

A clinical comparison of pure knitted silk and a complex synthetic skin substitute for the treatment of partial thickness burns

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Abstract

Currently, many dressings are commercially available for the treatment of burn wounds. Some of these wound dressings remain on the wound, prevent painful dressing changes, and reduce tissue scarring. Nevertheless, still a wound dressing that is cost-effective, produces good wound healing properties, and has a high patient satisfaction is needed. Standard care of superficial burn wounds differs between burn centres. This study aimed to determine a dressing with easy appliance, accurate pain control, favourable outcome, and cost-effectiveness. Therefore, we compared the widely used but expensive Suprathel with the rather new but much cheaper Dressilk in the clinical setting. In a prospective clinical study, the healing of partial thickness burn wounds after simultaneous treatment with Suprathel and Dressilk was examined in 20 patients intra-individually. During wound healing, pain, infection, exudation, and bleeding were evaluated. A subjective scar evaluation was performed using the Patient and Observer Scar Scale. Both dressings were easy to apply, remained on the wound in place, and were gradually cut back as reepithelisation proceeded *and showed similar times to wound closure*. Dressing changes were not necessary, and neither infections nor bleeding was detected. Overall exudation and pain were highest in the beginning but declined during the wound-healing phase without significant differences. In the follow-up scar evaluation *after 12 months*, patients reported overall high satisfaction. Overall, the modern dressings Suprathel and Dressilk (solely made out of pure silk) led to safe wound healing without infection and rapidly reduced pain. There was no need for dressing changes, and they had similar clinical outcomes in scar evaluation. Therefore, both dressings seem to be ideal for the treatment of superficial burns. Because acquisition costs remain one of the main factors in

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the treatment of burns, Dressilk, which is ~20 times cheaper than Suprathel, remains a good option for the treatment of partial thickness burns.

KEYWORDS

Dressilk, partial thickness burns, POSAS, Suprathel, wound healing

1 | INTRODUCTION

Worldwide, superficial burn wounds are treated with different synthetic and biological dressing materials.¹⁻⁴ Many of these commercially available dressing materials are expected to accelerate wound healing and reduce scarring. Additionally, patient satisfaction in terms of reduction of pain, dressing changes, and fluid loss is desired.^{3,5-10} Owing to the economic pressure in many hospitals, cost remains an important issue. Thus, an ideal cost-effective dressing with the best wound healing properties and high patient satisfaction is required. In this context, pure natural silk, which has been used for medical purposes for thousands of years, seems to be an interesting material. Silkworm silk, consisting of the protein fibroin, is biocompatible, has tunable mechanical properties, and leads to minimal inflammation in host tissue.^{3,11} With these advantages, it has become the focus of many wound healing studies in recent years.^{3,12} Dressilk (PREVOR, France) is a wound dressing made of pure knitted silkworm silk. After application to the wound, Dressilk first adheres to the wound base, to then slowly dry and peel off as wound healing proceeds.¹²

In a previous study, we showed that Dressilk is an equivalent alternative to Biobrane, a commonly applied biosynthetic skin substitute, regarding reepithelisation, patient satisfaction during cicatrisation,³ and better results than Polymem in terms of infection and exudation.⁴ Since then, Dressilk is the standard of care (SOC) for the treatment of superficial, partial thickness burn wounds in our burn centre.

Many other burn centres use the much more expensive Suprathel (Polymedics, Germany), a biosynthetic copolymer wound dressing mainly based on DL-lactic acid on the base of paraffin, for the treatment of partial thickness burns.¹³ It is expected to promote wound healing, reduce wound infection, and increase patient comfort.¹³

Therefore, we aimed to compare the widely used but very expensive Suprathel with the rather new and cheaper Dressilk in the clinical setting.

2 | METHODS

The present study evaluated prospectively the healing of partial thickness burn wounds after simultaneous

Key Messages

- our results showed that Suprathel and Dressilk had equal efficacy in wound healing
- they reduced the need for repeated dressing and scar formation
- this is the first study to compare the two wound dressings intra-individually for superficial partial-thickness burns

treatment with Suprathel and Dressilk in a clinical setting.

This study was reviewed and approved by the Ethical Review Committee of the University of Witten Herdecke, Germany (ethic approval number 5/2017), and the protocols adhere to the Declaration of Helsinki.

Altogether, between May 2017 and May 2018, a total of 20 patients with partial-thickness burns were treated simultaneously with Suprathel and Dressilk.

After hospital admission of a patient, burn depth was clinically assessed by a senior burn specialist according to standard clinical characteristics such as skin colour, capillary refill, skin pliability, sensation, presence of blisters, and presence of thrombosed vessels. In case the wound was assessed as superficial and the patient fulfilled the inclusion criteria, then the patient was offered to participate in the study. Complete informed consent was obtained from all patients before the start of the study. After inclusion in the study, the burn wound was mechanically debrided and cleaned with moist Prontosan cotton gaze, then the burned wound was treated partly with Suprathel and partly with Dressilk (Figures 1 and 2). During the first few days, an external dressing with fatty gauze and cotton gauze was placed on top of both dressings until exudation decreased. As reepithelisation proceeded, the dressings were gradually cut back until they could be removed completely.

2.1 | Patient enrolment

Inclusion criteria were that all patients must be at least 18 years old, have a partial-thickness burn wound



FIGURE 1 Partial thickness burn of the right forearm and hand; A, B, before and after debridement; C, during the wound healing with the two dressings (Suprathel marked with the green stripe; D, 3-month follow-up)

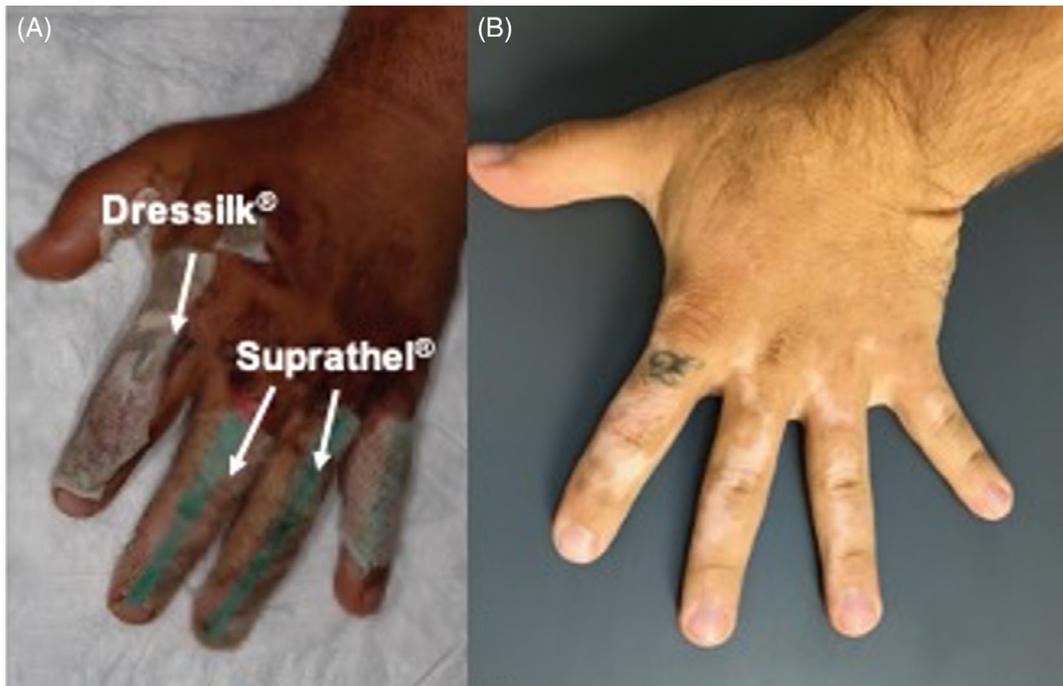


FIGURE 2 Partial thickness burn of the left hand; A, after debridement and treatment with the two dressings (Suprathel marked with the green stripe and covered with fatty gauze); B, 12-month follow-up

caused by contact with a hot surface, flames, or a hot liquid and a wound area $\geq 0.3\%$ of total burn surface area (TBSA).

Exclusion criteria were lack of acquiescence and understanding of the follow-up examination, presence of inhalation trauma, burns caused by electricity or

TABLE 1 Overview of the patient characteristics

Patient	Sex	Age	Trauma	Cause	Treated area with Dressilk	Treated area with Suprathel	TBSA (%)	Dressilk	Days until 95% wound closure	Suprathel	Days until 95% wound closure
1	M	40-60	05/2017	Flame	2% TBSA right forearm	2% TBSA right hand	10	14	14	14	14
2	M	>60	05/2017	Hot fluid	2% TBSA left thigh	3% TBSA right thigh	12	22	22	22	22
3	M	20-40	05/2017	Flame	4% TBSA left thigh	4% TBSA right thigh	9.5	17	17	17	17
4	M	40-60	06/2017	Flame	2% TBSA right hand and forearm	2% TBSA right forearm	5	22	22	22	22
5	M	40-60	06/2017	Hot fluid	2.5% TBSA right forearm	2.5% TBSA left forearm	15	13	13	13	13
6	M	40-60	09/2017	Flame	0.3% TBSA left D1 + D2	0.3% TBSA Left D3-D5	0.8	10	10	10	10
7	F	40-60	10/2017	Hot fluid	1% TBSA Right forearm	1% TBSA left upper arm	2	16-24	16-24	16-24	16-24
8	F	40-60	11/2017	Flame	0.3% TBSA Left hand	0.3% TBSA Right hand	5	8	8	8	8
9	F	<20	12/2017	Hot fluid	1.5% TBSA left distal thigh	0.5% TBSA left proximal thigh	2	16-24	16-24	16-24	16-24
10	M	20-40	12/2017	Explosion	2% TBSA left upper arm,	2% TBSA left forearm	11	12	12	12	12
11	F	20-40	01/2018	Hot fluid	1.5% TBSA right distal thigh	1% TBSA right prox. Thigh	2.5	16-24	16-24	16-24	16-24
12	F	40-60	01/2018	Hot fluid	2% TBSA Right breast	1% TBSA abdomen	16	19	19	19	19
13	M	20-40	02/2018	Hot fluid	3.5% TBSA left hand and forearm	3.5% TBSA Right hand and forearm	7	21	21	21	21
14	M	20-40	03/2018	Hot fluid	0.5% TBSA right prox. Forearm	0.5% TBSA Right hand and forearm	1	12	12	12	12
15	M	20-40	03/2018	Flame	2% TBSA right hip	0.5% TBSA Right hand	6	9	9	9	9
16	M	20-40	04/2018	Flame	2% TBSA Thorax, left forearm	2% TBSA Left upper arm and distal forearm	16	9	9	9	9

TABLE 1 (Continued)

Patient	Sex	Age	Trauma	Cause	Treated area with Dressilk	Treated area with Suprathel	TBSA (%)	Days until 95% wound closure Dressilk	Days until 95% wound closure Suprathel
17	M	>60	05/2018	Flame	3% TBSA Right upper arm	3% TBSA right forearm	7	16	16
18	F	20-40	05/2018	Hot fluid	1% TBSA abdomen	1% TBSA Abdomen, upper leg	4	13	13
19	F	40-60	05/2018	Hot fluid	2.5% TBSA right thigh	2.5% TBSA right shank	5	16-24	16-24
20	F	40-60	05/2018	Hot fluid	2% TBSA left upper leg and foot	3% TBSA left shank and forearm	5	16-24	16-24

Abbreviation: TBSA, total burn surface area.

chemical substances, localisation of the burned area in the face, or an ABSI score of 10 or more.

2.2 | Wound evaluation

The wounds were evaluated with the verbal rating scale from 0 to 10 on days 2, 4, 6, 8, 12, 16, 24, and 48 in regard to (1) pain, (2) infection, (3) exudation, and (4) bleeding. Additionally, the wounds were photo-documented regularly. External dressing changes were performed superficially to evaluate infection, exudation, and bleeding.

2.3 | Scar evaluation

Subsequently, scarring was evaluated after 12 months. The follow-up examination started with a photo documentation, followed by a scar assessment with the Patient and Observer Scar Scale (POSAS) a feasible and reliable assessment scale containing the opinion of both patients and observers.^{3,14-18}

2.4 | Statistical analysis

Microsoft Excel (2017, Microsoft) was used for data analysis and chart creation. After a thorough review of all data, SPSS (Version 21, IBM) was used for final statistical analysis. Statistical significance was accepted at $P \geq .05$.

With 20 pairs of data, a difference of two-thirds of SD could be detected ($\alpha < .05$) with sufficient power (80%). Statistically significant differences between the subgroups were identified with the Friedman and Wilcoxon tests.

3 | RESULTS

Between May 2017 and May 2018, 20 patients, 12 males and 8 females with partial thickness burn wounds, participated in the clinical trial and the follow-up examination (Table 1). Their mean TBSA was 7.1% (SD 4.88). The mean TBSA treated with silk was 1.8% TBSA (SD 1.05) and Suprathel 2.0% TBSA (SD 1.09). No adverse events occurred.

3.1 | Wound healing

All wounds healed in the first 24 days, with no complications in the form of infection or bleeding. The exact time

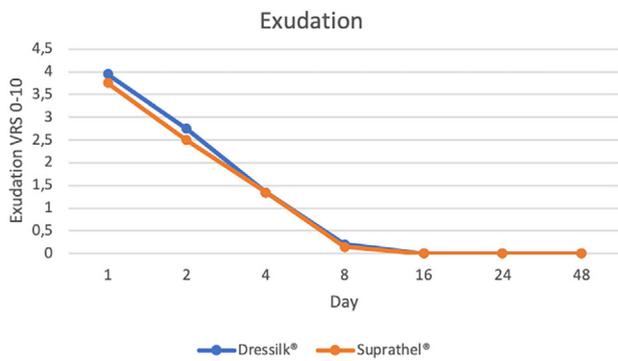


FIGURE 3 Mean exudation of wounds treated with Dressilk und Suprathel in the first 48 days

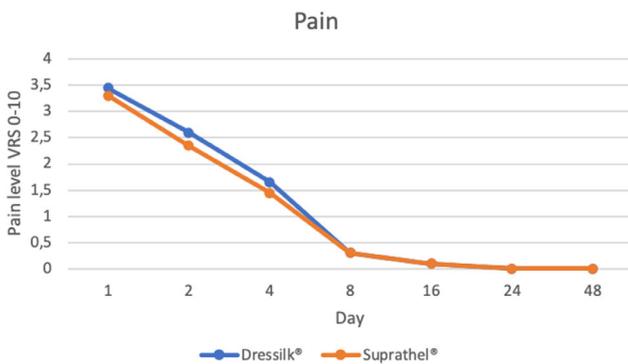


FIGURE 4 Mean pain level of wounds treated with Dressilk und Suprathel within the first 48 days

until wound close (defined as 95% initial wound area closed) was documented for 15 patients of which

14 patients showed no difference between the two dressings. The wounds of the remaining patients closed between the follow-up examination on days 16 and 24. Solely for one patient different time to wound closure was documented for Dressilk and Suprathel (Table 1). Hereby, the wounds treated with silk were closed 2 days earlier. The exudation of the wounds decreased continuously (Figure 3) without a significant difference between the wound dressings. After day 16, no exudation could be detected. Pain declined continuously (Figure 4) and solely differed significantly between the two dressings on day 2, where the wounds treated with Suprathel showed a lower pain level than the ones treated with Dressilk ($P = .025$).

3.2 | POSAS—Patient and Observer Scar Scale

In the 12-month follow-up examination, the *POSAS Patient Scale* showed no significant difference between the two dressings regarding pain, itching, skin colour, elasticity, skin thickness, and surface structure of the skin (Table 2). Additionally, the *POSAS Observer Scale* evaluated blood circulation, pigmentation, elasticity, thickness, and surface structure of the skin. Here, solely, the category vascularity (Dressilk mean 1.58, SD 0.84; Suprathel mean 2.05, SD 1.08; $P = .047$) and the overall opinion (Dressilk mean 1.68, SD 0.58; Suprathel mean 2.21, SD; $P = .013$) differed between the areas treated with the two dressings significantly (Table 3).

POSAS Patient Scale categories		Dressilk	Suprathel	P value
Pain	Mean	1.00	1.00	1.000
	SD	0.00	0.00	
Itching	Mean	1.21	1.16	.317
	SD	0.71	0.50	
Colour	Mean	1.94	2.39	.101
	SD	0.94	1.09	
Stiffness	Mean	1.00	1.33	.059
	SD	0.00	0.77	
Thickness	Mean	1.11	1.28	.414
	SD	0.32	0.75	
Skin irregularity	Mean	1.39	1.56	.429
	SD	0.85	1.20	
Overall	Mean	1.84	1.89	.739
	SD	0.96	0.81	

TABLE 2 POSAS Patient Scale after 12 months, no significant differences between the two dressings (Wilcoxon)

TABLE 3 POSAS Observer Scale after 12 months

POSAS Observer Scale categories		Dressilk	Suprathel	P value
Vascularity	Mean	1.58	2.05	.047
	SD	0.84	1.08	
Relief	Mean	1.11	1.32	.102
	SD	0.32	0.58	
Pigmentation	Mean	1.89	2.32	.244
	SD	0.66	1.49	
Pliability	Mean	1.00	1.11	.157
	SD	0.00	0.32	
Thickness	Mean	1.05	1.26	.102
	SD	0.23	0.65	
Surface area	Mean	1.00	1.11	.157
	SD	0.00	0.32	
Overall	Mean	1.68	2.21	.013
	SD	0.58	1.03	

Abbreviation: POSAS, Patient and Observer Scar Scale.

4 | DISCUSSION

To the best of our knowledge, this is the first clinical trial comparing the wound dressings Dressilk and Suprathel intra-individually in partial-thickness burns. The prospective intra-individual study design seemed particularly fitting to minimise pre-existing differences in patients, such as those in comorbidities, wound healing, pain sensation, or scarring.

4.1 | Pain and bleeding

Dressing changes in burn patients are found to be very painful and often result in bleeding. Poor pain control and disruption of the reepithelisation process through dressing changes leading to bleeding can hamper the healing process.¹⁹⁻²² One of the major advantages leading to the frequent use of Suprathel is the relatively painless and often unnecessary removal compared with other synthetic dressings.^{13,23} In congruence to this, we showed that, at day 2, the wounds treated with Suprathel seemed to be painless than the wounds treated with Dressilk. Further, one could assume that the less frequent use of analgesics minimises the cardiovascular risk of the patient. Overall, we could not show further significant differences between Suprathel and Dressilk in subjective pain assessment in the following phases of wound healing. Both dressings did not require dressing changes and no bleeding occurred. In previous studies, we showed that pain levels declined in the course of the wound healing, regardless of the type of dressing used.³ In

contrast to our recent results, in our previous study, significant differences in pain levels were found only at day 4, with a slightly higher pain level for Dressilk than for Biobrane.³ To the extent that painless healing and handling are supposed to be the supporting arguments for the use of the biosynthetic Suprathel,^{23,24} our findings show equal pain levels regardless of the applied wound dressing. These findings are very interesting in regard to a study that showed that pain and, in the later course, itch are the most disturbing scar parameters for the burn victim.²⁵

4.2 | Exudation and infection

During wound healing in burn injuries, accumulated wound fluid or wound infections have to be managed accurately.^{26,27} Burn wounds are associated with a large amount of inflammation with pro-inflammatory cytokines impairing wound healing.^{28,29} Dressilk, which consists of a natural material, was already shown to be anti-infective.^{12,30-35} Additionally, Ju et al were able to show in a burn rat model that silk fibroin significantly reduces the expression of the pro-inflammatory cytokine IL-1 α .³⁶ Because of these properties, a number of antibacterial wound dressings are based on silk fibroin.³⁷ Furthermore, silk sericin, a protein from the silkworm cocoon, was found to ameliorate wound healing by promoting the migration of fibroblast L929 cells.³⁴

Dressilk is also less exudative than other synthetic wound dressings, for example, PolyMem.⁴ Consistent with this, exudation of wounds dressed with Suprathel or

Dressilk continuously decreased until day 16, where wounds were closed and no exudation could be detected anymore (Figure 2). Similar to the well-known Biobrane, Suprathel has been shown to detach from the wound in case of an infection.³⁸ The available literature does not show a high rate of infections in wounds treated with Suprathel, which is in line with our results.^{24,38,39} Similarly, our previous study results showed not only a rapid decrease in exudation rates in dressings such as Dressilk and Biobrane but also no significant differences between the two materials.³

5 | SCAR ASSESSMENT

5.1 | Subjective scar assessment

The *POSAS Observer Scale* showed significant differences in vascularity and the overall opinion between the wounds treated with the two different dressings, with the areas treated with Dressilk being more similar to uninjured skin. Nevertheless, concerning burn rehabilitation, patient satisfaction concerning scarring among burn survivors is of high importance.⁴⁰ The appearance of the scar majorly influences the patients' opinion about the final result.^{16,41} We therefore assessed the scar focusing on patient satisfaction.

The *POSAS Patient Scale* as a validated tool^{3,15,42,43} showed no significant differences between Suprathel and Dressilk regarding pain, itchiness, skin colour, elasticity, scar thickness, surface structure, and overall evaluation for the patients after 12 months. Moreover, in our previous study, we were not able to detect significant differences between silk and the compared wound dressings.⁴⁴ As far as burn rehabilitation starts from the day of the injury,⁴⁵ both wound dressings seem to have subjectively equal efficacy for the patient according to our results.

6 | IMPACT

Ideally, scar assessment tools allow an objective statement about the benefits of different wound dressings. Overall, in our study, no major distinctions were found between the two products. In recent studies and skin engineering research, silkworm silk has gained increasing interest as a skin replacement material.^{31,46} Furthermore, the high acquisition costs of Suprathel support the use of Dressilk. Suprathel is ~20 times more expensive than Dressilk for a clinical setting. All other treatment costs for the two dressings are identical because, apart from the applied dressing, treatment is identical including costs for personnel, hospital stay, follow-up

examinations, and external dressings. Our study results showed that Dressilk is a cost-effective dressing material.

7 | LIMITATIONS

A critical pain evaluation is often difficult. In this intra-individual study design, with the two dressings being partly placed next to each other, it might be difficult for some patients to differentiate between the two dressings. If possible, the two dressings were placed on similar body parts far apart for better pain evaluation. Apart from this, every patient has an individual pain sensation. Through the intra-individual comparison, these individual pain sensations can be neglected. In a prospective randomised study setting, the individual pain assessment might be more precise, although much more patients would have to be included in the study to receive usable results.

In conclusion, in our clinic, Dressilk was already implemented in the SOC of superficial partial thickness burns. Both wound dressing materials produce a safe healing environment with similar pain and exudation levels and no infection. In this study, both materials showed good results in the subjective scar assessment after 12 months. Considering cost-effectiveness, Dressilk is a good alternative to Suprathel in the treatment of partial-thickness burns.

CONFLICT OF INTEREST

The authors disclose the following commercial associations that might create a conflict of interest in connection with the submitted manuscript: This research was supported in parts by Prevor (France). Hereby Prevor had no influence in planning and conducting the study. Furthermore, Prevor had no role in the data analysis and the submitted manuscript.

AUTHOR CONTRIBUTIONS

Lynn Schiefer, Janine Andreae, Mahsa Bagheri, Paul Christian Fuchs, Rolf Lefering, Wolfram Heitzmann, Alexandra Schulz: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content and (3) approved the final version to be submitted.

DATA AVAILABILITY STATEMENT

Data available on request from the authors

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