologist. At the end of the study, there was greater than 75% improvement in erythema (with 88% of improved patients), 68% in scaliness (82% of improved patients), 64% in itching (95% of improved patients) and 65% in dryness (100% of improved patients) compared to baseline (**Figure 1**). More than 70% of patients had a significant improvement in SCORAD (SCORing AD index) by week 4; overall, SCORAD improved by 18% by week 4 and 48% by week 12 (more than 90% of patients had improvement in SCORAD). Additionally, patients tested via corneometry showed improvement in skin hydration (elbow folds) by the end of the study, confirming the visual improvement in dryness and scaliness.

Patients' self-assessment of their skin condition echoed that of the dermatologist, with more than 80% of patients seeing improvement in all skin parameters by the end of the study. Furthermore, the soothing emollient cream was well tolerated by the majority (96%) of patients throughout the 3 months of use.

Previous reports indicated that emollients could have a steroid-sparing effect in AD, which is particularly

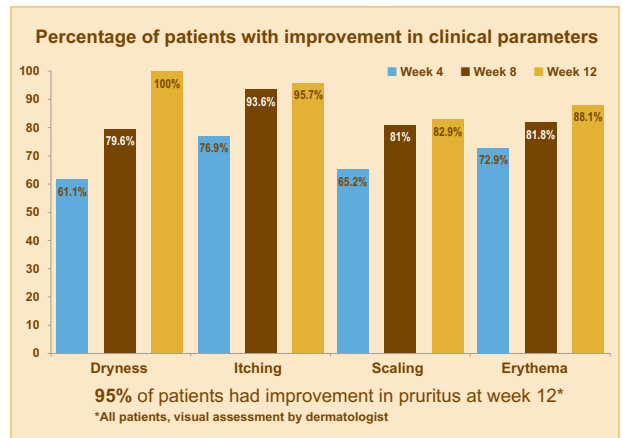


Figure 1. Multicenter European study: Progressive improvement of clinical eczema parameters. Dryness, scaling, itching and erythema were all significantly improved from baseline.

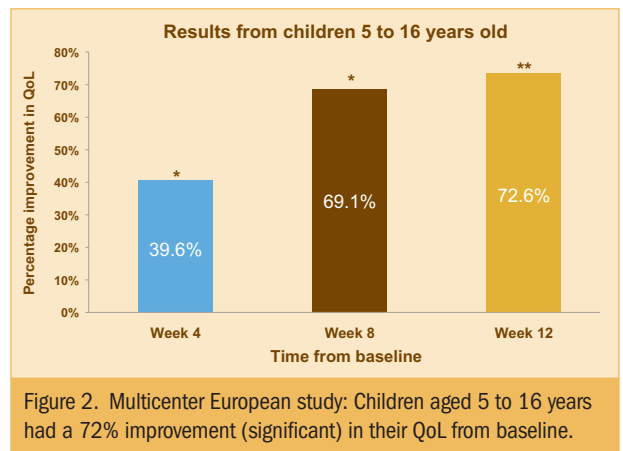


Figure 2. Multicenter European study: Children aged 5 to 16 years had a 72% improvement (significant) in their QoL from baseline.

important in the treatment of children.¹¹ The current multicenter study observed an analogous effect, with a reduction in the average amount of corticosteroid use during the study. Patients reported that they used less steroids because of amelioration in their skin condition.

In addition to patients being highly satisfied with the use of the cream, the QoL of children aged 5 to 16 years improved by 72% (significant) by the end of the study, indicating that the oat-based cream helped eczema patients live a better life (**Figure 2**).

A second study, conducted in Brazil, tested the soothing colloidal oatmeal emollient cream in an open trial in 75 AD patients aged 3 to 50 years (mean 18 years). This group was, therefore, older compared to the one in the European trial. Patients applied the cream for 12 weeks and were able to use their normal prescription medications as needed. SCORAD significantly improved from baseline as early as week 4. At the end of the study, the SCORAD improvement was very similar to that observed in the European study.

A third investigation was conducted in Greece as an observational study using the same oat-based soothing emollient cream. A total of 1,800 children (2 months to 16 years old) suffering from mild-to-moderate AD, with or with-

out concurrent use of topical steroids/immunomodulators, were enrolled from 46 pediatrician offices; more than 1,600 patients completed the study. About 90% of patients were below 10 years of age. Patients used the cream twice daily for 8 weeks on face, body and eczema areas. An oat-based body wash was also used once a day as part of the regimen. Clinical evaluations showed a statistically significant improvement in eczema severity throughout the study and the products were tolerated well by 98% of patients.

Conclusion

Atopic dermatitis is fairly common in children. This disease affects not only the body but also the social life of patients and their families, decreasing their quality of life. It is recognized that the use of emollients can be helpful during all stages of AD. In this regard, colloidal oatmeal has been known for decades to help AD signs and symptoms. Its avenanthramide fraction, in particular, has been recently shown to deliver anti-oxidant, anti-inflammatory and anti-pruritic benefits, helping mitigate the itch and erythema associated with AD. The anti-pruritic effect of colloidal oatmeal is particularly important because it helps reducing scratching and further barrier damage.

The three new studies reported here all support the efficacy of a soothing colloidal oatmeal emollient in improving the QoL and reducing the clinical signs of AD in adults and children as young as 8 months of age, living in Europe and Brazil. It is important to note that these studies employed the clinical index SCORAD, which is the more popular parameter for assessing eczema in Europe, while EASI (eczema area and severity index) is more common for studies conducted in the United States. Thus, colloidal oatmeal formulations have now shown excellent results in AD using different scoring modalities and across different continents.

This new research also confirmed the steroid sparing action of the test emollient, an effect that is particularly welcomed in children. The specific formulations used in this study were very well tolerated and received high patient satisfaction, which is important for treatment compliance in this patient population.

Overall, the results confirm previous data on the benefit of topical colloidal oatmeal formulations as adjunct treatment in AD. ■

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