

Antimicrobial Silk Clothing in the Treatment of Atopic Dermatitis Proves Comparable to Topical Corticosteroid Treatment

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Key Words

Atopic dermatitis • Silk fabric • Antimicrobial treatment

Abstract

Background: Atopic dermatitis (AD) is aggravated by mechanical irritation and bacterial colonization. **Objective:** This study compared the efficacy of an antimicrobial silk fabric (DermaSilk®) with that of a topical corticosteroid in the treatment of AD. **Methods:** Fifteen children were enrolled and wore a dress, where the left side was made of DermaSilk and the right side was made of cotton. The right arm and leg were treated daily with the corticosteroid mometasone for 7 days. The treatment efficacy was measured with a modified EASI (Eczema Area and Severity Index) and with an assessment by the patients/parents and by a physician. All patients were evaluated at baseline, as well as 7 and 21 days after the initial examination. **Results:** All parameters showed that, irrespective of the treatment, there was a significant decrease of eczema after 7 days. No significant difference between DermaSilk-treated and corticosteroid-treated skin could be observed. **Conclusion:** DermaSilk showed potential to become an effective treatment of AD.

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by severe pruritus and a relapsing course. Today, it affects 10–20% of children and its prevalence is increasing [1]. AD is often associated with elevated serum IgE levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Standard care includes topical corticosteroids and more recently also calcineurin inhibitors (tacrolimus and pimecrolimus), although long-term safety data do not yet exist. While topical corticosteroids are effective in the treatment of AD, chronic use is limited by the cutaneous and non-cutaneous side effects. Although side effects are currently reduced with more lipophilic topical corticosteroids, there is a near phobia against corticosteroids among AD patients, especially parents of affected children.

The skin of patients with AD is often colonized with *Staphylococcus aureus* and the quantity of *S. aureus* correlates with eczema severity [2–7]. Consequently, several studies demonstrated that reduction of *S. aureus* either by antibiotics, antiseptics or by anti-inflammatory treatment (e.g. steroids or tacrolimus) leads to clinical im-

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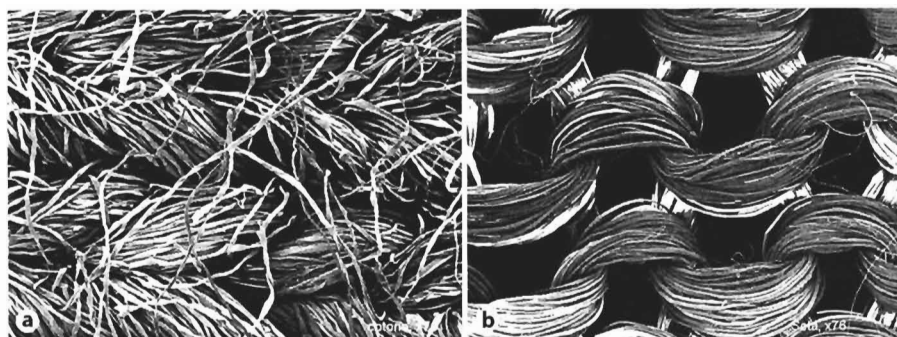
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Fig. 1. Structure of cotton versus silk. **a** Cotton fibres are partially irregular and short, so that endings produce stubs in the fabric. **b** Silk fibres are regular, rounded and very long. The fabric, therefore, shows no stubby endings and feels smooth ('silky').



provement of AD [4, 8–11]. Another trigger factor of AD is physical irritation, e.g. by harsh textile fibres. Direct contact with wool produces a characteristic itching in patients with AD that is probably caused by the prickly nature of wool fibres [12–14]. Also, the surface structure and diameter of synthetic fibres has a significant influence on how the respective fabrics are tolerated by patients [15]. Finally, a study demonstrating that treatment of cotton with fabric softeners exerted a beneficial effect on AD [16] attests to the aggravating role of mechanical irritation through harsh fabric fibres in AD. While cotton appears to be smoother and better tolerated than wool or synthetics [15], cotton threads consist of short and irregular fibres with a length of 1–3 cm that produce microscopic stubs (fig. 1). In contrast, silk threads consist of filaments that are several hundred meters long and have a regular and rounded shape (fig. 1). From this point of view, silk should produce very little friction against the skin.

With the aim to reduce mechanical friction by rough fibres as well as colonization with *S. aureus*, silk fabrics with antibacterial coatings may be used for skin care of children with AD. Such a commercially available fabric (DermaSilk®) has antibacterial properties thanks to treatment with AEGIS AEM 5772/5, a covalently linked water-resistant antimicrobial finish for textiles based on the compound alkoxy silane quaternary ammonium [17]. In a recent trial, patients wearing DermaSilk showed significant clinical improvement of AD when compared to patients wearing cotton clothes [5, 18]. The aim of our study was to compare the effectiveness of DermaSilk with that of standard care consisting of the application of a modern topical corticosteroid and the wearing of cotton clothes in children suffering from moderate AD. We also attempted to eliminate interindividual variability and to minimize a potential placebo effect by an intra-individual left versus right comparison.

Methods

Subjects

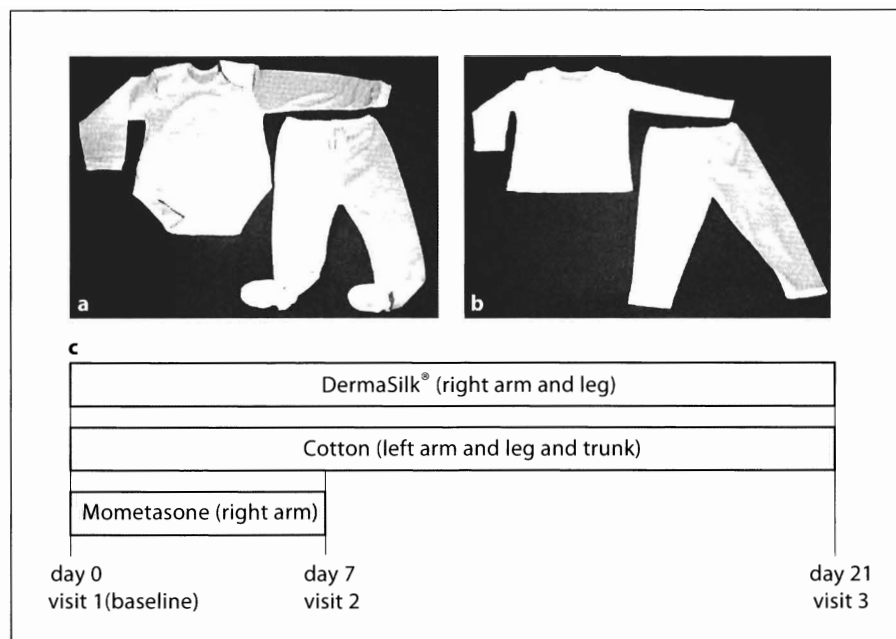
We enrolled 6 male and 8 female children aged between 0.6 and 9.2 years (mean 3.0 ± 2.2 years) by advertising in a local newspaper and in collaboration with a patient organization (aha: Allergie, Haut, Asthma, i.e., allergy, skin and asthma). Parents had to give signed informed consent and the child had to give oral consent, if possible. The study was performed in the Allergy Unit of the Department of Dermatology of the University Hospital Zurich and was approved by the local ethics committee and Swissmedic. The children were diagnosed with moderate AD in accordance with the criteria of Hanifin and Rajjka [19]. The wash-out phases for current treatment were 1 week for topical corticosteroids or antibiotics on the body areas treated with silk, 2 weeks for systemic corticosteroids or antibiotics, 1 week for topical antimycotics, 4 weeks for topical calcineurin inhibitors, and 8 weeks for systemic immunosuppressants other than corticosteroids, investigational agents, UV light therapy or systemic antimycotics. Children suffering from acute infections, neurological or psychiatric disorders, auto-immune diseases, and immune defects were excluded.

The tailored whole-body romper suits or long-sleeved T-shirts and panty hoses used in this study were produced by AL.PRE.TEC. (Venice, Italy). The left arms and legs of these clothes were made of DermaSilk, whereas the right arms and legs as well as the part covering the torso were made of cotton (fig. 2).

Study Plan

The participants of the study were given two sets of clothes. Parents were informed of the special characteristics of the fabric and were asked to dress their children with these clothes all day long. The dress was changed daily and washed. The right arms and legs, which were covered by cotton, received 7 days of additional daily treatment with the class III topical corticosteroid mometasone 17-furoate 0.1% (Elocom Creme® from Essex, Switzerland), whereas the left arms and legs covered with the silk fabric received no other treatment (fig. 2). The whole body, however, was treated with a topical nonmedicated emollient (Excipial Fettcreme® from Spirig Pharmaceuticals, Switzerland), which is a lipophilic and hydrating emulsion for the care of extremely dry skin. It contains the preservatives triclosan and chlorhexidin dihydrochloride, at concentrations, which are not sufficient to affect the burden of *S. aureus*. Patients returned to the clinic for a first follow-up visit on day 7 (visit 2) and then for another follow-up on day 21 (visit 3). At

Fig. 2. Clothes tailored for intra-individual left versus right comparison. Smaller children wore a romper and panty hose (a), while older children wore a combination of a T-shirt and panty hose (b). The left arm and leg were made of DermaSilk. The right arm and leg as well as the part covering the torso were made of cotton. **c** Patients had to wear their suit day and night for 21 days. During the first week of the study, the left arm and leg were additionally treated with Elocom Creme containing 0.1% mometasone 17-furoate, a class III topical corticosteroid. The left arm and leg received no further medical treatment other than an emollient.



all visits, four clinical parameters were evaluated: (1) the EASI (Eczema Area and Severity Index) modified for the evaluation of left or right arms and legs, respectively, (2) patient/parent assessment of pruritus, measured with a visual analogue scale of 10 cm, (3) patient/parent assessment of overall improvement measured on a 7-step scale ranging from 'much better' to 'much worse', and (4) physician's global assessment that was measured on a 7-step scale ranging from 'worsening' to 'complete clearance'.

Statistical Analysis

Parametric data were evaluated using the Student t test for independent and paired data. Non-parametric data were compared using the Mann-Whitney U test for independent data and the Wilcoxon signed rank test for dependent data. The significance level was set at 5%.

Results

Patient Enrolment

The targeted 30 patients could not be recruited, as many parents were reluctant to have their child participate in this study due to the involvement of a topical corticosteroid. Thus, the enrolment was stopped after the inclusion of 15 patients. Two of the 15 patients stopped the study prematurely. Of these, one patient stopped after 4 days due to an exacerbation of the eczema in both treated and untreated body regions. This patient was excluded from the analysis of efficacy. The other patient was lost to follow-up. Thus, patient numbers for efficacy analysis were 14 at baseline and visit 2, and 13 at visit 3.

Evaluation of AD at Baseline

Prior to the start of the treatment, pruritus was assessed by the patient/parent on a visual analogue scale of 10 cm. Baseline mean pruritus was 4.2 ± 2.6 . The median EASI for the left side was 3.7 and 2.8 for the right side. No significant left-right difference was found at baseline. The median EASI was 0.9 for both the head and neck and for the trunk, which, therefore, were much less affected by pruritus than the limbs.

Course of Disease during the Study

No differences in the EASI between the left and the right side were found at any time point during the study (fig. 3). The median EASI for both the DermaSilk-treated ($p < 0.05$) and the corticosteroid-treated side ($p < 0.01$) decreased very strongly between baseline and visit 3 (after 21 days), although it slightly increased again for both sides between visit 2 (after 7 days) and visit 3 (DermaSilk: $p < 0.05$; corticosteroid: $p < 0.01$). Interestingly, also the EASI of non-treated body parts such as head and neck ($p < 0.05$) as well as the torso ($p < 0.01$) decreased significantly between baseline and visit 3 (fig. 3). The EASI for head, neck and torso was already rather low at baseline. Hence, the decrease was moderate in comparison with the decrease of the EASI for the limbs. In order to visualize the overall pattern of changes in pruritus severity, the EASI was also analyzed for each individual patient (fig. 4). The EASI of both the right and the left side de-

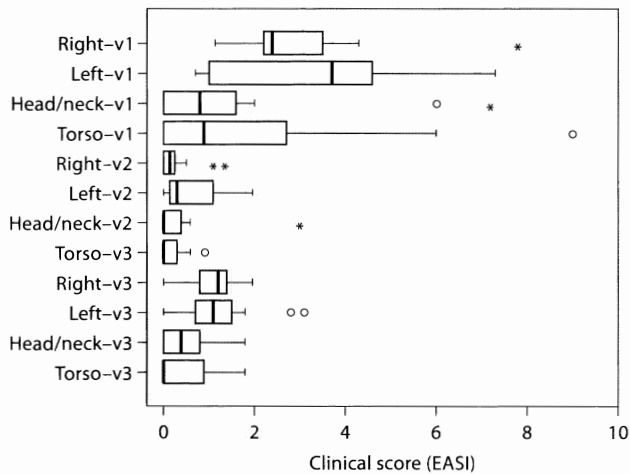


Fig. 3. Clinical course of AD: EASI of all body parts at different time points. EASI for the left side, the right side, head and neck and the torso at baseline (v1), visit 2 (v2), and visit 3 (v3). For both the right and the left side, there is a decrease between baseline and visit 2 ($p < 0.01$), as well as an increase between visit 2 and visit 3 (left $p < 0.05$, right $p < 0.01$). The overall decrease between baseline and visit 3 is also significant for both sides (left $p < 0.05$, right $p < 0.01$). The EASI of head and neck decreased between baseline and visit 2 ($0.1 > p > 0.05$), and between visit 1 and visit 3 ($p < 0.05$). The EASI of the torso decreased between baseline and visit 2 ($p < 0.01$) and between baseline and visit 3 ($p < 0.01$). The box plots illustrate the 25th and the 75th percentile with the median line, while the whiskers show the extreme values. Symbols illustrate outliers being 1.5–3 times (○) or more than 3 times (*) the box length away from the box edge.

creased for all patients between baseline and visit 2, after which the EASI of both sides increased again for all but 3 patients. The EASI of head and neck as well as the torso either stayed the same or decreased between baseline and visit 2, but later increased for head and neck in 5 patients and for the torso in 3 patients (fig. 4).

Similarly, global evaluation of efficacy by the patients/parents showed no significant difference between the left and the right side, neither at the second visit on day 7, nor at the third visit on day 21 (table 1). The ratings from the global evaluation was significantly worse at visit 3 compared to visit 2 for both sides. Furthermore, the severity of pruritus, as evaluated by the patient/parent on a visual analogue scale, decreased by 2.7 between baseline and visit 2 ($p < 0.01$, Wilcoxon signed rank test), and increased again by 1.1 between visit 2 and visit 3 ($p < 0.05$). The overall decrease in severity between baseline and visit 3 was not significant.

Table 1. Global evaluation of the treatment efficacy by patient/parent

Evaluation	Left: arm and leg		Right: arm and leg	
	visit 2	visit 3	visit 2	visit 3
Much better	10	2	11	1
Better	3	5	3	4
Moderately better		2		5
Unchanged		2		1
Moderately worse	1	1		1
Worse				1
Much worse		1		

Left-right comparison: $p = 0.605$ (visit 2); $p = 0.672$ (visit 3). Visit 2-visit 3 comparison: $p = 0.003$ (right side); $p = 0.011$ (left side).

Table 2. Global evaluation of the treatment efficacy by the investigator

Efficacy %	Visit 2/visit 3			
	left		right	
	arm	leg	arm	leg
100	4/2	3/1	6/1	4/1
90–99	6/1	5/3	7/0	8/2
75–89	2/4	4/2	1/6	2/5
50–74	2/2	1/3	0/1	0/2
30–49	0/1	1/2	0/2	0/1
0–29	0/1		0/1	0/1
Worsening	0/2	0/2	0/2	0/1

Left-right comparison: $p = 0.196$ (arm/visit 2); $p = 0.169$ (leg/visit 2); $p = 0.671$ (arm/visit 3); $p = 0.754$ (leg/visit 2). Visit 2-visit 3 comparison: $p = 0.027$ (left arm); $p = 0.058$ (left leg); $p = 0.003$ (right arm); $p = 0.011$ (right leg).

The global evaluation of efficacy by the physician showed no significant difference between the left and the right side on either of the two follow-up visits (table 2). At day 7, the median global evaluation by the investigator was 90–99% ('excellent') improvement for both arms and legs on either side. At day 21, the median global evaluation by the physician was 75–89% ('marked') improvement for the corticosteroid-treated arm and leg as well as for the DermaSilk-treated arm and 50–74% ('moderate') improvement for the DermaSilk-treated leg.

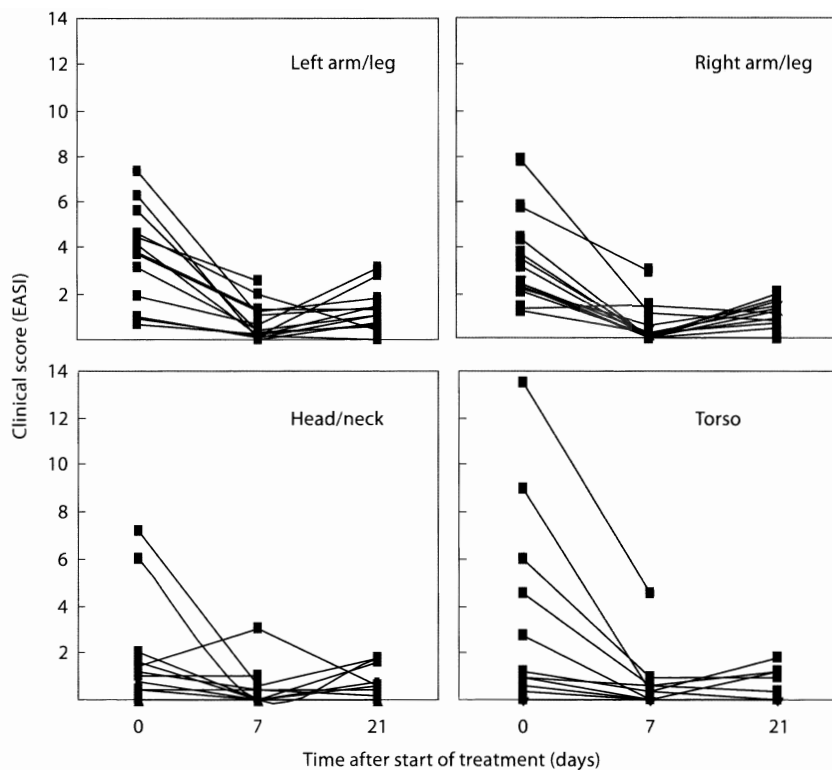


Fig. 4. Clinical course of AD: EASI for all 14 patients. EASI of the right and the left side, as well as of head and neck and the torso at baseline (day 0) and the two follow-up visits (day 7 and day 21).

Compliance

The compliance for both wearing DermaSilk and applying mometasone was high. Throughout the study 12 out of 14 patients reported to have worn DermaSilk 100% of the time and the remaining 2 patients wore it more than 75% of the time. Thirteen out of 14 patients used mometasone daily during the first 7 days, and 1 patient applied it more than half of the treatment period.

Adverse Events

Only one adverse event was recorded. One patient developed general exacerbation of eczema in treated and non-treated areas within 4 days of beginning study treatment.

Discussion

The standard care of AD usually comprises treatment with topical corticosteroids. Although such treatment is effective and side effects have been reduced with the modern more lipophilic products, corticosteroids are generally poorly accepted among AD patients, especially

parents of affected children. Therefore, the development of new textiles that prevent bacterial colonization with *S. aureus*, a trigger factor in AD, represents a promising path in the treatment of AD, as it might become a well-accepted therapeutic alternative to steroid treatment. A study by Gauger et al. [20] demonstrated that silver-coated textiles could significantly reduce colonization with *S. aureus*, which correlated with clinical improvement of AD. Similarly, patients wearing an antimicrobial silk dress of DermaSilk showed decreased eczema as compared to patients wearing cotton clothes [18]. We confirm and extend these latter findings by demonstrating that DermaSilk is not only superior to cotton, but even comparable in clinical effectiveness to treatment with a topical corticosteroid. Mometasone was administered daily for the 7 first days of the 3-week study, thus representing a usual intermittent corticosteroid treatment regimen. As expected, eczematous lesions on the treated right arms and legs cleared significantly within this treatment period. Quite surprisingly, however, the left-right inpatient comparison showed that lesions on the left arms and legs that were treated with DermaSilk cleared equally well. Seven days into the study, the treatment of the right

arm and leg with mometasone was stopped, which caused a minor relapse of the eczema by the follow-up visit on day 21. However, eczema had also slightly increased on the left arm and leg, despite continuous treatment with DermaSilk and good compliance. We speculate that parents may have neglected skin care with emollients towards the end of the study.

Interestingly, untreated body parts such as head, neck or trunk also improved. This may also be explained by excellent skin care with emollients at the beginning of the study, where parents and patients were optimally motivated. However, it must be noted that the improvement of the untreated body parts was on a much smaller scale. The mechanism of collateral healing [21], i.e. the fact that an improvement of eczema by a treatment in one region of the skin very often results in a parallel healing in other, untreated regions of the skin may also have contributed to the improvement of the untreated body regions. Another possible mechanism might have been that some of the topically applied mometasone was systemically absorbed and exerted a systemic effect. However, this is less likely, since mometasone enters the circulation only to a very small extent. On healthy skin in adults, merely 0.4% of the top-

ically applied mometasone is systemically absorbed [22], which is likely too little to produce a therapeutic effect. Furthermore, in another study that compared wet-wrap dressings with and without topical steroids, the result was much more beneficial for the steroid-treated body parts [23]. Finally, a certain placebo effect may have contributed to the general improvement of eczema in all areas of the body during the first week, and this placebo effect may have diminished towards the end of the study.

In conclusion, the present study demonstrates by a left-right inpatient comparison that a silk fabric with antimicrobial properties exerted clinical efficacy in the treatment of AD. This efficacy was comparable to that obtained by treating the patient with a modern class III topical corticosteroid and, thus, as good as the current standard care in AD. The fact that in our study DermaSilk-treated areas responded equally well as steroid-treated areas points out the efficacy of this coated textile as a therapeutic approach in AD. Hence, the treatment of AD with coated silk textiles might become a well-accepted therapeutic alternative to the treatment with corticosteroids, especially for children whose parents are reluctant to apply topical corticosteroids.

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