SEMMELWEIS EGYETEM BUDAPEST
Bőr- és Nemikórtani Klinika

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OF THE STUDY OF THE 'DR. MICHAELS' TOPICAL PRODUCT FAMILY

IN PSORIASIS

Lead investigator:	Prof. Dr. Attila Horváth
Institution:	Semmelweis University Dept. of Dermato - Venereology H - 1085 Budapest, Mária utca 41.
Study type:	Open
TÜKEB permit number:	26 / 2002
OÉTI permit number	6060 / 2001
Consent:	Prior to the beginning of the study, the participating patients signed an informed consent and an agreement of voluntary participation.

I. GENERAL POINTS

1. BACKGROUND

Psoriasis is a common (approximate prevalence of 2% in Hungary) chronic, recurring skin disease. Genetic predisposition as well as triggering factors play role in its etiology. The disease can occur at any age without any gender predominance. Although psoriasis can affect any regions of the body there are areas more frequently involved, such as the scalp, extensor surfaces of the extremities, skin folds, nails. The clinical presentation is variable, characterized by infiltration and parakeratosis. There are multiple topical and systemic treatment options available. In certain clinical presentations the topical anti-psoriasis therapy is sufficient.

REPORT

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The study of the Dr. Michaels topical product family was designed to determine whether its natural oil content (the composition and ratio of the natural oils) was able to decrease the psoriatic parakeratosis, inflammation, and infiltration.

2. OBJECTIVE

Evaluation of the Dr. Michaels topical product family in psoriasis, to determine its **efficacy, adverse effects**, and **tolerability.**

3. CHARACTERISTICS OF THE TESTED PRODUCT

Triphasic application: Successive use of a cleansing gel (Cleansing Gel – Scalp and Body), ointment (Scalp and body ointment), and skin conditioner (Skin conditioner).

3.1 Dr. Michaels cleansing gel for the scalp and body

Loose, white-opaque, easily applicable topical preparation.

Effect: decreases parakeratosis

Components: water, coal tar solution, sodium lauryl ether sulfate, coco amido dipropyl betaine, triethanolamine lauryl sulphate, organic acids, fruit acid complex, coconut diethanolamide, carbopol, triethanolamine, methylchloroisothiazolinone (and) methylisothiazolinone, tertasodium EDTA.

Application: Applied before the use of the ointment.

Scalp: Applied to the plaques on the scalp together with small amount of cleansing gel after previous wetting of the scalp. Washed off after 2-3 minutes using lukewarm water. Can not be applied to the face.

Body: Applied to the psoriatic plaques, washed off with lukewarm water after 2-3 minutes. Not to be applied to the face.

Formulation: 200 ml in plastic bottles

3.2 Dr. Michaels ointment – head and body

Yellowish-white ointment with characteristic scent.

Components: wheatgerm oil, sweet almond oil, evening primrose oil, pet jelly, zinc oxide, jojoba oil, apricot kernel oil, avocado oil, mineral oil, carrageenum, carrot oil, fruit acid complex, lavender oil, tea tree oil, bergamot oil, sandalwood oil, patchouli oil, pine oil, geranium oil, orange oil, neroli oil, calendula oil, frankincense oil, citronella oil, chickweed extract, chamomile extract, sesame seed oil, myrrh oil, preservatives.

Effect: Decreases inflammation, infiltration.

Application: Applied to the psoriatic plaques of the scalp and body after using and washing off the cleansing gel. On the scalp only recommended to apply to severely infiltrated plaques.

Formulation: 50 g and 200 g in plastic vials.

3.3 Dr. Michaels skin conditioner – head and body

White colored, viscous substance with characteristic scent.

Components: olive oil, sesame seed oil, mineral oil, beeswax, sunflower oil, emu oil, lavender oil, eucalyptus oil, rosemary oil, natural vitamin e, chickweed extract, calendula oil, preservatives

Application: Applied to the psoriatic plaques two minutes after using the ointment (without washing it off).

Application to the scalp without ointment: The conditioner is applied to the scalp at night and washed off in the morning using the cleansing gel. The conditioner is reapplied at night without washing the head, and washed off again using the cleansing gel in the morning.

Formulation: 50 or 200 ml in plastic bottles.

It is recommended to apply the three-component product family twice daily, in the morning and at night.

4. PATIENT EVALUATION

4.1 Inclusion criteria

- mild to moderately sever psoriasis without complications
- both genders, age above 18
- no other current anti-psoriatic therapy
- signed informed consent

4.2 Exclusion criteria

- pustular and erythrodermic psoriasis
- systemic, acitretin, cyclosporin, methotrexate, light therapy currently or within the past 3 months
- topical antipsoriatic therapy

- pregnancy, breast feeding
- known hypersensitivity to any of the components of the products
- lack of informed consent
- low compliance

4.3 Can not be applied to the face, genitals and folds

5. STUDY PROTOCOL

5.1 Time frame

2 weeks of wash out period. During this phase the patients used only emollients.

Application time of the Dr. Michaels products: 6 weeks

Total study length: 8 weeks

Evaluation points: -2, 0, 1, 2, 3, 4, 5, 6 week

Total number of medical evaluations: 8

Patients in the study: 30

Application frequency: twice daily

5.2 Evaluation of efficacy

The evaluation was based on the Psoriasis Area and Severity Index (PASI) at each of the 8 medical evaluations.

Evaluated features: erythema, infiltration, parakeratosis, size of affected area.

Score	0	1	2	3	4
Erythema	0= none	1= mild	2= moderate	3= severe	4= very severe
Infiltration	0= none	1= mild	2= moderate	3= severe	4= very severe
Parakeratosis	0= none	1= mild	2= moderate	3= severe	4= very severe

Score	0	1	2	3	4	5	6
Area %	0	<10	10<30	30<50	50<70	70<90	90<100

6. SIDE EFFECTS

6.1 Recording of side effects

The recording of side effects began on week 3. The characteristics of the side effects, their relation to the product and the additional steps taken were recorded on the datasheet.

6.2 Evaluation of side effects: summary evaluation of the side effects was performed after completion of the study.

7. EVALUATION OF THE RESULTS

7.1 Cosmetic effects – tolerability were evaluated at the end of the study based on the statements of the patients.

7.2 Efficacy was evaluated by the physician at the end of the study using the following descriptors: ineffective, moderate effect, good effect, outstanding effect, worsened. The physician's evaluation was based on the percent change of the PASI scores.

7.3 The patients stated if they would continue to use of the Dr. Michaels product family.

8. SUMMARY EVALUATION

Upon completion the physician conducting the study provides a summary evaluation.

II. DATA OF THE STUDY

Start date:	2/ 4/02
End date:	5/22/02
Patients included:	30
Patients excluded:	3
Patients completed, evaluated:	27

PATIENT CHARACTERISTICS

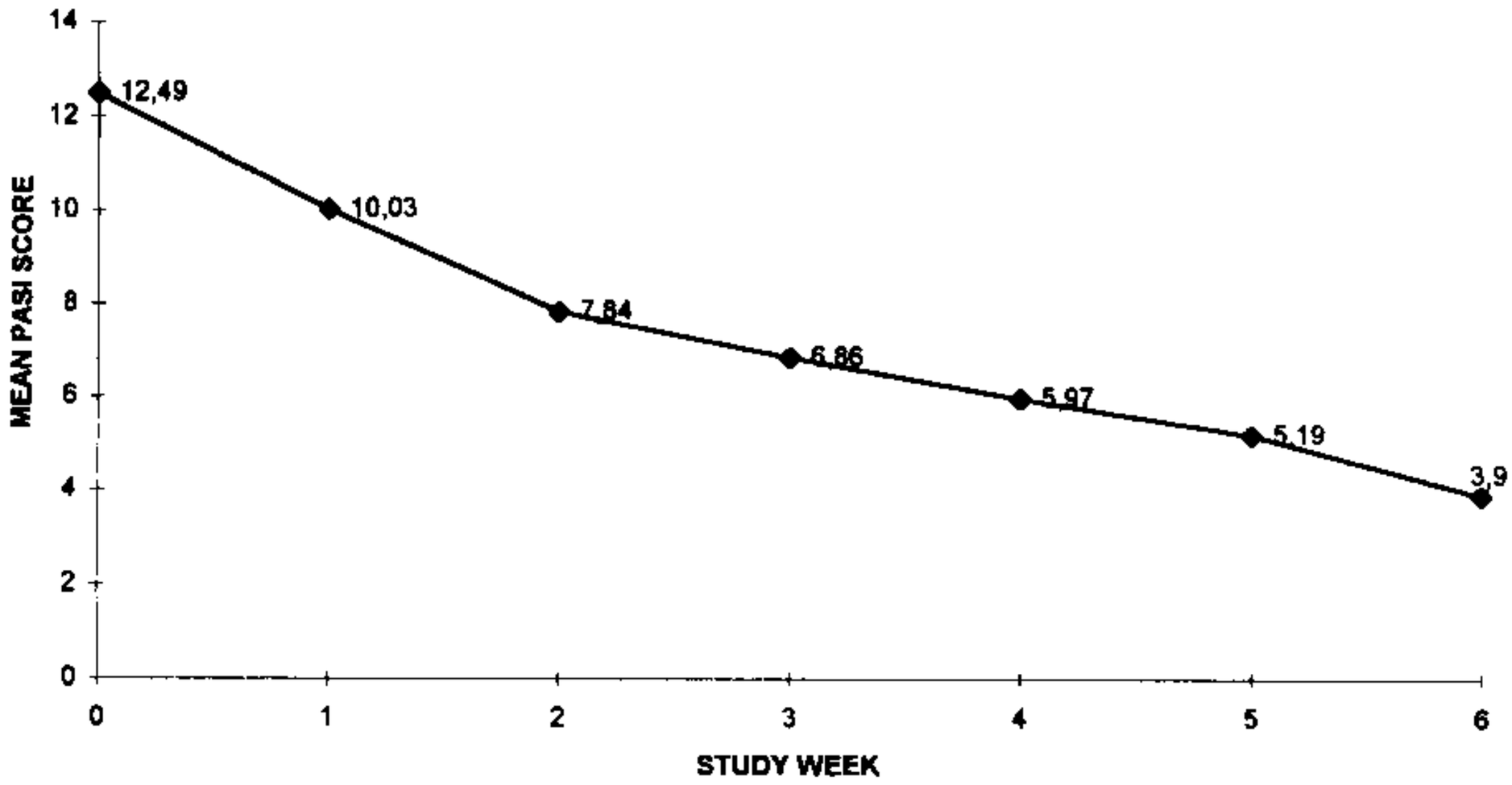
Mean age:	47,26.26 (18-80)
Mean duration of psoriasis:	17.56 years (2-47)
Gender distribution:	male: 18 female: 9
Psoriasis type:	plaque type, mild to moderately severe

EVALUATION OF IMPROVEMENT

Worsened	PASI score higher than baseline
Not improved	PASI decrease 0-25%
Moderate improvement	PASI decrease 26-50%
Good improvement	PASI decrease 51-75%
Outstanding improvement	PASI decrease76-100%

SUMMARIZED CHANGE OF PASI SCORE IN ABSOLUTE VALUES

(Number of patients: 27)



CHANGES OF SKIN SYMPTOMS OF THE STUDIED PATIENTS

Worsened	0 patient
Not improved	3 patients
Moderate improvement	5 patients
Good improvement	6 patients
Outstanding improvement	13 patients
Total	27 patients

The percentage values of the improvement fall between 0 - 98, 68 %

SIDE EFFECTS

Evaluation points of side effects:	1, 2, 3, 4, 5, 6 week
Recorded side effect:	folliculitis of lower extremities
	pruritus of the scalp, upper torso
Folliculitis occurrence:	7 total occurrences, 5 males, 2 females
Pruritus occurrences:	1 total occurrence (female)

COSMETIC EFFECT – EVALUATED BY THE PATIENTS

Good	8 patients
Indifferent	19 patients

SUBJECTIVE EVALUATION OF EFFICACY BY PATIENTS

Ineffective	2 patients
Moderate improvement	5 patients
Good improvement	11 patients
Outstanding improvement	9 patients
Total	27 patients

PHYSICIAN'S EVALUATION OF EFFICACY

Ineffective	3 patients
Moderate improvement	5 patients
Good improvement	6 patients
Outstanding improvement	13 patients
Total	27 patients

STATEMENT OF PATIENTS REGARDING FUTURE USE OF THE PRODUCT FAMILY

Would not continue to use	2 patients
Would continue to use	25 patients

SUMMARY

The study was completed in 27 patients out of the originally included 30. Three patients dropped out due to lack of compliance in two cases and due to the retraction of informed consent in one case.

We only studied patients with mild to moderately severe psoriasis.

The product proved to be **ineffective** in three of the 27 patients (11.21%). 5 patients(18.52%) had **moderate improvement**, 25-50% of the skin lesions cleared up. 6 patients (22.22%) had **good improvement**, 51-75% of the lesions disappeared. 13 patients (48.14%) showed **outstanding improvement** with the regression of 76-98.86% of the lesions.

7 patients developed folliculitis as **side effect** that was clearly related to the product family. The folliculitis was noted at a few treated plaques and the surrounding are on the lower extremities. In six cases the folliculitis regressed upon discontinuation of the application without further treatment. In one case the folliculitis cleared after topical therapy.

One patient developed pruritus of the scalp and upper torso which regressed without discontinuing the application.

No contact sensitization could be noted, which is probably due to the thorough screening applied during patient selection. No patient was included in the study with known hypersensitivity to any component of the product. Important that the information material should warn of this and other exclusion criteria. Although we did not notice such effects in this limited study, some of the components of the product may have potential photosensitizing effect.

Patients should be warned about folliculitis as a potential side effect.

Although this product is a cosmetic, due to the previously described circumstances it is recommended that the patients seek the advice of a dermatologist before starting the application. In case of noticing side effects the patients should consult a dermatologist.

The **cosmetic effect** was evaluated as indifferent by 19 patients, and as good by 8 patients.

The **evaluation of the treatment by the patients** differs from that **by the physician**. The only identical group is the 'moderately improved' (5-5). There was one more 'not improved' case according to the physician's evaluation compared to the evaluation of the patients (3-2). The patients in 11 the physician in 6 cases considered the improvement 'good'. The distribution of 'outstanding' evaluations is the other way around. The physician considered the improvement 'outstanding' in 13 cases while the patients considered it 'outstanding' in 9 cases. The differences can be explained by the fact that the physician's evaluation was based on a pre-determined scale and calculation of the percent-changes, while the patient evaluation was entirely subjective. The patients considered the improvement 'good' when it was only moderate based on the calculated scores. However, many patient would only have given 'outstanding' evaluation for complete clearing of the lesions.

25 patients stated that they **would continue to use the product**, including those who had only moderate improvement. They argued that they were less concerned about side effects since the product was a cosmetic not a medication.

Because the product family consists of three different components, it is important that the **package insert** should be clear, easy to understand, making the application easy for everyone.

Based on the results of this study, the Dr. Michaels product family can be successfully applied in mild to moderately severe psoriasis when considering the exclusion criteria.

Budapest, Hungary, June 21st 2002.

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