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Hashmi, F, Kirkham, SE, Nester, CJ and Lam, S
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The effect of topical anti blister products on the risk of friction blister formation on the foot

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Healthy volunteers
Test site: posterior heel skin

Interventions: anti-blister preparations

Controlled load application

Hot spot development measured using infrared thermography
The effect of topical anti blister products on the risk of friction blister formation on the foot.

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The effect of topical anti blister products on the risk of friction blister formation on the foot.

Abstract

Introduction: Foot blisters are a common injury, which can impact on activity and lead to infection. Increased skin surface hydration has been identified as a risk factor for blister formation, indicating that a reduction in hydration could reduce the risk of blister formation.

Method: Thirty healthy adults were randomised into 3 groups, each receiving a preventative foot blister treatment (2Toms® Blister Shield®; Flexitol® Blistop and Boots Anti–Perspirant Foot Spray). Cycles of compression and shear loads where applied to heel skin using a mechanism driven by compressed air. Temperature changes were measured during load application using a thermal imaging camera (FLIR Systems Inc. and Therm CAM™ Quick Report). Near surface hydration of the skin was measured using a Corneometer® (C & K, Germany).

Results: There was no significant difference in the rate of temperature change of the skin between the three groups compared to not using products (p=0.767, p=0.767, p=0.515) or when comparing each product (p = 0.551). There was a significant decrease in near surface skin hydration, compared to baseline, after the application of powder (-8.53 AU, p =0.01). There was no significant difference in hydration after the application of film former and antiperspirant (-1.47 AU, p = 0.26; -1.00 AU, p = 0.80, respectively).

Conclusion: With the application of external load we found no significant difference in the effect of the three products on temperature change. The powder product
demonstrated an effect on reducing the risk of blister. It is postulated that powder may have a barrier effect.

**Keywords**
Skin, barrier, moisture, antiperspirant, film, powder

**Abbreviations**
LAM  Load application mechanism
N    Newtons
1.0 Introduction

Friction blisters are a common injury [1, 2] of the hands and feet which can be encountered by anyone, although athletes [3] and military staff [4] are at particular risk. On the foot these lesions can be painful and gait adaptations, adopted to offload the painful site, can lead to lower limb problems and affect performance [5]. Blisters have a high risk of rupturing due to the fragile blister roof, predisposing the resultant wound to the risk of infection [6]. Such an injury can be considered to be trivial by many, however it can have serious implications if not managed effectively. This justifies the pursuit of effective blister prevention measures.

Skin surface hydration has been identified as a key risk factor in friction blister development [7-9]. The coefficient of friction of skin generally increases with increased moisture due to increased surface resistance [10-12]. The alterations in surface resistance, of palmar skin in particular, are complex and comprise a combination of viscous shearing effects; absorption of water by the skin and capillary adhesion effects [10, 13-15]. In addition, the plasticizing effect of water on keratin causes the stratum corneum to become less stiff and more deformable therefore increasing the area of contact and therefore increasing friction [16-18]. Indeed, using a laboratory based model of blister formation, the authors have already demonstrated that greater skin hydration is associated with greater risk of foot blisters [11].

Skin hydration is altered by environmental humidity [19], perspiration and topical preparations [17, 20, 21]. For example, foot sweat which is unable to wick away from the skin surface causes the skin to become moist and thereby increases the risk of
blister. Measures that reduce skin surface hydration could therefore aid blister prevention and use of powders [22, 23], antiperspirants [24-26] and socks [27-29] have been investigated in this context. Research studies testing the effects of sock type found that the risk of blistering was reduced by 12% with the use of acrylic compared to cotton socks [27]. In this study the participants who wore acrylic socks had drier foot skin (and socks) after exercise compared to those who wore cotton socks [28]. Another study reported that a wool polyester blend sock had the lowest blister incidence during the first 6 weeks of basic military training [29]. Man-made fibres, such as acrylic and polyester allow moisture to be drawn away from the foot. This is also referred to as a ‘wicking effect’ [5].

Powders are applied to the skin in order to absorb moisture and to keep foot skin as dry as possible during activity [30, 31]. The therapeutic use of powder in friction blister management has only been suggested and not fully tested in the literature, although it is known that when powder absorbs moisture (either from the skin or the environment) the coefficient of friction on the skin surface increases [31].

Aluminium-based antiperspirants, which aim to block the sweat glands, have been used to prevent excessive perspiration of foot skin [21, 32]. Knapik et al (1998) found that the risk of blister formation was reduced by 12% with the use of an antiperspirant and the lowest incidence of blisters was seen after 3 days of antiperspirant use [26]. Darrigrand et al (1992) found that sweat accumulation was reduced by 50% and there was a marked reduction in hot spots and blisters with the use of an antiperspirant [21]. However, these two studies also observed a degree of skin irritation caused by antiperspirants [25, 26].
Film formers produce transparent, water resistant protective covers for the skin. Several film former products claim to prevent blisters but there is no published research that supports these proposed effects. The mechanisms of action are purported to reduce skin surface friction and reduce the accumulation of sweat. However, there is no published research quantifying this reduction.

In previous studies product efficacy has been defined by the change in blister incidence after physical activity. This tells us about the real world impact of the product but prevents us from studying the precise circumstances that exist when friction blisters develop. ‘Real world’ outcomes also prevent us from investigating the effect of any single factor on blister formation because the in shoe environment is highly variable and difficult to control. Measures such as time to blister formation; inflammatory response of the skin to shear loads prior to blister formation; the loads required to create blisters and measurement of skin hydration as a covariate related to risk of blister may be more revealing. Research studies which tested blister prevention products, compared the effect of a product versus no product as a control, which tells us little of the comparative efficacy of the various approaches (e.g. powders, antiperspirants, film formers) which have different mechanisms of action.

The current study aimed to test the effect of three products on near surface skin hydration (i.e. moisture content using a measure of capacitance) and the subsequent risk of blister formation using a laboratory based model of blister formation. We have previously employed thermography as a sensitive, reliable measure for tracking blister development and to identify temperature changes at the point of blister
formation [11, 33]. This approach enables the effects of interventions and any role of skin hydration in these effects to be studied more sensitively than in previous studies.

2.0 Materials and methods

A convenience sample of 30 healthy individuals aged 18 years and over were recruited from staff and students at the University of Salford, UK. All participants were free of self-reported skin disorders, diseases affecting vascular and neurological systems, systemic diseases, and musculoskeletal disorders of the foot and ankle. Participants also confirmed they had not used anti-inflammatory medication, pain-killing medication, steroids and immunosuppressant medication 48 hours prior to data collection. Participants were also asked to discontinue the use of all foot products e.g. creams and sprays, before data collection. Foot sensation and vascular supply were tested using standard podiatric assessment techniques [34] and found to be normal in all cases. Participants were randomised to receive one of the three interventions. Written informed consent was obtained from all participants. Ethical approval was obtained from the Research Ethics Panel at the University of Salford.

2.1 Instrumentation

Near surface hydration (10 – 20 microns depth) was measured using a Corneometer® 825 CM (Courage and Khazaka, Colne, Germany) mounted on a MPA 5 multi-probe adapter. Skin temperature was measured using infrared thermography (FLIR Systems Inc, West Malling, UK) with a temperature range from
0°C to 250°C, accuracy ±0.2°C. Data were processed using Therm CAM™ Quick Report Version 1.1 software (FLIR Systems Inc, West Malling, UK).

2.2 Description of Load Application Mechanism (LAM)

The LAM (Figure 1a & b) used in this study comprised of a loading head and a lever arm which was displaced manually. The loading head has a curved anterior surface with a strip of textured rubber material (Ironman Rubber Covering, Black, OB2090, Algeos UK Ltd., Liverpool, UK) providing an interface with the skin (Figure 1c & d). The rough upper surface of the rubber creates friction between the device and skin. A new piece of rubber was used for each participant. The maximum contact pressure applied to the posterior aspect of the heel by the LAM was 15N for each participant. This was measured using a load sensor (ELF System, Tekscan) placed between the heel and the load applicator head prior to commencing the loading sequence. Once the appropriate force was detected, the position of the foot and LAM were fixed using strapping and bolts (respectively) after which the load sensor was removed.

The head of the LAM moves elliptically so that periods of contact and non-contact between the LAM head and the skin occur, mimicking the contact sequence between the heel and shoe during walking, i.e. an upward contact period followed by a downward non-contact period. A compressed air system was used to move the loading head forwards and backwards whilst the researcher manually displaced the head upwards and downwards to achieve the elliptical motion at a rate of one cycle every 2 seconds (30 contact passes/min) using a metronome.
2.3 **Skin sites tested**

Skin measurements were taken from two sites: 1) the posterior aspect of the heel (test site), and 2) below the medial malleolus (control site) (Figure 1d). Only the test site was loaded.

2.4 **Interventions**

Three commercially available anti-blister treatments were tested: 2Toms® Blister Shield® (powder comprising polytetrafluoroethylene and polyethylene wax); Flexitol® Blistop (film former comprising dimethylether and menthol); and Boots Anti-Perspirant Foot Spray (aerosol spray comprising: butane, isobutane, propane, hexamethyldisiloxane, aluminium chlorohydrate, cyclopentasiloxane, talc, disteardimonium hectorite, parfum, propylene carbonate, diethylhexyl adipate, hexyl cinnamol limonene, alpha-isomethyl ionone, hydroxycitronellal, hydroxyisohexyl -3-cyclohexene carboxaldehyde, coumarin, citronellol, linalool). The products were applied by the investigator according to the manufacturer instructions. The powder (2Toms® Blister Shield®) was lightly and evenly rubbed over the entire heel area; the film former (Flexitol® Blistop) and antiperspirant (Boots Anti-Perspirant Foot Spray) were sprayed onto the heel area at a distance of 10cm away from the skin and left to dry. For the purposes of this report, the terms Group 1, Group 2 and Group 3 will be used to represent cohorts treated with 2Toms® Blister Shield® (powder); Flexitol® Blistop (film former) and Boots Anti-Perspirant Foot Spray (antiperspirant), respectively.
2.5 Measurement protocol

All tests were carried out in the same room by the same investigator. Each participant was asked to remove all footwear and hosiery and remain seated in the test room for 15 minutes to acclimatize to the environmental conditions. Baseline near surface skin hydration measurements (5 consecutive readings and the mean value) were taken at the test and control sites for both feet.

One foot of each person was randomly allocated to an intervention group. The product was applied to the test skin site in accordance with the product application guidelines. No product was applied to the other foot (non-product foot). Near surface skin hydration measurements were taken post product application and baseline temperatures of the control and test skin sites were recorded using thermography.

The participant stood on a platform and the LAM device was positioned such that the head was perpendicular to the heel and load was applied, using the LAM, to the heel skin. Each load-rest cycle consisted of 2 minutes of continuous load application, at a rate of 30 contact passes/min, followed by a 30 second rest period, during which thermal images of the test and control sites were captured. During the rest period, the skin was visually inspected for any signs of tissue damage or blister onset. Participants were actively encouraged to self-report any discomfort, pain or other experience that might be indicative of blister formation. This procedure was repeated until the temperature change from baseline reached approximately 3°C, or the skin showed visible signs of damage, or a total of 20 minutes loading time had elapsed, at which point load application ceased and the final temperature and time taken to reach the end point were recorded. This was defined as the end point for each
participant. The 3°C threshold was based on prior research that identified this as the temperature change indicative of imminent risk of blister creation [33]. Thus, delay in this temperature change (in terms of either time taken or number of load-rest cycles required to create this temperature change) was indicative of reduced risk of blister. Finally, near surface skin hydration was recorded at the end point for each participant.

The same method was repeated on the control (non-product) foot.

2.6 Data and Statistical Analysis

All statistical analyses were carried out using SPSS 16 (Chicago, IL, USA). The primary data was the rate of temperature change from baseline up to the end point. The secondary data was the number of people whose end point was a 3°C change in skin temperature indicative of risk of blister formation and the time taken to achieve this change.

Normality assumptions were tested by the Shapiro-Wilk test for normality, which indicated the distribution of skin hydration and temperatures departed significantly from normality (p < 0.01). The Wilcoxon signed rank test was used to establish whether there were any differences in the baseline temperatures and skin hydration readings between the groups. The effect of each individual product compared to use of no product within each of the three groups (within group analysis) was tested using a Wilcoxon signed rank test. Comparisons between each product group (between group analyses) were tested using the Kruksal Wallis one way analysis of variance test.
To investigate the change in hydration, the hydration levels were measured before and immediately after the application of the products and compared using Wilcoxon signed rank test. Furthermore, the within group analysis (i.e. product vs. non product feet) assumes that hydration has been reduced in the product feet compared to the non-product feet. To test this assumption, the hydration of the product feet post application of the powder, film-former or antiperspirant products was compared to the hydration of the non-product feet using Kruksal Wallis one way analysis of variance test.

3.0 Results

3.1 Baseline data

Ten participants were randomly recruited to each intervention group. The 3 groups were not statistically significantly different in terms of age (Group 1: median (IQR) = 31 (18) years; Group 2: median (IQR) = 24 (10) years; Group 3: median (IQR) = 31 (18.5) years; p = 0.35) and sex (Group 1: 6:4; Group 2: 6:4; Group 3: 6:3; p = 0.88). The baseline data for the test and control sites for the product and non-product groups are described in Table 1. One blister was created in Group 3 and in the same group signs of abrasion were seen on a foot tested without any product. One participant from the Group 1 withdrew due to the discomfort experienced during loading (there were no signs of skin damage or early blister formation in this case). The data for this participant was withdrawn before data analysis was conducted.

Comparisons of baseline temperature and hydration data between groups and within groups showed no significant differences except for Group 2 where significantly
lower baseline temperatures were recorded for the product foot compared to non-product foot (median: 22.6°C vs. 25.3°C, p = 0.01). Therefore, changes in skin surface temperature were used for statistical analysis as opposed to absolute values.

3.2 Changes in skin temperature and hydration

The maximum temperature (MT) and time taken to reach that temperature (t) on heel skin with the product applied were as follows: Group 1: MT ± SD = 1.7 ± 1.2 °C, t = 10 min; Group 2: MT ± SD = 2.1 ± 0.9 °C, t = 4 min and Group 3: MT ± SD = 2.2 ± 1.1°C, t = 16. The maximum temperature (MT) and time taken to reach that temperature (t) on heel skin without product applied were as follows: Group 1: MT ± SD = 1.5 ± 0.9 °C, t = 2 min; Group 2: MT± SD = 1.6 ± 1.0 °C, t = 4 min and Group 3: MT ± SD = 1.2 ± 1.4˚C, t = 16. Control sites on the product foot showed a reduction in temperature with time (between 0.3°C to 0.9°C) except for Group 2 where an increase of 0.5°C was evident at the end of the load-rest cycle period (Figure 2).

Fifteen people who had product applied to their heels demonstrated a change in skin temperature of 3°C and above within the 20 minute loading period: Group 1: n = 3 (mean temperature change: 3.4°C; mean time: 7.3 min; Group 2: n = 5 (mean temperature change: 3.2°C; mean time: 6.7 min); and Group 3: n = 7 (mean temperature change: 3.3°C; mean time: 10 min). Seven people with no product on their heels demonstrated a change in skin temperature of 3°C and above within the loading period: Group 1: n = 2 (mean temperature change: 4.1°C; mean time: 3 min); Group 2: n = 1 (mean temperature change: 3.1°C; meant time: 6 min); and Group 3: n = 4 (mean temperature change: 3.9°C; mean time: 10 min).
Compared to using no product (within group analysis) there was no statistically significant difference in the rate of temperature change between all three groups (Group 1: \( p = 0.767 \); Group 2; \( p = 0.767 \); and Group 3 \( p = 0.515 \)). Comparing each product (between group analysis), there was no statistically significant difference in the rate of temperature change between the groups (\( p = 0.551 \)).

The only statistically significant decrease in near surface skin hydration immediately after the application of product was noted in Group 1 (-8.53 AU, \( p = 0.01 \)) (Figure 3).

4.0 Discussion

Although the statistical analyses showed no significant differences between the intervention groups, there are some trends in the data that are worth noting. In response to anti blister products, fewer people in Group 1 (\( n = 3 \)) achieved the 3°C change in temperature compared to the Group 2 (\( n = 5 \)) and Group 3 (\( n = 7 \)). Group 1 and 3 reached maximum skin temperatures at 10 and 16 minutes (respectively), compared to 2 and 4 minutes for the corresponding feet with no product. Only the Group 1 test feet showed temperature changes lower than that of the comparator (non-product) feet (Figure 2). This suggests a reduced risk of blister when using the powder and should be confirmed by studying a larger sample group than was used in this current study. That the powder product also significantly reduced near surface hydration compared to the film former and antiperspirant, suggests an association between reducing hydration and reducing risk of blister. Interestingly, the manufacturers of the Corneometer® purport that capacitance measurement is not influenced by substances in the skin such as salts or residues of topical applied products. Anecdotal evidence recommends keeping the feet as dry as possible in
A decrease in friction of 50% with the application of talcum powder to the skin (of the forearm) when the skin was loaded using a polished probe. Our results could be explained by other studies in the field of tribology. Carré et al (2012), tested the effects of powders on fingertip skin at different moisture levels and in contact with different types of materials [36]. The authors reported that the combination of moisture and powder increased viscous shear forces and therefore friction. However, they also suggested that the granular nature of sandstone (the contact material) could act as a lubricant, therefore reducing the coefficient of friction between the skin and powdered surfaces. Tomlinson et al (2011) noted that fingertip friction increased up until a moisture level of approximately 90 AU, after which the friction decreased [18]. They suggested that increased moisture could cause swelling of the skin and therefore increasing the contact area and capillary action. Translating these findings to our results, it is plausible that the powder prevents this capillary action and therefore acts as a physical protective barrier as opposed to altering the hydration within the skin itself. The powder used in our experiment could also be acting as a lubricant. It is likely that as the foot becomes moister during exercise the friction increases as a result of the increased viscous shear forces. It therefore necessary to test these hypotheses in a controlled way on foot skin.

Another point to note is the interaction between the powder and our choice of textured rubber contact material on the load applicator. El-Shimi [35] reported that when a ‘rough’ probe rather than a polished probe was used to apply shear loads to skin, the beneficial reduction in friction due to talcum powder was no longer evident. Thus, the effectiveness of our powder to reduce friction and thereby risk of blister
might be sensitive to the nature of the surface through which loads are applied to the foot skin (Figure 1c). Our choice of material was based on the need to ensure application of friction to the skin such that there is a realistic risk of blister within a practical experimental timeframe [11, 33]. However, in the testing of interventions this choice may require revision to enable a closer to real world loading between the applicator and the heel skin.

A greater absolute temperature change was observed with use of the film-former and antiperspirant compared to the non-product feet, suggesting an elevated risk of blister formation. This relates to the greater number of test sites reaching the 3°C increase in temperature for these two products. The lack of decreased risk of blister compared to the powder group could be because of the nil change in hydration, or the barrier effects of the compounds resulting in the trapping of moisture between the layer of product and the skin. It is important to note that the thickness of the film could exceed the 10 – 20 microns depth that the Corneometer® is designed to evaluate. In addition, both the film former and antiperspirant may have an insulation effect due to sealing of the skin surface over the area of application. Thus, compared to the non-product foot, heat may accumulate during the experiment. A further explanation could be that the tacky surface of film former may increase the contact area and therefore friction. Indeed, the resilience of the film former to the loads being applied was limited and the film was rubbed off the skin during load application. In no case was the film former fully intact at the end point for each participant. Therefore at some point during the experiment the data represent the response of the skin with only partial or no film former in place. Indeed, this would imply that loading during testing for this group was on bare skin for at least part of the loading regimen. This
limits the relevance and reliability of data from this test group. This would explain its non-beneficial effect, however we anticipate that this could represent the real world use of the product.

Whilst apparently having better results in terms of risk of blister, the powder also presented some difficulties in practical use, which tended to occur towards the end of the load-rest cycles. Some participants reported discomfort with the powder and anecdotally this appeared more frequent in those with dryer skin. It is possible that the type of friction behaviour (e.g. stick-slip vs sliding) could contribute to this discomfort, rather than the average effect of friction indicated by temperature changes. However, without further study the cause of this discomfort is unknown.

There was a lower baseline temperature in the Group 2 compared to the non-product feet in the same participants. Cooler skin might have different mechanical properties and respond differently to external loads, and the difference of 1.93°C is perhaps significant for the behaviour of a biological tissue. This could render the comparison of product and non-product feet as invalid for Group 2. However, since our primary outcome is the rate of temperature change rather than absolute temperature value this should not adversely affect our results. Furthermore, we believe the lower temperature is an effect of the product itself and thus represents a real intervention effect not a difference between feet that prevents group comparisons. Indeed, we postulate that a difference of 1.93°C is most likely to occur due to external factors acting local to the site of measurement rather than underlying physiological difference between the two feet of the same individual.
4.1 Study Limitations

A limitation to this study is that in the literature antiperspirants are applied up to 5 days prior to data collection [26]. In our study the antiperspirant was applied only once. Therefore the antiperspirant effect observed in this study is not representative of regular use. Antiperspirants prevent excessive sweating by plugging sweat glands [32] and when applied in successive days the action of the antiperspirant accumulated for greater efficacy. However, we would argue that for foot blisters, use of an antiperspirant is probably limited to specific events where a risk of blister is expected, such as a running event or use of new footwear. Therefore, users are unlikely to prospectively use the product over 5 days and our results are representative of real world use of the product.

Another limitation of this study was the consistency of the load applied to the heel between participants. The force sensor used was able to detect contact pressure at the interface between the load applicator and the heel skin; however it is possible that load changed over time. The machine has subsequently been adapted to give continuous measurement of load. The within subject repeatability was not tested for any of the three intervention groups. However, the LAM has previously been demonstrated to be a suitable model for interventions that might affect skin surface friction [11, 33].

This study uses a device to load the heel by mimicking the loading pattern at the back of the shoe which allows us to test products in controlled conditions which do not mimic in-shoe environment. However, the products are therapeutically used in an in-shoe environment and therefore the effect of sweat production; increased humidity
and increased in-shoe temperature on the product efficacy could not be simulated.
This is relevant because in real world conditions, feet may be more hydrated by
being in shoes than at the start of our tests and thus the capacity for reducing
hydration with the products tested might be different than in our tests.

5.0 Conclusion
In terms of rate of temperature change in response to externally applied loads, we
found no difference in the effect of a powder, film-former and antiperspirant products.
Fewer people in the powder group experienced the change in temperature we
previously reported to be indicative of elevated risk of blister. The powdered heel
skin showed measurable decreases in hydration; however caution should be taken in
assuming that powder reduces skin hydration. It is appreciated that powder may
absorb moisture to influence viscous shear forces but also has the capacity to
reduce capillary action and liquid bridges between the skin and contact material.
This is the first study that has tested the effects of anti-blister products on foot skin
using controlled laboratory conditions. Although, there are differences between real
world use and behaviour of these products compared to our experimental model, this
is a positive step towards exploring the real world efficacy of such products.
**Figure legends**

Figure 1: a) & b) Schematic diagram and photograph, respectively, of the Load Application Mechanism (LAM). A: contact probe. B: compression actuator. C: lever arm limitation switches. D: Manual lever arm providing vertical movement. E: fixing bracket. F: base plate; c) anterior view of the contact probe with textured contact material, labelled G. d) lateral view of the heel and contact probe: T represents the test site and C represents the control site.

Figure 2: The average change in temperature from baseline for a) Group 1, b) Group 2, and c) Group 3.

Figure 3: Data representing the near surface skin hydration before and after product application for the test site of the product and non-product foot groups in the three intervention groups (within group analysis) (p = 0.01, p = 0.26, p = 0.80, respectively).
Table 1 – Baseline median and interquartile range (IQR) values for near surface skin hydration and skin temperature. *There was no statistically significant difference between the groups except for between the test sites in the product and non-product groups (p = 0.004).

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<th>Non-Product Foot Median (IQR)</th>
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<td>19.4 (14.5 – 26.8)</td>
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References


Skin surface hydration [AU]

- Powder group Before
- Powder group After
- Film group Before
- Film group After
- Antiperspirant Before
- Antiperspirant After

p = 0.01
Highlights

- A method for testing the effects of anti-blister agents is proposed.
- The powder agent provides a degree of protection from risk of blister.
- The response of the skin to external loads did not differ between the agents tested.