



A Clinical Demonstration of the Spreadability of a Nonsteroidal Hyaluronic Acid Emollient Foam for the Treatment of Atopic Dermatitis

Zoe Diana Draelos, MD

Atopic dermatitis is a common skin condition characterized by inflammation, pruritus, and xerosis. While topical corticosteroids represent the mainstay of treatment, emollients to reduce skin roughness and moisturizers to enhance the water-holding capacity of the skin are important skin care adjuncts. Hyaluronic acid (HA), a naturally occurring glycosaminoglycan, recently has been formulated in a prescription, nondissipating, emollient foam. A study was undertaken to determine the spreadability of the foam as compared to a standard over-the-counter (OTC) oil-in-water emulsion cream. Ten participants with mild to moderate symmetrical forearm atopic dermatitis were enrolled in an Institutional Review Board–approved single investigator double-blind, split-body study. Equivalent amounts of HA emollient foam and OTC oil-in-water emulsion cream were pigmented with iron oxide and randomized for application to the back of the hand. The dermatologist investigator then spread the foam and cream from the hand as far up the forearms as possible leaving a therapeutic film over the skin surface. The HA emollient foam spread twice as far as the OTC oil-in-water emulsion cream, as documented by measurements on photographs taken during the study. In addition, 9 of 10 participants preferred the HA foam over the OTC oil-in-water cream in terms of ease of spreading over large skin surfaces. The HA emollient foam may be valuable in the treatment of atopic dermatitis because of the nongreasy aesthetic and ease of use, which are important factors in patient compliance. In addition, the ability of the HA emollient foam to cover a large body surface area decreases the cost per application of the prescription. Hyaluronic acid emollient foam technology offers an additional convenient therapeutic option in the treatment of atopic dermatitis.

Dr. Draelos is Consulting Professor, Department of Dermatology, Duke University School of Medicine, Durham, North Carolina.

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Correspondence: Zoe Diana Draelos, MD, 2444 N Main St, High Point, NC 27262 (zdraelos@northstate.net).

Atopic dermatitis is a common skin condition characterized by inflammation, pruritus, and xerosis. While topical corticosteroids represent the mainstay of treatment, emollients to reduce skin roughness and moisturizers to enhance the water-holding capacity of the skin are important skin care adjuncts. Implementing a daily skin care regimen to

maintain a healthy skin barrier is a crucial step in successfully managing atopic dermatitis. Emollients are a standard of care that are steroid-sparing and useful for both prevention and maintenance therapy.¹ Not only can the affected lesional skin of patients with atopic dermatitis become dry and inflamed, but clinically unaffected skin frequently manifests as increased dryness compared to that of healthy controls.² Thus, it is important for patients with atopic dermatitis to moisturize both affected and unaffected skin sites. Adherence to this topical regimen is paramount in controlling this skin condition, but it has been reported that patient adherence is abysmal.³ Therefore, it is essential to choose topical adjunct products that are cost effective, easy to apply, and provide immediate relief.

Currently, there are 2 categories of emollients available for the treatment of atopic dermatitis: over-the-counter (OTC) moisturizers and prescription-strength barrier repair agents. Prescription-strength barrier repair agents represent a relatively new addition to the dermatologic armamentarium as these are approved through the US Food and Drug Administration (FDA) 510(k) approval process and thus are considered *devices*. These devices modulate the water-holding capacity of the skin and effect a physical skin change without being metabolized by the body. One of the most important physiologic substances for holding water in the dermis is hyaluronic acid (HA), a naturally occurring glycosaminoglycan. An emollient foam formulation of HA recently was cleared by the FDA for use as a prescription device.

The development of an adjunctive skin care regimen for atopic dermatitis requires the consideration of cost, which is directly related to the body surface area covered by one application. This study evaluated a novel method to evaluate the spreadability of an FDA-cleared HA emollient foam compared to an OTC oil-in-water emulsion cream.

METHODS

Ten participants over the age of 18 years with symmetrical, mild to moderate atopic dermatitis on the forearm that signed an Institutional Review Board–approved consent (Concordia Institutional Review Board, Morristown, New Jersey) were entered into the spreadability study. Participants were randomized to receive the prescription HA emollient foam (Hylatopic; Onset Therapeutics, Cumberland, Rhode Island) to one forearm and the OTC oil-in-water emulsion cream (Eucerin cream; Beiersdorf, Hamburg, Germany) to

the opposite forearm. A half-inch application of the product was dispensed into a spoon and mixed with a quarter-inch of an iron oxide–pigmented facial foundation (Cover Girl Queen Collection Facial Foundation; Procter & Gamble, Cincinnati, Ohio). The pigmented product was applied by the dermatologist investigator to the back of the hand and rubbed as far up the forearm as possible while leaving an evenly pigmented film. The same measurement and application technique was used by the investigator for all participants to ensure consistency.

Photographs of the forearms of the study participants were taken for documentation and measurement purposes. The participants were asked to complete a questionnaire detailing their experience with the 2 products during the study.

RESULTS

All 10 participants successfully completed the spreadability study. A photograph demonstrating the final application appearance is shown in Figure 1. The HA emollient foam spread about twice as far as the OTC oil-in-water emulsion cream. The results of the participant questionnaire are presented in Figure 2. For all of aesthetic attributes surveyed, the HA emollient foam was preferred over the OTC oil-in-water emulsion cream. These attributes included spreadability, absorption, ease of use, relief of skin dryness, and use preference. Participants also were asked if they would prefer an OTC or prescription moisturizer from their dermatologist. Seven of 10 participants stated that they would prefer a prescription moisturizer. Finally,



Figure 1. Product spreadability comparison. The appearance of the forearms after the pigmented product application is visualized. Hyaluronic acid emollient foam was applied to the forearm at the bottom of the image and the over-the-counter oil-in-water emulsion cream was applied to the arm at the top of the image. The emollient foam spread approximately twice as far as the oil-in-water emulsion cream.

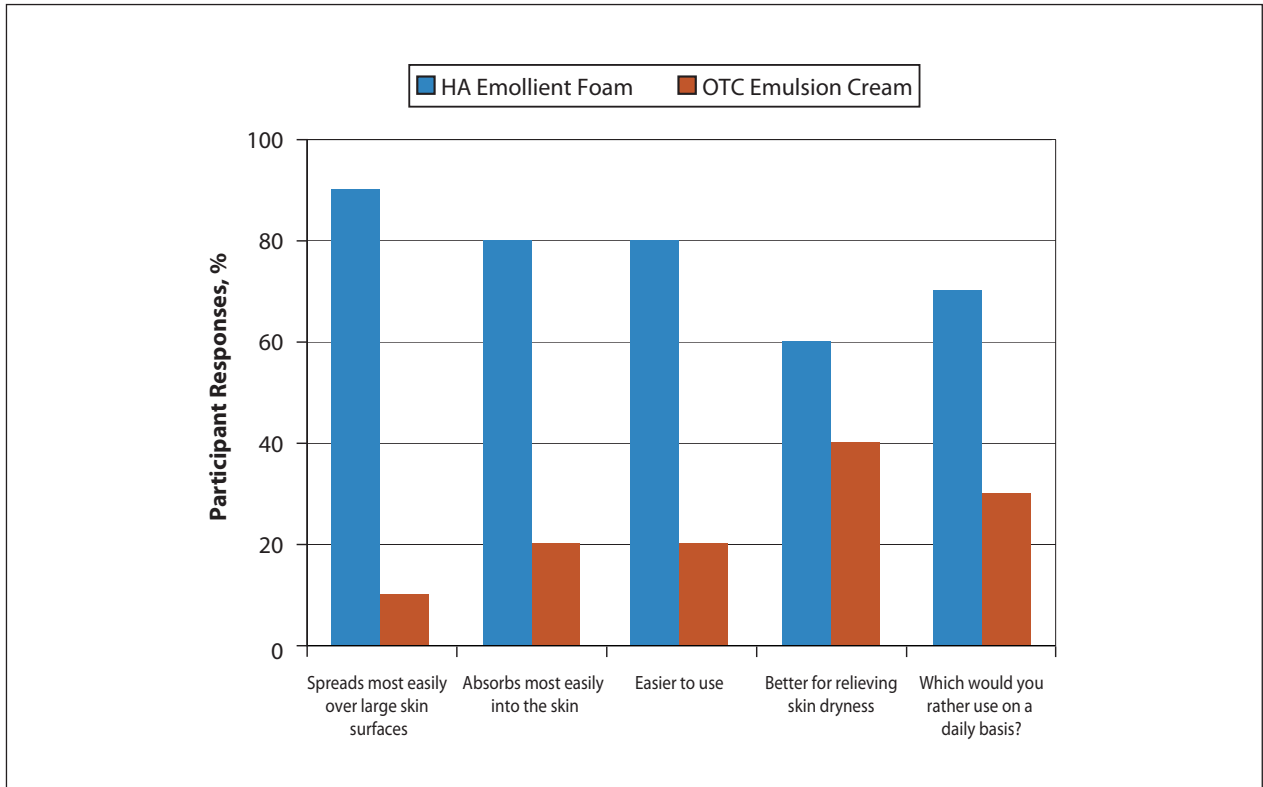


Figure 2. Study participants preferred the hyaluronic acid (HA) emollient foam over the over-the-counter (OTC) oil-in-water emulsion cream for all aesthetic attributes surveyed.

participants were asked whether they would rather purchase a \$17 OTC moisturizer or a \$25 prescription moisturizer. Again, 7 out of 10 responded that they would rather purchase the prescription moisturizer.

COMMENT

This study presented a method for comparing the spreadability of different formulations. The use of iron oxide pigment from a facial foundation was successful in visually capturing the spread characteristics of an HA emollient foam and an OTC oil-in-water emulsion cream. The implication of this finding is that the higher cost of the emollient foam may be offset by its ability to spread twice as far as the emulsion cream.

In light of historically poor compliance of patients with atopic dermatitis to topical regimens, this study sought to evaluate attitudes towards treatments and preferences for aesthetic attributes. Of the participants in this study, 70% (N=10) reported a preference for a prescription moisturizer over an OTC moisturizer, even if they would be required to pay slightly more for the prescription moisturizer, which suggests that participants placed a higher value on products

cleared or approved by the FDA. Participant preference for ease of use, ease of spreading, and ease of absorption favored the HA emollient foam over the OTC oil-in-water emulsion cream (Figure 2). These results indicate that the HA-based emollient foam has both the FDA regulatory status and aesthetic attributes that may improve adherence rates. Lastly, the prescription HA emollient foam may offer value as adjunctive nonsteroidal skin care in patients with mild to moderate atopic dermatitis that desire a product with excellent spreadability and other positive aesthetic attributes.

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