A Randomized Double-Blind Study to Investigate the Clinical Efficacy of Adding a Non-Migrating Antimicrobial to a Special Silk Fabric in the Treatment of Atopic Dermatitis


OBJECTIVE
To evaluate the clinical effect of adding an antimicrobial finish to knitted silk fibroin garments on eczema severity and on pruritus in patients with AD.

METHOD
This was the first "Randomised double blind trial" (RCT) conducted with DermaSilk. RCTs are considered by doctors to be the gold standard in clinical trial design as they provide the least possible opportunity for bias in a trial. In this case the trial compared the DermaSilk fabric with the antimicrobial to the DermaSilk fabric without the antimicrobial finish.

Thirty patients aged between 3 and 31 years {mean 14.2 ± 7.7} were enrolled. The inclusion criterion was that the patients presented with active AD with eczematous lesions located on the arms without any sign of infection.

Each participant was given a set of 4 pairs of knitted silk tubular sleeves marked with seams of different colours. Only one colour was treated with AEM 5772/5. This information was unknown to the clinicians and the patient's/parents. At baseline (T0) and after 7 (T7), 14 (T14), 21 (T21) and 28 (T28) days, the patients were evaluated using the following methods: photographic assessment, local modified SCORAD index adapted for only the arm, and parent/patient assessment of pruritus measured with a visual analogue scale.

RESULTS
The mean local SCORAD index of both the DermaSilk- and the unmodified-silk-covered arms decreased significantly between baseline (T0) and the end of study (T28). However, while the DermaSilk group showed a constant decrease each week, the unmodified-silk group showed a significant decrease only in the first 2 weeks of the study. Also the decrease in pruritus values between T0 and T28 was greater for the DermaSilk group.

CONCLUSION
This study demonstrates the importance of including the AEM 5772/5 finish to the specially knitted silk fibroin for a long-term improvement of atopic eczema symptoms. The study also confirms the usefulness of DermaSilk in older patients.