

Treatment Modalities of Oral Submucous Fibrosis: A Systematic Review

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Abstract

Oral submucous fibrosis (OSMF) is a premalignant condition of insidious onset which affects the oral mucosa, pharynx, and oesophagus. Oral submucous fibrosis (OSMF) is a well-known precancerous oral lesion, characterized by scarring, tissue fibrosis, and premalignant lesions. The goal of clinical treatment is to reduce inflammation and improve patients' quality of life by enhancing mouth opening among others. The muscles of mastication are known to be affected resulting in limited mouth opening. Despite numerous therapeutic approaches, an ideal and universally accepted treatment modality remains elusive. Numerous treatment approaches for Oral Submucous Fibrosis exist, but there is limited robust evidence confirming their individual or collective effectiveness. While these treatments can alleviate the signs and symptoms of OSMF, a definitive cure remains elusive. This systematic review aims to assess and compare these various treatment modalities, focusing on their impact on clinical symptoms, functional outcomes, and disease progression. To achieve this, a comprehensive literature search was conducted across PUBMED, MEDLINE, EMBASE, and COCHRANE Library, limited to English-language publications. The search utilized incorporating the published literature till 2025 using the MeSH terms and keywords such as 'treatment modalities', 'Oral submucous fibrosis', 'Mouth opening', 'Diagnostic', and 'Therapeutic'. This review underscores the significance of habit control, physical therapy, intraoral appliances, as well as medicinal and surgical interventions in managing OSMF. Furthermore, it identifies areas where current knowledge is lacking, encouraging further research to develop more targeted therapies.

Keywords: Treatment modalities, Oral submucous fibrosis, Mouth opening, Diagnostic, and Therapeutic.

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INTRODUCTION

Oral Submucous Fibrosis, initially described by Schwartz in 1952 as "atrophica idiopathica (tropica) mucosae oris," is a chronic, progressive, and debilitating precancerous condition with a high risk of malignancy. It leads to increased fibrosis beneath the epithelium of the oral mucosa, oropharynx, and occasionally the larynx, causing burning sensations, oral mucosa stiffness, and progressively limited mouth opening.[3] In advanced stages, the submucosa and deeper tissues may

also be affected. The risk of malignant transformation ranges from 7% to 30%, though one study by Vig *et al.*, reported only 2 out of 108 OSMF cases transforming into cancer.[1]

While the exact cause of OSMF is not fully understood, areca nut is recognized as the primary etiological factor. Arecoline and tannin, compounds found in areca nut, promote collagen synthesis and reduce its breakdown. Other contributing factors include chillies, tobacco, lime, nutritional deficiencies, impaired

iron metabolism, collagen disorders, bacterial infections, immunological disorders, genetic predispositions, and altered salivary composition.

OSMF is highly prevalent in India and Southeast Asia, affecting 0.2% to 0.5% of the Indian general population, with a gender variation of 0.2-2.3% in males and 1.2-4.5% in females. It typically affects individuals between 20 and 40 years of age. A ten-year study by Vig *et al.*, noted that almost all OSMF patients were South Asian, with nearly half being female, and 12% were under 30.

The symptoms of OSMF evolve with disease progression. Early signs include mucosal ulcerations and a burning sensation. As the disease advances, oral mucosa stiffening and blanching occur, with palpable fibrous bands being a hallmark feature. This leads to significant rigidity and a growing inability to open the mouth, and the expanding fibrosis also impairs normal tongue movements.

Numerous treatment approaches have been proposed for OSMF, though robust evidence for their individual or combined effectiveness is limited. While these treatments can mitigate the signs and symptoms, a complete cure remains elusive. The most crucial step in managing OSMF is the cessation of areca nut consumption; however, no effective substitute has been found to aid users in breaking this habit.[1]

OSMF management encompasses terminating areca nut use, medical interventions, physical therapy, surgery, and combined therapies. Medical treatments have included nutrients, micronutrients, antioxidants, biogenic stimulation, proteolytic enzymes, immune modulation, and blood flow promotion. Physical therapy incorporates exercise regimens, splints, and microwave diathermy. Surgical options include laser excision, coronoidectomy and muscle myotomy, and excision with flap procedures or grafts/stents. More recently, substances like circummuring, aloe vera, and tea pigments have been explored for their antioxidant properties in OSMF management. Clostridium histolyticum collagenase, imatinib, pirfenidone, and simtuzumab have also been investigated. The identification of possible molecular targets offers avenues for developing more targeted therapies.

This review emphasizes the importance of habit control, physical therapy, intraoral appliances, as well as medicinal and surgical interventions in OSMF management, while also highlighting knowledge gaps to stimulate further research for developing targeted treatments.

TREATMENT STRATEGIES

Habit Cessation Therapy

International Agency for Research on Cancer classifies areca nut as highly carcinogenic, and its use is

increasingly common among children and adolescents in India. Singhvi *et al.*, documented a study which aimed to explore the reasons behind early initiation of areca nut chewing. A survey of 2,846 students aged 4–18 years from rural government schools in Western Rajasthan was conducted using a structured questionnaire, along with a systematic oral examination. Students were grouped into 4–10 years and 11–18 years categories. Areca nut use was reported in 34.5% of younger children and 72.8% of older students. Social influences and the stimulant effects of areca nut were major factors for habit initiation and continuation. Additionally, 55 students were diagnosed with varying stages of Oral Submucous Fibrosis (OSMF).[2] The findings highlight the urgent need for areca nut cessation programs at the primary school level in Western Rajasthan [1].

Nutritional Supplements

A large number of patients with OSMF are found to have associated nutritional deficiencies. In a study conducted by Thakur N *et al.*, in this interventional study included 50 clinically diagnosed OSMF patients who received daily micronutrient supplementation containing essential vitamins and minerals. Mouth opening (interincisal distance) was assessed at baseline, one, three, and six months, along with secondary outcomes such as pain (VAS score), intolerance to spices, burning sensation, and ulceration. Statistical analysis ($P < 0.05$ considered significant) showed a significant improvement in mean mouth opening from 21.0 mm to 28.6 mm at six months ($P < 0.01$). Pain levels reduced from moderate to mild, intolerance to spices decreased from 96% to 48%, burning sensation from 54% to 26%, and ulceration resolved completely.[5] The findings suggest that micronutrient therapy is an effective, noninvasive, and economical treatment for early-stage OSMF, improving both functional and symptomatic outcomes, although long-term studies are recommended to standardize treatment protocols.

Enzymes and Fibrinolytic Agents

Enzymes and fibrinolytic agents help to break down collagen and hence are being used in the treatment of OSMF. Collagenase, hyaluronidase, chymotrypsin and colchicine are under use in the treatment of OSMF. Hyaluronidase acts by breaking down the intercellular cement substance, leading to improvement in burning sensation and ulceration; however, its combination with dexamethasone provides superior long-term outcomes. In a comparative 12-week study by Krishnamoorthy *et al.*, 50 OSMF patients were divided into two groups: one received oral colchicine with intralesional hyaluronidase, while the other received intralesional hyaluronidase combined with hydrocortisone. The colchicine–hyaluronidase group showed better clinical response [6]. Additionally, enzymes such as collagenase, which degrades collagen cross-links, and chymotrypsin, a proteolytic enzyme that cleaves peptide bonds, have demonstrated symptomatic improvement in OSMF patients.

Antioxidants

Pérez-Leal M *et al.*, conducted a PRISMA-guided systematic review in which analysed 19 clinical trials from PubMed, Web of Science, and Scopus, with quality assessment based on Cochrane guidelines, to evaluate the efficacy of antioxidant therapy in OSMF management. Antioxidants such as aloe vera, curcumin, and lycopene demonstrated significant improvement in burning sensation, mouth opening, tongue protrusion, and cheek flexibility [7]. The findings suggest that antioxidant therapy is an effective alternative or adjunct to conventional treatments like corticosteroids, though further standardized, large-scale studies are needed.

Human Placental Extracts

Thakur G *et al.*, conducted a prospective randomized controlled trial, 10 patients with mouth opening less than 20 mm were divided into a study group receiving topical placental extract and a control group without it. Postoperative assessment at 1, 2, and 4 weeks demonstrated greater improvement in wound healing, reduced discomfort, and a significantly higher increase in mouth opening in the study group (21.20 ± 2.77 mm) compared to the control group (13.8 ± 2.68 mm), indicating the beneficial role of placental extract as an adjunct therapy.[8]

Intralesional Corticosteroids Therapy

Intralesional therapy in OSMF involves direct injection of medications such as corticosteroids and hyaluronidase into fibrotic bands. It helps reduce inflammation, break down collagen fibers, and improve mouth opening and associated symptoms. Corticosteroids help reduce inflammation in OSMF lesions. They also inhibit collagen synthesis, thereby decreasing fibrosis and improving symptoms. R Shrivastva *et al.*, documented a study compared the effectiveness of TurmNova® curcumin lozenges with intralesional corticosteroid therapy (dexamethasone with hyaluronidase) in the management of Group III Oral Submucous Fibrosis (OSMF). Eighty patients were randomly divided into two groups: Group A received curcumin lozenges (100 mg turmeric extract with clove oil) three times daily for three months, while Group B received biweekly intralesional injections for the same duration. Clinical parameters were evaluated and analysed using IBM SPSS version 21. Results showed significantly greater improvement in mouth opening, tongue protrusion, and reduction of burning sensation and pain in the curcumin group compared to the steroid group. The study concluded that curcumin lozenges, due to improved bioavailability and reduced hepatic inactivation, offer a safe, cost-effective, and non-invasive alternative to conventional therapy, though larger long-term studies are recommended.[4] Curcumin also demonstrates potential as an effective chemo preventive agent in oral premalignant conditions.

Cytokines

Chan PK *et al.*, conducted a study examined the effect of arecoline on pro-fibrotic cytokines in human gingival fibroblasts and mast cells and found that higher concentrations (100–200 µg/mL) induced cytotoxicity and stimulated the release of IL-33, IL-13, and CTGF, along with mast cell degranulation.[10] These results highlight the significant role of the IL-33/IL-13 axis in the pathogenesis and progression of OSMF and indicate its potential as a therapeutic target.

Low-Level Laser Therapy (LLLT)

Sukanya D *et al.*, conducted a study assessed the efficacy of low-level laser therapy (LLLT) as a photo biomodulation technique in 30 OSMF patients. Laser therapy was administered to the buccal mucosa on days 0, 3, 7, and 15, with follow-up evaluations up to six months. A statistically significant improvement in mouth opening was observed, showing a mean increase of 9.91 mm by day 15 and 14.29 mm at six months, supporting LLLT as an effective adjunct in OSMF management.[11]

Tissue Therapy

Tissue therapy, proposed by Filatov in 1933 for the treatment of OSMF, is based on the principle that tissues separated from the body and subjected to adverse yet non-lethal conditions undergo adaptive changes, leading to the formation of substances that enhance their survival.[12] When these biologically active substances are reintroduced into the body, they promote tissue repair through a process termed “biogenic stimulation.” Placentrex, a sterile aqueous extract of human placenta, contains vitamins, trace elements, nucleotides, enzymes, amino acids, steroids, and fatty acids, and is utilized for its regenerative and biostimulatory effects.

Physical Exercise

Chitlange NM *et al.* conducted a study in which physiotherapy serves as an important adjunct through mouth-opening exercises, ultrasound, and other modalities. Clear protocols regarding pain control, optimal exercise regimens, and long-term management—particularly in advanced stages—are needed to improve treatment outcomes and standardize care.[13]

Hyperbaric Oxygen Therapy

Kumar MA *et al.*, conducted a study involves breathing 100% oxygen at 2.0–2.5 atmospheres for 60–120 minutes, enhances oxygen delivery to hypoxic tissues and exhibits anti-inflammatory effects.[14] By improving the hypoxic microenvironment of OSMF, HBOT may offer therapeutic benefits at the cellular and molecular levels, suggesting its potential role as an adjunctive treatment modality

Microwave Diathermy

Rae and co-workers observed that microwave diathermy was especially beneficial in treating fibrosis

and trismus, indicating its possible usefulness in managing oral submucous fibrosis (OSMF).[15]

Ultrasound

Mukul SK *et al.*, conducted a study evaluated ultrasound elastography as a noninvasive tool to objectively assess disease severity in 27 clinically staged OSMF patients. Transcutaneous ultrasonography using stress-strain elastography graded tissue stiffness across eight oral mucosal zones, correlating elastographic scores with clinical mouth opening stages. [16] A statistically significant correlation ($p = 0.007$) was observed between elastographic and clinical grading, with sensitivity of 90.9% and specificity of 20%. These findings suggest that ultrasound elastography is a promising adjunctive diagnostic tool for objectively assessing OSMF severity, though further refinement and quantitative studies are needed.

A New Intraoral Appliance for Trismus in OSMF

A newly designed intraoral appliance, "Nallan C-H," was introduced as a conservative management option for trismus in patients with oral submucous fibrosis (OSMF). The device is noninvasive, economical, and easy to use, resulting in satisfactory patient compliance. In this preliminary trial, three OSMF patients were advised to wear the appliance overnight for approximately 12 hours daily over a period of eight weeks, with evaluation conducted after two months. The intervention resulted in a measurable and clinically meaningful improvement in mouth opening, with increases ranging from 2 to 8 mm in all patients. These findings suggest that the Nallan C-H appliance may serve as a simple, patient-friendly adjunct in the management of OSMF-related trismus, although larger studies are required to validate its long-term efficacy and standardize its clinical use. [17]

Osteopathic Therapy

Goyal M *et al.*, conducted this case report assessed the effectiveness of osteopathic manipulative treatment (OMT) in a 30-year-old male with a four-year history of restricted mouth opening and discomfort while consuming spicy foods. Although previous medical therapy alleviated the burning sensation, it failed to improve mouth opening. Following OMT sessions conducted twice weekly for four weeks, along with a prescribed home exercise program, the patient demonstrated a substantial improvement in mouth opening from approximately 10 mm to 22 mm, indicating the potential role of OMT as an adjunctive therapeutic option in OSMF management. [18]

Surgical Therapy

Kholakiya Y *et al.*, conducted a study aimed to assess the effectiveness of a seagull-shaped nasolabial flap (NLF) combined with short-term oral pentoxifylline (PTX) in the surgical management of grade IV oral

submucous fibrosis (OSMF) following fibrotomy. A retrospective analysis of 18 patients (15 males and 3 females) with a mean preoperative mouth opening of 8.11 ± 3.38 mm was conducted. Postoperatively, patients received 400 mg of pentoxifylline three times daily for three months and were followed up at one month, six months, and one year to monitor mouth opening, relapse, malignant transformation, and complications. [19] A statistically significant improvement in mouth opening was observed, increasing to 37.67 ± 3.74 mm, with minimal surgical complications and no evidence of relapse or rebound fibrosis. Pentoxifylline was well tolerated and appeared to enhance postoperative outcomes, suggesting that its adjunctive use with surgical reconstruction may improve mouth opening, reduce symptoms, and help prevent recurrence in OSMF.

MATERIALS AND METHODS

Search Strategy: An extensive literature search was conducted using PUBMED, MEDLINE, EMBASE, and COCHRANE databases. The keywords used for the search included "treatment modalities," "Oral submucous fibrosis," "Mouth opening" "Diagnostic," and "Therapeutic." The search was limited to published literature till 2025 and incorporated the aforementioned MeSH terms. Only randomized controlled trials were included in this study. Exclusion criteria comprised articles not in English, those with only an abstract available, case reports, cohort studies, poorly designed studies, and review articles.

RESULT

Out of 27 publications, related to search strategy, 22 full articles which were related to the treatment modalities of oral submucous fibrosis were acquired for further inspection. Out of the 22 articles, 19 articles met the inclusion criteria. [Figure 1—PRISMA flowchart]. The data was collected and a brief summary of the studies regarding the oral submucous fibrosis.

PICOs

Population: Oral Submucosal Fibrosis, Adult, Aged

Intervention: Habit cessation therapy, Nutritional supplements, Enzymes and fibrinolytic agents, Antioxidants, Human placental extracts, Intralesional corticosteroid therapy, Cytokines, Low level laser therapy, Tissue therapy, Physical exercise, Hyperbaric oxygen therapy, Microwave diathermy, Ultrasound, A new intraoral appliance for trismus in OSMF, Osteopathic therapy, Surgery

Comparison: Jaw stretching exercises, Light Therapy, Surgery, Physiotherapy, Placebo, Systemic Topical Pharmacotherapy

Outcome: Speech normal, chewing normal, Oral Submucosal Fibrosis, Eating Normal, Maximal mouth opening, Finding Related to Ability to Move Jaw.

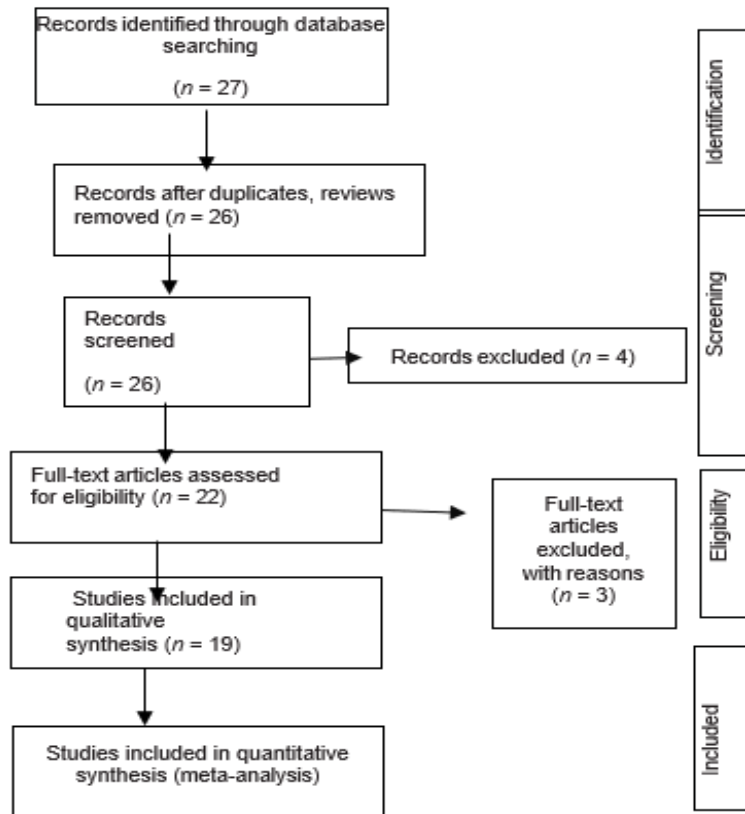


Figure 1: PRISMA 2009 Flow Diagram of the Study

DISCUSSION

Oral Submucous Fibrosis is recognized as a chronic, progressive, debilitating, and high-risk precancerous condition. First reported by Schwartz in 1952, who termed it “atrophica idiopathica (tropica) mucosae oris,” OSMF is characterized by an increase in juxtaepithelial fibrosis of the oral mucosa, the

oropharynx, and, less commonly, the larynx. This pathological process leads to burning sensations, stiffness of the oral mucosa, and a progressively reduced mouth opening. In later stages, the submucosa and deeper tissues can also be affected. The risk for malignant transformation of OSMF is reported to vary significantly, ranging from 7% to 30%.

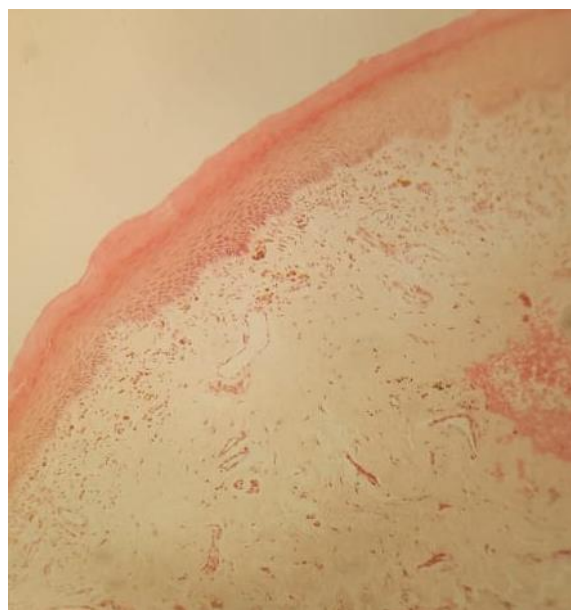


Figure 2: OSMF involving blanching left buccal mucosa



Figure 3: Histopathological features of OSMF with no dysplasia

Figure 2 shows, the clinical image which demonstrates characteristic features of Oral Submucous Fibrosis involving the left buccal mucosa. There is evident mucosal blanching with a pale, marble-like appearance, indicative of underlying fibrosis and reduced vascularity. The mucosa appears stiff and inelastic, with loss of normal suppleness. Areas of diffuse opacity and subtle fibrous band formation can be appreciated, contributing to restricted cheek mobility. The surface appears smooth and atrophic, consistent with progressive subepithelial collagen deposition. These findings correlate with the clinical presentation of burning sensation, mucosal rigidity, and gradual limitation in mouth opening, which are hallmark features of OSMF. Figure 3 depicts histopathology of OSMF which shows epithelial atrophy with flattened rete ridges and varying degrees of keratinization. The underlying connective tissue demonstrates dense, hyalinized collagen bundles with reduced vascularity. Chronic inflammatory cell infiltration may be present in early stages, while advanced lesions exhibit marked fibrosis and decreased cellularity.

The present review highlights the multifactorial nature of Oral Submucous Fibrosis (OSMF) and the wide spectrum of therapeutic approaches evaluated in recent studies. Habit cessation remains the cornerstone of management, as demonstrated by Singhvi *et al.*, who emphasized the early initiation of areca nut use and the urgent need for preventive interventions. Nutritional supplementation, as reported by Thakur N *et al.*, showed significant improvement in mouth opening and symptomatic relief, supporting its role in early-stage disease.

Pharmacological therapies such as intralesional corticosteroids combined with hyaluronidase have shown beneficial outcomes; however, Srivastava *et al.*, observed superior results with curcumin lozenges, suggesting promising noninvasive alternatives. Antioxidant therapy, reviewed by Pérez-Leal *et al.*,

further reinforced the value of agents like aloe vera and lycopene in reducing burning sensation and improving functional parameters. Adjunctive modalities including low-level laser therapy demonstrated measurable improvement in mouth opening, as reported by Sukanya *et al.*,

Advanced cases often require surgical intervention. Kholakiya *et al.*, reported significant postoperative improvement when nasolabial flap reconstruction was combined with pentoxifylline. Emerging approaches targeting cytokine pathways, such as the IL-33/IL-13 axis described by Chan *et al.*, offer potential for future targeted therapies. Overall, while multiple modalities show benefit, standardized long-term clinical trials are essential to establish definitive treatment protocols.

CONCLUSION

Management of Oral Submucous Fibrosis (OSMF) should be planned with consideration of the patient's overall systemic condition as well as their mental and emotional well-being. Preventive strategies, especially early education regarding the harmful effects of areca nut and related habits, play a crucial role in limiting disease progression. Timely habit cessation programs combined with appropriate medical and surgical interventions can significantly enhance treatment outcomes and quality of life.

A multidisciplinary approach involving dental professionals, physicians, and psychological support services may provide more comprehensive care. Regular follow-up and monitoring are essential to assess therapeutic response and detect any malignant transformation at an early stage. Patient motivation and long-term compliance remain key determinants of successful management. Furthermore, well-designed clinical studies with larger sample populations are required to establish standardized and integrated treatment protocols for OSMF.

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