INTEREST OF A SPECIFIC DERMO-COSMETIC PRODUCT IN THE MANAGEMENT OF HAND-FOOT SYNDROME INDUCED BY CHEMOTHERAPIES

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INTRODUCTION

Hand-Foot Syndrome (HFS) is the major adverse effect seen in patients undergoing anti-tumoral chemotherapies. HFS of any grade appears during the first 6 weeks of treatment on up to 71% of patients, and is characterized by dysesthesia, erythema, dryness, cracking, hyperkeratosis, pain, even ulceration, on palms, fingers, and soles. HFS can impair patients' quality of life, but it is associated with patients' treatment efficacy. The only effective method for HFS management is temporarily dose reduction or treatment discontinuation. Therefore, this study aims to evaluate the management of HFS with a specific dermo-cosmetic product in subjects treated by chemotherapies.

MATERIALS & METHODS

The **TEWL** (transepidermal water loss) was measured on 12 subjects aged 24 to 60, with dry and disrupted skin (TEWL ≥ 9) after 28-days (D28) twice-daily application, to evaluate skin barrier function. A **multicentric double-blind randomized clinical study** was performed under oncological control where 42 patients (average age 62.7), starting an anti-tumoral treatment known to induce HFS, applied the product on the hands and feet at least once a day (or as often as necessary) for 56 days. Several evaluations were performed by the oncologists at each visit (D0, D14, D28, D42, D56) (see **Table 1**) and by the patients (see **Table 2**).

RESULTS

At D28, the **TEWL significantly decreased by -23.0%** (vs -2.4% for the non treated zone; $p<0.05$), demonstrating that the product improved skin barrier function.

Table 1: *Clinical evaluation by the oncologists*

Evaluations at each visit	Results
Incidence of HFS (CTCAE v5.0)	Grade 1 HFS occurred on 7 out of 42 subjects during the study period
Time to onset of HFS to first occurrence after D0	Grade 1 HFS episodes occurred after 27.9 ± 16.2 days
Recovery time after D0	24.0 ± 9.5 days from grade 1 to no grade
Evolution from grade 1 to grade 2	No subject progressed to a grade higher than grade 1
Time until modification of the antitumoral treatment	No subject modified the antitumoral treatment because of HFS (neither dose reduction nor treatment interruption)
Time until the prescription of a treatment	No prescription of curative treatment for HFS among the subjects that developed HFS
Evolution of dermatological symptoms (4-point scale, or 100-point VAS for pain and pruritus)	No subject developed oedema, bleeding, blisters, hyperpigmentation, pain or dysesthesia, but the 7 subjects who developed HFS, presented other symptoms (**Figure 1**).
Global product's efficacy (5-point scale)	The product was effective to very effective on 97.4 to 100% of the patients.
Safety of the product (4-point scale)	Very well tolerated

Figure 1: *Details of the clinical observations of the 7 patients developing grade 1 HFS*

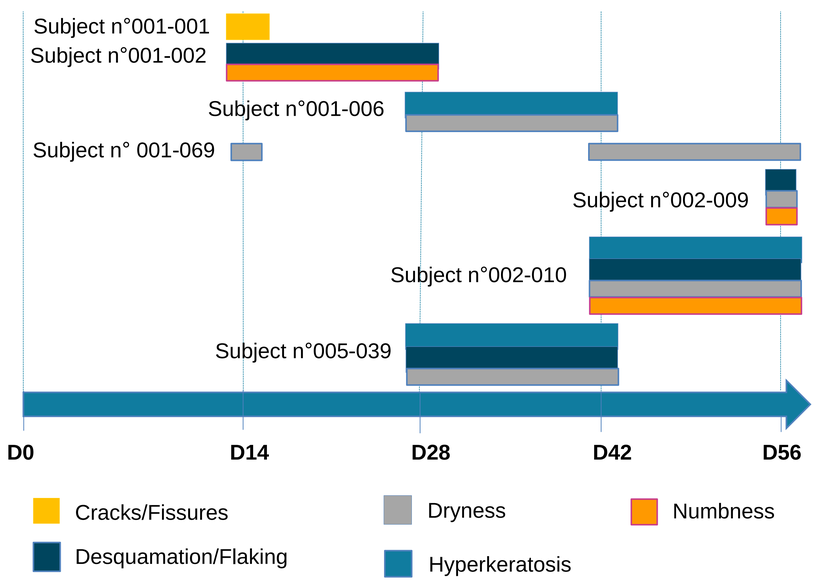

Table 2: *Subjective evaluations by the subjects*

Evaluations	Results
Lesions and symptoms (daily log answers)	The same symptoms reported by the oncologists (**Figure 1**).
Quality of life (DLQI every 7 days)	The impact on quality of life among all subjects remained stable (0.7/30) during the study period.
Product's efficacy (questionnaire at D56)	97.4% of them considered that their skin was hydrated, soothed, comfortable, and smoothed at D56
Safety of the product (daily log completion)	Very good tolerated for all of them

CONCLUSION

These results show that this specific dermo-cosmetic product improves skin barrier function and is suitable to patients prone to develop HFS. Daily application of a skincare by these patients should allow them to better manage their skin weakening, reducing further cutaneous complications, and improving their quality of life.

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