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# A new innovation for drug delivery and mucosal protection in patients with OSMF

**Dr Vishal Mehrotra , Dr Rahul Srivastava, Dr Kriti Garg**

Professor & HOD, Department Oral Medicine and Radiology, Rama Dental College Hospital and Research Centre, Rama University, Kanpur
Mobile No. : 9956575812,Email: vishal4march@rediffmail.com
Professor, Department Oral Medicine and Radiology , Rama Dental College Hospital and Research Centre, Rama University, Kanpur
Mobile No. : 9450326179,Email: drrahul_osmf@yahoo.com
Reader, Department Oral Medicine and Radiology , Rama Dental College Hospital and Research Centre, Rama University, Kanpur
Mobile No. : 9936434177,Email: drkritigarg@gmail.com

## Abstract:

Oral submucous fibrosis is a chronic, debilitating disease characterized by gradually increasing fibrosis of oral cavity and pharynx, mainly the buccal mucosa, resulting in trismus. Various flaps have been used to reconstruct the surgical defects following excision of fibrous bands. It is inevitable to prevent these flaps from trauma by occlusion. The main objective of this technical innovation is to protect the flaps in the post-operative period, prevent injury to buccal mucsa which is quiet stiff and also deliver drug over prolonged period of time.

**Keywords:** Oral submucous fibrosis, Appliance, Drug Delivery, Prolonged period

## Introduction:

Oral submucous fibrosis (OSMF) is an insidious, chronic, disabling disease of obscure aetiology that affects the entire oral cavity, sometimes the pharynx, and rarely the larynx .Since ancient era of Shushruta, OSMF has been reported in Indian population as “Vidari”. It was first described by Schwartz in 1952 and by

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

Joshi in modern India. [1] Trauma from occlusion is one of the major threats for reconstructive options, accounting for necrosis and subsequent failure of flaps ans also in OSMF patient this stiffness may lead to chronic trauma due to dentition on the mucosa. The problem of flap chewing needs to be addressed eminently, especially in the posterior region of oral cavity since, flap approximates the occluding teeth.

OSMF is defined as “an chronic insidious disease affecting any part of the oral cavity and sometimes the pharynx. It is always associated with juxta-epithelial inflammatory reaction followed by fibroelastic changes of the lamina propria with epithelial atrophy leading to stiffness of the oral mucosa and causing trismus and inability to speak” in 1966 given by Pindborg and Sirsat. [2]

Because the origin of OSMF is unknown and the condition is progressing, treatment for it primarily consists of patient counselling. [3] Different treatment modalities are there for OSMF one is conservative (includes iron supplements, intra-lesional injection, vitamins etc) & another one surgical intervention (severe condition when interincisal opening less than 20 mm). [4,5]

According to geologic distribution, more than 2.5 million individuals are affected worldwide, the majority being from South and South East Asia. [6] The prevalence of OSMF in India has been estimated to range from 0.2 to 2.3% in males and 1.2–4.6% in females, with a broad age range from 11 to 60 years. [7] The spurt in cases of OSMF especially within the youth is due to commercialization, widespread availability of products, and psychosocial impact of surrounding peer influences. [8,9]Transmigration of populations has resulted in a high prevalence of OSMF cases in European countries, USA and South Africa

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contributing to the global burden of the disease.[7]The major etiological factor contributing to the development of OSMF is areca nut chewing. [10] The other contributory factors, hypothesized to trigger the disease process include consumption of commercialized smokeless tobacco products, high intake of chilies in the diet, presence of harmful traces of copper in food products, micronutrient deficiencies, and genetic predisposition. [11,12]

The clinical presentation of OSMF depends on the stage of the disease at detection. The bulk of OSMF cases exhibit intolerance to spicy food, with a stiffness of intraoral soft tissue mucosa and lips, with ensuing restriction of mouth opening and tongue movement. The hallmark of the disease is submucosal fibrosis that affects most parts of the oral cavity, pharynx, and upper third of the esophagus. [13] The fibrosis leads to poor alimentation and malnutrition consequentially resulting in low levels of serum proteins and anemia and increases the risk of progression to malignancy. Paymaster was the first to define the premalignant nature of OSMF in 1956. The malignant transformation rate ranges from 7 to 30% according to various studies conducted in India, Pakistan, and Taiwan. [14,15,16]

The management of OSMF poses a significant challenge to the clinician as it lacks an established treatment regimen. The main objectives in the treatment of OSMF are fundamental to ameliorate the signs and symptoms, stop disease progression, and reduce the propensity for malignant transformation. [17] The interventions in the treatment of OSMF include a wide spectrum of medications comprising of dietary supplements (vitamins and antioxidants), anti-inflammatory agents (corticosteroids), proteolytic agents (such as hyaluronidase and placental extracts), vasodilators, immunomodulators, and anti-cytokines. These modalities may be

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

administered orally, topically, or via submucosal injection. The advanced cases of OSMF are managed by surgical interventions.[18] Physical therapy acts synergistically with other treatment regimens or may be used as a single modality to manage the OSMF patients. Various natural herbal ingredients like Aloe vera, Tulsi, Turmeric have evolved in the last decade for the treatment of OSMF. [19,20]

**Fabrication of appliance**

Alginate impressions of maxillary and mandibular arches were recorded and poured in dental stone. Both the casts were then articulated in occlusion. Wire bending was done by using 21 gauge wire on the mandibular cast to incorporate a passive labial bow and modified pin head clasps. After completion of wire bending, acrylization was done. Two buccal shields extending from premolar to second permanent molar on both sides were made using self-cure acrylic resin which were supported by lingual plate with the aid of modified pin head clasps. Buccal shields were made in such a way that they had minimal contact with the teeth and soft tissues while from the outer side, the shape was slightly convex in order to keep buccal mucosa away from teeth and promote healing even after the removal of appliance. After acrylization, the appliance was trimmed, polished, and checked for sharp extensions. Custom made pore were fabricated in which the drug was filled and will slowly release over time. (Figure 1)

After appliance delivery, postinsertion instructions were given to the patient and was recalled at 1, 3, and 6 months follow-up. After 6 months follow-up, it was observed that the patient had better healing of the buccal mucosa and also cheek flexibility had increased.

**Advantages of appliance:**

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

It is a custom made appliance with good retention and stability.

Buccal flanges have adequate durability and strength to separate the flaps.

It adapts the flap to contour of cheek.

It is made of a material which is readily available, and requires minimal technical skills for fabrication.

Active or passive mouth opening exercises can be carried out.

Oral seal is achieved easily.

Maintenance is easy and can be done by the patient regularly.

It is cost-effective.

Deivers drug over prolonged period of time

Easy adaptability by the patients

**Limitations:**

Difficulty to insert intraorally during the initial phases of treatment

Excessive salivation

Reduced strength of appliance after weeks of usage may be due to fabrication errors.

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

**Figure 1:** Patient wearing the appliance

This has been created and tested for the treatment of trismus, with positive results. For 8 weeks, patients were urged to wear the device 12 hours every night and followed up every week to check any improvement and encouraged to perform isometric mouth exercises daily according to their comfort. For every visit, the mouth opening was measured and the screw was released 1mm on each side to improve mouth opening. A follow-up of 2 months was performed on each patient.

## Conclusion

OSMF is relatively common disease and requires long term treatment for which various appliances have been fabricated to increase the mouth opening. As the disease is progressive in nature, constant improvement of these appliances is required. Long term studies using these appliances should be carried out for significance results. Patient councelling, patient co-operation, periodic recalling and further design improvement help in patient management.

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ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

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