

Treatment with specially manufactured silk clothes (DermaSilk®) in children with atopic dermatitis

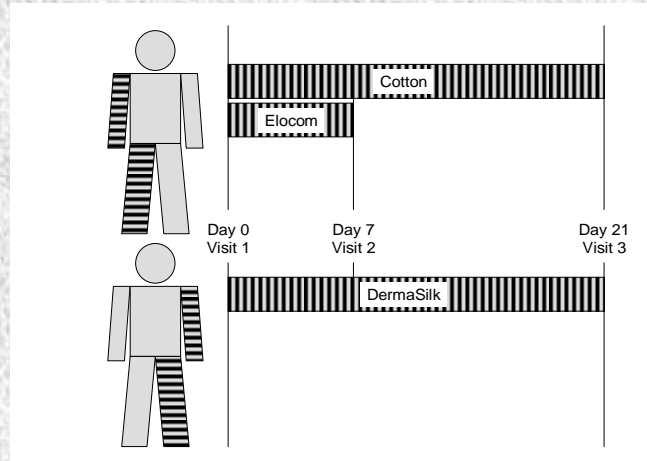
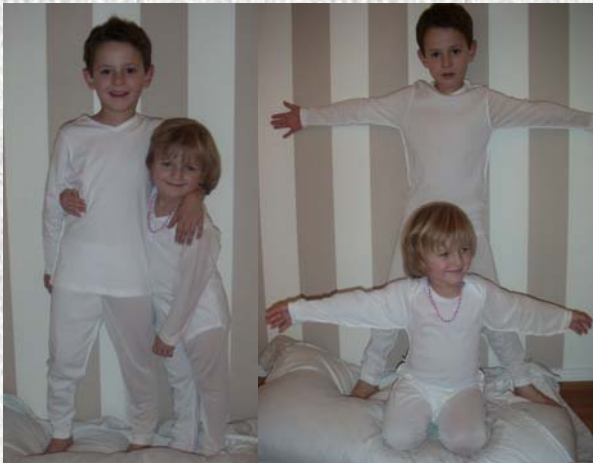


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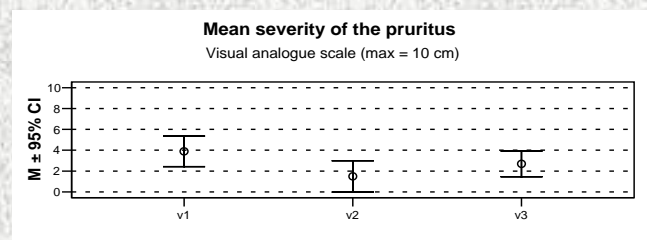
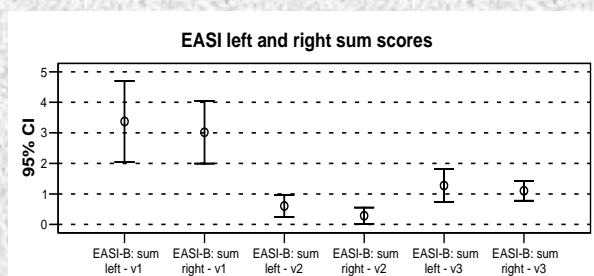


Methods:

The trial design was an open non-randomized study, with left-right intra-patient comparison. Fifteen children (age between 0.6 and 9.2 years) were included in the study. The study device was a silk fabric coated with AEGIS AEM 5772/5 (DermaSilk®) fashioned either as romper suit or as a T-shirt or pantyhose and worn over a period of 4 weeks (control side was composed of cotton). On the control side the class III corticosteroid momethason (Elocom Crème®) was applied once daily between baseline and visit 2 (7days). The Excipial Fatty Cream® was used as basis treatment throughout the study. For the side comparison (left-right) between DermaSilk® and the conventional corticosteroid therapy a modified EASI score was used. In addition, the overall severity of the disease was evaluated using a Visual Analogue Scale (VAS) for the pruritus. All patients were evaluated at baseline and 7 & 21 days after the initial examination.

Background:

In children with atopic dermatitis (AD), eczema is easily aggravated by contact with irritant factors (e.g. aggressive detergents, synthetic and woolen clothes). Also skin colonization with *Staphylococcus aureus* is known to play a major triggering role. The objectives of this phase I/II clinical trial was to evaluate the safety/tolerability and the effect of specially manufactured Silk clothes (DermaSilk®) in children with moderately severe AD compared to conventional topical corticosteroid therapy.



Results:

Both the left side treated with DermaSilk® and the right side treated with cotton and Elocom Crème® showed a significant reduction of the Eczema Area and Severity Index (EASI) after 7 days ($p < 0.01$). In correlation to the EASI, also the patient evaluation of pruritus and the global evaluation by the investigator showed a significant improvement within 7 days. Overall both treated sides showed a highly significant reduction of EASI by 6.6 ± 6.7 ($p < 0.01$) between baseline visit and the final visit after 21 days. At no time point a significant difference between DermaSilk® and treatment with cotton and the topical corticosteroid could be observed.

Conclusion:

Use of silk fabrics with an antimicrobial finish proved surprisingly effective in the treatment of childhood AD and was comparable to the efficacy of a modern topical corticosteroid in combination with cotton clothing.



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The trial design was an open non-randomized study, with left-right intra-patient comparison. Fifteen children (age between 0.6 and 9.2 years) were included in the study. The study device was a silk fabric coated with AEGIS AEM 5772/5 (DermaSilk®) fashioned either as romper suit or as a T-shirt or pantyhose and worn over a period of 4 weeks (control side was composed of cotton). On the control side the class III corticosteroid momethason (Elocom Crème®) was applied once daily between baseline and visit 2 (7 days). The Excipial Fatty Cream® was used as basis treatment throughout the study. For the side comparison (left-right) between DermaSilk® and the conventional corticosteroid therapy a modified EASI score was used. In addition, the overall severity of the disease was evaluated using a Visual Analogue Scale (VAS) for the pruritus. All patients were evaluated at baseline and 7 & 21 days after the initial examination.

In the left-right comparison between DermaSilk® and the conventional topical corticosteroid (Elocom-Crème®) there was a significant reduction of the Eczema and Severity Index (EASI) of 8.9 ± 6.9 ($p < 0.01$) on both sides after 7 days (between visit 1 & 2). Between visit 2 and 3 the EASI score was increasing slightly of 1.9 ± 2.2 ($p < 0.05$). Overall there was on both treated sides an EASI reduction of 6.6 ± 6.7 ($p < 0.01$) between baseline visit and visit 3 (after 21 days). The severity code of the pruritus correlated with the EASI score and showed also a significant improvement between baseline and visit 2/3.

In conclusion we could show under the therapy with DermaSilk® a significant improvement of the EASI score and the pruritus. There was at no time point a significant difference between the DermaSilk® side and the control side with conventional topical corticosteroid treatment. Because the anxiety of topical corticosteroid therapy is still a main motive for non-compliance, the alternative treatment with DermaSilk® has a high application potential.

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