



Original Research Article

Comprehensive Comparative Analysis Evaluating the Effectiveness of Two Distinct Physiotherapy Mouth-Opening Exercise Protocols and Mouth-Opening Devices in Improving Maximal Interincisal Distance among Patients Diagnosed With Oral Submucous Fibrosis: An Original Research Study

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Abstract: **Aim:** This study evaluates the effectiveness of two distinct physiotherapy mouth-opening exercise protocols and mouth-opening devices in improving maximal interincisal distance among patients diagnosed with oral submucous fibrosis. **Materials and Methods:** This study focused on 40 patients with restricted mouth opening and associated burning sensations, particularly after consuming spicy foods. Many faced difficulties with chewing, swallowing, and speaking, affecting their quality of life. Each participant was diagnosed with oral submucous fibrosis (OSMF), characterised by fibrous oral mucosa transformation. From the initial cohort, 30 patients, balanced in gender, were willing to pursue treatment, meeting strict inclusion criteria, including a maximum interincisal opening (MIO) of less than 35 mm and the cessation of areca nut use. Participants with systemic diseases, pregnancy, mental instability, or coexisting oral lesions were excluded to ensure safety and integrity. Informed consent was obtained before treatment. The management plan included topical Clobetasol Propionate for inflammation, oral antioxidants for tissue health, and interlesional injections for pain relief. Two physiotherapy protocols were introduced: Group 1 (15 patients) engaged in tailored mouth-opening exercises, while Group 2 (15 patients) used a Heister jaw opener for controlled stretching. The study aimed to evaluate the effectiveness of these interventions by measuring maximum intercuspal distance (MID) at 1, 3, and 6 months. The goal was to assess which physiotherapy approach better increased MIO in patients with OSMF, ultimately aiming to improve patient outcomes and quality of life. **Statistical Analysis and Results:** This study involved 30 patients, aged 35 to 60, diagnosed with oral submucous fibrosis (OSMF), who experienced restricted mouth opening and burning sensations with spicy foods. The cohort included 16 males and 14 females, all seeking management for their condition due to its impact on quality of life. Participants were divided into two groups of 15. Group 1 underwent physiotherapy, including mouth-opening exercises aimed at improving oral function, while Group 2 used a Heister jaw opener for controlled stretching. Outcomes were assessed by measuring the maximum intercuspal distance at baseline, and at 1, 3, and 6 months. Results showed that after one month, 2 patients in Group

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1 and 3 in Group 2 had an interincisal distance of less than 35 mm. After two months, 3 patients in Group 1 and 5 in Group 2 fell short of this measurement. By the six-month follow-up, Group 1 had 4 patients and Group 2 had 6 patients below the 35 mm threshold. Overall, the study provided insights into the management of OSMF, comparing the effectiveness of structured exercises and a jaw opener in improving mouth opening capabilities in affected patients. **Conclusion:** This study concluded that both protocols benefited patients with limited mouth opening, with basic exercises being advantageous and cost-effective. However, mouth-opening devices proved more effective due to their design and improved patient adherence. These findings offer valuable insights for developing more effective treatment approaches in managing OSMF, ultimately improving patient outcomes.

Keywords: Oral Submucous Fibrosis, Physiotherapy, Mouth-Opening Exercise, Mouth-Opening Devices, Maximal Interincisal Distance

INTRODUCTION

Oral submucous fibrosis (OSMF) is a significant precancerous condition that primarily impacts the oral cavity. This disorder is marked by a complex inflammatory response that instigates fibrosis within the submucosal layers of oral tissues. Over time, this pathological process results in a progressive thickening and stiffening of the affected tissues, which frequently manifests as trismus, a debilitating restriction of mouth opening that can be both uncomfortable and painful.^{1,2} The physical limitations resulting from OSMF can profoundly affect an individual's day-to-day activities, making essential functions such as eating, speaking, and even breathing difficult. As these fundamental actions become increasingly challenging, the overall quality of life for those affected can diminish drastically. Many individuals with OSMF report feelings of isolation and frustration, compounded by the condition's progressive nature, which can also lead to psychological distress, increasing the burden faced by patients as they navigate their daily lives.^{3,4} A significant risk factor contributing to the development of Oral Submucous Fibrosis is the habitual intake of betel nuts, particularly the areca nut. This nut is rich in a variety of alkaloids, with arecoline being the most prominent. Additionally, it contains trace elements such as copper, which can further influence its biological effects. The bioactive compounds present in areca nut adversely interact with fibroblasts, crucial cells for the synthesis and maintenance of the connective tissue's structural integrity. This detrimental interaction stimulates the formation of dense fibrotic bands within the delicate oral mucosa, exacerbating both the symptoms and functional limitations experienced by individuals suffering from OSMF.^{5,6} As the condition progresses, increased stiffness in the oral tissues not only heightens physical discomfort but can also result in severe complications, such as difficulty in swallowing and increased risk of

oral cancers. Awareness and early intervention are imperative in managing OSMF effectively. Continued research and education are essential to address this public health issue, aiming to mitigate the risk factors and improve the outcomes for those affected by this challenging condition.⁷ Patients afflicted with OSMF often report a distressing and diverse array of symptoms. Among these are recurrent oral ulcers, which can be intensely painful and debilitating. Additionally, many individuals endure a persistent sensation of dryness in the mouth, known as xerostomia, accompanied by burning discomfort that permeates the oral cavity. Over time, these patients experience a gradual and alarming decline in their ability to open their mouths, an impairment that can be quantitatively assessed as interincisal distance. Such debilitating symptoms not only lead to significant physical discomfort but also create formidable challenges in performing essential daily activities, ultimately diminishing the individual's quality of life. Disturbingly, even after individuals cease consuming areca nut, the progression of OSMF may continue unabated, highlighting the chronic nature of the fibrosis and the often irreversible consequences it imposes.^{8,9} Management strategies for OSMF focus on providing symptomatic relief while endeavouring to restore functional capabilities. Central to effective treatment is the absolute cessation of areca nut consumption, which is imperative to prevent further disease progression. In conjunction with this, physiotherapy plays a crucial role in managing the condition, utilising specialised mouth-opening devices and targeted therapeutic exercises meticulously designed to stretch the fibrotic tissues gently.^{10,11} This rehabilitative approach helps improve jaw mobility and alleviate the severity of trismus. In more advanced cases of OSMF, adjunctive therapies such as steroid injections may be employed to curtail inflammation, and surgical interventions might become necessary to restore functional capacity and

mitigate the potential cancer risk associated with this debilitating condition. Monitoring interincisal distance is essential for both the diagnosis and staging of OSMF. A noticeable decrease in mouth opening serves as a significant indicator of disease progression, providing vital insights that inform treatment planning and the evaluation of therapeutic responses.^{12,13} This study endeavours to rigorously evaluate the effectiveness of two distinct physiotherapy protocols focused on mouth-opening exercises. Additionally, the research will delve into the impact of specific mouth-opening devices on enhancing maximal interincisal distance among patients diagnosed with oral submucous fibrosis. By comparing these innovative rehabilitation approaches, the study aims to pinpoint the most effective therapeutic strategies for improving oral function and alleviating the burdens endured by individuals grappling with this challenging and debilitating condition.

Materials and Methods

This study began with a carefully selected cohort of 40 patients, all of whom presented with the primary complaint of restricted mouth opening. This condition is often accompanied by a distressing burning sensation in the oral cavity that significantly intensifies upon the consumption of spicy foods. Beyond these discomforts, many patients reported significant difficulties in performing essential daily functions such as chewing, swallowing, and speaking, which greatly impacted their quality of life. A notable number of individuals experienced persistent pain and mucosal stiffness, leading to an urgent and heartfelt desire for effective treatment solutions. After conducting a comprehensive clinical examination, all participants received a definitive diagnosis of oral submucous fibrosis (OSMF), a condition characterized by the fibrous transformation of oral mucosa. From the initial group of 40 patients, 30 individuals comprising a well-balanced mix of males and females expressed a willingness to pursue treatment. The study employed stringent inclusion criteria, requiring participants to exhibit a maximal interincisal opening (MIO) of less than 35 mm, clearly indicating a substantial limitation in mouth opening. Moreover, all participants had to agree to cease the habitual use of areca nut or related products, as extensive research has established these substances as significant contributors to both the onset and progression of OSMF. Conversely, individuals were excluded from the study if they had any underlying systemic diseases, were pregnant, displayed signs of mental instability, or presented with coexisting oral lesions that indicated a potential for malignant transformation. This meticulous selection process aimed to ensure the safety and integrity of the study, as well as the well-being of all participants involved. Prior to the initiation of any therapeutic intervention,

informed consent was meticulously obtained from each participant, ensuring adherence to ethical standards. Once diagnosed with OSMF, a comprehensive management plan was established, employing a multifaceted treatment approach aimed at alleviating the symptoms and improving oral functionality. This plan included the topical application of Clobetasol Propionate to the affected areas to reduce inflammation, a regimen of oral antioxidants to promote overall tissue health, and interlesional injections designed to provide pain relief. Additionally, two customized physiotherapy protocols were introduced to facilitate improvements in mouth opening and overall oral mobility. The study specifically focused on the 30 patients diagnosed with OSMF, who were subsequently divided into two distinct groups for comparative analysis. Group 1 consisted of 15 patients who participated in physiotherapy specifically tailored to mouth-opening exercises. These exercises comprised a wide range of activities, including both active and passive movements to enhance mobility, cheek stretching techniques, and targeted tongue mobility exercises, all designed to improve overall oral function and elasticity. Group 2 similarly included 15 patients, but this cohort incorporated the use of a Heister jaw opener into their physiotherapy routine. This device aimed to address the limitation of mouth opening through controlled stretching. To rigorously evaluate the effectiveness of the two distinct interventions, the maximum intercuspal distance (MID) was meticulously recorded at baseline and subsequently reevaluated at 1 month, 3 months, and 6 months following the initiation of treatment. The primary objective of this study is to critically assess the effectiveness of the two physiotherapy protocols—mouth-opening exercises and the use of a mouth-opening device—in increasing the maximal interincisal distance in patients diagnosed with oral submucous fibrosis. By undertaking this evaluation, the study seeks to provide valuable insights and recommendations regarding optimal management strategies for this complex and challenging condition, with the ultimate aim of improving patient outcomes and enhancing their quality of life.

Statistical Analysis

In this study, statistical analyses were conducted using SPSS software version 29.0, a full-bodied tool for statistical computing and data analysis in the social sciences. We employed the chi-square test to assess the significance of our findings, effectively examining differences in proportions across various groups. This approach facilitated a thorough and rigorous comparison of categorical data, ensuring that our results accurately reflect the underlying trends and relationships within the dataset.

RESULTS

This study involved a total of 30 patients, comprising both males and females, who presented with a chief complaint of restricted mouth opening and burning sensations during the consumption of spicy foods. All participants were diagnosed with oral submucous fibrosis (OSMF), and their ages ranged from 35 to 60 years. The patients sought management for the condition due to its significant impact on their quality of life. Table 1 provides a detailed statistical description based on age and gender of the patients involved in the study, indicating that the cohort consisted of 16 males and 14 females. The research aimed to evaluate the effectiveness of two distinct therapeutic approaches to improve mouth opening in these patients. The 30 participants were divided into two groups of 15 patients each. Group 1 underwent a regimen of physiotherapy that included structured mouth-opening exercises. These exercises focused on both active and passive movements, cheek stretching, and enhancing tongue mobility, all designed to improve oral function and increase the maximum intercuspal distance (MID). Group 2 also consisted of 15 patients; however, they utilized a Heister jaw opener as part of their treatment routine to facilitate controlled stretching and mouth opening. To assess the outcomes of both interventions, the maximum intercuspal distance was meticulously measured at baseline and subsequently at 1, 3, and 6 months. Table 2 presents the findings for Group 1, where the maximum interincisal distance was carefully evaluated one month after the completion of the mouth-opening exercise program. The statistical analysis, conducted using the Pearson Chi-Square test, revealed that 2 patients had an interincisal distance of less than 35 mm at this time point. Table 3 showcases the outcomes for Group 2, whose participants used the structured mouth-opening device. Similar to the previous group, the maximum interincisal distance was evaluated one month post-intervention. The analysis demonstrated that 3 patients exhibited an interincisal distance of less than 35 mm after one month, indicating a notable impact of the device. In Table 4, the results for Group 1 are illustrated again, this time focusing on evaluations two months after the exercise program. The Pearson Chi-Square test indicated that 3 patients continued to show an interincisal distance of less than 35 mm at this follow-up. Table 5 reflects the findings for Group 2 at the two-month mark, where the study noted that 5 patients had a maximum interincisal distance of less than 35 mm following their use of the mouth-opening devices, suggesting a positive trend towards improvement. Table 6 summarizes the results for Group 1 after a six-month follow-up, where the maximum interincisal distance was again assessed. At this interval, the analysis identified 4 patients with an interincisal distance of less than 35 mm, highlighting a gradual yet significant change over time. Table 7 outlines the outcomes for Group 2 at the six-month evaluation. The findings revealed that 6 patients from this group had an interincisal distance of less than 35 mm, offering further evidence of the effectiveness of the structured mouth-opening device over the extended period. Lastly, Table 8 presents a comprehensive estimation of the outcomes across all studied groups, analyzed using one-way ANOVA. This statistical overview serves to synthesize the data collected and highlights the comparative effectiveness of the therapeutic interventions. In summary, the study aimed to provide valuable insights into the management of oral submucous fibrosis, illustrating the varying impacts of structured mouth-opening exercises versus the use of a jaw opener on improving mouth opening capabilities in affected patients.

Table 1: Age & gender based statistical description of contributing patients

Age Group (Yrs)	Male	Female	Total	P value
35-40	4	3	7	0.03*
41-45	4	3	7	0.40
46-50	3	2	5	0.01*
51-55	2	4	6	0.30
56-60	3	2	5	0.20
Total	16	14	30	*Significant
*p<0.05 significant				

Graph 1: Patients demographic distribution and associated details

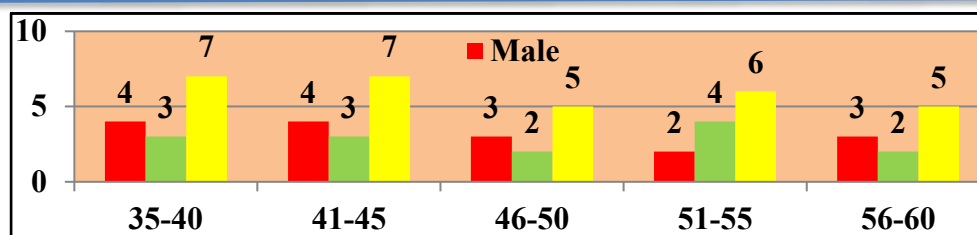


Table 2: Group 1 (n= 15) patients diagnosed with oral submucous fibrosis, participants engaged in a structured mouth-opening exercise. The maximum interincisal distance was meticulously evaluated one month following the completion of the exercise program. To determine the statistical significance of the outcomes observed, the Pearson Chi-Square test was employed, providing an analysis of the results

Maximum interincisal distance range	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Less than 20mm	9	1.16	1.04	1.05	1.07	1.05	1.08	0.01*
20-35mm	4	1.09	1.05	1.04	1.03	1.01	1.01	0.06
More than 35mm	2	1.07	1.02	1.09	1.03	1.05	1.02	0.07
*p<0.05 significant								

Table 3: Group 2 (n= 15) patients diagnosed with oral submucous fibrosis, participants engaged in a structured mouth-opening device. The maximum interincisal distance was meticulously evaluated one month following the completion of the exercise program. To determine the statistical significance of the outcomes observed, the Pearson Chi-Square test was employed, providing an analysis of the results

Maximum interincisal distance range	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Less than 20mm	7	1.12	1.05	1.02	1.05	1.03	1.07	0.01*
20-35mm	5	1.10	1.04	1.06	1.03	1.02	1.02	1.0
More than 35mm	3	1.08	1.03	1.45	1.23	1.20	1.25	0.6
*p<0.05 significant								

Table 4: Group 1 (n= 15) patients diagnosed with oral submucous fibrosis, participants engaged in a structured mouth-opening exercise, The maximum interincisal distance, was meticulously evaluated two months following the completion of the exercise program. To determine the statistical significance of the outcomes observed, the Pearson Chi-Square test was employed, providing an analysis of the results

Maximum interincisal distance range	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Less than 20mm	7	1.12	1.05	1.02	1.05	1.03	1.07	0.01*
20-35mm	5	1.10	1.04	1.06	1.03	1.02	1.02	1.0
More than 35mm	3	1.08	1.03	1.45	1.23	1.20	1.25	0.6
*p<0.05 significant								

Table 5: Group 2 (n= 15) patients diagnosed with oral submucous fibrosis, participants engaged in a structured mouth-opening devices, The maximum interincisal distance, was meticulously evaluated two months following the completion of the exercise program. To determine the statistical significance of the outcomes observed, the Pearson Chi-Square test was employed, providing an analysis of the results

Maximum interincisal distance range	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Less than 20mm	6	1.12	1.09	1.07	1.03	1.05	1.02	1.0
20-35mm	4	1.09	1.05	1.04	1.03	1.01	1.01	0.06

More than 35mm	5	1.10	1.04	1.06	1.03	1.02	1.02	1.0
*p<0.05 significant								

Table 6: Group 1 (n= 15) patients diagnosed with oral submucous fibrosis, participants engaged in a structured mouth-opening exercise, the maximum interincisal distance, was meticulously evaluated sixmonths following the completion of the exercise program. To determine the statistical significance of the outcomes observed, the Pearson Chi-Square test was employed, providing an analysisof the results

Maximum interincisal distance range	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Square Value	Chi- df	p value
Less than 20mm	6	1.12	1.09	1.07	1.03	1.05	1.02	1.0
20-35mm	5	1.10	1.04	1.06	1.03	1.02	1.02	1.0
More than 35mm	4	1.09	1.05	1.04	1.03	1.01	1.01	0.06
*p<0.05 significant								

Table 7: Group 2 (n= 15) patients diagnosed with oral submucous fibrosis, participants engaged in a structured mouth-opening devices, The maximum interincisal distance, was meticulously evaluated sixmonths following the completion of the exercise program. To determine the statistical significance of the outcomes observed, the Pearson Chi-Square test was employed, providing an analysisof the results

Maximum interincisal distance range	N	Mean	Std. Dev.	Std. Error	95% CI	Pearson Square Value	Chi- df	p value
Less than 20mm	3	1.08	1.03	1.45	1.23	1.20	1.25	0.6
20-35mm	6	1.12	1.09	1.07	1.03	1.05	1.02	1.0
More than 35mm	6	1.12	1.09	1.07	1.03	1.05	1.02	1.0
*p<0.05 significant								

Table 8: Estimation amongst all studied groups using one-way ANOVA

Variables	Degree of Freedom	Sum of Squares Σ	Mean Sum of Squares $m\Sigma$	F	Level of Sig. (p)
Between Groups	2	2.701	2.564	1.4	0.02*
Within Groups	20	2.194	1.931	–	
Cumulative	194.10	2.876	*p<0.05 significant		

DISCUSSION

Kumar J et al reviewed in their study that oral submucous fibrosis (OSMF) is a chronic, progressive disorder that primarily affects the delicate mucous membranes of the oral cavity, but it can also extend to the throat and upper oesophagus in certain instances. This condition is characterised by a cycle of inflammation that eventually leads to fibrosis, resulting in the thickening and hardening of the tissues involved. As OSMF advances, individuals often face considerable limitations in oral functionality, which can severely impair their ability to open their mouths comfortably or perform intricate movements with their tongues. Many patients report a range of distressing symptoms, including heightened sensitivity to spicy and hot foods, along with a persistent sensation of tightness or stiffness in the lips, tongue, and palate. These symptoms can make eating

and verbal communication particularly challenging, leading to a diminished quality of life.^{14,15} Prasad SR et al included in their study that central to the pathology of OSMF is the process of submucosal fibrosis, which entails excessive accumulation of collagen and fibrous tissue in the connective tissue layer beneath the mucosal surface. This aberrant fibrotic response primarily affects the complex structures of the oral cavity and oropharynx, and can extend to the upper oesophagus. The resultant complications may include considerable difficulties in swallowing (dysphagia), malnutrition due to inadequate dietary intake, and an increased risk for malignant transformations, particularly oral squamous cell carcinoma. Several factors have been identified as contributing to the onset and progression of this condition.^{16,17} Yuwanati M et al showed in their study that among these, the habitual chewing of areca nuts, common in various cultural

practices, emerges as a significant risk factor. Furthermore, the regular intake of capsaicin, the active compound found in chilli peppers, has also been linked to the severity of OSMF symptoms. Nutritional deficiencies, especially deficiencies in essential nutrients like iron, zinc, and specific vitamins, can exacerbate the condition and are often correlated with its severity. Recent research suggests the possible involvement of autoimmune mechanisms, as indicated by the presence of specific autoantibodies and human leukocyte antigen (HLA) markers observed in affected individuals.^{18,19} Saoji K Jr et al reviewed in their study that, as a complex and chronic disorder, OSMF presents substantial challenges for effective treatment and management. Classified as a precancerous condition, the importance of early detection and timely intervention cannot be overstated, as individuals with OSMF are at an elevated risk of developing oral cancers. Therefore, the primary goals of treatment focus on halting the progression of the disease and alleviating troublesome symptoms, which in turn enhances the patient's ability to eat, speak, and maintain adequate nutrition.²⁰ Arakeri G et al included in their study that management strategies for OSMF often necessitate a multifaceted approach that incorporates various therapeutic modalities. Pharmacological interventions may include the use of corticosteroids and antioxidants aimed at mitigating inflammation and fostering tissue healing. In more advanced cases, surgical options, such as mucosal grafting, may become necessary to restore oral functionality.²¹ Nichlani SS et al reviewed in their study that, in addition, physiotherapy plays a critical role in rehabilitation, utilising specialised devices designed to gently stretch and expand oral tissues. These devices, crafted from durable stainless steel or advanced 3D-printed materials, allow patients to engage in controlled exercises targeted at progressively improving mouth opening and overall oral mobility. Moreover, many of these therapeutic tools are frequently paired with supplementary kits that may comprise herbal remedies, oral sprays, and dietary supplements, all tailored to support and enhance the holistic rehabilitation process.^{22,23} Ye JR et al reviewed in their study that ultimately, OSMF can lead to severe complications that significantly affect nutritional intake, potentially resulting in profound nutritional deficiencies and a cascade of related health problems. The condition typically initiates with inflammation, which progresses into a stage of stiffness that drastically restricts the ability to open the mouth and swallow effectively. Consequently, early recognition, a comprehensive management plan, and a multidisciplinary approach are crucial for improving patient outcomes and enhancing the overall quality of life for individuals facing the challenges associated with this intricate and multifaceted condition.^{24,25}

Conclusion

In light of the constraints of this study, the authors undertook an examination of the efficacy of two distinct physiotherapy mouth-opening exercise protocols alongside the utilization of mouth-opening devices in enhancing maximal interincisal distance among patients diagnosed with oral submucous fibrosis (OSMF). The findings revealed that both physiotherapy protocols significantly benefited patients suffering from restricted mouth opening, leading to an increase in maximum interincisal distance. While basic exercises proved to be advantageous and cost-effective, the use of mouth-opening devices demonstrated superior effectiveness, attributed to their mechanical design and ability to promote better patient adherence. The insights gleaned from this research offer valuable direction for developing improved treatment protocols in complex clinical situations. Ultimately, this study contributes to the potential for more effective clinical practices and therapeutic interventions in the future, thus enhancing patient outcomes in the management of OSMF.

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