

# Are all emollients equally effective in hydrating dry skin? A single centre, double-blind, bi-lateral comparison of two commercially available emollient products in the UK

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## Introduction and Objectives

Prescribers tend to recommend emollient products based primarily on patient preference and cost. Performance as such tends to be overlooked because few studies compare product effectiveness *in vivo*. The aim of this clinical study conducted with full ethics committee and regulatory approvals was to compare skin hydration over a 24 hour period following single applications of two licensed emollients: a novel formulation called Doublebase Dayleve™ gel (DELP) and a well-established comparator Diprobace™ cream (DIPC).

## Materials and Methods

- The study was a single centre, double blind, bilateral comparison in female eczema sufferers with dry skin. 34 subjects took part, divided between two cohorts of 19 and 15. Each cohort took part at the test centre on different days. Written informed consents were obtained and witnessed on day 1.
- Two test sites each of 20cm<sup>2</sup> were demarcated on the volar (inside) aspects of both forearms, adjacent to the wrist and flexure, and baseline measurements of skin hydration performed at about 9am.
- 0.05ml DELP and DIPC were then applied to one test site on opposing forearms using a randomisation prepared in advance so that the right/left and wrist/flexure allocation was approximately equal for both products.
- Triplicate corneometry measurements at treated and adjacent untreated skin sites were repeated nominally at hourly intervals for the first four hours and at 6, 8, 12 and 24 hours using the Multiprobe Adapter MPA5 with Corneometer CM825 probe (Hydration) (ex Courage-Khazaka electronic, Germany). During this period subjects were not permitted to bath, shower or bathe, and they kept their arms uncovered.
- The primary efficacy variable (i.e. the Intention To Treat (ITT) analysis based on all 34 subjects randomised to treatment) was the improvement in skin hydration 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, after checking for normality, using the trapezoidal rule, and treatment effects were estimated using the within subject error term, after adjustment for any effect of arm (right/left). An additional sensitivity analysis for the primary efficacy variable was performed adjusting for the AUC of the untreated area, but these results are not presented because the conclusions are the same as those for the main analysis.

## Results and Discussion

Significant differences were observed between the two cohorts (probably owing to differing environmental conditions over their respective treatment days), and so the results are presented overall and for each cohort. Following single applications, sites treated with DELP and DIPC demonstrated statistically significant increases in skin hydration compared to adjacent untreated sites. However, the cumulative increase in skin hydration over the 24 hour period was significantly greater for the sites treated with DELP compared to the sites treated with DIPC.

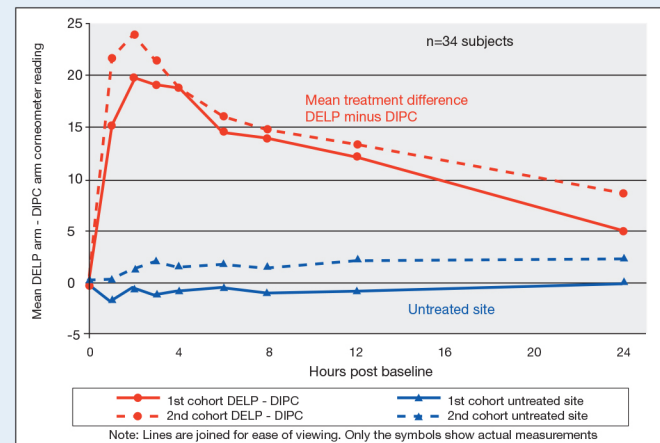
Overall the estimated treatment difference, DELP minus DIPC, was an increased AUC of 306 units (95% CI 273 to 338,  $p < 0.0001$ ), which represents an increase in skin hydration of DELP of at least three times that seen for DIPC. This improved skin hydration of DELP over DIPC was seen at all measurement times. Since the AUC was measured over a 24 hour period, dividing the treatment difference AUC by 24 gives a value which approximates to a 'mean corneometer reading', and corresponds to an estimated treatment difference for DELP over DIPC of more than 12 units (12.2 for the first cohort and 13.7 for the second cohort).

Table 1: 24 hour AUC change from baseline corneometer reading

	DELP (n=34)	DIPC (n=34)	Treatment Difference DELP minus DIPC
Adjusted mean	382.1	76.4	305.7
For 1 <sup>st</sup> cohort (n=19)	329.2	37.1	292.1
For 2 <sup>nd</sup> cohort (n=15)	442.0	112.4	329.5
95% confidence interval (CI) for adjusted mean	350 to 414	44 to 109	273 to 338
For 1 <sup>st</sup> cohort (n=19)	280 to 379	-12 to 87	243 to 341
For 2 <sup>nd</sup> cohort (n=15)	396 to 488	67 to 158	285 to 375
p-value for testing whether effect=0	<0.0001	<0.0001	<0.0001
For 1 <sup>st</sup> cohort (n=19)	<0.0001	0.13	<0.0001
For 2 <sup>nd</sup> cohort (n=15)	<0.0001	<0.0001	<0.0001
p-value for effect of cohort	N/A	N/A	0.0026
p-value for effect of arm (FVL)	N/A	N/A	0.0075
p-value for effect of allocation	N/A	N/A	0.078

The difference in mean corneometer readings between the DELP and DIPC arms are shown versus time for the treated and untreated sites. This clearly illustrates the long lasting nature of the moisturisation benefit of DELP over DIPC.

Figure 1: Mean corneometer readings for the treatment difference (DELP arm minus DIPC arm) vs untreated arm by cohort



## Conclusion

These results indicate substantial differences between the degree and duration of skin hydration achieved by two licensed emollients. After single application, the cumulative increase in skin hydration was significantly greater for the sites treated with Doublebase Dayleve™ gel compared to the sites treated with Diprobace™ cream.

# Are all emollients equally effective in hydrating dry skin?

When selecting an appropriate emollient for patients with dry skin conditions, consideration is often given to patient preference and cost. Preference matters because patients have to use their emollients routinely. However, the performance of the emollient is often overlooked, possibly due to lack of evidence or perhaps the assumption that all emollients are equally effective?

Now there are new comparative efficacy data for Doublebase Dayleve Gel. This is an advanced gel formulation combining high levels of emolliency with long lasting emollient protection, and the convenience of as little as twice daily application.

The trial compared the effects on skin hydration of Doublebase Dayleve Gel with a well-established emollient cream and demonstrated substantial differences in the degree and duration of skin hydration.

## Summary of Poster Overleaf

- The study was a single centre, double-blind, bilateral comparison in 34 female eczema sufferers with dry skin.
- Subjects applied single applications of Doublebase Dayleve Gel and a comparator emollient cream to test sites on opposing forearms.
- Triplicate corneometry measurements were taken at treated and adjacent untreated skin sites at hourly intervals for the first 4 hours and at 6, 8, 12 and 24 hours.
- Following single applications there were statistically significant increases in skin hydration at treated skin sites compared to untreated sites.
- The cumulative increase in skin hydration over the 24 hour period was significantly greater for skin sites treated with Doublebase Dayleve Gel compared to sites treated with the comparator emollient cream.
- There was an estimated treatment difference increase in skin hydration with Doublebase Dayleve Gel of at least three times that seen for the comparator emollient cream.

## Conclusion

“These results indicate substantial differences between the degree and duration of skin hydration achieved by two licensed emollients. After single application, the cumulative increase in skin hydration was significantly greater for the sites treated with Doublebase Dayleve™ gel compared to the sites treated with Diprobace™ cream.”