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Change in moisture and fat content of skin under the application of Callusan® EXTRA cream mousse

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Introduction:

In Germany, about 5-8 million people suffer from diabetes mellitus. Foot-related problems can occur as a direct consequence of this, and about 15% of this population is affected during their life. While treating diabetes mellitus, 20% of the hospital costs are attributable to foot problems. (1)

A predisposed factor for the occurrence of foot problems is skin changes promoted by neurological deficits. Thus, regulating functions such as for example, secretion of sweat are disturbed in case of patients suffering from diabetes. This leads to an over-heating of the foot, which can manifest itself as dry skin. (2, 3, 4)

The dry skin concept (Xerosis, Xerodermie) describes a skin condition characterised by reduced quantity and / or quality of moisture and lipids. Objectively, the appearance of dry skin is accompanied by roughness, scaling, loss of shine and elasticity. Subjectively, dry skin can cause tension and itching. These subjective symptoms can also manifest themselves in isolation.

Dry skin reacts more intensively than normal, non-dry skin to harmful external chemical and physical substances. Its resistance to mechanical influences too is reduced substantially. (5).

In the opinion of expert circles, dry skin occurs very frequently. In Germany alone, a few million people are affected. Epidemiological data is not available.

The precise aetio-pathogenesis of dry skin often remains unexplained. For persons oriented towards atopy, a defect in the barrier function of the horn layer can cause increased trans-epidermal water loss. Diabetes mellitus patients often have an autonomous poly-neuropathy (PNP). This leads to palsy of the sudomotor, which stops sweat formation. However, the dry skin can also be conditioned by a seborrhoea (reduced sebaceous gland activity). There can also be a reduced water-binding capacity.

The dry skin is either genetically conditioned, or inherited. It appears as the symptom of a skin disease, e.g., atopic dermatitis, an inner disease, e.g., a nerve disease or diabetes mellitus. The dry skin can also be caused by external influences, such as for example, too frequent and intensive

showers or baths with or without soap or syndet soap. Profession-specific stress, e.g., in case of wet professions (hair dressing etc.) as well as in the construction or metal industry, can also cause the appearance of dry skin. This is also true of climatic factors as well as cold or too little humidity (6).

Diagnosis of dry skin can be undertaken with the help of the data of the affected persons and the visual and palpatoric examination. Apparative diagnostic methods are, among others, measurement of skin roughness, **measurement of moisture content**, determination of trans-epidermal water loss and **fat content**, scaling as well as measurement of shine.

At present, the standard therapy for dry skin is mainly the application of fat-rich balms, creams etc., which the patients must apply regularly (2x daily, morning and evening).

Objective of the study:

The effects that can be achieved through the atypical application of the urea-containing cream mousse Callusan® EXTRA on the skin have been examined in this study.

Question:

The primary objective of the study was to prove whether the moisture content of the skin – so very important in the case of diabetic patients – can be increased through the application of urea-containing cream mousses (containing 10% urea).

Method:

This study deals with a process observation. The patients applied Callusan® EXTRA once daily on one foot during the period of observation.

The foot to be treated was defined before the start of the application with the help of a randomising list.

The study was conducted over a period of six weeks. A total of three visits were conducted during this period:

V0 = At the start of the observation period

V1 = After three weeks

V2 = After 6 weeks, i.e. at the end of the observation period

Changes in itching and patient satisfaction were highlighted with the help of a questionnaire. Digital photographs were taken during each visit to document the skin quality.

The extent of poly- neuropathy was determined through the neuropathy deficit score. In this method, the Achilles Heel Reflex (retained: 0 points, weakened: 1 point, missing: 2 points), the vibration sensitivity with the Rydel Seiffer tuning fork, neuro-filament detection and temperature sensitivity are assessed for the left and right foot (each not conspicuous: 0 points, pathological: 1 point). Point values of 9-10 represent severe poly-neuropathy (PNP), 6-8 points, a moderate, and 3-5 points, a mild PNP (7).

The measurement of the skin moisture and fat content was carried out with the help of a combo device called "Sebumeter / Corneometer / Skin-pH meter" manufactured by CK-Elektronik GmbH.

The skin moisture is calculated on the basis of a capacitive measuring process. Here, changes in the dielectric constants through changes in the water content of the skin lead to a change in the capacity of measuring capacitor. Dimensionless values of 0-150 are output here.

The fat content of the skin is calculated on the basis of the spot fat photometer. The light permeability of a plastic film wetted with fat is measured here. The film is housed in a special cassette. A corresponding test areal is held for 30 seconds on the main section to be measured, and finally, the transparency change in the film is evaluated electronically in the Sebumeter against the zero adjustment. The result is specified in $\mu\text{g}/\text{cm}^2$ (8-14).

The following table shows the leads for the evaluation of the corresponding results:

	Forehead, T-Zone, scalp	Hair	Cheeks, eyelids, temples	Corner of mouth, upper body, back, neck	Arms, hands, legs, feet, elbows
Dry, low fat	< 100	< 40	< 70	< 55	0 – 6
Normal	100 – 220	40 – 100	70 – 180	55 – 130	> 6
Fatty	> 220	> 100	> 180	> 130	Cannot be used

(Values in μg Sebum/cm² skin)

While measuring the skin moisture and skin fat content, mean values from the 3 measuring points on the sole (MTK I, V and heel) as well as one measuring point on the rear of the foot were calculated.

The dryness item was queried with the help of a questionnaire on the three measuring points with "Yes" and "No".

The items roughness, scaling, cracks and callus skin were queried on a scale of 0 to 5 where "0 = none, 2 = little, 3 = moderate, 4 = considerable". The item itching was also assessed on a scale of 0 to 5, where "0 = no itching to 5 = unbearable".

Results:

Patient data:

Within a period of 6 weeks, n = 40 patients were included in the examination. Age 63 (SD ± 13,8) years, 7 patients with diabetes mellitus Type 1, having Type 2 diabetes.
The average NDS score was 4.25 (SD ± 3.6).

1. Changes in skin moisture:

A **significant increase in the moisture content** of the skin could be established within the framework of this study.

The average skin moisture in the treated foot at the start of the examination was **32.2** (SD ± 8.2).

After 3 weeks of treatment, the skin moisture content of the treated foot increased to **44.89** (SD ± 14.4) at ($p < 0.001$). After 6 weeks of treatment, the moisture content in the treated foot worked out to **42.26** (SD ± 14.42) (p corresponding to $t_0 < 0.001$, p against $T_3 = 0.161$).

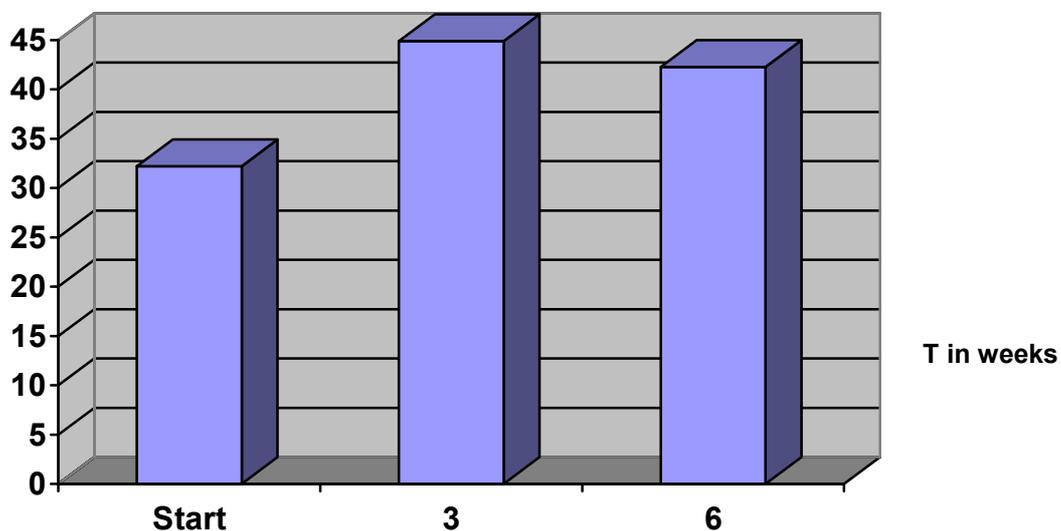


Figure 1: Changes in **skin moisture** (dimension-less)

2. Changes in skin dryness:

From **75% at the start**, only **8%** of the patients characterised the treated foot as **dry** at the end of study.

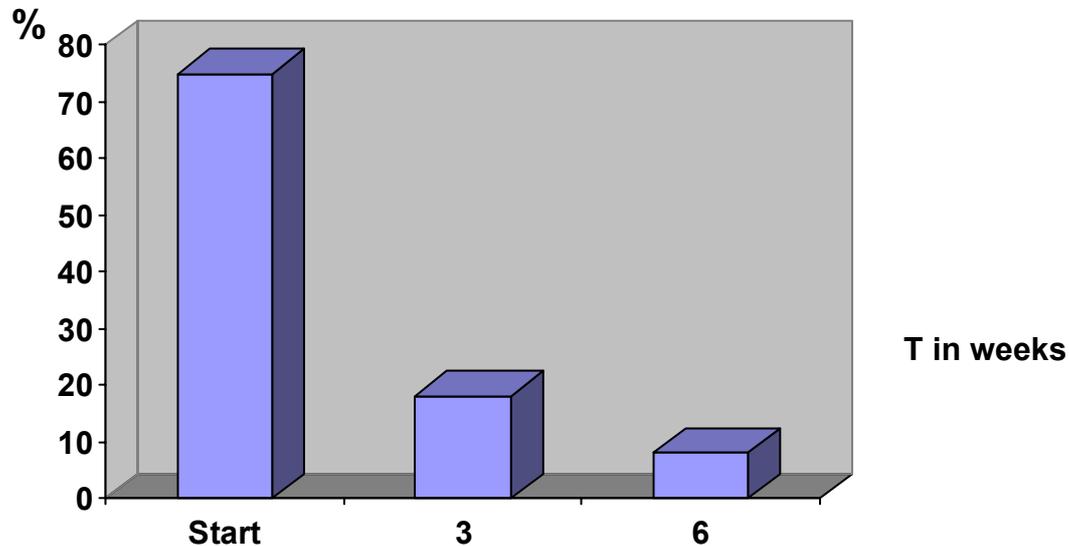


Figure 2: Data on the **dryness** of the treated foot in %

3. Roughness:

The **rough** skin condition was characterised as “not present at all” by 5% of the patients at the start, “a little” by 65%, “moderate” by 20% and “considerable” by 10% patients.

After three weeks, 31% of the patients characterised the roughness of their treated foot as “No longer there”, 63% as “a little”, 6% as “moderate” and no patient as “considerable”.

After 6 weeks, **61% of the patients characterised their treated foot as “No longer” rough**, 36% as “a little” and only 3% as “moderate”.

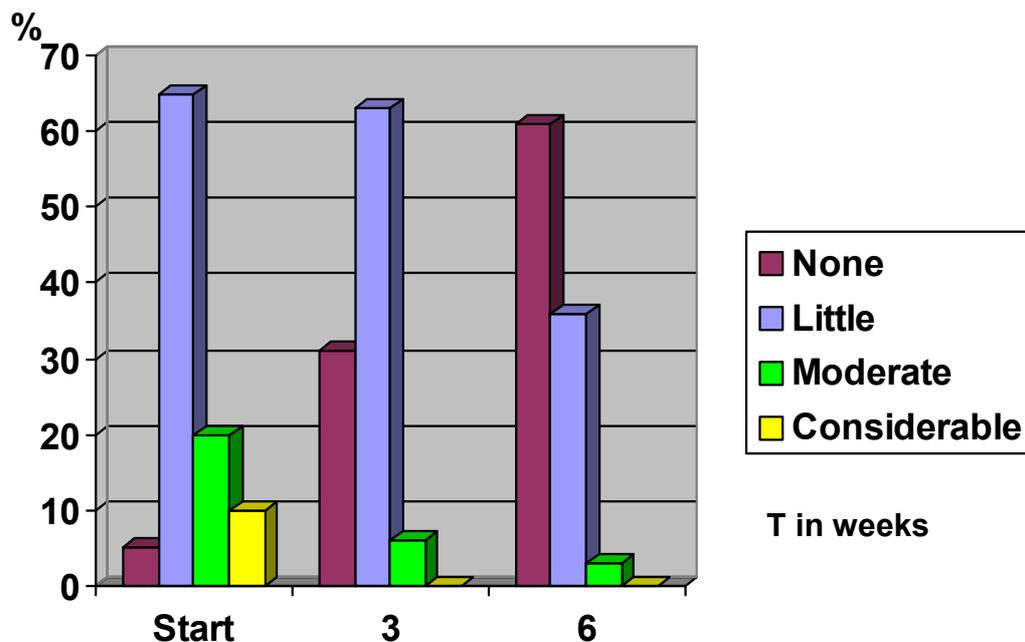


Figure 3: Evaluation of the **roughness** of the skin of the treated foot

4. Scaling:

The **Scaling** or flaking skin condition was characterised at the start by 28% of the patients as “does not exist”, by 60% as “a little”, by 8% as “moderate” and by 5% as “strong”. After 3 weeks, 71% of the patients characterised their skin as “no more scaling”, 23% as “little scaling” and 6% as moderate, and **no patient as strong**. After 6 weeks, the corresponding figures were **73%**, 24% and 3% respectively.

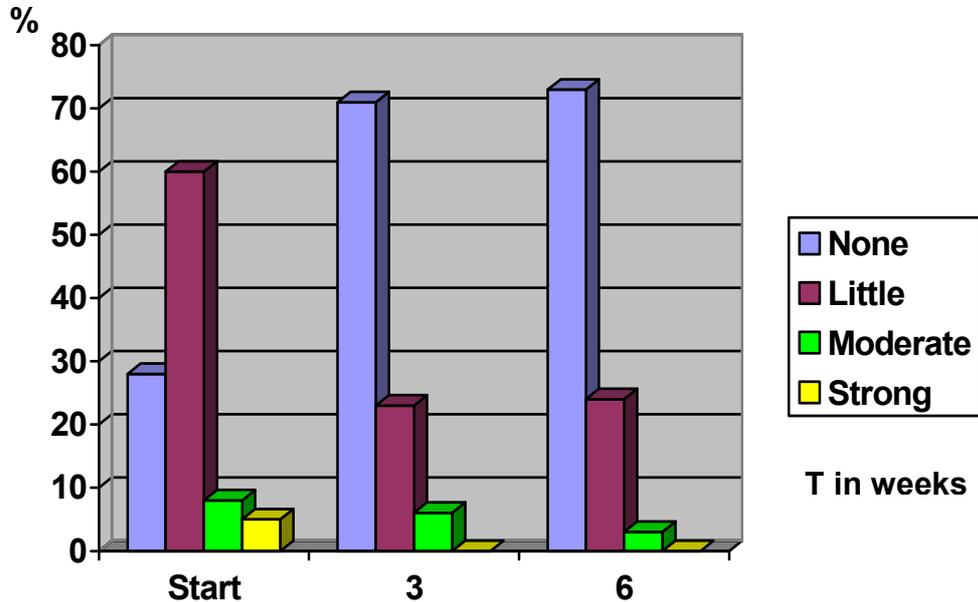


Figure 4: Evaluation of the **Scaling** of the skin of the treated foot

5. Skin cracks:

At the start of the study, 58% of the patients described the **crack formation** condition as “does not exist”, 38% as “a little”, and 5% as “moderate”. After 3 weeks of treatment, 77% said there were no cracks, 17% reported “a little” and 6% said “moderate”. After 6 weeks of treatment, **81% patients reported “no cracks”**, 16% said “a little” and 3% said “moderate”.

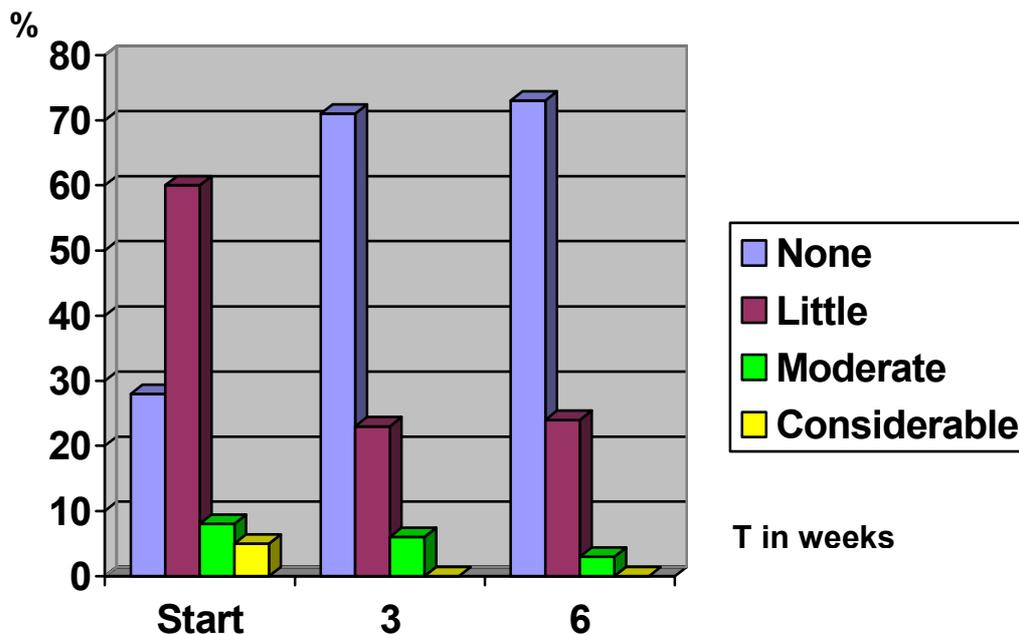


Figure 5. Evaluation of **crack formation** in the skin of the treated foot

6. Callus skin:

On the presence of **cornea or callus skin**, all **100%** patients complained of callus skin at the start of the study. 55% categorised their callus skin as “a little”, 25% as “moderate” and 20% as “considerable”.

After 3 weeks of treatment, the corresponding figures were 73%, 17% and 10% respectively. After 6 weeks, 11% characterised their treated foot as free of callus skin, 60% classified it as “a little”, 20% as “moderate” and 9% as “considerable”.

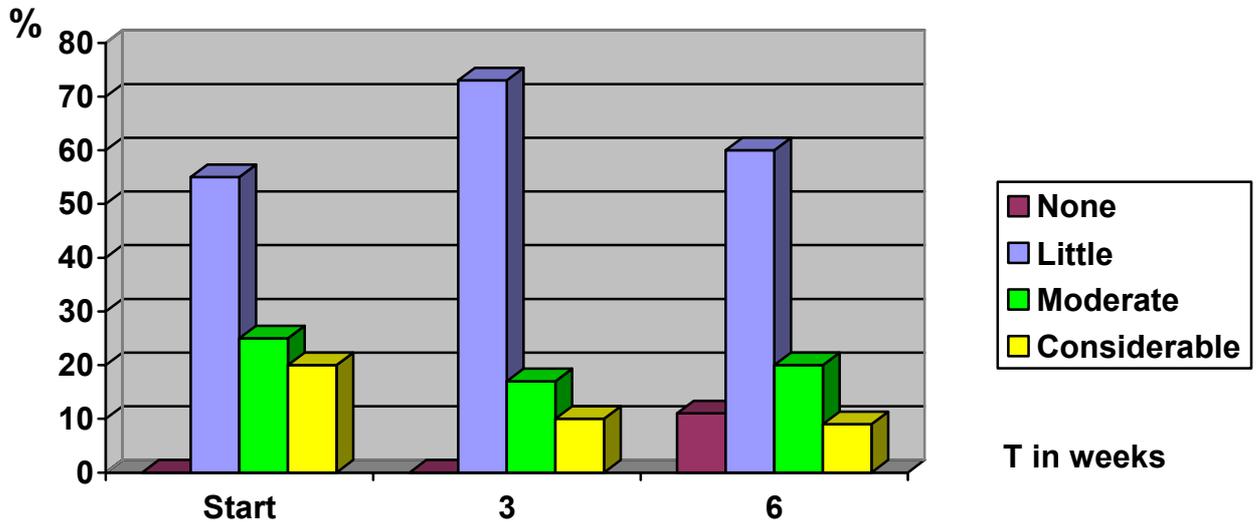


Figure 6: Evaluation of **callus skin formation** on the treated foot

7. Itching:

At the start of the study, 55% of the patients did not complain of any **itching** in the feet, 15% characterised the itching condition as “occasional”, 5% as “mild” and 3% as “strong”. After 3 weeks of treatment, the proportion of patients who did not feel any itching increased to 89%.

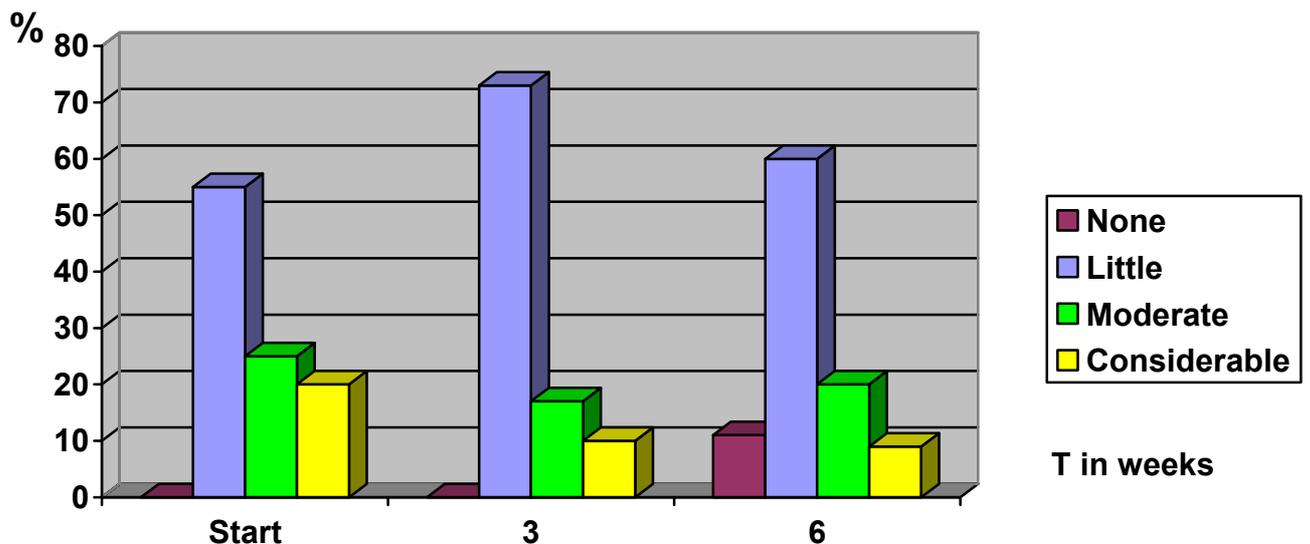


Figure 7: Evaluation of **itching** in the treated foot

8. Changes in fat content:

The average **fat content** in μg Sebum pro cm^2 of the skin of the treated foot was **0.84** ($\text{SD} \pm 1.77$) at the start of the study.

After 3 weeks of treatment, the fat content of the treated foot increased to **1.06** ($\text{SD} \pm 1.46$) ($p = 0.103$) and after 6 weeks of treatment, the treated feet showed a fat content of **2.56** ($\text{SD} \pm 4.82$) (p against $t_0 = 0.025$ und against $t_3 p = 0.075$) and thus, **came very close to the values of healthy skin**.

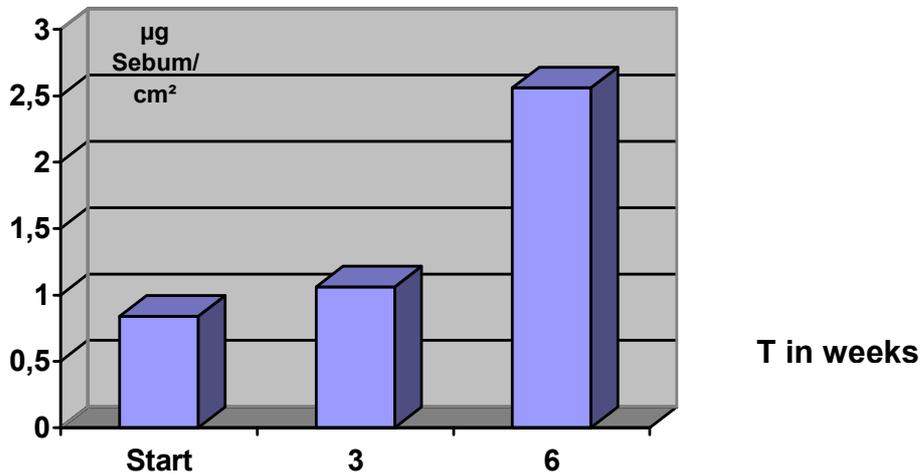


Figure 8: Change in **fat content**

9. User-friendliness:

The patients were asked to give their opinion on the user friendliness of the cream mousse at the end of the observation period.

The statement: **“The application is simple and pleasant“** was confirmed by **90%** of the patients.

The same percentage supported the statements about the foam: **“Leaves a pleasant feeling behind”** **“Makes the skin soft and sleek“**.

74% found the statement: “gets absorbed fully and fast“ to be appropriate, and 46% felt that stockings could be worn right away.

86% confirmed the statement that the product is worthwhile.

Foot samples during the process:



At the start



After 3 weeks



At the start



After 3 weeks

Discussion:

The effects of the urea-containing Callusan® EXTRA cream mousse on the skin were examined in this study.

The moisture content of the skin increased significantly in 98% of the patients. The increase between the first and second measurements was conspicuous, which underlines the fast effect of Callusan® EXTRA.

From **75% at the start**, only 8% of the patients characterised the skin of their feet at the end of the treatment period as **dry**. This clear and positive evaluation by the patients confirms the achieved measured values impressively.

While treating dry skin, in addition to **increasing the moisture content of the skin**, it is more important to **normalize the fat content**. It was illustrated within the framework of this study that the skin of diabetes patients is not only very dry but also almost fat-free at the beginning of the study (poor in hydro-lipids). On applying Callusan® cream mousse regularly, the determined fat values of the skin come close to the values of normal healthy skin (also refer to the table on Page 2). This normalisation of the skin structure also guarantees an optimal skin function.

This is especially remarkable, because this was achieved **without any fat-rich ointment base**. The high fat content of many other skincare products can lead to clogging of the skin pores, which – on account of neuropathic changes – prevents the already limited skin functions even further.

This type of a skin pore clogging, which is potentially dangerous for diabetes patients – is avoided effectively with Callusan® cream mousse.

The result is unambiguous even in the case of **roughness**, While only **5%** of the patients characterised their foot skin as “**not at all dry**” at the start of the study, the proportion increased to **61%** at the end of the study.

After 3 weeks, the proportion of patients who characterised their foot as “**no more scaling**” increased from **28% to 71%**; 23% characterised it as “less scaling” and 6% as moderate. **Not a single patient characterised the condition as strong**. After 6 weeks, the corresponding data was **73%**, 24% and 3% respectively.

Astounding success on the topic of callus skin: **Of the 100% participants who complained of callus skin** at the start, 11 % admitted that no more callus skin was evident after 6 weeks, 60% patients characterised their callus skin as “very little” and 20% as “moderate”.

Itching, which mostly goes hand in hand with dry skin, is of special importance to patients as it is exceptionally annoying and uncomfortable. After 3 weeks of treatment, 89% of the patients reported “**no more itching**”.

In the area of crack formation too, application of Callusan® EXTRA improves the quality of the skin conspicuously. If 42% of the patients detected cracks at the start of the study, **81% declared their skin to be free of cracks after 6 weeks**.

The data of the participating patients on user-friendliness too was very positive on the whole, which highlights the fact that the cream mousse concept is **very popular among users**.

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