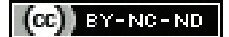


# Comparative Evaluation of Conventional Nasolabial Flap with and without Fishtail Modification in Patients with Oral Submucous Fibrosis: A Research Protocol

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## ABSTRACT

**Introduction:** Oral Submucous Fibrosis (OSMF) is a long-term condition characterised by the gradual buildup of fibrous tissue in the oral cavity, often extending to the throat and upper oesophagus. The primary symptoms include progressive limitation in mouth opening due to the formation of stiff fibrous bands in the oral mucosa, accompanied by muscle atrophy. However, the most concerning aspect of this restriction, known as trismus, is its hindrance to effective cancer monitoring. Surgical approaches typically aim to release these fibrotic bands, while medical interventions focus on managing inflammation and preventing further fibrosis.

**Need of the study:** A modification of the nasolabial flap has been suggested for the reconstruction of intraoral defects following ablative surgery for OSMF. The study will assess its merits in comparison to the conventional nasolabial flap.

**Aim:** To evaluate and compare the aesthetic and functional outcomes of the rima oris between the Conventional Nasolabial Flap and the Nasolabial Flap with Fishtail Modification in patients undergoing surgical intervention for OSMF.

**Materials and Methods:** A prospective, double-blinded, randomised controlled trial will be conducted in the Department of Oral and Maxillofacial Surgery at Acharya Vinoba Bhave Rural Hospital, associated with Jawaharlal Nehru Medical College, Wardha, Maharashtra, India, from November 2023 to November 2024. Patients older than 18 years of age diagnosed with OSMF, without any superimposing cancerous lesions, will be included in the study. They will be divided into two groups: Group A will be treated with bilateral fibrotomy, coronoidotomy and reconstruction with the conventional nasolabial flap, while Group B will undergo the same surgical intervention, except that the reconstruction will be performed using the fishtail modification of the nasolabial flap. The parameters that will be compared include interincisal mouth opening, intercommissural width, dehiscence and flap necrosis. The analysis will be conducted using the Chi-square test and Fisher's-exact test for categorical data and the independent t-test for continuous data that follow a normal distribution. These statistical tests will help evaluate the association between different demographic, clinical and etiological factors and the outcomes under consideration. A p-value of <0.05 will be considered statistically significant.

**Keywords:** Local flaps, Precancerous condition, Reconstruction

## INTRODUCTION

The OSMF is typically described as a persistent, gradual scarring ailment affecting the oral cavity, often extending to the pharynx and upper oesophagus [1]. Schwartz initially documented the condition in 1952, while Pindborg JJ et al., later reported a prevalence ranging from 0.2% to 0.5% in India [2,3]. OSMF can occur in a wide age range but is usually observed in individuals aged 20-30 years [3]. The characteristic feature of this condition is the gradual deposition of fibrous tissue in the lamina propria. Patients commonly complain of a progressive restriction in mouth opening, which results from rigid fibrous bands accumulating in the oral mucosa in the juxtaepithelial region, accompanied by atrophy of the surrounding muscles. In advanced stages of the condition, individuals may experience difficulty swallowing and may also report pain in the ears and throat. Severe trismus, or restricted mouth opening, can occur, causing the inflexible mucosa to press against the teeth. This pressure can lead to chronic ulceration and increase the risk of subsequent infections [4].

Severe trismus has a deleterious effect on mastication, deglutition, articulation and maintenance of oral hygiene, often leading to a marked compromise in quality of life. However, one of the most concerning implications of trismus in OSMF is its hindrance to

effective cancer surveillance, particularly among patients classified under Group IV [5]. Placing suitable grafts after surgically excising the fibrous bands to maintain the new mouth opening is of utmost importance in the management of advanced OSMF. Medical interventions have primarily focused on mitigating the inflammatory response and halting the progression of fibrosis [6].

The medical line of management consists of a multifaceted approach aimed at managing symptoms, potentially reversing pathological processes and improving overall oral health. One key aspect is the modulation of inflammation and immunity, emphasising the use of drugs like steroids, interferon gamma and colchicine to suppress inflammatory responses and fibroblast proliferation. These medications target the underlying inflammatory processes believed to contribute to fibrosis in OSMF. Another focus is on promoting oral mucosal blood flow to enhance tissue oxygenation and nutrient delivery. This involves the use of vasoactive drugs like pentoxifylline and buflomedil hydrochloride to improve peripheral blood flow, potentially aiding in tissue healing and reducing fibrosis [6,7].

Recent studies also emphasise the importance of Antioxidant, Nutrient and Micronutrient Therapy (AONMT) in combating the effects of Reactive Oxygen Species (ROS) and malnutrition, which can exacerbate OSMF [8,9]. Substances like beta-carotene, lycopene

and tea pigments are used for their antioxidant properties, while vitamins and minerals are emphasised for their roles in promoting tissue regeneration and cellular health [10].

Despite the diverse array of treatment options discussed, managing advanced stages of OSMF solely through medicinal intervention remains a challenge. While various drugs and therapies show promise in managing symptoms and potentially slowing disease progression, no definitive cure has yet been identified. Therefore, advanced stages of OSMF are generally managed through surgery [11].

The liberation of fibrotic bands is the cornerstone of all surgical methodologies utilised. The nasolabial flap has proven to be one of the most reliable methods for this purpose. It can be classified as a flap based on the angular artery in an axial pattern, which can be based inferiorly or superiorly. The blood supply derived from various vessels in close proximity makes the nasolabial flap quite versatile and dependable. It is recommended because it can be elevated quickly, aligns with the surgical defect and has an appropriate size for covering the defect. Speech and swallowing are minimally affected and the cosmetic outcome is relatively favourable, as the scar aligns with normal creases [12].

Various modifications have been made to overcome certain drawbacks of this flap. Given the different chewing patterns of betel nut, fibrotic bands can be palpated in any part of the oral cavity, such as the buccal mucosa, retromolar trigone area, or even the perioral region. The presence of perioral bands poses a significant challenge for reconstruction, as the fibrotomy incision required to release these bands may violate the commissural anatomy. This can lead to aesthetic deformity, such as the widening of the oral commissure [1,12]. Therefore, it is prudent to release the fibrous bands in a manner that does not distort the boundaries of the rima oris.

The authors advocate for the use of a fibrotomy incision that extends into the lip rather than into the commissure, ensuring that the commissural anatomy is not violated. It is essential that the nasolabial flap used to rehabilitate this surgical deformity is modified accordingly. Therefore, a modification of the conventional nasolabial flap, in which the anterior wing is bifurcated into an upper and lower arm, has been proposed. The hypothesis is that this modification eases the release of the rima oris bands without causing tearing and leads to better aesthetic and functional outcomes.

**Aim:** To evaluate and compare the aesthetic and functional outcomes of the rima oris between the 'Conventional Nasolabial Flap' and the 'Nasolabial Flap with Fishtail Modification' in patients undergoing surgical intervention for OSMF.

#### Primary Objectives:

- To evaluate the aesthetic and functional outcomes, as well as complications, in reconstruction with the 'Conventional Nasolabial Flap' in individuals undergoing surgery for OSMF.
- To evaluate the aesthetic and functional outcomes, as well as complications, in reconstruction with the 'Fishtail Modification of the Nasolabial Flap' in individuals undergoing surgery for OSMF.
- To compare the aesthetic and functional outcomes, as well as complications, in patients undergoing surgical intervention for OSMF and reconstruction with the 'Conventional Nasolabial Flap' versus the 'Fishtail Modification of the Nasolabial Flap.'

**Null hypothesis:** The fishtail modification of the nasolabial flap does not distort the rima oris when used for reconstruction after the release of fibrous bands in OSMF.

**Alternate hypothesis:** The fishtail modification of the nasolabial flap distorts the rima oris when used for reconstruction after the release of fibrous bands in OSMF.

## REVIEW OF LITERATURE

Multiple modalities of treatment are available for the management of OSMF, ranging from medicinal to surgical options. In cases that

require surgical intervention, the choice of reconstructive flaps is extensive, including local flaps like the nasolabial and buccal fat pad, along with free flaps based on the radial artery [8]. In a case series of 75 patients conducted by Ullah H et al., in 2023, good postoperative outcomes in terms of mouth opening were reported in 65.3% of patients [13]. Although the nasolabial flap is often favoured due to its reliability, proximity to the defect and ease of elevation, a number of modifications to this flap have been developed.

Kshirsagar R et al., conducted a retrospective study involving 32 patients with advanced OSMF who underwent reconstruction with bilateral inferiorly based nasolabial flaps. This study revealed various complications, including partial necrosis, intraoral hair growth, unacceptable extraoral scars, wound dehiscence, loss of the nasomaxillary crease, orocutaneous fistula and a pincushioning effect around the nasolabial fold. Despite these complications, the patients showed satisfactory improvement in mouth opening. The complications were managed through interventions such as excision of necrotic tissue, local treatments, or surgical corrections, highlighting the effectiveness of nasolabial flaps in treating OSMF [14].

Variations such as inferiorly based, islanded pedicled and extended nasolabial flaps have been employed. A retrospective analysis was conducted on 27 patients reconstructed with the Isolated Pedicled Nasolabial Flap (ipNLF) at two high-volume cancer centres: Homi Bhabha Cancer Hospital in Varanasi, India and Army Hospital Research and Referral in New Delhi, India. This study aimed to assess the versatility and reliability of the isolated pedicled nasolabial flap in head and neck cancer. Oral cavity ablative defects accounted for 22 cases, with oropharyngeal (four patients) and hypopharyngeal (one patient) defects following closely behind. The average operation time for flap harvesting and inset was 57.7 minutes. The average recovery times for tracheotomy and postoperative feeding tube removal were five and 10 days, respectively. The Speech Intelligible Rating (SIR) scores of 24 patients were I or II. There were no cases of orocutaneous fistula, donor site wound dehiscence, or flap loss. Additionally, there was no oral incompetence in 25 cases and little to no deviation of the angle of the mouth was observed in 26 subjects [15].

In a retrospective analysis, Kholakiya Y et al., evaluated 18 patients who received seagull NLF treatment for grade IV OSMF. The cohort consisted of fifteen men and three women. With a mean preoperative mouth opening of  $8.11 \pm 3.38$  mm, all patients were categorised as stage IV OSMF. Following surgery, patients received 400 mg of Pentoxifylline (PTX) three times a day for three months. Follow-ups were conducted at one, six and 12 month intervals, during which mouth opening, the presence or absence of malignant transformation, recurrence and complications were noted. In the postoperative phase, there was a statistically significant increase in mouth opening from  $8.11 \pm 3.3$  mm to  $37.67 \pm 3.74$  mm. The complications associated with the modified NLF were minimal, with no incidence of relapse or rebound fibrosis [16].

Ozkuş I designed a bifurcated nasolabial flap in 1992 for the reconstruction of the nose and this study utilises a similar technique for the reconstruction of intraoral defects [17].

## MATERIALS AND METHODS

A prospective, double-blinded, randomised controlled trial will be conducted in the Department of Oral and Maxillofacial Surgery at Acharya Vinoba Bhave Rural Hospital, associated with Jawaharalal Nehru Medical College, Wardha, Maharashtra, India, will include 36 patients with Stage 3A, 3B and 3C OSMF (Haider Classification) [18] reporting to Sharad Pawar Dental College and Siddharth Gupta Memorial Cancer Hospital over a period of one year (November 2023 to November 2024). The study will be conducted after obtaining approval from the Institutional Ethics Committee (Ref. no.: DMIMS (DU)/IEC/2022/774) (CTRI/2023/11/060376). Consent will

be obtained from patients willing to participate in the study and who have been diagnosed with OSMF during this period.

#### Inclusion criteria:

- Patients older than 18 years of age who have been diagnosed with OSMF.
- Patients with Stage 3A, 3B and 3C OSMF (Haider Classification) [18].
- Patients willing to undergo surgery for OSMF.
- Patients with palpable perioral fibrous bands.

#### Exclusion criteria:

- Patients who are medically compromised {American Society of Anaesthesiologists (ASA) class III and IV} [19].
- Patients who have undergone surgery for OSMF in the past.
- Patients with radiological presentations of any other cause of trismus.
- Patients with superimposed precancerous or cancerous lesions.
- Patients with a history of trauma or any traumatic injuries to the jaws.
- Patients who are unwilling to provide consent and participate in follow-up.

#### Sample size calculation:

Daniel formula for sample size:

$$n = Z^2 \cdot P(1-P) / d^2$$

Where,

Z/2 is the level of Significance at 5% i.e., 95%

Confidence interval=1.96

P=Prevalence of OSMF=2.3%=0.023 [1]

d=Desired error margin=7%=0.078

$$n = 1.962 \times 0.023 \times (1 - 0.023) / 0.072$$

$$= 17.61$$

18 patients needed in each group.

#### Study Procedure

These 36 patients will be randomly divided into two groups using a lottery system (n=18 each). Reconstruction in Group A patients is planned with conventional nasolabial flaps, while reconstruction in Group B patients is planned with the nasolabial flap with fishtail modification. The procedure will be explained to each patient.

The limitations will be explained and informed consent will be obtained from each patient. Patients will then undergo routine haematological and serological investigations. A chest X-ray and Electrocardiogram (ECG) will be performed, which are required for preanaesthetic clearance. Preoperative inter-incisal mouth opening and the width of the oral commissure will be measured. These preoperatively recorded measurements will be compared to measurements recorded postoperatively. An independent observer, blinded to the study and not involved in data extrapolation, will record these measurements.

A single operator will perform all procedures on each patient. After inducing general anaesthesia, the fibrous bands will be surgically released intraorally. Standard surgical marking for the nasolabial flap will be done bilaterally. The flap will be designed along the nasolabial crease to ensure that the final scar line is well concealed within the nasolabial fold. A pinch test will provide a fair approximation of the skin's laxity before designing the flap. The length and width of the flap will be based on the extent of the defect and will be designed from the point of rotation.

The flap's base will be left intact while the incision is carried out up to the subdermal tissues. The flap will be raised by blunt dissection, taking care to avoid disturbing the facial muscles. It is important to ensure that the flap does not shear off from the subdermal plexus. An attempt will be made to incorporate the facial artery within the

flap. After elevating the flap, a wide tunnel will be created toward the base of the flap to allow the flap to enter the oral cavity without compression. The flap will then be de-epithelialised at the base and along the section that will rest in the myomucosal tunnel, rotated intraorally and sutured 7-10 mm short of the commissure [20]. For the modification, before the setting is carried out over the fibrotomy defect sites, the anterior end of the flap will be bifurcated into a superior and inferior arm and sutured in the area where the perioral fibrotomy has been performed.

#### Functional parameters:

- Interincisal distance, or mouth opening, will be taken as the primary functional parameter. The mean average for maximal mouth opening in males is 51.3 mm, while for females, it is 44.3 mm [21]. The mouth opening of the patients will be measured using a Vernier calliper preoperatively, intraoperatively and postoperatively. The postoperative mouth opening in both groups will be measured at postoperative intervals of seven days, 15 days, one month and three months.
- Flap necrosis: The bifurcation of the anterior wing of the nasolabial flap may lead to compromised blood supply; hence, flap necrosis will be taken as a parameter to assess the rationale for using this modification. Discolouration at the anterior wing will be assessed separately for both the superior and inferior bifurcated tips at intervals of postoperative day 1, day 3 and day 7.

**Aesthetic parameter:** The aesthetic outcomes of this study will be evaluated based on the widening of the oral commissure, with the normal measurement taken to be 50.66 mm [22]. This will be measured using a Vernier calliper from one corner of the mouth to the other preoperatively and postoperatively at intervals of postoperative days 5, 7 and 10.

#### Complications:

- Dehiscence at the corner of the mouth that will be measured at day 5 postoperatively.
- Flap necrosis, which will be evaluated on postoperative days 1, 3 and 7.

## STATISTICAL ANALYSIS

Data entry will be conducted using a Microsoft Excel spreadsheet and subsequent statistical analysis will be performed using Stata 10 software. The analysis will involve employing the Chi-square test and Fisher's-exact test for categorical data, along with the independent t-test for continuous data that demonstrates a normal distribution. These statistical tests will be utilised to evaluate the relationship between various clinical parameters and the outcomes of interest, including inter-incisal mouth opening, inter-commissural width, dehiscence and flap necrosis. A p-value of <0.05 will be considered statistically significant.

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#### PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Apr 16, 2024
- Manual Googling: May 06, 2024
- iThenticate Software: Jul 17, 2024 (13%)

#### ETYMOLOGY: Author Origin

EMENDATIONS: 7

#### AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Apr 15, 2024**

Date of Peer Review: **May 02, 2024**

Date of Acceptance: **Jul 18, 2024**

Date of Publishing: **Oct 01, 2024**