

Herbal Alchemy: An Oral Submucous Fibrosis Healing Kit with the Goodness of Herbal Blends

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Abstract:

OSMF stands as a medical condition that influences the oral tissues through fibrous band formation while causing mouth-opening restrictions and additional symptoms. OSMF causes severe tissue inflammation and progressive fibrous tissue development throughout the submucosal layers, thus becoming one of the chronic disabling diseases affecting the mouth. The condition exhibits a cancer-prone nature because of tobacco and areca nut chewing patterns. Medical experts first identified OSMF during the early 1950s. Approximately 2.5 million people in India's subcontinent are affected by this condition, while Asian people, especially residents of India, Bangladesh, Sri Lanka, Pakistan, Taiwan, and China, are at the highest risk. People are increasingly choosing Ayurvedic medicine because the therapy shows exceptional results in treating conditions that doctors previously declared untreatable. Different plant-based compounds found in medicinal remedies intended for OSMF treatment demonstrate therapeutic potential for the condition. This research project aimed to create an OSMF healing kit consisting of three products: toothpaste, mouthwash, and gel ointment with additive herbal ingredients, including turmeric, triphala, spirulina, honey, aloe vera, and fennel seed oil. The selection of these ingredients was based on clinical data which has demonstrated that these are anti-inflammatory, antioxidant and collagen modifying.

Keywords: Oral submucous fibrosis; Inflammation; Submucosal layers; Ayurvedic medicines; OSMF healing kit; Toothpaste; Mouthwash; Gel ointment; Turmeric; Triphala; Spirulina; Honey; Aloe vera; Fennel seed oil

1. Introduction:

Mostly illnesses which are occurring within the human body arises due to various lifestyle and habit changes. Leading to significant stiffness and a progressive decrease in mouth opening, oral submucous fibrosis (OSMF) is a serious, long-term, debilitating condition caused by chewing areca nut, chillies, misri, and tobacco in different forms.^[1] Mostly found in the Indian subcontinent, this chronic disease affects juxta epithelial fatty tissue—soft tissue osteoporosis which further affects the oral mucosa, the oropharynx, and rarely the larynx. This disorder causes limited mouth opening (trismus), a burning sensation in the mouth, weakness of the tongue and soft palate, taste loss, trouble in consuming hot, spicy meals, and sometimes minor hearing loss due to Eustachian tube blockage.^[2]OSMF have been initially acknowledged

in the early 1950s. It mostly affects the subcontinent of India, including about 2.5 million people and is mostly seen in Asian people, especially in India, Bangladesh, Sri Lanka, Pakistan, Taiwan, and China. Indians have a 0.4 percent frequency of OSMF noted.^[3] If left unaddressed, the OSMF could progress to oral cancer. The conversion rate fluctuates from roughly 2-10 percent. This is the least recognized and least tackled condition. The younger the person, the faster the advance of the condition. OSMF is becoming more and more common, so there is a pressing need to find safe and efficient treatment choices to either totally cure or control patients with the possibility of side effects. Combining lifestyle modifications with natural Ayurvedic treatments for OSMF could help to relieve OSMF symptoms and might even go toward curing the disease.^[4] These days, Ayurveda has gained popularity because of its ability to effectively treat diseases that were once considered incurable. Ayurvedic therapies can be used to tackle various dental problems, including periodontitis, oral lichen planus (OLP), dental problems, mouth cancer, OSMF, and oral mucosa lesions (OML). Several studies have shown the effectiveness of ayurvedic treatments or drugs in OSMF treatment. In Ayurveda, combinations of herbs are utilized that are very effective in tackling different health issues.^[5] Through the combination of existing knowledge regarding ayurvedic medicine, herbal treatments and dental healthcare, this research focuses on the formulation and development of an OSMF healing kit which includes toothpaste, mouthwash and gel ointment for oral cleaning and therapeutic support. It will clean treat and protect oral health simultaneously.

1.1 Toothpaste:

The combination of surfactant and other ingredients in paste or gel form constitutes toothpaste – an oral hygiene product used with toothbrushes for cleaning teeth and achieving both, health benefits and aesthetic outcomes. The oral product known as dentifrice takes the form of a smooth homogeneous semisolid paste that contains surfactant, binders, polishing agent, humectants, abrasives and other appropriate materials to support oral health.^[6]

Some of the ideal properties of toothpaste are:

- Good abrasive properties
- Delivers fresh breath
- Non-toxic and non-irritant
- Tolerable taste
- No or very less side effects^[7]

1.2 Mouthwash:

An antiseptic aqueous solution named mouthwash provides oral and dental cleaning functions and breath freshness. Plaque control along with dental problem management serves as the main purpose for which mouthwash is used. Mouthwash stands as a medicated fluid which patients should swish around the oral area through perioral muscle movements to eliminate harmful oral microorganisms.^[8] There are multiple kinds of mouthwashes available in the market which falls under cosmetic or medicinal classifications. A cosmetic mouthwash combats bad breath through flavouring agents that produce short-term fresh breath results. Medical mouthwash contains active substances which help patients control their condition while sustaining oral health. Several mouthwashes also include components which assist your body's digestion processes. The market demand for herbal mouthwashes has increased because they demonstrate antibacterial actions while providing antioxidant protection. The multiple medical properties of herbal plants serve effectively in disease treatment because of their antibacterial and antifungal characteristics.^[9]

1.3 Gel:

The origin of 'gel' comes from 'gelatine' while 'gel' and 'jelly' share roots with the Latin gelu for 'frost' and gel meaning 'freeze' or 'congeal.'. A gel is a semi rigid system where the movement of dispersing medium becomes restricted because dispersed phase particles or solvated supermolecules form an interlinked three-dimensional network. The gel mass consists of separate small particles when organized into a network which defines it as a two-phase system. Two-phase systems define their gel mass as magma when the dispersed phase has relatively larger particles. Single-phase gels contain organic supermolecules which form a uniform distribution within a liquid medium. The dispersed supermolecules remain evenly distributed throughout the entire liquid without showing any detectable separation between them or the liquid.^[10] The market shows rising interest in herbal gel solutions both for therapeutic and preventive care of mouth ulcers. The synthetic gel contains various harmful toxins that could lead to severe unwanted effects.^[11] The potential benefits of herbal gels over ointments for topical medication make them suitable delivery systems because they avoid stickiness while requiring minimal manufacturing energy and provide stability with an appealing form. Herbal gels possessing right rheological properties allow drugs to stay on skin longer which enhances absorption of drugs that exhibit poor permeability.^[12]

2. Materials and Methods:

Bringing together previous understandings about ayurvedic therapies, herbal medicines and their actions, in this study a list of plants are selected for the formulation of oral submucous fibrosis (OSMF) healing kit including toothpaste, mouthwash and gel ointment. Products were made with less chemicals and more herbal ingredients as a new innovation. Following are the plants with their properties which are selected for the formulation and development of the toothpaste, mouthwash and gel ointment.

2.1 Turmeric:

Curcuma longa from the Zingiberaceae family produces the yellow-orange flavoured spice also known as turmeric which grows as a rhizome.^[4] Several aromatic plants and herbs contain well-known anti-oxidant and medicinal properties with polyphenols serving as one of the best-known compounds. The polyphenol chemical curcumin exists naturally as yellow coloured in plants of Curcuma longa that typically grow throughout South Asia. This compound shows medical advantages because it functions as an anti-inflammatory agent while providing antioxidant benefits and potential cancer cell protection.^[13] The antioxidant function of this compound consists of an ability to remove superoxide radicals, hydrogen peroxide and nitric oxide molecules from activated macrophages and to reduce iron complexing and inhibit lipid peroxidation. In vitro and in vivo conditions show that the compound can eliminate different reactive oxygen species formed by macrophages including superoxide anions, hydrogen peroxide and nitrite radicals.^[14]

2.2 Triphala:

Numerous diseases are treated by Triphala which stands as a widely utilized medicinal formula because of its extensive pharmacological properties. The traditional Ayurvedic medication called Triphala consists of three Ayurvedic products which are Terminalia chebula Retz. (Haritaki), Terminalia bellerica Roxb. (Bibhitaki) and Emblica officinalis Gaertn. (Amalaki) and has become a standard treatment in Ayurvedic medicine. Traditional Ayurvedic texts name Triphala as a Tridoshic Rasayana that acts as both a curative agent and a rejuvenating substance for the three fundamental Ayurvedic vital energies of vata, pitta and kapha.^[15] The herbal compound Triphala is widely recognized by its names of Triphala churna, Triphala choornam and Phalatrika. Three medicinal plant powders are combined into equal parts to make proper

triphala powder. The combination of three medicinal plants in triphala delivers all single benefits within one formulation.^[16] Additionally, its antioxidant and antibacterial properties promote healing.^[17] The scientific community has investigated triphala for possible therapeutic applications in OSMF management. The preparatory substance simultaneously enhances antioxidant strength and minimizes fibrotic growth while improving the condition of oral mucosa.^[18]

2.3 Spirulina

Spirulina represents blue green algae containing natural protein substance together with carotenoids and other micronutrient content. Researchers have mainly studied spirulina for its ability to treat leukoplakia while achieving beneficial outcomes. Spirulina shows chemo preventive properties for reversing precancerous lesions because of its antioxidant activity that results from high beta carotene content and superoxide dismutase.^[19] Scientific research indicates that spirulina shows potential for managing OSMF because it contains antioxidant elements that also serve as anti-inflammatory agents and immunomodulators. Various treatment approaches have been attempted but combinations of medical physical and surgical approaches have demonstrated the best results.^[20] Spirulina showed effectiveness in controlling burning sensations for patients because its composition includes beta-carotene and phenolic acid together with tocopherol and essential nutrients. The topical and systemic administration of beta-carotene assists in healing epithelial cells and promotes the transformation of dysplastic cells back to their normal state.^[21]

2.4 Aloe-vera

The Aloe vera plant belongs to the Asphodelaceae (Liliaceae) family and Aloe genus. Wild Aloe vera displays characteristics of cactus plants as it thrives in hot desert environments. The species *A. vera* *Barbadensis* stands as the primary choice from the Aloe variety. The two aloe plant species that appear in commercial applications includes, *Aloe barbadensis* Miller and *Aloe arborescens*. The Arabic term *Alloeh* provided the roots for the name 'Aloe' which means 'shining bitter substance' and 'Vera' means 'true'. Aloe vera thrives across the regions of Africa and Northern America as well as India, Egypt and Sudan.^[22] Medical research on Aloe vera shows the compound works for multiple dental treatments because of its pharmaceutical value. The antioxidants in Aloe vera possess Vitamin A, C and E to fight damaging free radicals. The vitamins participate in wound healing functions while strengthening the immune system. Aloe vera contains fatty acids and salicylic acid alongside auxins and Gibberellins which exhibit their anti-inflammatory activities^[23]. Aloe vera contains a set of vital enzymes known as aliase and alkaline phosphatase and amylase. When applied to the skin or oral tissues topically, bradykinase and other enzymes act to treat inflammation sites. The polysaccharide found in Aloe vera operates as an anticancer agent and an antioxidant substance.^[24]

2.5 Honey

Honey serves as a vital substance in both Ayurveda treatment along with Unani medical practices. Traditional Ayurvedic practitioners divide honey into eight distinctive categories which bring forth different therapeutic properties. The classification system depends on which specific plants and flowers bees use to obtain nectar. Health professionals employ honey both outside and inside the body to treat oral cavity-linked conditions such as gum issues and throat-related infections. Due to its antibacterial qualities this substance treats both, wounds and helps with coughs and sore throat symptoms. The antioxidants found in honey support different health promotions while providing multiple medical advantages to human bodies.^[25]

2.6 Fennel Seeds

Fennel (*Foeniculum vulgare* Mill Family-Apiaceae) represents an important aromatic plant with medicinal applications which demonstrates clear antimicrobial and anti-inflammatory properties. Throughout history this plant has functioned both as spicing agent and medicinal herb. Fennel functions as a preferred medical plant with anti-inflammatory properties and additional benefits as an intoxicant, anti-oxidant, gastrointestinal and spasmolytic and mucolytic agent. The pharmaceutical industry uses Fennel essential oil together with other segments in the field. The essential components of fennel seed oil include trans-anethole and methyl-chavicol together with fenchone.^[26]

The production of toothpaste along with mouthwash and gel ointment demands an integrated systematic method that enables the selection of appropriate substances while determining the right concentrations and precise product formulation for achieving both safety and effective performance. The following guide demonstrates the systematic process used to develop such formulations.

2.7 Extraction

Turmeric, triphala, and spirulina powders were sourced from the market for this study. To extract their beneficial components, a suitable solvent is needed. In this case, ethanol was chosen for the extraction process because it offers good stability and evaporates easily, making it a practical and efficient option. The powdered actives were extracted using a hot infusion method. For each extraction, 2:18 ratio has been taken which means 2 grams of powdered material is mixed with 18 grams of ethanol. The mixtures were placed in test tubes and heated in a water bath for one hour, ensuring the temperature stayed below 70°C throughout the process. Once the infusion was completed, each extract was carefully filtered using filter paper. After cooling, preservatives were added to help maintain their stability. The final extracts were then set aside and observed over the next 1–2 days for initial stability testing.



Figure 1: Extraction of powdered herbs

2.8 Toothpaste:

Formulation table:

Sr.no	Ingredients	Functions	F1 % w/w
1	Calcium carbonate	Abrasive	19.0gm
2	Gum tragacanth	Binder	2.5gm
3	Sodium lauryl sulphate	Foaming agent	1.25gm
4	Glycerine	Humectant	3.75gm
5	Turmeric extract	Active	1.5gm
6	Triphala extract	Active	1.5gm
7	Spirulina extract	Active	0.5 gm

8	Honey	Sweetening agent	5.0 gm
9	Menthol	Cooling agent	5.0gm
10	Fennel oil	Flavouring agent	2.5gm
11	Peppermint oil	Flavouring agent	1.0gm
12	Sodium benzoate	Preservative	1.25gm
13	DM Water	Solvent	Qs.

Table 1: Formulation Table for Toothpaste

Procedure:

- First, all the ingredients were carefully weighed using a weighing machine to ensure accuracy.
- Weighed calcium carbonate was added into the mortar (A) and then triturated evenly.
- In another mortar (B), Gum tragacanth was allowed to swell for half an hour by adding sufficient amount of water into it.
- In Beaker A, sufficient amount of water was heated to about 70°C, and sodium lauryl sulfate was dissolved in it.
- Meanwhile, in Beaker B, accurately weighed glycerine and honey were taken.
- The contents of Beaker B and swelled gum tragacanth were then gradually added to the powdered calcium carbonate in the mortar (A), and the mixture was grounded until a smooth paste formed.
- After that, all three extracts were taken into another beaker and menthol was dissolved into it.
- The content of the above beaker was then gradually added into the mortar (A) while triturating it to form even paste.
- Now, dissolved sodium lauryl sulfate was added into the mortar and triturated slowly to prevent bubbles formation.
- Additional water was added if needed, to achieve the desired paste consistency.
- Finally, a preservative and flavouring agents i.e. fennel oil and peppermint oil was incorporated and mixed thoroughly to complete the preparation of the paste.



(A)



(B)

Figure 2: (A) Formulated Toothpaste in mortar & pestle; (B) Formulated Toothpaste in a well labelled container

2.9 Mouthwash:

Formulation table:

Sr.no	Ingredients	Functions	F1 % w/w
1	Ethanol	Solvent	12.5gm
2	Glycerine	Humectant	2.5gm
3	Menthol	Cooling agent	3.75gm
4	Honey	Sweetening agent	6.25gm
5	Turmeric Extract	Active	5.0gm
6	Triphala Extract	Active	5.0gm
7	Spirulina Extract	Active	1.25gm
8	Fennel oil	Flavouring agent	2.5gm
9	Peppermint oil	Flavouring agent	2.5gm
10	Sodium benzoate	Preservative	1.25gm
11	Water	Solvent	7.5gm

Table 2: Formulation Table for Mouthwash

Procedure:

- In a beaker (A), ethanol was taken and menthol was dissolved into it.
- In another beaker (B) glycerine and honey were dissolved into water.
- Contents of beaker B were then gradually added into the beaker A.
- Now, all the three extracts were added slowly while mixing gradually.
- At last, fennel oil, peppermint oil and sodium benzoate were added and mixed properly to get a clear solution.

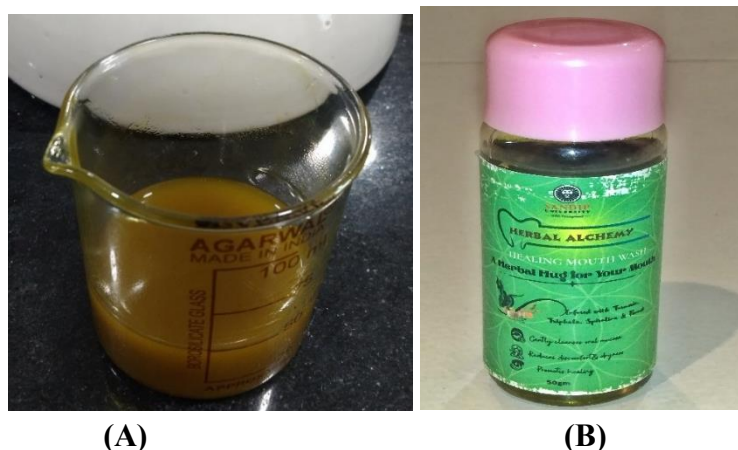


Figure 3: (A) Formulated mouthwash in a beaker; (B) Formulated Mouthwash in a well labelled container

2.10 Gel:

Sr.no	Ingredients	Functions	F1 % w/w
1	Carbopol	Gelling agent	7.5gm
2	Hydroxypropyl methyl cellulose	Thickening agent	3.75gm

3	Poly ethylene glycol	Co- solvent	3.75gm
4	Triethanolamine	pH adjuster	2.5gm
5	Honey	Sweetening agent	6.25gm
6	Turmeric Extract	Active	2.5 gm
7	Triphala Extract	Active	2.0 gm
8	Spirulina Extract	Active	1.0gm
9	Aloe vera	Active	5.0gm
10	Menthol	Cooling agent	2.5gm
11	Fennel oil	Flavouring agent	1.25gm
12	Peppermint oil	Flavouring agent	1.25gm
13	Sodium benzoate	Preservative	1.25gm
14	Water	Solvent	Qs.

Table 3: Formulation Table for Gel

Procedure:

- In beaker (A), Carbopol was allowed to swell for half an hour by adding sufficient amount of water into it.
- In another beaker (B), sufficient amount of water was heated up to 70°C, and hydroxypropyl methyl cellulose was added into it. It was then allowed to swell for half an hour.
- After half an hour, accurately weighed Carbopol was taken into the mortar, hydroxypropyl methyl cellulose and aloe vera was added into it gradually with the continuous trituration to achieve gel like consistency.
- Now, poly ethylene glycol and triethanolamine was added into the above mixture.
- All three extracts were taken into a beaker (C) and menthol was dissolved into it.
- Contents of beaker (C) were then added into the mortar with the continuous mixing.
- Then, honey, fennel oil, peppermint oil and preservative were added into the gel mixture.
- Additionally, water was added as needed to achieve the desired gel consistency.
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Figure 4: (A) Formulated Gel ointment in Mortar & Pestle; (B) Formulated Gel ointment in well labelled container

3. Results and Discussion:

Oral Submucous Fibrosis (OSMF) is a public health problem of great magnitude in the South and South East Asian regions, with the main cause among addicted areca nut and tobacco consuming population. OSMF is a chronic, progressive, fibrotic condition of the oral mucosa that significantly impacts quality of life because it compromises mouth opening and increases oral malignant transformation risk. Despite improvements in dental care, OSMF is a disabling condition with little response to treatment with conventional pharmacological agents. With such a degree of toxicity, there should be alternative therapeutic options with safer and more effective profiles.

Thus, the current research was focused on the formulation of an integrated OSMF (Oral Submucous Fibrosis) healing kit with three synergistic products: toothpaste, mouthwash and topical gel ointment containing specific herbs namely turmeric, triphala, spirulina, honey, aloe vera and fennel seed oil. The intention was to address OSMF symptoms, moderate inflammation, and restrain fibrosis and to increase oral function and quality of life with a plant-based solution. These findings suggest that Ayurvedic herbal compounds can have therapeutic value in the OSMF. Its anti-inflammatory and wound healing effects was mainly due to the addition of turmeric (*Curcuma longa*) and triphala. Cellular repair and immune modulation were a major role for spirulina and it also helped with mucosal act as well as hydration, whereas aloe vera played a specific role with mucosal act and hydration. By increasing its anti-fibrotic action with fennel seed oil, which can affect activity and remodelling of fibroblasts and collagen, honey added another antimicrobial and healing effect. Additionally, this herbal treatment conforms to the trend of alternative and integrative medicine in the world, especially in the South Asian population where Ayurveda is culturally accepted, making patient compliance normal.

4. Conclusion and Future prospects:

Oral Submucous Fibrosis (OSMF) concludes as a significant and odious oral health problem based on the consumption of areca nut and tobacco. The chronic and progressive nature of this disease, alongside its cancer-prone characteristics, demands more effective and safer therapeutic strategies. The objective of this research was to formulate a novel healing kit consisting of toothpaste, mouthwash, and topical gel which contain herbal ingredients such as turmeric, triphala, spirulina, honey, aloe vera and fennel oil. The selection of these ingredients was based on clinical data which has demonstrated that these are anti-inflammatory, antioxidant and collagen modifying. It presents a holistic, non-invasive and accessible method to the control of OSMF symptoms and inhibition of disease progression in populations with limited or no access to conventional treatment owing to its cost, unaffordability, or resistance to culture. Integrating traditional remedies into modern product formulations, is expected to bring in a promising route towards natural and patient friendly management of OSMF.

Nevertheless, there exist several research gaps unaddressed. Finally, although the formulated products are not yet tested in clinical settings, they lack real-world validation of their efficacy and safety. Furthermore, lack of standardization of herbal ingredients exists because of different sourcing, and bioactive concentration. Finally, there is limited data on the use of these herbal remedies for periods of time for the patient with chronic conditions such as OSMF. Another key area for further exploration involves the absence of patient-reported outcomes, in particular, improvements in quality of life and a comfort of use. Future research addressing therapeutic effects of the OSMF healing kit must conduct rigorous clinical trials to confirm mouth opening, mucosal flexibility and symptom relief, which can be measured based on those outcomes. Controlled phytochemical profiling of the herbal extracts should be standardized in order

to achieve consistency and reproducibility. In addition to this, mechanistic studies are in depth needed to understand how the herbal ingredients interact with the fibrotic pathways at the molecular level. Other bioactive herbs can also be added to the formulation while advancing to advanced delivery systems like nanocarriers in order to improve product efficacy. Additionally, patient participation in usability studies and obtaining feedback gives more customized and acceptable form. Finally, the development must be aligned to regulatory standards for eventually commercialization and wider access. Further research and cross disciplinary cooperation together make the novel herbal healing kit a promising solution that can transform the treatment of OSMF and perhaps other fibrotic oral conditions.

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