



COMPARISON OF SURGICAL OUTCOME IN MANAGEMENT OF ORAL SUB-MUCOUS FIBROSIS WITH AND WITHOUT BUCCAL PAD OF FAT GRAFTING

Clinical Research

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ABSTRACT

Background, Aim And Objectives: Oral sub-mucous fibrosis is a chronic progressive premalignant condition, characterized by gradually increasing fibrosis of sub mucosa resulting in trismus thereby, limiting mouth opening. Various surgical modalities have been tried in the surgical management, but each has its own limitations. In the present study, evaluate buccal fat pad (BFP) graft and without grafting used for reconstruction after release of fibrosis.

Methods: The study group consisted of 20 patients with bilateral clinically diagnosed cases of (OSMF) oral sub-mucous fibrosis. Treated surgically, Group 1 (buccal fat pad graft) was compared with group 2 (without grafting) post operatively for mouth opening up to 6 months follow up.

Results: The distribution of age between the groups, mean age of patients of Group 1 and Group 2 was 28.70 ± 6.78 and 30.40 ± 7.45 years respectively. There was no significant ($p > 0.05$) difference in age between the groups showing comparability of the groups in terms of age and the distribution of gender between the groups, majority of patients in both Group 1 (80%) and Group 2 (90%) were males. There was no significant ($p > 0.05$) difference in gender between the groups showing comparability of the groups in terms of gender

Conclusion: we concluded that the surgical site in OSMF cases should always be grafted with some graft material and could also be stated that the BFP has proven itself to be a satisfactory option when and wherever required, keeping in view the ease of harvesting and donor site morbidity.

KEYWORDS

Buccal Fat Pad (BFP), Oral Sub-Mucous Fibrosis (OSMF), Maximum Mouth Opening (MMO).

INTRODUCTION

Oral submucous fibrosis is an insidious chronic disease affecting various part of the oral cavity quite often extending to pharynx, characterized by formation of vesicles along with juxta-epithelial inflammatory reaction and fibroelastic changes in lamina propria with atrophy leading to stiffness of oral mucosa, formation of fibrotic bands in cheek leading to trismus, burning sensation of oral mucosa and inability to eat hot and spicy food¹. In india, the first mention of this disease in literature dates back to the time of "Sushruta" as "Vidari"². however, in modern literature, Schwartz in 1952³ first described it as 'atrophic acidopathica mucosae oris'. OSMF is a condition, which carries high risk of malignant transformation i.e. 3-7.6%^{4,5}. Its precancerous nature was first described by Paymaster⁶ in his study of 650 Indian patients and he found that one third of patients had onset of slowly growing squamous cell carcinoma. It causes significant morbidity (In terms of loss of mouth function) and mortality (When transformation into squamous cell carcinoma occurs). The term oral submucous fibrosis was finally given by Joshi in 1953⁷

Aim & Objectives:

To compare surgical management and healing of OSMF with and without BFP grafts in reconstruction of defects in OSMF and compare complications occurring in both the groups, to assess the increase in mouth opening in both groups.

MATERIALS AND METHOD:

20 patients reporting to the Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College Of Dental Sciences, Lucknow, with Grade III or Grade IV Oral Submucous Fibrosis (OSMF) and randomly divided into two groups. Group I (n=10) in which resection of fibrous band with coronoidectomy followed by reconstruction of the mucosal defect with BFP was done and Group II (n=10) in which resection of fibrous band was followed by coronoidectomy without

BFP. Grade III and Grade IV OSMF patients' followed Khanna and Andrade classification and written informed consent for the study were included. Patients whose below 18 years, not medically fit and taken any treatment for same previously excluded.

Methods Of Collection Of Data:

Clinically and histo-pathologically diagnosed Grade III and Grade IV OSMF patients, who were passed through under ASA Class I and relatively healthy ASA class II patients considered for our study. Pre and post surgical procedure, patients were evaluate on the bases of mouth opening, pain assessment (VAS), swelling, Suppleness and healing index (Laundry et al)⁵⁰ on regular follow-up by a single observer at 2nd day, 1week, 1 month, 3 months and 6 months post-operatively for all patients and studied complications encountered during and after the surgery.

In Group I:

Incision was given by using bard parker blade no-15 extended from behind 2 cm from the corner of mouth to the soft palate at a level of the linea alba, avoiding injury to stensons duct. Fibrotomy of the bands were done.

The coronoid processes would be approached through the same incision and a bilateral coronoidectomy was carried out. The maxillary and mandibular third molars were extracted bilaterally, interincisal opening was recorded.

In Group II:

The Buccal Fat of Pad was harvested through the posteriorsuperior margin of the buccal defect that created (raw area created after the fibrotomy procedure up to the retero molar trigone region). The average length of 3 cm and width of 4 cm were harvested depending on the size of the defect. The BFP was teased out gently until enough is obtained to cover the raw area without tension. The flap was sutured to

the defect with the help of interrupted and mattress sutures with 3-0 vicryl. The BFP was used to cover the entire defect. Physiotherapy was started from the 5th day of postoperative and patients were instructed to both group patients continue the physiotherapy themselves for up to 6 months to prevent relapse.

STATISTICAL ANALYSIS & RESULTS:

The results are presented in frequencies, percentages and mean±SD. The Chi-square test was used to compare the categorical variables between the groups. Unpaired t-test was used to compare the measurements between the groups. Paired t-test was used to compare the mean change in the study parameters from Day 2 to subsequent time periods in groups. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

The distribution of age between the groups, mean age of patients of Group 1 and Group 2 was 28.70±6.78 and 30.40±7.45 years respectively. There was no significant (p>0.05) difference in age between the groups showing comparability of the groups in terms of age and the distribution of gender between the groups, majority of patients in both Group 1 (80%) and Group 2 (90%) were males. There was no significant (p>0.05) difference in gender between the groups showing comparability of the groups in terms of gender.

Table-6: Comparison Of Mean Change In Mouth Opening (in Millimeter) From Day 2 To Subsequent Time Periods In Groups

Time period	Group 1 (n=10)			Group 2 (n=10)		
	Mean change	t-value, df	p-value ¹	Mean change	t-value, df	p-value ¹
Day 2 to week 1	13.40±4.47	9.46, 9	0.0001*	13.30±0.94	44.33, 9	0.0001*
Day 2 to 1 month	17.20±3.99	13.61, 9	0.0001*	15.40±3.20	15.19, 9	0.0001*
Day 2 to -3 months	19.60±2.79	22.16, 9	0.0001*	16.90±3.95	13.50, 9	0.0001*
Day 2 to 6 months	20.90±2.96	22.32, 9	0.0001*	18.50±4.17	14.09, 9	0.0001*
Week 1 to 1 month	3.80±1.81	6.62, 9	0.0001*	2.10±2.76	2.40, 9	0.04*
Week 1 to 3 months	6.20±3.19	6.14, 9	0.0001*	3.60±3.62	3.13, 9	0.01*
Week 1 to 6 months	7.50±4.19	5.65, 9	0.0001*	5.20±3.76	4.36, 9	0.002*
1 month to 3 months	2.40±2.11	3.58, 9	0.006*	1.50±1.50	3.14, 9	0.01*
1 month to 6 months	3.70±3.19	3.65, 9	0.005*	3.10±1.91	5.12, 9	0.001*
3 months to 6 months	1.30±1.25	3.28, 9	0.009*	1.60±1.36	3.36, 9	0.008*

¹Paired t-test, *Significant

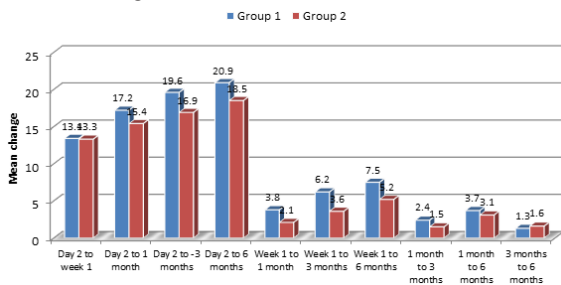


Fig.6: Comparison Of Mean Change In Mouth Opening (in Millimeter) From Day 2 To Subsequent Time Periods In Groups

Table-6 & Fig. 6 shows the comparison of mean change in mouth opening (in millimeter) from Day 2 to subsequent time periods in groups. There was significant (p<0.05) mean change in both the groups from Day 2 to subsequent time periods.

Table-7: Comparison Of Pain Score Between The Groups Across The Time Periods

Time period	Group 1 (n=10)	Group 2 (n=10)	t-value, df	p-value ¹
Day 2	8.60±0.69	9.40±0.51	2.91, 18	0.009*

Week 1	5.60±0.69	6.00±0.94	1.07, 18	0.29
1 month	0.00±0.00	0.00±0.00	-	-
3 months	0.00±0.00	0.00±0.00	-	-
6 months	0.00±0.00	0.00±0.00	-	-

¹Unpaired t-test, *Significant

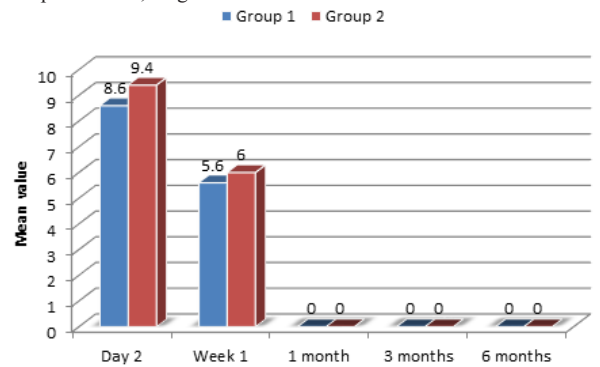


Fig. 7: Comparison Of Pain Score Between The Groups Across The Time Periods

Table-7 & Fig. 7 shows the comparison of pain score between the groups across the time periods. The pain score was significantly (p=0.009) lower in Group 1 (8.60±0.69) than Group 2 (9.40±0.51) at Day 2. The pain score became nil in both the groups at 1 month, 3 months and 6 months.

Table-8: Comparison Of Swelling Between The Groups Across The Time Periods

	Group 1 (n=10)		Group 2 (n=10)		χ ² d.f.	p-value ¹
	No.	%	No.	%		
Day 2						
Present	5	50.0	3	30.0	2.12, 1	0.07
Absent	5	50.0	7	70.0		
Week 1						
Present	0	0.0	0	0.0	-	-
Absent	10	100.0	10	100.0		
1 month						
Present	0	0.0	0	0.0	-	-
Absent	10	100.0	10	100.0		
3 months						
Present	0	0.0	0	0.0	-	-
Absent	10	100.0	10	100.0		
6 months						
Present	0	0.0	0	0.0	-	-
Absent	10	100.0	10	100.0		

¹Chi-square test

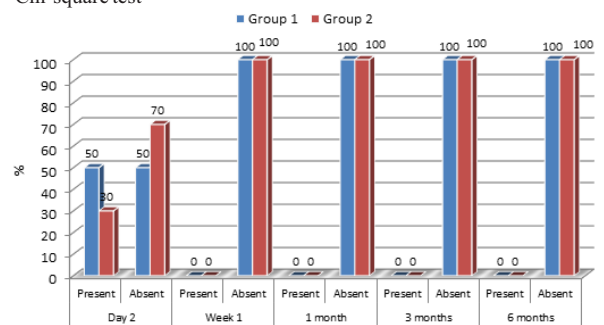


Fig. 8: Comparison Of Swelling Between The Groups Across The Time Periods

Table-8 & Fig. 8 shows the comparison of swelling between the groups across the time periods. Swelling became nil in both the groups at week 1, 1 month, 3 months and 6 months

Table-9: Comparison Of Suppleness Of Mucosa Between The Groups Across The Time Periods

	Group 1 (n=10)		Group 2 (n=10)		χ ² d.f.	p-value ¹
	No.	%	No.	%		
Day 2						

stiff	0	0.0	2	20.0	-	-
slightly stiff	10	100.0	8	80.0		
slightly supple	0	0.0	0	0.0		
supple	0	0.0	0	0.0		
Week 1						
stiff	0	0.0	0	0.0	-	-
slightly stiff	8	80.0	10	100.0		
slightly supple	2	20.0	0	0.0		
supple	0	0.0	0	0.0		
1 month						
stiff	0	0.0	0	0.0	-	-
slightly stiff	1	10.0	0	0.0		
slightly supple	9	90.0	10	100.0		
supple	0	0.0	0	0.0		
3 months						
stiff	0	0.0	0	0.0	-	-
slightly stiff	0	0.0	0	0.0		
slightly supple	10	100.0	10	100.0		
supple	0	0.0	0	0.0		
6 months						
stiff	0	0.0	0	0.0	-	-
slightly stiff	0	0.0	0	0.0		
slightly supple	5	50.0	8	80.0		
supple	5	50.0	2	20.0		

¹Chi-square test

Table-9 & Fig. 9 shows the comparison of suppleness of mucosa between the groups across the time periods. Slightly stiff was in all the patients of Group 1 and in 80% of Group 2 at Day 2.

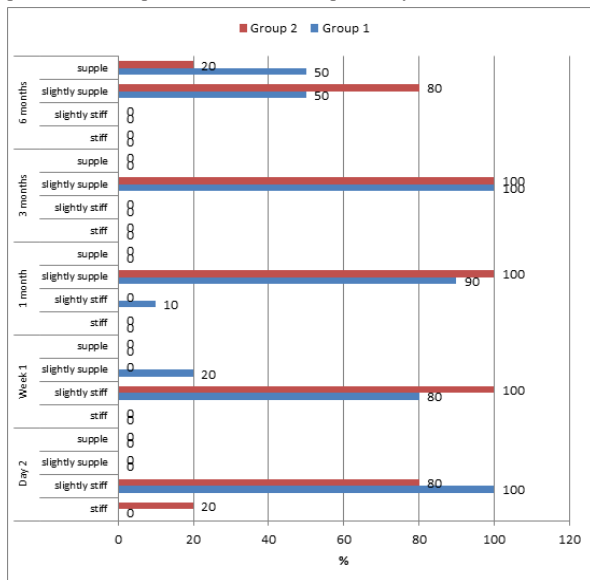


Fig. 9: Comparison Of Suppleness Of Mucosa Between The Groups Across The Time Periods

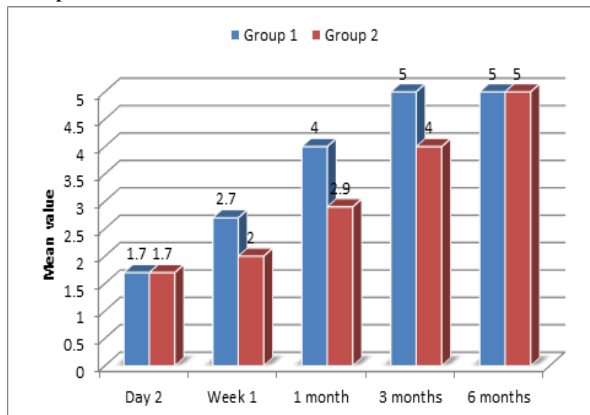


Fig. 10: Comparison of healing score between the groups across the time periods

Table-10: Comparison Of Healing Score Between The Groups Across The Time Periods

Time period	Group 1 (n=10)	Group 2 (n=10)	t-value, df	p-value ¹
Day 2	1.70±0.48	1.70±0.48	0.00, 18	1.00
Week 1	2.70±0.48	2.00±0.00	-	-
1 month	4.00±0.00	2.90±0.31	-	-
3 months	5.00±0.00	4.00±0.00	-	-
6 months	5.00±0.00	5.00±0.00	-	-

¹Unpaired t-test

Table-10 & Fig. 10 shows the comparison of healing score between the groups across the time periods. Healing score was almost same in both the groups at all the time periods.

DISCUSSION AND CONCLUSION:

The mainstay in the treatment of OSMF is concentrated on attempts to improve the mouth opening and relieve the symptoms by medicinal or surgical means. All conservative treatment is not giving good results or time taken but apart from this surgical treatment given good results along with conservative treatment. Medicinal treatment as we Very early without limitation of mouth opening of <35 mm and early cases with mouth opening of n<35 mm were treated by local injection of triamcinolone acetonide, while advanced cases with limitation of mouth opening of <25 mm were treated by surgical intervention ⁸.

The surgical treatment is the method of choice in patients with marked limitation of mouth opening. The following surgical modalities have been used: release of fibrous bands and covering of the raw areas with split thickness skin grafting, bilateral nasolabial flaps, palatal island flaps, tongue flaps, temporalis myotomy, and coronoidectomy surgical therapy is beneficial in cases presenting severe trismus and which are not responding to the medicinal treatment. After surgical therapy, oral mucosa should regain and retain its normalcy and there should be reduction in the risk of oral cancer.

Relapse is the common complication after surgical release of trismus. Mere cutting of the fibrotic bands followed by forcible mouth opening and allowing secondary epithelization left an unsatisfactory rigid buccal mucosal surface even when attempts were made to reduce collagen formation by insertion of steroid impregnated packs. It resulted in scar formation and recurrence of trismus. Additional procedures like temporalis myotomy and bilateral coronoidectomy can be performed to enhance mouth opening.

Results with skin grafting to cover the raw areas have been disappointing as the incidence of shrinkage, contracture and rejection of graft was found to be very high because of the poor oral conditions and subsequent recurrence of symptoms. Split thickness skin grafts along with bilateral temporalis muscle myotomy or coronoidectomy were effective, but have the drawbacks of secondary contracture formation in temporalis tendon and muscle and pterygomandibular raphae, which appears to be the principal cause of restricted mouth opening. Recurrence of symptoms was common in the studies conducted by Khanna & Andrade ⁸, Lai. D.R. ⁹ and Glenn Morawetz et al ¹¹. The other limitation split thickness skin graft is the morbidity associated with donor site along with maintenance of mouth opening post operatively for 7 to 10 days which is the most unpleasant and uncomfortable experience for the patient.

Palatal island flaps based on greater palatine artery to cover the defects of OSMF has been employed by Khanna and Andrade ⁸. The technique of utilizing the palatal island flaps was found to be simple. But the use of island palatal flap has limitations such as its involvement with fibrosis and second molar tooth extraction is required for flap cover without tension ⁹. Bilateral palatal flaps leave a large raw area on the palatal bones. Sometimes the defect created may be large and local flaps may not be able to cover the entire defect.

Tongue flaps have also been used for treating OSMF but have disadvantages such as, postoperative dysphagia, disarticulation, the risk of postoperative aspiration and need for additional surgery for detachment of the pedicle ⁸. The involvement of tongue in OSMF often precludes its use in treating OSMF ⁸. Application of amniotic membrane is of little benefit when used in single layer over deep buccal defects ⁹. Human placental grafts can also be applied to cover the defects. It has shown little beneficial results when combined with

submucosal injection of Dexamethasone. Bilateral radial artery forearm free flaps and the bi-paddled radial forearm flap from single donor site require micro vascular expertise¹⁰. The procedure is time consuming and technically demanding. Donor site morbidity as well as unsightly scar formation is other disadvantages. The flaps are hairy and 40% of the patients require secondary de-bulking procedures. Extractions of third molars are required to avoid flap inclination between teeth. Flaps from anterolateral thigh¹² were used for reconstruction of buccal defects after release of fibrosis but drawbacks include donor site morbidity and need for de-bulking of flap.

Fat transplantation has been known since 1892 when Neder first described it. Since inception the first report of the use of the BFP as a pedicle graft for defects up to 4 cm in diameter covering it with a free-split thickness skin graft was made in 1977. However, it has been a controversial subject. The use of the BFP for reconstruction in oral defects was studied to evaluate its feasibility as a flap for the reconstruction of oral defects, comparison with the buccal flap and to determine suitable sites for its use. It was found that harvesting of the BFP did not produce any marked defect in the cheek. In reference to the oral cavity, buccal fat pad harvesting is a technically easy procedure, both donor and recipient sites are contiguous in the oral cavity, there is no visible scar in the donor area, the problem of losing transplanted fatty tissue in the long-term is a negligible factor as the anatomic proximity of the donor and recipient sites permits rapid grafting without having the fatty graft too long outside the body of the patient. On average, the volume of BFP is 9.6 ml 20 (range, 8.3 -11.9 ml) Defects covering with this without compromising the blood supply according to **Stuzln et al 60 (1990)**. The BFP is not totally free of complication. It can cause severe atrophy in chronic cases and the anterior reach is something inadequate, leaving a raw area which heals by secondary intension and subsequently leading to relapse according to **Gupta and Sharma 61(1998), Tideman et al 62(1986)**.

As the growing age people are more attracted towards such habits as they feel it to be more fascinating style icon added by the ease of availability. Most of the OSMF patients belong to low socio economic class. The reason for OSMF cases coming from low socio economic classes might be due to poor quality of food, low vitamins particularly in iron deficiency and use of more spices and chillies to make food tasty, coupled with lack of health consciousness. In that study showing male predominance as female are still under social constraints as observed in previous study conducted by **N. Afroz et al¹⁵(2006), Yueh Huang et al(2008), M.S Ahmad et al¹⁴(2009)**. Pain intensity on each follow up day was evaluated on VAS from 0-10. At all the time intervals i.e 2nd day, 7th day, 1 months, 3 months, 6 months pain score of group II was found to be higher than group I. Decline in pain score from that at 2nd day was found significantly (p=0.009) lower in group I (8.60 ± 0.69) than Group II (9.40±0.51) at 2nd day. The pain score became nil in both the group at 1 months, 3 months and 6 months. Postoperative pain was controlled using the same analgesic of the same dosage, frequency, and prescribed for the same length of time **Gupta et al**. At all the time intervals from day 7 to 6 months in each group owing to the fact of progressive healing process. By secondary intension as the raw surface to oral environment. This was in accordance with the study of **Kshirsagar R et al, Anil Shah et al¹³**. Decline in grade of swelling from that at day 2 was observed was higher in group I due to BFP require deeper dissection(**Gupta et al**) and on day 7 in both the groups which was found to be statistically significant owing to the inflammatory response towards surgical exploration. At day 7 no swelling found, grade of swelling was 0 for all the subjects and thereafter at follow up at 1 month, 3 month, 6 month no further swelling was observed and nil in both groups, indicative of progressive healing. This was in accordance with the study of **Nagendra et al**.

The comparison of suppleness of mucosa between the groups across the time period showed was slight supple in group I as compared to group II. Difference in grade of suppleness between both the groups is attributed to the fact that the dense fibrous connective tissue in the subepithelial stroma lacking lamina propria and submucosa lead to retraction of the BFP and limitation in mouth opening. Less scar formation led to more flexible and elastic mucosa due to this there no shrinkage of tissue led to more supple and elastic mucosa **Koneru et al**. In both the groups a trend of increase in grade of suppleness at subsequent follow ups visits was observed and in both the groups change in suppleness from that at day 2 was found to be statistically significant at every follow up. Suppleness and elasticity was increased in group I due to restored height of the buccal vestibule (**Noor UI**

Wahab et al (2016). Improvement in the physiologic functions like suppleness and elasticity of the buccal mucosa on clinical examination did indeed had a good correlation with the original study conducted by **Yeh et al, and Sharma et al (2011)**.

At day 2, grade of healing index of group I (1.70±0.48) was found to be almost similar of group II (1.70±0.48), but was not statistically significant (p=1.00). At day 7, 1 month, 3 month, 6 month grade of healing index of group I was found to be significantly higher than that of group II. In group I, an increase in healing index from that at day 2 was found to be statistically significant. In group II, no change in healing index between day 1 and day 7 observed. At day 1 month group I showed complete epithelisation were as in group II was still under process of healing. At each follow up visit healing on group I was ahead of group II. Healing of the graft usually occurred within 2-3 weeks leaving a good mucosal surface was first reported by **Samman et al¹⁶ (1993)** indicating fibrosis of the fatty tissue. In our study we observed that healing started from the first postoperative day and was complete within 2-3 weeks post operatively. Results of their study support our research work. The same result was obtained in the study carried by **C.Y.yeh et al, Dolanmaz D et al**.

An increase in maximum mouth opening was observed at each follow up and was found to be statistically significant higher in group I than group II at 3 months (P=0.008) and 6 months (P=0.02) follow ups visits. **Mehrotra et al (2009) Rohit Sharma et al**. conducted a clinical study in which they experienced better results with buccal fat pad graft with respect to postoperative mouth opening in duration of one year post operative review their results were in accordance with our study. **K. Saravan and Vinod Narayan (2012)** conducted a clinical study in which they experienced better result with BFP of mean mouth opening of 25 mm to 36 mm in follow up of 6 months (**Gupta et al**). In group I being a case healed by primary intension, while in non grafted site healing occur by secondary intension following the granulation tissue formation there by having relatively more wound contracture and fibrosis.

A satisfactory surgical release can be negated by an adequate post-operative physiotherapy or poor patient compliance. It is important to note that early postoperative exercise, active postoperative physiotherapy and strict follow up are essential to prevent postoperative shrinkage and adhesions in OSMF.

BFP harvesting is a technically easy procedure with an advantage of contiguous donor and recipient sites (**Saravanan and Vinod Narayan, Lai et al**). There is no visible scar in the donor area; the problem of losing transplanted fatty tissue in the long-term is a negligible factor as the anatomic proximity permits good holding of grafts and its carries blood supply along. On average, the volume of BFP is 9.6 ml (range, 8.3 -11.9 ml) which is adequate for almost complete defects coverage without compromising the blood supply **Stuzln et al (1990)**. The BFP is not totally free of complication. It can cause severe atrophy in chronic cases and the anterior reach is something inadequate, leaving a raw area which heals by secondary intension and subsequently leading to relapse according to **Gupta and Sharma (1998); Tideman et al (1986)**.

We studied the surgical approach prospectively and measured outcomes and compared the results with each other to determine the versatility of buccal fat pad flap. Its use is contraindicated in the patients with prior local radiotherapy, malar hypoplasia, thin cheeks or Down's syndrome. BFP should be handled gently with extra care as the overstretching can lead to ischemic necrosis. All surgical variables such as pain, mouth opening and area of wound showed positive results, with very mild fibrosis at the surgical site and complete epithelization of the wound. Unlike skin grafting, no shrinkage that could cause fibrosis and associated reduced MMO occurred. So we concluded that the surgical site in OSMF cases should always be grafted with some graft material and could also be stated that the BFP has proven itself to be a satisfactory option when and wherever required, keeping in view the ease of harvesting and donor site morbidity.

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