

EPIFIBROIN 0039 DRESSING AND POWDER: USE IN THE TREATMENT OF ULCERATED AND EROSIVE LESIONS AND OF PERILESIONAL ALLERGIC CONTACT DERMATITIS

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Erosive and ulcerative dermatosis require the use of topical medications, in both the acute and the chronic phase. Epifibroin 0039 Dressing and Powder are indicated in the treatment of open wounds and are able to preserve the perilesional tissue from possible irritations or contact allergies. They are a bandage and a powder¹ for topical use made of pure silk fibroin protected by a permanent antimicrobial, biocompatible with skin and mucosa because it is composed mainly of the amino acids glycine, serine and alanine, derived from Dermasilk technology².

Objectives.

To evaluate the efficacy, tolerability and safety of the use of Epifibroin 0039 dressing and powder in the treatment of burns, chronic ulcers of the lower limbs, genital ulcers and bullous diseases.

Materials and methods.

49 patients of both sexes were enrolled, aged between 27 and 92 years, referred to the Dermatology Operative Unit of Bologna University in the period between May 2016 and April 2017. Of these patients, 15 presented 1st degree, 2nd degree and deep 2nd degree burns, 15 genital ulcers, 10 bullous diseases and 9 atypical chronic ulcers of the lower limbs. The protocol envisaged an examination on enrolment and two follow-up examinations, with different timing depending on the pathology considered.

In particular, both objective parameters (clinical aspect of the wounds, overall improvement of the surface treated and of the perilesional skin) and subjective parameters were evaluated, in order to verify the tolerability and ease of use of the product.

The treatment envisaged cleaning the area to be treated with saline solution, the skin was dried and then medicated with Epifibroin powder. In the case of burns, genital ulcers and chronic ulcers, Epifibroin dressing was then applied in one or more layers to absorb the exudate properly. In the specific case of chronic ulcers, the Epifibroin dressing was covered with specific Dermasilk tubular bandages and the compressive medication was applied (Figure 1).

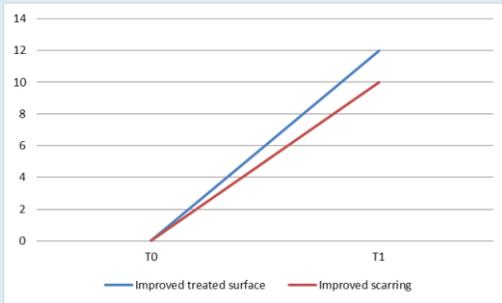
The assessment of the objective parameters (erythema, oedema, the presence of blisters or vesicles, erosions and/or ulcerations, grazes and/or fissuring, signs of superinfection) was carried out assigning values from 0 to 3 (absent, slight, moderate and severe); the improvement of the treated surface was measured assigning a score of 0 for no improvement, 1 or slight, 2 for moderate, 3 for high. To record any adverse effects, at each follow-up the patients were asked to assign a value from 0 to 10 for itching, burning and pain.



Figure 1. The 4 phases of application of the medication Epifibroin 0039 Powder, Dressing and Dermasilk tubular.

Results.

• In the treatment of **atypical chronic ulcers**, considering the observation times, the co-morbidities present and the different aetiologies treated, the best results were obtained in erosive pustular dermatoses and at the level of the perilesional skin in the care of contact dermatitis in patients polysensitised to the various medications available (Graph 1 and Figure 2).

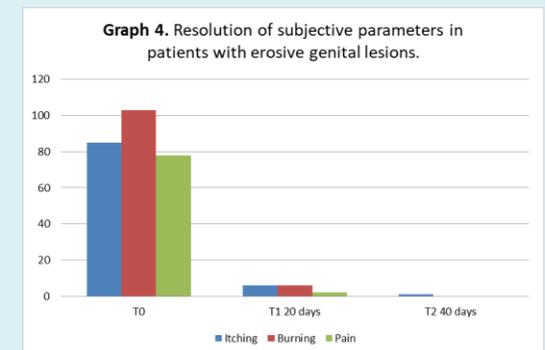
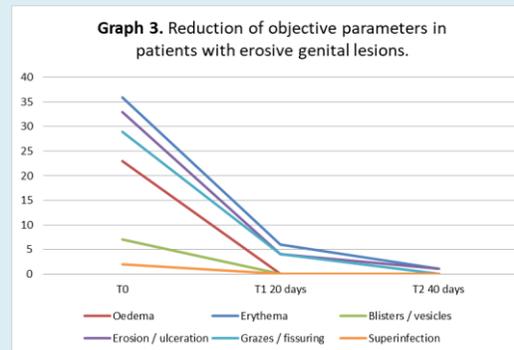
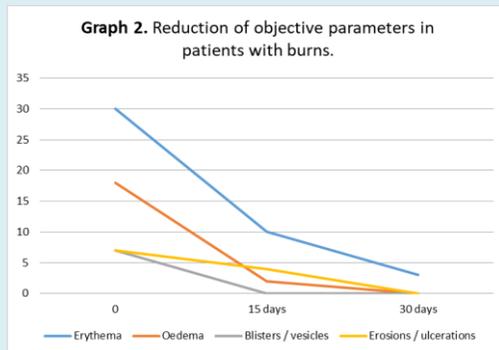


Graph 1. Improvement of treated skin at T1 after 7 days of treatment in patients with atypical ulcers.



Figure 2. State of the ulcer at enrolment (T0) and after 14 days (T2)

- In **burns** a rapid re-epithelisation of the lesions was observed with a reduction of all the objective parameters before the follow-up examination at 15 days and complete healing in 12 patients out of 15 before the second follow-up (Graph 2).
- In **erosive genital lesions** and in **bullous pathologies**, an improvement was noted at objective (Graph 3) and subjective level (Graph 4).
- No adverse events were reported.



Conclusions.

Epifibroin 0039 dressing and powder is a valid aid in the management of burns, erosive genital pathologies and in bullous pathologies. In the treatment of atypical chronic ulcers, the best results were obtained at the level of the perilesional skin, with a rapid improvement of contact dermatitis.

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3. Vinci et al. "Clinical effectiveness of Dermasilk in the treatment of diabetic ulcers" GIDM 2003, 23, 211-200.
4. Osti E. Skin ph variations from the acute phase to re-epithelialization in burn patients treated with new materials (burnshield®, semipermeable adhesive film, dermasilk®, and hyalomatrix®). Non-invasive preliminary experimental clinical trial. Ann Burns Fire Disasters. 2008 Jun 30;21(2):73-7.