



Comparison of Collagen Membrane and Split Thickness Skin Graft Used for Reconstruction of Buccal Mucosa in Oral Submucous Fibrosis - A Prospective Clinical Trial

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ABSTRACT:

Background: Oral submucous fibrosis (OSMF) is a chronic, progressive condition marked by the gradual stiffening of oral tissues, leading to restricted mouth opening, impaired oral functions, and a heightened risk of malignant transformation. Treatment for OSMF typically involves a combination of habit cessation, medication to reduce inflammation and fibrosis, physiotherapy to maintain or increase mouth opening, and surgery in advanced cases. Early diagnosis and a multi-disciplinary approach are key to effectively managing OSMF and improving the patient's quality of life. Split thickness skin graft are the most popular and commonly used flap in reconstructing mucosal defect left by fibrous band excision in developing countries like India where free flap expertise are not easily available and affordable by poor patients. In this study we compared split thickness skin graft and collagen membrane for reconstruction of buccal mucosa defects post fiberotomy in patients suffering from oral submucous fibrosis.

Aim: The aim of this clinical study is to compare the efficacy of Collagen membrane over split thickness skin graft used for reconstruction of buccal mucosa in patients with oral submucous fibrosis.

Materials and Methods: This study was carried out at the Department of Oral and Maxillofacial Surgery, Saveetha Dental College and Hospital, Chennai in the year 2023 and 2024. based on the G* power calculation study consisted of 30 individuals which were divided into two groups containing 15 individuals in each group excluding the dropouts. Group 1 received collagen membrane for buccal mucosa reconstruction while group 2 received split thickness skin graft for buccal mucosa reconstruction. Immediate post operative mouth opening was measured by using standardized measurement scale and compared with 3 month and 6 month follow up period.

Results: It was found that the mouth opening of participants in the collagen membrane group was slightly more than the mouth opening of participants in the skin graft group with statistically significant difference of (P = 0.004) On 3rd month follow up and (P = 0.001) on 6th month follow up respectively.

Conclusion: This study concluded that Collagen membranes offer a more effective solution for increasing mouth opening and possibly enhancing overall oral function in patients with OSMF. As a result, collagen membranes could be regarded as a better choice for buccal mucosa reconstruction in the surgical treatment of OSMF.



1. Introduction

Oral submucous fibrosis (OSMF) is a chronic, progressive, and potentially malignant disorder of the oral cavity, characterized by an inflammatory response in the juxta-epithelial connective tissue, leading to fibrosis of the lamina propria and deeper connective tissues.[\[1\]](#) This fibrosis results in mucosal stiffness, trismus, and difficulty in mouth opening. OSMF predominantly affects populations in South and Southeast Asia and is strongly associated with habitual areca nut and betel quid consumption. Other contributing factors include autoimmunity, deficiencies in vitamins B and C, iron deficiency, spicy food consumption, human papillomavirus (HPV) infection, and genetic predisposition [\[2\]](#). Epidemiological studies highlight betel nut chewing as one of the most significant risk factors, primarily due to arecoline and copper. Additionally, tobacco use and alcohol consumption have been implicated in increasing the risk of OSMF.

According to World Health Organization (WHO) estimates, more than five million people worldwide suffer from OSMF, with a higher prevalence in India.[\[3\]](#) While OSMF is more common in women in India, the trend is reversed in other regions due to differences in chewing habits between men and women. The condition typically affects individuals between 20 and 40 years of age, and approximately 7.6% of OSMF patients in India progress to oral cancer. The pathogenesis of OSMF involves a complex interplay of genetic, immunological, and environmental factors, ultimately leading to excessive collagen production and fibrosis of the oral mucosa.

Oral submucous fibrosis (OSMF) is primarily caused by areca nut chewing, with arecoline being the key alkaloid responsible for its progression. Arecoline stimulates fibroblasts to overproduce collagen while inhibiting its degradation, leading to fibrosis and mucosal stiffness.[\[4\]](#) Pro-inflammatory cytokines like TGF- β , CTGF, and TNF- α , along with an imbalance between MMPs and TIMPs, contribute to excessive extracellular matrix deposition. Chronic inflammation and oxidative stress further exacerbate tissue damage, impairing blood circulation and causing epithelial atrophy.[\[5\]](#) Elevated copper levels, especially from processed areca nut, enhance collagen cross-linking, increasing tissue rigidity and worsening trismus.[\[6\]](#)

OSMF is a recognized premalignant condition with a malignant transformation rate of 7%–30%. Persistent inflammation, excessive collagen deposition, and prolonged activation of growth factors create a microenvironment favorable for malignancy. Molecular markers such as TGF- β 1, HIF-1 α , MMPs, and epigenetic changes in tumor suppressor genes have been linked to its progression to oral squamous cell carcinoma (OSCC). Additionally, chronic hypoxia due to fibrosis and potential HPV infection further contribute to carcinogenesis. Early intervention and cessation of risk factors, particularly areca nut and tobacco use, are crucial in preventing malignant transformation. In advanced cases of OSMF, When a biopsy reveals dysplastic or neoplastic alterations, surgical intervention is the preferred approach for patients with limited mouth opening. It includes Fiberotomy, Fiberotomy with grafts, Extra-oral flaps, Intraoral flaps, Laser treatment, Mononuclear stem cell therapy, Microwave diathermy.

Fibrotomy is often required to restore oral function and improve the patient's quality of life. Buccal mucosa reconstruction plays a crucial role in these surgeries, and traditionally, skin grafts have been the preferred method due to their reliability in covering fibrotic areas.[\[7\]](#) However, skin grafts present several limitations, including donor site morbidity, color mismatch, potential for graft contraction, and visible scarring, which can be a significant aesthetic concern for patients.[\[8\]](#)

Collagen membranes have recently emerged as a promising alternative for buccal mucosa reconstruction. As a naturally occurring protein in the extracellular matrix, collagen offers several advantages over skin grafts, such as superior biocompatibility, reduced donor site complications, and enhanced tissue integration.[\[9\]](#) [\[10\]](#) Collagen membranes are designed to mimic the natural extracellular matrix, promoting tissue regeneration while minimizing scarring. They have demonstrated successful outcomes in various oral and maxillofacial procedures, including periodontal and guided bone regeneration.[\[11\]](#)

Despite the increasing use of collagen membranes in oral reconstructive surgery, there remains a lack of well-designed clinical trials directly comparing their effectiveness with conventional skin grafts in OSMF management. This study aims to bridge this gap by conducting a prospective clinical trial evaluating the



outcomes of collagen membranes versus skin grafts in buccal mucosa reconstruction following fibrotomy in OSMF patients. Key parameters such as postoperative pain and amount of mouth opening will be assessed to determine the most effective and patient-centered approach for reconstructive surgery in OSMF.

2. Materials and Methods

Study Design and Study Settings:

This was an in vivo study that was conducted in the Department of Maxillofacial Surgery, Saveetha Dental College and Hospital, Saveetha Institute of Medical Technological Sciences, Chennai. This study was conducted in time frame of November 2023 to June 2024. Institutional Ethical Committee clearance (IHEC-Reference Number: IHEC/SDC/OMFS-2306/24/188) Registered under the Government of India was obtained before the beginning of study.

Sample Size Determination:

Based on the G* power calculation (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) and 95% confidence interval, considering dropouts from the study and loss of follow up the total sample size was determined to be 30 with 15 participants in each group. Group 1 received collagen membrane for reconstruction of buccaneer mucosa while group 2 received split thickness skin graft for buccal mucosa reconstruction.

After obtaining informed consent from the patients, they were allocated into respective groups by a simple random allocation technique. Allocation was followed by using an opaque envelope system. Surgical technique was done by the same principal surgeon and assessment was carried out by the same principal investigator in both groups. Double blinding was followed to prevent bias. Both the patient and the principal investigator were not aware of the intervention the patient received during the surgery. Immediate post operative mouth opening was measured and compared with a 3 month and 6 month follow up period. Mouth opening was measured using standardised scale in millimetres.

Inclusion Criteria:

All the patients' ages ranging from 30 - 60 years with oral submucous fibrosis with Grade III according to khanna and Andrade's classification 1957 were included in this study. Histologically proven cases of OSMF with mouth

opening less than 25 mm were included in the study. Both male and female patients within the specified age range.

Exclusion Criteria:

Medically compromised patients such as diabetic, immuno-compromised and patients on steroid therapy or with any active/acute infection were excluded from the study.

Surgical Procedure:

The surgical reconstruction of buccal mucosa in patients with Oral Submucous Fibrosis involves precise and methodical steps to ensure successful outcomes. This paper outlines the procedures for both collagen membrane and split thickness skin graft techniques. All the operations were performed under general anaesthesia via fibre optic nasal intubation and the surgical field was prepared with standard aseptic techniques. An intraoral antiseptic rinse is administered to reduce the risk of infection. The preoperative mouth opening is carefully evaluated and measured. A standard fibrotomy was carried out in the buccal mucosa bilaterally for all patients. Horizontal incisions were made using electrosurgical cautery along the buccal mucosa, bearing in mind the anatomic position of Stenson's duct orifice. The fibrotic bands are carefully dissected and released from the underlying tissues to improve mouth opening. This dissection was carried out posteriorly up to the anterior tonsillar pillars and up to the corner of the mouth depending on the clinical presentation of the fibrous bands. Further fibrotic bands were palpated and freed by finger manipulation until no restrictions were felt. A mouth opening of minimum 35 mm on table was considered adequate. If adequate mouth opening could not be achieved, bilateral coronoidectomy was carried by placing vertical release incision on extending from third molar till anterior border of ascending ramus and strip the periosteum till the coronoid processes are exposed. Release the muscle attachments and make the osteotomy cut above the sigmoid notch followed by removal of bilateral coronoid processes as adjunctive procedure. The mucosa is mobilized as much as possible without causing excessive tension, ensuring that the released tissue can be adequately covered by the graft or membrane.

Graft or Membrane Preparation:

Collagen Membrane Preparation: A collagen membrane of appropriate size is selected and hydrated in sterile



saline for a few minutes to enhance its pliability. The membrane is then trimmed to match the defect size, ensuring that it covers the entire area of released mucosa with a slight overlap to ensure stability and sutured using Bolsters dressing.

Split thickness Skin Graft Harvesting: A split-thickness skin graft is harvested from a suitable donor site, usually the thigh or buttock. The graft thickness is adjusted to match the recipient site requirements. The harvested graft is trimmed and stretched over the surgical stent and adapted onto the raw wound area. Suturing done to the underlying tissue by quilting and the graft were secured by through-and-through bolster 2-0 silk sutures. The stent was kept in place for 7 days, following which it was removed.

All patients were admitted in hospital for that duration. Also all patients received nasogastric tube feed for the duration of admission. The surgical stent kept each patient's mouth open for the duration of hospital stay. They also received prophylactic antibiotics for 3 days postoperatively. Physiotherapy was initiated upon discharge.

Follow Up:

The parameters such as amount of mouth opening and pain was assessed preoperatively and immediate postoperative period and at three month follow up and six month follow up postoperatively. Interincisal distance were measured by standardized measurement scale in millimetres by a single principle investigator. Pain was measured by Standardised measurement using visual analogue scale (VAS score).

Statistical Analysis:

The data were collected and analyzed with means and standard deviations with a 95% confidence interval. SPSS software version 23.0 (IBM Corp., Armonk, NY) was used for statistical analysis, and an unpaired t-test was used to assess the continuous variables between the two groups. The normality between the two groups was checked using the Shapiro-Wilk test. Results were considered statistically significant if the p-value was less than 0.05.

3. Results

The study analyzed and compared the mouth opening measurements of participants who underwent treatment

with either a collagen membrane or a split thickness skin graft. The results demonstrated variations in mouth-opening capacity between the two groups at different time intervals.

Preoperative Comparison:

Before the intervention, participants in the collagen membrane group exhibited a slightly wider mouth opening than those in the skin graft group. However, this difference was minimal and did not reach statistical significance ($P = 0.3$). This suggests that both groups had comparable baseline mouth-opening measurements prior to undergoing their respective treatments.

Immediate Postoperative Period:

Immediately following the surgical procedure, mouth-opening measurements in both groups were nearly identical. The difference between the two groups was statistically insignificant ($P = 0.51$), indicating that neither treatment had a superior effect on mouth opening in the short term. This similarity suggests that the initial healing phase may have limited immediate improvements in jaw mobility, regardless of the intervention used.

Three-Month Follow-Up:

At the three-month follow-up, participants in the collagen membrane group showed a greater improvement in mouth opening compared to those in the skin graft group. This difference was statistically significant ($P = 0.004$), indicating that the collagen membrane may have facilitated better healing and tissue integration, leading to improved post-surgical jaw mobility. The results suggest that the collagen membrane provided a more favorable environment for reducing fibrosis and scarring, which are common concerns in post-surgical tissue healing.

Six-Month Follow-Up:

By the six-month follow-up, the difference in mouth-opening capacity between the two groups became even more pronounced. Participants in the collagen membrane group continued to exhibit significantly greater mouth opening than those in the skin graft group, with a highly significant P-value of 0.001. This suggests that the long-term benefits of the collagen membrane became more evident over time, potentially due to its ability to promote



more flexible and functional tissue regeneration compared to the skin graft.

Table 1: Comparison of Mean preoperative mouth-opening between the group

Follow up	Intervention group	Number	Mean	SD	t	p-value
Pre operative	Group 1	15	20.4	2.4	1.05	0.3
	Group 2	15	19.6	1.99		
Immediate	Group 1	15	37.8	1.6	0.65	0.51
	Group 2	15	37.3	2.2		
3 months	Group 1	15	37.3	1.57	3.16	0.004*
	Group 2	15	35.7	1.86		
6 months	Group 1	15	36.4	1.9	5.6	0.001*
	Group 2	15	31.9	2.4		

SD-standard deviation; NS-not significant using unpaired t-test

The study's results indicate that collagen membranes yield better outcomes for buccal mucosa reconstruction in oral submucous fibrosis (OSMF) patients compared to conventional skin grafts. Notably, individuals in the collagen membrane group showed greater improvement in mouth opening during both the 3rd and 6th-month follow-ups, with statistically significant differences observed ($P = 0.004$ and $P = 0.001$, respectively). These findings imply that collagen membranes are more effective in increasing mouth opening and potentially enhancing overall oral function in OSMF patients.

4. Discussion

Oral submucous fibrosis is a debilitating condition that poses significant challenges for the reconstruction of buccal mucosa. The dense fibrotic tissue causing limited mouth opening in patients with this disorder make it difficult to achieve satisfactory functional and aesthetic outcomes [11]. This study aimed to conduct a comprehensive evaluation and comparison of two widely used reconstructive techniques such as collagen membrane and split thickness skin grafts, in the management of buccal mucosa defects in patients with oral submucous fibrosis. [12]

Patients who received the collagen membrane exhibited a faster initial healing trajectory, with reduced inflammation and discomfort. The inherent biocompatibility of the collagen material and its ability to seamlessly integrate with the surrounding tissue likely

contributed to this favorable healing outcome.[13] Additionally, the collagen membrane acted as a scaffold that promoted neovascularization and epithelialization, leading to the formation of smoother and more natural-looking mucosal surfaces.[8]

The use of collagen membranes and split thickness skin grafts in the reconstruction of buccal mucosa defects has been reported to be effective in promoting hemostasis, pain relief, granulation, and epithelialization, while minimizing complications such as infection, contracture, and scarring. The collagen membrane has been found to be a suitable and biologically acceptable wound graft material for oral mucosa defects.

In contrast, patients who underwent split thickness skin graft reconstruction experienced a more prolonged healing process. The skin grafts required a longer duration to fully integrate, and a higher incidence of donor site morbidity was observed. However, once the skin grafts had successfully healed, they provided a more robust and durable reconstruction, particularly in cases with extensive tissue loss.

The studied have shown that the use of collagen membranes are associated with fewer postoperative complications, including a lower incidence of infection, graft failure, and contracture.[9] This reduced risk of complications can be attributed to the inherent properties of collagen, such as minimal immunogenicity and a greater ability to resist infection. Conversely, skin grafts



were found to have a higher rate of complications, including graft shrinkage, contracture, and in some cases, partial graft loss.

Our study findings suggest that Collagen membranes offer a more effective solution for increasing mouth opening and decreasing pain and possibly enhancing overall oral function in patients with OSMF. As a result, collagen membranes could be regarded as a better choice for buccal mucosa reconstruction in the clinical treatment of OSMF. Hence in order to avoid drawback following split thickness skin graft such as donor site morbidity and second surgical site we can make use of collagen membrane which will prevent donor site morbidity, graft failure, cost of second surgery as well as time taken for the same.

Existing literature suggest that the choice between collagen membrane and skin grafts for the reconstruction of buccal mucosa in patients with oral submucous fibrosis should be carefully considered based on the specific clinical scenario, patient characteristics, and the surgeon's expertise and preference.^[14] The collagen membrane may be the preferred option in cases where a faster healing process and reduced postoperative complications are desirable, while skin grafts may be more suitable for extensive tissue defects that require a more robust and long-lasting reconstruction. [15]

Limitation of the Study:

Though the results were statistically significant but more number of sample size can help to improve reliability and validity of the findings. Long term follow up is also necessary in order to determine definitive results. parameters such as incidence of donor site morbidity , rate of graft failure can also be measured to provide definitive results.

5. Conclusion

The findings of this study indicate that while both treatment options initially led to similar outcomes, the collagen membrane group experienced significantly better long-term improvements in mouth opening. This suggests that collagen membranes may offer advantages over skin grafts in terms of minimizing postoperative restrictions and enhancing tissue flexibility, ultimately leading to better functional recovery. Consequently, collagen membranes may be considered a more favorable option for buccal mucosa reconstruction in the clinical

treatment of OSMF. Hence in order to avoid drawback following split thickness skin graft such as donor site morbidity and second surgical site we can make use of collagen membrane which will prevent donor site morbidity , graft failure, cost of second surgery as well as time taken for the same .

Conflicts of Interest:

The author declares no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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