



Maxillofacial Surgery

POSTOPERATIVE OUTCOMES OF COLLAGEN SHEET VERSUS BUCCAL FAT PAD IN THE RESURFACE OF THE RAW AREA FOLLOWING THE EXCISION OF FIBROUS BANDS IN OSMF- PROSPECTIVE CLINICAL STUDY.

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ABSTRACT This study was designed to compare the use of collagen sheet, on one side and BFP on the contra lateral side to resurface the raw area following the excision of fibrous bands. This prospective study comprised 46 patients reporting to the department of Oral and Maxillofacial Surgery, SSCDS, Hyderabad with a chief complaint of reduced mouth opening. Patients were examined postoperatively on the first day, first week, second week, third week, fourth week, eighth week, three months, and six months. Pain, interincisal opening, edema, and graft epithelialization were examined postoperatively. The findings were analyzed with SPSS software version 21. Intraoperatively, the average time for BFP was 20.91 minutes and 15.91 minutes for collagen sheet. VAS values for pain differed significantly between groups. On the first postoperative day, pain was moderate to severe at the BFP site and mild to moderate at the collagen sheet site; these differences were statistically significant ($p=0.002$). On the 7th day, the VAS scores for both sites had decreased, but the disparities remained statistically significant, resulting in a mean VAS score of 2.00 and 1.00 on BFP and collagen sheet sites, respectively ($p=0.001$). Both methods resulted in almost normal mouth opening with no significant difference in relapse proportion, in terms of postoperative healing and surgical convenience. The use of a collagen sheet is better than BFP transposition. **Summary:** Collagen sheet had an edge over BFP intraoperated adaptation time and post operative pain.

KEYWORDS : Oral Submucous Fibrosis, Buccal Fat Pad, Collagen sheet, surgical management, epithelialization.

INTRODUCTION:

Oral Submucous Fibrosis (OSMF), according to Jens Jorgen Pindborg, is a chronic insidious disease that can affect any part of the oral cavity and occasionally the pharynx¹. It is sometimes preceded by or associated with vesicle formation. The disease is always associated with a juxta-epithelial inflammatory reaction that is followed by a fibro elastic change of the lamina propria. It is found in Sri Lanka, Malaysia, Nepal, South Vietnam, Thailand, and has a prevalence of 0.2-0.5% in India.² There are many different ways that OSMF manifests itself. It can begin with excessive salivation, burning sensations, decreased gustatory perception, and progress to a mouth opening limitation that impairs oral hygiene, chewing, swallowing, articulation, and poor oral hygiene.

The literature on this chronic condition revealed a number of management strategies. The conservative approach to treat OSMF includes using minerals and micronutrients, intralesional injections of hyaluronidase, placenta extract, steroids, pentoxifylline, lycopene, interferon gamma, turmeric, hyalase, chymotrypsin, and collagenase.^{3,4} In severe conditions, surgery is the preferred course of treatment and the current approved remedies concentrate more on improving mouth opening and reducing the symptoms.⁵ Surgical release of fibrous bands and masticator myotomy or coronoidectomy followed by reconstruction with autogenous or allografts is the most preferred option. Artificial dermis and lateral thigh dermal fat pad,⁶ temporalis fascia flap and radial forearm flap,⁷ greater palatine pedicled flap,⁸ buccal fat pad (BFP) flap, skin grafts,⁹ tongue flap, placental graft, and nasal labial flap¹⁰ can be used for reconstruction. Although there are several alternatives for covering the raw surface area, each and every flap or graft has its own limitations and disadvantages. This study was designed to compare the use of alloplastic material, collagen sheet, on one side and autogenous flap BFP on the contra lateral side to resurface the raw area following the resection of fibrous bands.

MATERIALS:

This prospective study was carried out as a split-mouth study, with patients presenting to the department of Oral and Maxillofacial Surgery, SSCDS, Hyderabad, with a chief complaint of restricted mouth opening. OSMF was confirmed clinically by focusing on

reduced mouth opening and visible, palpable fibrous bands. Only stage III and stage IV OSMF patients were included in the study based on the Khanna and Andrade classification.¹¹ Patients with systemically compromised conditions and positive lymph nodes were excluded from the study. Malignancy was ruled out in all the patients based on histopathological examination. Sample size estimation was done based on the results of previous studies. G * Power software version 3.1.9.2 was used for sample size computation. The effect size obtained was 0.5. Level of significance was set at 5%. Power was set at 90%. Two sided test was used. The final sample size was estimated to be 46(N). Thus, 46 patients with mouth opening less than 25mm were included in the study. The research protocol was approved by the institutional review board and was in compliance with the World Medical Association Declaration of Helsinki on medical research protocols and ethics. Informed consent was obtained from all the patients.

All the patients underwent standard surgical procedures under general anesthesia only. All patients had their surgical procedures performed by the same surgeon. A standard incision was made at the level of the occlusal plane using a surgical knife or electrocautery. After the release of fibrous bands, if the interincisal opening was less than 35mm, temporalis myotomy and coronoidectomy were carried out bilaterally. At site A, BFP was extracted at the defect's postero-superior margin and gradually teased out to cover the raw area. At Site B, the surface was covered with a 5x5cm collagen sheet (sterile biological sheet, 10x10cm). Resorbable sutures (3-0 Vicryl) were utilized to stabilize the graft at its periphery, with quilt sutures in the core. The duration of surgery for site A was measured from the time of BFP harvest to the completion of suturing, while the duration for site B was computed from the time of collagen sheet opening to the completion of suturing. Ryles tube feeding was implemented for one week to maintain oral hygiene. From the 1st postoperative week, patients were instructed to perform mouth opening exercises utilizing Heister's mouth opener.

Postoperatively pain, interincisal opening, edema, and graft epithelialization were examined. Pain was assessed using Visual Analogue Scale (VAS) on a range of 0 to 10. The interincisal opening was measured using a metallic scale to measure the distance between the incisor tips. Swelling was assessed as the mean of a 9-line

measurement using measuring tape. 1. Gonion to lateral canthus of eye bilaterally; 2. Tragus to lip commissure bilaterally; 3. Tragus to chin midline bilaterally; 4. Tragus to nose ala bilaterally; 5. Right gonion to left gonion.¹² Epithelialization was measured on Day 1: Raw area (score 1), Day 7: Raw area to the beginning of epithelialization (score 2) Day 28: Epithelialization in progress (score 3); 6th week: Complete epithelialization (score 4); 8th week: Complete epithelialization with normal pigmentation (score 5).

RESULTS:

The findings were analyzed with SPSS software version 21. The study comprised a total of 46 individuals, with 12 females and 34 males. The mean age was 30.95 years. Intraoperatively, the average time for BFP was longer compared to collagen sheet, with a statistically significant difference ($p < 0.001$). The surgeon found that using a collagen sheet made intraoperative tissue handling and adaptation easier. All patients were examined post-operatively on the first day, 7th day, 28th day, 6th week, 8th week and six months. The pain VAS scores differed significantly between groups at each study interval. BFP site caused higher discomfort than the collagen sheet site on the first postoperative day ($p < 0.002$), 7th day ($p < 0.001$), and 28th day ($p < 0.001$) as shown in Table: 1.

Table 1: Analysis Showing Epithelialization, VAS Scores, Swelling And Duration Of Surgery.

Parameters		Site A		Site B		t value	p value
		Mean	SD	Mean	SD		
Epithelisation	1st day	1.00	0.00	1.00	0.00	-	-
	7th day	1.80	0.41	1.30	0.47	3.684	0.002*
	28th day	2.60	0.50	2.70	0.47	-0.809	0.428
	6 th week	4.89	0.32	5.00	0.00	-1.455	0.163
VAS Scores	8 th week	5.00	0.00	5.00	0.00	-	-
	1st day	4.35	1.09	3.75	1.02	3.559	0.002*
	7th day	3.45	0.51	1.95	0.76	8.816	<0.001*
	28th day	2.00	0.32	1.00	0.00	13.784	<0.001*
Swelling	1st day	2.25	0.44	2.20	0.41	0.438	0.666
	7th day	1.40	0.50	1.15	0.37	2.517	0.021*
	28th day	0.60	0.50	0.45	0.51	1.371	0.186
	Duration of surgery	20.91	3.03	15.91	1.84	10.820	<0.001*

*statistically significant

Postoperatively, mouth opening increased gradually in all the patients. Swelling was comparatively higher on the BFP site on 7th postop day, which showed a significant difference ($p=0.021$) and on other days it was statistically insignificant, as shown in Table 1. On the 7th postoperative day, there was a significant difference ($p=0.002$) in the amount of epithelialization at the collagen site. The two sites did not differ significantly on the 28th day. There was slightly reduced pigmentation on the BFP site at the end of the 6th week, and by the 8th week, complete epithelialization had occurred, as shown in Table: 1.

DISCUSSION:

The ultimate goal of treating OSMF is to reduce symptoms and improve mouth opening. Surgical excision of fibrous bands is the standard course of treatment in advanced cases. Scarring and an additional reduction in mouth opening may result from the excision of fibrous bands. Therefore, some sort of graft material needs to be applied to the raw area. In addition to stopping habits, physiotherapy, and medication therapy, Arakeri and Brennan indicate that in the late stages of OSMF, surgery with autogenous flaps or allografts is also required.¹³ The easily accessible autograft in the lesion's immediate vicinity is BFP. Heister (1732) was the first to describe BFP, referring to it as "glandula molaris." Scammon and Goughran were the first to characterize the anatomy of BFP.¹⁴ BFP is a flexible, lobulated mass that allows for sufficient graft mobility. It is emptied by corresponding veins and receives a substantial blood supply from the branches of the superficial temporal artery, internal maxillary artery, and facial artery.¹⁵ BFP has an average capacity of 9.6 ml (with a range of 8.3-11.9 ml). BFP can be used to cover defects up to 3 to 5 centimeters in size without endangering the blood supply.^{16,17} As an allograft, collagen sheet offers a number of benefits, like easy availability, unlimited supply, reduced donor site morbidity, biocompatibility, and affordability.¹⁸ The majority of the drawbacks of applying BFP can be minimized by these features. Collagen acts as a physical barrier, attracts monocytes, aids in the deposition of ordered, oriented fibers that improve tissue integrity, and provides a matrix for the growth of tissue and arteries.¹⁶ So, we designed the present study to compare the BFP and collagen sheets in

the same patient.

In our study, 30 patients had undergone bilateral coronoidectomy. They had the habit of areca nut chewing, which, on account of increased muscular activity, may have contributed to the elongation of the coronoid process.¹⁹ The pain score was relatively high on the BFP site on the 1st postop day, which continued till the end of the 7th postop day, which may be attributed to donor site morbidity, which was similar to the observations reported in the study by Divya Mehrotra.³ It gradually decreased over a period of time. Mouth opening gradually increased in all the patients. The effect of BFP and collagen sheets on the amount of mouth opening cannot be evaluated and justified as both were used simultaneously at the same time in all the patients. Swelling also contributes to pain, trismus, and discomfort. All patients had comparatively more swelling at the BFP site which was probably due to the pull of BFP pedicle. Studies indicated that BFP flaps were not so efficient in terms of oral commissural width restoration when compared with other flaps.²⁰ Borle et al¹⁰ have evaluated the use of an extended nasolabial flap, and Pradhan et al²¹ have compared BFP and collagen sheets in OSMF management. They also stated that the amount of postoperative pain and swelling was higher on sites treated with BFP.

The rate of epithelialization was significantly higher with collagen sheet on the 7th day when compared to BFP. But, by the end of 28th day, epithelialization in both groups was almost the same, which is similar to the studies conducted by Pradhan.²¹ BFP after grafting becomes yellowish-white in 3 days and then gradually becomes red within 1 week, likely due to the formation of granulation tissue. This further changes into firmer granulation tissue during the 2nd week and becomes completely epithelialized with a slight contraction of the wound by 3rd week.^{22,23} Collagen epithelialization is dependent on adherence to the raw surface, which is a key factor for the survival of the collagen membrane due to the fibrin-collagen interaction.²⁴ Adherence takes approximately 5 to 10 days. In our study, all collagen membranes sloughed off over time, and epithelialization occurred rapidly at the collagen sheet site as shown in Figure 01 and Figure 02. This is contrary to Kothari et al,²⁵ findings who stated that the BFP showed the fastest epithelialization and the least amount of wound contracture.



Figure 1: Adaptation and epithelialization of BFP

1a-Intraoperative,
1b-7th day
1c-28th day
1d-6th week

Our study's findings indicate that using collagen sheet and BFP together following the excision of fibrous bands in OSMF produced acceptable long-term results. However, the use of collagen sheets improved the patient's comfort and the surgical site's healing significantly in the immediate postoperative period. Additionally, the VAS score showed that collagen sheets caused less physical trauma than BFP. However, the long-term data indicate that BFP and collagen

do not significantly differ from one another. BFP has drawbacks, like the fact that its use for larger defects is limited since severe stretching of BFP usually affects vascularity hence, closure of larger defects cannot be ensured. In such circumstances, a collagen sheet may be an appropriate solution without sacrificing the results.

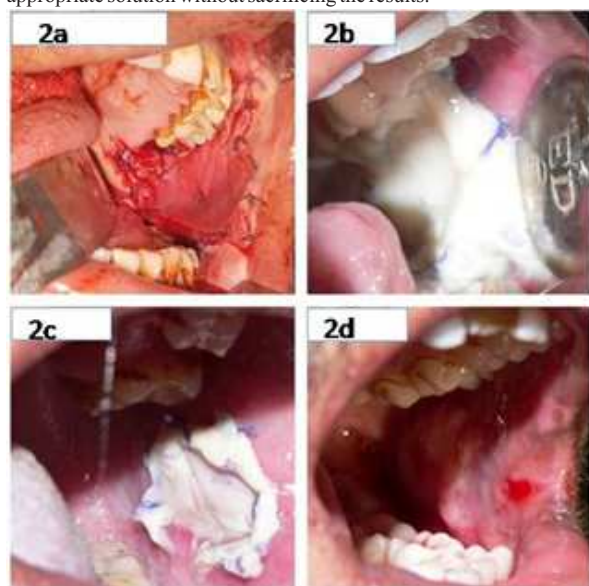


Figure 2: Adaptation and epithelialization of Collagen sheet

2a-Intraoperative

2b-7th day

2c-28th day

2d-6th week

CONCLUSION:

The Collagen sheet grafted on one side was strong enough to withstand intense masticatory forces for long enough to allow granulation tissue to develop, and it seemed evenly and clinically healthy. Collagen is well tolerated in clinical settings and has no negative side effects. Although both techniques produced almost normal mouth openings with no significant difference in relapse proportion, the use of a collagen sheet outperformed BFP transposition in terms of post-operative healing and surgical convenience. However, more large-sample research is needed to support the above findings. To shed light on the true impact on mouth opening and postoperative sequelae, an extensive research comparing BFP with collagen sheet in a varied patient population group is needed.

Conflict Of Interest: None

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