

Comparative study of the moisturising properties of petrolatum spray vs hand-applied petrolatum

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Citation: Waring M, Bielfeldt S, Lunau N, Wilhelm K-P (2013) Comparative study of the moisturising properties of petrolatum spray vs hand-applied petrolatum. *The Diabetic Foot Journal* 16: 154–7

Article points

1. It is important to moisturise the diabetic foot in order to maintain healthy skin.
2. Petrolatum is an effective skin moisturiser but difficult to apply.
3. Spray application of petrolatum using a bag-on-valve system provides equivalent moisturising properties to petrolatum applied by hand.
4. Petrolatum spray is easy to apply and may improve compliance.

Key words

- Petrolatum
- Skin moisturiser
- Barrier function
- Trans-epidermal water loss

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Petrolatum is well established as a safe and effective product for moisturising the skin and providing a barrier for skin protection (Morrison, 1996). It may therefore be used where continence is a problem or skin is at risk from damage by shear forces due to bedding, clothing or, more specifically, footwear. However, its high viscosity makes it difficult to apply and to deliver an effective quantity. An excess of petrolatum may stain clothing and more than is necessary to provide the moisturising/barrier properties may be applied. This study examined the moisturising properties of petrolatum delivered by two systems: spray and traditional hand application. The results show that when equivalent quantities of petrolatum are delivered, they provide equivalent levels of moisturisation when measured by trans-epidermal water loss. The moisturising property of a 50% quantity of petrolatum applied by spray was equivalent to that of a 100% quantity of petrolatum applied by hand or spray.

Skin protection and avoidance of dry skin are important for the diabetic foot, as skin damage and dry skin may be indicators of possible ulceration (Tentolouris et al, 2010). Self-application of a moisturiser to the feet can be difficult and is likely to lead to non-compliance. Petrolatum is a safe and effective moisturiser; however, it can be difficult and messy to apply. It can also be difficult to control the quantity of petrolatum delivered, and more than is necessary to be effective may be applied.

Hoggarth et al (2005), using a washing model on dyed skin, showed that a one-second spray application of petrolatum (Aloe Vesta® Protective Barrier Spray, ConvaTec Inc) can be as effective as a hand application of petrolatum in protecting the skin. Although the spray used by Hoggarth et al (2005) had a different formulation from that used in this study, it did suggest that a continuous film had been formed on the skin, which created a barrier to trans-epidermal water loss (TEWL), thus providing moisturising properties.

This volunteer study compared the barrier properties, and thus the potential to moisturise the

skin, of petrolatum spray (Aurena Barrier Spray) and hand application of petrolatum, by measurement of TEWL.

In order that a true comparison could be made, equivalent weights of petrolatum were delivered by spray and by hand application. A spray delivering 50% of the equivalent weight was also evaluated for TEWL.

Materials

Aurena Barrier Spray (Aurena Ltd, Karlstad, Sweden) consists of petrolatum dispersed in a volatile silicone. The hand-applied product was pure petrolatum. Details of the products used in the study are shown in *Table 1*.

Methods

Blinding was not possible because of the different methods of application. Three areas on the volar forearm (one on one arm, two on the other) of each volunteer were used for the study and were randomised as far as possible. The two spray deliveries were always on different arms to avoid them running together.

Calculation of the weight of petrolatum delivered before the volunteer study

The weight of petrolatum used for the hand application in the study (designated the 100% value) was determined by first spraying an appropriate quantity with the spray barrier product. An excess of the spray product will flow away from the applied area. The optimum value was determined by spraying onto a circular plastic target with a diameter of 3.8 cm from a distance of 15 cm. The time taken for application of an optimum quantity was measured and controlled by recording the sound of the spray action, and was determined to be 0.3 second. To ensure a perpendicular spray angle, the spray can and the target were fixed in position 15 cm apart.

The weight of petrolatum delivered by the spray in 0.3 second was assessed on a plastic target after 20 minutes (to allow for evaporation) and was designated the 100% dosage. The average weight of petrolatum delivered to the target surface was calculated to be 24.1 mg/cm².

In order to obtain the 50% spray dosage experimentally, the above procedure was repeated and the spraying distance was varied between 25 and 30 cm in 1 cm increments. Approximately 50% of the weight of petrolatum delivered (12.2 mg/cm²) was obtained using a spraying distance of 27–30 cm.

To ensure consistency of technique, the procedure was repeated the day before the study using the same test samples used for spraying the skin of the volunteers (the pre-test).

As two test days were required for the volunteer study, the pre-test was repeated before the second test day using the model described earlier. The 50% spray was delivered from a distance of 30 cm in the first pre-test, and from a distance of 27 cm in the second pre-test. The shortest and most reproducible spraying time was 0.4 second.

Methodology during the volunteer study

To ensure that the application area on the skin was the same size as the plastic target used in the development work, the spray product was applied across a circular template that had a hole with the same diameter as the plastic target (3.8 cm). The equipment used to fix the spray can in position was identical to that used in the development study, to ensure the correct distance and perpendicular angle to the test area on the volar forearm of volunteers.

Table 1. Petrolatum products used in the study

Code	Product*
A	Barrier Spray (100% spray dosage) Aurena Ltd, Karlstad, Sweden (Lot no 1201161101)
B	Barrier Spray (50% spray dosage) Aurena Ltd, Karlstad, Sweden (Lot no 1201161101)
C	Petrolatum (equivalent to the 100% spray dosage) (Pionier® 3476 H&R Group)

*The same grade of petrolatum was used in treatments A, B and C.

Product A (100% spray dosage) was applied to one test area on the volar forearm from a distance of 15 cm. Product B (50% spray dosage) was applied to a second test area from a distance of 27 or 30 cm, according to the pre-test result. Spray time was approximately 0.4 second. Product C, containing a similar quantity of petrolatum to the 100% spray dosage (24.1 mg/cm²) was applied by hand to a third test area, by a technician using a finger cot.

During the study, control measurements were performed using the same procedure as in the pre-tests to ensure that all parameters such as can pressure and the relationship between the 100% and 50% spray deliveries remained constant. The spray delivery system was similar to an aerosol but used a bag-on-valve technique which separated the propellant (nitrogen) from the product being sprayed. This has the advantage that the product is unaffected by the propellant and can be sprayed at any angle, although there may be a slight pressure drop as the can empties (*Figure 1*).

Details of the volunteers taking part in the study are shown in *Table 2*. The study was conducted following the study protocol (drawn up by proDERM) and the main principles of good clinical practice (WHO, 1995).

Test procedure

At the start of the study, the volunteers were informed about the study and provided written consent to participation in the study.

The participants remained in a climatized room (21 ± 1°C and 50 ± 5% relative humidity) for at least 30 minutes before baseline assessment and application of the test products.

Baseline skin barrier function was assessed by measurement of TEWL, after which the test products were applied. Twenty minutes later (to allow for evaporation), skin barrier function was again assessed by measurement of TEWL.

Page points

1. Product A (100% spray dosage) was applied from a distance of 15 cm to one test area on the volar forearm, and product B (50% spray dosage) was applied to a second test area on the other arm from a distance of 27 or 30 cm, depending on the pre-test result.
2. Product C, containing a similar quantity of petrolatum to the 100% spray dosage, was applied to a third test area by hand by a technician using a finger cot.
3. The spray delivery system used a bag-on-valve technique which separates the propellant (nitrogen) from the product being sprayed, hence the product is unaffected by the propellant and can be sprayed at any angle.

Page points

1. Trans-epidermal water loss (TEWL) is a non-invasive method of assessing skin barrier function and a sensitive parameter for quantifying skin barrier damage.
2. TEWL values are given in g/m h units. The usual range for intact skin lies between 3 and 9 g/m h. Damage to the skin barrier may raise this value to 50 g/m h or more.
3. In this study, mean TEWL values were significantly decreased 20 minutes after product application compared with baseline for products A, B and C.
4. A significantly higher decrease in the mean TEWL value, and therefore a higher difference from baseline, was detected for product C than for product A.

Figure 1. Spray application of petrolatum using a bag-on-valve system, showing ease of delivery. This delivery system is effective at any angle (unlike a traditional aerosol).



Instrumental measurement

TEWL is a non-invasive method of assessing skin barrier function and a sensitive parameter for quantifying skin barrier damage. TEWL was measured with a Tewameter® TM 300 (Courage + Khazaka electronic, Cologne, Germany), where evaporation from the skin is measured by placing a cylindrical open chamber with two hygrosensors at defined distances from the skin on the test areas.

TEWL values are given in g/m²h units. The usual range for intact skin lies between 3 and 9 g/m²h. Damage to the skin barrier may raise this value to 50 g/m²h or more.

Results

Product application

With an average spraying time of 0.4 second, the mean amount of product A (100% Aurena Barrier Spray) applied at a distance of 15 cm was 8.6 mg/cm², the mean amount of product B (50% Aurena

Barrier Spray) applied from a distance of 27 cm or 30 cm was 4.0 mg/cm², and the mean amount of product C (applied by hand) was 9.9 mg/cm².

It was not technically possible to spray exactly the same amount of products A and B onto the test areas as was applied by hand (product C). If the amount of product C applied by hand is designated 100%, an average of 87.5% of petrolatum from product A and 41.6% of petrolatum from product B were applied.

Trans-epidermal water loss

Table 3 shows a comparison of mean TEWL values at baseline and 20 minutes after application for each of the test products, performed with paired t-tests.

The homogeneity of TEWL values at baseline was checked with a repeated measurement ANOVA. No significant differences were detected between the test areas to be treated (P=0.802). The ANOVA with factors product (3 levels), time (2 levels) and interactions between time and product detected significant differences between time points (P<0.001) but no significant differences between products (P=0.277) and interactions (P=0.386).

Mean TEWL values were significantly decreased 20 minutes after product application compared with baseline for all test products (A, B and C). A significantly higher decrease in the mean TEWL value, and therefore a higher difference from baseline, was detected for product C than for product A.

Conclusion

This study compared the barrier properties, and hence the potential to moisturise the skin, after a defined single spray of Aurena Barrier Spray at two dosage levels (100% [product A] and 50% [product B]) with that of hand application of petrolatum (product C; petrolatum quantity equivalent to the 100% spray dosage) by TEWL measurement.

The quantities of petrolatum delivered by the spray were, on average, 87.5% of petrolatum from product A and 41.6% from product B compared with petrolatum applied by hand (designated 100%). The occlusive layer as assessed by TEWL measurement of the 41.6% sprayed dosage (-3.34 TEWL units) was found to be comparable to 100% of hand-applied petrolatum (-3.79 TEWL units).

The TEWL values observed for the nominal 100% and 50% sprays, although not significantly different, suggest that the 50% dosage (5.28 TEWL

Table 2. Details of the volunteer participants

No. of volunteers enrolled	29
Complete data exclusions	6 (for reasons unrelated to test products)
No. of participants analysed (valid cases)	23
Age of participants	51.2 ± 13.7 years (mean ± standard deviation)
Gender	6 male (26%) and 17 female (74%)

units) is more effective than the 100% (5.50 TEWL units). It is likely that this is because the test areas were arranged vertically and not horizontally. It was observed that in several cases the test product was forming droplets that ran down from the test area even before the volatile silicone carrier of the petrolatum had evaporated. As a result, less of the larger dose is likely to have stayed on the skin. However, this is unlikely to happen in the clinical situation unless too much spray product is applied.

It can be concluded that the petrolatum barrier spray is able to form a protective film at both 50% and 100% levels, which is equivalent to that formed when petrolatum is applied by hand, when assessed by TEWL measurement. Hence the moisturising property of a 50% quantity of petrolatum applied by spray was equivalent to that of a 100% quantity applied by hand or spray. ■

Table 3. Comparison of mean TEWL values at baseline and 20 minutes after application of the test product (n=23)

Test product	Mean TEWL values (g/(m h))		P-value of paired t-test 20 min after application compared with baseline
	Baseline	20 min after application	
A	8.30	5.50	<0.001*
B	8.62	5.28	<0.001*
C	8.32	4.53	<0.001*

*Significant; TEWL=trans-epidermal water loss.

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