Effects of a urea-based moisturiser on foot xerosis in people with diabetes

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This article describes a single-blind controlled pilot study examining the effects of a urea-based moisturising cream on foot xerosis in people with diabetes. Both clinical effectiveness and participant satisfaction were assessed. The promising clinical improvements, and the high level of participant satisfaction, seen suggest that a further, larger-scale study of urea-based moisturisers in people with diabetes is warranted.

The skin is the largest organ of the body, and varies in both its morphology and function depending upon location. Although the skin on the plantar surface of the foot is very thick, it is highly visco-elastic and is able to cope with the high levels of frictional, compressive and shear stress applied to it during weight bearing. The reactive dynamic deformation of dermal tissue to these applied forces also has to be accommodated by the epidermis. This is achieved predominately by epidermal hysteresis and distensibility, made possible by the moisturising effect of eccrine sweat gland secretions (Ryder et al, 1988).

Dryness of the skin (xerosis), due to decreased moisture and lipid content within the stratum corneum, is common, and is considered to be concomitant with normal skin ageing processes (Pigatto et al, 1996; Nicander, 1998). Xerosis is also associated with several medical conditions, including diabetes, where autonomic denervation leads to decreased sweat secretion and loss of thermoregulatory control (Tzeng et al, 1993). Autonomic neuropathy has been reported to be present in 6% of people with diabetes (Ziegler, 2001), although it may be more common than this. Clinically, autonomic neuropathy presents as a warm, dry, insensitive foot (Dyck et al, 1992; Ziegler, 2001), commonly with associated plantar callus and skin fissures, the latter increasing the potential for subsequent infection and foot ulceration (Gilmore et al, 1993; Murray et al, 1996; Ziegler, 2001; Vinik et al 2003).

Replenishing the moisture lost from the stratum corneum by the regular use of moisturisers, and thus increasing plantar skin flexibility and suppleness, should be encouraged for people with diabetes (Loden, 1996). This simple activity may help to reduce xerosis and its associated complications, including fissure and callus formation, which may lead to limb-threatening infection or ulceration. Despite its apparent importance, there is very little discussion in the literature of the effectiveness of foot moisturisers in people with diabetes (Pham et al, 2002).

The regular use of moisturisers is an integral component of diabetic foot care, but one which is, in the authors' clinical experience, frequently not adopted or maintained by people with diabetes. Commonly given reasons for failing to adhere

Article points

1. Regular use of moisturisers to reduce xerosis and subsequent fissures and callosities reduces the risk of ulceration in people with diabetes.
2. This pilot study aimed to evaluate the clinical effectiveness and patient satisfaction with use of a 10% urea-based moisturiser.
3. Use of the urea-based moisturiser improved clinical parameters and patient satisfaction. A full investigation of urea-based moisturisers for preventative treatment of the diabetic foot is warranted.

Key words

- Xerosis
- Urea-based moisturisers
- Patient satisfaction

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Page points

1. Three clinical parameters were assessed in the evaluation of Allpresan 3's effectiveness: (i) skin dryness, (ii) skin flexibility and (iii) callus formation. An evaluation of participant satisfaction was also undertaken.
2. A 5-point scale was used to record a baseline assessment score on the three clinical parameters at baseline. The same scale was utilized again at week 2.
3. Control moisturisers were those that the study participants were already using at the time of recruitment.

to a foot moisturisation regimen include: no perceived beneficial moisturising effect, poor skin absorption, and that the creams are too greasy.

There are a large number of creams available, some of which contain humectants (e.g. urea, glycerine), which increase the water-binding capacity of the skin (Miettinen et al, 1999) and can be used to treat xerosis. Urea, a normal constituent of healthy stratum corneum, is thought to disperse keratin and expose otherwise unavailable water-binding sites (Swanbeck, 1968) and so enhance rehydration. Herein the effectiveness of a urea-based, foaming foot moisturiser containing 10% urea, Allpresan 3 (Neubourg Skin Care, Greven), on foot xerosis in people with diabetes is reported.

Aims

This single-blind controlled pilot study aimed to evaluate the clinical effectiveness of the urea-based moisturiser, Allpresan 3. Three clinical parameters were assessed in the evaluation of the agent's effectiveness: (i) skin dryness, (ii) skin flexibility and (iii) callus formation. An evaluation of participant satisfaction was also undertaken.

Methods

Study population

Twenty-six people with diabetes were recruited from either diabetes outpatient clinics, or foot clinics (*Table 1*). Participants were consecutively recruited and included in the study group if they had type 1 or type 2 diabetes, xerosis present on both feet and neuropathy. The ability to apply cream, and a willingness to adhere to the study requirements, were also inclusion criteria.

People were excluded from the study if they had peripheral vascular disease (non-palpable pulses, and an ankle–brachial pressure index of <0.8). Those with known skin allergies, skin sensitivities or non-diabetes related skin disorders (e.g. psoriasis, eczema) were also excluded.

Table 1. Study group demographics.

	Men	Women	Overall
Participants (*n*)	12	14	26
Mean age (years)	64	57	60 (range 40–74)
Type 1 diabetes (*n*)	1	5	6
Type 2 diabetes (*n*)	11	9	20
Mean diabetes duration (years)	16	17	16 (range 1–45)

Study design

The presence of sensory peripheral neuropathy was determined by a 10g nylon monofilament (Owen Mumford, Woodstock) applied to non-callused, non-indurated or unscarred skin over the first, third and fifth metatarsal heads and plantar surface of the hallux. Vibration perception thresholds were measured (mean of three consecutive values), using a neurothesiometer at the apex of the first toe. Sharp sensation was tested on the skin at the base of the first nail plate using a Neurotip placed in a Neuropen (Owen Mumford). All peripheral pulses were palpated, and ankle systolic pressures were obtained at all pulse sites using a hand-held doppler and a standard sphygmanometer. Brachial blood pressures were obtained to determine the ankle–brachial pressure index for each participant. The principal investigator performed all neurological and vascular assessments.

A 5-point scale (1 being normal, supple plantar skin without dryness or callus; 5 being extremely dry, very inflexible, plantar skin with thick callus) was used to record a baseline assessment score for the three clinical parameters (skin dryness, skin flexibility, callus formation). Each subject's baseline assessment was placed in a folder, which was held in a locked cupboard until the end of the study; thus, the investigator was blind to all baseline scores at subsequent visits. Participants were instructed not to reveal to the investigator which foot was being treated with Allpresan 3 or control.

Allpresan 3 was given to each participant and use of the agent was randomly allocated to one of the participant's feet. This was achieved by an independent person marking "R" or "L" (denoting right or left foot) inside the lid of each Allpresan 3 can. All participants were asked to apply Allpresan 3 to the allocated test foot, and their regular moisturising cream to the contra-lateral non-test foot. Each moisturiser (test and control) was to be applied to its assigned foot, over the whole surface but not between the toes, twice daily for 2 weeks. Control moisturisers were those that the study participants were already using at the time

of recruitment. These were: aqueous cream (made to the British Pharmacopoeia formulation), E45 (Reckitt Benckiser, Slough), Diprobase (Schering–Plough, Welwyn Garden City) and Unguentum Merck (Hermal, Reinbeck). There was a 2-week wash-out period, during which no moisturisers were used, before commencement of the study.

Following 2 weeks of twice-daily moisturiser application, the same 5-point scale was used to reassess the same set of clinical parameters taken at baseline for each participant. Participants also completed a satisfaction questionnaire at this time, comparing Allpresan 3 and their regular moisturiser (control) for a range of factors.

Statistics

The mean value of each parameter for Allpresan 3 and the control moisturisers was calculated for the baseline and the reassessment visit (2 weeks from baseline). Mean differences between the test and control feet were then calculated, and a Student's paired *t*-test was used to analyse these data. Subject satisfaction was expressed as a percentage value for each parameter measured.

Results

Twenty-six people were recruited; all participants completed the study. Similar numbers of men and women were recruited, and the mean ages were similar between the sexes (*Table 1*).

Clinical parameters

For both skin dryness and skin flexibility, Allpresan 3 was shown to be significantly more effective than the control moisturisers by the end of the 2-week study period (P=0.0001 for both parameters; *Table 2*). When callus formation was considered, there was a small reduction seen in the Allpresan 3 group compared with the control moisturisers, though it was not statistically significant (P=0.09; *Table 2*).

Participant satisfaction

In terms of satisfaction, when compared with the control moisturisers, Allpresan 3 was rated "high" for ease of application, absorption, post-application skin feel, improved skin hydration and overall satisfaction by ≥83% of participants (*Figure 1*). However, only 63% rated their satisfaction with Allpresan 3 as "high" for smell (*Figure 1*). When asked which cream they preferred and wished to continue using, 25 of the 26 participants (96%) answered Allpresan 3.

Discussion

Advising people with diabetes complicated by peripheral neuropathy or vascular disease to use moisturisers on a daily basis is a cornerstone of good foot health education. The rationale is to keep the skin of the foot soft and pliable, helping to prevent complications which may lead to limb-threatening infection or ulceration. Although moisturiser use as a part of preventative care

Page points

1. For both skin dryness and flexibility, Allpresan 3 was significantly more effective than the control moisturisers.
2. When asked which cream they preferred and wished to continue using, 96% of participants answered Allpresan 3.
3. People with diabetes should be advised to use foot moisturisers on a daily basis to help prevent fissure and callus formation, which may lead to limb-threatening infection and ulceration.

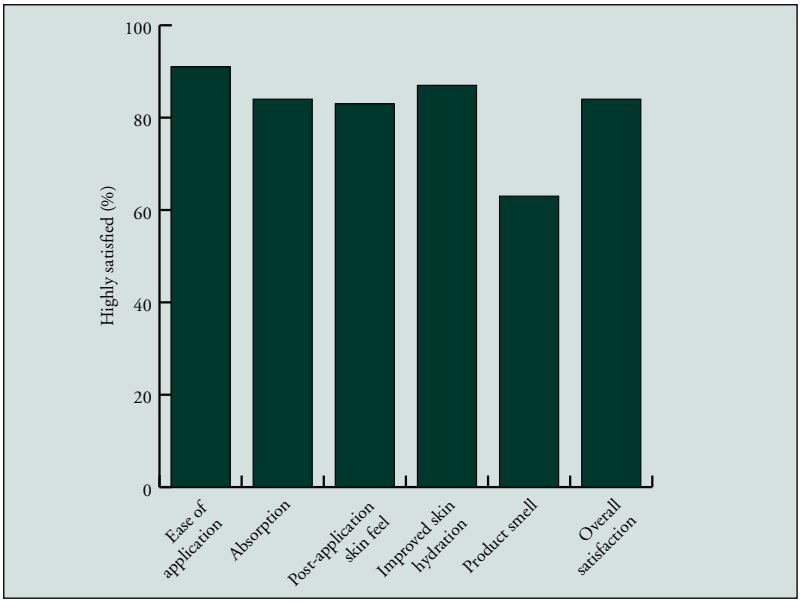

Figure 1. Results from the participant satisfaction survey showing the percentage of people who rated their satisfaction with Allpresan 3 as "high", in comparison with their control moisturiser, for the listed categories.

Table 2. Mean scores and standard deviation for each of the clinical parameters tested.

	Allpresan 3			Control moisturiser		
	Baseline	Week 2	Score difference	Baseline	Week 2	Score difference
Skin dryness	3.81 (0.90)	1.73 (0.67)	2.08 (0.74)	3.77 (0.86)	3.46 (0.81)	0.31 (0.47)
Skin flexibility	3.42 (0.64)	2.19 (0.69)	1.23 (0.65)	3.42 (0.64)	3.35 (0.63)	0.07 (0.27)
Callus formation	2.88 (1.34)	3.23 (1.11)	−0.35 (0.75)	3.04 (1.37)	3.12 (1.34)	−0.08 (0.27)

Page points

1. There are few data available regarding the effectiveness of the mositurising products available for the care of the diabetic foot.
2. Concordance with foot moisturisers appears to be short lived among people with diabetes.
3. An investigation into the longer-term effects of urea-containing moisturisers on plantar callus formation would be of use in the preventative treatment of the diabetic foot.

is widely accepted, there are few data available regarding the effectiveness of the products available for this purpose in people with diabetes.

Anecdotally, it appears commonplace for concordance with daily application of foot moisturisers to be short lived among people with diabetes (cessation often occurring within 2–3 weeks of commencement), due to a perceived lack of skin moisturising effect. Other creams may be tried with similarly disappointing results, perhaps leading ultimately to the person's disbelief in the advice given by their healthcare professional on foot care. In the authors' experience, it is important that healthcare advice, when put into practice, is perceived to have worthwhile and noticeable benefits, especially if the task is to become a part of everyday life. For this reason, a participant satisfaction questionnaire was used in this study.

When completing the satisfaction questionnaire, study participants were asked to rate their satisfaction with Allpresan 3 against that with their control moisturiser. It was found that Allpresan 3 was considered superior in terms of application, absorption, rehydration and overall effectiveness by the majority of participants. This satisfaction was substantiated by the measurably better clinical results achieved with Allpresan 3.

It could be argued that the validity of measurements used in this study were poor, due to their subjective nature. However, all assessments were performed by the same investigator, who was blind to baseline scores and treatment/control allocation. Despite some elements of subjectivity in this study, the clinically observed improvements in both skin dryness and flexibility with Allpresan 3 were statistically significant, and achieved within a short time period. It is unknown if these effects would be maintained, or if the control moisturisers would have had a similar effect, with longer-term use.

There also appeared to be a reduction in the amount of visible callus on the feet to which Allpresan 3 was applied, though it was not found to be statistically significant. It is difficult to determine whether this was a real reduction, or only the appearance of a reduction, due to the skin becoming more hydrated. It would be interesting to investigate the longer-term effects of urea-containing moisturisers on plantar callus formation. No doubt it would not prevent callus production – as this is in part due to trauma – but it may reduce its quantity by increasing skin flexibility and so reducing shear and frictional forces. There were no reported skin reactions to Allpresan 3 among the study population.

Conclusion

The urea-based moisturiser, Allpresan 3, significantly reduced plantar skin dryness and maintained skin flexibility, compared with control moisturisers, in this study of people with diabetes and xerosis. Overall, participants were more satisfied with Allpresan 3 than their existing moisturiser. This pilot study suggests that a longer-term, objective study to confirm these subjective results is warranted. ■

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