

## ORIGINAL ARTICLE

# Efficacy and functionality of silver-coated textiles in patients with atopic eczema

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## Keywords

antibacterial effect, atopic eczema, silver ions, *Staphylococcus aureus*, textiles

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Received: 14 November 2004, accepted: 7 April 2005

DOI: 10.1111/j.1468-3083.2006.01526.x

## Abstract

**Background** Microbial skin colonization with *Staphylococcus aureus* is known to play an important role in atopic eczema (AE). Recently, an antibacterial effect of silver-coated textiles on *S. aureus* colonization has been demonstrated.

**Objectives** To investigate clinical efficacy and functionality of silver-coated textiles in AE, a multicentre, double-blind, placebo-controlled trial was conducted.

**Patients/methods** From November 2001 to August 2002, 68 consecutive outpatients clinically diagnosed with generalized AE were included in the study. Inclusion criteria were the clinical diagnosis of AE with a moderate severity as measured by the scoring of atopic dermatitis (SCORAD) index with at least 20. Patients were instructed to wear either silver-coated (verum, 35 patients + 2 dropouts) or cotton garments (placebo, 22 patients + 9 dropouts) directly on the skin for 2 weeks. Only basic skin care and ongoing therapy with topical steroids or oral antihistamines was permitted. Clinical severity was assessed using the 'SCORAD' before, during and at the end of study. Quality of life (QOL), wearing comfort (WC) and functionality (FU) of study clothes were measured in parallel. Patients documented their subjective and objective symptoms daily.

**Results** In the verum group, eczema improved significantly after 1 week with further enhancement until the end of study ( $P = 0.03$  and  $P < 0.001$ ). Silver-coated textiles were comparable to cotton in WC and FU. Pruritus and self-assigned skin condition improved significantly more than with placebo ( $P < 0.001$  and  $P = 0.003$ ).

**Conclusions** In conclusion, silver-coated textiles are able to improve objective and subjective symptoms of AE significantly within 2 weeks, showing a good wearing comfort and functionality comparable to cotton.

## Introduction

Apart from many other pathophysiological influences, such as general and individual irritant and allergic factors, skin colonization with *Staphylococcus aureus* is known to play a major role in triggering and maintaining atopic eczema (AE).

The knowledge regarding the pathophysiological role of *S. aureus* in AE has increased over the last years. Understanding of the mechanisms underlying enhanced *S. aureus*-colonization in AE and identification of the molecules involved in triggering skin inflammation has important influence on the therapeutic approach of the disease.<sup>1-9</sup>

Individual provocation factors play an important role in disease activity and therefore have to be diagnosed for each patient.<sup>7,10</sup>

Provocation factors also include non-specific exogenous irritants affecting the skin barrier and leading to exacerbation. Adequate textile protection can be helpful in reducing the exposure to exogenous trigger factors.

However, textiles themselves can act as powerful irritants, depending on their material and their texture. Therefore, adequate clothing with textiles of low irritant potential is essential for patients with AE. Until now, cotton fabric is the best in recommended textiles for

patients with AE, which are also frequently used in the therapeutic management of the disease.<sup>11</sup>

Recently we demonstrated in a placebo-controlled study the antibacterial effect of silver-coated textiles on *S. aureus* colonization of affected sites (flexures of both elbows) in 15 patients diagnosed with localized AE.<sup>12</sup> The reduction of *S. aureus* density was paralleled by improvement of eczema severity (local SCORAD).

Silver products have been under intensive investigation during recent years with special regard to wound healing. The antibacterial activity of silver is known as well as its low side-effect potential.<sup>13–15</sup> The exact antimicrobial mechanisms of silver are not yet fully understood. Investigations with silver nitrate treatment and bacteria showed a detachment of the cytoplasm membrane from the cell wall. A remarkable electron-light region appeared in the centre of the cells, which contained condensed DNA molecules. The existence of elements of silver and sulphur in the electron-dense granules and cytoplasm detected by X-ray microanalysis suggested the antibacterial mechanism of silver: DNA lost its replication ability and the protein became inactivated after Ag<sup>+</sup> treatment.<sup>13</sup>

Therefore, silver textiles may offer new treatment modalities in AE with the two key advantages of showing broad-spectrum antimicrobial activity with negligible drug resistance.<sup>16</sup> Protective effects of comfortable clothes together with antibacterial effects may contribute to clinical improvement of AE by eliminating important trigger factors.

The aim of the present study was to investigate the clinical efficacy and functionality of silver-coated textiles with special regard to the wearing comfort in patients with generalized AE in a controlled study.

## Materials and methods

### Patients and study design

From November 2001 to August 2002, 68 consecutive outpatients clinically diagnosed with generalized AE<sup>17</sup> were included in the study. Two study centres, the Department of Dermatology and Allergy of the Technical University of Munich and the Department of Dermatology of the University of Kiel in Germany, participated in the trial. Inclusion criteria were the clinical diagnosis of AE with a moderate severity as measured by the SCORAD index<sup>18,19</sup> with at least 20. Patients under systemic or topical antibiotic treatment 4 weeks prior to the study period were excluded. Basic skin care with emollients was allowed, ongoing therapy with mild to moderate topical steroids [up to class III (Niedner)] was continued.<sup>20</sup> No topical immunomodulators (pimecrolimus or tacrolimus) were allowed in the study setting. In addition, no change

in topical steroid therapy was permitted during the study period. Patients were instructed to wear the study clothes daily directly on the skin over the 2-week period. It was recommended to wear them during the day like underwear and at night like a pyjama. Washing and cleaning behaviours were continued as usual. The textiles could be washed daily at 30 °C.

The study was performed as a prospective, randomized, placebo-controlled, double-blind trial. Study onset followed recruitment at once if inclusion criteria were fulfilled.

Of the 68 recruited patients, 37 were assigned to the verum and 31 patients to the placebo group. With 11 dropouts (16.2%) in total, the number of analysable patients was restricted to 57. Median age of all patients was 17.65 years with a predominance of female patients (66.7%). Family history of atopy was positive in 63% for allergic rhinoconjunctivitis (ARC), 40.4% for AE and 42.1% for allergic asthma (AA). The patients' history revealed ARC in 63.2% and AA in 33.3%. Most common individual provocation factors of AE were sweating (87.7%), exposure to wool (84.2%), heat (80.7%), psychological factors/stress (78.9%) and textiles/clothing in general (70.2%) (Table 1).

Patients were observed over a period of 2 weeks in total; evaluation visits were performed at initiation of the study,

**Table 1** Basic characteristics of participants

	Silver n = 35	Placebo n = 22	P	Total n = 57
Age (months)	214.7	207.1	0.78	211.8
Weight (kg)	39.7	41.1	0.91	40.3
Gender (female)	64.7	72.7	0.39	66.7
SCORAD TO	47.8	45.9	0.81	47.2
Extent-TO	36.5	31.5	0.38	
Intensity-TO	9.4	8.9	0.58	
Subjective symptoms-TO	8.2	8.6	0.58	
QOL (DIELH) – TO	55.7	53.3	0.68	54.8
Family history of				
RCA	68.6	54.5	0.29	63.2
AE	51.4	22.7	0.051	40.4
Asthma	40.0	45.5	0.69	42.1
Patient's history				
RCA	48.6	31.8	0.21	42.1
Asthma	34.3	31.8	0.85	33.3
Provocation factors				
Wool	91.4	72.7	0.08	84.2
Clothes in general	80.0	54.5	0.07	70.2
Sweating	88.6	86.4	1.0	87.7
Heat	82.9	77.3	0.73	80.7
Food	48.6	68.2	0.12	56.1
Psychic/stress factors	80.0	77.3	1.0	78.9
Animals	57.1	50.0	0.79	54.4
Pollen	45.7	45.5	1.0	45.6

TO, time of initiation; RCA, allergic rhinoconjunctivitis; AE, atopic eczema.

after 1 week and at the end of study (week 2). Patients were not allowed to wear study textiles during their consultation. This measure was taken in order to eliminate the risk of recognizing the patient's affiliation to the study clothes by the investigator.

At the first visit, personal and family history was taken and dermatologic examination was performed. Disease severity was assessed using the SCORAD.<sup>18,19</sup> This cumulative index combines objective (extent and intensity of different skin lesions) and subjective (daytime pruritus and sleep loss) criteria. Extent (A) of eczema lesions is assessed using the rule of nine; for intensity (B) five items are used: erythema (1), oedema/papulation (2), oozing/crusts (3), excoriations (4), lichenification (5). Each item is graded on a 4-point scale: 0 = absent, 1 = mild, 2 = moderate, 3 = severe. Daytime pruritus and sleep loss (C) are evaluated by the patient using a visual analogue scale from 0 to 10. The SCORAD is calculated by the following mathematical formula:  $SCORAD = A/5 + 7B/2 + C$ .

## Textiles

As placebo, textiles made of pure cotton of equal size were used. Silver-coated textiles as verum (Padycare®) consisted of micromesh material (82% polyamide, 18% lycra) with woven silver filaments with a silver content of 20% in total. According to the body size of patients, different sizes of clothes were used: European sizes 98/104 up to 158/164 were used in children, size S(mall), M(edium) and L(arge) in adults. For infants, all-in-one suits size 74/80, for children and adults long-sleeved and long-legged clothes were chosen (see fig. A).

## Functionality, wearing comfort and quality of life

To assess functionality and wearing comfort of the textiles, a specially designed questionnaire was used after 1 week as well as at the end of study and documented by the investigator. The questionnaire comprised information on objective and subjective symptoms (including sleep loss and pruritus) as well as functionality and wearing comfort of the clothes worn (Table 2).

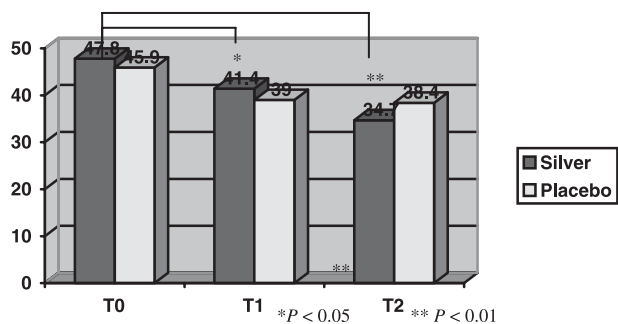
In addition, patients were instructed to record daily pruritus intensity during day and night, sleep characteristics (sleep loss, frequency of waking up) and wearing comfort of study textiles during day and night. Furthermore, the status of the skin was recorded in a preprinted diary. Symptoms were recorded on a 10-point scale from 0 (= minimum) to 10 (= maximum) of symptoms. Patients were instructed to document any additional therapy for AE (topical or systemic) except basic skin care with emollients (i.e. topical corticosteroids or antihistamines).

**Table 2** Questionnaire

1.	Wearing the study clothes, itching/pruritus has become better equal worse
2.	After 7 days of wearing the study clothes, eczema condition has become better equal worse
3.	Waking up during the night – while wearing the study clothes – has decreased not changed increased
4.	Study clothes on the skin are conveniently soft rough and scratchy neither soft nor rough
5.	Study clothes have a good temperature regulation lead to heat accumulation and sweating have no influence on temperature regulation
6.	Study clothes are comfortable during sportive activities become easily sweaty and stick to the skin are comparable to normal clothes when sweating
7.	After therapy with emollients and cremes, study clothes are comfortable uncomfortable neutral
8.	Stains in the study clothes can be removed easily by an ordinary washing programme can be removed by intensive treatment only cannot be removed even by intensive treatment
9.	When compared to normal textiles, study clothes dry after washing quicker equally slower

In addition, all other medications as well as all side-effects noted were documented in the diary.

For assessment of quality of life (QOL), a recently established questionnaire was answered at the beginning (T0), after 1 week (T1) and at the end of the study (T2). This 'German Instrument for the assessment of Quality of Life in Skin Diseases' (DIELH), comprises the main seven sections of QOL items in skin diseases: symptoms, psyche, everyday life, leisure, work, social environment and therapy<sup>21</sup>. Each section has different items (e.g. up to 22 items in section 'psyche' considering self-confidence, listlessness, sense of inferiority and others) which have to be assessed by the patient answering the question 'How much are you affected by/how much do you suffer from ...?' using a 5-point scale: 1 = not at all; 2 = a little; 3 = moderately; 4 = strongly; 5 = very strongly. The DIELH has been proven to be representative for impairment of QOL in patients suffering from AE.<sup>12</sup>



**fig. 1** General SCORAD (severity of eczema): significant improvement of general SCORAD after 1 week and after 2 weeks in the verum group (silver textiles). No statistical difference in the placebo group (cotton) between the condition before, during and after the study.

### Statistical analysis

As descriptive statistical methods chi-square test, Fisher's exact test and Mc Nemar non-parametric measures for dependent and independent random samples (Mann-Whitney-*U*-test, Wilcoxon ranked pair test) were taken. A significance level of  $P = 0.05$  was chosen. Analysis was done according to the intention-to-treat principle.

### Results

The demographic characteristics of patients are shown in Table 1. No significant differences were observed in state of eczema, age or quality of life state at beginning between the two groups (verum vs. placebo).

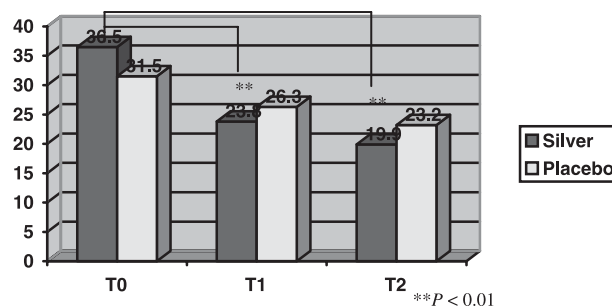
To analyse possible distortion effects of the results, participants and dropouts were evaluated and did not differ in basic characteristics.

Eleven of the 68 patients (16.2%) dropped out, leading to 57 analysable patients. Nine of the 11 dropouts were from the placebo group, due to either systemic antibiotics or assignment to the placebo group by the patient.

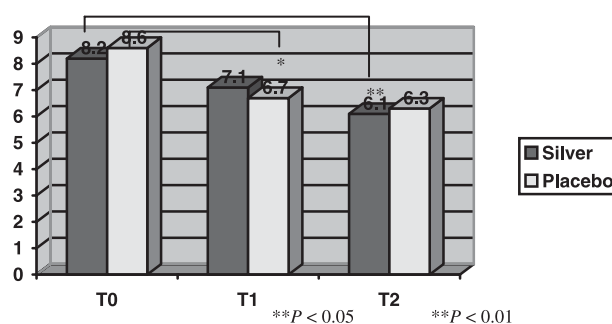
### Severity of eczema

#### SCORAD

The intensity of eczema (measured by SCORAD) was reduced in the silver group by 13.1 absolute points (27.4%) and in the placebo group by 7.5 points (16.3%) between initiation and end of study (T0 and T2). During the study period, improvement in SCORAD was statistically significant in the silver group already after 1 week [between T0 (initiation) and T1 (day 7)] ( $P = 0.03$ ) and more pronounced at the end of study ( $P < 0.001$ ) (fig. 1). In the placebo group, no statistically significant differences between the condition before, during and after the study



**fig. 2** Eczema extent in the SCORAD: significant reduction of eczema extension in the first and second week in the verum group (silver textiles). Reduction of eczema extent in the placebo group (cotton) without statistical significance.



**fig. 3** Subjective symptoms in SCORAD evaluation (sleeploss and itching): significant reduction of subjective symptoms in the placebo group (cotton) in the first week, but not at the end of the study. In the verum group (silver textiles), significant reduction of sleeploss and itching after the study when compared to baseline.

were noted. At the end of the study, significant differences between the two groups were not observed.

Looking closer at extent of eczema recorded in the SCORAD, a reduction of 16.6% was seen in the verum group between initiation and end of study. The reduction of eczema extent during the study period was statistically significant in the silver group in the first and second week (see fig. 2). In the placebo group, there was also a relative reduction of 8.3%, but without statistical relevance. However, no significant differences between the two groups could be seen.

The intensity score as part of the SCORAD was reduced in the silver group absolutely by 2.3 points (24.5%, respectively) until the end of the study period (T2) with statistical significance ( $P < 0.001$ ). Whereas in the placebo group, no significant difference could be observed (reduction by 13.5%).

As shown in fig. 3, subjective scores of the SCORAD (pruritus and sleep loss) were reduced by 25.6% until the end of study in the silver group ( $P = 0.009$ ). In the placebo

group, reduction amounted to 26.7% until the end of study being also statistically significant in the first week (T0 vs. T1:  $P = 0.01$ ). There were no statistically significant differences between both treatment groups.

### Self-assigned skin condition

As recorded in the questionnaire (Table 2), significant differences between the silver group and the placebo group were observed after 7 days' wearing period concerning the subjective assessment of pruritus improvement ( $P = 0.02$ ).

After 2 weeks, improvement of pruritus was still highly significant in the verum group when compared to placebo ( $P < 0.001$ ). Even the skin condition was assessed significantly better ( $P = 0.003$ ) in the silver group and so was sleep improvement ( $P = 0.02$ ), when evaluating the questionnaire (Table 2).

Improvement of pruritus was also seen as the most significant difference between silver and placebo groups when evaluating the daily recorded symptoms (diary). Pruritus during day and night were reduced consequently during the 2-week wearing period, showing statistically significant reduction at day 14 when compared to day 1 ( $P = 0.008$  and  $P = 0.011$ , respectively). Day and night pruritus decreased also in the placebo group, lacking statistical significance, however. A statistically significant difference between the two groups could not be observed at any point of time.

Waking-up frequency was also reduced significantly at the end of study in the silver group when compared to baseline ( $P = 0.011$ ), whereas no significant decline could be observed in the placebo group.

Sleep loss and subjective evaluation of skin condition as recorded in the diary did not show any significant differences between the two groups or definite points of time during the study period. A tendency of better assessment of the skin condition was noted in the silver group.

### Functionality and wearing comfort of textiles

Between the verum and placebo group significant differences were observed after 7 days concerning the subjective assessment of wearing comfort ( $P = 0.004$ ) and easy drying of the study textiles ( $P < 0.001$ ). In addition, silver-coated study textiles showed a better temperature regulation than cotton (73.5% and 50%, respectively) without relevant heat sensation (8.8% vs. 13.6%), the differences lacking statistical significance, however.

Silver textiles demonstrated an accelerated drying behaviour ( $P < 0.001$ ) in comparison to normal textiles as the only significant difference in functionality between the two groups (verum vs. placebo).

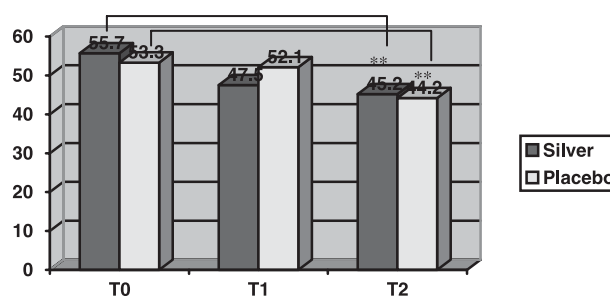


fig. 4 Impairment of quality of life (QOL): significant improvement at the end of study in placebo (cotton) and verum (silver) group.

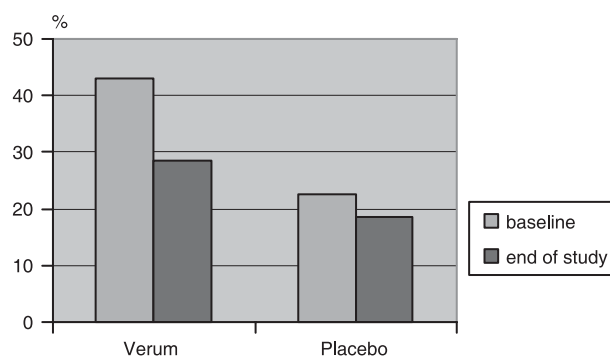


fig. 5 Concomitant topical steroid therapy: tendency of more pronounced reduction of steroid use in the verum group (silver textiles) without statistical significance.

### Quality of life

Impairment of QOL was reduced in the silver group by 10.5 points (or 18.9%) and in the placebo group by 9.1 points (or 17.1%) after 2 weeks (T2). QOL was felt to be significantly better in both groups at the end of study ( $P = 0.009$  and  $P = 0.01$ , respectively) as demonstrated in fig. 4. No significant differences were observed between the two groups.

### Concomitant use of medication

In total, 43 patients (75.4%) were using topical steroids. More patients applied topical steroids in the placebo group than in the silver group (84.4% vs. 68.6%, respectively) without statistical significance.

At baseline, 42.9% of the silver group and 22.7% of the placebo group had been using topical steroids. After 2 weeks, steroid consumption was reduced to 24.6% in total, 28.6% in the silver and 18.2% in the placebo group.

A tendency of a more pronounced difference in steroid use was noted in the silver group (fig. 5). However, no statistical differences between the two study groups or during the course of treatment were observed.

## Side-effects

No side-effects related to the study textiles and not answered in the questionnaire were noted during the study.

## Discussion

In the present study, the clinical efficacy of silver-coated textiles was shown in AE together with a high functionality and high wearing comfort.

Textiles in the treatment of AE are commonly used to provide a barrier from trauma including scratching and exogenous provocation.<sup>22</sup> A wide spectrum of exogenous provocation factors of AE has been identified. Relevant trigger factors can either be unspecific, such as irritants, or individually specific, such as allergies.<sup>10</sup> Irritative factors include UV radiation, water and detergents, sweat or extreme temperatures or temperature wavings – from heat to cold or vice versa. Silver-coated study textiles have proven to show a better, but not statistically relevant, temperature regulation than cotton (73.5% and 50%, respectively) without relevant heat development (8.8% vs. 13.6%). Beside irritant mechanisms, allergic reactions to aeroallergens are known to be major triggering factors and exposure to relevant allergens may lead to exacerbation and/or maintenance of AE. Most important aeroallergens are house dust mites, pollen and animal dander, such as cat, dog or horse. Relevance of the respective allergen can be best evaluated by the atopy-patch test, which shows a higher specificity than specific IgE and skin prick test.<sup>23,24</sup> Beside allergen avoidance, which may be problematic in case of ubiquitous aeroallergens such as pollen, protection of the exposed skin from provocation factors by suitable textiles is the most important measure. In addition, textiles protect the inflamed or sensitive skin from scratching sequelae (disruption of the 'itch-and-scratch-cycle') and are in common use as therapeutic tools.<sup>11,22</sup> Wet tubular bandages or even wet clothes ('wet wrap dressings') over topical corticosteroids or emollients are known to reduce pruritus and inflammation.<sup>25</sup> All-in-one suits made of cotton for infants are in regular therapeutic use. Therefore, suitable clothes may help to contribute to barrier and eczema stabilization.<sup>11,22,26</sup> These effects of textiles in the therapy of AE may explain the observed improvement in clinical severity (SCORAD) in the study in the verum as well as the placebo group.

In addition, microbial stimuli such as bacteria or fungi, especially *Staphylococcus aureus*, are recognized as important provocation factors of AE.<sup>3,5,6</sup>

The degree of colonization has been found to be associated with disease severity.<sup>2,4,8</sup> Recently we have shown that silver-coated textiles were able to significantly reduce

*S. aureus* colonization already 2 days after initiation of textile treatment as well as 7 days later and even 7 days after cessation of treatment. The reduction of *S. aureus* was paralleled by a reduction of clinical severity, supporting the clinical experience that antiseptic therapy is essential for an efficient therapy of affected lesions in AE.<sup>12</sup>

In the present study, improvement of eczema was clearly shown by significant reduction of SCORAD. Reduction was significant only in the silver group after 7 and 14 days, whereas in the placebo group no statistical difference was noted between before and after the study. This may be explained by the antibacterial effect of silver leading to a reduction of the provocation factor *S. aureus*. These findings are in accordance with earlier studies showing that antibiotic or antiseptic therapy is essential for a faster clearance of AE.<sup>27,28</sup> Clinical improvement was also seen in the placebo group, probably because of the additional treatment regimen with cotton textiles and the placebo effect of investigator and medical care. These findings further support the effect of textiles in the therapy of AE by protection from provocation factors, as mentioned above.

The disruption of the skin barrier function in patients with AE is known to be one of the major pathophysiological aspects of the disease.<sup>26</sup> Quantitative and qualitative changes in lipid composition<sup>29-31</sup> result not only in an increased transepidermal water loss (TEWL)<sup>32</sup> but also in a higher susceptibility for external irritants in affected and non-affected skin.<sup>22,26</sup>

The selection of a suitable textile is of high importance since textiles are known to serve as major irritants and provocation factors themselves depending on the fibre quality. The irritant potential of fabric depends on fibre diameter, temperature and humidity of the material that is worn directly on the skin.<sup>33,34</sup> In the study conveyed it could be shown that wearing comfort, functionality and acceptance of the study textiles are comparable to cotton, i.e. the irritant potential of micromesh material of study silver-coated textiles is as low as in cotton, which is the fabric that is recommended for patients with AE to wear directly on the skin. In the first week of the study, wearing comfort of the silver-coated textiles was even assessed significantly higher than cotton. In addition, silver-coated textiles were able to reduce pruritus significantly better when compared to cotton, already after 7, but still after 14 days. Overall, improvement in pruritus was seen as one of the major hallmarks of the silver-coated textiles.

In summary, it was clearly shown that silver-coated textiles are able to reduce clinical severity of AE within a wearing period of 2 weeks significantly without side-effects. Silver-coated textiles were comfortable and comparable to cotton concerning their wearing comfort and functionality;

pruritus could be diminished even more effectively than with cotton. These therapeutic effects lead to a significantly lower impairment of quality of life, already after 2 weeks. Superior effects of silver-coated textiles might be explained by their proven antibacterial quality, which may offer the advantage to enhance the clinical efficacy of glucocorticosteroid or other anti-inflammatory therapy and possibly lead to less frequent use of topical corticosteroids or use of less potent corticosteroids. This tendency could be observed in a greater reduction of steroidal consumption in the silver group.

Although no obvious side-effects could be noted during the study period, the amount and the effect of silver ions detached from the textiles as well as resorption effects in patients wearing silver-coated textiles need to be further investigated.

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