

Cosmetic acceptability of licenced emollients - an *in vivo* comparison of two commercially available products, DEL P gel and DIPC cream

J. Gallagher¹, P. Rosher¹, K. Sykes¹, J. Walker¹, V. Hart²

¹Dermal Laboratories Ltd, Hitchin, UK

²RSSL, Reading, UK

Introduction and Objectives

Atopic eczema is the most common form of eczema, which usually develops in early childhood. In the UK, the National Institute of Clinical Excellence (NICE) clinical guidance on atopic eczema management in children from birth to the age of 12 years establishes emollient therapy as the treatment modality that should underpin all else.

Healthcare professionals are advised to offer patients with atopic eczema a regime of 'complete' emollient therapy involving a choice of non perfumed emollients to use every day, both as leave on moisturisers and as soap substitutes for routine washing and bathing. Although emollient effectiveness is of primary importance, treatment concordance depends upon patient satisfaction with the physical characteristics of their chosen product. The correct emollient for any particular patient is the one that the patient will actually use.

The aim of this study was to compare the cosmetic acceptability of a novel, proprietary emollient gel, Doublebase Dayleve™ gel (DEL P) with that of a marketed cream comparator, Diprobace™ cream (DIPC).

Materials and Methods

- The study was a single centre, double blind, concurrent, bilateral left/right leg comparison between the two products when applied twice daily for 5 consecutive days by 36 female eczema sufferers with dry skin.
- Written informed consents were obtained and witnessed on Day 1. Exclusion criteria were: significant concurrent illness or skin disease; history of allergy relevant to the test products or their ingredients; use of any topical or systemic treatment likely to affect the skin condition; visible skin abnormality, excessive hair growth, irritation, tattoos, scars or birthmarks at the treated sites; participation in any other study presently or within the past 3 months; breastfeeding and pregnancy (actually or potentially).
- The cosmetic acceptability of the product on each leg was assessed by the subject and recorded at the end of Day 5 as follows:
 - Overall product acceptability* (5 point scale, "Like Strongly", "Like slightly", "Neither Like nor Dislike", "Dislike Slightly" and "Dislike Strongly"). The percentage of subjects selecting either "Like Strongly" or "Like Slightly" for each product was compared within subjects (using Prescott's test to allow for effect of leg).
 - Willingness to use the product again* (Yes or No). The percentage of subjects reporting that they would use each product again was compared within subjects (using Prescott's test to allow for effect of leg).

Results and Discussion

Acceptability

69% of subjects selected either "Like Slightly" or "Like Strongly" for DEL P compared to only 33% for DIPC. This difference in overall product acceptability was statistically significant (Prescott's test, $p=0.025$). 53% of subjects disliked ("Dislike strongly" or "Dislike slightly") DIPC compared to 12% disliking DEL P.

Overall product acceptability of...	No. of subjects* selecting Like Slightly or Like Strongly	% of subjects* selecting Like Slightly or Like Strongly
DEL P	25	69%
DIPC	12	33%
<i>p</i> -value for DEL P vs DIPC**	$p=0.025$	

* From total of 36 subjects who were randomised.

** Using Prescott's test taking into account effect of leg.

Willingness to use again

One third of subjects answered that they would use DIPC again compared to 72% for DEL P. This difference was statistically significant (Prescott's test $p=0.033$).

Willingness to use the product again...	No. of subjects* selecting Yes	% of subjects* selecting Yes
DEL P	26	72%
DIPC	12	33%
<i>p</i> -value for DEL P vs DIPC**	$p=0.033$	

* From total of 36 subjects who were randomised.

** Using Prescott's test taking into account effect of leg.

Conclusion

Apart from clinical performance, the cosmetic acceptability of emollient products is very important because patients are unlikely to use products with poor cosmetic appeal, resulting in no clinical benefit. In this study overall product acceptability and patients' willingness to use the emollient again were significantly greater for DEL P compared with DIPC.

The importance of cosmetic acceptability of an emollient to treatment concordance

Emollients form the basis of treatment for atopic eczema and other dry skin conditions. This involves using emollients routinely and regularly. Involving patients in their choice of an emollient will ensure that patients can find an emollient they like to use. After all the most beneficial emollient for a patient is the one they will actually use.

Although emollient effectiveness is of primary importance, treatment concordance depends upon patient satisfaction with the physical characteristics of their chosen emollient.

This trial compared the cosmetic acceptability of a novel gel emollient, Doublebase Dayleve Gel with a marketed comparator emollient cream. Statistically significantly more subjects stated that they 'liked' Doublebase Dayleve Gel and would be willing to use the product again.

Summary of Poster Overleaf

- The study was a single centre, double-blind, concurrent bilateral left/right leg comparison between the two products in 36 female eczema sufferers with dry skin.
- Doublebase Dayleve™ Gel (DELP) or a comparator cream, Diprobace™ Cream (DIPC) were applied to the lower leg twice daily for five days.
- Cosmetic acceptability was evaluated by subjective assessment of overall product acceptability and willingness to use the product again.
- Doublebase Dayleve Gel was 'strongly liked' or 'slightly liked' by 69% of subjects which was statistically significantly greater compared to 33% for the comparator emollient cream.
- 53% of subjects disliked ('dislike strongly' or 'dislike slightly') the comparator cream compared to only 12% of subjects disliking Doublebase Dayleve Gel.
- Statistically significantly more subjects, 72%, selected Doublebase Dayleve Gel as an emollient they would use again compared with 33% for the comparator emollient cream.

Conclusion

“Apart from clinical performance, the cosmetic acceptability of emollient products is very important because patients are unlikely to use products with poor cosmetic appeal, resulting in no clinical benefit. In this study overall product acceptability and patients' willingness to use the emollient again were significantly greater for DELP compared with DIPC.”