THE MOISTURISING PROPERTIES OF A HEEL BALM IN PATIENTS WITH ROUGH DRY SKIN

Dry plantar skin affects many older people and can result in callous and fissuring, which can reduce mobility of sufferers, cause pain, and in the case of patients with diabetes, is associated with increased risk of ulceration. This article compares the use of two specialist foot creams, one a daily application and the other a twice-daily application, to examine the effect on patient compliance.

KEY WORDS

Dry skin
Diabetes
Compliance
Emollient

PETER DYKES
BSc, PhD, Director, Cutest Systems Limited
www.cutest.co.uk

Patients' non-compliance and difficulties in following an effective emollient application regimen are well-documented in the dermatology literature (Holden et al, 2002).This is exacerbated where the application is to the feet, particularly in the elderly and in patients with limited dexterity and flexibility who often struggle to reach their feet to apply emollient creams.

Dry plantar skin affects many elderly patients and can result in callous and fissuring, which can reduce mobility, cause pain, and in the case of patients with diabetes, is associated with increased risk of ulceration.

The skin of the plantar aspect of the feet is more than six times thicker than that on the trunk of the body (Ya-Xiang, 1999) resulting in the availability of specialist foot creams on the NHS Drug Tariff. These creams require a twice-daily application, with the patient having to wash and dry their feet first, which makes the application process even more time-consuming and difficult.

This study was designed to test the efficacy of a treatment that only requires a daily application, which would make it more convenient for patients and lead to better compliance.

THE STUDY

This study was performed at home by 25 normal volunteer subjects, all with visibly dry and rough skin on their feet. The study was monitored by nurses employed by Cutest Systems Ltd as clinical trial nurses.

Aim

This study was designed to determine the effectiveness and moisturising properties of two heel balm treatment regimens on the feet of normal volunteer subjects with rough dry heels.

Study design

The study was designed as a two-week home user programme, where the subjects used the products according to instructions after normal washing procedures. The study was a within-subject comparison of two treatment regimens — Treatment A (Dermatonics Heel Balm, Dermatonics Ltd [*Figure 1*]) used once daily; and Treatment B (urea-containing cream) used twice daily. One regimen was applied to each foot, the allocation to the left or right foot being arrived at by means of a pre-prepared randomisation code generated by Cutest Systems Ltd.

The study nurses assessed the test area (heel) using a six-point ranking photographic scale. The test areas were also assessed for dryness by measuring the capacitance of the stratum corneum using a Corneometer® (Courage + Khazaka). This machine uses an electrical pulse, the resistance to which is proportional to the water content of the

References

Baird S, Skinner C, Trail S, Frankis JS (2003) Anhydrosis in the diabetic foot: a comparison of two urea creams. *Diabetic Foot* 6(3): 122–36

Holden C, English J, Hoare C, et al (2002) Advised best practice for the use of emollients in eczema and other dry skin conditions. *J Dermatol Treat* 13: 103–06

Ya-Xian Z, Suetake T, Tagami H (1999) Number of cell layers of the stratum corneum in normal skin – relationship to the anatomical location on the body, age, sex and physical parameters. *Arch Dermatol Res* 291(10): 555–59

skin. Digital photographs were also taken of each patient at each assessment . These photographs were for reference only and were not evaluated.

Subjects

A total of 25 female volunteers aged 18 years or above with visibly dry and rough skin on their heels were recruited for the study by word of mouth. Volunteers of the same sex were used to produce a more uniform population in this small group. They were selected by telephone from a test panel of volunteers, maintained by Cutest Systems Ltd.

The mean age of the 25 subjects was 49 years with an age range of 33 to 64 years. In addition, all subjects fulfilled the inclusion and exclusion criteria as detailed below.

Inclusion criteria

The inclusion criteria for the study was:

- Female subjects aged 18–65 years
- Subjects who are healthy with no significant concurrent illnesses or skin disease
- Subjects with visibly dry and rough skin on their heels (grades 3, 4 or 5) The grading system used comprised a series of photographs from a previous unpublished trial (*Figure 2)*
- Subjects who have signed the consent form after the nature of the study has been fully explained.

Exclusion criteria

The exclusion criteria included the following:

- Pregnant or lactating females or females of reproductive age not using a reliable form of contraception
- Subjects who take any medication likely to interfere with the study
- Subjects with a history of significant skin disease (e.g. eczema, psoriasis)
- Subjects with an allergy likely to interfere with the study
- Subjects who are unwilling or unable to give written consent
- Subjects with a recent history (previous 12 months) or evidence of alcohol, substance or drug abuse.

Ethical approval

Ethical approval was obtained from the Cardiff Independent Research Ethics Review Committee (CIRERC).
All subjects had the nature of the study explained to them and were given written information concerning the study. They were informed that they were able to withdraw from the study at any stage without obligation and without being required to state a reason. All subjects gave their written, witnessed, informed consent before starting the study.

Study materials

The study used a Heel Balm (Treatment A, Dermatonics Heel Balm), which was to be applied once per day. Dermatonics Heel Balm contains 25% urea and high-concentration urea creams have been shown to be particularly effective in the treatment of dry plantar skin (Baird et al, 2003).

Treatment B was a urea-containing cream supplied by the study sponsor (Dermatonics Ltd), which was to be used twice daily.

The subjects were unaware of the make-up of the treatments as they were simply labelled as Treatment A or Treatment B.

Figure 1: The Heel Balm used as Treatment A in the study.

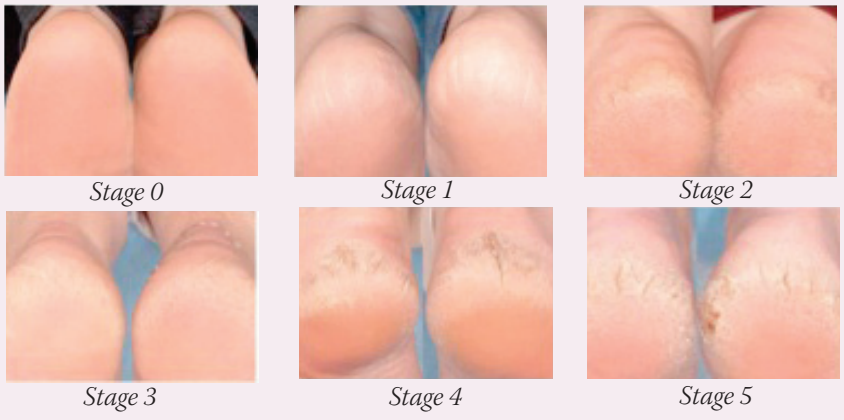

Figure 2: Photographs used to classify the subjects' heel damage.

Test area

The test site for the study was the foot. The area of the foot to be assessed and photographed was the centre of the posterior part of the heel of the foot. This area of the foot was chosen to be consistent with the study mentioned above (Baird et al, 2003). All measurements of skin hydration were taken from the side of the heel as instructed by the study sponsor. Both feet were assessed independently. Each subject applied one cream to each foot according to a randomisation code.

Assessment scale

The following scale has been supplied by the sponsor and was used by the study nurse to assess the heels of the subjects (*Figure 2*):

- Grade 0: smooth, fine lines, and no dryness
- Grade 1: dry lines, slight scaling, and skin thickening
- Grade 2: small fissures, moderate scaling, and skin thickening
- Grade 3: deep fissures, obvious scaling, and skin thickening
- Grade 4: small gaps on fissures, severe scaling, and skin thickening
- Grade 5: big gaps and openings on fissures, bleeding, extreme scaling, and skin thickening.

Each heel was assessed separately.

Clinical assessment

The study nurse screened all subjects at the start of the study to ensure that the subjects' heels fell into grades 3, 4 or 5 for the purposes of this study.

The posterior part of each subject's heel was assessed clinically using a six-point ranking photographic scale supplied by the study sponsor. All assessments were carried out on day 0, day three and day 14 of the study.

The assessments were carried out in a blind manner with the study nurse not being aware of product allocation. Each heel was assessed separately.

Objective assessment

Conditions

All measurements took place in a clinic room with controlled temperature and relative humidity. Subjects sat for 15 minutes in the controlled environment without any tights or footwear on before any measurements were taken.

Dryness – corneometer

Dryness was assessed by measuring the capacitance of the stratum corneum using a corneometer. Three measurements were taken from each of the test sites to the side of the heel and the mean of these three values was used in subsequent analysis.

'All measurements took place in a clinic room with controlled temperature and relative humidity'

Table 1
The results of the clinical scores and the difference values of Treatment A

N = 25	*Day 0*	*Day 3*	*Day 14*	*Difference, day 14 – day 0*
Mean	*3.60*	*3.00*	*1.40*	*-2.20*
SD	*0.50*	*0.76*	*0.87*	*0.76*
Median	*4*	*3*	*2*	*-2*

‘Analysis of foot cream prescription data from the NHS Drug Tariff suggests that current practice largely consists of prescribing a twice-daily treatment’

Table 2
The results of the clinical scores and the difference values of Treatment B

N = 25	*Day 0*	*Day 3*	*Day 14*	*Difference, day 14 – day 0*
Mean	*3.44*	*2.88*	*1.32*	*-2.12*
SD	*0.58*	*0.78*	*0.75*	*.78*
Median	*3*	*3*	*1*	*-2*

Digital photography
Digital photographs were taken of the heels at each of the assessment time points. These photographs were for illustrative purposes only and have not been evaluated.

Instructions for use
Subjects were instructed to use the allocated products at home daily for a period of two weeks. The test products were to be used after normal washing procedures to the allocated foot only. The allocation of the test products to the left or right foot was randomised. The test products were applied around, but not in, any split skin. The treatments were applied once daily, in the morning (Treatment A) or twice daily, morning and evening (Treatment B).

Subject restrictions
Subjects were instructed not to change their washing or bathing habits or products for the duration of the study. Subjects were also instructed not to use any additional moisturising foot products on their feet or have any pedicures or treatments (including filing, buffing or prolonged soaking) of the feet.

Subject compliance
Subjects were contacted by telephone on day 10 in order to assist in determining subject compliance — with no contact between day three and 14, the protocol included a phone call to check and ensure continued compliance. No problems in subject compliance were detected at this time or at the end of the study period.

Data analysis
The data from the corneometer and the clinical assessments were entered into a spreadsheet using a format that generated summary statistics (mean, standard deviation [SD], median) for each time point.

The data were subject to a 100% quality control procedure, whereby the printed output from the spreadsheet was checked against the original case report form. Each site was measured three times using the corneometer. The average of the three readings was used in subsequent analysis.

In order to determine any overall treatment effect for individual treatment regimens, the values at day 0 and day 14 were compared statistically. The clinical scores were compared using a non-parametric Wilcoxon Signed Rank Test. The corneometer readings were compared using a paired t-test. In addition, the values at day 14 were baseline subtracted and comparisons made between regimens. All comparisons were made using Unistat for Windows (www.unistat.com) and results were considered significantly different if $p \leq 0.05$.

RESULTS
Test panel attendances
All 25 subjects who entered the study

Table 3
Results of the corneometer readings and the difference values – Treatment A

N = 25	*Day 0*	*Day 3*	*Day 14*	*Difference, day 14 – day 0*
Mean	*33.96*	*40.42*	*41.39*	*7.42*
SD	*6.32*	*8.96*	*8.52*	*7.67*
Median	*33.93*	*39.67*	*39.00*	*6.80*

Table 4
Results of the corneometer readings and the difference values – Treatment B

N = 25	*Day 0*	*Day 3*	*Day 14*	*Difference, day 14 – day 0*
Mean	*34.24*	*42.22*	*43.67*	*9.43*
SD	*6.29*	*10.48*	*10.06*	*8.63*
Median	*34.17*	*40.33*	*41.97*	*8.40*

attended all of the assessment times and were deemed to have completed the study. No adverse events were recorded during the study.

Clinical scores

The results of the clinical scores and the difference values (day 14 minus baseline) for Treatment A are given in *Table 1*. Treatment A showed a small decrease in mean clinical score at day three but a much larger decrease at day 14.

When compared statistically the difference between day 0 and day 14 values for treatment A was highly significant in improving the health of the foot skin as indicated by a large decrease in the clinical signs of dryness (scaling, fissuring) ($p < 0.0001$).

Results from Treatment B, which was applied twice a day, are given in *Table 2*. The changes seen were very similar and when compared statistically, the difference between day 0 and day 14 values for was highly significant ($p < 0.0001$). The magnitude of the change (day 14 minus baseline) was almost identical for both regimens and when analysed statistically there was no significant difference ($p > 0.05$).

Corneometer readings

The results of the corneometer readings are summarised in *Tables 3* and *4*. Treatment A showed an increase in mean corneometer readings at day three and a further increase at day 14 indicating increased hydration of the skin surface When compared statistically, the differences between the day 0 and day 14 values for treatment A was highly significant ($p < 0.0001$).

Results from treatment B, which was applied twice a day, were similar to those for treatment A. When compared statistically the differences between the day 0 and day 14 values for treatment A was highly significant ($p < 0.0001$). Again when the difference values were compared there was no significant difference between the two regimens.

DISCUSSION

The outcome of the trial demonstrates that Dermatonics Heel Balm is effective as a once-a-day treatment for dry feet. This has important implications for users of specialist foot creams on the NHS Drug Tariff as compliance will be far easier with a daily treatment than with treatments that require twice-daily applications. It will also reduce costs to the NHS as a result of the lower usage accruing from 50% fewer applications.

Analysis of foot cream prescription data from the NHS Drug Tariff suggests that current practice largely consists of prescribing a twice-daily treatment. Given the evidence of patient non-compliance (Holden, 2002), it would seem appropriate where competing products have otherwise similar claims to move prescribing from a twice-daily to a daily regimen.

CONCLUSIONS

The results of this study clearly show an improvement in the rough dry heels of the subjects over a 14-day period with both treatment regimens.

There was a significant decrease in the mean clinical scores for both regimens over the study period.

Similarly, there was an increase in skin surface hydration as measured by the corneometer. It may, therefore, be concluded that Dermatonics Heel Balm is not only clinically effective in improving rough dry heels but that when used once a day it is as effective a twice-daily regimen. WUK

‘The outcome of the trial demonstrates that Dermatonics heel balm is effective as a once-a-day treatment for dry feet