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# A comparative evaluation of buccal fat pad alone versus buccal fat pad with collagen as Interpositional grafts in the management of OSMF Patients

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**Abstract**
The study was done to evaluate the treatment of OSMF using buccal fat pads alone vs buccal fat pads combined with collagen as interpositional grafts. 50 individuals with a clinical diagnosis of OSMF were selected. According to Khanna and Andrade (1995), clinical staging was performed. Group I and group II were created at random from the pool of patients. Buccal fat pad (BFP) with collagen membrane was used as an interpositioning material in group II, while buccal fat pad (BFP) alone was given to Group I. On the 3rd, 5th, 1 week, 2 weeks, 3 weeks, 1 month, 3 months, and 6 months after surgery, the patients were assessed for edema, pain, cheek flexibility, interincisal distance (mouth opening).
Faster reduction in pain scores and swelling in Group II was observed as compared to Group I. Cheek flexibility was found to be significantly different between the two groups at the three-week and one-month follow-ups. Nonetheless, both groups exhibited nearly identical cheek flexibility at the 3-and 6-month follow-ups. Following surgery, the interincisal opening significantly increased in both groups. Nonetheless, compared to Group I, patients in Group II did show a greater post-operative interincisal distance.

**Keywords:** OSMF, buccal pad of fat, bovine collagen membrane, interincisal distance, cheek flexibility

## Introduction
Recent decades have seen a marked improvement in living standards, but it has also contributed to the ever-increasing stress levels that contemporary man must manage.[1]Many people turn to unhealthy habits like drinking, smoking, chewing paan, tobacco, or betel nuts as a means of reducing stress. Since the majority of these stress-relieving medicines enter the body through the mouth, it stands to reason that this area would be the first and most negatively impacted by such practices. Oral Submucous Fibrosis (OSMF) is one of several pathological abnormalities that can be found in the oral mucosa.
Pindborg and Sirsat[2] defined oral submucous fibrosis as "an insidious chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with a juxta epithelial inflammatory reaction followed by a fibroelastic change of the lamina propria, with epithelial atrophy leading to stiffness of the oral mucosa and causing trismus and inability to eat". It is a potentially malignant and precancerous condition.
While there are a number of approaches to treat OSMF, there is currently no universally accepted standard for doing so. The patient only experiences temporary relief from symptoms when they undergo all of the available conservative treatments. In the patients with marked reduction in mouth opening and not responding to medical management, surgical release of fibrous bands remains the only effective procedure.[3]Uncovered surgical wounds might develop scars, infections, and secondary intention healing, which can cause severe fibrosis. Reconstruction of the gap left by the removal of buccal mucosal fibrotic bands has involved the use of a variety of materials. Buccal Pad of Fat, a supple and lobulated mass, is easily accessible and retrieved.

BFP mobilization has advantages like easy surgical procedure, good patient acceptance, no extra oral scar, no intraoral hair growth on the graft, negligible post-operative morbidity, and availability in most of the patients [4].

Collagen, is a bovine or porcine derived xenogenous graft [5]. Its low antigenicity, ease of extraction, and purifying methods make it a common wound dressing material. Furthermore, collagen membrane does away with donor site morbidity and the necessity for a second surgical site. Biochemistry and micro-porosity of collagen membrane enhances neo-vascularisation and rapid cell penetration. The type I collagen membrane is responsible for fast epithelization and granulation tissue production, as well as for resisting masticatory stresses, inducing chemotaxis, and maintaining hemostasis [6]. Collagen is an important element in all stages of wound healing [7]. When exposed to the cells of open wounds, the surface chemistry of type I collagen initiates wound healing, and it also possesses good hemostatic properties. Collagen, according to several studies, is superior to non-biological wound healing materials when it comes to tissue regeneration. It encourages platelets to clump together over the biomaterial, making the clot stronger; it is a specialized platelet activator. Its chemo-tactic impact on fibroblasts and endothelial cells considerably lessens inflammation and pain [8]. Good granulation tissue development is also observed as a result of the early migration of fibroblasts.

**Methodology**

50 individuals with limited mouth opening and clinical diagnosis of Oral Submucous Fibrosis (OSMF grade III & IV) made up the study sample. In order to determine the functional staging of OSMF, a simple ruler was used to measure the interincisal distance (IID) between the incisal edges of the maxillary and mandibular central incisors and expressed in millimeters. The local examination also included checking for the presence or absence of anterior and posterior fibrous bands, cheek flexibility, and sites of involvement. According to Khanna and Andrade (1995), clinical staging was performed. Buccal fat pad (BFP) with collagen membrane was used as an interpositioning material in group II, while buccal fat pad (BFP) alone was given to Group I. On the 3rd, 5th day, 1st, 2nd, 3rd week, 1 month, 3 months, and 6 months after surgery, the patients were assessed for edema, pain, cheek flexibility, interincisal distance (mouth opening).

**Surgical procedure**

The aimed incision line was followed by an intraoral infiltration bilaterally with lignocaine with epinephrine (1:2,00,000). The buccal mucosa on both sides was incised at the level of the occlusal plane, to create "Y" incisions, which are two wings pointing towards the mouth corner (Mehta *et al.* 2021) [9].

Heister mouth gag was used to achieve at least 35mm of interincisal opening. U/L third molars were extracted if found to restrict mouth opening. A coronoidectomy was performed if the intraoperative mouth opening was found to be smaller than 35 mm.

The generated buccal defect was used to reach the pedicled BFP through its postero-superior margin. In group I, BFP grafts were used to treat bilateral buccal lesions Reconstruction was performed on patients in group II by placing Bovine Collagen Membrane over a pedicled BFP graft that had been placed over the defect. A collagen membrane of 0.6 mm x 5 cm x 5 cm was used. Bactigras was placed bilaterally.

Antibiotic prophylaxis was provided to all patients. Intense physiotherapy using Heister's mouth gag began on the seventh day after surgery till six months post operatively.

During the follow-up phase, the patient's post-operative state was clinically evaluated based on specified factors.

**Statistical analysis**

An analysis was performed on the collected data using SPSS Version 23, developed by Chicago Inc., IL, USA. To compare the results of the two treatment methods, the Kolmogorov Smirnov test was run to see whether the data was normally distributed. The results of the test were in agreement with the hypothesis of regularly distributed data as they revealed no statistically significant difference. The standard deviation, percentage, and mean values of the variables were compared. Following surgery, the groups were compared using a student t-test to determine the average of pain and intercisal readings. To identify statistically significant changes in parameters between the pre- and post-operative periods, a paired t-test was used. A statistically significant result was defined as a P value below 0.05

**Results**

Group 2's mean interincisal distance was marginally greater at 39.36 mm after 1 week than Group 1's 38.80 mm. At 3 weeks, Group 2 had a 2.16 mm advantage over Group 1. There was no statistically significant difference between the groups on postoperative 1 week, 2 weeks, 3 weeks, 1 month, 3 months, and 6 months when it came to interincisal distance. However, Group 2 patients did demonstrate a higher distance than Group 1 patients (Table 1).

Patients of Group 2 showed lesser pain scores than the patients of Group 1 on day 3, day 5 and day 7, but the difference was not statistically significant (Table 2).

Until 1 month after treatment, cheek flexibility was significantly better in the patients of Group 2 than Group 1. After 3 and 6 months, both groups showed similar improvement in cheek flexibility with no statistically significant difference (Table 3).

On day 3, all the patients in both groups had swelling. On day 5, less number of patients of Group 2 had swelling than Group 1 which was statistically significant. On day 7, none of the patients in both groups had swelling (Table 4).

Group 1 had mean post-operative interincisal distance of 33.84mm with a mean increase of 18.52mm and Group 2 had 38.33mm with a mean increase of 23mm. Average mean increase in mouth opening of both the groups was 20.76mm (Table 5).

Both groups showed significant improvement in Cheek flexibility after intervention (Table 6).

**Discussion**

Oral submucous fibrosis is a slowly progressing, disabling condition that causes the oral mucosa to become rigid. It often begins with vesicle formation or stomatitis and is always accompanied by an inflammatory reaction between

the epithelium and the lamina propria, as well as fibroelastic changes and epithelial atrophy [10]. This disease has the potential to progress to malignancy. Ulcerations, xerostomia, a burning feeling in the mouth, blanching, and a decreased ability to open the mouth are the most typical first signs of oral stomatitis.

Following the guidelines established by Izumi *et al*. (2003) [11], pain was evaluated on the third, fifth, and seventh days following surgery using the Visual Analog Scale (VAS). Overall, Group 2 showed lesser pain scores than Group 1 on 3rd, 5th day and 7th day, but was not significant. However, mean difference in pain scores between both groups was greatest on 5th day with Group 2 having lesser score. This may be due to the coverage of sensitive nerve endings by collagen (Gupta D, 1988) [12]. Both the groups showed reduction of pain by the end of 1 week. Proper healing is shown by the gradual reduction of pain as time goes on Yeh, 1996 [4], Rastogi *et al.*, 2009 [5], Sowjanya *et al.*, 2016 [13] in both the groups.

Swelling was assessed using the scoring criteria laid by Siddiqui *et al*. (2010) [14] on postoperative 3rd, 5th and 7th day. On day 3, all the patients in both groups had swelling. On day 5, lesser number of patients in Group 2 (6 patients) had swelling than Group 1(16 patients) which was statistically significant. There was faster reduction in swelling in Group 2 due to reduced inflammation because of collagen membrane Shanmugam 2019 [15], YR Reddy, 2012 [16]. On day 7, none of the patients in both groups had swelling. Pradhan *et al*. (2012) [17] found a similar trend of decreased swelling.

The cheek flexibility was evaluated after one week, two weeks, three weeks, one month, three months, and six months postoperatively using a grading method established by Bhavika M Khated (2020) [18]. Group 2 patients had 84% grade II cheek flexibility after one week, whereas Group 1 patients had 96%. Group 2 had 80% of patients with grade II cheek flexibility, whereas Group 1 had 88% at week 2. At the three-week mark, 36% of Group 1 patients and 80% of Group 2 patients exhibited Grade I cheek flexibility, a difference that was statistically significant. At the one-month follow-up, 96% of Group 2 patients exhibited Grade I cheek flexibility. Group 2 showed better cheek flexibility since there was lesser wound contracture (Omura S, 1997 [19], Natraj S, 2011 [20], Agarwal D, 2012 [21], Shanmugam D, 2018 [16]) and appearance of grafted area was restored to normal in about 3-4 weeks since uptake of BFP was catalysed by collagen membrane. Collagen induces granulation tissue formation and also promotes rapid epithelisation in 7-14 days (Rastogi S, 2008) [5]. It also acted as a covering material over BFP in Group 2 which helped to maintain structural integrity of BFP during healing phase (Singh G, 2018, Dwivedi S, 2021) [22, 23]. Furthermore, in Group 1 only BFP was used which sometimes, has limitations in anterior reach thus, leaving a raw area which heals by secondary intention subsequently less flexibility (Khan GR, 2021, Tideman H, 1986) [24, 25]. Group II had more mucosal suppleness in the early follow-up period, suggesting that the collagen sheet improved mucosal suppleness with shorter intervals of time. There was no statistically significant difference between the groups at the end of 3 months and 6 months, but both groups showed Grade I cheek flexibility in maximal patients.

Mouth opening was assessed on postoperative 1 week, 2 weeks 3 weeks, 1 month, 3 month and 6 months. Group 2's mean interincisal distance was marginally greater at 39.36 mm after 1 week than Group 1's 38.80 mm. At 3 weeks the difference between both groups was highest being 2.16mm favouring Group 2 which might be due to better cheek flexibility. There was no statistically significant difference between Group 2 and Group 1 patients on postoperative 1 week, 2 weeks, 3 weeks, 1 month, 3 months, and 6 months when it came to interincisal distance. However, Group 2 patients did demonstrate a higher distance than Group 1 patients. After the surgery, the interincisal groups [26-32, 17, 33] opening significantly increased in both Pradhan *et al.* 2012[17] recorded mean post-operative inter incisal distance of 36.53mm & 39.87mm at the end of their study. Natraj *et al.* 2012 [20] had a mean of 33mm. Singh *et al*. [22] noted mean post-operative mouth opening as 38.96mm and 39.62mm in their study. The mean interincisal distance after a follow up period of 6 months in our study was 33.84 mm in Group I and 38.33mm in Group II. The mean rise in Group 2 was 23 mm, while in Group 1 it was 18.52 mm. Mouth openings increased by an average of 20.76 mm in both groups.

To avoid stress to the flap in the retromolar region and to alleviate restrictions in mouth opening, third molars were extracted as a preventative measure. For patients with severe trismus in stages III and IV, some publications suggest adjuvant operations such as masticatory muscle myotomy and coronoidectomy [30, 31, 34, 35]. BFP can be approached through the extension of same intraoral incision during the procedure thus, eliminating the need for second surgery. It is a pedicled graft with good vascularization and resistance to infection as compared to other grafts [4]. Collagen membrane is readily available, easy to place, robust to withstand masticatory trauma, gives good hemostasis, and induces granulation and epithelization thus, preventing wound contracture and scarring. Treatment of early and advanced OSMF is dependent on the patient's ability to quit smoking, perform appropriate physiotherapy exercises, and maintain a healthy diet, regardless of the type of graft utilized.

**Group I**

**Fig 1&2:** Pre-operative

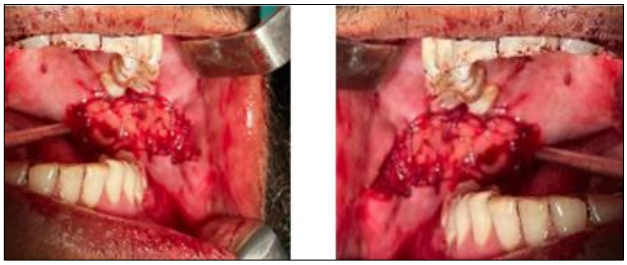

**Fig 3&4:** Intra op with BFP as interpositional graft

**Fig 5:** Post op increase in mouth opening

**Fig 8&9:** Intra op with BFP+collagen membrane as Interpositional graft

## Group II

**Fig 6&7:** Pre-operative

**Fig 10:** Post op increase in mouth opening

**Table 1:** Comparative evaluation of Interincisal distance between groups on various intervals

| Intervals | Groups | N | Mean | St. Deviation | Mean difference | 'T' Statistic | DF | P Value |
|---|---|---|---|---|---|---|---|---|
| Day 1 | Group 1 | 25 | 15.32 | 4.91 | 0.28 | .192 | 48 | .849 (NS) |
| | Group 2 | 25 | 15.04 | 5.39 | | | | |
| 1 week | Group 1 | 25 | 38.80 | 2.23 | -0.56 | -.854 | 48 | .397 (NS) |
| | Group 2 | 25 | 39.36 | 2.39 | | | | |
| 2 weeks | Group 1 | 23 | 38.52 | 2.62 | -0.68 | -.940 | 45 | .352 (NS) |
| | Group 2 | 24 | 39.20 | 2.37 | | | | |
| 3 weeks | Group 1 | 25 | 35.16 | 10.97 | -2.16 | -.790 | 48 | .433 (NS) |
| | Group 2 | 25 | 37.32 | 8.13 | | | | |
| 1 month | Group 1 | 23 | 37.82 | 3.05 | -0.76 | -.934 | 45 | .355 (NS) |
| | Group 2 | 24 | 38.58 | 2.48 | | | | |
| 3 month | Group 1 | 25 | 34.12 | 11.47 | -2.72 | -.970 | 48 | .337 (NS) |
| | Group 2 | 25 | 36.84 | 8.05 | | | | |
| 6 months | Group 1 | 25 | 33.84 | 11.84 | -2.96 | -1.034 | 48 | .306 (NS) |
| | Group 2 | 25 | 36.80 | 8.02 | | | | |

**Table 2:** Comparative evaluation of pain between groups on various intervals

| Intervals | Group | N | Mean | Std. Deviation | Mean difference | T Statistic | DF | P Value |
|---|---|---|---|---|---|---|---|---|
| Day 3 | Group 1 | 25 | 2 | 0.29 | 0.12 | 0.827 | 48 | 0.412 (NS) |
| Day 3 | Group 2 | 25 | 1.88 | 0.67 | | | | |
| Day 5 | Group 1 | 25 | 1.48 | 0.51 | 0.36 | 1.973 | 48 | 0.072 (NS) |
| Day 5 | Group 2 | 25 | 1.12 | 0.44 | | | | |
| Day 7 | Group 1 | 25 | 0.68 | 0.56 | 0.2 | 1.237 | 48 | 0.222 (NS) |
| Day 7 | Group 2 | 25 | 0.48 | 0.59 | | | | |

**Table 3:** Comparative evaluation of cheek flexibility between groups on various intervals

| Intervals | Cheek flexibility | Group 1 | Group 2 | Total | Chi square statistic | DF | P Value |
|---|---|---|---|---|---|---|---|
| Preoperative | II | 1 | 1 | 2 | 0.223 | 2 | 0.894 (NS) |
| | | 4.0% | 4.0% | 4.0% | | | |
| | III | 22 | 21 | 43 | | | |
| | | 88.0% | 84.0% | 86.0% | | | |
| | IV | 2 | 3 | 5 | | | |
| | | 8.0% | 12.0% | 10.0% | | | |
| 1week | I | 0 | 1 | 1 | 2.2 | 2 | 0.333 (NS) |
| | | 0.0% | 4.0% | 2.0% | | | |
| | II | 24 | 21 | 45 | | | |
| | | 96.0% | 84.0% | 90.0% | | | |
| | III | 1 | 3 | 4 | | | |
| | | 4.0% | 12.0% | 8.0% | | | |
| 2 weeks | I | 0 | 3 | 3 | 3.429 | 3 | 0.330 (NS) |
| | | 0.0% | 12.0% | 6.0% | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | II | 22 | 20 | 42 | | | |
| | | 88.0% | 80.0% | 84.0% | | | |
| | III | 1 | 1 | 2 | | | |
| | | 4.0% | 4.0% | 4.0% | | | |
| 3 weeks | I | 9 | 20 | 29 | 10.061 | 2 | 0.007* |
| | | 36.0% | 80.0% | 58.0% | | | |
| | II | 14 | 4 | 18 | | | |
| | | 56.0% | 16.0% | 36.0% | | | |
| 1 month | I | 16 | 24 | 40 | 8.933 | 3 | 0.030* |
| | | 64.0% | 96.0% | 80.0% | | | |
| | II | 6 | 0 | 6 | | | |
| | | 24.0% | 0.0% | 12.0% | | | |
| | III | 1 | 0 | 1 | | | |
| | | 4.0% | 0.0% | 2.0% | | | |
| 3 months | I | 20 | 24 | 44 | 3.697 | 3 | 0.296 (NS) |
| | | 80.0% | 96.0% | 88.0% | | | |
| | II | 2 | 0 | 2 | | | |
| | | 8.0% | 0.0% | 4.0% | | | |
| | III | 1 | 0 | 1 | | | |
| | | 4.0% | 0.0% | 2.0% | | | |
| 6 months | I | 20 | 24 | 44 | 3.697 | 3 | 0.296 (NS) |
| | | 80.0% | 96.0% | 88.0% | | | |
| | II | 2 | 0 | 2 | | | |
| | | 8.0% | 0.0% | 4.0% | | | |
| | III | 1 | 0 | 1 | | | |
| | | 4.0% | 0.0% | 2.0% | | | |

**Table 4:** Comparative evaluation of swelling between groups on various intervals

| Intervals | Swelling | Group 1 | Group 2 | Total | Chi square statistic | DF | P Value |
|---|---|---|---|---|---|---|---|
| Day 3 | Absent | 0 | 0 | 0 | - | - | - |
| | | 0.0% | 0.0% | 0.0% | | | |
| | Present | 25 | 25 | 50 | | | |
| | | 100.0% | 100.0% | 100.0% | | | |
| Day 5 | Absent | 9 | 19 | 28 | 8.116 | 1 | 0.004* |
| | | 36.0% | 76.0% | 56.0% | | | |
| | Present | 16 | 6 | 22 | | | |
| | | 64.0% | 24.0% | 44.0% | | | |
| Day 7 | Absent | 25 | 25 | 50 | - | - | - |
| | | 100.0% | 100.0% | 100.0% | | | |
| | Present | 0 | 0 | 0 | | | |
| | | 0.0% | 0.0% | 0.0% | | | |

**Table 5:** Comparative evaluation of interincisal distance between pre-operative and post-operative between groups

| Groups | Intervals | Mean | St. Deviation | Mean difference | 't' statistic | DF | P Value |
|---|---|---|---|---|---|---|---|
| Groups 1 | Pre-treatment | 15.32 | 4.91 | -18.52 | -8.688 | 24 | 0.000* |
| | Post-treatment | 33.84 | 11.84 | | | | |
| Group 2 | Pre-treatment | 15.33 | 5.30 | -23.00 | -30.891 | 23 | 0.000* |
| | Post-treatment | 38.33 | 2.42 | | | | |

**Table 6:** Comparative evaluation of Cheek flexibility between pre-operative and post-operative between groups

| Groups | Cheek flexibility | Preoperative | Postoperative | Chi square statistic | DF | P Value |
|---|---|---|---|---|---|---|
| Group 1 | I | 0 | 20 | 41.496 | 3 | 0.000* |
| | | 0.00% | 80.00% | | | |
| | II | 1 | 2 | | | |
| | | 4.00% | 8.00% | | | |
| | III | 22 | 1 | | | |
| | | 88.00% | 4.00% | | | |
| | IV | 2 | 0 | | | |
| | | 8.00% | 0.00% | | | |
| Group 2 | I | 0 | 24 | 49.000 | 3 | 0.000* |
| | | 0.00% | 96.00% | | | |
| | II | 1 | 0 | | | |
| | | 4.00% | 0.00% | | | |
| | III | 21 | 0 | | | |
| | | 84.00% | 0.00% | | | |
| | IV | 3 | 0 | | | |
| | | 12.00% | 0.00% | | | |

**Conflict of Interest**
Not available

**Financial Support**
Not available

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