

EFFICACY OF ADJUVANT PROCEDURES IN SURGICAL TREATMENT OF ORAL SUBMUCOUS FIBROSIS

Dissertation Submitted to

BABU BANARASI DAS UNIVERSITY LUCKNOW, UTTAR PRADESH.



In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

IN

ORAL AND MAXILLOFACIAL SURGERY

By

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(Faculty of Babu Banarasi Das University)

BATCH: 2022-2025

**DEPARTMENT OF ORAL AND MAXILLOFACIAL
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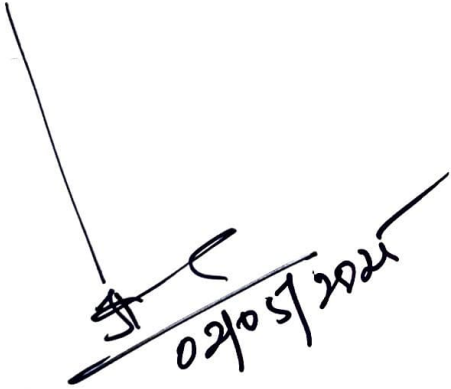
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ACKNOWLEDGEMENT

“Excellence is never an accident. It is always the result of high intention, sincere effort, and intelligent execution; it represents the wise choice of many alternatives – choice, not chance, determines your destiny.” - Aristotle

With profound humility and gratitude, I bow my head before the Almighty, whose infinite blessings, grace, and benevolence have enveloped me throughout my life's journey, providing the strength, resilience, and favourable circumstances that have led me to this milestone.

The greatest fortune of my life has been being born to my cherished parents and having had the privilege of learning under the tutelage of eminent, skilful, and immensely knowledgeable teachers, who, with great magnanimity, imparted their wisdom and expertise to me. Their mentorship has left an indelible imprint on my professional and personal growth.

I express my deepest gratitude to **Professor Dr. Jitender Kumar Aurora**, Head of the Department of Oral and Maxillofacial Surgery, **Babu Banarasi Das College of Dental Sciences, Lucknow**, for his unwavering guidance, constant encouragement, and profound insights throughout my postgraduate journey. His surgical precision, confidence, and speed have been a source of awe and inspiration, etching memories that I shall treasure forever. His timely suggestions, intellectual mentorship, and motivational support have been instrumental in shaping my academic path.

My heartfelt thanks extend to **Dr. Amartya Prakash Srivastava**, Reader, Department of Oral and Maxillofacial Surgery, for his prompt guidance, enlightening discussions, and steadfast support that enriched my academic endeavours. His invaluable inputs have been a beacon of knowledge and clarity throughout my postgraduate studies.

I am equally grateful to my esteemed teachers, **Dr. Mohit Saxena** and **Dr. Ashish Uppal**, Readers, Department of Oral and Maxillofacial Surgery, for their insightful advice, clinical expertise, and encouragement that continually motivated me to strive for excellence.

A special word of thanks is reserved for **Dr. Pooja Sehrawat**, Senior Lecturer, Department of Oral and Maxillofacial Surgery, whose constant support, patient guidance, and unwavering encouragement made the completion of this dissertation possible. Her commitment and kindness have been a source of immense strength.

I express heartfelt appreciation to **Dr. Hemant Gupta**, **Dr. Hemant Mehra**, **Dr. Rashmi Agarwal**, and **Dr. Abhigyan Manas** for their invaluable mentorship and steadfast belief in my abilities. Their enduring support has helped shape my skills, knowledge, and confidence.

I am deeply indebted to **Dr. Puneet Ahuja**, Dean, Babu Banarasi Das College of Dental Sciences, Lucknow, whose administrative support, motivation, and facilitation made this research endeavor possible.

I sincerely thank my seniors **Dr. Pallavi Rai**, **Dr. Abhijeet Humne**, and **Dr. Maruf Sheikh** for generously sharing their clinical experience and perspectives, enriching my learning during the formative years of my postgraduation.

I am grateful to my batchmates, **Dr. Jaya Mahato** and **Dr. Shiwangi Singh**, for fostering a healthy, competitive, and collaborative learning environment. Their companionship and intellectual camaraderie have been vital sources of motivation.

A warm acknowledgment is due to my juniors **Dr. Aditya**, **Dr. Sarvgaya**, **Dr. Vineet**, **Dr. Shipra**, **Dr. Madhurjya**, and **Dr. Nitish** for their enthusiastic assistance and unrelenting support during the course of my dissertation work.

I am equally grateful to the non-teaching staff — **Mr. Nankan, Mr. Haider, Simon, Awadesh, Sister Priyanka, Sister Shashilata**, and others — whose silent yet crucial contributions greatly facilitated my three-year journey. Their kindness, cooperation, and assistance have been deeply appreciated.

I owe a special debt of gratitude to my friends **Dr. T.Adarsha** and **Dr. Pathou**, whose unwavering support, loyalty, and friendship have enriched my life in countless ways, both academically and personally.

No words are sufficient to convey the depth of my gratitude to my beloved parents, **Mr. Manoj Kumar Tyagi** and **Mrs. Vidushi Tyagi**, and my loving siblings, **Aditya** and **Suryanshi**. Their unconditional love, endless sacrifices, unwavering belief in my abilities, and constant encouragement have been the bedrock of my achievements. Every milestone I have crossed and every success I have earned is a testament to their faith, perseverance, and relentless support.

I humbly dedicate this dissertation and all my academic achievements to my parents — the architects of my dreams. Their selflessness, resilience, and boundless affection have been my guiding light, propelling me to greater heights. I consider myself profoundly blessed and fortunate to have been born into their nurturing embrace.

DR. SHIVANKAR TYAGI

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LIST OF ABBREVIATIONS

S.NO.	ABBREVIATED FORM	FULL FORM
1.	%	Percentage
2.	OSMF	Oral Sub Mucous Fibrosis
3.	ASA	American Society of Anesthesiologists
4.	VAS	Visual Analogue Scale
5.	BFP	Buccal Fat Pad
6.	LA	Local Anesthesia

ABSTRACT

Background of the Study: Oral Submucous Fibrosis (OSMF) is a chronic, progressive, and potentially malignant condition of the oral cavity primarily associated with the habitual chewing of areca nut and its derivatives. The condition is characterized by epithelial atrophy, submucosal fibrosis, and progressive trismus, often leading to functional disability and an increased risk of malignant transformation. In cases of advanced OSMF, conservative treatments often fail to yield significant improvement, thereby necessitating surgical intervention. The present study aimed to assess the efficacy of a multi-modality surgical approach involving fibrotomy, third molar extraction, buccal fat pad (BFP) grafting, and bilateral coronoidectomy in restoring functional mouth opening and improving clinical outcomes in advanced-stage patients.

Study Design: A prospective clinical interventional study was conducted on eight histologically and clinically confirmed cases of Grade III and IV A OSMF, as classified by Khanna and Andrade. Patients included in the study had a minimum six-month history of habit cessation and presented with significant trismus. The surgical procedure comprised intraoral fibrotomy for the release of fibrotic bands, removal of all third molars, interpositional grafting using the buccal fat pad, and bilateral coronoidectomy. Patients were followed for a minimum of three months postoperatively.

Materials and Method: Comprehensive preoperative assessments, radiological imaging, and systemic evaluations, were undertaken. Clinical parameters—pain, swelling, infection, interincisal mouth opening, and relapse—were recorded preoperatively, intraoperatively, and postoperatively at specific intervals (1st, 3rd,

and 5th day; 1 week; 1 month; and 3 months). Postoperative active physiotherapy protocols were strictly implemented to ensure sustained outcomes.

Results: The study demonstrated a statistically significant improvement in interincisal mouth opening from a preoperative mean of 16.15 mm to 41.5 mm at the 3-month follow-up. Pain levels decreased progressively and significantly over time, with near-complete resolution by the first postoperative week. No postoperative infections were reported, and only one case (12.5%) was undergone relapse. Swelling remained minimal and statistically non-significant across time intervals, indicating effective perioperative management.

Conclusion: The combination of fibrotomy, third molar extraction, buccal fat pad interposition, and bilateral coronoidectomy proved to be an effective and comprehensive surgical approach for managing advanced OSMF. The protocol led to significant and sustained improvement in mouth opening with minimal complications, affirming its clinical utility in restoring oral function and preventing disease recurrence.

Keywords: Oral Submucous Fibrosis, Buccal Fat Pad, Coronoideotomy, Fibrotomy, Mouth Opening, Third Molar Extraction, Advanced OSMF, Surgical Management.

INTRODUCTION

Oral Submucous Fibrosis (OSMF) is recognized as a chronic, progressive, and pre malignant disorder of the oral cavity, predominantly affecting populations in South Asia due to the widespread and culturally embedded habit of areca nut consumption. Once confined to specific demographic regions, the condition has increasingly been reported across global populations, highlighting its significance as both a clinical and public health concern¹.

Pathologically, OSMF is characterized by excessive and aberrant deposition of collagen in the subepithelial connective tissue, leading to irreversible fibrosis, epithelial atrophy, and loss of mucosal pliability². This fibrogenic process is primarily driven by alkaloids and polyphenols present in areca nut — especially arecoline and tannins — which stimulated fibroblast proliferation and collagen synthesis while inhibiting collagen degradation. Over time, affected individuals exhibited progressive trismus, mucosal rigidity, restricted tongue movements, difficulty in mastication and deglutition, and in advanced cases, significant impairment of speech and overall oral function³.

The malignant transformation potential of OSMF remained one of its most serious clinical implications. Numerous studies reported transformation rates ranging from 3% to 19%, particularly in cases involving concurrent use of tobacco and alcohol. The transition from a fibrotic lesion to oral squamous cell carcinoma placed OSMF among the high-risk oral potentially malignant disorders, necessitating prompt and effective intervention⁴.

Despite decades of clinical observation and research, there remained no universally accepted curative treatment for OSMF, particularly in its moderate to advanced stages. Conservative approaches — including corticosteroids, enzymatic agents, antioxidants, and habit cessation — provided only limited and often temporary symptomatic relief. In cases of established fibrosis with functionally significant trismus, surgical intervention was considered essential for restoring oral mobility and quality of life⁵.

In this context, the present study is undertaken to evaluate the efficacy of a comprehensive surgical protocol tailored for the management of advanced OSMF (Grade III and IV A)^{6,7}. The surgical approach integrated multiple procedures: intraoral fibrotomy for the release of fibrotic bands, third molar extractions to eliminate posterior obstruction and reduce mucosal tension, interpositional grafting using the buccal fat pad (BFP) to prevent recurrence and enhance healing, and bilateral coronoidectomy to release the insertion of the temporalis muscle and significantly improve mouth opening⁸.

The study sought to offer clinical insights and evidence-based recommendations for practitioners involved in the surgical management of OSMF. It aimed to support the development of a structured, reproducible operative framework capable of delivering functional rehabilitation and minimizing recurrence. By addressing both the anatomical and pathophysiological components of advanced OSMF, this research intended to contribute meaningfully to the evolving landscape of oral precancer therapy and surgical oral medicine.

PATHOGENESIS

Thus various experimental and demographic studies provide strong evidence for areca nut as the etiology of OSMF, its premalignant nature and high risk for transformation into oral cancer. Numerous investigators have now focused their attention on pathogenesis. An understanding of these is essential for the management and prevention of OSMF and its sequelae.⁹

1. Increased collagen production due to
 - a. Stimulation of fibroblasts by areca nut alkaloids.
 - b. Clonal selection of high collagen producing fibroblasts.
 - c. Stimulation of fibroblasts by cytokines produced by macrophages and lymphocytes¹².
2. Decreased collagen degradation/turnover due to
 - a. Decreased secretion of collagenase.
 - b. Reduced collagen phagocytosis by fibroblasts.
 - c. Increased stability of collagen formed (collagen type I trimer).
 - d. Stabilization of collagen structure by catechin and tannins in areca nut.
 - e. Up regulation of tissue lysyl oxidase and resulting increased cross linking of collagen.

The pathogenesis of OSMF is thus a complex process involving both collagen and the fibroblasts, in the connective tissue, which produce and phagocytose the collagen. Cytokines and elements in the extra cellular space such as

copper play a significant role in the development of the fibrosis. Genetic predisposition and systemic factors such as nutritional deficiencies may contribute to the disease process directly or secondary to the immune alterations induced by areca nut / areca nut containing products. In addition to the morbidity associated with the fibrosis, the mucosa also exhibits changes in the epithelium which eventually results in malignant transformation to oral squamous cell carcinoma (oral cancer), making OSMF a precancerous condition.

There are numerous alterations in the molecular biology of the cells that are involved in carcinogenesis. Premalignant lesions of such as leukoplakia have been widely studied. The studies have shown that alterations in markers of proliferation (Ki67), apoptosis (bcl2, bax), differentiation (Cytokeratins) and tumor suppressor gene products (p53) are good indicators of malignant transformation. Currently, no treatment has been uniformly successful in treating OSMF. Consequently, chemoprevention has been gaining increasing attention. In this context, curcumin and free radical scavenger glutathione have been proposed as potential chemopreventive agents.

AIM & OBJECTIVES

AIM: Aim of the study to access the efficacy of adjuvant surgical procedure in treatment of oral submucous fibrosis

OBJECTIVE: The objective of the study is to evaluate inter incisal mouth opening during various surgical procedures, after B/L fibrotomy, after extraction of all 3rd molars and after B/L coronoidectomy and the following parameters at the following intervals (preoperatively, intraoperatively 1st, 3rd, 5th day ,1 week, 1 month and 3rd month postoperatively) were recorded.

- INTERINCISAL MOUTH OPENING
- PAIN
- SWELLING
- INFECTION
- RELAPSE

REVIEW OF LITERATURE

- **Paymaster JC (1956)** was the first to describe oral submucous fibrosis as a precancerous condition. A retrospective clinical study of 650 cases in Indian patients was done and it was concluded that intraoral and pharyngeal neoplasms together account for 45% of all malignant growth. Cancer of the tongue was the most frequent intraoral cancer, next in frequency was cancer of buccal mucosa. Malnutrition with subsequent avitaminosis and long-continued chewing of betel nut with tobacco were evaluated as predisposing factors.¹
- **Pindborg (1966)** defined oral submucous fibrosis. A literature review was done and concluded that the clinical manifestation includes blanching and stiffness of the oral mucosa leading to limitations in oral opening. The presence of fibrous band in lips, cheeks, soft palate is a hallmark of the disease. The disease extends over time to include the oropharynx and the upper third of the esophagus.²
- **Caniff JP Harvey w (1986)** analyzed clinical signs and symptoms in cases of oral submucous fibrosis in his retrospective study which had transformed into squamous cell carcinoma. The stimulation of collagen synthesis by extracts of areca nut was found the main etiological factors 29% patients with oral squamous cell carcinoma were diagnosed as cases of oral submucous

fibrosis transformed into oral cancer. their ages ranges from 2to 15years with an average of 6.69yrs. He concluded that OSMF depends on clinical pathological diagnostics standards.³

- **Sharma JK et al. (1987)** used ninhydrin hydrochloride in conjugation with conventional therapy (vitamin complexes and corticosteroid) to treat oral submucous fibrosis. Their success rate was 6.06% and found to be more effective in younger patients.⁴
- **Rajendra R et al (1989)** in their review article described oral submucous fibrosis, a precancerous condition of the oral cavity. The epidemiological data showed a clear-cut geographical and ethnic predisposition, which suggested that certain customs/habits prevalent among the population groups in Southeast Asia might be possible etiological factors. this led some workers to consider the importance of systemic predisposition, in addition to the effects of local factors on the oral mucosa.⁵
- **Rajendran R (1994)** in his review article described oral submucous fibrosis, a precancerous condition of the oral cavity. The epidemiological data showed a clear-cut geographical and ethnic predisposition, which suggested that certain customs/habits prevalent among the population groups in south east Asia might be possible etiological factors. This led some workers to consider the importance of systemic predisposition, in addition to the effects of local

factors in on oral mucosa.⁶

- **Khanna J.N Andrade N. N (1995)** studied a series of 100 OSMF patients in his retrospective study. All lesions were biopsied. The condition was staged into four categories. very early and early cases were treated by injection while advanced cases were treated surgically. A new surgical technique of palatal island flap based on greater palatine artery in combination with temporalis myotomy and bilateral coronoidectomy was used in 5 cases. a follow up ranging from 6 months to .5 years showed a good result.⁷
- **Dr. Lai (1995)** conducted a comparative study over a 10-year period (1982–1991), a total of 150 patients divided into two groups with varying degrees of oral submucous fibrosis (OSF) were treated by either medical or surgical therapies. Treatment was chosen according to the stage of clinical progression to gain maximal interincisal distance (ID). The cases were followed up by monthly examinations for at least two years, or when possible, even longer. Together with a cessation of the betel quid chewing habit before and after therapy, these treatment regimens combined with daily mouth opening exercises were found to be necessary to manage OSF cases in early and advanced stages of progression.⁸
- **Yang-Ming Chang (2004)** conducted retrospective clinical study and concluded that Less severe trismus from long-standing submucous fibrosis in betel nut chewers can be improved with scarred soft-tissue release only, but severe cases also require myotomy of the masticatory muscles and

coronoidotomy to obtain adequate mouth opening.⁹

- **Chambers et al (2005)** one of the striking results after meta-analysis was consistent finding of Wong – bakers face scale for preference among every scale to which it was compared by children's, parents & adults.¹⁰
- **W.M. Tilakaratne (2006)** In his review article stated data from recent epidemiological studies provide overwhelming evidence that areca nut is the main etiological factor for OSF. It was observed that there was clear dose-dependent relationship for both frequency and duration of chewing areca nut (without tobacco) in the development of OSF.¹¹
- **N. Shah, P. P. Sharma (2007)** In his research, 236 consecutive cases of OSF were contrasted with 221 control participants. OSF was found to be directly associated with the consumption of areca nut/quid or pan masala, which is a commercial mixture of areca nuts, lime, catechu, and unidentified coloring, flavoring, and sweetening chemicals. Additionally, chewing pan masala was linked to OSF changes earlier than chewing areca nut or quid, and it was consumed by a relatively younger age group. It was observed that OSF was directly connected with the frequency of chewing rather than the length of the habit.¹²

- **Fearmonti R, et al (2010)** Pathologic scarring affects millions of people worldwide. Quantitative and qualitative measurement modalities are needed to effectively evaluate and monitor treatments. This article reviews the literature on available tools and existent assessment scales used to subjectively and objectively characterize scar.¹³
- **Ramanathan Arvind et al (2012)** conducted a comprehensive literature review and concluded that exodontia in patients with OSMF, poses significant surgical challenges but is often clinically necessary. These patients frequently present with mucositis, trismus, compromised wound healing, and an increased susceptibility to postoperative infections. Additionally, dentoalveolar surgical procedures in OSMF cases may lead to severe complications, with the diagnosis and management of secondary infections, such as space infections, being particularly challenging due to restricted mouth opening and fibrotic tissue changes. Given these complexities, OSMF patients should be categorized as a special care group, requiring meticulous preoperative planning, atraumatic surgical techniques, and postoperative management strategies to mitigate risks and enhance treatment outcomes. The literature review was conducted to elucidate the pathophysiology of OSMF and the factors contributing to these surgical difficulties.¹⁴

- **Gupta Hemant et al (2014)** conducted a clinical interventional study to evaluate the effectiveness of coronoidectomy in advanced (stage III-IV) oral submucous fibrosis (OSMF) and (TMJ) ankylosis. In their article they stated that in the management of OSMF, coronoidectomy plays an important role in increasing mouth opening. They concluded that 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.¹⁵
- **Hebbar PB et al (2014)** Oral submucous fibrosis (OSMF) a condition first described in the 1950s in the modern literature still remains elusive of a cure. For many years this condition had been confined to countries like India, Pakistan, Bangladesh, etc., but now this condition is being reported from Western countries as well.¹⁶
- **Venkatesh V. Kamath (2015)** This review aims to collate and analyze from world literature the different modalities utilized in the surgical management of OSMF. The reasons for the choice of a particular surgical procedure, the study protocol, the average follow-up period and the results were scrutinized.¹⁷

- **Handa et al. (2015)** reviewed the complexities of third molar extractions in patients with OSMF, emphasizing the necessity of such procedures despite significant surgical challenges. Mucositis, trismus, compromised wound healing, and increased susceptibility to infection are common concerns in these patients. Additionally, exodontia and dentoalveolar surgeries may lead to postoperative complications, with diagnosing conditions like space infections being particularly difficult due to restricted mouth opening and fibrotic tissue changes. Given these challenges, OSMF patients require specialized perioperative management, including modified surgical techniques and tailored postoperative care to minimize complications. A comprehensive review of the literature highlights the pathophysiology of OSMF, factors contributing to surgical difficulties, and evidence-based strategies for optimal management.¹⁸
- **Narang RS, Arora A. (2017)** conducted a review and concluded that OSMF affects most areas of the oral cavity and extends to the upper third of the esophagus. The disease leads to abnormal fibrosis, causing blanching, stiffness, and progressive restriction of movement in the lips, cheeks, tongue, soft palate, and uvula. Currently, there is no definitive cure for OSMF, though conservative and surgical treatments may offer some improvement. Reducing or eliminating areca nut chewing is a key preventive strategy, especially in the early stages, as it may help slow disease progression. Intralesional steroids and hyaluronidase remain the primary treatment options available.¹⁹

- **Rai Sachin et al (2017)** conducted a comparative study on 48 patients to assess the effectiveness of combining intralesional injections of hyaluronidase and triamcinolone with third molar extraction in managing Stage II and III oral submucous fibrosis (OSMF). The results showed that patients with Grade II OSMF experienced significant improvement in mouth opening and reduced hypersensitivity to food. However, patients with Grade III OSMF exhibited variable responses, with some showing little to no improvement, making surgical intervention the only definitive option. The removal of the third molar was found to help reduce inflammation and fibrosis in the retromolar region, facilitating better mouth opening. This combined approach may serve as a viable conservative treatment option for patients with moderately advanced OSMF.²⁰
- **Chauhan S. Anil et al (2017)** conducted a comparative study on 30 histologically confirmed cases of advanced oral submucous fibrosis (OSMF) with a mouth opening of less than 20 mm. Surgical management involved bilateral release of fibrotic bands, bilateral coronoidectomy, and coverage of buccal mucosal defects using a collagen membrane. Postoperative outcomes were assessed by comparing preoperative and postoperative maximum mouth opening. The study concluded that the use of collagen membrane effectively covered the buccal defects, yielding excellent results while eliminating the need for flap reconstruction.²¹

- **Bhatt P et al (2018)** conducted a hospital-based study on 60 OSMF patients, recording detailed histories and categorizing them into functional stages based on mouth opening. Punch biopsies were performed, and histological staging was assigned using standard criteria. The collected data were analyzed statistically using the Chi-square test to assess correlations between functional and histological stages. The study concluded that there is a strong correlation between functional and histological stages of OSMF, indicating that clinically advanced cases exhibit extensive fibrosis at the histological level.²²
- **Yin-Hwa Shih (2019)** In this review introduces OSF from a molecular perspective and summarizes what is known about its underlying mechanisms, diagnostic biomarkers, and therapeutic interventions. In addition to the aggressive treatment of OSF, its prevention is also important. Future research should, therefore, focus on improving the oral health literacy of the patients susceptible to OSF.²³
- **Yen-Wen Shen (2020)** Oral submucous fibrosis (OSF) is a collagen deposition disorder that affects a patient's oral function and quality of life. It may also potentially transform into malignancy. This review summarizes the risk factors, pathogenic mechanisms, and treatments of OSF based on clinical and bio-molecular evidence. Betel nut chewing is a major risk factor that

causes OSF in Asia.²⁴

- **Chauhan H et al (2020)** conducted an observational study on mucosal suppleness in OSMF patients. Loss of mucosal suppleness is majorly due to development of fibrotic bands and recurrent scarring in OSMF patients. They stated a potentially reliable method which they called it as maximum water holding capacity within the oral cavity to assess the buccal mucosa suppleness.²⁵
- **Bandekeri JS et al (2021)** conducted a comparative study on 10 patients and proposed that third molar extraction, reciprocal coronoidotomy, masticatory muscle myotomy, and sinewy group resection are the preferred careful management for long-term results and recreation, with collagen film filled in as a superior replacement option to buccal fat cushion because it offered a wide zone of inclusion, quicker healing, and excellent patient acceptance.²⁶
- **Hui Xu et al (2021)** conducted a comprehensive review and concluded that OSMF is a multifactorial disease triggered by various etiological factors, including areca nut chewing, excessive chili consumption, copper toxicity in food and chewing agents, vitamin deficiencies, malnutrition, anemia, and genetic predisposition. Among these, areca nut consumption remains the primary causative factor. The review emphasized the importance of prevention as the first-line strategy in managing OSMF. By advancing the understanding of its pathogenesis and potential malignant transformation, along with ongoing scientific and medical developments particularly in stem cell research, exosome therapy, and other emerging fields it may be possible

to reduce the incidence, recurrence, and malignant progression of OSMF.²⁷

- **Amal Suresh, Venkatesh Anehosur (2022)** The primary objective of this study was to evaluate the histopathological changes in temporalis muscle fibers in patients undergoing surgical treatment for OSMF and to authenticate the importance of temporalis myotomy and coronoidectomy in surgical treatment protocol. A 3-year prospective study was conducted to assess the histopathological changes in temporalis muscle in surgically treated OSMF cases. In conclusion the results of this study suggested involvement of temporalis muscle with disease itself and the justification for coronoidectomy and temporalis myotomy in the surgical protocol was established.²⁸
- **Gupta S et al (2023)** reviewed various classification systems for OSMF, analyzing their advantages and limitations. Their search identified 31 relevant articles, revealing seven different classification methods, each with inherent drawbacks. Despite multiple systems, none are fully reliable for accurately assessing disease progression. Classifying OSMF remains a challenge for clinicians, surgeons, and pathologists, underscoring the need for a standardized and effective classification system.²⁹
- **Rai A. et al (2023)** A systematic review of 47 randomized clinical trials (RCTs) involving 2,393 patients and assessed the efficacy of different treatments in improving mouth opening, burning sensation, tongue protrusion, and cheek flexibility. The results indicate that the combination of steroids, hyaluronidase, and antioxidants is the most effective treatment for

both mouth opening (MD 7.05, 95% CI 1.76–12.34) and burning sensation (MD -8.62, 95% CI -10.95 to -6.30). Curcumin and antioxidants showed the highest efficacy in improving tongue protrusion. Most of the tested interventions had minimal adverse effects. Despite these findings, the methodological quality of the included RCTs was low, emphasizing the need for well-structured studies to establish stronger clinical evidence. This review highlights the importance of combination therapies in enhancing treatment outcomes for OSMF.³⁰

- **Chitlange N. M. and Phansopkar P.(2023)** conducted a literature review (2009–2022) and concluded that physiotherapy, alongside other treatments, can aid in managing oral submucous fibrosis. The review highlights mouth-opening exercises, ultrasound, and other therapeutic interventions, emphasizing the need for further research on pain management, physiotherapy for advanced cases (grades III & IV), optimal exercise dosage, and long-term treatment strategies.³¹
- **Chen, X. et al (2023)** Conducted a review (2011–2022) evaluated medicinal interventions for OSMF, analysing 29 RCTs and five CCTs. Various drugs, including steroids, hyaluronidase, pentoxifylline, lycopene, curcumin, spirulina, aloe vera, omega-3, omeprazole, allicin, and colchicine, were assessed. High-quality evidence supported salvia miltiorrhiza with triamcinolone acetonide, lycopene, pentoxifylline, curcumin, and aloe vera, while moderate-quality evidence supported allicin, colchicine, omega-3, and

oxitard. Lycopene was found to be the best for long-term use with minimal side effects, while aloe vera was most effective for severe burning sensation. However, drug therapy for OSMF remained inconclusive, requiring further high-quality RCTs.³²

- **Chhabra A. K. et al. (2023)** reviewed the literature on OSMF management and concluded that various treatments, including corticosteroids, hyaluronidase, placentex, IFN, and microwave diathermy, showed effectiveness. Surgical excision with grafting was also under study. However, no single treatment was identified as definitive. They emphasized the need for larger clinical trials to determine the most effective approach, noting that recent research indicated positive outcomes with pharmacological combinations.³³
- **Koul, D. et al. (2023)** conducted a comparative study to evaluate the efficacy of different flaps and physiotherapy in managing OSMF. Thirty-three patients with advanced bilateral OSMF (interincisal distance <20 mm) underwent surgical treatment using buccal pad of fat, nasolabial flap, or temporo-parietal fascia flap. Postoperative physiotherapy began on the 5th day, and patients were followed for one year. Results showed significant improvement in mouth opening with regular physiotherapy, exercise, and habit cessation, regardless of the flap used. The study concluded that

postoperative physiotherapy and quitting harmful habits were as crucial as surgery for better prognosis in OSMF patients.³⁴

- **Singh A. K. et al. (2023)** conducted a comparative study on the surgical management of advanced OSMF (stage III & IVa/b) and evaluated different reconstruction techniques for post-OSMF buccal mucosal defects. Patient records were analyzed and categorized into three groups: buccal fat pad (Group A), nasolabial flap (Group B), and platysma flap (Group C). Outcomes were assessed based on maximal mouth opening and intercommissural distance using statistical tests, with a significance threshold of $p < 0.05$. After one year, the platysma flap showed superior results, achieving significantly better mouth opening (39.84 ± 1.65 mm) and intercommissural distance (59.21 ± 0.99 mm) compared to the buccal fat pad (36.69 ± 3.41 mm, 54.11 ± 1 mm) and nasolabial flap (37.94 ± 0.43 mm, 56.84 ± 1.48 mm). While both buccal fat pad and nasolabial flap provided comparable mouth opening, the platysma flap was the most effective for improved oral function and esthetics.³⁵

Khan, F.R. and Nazeer M. R. (2023) presented a case report on the full-mouth prosthetic rehabilitation of a 50-year-old female with generalized compensated tooth wear and oral submucous fibrosis (OSMF). The patient underwent a sequential treatment approach, including occlusal splint therapy, extractions of non-restorable teeth, root canal treatments, surgical crown lengthening, and dental implants for missing teeth. The final rehabilitation

was completed with crowns and bridgework, following the principles of reorganized occlusion. Achieving increased mouth opening in OSMF patients is often challenging, typically managed with muscle stretching exercises, medications, or surgery. However, in this case, occlusal splints were successfully used to improve mouth opening, a novel approach not previously reported. The treatment resulted in a functional and aesthetically pleasing dentition, significantly enhancing the patient's oral function and satisfaction.³⁶

- **Jones A. et al. (2024)** conducted a review to assess the benefits and harms of various interventions for managing oral submucous fibrosis (OSF). The study included 30 randomized controlled trials (RCTs) with 2176 participants diagnosed with OSF. Treatments evaluated included systemic, local, and topical drugs, surgical procedures, physiotherapy, ultrasound, and alternative therapies. The primary outcomes assessed were improvements in mouth opening, jaw movement, burning pain relief, and quality of life, while secondary outcomes included patient satisfaction, postoperative discomfort, adverse effects, and treatment costs. The findings indicated that antioxidants may slightly improve mouth opening within three months (MD 3.11 mm, low-certainty evidence) and probably increase it further at three to six months (MD 8.83 mm, moderate-certainty evidence), though no significant long-term benefit was observed. Pentoxifylline showed a minor improvement in mouth opening (MD 1.80 mm, low-certainty evidence), while evidence for other interventions such as intralesional dexamethasone, hydrocortisone plus hyaluronidase, and physiotherapy remained highly uncertain. In terms of pain

relief, antioxidants likely reduced burning sensation at various time points, with moderate-certainty evidence supporting improvements from less than three months to beyond six months. However, data on other treatments for pain relief remained inconclusive. Adverse effects were reported in 15 studies, with six studies finding no adverse events. Serious complications, such as prolonged hospital stays, were noted in some cases of abdominal dermal fat grafting, while mild and transient side effects like nausea, bloating, and gastritis were linked to systemic drugs such as antioxidants and vasodilators. The review concluded that while antioxidants may offer slight improvements in mouth opening and pain relief, overall evidence for most treatments remains low or uncertain. More high-quality, well-powered trials with patient-reported outcomes are necessary to determine the most effective interventions for OSF.³⁷

- **Dubey V et al. (2024)** conducted a study on eight patients to evaluate the effectiveness of the buccal fat pad (BFP) with a collagen membrane as an alternative treatment for oral submucous fibrosis (OSF). The procedure was performed on all patients, and outcomes were assessed. Results showed a significant improvement in mouth opening, with a mean gain of 5.29 ± 2.11 mm, along with a notable reduction in pain levels by 2.62 ± 1.05 . No complications or recurrences were observed during the four-month follow-up period. The study concluded that BFP with a collagen membrane could be a promising surgical option for OSF management, though further research with larger sample sizes and longer follow-ups is needed to validate these

findings.³⁸

- **Sharma M. et al (2024)** concluded that oral submucous fibrosis (OSF) is a pathological condition resulting from excessive tissue healing due to physical, chemical, or mechanical trauma, with areca nut consumption being a major contributing factor. OSF has a high risk of malignant transformation, necessitating a deeper understanding of its pathophysiology. Areca nut triggers fibrotic pathways by upregulating inflammatory cytokines like TGF- β and converting fibroblasts into myofibroblasts, leading to increased collagen production. Arecoline, a key component, induces oxidative stress and activates signaling pathways (MEK, COX2, PI3K), further promoting fibrosis. Given its distinct association with areca nut, Sharma proposed redefining OSF as "Areca Nut-Induced Oral Fibrosis" (AIOF) to better reflect its etiology and facilitate targeted interventions. This redefinition is crucial for distinguishing AIOF from other fibrotic conditions and improving prevention and treatment strategies globally.³⁹
- **Al-Madhoon, H. W. et al (2024)** conducted a comparative study to assess the efficacy of the buccal fat pad flap versus the nasolabial flap in managing oral submucous fibrosis (OSMF). A systematic review of studies published between 1982 and November 2021 was conducted using four databases. The risk of bias was evaluated through the Cochrane Handbook and Newcastle- Ottawa Scale. Data from six studies, out of 917 screened, were included in the meta-analysis. Results showed that the nasolabial flap was significantly more effective in improving maximal mouth opening (MD -2.52; 95% CI -

4.44 to -0.60; $P = 0.01$) after OSMF reconstructive surgery. However, the buccal fat pad was preferred for better aesthetic outcomes. The study concluded that while the nasolabial flap is superior in restoring mouth opening and oral commissural width, the buccal fat pad flap provides better aesthetic results. Further research with larger and more diverse populations is recommended to validate these findings.⁴⁰

- **Pethani F. H. and Borate S. J. (2024)** conducted a retrospective study on 89 patients to assess the effectiveness of a novel drug combination in managing OSMF. The study demonstrated that this new treatment significantly improved burning sensation scores, mouth opening, and tongue protrusion in patients with OSMF grades I, II, and III. The results remained consistent even after one year of follow-up.⁴¹
- **Kumar V. et al. (2024)** conducted a study on 80 patients to assess serum and salivary trace element levels in OSMF and OSCC. Patients were divided into four groups: gutkha users without OSMF, gutkha users with OSMF, OSCC patients, and controls. Results showed increased Cu levels and decreased Zn, Se, and Mo levels in OSMF and OSCC patients compared to controls. Salivary trace element levels were lower than serum levels, with no significant impact of age or sex. The study highlights the potential of serum trace elements as diagnostic and prognostic markers for early disease detection and treatment monitoring.⁴²

- **Guo J. et al. (2025)** conducted a meta-analysis to investigate oxidative stress and antioxidant markers in the saliva and serum of OSMF patients compared to healthy controls. A total of 14 studies were analyzed, revealing significantly higher levels of malondialdehyde and 8-hydroxy-deoxyguanosine in OSMF patients, while vitamin C, vitamin E, and superoxide dismutase levels were significantly lower. The study concluded that elevated oxidative stress and reduced antioxidant markers in OSMF patients could serve as valuable indicators for clinical diagnosis and management.⁴³
- **Tang, J. et al. (2025)** conducted a literature review on oral sub mucous fibrosis and concluded that it is a chronic, progressive fibrotic disease marked by excessive extracellular matrix deposition, leading to tissue sclerosis and potential cancer transformation. Despite recent advancements, no targeted antifibrotic therapies have been approved due to the unclear mechanisms driving fibrosis. The review discussed OSF epidemiology, etiology, the role of structural and immune cells in fibrosis, and potential therapeutic strategies, including ECM modulation, inflammation inhibition, and vascular improvement, highlighting possible avenues for new treatments.⁴⁴

SAMPLE SIZE DETERMINATION

The sample size was calculated using G Power software (version 3.1.9.4). Based on the previous studies, keeping the standard values of alpha error at 0.05 and power of the study at 90% and effect size at 0.45 (as determined from the previous studies) the minimum sample size of the study is **8**.

STATISTICAL ANALYSIS

Data was entered in Microsoft Excel spreadsheet and will be analyzed using SPSS Version 26. Data will be summarized using tables and graphs. The level of significance was set at p value less than 0.05, at 95% confidence interval and 80% power of the study. Normality tests like Kolmogorov–Smirnov test and Shapiro-Wilk test was done to assess if data is normally distributed. Following which Parametric or Non-parametric tests of significance was used for data analysis.

STUDY/RESEARCH DESIGN

The prospective study was conducted in the Department of Oral and maxillofacial surgery, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh, after taking approval from the 'Institutional Human Ethical Committee' and 'Institutional research development committee' (*ANNEXURES I&II*).

The present study contains minimum sample of 8 patients i.e. irrespective of their gender, caste, creed, socioeconomic status and religion on the basis of inclusion criteria. All selected cases were evaluated based on detailed history

A detailed case history of included patients was recorded and all underwent clinical examination, routine blood investigation, incisional biopsy and radiological investigation along with ECG, PA chest.

The proposed treatment was conveyed to the patient and an informed, written consent was obtained.

SAMPLE SELECTION

INCLUSION CRITERIA

1. Patients who are healthy and can be categorized as ASA – I and II health status.
2. Histologically & clinically confirmed Grade III and IV A patients (As per Khanna JN & NN Andrade).
3. Patients willing to participate in the study and agree for follow up for at least 3 months.
4. Patients with long standing positive history of adverse habits for at least 3-4 years.
5. Patients with a minimum 6 months' history of habit cessation and evident motivation to give up the deleterious habit.

EXCLUSION CRITERIA

1. Patients who are not willing to quit the habit or participate in the study.
2. Patients not willing for consent and regarding minimum one year of follow up.
3. Patients with history of previous surgical treatment for oral submucous fibrosis.
4. Patients with clinical or radiological presentation of any other cause of trismus.
5. Medically compromised patients (ASA class III and IV).
6. Pregnant lady and lactating mother

MATERIALS

Materials and Equipment's Used in the study with specifications and Company

- Surgical Drapes
- Sterile Gauze
- Povidine Iodine 5%
- Normal Saline (0.9 % w/w)
- Surgical Spirit (95%V/V Denatured Alcohol)
- 3ml, 5ml, 10ml Syringe
- General surgery instrument kit
- Surgical straight handpiece
- Tungsten burs (flame shaped)
- Suture material 3-0 mersilk /vicryl (round body)
- Bactiguaze (chlorhexidine gauze dressing)
- Kochers forcep



METHODOLOGY

PREOPERATIVE EVALUATION

All selected patients underwent a comprehensive preoperative evaluation, including:

- Detailed Case History:
 - A thorough history was taken, documenting symptoms, duration, habits (such as areca nut or tobacco chewing), and any previous treatments. (ANNEXURES VII)
- Clinical Examination:
 - The extent of fibrosis, mouth opening (interincisal distance), oral hygiene status, and the presence of any associated conditions such as restricted tongue movement or difficulty in speech and chewing were assessed.
- Routine Blood Investigations:
 - Complete blood count (CBC), liver function tests (LFTs), kidney function tests (KFTs), and coagulation profiles were performed to ensure the patient was fit for surgery.
- Incisional Biopsy:

- A biopsy of the affected buccal mucosa was performed to confirm the diagnosis of oral submucous fibrosis (OSMF) and to rule out dysplasia or malignant transformation.
- Radiological Investigations:
 - Orthopantomogram (OPG) the extent of fibrosis, coronoid process size, and bone involvement.
- Cardiac and Respiratory Assessment:
 - Electrocardiogram (ECG) and PA chest X-rays were obtained to rule out any underlying cardiac or pulmonary conditions before surgery.
- Pre-Anesthetic Check-up:
 - Patients underwent a full anesthetic assessment, including airway evaluation, to determine the risks associated with general anesthesia.
- Written Informed Consent:
 - The surgical procedure, possible risks, postoperative care, and expected outcomes were thoroughly explained to each patient. A written informed consent form was obtained before proceeding with treatment. (ANNEXURES V&VI)

SURGICAL PROCEDURE

- All procedures were performed under general anesthesia with nasotracheal intubation to maintain an unobstructed surgical field.
- Under proper aseptic protocol intraoral and extra oral painting and draping was done and 5 ml local anesthesia 1:80000 with adrenaline was administered.
- **Intraoral Incisions and Fibrotic Band Release**
 - A Bard-Parker blade no.15 was used to create bilateral linear incisions along the buccal mucosa.
 - The incisions were made 1 cm away from the corner of the mouth intraorally, extending posteriorly up to the anterior faucial pillars or soft palate, depending on the severity of fibrosis.
 - Blunt dissection was performed using metzenbaum scissors to undermine the tissue and release fibrotic bands.
 - The circumoral bands and buccal mucosal fibrotic bands were carefully excised and was sent for biopsy.
 - Palpation was done intermittently during the procedure to ensure that no fibrotic restrictions remained, allowing for improved mouth opening.

- **Third Molar Extraction**

- If the archived mouth opening archived is less than 40 mm third molars were indicated for removal, they were extracted using extraction forceps and elevators.
- The socket was carefully compressed to promote hemostasis.
- Sutures were placed at the extraction sites using 3-0 silk round body sutures to ensure desired healing.

- **Bilateral Coronoidectomy**

- The coronoid process was accessed through the same intraoral incision.
- The temporalis muscle attachment on the anterior border of the ramus was stripped using periosteal elevators.
- An initial osteotomy cut was performed using a tungsten flame shaped bur from the depth of the sigmoid notch to the anterior border of the ramus which was later revised and deepened with the help of chisel and mallet.
- Once the osteotomy was completed, the coronoid process was placed under traction using Kocher's forceps.
- The remaining temporalis muscle and tendon attachments were carefully severed using Mayo scissors or electrocautery, facilitating complete removal of the coronoid process.

- **Interposition of Buccal Fat Pad**

- Reconstruction of the defect was done with BFP after measuring the size of defect.
- After adequate release of the fibrosis, the buccal fat pad (BFP) was mobilized to cover the raw surgical area.
- A small incision 1.5 mm below the opening of parotid duct opposite to the occlusion plane of 2nd Maxillary molars was made in the buccal mucosal membrane (Matarasso's Method) and the buccal extension of buccal fat pad was gently teased out using blunt dissection.
- The fat pad was then sutured into position using resorbable 3-0 round body Vicryl sutures to prevent recurrence of fibrosis and facilitate vascularity.
- A 0.2 % chlorhexidine-soaked gauze dressing was placed over the area to reduce infection risks and aid in initial healing

POSTOPERATIVE CARE AND FOLLOW-UP

Immediate Postoperative Care

- All patients received prophylactic antibiotic coverage for one week to minimize the risk of opportunistic infection.
- Analgesics and anti-inflammatory medications were administered to manage postoperative pain and swelling.
- All the patients were advised for nasogastric feed for at least 10 days.

- Patients were kept on a liquid diet for the first 48 hours to allow initial healing.
- Regular antiseptic mouth rinses (chlorhexidine 0.2%) were prescribed to maintain oral hygiene and prevent infections.

Early Active Physiotherapy (Within 48 Hours Postoperatively)

- Mouth opening exercises were initiated within 48 hours of surgery.
- A mouth prop was placed interincisal to gently stretch the tissues.
- Patients were encouraged to perform controlled opening and closing movements under supervision.

Intensive Physiotherapy Protocol (From 10th Postoperative Day)

- Patients started using Heister's mouth gag to achieve maximum mouth opening.
- The exercise involved opening the mouth to the optimal range using the gag and then maintaining that position for 15–20 minutes.
- This exercise was repeated five times a day.
- In addition, patients were instructed to use ice cream sticks, progressively increasing their number to further improve mouth opening.
- The frequency of exercises was gradually increased to 10 times per day.

Long-Term Follow-Up and Monitoring

- Patients were motivated to continue physiotherapy for at least six months to prevent fibrosis recurrence.
- Mouth opening measurements (interincisal distance in mm) were recorded with the metric scale.

Expected Outcomes

- Improved mouth opening and reduction in fibrosis-related restrictions.
- Enhanced masticatory function, speech, and overall oral health.
- Minimized risk of recurrence with consistent physiotherapy.
- Satisfactory healing of extraction and surgical sites with no major complications.

EVALUATION OF CLINICAL PARAMETERS

The clinical parameters evaluation divided into two groups:
(ANNEXURES VII)

OBJECTIVE PARAMETERS:

- Interincisal Mouth Opening.
- Swelling

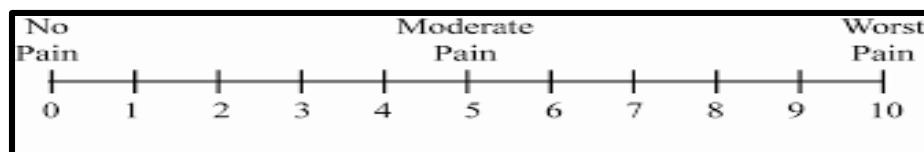
SUBJECTIVE PARAMETERS:

- Pain
- Infection
- Relapse

SUBJECTIVE PARAMETERS

Pain

Pain will be recorded by using the VISUAL ANALOGUE SCALE
on 1st, 3rd, 5th, 7th day postoperatively.



Infection

Relapse

(Infection and Relapse are complication that can occur after surgery)

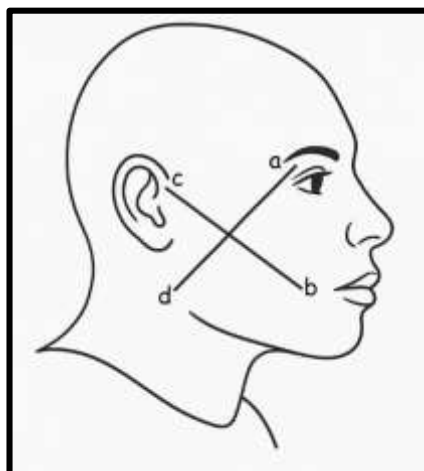
OBJECTIVE PARAMETERS

Assessment of interincisal opening will be done with metallic scale at preoperatively, intraoperatively & 1st week, 1-month and 3rd month postoperatively. This will be recorded by using a scoring system.

- Poor (decreased) = 1
- Fair (same or slightly increased) = 2
- Good (increased > 5mm) = 3

Assessment of swelling Facial swelling was evaluated using a horizontal and vertical guide with a tape measure at four reference points: the tragus, the outer corner of the mouth, the outer canthus of the eye, and the angle of the mandible. The horizontal measurement corresponded to the distance between the outer corner of the mouth and the tragus, while the vertical measurement corresponded to the distance between the outer canthus of the eye and the angle of the mandible. (measurement of the craniometric point as described by *SOUZA* and *CONSONE*).

$$\frac{\text{POST-OPERATIVE VALUE} - \text{PRE-OPERATIVE VALUE}}{\text{PRE OPERATIVE VALUE}} \times 100 = \% \text{swelling}$$



CASE-I
PRE-OPERATIVE PHOTOGRAPHS



Inter Incisal Mouth Opening :20mm



Pre-Operative Radiograph

INTRA OPERATIVE PHOTOGRAPHS



Fibrotomy



Interincisal Mouth Opening Measurement and All 3rd. Molars Extraction



Harvesting and Stabilizing of Buccal Fat Pad

POST OPERATIVE PHOTOGRAPHS



Day-1ST



Day-14TH



a) Inter Incisal Mouth Opening :44mm b) Tongue Protrusion 47mm
c) Adaption of Buccal Fat Pad at The Surgical Site



Post-Operative Radiograph

**CASE-II
PRE-OPERATIVE PHOTOGRAPHS**



Pre-Operative Occlusion and Mouth Opening



Pre-Operative Radiograph

INTRA OPERATIVE PHOTOGRAPHS



a) Pre-operative mouth opening b) Fibrotomy c) Extraction of all 3rd molars



Interincisal Mouth Opening and All 3rd Molars Extraction



B/L Coronoidectomy

POST-OPERATIVE PHOTOGRAPHS



Day 1ST



Day 5TH



Post-operative Radiograph

STATISTICAL ANALYSIS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation frequency and percentage. The level of the significance for the present study was fixed at 5%.

The intergroup comparison was done using /Paired t test The ordinal variable were compared using the Chi square test The Shapiro–Wilk test was used to investigate the distribution of the data and Levene’s test to explore the homogeneity of the variables.

Mean

$$\bar{X} = \frac{\sum X}{N}$$

Where:

$\bar{X}$ = the data set mean

$\sum$ = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$X_{highest}$ = largest score

X_{lowest} = smallest score

Variance

$$SD^2 = \frac{\Sigma(X - \bar{X})^2}{N}$$

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

SD^2 = the variance

Σ = the sum of

X = the obtained score

$\bar{X}$ = the mean score of the data

N = the number of scores

Standard Deviation (N)

$$SD = \sqrt{\frac{\Sigma(X - \bar{X})^2}{N}}$$

The simplified standard deviation formula

$$SD = \sqrt{\frac{\sum X^2 - \frac{(\sum X)^2}{N}}{N}}$$

Where:

SD = the standard deviation

$\sum$ = the sum of

X = the obtained score

$\bar{X}$ = the mean score of the data

N = the number of scores

Independent t-test

Independent t Test can be used to determine if two sets of data are significantly different from each other, and is most commonly applied when the test statistic would follow a normal distribution. The independent samples t -test is used when two separate sets of independent and identically distributed samples are obtained, one from each of the two populations being compared

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\left(\frac{(N_1 - 1)s_1^2 + (N_2 - 1)s_2^2}{N_1 + N_2 - 2} \right) \left(\frac{1}{N_1} + \frac{1}{N_2} \right)}}$$

Where $\bar{X}_1$ = Mean of the first Group, $\bar{X}_2$ = Mean of the Second Group

Paired t test

$$t = \frac{\bar{x} - 0}{SE(d)} = \frac{\bar{x}}{\frac{SD(x)}{\sqrt{n}}}$$

A paired t -test is used to compare two population means where you have two samples in which observations in one sample can be paired with

observations in the other sample. Examples of where this might occur are: -
Before-and-after observations on the same subjects (e.g. students' diagnostic test results before and after a particular module or course) or A comparison of two different methods of measurement or two different treatments where the measurements/treatments are applied to the same.

RESULT AND OBSERVATION

TABLE 1: INFECTION AND RELAPSE IN STUDY SUBJECTS

	No	Yes
Infection	08 (100%)	00(0%)
Relapse	07(87.5%)	01 (12.5%)

Among the study participants, none of them developed postoperative infection/s, with 100% (n = 8) of the subjects remaining infection-free. In terms of relapse, 1 out of 8 subjects (12.5%) experienced a relapse during the follow-up period, while the remaining 87.5% (n = 7) showed no signs of relapse.

These results indicate a very low complication rate, with excellent infection control and a high success rate in preventing relapse post-treatment.

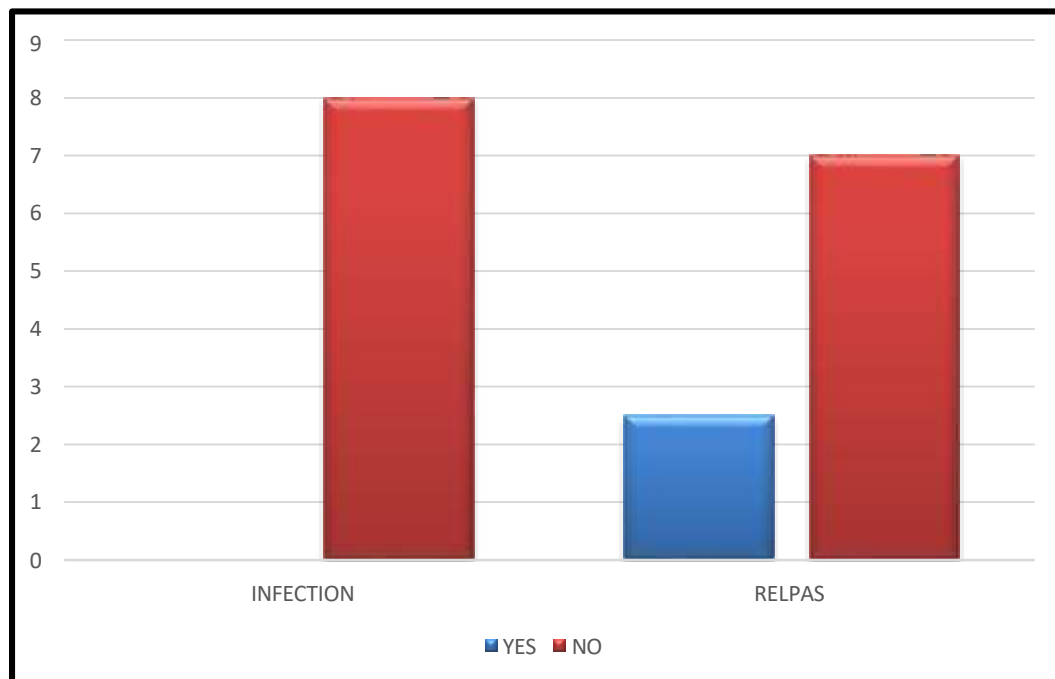
**GRAPH 1: INFECTION AND RELAPSE IN STUDY SUBJECTS**

TABLE 2: INTRAGROUP COMPARISON OF MOUTH OPENING BETWEEN DIFFERENT TIME INTERVALS

Group	Mean	Std. Deviation	Std. Error	95% CI Lower Bound	95% CI Upper Bound	Minimum	Maximum
Pre-Operative	16.150	6.243	2.207	10.930	21.370	7.000	24.000
After Resection of bands	27.500	4.690	1.658	23.579	31.421	23.000	36.000
3rd Molar extraction	37.500	5.904	2.087	32.564	42.436	32.000	50.000
Coronoidectomy	50.000	3.786	1.431	46.499	53.501	44.000	54.000
1st Day Post Op	32.375	7.855	2.777	25.808	38.942	22.000	46.000
1st Week Post Op	36.125	3.944	1.394	32.828	39.422	28.000	41.000
1st Month	40.375	5.829	2.061	35.502	45.249	29.000	48.000
3rd Month	41.500	11.123	3.932	32.201	50.799	21.000	57.000

Post Hoc Analysis

I (Time)	J (Time)	Mean Difference (I-J)	Std. Error	Sig.
Pre-Operative	After Resection of bands	-11.350*	3.304	0.001 (Sig)
Pre-Operative	3rd Molar extraction	-21.350*	3.304	0.001 (Sig)
Pre-Operative	Coronoidectomy	-33.850*	3.420	0.001 (Sig)
Pre-Operative	1st Day Post Op	-16.225*	3.304	0.001 (Sig)
Pre-Operative	1 st Week Post Op	-19.975*	3.304	0.001 (Sig)
Pre-Operative	1st Month	-24.225*	3.304	0.001 (Sig)

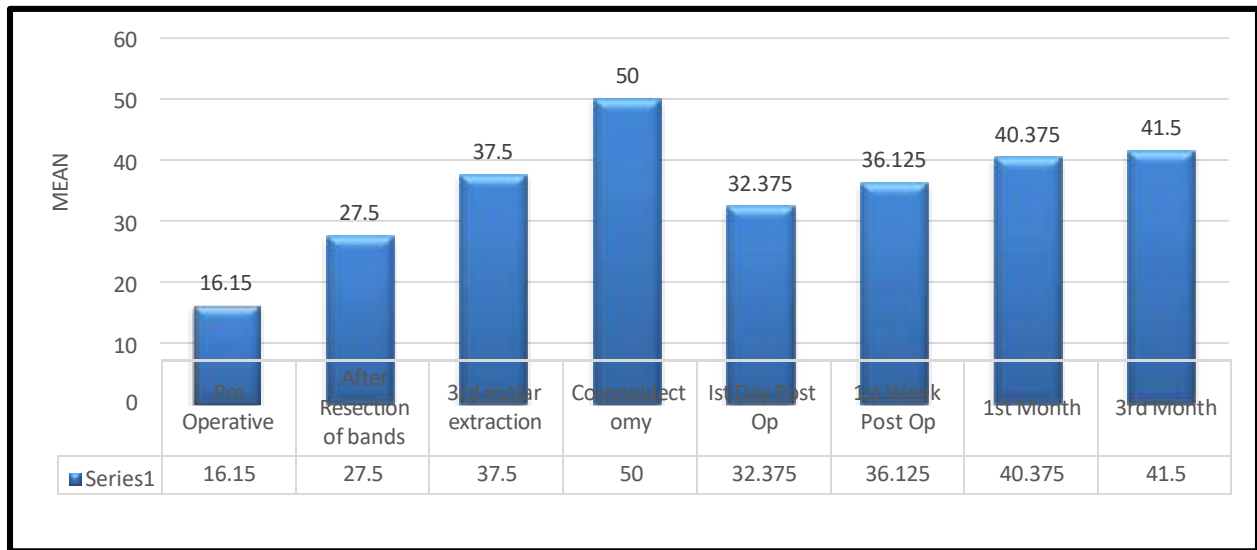
I (Time)	J (Time)	Mean Difference (I-J)	Std. Error	Sig.
Pre-Operative	3 rd Month	-25.350*	3.304	0.001 (Sig)
After Resection of bands	3 rd molar extraction	-10.000*	3.304	0.001 (Sig)
After Resection of bands	Coronoidectomy	-22.500*	3.420	0.001 (Sig)
After Resection of bands	1 st Day Post Op	-4.875	3.304	0.046 (Sig)
After Resection of bands	1 st Week Post Op	-8.625*	3.304	0.012 (Sig)
After Resection of bands	1 st Month	-12.875*	3.304	0.001 (Sig)
After Resection of bands	3 rd Month	-14.000*	3.304	0.001 (Sig)
3rd molar extraction	Coronoidectomy	-12.500*	3.420	0.001 (Sig)
3rd molar extraction	1 st Day Post Op	5.125	3.304	0.127 (Non-Sig)
3rd molar extraction	1 st Week Post Op	1.375	3.304	0.679 (Non-Sig)
3rd molar extraction	1 st Month	-2.875	3.304	0.388 (Non-Sig)
3rd molar extraction	3 rd Month	-4.000	3.304	0.231 (Non-Sig)
Coronoidectomy	1 st Day Post Op	17.625*	3.420	0.001 (Sig)
Coronoidectomy	1 st Week Post Op	13.875*	3.420	0.001 (Sig)
Coronoidectomy	1 st Month	9.625*	3.420	0.007 (Sig)
Coronoidectomy	3 rd Month	8.500*	3.420	0.016 (Sig)
1st Day Post Op	1 st Week Post Op	-3.750	3.304	0.261 (Non-Sig)
1st Day Post Op	1 st Month	-8.000*	3.304	0.019 (Sig)
1st Day Post Op	3 rd Month	-9.125*	3.304	0.008 (Sig)
1st Week Post Op	1 st Month	-4.250	3.304	0.204 (Non-Sig)
1st Week Post Op	3 rd Month	-5.375	3.304	0.109 (Non-Sig)
1st Month	3rd Month	-1.125	3.304	0.735 (Non-Sig)

The intragroup comparison of mouth opening at different time intervals revealed a statistically significant improvement in mouth opening across the stages of

treatment. The mean pre-operative mouth opening was 16.15 mm, which significantly increased following the resection of fibrous bands to 27.50 mm ($p = 0.001$). This improvement continued after third molar extraction (mean: 37.50 mm) and peaked following coronoidectomy at 50.00 mm ($p = 0.001$ for both).

However, a slight reduction in mouth opening was observed postoperatively. On the first postoperative day, the mean dropped to 32.38 mm, which was significantly lower than after coronoidectomy ($p = 0.001$) but still higher than the pre-operative value. Over time, the mouth opening showed a gradual increase: at the first postoperative week, it was 36.13 mm; at one month, 40.38 mm; and by the third month, it reached 41.50 mm.

Post hoc analysis confirmed significant differences among most of the stages, especially between the pre-operative phase and all subsequent phases ($p < 0.001$), indicating a consistent and marked improvement in mouth opening as treatment progressed. The largest gains were seen immediately after coronoidectomy, with sustained improvements through the third postoperative month. These findings suggest that the surgical protocol was effective in significantly enhancing mouth opening in patients, with gradual stabilization of results postoperatively.



GRAPH 2: INTRAGROUP COMPARISON OF MOUTH OPENING BETWEEN DIFFERENT TIME INTERVALS

TABLE 3: INTERGROUP COMPARIOSN OF MEAN PAIN SCORES BETWEEN DIFFERENT TIME INTERVALS

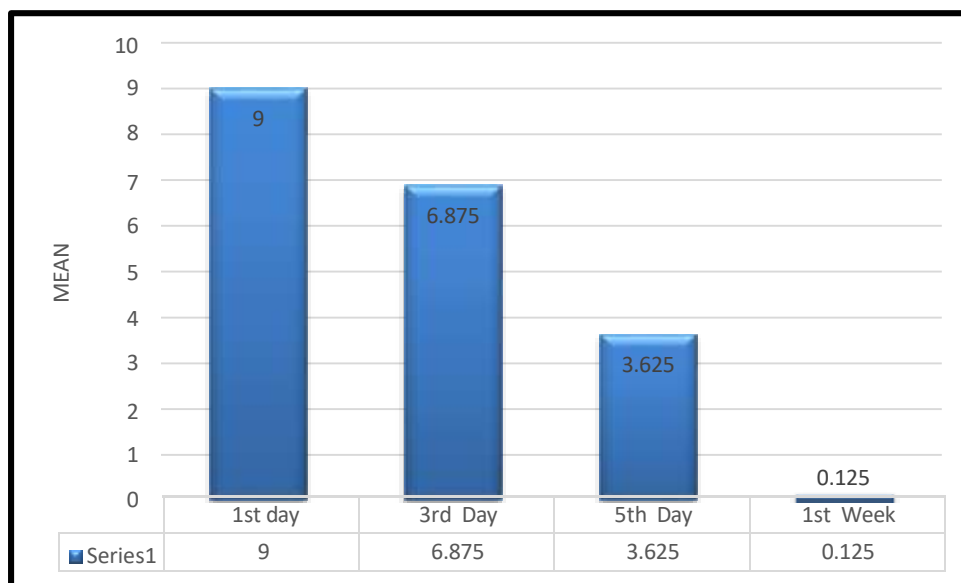
Evaluation days	Mean	Std. Deviation	Std. Error	95% CI Lower Bound	95% CI UpperBound	Minimum	Maximum
1 st day	9.000	0.756	0.267	8.368	9.632	8.000	10.000
3 rd Day	6.875	0.835	0.295	6.177	7.573	6.000	8.000
5 th Day	3.625	1.302	0.460	2.536	4.714	2.000	5.000
1 st Week	0.125	0.354	0.125	-0.171	0.421	0.000	1.000

Post Hoc Analysis

Intra-Group Comparison		Mean Difference	Std. Error	P value	Significance
1 st day	3 rd Day	2.125*	0.439	0.001	Significant
1 st day	5 th Day	5.375*	0.439	0.001	Significant
1 st day	1 st Week	8.875*	0.439	0.001	Significant
3 rd Day	5 th Day	3.250*	0.439	0.001	Significant
3 rd Day	1 st Week	6.750*	0.439	0.001	Significant
5 th Day	1 st Week	3.500*	0.439	0.001	Significant

The intragroup comparison of mean pain scores over different time intervals demonstrated a consistent and statistically significant decrease in pain levels as time progressed postoperatively. On the 1st day, the mean pain score was 9.000 ± 0.756 , indicating high discomfort immediately after surgery. By the 3rd day, the pain score dropped to 6.875 ± 0.835 , showing a notable reduction. This trend continued on the 5th day, with pain levels further decreasing to 3.625 ± 1.302 , and by the 1st week, pain was nearly resolved with a mean score of just 0.125 ± 0.354 .

Post hoc analysis confirmed that all pairwise comparisons between the time intervals were statistically significant ($p = 0.001$). Specifically, the largest reduction in pain occurred between the 1st day and 1st week (mean difference = 8.875), highlighting the effectiveness of the postoperative pain management and the natural course of healing. These findings suggest a rapid and steady improvement in patient comfort within the first week following the procedure.



GRAPH 3: INTERGROUP COMPARIOSN OF MEAN PAIN SCORES BETWEEN DIFFERENT TIME INTERVALS

**TABLE 4: INTRAGROUP COMPARIOSN OF MEAN SWELLING SCORES BETWEEN
DIFFERENT TIME INTERVALS**

Lines	Evaluation days	Mean	Std. Deviation	Std. Error	95% CI Lower Bound	95% CI Upper Bound	Minimum	Maximum
Outer Corner of the Mouth and the Tragus	Pre-op	11.750	1.748	0.618	10.289	13.211	9.800	14.700
	2nd day	12.350	1.638	0.579	10.981	13.719	10.600	14.900
	7th day	12.000	1.739	0.615	10.547	13.454	10.300	14.800
Outer Canthus of the Eye and the Angle of the Mandible	pre op	8.338	1.010	0.357	7.493	9.182	7.100	10.200
	2nd day	9.050	1.559	0.551	7.746	10.354	7.200	12.500
	7th day	8.538	0.870	0.308	7.810	9.265	7.100	10.100

Post Hoc Analysis

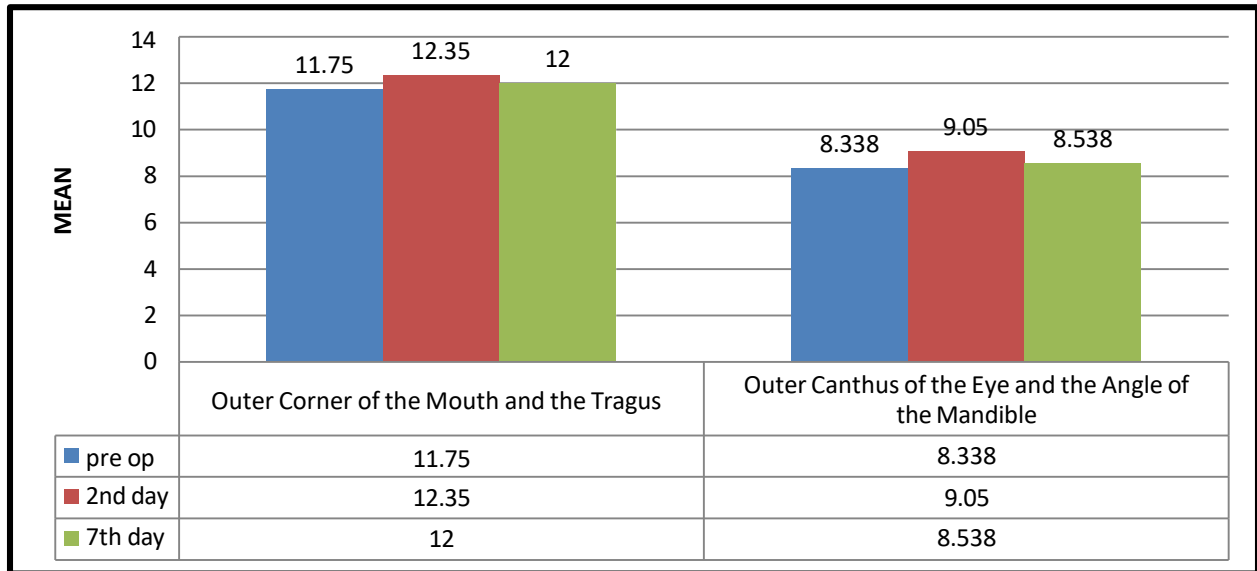
	Intra-Group Comparison		Mean Difference	Std. Error	P value	Significance
Outer Corner of the Mouth and the Tragus	Pre op	2nd day	-0.600	0.854	0.490	Non-Significant
	Pre op	7th day	-0.250	0.854	0.773	Non-Significant
	2nd day	7th day	0.350	0.854	0.686	Non-Significant
Outer Canthus of the Eye and the Angle of the Mandible	Pre op	2nd day	-0.713	0.592	0.242	Non-Significant
	Pre op	7th day	-0.200	0.592	0.739	Non-Significant
	2nd day	7th day	0.513	0.592	0.397	Non-Significant

The intragroup comparison of mean swelling scores at different time intervals for two anatomical regions — Outer Corner of the Mouth to the Tragus and Outer Canthus of the Eye to the Angle of the Mandible — revealed no statistically significant changes over time.

For the Outer Corner of the Mouth to the Tragus, the swelling score slightly increased from a preoperative mean of 11.750 ± 1.748 to 12.350 ± 1.638 on the 2nd day, before slightly decreasing to 12.000 ± 1.739 by the 7th day. However, the post hoc analysis showed that none of these differences were statistically significant ($p\text{-values} > 0.05$), indicating that the changes in swelling were minimal and clinically insignificant.

Similarly, in the Outer Canthus of the Eye to the Angle of the Mandible region, the mean swelling score increased from 8.338 ± 1.010 preoperatively to 9.050 ± 1.559 on the 2nd day, then slightly decreased to 8.538 ± 0.870 on the 7th day. Again, all differences were statistically non-significant ($p > 0.05$).

Overall, the findings suggest that postoperative swelling in both facial regions remained relatively stable throughout the observation period, with no significant intragroup variation, indicating effective management and minimal postoperative facial edema.



GRAPH 4: INTRAGROUP COMPARIOSN OF MEAN SWELLING SCORES BETWEEN DIFFERENT TIME INTERVALS

DISCUSSION

Oral Submucous Fibrosis (OSMF) stands as a debilitating, progressive, and pre malignant disorder, particularly prevalent among populations with habitual areca nut consumption. While its historical underpinnings have been well-established through seminal works by Paymaster (1956)¹ and Pindborg and Sirsat (1966),² contemporary focus has rightly shifted towards the evaluation of treatment outcomes, pathophysiological mechanisms, and long-term rehabilitation strategies. The present study critically examines the clinical efficacy of a standardized surgical protocol—comprising fibrous band release, bilateral coronoidectomy, third molar extraction, and buccal fat pad (BFP) grafting—in patients diagnosed with advanced-stage OSMF.

In the studied cohort, the mean preoperative interincisal mouth opening was severely restricted at 16.15 mm, reflecting the advanced fibrotic entrapment characteristic of late-stage disease. Following surgical intervention, intraoperative measurements demonstrated a noteworthy enhancement: post-fibrotomy mouth opening improved to 27.50 mm, and further escalated to 50.00 mm after bilateral coronoidectomy ($p < 0.001$). This remarkable functional rehabilitation underscores the indispensable role of coronoidectomy in addressing not merely fibrous bands but also temporalis muscle fibrosis and coronoid hyperplasia, a view consistently emphasized by Borle and Borle⁵¹, and more recently corroborated by Rao et al. (2020)⁵⁸ from Griffith University, who highlighted the synergistic contribution of osseous and muscular elements to trismus in advanced OSMF.

In our study sustainability of these intraoperative gains was affirmed by postoperative evaluations, where mean mouth opening at three months

stabilized at 41.50 mm, indicating that substantial intraoperative stretching, coupled with diligent postoperative physiotherapy, mitigates relapse. Our findings resonate with Lambade et al. (2016)⁵⁷ and Gupta et al. (2023)²⁹, who asserted that intraoperative mouth opening exceeding 35 mm is predictive of favorable long-term outcomes. Griffith's recent interdisciplinary recommendations further stress that achieving maximal intraoperative release forms the cornerstone for minimizing relapse rates in fibrotic oral disorders.

Pain, being a subjective sign, demonstrated a rapid and substantial decline in our study. Mean pain scores decreased from an intense 9.0 on the first postoperative day to a negligible 0.125 by the end of the first postoperative week ($p < 0.001$). This significant amelioration parallels findings by Suresh and Anehosur (2022)²⁸, who underscored that minimally invasive, atraumatic surgical techniques are paramount in enhancing postoperative comfort. In alignment, Rao et al. (2020)⁵⁸ advocated for early multimodal pain management strategies combined with structured physiotherapy to expedite functional recovery and improve patient-reported outcomes.

Postoperative facial swelling, measured through reproducible anatomical landmarks (lateral canthus of eye to angle of mandible and corner of mouth to tragus), exhibited no statistically significant variation across postoperative days. This finding is noticeable, as minimal postoperative edema facilitates early initiation of physiotherapy, a critical determinant of long-term mouth opening maintenance. Chauhan et al. (2020)²⁵ introduced the Maximum Water Holding Capacity (MWHC) as an objective tool to evaluate mucosal pliability, reinforcing the notion that less traumatic dissection correlates with

improved soft tissue resilience—an observation substantiated by the present study.

The absence of postoperative infections (infection rate 0%) and a low relapse rate of 12.5% within three months' post-surgery testify to the clinical robustness of the surgical protocol employed. These encouraging figures are congruent with the outcomes reported by Dubey et al. (2024)³⁸, who highlighted the efficacy of BFP grafting in providing durable mucosal coverage and rapid epithelization. Furthermore, Rao et al. (2020)⁵⁸ emphasized that rigorous infection control measures, meticulous tissue handling, and patient-specific rehabilitation protocols are integral to minimizing postoperative complications and recurrence.

Nonetheless, a critical appraisal of the existing literature reveals divergent perspectives. Seedat and van Wyk (1988)⁵² and More et al. (2012)⁵³ posited that without absolute cessation of the areca nut habit, surgical gains may be ephemeral. Their cautionary stance is pivotal, advocating that surgical intervention, while addressing anatomical constraints, must be concomitantly reinforced with behavioral interventions for sustained efficacy. Pogrel's (1993)⁵⁴ critical reflections on indiscriminate coronoidectomy further underscore that while coronoid resection substantially improves mouth opening, its unwarranted use may introduce complications such as masticatory weakness or facial asymmetry. Therefore, Griffith's guidelines aptly recommend that coronoidectomy be judiciously reserved for cases demonstrating intraoperative trismus post-band release, a protocol meticulously adhered to in the present study.

Alternative conservative modalities have also garnered attention, particularly

for early-stage disease. Ariyawardana and Sitheequ (2006)⁵⁶ demonstrated that a combination of intralesional corticosteroids, hyaluronidase, and rigorous habit cessation could substantially improve mouth opening in compliant individuals. However, in advanced OSMF where extensive fibrosis ensnares the oral musculature, conservative measures yield suboptimal results. Kamath (2015)¹⁷ and Griffith scholars have consistently advocated for a stage-specific, stratified treatment approach, wherein surgical intervention becomes indispensable beyond clinical stage III.

The role of the buccal fat pad (BFP) as an intraoral graft material warrants special mention. The anatomical proximity, rich vascularity, and ease of harvest render BFP an ideal choice for covering mucosal defects post-band release. Lambade et al. (2016)⁵⁷ demonstrated sustained mouth opening improvements over two years following BFP reconstruction, findings mirrored in the present study. Suresh and Anehosur (2022)²⁸ and Bandekeri et al. (2021)²⁶ further validated that combining BFP with adjunctive materials such as collagen membranes enhances graft stability and expedites mucosal epithelialization.

The indispensable role of postoperative physiotherapy was vividly reflected in this study. Initiating active and passive mouth opening exercises within five days' post-surgery, reinforced with devices such as Heister's mouth gag, was instrumental in preserving surgical gains. Chang et al. (2004)⁹ and Koul et al. (2023)³⁴ consistently highlighted that regular, structured physiotherapy spanning six months or more significantly reduces relapse risk, an observation echoed by the sustained mouth opening in the present cohort.

Emerging assessment techniques such as Maximum Water Holding Capacity

(MWHC) introduced by Chauhan et al. (2020)²⁵ offer promising adjuncts to traditional interincisal measurements, allowing more nuanced evaluation of mucosal elasticity and hydration status, parameters directly influenced by surgical technique and graft selection.

On the molecular front, studies by Haque et al. (2000)⁴⁶ and Gupta et al. (2023)²⁹ underscored the role of oxidative stress, cytokine dysregulation (notably TGF- β , IL-6, TNF- α), and fibroblast activation in the pathogenesis and progression of OSMF. While these findings enrich etiological understanding, their clinical translation into therapeutic targets remains nascent. Rao et al. (2020)⁵⁸ recommended future integration of molecular biomarkers such as 8-hydroxydeoxyguanosine (8-OHdG) and malondialdehyde (MDA) in monitoring disease activity and therapeutic response.

Despite the compelling outcomes observed, the present study acknowledges inherent limitations. The modest sample size and relatively short follow-up constrain definitive extrapolation to the broader population. Although preoperative CBCT imaging facilitated precise surgical planning, dynamic postoperative assessments of bone remodelling and fibrosis resolution were beyond the study scope. Griffith's team emphasized the need for multicentre longitudinal studies, incorporating standardized imaging, molecular diagnostics, and patient-reported outcome measures to holistically appraise treatment efficacy.

In synthesizing the collective evidence, the current study aligns with the contemporary paradigm that surgical intervention remains the mainstay for advanced OSMF, provided it is tailored meticulously to individual

anatomical and pathological profiles. A comprehensive treatment strategy—integrating habit cessation counseling, optimal surgical release, appropriate grafting, early physiotherapy, and rigorous postoperative monitoring—is pivotal to achieving sustained rehabilitation.

In conclusion, the present study reinforces that a meticulously executed surgical protocol involving fibrotomy, bilateral coronoidectomy, and buccal fat pad grafting yields substantial and sustainable improvements in mouth opening, pain alleviation, and soft tissue recovery in advanced OSMF. The integration of emerging objective assessment tools, adoption of minimally invasive yet effective surgical techniques, and interdisciplinary postoperative rehabilitation models as advocated by Griffith University present a promising blueprint for future management paradigms. Going forward, a nuanced, biomarker-driven, patient-centered approach, grounded in longitudinal evidence, holds the potential to redefine the therapeutic landscape of OSMF and mitigate its debilitating functional and oncological sequelae.

CONCLUSION

The present study furnishes compelling evidence supporting an integrated surgical protocol as a highly effective modality for the management of advanced-stage Oral Submucous Fibrosis (OSMF), particularly among patients presenting with severe trismus and extensive submucosal fibrosis classified as Grade III and IVa according to Khanna and Andrade's clinical classification system⁷. The multimodal surgical strategy encompassed four pivotal elements: (i) meticulous excision of fibrotic bands, (ii) extraction of impacted or partially erupted third molars to eliminate potential foci of postoperative inflammation, (iii) bilateral coronoidectomy to release temporalis muscle fibrosis, and (iv) reconstruction of intraoral defects utilizing the buccal fat pad (BFP) as a well-vascularized interpositional graft. This comprehensive approach was designed to simultaneously alleviate mechanical restrictions and provide durable mucosal coverage, thereby minimizing relapse risk and optimizing functional rehabilitation.

A remarkable and statistically significant improvement was documented in interincisal mouth opening, which escalated from a severely restricted preoperative mean of 16.15 mm to an intraoperative peak of 50.00 mm following coronoidectomy ($p < 0.001$). Critically, this functional gain was largely sustained during the postoperative period, with a mean mouth opening of 41.50 mm recorded at three months' post-surgery. The retention of substantial mouth opening over time accentuates the indispensable role of coronoidectomy and

structured physiotherapy in mitigating muscle retraction and preventing re-fibrosis—a finding strongly corroborated by Griffith University's recommendations (Rao et al., 2020)⁵⁸ emphasizing maximal intraoperative release as a predictor of long-term surgical success.

Pain trajectories further substantiated the procedural efficacy. Pain scores, evaluated using the Visual Analogue Scale (VAS), demonstrated a precipitous decline from a mean of 9.0 on Day 1 to a negligible 0.125 by the seventh postoperative day ($p < 0.001$). Such a dramatic reduction reflects not only the success of the surgical methodology but also the effectiveness of the perioperative analgesic protocols and the minimally traumatic dissection principles employed. The swift attenuation of pain mirrors the findings of Suresh and Anehosur (2022)²⁸ and echoes Griffith's interdisciplinary focus on enhancing postoperative recovery through careful intraoperative handling (Rao et al., 2020)⁵⁸.

Evaluation of postoperative facial swelling using standardized anthropometric landmarks (outer canthus to angle of mandible and corner of mouth to tragus) revealed no significant postoperative edema, underscoring the low morbidity associated with this protocol. This outcome is particularly noteworthy as it facilitates early initiation of physiotherapy—recognized by Griffith scholars as a critical component of successful rehabilitation—and contributes to superior patient comfort and compliance.

An exemplary aspect of this study was the complete absence of postoperative infections, reflecting meticulous adherence to sterile protocols and effective prophylactic antibiotic measures. Furthermore,

a relapse rate limited to a single patient (12.5%)—substantially lower than relapse rates reported in many comparable studies—strengthens the argument that rigorous surgical technique, combined with aggressive physiotherapy and sustained counselling for areca nut cessation, forms a paradigm for durable clinical success. These observations are consistent with the long-term analyses of Borle and Borle (2000)⁵¹ and further validated by Griffith University's call for multidisciplinary follow-up in chronic fibrotic conditions (Rao et al., 2020)⁵⁸.

The buccal fat pad (BFP) graft emerged as a particularly efficacious reconstructive modality. Its anatomical contiguity, rich vascular network, minimal donor site morbidity, and rapid epithelialization make it a superior choice compared to more complex flaps or free grafts. The successful integration and minimal postoperative complications observed align with the contemporary literature, including the systematic evaluations by Lambade et al. (2016)⁵⁷ and Dubey et al. (2024)³⁸, reinforcing BFP as the gold standard in intraoral reconstruction for OSMF patients.

Notwithstanding these promising outcomes, the present study's findings must be contextualized within its limitations. The modest sample size and relatively short follow-up period may constrain broader generalizability. As Rao et al. (2020)⁵⁸ and Griffith colleagues emphasize, multicentre randomized controlled trials with extended observation periods are essential to establish definitive therapeutic algorithms for OSMF. Moreover, while this study meticulously assessed clinical parameters such as mouth opening, pain, swelling, and

infection rates, the integration of molecular and biomarker-based monitoring (e.g., 8-hydroxydeoxyguanosine, malondialdehyde levels) could provide a more nuanced understanding of fibrosis reversal and recurrence prediction, an avenue strongly advocated in contemporary OSMF research.

In a nut shell, the results of this study robustly validate that a comprehensive surgical strategy encompassing fibrotomy, third molar extraction, coronoidectomy, and BFP grafting offers a highly effective, durable, and patient-centred solution for the management of advanced-stage OSMF. Furthermore, these outcomes reaffirm that surgical excellence must be complemented by stringent postoperative rehabilitation, nutritional optimization, behavioural modification, and long-term surveillance to achieve sustained functional rehabilitation and quality-of-life improvement. As the understanding of OSMF pathobiology deepens, future paradigms will likely pivot towards integrating surgical precision with molecular diagnostics and personalized antifibrotic therapies, thereby ushering a new era in the management of this challenging disorder.

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ANNEXURES I



BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES

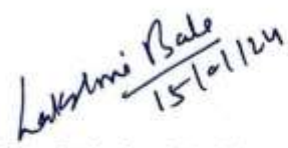
(Faculty of BBD University, Lucknow)

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Efficacy Of Adjuvant Procedures In Surgical Treatment Of Oral Submucous Fibrosis."** submitted by **Dr. SHIVANKAR TYAGI** Postgraduate student in the **Department of Oral and Maxillofacial Surgery** for the Thesis Dissertation as part of MDS Curriculum for the academic year 2022-2025 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on **16th October, 2023** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.


(Prof. Dr. Puneet Ahuja)
 Chairperson (IRC)
 Principal
 BBD College of Dental Sciences
 BBD University, Lucknow


(Dr. Lakshmi Bala)
 Co-Chairperson (IRC)
 HOD Biochemistry
 BBD College of Dental Sciences
 BBD University, Lucknow.

ANNEXURES II



BBD UNIVERSITY

Dr. Lakshmi Bala

Professor and Head, Deptt of Biochemistry and

Member-Secretary, Institutional Ethics Committee (IEC) of BBD University, Lucknow

Communication of the Decision of the VIIIth Institutional Ethics Committee Meeting

IEC Code: 17

BBDU/MDS/17/2024

Date: 07/03/2024

Title of the Project: Efficacy Of Adjuvant Procedures In Surgical Treatment Of Oral Submucous Fibrosis**Principal Investigator:** Dr. SHIVANKAR TYAGI**Department:** Department of Oral and
Maxillofacial Surgery**Name and Address of the Institution:** BBD University, Lucknow**Type of Submission:** New, MDS Dissertation proposal

Dear Dr. Shivankar Tyagi

The meeting of the Institutional Ethics Committee (IEC) was held on 06-02-2024 in Conference room, First Floor, BBDCODS, BBD University, Lucknow. Following members were present:

- | | | |
|---|---|------------------|
| 1 | Dr. Chandishwar Nath
Rtd. Chief Scientist, CDRI, Lucknow. | Chairman |
| 2 | Dr. JS Srivastava,
Rtd. Chief Scientist, CDRI, Lucknow. | Member |
| 3 | Dr. Manodeep Sen,
Professor, Department of Microbiology, RMLIMS, Lucknow | Member |
| 4 | Dr. Shaleen Chandra, Professor & Dean, Dental Sciences, Atal Bihari
Vajpai Medical University (ABVM University), Lucknow | Member |
| 5 | Dr. Manuka Khanna,
Professor, Deptt. of Political Science, Lucknow University, Lucknow | Member |
| 6 | Mr Abhishek Chaudhary, Advocate, Lucknow | Member |
| 7 | Dr. Puneet Ahuja, Professor of Oral Pathology and Principal, BBD
College of Dental Sciences, BBD University, Lucknow | Member |
| 8 | Dr. Lakshmi Bala, Professor & Head, Department of Biochemistry,
BBD College of Dental Sciences, BBD University, Lucknow | Member-Secretary |

The committee reviewed and discussed your submitted documents of the research proposal in the meeting.
Decisions: The committee approved the above proposal from ethics point of view.

Lakshmi Bala
07/03/24
(Dr. Lakshmi Bala)
Member-Secretary IEC
BBD University
Ethics Cell (Vth Floor, BBDCODS)
ethics@bbdu.ac.in

Dr. LAKSHMI BALA
Member-Secretary
Institutional Ethics Committee
BBD University, Lucknow-28

ANNEXURES III

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय)
वीवीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

1. अध्ययन शीर्षक

ओरल सबम्यूकस फाइब्रोसिस के सर्जिकल उपचार में सहायक प्रक्रिया की प्रभावशीलता।

2. आमंत्रण पैराग्राफ

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि शोध क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो मित्रों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें। हमसे पूछें कि क्या कुछ ऐसा है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं।

3. अध्ययन का उद्देश्य क्या है?

ओरल सबम्यूकस फाइब्रोसिस के सर्जिकल प्रबंधन में सहायक प्रक्रिया की प्रभावकारिता का अध्ययन करना।

4. मुझे क्यों चुना गया है?

आपको चुना जाता है क्योंकि आप अध्ययन के मानदंडों को पूरा करते हैं।

5. क्या मुझे भाग लेना है?

यह आपको तय करना है कि भाग लेना है या नहीं। यदि आप भाग लेने का निर्णय लेते हैं, तो आपको यह सूचना पत्रक रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं, तब भी आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. यदि मैं भाग लेता हूँ तो मेरा क्या होगा?

जरूरत पड़ने पर फॉलो-अप के लिए आपको सर्जरी से पहले और बाद में कई बार आना होगा।

7. मुझे क्या करना होगा?

कुछ अन्य एहतियाती उपायों के साथ आहार सेवन में कुछ बदलाव किए जाएंगे और आपसे इसका पालन करने की अपेक्षा की जाएगी।

8. किस प्रक्रिया का परीक्षण किया जा रहा है?

ओरल सबम्यूकस फाइब्रोसिस रोगी में सर्जिकल उपचार में सहायक प्रक्रिया की भूमिका।

9. अध्ययन के लिए क्या हस्तक्षेप है?

जी के तहत फ़ाइब्रोटिक बैंड का रिसेवशन किया जाएगा। इसके बाद सभी तीसरी दाढ़ और द्विपक्षीय कोरोनोइडक्टोमी को हटा दिया गया

10. भाग लेने के दुष्प्रभाव क्या हैं?

हालांकि प्रक्रिया के गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागियों को मतली और पोस्ट ऑपरेटिव उल्टी जैसी दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं। यदि प्रक्रिया के दौरान कुछ भी होता है तो हमारे पास किसी भी आपात स्थिति को प्रबंधित करने के लिए कुशल कार्मिक और विशेष उपकरण हैं। यदि प्रतिभागियों को ऑपरेशन के बाद कोई अन्य लक्षण दिखाई देते हैं, तो अभिभावक को तुरंत डॉक्टर से बात करनी चाहिए।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

अध्ययन में भाग लेने के कोई नुकसान नहीं हैं, दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं।

12. भाग लेने के संभावित लाभ क्या हैं?

चेहरे की सुंदरता और कार्यात्मक दक्षता के लिए मुंह खोलने में वृद्धि के लिए फाइब्रोटिक बैंड जारी करना।

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपको इसके बारे में सूचित किया जाएगा और अध्ययन में होने वाले परिवर्तनों के बारे में सूचित किया जाएगा। आप अध्ययन के बीच में हटने के लिए स्वतंत्र हैं। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

यदि अध्ययन निर्धारित समय से पहले समाप्त / बंद हो जाता है, तो इसका कारण रोगियों को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो बीबीडीसीओडीएस ओपीडी में क्षेत्र में विशेषज्ञता रखने वाले डॉक्टरों द्वारा शिकायतों का निपटारा किया जाएगा।

16. क्या इस अध्ययन में मेरे भाग लेने को गोपनीय रखा जाएगा?

आपका नाम, पता या कोई व्यक्तिगत या अन्य जानकारी बीबीडीसीओडी के बाहर साझा नहीं की जाएगी।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणामों का उपयोग 4 विभिन्न प्रकार के माउथवॉश की प्रभावशीलता का मूल्यांकन और तुलना करने के लिए किया जाएगा। किसी भी परिणाम/रिपोर्ट/प्रकाशन में प्रतिभागियों की पहचान का खुलासा नहीं किया जाएगा।

18. शोध का आयोजन कौन कर रहा है?

यह शोध अध्ययन शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाता है।

19. क्या अध्ययन समाप्त होने के बाद अध्ययन के परिणाम उपलब्ध कराए जाएंगे?

यदि रोगी चाहे तो अध्ययन का परिणाम उसे उपलब्ध कराया जाएगा।

20. अध्ययन की समीक्षा किसने की है:

संस्थान के एचओडी/आईआरसी/आईईसी ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

21. अधिक जानकारी के लिए संपर्क करें

डॉ. शिवांकर त्यागी

ओरल और मैक्सिलोफेशियल सर्जरी विभाग।

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-226028

मोबा: 8755271996

डॉ लक्ष्मी बाला,

संस्था की आचार समिति के सदस्य सचिव,

पता: बाबू बनारसी दास विश्वविद्यालय, फैजाबाद रोड, आतिथ विहार,

लखनऊ, यूपी। 226028

ईमेल: bbdcods.iec@gmail.com

पं. का नाम -

पता -

ईमेल -

टेलीफोन नंबर। -

पीआई के हस्ताक्षर

नाम.....

तारीख.....

प्रतिभागी को सूचना पत्र की एक प्रति और हस्ताक्षरित सहमति प्रपत्र दिया जाएगा।

अध्ययन में भाग लेने के लिए धन्यवाद।

ANNEXURES IV

Babu Banarasi Das College of Dental Sciences
 (Babu Banarasi Das University)
 BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

PARTICIPANT INFORMATION DOCUMENT**1. Study Title**

EFFICACY OF ADJUVANT PROCEDURE IN SURGICAL TREATMENT OF ORAL SUBMUCOUS FIBROISIS

2. Invitation Paragraph

You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

To study the efficacy of adjuvant procedure in surgical management of oral submucous fibrosis.

4. Why have I been chosen?

You have been chosen for the study as you are fulfilling the required criteria for the study.

5. Do I have to take part?

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a reason.

6. What will happen to me if I take part?

You will have to come multiple times before and after surgery for follow up as and when required.

7. What do I have to do?

There will be certain changes made in the dietary intake with few other precautionary measures and you will be expected to follow that.

8. What is the procedure that is being tested?

Efficacy of adjuvant procedure in surgical treatment in oral submucous fibrosis patient.

9. What are the interventions for the study?

Under G.A resection of fibrotic band will be performed. Followed by removal of all 3rd molar and bilateral coronoidectomy.

10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure but the participants may have minimum side effects of the drugs like nausea and post operative vomiting. If anything happens during the procedure we have skilled personnel and specialized equipments to manage any emergency.

If the participants suffers any other symptoms postoperatively, the guardian should immediately talk to the doctor.

11. What are the possible disadvantages and risks of taking part?

There are no disadvantages of taking part in the study, there can be minimum side effects of the drugs.

12. What are the possible benefits of taking part?

Release of fibrotic band for increase in mouth opening for facial esthetics and functional efficiency.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will need to tell the patient about this. States:

-Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

the problem/complain will be handled by HOD or the IRC. If something serious happen the institute will take care of the problem.

16. Will my taking part in this study be kept confidential?

Yes, it will be kept confidential.

17. What will happen to the results of the research study?**18. Who is organizing the research?**

the research is being done in the department of Oral and Maxillofacial Surgery, BBDCODS. The research is self funded. The participants will have to pay for procedural charges as given by the institution.

19. Will the results of the study be made available after study is over?

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/ IEC of the institution have reviewed and approved the study.

21. Contact for further information**Dr. Shivankar Tyagi**

Department of Oral & Maxillofacial Surgery,
Babu Banarasi College of Dental Sciences,
Lucknow-226028
Mob: 8755271996

Dr. Laxmi Bala

Member Secretary of Ethics Committee of the Institution
Babu Banarasi College of Dental Sciences,
Lucknow
Email: bbdcods.iec@gmail.com

Signature of PI.....

Name.....

Date.....

ANNEXURES V

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study : EFFICACY OF ADJUVANT PROCEDURES IN SURGICAL
TREATMENT OF ORAL SUBMUCOUS FIBROSIS

Study Number.....

Subject's Full Name.....

Date of Birth/Age

Address of the Subject.....

Phone no. and e-mail address.....

Qualification

Occupation: Student / Self Employed / Service / Housewife/

Other (Please tick as appropriate)

Annual income of the Subject.....

Name and of the nominees(s) and his relation to the subject.....(For the purpose of
compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes** [☐] **No** [☐]
Not Applicable [☐]
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable
Representative:.....
Signatory's Name..... Date
Signature of the Investigator..... Date.....
Study Investigator's Name..... Date.....
Signature of the witness..... Date.....
Name of the witness.....
Received a signed copy of the PID and duly filled consent form
Signature/thumb impression of the subject or legally Date.....

Acceptable representative

ANNEXURES VI

**Babu Banarasi Das College of Dental
Sciences**
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105
(INDIA)

सहमति पत्र

अध्ययन का शीर्षक: ओरल सबम्यूकस फाइब्रोसिस के सर्जिकल उपचार में सहायक प्रक्रियाओं की प्रभावशीलता।

स्टडी नंबर.....

विषय का पूरा नाम

जन्म तिथि/आयु

विषय का पता.....

फोन नंबर। और ई-मेल पता

योग्यता

व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)

विषय की वार्षिक आय.....

नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए)

मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. मैं पुष्टि करता हूँ कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक को पढ़ और समझ लिया है। उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।
2. मैं समझता हूँ कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूँ।

- स्वीकार्य प्रतिनिधि

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY
BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW.

CASE HISTORY

OPD NO:

Date:

Address

- **CHIEF COMPLAINT:**
- **HISTORY OF PRESENT ILLNESS:**
- **PAST MEDICAL HISTORY:**
- **PAST DENTAL HISTORY:**
- **FAMILY HISTORY:**
- **PERSONAL HISTORY:**
- **PRE-OPERATIVE EVALUATION**
- **GENERAL PHYSICAL EXAMINATION**

Gait

- **VITAL SIGNS**

Temperature
Respiratory rate

Pulse rate
Blood pressure

- **EXTRAORAL EXAMINATION**

Sunken cheeks
Vermilion border
Malar bone
Trismus

- **INTRAORAL EXAMINATION**

Number of teeth
Interincisal opening
Buccal/Labial mucosa
Swallowing
Extent of bands

burning sensation
Tongue protrusion
Cheek flexibility
speech

- **PRE-ANAESTHETIC EVALUATION AND MEDICATION**

- **DATE OF SURGERY**

- **POST OPERATIVE NOTE**

- **POST OP MEDICATION**

- **SIGNATURE OF OPERATING SURGEON**

- **SIGNATURE OF DOCTOR**

ANNEXURES VIII

ORAL AND MAXILLOFACIAL SURGERY, BBDCODS

Evaluation Sheet

Name -

Age /sex-

OPD no -

Address-

Contact no-

Serial no-

Duration →	PRE- OPERATIVELY	INTRA OPERATIVELY	POST-OPERATIVELY				
Criteria ↓			1 st day	1 week	1 month	3 rd month	6 th month
Pain							
Swelling							
Infection							
Inter- incisal mouth opening		• Resection of band • Removal of molars • B/L coronoidectomy					
Relapse							

ANNEXURES IX

EFFICACY OF ADJUVANT PROCEDURES IN SURGICAL
TREATMENT OF ORAL SUBMUCOUS FIBROSIS.pdf

 Turnitin

Document Details

Submission ID:
tm:oid::15229:93548271

Submission Date:
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File Name:
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File Size:
1.6 MB

61 Pages
5,894 Words
35,534 Characters



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- Cited Text

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Matches with neither in-text citation nor quotation marks
- 0 Missing Quotations 0%
Matches that are still very similar to source material
- 0 Missing Citation 0%
Matches that have quotation marks, but no in-text citation
- 0 Cited and Quoted 0%
Matches with in-text citation present, but no quotation marks

Top Sources

- 4% Internet sources
- 7% Publications
- 3% Submitted works (Student Papers)

Integrity Flags

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Our system's algorithms look deeply at a document for any inconsistencies that would set it apart from a normal submission. If we notice something strange, we flag it for you to review.

A flag is not necessarily an indicator of a problem. However, we do recommend you focus your attention there for further review.





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- Quoted Text
- Cited Text

Match Groups

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Matches with neither in-text citation nor quotation marks.
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Matches that are still very similar to source material.
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Matches that have quotation marks, but no in-text citation.
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Matches with in-text citation present, but no quotation marks.

Top Sources

- 4% Internet sources
- 7% Publications
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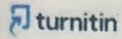
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- 0 Missing Quotations 0%**
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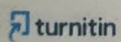
Top Sources

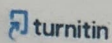
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Top Sources

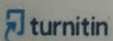
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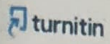
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