Formulation And Evaluation of Safflower Oil and Calcium Hydroxide Ointment for Healing Burn Skin

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***Abstract*—Burn injuries represent a global public health challenge, often resulting from accidents or disasters, and in some cases, indicating child abuse. Large burns can lead to systemic complications such as burn shock and require comprehensive treatment strategies including inflammation management, infection control, nutritional support, fluid resuscitation, and wound coverage. Modern therapies involve advanced techniques like stem cells and engineered skin substitutes but are often expensive and inaccessible in developing regions. Traditional Iranian Medicine (TIM) offers affordable, time-tested alternatives, such as Lime Salve (L.S.), composed of calcium hydroxide (lime water), sesame oil, and beeswax. Calcium hydroxide promotes tissue healing through mineralization, antimicrobial action, and regulation of wound healing phases including hemostasis, inflammation, proliferation, and remodeling. Safflower oil, rich in linoleic acid and antioxidants, provides anti-inflammatory, antimicrobial, and anti-aging benefits while promoting collagen synthesis and angiogenesis.A novel herbal ointment was formulated using lime water, safflower oil, methyl paraben (as preservative), and rose oil via an emulsifying ointment method. The formulation was evaluated for physical parameters including pH, colour, odour, spread ability, solubility, washability, and skin irritation. Results confirmed good spreadability, solubility, ease of washing, and non-irritant properties, suggesting this traditional formulation as a promising, accessible alternative for burn wound management.**

I. INTRODUCTION

Traumatic burn injuries are a major public health problem on a global scale, resulting in millions of people seeking medical attention each year. Natural disasters, industrial accidents and domestic incidents are often the cause of these injuries. In addition, in certain cases, burns can be an indication of child abuse, highlighting a serious underlying social issue that requires immediate attention.[1]

A burn is an injury to the skin or other organic tissue primarily caused by heat or due to radiation, radioactivity, electricity, friction or contact with chemicals.[2]

Burns are classified by depth and extent (Total Body Surface Area - TBSA).

Large burns (>20% TBSA) induce burn shock, involving increased vascular permeability and systemic inflammation.2 Burns progress through three zones,Coagulation (central necrosis), Stasis (ischemic but potentially viable),Hyperemia (inflammatory but viable).[3]

Phases of burn wound healing: -Inflammatory Phase: Neutrophils and macrophages clean the wound and initiate repair.[4]. Proliferative Phase: Fibroblasts and keratinocytes promote closure and vascular regeneration.[5]

Remodeling Phase: Collagen and elastin form the scar, guided by myofibroblasts[6].

For burn skin above treatment strategies are used Inflammation Management:Essential early but excessive inflammation delays healing. Traditional anti-inflammatories (NSAIDs, steroids) have mixed effects. Early excision and grafting reduce inflammation and infection risk[7]. B. Infection Control:Burn wounds are highly susceptible to infections (bacterial and fungal). Early use of topical antimicrobials, accurate diagnosis, and appropriate antibiotics is crucial[8]. C. Nutrition Burns induce hypermetabolism; nutritional support is vital. Protein and carbohydrate balance is key; anabolic agents like insulin and oxandrolone help preserve lean mass.[9]. D. Fluid Resuscitation Fluid therapy must balance perfusion and risk of edema. Lower volumes may improve wound healing and reduce complications[10]. E. Wound Coverage: Split-thickness autografts are the gold standard. Allografts, xenografts, and engineered skin substitutes (e.g., Biobrane, Integra) are used for

temporary coverage. New options include keratinocyte sprays (ReCell) and stem cell-based therapies[11].

Modern burn treatments include stem cells, tissue scaffolds, gene therapy, bioengineered skin substitutes, new dressings, and healing promoters. Pereira and Bartolo (2016) state that these methods are typically costly and difficult to apply, particularly in developing countries. Therefore, further research is required to identify more effective, affordable, and readily available drugs for the best burn care. From the ninth to the nineteenth centuries AD, traditional Iranian medicine (TIM) extensively recorded lime salve (L.S.) as a successful burn healing treatment. Because of its potent antibacterial qualities and capacity to release growth factors that promote pulp repair, calcium hydroxide (CH), a material with poor water solubility, is frequently utilized in medicine as the gold standard for direct pulp capping. Research can be greatly aided by the traditional usage of medicines by many communities. Comprehensive, centuries-old experimental methods for treating burn injuries are found in Traditional Iranian Medicine (TIM), with numerous topical treatments that have been proven effective over time. Products derived from plants, animals, and minerals are used in these treatments. Lime Salve (L.S.), a concoction of hydrated lime (calcium hydroxide powder), sesame oil, and beeswax, is one well-known example. TIM sources from the 9th to the 19th century AD mention L.S., which is highly recommended for treating burns. After a burn, it should be used right away, ideally before blistering develops. Furthermore, complementary and alternative medicine, including traditional Chinese medicine, acknowledges the benefits of lime-based treatments, which have been demonstrated to lessen pain and hasten healing[12]

II. CALCIUM HYDROXIDE ACTIVITY

1. Biological Effects

Calcium hydroxide dissociates into calcium and hydroxyl ions, responsible for tissue healing and mineralization.

Stimulates alkaline phosphatase, facilitating hard tissue formation such as a mineralized bridge over pulpal tissue.

Histological studies in animals confirmed calcified barrier formation and pulp healing.

Calcium hydroxide creates a necrotic layer upon contact with pulp, initiating reparative processes.

2. Antimicrobial Effects

Its high pH (12.6) disrupts bacterial enzyme activity by denaturing proteins and damaging cytoplasmic membranes.

Effective against a broad spectrum of bacteria: Gram-positive, Gram-negative, aerobic, and anaerobic.

Requires adequate contact time to ensure microbial inactivation[13].

Key Roles of Calcium in Wound Healing

1. Hemostasis: Calcium is essential for blood clotting. facilitating the formation of a fibrin matrix that serves as a scaffold for cell migration.

2. Inflammation: It aids in the activation and migration of immune cells to the wound site.

initiating the inflammatory response necessary for healing.

3. Proliferation: Calcium influences keratinocyte and fibroblast functions, including proliferation, differentiation, and collagen synthesis, which are crucial for tissue regeneration.

4. Remodeling: It contributes to extracellular matrix remodeling and angiogenesis, ensuring the restoration of tissue integrity and function[14].

Safflower oil activity

Anti imflammatory activity

Safflower oil anti imflammatory activity on skin due to its high linoleic acid content which helps to reduce inflammation and promote skin healing

Antiaging and anti-wrinkle activity safflower oil active compounds acacetin. Acacetin can inhibit the expression of MMP - 1 an enzyme involved in breakdown of collagen which can help to reduce wrinkle and sign of aging[15].

Antimicrobial activity: safflower oil possesses antibacterial and antifungal properties which an help prevent infection at wound site.

Antioxidant activity: safflower oil antioxidant properties can help protect the wound tissue from damage caused by free radicals, further promoting healing.

Wound healing activity safflower oil exhibit promising wound healing activity due to its ability to reduce inflammation, stimulate collagen synthesis and promote angiogenesis. Additionally, safflower oil antioxidant and antimicrobial properties can

contribute to wound healing by protecting against damage and inhibiting microbial growth[16].

Formulation table:-

Ingredient	Quantity
Lime water	50ml
Safflower oil	50ml
Bees wax	5gm
Preservative (methyl paraben)	0.1%-0.2%
Rose oil	0.5gm %

III. MATERIAL AND METHOD

Material: - lime water, safflower oil, methyl paraben, rose oil

Method: - (Emulsifying ointment method)

Step 1: preparation of aqueous and oil phase

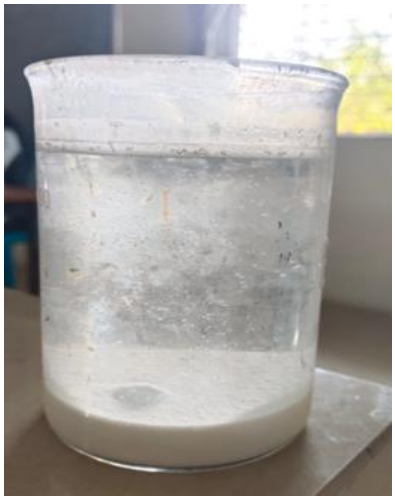
Aqueous phase: Make lime water and leave it in a stable state for six to ten hours. They change into two phases at the end of the time period: a white solid layer and an aqueous, transparent, and clear layer. In another beaker, remove the top layer of water.

Oil phase: only safflower oil is used in the oil phase.

Step 2: Oil and aqueous phase mixing: the oil phase is gradually added to the aqueous phase while being stirred until it turns into a thick solution.

Step3.Add preservative and perfume. After making thick solution add methyl paraben and rose oil and stir it.


Preparation of Lime water


Two layers of lime water are separated and collected

Evaluation test-

1.Colour and Odour: -Physical parameters like colour and odour were examined by visual examination.

2.pH: -pH of prepared ointment was measured by using digital pH meter. The solution of ointment 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.

3.Spreadability: - The spreadability was determined by placing excess of sample in between two slides which was compressed to uniform thickness by placing a definite weight for definite surface. The surface required to separate the two slides was measured as spreadability. Spreadability measured in cm within diameter. A larger diameter indicates better spreadability.

4.Solubility: - Soluble in boiling water, miscible with alcohol, ether, chloroform.

5.Washability: -Formulation was applied on the skin and then easy+ extend of washing with water was checked.

6.Non irritancy test: -Herbal ointment prepared was applied to the skin of human being and observed for the effect.1 The test is performed by applying the small amount sample to the hand and observed for 24hours to check the effect like redness, erythema, inflammation etc. Hence, no such effect was observed, it is non-irritant to the skin[17].

IV. RESULT

The present study was done to prepare and evaluate the ointment. For this the ointment were prepared by using emulsion process to obtain a good yield of and were was no any harm to the chemical constituents and their activity. The emulsifying method was used to prepare ointment so that uniform mixing of the oil and water occurred ointment which was stable during the storage. The physicochemical properties were studied which shows satisfactory results for spreadability, Washability, Solubility, Loss on drying and others.

Physical properties of ointment

The formulated ointment is evaluated for its physical properties like colour, odour and state. The Formulated ointment is semisolid in nature; pleasant odour is occurred and yellowish white in colour. The texture of ointment is smooth. By visual appearance and touch its confirm that all formulation produces uniform distribution of extract in ointment.

Sr.no.	Specification	Limit
1.	State	Semi-solid
2.	Colour	Yellowish white
3.	Odour	Pleasant
4.	texture	Smooth

Determination of pH

The pH of the ointment was found to be in range of 7-13 which is good for skin pH. All the herbal formulation of ointment were shown pH near to the skin required. i.e. F1- 9.8, F2-7.6 and F3-12.5. The observed pH is near to the skin pH.

Sr.no	Formulation	Ph
1.	F1	9.8
2.	F2	7.6
3.	F3	12.5

Formulation F1 ph-9.8

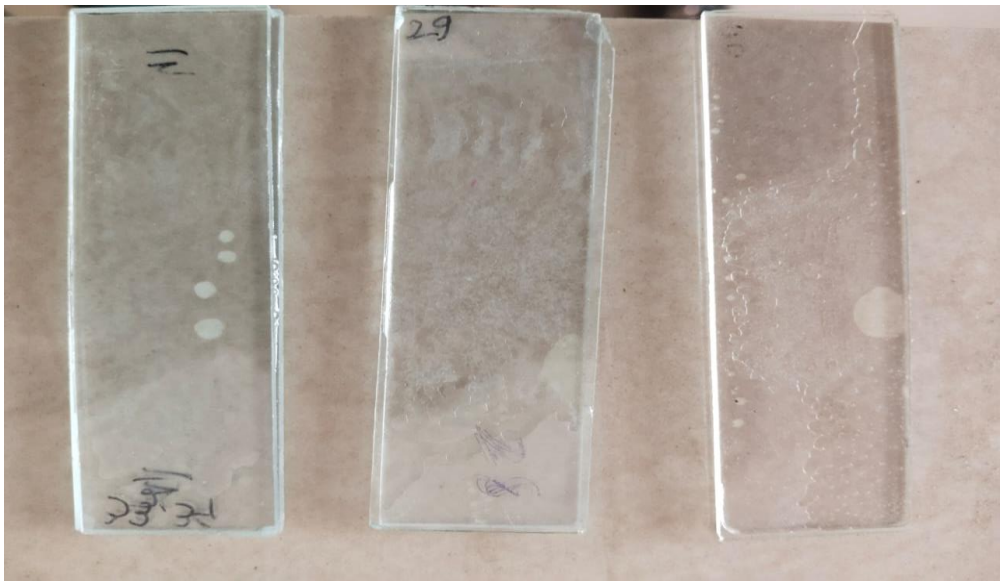
Formulation F2ph-7.6

Formulation F3ph-12.5

Determination of Spreadability

The Spreadability plays a considerable role in patient compliance and ensures uniform application of ointment to a large area of the skin. The low value of spreadability coefficient of the ointment was sufficient suggesting easy spreading. The lower value of spreadability indicates the lesser work required to spread the ointment over the skin. Which means formulation was easily spreadable by applying small amount of shear. The spreadability test showed that formulation has good spreadable property.

Sr.no	formulation	Spreadability
1.	F1	6.5cm
2.	F2	6cm
3.	F3	5.5cm



Spreadability test slides

Evaluation parameters of ointment

Sr.no	colour	Ph	Spreadability	Texture
F1.	White	9.8	6.6cm	Smooth
F2.	Yellowish	7.6	6cm	Smooth
F3.	Yellowish white	12.5	5.5cm	Smooth

Physicochemical evaluation of formulated ointment

Physiochemical parameter	Observation
Colour	Yellowish white
Odour	Pleasant
Ph	12.5
Texture	Smooth
Solubility	Insoluble im
Spreadability	5.5cm
washability	Good
Non irritant	Non-irritant

V. CONCLUSION

From the ancient time safflower oil and calcium hydroxide is used for their various medicinal properties like antibacterial, antifungal, anti-inflammatory etc. thus this ointment could become a media to use these medicinal properties effectively and easily as a simple dosage form. The results of different tests of ointment showing that the formulation could be used topically in order to protect skin against damage the comparison of F1, F2 and F3 the F3 produce better activity than F1and F2.

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