EPIFIBROIN 0039 DRESSING and POWDER: a valid alternative for the treatment of first-degree, second-degree and deep second-degree burns.

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First- and second-degree and deep second-degree burns often require a combination of topical treatment, to repair the tissue, combined with antibiotic prophylaxis to avoid the development of superinfections. Many products are used for the medication of these lesions, some of which are prevalently used in hospital. This involves frequent medical check-ups that could cause logistic difficulties for elderly patients and stress for younger ones.

- We therefore carried out a single-site observational study at the Policlinico Sant'Orsola Malpighi in Bologna between May 2016 and April 2017 using EPIFIBROIN 0039 DRESSING and POWDER on first-degree, second-degree and deep second-degree burns.
- This dressing is a bandage and powder made of pure silk fibroin, without sericin, protected by a permanent antimicrobial[1]. They are derived from the technology of the Dermasilk medical device, therapeutic clothing made of pure silk fibroin, which has also been used in the treatment of burns[2]. Silk fibroin is biocompatible with human skin because it shares the same amino-acid composition with a base of glycine, serine and alanine. The antimicrobial is a silane of quaternary ammonium and is not released in the surrounding micro-environment, remaining always attached to the medication[3,4].
- The primary objective was to evaluate the OBJECTIVE parameters: erythema, oedema, the presence of blisters or vesicles, erosions or ulcerations, the onset or absence of superinfection and the overall improvement of the treated surfaces and of any scarring.
- The second objective, on the other hand, was to evaluate the SUBJECTIVE parameters: itching, burning and pain, but also the ease of use of the product and its tolerability. The patients were also asked about the reduction or non-assumption of pain-killers.

THE PROTOCOL:

- After written informed consent, 15 patients were enrolled from those attending our Dermatological First Aid department for first-degree, second-degree and deep second-degree burns of various kinds and we treated them with EPIFIBROIN 0039 devices.
- After accurate cleansing with saline water, the skin was dried and the whole surface was medicated by applying EPIFIBROIN powder followed by covering with EPIFIBROIN dressing and, if necessary, specific tubular bandages or socks or gloves of Dermasilk therapeutic clothing, depending on the site affected. The medication was then repeated autonomously at home by the patient once a day until follow-up.

THE RESULTS

- Two follow-up visits were established, at 15 (T1) and 30 (T2) days, during which both the objective and the subjective parameters were evaluated. The evaluation was made by assigning a value from 0 to 3 (absent, slight, moderate, severe) to the objective parameters indicated above and as shown in Table 1; while for the symptoms of itching, burning and pain a score was assigned, ranging from 0 for absent to 10 for intolerable. During the T1 and T2 examinations, values from 0 to 3 (none, slight, moderate, high) were also attributed to the visible improvements of the lesion, referring both to the improvement of the treated area and to the improvement of scarring.

- In all cases, irrespective of the site affected by the burn, a reduction of all the **OBJECTIVE** parameters was observed before the 15-day follow-up and complete healing before the second follow-up in 12 patients out of 15 before the second follow-up (Figure 1 and 2).

Figure 1. Sum of the scores assigned to the objective parameters

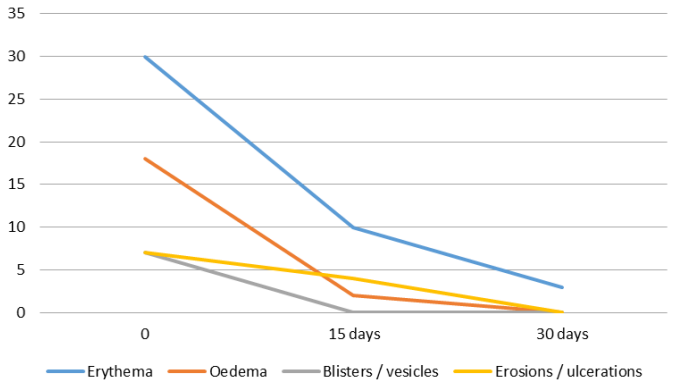
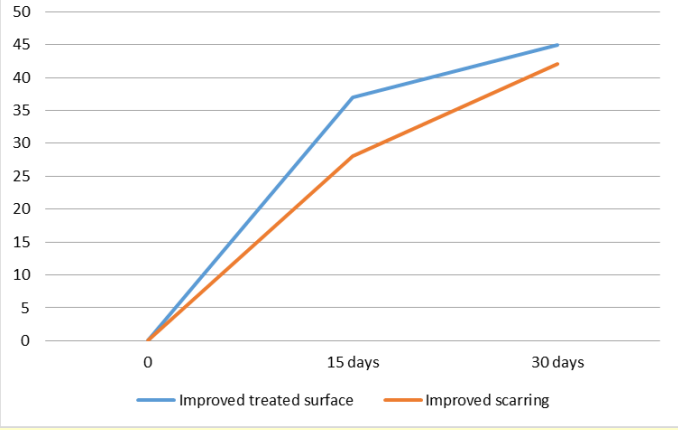


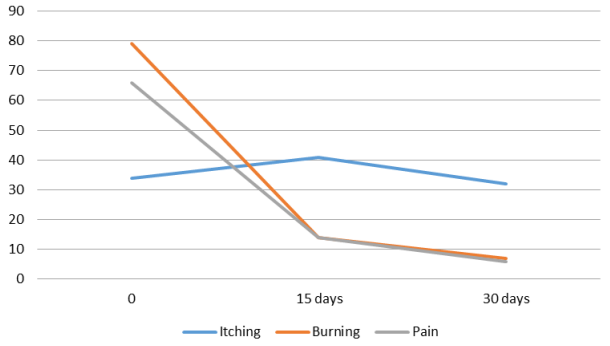
Figure 2. Improvement of treated skin



- As regards the evaluation of the **SUBJECTIVE** parameters: all patients appreciated a reduction of pain, of the need to take pain-killers, and of a burning sensation, while all reported a slight increase of itching coinciding with the repair of the tissues. This was easily solved by using moisturiser or by damping the Epifibroin 0039 Dressing bandage (Figure 3). On the whole, the product was well tolerated and easy to use.

Score	Erythema			Oedema			Blisters / vesicles			Erosions /ulcerations		
	T0	T1	T2	T0	T1	T2	T0	T1	T2	T0	T1	T2
0 Absent	0	5	12	0	13	15	11	15	15	9	11	15
1 Slight	1	10	3	12	2	0	5	0	0	5	4	0
2 Moderate	13	0	0	3	0	0	1	0	0	1	0	0
3 Severe	1	0	0	0	0	0	0	0	0	0	0	0

Figure 3. Sum of the scores assigned to the subjective parameters



CONCLUSION

- We therefore consider EPIFIBROIN 0039 DRESSING and POWDER a valid alternative to the pre-existing topical therapy for the treatment of first and second-degree and deep second-degree burns, both in hospital and for home medication, easy to manage for both elderly and young persons.

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