

An *in vivo* comparison of two commercially available topical emollients in the UK, DELP gel and DIPC cream

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Emollients

The most popular emollients (and therefore the most effective ones because these are the only products that patients are prepared to use properly) have a lightweight 'feel' and are readily absorbed into the skin. Dermatologists encourage patients to use their emollients generously and frequently in order to maintain the hydration of the stratum corneum. In practice, however, frequent reapplication throughout the day is not always practical, particularly for patients who work or go to school. So, an emollient that is cosmetically acceptable and long lasting is likely to offer significant therapeutic advantages.

Objectives and Methodology

The aim of this clinical study conducted with full ethics committee and regulatory approvals was to compare the efficacy and acceptability of two licensed emollients used with a twice daily treatment regimen to simulate the practical situation for many patients who can only apply their emollients morning and evening: a novel formulation called Doublebase Dayleve[®] gel (DELP) and a comparator Diprobace[®] cream (DIPC).

- The study was a single centre, double blind, bilateral comparison of the skin moisturisation effects and acceptability of the two products when used twice daily by 36 female eczema sufferers with dry skin for 5 consecutive days.
- 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 skin response; visible skin abnormality, excessive hair growth, irritation, tattoos, scars or birthmarks at the test measurement sites; participation in any other study presently or within the past 3 months; breastfeeding and pregnancy (actually or potentially).
- Baseline measurements of skin hydration at sites on both lower legs were performed at about 9am on day 1. Subjects were then given the two test products, presented in identical 500g pre-weighed pump containers randomly labelled left and right, to apply to their lower legs twice daily (immediately after the 9am corneometry measurement and at 9pm) for the next 4 days and on the morning of day 5. Corneometry measurements were performed three times each day (nominally 9am, 1pm and 5pm) after at least 30 minutes acclimatisation, using the Multiprobe Adapter MPA5 with Corneometer CM825 probe (Hydration) (ex Courage-Khazaka electronic, Germany). Measurements were performed in triplicate to the same skin areas, located by a template for each subject. At the end of the study subjects completed a questionnaire addressing the physical properties/acceptability of the two products, including whether they preferred either product.
- The primary efficacy variable was the improvement in skin moisturisation by measurement of the area under the curve (AUC) of the change from baseline corneometer readings. AUC, using the actual corneometer measurement times, was calculated using the trapezoidal rule and treatment effects were estimated using the within subject error term, after adjustment for any effect of leg (right/left).

Results & Discussion

Analysis of the AUC change from baseline corneometry readings over a 5 day period (104 hours from 09:00 on day 1 to 17:00 on day 5) is tabulated below. There were no significant differences in the amounts of product used.

	DELP (n=36)	DIPC (n=36)	Treatment Effect DELP minus DIPC
Adjusted mean AUC	1748	349	1399
95% confidence interval (CI) for adjusted mean AUC	1573 to 1923	174 to 524	1180 to 1618
p-value for testing whether effect=0	<0.0001	0.0002	<0.0001

Both products significantly improved skin hydration from baseline. However, DELP performed statistically significantly better than DIPC such that the cumulative increase in skin hydration over the 5 days was estimated to be an increased AUC of 1399 units which represents an increase in skin hydration of approximately five times that seen for DIPC.

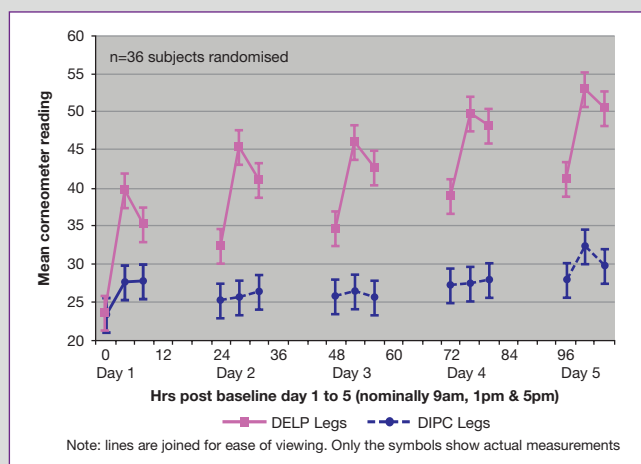


Figure 1: Mean corneometer readings with 95% confidence intervals

The improved skin hydration of DELP over DIPC was seen at every time point over the 5 day period. The mean corneometer readings are shown in Figure 1. The long lasting and cumulative benefit of DELP over DIPC is particularly illustrated by the morning readings each day (which were typically 12 hours after the latest application of the product the day before) which were significantly greater than the baseline reading (day 1, 9:00) and increased step-wise from day 2 through to day 5.

Subjects' responses as to which product they preferred are tabulated below.

Preferred leg with...	No. of subjects*	% of subjects*
DELP	27	75%
DIPC	6	17%
No preference**	3	8%
p-value for DELP vs DIPC***	p=0.0004	

* From total of 36 subjects who were randomised. ** Includes one subject who did not answer despite answering the rest of the questionnaire. *** Using Prescott's test of preference.

Conclusion

This study has indicated that there are significant differences in performance and patient acceptability between branded emollients - something that healthcare professionals should be aware of when prescribing these products. When used twice daily, DELP gel achieved significantly longer lasting and cumulative skin hydration and was generally preferred by subjects when compared with DIPC cream.

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When choosing a suitable leave-on emollient, consider the practical challenges of daytime reapplication

Patients are encouraged to reapply their emollient frequently through the day. However, in many circumstances this can be impractical, especially when patients are away from home - such as at school or work. As a result, many patients can only apply their emollients twice a day.

Doublebase Dayleve Gel is a new, advanced gel formulation combining high levels of emolliency with exceptionally long lasting protection, and the convenience of as little as twice daily application.

This trial compared the efficacy and acceptability of Doublebase Dayleve Gel with a comparator emollient cream, when used on a twice daily basis to simulate the practical situation for many patients.

Summary of Poster Overleaf:

- The study was a double blind, bilateral comparison in 36 female eczema patients with dry skin
- The two emollients were presented in identical 500g pump containers, randomly labelled left and right
- Patients applied each emollient to their respective lower leg twice daily, at approximately 9am and 9pm, for 5 days. There were no significant differences in the amounts of product used
- Corneometry measurements of skin hydration were performed three times each day (nominally just before the 9am application, at 1pm and 5pm)
- Both products significantly improved skin hydration from baseline. However, Doublebase Dayleve Gel performed statistically significantly better, such that the cumulative increase in skin hydration over the 5 days, estimated by area under curve (AUC) analysis, was 1399 units greater than from the comparator emollient cream. This represents a five fold improvement in skin hydration
- 75% of the patients preferred Doublebase Dayleve Gel

Conclusion:

This study has demonstrated that there are significant differences in performance and patient acceptability between branded emollients – something that healthcare professionals should be aware of when prescribing these products. When used twice daily, Doublebase Dayleve Gel achieved substantially better and longer lasting skin hydration and was generally preferred by subjects when compared with an established comparator emollient cream.