

A case report and critical appraisal of the literature on the use of DermaSilk® in children with atopic dermatitis

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Summary

Atopic dermatitis (AD) is easily aggravated by detergents, synthetic and woollen clothing, and bacterial colonization. Cotton clothing is often recommended for children with AD, but cotton can contain rough fibres that may act as skin irritants. In contrast, silk is characterized by smooth fibres with minimal potential for irritation. We report a sericin-free silk (DermaSilk®), which is treated with AEGIS AEM5772/5, a product that has antibacterial properties, and evaluate its use in the treatment of AD.

We report the use of a sericin-free silk in a child with severe atopic dermatitis (AD) and assess the literature to determine the effectiveness of this product in treating children with AD, compared with other forms of clothing such as cotton or with established pharmacological treatments such as topical corticoids.

Report

The patient was a 5-year-old boy with severe AD, who had no known allergies. He had been on a range of treatments since his first presentation to us, including emollients, topical corticoids, wet wraps, ichthopaste bandages, systemic antibiotics and ciclosporin. In addition, he had been hospitalized several times because of flares of his AD. Ten months before his latest presentation, his mother had obtained body suits made from a sericin-free silk impregnated with an antibacterial product, AEGIS AEM 5772/5 (MICROAIR DermaSilk®; AL.PRE.TEC., Venice, Italy) to augment the boy's treatment. The garments covered the child's trunk and limbs, and he wore them each day for the full day. Even though the child's AD was still not fully controlled, the

child's mother felt that the body suits provided additional benefit for the child's skin. When cotton body suits were worn instead of the silk suits, the boy's eczema seemed to flare more rapidly. For this reason and due to the fact that we had exhausted most other treatments, we supported the use of DermaSilk® in this particular child and reviewed the literature to determine its effectiveness.

We searched MEDLINE, EMBASE and the Cochrane Controlled Trials Register from 1966 to June 2008 using the terms 'AD' and 'eczema', 'DermaSilk®', 'silk', 'fabric', 'material', 'cotton' and 'cloth', and search terms for randomized controlled trials (RCTs). No systematic reviews of specialized clothing in AD were found. We identified two RCTs^{1,2} and used these to try to obtain objective results. The two studies were small and of relatively poor methodological quality. Two further studies,^{3,4} which were not randomized, were also identified and evaluated.

The first study was a left-right comparison in which treatment interventions were allocated randomly to each side.¹ In total, 22 children (mean age 8 years) with mild to moderate AD were enrolled into the 3-month trial. The study interventions were unusually complicated and the reasons for this were not clearly explained. Instead of simply comparing continuous use of DermaSilk® tubular bandages against cotton tubular bandages, the investigators compared continuous use of DermaSilk® tubular bandages on one arm of the child for 3 months against 2 weeks of sericin-free silk fabric

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without AEGIS AEM 5772/5 (i.e. without the antimicrobial properties of DermaSilk®) on the opposite arm of the child, followed by cotton bandages for the remaining 10 weeks. Antihistamines and emollients were the only concomitant medications allowed. Evaluations in the form of a modified Scoring Atopic Dermatitis (ScorAD) Index limited to the local area of skin (cubital area) took place at baseline and weeks 2, 4, 8 and 12. These were always performed by the same investigator, who was blinded to treatment allocation. The median intensity ScorAD in the DermaSilk® arm was 9 at baseline and 6 at week 12, compared with 9.5 and 8 in the simple silk and cotton covered arm. The 1.5-unit difference in change of score between these two groups was reported as being highly significant ($P < 0.01$) at 12 weeks. However, multiple significance tests were conducted and it was unclear what the primary outcome was intended to be. Differences in intensity score were not significant at 2 weeks (corresponding to the time period for comparing DermaSilk® vs. ordinary silk without the added antibacterial agent), yet the authors still claimed that the beneficial effect of DermaSilk® was partly due to the addition of the antibacterial agent. It was also unclear how many of the original 22 participants were included in the final analysis and what the clinical interpretation of a difference of 1.5 units on a subscale of ScorAD means for clinical practice.

The second study² comprised 16 children (mean age of 4 years); 12 with AD and 4 healthy, age-matched controls. The aim was to evaluate the effectiveness of the antimicrobial activity of DermaSilk® in children with AD. Each patient received two pairs of tubular arm covers clearly marked 'right' and 'left', made of DermaSilk®, but only one cover of each pair was treated with the AEGIS AEM 5572/5 with antimicrobial properties. The authors and parents did not know which one had been coated. These arm covers were worn continuously for 7 days and nights, and were changed and washed every day. The use of an emollient was allowed. Disease severity was measured by two investigators by means of a 'local ScorAD' protocol at baseline and after 7 days. Swabs were taken from the antecubital fossa of both affected children and controls for identification of *Staphylococcus aureus* and for culture on agar plates, aiming at identifying the total number of bacterial colonies, which was expressed as colony forming units (cfu) per centimetre square antecubital area. Microbiological evaluations took place at baseline, after 1 h and at 7 days. Two children with AD withdrew from the study and were not included in the data analysis. In the 10 affected children who completed the study, there was a reduction in the mean value of local ScorAD from 7.3

at baseline to 4.4 after 7 days ($P = 0.019$) in the area covered with the treated silk and from 7.1 to 5 ($P = 0.02$) in the area covered by untreated silk. This result was reported as being significant, although corrected analysis comparing the change in ScorAD scores between the two groups was not carried out. The reduction in the mean number of cfu/cm² was similar in both areas. In addition, there was no significant difference in the microbiological cultures positive for *S. aureus* in the affected children at baseline (42%) and at 7 days (30%) ($P = 0.05$ was considered significant). In the unaffected children, no microbiological culture was positive for *S. aureus* and the number of cfu/cm² remained similar to baseline. This trial was too small and too poorly reported to add to our understanding of the effects of DermaSilk® fabric in children with eczema. Given that the study was designed to explore the antimicrobial properties of AEGIS AEM 5572/5, it might also have been more relevant to have enrolled children with infected eczema into the study.

In the third trial,³ 46 children with AD (mean age 2 years) were included in a 7-day study. Participants were not randomized. They were divided into one of two groups: group A received DermaSilk® clothes ($n = 31$) and group B used cotton clothing ($n = 15$). Twice as many patients were enrolled in group A to compensate for a presumed higher level of noncompliance. The type of clothing issued varied according to the site of involvement for each child. The use of topical steroids and/or antibiotics was prohibited, although participants were allowed to use emollients. The investigator conducting the skin assessment was blinded to the treatment allocation throughout. All participants were assessed using the ScorAD index at baseline and at 7 days.⁵ The investigators reported a significant decrease in disease severity at 7 days compared with baseline for the DermaSilk® group (reduced from 43 to 30; $P < 0.01$). No such reduction was seen in the control group (mean score 47 at baseline and 46 at 7 days). However, the key comparison (i.e., difference in change of scores between the two groups) at 7 days was not reported, and there was no intention-to-treat analysis. Eight children (26%) in the active arm were excluded from the analysis because they did not wear the clothing in accordance with the instructions. It is unclear how to interpret these study findings, due to limitations in the trial reporting. The fourth study⁴ was a nonrandomized right-left comparison trial. Fifteen children with moderate AD with a mean age of 3 years were enrolled to compare the efficacy of DermaSilk® with that of a topical corticosteroid in the treatment of AD. All patients were given two sets of clothes, the left

side made of DermaSilk[®] and the right made of cotton. A topical nonmedicated emollient was used all over, whereas on the right side (cotton-covered) a class III topical corticosteroid was also applied for 7 days. Patients were evaluated at baseline and at 7 and 21 days. Clinical parameters used included: (i) a modified Eczema Area and Severity Index (EASI), (ii) patient/parent visual analogue scale (VAS) for itching, (iii) patient/parent assessment of overall improvement and (iv) Physician's Global Assessment. Data analysis showed no significant difference between the special silk and cotton dressed sides in any of the four parameters throughout the study. The authors concluded that DermaSilk[®] was clinically effective in the treatment of AD and its efficacy was comparable to that obtained by treating a patient with a class III topical corticosteroid. However, this was not designed as an equivalence study, and with just 15 participants, the study clearly has insufficient power to support this claim.

All four clinical trials were poorly reported, complicated in their design and involved very small numbers of patients, making them almost impossible to interpret. Despite the lack of good studies, it is still possible that these special silk fabrics have something to offer patients with AD. None of the studies identified any adverse effects and the garments appeared to be well tolerated

by the children. A good-quality, independent clinical trial is needed to answer the clinical questions of whether simple silk underclothing or tubular bandages offers any advantage over cotton clothing and whether the addition of an antibacterial agent (as contained in DermaSilk[®]) offers any further benefit compared with silk alone.

References

- 1 Koller DY, Halmerbauer G, Böck A, Engstler G. Action of a silk fabric treated with AEGIS[™] in children with atopic dermatitis: a 3 month trial. *Pediatr Allergy Immunol* 2007; **18**: 335–8.
- 2 Ricci G, Patrizi A, Mandrioli P *et al*. Evaluation of the antibacterial activity of a special silk textile in the treatment of atopic dermatitis. *Dermatology* 2006; **213**: 224–7.
- 3 Ricci G, Patrizi A, Bendandi B *et al*. Clinical effectiveness of a silk fabric in the treatment of atopic dermatitis. *Br J Dermatol* 2004; **150**: 127–31.
- 4 Senti G, Steinmann LS, Fischer B *et al*. Antimicrobial silk clothing in the treatment of atopic dermatitis proves comparable to topical corticosteroid treatment. *Dermatology* 2006; **213**: 228–33.
- 5 Severity Scoring of Atopic Dermatitis. The ScorAD index consensus report of the European task force on atopic dermatitis. *Dermatology* 1993; **186**: 23–31.