

First Prescription Barrier Protection for Hand Eczema/Dermatitis Improves Appearance and Provides Relief

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Hand eczema/dermatitis is a widespread disorder that is often difficult to treat and may be debilitating because of its effects on personal appearance and physical health. Direct costs associated with occupational contact dermatitis in the United States have been estimated at more than \$1 billion. Tetric Cream, the first prescription protectant for these disorders, enhances treatment and prevention with an innovative barrier protection cream that is water resistant, long lasting, nongreasy and nonirritating, and also reduces itching and burning.

Hand eczema, sometimes called hand eczema/dermatitis, involves an inflammatory response of the skin, with distinctive features affecting both personal appearance and physical health. Often beginning with minimal signs and symptoms, such as mild scaling and itching, more severe findings include intense itch, erythema, fissures, crusting, papules, edema, and vesicles. Caused by various endogenous or exogenous factors, hand

eczema/dermatitis includes occupational, contact, and atopic dermatitis, as well as dyshidrosiform eczema.

Though it is difficult to establish the precise prevalence of hand eczema/dermatitis, it is estimated to affect between 2% and 10% of the general population, with 20% to 35% of all cases of dermatoses involving the hands.¹

Economically, figures from 2004 indicate that the direct costs associated with occupational contact dermatitis in the United States were approximately \$1.6 billion, of which \$870 million were attributed to physician and clinical services and \$747 million to prescription drugs. In addition, the indirect costs attributed to lost productivity were estimated to be approximately \$566 million.²

Beyond its physical effects, people with hand eczema/dermatitis may experience emotional distress, depression, mood disorders, and disrupted sleep.^{3,4} This article will examine both the psychological and physical consequences of the disorder and review clinical data and efficacy of the first prescription barrier protectant, Tetric Cream.

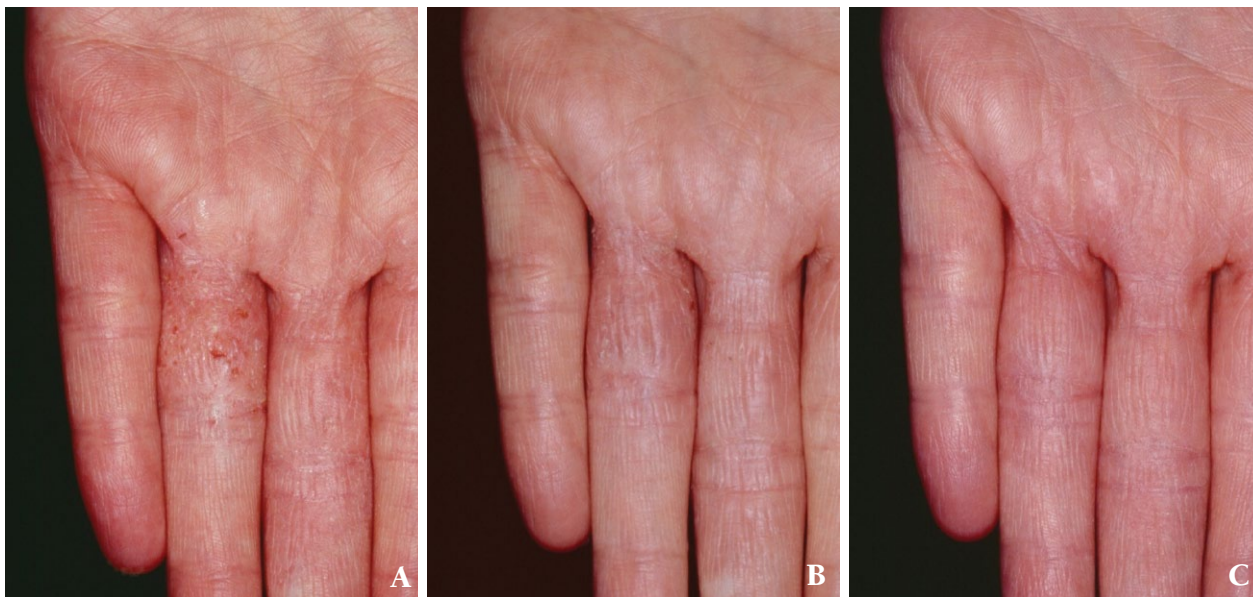
PHYSICAL EFFECTS

Disruption of the skin barrier may lead to a number of consequences, including increased transepidermal water

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Hand eczema/dermatitis at baseline (A) and 10 days posttreatment with CeraVe moisturizer, desonide ointment, and Tetrax Cream twice daily (B), and 42 days posttreatment with CeraVe moisturizer and Tetrax Cream twice daily used from day 11 to day 42 (C).

loss, secondary bacterial infection, and allergic or irritant contact dermatitis. Care must be taken to protect the skin from these consequences even after successful therapy because even though the skin may appear to be normal, the skin barrier may not normalize for several months (Joseph Fowler, MD, oral communication, April 2008).

PSYCHOLOGICAL EFFECTS

Hand eczema/dermatitis can be a major source of distress, appearing on a conspicuous and constantly used area of the body that is not easily disguised because makeup or other cover-ups are easily rubbed or washed off. In a study of 16,584 randomly chosen participants in Sweden who responded to a survey questionnaire,³ approximately 81% reported that their condition had produced some type of emotional or social disturbance. Approximately half of the participants described their hand eczema/dermatitis as a handicap to occupational and leisure activities, and a third of the participants reported a modification in daily activities. Others noted mood and sleep disturbances; some participants avoided social contact and reported that people kept a distance from them.

A study of 416 participants found a significant correlation between reduced quality of life (QOL) and the severity of hand eczema/dermatitis.⁵ In another study, the Dermatology Life Quality Index reported hand eczema/dermatitis to be just below psoriasis and atopic dermatitis for impairment of QOL.⁴

A study of 758 participants with occupational hand eczema (OHE) found strong associations between mild to moderate OHE, including severe OHE and low QOL,

as compared with individuals with no minimal OHE. Depressive symptoms were also strongly associated with low QOL.⁴

MANAGEMENT

The persistent and recurring nature of the disorder is frustrating to both dermatologists and patients. However, in 2008 the first prescription protectant barrier cream for hand eczema/dermatitis was approved by the US Food and Drug Administration, adding to the physician's therapeutic armamentarium. Tetrax Cream consists of dimethicone and cyclomethicone combined with aluminum magnesium hydroxide stearate in a unique formulation that is nongreasy and nonsensitizing. It has been clinically proven to be both safe and effective for patients with irritant and allergic contact dermatitis.

Clinical studies conducted and reported on Tetrax Cream have demonstrated its safety in healthy adults with respect to sensitization, irritation, and effect on the healing of existing skin lesions. In addition, 4 efficacy studies were designed to assess the barrier properties of this novel cream, as well as its ability to control the itching and burning associated with contact dermatitis when applied to lesions on the skin.

CLINICAL TRIALS

A substantivity trial compared Tetrax Cream versus Vaseline Intensive Care hand cream following a single-controlled hand wash. A cosmetic facial foundation was mixed with each product to a uniform color and applied to the dorsal part of the left or right hand according to

a randomization scheme. Fifteen minutes after application of Tetrax Cream and the control, the investigator performed a controlled wash on each participant's hand using lukewarm tap water and Dove liquid soap. The amount of residual pigment on the skin was rated on a 5-point scale, with the mean assessment score for residual pigment on hands exposed to Tetrax Cream at 3.4 (range, 2–4) compared with 0 for participants exposed to the control product.⁶

In a nonrandomized, controlled, closed-patch barrier trial, the barrier effect of Tetrax Cream was tested with 3 antigens: nickel sulfate, neomycin, and a fragrance mixture. Trial participants had a known sensitivity to 1 of the 3 antigens. Tetrax Cream was applied to 1 site in each of the 4 test pairs. After allowing the cream to dry, the antigen (dispersed in petrolatum) to which the participant had a known sensitivity was applied to both sites using a patch test device. Of the 35 evaluable participants, 12 were sensitive to nickel sulfate, 12 were sensitive to neomycin, and 11 were sensitive to the fragrance mixture. Statistically favorable differences were observed between Tetrax Cream plus all antigens versus all antigens alone regarding median skin reaction scores.⁶

A lactic acid barrier test trial was conducted to determine the effectiveness and duration of Tetrax Cream as a barrier to the stinging effect induced by a solution containing lactic acid 10% when applied to the nasolabial fold of participants with a predetermined sensitivity. Protection against stinging was found to be as effective at 6 hours than at earlier time points; therefore, 6 hours was determined to be the longest duration of effect within the limits of the study. Barrier effectiveness was substantiated at both 4 hours with a mean score of 0.87 and 6 hours with a mean score of 0.83 on a scale of 1 to 3 where 0=no discomfort, 1=slight discomfort, 2=moderate discomfort, and 3=severe discomfort.

A trial was conducted to determine the therapeutic effect of Tetrax Cream on participant-assessed symptoms of itching and burning associated with irritant and allergic contact dermatitis. Participants had to assess symptoms of burning or itching as being greater than 50 on a visual analogue scale (VAS) where 0=no burning or itching and 100=the worst possible burning or itching.

Forty-four participants (22 with hand eczema/dermatitis and 22 with sensitivity to nickel sulfate) were enrolled. There were no significant differences between the

2 groups at baseline. Following initiation of therapy, the sites treated for hand eczema/dermatitis consistently showed a lower score at each visit compared with the untreated sites. The difference became significant by visit 3 and remained so through visit 7.

For the sites with hand eczema/dermatitis that were treated with Tetrax Cream, the VAS scores for burning and itching were in the range of 65.8 and 66.2 at baseline. At visit 7, the VAS scores decreased to 25.8 and 22.0, respectively. On the untreated side, the VAS scores for itching and burning at baseline were 67.4 and 68.8, respectively, and decreased at visit 7 to 48.7 and 48.1, respectively.

In participants with nickel-induced allergic contact dermatitis, sides treated with Tetrax Cream demonstrated faster improvements in itching and burning, although the differences did not reach statistical significance. From visits 4 to 7, the VAS scores for sides treated with Tetrax Cream were consistently lower than for the untreated side (Figure).⁶

CONCLUSION

Hand eczema/dermatitis is a widespread disorder that may be debilitating because of its effects on personal appearance and physical well-being. Moreover, it is often difficult to treat, as its diverse causes may involve activities necessary for work or daily living. As the first prescription protection for these disorders, Tetrax Cream enhances treatment and prevention with an innovative barrier protection cream that is water resistant, long lasting, nongreasy and nonirritating, and also reduces itching and burning.

REFERENCES

1. Elston DM, Ahmed DD, Watsky KL, et al. Hand dermatitis. *J Am Acad Dermatol*. 2002;47:291-299.
2. Society for Investigative Dermatology and American Academy of Dermatology Foundation. The burden of skin diseases 2004. <http://www.sidnet.org/pdfs/Burden%20of%20Skin%20Diseases%202004.pdf>. Accessed June 19, 2009.
3. Meding B, Swanbeck G. Consequences of having hand eczema. *Contact Dermatitis*. 1990;23:6-14.
4. Cvetkovski RS, Zachariae R, Jensen H, et al. Quality of life and depression in a population of occupational hand eczema patients. *Contact Dermatitis*. 2006;54:106-111.
5. Agner T, Andersen KE, Brandao FM, et al. Hand eczema severity and quality of life: a cross-sectional, multicentre study of hand eczema patients. *Contact Dermatitis*. 2008;59:43-47.
6. Slade HB, Fowler J, Draelos ZD, et al. Clinical efficacy evaluation of a novel barrier protection cream. *Cutis*. 2008;82(suppl 4): 21-28. ■