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by Psoriasis & Skin Clinic

REPORT

OF THE STUDY OF THE "DR MICHAELS" TOPICAL PRODUCT FAMILY IN PSORIASIS (AUSTRALIAN TRIALS)

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Study Type: **Open**

1. General Points

1.1 Background

Psoriasis is a chronic, recurring skin disease affecting 2-4% of the population. Genetic predisposition, primary as well as primary and secondary provoking factors play a role in its etiology. The disease can occur in any age or gender group. The most frequently affected areas of the body include scalp, extensor surfaces of the extremities, skin folds and nails.

1.2 Introduction

The skin is a protective barrier whose permeability allows for loss of material from within its surface while preventing invasion by microbiotic agents and deleterious exogenous substances. The cellular component of the epidermal layer is composed of a number of specialised cells, grounded in connecting tissue which function to control a wide range of immune reactions (1). For example, lymphocytes are responsible for cell mediated immunity, lymphokine secretion, regulation of inflammation and cytotoxicity. Such reactions may arise from entry through the skin by infectious agents and are signalled by the inflammatory responses of cell types in the perivascular region (2).

The integrity of the epidermal layer is maintained by a fine balance involving loss of cellular material from the outermost surface of the skin and the replacement of cellular components from within. For the skin cells to remain viable and fulfil their function a continuous input of nutrients and protective agents are required which are ubiquitously delivered by the circulatory system of the blood stream whose fine capillaries reach to within 1 mm of the outer surface. Antigens introduced by skin lesions may interact with dermal and epidermal cells soliciting an immune response involving an inflammatory cascade. This results in the egress of immune cells into the skin with uncontrolled keratinocyte proliferation and altered differentiation such that epidermal hyperplastia and polymorphonuclear leucocytes lead to skin thickening, a breakdown in skin structure becoming papulosquamous with skin lesions and disruption of blood capillary circulation (3).

A family of disease states becomes established, one of which is known as cutaneous psoriasis whose prevalence in the population of many western cultures is between 2% to 4%. In a smaller number of cases, 4% to 5% the condition may be accompanied by nail involvement (paronychia, onycholysis), a rheumatoid factor and spinal arthropathy. In the psoriatic condition there is an increase in DNA synthesis in keratinocytes, which is ultimately linked to the genetic make up of the individual with the inevitable genetic predisposition to the disease. In addition, there is an increased risk of diabetes and heart disease.

The itching and extreme discomfort to the individual afflicted by the complaint in itself causes a degree of anxiety, while it is a common clinical observation that a high percentage of those afflicted also suffer from anxieties arising from life-style issues, which encourage the progress of the disease.

While the pathenogenesis of psoriasis remains obscure there is some evidence that malfunction of the cytokine network may contribute to the cause (4,5). It has been put forward that the disease results from a malfunction of the mechanism involved in lesion repair, which at the cellular level arises from an impaired control of Langerhans cell mediation of nitric oxide production and keratinocyte proliferation (6). In addition, certain therapies have assisted in focusing attention on aspects of the complaint. The topical treatment with tazarotene, a retinoic acid receptor–specific retinoid, down–regulates markers of keratinocyte differentiation, keratinocyte proliferation and inflammation while up-regulating genes, which may mediate anti-proliferative effects (7). Corticosteroids affect the skin immune system, T-lymphocytic proliferation, a decrease in Langerhans cell surface markers and antigen presenting capacity (8). Dithranol prevents keratinocyte proliferation and has immuno-suppressive properties. Calcipotriol used in the management of stable plaque psoriasis inhibits keratinocytic proliferation. The therapeutic value of cyclosporin A implicates an immunological cause of psoriasis, its use leading to reversible inhibition of immune suppression of lymphoid cells (9,10). In clinical practice, a protocol for the treatment of psoriasis has been outlined which includes stress management, it being noted that smokers run an increased risk.

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The use of topical agents such as coal tar preparation, dithranol, methotrexate, cyclosporine and phototherapy has been described with a rotation of treatments reducing the risk of severe side effects (11).

Psoriasis is a genetic auto-immune condition which may lie dormant until activated. It has long been recognised that there are a number of provoking factors that can initiate the onset of the psoriatic state. These include injury to the skin (Koebner phenomenon), systemic infections (streptococcal), taking or cessation of certain drugs such as steroids, lithium, antimalarials and anti-inflammatory agents, and emotional stress and worry.

Once initiated the condition persists with the sufferers for many years which indicates that there must be other factors apart from the initial provoking factor involved in the manifestation of this complaint.

While a number of therapies exist for the treatment of psoriasis with a total resolution of the skin, achieving remission in a high percentage of sufferers, a treatment which results in the maintenance of remission and is free of side effects is a desirable goal (12).

This report describes a therapy for the treatment of psoriasis with topical agents derived from natural products.

2. Objectives of the Study

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

To determine the efficacy, adverse effects and tolerability of Dr Michaels topical product family when used alone.

3. SUBJECTS AND METHODS

3.1 Subjects

The clinical records for 392 subjects consisting of 205 males and 187 females were considered for the main part of the study, the observations being subjected to statistical analysis. In addition, a further group of 16 subjects taking anti-inflammatory agents for the management of psoriatic arthritis (PsA) were considered for other assessments of the therapy. Also studied were a group of 12 females on hormone replacement therapy. To study the effects of tobacco smoking, a group of 42 male smokers and 36 female smokers were observed after receiving treatment for their psoriatic condition.

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3.2 Characteristics of the Tested Products

Triphasic application: Successive use of Dr Michaels Cleansing Gel, Scalp & Body Ointment and Skin Conditioner

3.2.A: Dr Michaels Scalp and Body Cleansing Gel (tar)

Loose, brown-opaque, easily applicable topical preparation

Effect: Decreases parakeratosis

Application: Applied before the use of the ointment.

- **Scalp: Wet scalp and apply a small amount of cleansing gel. Massage thoroughly and leave for 2-3 minutes. Wash off with lukewarm water. (Can be applied to forehead but avoide cheek area).**
- **Body: Wet body. Apply small amount of cleansing gel to the psoriatic plaques. Leave for 2-3 minutes then rinse off with lukewarm water.**
- **Ingredients: Water, coal tar solution, sodium lauryl sulphate, coco amido dipropyl betaine, TEA lauryl sulphate, triethanolamine,salicylic acid,cocamide DEA,carbopol, citric & glycolic acids,tetrasodium EDTA, methylchloroisothiazolinone &methylisothiazolinone**
- **Package: 200ml plastic bottles.**

3.2.B: Dr Michaels Scalp and Body Cleansing Gel (NO tar)

Loose, white-opaque, easily applicable topical preparation

Effect: Decreases parakeratosis

Application: Applied before the use of the ointment.

- **Scalp: Wet scalp and apply a small amount of cleansing gel. Massage thoroughly and leave for 2-3 minutes. Wash off with lukewarm water. (Can be applied to forehead and also cheek area).**
- **Body: Wet body. Apply small amount of cleansing gel to the psoriatic plaques. Leave for 2-3 minutes then rinse off with lukewarm water.**
- **Ingredients: Water, ethanol, sodium lauryl sulphate, coco amido dipropyl betaine, TEA lauryl sulphate, triethanolamine,salicylic acid,cocamide DEA,carbopol, citric & glycolic acids,tetrasodium EDTA, methylchloroisothiazolinone &methylisothiazolinone.**

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- **Package: 200ml plastic bottles.**

3.2.C: Dr Michaels Scalp and Body Ointment.

Yellowish-white ointment with characteristic scent.

Effect: Decreases inflammation and infiltration.

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

Ingredients: Paraffinum liquidum, Paraffinum solidum, solanum tuberosum, Zinc oxide (C.I. 77947) Salicylic acid, Prunus amygdalus dulcis oil, Simmondsia chinensis oil, Persea gratissima oil, Daucus carota oil, Calendula officinalis extract, Citrus sinensis oil, Triticum vulgare germ oil, Prunus armeniaca kernel oil, Lavendula augustifolia, Santalum album oil, Pogostemon cablin oil, Pelargonium graveolens, Rosemary officinalis extract, Dromiceius oil, Citrus aurantium SSP bergamia oil, Pinus sylvestris leaf oil, Chamomilla recutita oil, Commiphora myrrha oil, Citrus aurantium amara flower oil

- **Package: 50g or 200g plastic vials.**

3.2.C: Dr Michaels Skin Conditioner.

White coloured, viscous substance with characteristic scent.

Effect: Prevent the loss of flexibility and elasticity in the skin.

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, left on over night and then washed off in the morning using the cleansing gel.

Ingredients: Olive oil, sesame seed oil, emu oil, lavender oil, eucalyptus oil, natural vitamin E.

Packaging: 50ml or 200ml plastic bottles.

IT IS RECOMMENDED TO APPLY THE THREE-COMPONENT PRODUCT FAMILY TWICE DAILY, IN THE MORNING AND AT NIGHT.

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4. PATIENT EVALUATION

4.1 Inclusion criteria

- **Mild to severe 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, cyclosporine, methotrexate, light therapy currently or within the past 3 months.**
- **Topical anti-psoriatic therapy.**
- **Pregnancy, breast feeding.**
- **Known hypersensitivity to any of the components of the products.**
- **Lack of informed consent.**
- **Low compliance.**

5. STUDY PROTOCOL

5.1 Time frame

- **Two week wash out period -Two weeks prior to beginning the treatment with Dr Michaels product family, the patients used only emollients.**
- **Application time of Dr Michaels products was 8 weeks.**
- **Total study length was 10 weeks.**
- **Application frequency was twice a day.**
- **Evaluation Points: -2,0,1,2,3,4,5,6,7& 8 weeks**
- **Total number of medical evaluations: 10**
- **Patients in study: 345**
- **Type of psoriasis determined –plaque, mild to moderately severe.**

5.2 Evaluation of Efficacy

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

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

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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

5.3 Evaluation of the Results

- **Cosmetic Effects – tolerability were evaluated at the end of the study based on the statements of the patients.**

- **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 percentage change of the PASI scores.**

- **The patients stated if they would continue the use of the Dr Michaels product family.**

6. SUMMARY EVALUATION

6.1 Data of the Study

- **Start date: 23/08/1999**
- **End date: 01/11/1999**
- **Patients included = 392**
- **Patients excluded = 47**
- **Patients completed & evaluated = 345**

6.2 Patient Characteristics

- **Mean age: 42.3(18-68)**
- **Mean duration of Psoriasis: 21.6 years.**
- **Gender distribution:**
  - **male = 177**
  - **female = 168**
- **Psoriasis type:- mild to moderately severe plaque.**

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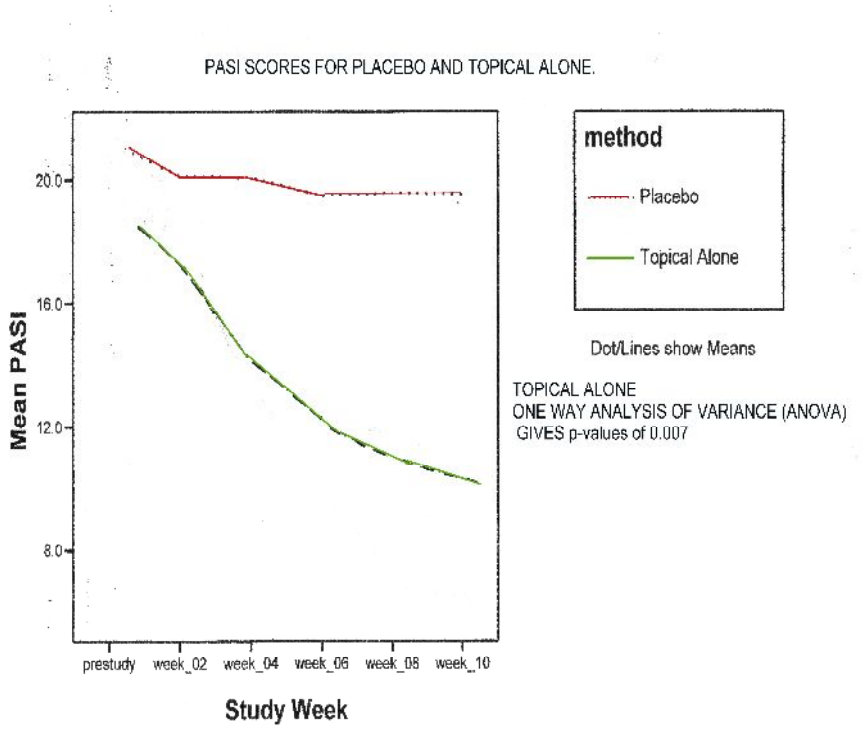
6.3 Evaluation of Improvement

- **Worsened** **0 patients**
- **Not improved** **9 patients**
- **Moderate improvement** **36 patients**
- **Good improvement** **44 patients**
- **Outstanding improvement** **256 patients**

Total **345 Patients**

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 decrease 76-100%**



SUMMARIZED CHANGE OF PASI SCORE IN ABSOLUTE VALUES
Number of patients- 345:

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6.4 Side Effects from Treatment

Patients were monitored for side effects on weeks 1,2,3,4,5,6,7 and 8. Recorded side effects were:

- **Folliculitis of lower extremities**
- **Pruritus of the scalp, upper torso.**

Folliculitis occurrence: 16 males; 19 females (total 35)
Pruritis occurrence: 3 female; 4 male (total 7)

6.5 Cosmetic Effect Evaluated by Patients

- **Good** — **280 patients**
- **Indifferent** — **65 patients**

6.6 Subject Evaluation of Efficacy

BY PATIENTS

- **Ineffective** — **12 patients**
- **Moderate improvement** — **47 patients**
- **Good improvement** — **55 patients**
- **Outstanding improvement** — **241 patients**

TOTAL 345 PATIENTS

BY PHYSICIAN

- **Ineffective** — **9 patients**
- **Moderate improvement** — **36 patients**
- **Good improvement** — **44 patients**
- **Outstanding improvement** — **256 patients**

TOTAL 345 PATIENTS

6.7 Patients Statement Regarding Future Use of the Product Family.

- **Patients who would not continue use = 18**
- **Patients who would continue use = 327**

7. SUMMARY

The study was completed in 345 patients out of the originally selected 392. Forty seven patients dropped out due to lack of compliance, pregnancy and the retraction of informed consent.

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Only patients with mild to moderately severe psoriasis without complications were studied.

No patient worsened. The treatment proved ineffective for 9 patients (2.6%) out of 345.

Thirty-six patients (12%) had moderate improvement with 26-50% of skin lesions cleared up.

Forty-four patients (13.0%) had good improvement with 51-75% of skin lesions cleared up.

Two hundred and fifty-six patients (72.1%) experienced outstanding improvement with 76-100% of the skin lesions cleared up.

35 patients developed folliculitis as a side effect. The folliculitis was clearly related to the products. This was evident on the plaques located on the lower extremities. In 30 cases the folliculitis regressed upon discontinuation of the application of the products without further treatment. The other five patients cleared up with topical therapy.

Seven patients developed pruritis of the scalp, upper torso and lowere extremities. This 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 side effects in this study, some 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 patient seek the advice of a dermatologist before starting the application. In case of noticing side effects the patient should consult a dermatologist.

The Cosmetic effect was evaluated as good by 280 patients and indifferent by 65 patients.

The evaluation of the treatment by the patients differs marginally from that of the physician. 12 patients described the treatment as "ineffective" compared to 9 by the physician. 47 patients considered the improvement as "moderate" compared to 36 by the physician. 55 patients described the improvement as "good" compared to 44 by the physician, while 241 patients listed "outstanding" improvement compared to 256 by the physician.

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In many patients, "outstanding" improvement would have only been described for total resolution of the lesions.

18 patients stated that they would not continue to use the treatment, with 12 patients coming from the ineffective group and 6 coming from the moderate group. 327 patients stated that they would continue to use the products. They argued that they were less concerned about the possible side effects as the product was a cosmetic and not a medicine.

As the product family consists of three differed components, it is important that the packing insert to be clear and easy to understand. The directions for application should also be easy to understand 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.

Frankston, Australia, December 1999

Dr. Michael Tirant
Lead Investigator

Dr. Thomas Smith
Independent Physician

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