

Clinical efficacy of FootCare Cream in the management of foot cracks

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Abstract

Aim: The purpose of this study was to evaluate the safety and efficacy of FootCare Cream in the management of foot cracks, when applied twice daily for 4 weeks. **Methods:** This study was an open, prospective, non-comparative, phase III clinical trial carried out. After initial examination, each subject was given a tube containing FootCare Cream. The investigator applied the cream at the initial visit to demonstrate proper technique, all patients were instructed to wash feet properly and then apply cream, twice daily. All the patients were followed up at weekly intervals for a period of 4 weeks, and the symptom score evaluation was done during each follow-up visit. **Results:** A total of 50 patients with mean age 44.26 years were enrolled in the study. All subjects completed the study as planned. Significant reduction in number of cracks was seen at the end of the study. Also there was significant reduction in other symptoms such as scaling, pruritus, wrinkles, pain, pigmentation and laxity of skin over the foot. There were no adverse effects reported during the study and compliance to the use of formulation was excellent. **Conclusion:** The findings reported demonstrate that Himalaya's FootCare Cream helps in healing of cracks, reducing scaling and pain. None of the volunteers experienced any hypersensitivity reactions. Therefore, it may be concluded that the test medication FootCare Cream is safe and efficacious in management of foot cracks.

Key words: Foot cracks, Pain, Pruritus, FootCare Cream.

Introduction

Dry cracking heels are a condition of thickening and fissuring (cracking of the bottom part of the heels). It is a common foot problem that is often referred to as heel fissures. Cracked heels are commonly caused by dry skin (xerosis), and become more complicated if the skin around the rim of the heel is thick.

In normal skin, the stratum corneum serves as a protective barrier against excessive evaporative water loss and environmental insults. The stratum corneum of the foot must contain more than 10% of water to remain soft and pliable; when water content drops below 10% it becomes rough, with possible scaling and cracking. The loss of moisture from the stratum corneum and intercellular matrix leads to xerosis or dry skin. People with excessively dry skin have a

predisposition to heel cracks, edges of heels with thick and dry skin gets cracked easily.

Other Causes of cracked heels can be inactive sweat glands, prolonged standing, wearing shoes with an open back, going barefoot, obesity, surgery to the lower extremities, diabetes, thyroid disease, psoriasis, athlete's foot, improperly fitting shoes, high arches, heel spurs and mal-alignment of the metatarsal bones of the feet. Zinc deficiencies can also contribute to the condition.

Cracked heels are seen often in the elderly and females suffer more frequently than males. The problem becomes worse during cold climatic conditions

These cracks and fissures, serve as a portal of entry for bacteria. They are associated with an increased risk of cellulitis and foot ulceration that, if left unchecked, can eventually lead to amputation.^{1,2}

Maintaining the proper hydration of the epidermis, particularly the stratum corneum, can control this condition. Treatment now is limited to application of moisturizers designed to soften the stratum corneum and alleviate the scaliness.³

FootCare Cream manufactured by The Himalaya Drug Company, Bangalore, India is a novel herbal formulation with anti-microbial, analgesic, and wound healer activities. It contains Madhu and extracts of *Shorea robusta*, *Zingiber officinale*, *Trigonella foenum-graceum* and *Curcuma longa*.

This clinical study was conducted to evaluate the safety and efficacy of FootCare Cream in management of foot cracks. As this condition is seen more in females, this study was conducted on female subjects only.

Aims of the Study

The purpose of this study was to evaluate the safety and efficacy of FootCare Cream as a result of twice daily application for 4 weeks.

Materials and Methods

This study was an open, prospective, non-comparative, phase III clinical trial conducted at D.Y. Patil Medical College, Pimpri, Pune, India.

All the volunteers who were willing to participate in the trial were screened for inclusion in the study. To be included, patients had to be only females, 18 years of age or older with

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cracks in both feet. The main exclusion criteria included history of peripheral vascular disease, pre-existing immunosuppressive disease, known dermatologic diseases such as psoriasis, eczema, ichthyosis vulgaris, use of any topical steroids or moisturizers on the feet in the previous 2 weeks, known hypersensitivity to topical preparations, presence of erysipelas and vasculitis. Patients who had participated in a clinical study with a moisturizing product within the previous 4 weeks or who had a history of poor compliance with medical treatment also were excluded.

Patients who met eligibility criteria were enrolled and their informed consent was obtained. After initial examination, each subject was given a tube containing FootCare Cream. The investigator applied the cream at the initial visit to demonstrate proper technique, all patients were instructed to wash feet properly and then apply cream, twice daily.

Primary and Secondary Endpoints

The predefined primary efficacy endpoint was a decrease in the number of cracks, scaling, pruritus, wrinkles, pain, pigmentation and laxity of skin. The predefined secondary safety endpoints were short and long-term safety, as assessed by the incidence of adverse events and patient compliance to therapy.

Follow-up and Assessment

All the patients were followed up at weekly intervals for a period of 4 weeks, and the symptom score evaluation was done during each follow-up visit.

The following 4-point scale was used for assessment of symptoms: 0-Nil, 1-Mild, 2-Moderate, 3-Severe. The patients were questioned at each visit regarding pruritus and pain.

After fourth week patients and investigator independently rated the overall improvement on the following 5-point scale: 1-Nil, 2-Mild, 3- Moderate, 4- Good, and 5-Excellent.

Adverse events

All the adverse events, either reported or observed by the patients, were recorded with information about severity, date of onset, duration, and action taken regarding the study drug. Relation of adverse events to study medication was predefined as "Unrelated" (a reaction that does not follow a reasonable temporal sequence from the administration of the drug), "Possible" (follows a known response pattern to the suspected drug, but could have been produced by the patient's clinical state or other modes of therapy administered to the patient), and "Probable" (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient's clinical state).

Patients were allowed to voluntarily withdraw from the study, if they had experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing from the study, efforts

were made to ascertain the reason for dropout. Non-compliance (defined as failure to take less than 80% of the medication) was not regarded as treatment failure, and reasons for non-compliance were noted.

Statistical Analysis

Statistical analysis was carried out using repeated measures of ANOVA followed by appropriate Posthoc test. Parametric repeated measures of ANOVA was analyzed using Bonferroni's multiple comparison test and non-parametric repeated measures of ANOVA was analyzed using Friedman test followed by Dunnett's multiple comparison tests to find out the level of significance. The minimum level of significance was fixed at $/K0.05$. The severity score was expressed as mean $\pm$ SD, and signs and symptoms were evaluated using 0-4 grading scale. Statistical analysis was carried out using Graph Pad Prism software Version 4.01.

Results

A total of 50 patients with mean age 44.26 years were enrolled in the study. All subjects completed the study as planned. Significant reduction in number of cracks was seen at the end of the study. Also there was significant reduction in other symptoms such as scaling, pruritus, wrinkles, pain, pigmentation and laxity of skin (Table 1). This effect was seen as early as two weeks and remained so till the end of the study.

Results indicated that FootCare Cream shows reduction in foot cracks and other associated symptoms. It is well tolerated by all the patients.

There were no adverse effects reported during the study and compliance to the use of formulation was excellent (Table 2).

Discussion

For most people foot cracks are a cosmetic problem, but when the fissures or cracks are deep the skin becomes painful. If treatment is not initiated early, not only can the pain become intense, but the cracks/fissures may bleed. Once bleeding occurs, the skin is prone to bacterial infections and athletes foot.

Cracks in the feet can be controlled with consistent application of moisturizer. Himalaya's FootCare Cream has ingredients which have moisturizing, analgesic, and wound a healer promotive activity which helps in healing cracks and reducing pain associated with it. The main objective of this study was to evaluate the safety and efficacy of FootCare Cream in management of foot cracks. Results showed significant reduction in number of cracks and other symptoms associated with foot cracks in studied population. The synergistic action of all the ingredients of FootCare Cream provides continuous healing process.

Honey has been shown to be clinically useful in various settings involving soft-tissue infections and non-healing

wounds.¹ Chrysin from honey is a natural, biologically active compound extracted from honey possesses potent anti-inflammation, anti-cancer and anti-oxidation properties.² It also possess antimicrobial activities.³ Honey is reported to be soothing applied to wounds and to reduce pain from burns, in some cases giving rapid diminution of local pain.⁴ Unlike other topical antiseptics, honey causes no tissue damage: in animal studies it has been demonstrated histologically that it actually promotes the healing process⁵. The effectiveness of honey as a dressing on infected wounds is attributed in part to its antibacterial properties.⁶⁻⁹

Oleanolic acid, tannins are the prime alkaloids present in *Shorea robusta*. The plant has astringent, detergent, antiseptic activities. It is used in different skin disorders.¹⁰ It possess wound healing activity.¹¹

Rhizome of *Zingiber officinale* contains an essential oil containing monoterpenes and sesquiterpenes, pungent principles etc., which are beneficial in multiple therapeutic

activities. Shagol and Ginegrol present in the rhizome have anti-inflammatory and analgesic effect.¹² German Commission E reported that the seed of *Trigonella foenum-graceum* is with secretolytic, hyperemic, and mild antiseptic activity.¹³ Root extract of *Curcuma longa* has antimicrobial activity against commonly encountered micro-organisms.¹⁴ It also has anti-inflammatory and spasmolytic activities.¹⁵ Extract of *Curcuma longa* and honey have potent wound healing activity.^{16,17}

Conclusion

The findings reported demonstrate that Himalaya's FootCare Cream helps in healing of cracks, reducing scaling and pain. It is useful in making feet soft and smooth. None of the volunteers experienced any hypersensitivity reactions. Therefore, it may be concluded that the test medication Himalaya's FootCare Cream is safe and efficacious in management of foot cracks.

Table 1 : Evaluation of Effect of Himalaya's FootCare Cream

Assessment Measure		Baseline	Week1	Week 4	Significance
No. cracks	Left foot	10.91±4.39	5.61±3.09 ^a	1.61±2.41 ^{b,c}	^{a,b,c} p<0.001
	Right foot	10.52±5.21	5.57±3.20 ^a	1.48±2.45 ^{b,c}	^{a,b,c} p<0.001
	Both feet	21.43±9.28	11.17±6.09 ^a	3.09±4.80 ^{b,c}	^{a,b,c} p<0.001
Scaling		1.022±0.612	0.304±0.446 ^a	0.130±0.310 ^b	^a p<0.01
Pruritus		1.065±0.728	0.370±0.458 ^a	0.043±0.209 ^b	^b p<0.001
Wrinkles		0.261±0.423	0.043±0.209	0.000±0.000	NS
Laxity of skin		0.109±0.300	0.000±0.000	0.000±0.000	NS
Pigmentation		0.152±0.318	0.022±0.104	0.022±0.104	NS
Pain		0.065±0.229	0.043±0.144	0.022±0.104	NS

Values are expressed in Mean ±SD.

^a: as compared to Baseline vs. Week 2;

^b: as compared to Day 0 vs. week 4;

^c: as compared to Week 2 vs. week 4;

NS: Not significant

Table 2: Study of adverse effects after use of FootCare

Parameters	On 1 st application	At the end
Erythema	Nil	Nil
Edema	Nil	Nil
Pruritis and urticaria	Nil	Nil
Heat sensation	Nil	Nil

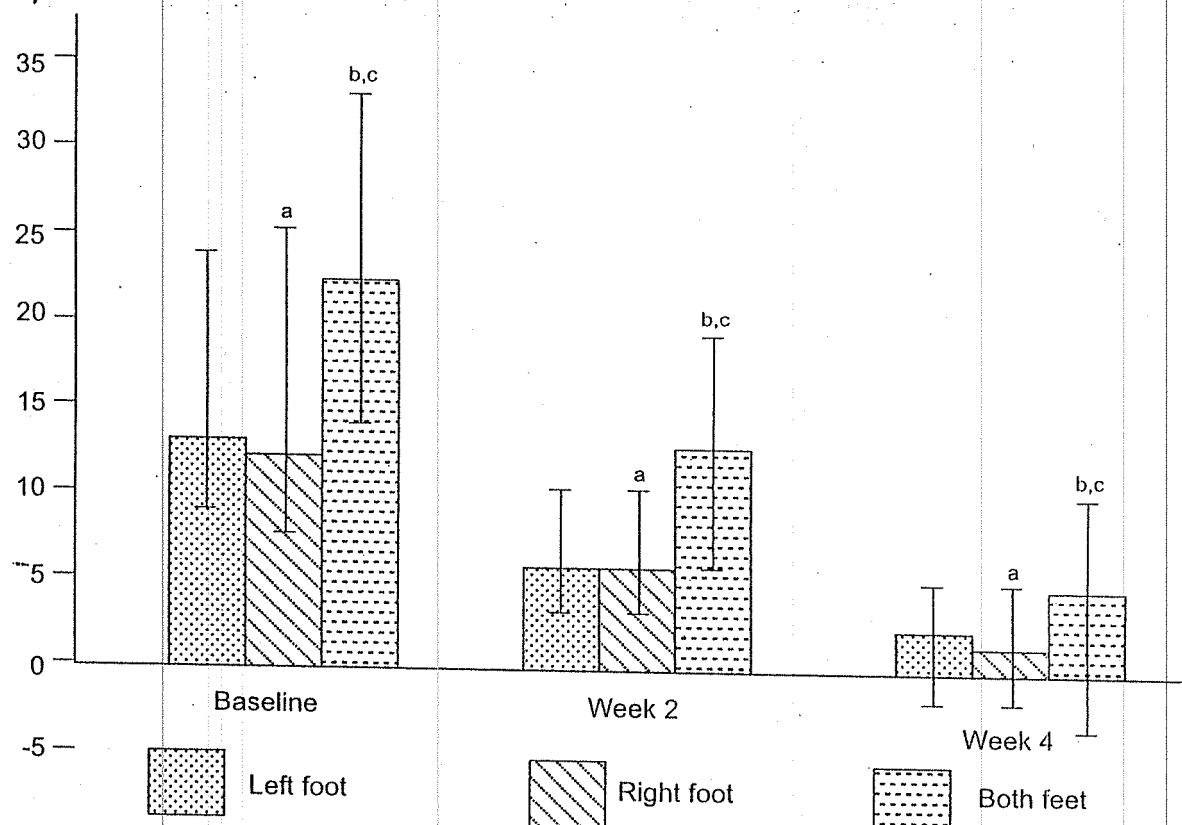


Figure 1 : Effect of FootCare Cream.

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