Expert opinion on innocuousness of the use of
PADYCARE® silver-coated textiles for atopic eczema
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School of Human Sciences- Universitätsklinik Osnabrück
apl. Prof. Dr. med. habil. Christoph Skudlik
Dermatology, Environmental Medicine and Health Theory

„Science-based dermatological expert opinion on the risk assessment of the use of silver-coated PADYCARE® textiles in patients with atopic dermatitis“

Conclusion:

„From a dermatological perspective, no relevant risk is posed by using silver-coated PADYCARE® textiles in patients with atopic dermatitis, including use by children and infants, even in the event of extensively affected skin.“

TEXAMED GmbH
Oskar-Messter-Str. 29
D-85737 Ismaning

Tel. +49 89 – 9233 469 – 0
Fax. +49 89 – 9233 469 – 23
www.texamed.de

UNIVERSITÄT OSNABRÜCK

School of Human Sciences

Universität Osnabrück · FB8 · D-49069 Osnabrück – apl. Prof. Dr. C. Skudlik

apl. Prof. Dr. med. habil.
Christoph Skudlik
Dermatology
Environmental Medicine and Health Theory

Sedanstr. 115 (Ward D1)
D-49090 Osnabrück
Tel. (0541) 405-1820
Fax (0541) 969-24 42
E-mail: cskudlik@uos.de

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Science-based

dermatological expert opinion on

the risk assessment

of the use of silver-coated PADYCARE® textiles

in patients with atopic dermatitis

1. Introduction

Atopic dermatitis is a chronic or chronic recurrent, non-contagious dermatosis. Its classic morphology and localisation differ depending on age, and the condition is usually accompanied by acute itching. The extent of affected skin can vary from discrete, localised areas to extensive affliction of the whole skin (21). In approximately two out of three cases of atopic dermatitis, the disease first appears in children under the age of 5 (19). The prevalence of atopic dermatitis has grown in recent years throughout the world, particularly in industrial nations; here, children currently exhibit an estimated lifetime prevalence of 10 to 20 % (19). The reason for this growth has not yet been clarified. However, a series of epidemiological studies led to striking proof of such developments, especially in children. In a study conducted in Aberdeen, Great Britain, for example, prevalence rates of atopic dermatitis in schoolchildren between the ages of 9 and 12 were found to be 5 % in 1964, 12 % in 1989, 18 % in 1994 and 21 % in 1999 (19).

All kinds of factors are known to trigger and aggravate atopic dermatitis, including, in particular, secondary bacterial infections, usually involving staphylococcus aureus (11, 21). Approximately 90 % of all patients with atopic dermatitis exhibit colonisation with staphylococcus aureus. This may have a pathogenetic significance for the severity of the eczema, but need not always be associated with clinical signs of impetiginisation (1). Against this backdrop, reducing the bacterial colonisation of the skin organ in patients with atopic dermatitis constitutes a medically justifiable therapeutic option consistent with guidelines (21); the use of antibiotics is not favoured, due to the development of resistance (2, 18). The germ-reducing, antiseptic properties of

silver have been known since antiquity. In modern times, silver applications were initially used for the prevention or adjuvant therapy of infections when treating patients with burn wounds (12).

Silver-coated textiles have been used for over 10 years in the context of prevention and the treatment of patients with atopic dermatitis. In the process, several studies have proven that such textiles reduce germs and have a positive impact on the course of chronic eczema affliction (5, 6, 7, 8, 11, 12, 14, 17). In these studies, a broad spectrum efficacy was observed with regard to the antimicrobial efficacy of the silver-coated materials used; no development of resistance specifically with regard to their use in atopic dermatitis has so far been observed (20). In the course of applying silver in other indications, however, developments of resistance have been reported in individual cases. For instance, silver-resistant escherichia coli bacteria occurred in the treatment of burn patients (17). All in all, however, the risk of developing a resistance to silver is generally characterised as being extremely low (11). In particular with regard to the use of materials containing silver in prevention and the treatment of atopic dermatitis, no medically relevant side-effects or complications have so far been described (5, 6, 7, 8, 11, 14, 17).

In this dermatological expert opinion, a risk assessment of the use of PADYCARE® textiles in patients with atopic dermatitis is to be carried out, taking into account the scientific literature and current findings on silver-coated PADYCARE® textiles.

2. Biological effect and risk potential of silver to the human body from systemic and topical exposure

Silver is said to play no physiological role in the human organism; due to factors such as food or liquid intake, inhalation or occupational exposure, however, it can be found in concentrations of less than 2.3 μg x l^{-1} (17).

The chronic absorption of silver via food, liquid or inhalation can lead to tiny silver depositions in the skin or mucous membranes, causing the grey to greyish-black discoloration of the skin (argyria). Localised argyria occurs at conjunctiva or oral mucosa following long-term local treatment with silver salt solutions. Universal argyria can develop, e.g. following internal treatment using medication containing silver salt. In addition, the occurrence of argyria is known as an occupational disease in workers exposed to silver dust (17). In addition to such visible depositions in the skin organ, the brain, the liver, the kidneys, the eyes and bone marrow also have a particular affinity to accumulating depositions of silver in the body (16). Understandably, (visible) depositions in the event of argyria have a cosmetically undesirable effect. Beyond this, however, silver depositions do not constitute any toxicologically appreciable risk (16, 17).

In the context of some surgical or medical therapeutic measures, silver-coated materials such as catheters coated with silver compounds are inserted into the body for germ-reducing purposes. Silver can also generally be released and absorbed by the body in this way, although the release of silver into the body from such systems has not yet been adequately studied (11, 17). However, it should be noted that there has not yet been any indication of the occurrence of increased clinically verifiable silver absorption

(argyria) in the organism in the relevant literature about such exposure to silver-coated materials.

Exposure to materials containing silver solely in the integument region in the form of silver-coated textiles must be distinguished from the aforementioned incorporation routes of silver absorption in the organism by food or liquid intake, therapeutic measures involving the insertion of silver-coated materials in the body or the absorption/inhalation of silver following significant (e.g. occupational) exposure to silver dust. Concerning this matter, over 10 years of clinical experience has been gained in caring for patients with chronic dermatoses, such as atopic dermatitis, using silver-coated textiles; there has been no indication of a relevant clinically verifiable increase in silver absorption, e.g. in the form of argyria, in the literature (5, 6, 7, 8, 11, 14, 15, 17, 20). According to the literature, it can particularly be assumed that there will be no appreciable absorption of silver from textiles containing silver through intact skin because free silver ions are shed as silver sulphide from the top layer of the epidermis (stratum corneum) (17).

In several studies involving the investigation of the wearing comfort as well as the antimicrobial and therapeutic efficacy of silver-coated textiles in patients with atopic eczemas, no clinical side-effects of silver textiles were detected (5, 6, 7, 8, 14), nor was any silver detectable in the blood of subjects in the context of serological controls (5, 6, 7, 8). For instance, in a study involving n=37 subjects with atopic dermatitis who wore T-shirts made of a silver-coated material, Fluhr et al. were able to test blood samples from a subcollective of 4 patients. No levels of silver were detected in the serum. In addition, ex vivo scanning electron microscope

analysis of the stratum corneum revealed no silver ions in this subcollective (5). In studies published by Gauger et al., a total of 50 patients that used silver-coated textiles were examined (15 patients in a non-controlled study (6), 35 patients (=verum group) in a controlled study, N=68) (7). Some of these studies also involved taking blood tests; here, too, no increase in the level of silver in the serum was detectable (8). In the literature, these observations are in particular justified by the very limited systemic absorption of silver, even in the case of dermal wounds (11, 13). According to the scientific literature, the decisive factor for this is that the quantity of silver absorbed is a thousand-fold below the "toxic level" with regard to the clinical cause of argyria, even when silver-coated textiles are used on inflamed skin for several years (15).

3. Atopic dermatitis: evaluation of severity based on the clinic and scoring systems

As mentioned above, atopic dermatitis is a chronic or chronic recurrent, non-contagious dermatosis. Its classic morphology and localisation differ depending on age; the extent of affected skin can vary. Atopic dermatitis exhibits different age-dependent infection patterns. Skin lesions can be localised or extensive; inflammations are usually limited to the epidermis and the upper corium (21). (Sub)acute eczema is characterised by intensive redness usually with indistinct borders, slight infiltrations and papulo-vesicles. At this stage, oozing areas and punctiform or linear excoriations can frequently be found. Chronic eczema is accompanied by paler redness, fine scaling and a thickening of the skin and, in the event of a highly chronic course, a coarsening of skin markings

(lichenification). Complications in atopic eczema may particularly be caused by local infections; here, particular importance can be attached to secondary bacterial infections (in most cases, staphylococcus aureus), whereby such secondary infections can also appear clinically within impetiginisation (pustulation, considerable oozing, yellowish scabs) or subclinically.

Skin scoring systems are ideal for ensuring the severity of atopic dermatitis can be viewed objectively. The scoring index SCORAD has gained acceptance in the European literature. Both the extent of skin change (A) and objective intensity (B) are assessed in this index; in addition, subjective parameters (itching and sleeplessness) (C) are included in the score. The SCORAD score is calculated from the above-mentioned parameters according to the formula A/5 + 7 B/2 + C; the maximum score is 103 (4).

4. Model risk assessment of the use of silver-coated PADYCARE® textiles in patients with atopic dermatitis based on the scientific literature and current findings on PADYCARE®

Current findings on PADYCARE®

Using anodic stripping voltammetry, it was proven for silver-coated PADYCARE® textiles that around 1 g of the product releases approximately 14 to 17 µg silver ions in the first six hours of a 24-hour in vitro test and approximately 7 to 9 µg silver ions over the 24 hours. This means that 1 m^2 PADYCARE® releases a maximum of 2.21 mg silver ions (9).

In microbiological terms, a significant antimicrobial effect of PADYCARE® was proven in both an unused state and after 200 washes (3).

The permeation and penetration of silver ions from silver-coated PADYCARE® textiles were investigated in the in vitro model of the Franz diffusion cell system (10). In this connection, permeation testing was performed using models on both intact and damaged dermatomised skin. Damaged skin was achieved by tape stripping the skin 20 times to remove the stratum corneum from intact skin. PADYCARE® textiles were then applied to both skin models in the Franz diffusion cell system. Based on 100 % total silver content in the region of intact skin, 0.019 % silver was detectable in the stratum corneum, 0.001 % silver in the epidermis and 0.004 % silver in the dermis after a 24-hour application. After a 24-hour application, 0.023 % silver was detectable in the region of the epidermis and 0.005 % silver in the dermis in the case of damaged skin (without stratum corneum). No silver was detectable in the acceptor medium below the dermis — representing as models further layers of tissue below the dermis in the Franz diffusion cell system — in either of the two test approaches. Consequently, it can be summarised that only a dose of absorbed silver totalling 0.005 % (in the dermis and epidermis without stratum corneum) was evident in intact skin, without further absorption in deeper skin layers in this in vitro model using human skin after 24-hour incubation. In the case of damaged skin, the total dose absorbed was 0.028 %, also without any further absorption in deeper skin layers (10). It was therefore in particular apparent that, as a result of in vitro testing using the Franz diffusion cell system, there was no indication of silver entering the bloodstream following the

application of PADYCARE® to the skin organ (even when damaged).

Based on these results, model calculations were performed for silver expected to be absorbed when using various silver-coated items of clothing at different ages (infants, children and adults) in relation to the percentage of damaged skin (generally on the basis of damaged areas of 5, 15, 25 and 30 %, partly on the basis of a damaged area of 35 %). This analysis was carried out based on the assumption of the threshold value of 5 µg/kg/day for silver in humans (equivalent to 0.005 mg/kg/day according to EPA (US Environmental Protection Agency; www.epa.gov)) (10).

For respective worst-case scenarios, taking as an exemplary basis various models with very large areas of damaged integument related not only to infants but also to children and adults, it was revealed that the respective percentage of assumed silver absorption derived from in vitro testing is always significantly below the above-mentioned threshold value, or the threshold value is only reached with the special constellation of an infant with extensively affected skin wearing (full-body) overalls.

In the following, the percentages of silver absorption determined on the basis of preliminary examinations are presented exemplarily in view of the above-mentioned threshold value for the constellation with a very high percentage of damaged skin: for infants wearing a romper suit (minus nappy region and head), 52 % silver absorption is expected with regard to the above-mentioned threshold value in the event of 30 % damaged skin; when tights are worn, 52 % silver absorption is expected in the event of 30 % damaged skin; when overalls are worn, 103 % of silver absorption is expected if 30 % of the body surface was damaged.

For children wearing a long-sleeved shirt, 59 % silver absorption is expected in the event of 30 % damaged skin; when long pants are worn, 46 % of silver absorption is expected in the event of 30 % damaged skin; for children wearing shorts or gloves, 21 % and 20 % of silver absorption respectively are expected in the case of 30 % damaged skin.
For adults wearing a long-sleeved shirt, 11 % silver absorption is expected in the event of 30 % damaged skin; when long pants are worn, 9 % silver absorption is expected in the event of 30 % damaged skin; for adults wearing shorts or gloves, 5 % and 2 % of silver absorption respectively are expected in the case of 30 % damaged skin. The expected absorptions of silver below the above-mentioned 30 % area of damaged skin were always below the assumed silver absorption doses mentioned above determined on the basis of in vitro testing (10).

Model risk assessment of the use of PADYCARE® in patients with atopic dermatitis, based on current findings on PADYCARE® described above.

In order to assess the risk involved in the use of PADYCARE® in patients with atopic dermatitis, the in vitro findings on PADYCARE® described above were transferred to constellations of clinical findings for infants, children (aged around 5) and adults. In this connection, average values for body surface area and body weight were assumed (Table 1). With regard to the total percentage of the respective area of affected skin that is assumed to be covered by PADYCARE® textiles, the respective total integument minus the head or, in the case of infants, also minus

the nappy region, was used as the basis, also as the worst-case scenario (Table 2).

Based on the findings of in vitro preliminary tests as described above, the percentage of assumed silver ions released with regard to the body surface area covered with PADYCARE® was initially calculated (in mg) (Table 2); this quantity was then related to the respective assumed body weight (mg/kg). The results showed that, on average, a roughly tenfold magnitude of silver ions is released from the textile for the various clinical constellations involving infants, children and adults, compared to the assumed threshold value for the absorption of silver ions of 0.005 mg per kg per day according to EPA (10) (Table 3). However, it must explicitly be pointed out that the quantity of silver ions released per kg of body weight can by no means be equated to the quantity of silver ions actually absorbed and incorporated.

In the next step of the analysis, findings from silver absorption testing using the Franz diffusion cell system were included in the expert evaluation. As a result, it can be stated that, assuming intact skin, the quantity of silver ions absorbed is more than ten times below the threshold value for silver in humans according to EPA for all of the above-mentioned age groups (Table 3). Under the assumption of extensively damaged skin of the whole integument (minus the surface area for the head and, for infants, the nappy region), i.e. in the worst-case scenario, the percentage of silver absorbed in adults calculated on the basis of in vitro tests was approximately one quarter of the threshold value according to EPA (0.0013 mg/kg, corresponding to 26 % of the above-mentioned threshold value of 0.005 mg/kg) or less than half of the assumed threshold value for infants and children according to EPA (0.002 mg/kg each, corresponding to 40 % of the above-mentioned threshold value of 0.005 mg/kg) (Table 3).

Table 1

	Body surface in m^2	Body weight in kg
Adult (average)	1.7	75
Adult male (average)	1.9	83
Adults female (average)	1.6	68
Child, 5 years	0.75	20
Infant	0.2	5

Table 2

	Body surface area minus the head and, for infants, the nappy region (according to the rule of nines in %) in m^2	Quantity of Ag^+ released when the whole body (minus the head) is covered with PADYCARE® in mg Ag^+ ($1\ m^2 = 2.21$ mgAg+)
Adult (average)	1.55 (91 %)	3.43
Adult male (average)	1.73 (91 %)	3.82
Adults female (average)	1.46 (91 %)	3.23
Child, 5 years	0.64 (85 %)	1.41
Infant	0.16 (78 %)	0.35

Table 3

	Released quantity of Ag^+ per kg body weight (mg/kg)	Absorption in intact skin in mg/kg (assumed according to permeation test: 0.005 %)	Absorption in damaged skin in mg/kg (assumed according to permeation test: 0.028 %)
Adult (average)	0.046	0.00023	0.0013
Adult male (average)	0.046	0.00023	0.0013
Adults female (average)	0.048	0.00024	0.0013
Child, 5 years	0.071	0.00036	0.002
Infant	0.07	0.00035	0.002

In summary, it can be seen that, even when assuming a maximum area of damaged skin covered with PADYCARE®, the quantity of silver ions absorbed, taking into account these in vitro test results, is significantly below the respective threshold value assumed for silver in humans according to EPA.

In this respect, it must also be emphasised from an expert perspective that there was no indication of absorbed silver ions entering the bloodstream or being systemically absorbed using in vitro permeation testing in compliance with findings from the literature (5, 6, 7, 8, 11, 14, 15, 16, 20). Based on these test results (10) and the above-mentioned literature, it can rather be assumed that the quantity of silver ions absorbed de facto remains solely in the skin.

In this context, the fact that atopic dermatitis is also characterised in part by excoriations, which in individual cases may be accompanied by relatively deep skin lesions down to the corium is recognised from the expert perspective. These are usually striated

skin lesions in the region of predilection sites of atopic dermatitis, such as the elbow pit; in contrast, any extensive excoriation of the integument would not correspond to clinical reality. Even assuming that in the case of lesions, silver ions would not automatically be "captured" in the epidermis and dermis due to individual deep excoriations, most of the silver ions absorbed by the adjacent deeper layers would be expected to be shed as silver sulphide (17). In addition, silver ions are expected to be bound by chloride ions (e.g. in sweat) (17). As described above, no systemic absorption of silver ions in the organism can be expected following the use of silver textiles, neither on the basis of the literature, e.g. by determining levels of silver in the serum after wearing silver textiles, nor on the basis of in vitro testing involving PADYCARE® textiles. If tiniest quantities of silver ions were nevertheless systemically absorbed, e.g. via the bloodstream, it can be assumed that they would be bound to albumin and other proteins, and eliminated via the liver and kidneys (17).

For the practical use of silver-coated PADYCARE® textiles, it is important to exemplarily transfer the findings presented above concerning the safety of the textiles' use to various typical clinical constellations. Model use of SCORAD is appropriate for this. In the course of the expert evaluation, worst-case scenarios were again consciously assumed, involving the assumption of the maximum area of affected skin of the whole integument covered with PADYCARE®, except for the head for adults and children and the head and nappy region for infants.

As shown at the beginning, a maximum SCORAD score of 103 can be achieved (4). If SCORAD is applied *as a model* for the above-mentioned relatively large areas in adults, children and infants, then the SCORAD scores gained are between 41 and 43

assuming a mild intensity for the individual morphs and only minor subjective impairment; between 68 and 70 in the case of moderately intensive morphs and a moderate subjective impairment; and between 99 and 101 in the case of a severe intensity of individual morphs and a maximum subjective impairment of those affected (Table 4).

The model SCORAD ranges assumed reflect constellations in the everyday provision of clinical care in patients with atopic dermatitis. For example, the average initial SCORAD score in a randomised study on effectiveness and safety of silver textiles in patients with atopic dermatitis conducted by Jünger et al. was 61.6, ranging from 30.6 to 99.9 (14).

Table 4

Model SCORAD scores in the case of extensive damage to the integument with corresponding covering of affected skin areas with PADYCARE® (adults: A = 91 %, child, 5 years: A = 85 %, infant: A = 78 %). Applicable SCORAD formula: A/5 + 7B/2 + C.

	Severe intensity for all six morphs (B = 6 x 3) and maximum subjective impairment (C = 20)	Moderate intensity for all six morphs (B = 6 x 2) and moderate subjective impairment (C = 10)	Mild intensity for all six morphs (B = 6 x 1) and minor subjective impairment (C = 4)
Adult	101	70	43
Child, 5 years	100	69	42
Infant	99	68	41

It was assumed for all of the constellations shown above that extensive areas of the whole integument minus the head are affected (in the case of infants also minus the nappy region).
As scientifically justified in detail above, even if the maximum area of the integument is assumed to be affected by atopic dermatitis and covered with a suitable silver-coated PADYCARE® textile, the absorption of silver ions in the skin is expected to be significantly below the assumed threshold value for silver in humans according to EPA, and that no relevant systemic absorption can be assumed. Consequently, it can be seen that, when considering models, the use of PADYCARE® is harmless from a dermatological/expert perspective, even in the case of virtually maximum SCORAD scores.

5. Conclusion

From a dermatological perspective, no relevant risk is posed by using silver-coated PADYCARE® textiles in patients with atopic dermatitis, including use by children and infants, even in the event of extensively affected skin. The use of PADYCARE® silver textiles is not primarily intended for case constellations with an impairment of the epidermal barrier of the skin exceeding 30 %. Notwithstanding the above, however, even such constellations do not give rise to any reservations against using PADYCARE® silver textiles as an appropriate adjuvant measure against the indicated stage and guideline-compliant dermatological therapy of atopic dermatitis from an expert perspective.
Since earlier studies on the effect of silver-coated textiles in atopic dermatitis demonstrated the positive impact on the course of chronic eczema (5, 6, 7, 8, 11, 12, 14, 17), antibacterial silver

textiles can also be considered an appropriate therapy-supporting measure for those severely affected, since there have been no observations of a development of resistance yet, even when treating patients with atopic dermatitis using silver-coated textiles (11, 18, 20). Earlier studies also demonstrated no indication of a systemic incorporation of silver ions following the use of silver-coated textiles in patients with atopic dermatitis (5, 6, 7). These findings have since been emphatically confirmed by in vitro tests that have since been conducted involving PADYCARE® textiles. Accordingly, from an expert perspective, there was no indication of the risk of the absorption of silver into the skin exceeding the threshold value nor, in particular, any indication of appreciable systemic uptake resulting from the model transfer of these findings to constellations of findings for patients of different age groups with atopic dermatitis.

Even in the hypothetical case that small quantities of silver ions enter the bloodstream nevertheless, it is clear that corresponding elimination mechanisms are known (17) and, in particular, that doses that could cause clinical symptoms of silver contamination in the body (argyria) are not any way near expected (15). Even if therefore, the issue of a risk assessment of the use of silver-coated textiles on which this expert opinion is based is irrelevant, it must be added from an expert perspective that even in the event of argyria, no toxicologically appreciable risk would be caused by the silver contamination of the body existing in this case.

The German *Atopic Dermatitis S2 guidelines* refer to the positive effects of antiseptic underwear in the treatment of atopic dermatitis, particularly encouraging their use in patients with chronic atopic dermatitis (21). From an epidemiological viewpoint, an increase in the prevalence of atopic dermatitis in the past decades, particularly in infancy, has been proven (19), from which

an increased demand for preventive measures and measures supporting pharmacological therapy can be derived.

In light of this risk assessment of silver-coated PADYCARE® textiles, it can be stated that, following German *Atopic Dermatitis S2 guidelines*, there are no reasons from an expert perspective against using these textiles in patients of different age groups.

Prof. Dr. med. Christoph Skudlik Osnabrück, 20 September 2013

Dermatologist and Venereologist
Allergology
Nutrition Medicine
Occupational Dermatology (ABD)

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