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The Low Prevalence of Allergic Contact Dermatitis Using a Petrolatum Ointment Containing Lanolin Alcohol

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ABSTRACT

Lanolin alcohol is a high cholesterol containing naturally derived material used as a skin protectant in wound healing petrolatum-based ointments. It is a highly purified fraction of lanolin wool wax that has been identified as a possible cause of allergic contact dermatitis. This 3-center study enrolled 499 subjects who underwent a variety of in-office surgical procedures followed by application of a wound healing ointment containing lanolin alcohol without antibiotics. No allergic contact dermatitis was identified in the 499 subjects who completed the study. The lack of allergic contact dermatitis observed may be due to the proprietary highly purified lanolin alcohol utilized in the study formulation. This is not the lanolin alcohol preparation found on the standard dermatology patch test tray. Not all lanolin alcohols are equal. This is an important consideration when examining the reported incidence of allergic contact dermatitis to lanolin alcohol and the absence of allergic contact dermatitis demonstrated in this research.

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INTRODUCTION

Lanolin alcohol (LA) is an ingredient used in skin protectant ointments for wound healing for its high concentration of cholesterol, a key component of the intercellular lipids.[1,2] Purification and fractionation of lanolin (wool wax) yields a subfraction of lanolin alcohol, an ingredient used for over 100 years in skin care products; however many different purities of lanolin alcohol are present in the marketplace.[1,2,3] Lanolin alcohol has been identified as an allergen causing allergic contact dermatitis, and for many years was patch tested in concentrations of 30% in petrolatum. In 2011, the concentration of lanolin alcohol, in the standard dermatology patch test series (Amerchol L101 supplied by the manufacturer as 10% in mineral oil) was increased from 30% (final 3% LA) to 50% (final 5% LA).[4] In recent publications, this concentration increase has corresponded to higher reported LA allergy rates among those patch tested in clinics due to suspicion of allergy, from about 1.8%-2.5% to 4.6%-5.7%.[4,5,6,7] Two manuscripts have cited an increase in the incidence of LA allergy; however they compared allergy rates from 30% LA patch data to more recent 50% data.[4,8]

A lanolin alcohol containing wound healing ointment is commonly used after various in-office surgical and biopsy procedures, and as post-laser treatment.[9,10,11] The incidence of allergic contact dermatitis to LA is unknown in this patient population. This research was undertaken to evaluate the tolerability and safety of an OTC lanolin alcohol-containing skin protectant (Aquaphor Healing Ointment (AHO), Beiersdorf Inc. USA) used for post-surgical skin care.

METHODS

This was a 3 center, open label study of subjects undergoing a variety of in-office surgical procedures. 499 adult male or female subjects age 18-75 years presenting with a lesion that required surgical removal were enrolled in 2 cohorts. Following the completion of informed consent (Allendale IRB, Old Lyme, CT), subjects were evaluated for their ability to meet all of the inclusion criteria and none of the exclusion criteria. Subjects with a lesion on the face, neck, trunk, arms, or legs that required surgical removal accessible to proper wound care and application of the study product were enrolled. Pregnant or breastfeeding females were not enrolled. Subjects with active skin disease, hepatitis, immune deficiency/HIV, autoimmune disease, peripheral vascular impairment, dysfunctional blood clotting, uncontrolled metabolic disease (diabetes, hypertension, hyperthyroidism, or hypothyroidism) as determined by the health questionnaire were not enrolled. Subjects with poor healing, such as keloid formation, were also not enrolled. Subjects had to posses no known allergy or sensitivity to petrolatum, lidocaine, latex, lanolin or lanolin alcohol, or any component of the study wound healing product. No subjects were excluded from the study based on these allergies.

Subjects who had not used creams, ointments, or topical medications in the test area 24 hours prior to the start of the study underwent a surgical procedure appropriate for secondary intention healing. No sutured wounds were allowed. The patients were given post-surgical written and oral at home wound care

instructions and were provided with tubes of the study product healing ointment along with latex free adhesive bandages to apply at least once daily to the wound and up to 3 times daily. Subjects cleansed the wound daily or as ordered by the physician with a mild cleanser. They did not use any other topical products or medications on the wound. Subjects were given a compliance diary to record the date and time of wound treatments.

Approximately 10-14 days later the patients returned for wound site evaluation for erythema, itching, and pain (0=none or absent, 1 = mild, 2 = moderate, 3 = marked or strong, and 4 = severe or extreme), signs of infection (purulent discharge), and allergic contact dermatitis (erythema, edema, papules, vesicles, bullae, weeping). In the event an allergic contact dermatitis was suspected, the subject was patch tested with the product at a naïve site under occlusive patch conditions. Pictures were taken of the allergic contact dermatitis as determined by the investigators. Patch test sites were evaluated on the following scale 1 hour after removal: 0=none or absent, +/- = equivocal, + = weak, ++ = strong, +++ = severe.

RESULTS

499 subjects successfully completed the study. 99 subjects were enrolled in cohort 1 in 2010 (Rigel) and 400 subjects were enrolled in cohort 2 in 2019 (Draelos, Rigel, Kircik). No adverse events or serious adverse events occurred during the conduct of the study. Table 1 presents the erythema, itching, and pain incidence where 5.8% of subjects experienced an erythema score of 1 and 1.0% of subjects experienced an itching score of 1. No subjects reported pain. Table 2 presents the incidence of adhesive reactions, purulent discharge, and suspicion of infection. None experienced purulent discharge, and 0.5% of subjects experienced an adhesive reaction. 0.4% experienced induration, but no subjects were found to possess edema, papules, or vesicles. No allergic contact dermatitis was observed and no patch testing was conducted.

TABLE 1.

Descriptive Statistics for Incidence of Erythema, Itching, and Pain (0 to 4 severity scale). Combined 2010 and 2019 data, N=499.

	Erythema	Itching	Pain
Mean score	0.060	0.010	0.000
Standard deviation	0.246	0.100	0.000
Minimum score	0	0	0
Maximum score	1	1	0
Frequency / (%) 0 scores	470 (94.2%)	494 (99.0%)	499(100%)
Frequency / (%) 1 scores	29 (5.8%)	5 (1.0%)	0 (0%)
Frequency / (%) 2 scores	0 (0%)	0 (0%)	0 (0%)
Frequency/(%) 3 scores	0 (0%)	0 (0%)	0 (0%)
Frequency / (%) 4 scores	0 (0%)	0 (0%)	0 (0%)

TABLE 2.

Descriptive Statistics for Presence of Adhesive Reactions, Purulent Discharge, and Suspicion of Infection. Combined 2010 and 2019 data, N=499.

	Adhesive Reaction*	Purulent Discharge	Infection Suspected
Mean score	0.005	0.000	0.000
Standard deviation	0.071	0.000	0.000
Frequency No / (%)	398 (99.5%)	499 (100%)	499 (100%)
Frequency Yes / (%)	2 (0.5%)	0 (0%)	0 (0%)

*Only recorded in the 2019 cohort (n=400)

DISCUSSION

This study was conducted to assess the incidence of allergic contact dermatitis in 499 subjects who used the study wound healing ointment, containing lanolin alcohol, for wound care following a surgical procedure at one of 3 clinical sites. No incidence of allergic contact dermatitis was observed in 499 subjects. In addition, prior RIPT testing of the study wound healing ointment in 108 and 203 subjects showed no induction of allergic contact dermatitis or cumulative dermal irritation.[12] The company has also reported 72 skin irritation complaints received from consumer contacts for more than 53 million units distributed over a 5 year period (2002-2006), corresponding to a very low rate of 1.4 complaints per million units.[13]

One reason for the lack of allergic contact dermatitis observed with the wound healing ointment in this study may be its formulation with a proprietary highly purified lanolin alcohol (Eucerit®); in Europe, a compounding base is commercially available containing 6% Eucerit® (same LA as AHO) in 93.5% petrolatum, known as Eucerinum Anhydricum (EA). This preparation of LA is not the material found on the dermatology standard patch test tray (Amerchol L101). Uter and Knijp demonstrated higher rates of allergy to the patch test lanolin alcohol than other sources of lanolin alcohol.[2,3] Knijp compared the LA used in AHO and EA to the patch test lanolin alcohol (Amerchol L101, 50% in pet, final LA 5%). Amerchol L101 demonstrated an incidence of allergic contact dermatitis 16.7 times greater than that observed for EA.[2]

Since lanolin alcohol is a natural substance requiring processing and purification, the quality of the materials used in skin care preparations and patch test trays may differ. These data support the observation that LA preparations can differ in allergenicity based on the quality of their purification, demonstrated in a comparison of 30% LA in pet and 6 pharmaceutical grade preparations of LA.[14]

Not all lanolin alcohols are equal. This is an important consideration when examining the reported incidence of allergic contact dermatitis to lanolin alcohol and the absence of allergic contact dermatitis demonstrated in this research.

No incidence of wound infection was observed in this research, in agreement with prior studies. Thus, petrolatum ointment with lanolin alcohol is suitable as a dressing for wounds healing by secondary intention.

SUMMARY

Allergic contact dermatitis to a wound healing ointment containing lanolin alcohol should be of minimal concern to dermatologists. A wound healing ointment containing lanolin alcohol without antibiotics is a suitable post-surgical wound dressing.

DISCLOSURES

Drs. Draelos, Rigel, and Kircik received an educational grant from Beiersdorf to conduct this research.

REFERENCES

1. Hoppe U, Clark EW, Jacob J, Steel I. *The Lanolin Book.* Ed. 20.000. Hamburg, Germany: Clausen & Bosse, Leck. 1999.
2. Knijp J, Bruynzeel DP, Rustemeyer T. Diagnosing lanolin contact allergy with lanolin alcohol and Amerchol L101. *Contact Dermatitis.* 2019; 80:298–303
3. Uter W, Schnuch A, Geier J for the IVDK. Contact sensitization to lanolin alcohols and Amerchol® L101-analysis of IVDK data. *Contact Dermatitis.* 2018; 78:355-371
4. Warshaw EM, Maibach HI, Taylor JS, et al. North American Contact Dermatitis Group patch test results: 2011-2012. Dermatitis. 2015:26(1):49-59
5. Zug KA, Khoa A, Belsito DV, et al. Patch testing in children from 2005 to 2012:results from the North American Contact Dermatitis Group. *Dermatitis.* 2014; 25 (6):345-355
6. Warshaw E, Belsito D, Taylor J, et al. North American Contact Dermatitis Group patch test results: 2009 to 2010. *Dermatitis.* 2013. 24(2): 50-59
7. Warshaw E, Nelsen D, Maibach H, et al. Positive patch test reactions to lanolin: cross-sectional data from the North American Contact Dermatitis Group, 1994 to 2006. *Dermatitis.* 2009; 20(2):79–88
8. DeKoven J, Warshaw E, Belsito D, et al. North American Contact Dermatitis Group patch test results 2013-2014. *Dermatitis.* 2016. 28 (1): 33-46
9. Draelos Z, Rizer R, Trookman N. A comparison of postprocedural wound care treatments: Do antibiotic-based ointments improve outcomes? *J Am Acad Dermatol.* North Carolina/Colorado. 2010. 64(3): S23-29
10. Taylor SC, Averyhart AN, Heath CR. Postprocedural wound-healing efficacy following removal of dermatosis papulosa nigra lesions in an African American population: A comparison of a skin protectant ointment and a topical antibiotic. *J Am Acad Dermatol.* Philadelphia. 2010. 64(3): S30-S35
11. Sarnoff DS. A comparison of wound healing between a skin protectant ointment and a medical device topical emulsion after laser resurfacing of the perioral area. *J Am Acad Dermatol.* New York. 2010. 64(3): S36-S43
12. Trookman N, Rizer R, Weber T. Irritation and allergy patch test analysis of topical treatments commonly used in wound care: Evaluation on normal and compromised skin. *J Am Acad Dermatol.* 2011. 64(3): S16-22
13. Weber T, Gottlieb A, Kowcz A, Schoelermann A. A current review of the lanolin alcohol contact allergy literature. J Am Acad Dermatol. 2007. 58:AB57
14. Fowler J, Perryman J, Fowler L, Langley N. Lanolin allergy: A 500 patient patch test assessment of six pharmaceutical grade lanolins. *J Am Acad Dermatol.* 2009. 60: AB72

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