



Nasolabial Flap versus Buccal Fat Pad in the Surgical Management of Oral Submucous Fibrosis-A Systematic Review and Meta Analysis

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ABSTRACT

BACKGROUND: To systematically review the existing scientific literature to determine whether buccal pad fat (BPF) or nasolabial flap (NLF) is a better treatment alternative for the patients with oral submucous fibrosis (OSMF) through a meta-analysis.

METHODS: Review was performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and registered in PROSPERO - Electronic databases like PubMed, google scholar and Ebsco Host were searched from 2000 to December 2022 for studies reporting treatment of OSMF through buccal pad fat and nasolabial flap and reporting the outcome in terms of maximum interincisal opening (MOI) and increase in commissural width (CW).

RESULTS: Eight studies fulfilled the eligibility criteria and were included in qualitative synthesis, of which only seven studies were suitable for meta-analysis. The pooled estimate through the Standardized Mean Difference (SMD) signifies that maximum interincisal opening on an average is 1.41 (-2.75 – 0.06) times more by buccal pad fat as compared to nasolabial flap while the post operative increase in commissural width on an average is 0.25 (-1.41 – 0.90) times more by buccal pad fat compared to nasolabial flap ($p > 0.05$). Publication bias through the funnel plot showed asymmetric distribution with systematic heterogeneity.

CONCLUSION: buccal fat pad offers better mouth opening and commissural width than nasolabial flap as it provides excellent closure without giving major complications extraorally. Buccal fat pad offers ease of surgery in terms of harvesting the fat and it is easily performed.

KEYWORDS: oralsubmucousfibrosis, nasolabialflap, buccal fat pad, maximum mouth opening, commissural width

I. INTRODUCTION

Oral Submucous Fibrosis (OSMF) is a chronic, progressive, scarring precancerous condition, It is linked with the chronic placement of betel quid in the mouth⁵. It involves the pharynx or oesophagus and may precede or be associated with vesicle formation. It is associated with chronic inflammation, excessive collagen deposition in the connective tissues below the oral mucosal epithelium, local inflammation in the lamina propria or deep connective tissues, and degenerative changes in the muscles leading to stiffness.¹ In 1952, Schwartz described a condition of the oral mucosa as “atrophica idiopathica (tropica) mucosae oris.”² He first described OSMF as a chronic, premalignant condition of the oral mucosa that can progress to malignancy when left untreated with an incidence of 4.5% to 7.6%. In 1953 Joshi coined the term “Oral Submucous fibrosis.”³ It is an established precancerous condition commonly seen in Indian subcontinent and in the patients who migrated to Western countries from the Indian subcontinent.⁶ The condition predominantly affects women with a female: male ratio of 3:1. Although the pathogenesis is not well established, it is believed to be multifactorial. Numerous factors trigger the disease process by causing a juxta-epithelial inflammatory reaction in the oral mucosa.⁷ Common contributory factors to this chronic disease include areca nut chewing, intake of spicy food, nutritional deficiencies, genetic and immunological processes, and other factors. Symptoms of the disease are stomatitis, vesicle formation, erythematous mucosa, burning sensation, ulceration, mild blanching, melanotic mucosal pigmentation, petechiae and dry mouth, followed by fibrosis. symptoms become severe in later stages resulting in blanching involving the posterior parts like the palate and uvula, broad thick fibrous palpable bands at cheeks, lips and the floor of the mouth, rigid mucosa, stiff, small,



depapillated tongue with restricted movements, restricted mouth opening leading to trismus shrunk bud-like uvula (hockey stick shape), speech and deglutition defects hoarseness of voice, sunken cheeks, loss of nasolabial fold, prominent ante gonial notch, hearing impairment.⁸ OSF causes reduction in the mouth opening, which needs to be corrected surgically.⁹ Medicinal treatment with agents like lycopene, micronutrients, steroids, chymotrypsin, hyaluronidase, turmeric and placental extracts along with oral physiotherapy.¹⁰ Surgery is the only option available for advanced stages of OSMF, which involves resection of the fibrotic bands and reconstruction of the defect using various techniques.¹⁰ Various reconstruction modalities over the raw area created after surgical release of fibrous bands have been mentioned in the literature, these include nasolabial flap, buccal pad of fat, radial forearm flap, temporalis myocutaneous flap, palatal island flap, tongue flap, placental grafts, skin grafts, or lingual pedicle flaps.¹⁰ The surgical management of OSMF, which presents with a severe degree of trismus, is a great surgical challenge.¹¹ Surgical procedures for this disease include excision of fibrous bands with or without coverage of the surgically created defect. Skin or placental grafts, tongue flaps, buccal fat pad (BFP) grafts, nasolabial flaps (NLFs), and others are used for the coverage of the related defects.¹²

The nasolabial flap was described for nasal reconstruction by Sushruta in 600BC, and thus plastic surgery was born about 2000 years ago in India. Ever since, the nasolabial flaps have been a workhorse for face and oral cavity reconstructions.¹³ Egyedi first described the use of the buccal fat pad for closure of persistent oro-nasal or oro-antral communications in 1977.¹⁴ Stajcic (1992)¹⁵ too used BFP in closure of oro-antral communications and described in 1801 by famous French anatomist Xavier Bichat and was introduced in medical literature as the “boule de Bichat”.¹⁵

Going through evidences, till date no study has provided a comprehensive, quantitative analysis of comparison of nasolabial flap with buccal pad fat on which best treatment option for oral submucous fibrosis could be established. Therefore, we updated our research for related articles and conducted a systematic review with the aim to compare and evaluate the effectiveness between nasolabial flap and buccal pad fat as a treatment modality according to the effect on maximum interincisal opening, commissural width for treating oral submucous fibrosis in adults through a novel meta-analysis.

II. METHODOLOGY

PROTOCOL DEVELOPMENT

This review was conducted and performed in according to the preferred reporting items for systematic review and meta-analysis (PRISMA) statement¹⁶ and registered in Prospective Registration of Systematic Review (PROSPERO)-CRD42023409399.

STUDY DESIGN

The review question was to evaluate the better effectiveness of buccal pad fat with nasolabial flap surgical procedures in relation to maximum interincisal opening and commissural width. The following focused research question in the Participants (P), Intervention (I), Comparison and Outcome (O) format was proposed “What is the effectiveness of buccal pad fat compared to nasolabial flap in treatment of oral submucous fibrosis?”

The PICO criteria for this review were as follows:

P (Participants) – Patients with oral submucous fibrosis

I (Intervention) – patients underwent treatment of OSMF with buccal pad fat procedure

C (Comparison) – patients underwent treatment of OSMF with nasolabial flap procedure

O (Outcome) – to assess the better treatment modality for OSMF treatment in terms of maximum interincisal opening and increase in commissural width

S (Study designs) – Clinical studies, comparative studies, prospective studies and retrospective studies

ELIGIBILITY CRITERIA

a) INCLUSION CRITERIA: following were the inclusion criteria

- 1) Articles published in English language
- 2) Articles having sufficient comparative data on nasolabial flap and buccal pad fat in the treatment of oral submucous fibrosis
- 3) Studies published between January 2000 – December 2022 and having relevant data on maximum interincisal opening and commissural width on the nasolabial flap and buccal pad fat in the treatment of oral submucous fibrosis
- 4) Clinical studies, comparative studies, prospective studies and retrospective studies
- 5) Articles from open access journals
- 6) Articles reporting the study outcomes in terms of mean and standard deviation
- 7) Studies with follow up of less than six months



b) EXCLUSION CRITERIA: following were the exclusion criteria

- 1) Any studies conducted before 2000
- 2) Articles in other than English language
- 3) Reviews, abstracts, letter to the editor, editorials, animal studies and in vitro studies were excluded
- 4) Studies will follow up of more than six months

DATA EXTRACTION

For all included studies, following descriptive study details were extracted by two independent reviewing authors and using pilot-tested customized data extraction forms in Microsoft excel sheet with the following headings included in the final analysis: author(s), country of study, year of study, mean age of the participants, sample size, study design, intervention, comparator, duration of follow up, conclusion.

SEARCH STRATEGY

A comprehensive electronic search was performed till December 2022 for the studies published within the last 22 years (from 2000 to 2022) using the following databases: PubMed, google scholar and EBSCOhost to retrieve articles in the English language. The searches in the clinical trials database, cross-referencing and grey literature were conducted using Google Scholar, Greylist, and OpenGrey.

A manual search of oral and maxillofacial surgery journals, including the International Journal of Oral and Maxillofacial Surgery, British Journal of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, international journal of oral and maxillofacial surgery, Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology, Journal of Cranio-Maxillofacial Surgery, Journal of Craniofacial Surgery, Journal of Maxillofacial and Oral Surgery and the journal of American Dental Association was also performed.

Appropriate key words and Medical Subject Heading (MeSH) terms were selected and combined with Boolean operators like AND, OR, NOT. The relevant data was searched using the following keywords and their combinations: “buccal pad fat” (MeSH term) AND “oral submucous fibrosis” (MeSH term); “nasolabial flap” (MeSH term) AND “oral submucous fibrosis” (MeSH term); “surgery” (MeSH term) AND “trismus” (MeSH term) AND mouth opening (MeSH term); “flap” (MeSH term) AND “prospective study” (MeSH term) AND “retrospective study” (MeSH term); “randomized

trials” AND “oral submucous fibrosis” (MeSH term).

In addition to the electronic search, a hand search was also made, and reference lists of the selected articles were screened. The reference lists of identified studies and relevant reviews on the subject were also scanned for possible additional studies.

SCREENING PROCESS

The search and screening, according to previously established protocol were conducted by two authors. A two-phase selection of articles was conducted. In phase one, two reviewers reviewed titles and abstracts of all articles. Articles that did meet inclusion criteria were excluded. In phase-two, selected full articles were independently reviewed and screened by same reviewers. Any disagreement was resolved by discussion. When mutual agreement between two reviewers was not reached, a third reviewer was involved to make final decision. The final selection was based on consensus among all three authors. The corresponding authors of study were contacted via email where further information was required.

QUALITY ASSESSMENT OF INCLUDED STUDIES

The quality of included studies for observational studies was evaluated based on Newcastle Ottawa Scale and accordingly a numeric score (NOS Score) was assigned¹⁷. It was designed to evaluate bias based on participant selection, study group comparability in cross-sectional study, attainment of exposure in case-control studies and outcome of interest in cohort study. It is a valid and reliable tool for assessing the quality of non-randomized studies, supported by the Cochrane Collaboration for the quality appraisal of non-randomized trials. The NOS uses a nine-star rating system with a maximum of four points available for selection, two for comparability and three for the assessment of the outcome or exposure. The tool was deemed acceptable for the appraisal of cross-sectional studies as the effectiveness of an intervention was not being measured. Quality appraisal of the included studies was undertaken by the two authors and a third author was consulted in the event of any discrepancy. A study with a score from 7 to 9 will be considered as high quality, 4 to 6 will be considered as moderate quality and 0 to 3 will be considered as low quality or very high risk of bias.

The methodological quality among included studies was executed by using Cochrane collaboration risk of bias (ROB) -2 tool¹⁸. The tool



has various domains like random sequence generation (selection bias), allocation concealment (selection bias), blinding of personnel and equipments (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases through their signalling questions in Review Manager (RevMan) 5.3 software. The overall risk for individual studies was assessed as low, moderate or high risk based on domains and criteria. The study was assessed to have a low overall risk only if all domains were found to have low risk. High overall risk was assessed if one or more of the six domains were found to be at high risk. A moderate risk assessment was provided to studies when one or more domains were found to be uncertain, with none at high risk.

STATISTICAL ANALYSIS

The standardized mean difference (SDM) with 95% CI was calculated for continuous outcomes. A fixed effects model (Mantel-Haenszel method) was used if there was no heterogeneity ($p > 0.05$ or $I^2 \leq 24\%$), otherwise a random effects model (Der Simonian-Laird method) was used¹⁹. All statistical analyses were performed using the RevMan 5.3 (Cochrane Collaboration, Software Update, Oxford, UK). The significance level was kept at $p < 0.05$.

ASSESSMENT OF HETEROGENEITY

The significance of any discrepancies in the estimates of the treatment effects of the different trials was assessed by means of Cochran's test for heterogeneity and the I^2 statistics, which

describes the percentage of the total variation across studies that is due to heterogeneity rather than chance. Heterogeneity was considered statistically significant if $P < 0.1$. A rough guide to the interpretation of I^2 given in the Cochrane handbook is as follows: (1) from 0 to 40%, the heterogeneity might not be important; (2) from 30% to 60%, it may represent moderate heterogeneity; (3) from 50% to 90%, it may represent substantial heterogeneity; (4) from 75% to 100%, there is considerable heterogeneity²⁰.

INVESTIGATION OF PUBLICATION BIAS

To test for the presence of publication bias, the relative symmetry of the individual study estimates was assessed around the overall estimates using Begg's funnel plot. A funnel plot (plot of the effect size versus standard error) was drawn. Asymmetry of the funnel plot may indicate publication bias and other biases related to sample size, although asymmetry may also represent a true relationship between trial size and effect size²¹.

III. RESULTS

STUDY SELECTION

After duplicates removal, reference list of included studies was screened. Of which 121 studies were excluded. After this full text articles were assessed for eligibility and articles that did not meet inclusion criteria were excluded. Only eight studies fulfilled eligibility criteria and were included in qualitative synthesis. Of which only seven studies were included in meta-analysis. A flowchart of identification, inclusion and exclusion of studies is shown in **Figure 1** below.

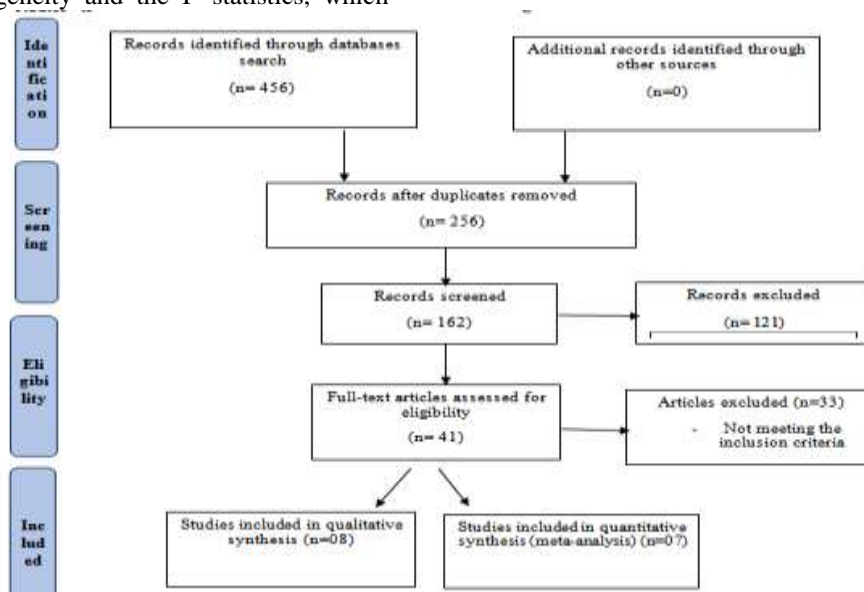


Figure 1. PRISMA 2009 Flow Diagram Assessment



STUDY CHARACTERISTICS

A summary of descriptive characteristics all included studies is shown in **Table 1**. Data was evaluated from eight studies²²⁻²⁹ from an aggregate of 174 (n) patients with a mean age of 34.62 years. Data of buccal pad fat procedure was evaluated from 92 (n) patients while data of nasolabial flap procedure was evaluated from 82 (n) patients. All the included studies were conducted in India.

Among the included studies, four studies^{22-23,25-26} concluded that Nasolabial flaps are a good option for the coverage of surgically treated defects in OSMF compared with the buccal fat pad while three studies²⁷⁻²⁹ concluded that BFP is the better choice for reconstruction in comparison to nasolabial flap while one study²⁴ concluded that both are viable reconstruction method in surgical treatment of late stage OSMF.

S.no	Author(Year)	Country	Sample Size (n)	Mean Age (years)	Follow up	Intervention	Comparator	Conclusion
1.	Agrawal et al (2017) ²²	India	32	21-30 years	6 months	Buccal pad fat	Nasolabial Flap	Nasolabial flaps are a good option for the coverage of surgically treated defects in OSMF compared with the buccal fat pad
2.	Anehosur et al (2020) ²³	India	30	39.5 years	Not mentioned	Buccal pad fat	Nasolabial Flap	The proposed surgical protocol for the management of OSMF found NLF superior to BFP for the reconstruction of intraoral defects after the release of fibers in patients with OSMF, with a minimal residual scar
3.	Gupta et al (2021) ²⁴	India	20	Not mentioned	6 months	Buccal pad fat	Nasolabial Flap	Buccal fat pad and Nasolabial flap are both viable reconstruction method in surgical treatment of late stage OSMF



4.	Jain et al (2022) ²⁵	India	10	Not mentioned	6 months	Buccal pad fat	Nasolabial Flap	Nasolabial flaps are a viable, reliable and a better option, that has withstood the test of time for reconstruction of intraoral defects in oral submucous fibrosis
5.	Lathi et al (2022) ²⁶	India	20	32.4 years	3 months	Buccal pad fat	Nasolabial Flap	NLF proved to give better results as the interposition material for better incisal mouth opening in stage IV cases with minimal chances of relapse while BFP for stage III cases.
6.	Pardeshi et al (2016) ²⁷	India	22	67.2 years	6 months	Buccal pad fat	Nasolabial Flap	BFP is an effective method for the reconstruction of defect up to 5 cm in diameter
7.	Rai et al (2013) ²⁸	India	20	30.23 years	6 months	Buccal pad fat	Nasolabial Flap	BFP is the better choice for reconstruction in comparison to nasolabial flap
8.	Sikkerimath et al (2021) ²⁹	India	20	29.6 years	6 months	Buccal pad fat	Nasolabial Flap	authors concluded buccal fat pad yields superior results with respect to postoperative mouth opening and



								related complications
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Table 1: showing descriptive study characteristics of included studies

ASSESSMENT OF METHODOLOGICAL QUALITY OF INCLUDED STUDIES

Among the included case control study, it did not reach the maximum quality score of the Newcastle Ottawa scale. It did not gain the maximum score in the selection criteria and was considered to have the moderate level of quality with an estimated low risk of bias; in the

comparability outcome it was considered to have the moderate level of quality with an estimated low risk of bias; and it had a partial score in the exposure outcome. The study had an overall moderate level of quality with low risk of bias. Risk of bias of included case control study through Newcastle Ottawa scale is depicted in **Figure 2** below.

Author, year	Selection (Max = 4)	Comparability (Max = 2)	Exposure (Max = 3)	Overall quality score (Max = 9)
Sikkerimath et al, 2020 ²⁹	**	**	**	6

Figure 2: shows risk of bias of included case control study through Newcastle Ottawa scale

All the included studies were largely comparable in methodological quality. All the included studies had moderate to high risk of bias with all the respected domains. The highest risk of bias was seen for blinding of participants and personnel (performance bias). Among the included studies, Pardeshi et al 2016²⁷, Anehosur et al 2020²³ and Sikkerimath et al 2021²⁹ had the high risk of bias compared to all other studies. Jain et al 2022²⁵ reported lowest risk of bias. Domains of

blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other bias were given the lowest risk of bias by included studies while blinding of participants and personnel (performance bias) was given highest risk of bias. Risk of bias of included studies through Cochrane risk of bias (ROB)-2 tool is depicted in **Figure 3 and 4** as shown below.

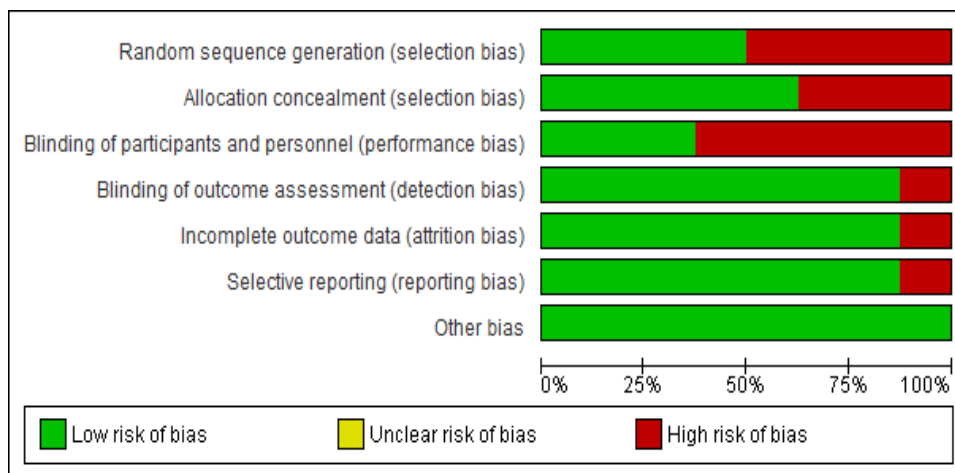


Figure 3: showing risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

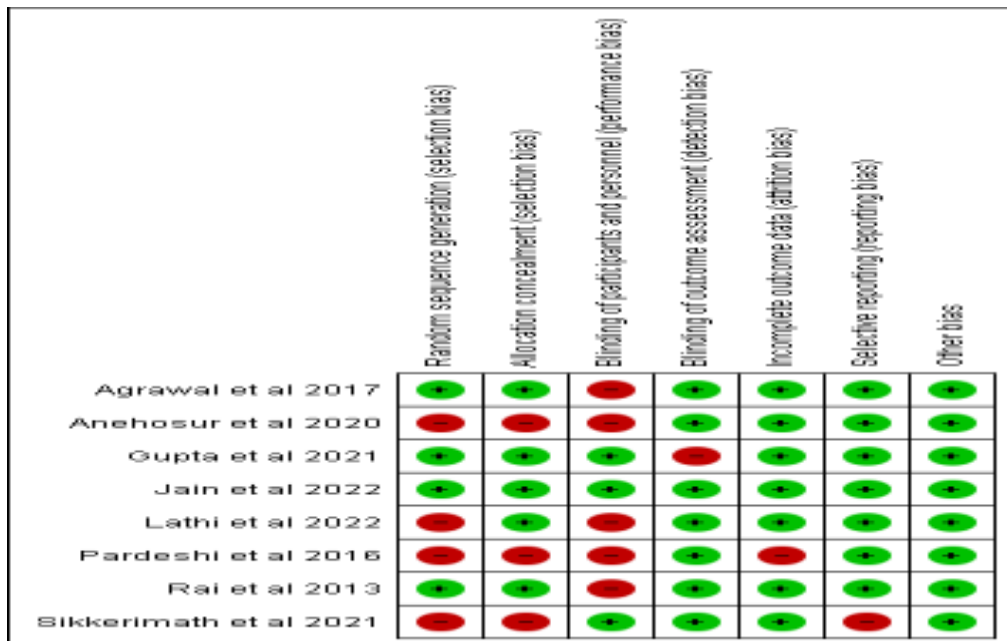


Figure 4: showing risk of bias summary: review authors' judgements about each risk of bias item for each included study.

SYNTHESIS OF RESULT

A) MAXIMUM INTERINCISAL OPENING (MIO)-

Seven studies^{22-26,28-29} containing data on 152 (n=152) participants, of which (n=81) participants were evaluated by buccal pad fat and (n=71) patients were evaluated by nasolabial flap for the evaluation or the better effectiveness between the two procedures in terms of maximum interincisal opening as an outcome. The mean age of participants was 34.67 years.

As shown in **Figure 5**, the Std. Mean Difference is -1.41 (-2.75 – 0.06) and the pooled estimates favours buccal pad fat procedures. This

signifies that the maximum interincisal opening on an average is 1.41 times more by buccal pad fat as compared to nasolabial flap but this difference is statistically significant (p=0.04). Buccal pad fat procedures is superior to nasolabial flap.

Among all the included studies, Agrawal et al 2017²² had highest weightage at the overall pooled estimate while the lowest weightage was observed for Anehosur et al 2020²³ at the pooled estimate.

By employing the random effect model the I² statistic showed 91%, the heterogeneity for Tau² was 2.83, x² being p<0.00001 and the overall effect for Z value being 2.05(P=0.04).

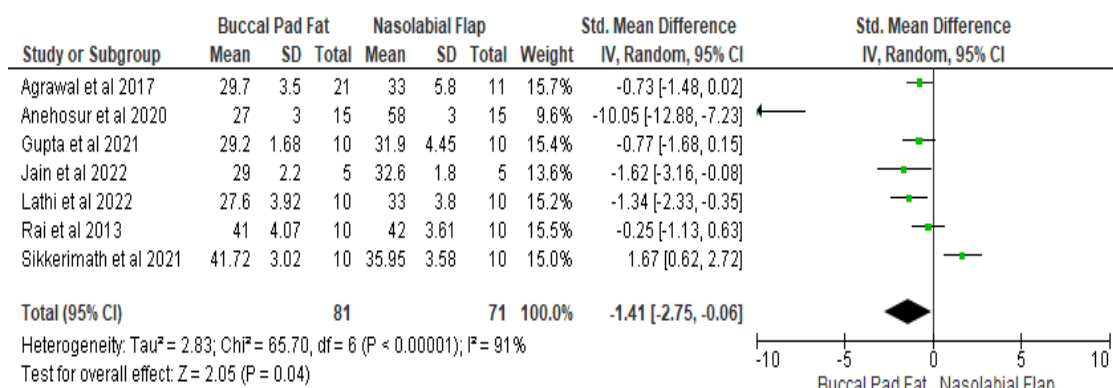


Figure 5: showing Forest plot showing buccal pad fat versus nasolabial flap with regards to the inter-incisal opening as an outcome



The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in **Figure 6**. Funnel plot showing symmetric distribution with absence of systematic

heterogeneity of individual study compared to the standard error, showing an absence of publication bias in the meta-analysis.

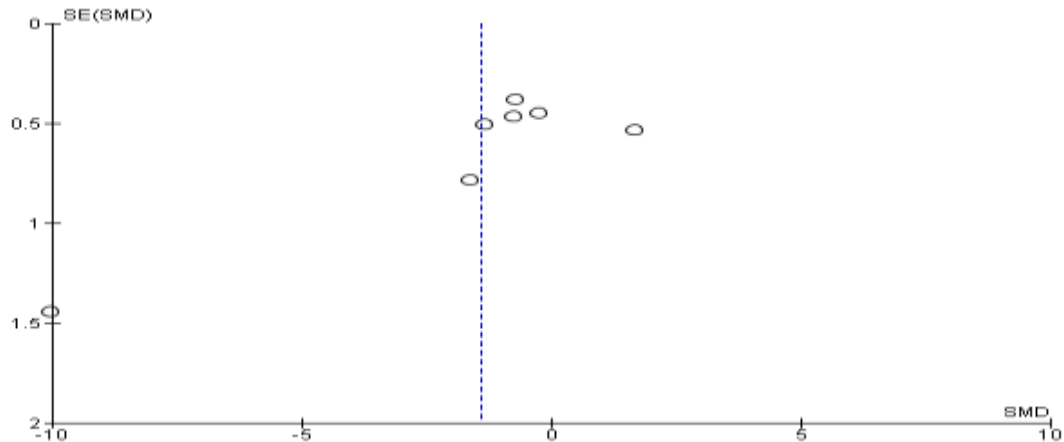


Figure 6: showing Begg's Funnel plot with 95% confidence intervals demonstrating symmetric distribution without systematic heterogeneity of individual study compared with the standard error of each study, indicating an absence of publication bias.

A) COMMISSURAL WIDTH (CW) -

Three studies^{26,26,28} containing data on 70 (n=70) participants, of which (n=35) participants were evaluated by buccal pad fat and (n=35) patients were evaluated by nasolabial flap for the evaluation or the better effectiveness between the two procedures in terms of increase in commissural width post operative as an outcome.

As shown in **Figure 7**, the Std. Mean Difference is -0.25 (-1.41 – 0.90) and the pooled estimates favours buccal pad fat procedures. This signifies that the post operative increase in commissural width on an average is 0.25 times

more by buccal pad fat as compared to nasolabial flap but this difference is not statistically significant (p=0.67).

Among all the included studies, Anehosur et al 2020²³ had highest weightage at the overall pooled estimate while the lowest weightage was observed for Lathi et al 2022²⁶ at the pooled estimate.

By employing the random effect model the I² statistic showed 81%, the heterogeneity for Tau² was 0.84, x² being p<0.00001 and the overall effect for Z value being 0.43 (P=0.67).

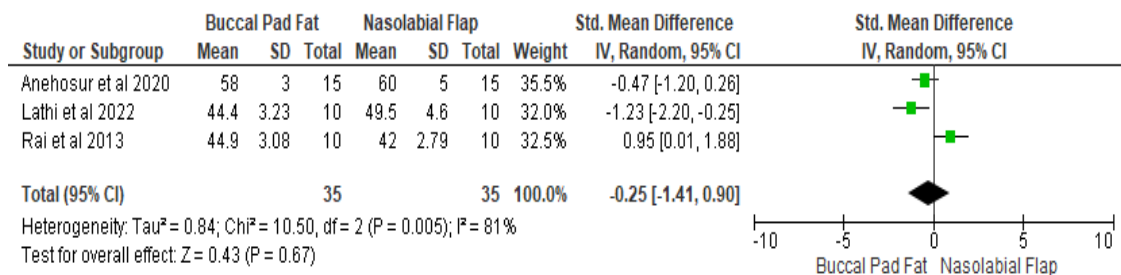


Figure 7: showing Forest plot showing buccal pad fat versus nasolabial flap with regards to the increase in commissural width as an outcome

The funnel plot did not show significant asymmetry, indicating absence of publication bias as shown in **Figure 8**. Funnel plot showing symmetric distribution with absence of systematic

heterogeneity of individual study compared to the standard error, showing an absence of publication bias in the meta-analysis.

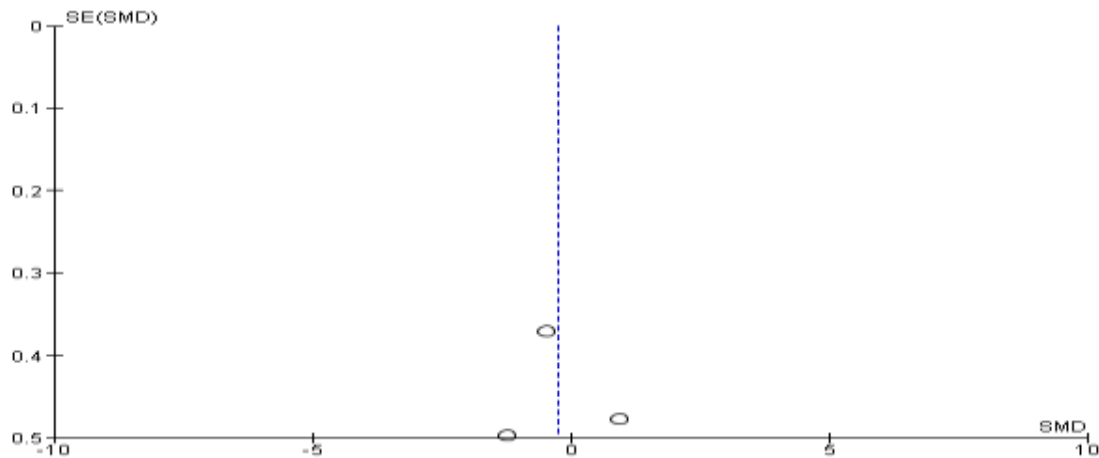


Figure 8: showing Begg's Funnel plot with 95% confidence intervals demonstrating symmetric distribution without systematic heterogeneity of individual study compared with the standard error of each study, indicating an absence of publication bias.

IV. DISCUSSION

Oral submucous fibrosis is one of the most popular premalignant diseases that may impact the buccal cavity in people who consume bitter nuts. In India, the highest prevalence is seen in southern regions. Patients with severe trismus should consider surgery if other treatments have not successfully treated the condition³¹. According to World Health Organization, >5 million people are affected by oral submucous fibrosis globally³². OSMF also can transform into cancerous lesions, particularly oral squamous cell carcinoma, with a malignant transformation rate of 7.6%³³. This is significantly higher than the reported malignant transformation rate for other oral potentially malignant disorders such as oral lichen planus (1.4%) and oral lichenoid lesions (3.8%)³⁴. Even though a wide variety of interventions are available, currently there is no consensus or recommended guidelines for the management of OSMF³⁵.

In our review Eight studies²²⁻²⁹ fulfilled the eligibility criteria while only seven studies were included in meta-analysis. All the studies were conducted in India. The data was evaluated from an aggregate of 152 patients. It was observed that maximum interincisal opening on an average is 1.41 times more by buccal pad fat as compared to nasolabial flap while the post operative increase in commissural width on an average is 0.25 times more by buccal pad fat compared to nasolabial flap. Our results suggested that Buccal pad fat is superior to nasolabial flap in treating OSMF with regards to maximum interincisal opening and post operative increase in commissural width.

The result of this study was in hand with a systematic review conducted by Bhujbal et al.³⁰

All studies included were from India from year 2000 to 2017. Each study was carried out in hospital. Total number of 78 patients were studied. Patients included in these studies were suffering from reduced mouth opening, blanched mucosa, and fibrosis of lip, reduced tongue movement, ulcerations and burning sensation and intolerance of spicy food. Extractions with all four third molars were carried out and buccal fat pad was teased out and sutured into the defect in group I patients. In group II patient's nasolabial flap was used for covering the defect. Initial physiotherapy was carried out with Heister's jaw opener postoperatively. Post-operative complications like intraoral hair growth, and extraoral scarring in nasolabial flap patients were not acceptable in some patients. Increased mouth opening was achieved in both surgical procedures. Hereby we concluded that buccal fat pad provides increased interincisal opening with better patient compliance compared to nasolabial flap.

However, few limitations were also present. Going through the evidences, there is a scarcity and paucity of literature on comparative evaluation between buccal pad fat and nasolabial flap procedure on assessing outcomes like wound healing, facial aesthetics and post-operative complications. Even after going through an unrestricted search and eligibility criteria, the number of included studies for qualitative synthesis as well as for quantitative synthesis was very less. Only eight studies were included in our systematic review, while only seven studies were included for our meta-analysis. There is a need to conduct more follow up studies on the comparative evaluation between buccal pad fat and nasolabial flap.



V. CONCLUSION

This systematic review answers the focused question and offers some definitive conclusions. This systematic review shows that buccal fat pad offers better mouth opening and commissural width than nasolabial flap.

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