

Comparison of emollient efficacy – a single centre, randomised, double-blind, bi-lateral comparison of two emollients prescribed in the UK for the management of dry skin conditions such as atopic eczema

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Introduction and Objective

Despite universal acceptance of the importance of emollient therapy, there remains a lack of good quality evidence for some emollients on their effectiveness in hydrating the skin. Some healthcare professionals are under the impression that all emollient preparations are generally equally effective. As a result, these products tend to be recommended based primarily on patient/consumer preference and cost, with cheaper options assumed to be therapeutically equivalent. However, NICE recognise that there is a lack of comparative data on emollients and has urged more research to be conducted in this area.

The aim of this study was therefore to compare the effects on skin hydration of two emollients prescribed in the UK, Doublebase Dayleve™ gel (DELP) and Zerobase™ cream (ZBC), using a dosage regimen consistent with most patients' practical circumstances which limits their use of emollients to twice daily only.

Materials and Methods

- This was a single centre, randomised, double-blind, concurrent bi-lateral (within-patient) comparison in 18 females with atopic eczema and dry skin of similar severity on both their lower legs.
- Following 7 days' run-in with no use of emollients or moisturisers on the lower legs, DELP gel and ZBC cream were each applied to one lower leg twice daily (approximately at 9am and 9pm) for 4 days and on the morning only on day 5.
- Washing of the lower legs was permitted only during the evening on days 2 and 4 prior to applying the products.
- The efficacy of both products was assessed by hydration measurements using a Corneometer CM825 probe (Courage-Khazaka electronic).

- The measurements were made three times daily on days 1 to 5 at approximately 9am immediately prior to the first daily application (the measurement on day 1 being the 'baseline'), and around 1pm and 5pm.
- The primary efficacy parameter was the degree and duration of skin hydration as determined by the area under the curve (AUC) of the change from baseline corneometer readings over the 5 days.

Results

The two emollients showed very different effects on skin hydration, with DELP gel significantly outperforming ZBC cream (p -value <0.0001). The increase in skin hydration for legs treated with DELP gel was estimated to be approximately ten times that seen for ZBC cream (Table 1).

Table 1. 5 day AUC change from baseline corneometer reading

	DELP (n=18)	ZBC (n=18)	Treatment Effect DELP minus ZBC
Adjusted mean AUC	1772	172	1601
95% confidence interval (CI) for adjusted mean AUC	1487 to 2058	-114 to +457	1277 to 1924
p -value for testing whether effect=0	<0.0001	0.22	<0.0001

Estimates and p -values are calculated from a model with subject as a random effect and leg, randomised group & treatment as fixed effects with baseline corneometry measurement as covariate

The cumulative increase in skin hydration observed for DELP gel (as measured by AUC) was substantial and long lasting.

For DELP gel, the corneometry readings generally increased over the treatment period.

Even the morning readings on days 3 and 5, after washing on the previous evening, were significantly better than baseline (p -value <0.0001).

In contrast, for ZBC cream, no morning readings were significantly different from baseline, and there was also no significant improvement in the cumulative skin hydration as measured by the AUC (p =0.22).

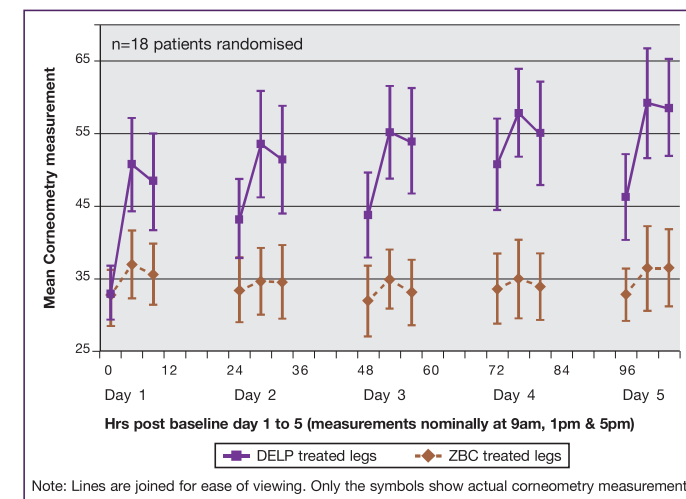


Figure 1. Mean corneometer readings with 95% confidence interval

Conclusion

This study has demonstrated very significant performance differences between two marketed emollients. Whereas DELP gel achieved substantial, long lasting and cumulative skin hydration when used twice daily, ZBC cream achieved no measurable improvement compared to before treatment. Healthcare professionals should be aware that different emollients can perform differently and that, as exemplified in this study, such differences can be highly significant.