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Research Article

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Epifibroin Powder 0039 for the Treatment of Seborrhoeic Dermatitis

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Abstract

Background: *Seborrhoeic dermatitis is a chronic inflammatory skin disease with a high recurrence rate. This skin disease is usually treated topically with either antimycotics or corticosteroids, which temporarily lead to an improvement. In all known options discontinuation of the treatment leads to recurrence of the symptoms. For other chronic inflammatory dermatoses a silk-fibroin with AEM5772 / 5 antimicrobial has shown positive effects.*

Objective: *In a pilot study the therapeutic impact of a powder consisting of this fibroin (Epifibroin Powder 0039) on seborrheic skin lesions was compared with the effect of topical antimycotics and corticosteroids.*

Materials and Methods: *20 patients with recurrent chronic seborrhoeic dermatitis applied Epifibroin Powder 0039, methylprednisolone 0.1% cream and ketoconazole 2% cream in scalp/ facial region for 1 week each. Therapy- free breaks were mandatory between the individual cycles. Standardized photo documentation was performed before and after each treatment period.*

Subject satisfaction was assessed on the basis of a questionnaire with regard to all three therapy options, treatment outcome was classified into 3 categories of improvement: moderate, mild, and no improvement.

Results: *Evaluation of the results showed that all three treatment options including Epifibroin Powder 0039 lead to comparable results. None of these options achieved sustainable clearance of the lesions.*

Discussion: *In summary Epifibroin Powder 0039 had about the same efficacy as methylprednisolone 1% cream and ketoconazole 2% cream in the treatment of SD without statistical significance. However, Epifibroin Powder 0039 could be of great benefit for the treatment of SD. Unlike corticosteroids or antimycotics, Epifibroin Powder 0039 has no known side effects. This is the first clinical trial on the safety and effectiveness of Epifibroin Powder 0039 for the treatment of seborrheic dermatitis.*

Introduction

Seborrheic dermatitis (SD) is a common recurring skin condition located in centrofacial, scalp, and presternal areas. It is evident that the skin microbiota play an important role in the pathogenesis of SD, distinctive attention should be payed to malassezia species, commensal yeasts adherent to the skin [1].

According to the literature the gut-skin axis of the microbiota may be violated by lifestyle habits like smoking, alcohol intake, and a lack of vitamin B [2].

Last but not least distress is triggering the production of renal cortex stereoids thus increasing sebum production maintaining an ideal environment for malassezia [3].

SD is a skin condition of minor illness value but of severe impact on the quality of life in aesthetical terms. A standard treatment algorithm does not exist. Empirically topical corticosteroids promptly resolve the inflammation but rapid recurrence follows cessation of the treatment. Good response to antifungal topicals is well documented, but after discontinuation of the treatment recurrence occurs within days. Antifungal systemic treatment has shown good therapeutic effects in severe cases. Also systemic treatment with biotin is an option for the treatment of SD as it has shown positive results in skin conditions with a high rate of seborrhea [4]. A wide variety of topicals have been used in SD, such as zinkpyritione, herbal formuations containing e.g. fenugreek leaf extract or other non-pharmacological preparations like bacterial-wall-derived glycoprotein, glycyrretinic acid, piroctone olamine and climbazole [5-7].

There are some reports in the literature proving that the use of a special silk fabric (Dermasilk®) has the ability of reducing general symptoms of chronic inflammatory skin diseases. The fabric is made of an insoluble scleroprotein containing glycine, alanine, and serine with an antimicrobial agent AEM5772/5 trough silanisation [8].

Females suffering from genital lichen sclerosus wearing Dermasilk® underwear experienced a reduction of disturbing symptoms [9]. In children with atopic dermatitis Dermasilk® underwear led to reduction of itching and distress [10]. It is stated that the use of Dermasilk® products resulted in lowering the need for topical corticosteroids in the treatment of atopic children [11]. In diabetic ulcers the use of Dermasilk® stockings were also quoted positively as the size of the ulcerations was reduced in this study [12]. In a controlled study design vulvovaginal candidosis in females Dermasilk® underwear showed on a better outcome compared to the use of underwear made of plain cotton [13].

As the use of this special silk fabric (Dermasilk®) in various chronic inflammatory skin diseases mentioned above has shown positive results, we designed a clinical setting for its use in patients with acne vulgaris papulopustulosa on the back and were able to show clearing of acne lesions after six weeks of wearing Dermasilk T-shirts every night without any concomitant medical treatment [14]. The fact that fibroin enhances collagen synthesis and reduces inflammatory processes may give a possible explanation for its positive effect [15].

Searching for new indications for the positive effect of this antimicrobial silk product this pilot study for the treatment of SD was developed.

Material and Methods

For the use in facial areas the silk-fibroin with antimicrobial AEM5772/5 was modified to microscopically small particles resulting in a powder with antimicrobial abilities.

To prove the effect of this powder for the treatment of SD a clinical pilot-study was designed and permitted by the local ethics committee.

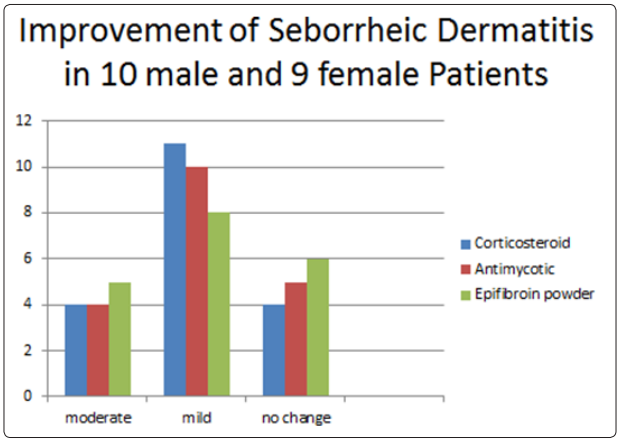
Twenty volunteers with recurring seborrheic dermatitis in face and scalp areas were recruited (9 females, 11 male, age range from 26 to 79 years, median 54,3). No treatment was allowed for consecutive 14 days before study start. All patients applied Epifibroin Powder 0039 twice daily for 7 days using their fingers rubbing it in without washing the face before application. Thus, because Epifibroin Powder is highly lipophilic and highly hydrophobic and evolves its antimicrobial abilities on oily skin better than on a degreased clean skin. After 7 days they stopped this treatment followed by a treatment pause for 7 days. Then an antifungal topical (ketoconazole 2% cream) had to be applied for 7 days twice daily, followed by a pause of 7 days. Finally, a mild topical corticosteroid (methylprednisolone 1% cream) had to be used once daily for 7 days. Photographic documentation was performed before study start and at the end of all treatment phases. All patients had to document the effect of the treatments, the outcome, and the recurrence of the seborrheic lesions in a specifically designed diary.

Results

One male participant was lost to follow up, 19 patients finished the study. In the corticosteroid group 4 patients reported moderate decrease of the seborrheic lesions, 11 felt mild improvement and 4 had no change. In the antifungal group 4 reported moderate, 10 mild, and 5 no improvement. Lastly in the Epifibroin Powder 0039 group 5 reported moderate, 8 mild, and 6 no improvement. (Tab. 1, Fig. 1 a+b, Fig. 2 a+b)

There was no statistical significance to these results.
Recurrence occurred in all three groups within one to six days (median values:
3.5 days in the corticosteroid group, 3.2 days in the antimycotic group, and 3.6 days in the Epifibroin Powder 0039 group).

Table 1: Outcome after one week of topical treatment each: Corticosteroid, Antimycotic, and Epifibroin Powder 0039:



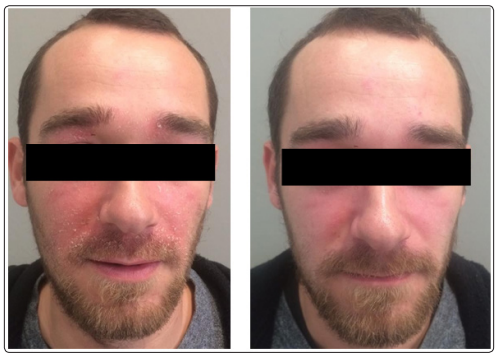


Figure1 a+b: Facial seborrheic dermatitis before and after 7 days topical application of Epifibroin Powder 0039

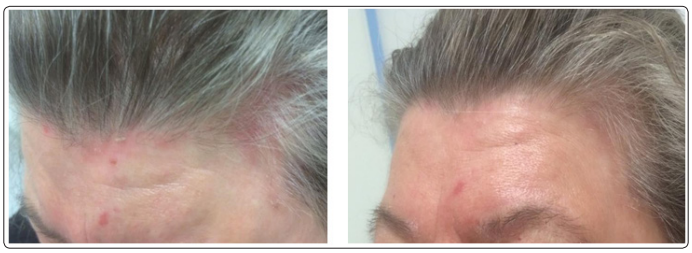


Figure 2 a+b: frontal hairline seborrheic dermatitis before and after 7 days topical application of Epifibroin Powder 0039.

Discussion

For its disturbing skin redness, scaling, and its unpredictable recurrence SD is causing severe impact on the quality of life in aesthetical terms.

A standard algorithm for sustainable clearence of SD does not exist. Among a vast variety of treatment options topical steroids and antimycotics are most commonly prescribed ones. Frequent use of topical steroids may have side effects like skin atrophy, development of teleangiectasias or even diabetes mellitus [16,17]. Topical antimycotics have lesser side effects but they are not available over the counter (OTC) in several countries [18]. Therefore the search for new treatment modalities being accessible more easily is going on.

The fact that fibroin enhances collagen synthesis and reduces inflammatory processes may give a possible explanation for its positive effect., referring to Sugihara et al [15]. and thus giving a possible explanation of the positive effects as a combination of the anti-microbial effect of AEM5772/5 together with the positive effects of fibroin.

In this pilot study introducing Epifibroin Powder 0039 for the treatment of SD it has shown about the same efficacy as methylprednisolone 1% cream and ketoconazole 2% cream without statistical significance. Unlike corticosteroids or antimycotics, epifibroin powder 0039 has the features to become in the future a cosmeceutical available over the counter (OTC). As it has no known side effects it could be of great benefit for the treatment of SD applied over longer periods maintaining SD clearance.

This is the first clinical trial on the safety and and effectiveness of Epifibroin Powder 0039 in the treatment of seborrheic dermatitis in facial/scalp areas.

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