

# TATTOOS AS WOUNDS: A CLINICAL EFFICACY STUDY OF TWO SKIN AFTERCARE PREPARATIONS

## KEY WORDS

- ▶▶ Tattoos
- ▶▶ Skin barrier
- ▶▶ Skin preparation

## Abstract

**Background:** Tattooing is defined as 'the practice of producing an indelible mark on the human body by inserting pigment under the skin using needles or other sharp instruments' (Sperry, 1991). It has probably been practised for as long as man has walked the earth. **Aims:** The objective of the study was to compare the effects of a new post-tattoo cream with a control ointment on newly tattooed skin. **Method:** Subjects attended for visits on day 0 (approximately four hours after their tattoo was completed), then on day four, seven, 11, 14, 21, and 28. The study duration was 28 days, or less if the skin had returned to normal for both test sites. At each visit the same assessments, measures and questionnaires were completed and photographs were taken of the tattoo. The products investigated were Forever Ink Balm® (Forest Laboratories), which, in addition to manuka honey of UMF 10+, also contains panthenol, vitamin E, and a hyaluronic acid derivative; and a proprietary cream for 'nappy area care' which is water petrolatum-based and contains lanolin and lanolin alcohol. **Results:** No statistical differences were found between the purpose-designed post-tattoo cream and the nappy care cream.

While tattooing has, for many years, had connotations of crime, gangs and behavioural problems (Armstrong, 1994; Roberts and Ryan, 2002), it has now largely become an established 'art form', made very public by celebrities and reputable by highly skilled artists. The general public's perception has also changed as a consequence with a huge increase in popularity in recent years. It is reported that in the UK, 20% of the population has a tattoo (*The Guardian*, 2010).

However, for the clinician, the tattoo can present as a medical problem. Firstly, the creation of the tattoo, i.e. the introduction of pigment into the dermis, is achieved through a wounding process. The act of repeatedly puncturing the skin with a sharp object (usually a needle) disrupts the skin barrier. While this will recover uneventfully in most cases, the whole process can lead

to dermatological problems (Mataix and Silvestre, 2009). These *may* be attributed to the techniques, products and instruments used, as well as to inadequate aftercare.

This report focuses on 'appropriate' tattoo aftercare and, in particular, the evidence-based use of skin creams and ointments. The intention being to facilitate skin healing and so restore full function, as well as to preserve and protect the tattooed area as the artist intends and the subject desires.

Even in the most expert hands, the creation of the tattoo is a trauma that will elicit reactions requiring careful attention if the skin is to recover promptly and the tattoo to endure. Those planning or receiving a tattoo will be presented with advice from the artist, internet, or friends on how best to protect the area and care for their skin. This will be largely anecdotal and not evidence-based. The use of non-specific

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topical applications, such as creams and ointments, while widely recommended, is so far, entirely without objective evidence.

Forest Laboratories UK Ltd has recently developed and launched a new range of skincare products specifically designed for the immediate and long-term care of tattooed skin. Forever Ink Balm contains antibacterial manuka honey and vitamins B and E in an emollient vehicle. This preparation is formulated to moisturise, nourish and protect the skin, helping to restore an effective barrier. It is free from potential sensitisers, such as fragrances, colour, lanolin, parabens (preservative) and alcohol, making it suitable for use even on the most sensitive skin.

It is generally not recognised that the creation of a tattoo is a wounding process (Figure 1) and, as such, causes temporary physical and functional damage to the skin. Such damage renders the skin susceptible to infection from environmental micro-organisms. Functionally, the water permeability barrier is disrupted, making the skin more porous and increasing transpiration. In addition, the damage to the superficial vascular plexus in the dermis leads to bleeding and to leakage of blood serum, this will lead to scab formation.

The trauma that provokes bleeding is inevitable, however, the scabbing process and recovery of full skin function can be optimised by appropriate care. Similarly, reduction of inflammation and risk of local infection may be achieved through the use of manuka honey, a naturally-occurring material well-known for its proven activity (Lusby et al, 2002; Al-Waili et al, 2009).

At the time of writing, no reports of post-tattoo healing studies were available through literature searches using the major databases. Consequently, the current report is believed to be the very first of its kind. A randomised, controlled, double-blind clinical trial has been conducted to evaluate two topical preparations in the treatment of post-tattoo skin function.

In this study, it was decided to use quantitative, objective measurements of skin function, rather than rely upon subjective, visual techniques. Consequently, the controlled hydration of the stratum corneum, was measured by capacitance (Corneometer®; Courage+Khazaka), a method demonstrated to give reliable estimates of hydration (Clarys et al, 2012); and transepidermal water loss (TEWL) (Serup, 1994) as two validated functions of the permeability barrier.

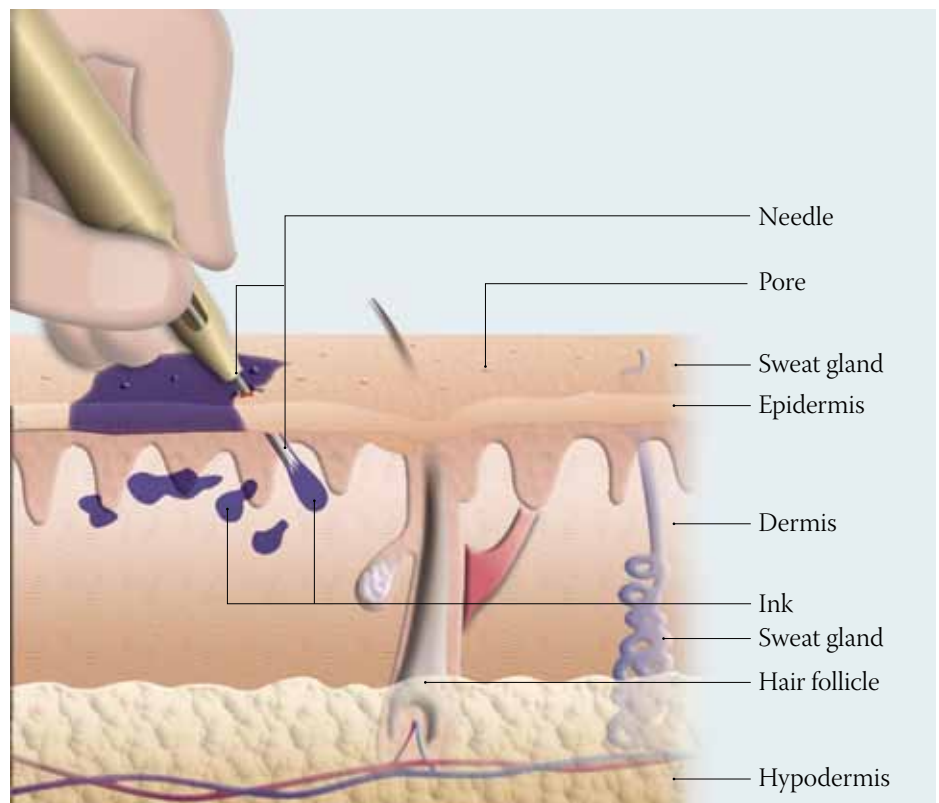


Figure 1: A diagrammatic view (not to scale) of the typical tattoo process; note that the needle penetrates into the dermis to deposit the ink.

## 'It is generally not recognised that the creation of a tattoo is a wounding process'

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### OBJECTIVES AND METHODS

The aim was to compare the effects of a new post-tattoo cream with a control ointment on newly tattooed skin. The study was a double-blind, randomised, single centre, parallel within-subject comparison, which was conducted in compliance with a protocol implemented after having received written Ethics Committee authorisation. All subjects gave written, informed consent prior to any study-related procedure being carried out. Subjects applied the two products, twice daily, to the respective areas of their tattoos and attended for visits on day 0 (approximately four hours after their tattoo was completed), then on day four, seven, 11, 14, 21 and 28. (It should be noted that the control product is described by the manufacturer as an ointment, however, it contains water and is, therefore, technically a cream).

The study duration was 28 days, or less if the skin had returned to normal for both test sites. At each visit, the same assessments, measures and questionnaires were completed and photographs were taken of the tattoo. Quantitative measurements of skin hydration (using a Corneometer) and TEWL (using a Tewameter®; Courage+Khazaka) were taken from Day four onwards.

The products investigated were Forever Ink Balm, which, in addition to manuka honey of UMF 10+, also contains panthenol, vitamin E, and a hyaluronic acid derivative; and a proprietary cream for 'nappy area care' which is water-petrolatum-based and contains lanolin and lanolin alcohol (control treatment). This is one of the many skin preparations that has been used in recent years to provide some form of skin care after tattooing, however it has no published evidence in this indication.

Subjects who had been recently tattooed, attended the study site and were willing to take part, gave informed consent and were screened. In total, 36 subjects were scheduled to start the treatment period and this was split over three groups.

The inclusion criteria comprised:

- ▶ Healthy subjects aged 18–50
- ▶ Written informed consent
- ▶ Either: new tattoo in an accessible area and on a suitable surface large enough to have two separate (but similar in

colour and size) areas and with two test sites (3cm x 3cm); or two separate new tattoos of sufficient size and similar in colour.

The exclusion criteria included:

- ▶ Pregnant or lactating
- ▶ Had any skin conditions or factors that may affect the response of the skin or the interpretation of the test results, including any active generalised skin condition or diseases
- ▶ Concurrent medication, which the investigator believed may influence the response of the skin or the interpretation of the data, such as topical and systemic corticosteroids, regular use of anti-histamine, anti-inflammatory medication or antibiotics
- ▶ Known sensitivity to the test articles or similar products.

### Products administered

The study products were Forever Ink Balm, coded product 'A' while the control cream was coded 'B'. The test and comparator products were applied to designated areas of the tattoo twice daily, according to the randomisation. The subjects were instructed to wash the test area using their normal soap, rinse and dry prior to applying the product.

Products were weighed before first application and at each subsequent clinic visit, and the weights recorded. Subjects were instructed to apply each product to evenly cover the relevant area of the tattoo. Single tattoos were divided into two roughly equivalent areas. As the study was double-blind, neither study staff nor subjects were aware of which product was the test or the control.

The products were supplied in identical packaging and:

- ▶ No topical products were applied to the tattoo other than those issued for the duration of the study. Products were applied to their respective area as instructed on Day 0
- ▶ Subjects had to ensure that they did not change the brand of soap/shower gel they usually use for the duration of the study
- ▶ There was to be no exposure of the tattoo to excessive sunlight for the duration of the study
- ▶ There was to be no showering until at least one hour post-product application

Table 1: Subject demographics

Population	Number	Gender		Age range	
		Male	Female	Male	Female
Randomised	31	13	18	18–47	19–42
Completed	25	11	14	18–42	19–42

for the duration of the study  
 ▶ Subjects were asked to wash the tattoo area(s) at least one hour before their appointment.

**Efficacy variables**

At each visit, the following were assessed:

- ▶ Erythema
- ▶ Dryness
- ▶ Oedema
- ▶ Scabbing.

**Statistical and analytical plans**

The statistical analysis was performed using SAS version 9.2 (a software package for statistics). All statistical analyses had a two-sided test and a significance level of 5%

(i.e.  $p < 0.05$ ). The adjusted mean product estimates, mean product differences, standard errors, p-value and 95% confidence interval were calculated.

**Skin hydration and TEWL measurements**

For hydration, six measurements were taken on each treated site and the mean used in the statistical analysis. For hydration and TEWL, the following analyses were performed on the intention to treat analysis population: basic summary statistics (N, mean, SD, median, min, max) and presented for each product at each time point.

To estimate and compare the mean product scores on each assessment day of the study, a repeated measures analysis was performed. To account for any imbalance in the mean scores between the two products at baseline, the day 0 assessment scores were included in the model as a covariate.

This gave adjusted estimates of mean product differences for days four, seven, 11, 14, 21 and 28. To estimate the mean change over the course of the study for each product, the scores on day 0 would be taken as a repeated measure and a Tukey honestly significant difference (HSD) adjustment used to correct for multiple testing.

Within each treatment group, the baseline scores were compared with the final score using the Wilcoxon signed rank test for matched pairs.

Sample size was based on subjects available rather than calculated based on comparisons — the target was 36 subjects. The rationale being that this was a study for a ‘first look’ evaluation of the test product. The results of this study may be used in a formal sample size calculation for future studies.

**Study subjects**

Thirty-one subjects were screened and all were accepted onto the study and randomised. During the study, there were six withdrawals (Table 1), with 25 subjects completing the study, 20 subjects on both products, five subjects using product B only.

**VISUAL ASSESSMENTS**

Erythema grading for both products

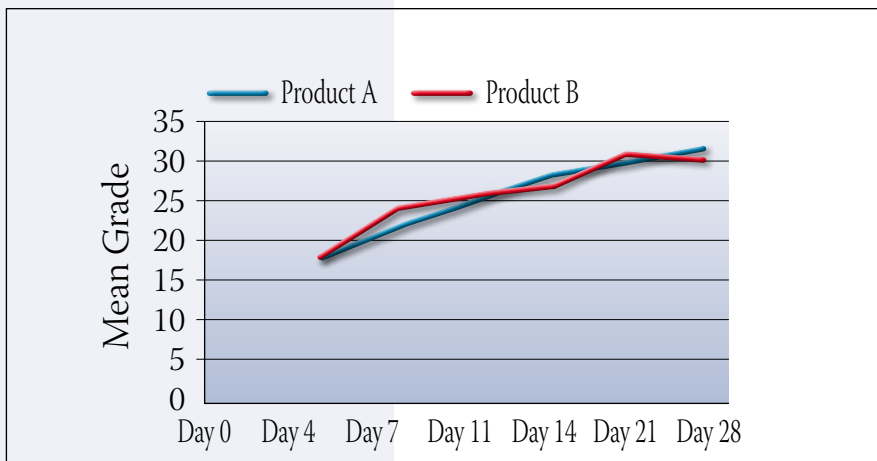


Figure 2: Mean skin hydration value for each treated area over time.

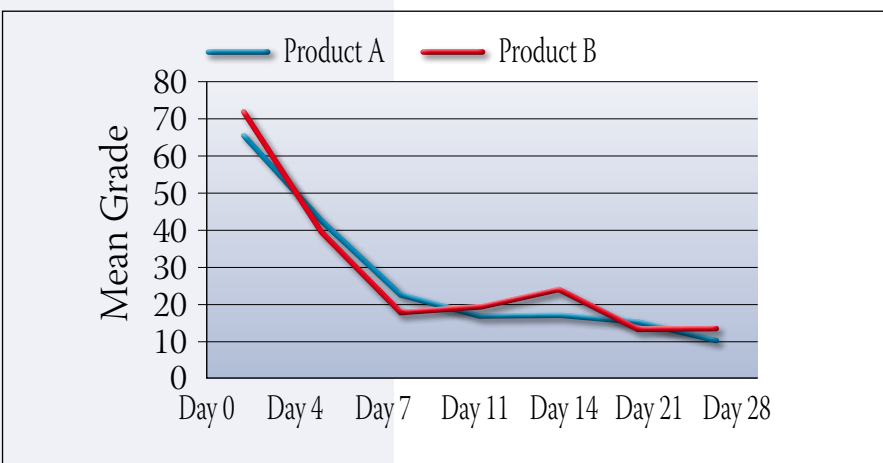


Figure 3: Mean TEWL values for each treated area over time.



*Figure 4: A typical tattoo area on day 0, i.e. shortly after creation. This tattoo was performed using black ink only. It has been selected in order to illustrate the key visual observations, and to point out areas of significance. A slight erythema can be seen surrounding each line. The 'black keys' areas exhibit a degree of oedema.*



*Figure 5: The same area as in Figure 4, at the end of the study. The local erythema has dissipated as has the oedema.*

improved over time (i.e. by day 21, there was no sign of erythema on either test site for any of the subjects). There were no statistically significant differences detected.

The mean dryness grading for each product also improved over time with no statistically significant differences between products. Oedema grading for both products improved the most between days 0 (*Figure 4*) and four — by day 14 there was no oedema reported at all for either product.

There were no statistically significant differences in the mean oedema grading between the products, at any time point. Scabbing grading for both products also improved over time. By day 28, both products showed very little scabbing

(*Figure 5*). There were no statistically significant differences in the mean scabbing grading between the products

## CONCLUSION

This study is the first known comparative trial of skin products on post-tattoo skin or, indeed, of skin assessment per se post-tattoo. In this respect, it provides the first published evidence for post-tattoo skin care.

The study methodology included visual assessments of various skin parameters, and two validated instrumental techniques for the quantitative measurement of epidermal permeability barrier function (Ashcoff et al 2009). This provides objective evidence for restoration of skin physical function after wounding.

Given the sample size and the duration of the study period, there was no opportunity to measure antimicrobial outcomes related to the inclusion of Manuka honey in the test product. Any effect of this ingredient on prevention of infection and reduction of non-irritant inflammation and oedema over time can be extrapolated from the many publications on the use of Manuka honey in clinical wound care.

The visual assessments provided no statistical differences between treatments for any parameter. In this respect, they all proved to be insufficiently sensitive to detect any statistically-significant changes. Given the nature of the 'lesions' created, this is not surprising. The subjective assessment of erythema, oedema and scabbing are intended for gross dermatological disease-related changes as opposed to the subtle nature of post-tattoo skin signs.

Thus, the study served to demonstrate that, given the sample size and the test methodologies, no statistical differences were found between the purpose-designed post-tattoo cream and the nappy care cream. The differentiating factors are, therefore, the inclusion of agents known to aid skin healing, and an absence of lanolin. **WUK**

## DECLARATION

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