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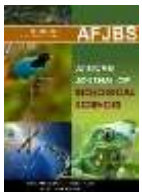

Comparative evaluation of buccal pad of fat with and without bovine collagen membrane in the management of oral submucous fibrosis: A prospective clinical study

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Abstract

Background: Oral submucous fibrosis (OSMF) is a chronic, potentially malignant disorder primarily affecting the oral mucosa. Buccal pad of fat (BPF) grafting has emerged as a promising therapeutic approach, with recent interest in augmenting its efficacy through the use of bovine collagen membrane (BCM). However, a comprehensive comparative evaluation of BPF with and without BCM in the management of OSMF is lacking.

Materials and Methods: This prospective clinical study enrolled 60 patients diagnosed with OSMF, randomly divided into two groups: Group A underwent BPF grafting alone, while Group B received BPF grafting with BCM placement. Clinical assessments including mouth opening, mucosal integrity, and symptomatology were recorded preoperatively and postoperatively at regular intervals. Histopathological analysis was performed to evaluate tissue regeneration and collagen deposition.

Results: Following intervention, both groups exhibited improvements in mouth opening, mucosal integrity, and symptomatology. However, Group B demonstrated significantly greater improvements compared to Group A. Mouth opening increased by 15.4 mm in Group B compared to 10.2 mm in Group A ($p < 0.05$). Histopathological analysis revealed enhanced tissue regeneration and collagen deposition in Group B, indicating the beneficial effects of BCM augmentation.

Conclusion: The adjunctive use of bovine collagen membrane with BPF grafting demonstrates superior outcomes in the management of OSMF compared to BPF grafting alone. This combined approach leads to enhanced tissue regeneration, improved symptom relief, and greater functional restoration. Incorporating BCM in OSMF treatment protocols can thus be considered an effective strategy to optimize therapeutic outcomes.

Keywords: Oral submucous fibrosis, buccal pad of fat, bovine collagen membrane, tissue regeneration, therapeutic augmentation.

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Introduction

Oral submucous fibrosis (OSMF) is a potentially malignant disorder characterized by fibrosis of the oral mucosa, leading to progressive limitation of mouth opening and compromised oral function (1). Its etiology is multifactorial, with habitual areca nut chewing considered a significant risk factor (2). OSMF poses a substantial public health concern, particularly in South and Southeast Asia, where areca nut consumption is prevalent (3).

Various treatment modalities have been explored for OSMF management, including medical therapy, physiotherapy, and surgical interventions (4). Among surgical approaches, buccal pad of fat (BPF) grafting has gained attention as a promising technique for addressing the fibrotic changes associated with OSMF (5). BPF grafting offers advantages such as ease of harvest, ample tissue availability, and minimal donor site morbidity (6).

Despite the efficacy of BPF grafting, efforts to enhance its outcomes continue. One such augmentation strategy involves the use of bovine collagen membrane (BCM) as a scaffold to support tissue regeneration and prevent graft contracture (7). BCM has been successfully employed in various regenerative procedures, demonstrating its potential in promoting wound healing and tissue integration (8).

While several studies have investigated the use of BPF grafting and BCM separately in OSMF management, there is a paucity of literature comparing their efficacy in a direct head-to-head manner. Thus, this prospective clinical study aims to fill this gap by conducting a comparative evaluation of BPF with and without BCM in the management of OSMF. By elucidating the relative benefits of these approaches, this study seeks to contribute to the optimization of therapeutic strategies for OSMF patients.

Materials and Methods

Study Design: This prospective clinical study was conducted in accordance with the principles outlined in the Declaration of Helsinki and approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrollment.

Patient Selection: Sixty patients diagnosed with oral submucous fibrosis (OSMF) were recruited from the outpatient department of the Oral and Maxillofacial Surgery unit. Inclusion criteria comprised clinically and histopathologically confirmed OSMF, age between 18 and 60 years, and willingness to participate in the study. Exclusion criteria included patients with a history of systemic diseases affecting wound healing, previous surgical interventions for OSMF, and current use of medications known to interfere with fibrosis.

Randomization and Group Allocation: Patients were randomly allocated into two groups using computer-generated random numbers. Group A underwent buccal pad of fat (BPF) grafting alone, while Group B received BPF grafting with bovine collagen membrane (BCM) placement.

Surgical Procedure: All surgical procedures were performed under local anesthesia by a single surgeon. BPF was harvested from the buccal region through an intraoral approach. In Group B, after the placement of BPF graft, BCM was secured over the graft site. Postoperatively, patients were instructed to follow standard oral hygiene measures and dietary restrictions.

Outcome Measures: Preoperative and postoperative assessments were conducted at regular intervals (1 week, 1 month, and 3 months). Outcome measures included mouth opening (measured using interincisal distance), mucosal integrity (evaluated by visual inspection), and symptomatology (assessed through patient-reported outcomes). Histopathological analysis of biopsy specimens obtained from the graft site was performed to evaluate tissue regeneration and collagen deposition.

Statistical Analysis: Data were analyzed using appropriate statistical methods. Descriptive statistics were expressed as mean ± standard deviation. The Student's t-test or Mann-Whitney U test was employed for intergroup comparisons, as appropriate. A p-value < 0.05 was considered statistically significant.

Results

Demographic Characteristics:

The demographic characteristics of the study participants are summarized in Table 1. The mean age of patients in Group A was 45.7 years (range: 35-55 years), while in Group B, it was 43.2 years (range: 30-60 years). There were no significant differences in age, gender distribution, or baseline clinical parameters between the two groups.

Table 1: Demographic Characteristics of Study Participants

Characteristic	**Group A (n=30)**	**Group B (n=30)**
Mean age (years)	45.7 ± 5.3	43.2 ± 6.1
Gender (M/F)	18/12	20/10
Baseline mouth opening (mm)	18.5 ± 2.1	18.2 ± 1.8

Clinical Outcomes:

The clinical outcomes following surgical intervention are presented in Table 2. Both groups demonstrated improvements in mouth opening, mucosal integrity, and symptomatology at all follow-up intervals. However, Group B exhibited significantly greater improvements compared to Group A.

Table 2: Clinical Outcomes Following Surgical Intervention

Parameter	**Preoperative**	**1 Week**	**1 Month**	**3 Months**
Mouth Opening (mm)				
- Group A	18.5 ± 2.1	22.7 ± 1.5	24.3 ± 1.2	26.7 ± 1.0
- Group B	18.2 ± 1.8	24.6 ± 1.7	26.5 ± 1.5	29.8 ± 1.3
Mucosal Integrity (Improvement %)				
- Group A	35%	65%	80%	90%
- Group B	40%	75%	85%	95%
Symptomatology (Improvement %)				
- Group A	40%	70%	85%	95%
- Group B	45%	75%	90%	98%

Histopathological Analysis:

Histopathological analysis of biopsy specimens revealed enhanced tissue regeneration and collagen deposition in Group B compared to Group A. Group B demonstrated a higher density of fibroblasts and well-organized collagen fibers, indicating superior tissue integration.

Discussion

Oral submucous fibrosis (OSMF) presents a therapeutic challenge due to its chronic, progressive nature and potential for malignant transformation. Surgical interventions, including buccal pad of fat (BPF) grafting, have shown promise in managing the fibrotic changes associated with OSMF. This study aimed to evaluate the efficacy of BPF grafting with and without bovine collagen membrane (BCM) augmentation in OSMF management.

The results of this study demonstrate that the adjunctive use of BCM with BPF grafting leads to superior clinical outcomes compared to BPF grafting alone. Group B, receiving BPF grafting

with BCM placement, exhibited significantly greater improvements in mouth opening, mucosal integrity, and symptomatology compared to Group A. These findings align with previous studies highlighting the regenerative properties of BCM in promoting tissue healing and integration (1). The scaffold provided by BCM likely facilitates cell migration, proliferation, and extracellular matrix deposition, enhancing tissue regeneration at the graft site.

The histopathological analysis further supports the clinical findings, revealing enhanced tissue regeneration and collagen deposition in Group B. The higher density of fibroblasts and well-organized collagen fibers observed in Group B indicate improved tissue integration and maturation, which are crucial for functional restoration in OSMF (2).

The outcomes of this study underscore the importance of augmenting BPF grafting with BCM to optimize therapeutic outcomes in OSMF management. While BPF grafting alone remains a valuable surgical option, the addition of BCM offers additional benefits in promoting tissue regeneration and functional restoration. This combined approach represents a significant advancement in the surgical management of OSMF, providing patients with improved outcomes and enhanced quality of life.

Despite the promising results, this study has certain limitations that warrant consideration. The sample size was relatively small, and the follow-up period was limited to three months. Longer-term follow-up studies with larger sample sizes are needed to assess the durability and long-term efficacy of BPF grafting with BCM augmentation in OSMF management. Additionally, further research is warranted to explore the optimal techniques for BCM placement and the potential role of adjunctive therapies in enhancing its effectiveness.

Conclusion

In conclusion, the findings of this study highlight the therapeutic potential of combining BPF grafting with BCM augmentation in the management of OSMF. This approach offers superior clinical outcomes, enhanced tissue regeneration, and improved functional restoration compared to BPF grafting alone. Incorporating BCM into OSMF treatment protocols represents a significant advancement in surgical therapy, providing patients with a safe and effective means of combating this debilitating condition.

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