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Lidia Sacchelli

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EPIFIBROIN 0039 dressing and powder as a therapeutic aid for erosive and ulcerated dermatoses of the skin and mucosa: an investigative study

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of paraesthesia three months before MDT completion suggested unresolved type 1 reaction, rather than leprosy itself. The combination of a rash with dysesthesia, trauma and burn scars, and tender nerve thickening suggest leprosy. Our patient's resistance to dapsone (without previous use of this drug) suggests infection with dapsone-resistant *M. leprae* [7]. In the presence of an undiagnosed rash with neurological symptoms, leprosy should be considered as a differential diagnosis even in developed countries with a low incidence of leprosy. ■

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[1] The University of Tokyo, Department of Dermatology, Tokyo, Japan
[2] Tokyo Women's Medical University, Department of Dermatology, Tokyo, Japan
[3] The University of Tokyo, Department of Pathology, Tokyo, Japan
[4] National Sanatorium Tamazenshoen, Tokyo, Japan
<ytsun-tky@umin.ac.jp>

Miki NODA[1]
Yuichiro TSUNEMI[2]
Yuri MASUI[1]
Asako YOSHIZAKI[1]
Hanako OHMATSU[1]
Yutaka TAKAZAWA[3]
Norihisa ISHII[4]

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EPIFIBROIN 0039 dressing and powder as a therapeutic aid for erosive and ulcerated dermatoses of the skin and mucosa: an investigative study

EPIFIBROIN 0039 dressing and powder are two class IIb medical devices made of pure sericin-free silk fibroin, protected with a permanent antimicrobial agent [1]. Silk fibroin is a biofunctional textile, which is compatible with the skin due to its amino acidic formulation including glycine, serine, and alanine, while the permanent antimicrobial agent is based on the compound, silane quaternary ammonium [1]. EPIFIBROIN 0039 dressing and powder have been created using the same technology as the class I medical device, DermaSilk®, biofunctional therapeutic medical clothing made of knitted silk fibroin fabric, protected with a lasting antimicrobial finish, particularly used by patients affected by atopic dermatitis [1, 2], but also genital lichen sclerosus [3] and vulvovaginal candidosis [4]. Sambri tested the efficacy of DermaSilk®, comparing nine different fabrics against *Lactobacillus acidophilus*, *Staphylococcus epidermidis*, *Staphylococcus aureus* and *Candida albicans*; only DermaSilk® was active an hour after application with no leaching out [5, 6].

We therefore carried out a monocentric, investigative study to evaluate the efficacy and safety of EPIFIBROIN 0039 dressing and powder for the treatment of erosive and ulcerative diseases, both acute and chronic, affecting the skin and mucosa (I and II degree burns, both superficial and deep, and chronic genital erosive diseases, such as lichen sclerosus and plasmacellular balanitis, chronic leg ulcers, and autoimmune bullous disease) in adult patients of both sexes, from May 2016 to April 2017.

A proven allergy to silk fibroin was an exclusion criterion. For every type of dermatoses, the enrolment visit was set at time zero (T0) and two follow-up visits as intermediate and final visits (T1 and T2) at different times depending on the pathology considered; at day 15 and 30 for burns, 20 and 40 for chronic genital erosive disease, 7 and 14 for chronic leg ulcerations, and 14 and 28 for autoimmune bullous disease. All patients were given instructions on how to medicate themselves at home, except for those with chronic leg ulcerations, who were dressed by registered nurses performing compression treatment (*figure 1A-D*). Note that the sched-

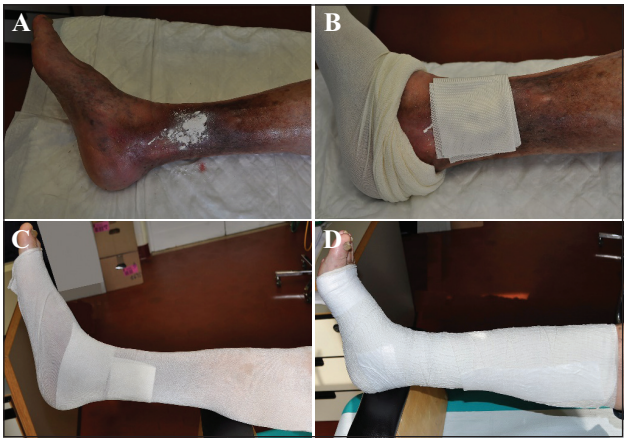

Figure 1. Visual representation of how to apply EPIFIBROIN 0039 powder and dressing. The images show the procedure for chronic leg ulcerations, but this is the same for all dermatoses analysed, apart from the compression treatment. **A)** After cleansing the area with saline water and drying thoroughly, an appropriate amount of EPIFIBROIN 0039 powder is applied on the entire ulceration; **B)** the powder is covered with a disposable EPIFIBROIN 0039 dressing; **C)** DermaSilk® tubular sleeves (or other specific garments) are applied; **D)** compression treatment is performed.

ule for ulcer treatment required at least two changes per week.

The primary endpoint of the study was to evaluate the therapeutic aid of EPIFIBROIN 0039 dressing and powder as an add-on therapy to usual care or as the only therapy for the different types of erosive and ulcerated dermatoses analysed. At every follow-up visit, scored from 0 (absent) to 3 (highest score), we evaluated erythema, oedema, blisters/vesicles, erosions/ulcerations, grazes/fissuring, and superinfections. For the secondary endpoints, the patient's evaluation of the medical device in terms of ease of use, tolerability, and reduction of need for treatment with antihistaminic or pain killer drugs was considered. We then scored, from 0 (absent) to 10 (intolerable), symptoms such as burning, pain, and itching as patient oriented evidence that matters (POEM).

We enrolled 49 adult patients (aged 27 to 92 years) of both sexes (24 males and 25 females); 15 with burns, 15 with chronic genital erosive disease, nine with a chronic leg ulceration, and 10 with an autoimmune bullous disease such as pemphigus vulgaris and bullous pemphigoid. Both primary and secondary endpoints of the study were achieved. EPIFIBROIN 0039 dressing and powder proved to be a useful therapeutic aid, not only as an add-on therapy to usual care, but also as the sole therapy for the different types of erosive and ulcerated dermatoses analysed. Moreover, patients rated these medical devices as easy to use and generally well tolerated. Furthermore, the therapeutic improvements were obtained before the first follow-up visit regarding both signs and symptoms.

Of particular note, burns achieved complete recovery within 30 days and no superinfection of the area was recorded, while all patients reported an itching sensation due to the re-epithelization process, which was easily improved by applying a lipid-rich moisturizing cream or a dampened EPIFIBROIN dressing bandage. With regards to chronic leg ulcerations, the best results were obtained in the perilesional skin, especially in polysensitized patients with contact dermatitis and in the rare cases of erosive pustular dermatosis.

In conclusion, on the basis of our experience, EPIFIBROIN 0039 powder and dressing and DermaSilk® garments may be considered valid alternatives for the treatment of chronic erosive and ulcerated dermatoses. ■

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University of Bologna, Department of Experimental, Diagnostic and Specialty Medicine, Dermatology Unit, Bologna, Italy
<lidia.sacchelli@gmail.com>

Lidia SACCHELLI
Alessia BARISANI
Paola SGUBBI
Camilla LOI
Antonietta D'ANTUONO
Valeria GASPARI
Federico BARDAZZI
Annalisa PATRIZI

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Comparison of clinical and sonographic scores in a cohort of 140 patients with hidradenitis suppurativa from an Italian referral centre: a retrospective observational study

Hidradenitis suppurativa (HS) is a chronic-relapsing, debilitating, autoinflammatory disease characterized by painful nodules, abscesses, and sinus tracts in the apocrine gland-bearing skin [1-4]. In order to assess disease severity and response to treatment, many scoring systems have been proposed [1], among which Hurley classification [5], used to distinguish between three stages from mild to severe, is the most frequently used.

Ultrasonography was introduced to better assess disease severity [6-8]. A three-stage scoring system, SOnographic Score in Hidradenitis Suppurativa (SOS-HS), was suggested by Wortsman *et al*. [7]. Kimball *et al*. [9] adopted a six-stage clinical scoring system, the Physician Global Assessment (HS-PGA), based on the number of inflammatory nodules, abscesses, and fistulae, which is potentially useful also for sonographic evaluation.

Here, we report the results of a retrospective observational study of a large cohort of HS patients in which concordance between clinical and ultrasonographic data was assessed. Only HS patients with visible lesions were included. Each patient was clinically classified according to Hurley [5] and HS-PGA [9]. Ultrasonography was performed on the same day as the clinical consultation for axillae, inguinal folds, and perineal and perianal regions. We used a Hitachi Arietta V70 sonographer with a linear 18-5-MHz multifrequency probe and classified each patient according to SOS-HS [7] and US HS-PGA, a scoring system set up by our group, although not yet validated. US HS-PGA is based on definitions of anatomical abnormalities used for diagnosing HS and assessing disease severity in SOS-HS [8], namely:

– a pseudocyst corresponding to a nodule on clinical examination;