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# A COMPARATIVE STUDY ON EFFICACY OF INTRALESIONAL DEXAMETHASONE/ HYALURONIDASE, METHYLPREDNISOLONE /HYALURONIDASE AND TRIAMCINOLONE/ HYALURONIDASE IN PATIENTS WITH ORAL SUBMUCOUS FIBROSIS

Dentistry

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## ABSTRACT

**Background-** Oral submucous fibrosis (OSMF) is a potentially malignant disorder affecting the oral cavity, causing progressive trismus and dysphagia. Patients experience a burning sensation and trismus, affecting normal function. Intralesional corticosteroids combined with Hyaluronidase can reduce these symptoms. However, the efficacy of these steroids varies, leading to clinical outcomes. This study aimed to compare the efficacy of Dexamethasone, Methylprednisolone and Triamcinolone in OSMF patients. **Objectives-** To compare and evaluate the clinical efficacy of Intralesional Dexamethasone 8mg/2ml, Methylprednisolone 40mg/ml and Triamcinolone 40mg/ml in combination with Hyaluronidase 1500 IU in patients with Oral Submucous Fibrosis. **Materials and Methods-** The present study was performed with a total of 30 patients grouped into Group A ( Intralesional infiltration of Dexamethasone 8mg/2ml & Hyaluronidase 1500IU dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution once a week for 8 weeks), Group B (Intralesional Methylprednisolone 40mg/ml + 0.5ml of distilled water and Hyaluronidase 1500 IU dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution once a week for 8 weeks ) and Group C (intralesional Triamcinolone 40mg/ml + 0.5ml of distilled water and Hyaluronidase 1500IU dissolved in 0.5ml of 2 % Lignocaine HCl with adrenaline in 1:80,000 dilution once a week for 8 weeks). **Results:** Statistical analysis revealed statistically significant improvement in Maximum Mouth Opening (M.M.O) in Group A (6.05 ± 1.9mm), Group B (3.6 ± 1.5) and Group C (2.4 ± 1.1) and reduction in VAS scores of 2.9 ± 1.3, 3 ± 2.6 and 2.4 ± 2.3 respectively after treatment. When intergroup comparisons were made there was statistically significant improvement in M.M.O in Group A compared to Group B and Group C. A comparison between Groups B and C revealed slightly greater improvement in M.M.O in Group B compared to Group C. There was a statistically insignificant difference in the reduction of a burning sensation among the three groups. **Conclusion:** The study found that patients receiving intralesional Dexamethasone / Hyaluronidase therapy showed better improvement in OSMF symptoms, followed by those receiving Methylprednisolone/Hyaluronidase and Triamcinolone/Hyaluronidase.

## KEYWORDS

Oral Submucous Fibrosis. Intralesional Injections. Trismus.

## INTRODUCTION

Indians and Southeast Asians are susceptible to the chronic, progressive, and potentially fatal illness known as oral submucous fibrosis (OSMF). The most powerful risk factor for this multifactorial illness is chewing betel quid, which contains areca nut. [1,2] Tobacco, chillies, spices, inadequate diet, iron and vitamin deficiencies, genetic predisposition, and autoimmune are other contributing factors. Patients with OSMF have trismus and a burning feeling that interferes with their ability to operate normally.[3] Utilizing intense physical therapy to take advantage of the disease's capacity for tissue remodelling, treatment focuses on enhancing mouth openness and quitting the quid habit.[4]

This study aims to compare the efficacy of intralesional Dexamethasone 8mg/2ml & Hyaluronidase 1500 IU, Triamcinolone 40 mg/ml & Hyaluronidase 1500 IU and Methylprednisolone 40mg/ml & Hyaluronidase 1500 IU in OSMF patients.The effectiveness depends on their pharmacokinetics and pharmacodynamics, and further evaluation is needed to determine optimal clinical outcomes.

## AIMS & OBJECTIVES

1. To evaluate and compare the clinical efficacy of intralesional Dexamethasone 8mg/2ml & Hyaluronidase 1500 IU and intralesional Methylprednisolone 40mg/ml & Hyaluronidase dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution in patients with OSMF.
2. To evaluate and compare the clinical efficacy of intralesional Methylprednisolone 40mg/ml & Hyaluronidase 1500 IU and intralesional Triamcinolone 40mg/ml & Hyaluronidase 1500 IU dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution in patients with OSMF.
3. To evaluate the clinical efficacy of intralesional Dexamethasone 8mg/2ml & Hyaluronidase 1500 IU and intralesional Triamcinolone 40mg/ml & Hyaluronidase 1500 IU dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution in patients with OSMF.

## MATERIALS AND METHODS

**A. Source of Data:** Patients attending the Department of Oral medicine and Radiology in Panineeya Mahavidyalaya Institute of Dental Sciences and Research Centre, Hyderabad with signs and symptoms suggestive of OSMF Group II (Khanna JN and Andrade NN) were included in the study. Institutional ethical clearance was obtained before the conduct of the study by the Institutional Ethical Committee (PMVIDS & RC/IEC/OMR/DN/0089-16) and written consent was obtained from each patient following the Helsinki guidelines.

**B. Method of Collection of Data**

**Study Design:**

In a prospective randomized single-blinded clinical control trial, a total of 30 patients, were randomly divided into 3 groups by simple sampling method with 10 patients in each group.

**Inclusion Criteria**

1. Patients with OSMF who are willing to participate in the study.
2. Patients of Group II OSMF (Khanna JN and Andrade NN).

**Exclusion Criteria**

1. Patients with OSMF other than Group II OSMF (Khanna JN and Andrade NN).

2. Patients below the age of 18 years.
3. Patients allergic to medications used in the study.
4. Patients with a known history of systemic diseases, where steroids are contraindicated.
5. Pregnant women.
6. OSMF associated with malignancy.
7. Patients with a previous history of treatment with intralesional corticosteroids within 1 year.
8. OSMF patients with oro-facial infections.
9. Patients who are unwilling to quit various deleterious habits containing areca nut or tobacco-related products.

**Methodology**

A detailed case history was obtained after having selected the subject. Patients who were diagnosed with OSMF by clinical examination were subjected to routine blood investigations and were randomly assigned to different treatment groups burning sensation was measured by the Visual Analog Scale (VAS scale), and the mouth opening and tongue protrusion were recorded with vernier callipers. The patient's hypersensitivity to medications was checked with a test dose and then administered.

**Group A:** Intralesional Dexamethasone 8mg/2ml and Hyaluronidase 1500 IU dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution once a week for 8 weeks.

**Group B:** Intralesional Methylprednisolone 40mg/ml + 0.5ml of distilled water and Hyaluronidase 1500IU dissolved in 0.5 ml of 2% Lignocaine HCl with adrenaline in 1:80,000 dilution once a week for 8 weeks.

**Group C:** Intralesional Triamcinolone 40mg/ml + 0.5ml of distilled water and Hyaluronidase 1500IU dissolved in 0.5ml of 2 % Lignocaine HCl with adrenaline in 1:80,000 dilution once a week for 8 weeks.

All 30 patients were advised to engage in physical exercises, including ice-cream sticks and cheek-blowing exercises, at least thrice daily for 10 minutes to increase mouth opening.

The VAS ordinal scale was used to assess the clinical improvement in burning sensation. Weekly mouth-opening measurements were taken using vernier callipers, and the data was recorded while patients were frequently checked for indications of adrenal suppression.

**OBSERVATIONS AND RESULTS**

The obtained data was subjected to statistical analysis by an expert statistician using SPSS 20.0 software. A paired sample T-test was used to analyse the changes in mouth opening and burning sensation with respective treatment modalities. An Independent t-test was used to compare the change in mean mouth opening and mean VAS scores between the two groups. (Group A & B; Group B & C; Group A & C). ANOVA test was used to compare the change in Mean Mouth opening (M.M.O) and Mean VAS scores among three groups Group A, Group B, and Group C. The p-value < 0.05 was considered to be statistically significant.

A prospective clinical randomised control trial of a total of 30 patients was done and 10 patients were assigned each Group A, B and C treatment modalities respectively by simple sampling method.

**Age Distribution**

The distribution of subjects according to age showed no significant difference in the three groups, representing a homogeneity in age distribution among 3 groups.

**Group A (Intralesional Dexamethasone/Hyaluronidase):**

There was a significant improvement in mouth opening following Dexamethasone injection from 29.65 ± 2.4 mm (1st week) to 32.35 ± 3 mm (4th week) with p-value 0.000, with an improvement of 2.7 ± 0.9 mm and to 35.7 ± 3.6mm (8th week) with p-value 0.000, with a total improvement of 6.05 ± 1.9 mm. It also revealed a significant decrease in burning sensation following Dexamethasone injection from 3.4 ± 1.5 (1st week) to 1.8 ± 1.3 (4th week) with p-value 0.000, a decrease of 1.6 ± 0.6 and to 0.5 ± 0.7 (8th week) with p-value 0.000, a total reduction of 2.9 ± 1.3.

**Group B (Intralesional Methylprednisolone/Hyaluronidase)**

There was significant improvement in mouth opening following Methylprednisolone injection from 29.50 ± 4.4 mm (1st week) to 31.30 ± 4.8mm (4th week) with p-value 0.000, an increase of 1.8 ± 0.8 and to 33.10 ± 4.8 mm (8th week) with p-value 0.000, a total increase of 3.6 ± 1.5 Significant decrease in burning sensation following Methylprednisolone injection from 3.5 ± 2.9 (1st week) to 1.30 ± 1.5 (4th week) with p-value 0.011, a reduction of 2.2±2.1 and to 0.50 ± 1.08 (8th week) with p-value 0.006, a total decrease of 3 ± 2.6.

**Group C (Intralesional Triamcinolone/Hyaluronidase)**

There was a significant improvement in mouth opening following the Triamcinolone injection from 28.8 ± 3.4 mm (1st week) to 30.2 ± 3.8 mm (4th week) with p-value 0.002, an increase of 1.4 ± 1 and to 31.2 ± 3.8 mm (8th week) with p-value 0.000, an increase of 2.4 ± 1.1. With a significant decrease in burning sensation following Triamcinolone injection from 3.5 ± 3.4 (1st week) to 1.8 ± 2.6 (4th week) with p-value 0.022, a reduction of 1.7 ± 1.9, and to 1.1 ± 1.9(8th week) with p-value 0.011, a decrease of 2.4 ± 2.3.

**Comparison Between Group A and Group B**

Group A had greater mouth opening when compared to Group B at the end of the 4th and 8th week, which was statistically significant. [Table 1] Group B had a slightly greater reduction in burning sensation when compared to Group A at the end of the 4th and 8th week, which was not statistically significant. [Table 2]

**Comparison Between Group A and Group C**

Group A had a statistically significant increase in mouth opening when compared to Group C at the end of the 4th and 8th weeks. [Table 3] Depending on the VAS scores, Group A and Group C had almost similar efficacy in reducing the burning sensation at the end of the 4th and 8th week which was not statistically significant. [Table 4]

**Comparison Between Group B and Group C**

For Group B and Group C, the mouth opening revealed no satisfactory difference at the end of the 4th week. Group B had a higher increase in mouth opening when compared to Group C at the end of the 8th week, which was not statistically significant. [ Table 5] with a greater reduction in burning sensation than Group C at the end of the 4th and 8th week, which is not statistically significant. [Table 6]

**Comparison of Mouth Opening Between Group A, Group B & Group C**

A one-way analysis of Variance (ANOVA) was done to determine significant differences in the mean among the three groups. Analysis revealed a statistically significant difference in mouth opening among three groups at the end of the 4th and 8th week with a p-value of 0.016 and 0.000 respectively.

**Comparison of Burning Sensation Between Groups A, B & C**

ANOVA revealed a statistically insignificant difference in burning sensation among the three groups at the end of the 4th and 8th week with a p-value of 0.710 and 0.810, respectively.

**DISCUSSION**

With a high mortality rate of 7.6%, OSMF is a chronic oral cavity illness that can lead to malignant consequences and nutritional deficits. It is associated with chewing areca nuts and is typified by a reduction in fiber breakdown and an increase in collagen formation. With particular TGF-beta targets (CoL1A2, COL3A1, CoL6A1, COL6A3, and COL7A1) discovered in early fibroblast development, the quid's constituents may alter collagen-associated genes. [5]

Most patients chew on Gutka, a mixture of areca nut, tobacco, and flavourings. The prevalence of OSMF in younger age groups may be related to peer influence, stress, and addiction.The present study reveals male predominance (82% male vs 18% female) with a male: female ratio of 9:1 in OSMF cases following the studies conducted by Punnya V et al [6] and Ranganathan K et al [7] with a ratio of 11:1 and 9.9:1 respectively, and also with Rupak S et al, [8] KS Ganapathy et al, [9] Lavina Taneja et al and Vanaja Reddy et al. [10]

According to this study, patients who chewed tobacco and commercially available areca nut products reported symptoms including burning, soft palate, reduced cheek flexibility and mouth opening, and blanching of the buccal mucosa. Clinical characteristics that were taken into consideration in this investigation were burning sensation and limited mouth opening.

Intralesional corticosteroids are widely used to treat OSMF; however, there are only two studies on methylprednisolone, and several on triamcinolone acetonide, dexamethasone, and hydrocortisone. [11]

The primary mechanism of action of corticosteroids is immune modulation. Fibrosis is caused by inflammation inhibition and a rise in immune-mediated fibrinolytic pathways. [12] The mucopolysaccharide hyaluronic acid is broken down by the enzyme hyaluronidase.

Intralesional Hyaluronidase in combination with intralesional Dexamethasone was used in the treatment of OSMF in studies by Leena James et al [13], Palak Hashmukh Bhai et al [14], Patel TL and Surjeeth Singh et al [15], Pokharel K Prenit et al [16], used intralesional Hyaluronidase in combination with intralesional Triamcinolone acetonide.

The synthetic counterpart of prednisolone employed in this study, dexamethasone, has a stronger anti-inflammatory therapeutic impact as well as a variety of hormonal and metabolic effects. When compared to other corticosteroids, the modification of the fundamental corticoid structure provided by the 4 mg/ml injection of dexamethasone provides a stronger anti-inflammatory impact. Compared to topical and oral steroid therapy, intralesional injection has the benefit of having stronger anti-inflammatory effects, which makes it more beneficial for deep-seated disorders that impact the injected region. [17]

The mouth opening and burning sensation VAS ratings significantly improved in Group A patients of the current research who received intralesional infiltration of 2 ml Dexamethasone 4 mg/ml and Hyaluronidase 1500IU with 2% Lignocaine HCl.According to James et al.'s evaluation of the effectiveness of the Hyaluronidase and Dexamethasone combination in treating OSMF, there was a noticeable improvement in mouth opening (92.85%) and a decrease in burning sensation (89.28%). In line with the current study, the net gain in mouth openness was 6 ± 2 mm [13]

The effectiveness of hyaluronidase and dexamethasone intralesional injections in the treatment of OSMF was assessed by Santosh R. Patil et al. [18] Patients received intralesional injections of hyaluronidase 1,500 IU combined with 1.5 ml of dexamethasone and 0.5 ml of lignocaine HCL twice a week for a month, in addition to a basic physiotherapy regimen that included mouth exercises twice a day. Following therapy, mild to severe instances of OSMF showed a notable improvement in mouth opening and a decrease in burning sensation.

A statistically significant increase in mouth opening and a decrease in burning sensation (VAS ratings) were observed in Group B patients who received intralesional infiltration of methylprednisolone (40 mg/ml) and hyaluronidase (1500 IU) with 2% lignocaine. This finding aligns with the results of a study conducted by Omar Arshad et al., which remains the only investigation on 45 OSMF patients utilizing a similar protocol. In their study, patients receiving intralesional methylprednisolone acetate (40 mg/ml) demonstrated an average increase in mouth opening of 3.46 mm [19].Further supporting the current findings, Chhabra AK et al. evaluated the efficacy of intralesional methylprednisolone therapy in patients with active Peyronie's disease. Administered once weekly for eight weeks at a dose of 40 mg, the treatment led to a reduction in mean ratings of penile pain, discomfort, and symptom severity from 12.3, 19.1, and 6.2 to 8.9, 9.6, and 4.4, respectively. Notably, no adverse effects were reported during or after therapy [20]. A similar therapeutic regimen was employed in the present study.

Triamcinolone is a long-acting glucocorticoid that inhibits the immune response by preventing sensitized cells from releasing cytokines once a particular antigen is activated.Group C, which received an intralesional injection of Triamcinolone 40 mg/ml and Hyaluronidase 1500 IU with 2% Lignocaine HCl, shown a substantial improvement in mouth opening in the current research. After eight weeks of therapy, a notable decrease in the burning feeling was seen.

In a prospective trial of OSMF patients, Panigrahi R. and Maheshwari A. treated Group A with a combination of 1 ml Triamcinolone acetonide (10 mg/ml) and Hyaluronidase (1500 IU), whereas Group B received 1 ml Triamcinolone acetonide (10 mg/ml) alone. They came to the conclusion that, in terms of symptom relief and patient convenience, an intraoral injection of a combination of triamcinolone acetonide and hyaluronidase is better than triamcinolone alone. [21]

An independent sample test used in this study to compare the intralesional Dexamethasone group A and the intralesional Methylprednisolone group B revealed that patients in the Dexamethasone group had significantly more mouth opening than those in the Methylprednisolone group. After four weeks, the mean difference and standard deviation in burning sensation between the two groups were determined to be statistically insignificant, suggesting that both groups were equally effective in reducing burning sensation. Comparing the effectiveness of intralesional Dexamethasone/Hyaluronidase with intralesional Methyl-prednisolone/Hyaluronidase has never been done before.

When the intralesional Dexamethasone group (A) and the intralesional Triamcinolone group (C) were compared in this study, the mean difference in mouth opening and SD after four weeks were found to be statistically significant, indicating that the intralesional Dexamethasone group had significantly improved mouth opening when compared to the intralesional Triamcinolone group. After four weeks, the mean difference between the burning feeling and SD was determined to be statistically insignificant, suggesting that both methods were equally effective in lessening the burning sensation.Similar to the current study, Patel TL and Surjeeth Singh's study on 84 OSMF patients found that at the end of treatment with intralesional Dexamethasone/Hyaluronidase 4 mg/ml and intralesional Triamcinolone/Hyaluronidase 10 mg/ml, there was a mean difference and SD in mouth opening 2.38 ± 0.75 and burning sensation 0.86 ± 0.85. [15]

Comparison between the intralesional Methylprednisolone group (B) and intralesional Triamcinolone group (C) in the present study had a mean difference in mouth opening and SD. Though intralesional Methylprednisolone showed slightly greater improvement in mouth opening, the difference was found to be statistically insignificant, showing almost similar efficacy of the intralesional Methylprednisolone group and intralesional Triamcinolone group in improving mouth opening. Mean difference and SD in reducing burning sensation after 4 weeks was found to be statistically insignificant, showing their equal efficacy in reducing burning sensation in OSMF patients. No similar studies were reported in the literature previously comparing the efficacy of intralesional Methylprednisolone/ Hyaluronidase and intralesional Triamcinolone/ Hyaluronidase.

In this study, the three groups' improvements in mouth opening were statistically significant, whereas the burning sensation was statistically inconsequential. The intralesional Dexamethasone group showed the most improvement in mouth opening, with a maximum improvement of 8.5 mm. This was followed by the intralesional Methylprednisolone group, which showed a maximum improvement of 6 mm, and the intralesional Triamcinolone group, which showed a maximum improvement of 4 mm. Nonetheless, the three groups are equally effective in lessening the burning feeling.

Mohammed Khareemullah Khan et al. conducted a comparative study between the groups' Hydrocortisone (50 mg/ml), Dexamethasone (4 mg/ml), and Triamcinolone (40 mg/ml) in combination with Hyaluronidase (1500 IU). The results showed that the Hydrocortisone & Hyaluronidase group improved mouth opening by 80% and reduced burning sensations by 100%, the Dexamethasone & Hyaluronidase group showed 77.7% improvement in mouth opening and 90% reduction in burning sensations, and the Triamcinolone group showed 90% improvement in mouth opening and 100% reduction in a burning sensation. [22]While previous literature highlights triamcinolone's efficacy in managing OSMF, the present study demonstrated better clinical outcomes with Dexamethasone, This difference may be due to variations in patient selection, staging ,uniformity in dosing, follow-up protocol.

Corticosteroid side effects include weight gain, impaired growth, adrenal insufficiency, increased susceptibility to infection, myopathy, osteoporosis, osteonecrosis, cataract, glaucoma, fractures, hypertension, insomnia, diabetes, and peptic ulcers, according to a review of the drug by Vigneshwar Sambandam and Prasanna Neelakantan. [23] The current study did not report any such negative effects.

To help break the fibrous bands and improve local vascularity, patients in the current investigation were advised to perform physical mouth-opening exercises of the oral cavity by placing fingers in the mouth and the thumb over the cheek. They were also instructed to perform physical exercises to increase mouth opening with the aid of ice-cream sticks and cheek blowing exercises at least three times a day for ten

minutes each time. This was done in addition to intralesional steroid therapy.

## CONCLUSION AND LIMITATIONS

Intralesional administration of hyaluronidase combined with corticosteroids remains an effective and economical treatment modality for Grade II Oral Submucous Fibrosis (OSMF), with significant improvement in mouth opening and reduction in morbidity. Among the various steroid options, the combination of dexamethasone and hyaluronidase consistently demonstrated superior clinical outcomes. Additionally, methylprednisolone was evaluated and found to yield outcomes comparable to other corticosteroids; however, it did not demonstrate statistically significant superiority. Therefore, while multiple steroidal options appear effective, dexamethasone remains the preferred agent due to its consistent efficacy profile. Long-term studies are warranted to assess relapse rates and to solidify the most effective maintenance strategy.

**Table 1- Comparison Of Mean Difference In Mouth Opening Between Group A And Group B At Mid-treatment (after 4 Weeks) And After Treatment (after 8 Weeks).**

| Independent Sample test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | | |
| | t | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% CI of the Difference | |
| | | | | | | Lower | Upper |
| Mouth opening After 4 weeks | 2.190 | 18 | 0.042* | 0.900 | 0.4110 | 0.0366 | 1.7634 |
| Mouth opening After 8 weeks | 3.145 | 18 | 0.006** | 2.450 | 0.7791 | 0.8132 | 4.0868 |

**Table 2- Comparison Of Mean Difference In Burning Sensation Between Group A And Group B At Mid-treatment (after 4 Weeks) And After Treatment (after 8 Weeks).**

| Independent Sample test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | | |
| | t | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% CI of the Difference | |
| | | | | | | Lower | Upper |
| Burning sensation After 4 weeks | 0.835 | 18 | 0.415 | 0.600 | 0.7188 | -0.9101 | 2.1101 |
| Burning sensation After 8 weeks | 0.105 | 18 | 0.917 | 0.1000 | 0.9481 | -1.8919 | 2.0919 |

**Table 3- Comparison Of Mean Difference In Mouth Opening Between Group A And Group C At Mid-treatment (after 4 Weeks) And After Treatment (after 8 Weeks).**

| Independent Sample test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | | |
| | T | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% CI of the Difference | |
| | | | | | | Lower | Upper |
| Mouth opening after 4weeks | 2.948 | 18 | 0.009* | 1.300 | 0.4410 | 0.3736 | 2.2264 |
| Mouth opening After 8 weeks | 5.243 | 18 | **0.000**** | 3.650 | 0.6962 | 2.1873 | 5.1127 |

**Table 4- Comparison Of Mean Difference In Burning Sensation Between Group A And Group C At Mid-treatment (after 4 Weeks) And After Treatment (after 8 Weeks).**

| Independent Sample test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | | |
| | t | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% CI of the Difference | |
| | | | | | | Lower | Upper |
| Burning sensation After 4 weeks | 0.153 | 18 | 0.880 | 0.100 | 0.6540 | -1.2741 | 1.4741 |
| Burning sensation After 8 weeks | 0.578 | 18 | 0.570 | -0.500 | 0.8647 | -2.3168 | 1.3168 |

**Table 5- Comparison Of Mean Difference In Mouth Opening Between Group B And Group C At Mid-treatment (after 4 Weeks)**

| Independent Sample test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | | |
| | T | Df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% CI of the Difference | |
| | | | | | | Lower | Upper |
| Mouth opening After 4 weeks | -0.934 | 18 | 0.364 | -0.400 | -0.4282 | -1.2996 | 0.4996 |
| Mouth opening After 8 weeks | -1.988 | 18 | 0.062 | -1.200 | 0.6037 | -2.4683 | 0.0683 |

**Table 6- Comparison Of Mean Difference In Burning Sensation Between Group B And Group C At Mid-treatment (after 4 Weeks) And After Treatment (after 8 Weeks).**

| Independent Sample test | | | | | | | |
|---|---|---|---|---|---|---|---|
| | t-test for Equality of Means | | | | | | |
| | T | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% CI of the Difference | |
| | | | | | | Lower | Upper |
| Burning sensation After 4 weeks | 0.543 | 18 | 0.594 | 0.5000 | 0.9201 | -1.4332 | 2.4332 |
| Burning sensation After 8 weeks | 0.532 | 18 | 0.601 | 0.6000 | 1.1274 | -1.7687 | 2.9687 |

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