



Formula II Skin Care Cream Drug Study
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Intro:

Fissures in the plantar foot are a common dermatological condition that is encountered by many dermatologists, internists, and podiatric surgeons. A fissure is defined as “a linear loss of continuity of the skin's surface or mucosa that results from excessive tension or decreased elasticity of the involved tissue¹.” A study in 2004 in the American Journal of Epidemiology showed that in a random sample of 784 adults aged 65 years or greater, 14.1% of the population was found to have a crack/fissure in their foot². Fissures are more commonly present in the elderly and diabetics; however, they can be seen in every patient demographic.

The skin is the largest organ of the body and has a vast array of components to it; some of which include its depth, sensory components, sweat glands, and moisture content. The plantar epidermis of the foot is approximately 1.5mm thick. The outermost cells in epidermis, the keratinocytes, are layered in just such a manner to “prevent harmful environmental intrusion, but to aid in resistance to water loss³”. As one ages, the water content starts to decrease, which leads to a lack of elasticity, and as this occurs, it is common to see dry skin that will lead to fissuring of the skin. Fissuring of the skin can become painful due to an increase in mast cells and histamine levels which result in chronic itch and inflammation⁴. They are also a break in the body's defense mechanism and can lead to serious infections. As these become very painful, many people seek out needed treatment.

Many treatments for fissures include creams, emollients, and lotions. These treatments are intended to moisturize the skin and to keep the water content in the keratinocytes from being lost, which in turn decreases the inflammatory response from the dry skin and itching to the areas which will also cause an inflammatory response. When one starts to scratch the area of fissures, this can break down the skin further and cause open wounds which can lead to infections. This is commonly seen in

people who have sustained burns. This is known as the post-burn itch, which is known to cause dry skin and wounds⁵. Also, by keeping the water content in the cells by creating these moisture barriers, the epidermis has less chance of breaking down and cracking. Formula II Skin Care Cream is formulated specifically for this use. It contains Mineral Oil, Purified Water, Beeswax, Paraffin, Ceresin, Sodium Borate, and Sodium Stearate. Compounds found in the product, such as mineral oil and beeswax, create a lipophilic or hydrophilic barrier over the epidermal skin layer. They also decrease prostaglandins and leukotriene B4 which are both in the inflammatory pathways⁶. Blocking these inflammatory pathways leads to a decrease in pain, which is usually the most symptomatic problem that a patient complains about when they have a fissure in the foot.

The reason for this drug study is to examine the efficacy of Formula II Skin Care Cream in the treatment of plantar foot fissures over a 3 month consecutive period of time. To our knowledge, there is no official study to show that the Formula II Skin Care Cream is useful for the treatment of plantar foot fissures. The inclusion criterion for this study was any person willing to participate regardless of medical comorbidities, age, gender, or sex. The exclusion criteria are patients who are allergic to any of the compounds in this product, or anyone associated with the Formula II Skin Care Cream product. This study was conducted by David Haley DPM, Section Chief, Podiatric Medicine & Surgery at Christiana Care Health System, Newark, Delaware; as well as Michael Budzinski DPM PGY-3, Chief Resident, Podiatric Medicine & Surgery Residency at Christiana Care Health System, Newark, Delaware.

Methodology:

There were a total of 39 patients who took part in this study from January of 2014 to February of 2015. Day one of the study is considered the first instance the patient presented to the secondary author's private office (DH). All patients were given a 4oz sample bottle of the Formula II Skin Care Cream on their first visit. At the start of the study, each patient had a subjective complaint of the fissure described on a numeric scale 1-5 with 1 being severe, 2 as bad, 3 as significant, 4 as mild, or 5 as resolved. The fissures were also classified by the podiatric surgeon/author DH as a full thickness fissure as 1, partial thickness fissure as 2, superficial thickness fissure as 3, and a resolved fissure as 4. From the start day of the study to each subsequent month follow up, the patients' subjective compliance was also measured on a scale with 1 as full compliance, 2 as good compliance, and 3 as resolved. The numeric scales used was subjectively created for the patients by author DH. At the first evaluation, each subject was instructed to apply the cream to the fissure once a day until the fissure was completely resolved. Each patient followed up once a month for 3 consecutive months. At each follow up visit, author DH classified the wound before questioning each patient about his or her subjective compliance to the daily usage of the cream as well as their subjective description of the fissure.

Results/Statistical Analysis:

Of the 39 total patients who took part in this study, the majority of patients were female (N=24; 61%) and all (N=39, 100%) had a baseline compliance score of Full. The age at baseline ranged from 13 to 86 years with a mean age of 61 years (Standard Deviation (SD) = 171). The percentage of patients in each compliance score, class score, and subjective complaint score category at each time period are

listed in Table 1. In Table 2, the mean (standard deviation (SD)) compliance score, class score and subjective complaint scores over time are displayed.

Generalized estimating equations were fit to examine the rate of change over time for subjective compliance scores, DH assessment classification scores, and subjective complaint measures. There was a statistically significant increase in the average class score over time ($\beta = 0.46$; 95% CI: 0.41, 0.51) as well as the average subjective complaint over time ($\beta = 0.62$; 95% CI: 0.55, 0.68), where higher scores indicated more resolution. Improvements in these two metrics were observed at each time point (see Figure 1). Compliance scores increased slightly between baseline and the one-month time period, but then the overall rates remained constant over the next 3 months with no statistically significant change between 1 month, 2 months or 3 months ($p > 0.1$).

Table 1. Baseline, 1 month, 2 month and 3 month measures of compliance, class and subjective complaint scores

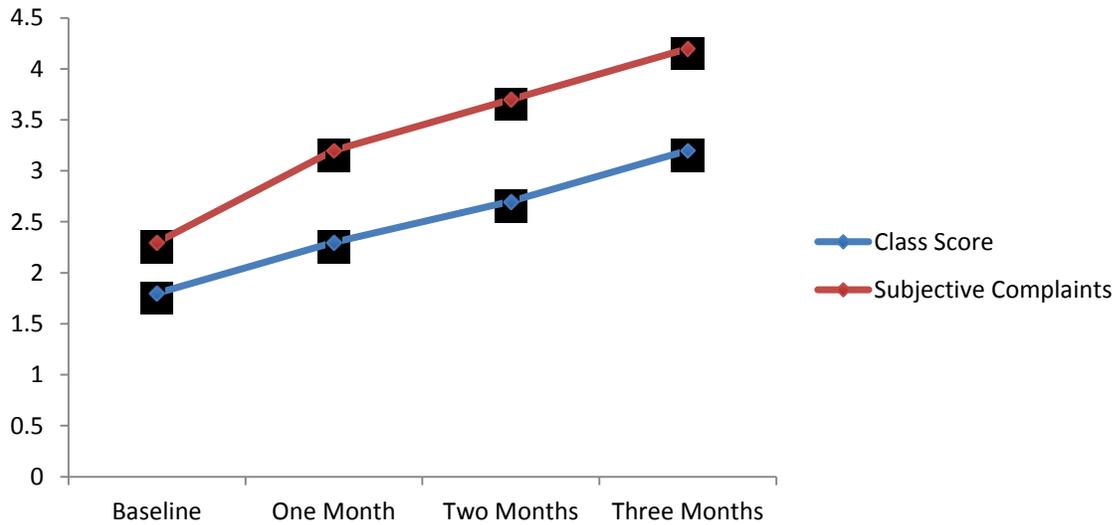
	Baseline N=39	1-Month	2-Month	3-Month	
Compliance, N (%)					
Full	39 (100%)	32 (82%)	32 (82%)	35 (90%)	
Good	0	7 (18%)	6 (15%)	2 (5%)	
Resolved	0	0	1 (3%)	2 (5%)	
Class Score, N (%)					
Full	9 (23%)	3 (8%)	0	0	
Partial	28 (72%)	24 (61%)	12 (31%)	2 (5%)	
Superficial	2 (5%)	11 (28%)	26 (66%)	27 (69%)	95% *
Resolved	0	1 (3%)	1 (3%)	10 (26%)	success rate
Subjective Complaint, N (%)					
Severe	9 (23%)	0	0	0	
Bad	10 (26%)	6 (15%)	3 (8%)	1 (3%)	
Significant	20 (51%)	20 (51%)	8 (21%)	4 (10%)	
Mild	0	12 (31%)	26 (66%)	21 (54%)	87% *
Resolved	0	1 (3%)	2 (5%)	13 (33%)	success rate

* Side annotations inserted by MSI Enterprises, Inc.- makers of Formula II Skin Care Cream.

Table 2. Mean scores for compliance, class, and subjective complaint over time

	Baseline N=39	1-Month	2-Month	3-Month
Compliance				
Mean (SD)	1.0 (0)	1.2 (0.39)	1.2 (0.47)	1.1 (0.49)
Class Score				
Mean (SD)	1.8 (0.51)	2.3 (0.64)	2.7 (0.51)	3.2 (0.52)
Subjective Complaint				
Mean (SD)	2.3 (0.83)	3.2 (0.73)	3.7 (0.70)	4.2 (0.72)

Figure 1. Graph of mean class score and subjective complaint score over time.



Discussion:

Various creams and products on the market are used in treating fissures in the foot. Many of these products do not have studies showing their efficacy to time of healing fissures in the foot. Some studies show various compounds that are in Formula II Skin Care Cream, beeswax and mineral oil, as being effective and safe for the treatment of anal fissures, burns, dermatitis, and xerotic skin^{5,6,7}. The effectiveness lies in that many of these compounds act as a barrier to keep water and moisture within the epidermis. There are some studies that even look at how far into the dermal layers of skin that these compounds penetrate^{4,8}.

Formula II Skin Care Cream is an effective treatment to use on plantar foot fissures. In this study, we observed the rate of change over a three month period of time had statistically improved for the average class score and the average subjective complaint. Even though the compliance score was statistically insignificant, we noted most patients used the cream on a daily basis. This is likely because of the statistical improvement seen in the class scores and the subjective complaint. As the wounds were starting to heal and become less painful, it appears patients continued using the product or began to use the product more.

Although this study is effective, it does have many limitations. For one, the data is gathered from a low sample size. There is no assessment of how far the cream was penetrating the dermis, if at all^{4,8}. A bias may be present as patients were aware they were participating in a study testing the efficacy of the cream and this could have an effect on the subjective complaints as well as the amount of times the patients would have used the product. Another bias present may be that only one clinician examined the feet and collected all of the data. Lastly, the patients were told to apply the cream to their feet daily; and the amount of cream was not specified. Potentially, the amount of cream could affect the rate at which the fissures could heal.

In conclusion, this drug study found Formula II Skin Care Cream effective in reducing the severity of plantar foot fissures. Over time, a patient can eventually heal plantar foot fissures due to the daily use of Formula II Skin Care Cream, as shown with the class scores and the subjective complaints of the patients. Therefore, we recommend the usage of Formula II Skin Care Cream for the treatment of fissures in the foot as long as there are no contraindications to its use.

References:

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