

## Foot care in diabetes: Adequate care of dry and sensitive skin for diabetic foot

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**KEYWORDS:** Diabetic foot, diabetes, dry foot skin, foam cream, xerosis

### SUMMARY

Despite of good hydrating effects following application with three foot foam creams (with microsilver, with polyhexanid or without additive) in diabetic subjects with xerosis, no change in bacterial colonisation was seen for gram-positive and no colonisation with gram-negative bacteria in the inter-digital area of the foot during the 4-week treatment period.

### INTRODUCTION

With a prevalence of about 285 million affected adults, diabetes mellitus is one of the most common diseases worldwide [15]. At least 30% of all diabetic patients suffer from specific skin conditions in the course of their lives [4, 13]. The pathological mechanisms through which diabetes mellitus damages skin function are varied and complex [7]. Of special importance are pathological glucose concentrations, the formation of reactive oxygen radicals and what are known as advanced glycation end products, which interact with intercellular and extracellular protein. These mechanisms lead to diabetic micro- and macroangiopathy resulting in tissue hypoxia, which can also damage the nerves and lead to the known condition of diabetic neuropathy with impairment of sensorimotor and autonomic nerve functions [4, 7]. The patients suffer from diminished pain perception, an increased vulnerability of the skin to exogenous trauma, and very frequently from circulatory disorders as well as anhidrosis and pronounced dryness of the skin (xerosis cutis) [8, 10].

The risk of complications can be further increased by pronounced xerosis with desquamation, rhagades, erosions and an impaired barrier function. On the sole of the foot, dry skin leads commonly to local thickening with hyperkeratosis (callus), which increases pressure selectively and can lead to fissures and ulcerations [12]. A causal relation between

pathological plantar pressure and the formation of an ulcer has been demonstrated in several studies [2, 16]. Dry, cracked skin presents a possible entry point for bacteria and fungus with an increased risk for difficult-to-treat mixed infections and the development of a diabetic foot syndrome. Regular, adequate foot care plays an important role in the prophylaxis of foot and nail infections, because increased skin humidity and regeneration of the skin barrier can significantly reduce the risk of infections.

The recommendation to care for dry, cracked diabetic skin with sufficiently lipid-rich, moisturising products is always accompanied by the notice that these products should not be used in the interdigital spaces. The reason for this is that due to the skin-on-skin situation and general constriction in the interdigital spaces, residue of creams often remain that may impede the exchange of moisture in these regions. This, together with the warm, moist conditions in the interdigital spaces increases the risk of macerations and thus of infections.

The aim of this study was to test three different foam creams with specific pharmaceutical formulations for their skin-moisturizing properties and for potential application in the interdigital spaces of diabetic patients. To accomplish this, swabs were taken from the interdigital spaces at different application times and tested for bacterial colonisation.

## MATERIAL AND METHODS

The study included 60 type I or type II diabetic patients with dry foot skin. The participants of the study were divided into three test groups of 20 persons each. Each test group used a different foam cream for the care of dry foot skin. Test group 1 used Allpresan® Diabetic INTENSIVE, test group 2 used Allpresan® Diabetic INTENSIVE CARE with microsilver and test group 3 used Allpresan® Diabetic INTENSIVE CARE with polyhexanide. The study participants applied the foam cream to their feet themselves twice a day. The interdigital spaces were not excluded. The application period was 29 days. On day 1, a dermatologist examined the foot skin of the participants and the condition of the skin was documented according to a clinical evaluation scale. Furthermore, the humidity of the skin was measured and swabs were taken from the interdigital spaces. Clinical and subjective evaluations as well as renewed measurements of the skin humidity were conducted on days 8 and 15. On day 29, the skin humidity was measured again, clinical and subjective evaluation was made, and swabs were taken from the interdigital spaces. Furthermore, the test persons were asked about the general application and assessment of the test product used.

## ACCLIMATIZATION

The test persons went through an acclimatization process of 30 minutes duration before the skin humidity was measured through corneometry. The test persons remained seated in a room at room temperature of  $20 \pm 2^\circ\text{C}$  and a relative humidity of  $50 \pm 10\%$ . The feet of the test persons were not covered

during the acclimatization process, i.e. shoes and stockings were taken off.

## CORNEOMETRY

The hydration of the stratum corneum was determined using a corneometer (Courage & Khazaka Electronic, Cologne). Corneometry is based on the measurement of the dielectric constant of the water found on the outer layer of the skin. Changes of the water content are reflected in the dielectric constant. Three measurements on the ankle of the test persons were made at each measurement time point and the respective mean value was included in the analysis.

## DERMATOLOGICAL ASSESSMENT OF THE FOOT SKIN

A dermatologist performed the dermatological assessment. Based on a defined scale, the parameters skin redness, dryness, desquamation, cracking, oedema, papules, blisters, oozing skin areas, and skin erosions were assessed.

## SUBJECTIVE ASSESSMENT OF THE FOOT SKIN BY THE TEST PERSON

The subjective perception of the test person was documented based on a 4-point scale ranging from “not perceived” to “very strongly perceived” for the parameters itching, stinging, burning sensation, dryness and tightness.

## SWABS FROM THE INTERDIGITAL SPACES

A study nurse took the swabs from the interdigital spaces I/II (between the 1st and 2nd toe) and III/IV (between the 3rd and 4th toe) on day 1 and day 29 of the observation period. A swab moistened with a 0.9% saline solution was used. The quantification of the bacterial colonisation and the determination of the bacteria present were performed by a microbiological laboratory (Technical laboratory, Dr. Jutta Hoeffer GmbH, Hamburg).

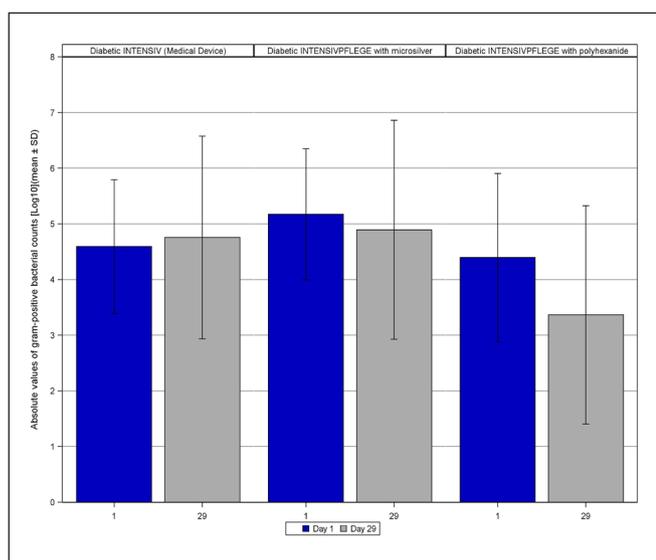
## RESULTS

All 60 test persons completed the data collection with no deviations from the study protocol. The test persons (complete collective) were an average of 58.8 years old; 33.3% were male and 66.7% were female.

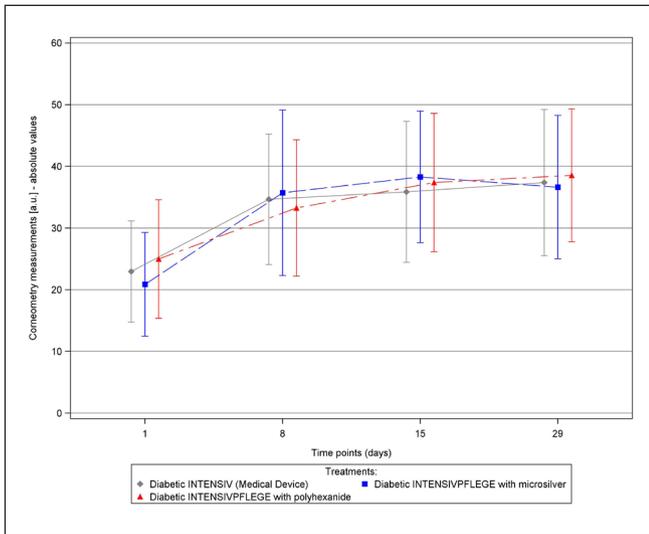
## BACTERIAL COLONISATION

### Gram-positive bacteria

Before the start of the application, colonisation with gram-positive bacteria (Fig. 1) of the interdigital spaces examined had an absolute value of  $\log_{10}$  4.6 for the test group “Diabetic INTENSIVE”. In the test group “Diabetic INTENSIVE CARE with microsilver” the value was  $\log_{10}$  5.2 and in the group “Diabetic



**Fig. 1:** The mean colonisation of the interdigital spaces with gram-positive bacteria before (day 1) and after 4 weeks of application of different foam creams (day 29). Application of the foam creams in the interdigital spaces had no effect on local colonisation with gram-positive bacteria.



**Fig. 2:** The development of the moisture content in the stratum corneum in relation to the application of different foam creams. After 8 days of application, skin moisture was increased in all three test groups in comparison with the baseline value. This moisture level was maintained in all test groups at the end of the study (day 29).

INTENSIVE CARE with polyhexanide”, the value was  $\log^{10}$  4.4. The bacterial colonisation with gram-positive bacteria was not changed during the entire examination period for any of the three test groups. In the “Diabetic INTENSIVE” group, bacterial colonisation had an absolute value of  $\log^{10}$  4.8 after 29 days, in the test group “Diabetic INTENSIVE CARE with microsilver” it was  $\log^{10}$  4.9 and in the test group “Diabetic INTENSIVE CARE with polyhexanide” it was  $\log^{10}$  3.4.

### Gram-negative bacteria

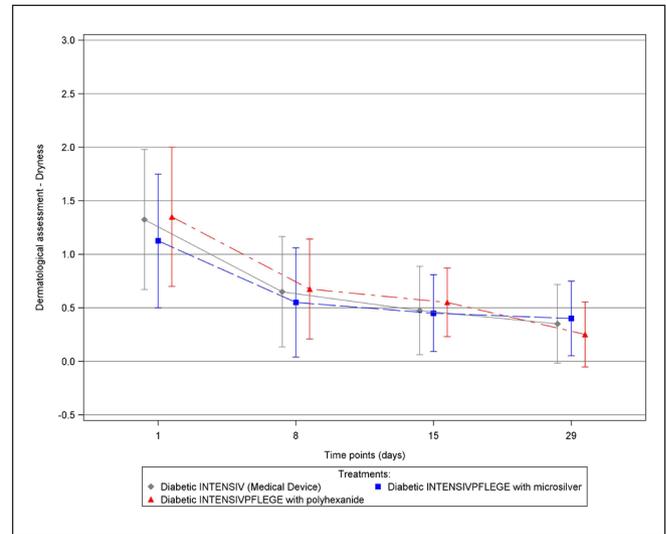
The colonization of the interdigital spaces with gram-negative bacteria was nearly zero both before the start of the application (day 1) and after the completion of the study (day 29) so we dispensed with the presentation and discussion of the results.

### SKIN HYDRATION

In the test group that used “Diabetic INTENSIVE” during the test period, the mean skin hydration (Fig. 2) was 23.0 a.u. on day 1 of the test period, the mean skin hydration was measured at 20.9 a.u. in the test group that used “Diabetic INTENSIVE CARE with microsilver”, and in the group that used “Diabetic INTENSIVE CARE with polyhexanide” in the study, the mean skin hydration was measured at a value of 25.0 a.u.

After one week of application (measurement on day 8), the mean skin hydration in all three test groups was increased by a comparable extent (“Diabetic INTENSIVE” – 34.7 a.u.; “Diabetic INTENSIVE CARE with microsilver” – 35.7 a.u.; “Diabetic INTENSIVE CARE with polyhexanide” – 33.2 a.u.).

During the remaining study period, skin hydration remained around the same level as it was on test day 8 in all three groups (“Diabetic INTENSIVE” group – day 15 = 35.9 a.u. and



**Fig. 3:** Course of the parameter “dryness” evaluated by a dermatologist in relation to the use of different foam creams over a study period of 4 weeks. In all three test groups, the extent of skin dryness decreased during the course of the application period.

day 29 = 37.4 a.u.; “Diabetic INTENSIVE CARE with microsilver” – day 15 = 38.3 a.u. and day 29 = 36.6 a.u.; “Diabetic INTENSIVE CARE with polyhexanide” – day 15 = 37.4 a.u. and day 29 = 38.5 a.u.).

### DERMATOLOGICAL ASSESSMENT

Corresponding to the increase of skin hydration, the skin dryness was markedly reduced in the test period in all three test groups (Fig. 3). The parameters skin redness, desquamation, oedema, and cracking were very mild from the start of the application.

Under application of each of the three foam creams, the manifestation of all four parameters named was regressive (not represented). No papules and blisters and skin erosions occurred in any of the participating test persons at any time (not represented).

### SUBJECTIVE ASSESSMENT OF SKIN CONDITION

The parameter itching was reduced on average by around one point, so that the majority of the test persons in all three test groups ( $\geq 90\%$  respectively) reported no itching after two weeks of treatment (Fig. 4). Stinging and burning sensation were described in all three test groups as negligibly weak. All three test groups had comparable courses for the parameters observed. The test persons in all three groups described their skin condition as dry at the beginning of the study period. During the course of the application period, the test persons of all three test groups assessed their skin condition regarding the parameter dryness as continuously better. The extent of improvement of skin condition was comparable in all three

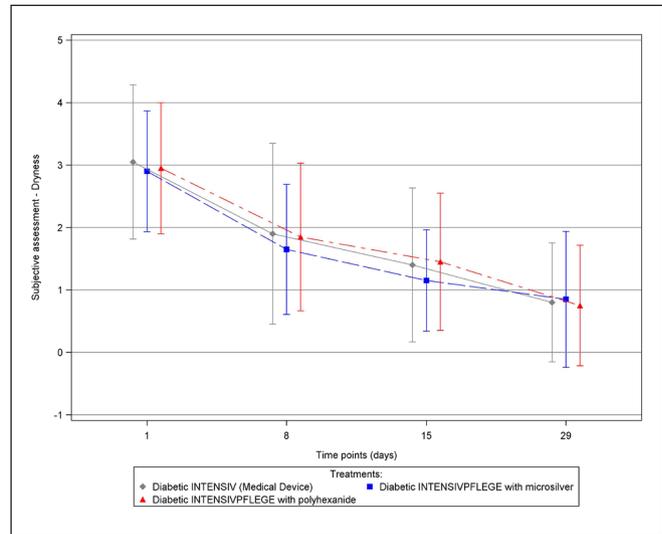
test groups (Fig. 5). The test persons in all test groups reported that they suffered from tightness at the beginning of the application. In all three test groups, a marked improvement regarding the tightness was described as early as day 8 of the study period. During the course of the study, the assessment of the tightness remained at the same level as it was described in day 8 (Fig. 6).

## QUESTIONNAIRE

The analysis of the questionnaires revealed that over 80% of all participating diabetic patients described very good or good improvement of their skin condition after the application of the foam creams. More than 80% assessed the tolerability of the product used to be very good. About 90% of the "Diabetic INTENSIVE CARE with microsilver" group and 90% of the "Diabetic INTENSIVE CARE with polyhexanide" group perceived the application of the foam cream in the interdigital spaces to be very good or good; this was the case for 95% in the "Diabetic INTENSIVE" group. Absorption of the foam cream was described as very good or good in comparison with other creams and lotions by 85% of the study participants.

The risk of slipping was perceived by over 95% to be moderate to negligible. Between 75% and 90% of all diabetic patients who were included in the study declared that they were able to put on their socks after the application of the corresponding foam cream very quickly or quickly and 80% of all study participants declared that they preferred foam creams over other creams or lotions for daily foot care.

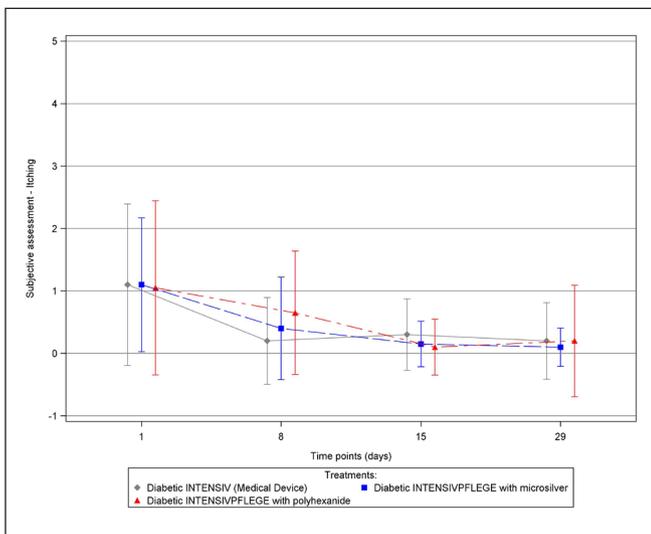
Between 85% and 90% of the test persons reported that the option of using foam cream increased their own willingness to conduct daily foot care. All participating diabetic patients would recommend the foam cream they used to other diabetic patients. During the test period there were no adverse effects of the foam creams used.



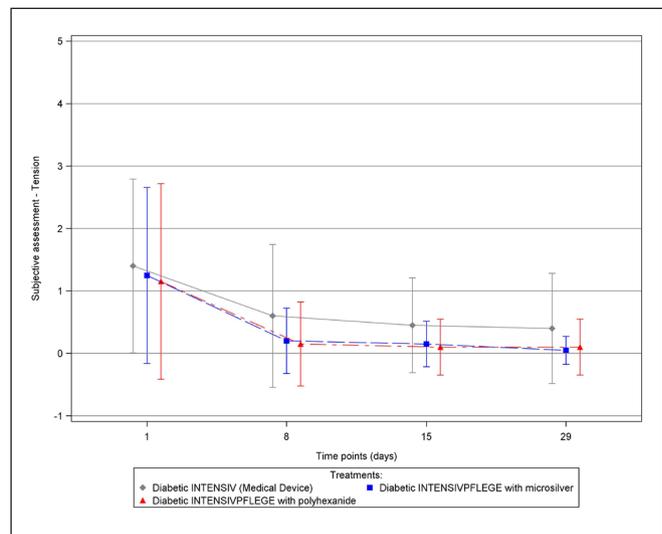
**Fig. 5: Course of the subjectively assessed parameter dryness in relation to the use of different foam creams over a test period of 4 weeks.**

## DISCUSSION

Xerosis is often observed in diabetic patients; data indicate it occurs in about 80% of patients [9]. Of course, diabetes management is one of the most important general measures for the prevention of diabetic foot syndrome. To prevent callus formation associated with severe xerosis, in addition to skin care adapted to the individual needs of diabetics, special attention must be given to the specific prevention of pressure, e.g. through special socks, walking dressings, braces or special shoes [1, 12, 14]. The basis for the corresponding prevention is the regular use of topical skin moisturising foot care products [6, 11].



**Fig. 4: Course of the subjectively assessed parameter itching in relation to the use of different foam creams over a test period of 4 weeks.**



**Fig. 6: Course of the subjectively assessed parameter tightness in relation to the use of different foam creams over a test period of 4 weeks.**

The skin moisturising effect of all three test products was demonstrated in the framework of the study in diabetic patients with dry, sensitive skin. This is especially interesting because the product was applied and measurements were made in the relevant application area on the feet. In many cases, tests of the effectiveness of foot care products in dry skin have been made at the forearms [5], which reflect actual application in practice to a limited extent only.

The assessment of bacterial colonisation in the interdigital spaces after application of the three foam creams was also of particular interest. A crucial factor for this study was the fact that in the care of dry diabetic foot skin, a compromise has to be made even today between adequate care of dry skin and avoiding macerations in the interdigital spaces, which can be encouraged by conventional foot care creams, ointments and other products. This compromise is reflected in the patient guidelines of the national care guideline “Type II Diabetes – prevention and treatment strategies for foot complications”, which in addition to daily washing with lukewarm water, recommends adequate care of the foot skin that excludes the interdigital spaces. Due to the increased predisposition of dry cracked skin for infections, the intensity of care should be tailored depending on the grade of the skin dryness [3]. Considering the risk of infection for dry cracked skin, the dryer the skin, the more frequently it should be creamed.

The immense importance of the care of dry foot skin is taken into account here. Nevertheless, this guideline explicitly recommends that due to possible maceration and the increased risk of infection this entails, the interdigital spaces should be excluded from these care procedures. These considerations were the starting point for the present study – to investigate the extent to which the foam creams applied in the interdigital spaces increase the risk of infection.

There are contradictory recommendations for the care of interdigital spaces. On the one hand, dry skin should be supplied with moisture and lipids to reduce the increased risk of infections in dry, cracked skin. On the other hand, conventional creams and ointments present a higher risk for the development of macerations. The reason for this is that the absorption time of care products with a cream or ointment base is prolonged in the interdigital spaces due to the respective pharmaceutical formulations.

The cream residue remaining on the skin surface impedes moisture exchange and leads to moist-fatty conditions on the surface of the skin in the interdigital spaces that soften the skin and can trigger macerations.

As a result of this dilemma, and according to the guidelines, it is recommended that the interdigital space should be excluded during care of the foot skin with creams and ointments. It is also recommended to use moisturising emulsions and foams containing urea in foot care [3]. Therefore, optimal care of foot skin necessitates supplying the whole foot with sufficient moisture and lipids, without – especially in the interdigital spaces – creating macerations that increase the risk of infections.

In this study, none of the test persons at any time had clinically relevant indications of a bacterial infection. This study

demonstrated that the foam creams used could be applied in the interdigital spaces of diabetic patients without resulting in increased bacterial colonisation. The results show that this is not attributed to the antibacterial components microsilver and polyhexanide. The study allows the conclusion to be made that these effects can be attributed solely to the particular texture of the foam creams used and its known advantages. No conclusions can be made about conventional foams and emulsions based on these results. This study also demonstrates that the applicable guideline recommendation not to use ointments, creams, or other care products in the interdigital spaces is no longer valid for the foam creams tested.

In addition to the possibility of using the tested foam creams in the interdigital spaces without an increased risk of infection, a marked moisturising effect was demonstrated for all products tested. All three used products were well tolerated, which is especially important for use by persons with diabetes.

## SUMMARY

The tested foam creams fulfil all the requirements of products for foot care of persons with diabetes. They supply the skin with moisture, can be used on the entire foot including the interdigital spaces and are very well tolerated by persons with diabetes. This makes it possible to provide the necessary care for dry foot skin in diabetes patients and the resulting reduction of potential entry ports for bacteria, fungus and other contaminants without increasing the risk of infection at other locations through macerations in the interdigital spaces.

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