



Formulation And Evaluation Of Heel Fissure Cream Using Mustard Oil

¹Bhushan R. Rathod, ²Aniket A. Sathe, ³Pranoti B. Ohal, ⁴Rushikesh G. Bachal, ⁵Mayuri N. Shrikhande

¹Student, ²Student, ³Student, ⁴Student, ⁵Guide

¹Department of Pharmacy

Arihant College of Pharmacy, Ahmednagar, Maharashtra, India – 414005.

I. ABSTRACT

Objective : The main aim of our research was to develop cream for cracked heel & formulation consisting of mustard oil for the treatment of cracked heels.

Methods: Cracked heel cream formulation consisting of mustard oil, Paraffin wax, camphor, Glycerine, rose water was prepared. Evaluation parameters such as irritancy, spreadability, stability, after feel & washability are studied on the cream & used appropriate amount of ingredients in formulation for safety purpose.

Results: The developed cream consisting of Mustard oil was found to be safe, effective & satisfying for the Treatment of cracked heels.

Conclusion: It can be concluded that prepared cracked heel cream without irritancy having anti-inflammatory, analgesic, moisturizing property can be used to protect the skin & treatment of cracked heel.

Keywords: Cracked Heel Cream, Mustard oil, Herbal Cream.

II. INTRODUCTION

India's Cosmetic Cream market is evolving at rapid speed, filled by Television advertisement by the celebrities and the rapidly changing Lifestyles. India's proactive Fast Moving Consumer Goods (FMCG) market has seen the significant Growth in last two decades and Average growth rate of 20% per annum. Indians are witnessing a Paradigm shift from traditional methods of using home products to Modern methods of using branded cosmetics and Kind of cream.

Along With Plantar skin has a unique structure compared to skin on Other parts of the body. Cracks on heel have no age limit and it can Affect anyone for that matter irrespective of the sex, Colour and origin. Most of the time, cracks are Occupational like farming or those people whose job Demands continuous standing. Age, excessive walking On uneven surface, prolonged standing on hard floors, Uncomfortable, not so fitting or open back footwear, Unhealthy diet, obesity, diabetes, psoriasis and other Skin allergies, unhygienic condition of feet or high Exposure of feet to dust, dirt, germs etc. are common Causes. Cracked heels are commonly observed in Females because of their household works performing Without any precautions like working in unhygienic area With bare foot or in field workers and labourers. Patients of cracked heels are observed in all Socioeconomic to higher groups in society. It also Occurs recurrently due to seasonal variations.

Healthy skin is the primary requirement of the Beauty as well as attractive personality. Any weakness Or breach in beauty of skin leads to great handicap or Social stigma. It may reduce confidence of the person.

In Ayurveda cracked heels are called as padadari. It is now Considered as one of the major cosmetic health problem in both Sex. Its major incidence is seen in people who cover long Distances daily often without proper foot care. It directly affects Routine of an individual. Heel fissures are a sign of lack of Attention to foot care or lack of moisturizing. Medically, Cracked heels are also known as heel fissures. Fissures are Regular linear cut wounds on the epidermis. Sometimes it may Get deep into the dermis and become painful. Excessive Pressure on the feet pads make the feet expand sideways. As the Skin, surrounding the sides of the feet are dry they crack and Cause cracked heels.

Fissures are splits in the epidermis that can extend to and involve the dermis. These are usually found at sites where the skin is under tensile stress, for example around the heel margin, being associated with Hyperkeratosis and anhidrosis. The main Symptoms for patients are pain, itching, Bleeding and embarrassment. Discomfort Can make walking and weight bearing Difficult, whilst the embarrassment of Thick, callused heel fissures can Psychologically affect a person. Moreover, such lesions can act as a Portal of entry for secondary infection. Systemic and peripheral states that affect Skin quality can render some people more Prone to the condition than others, such As patients with diabetes, peripheral Vascular disease, rheumatoid arthritis, Pregnancy, obesity, systemic sclerosis, Dermatitis, ichthyosis, palmoplantar Keratoderma, psoriasis and tinea pedis. Historically, management of dry fissures Has required removal of the source if Possible. For instance, in-shoe devices can Be used to alter forces on the tissue under Stress, or the removal of allergens or Treatment of tinea pedis etc. can reduce or Eliminate the underlying cause. Debridement of hyperkeratotic tissue and Optimising epidermal strength is also Paramount to assist resolution. This can be Achieved in controlling stratum corneum Water content, by hydrating anhidrotic Skin with an emollient or hydrocolloid Dressing. However, anecdotally, dry heel Fissures are difficult to heal because of the Mechanical stresses brought about by Weight bearing. Standard treatments for Hyperkeratosis are of little use once a Painful fissure develops. Thus, the Requirement to promote healing and, more Importantly, instant and lasting pain relief By means of closing the fissure should be explored. Fissures are generally Considered to develop with dry skin resulting from decreased perspiration associated With autonomic neuropathy.

The purpose of this study was to investigate the cut-off Point of skin hydration with fissure and factors associated With low skin hydration in patients. Our findings Are expected to contribute to preventive care for foot fissure In patients. The heel fissures conditions are often unsightly and can be The source of discomfort and pain leading to the deterioration of The quality of life of the affected persons. The elderly patient And people with diabetes added complications of peripheral Vascular disease place the foot at risk of ulceration, infection And amputation. In the older population callus can affect Balance and consequently increase the risk of falls.

III. MATERIAL AND METHOD

3.1. Raw Materials

3.1.1. Paraffin wax

Paraffin wax Penetrate Through the Hard skin to allow oil to go in and soften Hard skin. Paraffin wax Have antiseptic, Moisturizing, Exfoliating properties and used in many foot treatment, which is also improves the Blood circulation. Paraffin wax is obtained from petroleum by dewaxing light lubricating oil stocks. It is used in candles, wax paper, polishes, cosmetics and forms a base for medical ointments. It's different from Bees Wax. *Deanna montrose et al.* Paraffin wax can help with the aches and pains. individuals who soaked their hands in paraffin wax experienced immediate pain relief. A good paraffin wax soak can improve skin in many ways, even for those with conditions such as scleroderma, or hardening of the skin. A study conducted by *Sandqvist, Akesson, and Eklund (2004) et al.* found those who soaked in paraffin had softer, more elastic skin than those who did not. Along with improved elasticity, paraffin can reduce stiffness in the joints. The heat used in warm paraffin soaks can help soothe muscles and improve blood flow making joints and hands feel more relaxed. Paraffin is wax, which hardens when cool. When this wax is removed from the skin it takes with it dead skin and dirt leaving the hands smoother. Paraffin is also an emollient, which means it helps make skin soft. The heated wax also helps trap in moisture by opening pores, leaving hands feeling softer, smoother, and better than ever.

3.1.2. Mustard Oil

Mustard oil Have Anti-inflammatory, Analgesic, Antimicrobial, Antifungal and Antibacterial properties. Which is helps to reduce inflammation, pain, Block microbial growth, prevent fungal infections and fight bacterial infections. Other properties or benefits like improve circulation, boosts your appetite, promote sweating, prevents phlegm and also used as tonner. Mustard oil contains a high amount of selenium and magnesium, which gives it anti-inflammatory properties[22]. Mustard oil has several vitamins like A, B complex and E along with omega-3 fatty acids and alpha-linolenic acid. These ingredients help in hydration and prevent the damage caused by free radicals which eventually cause premature ageing. Mustard oil also encourages collagen production.

3.1.3. Camphor

Camphor is analgesic and antifungal. Which helps to reduce pain and heal wounds in Heel fissure. Also soften calloused heels and Stops the growth of fungus. In cosmetics and personal care products, Camphor functions as a fragrance ingredient , denaturant and plasticizer . It is also used in OTC drug products (external analgesics, topical antitussives, anorectal products). Many people use it to relieve irritation, itching, and pain. As an ingredient in different products, it can also help ease inflammatory conditions and chest congestion. Camphor exhibits a number of biological properties such as insecticidal, antimicrobial, antiviral, anticoccidial, anti-nociceptive, anticancer and antitussive activities, in addition to its use as a skin penetration enhancer. Camphor exerts an analgesic action when applied topically by producing a warm sensation. It excites and desensitizes sensory nerves by activating heat-sensitive TRP vanilloid subtype 1 (TRPV1) and TRPV3 receptors.

3.1.4. Glycerine

Glycerine is a humectant. Glycerine is a type of Moisturizing agent that pulls water into the outer layer of your skin from deeper levels of your skin and the air. In skin care products, glycerine is commonly used with occlusives, another type of moisturizing agent, to trap the moisture it draws into the skin. Emollients/moisturizers work by forming an oily layer on the top of the skin that traps water in the skin. Petrolatum, lanolin, mineral oil and dimethicone are common emollients. Humectants, including glycerin, lecithin, and propylene glycol, draw water into the outer layer of skin.

3.1.5. Rose Water

Rose water is use in cream for the odour (smell) and fragrance. It's aroma gives stress relieving and anti-depressive effects. Most often used for mental health. It contains vegetable oils, extracts and vitamins for softening and nourishing of the skin. It stimulates blood circulation and prevents the cracking of the heels. Rose water have anti-depressant, antiseptic, antispasmodic and antiviral properties. Also it is an astringent, cleansing agent and used in Aromatherapy. Rose water is also known for its ability to fight acne-causing bacteria. It soothes acne inflammations.

3.1.6. Ethyl Paraben

Ethyl Paraben is mainly used as antiseptic for Bacteria and preservatives. Ethyl Paraben is readily absorbed through the skin. According to research it is safe for used in cosmetics and preferred as preservatives to keep a formula stable. These studies also showed parabens did not have any effect when compared to natural hormones in the body. Ethyl Paraben is ethyl ester of p-hydroxybenzoic acid, used as an antifungal preservative. Ethyl Paraben also called ethyl-4-hydroxybenzoate. It is an odourless & white powder.

IV. FORMULATION OF CREAM

Heel fissures cream is very easy and simple to prepare formulation. Take the appropriate amount of required ingredients (Paraffin wax, Mustard oil, Camphor, Glycerine, Rose water, Ethyl Paraben). Paraffin wax for soften hard skin. Mustard oil for reduce inflammation and pain. Camphor for soften calloused heels and heel wound. Glycerine for an humectant and moisturizer. Rose water for smell & Ethyl paraben used as Preservative. Mixed all ingredients in a beaker as mentioned above one by one. Then put it in Water bath for heating until all ingredients are become liquid form. Essential it takes 7-8 minutes to melt upto 60-75 degree heat. After forming liquid take out from water bath and stir it for settle down. Then weigh the container without

filling (i.e. 12.60 gm) cream note it down and after that fill container with formulation. Put it in freezer or at cold place until cool and forms thick or semi-solid. Usually it take 10-12 minutes for freeze in room temperature. After freeze the cream once again measure the container filled with cream (i.e. 42.48 gm). Calculate the Total net weight of cream (i.e. 30.2 gm).

Required quantity of each ingredients can calculate by the given formula is

Quantity Required/Quantity Available or taken or given = answer*Quantity Available or Taken.

The answer is use for formulation.

Table 1 : Composition of Cream

Sr. No	Ingredients	Quantity (F1)	Quantity (F2)	Role
1	Paraffin wax	4 gm	5 gm	Soften hard skin, Antiseptic, Moisturizing
2	Mustard oil	15 ml	14 ml	Anti-inflammatory, Analgesic
3	Camphor	2 gm	1 gm	Skin Penetration enhancer, analgesic
4	Glycerine	5 ml	4 ml	Humectant, Moisturizing agent
5	Rose Water	2 ml	4 ml	Fragrance
6	Ethyl Paraben	0.02 gm	0.08 gm	Preservative



Figure 3 : Prepared Heel Fissures Cream Formulation 1 & 2

V. EVALUATION OF CREAM

5.1. Physical properties

The cream was observed for the colour, odour and appearance.

5.2. Washable

The cream was applied on the hand and examined under the running water.

5.3. pH of the Cream

PH of prepared herbal cream was measured by using digital PH meter. The solution of cream was prepared by using 100ml of distilled water and set aside for 2hrs. PH was determined in triplicate for the solution and average value was calculated.

5.4. Dye Test

The Sudan III dye is mixed with the cream. Place a drop of the Cream on a microscopic slide covers it with a cover slip, and Examines it under a microscope. If the disperse globules appear red The ground colourless. The cream is o/w type. The reverse condition Occurs in w/o type cream i.e. the disperse globules appear colourless In the red ground.

5.5. Homogeneity

Homogeneity was tested by the visual appearance and touch.

5.6. Appearance

The appearance of the cream was judged by its colour, pearlscence And roughness and graded.

5.7. After feel

Emolliency, slipperiness and amount of residue left after the Application of fixed amount of cream was checked.

5.8. Type of smear

After application of cream, the type of film or smear formed on the Skin were checked.

5.9. Spreadability Test

The cream sample can apply between the two glass slides and can compressed between The two-glass slide to uniform thickness by placing 100 gm of weight for 5 minutes then weight should added to The weighing pan. The time in which the upper glass slide moved over the lower slide should taken as a measure of Spreadability.

$$\text{Spread ability} = m * l / t$$

M -- weight tight to upper slide, L -- length moved on the glass slide, T -- time take

5.10. Irritancy Test

The cream was applied on the cracked heel skin and time was noted. Irritancy, Erythema, edema, was checked if any for regular intervals up to 24 Hrs and reported.

5.11. Stability Test

Cream placed at room temperature for 14 days and observed.

VI. RESULT AND DISCUSSION

6.1. Physical properties

The physical properties of formulated cream were judged by colour, odour and texture.

Table 2 : evaluation of physical properties

Sr. No.	Parameters	Evaluation (F1)	Evaluation (F2)
1	Colour	Yellow	Yellow
2	Odour	Pleasant	Pleasant
3	Texture	Smooth	Smooth

6.2. Washable

The cream applied on skin was easily removed by washing with tap water.

6.3. pH of the Cream

The pH of the cream found to be average F1 is 8 & F2 is 7. which is good for skin pH. The Herbal formulation was shown pH nearer to skin required i.e. pH 6.8.

6.4. Dye Test

The Sudan III dye is mixed with the cream. Place a drop of the cream on a microscopic slide covers it with a cover slip, and examines it under a microscope. The dispersed globules appear colourless in the red ground i.e. w/o type cream.

6.5. Homogeneity

The homogeneity of the formulated cream was judged by the visual appearance and touch. The F2 appearance and touch of the cream were better than F1.

6.6. Appearance

When formulations were kept for long time, it was found that F1 had no change in colour but it appears gelly like after 7-12 days. F2 had no changes in colour and roughness.

6.7. After Feel

Emolliency, slipperiness and amount of residue left after the application of fixed amount of F1 & F2 was found fair after feel.

6.8. Type Of Smear

After application of cream base, the type of smear formed on the skin were non greasy. But looks oily.

6.9. Spreadability Test

The spreadability of both cream formulations should range from 5.20 to 6.30 g cm/s. Spreadability test was applied on dorsal and palmar surface of hand. It was found that good spreadability.

6.10. Irritancy Test

In this test cream was applied on the skin of cracked heel and the effect to the skin on application of cream was compared with the market product. It was found that no irritancy and edema.

6.11. Stability Test

Cream F1 & F2 placed at room temperature for 14 days and observed. The result of F2 cream was stable for 14 days. Also no microbial growth/contamination. There are no changes in F2 cream stability under room temperature.

Table 3 : Result of Evaluation Parameters

Sr. No.	Parameters	Evaluation (F1)	Evaluation (F2)
1	Physical properties	Satisfactory	Satisfactory
2	Washable	Washable	Washable
3	pH of the Cream	8	7
4	Dye Test	W/O type cream	W/O type cream
5	Homogeneity	Good	Better
6	Appearance	Gelly like	No changes
7	After feel	Fair	Good
8	Type of Smear	Greasy	Greasy
9	Spreadability Test	Good	Good
10	Irritancy Test	No irritancy	No Irritancy
11	Stability Test	Poorly stable	Stable

The main aim of our research was to develop an anti-cracked heels cream formulation consisting of Mustard oil, Paraffin wax, camphor, glycerine, rose water for the treatment of cracked heels prepared. Stability and irritancy Studies were performed for the safety of cream for patients compliance. The developed cream consisting of paraffin wax, Mustard oil was found to be safe and effective for the treatment of cracked Heel. It can be concluded that herbal creams without side effects having anti-inflammatory, Analgesic, Antifungal, Antimicrobial & Antibacterial property can be used for reduce pain and prevention. Also used as Barrier to protect, soften and moisturizing the foot skin. Prepared crack cream formulations were subjected to check parameters for safety, efficacy and the findings Obtained which are Better in F2. The F2 were found to be stable in stability test. No irritancy found in irritancy test. This F2 cream have Better results in spreadability, after feel & homogeneity. Other parameters of F2 such as type of Smear is Greasy, there is no changes in appearance and easy washable in tap water or running water. Satisfying in physical properties with yellow in colour & pleasant in smell.

VII. CONCLUSION

The Heel fissures cream we formulated for the purpose of use in treatment and prevention of cracked heel. As we know heel fissures can cause bacterial, fungal as well as infections. This cream is help to patients who have that type of infection related to heel fissures or cracked heel. This cream is formulated by using Mustard oil. Mustard oil function like Anti-inflammatory, Analgesic, Antimicrobial, Antifungal and Antibacterial. Which is helps to reduce inflammation, pain, Block microbial growth, prevent fungal infections and fight bacterial infections. As per mentioned in *table 1* ingredients we used for composition of cracked heel cream, known as Heel fissures cream. We used above ingredients in appropriate quantity for the best results. We tested cream as per parameters mentioned in *table 3*. And their evaluation results are satisfying. We observed the cream according to parameters for to check their stability, after feel, irritancy, spreadability. Which gives the good results.

From the above results it is concluded that the formulated F2 cream showed good consistency and spread ability, Homogeneity, no irritancy and there is no change in appearance during study period of research. From the above Study it can be concluded that the Heel fissure cream is safe to use. Natural remedies are more acceptable in the belief that they are safer with fewer side effects than the synthetic Ones. There is a great demand for the herbal cosmetics nowadays. An herbal cream which is non-toxic, safe, effective And improves patient compliance by the utilization of herbal extracts would be highly acceptable than others.

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