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Clinical Trial of Gripin® Cream (Maitake Mushroom Extract Cream) for Xerosis Therapy

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Introduction

Xerosis is defined as dehydration of stratum corneum and characterized by scales, fissures, erosions, and callus in the skin which impairs the skin barrier function. Xerosis is considered to be caused by aging and various environmental factors and is also a common symptom that occurs in chronic skin diseases such as atopic dermatitis. Since patients with xerosis exhibit symptoms, including a scaly and rough skin surface and uncomfortable feeling of itching or pain, effective candidate(s) to structurally and functionally improve the impaired skin barrier may be of benefit to these patients. We have found novel evidence that *Grifola frondosa* (Maitake mushroom) extract (Gripin ®) facilitates the biosynthesis of sebum, which plays an important role in maintaining the skin barrier, in hamsters and humans *in vivo* and *in vitro* (***POSTER No. 113***). In the present study, to clarify whether or not Gripin™ may be effective for xerosis, we performed a clinical trial investigation of 0.2% Gripin® cream (**舞潤®**, MaiJun) (**Fig. 1**) in the antebrachial and crural of patients with mild to severe xerosis.

Patients and Methods

Sixty patients (25 males and 35 females, 75-97 years old) were initially enrolled in the trial. Twelve and thirty-five patients completed the entire 1- and 5-week treatment (once a day) with 0.2% Gripin® cream, respectively. Evaluation of treatment benefit was based on measurement of skin desquamation.

Fig. 1 Gripin® cream, 舞潤® (*MaiJun*)

Results

1. After 1-week of treatment with Gripin® cream, scales and fissures in the antebrachial and crural regions of patients were in remission (Fig. 2). In addition, clinical improvement was observed in most patients (Table 1).
- The 3-weeks treatment with Gripin® cream was found to decrease the grade from severe to moderate and mild by evaluation of the skin conditions in antebrachial [A] (36 regions in 18 patients, $p<0.01$) and crural regions [B] (34 regions in 17 patients, $p<0.05$) (Fig. 3).
- Gripin® cream was more effective for mild and moderate conditions (<grade 3) rather than severe (grades 4 and 5) in xerosis patients (Fig. 4).

Conclusion

These results suggest that Gripin® cream is likely to be useful for remission and/or cure of xerosis by the possible mechanism that it augments the level of sebum to restore barrier function in the skin.

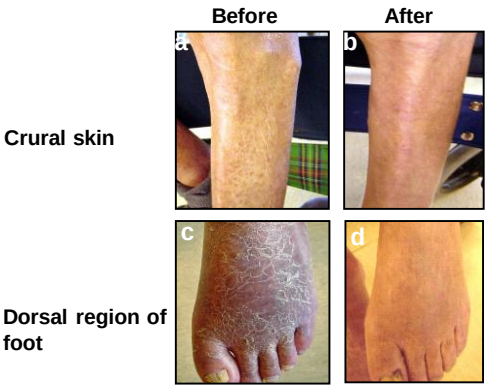

Fig. 2 Gripin® cream is responsible for the cure of xerosis
Data shows a male patient (77 years old) with moderate xerosis (*panels a and c*, *Before*). When the crural region and dorsal region of the feet of the patient were treated once a day with Gripin® cream for 1 week, the skin condition improved (*panels b and d*).

Table 1 Improvement of the skin condition in antebrachial and crural regions of patients with xerosis

	Antebrachial regions		Crural regions	
	Right	Left	Right	Left
Number of patients	9	11	12	12
Number of improved patients	7	10	12	10
Improvement rate (%)	77.8	90.9	100.0	83.3

When the antebrachial and crural regions of patients with xerosis were treated once a day with Gripin® cream for 1 week, the improvement of skin condition was evaluated by measurement of skin desquamation.

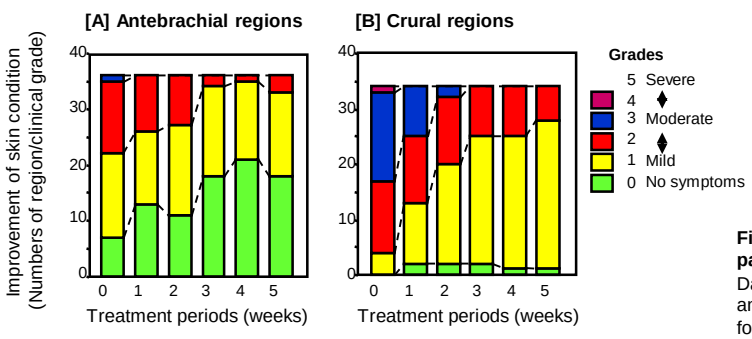

Fig. 3 Long-term treatment of Gripin® cream improves skin condition in patients with xerosis
Statistical analysis was performed using Friedman test.

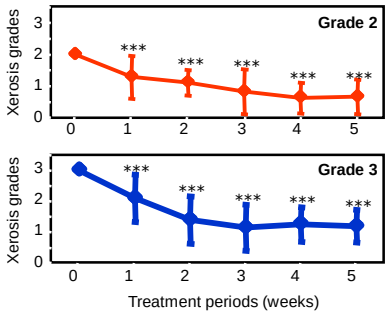

Fig. 4 Clinical evaluation of disease grades in Gripin® -treated patients with mild (Grade 2) and moderate (Grade 3) xerosis
Data are shown as mean ± SD of disease grades in anterior antebrachial and crural regions of patients treated with Gripin® cream for 5 weeks. Statistical analysis was performed using ANOVA and Fisher test. ***, significantly different from untreated patients (0 week) ($p<0.001$).