Epifibroin 0039 Powder and Dressing: a therapeutic aid for erosive genital and perineal inflammatory diseases

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We present the data on a study conducted in our Dermatology O.U. using the Medical Device Epifibroin 0039 Powder and Dressing in the treatment of various erosive and inflammatory conditions of the genital and perineal area, in both male and female patients, examined in the outpatients department for Sexually Transmitted Diseases of the Policlinico Sant'Orsola Malpighi in Bologna, at the regular follow-up of a basic pathology or referred to the outpatients department for a single episode. Epifibroin 0039 Powder and Dressing are a powder for topical use and a bandage 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 already been used in managing pathologies of the genital tract[2,3]. Silk fibroin is biocompatible with human skin because it is composed of the same amino-acids (glycine, serine and alanine). The antimicrobial protects the powder and the bandage permanently because it is a silane of quaternary ammonium that remains always attached to the medication[4,5].

MATERIALS AND METHODS.

The data we analysed were: age and sex of the patients, type of erosive pathology, location of the disease, use of systemic medicines (including pain-killers) and topical medicines at the time of enrolment, clinical signs and symptoms: erythema, oedema, presence of blisters or vesicles, erosions or ulcerations, grazes or fissuring, signs of superinfection, presence of itching, pain or burning.
We enrolled 15 patients (8 females, 7 males) mainly suffering from erosive pathologies such as: contact dermatitis, sclero-atrophic lichen[5], balanopostitis (from Candida or irritative) and others indicated in the table alongside (Table 1). The patients were assessed at the time of enrolment (T0), when treatment with Epifibroin Powder and Dressing was described, then after 20 days (T1), and in some cases, when necessary, after further 20 days (T2), reassessing the parameters listed above and also analysing the improvement of the treated surface, the presence of any scarring, the ease of use of the devices, their tolerability, any use of pain-killers and the onset of any adverse effects.

Table 1. Characteristics of the enrolled patients

Patient No	Age	Gender	Pathology
1	51	F	Radiodermatitis and vulvar erosion
2	74	M	Erosive balanitis
3	65	F	Contact dermatitis
4	34	M	Intergluteal erosion
5	55	M	Erosive sclero-atrophic lichen
6	75	F	Sclero-atrophic lichen and inguinal intertrigo
7	79	M	Erosive sclero-atrophic lichen
8	72	F	Erosive sclero-atrophic lichen
9	74	M	Erosive balanitis
10	85	F	Sclero-atrophic lichen and contact dermatitis
11	46	F	Vulvitis and thrush
12	84	M	Erosive balanitis
13	46	M	Erosion post-treatment with Imiquimod
14	44	F	Post-traumatic erosion
15	31	F	Post-traumatic erosion

The treatment envisaged cleaning the area to be treated with saline solution, applying Epifibroin 0039 Powder and then covering the wound with the Epifibroin 0039 Dressing gauze bandage. Treatment was to be repeated at home every 12 hours until reassessment.
At the time of enrolment and at each follow-up, we recorded a score from 0 to 3 (from absent to severe) for objective signs as indicated in table 2; for the symptoms of itching, pain and burning reported by the patients, a score was assigned from 0 for absent to 10 to intolerable; for the assessment of the treated skin, a score from 0 for none to 3 for high.

Table 2. Number of patients and respective score assigned to the objective signs, at enrolment, after 20 days and after 40 days.

Score	Erythema			Oedema			Blisters / vesicles			Erosion / ulceration			Grazes / fissuring			Signs of superinfection		
	T0	T1	T2	T0	T1	T2	T0	T1	T2	T0	T1	T2	T0	T1	T2	T0	T1	T2
0 Absent	0	10	14	2	15	15	11	15	15	0	12	14	2	12	15	13	15	15
1 Slight	1	4	1	6	0	0	2	0	0	1	2	1	1	2	0	2	0	0
2 Moderate	7	2	0	4	0	0	1	0	0	10	1	0	8	1	0	0	0	0
3 Severe	7	0	0	3	0	0	1	0	0	4	0	0	4	0	0	0	0	0

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

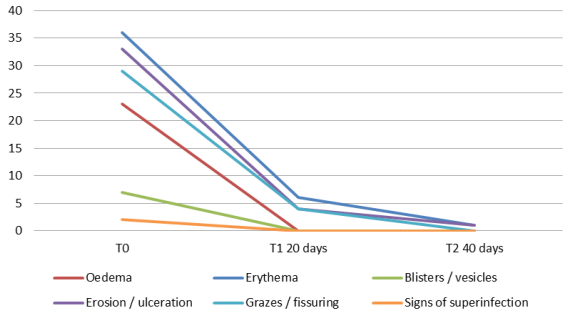


Figure 2. Sum of the scores assigned to the subjective symptoms

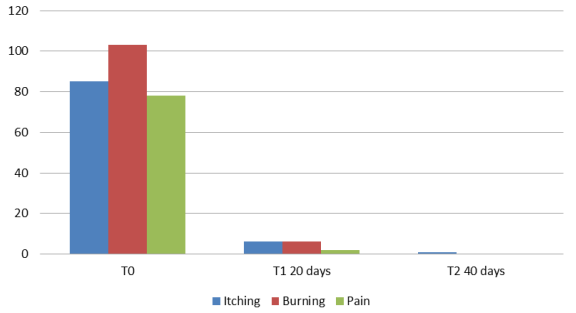
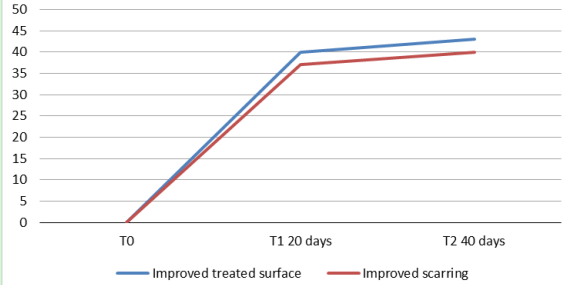


Figure 3. Improvement of treated skin



RESULTS.

During the study we witnessed an improvement of all the patients, in terms of objective signs (Figure 1), symptoms reported by patients (Figure 2) and overall improvement of the skin (Figure 3).
In particular, we recorded complete healing in 14 patients out of 15 (score zero for all the objective signs). The fifteenth patient had a complete improvement in nearly all the objective signs, while for erythema and erosion/ulceration the score decreased from severe to light.
Moreover, only 3 patients required a second assessment (T2), while in the remaining 12 (80%) the signs and symptoms cleared up within 20 days of use of the devices.
All patients expressed positive judgements regarding the tolerability of the devices, they found no difficulty in using them, they did not have to take pain-killers and no adverse effects were found resulting from their use.

CONCLUSION.

In conclusion, the results of our study show that Epifibroin 0039 Powder and Dressing can be considered a valid therapeutic aid in many different erosive inflammatory conditions of the genital and perineal area, allowing the reduction of use of topical antibiotics, antiseptics and other products habitually used for the regeneration of skin and mucosa. Our results, which were obtained rapidly, lead us to believe that Epifibroin 0039 Powder and Dressing can speed up the solution of the pathologies treated.

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