

Exploratory evaluation of tolerability, performance, and cosmetic acceptance of dexpanthenol-containing dermo-cosmetic wash and sun-care products for tattoo aftercare

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Abstract

Background and Aims: Tattoo prevalence has significantly increased over the last decades. Proper tattoo aftercare, such as cleansing, moisturizing, and protection against sunlight, is essential to prevent complications and to keep the beauty of the tattoo. The tolerability, performance, and cosmetic acceptability of two dexpanthenol-containing dermo-cosmetic products, a wash and a sun-care, were investigated on tattooed skin in two separate trials.

Methods: Two single-center, exploratory, open-label cosmetic studies were conducted between August and November 2020 to evaluate the dexpanthenol-containing dermo-cosmetic products. In the first study, healthy adults applied the 2.5% dexpanthenol-containing wash right after their tattoo session daily for 14 consecutive days. In the second study, healthy adults applied the 2.5% dexpanthenol-containing sun-care sun protection factor 50+ cream on existing tattoos that were daily exposed to sunlight for 28 consecutive days. Clinical examination by a dermatologist and self-assessment through subject questionnaires were used to assess the tolerability, acceptance, ease of use, and cosmetic outcomes of both products. Additionally, transepidermal water loss and moisturization assessments were performed to evaluate skin hydration after use of the sun-care product.

Results: Both study products were well tolerated, and no product related adverse events were reported during the studies. At least 90% of the study participants appreciated the performance of the dexpanthenol-containing wash and sun-care product, including moisturizing properties, relief of unpleasant sensations, and preservation of the cosmetic appearance of the tattoo. For the sun-care, it was shown that its application supported maintaining the skin barrier of tattooed skin, while keeping it hydrated.

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Conclusion: The 2.5% dexpanthenol-containing wash and sun-care products are well tolerated and appreciated by tattooed subjects. Hence, they represent valid options for tattoo aftercare in line with current recommendations and practice.

KEYWORDS

dexpanthenol, moisturization, sun-care, tattoo aftercare, tolerability, wash

1 | INTRODUCTION

Tattoos have grown significantly in popularity over the last decades. As a result, their prevalence has kept increasing on a global scale and reached an overall prevalence of 10%–20%.^{1,2} Yet, even with appropriate hygiene and strict sanitary precautions, getting a tattoo can be associated with several common acute complications, including bleeding, crusting, itching, edema, pain, burning sensations, scarring, swelling, tenderness, redness, sun sensitivity, and pus-filled skin area.^{3–5} A certain number of these complications are a part of the tattoo healing phase.⁶ After all, the process of tattooing consists of puncturing through the epidermis with pigmented particles using solid needles and creating superficial wounds.⁷ Tattoo aftercare instructions should therefore support optimal healing and prevent local infection and scarring of the tattooed skin to preserve the esthetic appearance.^{8,9}

However, standardized guidelines on tattoo aftercare are scarce and the advice given can vary both in quality and practicality.¹⁰ To date, the most recently published available guidelines are the European standards on safe and hygienic practice for tattooing.¹¹ In brief, the tattooed area should be rinsed with water and dabbed dry immediately after the procedure. The tattoo then needs to be protected with a hypoallergenic ointment and covered with a pad, bandage, or plaster for a few hours. Once at home it is advised to gently wash the tattooed skin with cold or lukewarm water and a hypoallergenic mild soap after removal of the dressing. The tattoo needs to be kept moist by using a hypoallergenic ointment or unperfumed moisturizing lotion to prevent the tattoo from drying out. Moisturization of the tattooed skin needs to be repeated daily for 2–3 weeks to support wound healing until skin recovery is complete. Throughout and after the healing process, it is important to avoid sun-exposure and artificial tanning to reduce the risk of skin barrier dysfunction and subsequent abnormal skin pigmentation, fading, or cracking of the tattoo.^{12,13}

Keeping tattooed skin moist and reduce discomfort sensations while preserving the skin barrier physiology are thus key requirements for proper aftercare and maintenance of the cosmetic appearance of tattoos.¹¹ The use of topical dexpanthenol has been well studied for these purposes—to date mainly outside of the tattoo research field—and its beneficial characteristics with regard to moisturizing capacity, prevention of skin irritation, and stimulation of skin regeneration have been demonstrated repeatedly.^{14–16} The exact mechanism of how dexpanthenol restores and protects the skin

barrier is not yet fully elucidated. After absorption, dexpanthenol is rapidly converted into pantothenic acid, a coenzyme A constituent indispensable for the physiological epithelial function.^{16–18} Dexpanthenol contributes to skin barrier recovery in dry skin conditions and helps to re-establish the normal epidermal differentiation.¹⁹ It has a beneficial effect on proteins and lipid components in the stratum corneum by increasing their mobility and retaining high skin permeability, even in dehydrated conditions.²⁰ As a result, topical dexpanthenol acts as a moisturizer, reduces transepidermal water loss (TEWL), and keeps the skin hydrated, soft, and elastic.²¹

These versatile properties make dexpanthenol a suitable candidate for tattoo aftercare, as previously shown for a 5% dexpanthenol-containing ointment (Bepanthen® Ointment/Bepanthen® Tattoo Intensive Care Ointment; Bayer Consumer Care AG).²² In this study, Bepanthen® Ointment use after tattooing was associated with a virtually complete skin barrier restoration, was well tolerated, and correlated with well perceived cosmetic performances.²² In addition, all study subjects presented with an uncomplicated tattoo healing process.

In light of these findings, two additional dexpanthenol-containing skin care products were developed, a wash product (Bepanthen® Tattoo Gentle Wash; Bayer Consumer Care AG) and a sun-care cream with sun protection factor (SPF) 50+ (Bepanthen® Tattoo Sun Protect Cream; Bayer Consumer Care AG), to complement tattoo aftercare. The composition of both formulations is provided in Supporting Information: Table 1. The wash was evaluated for mild cleansing and hydration of freshly tattooed skin in addition to standard tattoo aftercare with an ointment. The sun-care was evaluated to protect tattoos from ultraviolet(UV) rays, replenish tattooed skin with moisture and to preserve the beauty of the tattoo.

The current manuscript presents the results of two original studies assessing the tolerability and performance of the 2.5% dexpanthenol-containing wash (hereafter referred to as wash) and 2.5% dexpanthenol-containing sun-care SPF50+ cream (hereafter referred to as sun-care) products. In addition, the effect of the sun-care on the tattooed skin barrier function and moisturization was evaluated.

2 | METHODS

Tolerability and performance of the wash and sun-care were evaluated in two separate studies. Both studies were designed as single-center, exploratory, open label cosmetic studies and were conducted at

EUROFINS EVIC Product Testing Romania SRL (Bucharest, Romania) between August and November 2020. The trials were performed according to the requirements of the Declaration of Helsinki with all its amendments and in accordance with the guidelines for the evaluation of the efficacy of cosmetic products.

In both studies, healthy male and female subjects aged 18–60 years with skin types II–IV according to Fitzpatrick were recruited. No formal calculation was used for the determination of the sample size. The goal to recruit 50 study participants per study was based on historical data for TEWL studies and previous studies in tattoo settings with a similar investigational setup and study products.²² Subjects with a history of atopic reactions, allergy or skin reactivity, photoreactivity to cosmetic products, or who were breastfeeding, pregnant or planning a pregnancy during the study were not eligible to participate. Informed consent forms were obtained from study participants before study initiation.

2.1 | Study 1: 2.5% dexpanthenol-containing wash

The wash was used by subjects on a fresh, black ink tattoo. There were no instructions given regarding the size of the tattoo in cm², except that it needed to be completed in a maximum of 2 h at the selected tattoo center in Bucharest, Romania (2nd face tattoo & body piercing). Standardized tattoo areas included the upper and lower arms, lower legs, chest, abdomen, and hands. The first application of the investigational product was done at the EUROFINS investigational center under supervision of the investigator at Day 0, 3–4 h after tattoo completion. The wash was thereafter applied daily at home for 14 consecutive days up to 4 times, but not less than 2 times a day according to the product instructions. In addition to the wash, a 5% dexpanthenol-containing ointment (Bepanthen[®] Ointment; Bayer Consumer Care AG) was applied daily as a standard of care according to product instructions. Subjects were informed about general tattoo aftercare as stated in the European guidelines.^{11,22}

2.1.1 | Tolerability and product performance

A physical examination of the tattoo was performed at every study visit (Day 0, 1, 7, and 14) by a dermatologist to assess visible clinical signs such as erythema, edema, dryness, or desquamation. In addition, sensations of discomfort declared by the subjects were noted, including heating, burning, stinging, itching, redness, and tightness. The intensity of the visible clinical signs and the sensations of discomfort were assessed according to ordinal scales (Supporting Information: Table 2). Adverse events (AEs) were recorded in a daily log and collected at each study visit.

Study participants captured their subjective observations and assessments at each study visit with respect to skin reactions and test product characteristics in a validated questionnaire, based on the guidance provided by the American Society for Testing and Materials (ASTM, 2016). The questions concerning the product cosmetic

qualities and performance had to be answered by an ordinal scale (1 = strongly disagree, 2 = disagree, 3 = slightly disagree, 4 = neither agree or disagree, 5 = slightly agree, 6 = agree, 7 = strongly agree).

2.2 | Study 2: 2.5% dexpanthenol-containing sun-care SPF50+ cream

The sun-care was evaluated on tattoos (>6 months) that were daily exposed to sunlight for at least 30 min, but no more than 2 h per day during the study period and included areas on the forearms, arms, hand wrists, legs, shoulders, shoulder blades, upper back, feet, and ankles. Application of the product under investigation was done at least once a day, and before and during each sun exposure over the beach and bath time during 28 days.

2.2.1 | Tolerability and product performance

The assessments to evaluate the tolerability and product performance were identical to study 1, and were performed on Day 0 and Day 28 of the investigation.

In addition, the study participants assessed the appearance of their tattoo under investigation with regard to color intensity, sharpness of the contour and uniform filling at baseline and at the end of the study through an ordinal scale ranging from 0 to 9, with 0 representing the lowest score and 9 equalizing the highest score.

2.2.2 | Skin barrier function and moisturization

TEWL analyses were performed with the Tewameter[®] TM 300 (Courage + Khazaka). Before each measurement, study participants underwent 15–20 min of acclimatization in an unventilated room at a controlled temperature of 20 ± 2°C and relative humidity of 45 ± 15%. After the acclimatization period, the Tewameter sensor was placed on tattooed skin and left in contact on that specific point for 2 min, recording values every 30 s.

The hydration levels of the upper layers of the skin were measured with a Corneometer[®] CM 825 (Courage + Khazaka) during which the corneometer probe was applied to the tattooed skin and three consecutive measurements (triangle with the tip down) were conducted.

Measurements were performed at baseline (Day 0) and at the end of the study (Day 28) at the investigation site. In case of multiple tattoos, evaluations were performed on the one chosen at the time of the first visit. Minimalization of potential sources of errors of the measurements, besides ensuring equality of environmental conditions, was optimized by performing measurements on the same precise site of the tattooed area on each time point, following the same pattern, by the same technicians. Test subjects served as their own control.

2.3 | Data analysis and statistics

For both studies, a global comparison using analysis of variance with "Visit" as factor was performed on values, followed by a two-sided Dunnett's test with the baseline visit, Day 0, as reference for comparisons. For the statistical analysis of the instrumental measurements, a Wilcoxon signed-ranks test for paired samples was performed. The 5% significance degree was used for the statistical tests and 1% for the normality tests. Analyses were performed using IBM SPSS Statistics 22.

3 | RESULTS

3.1 | Study 1: 2.5% dexpanthenol-containing wash

3.1.1 | Baseline data

Seventy-three subjects were screened and 68 subjects were included in the study. Fifty-seven subjects completed the study without major

protocol deviations and were analyzed (Figure 1A). Baseline characteristics of the study participants are presented in Table 1.

3.1.2 | Tolerability and product performance

No AEs related to the study product under investigation were reported. The wash was generally well tolerated by all subjects, with only limited clinical signs such as edema, erythema, dryness, and desquamation, and discomfort sensations. These were not severe and expected as a result of the tattooing procedure.

Overall, the wash was very well accepted and appreciated for its cosmetic qualities and performance as illustrated by a majority of participants that indicated to be satisfied with the product ($p < 0.001$, Table 2). At least 93% of the study participants agreed that the investigational product was easy to apply, gently cleansed their skin, reduced skin irritation, provided beneficial effects such as soothing, cooling, relief of unpleasant sensations, and hydration of the tattooed skin, and they would continue using the wash on a daily basis.

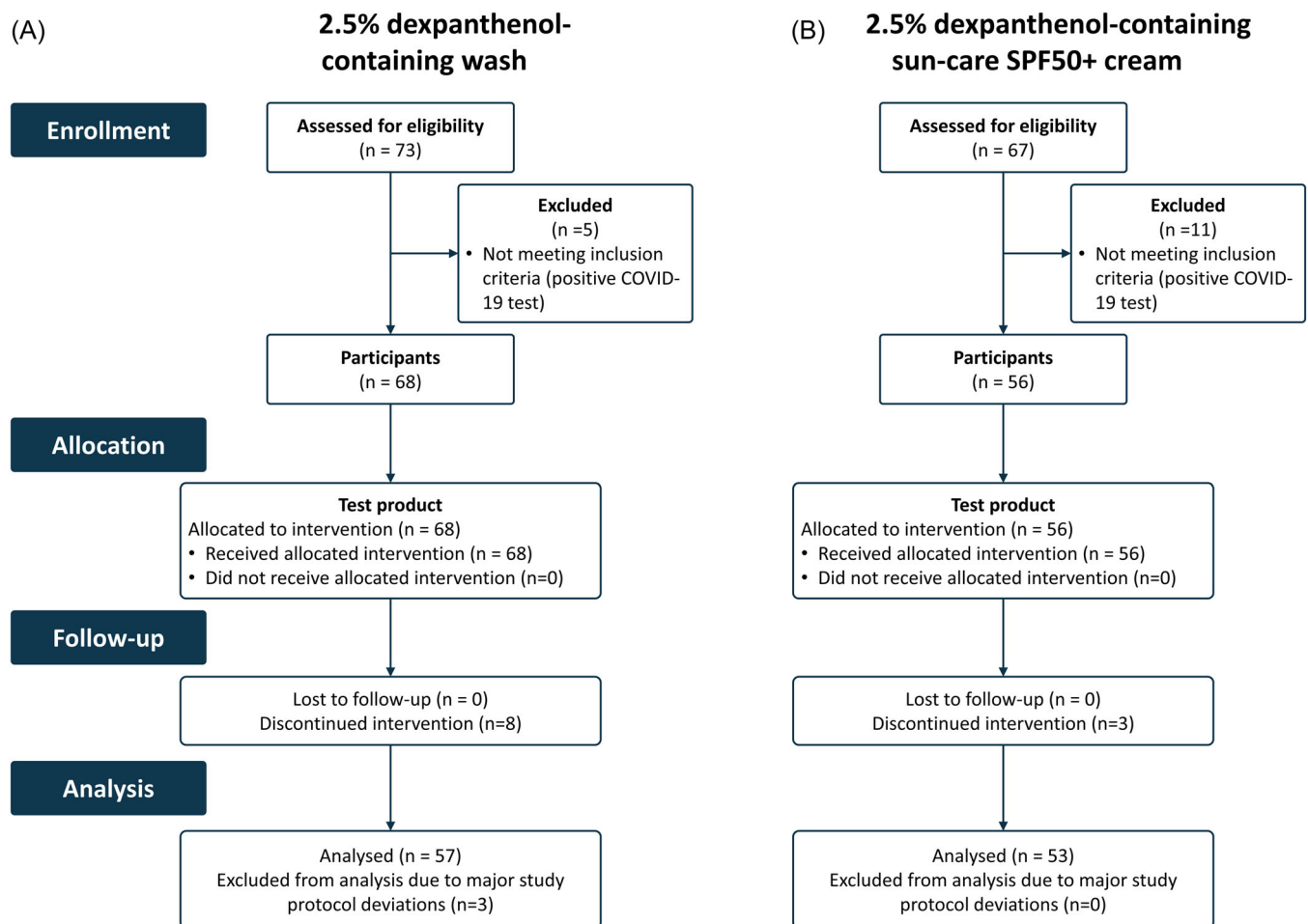


FIGURE 1 Flow diagram of (A) the 2.5% dexpanthenol-containing wash and (B) the 2.5% dexpanthenol-containing sun-care SPF50+ cream study participants. SPF, sun protection factor.

TABLE 1 Subject demographics and baseline characteristics

	2.5% dexpanthenol-containing wash	2.5% dexpanthenol-containing sun-care SPF50+ cream
Number of subjects (n)	57	53
Age (years ± SD)	35.4 ± 9.1	38.3 ± 8.1
Skin type (Fitzpatrick)		
II (n [%])	12 (21)	16 (30)
III (n [%])	41 (72)	30 (57)
IV (n [%])	4 (7)	7 (13)
Sex		
Male (n [%])	39 (68)	18 (34)
Female (n [%])	18 (32)	35 (66)
Ethnic group, Caucasian (n [%])	57 (100)	53 (100)

Abbreviations: SD, standard deviation; SPF, sun protection factor.

3.2 | Study 2: 2.5% dexpanthenol-containing sun-care SPF50+ cream

3.2.1 | Baseline data

Sixty-seven subjects were screened and 56 were included, of which 53 successfully completed the study (Figure 1B). Baseline characteristics of the study participants are presented in Table 1.

3.2.2 | Tolerability and product performance

The sun-care was well tolerated by all study subjects. No AEs were reported during the study. 96.2% of study participants indicated that the sun-care protected their tattooed skin against UV radiation and preserved the vibrant colors of their tattoo ($p < 0.001$, Table 3). Study subjects did not perceive any significant difference in tattoo color intensity ($p = 0.144$), sharpness of the contour ($p = 0.336$), and uniform filling ($p = 0.127$) at the end of the study in comparison to baseline assessments after daily product application and sun exposure. Further, 90% or more of the study participants agreed that the product was easy to apply, absorbed nicely, and hydrated the tattooed skin ($p < 0.001$, Table 3).

3.2.3 | Skin barrier function and moisturization

TEWL measurements provide an indication of the skin barrier function by assessment of epidermal water loss in vivo under stable environmental conditions. The significant decrease in TEWL from baseline to the end of the study after daily use of the sun-care

TABLE 2 Subject self-assessment questionnaire concerning product acceptability and performance of the 2.5% dexpanthenol-containing wash at Day 14

No	Question	"Agree", % (N) ^a	
1	You would say that the investigational product		
	Is easy to apply	98.2 (56)	
	Is quick to apply/allows quick application	98.2 (56)	
	Gently cleanses tattooed skin	98.2 (56)	
	Is convenient to apply to tattooed skin	98.2 (56)	
	2 After application, your tattooed skin is	Softer	98.2 (56)
		Suppler	94.7 (54)
		More comfortable	98.2 (56)
Soothed		98.2 (56)	
Smooth		96.5 (55)	
Less tightened		98.2 (56)	
Less irritated		98.2 (56)	
Clean		96.5 (55)	
3 After application, would you say that the investigational product		Leaves your tattooed skin feeling moisturized	96.5 (55)
		Leaves your tattooed skin feeling moisturized immediately after	96.5 (55)
	Provides an immediate refreshing sensation	96.5 (55)	
	Reduces unpleasant skin sensations	96.5 (55)	
	Is suitable for aftercare of tattooed skin	96.5 (55)	
	Leaves tattooed skin cleaned	96.5 (55)	
	4 Overall, the investigational product	Totally satisfies me	96.5 (55)
		Is the perfect daily cleansing product for my tattooed skin	94.7 (54)
I would like to continue using this product regularly/daily		93.0 (53)	
I would recommend this product to a friend		96.5 (55)	

^aThe number of subjects and percentage indicated reflect the proportion of subjects that answered "Strongly agree," "Agree," or "slightly agree" to the provided question.

(Figure 2A, $p = 0.0170$) indicated that additional use of the sun-care contributed to strengthening the skin barrier. Moreover, moisturization evaluation of the skin after use of the sun-care for 28 days showed no significant difference in hydration level in comparison to baseline ($p = 0.263$). These results indicate that there was no epidermal hydration loss after repeated sun exposure when using the sun-care (Figure 2B) and that the skin moisture level was maintained.

No	Question	"Agree", % (N) ^a
1	Was in your opinion the product easy to apply to tattooed skin?	98.1 (52)
2	In your opinion did the product absorb quickly?	96.2 (51)
3	In your opinion did the product leave white streaks after application?	0.0 (0)
4	In your opinion did the product absorb nicely and did not leave any unpleasant residue after application?	90.6 (48)
5	In your opinion did the product effectively protect your tattoo colors against sunlight/UV radiation?	96.2 (51)
6	In your opinion did the product leave your tattooed skin feeling smooth and hydrating?	96.2 (51)
7	In your opinion did the product leave your tattooed skin with vibrant colors?	96.2 (51)

Abbreviations: SPF, sun protection factor; UV, ultraviolet.

^aThe number of subjects and percentage indicated reflect the proportion of subjects that answered "Strongly agree," "Agree," or "slightly agree" to the provided question.

TABLE 3 Subject self-assessment questionnaire concerning product acceptability and performance of the 2.5% dexpanthenol-containing sun-care SPF50+ cream at Day 28

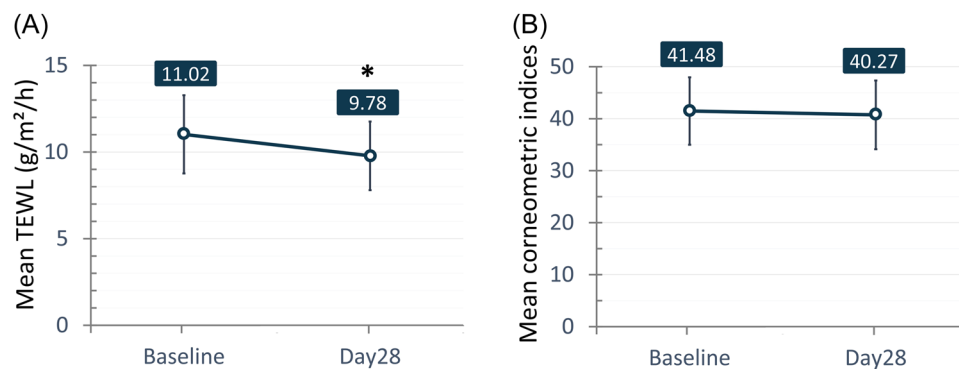


FIGURE 2 TEWL and corneometric measurements at baseline and the end of the study at Day 28 after application of the 2.5% dexpanthenol-containing sun-care SPF50+ cream on healed tattooed skin. (a) There is a significant difference in TEWL between baseline and Day 28 ($p \leq 0.001$). (b) There is no significant difference in corneometric indice between baseline and Day 28 ($p \leq 0.263$). * $p \leq 0.001$ in comparison with baseline value. SPF, sun protection factor; TEWL, transepidermal water loss level.

4 | DISCUSSION

Tattoos have become mainstream over the last decades.¹ Yet, despite their growing global popularity and overall improved hygiene, getting tattooed still carries risks.⁵ Predominant complaints after tattooing include swelling and itching and occur in about 30% of individuals, while 20% of people with tattoos suffer from problems related to sun exposure.⁹ This high prevalence might not be unexpected, as some of these complaints are associated with the healing process after tattooing.⁶ To minimize potential complaints, proper tattoo aftercare is strongly recommended.¹² Ideally, aftercare should support healing, prevent infections, minimize scarring, and make sure the tattoo color and esthetic appearance is preserved.⁸⁻¹⁰

Dexpanthenol has gained tremendous attention in the field of dermatology over the last decades thanks to its moisturizing properties, healing potential, and anti-inflammatory characteristics.^{15,16,23} As such, many formulations with dexpanthenol have been used for skin care as well as for the promotion of minor wound healing, including abrasions, cuts, and scratches, similar to wounds created by the tattooing

process.^{10,14,16,19,24} A recent publication confirmed the beneficial use of a dexpanthenol-containing ointment on freshly tattooed skin by demonstrating a virtually complete restoration of the disturbed skin barrier function induced by tattooing.²²

To complement appropriate tattoo aftercare, a dexpanthenol-containing wash and sun-care product were developed, and their safety and performance were clinically confirmed.

Effective cleansing of freshly tattooed skin with a mild wash product is an essential part of tattoo aftercare.¹¹ The 2.5% dexpanthenol-containing wash demonstrated to be suitable for mild effective cleansing of fresh tattoos to complement standard tattoo aftercare with a dexpanthenol-containing ointment. Daily application of the wash provided comfort and hydration of the tattooed area, and could be used safely, easily, and early on after tattooing in accordance with hygiene requirements for tattoo cleansing.¹¹ As dexpanthenol has been well documented for its moisturizing properties, addition hereof to the wash may have an additional beneficial effect on providing moisture to the tattooed skin.^{16,22}

Besides cleansing and moisturization of tattooed skin to support optimal healing, preservation of the beauty of tattoos is another important aspect of tattoo aftercare. After all, embellishment of the body is a major motivation for getting a tattoo.² Although tattoo fading is a multifactorial process, one of the most common preventable risk factors that affects the cosmetic appearance of tattooed skin is exposure to direct sunlight.^{12,13} Sun avoidance or protection with at least SPF30 is therefore essential in tattoo aftercare.¹¹ Surprisingly, excessive sun exposure and indoor tanning is generally higher among young adults with tattoos than the national estimate according to an on-line national survey conducted in the United States, emphasizing the need for creating awareness regarding protection during sun exposure.²⁵ In addition, it has been shown that UV exposure has dramatic effects on the cellular cohesion and mechanical integrity of the skin leading to compromised skin barrier function. Sunscreens are effective at preventing erythema and nonmelanoma skin cancer, but their ability to maintain the mechanical barrier properties of the skin is hence also an important property.²⁶

In the current study, 2.5% dexpanthenol-containing sun-care SPF50+ cream was demonstrated to maintain the esthetic appearance of existing tattoos by preserving vibrant colors and preventing fading of the tattoos, while it was easy to apply and keeping the tattooed skin smooth and hydrated. Assessment of the skin barrier function showed a decrease in TEWL, or outward diffusion of water through the skin, after 28 days of daily application, an observation which confirms the ability of the 2.5% dexpanthenol-containing sun-care SPF50+ cream to maintain the skin barrier and prevent the drying out of tattooed skin in addition to providing protection against UV radiation. Corneometer measurements correlate to the water content of the skin, which remained similar between baseline and after 28 days implying that application of the sun-care maintained the hydration level of the skin during sun exposure, counterbalancing the drying effect of UV exposure.

A limitation of both studies is the lack of a comparison with a tattooed area where a placebo or no application was applied. However, the standard of care for freshly tattooed skin recommends regular moisturization and cleansing of the tattooed area and it would be unethical to not provide this aftercare. In line with this reasoning, it is considered unethical to not apply any protection of the skin against sun exposure. Moreover, comparison of the test products with placebo would entail practical challenges that would influence the reliability of the measurements. As such, the test product and placebo should be intraindividual compared to minimize variability, meaning that the tattoo under investigation should be divided in two test areas, a criterion that would be difficult to meet in tattoos obtained in maximum 2 h as was the case for the evaluation of the 2.5% dexpanthenol-containing wash. Using different formulation of sun protection at the other hand, could lead to different appearance on the site of application. Given that the intention of the current investigation was to evaluate the efficacy and tolerability of both test products rather than making a comparison with placebo, evaluation of the endpoints based on the

comparison of baseline measurements with end-of-study results was considered sufficient to address this goal.

In conclusion, these data complement previous observations and provide additional scientific evidence supporting the safe and efficacious use of the dexpanthenol-containing dermo-cosmetics in tattoo aftercare. The wash provided mild cleansing of freshly tattooed skin in addition to standard care and the sun-care preserved the cosmetic appearance of existing tattoos by keeping the skin moist and maintaining the skin barrier. The results of our studies provide scientific evidence for the integration of the 2.5% dexpanthenol-containing wash, in combination with the 5% dexpanthenol ointment, and the 2.5% dexpanthenol-containing sun-care SPF50+ cream into tattoo aftercare in line with current guidelines and recommendations.

AUTHOR CONTRIBUTIONS

Conceptualization: Daphné A. Schmid, Marisa P. Domingues, Alina Nanu, and Raffaella de Salvo and Sonja Trapp. *Methodology:* Daphné A. Schmid, Marisa P. Domingues, Raffaella de Salvo, and Sonja Trapp. *Formal Analysis:* Alina Nanu and Nicolas Kluger. *Investigation:* Alina Nanu. *Project Administration:* Raffaella de Salvo. *Writing—review and editing:* Daphné A. Schmid, Marisa P. Domingues, Alina Nanu, Nicolas Kluger, Raffaella de Salvo, and Sonja Trapp.

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CONFLICTS OF INTEREST

Daphné A. Schmid, Marisa P. Domingues, Raffaella de Salvo and Sonja Trapp are employees of Bayer Consumer Care AG, Basel, Switzerland. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data generated during the studies are disclosed in the publication and are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The studies were performed in accordance with the general principles of medical ethics in clinical research coming from the Declaration of Helsinki (June 1964) and its successive amendments, and according to the recommendations of Colipa—August 1997: “guidelines for the assessment of human skin compatibility.” In addition, the clinical investigation complied with the European Directive 95/46/EC and the Romanian Order No 677/2001 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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