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

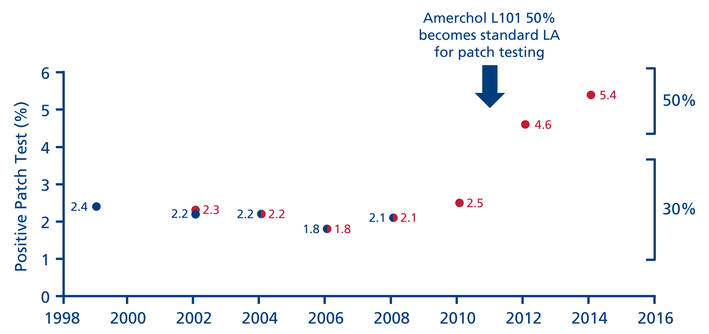
Z Draelos,[1] L Kircik,[2] D Rigel[3]

[1]Dermatology Consulting Services, PLLC, High Point, NC; [2]Icahn School of Medicine at Mount Sinai, New York, NY, and Indiana Medical Center, Indianapolis, IN; [3]New York University Medical Center, New York, NY

INTRODUCTION

- Lanolin alcohol (LA) is an ingredient used in wound healing ointments for its high cholesterol content, a key component of intercellular lipids[1]
- LA reduces transepidermal water loss (TEWL), and has been shown to have anti-inflammatory, skin-protecting, and barrier repair properties[1]
- LA is a subfraction of lanolin (wool wax), a natural product derived from the sebaceous glands of sheep
- The purification process of LA can vary, leading to many different purities of LA being available in the marketplace, and reports of allergic contact dermatitis (ACD) have raised concerns for its use
- Standard dermatology patch testing uses a specific LA preparation (Amerchol L101®, available as 10% in mineral oil) that has been shown to result in higher rates of allergy in patch testing than other sources of LA[2–4]
- In 2011, the concentration of Amerchol L101 in patch testing was increased from 30% in petrolatum (final 3% LA) to 50% (final 5% LA), resulting in an increase in reported LA allergy rates (Figure 1)[5,6]

Figure 1. North American Contact Dermatitis Group lanolin alcohol (LA) testing results, 1998–2016[5,6]



- In previous clinical trials and patch testing, an OTC LA-containing skin protectant ointment (SPO; Aquaphor Healing Ointment, Beiersdorf Inc., USA) has demonstrated efficacy in accelerating wound healing with no incidence of ACD[7–10]
- SPO contains a highly purified LA from a different manufacturer than that used in the standard patch test series
- This study specifically tested the incidence of ACD with SPO in a clinical setting

OBJECTIVE

- To evaluate the tolerability and safety of an OTC LA-containing SPO used for postsurgical skin care

METHODS

Subjects

- Male and female subjects age 18–75 years
- Subjects had a lesion located on the face, neck, trunk, arms, or legs that required surgical removal
- Subjects with lanolin-related allergies were excluded

Study design

- Three-center, open-label study
- Subjects underwent a surgical procedure to remove lesion appropriate for healing by secondary intention
- Each subject had one lesion surgically removed by shave removal using a blade, or by excision with a scalpel. No sutured wounds were allowed
- Subjects were instructed to clean the wound daily with a mild cleanser and apply SPO one to three times per day for 10–14 days
- After SPO application, wounds were covered with latex-free adhesive bandages or dressing deemed appropriate by the investigator
- Bandages were used each day for 7 days or as instructed by the physician

Assessments

- Wound sites were evaluated 10–14 days after surgery for:
  - Erythema, itching, and pain (0 = none, 1 = mild, 2 = moderate, 3 = marked, and 4 = severe)
  - Signs of infection (purulent discharge)
  - ACD (erythema, edema, papules, vesicles, bullae, weeping)
- If ACD was suspected, the subject was photographed and patch tested with the product and individual ingredients at a naïve site under occlusive patch conditions and evaluated on the following scale 1 hour after removal: 0 = none/absent; +/- = equivocal, + = weak, ++ = strong, +++ = severe

RESULTS

- 499 subjects were enrolled and completed the study
- No subjects were excluded during screening for lanolin-related allergies
- Each subject had one lesion removed; procedures included shave biopsies, shave excisions, punch biopsies, and excisions
- The incidence of erythema and itch was very low, with only mild scores being recorded; no incidence of pain was reported (Figure 2, Table 1)
- No ACD was observed, and consequently no patch testing was conducted (Figure 3, Table 2)
- There were no signs of infection in any subject
- 0.5% of subjects experienced an adhesive reaction

Figure 2. Incidence and scores for erythema, itching, and pain (N=499)

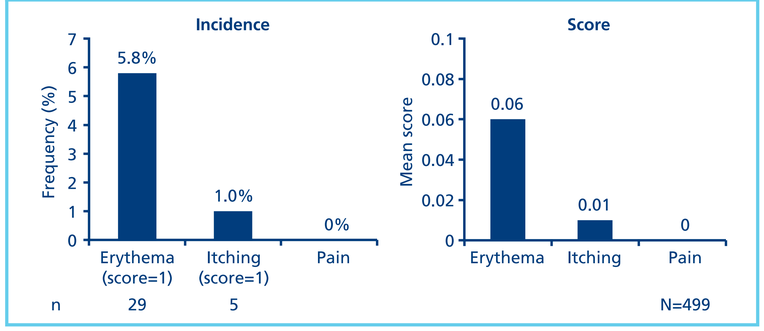
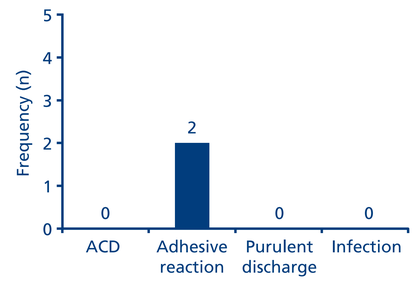


Table 1. Descriptive statistics for incidence of erythema, itching, and pain (0 to 4 severity scale; N=499)

	Erythema	Itching	Pain
Mean score	0.060	0.010	0.000
Standard deviation	0.246	0.100	0.000
Severity score, n (%)			
0	470 (94.2)	494 (99.0)	499 (100)
1	29 (5.8)	5 (1.0)	0 (0)
2	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)

Figure 3. Tolerability results (N=499)



ACD, allergic contact dermatitis

Table 2. Descriptive statistics for presence of ACD, adhesive reactions, purulent discharge, and suspicion of infection (N=499)

	Suspicion of ACD	Adhesive reaction*	Purulent discharge	Infection suspected
Mean score	0.000	0.005	0.000	0.000
Standard deviation	0.000	0.071	0.000	0.000
Frequency, n (%)				
No	499 (100)	398 (99.5)	499 (100)	499 (100)
Yes	0 (0)	2 (0.5)	0 (0)	0 (0)

*was not evaluated in 99 patients

CONCLUSIONS

- No incidence of ACD was observed in 499 subjects
- The absence of ACD with SPO in clinical studies may be due to its formulation containing a proprietary highly purified LA, and not the LA used in the standard dermatology patch test tray
- These data support the observation that LA preparations can differ in allergenicity based on the quality of their purification
- SPO has been clinically demonstrated to be well tolerated and safe for use in postsurgical wound care

REFERENCES

1. Hoppe U, et al. *The Lanolin Book*. Hamburg: Clausen & Bosse, 1999
2. Knijp J, et al. *Contact Dermatitis*. 2019; 80:298–303
3. Uter W, et al. *Contact Dermatitis*. 2018;78:355–371
4. Meist RYN, et al. *Dermatitis*. 2013;24:119–123
5. Warshaw E, et al. *Dermatitis*. 2009;20:79–88
6. DeKoven J, et al. *Dermatitis*. 2016;28:33–46
7. Draelos Z, et al. *J Am Acad Dermatol*. 2011;64:S23–S29
8. Taylor SC, et al. *J Am Acad Dermatol*. 2011;64:S30–S35
9. Sarnoff DS. *J Am Acad Dermatol*. 2011;64:S36–S43
10. Trookman N, et al. *J Am Acad Dermatol*. 2011;64:S16–S22

Sponsorship: Research sponsored by Beiersdorf Inc., Wilton, CT