



Research Article

Comparing Different Modes of Mouth Exercise in Oral Submucous Fibrosis (OSMF) Grade II Patients– A Randomised Clinical Trial

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Aims- The aims of this study was to compare the clinical efficacy of three different modes of mouth exercise in the management of Oral Submucous Fibrosis (OSMF). **Methods-** The study included a total of 45 subjects diagnosed with oral submucous fibrosis (OSMF), all of whom had no other systemic diseases. The participants were randomly divided into three groups, with 15 patients in each group. Group I performed balloon-blowing exercises, Group II followed an exercise regimen using ice-cream sticks, and Group III used a mouth opener device. The interincisal distance (IID) was measured using a digital Vernier caliper at the beginning of the study and after two months of intervention. **Results:** All three groups showed a statistically significant increase in mouth opening over 8 weeks, with Group 1 improving from 29.20 ± 3.73 mm to 31.40 ± 3.98 mm, Group 2 from 30.27 ± 3.01 mm to 34.33 ± 3.04 mm, and Group 3 from 29.33 ± 2.44 mm to 33.27 ± 2.37 mm, with the greatest percentage increase observed in Group 2 (13.60%), followed by Group 3 (13.57%) and Group 1 (7.60%). **Conclusion:** The management of OSMF patients should primarily be focused towards improving the MO and increasing flexibility of the oral mucosa to halt the possibility of malignant changes and thus mouth exercise physical therapy independently or in combination with other modalities may be useful to improve mouth opening (MO) in OSMF.

Keywords: Mouth Opening, Physical Therapy, Mouth Opener Device, Interincisal Distance, Exercise Therapy.

INTRODUCTION

Oral Submucous Fibrosis (OSMF) is a long-term, progressively worsening condition that affects the mouth, throat, and upper part of the food pipe (oesophagus). It leads to thinning of the oral lining, inflammation beneath the surface, and the buildup of dense fibrous tissue, which causes hallmark symptoms such as increasing difficulty in opening the mouth (trismus), trouble swallowing (dysphagia), a burning sensation, and sensitivity to spicy foods [1]. Over time, the mouth becomes increasingly stiff,

making normal jaw movements more difficult [2]. One of the most common and troubling signs experienced by people with OSMF is the gradual reduction in their ability to open their mouth fully [3]. In more advanced stages, the condition may also affect other parts of the oral and throat region, including reduced movement of the soft palate and tongue, dryness of the mouth (xerostomia), loss of taste, and hardening of tissues in the throat and upper esophagus [2,3]. It can also lead to hearing issues, sunken cheeks due to muscle weakening, voice changes such as hoarseness, and serious limitations in

day-to-day activities [3]. OSMF is especially concerning because it carries a high risk of turning into oral cancer, making it a potentially life-threatening condition [4]. It can affect people of any age—even children and teenagers—but is most frequently seen in individuals between 18 and 35 years of age. In the past forty years, the number of reported cases has increased dramatically—from just 0.03% to 6.42%—highlighting its emergence as a major public health concern in India [2,3]. Prevalence estimates in India range from 0.2–2.3% in males and 1.2–4.6% in females, across an age range of 11 to 60 years [5]. This alarming rise is closely linked to the widespread marketing and use of commercially available tobacco and areca nut products. In fact, it is currently estimated that 10–20% of the global population consumes areca nut in various forms [4]. While the exact cause of Oral Submucous Fibrosis (OSMF) involves multiple contributing factors, the most well-established and primary cause is the habitual chewing of areca nut [6]. Other potential influences include the consumption of spicy foods such as chilies, genetic or immune system factors, and nutritional deficiencies [6]. Clinically, the disease is categorized into early, moderate, and advanced stages. These classifications are based on both the patient's symptoms and histopathological features, including thinning of the epithelium (epithelial atrophy), loss of rete pegs, and dense collagen deposition in the connective tissue (lamina propria hyalinization) [4]. Unfortunately, no definitive cure for OSMF currently exists. Although conservative surgical interventions may provide some relief, symptoms like burning sensations and difficulty in opening the mouth (trismus) often persist [7]. The goal of treatment is to alleviate discomfort and slow down the fibrotic progression of the disease. Management strategies vary depending on the stage of OSMF: early stages focus on quitting harmful habits and using nutritional supplements; moderate stages typically involve intralesional injections; and in more advanced cases, surgical options may be necessary. Non-surgical treatments, such as medications and nutrient-rich diets, can also offer supportive benefits [7]. In the early stages, inflammation leads to increased blood supply (vascularity), whereas in advanced stages, vascularity significantly reduces, making the tissues more prone to degeneration and cancerous changes [8]. Given the

estimated 6% risk of malignant transformation in OSMF, timely and proactive treatment is critical [9]. One of the major challenges in OSMF is the progressive reduction in mouth opening due to fibrosis. While stopping the use of areca nut can be beneficial in early stages, once the disease advances, reversing the condition becomes increasingly difficult [5]. Moreover, there is no standardized treatment protocol specifically for improving mouth opening in OSMF, and most current interventions show only limited long-term success with a risk of relapse [10]. In this context, physiotherapy — particularly in the form of structured mouth exercises — has emerged as a helpful adjunct to improve mouth opening and reduce the chances of post-treatment relapse [8]. The devices used for these exercises are often tooth-supported, applying force between dental arches. However, these are not ideal for individuals who are edentulous or have severely compromised teeth. In such cases, alternative non-tooth-borne devices using vestibular screws have shown better adaptability [11]. These exercises are simple to perform, minimally invasive, cost-effective, and can easily be incorporated into daily routines [12,13]. Today, such physiotherapeutic aids are widely used to complement other treatment modalities and enhance overall outcomes [4,6]. To the best of our knowledge, no prior study has directly compared the effectiveness of different types of mouth exercises in managing OSMF. Therefore, the present study aims to evaluate and compare the therapeutic outcomes of three distinct mouth exercise modalities in patients with Oral Submucous Fibrosis.

MATERIALS AND METHODS-

The study was designed as a randomized, assessor-blinded, parallel-group clinical trial involving 45 clinically and histopathologically diagnosed patients with Oral Submucous Fibrosis (OSMF).

Patient's selection and sample size calculation

The inclusion criteria consisted of patients aged 18 to 70 years who presented with clinical signs and symptoms of Grade II Oral Submucous Fibrosis (OSMF) and an inter-incisal mouth opening between 26 and 35 mm. Only patients who had quit the habit associated with OSMF were included. The exclusion criteria included patients with OSMF Grade I or III,

the presence of any other mucosal lesions such as malignant or suspicious ulcerative/proliferative lesions, a history of smoking, oral or systemic inflammatory conditions, temporomandibular joint disorders, pericoronitis of the lower third molars, dysplastic changes, and those who had previously received treatment such as intralesional steroids or other medical or surgical interventions. A detailed case history was obtained from all patients reporting to the outpatient department with complaints of reduced mouth opening and a history of tobacco/areca nut chewing habits. Clinical signs and symptoms of OSMF were assessed and recorded in a standardized study proforma. Patients fulfilling the inclusion and exclusion criteria and diagnosed clinically and histopathologically with OSMF, irrespective of gender, were included in the study. The sample size was calculated based on the expected difference in mean mouth opening between the three intervention groups, with a significance level of 5% and study power of 80%, resulting in a total sample of 45 participants, who were equally allocated into three groups of 15 each.

Randomization, clinical assessment, intervention and blinding

Patients meeting the eligibility criteria were randomly allocated into three groups using a computer-generated block randomization method. Allocation concealment was maintained using sealed, opaque envelopes containing the randomization codes, prepared by an independent individual not involved in the study. Due to the nature of the exercise interventions, participant blinding was not feasible. However, the investigator responsible for outcome assessment and measurement of interincisal distance was blinded to group allocation throughout the study period. The assigned interventions were administered by a separate investigator who was not involved in data collection or analysis (Figure 1). Prior to initiating the intervention and at each follow-up visit, a comprehensive intraoral examination was conducted. Interincisal distance was assessed using a vernier caliper, and patients were staged according to the classification proposed by Khanna JN and Andrade NN (1996). To confirm the diagnosis and evaluate for any dysplastic changes, a punch biopsy

of the lesion was performed for histopathological examination.

Interventions Common to All Groups

All patients were advised of the association between areca nut and OSMF, and recommended to cease areca nut/ tobacco use in any form, and advised to consume a bland diet avoiding spicy foods.

Group I – Ballooning Exercises: Participants in Group I were instructed in ballooning exercises. They were advised to blow into a balloon 4–5 times daily over a period of 8 weeks (Figure 2).

Group II – Ice-cream Stick Exercises: Participants in Group II were taught the ice-cream stick exercise for jaw stretching. They were instructed to perform the exercise five times daily for 8 weeks. The exercise involved passively inserting ice-cream sticks between the anterior teeth, with the number of sticks based on the participant's maximum comfortable mouth opening. The jaws were opened five times in each session and held in position with the teeth resting on the sticks for 1 minute per repetition. An additional stick was added every fifth day based on individual progress (Figure 3).

Group III – Mouth Opener Device Exercises: Participants in Group III were instructed to use a mouth opener device. They were advised to place the device between the incisor teeth and manually rotate it in a clockwise direction ten times, twice daily for 8 weeks (Figure 4).

Follow-Up and Assessment: All participants were evaluated at 2, 4, 6, and 8 weeks. During each follow-up visit, clinical assessments were conducted, and the relevant parameters were recorded and documented.

Statistical analysis

The data collected was entered into a Microsoft Excel sheet and then transferred to SPSS version 11.5 (Statistical Package for Social Sciences) for statistical analysis. Coding was assigned for data entry, and the data was monitored weekly. Friedman's two-way ANOVA test was used for intragroup comparisons, while the Kruskal-Wallis test was employed for

intergroup comparisons. The significance level was set at $\alpha = 0.05$.

RESULTS-

A total of 45 participants clinically diagnosed with Oral Submucous Fibrosis (OSMF) were included in this randomized clinical trial (Figure 1). Participants were equally allocated into three groups ($n = 15$ each). The mean age of participants was comparable among the groups, being 41.93 ± 8.09 years in Group I, 42.67 ± 10.40 years in Group II, and 41.20 ± 6.63 years in Group III. Male participants predominated in all groups, with Group I comprising 13 males and 2 females, Group II comprising 12 males and 3 females, and Group III comprising 13 males and 2 females.

Intragroup Comparison of Mouth Opening

All intervention groups demonstrated improvement in mouth opening over the 8-week follow-up period.

In Group I (Balloon Exercise), the mean mouth opening increased significantly from 29.20 mm at baseline to 31.40 mm at 8 weeks ($p < 0.001$). No statistically significant improvement was observed at 2 weeks ($p = 1.000$) or 4 weeks ($p = 0.130$); however, significant improvement was evident from the 6-week follow-up onward (Table 1).

In Group II (Ice Cream Stick Exercise), mean mouth opening progressively increased to 34.33 mm at 8 weeks, with an overall statistically significant improvement ($p < 0.001$). Although the change at 2 weeks was not significant ($p = 0.833$), significant increases were observed at 4, 6, and 8 weeks (Table 2).

In Group III (Mouth Opener Device), mean mouth opening improved from 29.33 mm at baseline to 33.27 mm at 8 weeks ($p < 0.001$). Similar to Group II, no significant change was noted at 2 weeks ($p = 0.941$), whereas statistically significant improvement was observed from 4 weeks onward (Table 3).

Intergroup Comparison

Comparison of percentage improvement in mouth opening among the three groups revealed superior outcomes in Group II, followed by Group III, whereas

Group I demonstrated the least improvement. These intergroup differences were statistically significant at all follow-up intervals (2, 4, 6, and 8 weeks) ($p < 0.001$) (Table 4, Figure 5).

Pairwise Comparison

Post hoc pairwise analysis demonstrated that both Group II and Group III achieved significantly greater improvement in mouth opening compared with Group I at all time points ($p < 0.05$). However, no statistically significant difference was observed between Group II and Group III ($p = 1.000$), indicating comparable clinical efficacy between these two interventions (Table 5). A subjective reduction in burning sensation was reported by participants in all three groups during the follow-up period.

DISCUSSION-

The present study evaluated and compared the clinical efficacy of three different mouth exercise modalities for improving mouth opening in patients with Oral Submucous Fibrosis (OSMF). The three study groups were demographically comparable, thereby minimizing potential confounding related to age and gender distribution and allowing a more reliable comparison of treatment outcomes. In the present study, the age of participants ranged from 26 to 65 years, with mean ages of 41.93 ± 8.09 years in Group I, 42.67 ± 10.40 years in Group II, and 41.20 ± 6.63 years in Group III. These findings are consistent with previous reports demonstrating that OSMF commonly affects individuals in the third to fifth decades of life. Srivastava et al. [14] reported patients aged 15–60 years, with the highest prevalence in the 30–40-year age group, followed by the 20–30-year group. Similarly, Nigam et al. [15] observed peak prevalence in the 36–40-year age group, while Kanjani et al. [16] reported an age range of 19–70 years. The predominance of disease in economically productive age groups may be related to increased social exposure, occupational stress, and easier access to areca nut and tobacco products. Male predominance was observed in the present study, with 84.4% males and 15.6% females. This is in agreement with previous epidemiological studies by Sinor et al. [17] and Srivastava et al. [14], who reported male prevalence rates of 97.67% and 97.33%, respectively. The higher prevalence among males may reflect

sociocultural patterns of areca nut, gutkha, and tobacco consumption. Chronic use of areca nut products remains a well-established etiological factor in OSMF, primarily through stimulation of fibroblast proliferation, increased collagen synthesis, and reduced collagen degradation, leading to progressive fibrosis of the oral mucosa [17]. All three intervention groups demonstrated significant improvement in mouth opening from baseline to the end of the 8-week follow-up period, indicating that regular physiotherapy can play an important role in the conservative management of OSMF-associated trismus. However, the magnitude and timing of improvement varied among the exercise modalities.

Group I (balloon exercise) showed progressive improvement in mouth opening from 29.20 mm at baseline to 31.40 mm at 8 weeks, with statistically significant improvement evident from the sixth week onward ($p < 0.001$). The relatively delayed response may be attributed to the lower intensity of the intervention and possible variability in patient compliance. Balloon exercise depends largely on self-motivation and consistent home-based performance, and delayed benefit may reflect irregular adherence during the early treatment period. Similar observations regarding the role of compliance in conservative therapy have been reported by Asha et al. [18]. Yadav et al. [19] also emphasized that successful management of OSMF requires cessation of deleterious habits together with regular physiotherapy exercises such as balloon blowing, water retention exercises, and jaw-stretching regimens.

Group II (ice cream stick exercise) demonstrated the greatest overall improvement, increasing from 30.27 mm at baseline to 34.33 mm at 8 weeks, with significant changes beginning from the fourth week onward. This suggests that incremental passive stretching using ice cream sticks may provide a more effective and controlled mechanical stimulus for improving mucosal flexibility and reducing fibrosis-related restriction. Cox et al. [8] similarly reported substantial improvement in mouth opening using tongue spatulas or ice cream stick physiotherapy, particularly in patients with more severe baseline restriction. Patil et al. [20] also observed improvement in mouth opening and symptomatic relief with

structured physiotherapy devices, supporting the value of mechanical stretching in OSMF management.

Group III (mouth opener device) also showed marked improvement, from 29.33 mm at baseline to 33.27 mm at 8 weeks, with statistically significant gains from the fourth week onward. Although slightly lower than Group II, the improvement was clinically meaningful and indicates that device-assisted stretching can be an effective alternative. Mechanical devices may help deliver more standardized and reproducible force compared with unsupervised exercises. Patil et al. [20] and Arora et al. [12] have similarly reported favorable outcomes with jaw-opening devices and adjunctive physiotherapy approaches. Furthermore, Van Beekvelt et al. [21] demonstrated that moderate exercise improves local blood flow and oxygen uptake, which may contribute to enhanced tissue remodeling and functional recovery. Comparison of percentage improvement provided additional insight into treatment efficacy. Group II consistently showed the highest percentage increase in mouth opening (13.60% at 8 weeks), followed closely by Group III (13.57%), whereas Group I demonstrated comparatively lower improvement (7.60%). Intergroup differences were statistically significant at all measured intervals. These findings suggest that structured passive stretching techniques may be superior to balloon exercise alone in overcoming fibrotic restriction. Pairwise comparisons further confirmed that Groups II and III achieved significantly greater improvement than Group I at all follow-up intervals ($p < 0.01$). However, no statistically significant difference was observed between Groups II and III ($p = 1.000$), indicating comparable efficacy of these two modalities. This suggests that both low-cost manual methods such as ice cream stick exercises and commercially available mouth-opening devices may provide similar clinical benefit when used consistently. Therefore, treatment selection may reasonably depend on patient affordability, convenience, availability, and expected compliance rather than efficacy alone. The findings of the present study reinforce the importance of structured physiotherapy as a core component in the management of OSMF-related trismus. Several authors have advocated early multimodal

intervention, including habit cessation, nutritional support, pharmacotherapy, and physiotherapy, to reduce morbidity and prevent disease progression [16,19]. In clinical practice, patient motivation and adherence remain critical determinants of treatment success, particularly for home-based exercise programs. Mouth exercises demonstrated promising results in improving mouth opening and enhancing oral mucosal flexibility in patients with OSMF. As OSMF is a potentially malignant disorder with risk of malignant transformation, early and sustained intervention is essential. Incorporation of mouth-opening exercises, either alone or in combination with other therapeutic modalities, may significantly improve functional outcomes and quality of life. Nevertheless, larger randomized studies with longer follow-up periods are required to validate these findings and establish standardized evidence-based exercise protocols for routine clinical use.

CONCLUSION-

Within the limitations of the present study, all three exercise modalities demonstrated beneficial effects in improving mouth opening in patients with Oral Submucous Fibrosis (OSMF). However, the ice cream stick exercise and mouth opener device produced significantly greater improvement compared with balloon exercise, with comparable efficacy between these two modalities. These findings suggest that structured physiotherapy, particularly progressive stretching exercises, plays an important role in the conservative management of OSMF-related trismus. As OSMF is a chronic, progressive, and potentially malignant disorder, early intervention

combined with habit cessation and regular follow-up is essential. Mouth exercise therapy, either as a standalone supportive measure or in combination with pharmacological and other treatment approaches, may help improve functional outcomes and oral quality of life. Further large-scale randomized controlled trials with longer follow-up periods are recommended and develop standardized rehabilitation protocols for OSMF management.

Limitations of the Study

This study has certain limitations. The relatively small sample size and single-center design may limit generalizability. The 8-week follow-up period was short for assessing long-term outcomes or recurrence. Participant blinding was not feasible due to the nature of the interventions, and compliance with home-based exercises could not be fully standardized. Only Grade II OSMF patients were included, limiting applicability to other stages of the disease. In addition, burning sensation was not quantitatively recorded using a validated scale, which limited objective assessment of symptomatic improvement. Future studies with larger samples and longer follow-up are recommended.

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Conflict of Interest: The authors declare no potential conflict of interest.

Data Availability: The data is available through contact with the corresponding author.

Figures-

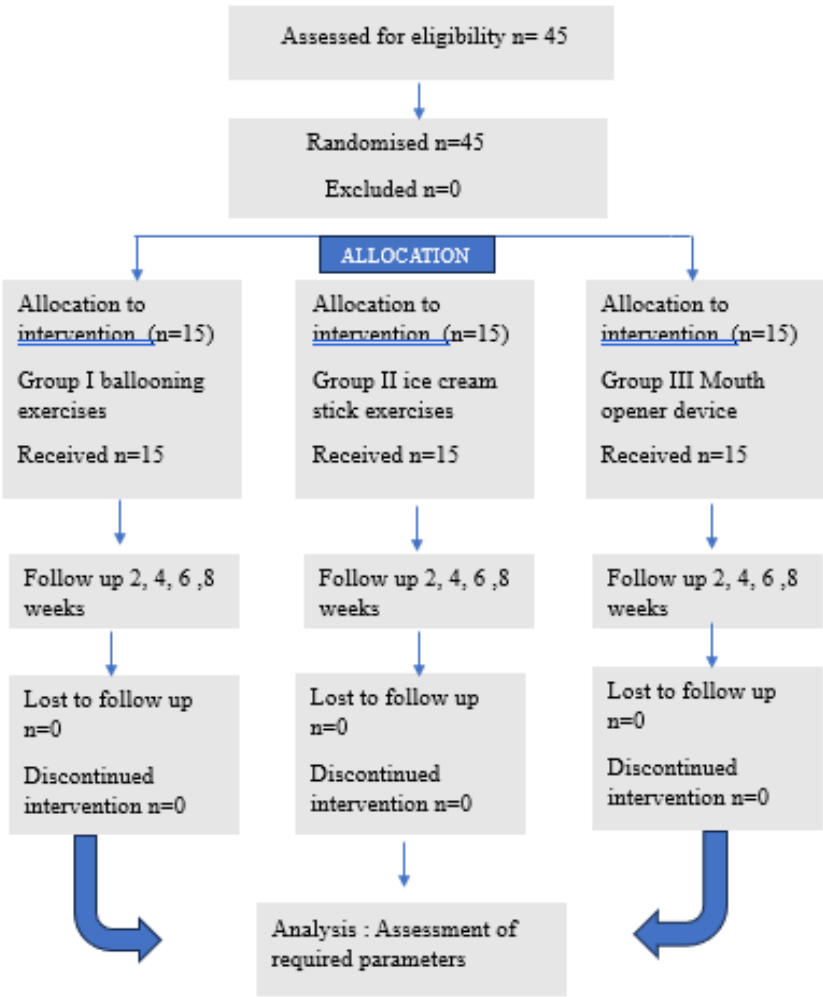


Figure 1. CONSORT Participant Flow Diagram



Figure 2 – Balloon blowing exercise



Figure 3- Ice cream stick exercise



Figure 4- Mouth opener device

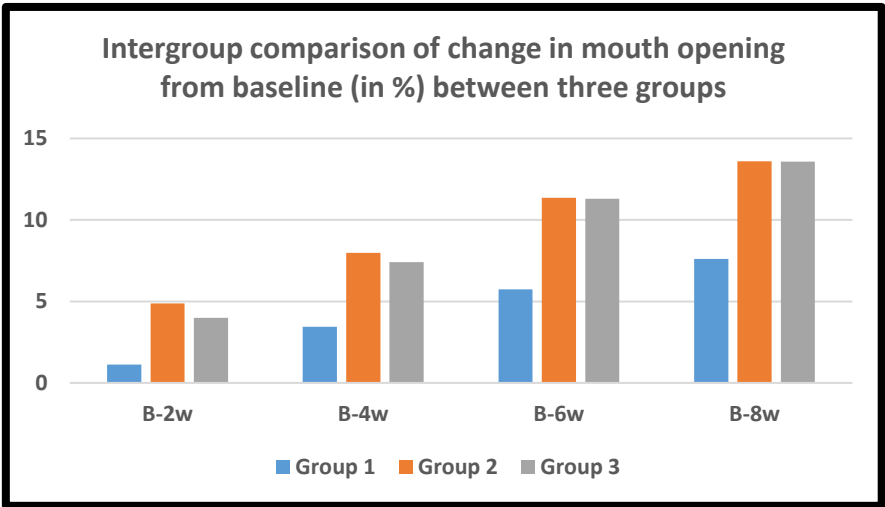


Figure 5: Intergroup comparison of change in mouth opening from baseline (in %) between three groups

Table 1: Intragroup comparison of mouth opening at different time points within Group 1

Interval	Mean	SD	p-value	Change from baseline
MOB	29.20	3.73	<0.001*	
MO2W	29.53	3.87		2w = 1.000
MO4W	30.20	3.93		4w = 0.130
MO6W	30.87	3.94		6w = <0.001*
MO8W	31.40	3.98		8w = <0.001*

Friedman's Two-way ANOVA test; * indicates a significant difference at $p \leq 0.05$

Table 2: Intragroup comparison of mouth opening at different time points within Group 2

Interval	Mean	SD	p-value	Change from baseline
MOB	30.27	3.01	<0.001*	
MO2W	31.73	3.13		2w = 0.833
MO4W	32.67	3.16		4w = 0.004*
MO6W	33.67	3.11		6w = <0.001*
MO8W	34.33	3.04		8w = <0.001*

Friedman's Two-way ANOVA test; * indicates a significant difference at $p \leq 0.05$

Table 3: Intragroup comparison of mouth opening at different time points within Group 3

Interval	Mean	SD	p-value	Change from baseline
MOB	29.33	2.44	<0.001*	
MO2W	30.47	2.13		2w = 0.941
MO4W	31.47	2.20		4w = 0.015*
MO6W	32.60	2.23		6w = <0.001*
MO8W	33.27	2.37		8w = <0.001*

Friedman's Two-way ANOVA test; Post hoc Bonferroni test; * indicate a significant difference at $p \leq 0.05$

Table 4: Intergroup comparison of change in mouth opening from baseline (in %) between three groups

Change	Group 1		Group 2		Group 3		p-value
	Mean	SD	Mean	SD	Mean	SD	
B-2w	1.13	2.18	4.88	2.25	4.00	2.47	0.002*
B-4w	3.44	3.09	7.99	2.57	7.42	2.90	<0.001*
B-6w	5.74	2.79	11.36	3.70	11.31	3.51	<0.001*
B-8w	7.60	3.46	13.60	3.52	13.57	3.91	<0.001*

Kruskal Wallis test; * indicates a significant difference at $p \leq 0.05$

Table 5: Pairwise comparison of the change in mouth opening from baseline (in %) between three groups

Change	Group 1 vs Group 2	Group 1 vs Group 3	Group 2 vs Group 3
B-2w	0.002*	0.018*	1.000
B-4w	0.001*	0.003*	1.000
B-6w	0.001*	0.001*	1.000
B-8w	0.001*	0.003*	1.000

Post hoc Bonferroni test; * indicates a significant difference at $p \leq 0.05$.

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