Skin regeneration in dermatological practice: Real-world-evidence insights on usage and indications of Skin Regeneration Ointments

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INTRODUCTION & OBJECTIVES

The regeneration of healthy and functional skin is not always easy. Despite recent advances in therapeutic medicine skin repairing ointments (SRO), based on Glycerin, Dexpanthenol, and Bisabolol are interesting adjunctive measures to optimize the regeneration environment after iatrogenic and/or other acquired and/or inherited skin conditions that go along with degeneration of the skin barrier and can avoid formation of permanent skin lesions. New insights in the traditional recommendation behaviour of dermatologists in regard to skin regeneration are highlighted below.

MATERIAL & METHODS

We conducted a prospective, clinical, uncontrolled, real-world, multicentre study over a period of 2 weeks. Dermatologists were asked to record their recommendation behaviour of Skin Repairing Ointments (SRO) and the type of skin indications where they recommended to apply an SRO. None of the subjects was allowed to apply topical medication (e.g. topical or systemic antifungal, antibiotics, glucocorticosteroids) during the study and one week before entry of the study. As a prerequisite, dermatologists were advised to not apply SRO on open or bleeding wounds but only in situations where the skin barrier was intact.

Study intervention was once daily application of a commercially available SRO containing Glycerin, Bisabolol, and Dexpanthenol. Expert Grading and Self-Assessment was assessed on a 10-point scale (0=healthy skin and 10=very severe skin condition). All adverse events were recorded. Results were recorded at beginning, at 4 weeks and at 8 weeks.

RESULTS

In this multicentre study in 9 countries 847 patients' questionnaires were received and in 841 cases an expert assessment was additionally available. Patients mean age was 39.3 years. 591 (69.8%) where female, 255 (30.1%) male participants. 190 (22.8%) patients reported to suffer from allergies (all types). 39 (4.6%) of subjects were excluded from the efficacy & tolerability evaluation because they were in need to use pharmaceuticals during the study period. All but two participants applied the product at least once daily and 627 (75.2%) applied the product at least twice daily.

In 209 (24.9%) the SRO was recommended by dermatologists to treat cracked hands and cuticles and in 191 (22.7%) cases to treat cracked feet, especially heels. In 68 (8.1%) of cases the SRO was indicated in order to accelerate skin regeneration after (chemical) peelings, ablative and non-ablative laser interventions. In additional 115 (13.7%) subjects the dermatologist recommended the regular use of an SRO after other iatrogenic and non-iatrogenic superficial skin lesions. 29 (3.4%) paediatric patients received an SRO to prevent from diaper rash. Other indications (298 cases, 35.4%) included the preventive use of an SRO for anti-chafing and protection from friction during fitness and sport or to prevent from intertriginous inflammations (inguinal, axillar) but also was recommended for eczema relief (e.g. atopic dermatitis, contact dermatitis).

After two weeks of use the vast majority (786/93%) of subjects liked the product a lot or even very much, whereas 59 (7%) liked the product only a little. In 90.8% (769) patients assessed their improvement as good or very good whereas 63 cases (7.4%) improved only moderately. In 1.2% (10 cases) the application did only poorly work (figure 1). 4 cases

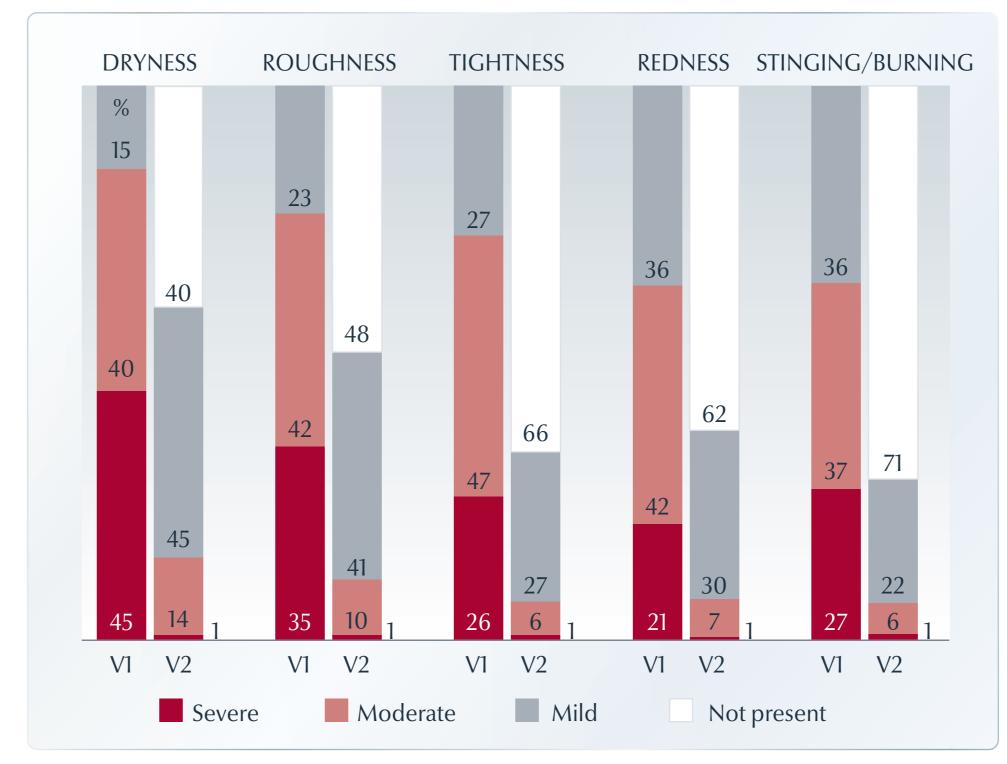


Figure 1: Patient Assessment – Severity of symptoms at visit 1 and visit 2. Patients without symptom at visit 1 excluded; 'No answer' excluded +McNemar's Test for homogeneity, test not performed if fewer than 20 relevant pairs of values. *Significant difference between visit 1 and visit 2, Bonferroni-Holm correction of significance level for multiple comparisons (p<0.001).

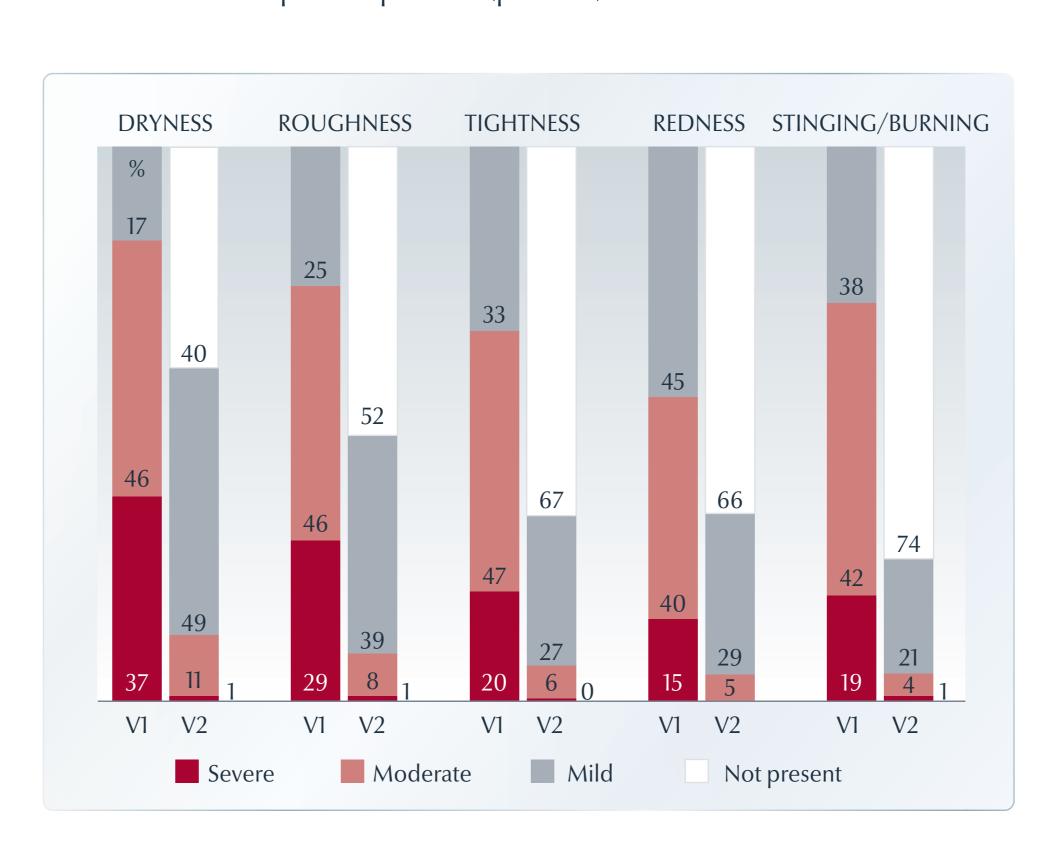


Figure 2: Expert Grading – Severity of symptoms at visit 1 and visit 2. Patients without symptom at visit 1 excluded; 'No answer' excluded +McNemar's Test for homogeneity, test not performed if fewer than 20 relevant pairs of values. *Significant difference between visit 1 and visit 2, Bonferroni-Holm correction of significance level for multiple comparisons (p<0.001).

(0.5%) did not improve at all. Product tolerability was vastly assessed as satisfactory (5%/42), good (29.8%/252 cases) or very good (63.4%/537 cases), whereas only 13 (1.6%) subjects reported fair or even poor skin compatibility. 95% confirmed effective skin protection and even 97% confirmed reduction of skin dryness. 93.5% of panellists agreed that the

product leads to faster skin regeneration. At the end of study, 97% of participants plan to use the product in the future and more than 98% willing to recommend the SRO formulation to family and friends.

Expert assessment after 2 weeks of use showed a significant improvement in skin dryness, roughness, tightness, erythema and stinging/burning sensation, if they were present at beginning of study (figure 2). In all but two cases the investigator rated the skin tolerability as satisfactory (17/2.1%), good (184/22.9%) and mostly as very good (599/74.7%). 2 cases reported slight stinging and burning sensation and also showed an erythema. 99.3% of dermatologists plan to integrate the product in future recommendations. 99.5% confirmed accelerated skin regeneration after superficial iatrogenic and non-iatrogenic skin lesion and effectiveness against dry and rough skin.

CONCLUSION

Taken together, the results of this study illustrate the multiple purposes and most of all the efficacy of an SRO in a multitude of skin conditions and shed light on the recommendation behaviour of dermatologists in regards to postlesional skin regeneration, prevention of eczema in sensitive skin and recurrent intertrigo or diaper rash as well as functional treatment of hyperkeratosiform conditions like dry or even cracked heels and cuticles of nails. Only some panellists needed a pharmaceutical treatment during the study period. Further studies are needed in order to assess the impact on drug-prescription behaviour of a regular SRO application.