

## Efficacy profile of a re-epithelializing ointment in the healing of abrasions

### Efectividad de una pomada reepitelizante en la evolución de heridas abrasivas

The integrity of the skin is essential for health, as it acts as a barrier against physical aggression, pathogens, and adverse factors, while maintaining internal homeostasis.

Most dermatological diseases are associated with defects in the skin barrier function. Cutaneous lesions, such as abrasion wounds or first- and second-degree thermal, physical, or chemical burns, are among the most common conditions that disrupt this barrier.

As the largest and most exposed organ of the human body, the skin is subjected to multiple factors that may alter wound healing, including inadequate oxygenation,<sup>1</sup> medical history,<sup>2</sup> age,<sup>3</sup> and the patient's nutritional status.<sup>4</sup> Infections represent the complications with the greatest impact on re-epithelialization,<sup>5</sup> and their prevention is approached through multidisciplinary strategies to minimize complications and ensure proper healing.

The objective of this study was to evaluate the safety and efficacy profile of a barrier-effect ointment in the re-epithelialization of skin lesions, without comparison with other treatments or placebo.

Over a 3-month period,

an open-label, non-controlled, single-center observational study was conducted in the Emergency Department of *Hospital Universitario Donostia* (recruitment) and at the *Biodonostia Health Research Institute* (intervention).

The product evaluated was a re-epithelializing repair ointment containing the RC5® complex, Skin Barrier Protection®, and lanolin. The ointment was applied three times daily by spreading a generous layer over clean, dry skin until complete absorption, without covering the lesion.

Patients older than 18 years, functionally independent, and presenting with non-exudative, non-infected skin lesions at the emergency department were included. Exclusion criteria were pregnancy or hypersensitivity to any component of the medical device. Withdrawal criteria included the appearance of abundant exudate, bleeding, signs of infection, allergy, voluntary withdrawal, or non-compliance with the protocol.

After signing informed consent, patients started treatment at Visit 1 (V1), with follow-up at 7 days (V2), end of treatment at 14 days (V3), and post-treatment visit at 21 days (V4). At each visit, the principal investigator and sub-investigator captured high-resolution photographs using a Canon® IXUS 185 camera. Images were independently analyzed by two observers using the FEDPALLA perilesional skin assessment scale and a 6-category scale (0–5 points) for percentage of re-epithelialization.<sup>6</sup> Further-

more, a subjective evaluation questionnaire (1–4 scale: completely disagree to completely agree) assessed wound progression and product efficacy. Patient satisfaction was rated on a 1–7 scale (dislike completely to like very much). This scale was also used to calculate the Net Promoter Score (NPS) using the formula:  $NPS = (\text{Promoters } 1-3 - \text{Detractors } 6-7) / \text{Total responses} \times 100$ . A NPS score  $> 0$  was considered good and  $> 50$  excellent. Data analysis was conducted in Python using NumPy, pandas, SciPy, and Matplotlib. Sample size calculation followed the infinite population formula to estimate the mean re-epithelialization score with  $\pm 0.5$  precision and 95 % confidence. Adverse events were recorded throughout the study.

The study was approved by the Medical Research Ethics Committee of Euskadi (Code PS2018039).

The sample included a total of 25 patients; 60 %, men aged 19–83 years. Lesions were mainly abrasions (88 %), burns (4 %), chafing injuries (4 %), and other lesions (4 %). Most lesions (88 %) involved  $< 1$  % of total body surface area according to Wallace's Rule of Nines.<sup>7</sup> Lesions were located on the arms (36 %), legs (44 %), trunk (12 %), and face (8 %), primarily on the right elbow and knee (40 %). Three patients withdrew from the study.

Patients treated with the repair ointment showed that their mean FEDPALLA score had improved from 19.32 at baseline to 24.64 at day 21. At V1, re-epithe-

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lialization was 0 %. After 21 days, wound re-epithelialization reached 96.36 %. The most pronounced improvement occurred within the first 7 days (47.5 %). At V4, 19 patients (86.36 %) achieved complete (100 %) re-epithelialization (Figure 1).

A total of 50 % of the patients treated with the ointment reported that they liked the product. Reductions in redness, itching, and irritation, as well as increased hydration and softness, were confirmed by 80 % of patients. A total of 75 % of patients perceived improvement in their wounds within the first 10 days. In the calculation of the NPS value, 50 % of patients treated with the ointment reported that they liked the product and 40 % stated that they liked it quite a lot, yielding an NPS of 90.9. During the study, two treatment-related adverse events were recorded (dry pustules).

The healing of traumatic wounds presents a nursing challenge that requires appropriate assessment, treatment, and follow-up to optimize outcomes. The FEDPALLA scale—which measures hydration, dermatitis, vascularization, wound edge condition, and perilesional deposits—increased by 5.32 points from V1 to V4, reflecting a 21.6 % improvement in perilesional skin assessment and in the prognosis of re-epithelialization after 21 days of application. Furthermore, wound re-epithelialization increased by 96.36 %, with the most pronounced improvement occurring during the first 7 days of use.

These findings are consistent with former studies involving the RC5® complex and Skin Barrier Protection®. Extracts of *Opuntia ficus-indica* promote the formation of a protective film on the skin due to the bioadhesive properties of their polysaccharides.<sup>8-10</sup> In addition, randomized clinical trials indicate that hyaluronic acid reduces wound area following laser surgery and is associated with high patient satisfaction.<sup>1</sup> This effect may also be related to its ability to form a protective viscoelastic film that facilitates solute transport and re-epithelialization.<sup>12,13</sup> Similarly, *in vivo* studies indicate that lanolin can increase the rate of wound re-epithelialization and

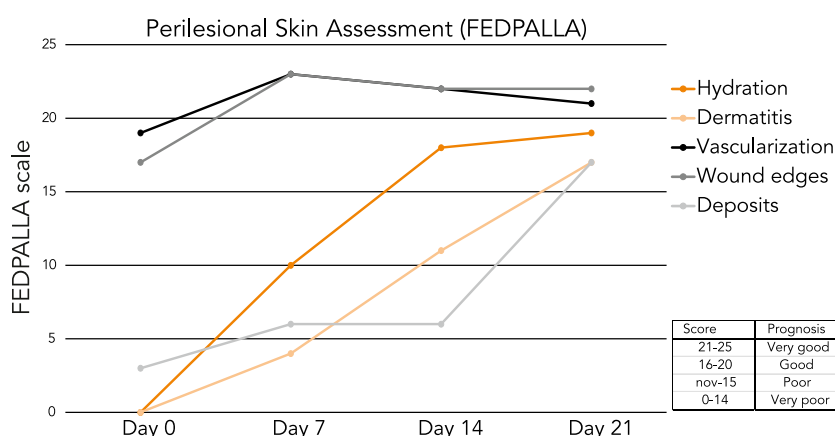


Figure 1. Evolution of parameters according to the FEDPALLA scale.

dermal thickness.<sup>14</sup> The improvement in the evaluated parameters may be attributed to the synergy of the components and the barrier-protective properties of the product.

During re-epithelialization, complications may arise that psychologically affect patients. Therefore, patient satisfaction with the effectiveness of the product in wound evolution and its use was monitored. In addition to the evaluated treatment, prior wound cleansing remains essential.<sup>15</sup>

This study has limitations, including the absence of a control group, the small sample size, and the lack of blinding during data collection, which may have introduced some degree of bias.

In conclusion, the repair ointment is safe and effective in the healing of abrasive wounds. Both quantitative and qualitative patient evaluations support its clinical utility.

## ARTICLE INFORMATION

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