e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(2); 1941-1947

Original Research Article

Use of Pre- and Post-Treatment Comparison of Intralesional Dexamethasone Plus Hyaluronidase in the Management of Patients with Oral Submucous Fibrosis: A Retrospective Study

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Received: 24-12-2025 / Revised: 23-01-2026 / Accepted: 25-02-2026
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Conflict of interest: Nil

Abstract:

Background: Oral submucous fibrosis (OSMF) is a chronic, progressive, and potentially malignant disorder characterized by fibrosis of the oral mucosa leading to restricted mouth opening and burning sensation. Intralesional corticosteroid therapy combined with hyaluronidase has been widely used as a conservative treatment modality. However, limited retrospective data exist evaluating the effectiveness of this combination therapy using objective pre- and post-treatment comparisons.

Aim: To evaluate the effectiveness of intralesional dexamethasone combined with hyaluronidase in patients with oral submucous fibrosis by comparing pre- and post-treatment clinical parameters.

Materials and Methods: This retrospective observational study was conducted in the Department of ENT DMCH over a period of one year. A total of 100 patients with Grade II and Grade III OSMF were included. Weekly bilateral intralesional injections of dexamethasone (4 mg/mL, 2 mL) and hyaluronidase (1500 IU) were administered for 6 weeks. Clinical parameters assessed included maximal interincisal mouth opening, burning sensation using Visual Analog Scale (VAS), and cheek flexibility. Pre- and post-treatment values were compared using paired Student's t-test. A p-value <0.05 was considered statistically significant.

Results: The mean mouth opening improved significantly from 23.6 ± 4.1 mm to 33.1 ± 4.8 mm ($p < 0.001$). Burning sensation decreased from 7.5 ± 1.2 to 2.4 ± 1.0 ($p < 0.001$). Cheek flexibility increased from 6.4 ± 1.3 mm to 9.8 ± 1.7 mm ($p < 0.001$). All parameters showed highly significant improvement following treatment.

Conclusion: Intralesional dexamethasone combined with hyaluronidase is an effective and reliable non-surgical treatment modality for moderate oral submucous fibrosis. Significant improvements in mouth opening, mucosal flexibility, and symptomatic relief were observed.

Keywords: Oral Submucous Fibrosis, Dexamethasone, Hyaluronidase, Intralesional Therapy, Mouth Opening.
DOI: 10.25258/ijcpr.18.2.321

Introduction

Oral submucous fibrosis (OSMF) is a chronic, progressive disorder of the oral cavity characterized by juxta-epithelial fibrosis and progressive rigidity of the oral mucosa leading to trismus and functional impairment. The disease has a strong association with areca nut chewing and is widely prevalent in South and Southeast Asia. [1]

OSMF is recognized as a potentially malignant disorder with malignant transformation rates ranging between 3% and 19%, making early diagnosis and treatment essential. [2] The pathological hallmark of the condition is excessive collagen deposition within the lamina propria and submucosa, resulting in stiffness of oral tissues and progressive limitation of mouth opening. [3]

The disease commonly affects young and middle-aged individuals and presents clinically with burning sensation, intolerance to spicy foods, blanching of mucosa, and restricted mouth opening. [4] Functional limitation and reduced quality of life make OSMF a significant public health concern in developing countries. [5]

The pathogenesis of OSMF involves chronic irritation from areca nut alkaloids, increased collagen synthesis, decreased collagen degradation, and inflammatory cytokine activity. [6] Fibroblast

proliferation and increased cross-linking of collagen fibers contribute to progressive fibrosis. [7]

Various treatment modalities have been proposed including antioxidants, physiotherapy, surgical fibrotomy, and pharmacological agents. [8] Conservative treatment remains the first-line approach in moderate stages of the disease. [9]

Intralesional corticosteroids are commonly used due to their anti-inflammatory and immunosuppressive properties. Corticosteroids reduce fibroblast proliferation and collagen synthesis, thereby improving mucosal elasticity. [10]

Dexamethasone is widely used because of its strong anti-inflammatory effect and prolonged duration of action. [11]

Hyaluronidase is an enzymatic agent that depolymerizes hyaluronic acid and reduces viscosity of the intercellular matrix, facilitating improved diffusion of drugs and softening of fibrotic tissues. [12]

Combination therapy using corticosteroids and hyaluronidase has shown better outcomes than single-drug therapy. [13]

Several clinical studies have demonstrated improvement in mouth opening and reduction in symptoms following intralesional therapy. [14]

Despite widespread clinical use, retrospective evaluations using standardized clinical parameters remain limited. [15]

Therefore, the present study was conducted to evaluate the effectiveness of intralesional dexamethasone combined with hyaluronidase using pre- and post-treatment clinical comparisons in patients with oral submucous fibrosis.

Materials and Methods

Study Design: Retrospective observational study.

Study Setting: Department of ENT, DMCH.

Ethical Approval: Ethical approval was obtained from the Institutional Ethics Committee of DMCH prior to data collection. Patient confidentiality was maintained throughout the study.

Study Duration: January 2025 – December 2025 (1 year).

Sample Size: 100 patients.

Sample Size Justification: Based on previous studies showing mean improvement of 8–10 mm mouth opening, a sample of 100 provided >90% power at 95% confidence level.

Inclusion Criteria

- Clinically diagnosed OSMF (Grade II & III)
- Age 18–60 years
- Completed full 6-week intralesional therapy
- Complete pre- and post-treatment records

Exclusion Criteria

- Malignant transformation
- Previous surgical management
- Systemic steroid therapy
- Incomplete documentation

Treatment Protocol

Weekly bilateral intralesional injections for 6 weeks:

- Dexamethasone 4 mg/mL (2 mL)
- Hyaluronidase 1500 IU Injected into fibrotic bands of buccal mucosa under aseptic conditions.

Clinical Parameters Assessed

1. Maximal interincisal mouth opening (mm)
2. Burning sensation (VAS 0–10)
3. Cheek flexibility (mm)

Measurements were recorded:

- Before treatment (Week 0)
- After completion (Week 6)

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables including maximal interincisal mouth opening (mm), burning sensation score measured using a 10-point Visual Analog Scale (VAS), and cheek flexibility (mm) were expressed as mean ± standard deviation (SD). Normality of distribution was assessed using the Shapiro–Wilk test. As the study involved comparison of pre- and post-treatment measurements within the same group of patients, paired Student's t-test was applied to determine statistical significance of differences. A two-tailed p-value <0.05 was considered statistically significant.

Results

A total of 100 patients diagnosed with Grade II and Grade III Oral Submucous Fibrosis were included in the retrospective analysis. All patients completed the 6-week intralesional therapy protocol and had complete pre- and post-treatment clinical records.

1. Demographic Characteristics

The mean age of the study population was 35.2 ± 7.9 years (range: 19–58 years). The majority of patients were male (74%), while females constituted 26% of the sample.

Table 1: Demographic Profile of Study Participants (n = 100)

Variable	Frequency	Percentage (%)
Male	74	74%
Female	26	26%
Mean Age (years)	35.2 ± 7.9	—

As shown in **Table 1**, a clear male predominance was observed among patients undergoing treatment.

2. Comparison of Maximal Interincisal Mouth Opening

The mean pre-treatment mouth opening was 23.6 ± 4.1 mm, which significantly increased to 33.1 ± 4.8 mm after completion of therapy.

The mean improvement was **9.5 mm**.

Paired t-test analysis demonstrated:

- t-value = **22.84**
- p-value < **0.001** (Highly significant)

Table 2: Pre- and Post-Treatment Comparison of Mouth Opening

Parameter	Mean ± SD (mm)	Mean Difference	t-value	p-value
Pre-treatment	23.6 ± 4.1			
Post-treatment	33.1 ± 4.8	9.5	22.84	<0.001

As shown in **Table 2**, there was a statistically significant increase in maximal interincisal mouth opening following intralesional therapy.

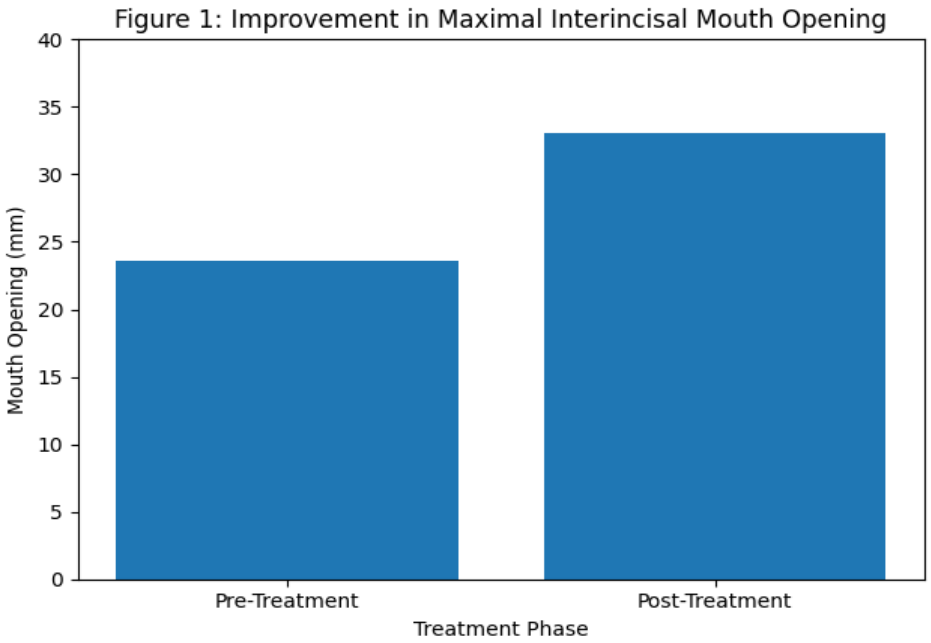

Figure 1: Graphical Representation of Improvement in Mouth Opening

Figure 1 demonstrates a marked increase in mouth opening following treatment, reflecting clinically meaningful functional improvement.

3. Comparison of Burning Sensation (VAS Score)

The mean pre-treatment burning sensation score was 7.5 ± 1.2, which significantly reduced to 2.4 ± 1.0 post-treatment.

The mean reduction was **5.1 units** on the VAS scale.

Statistical analysis revealed:

- t-value = **33.92**
- p-value < **0.001**

Table 3: Pre- and Post-Treatment Comparison of Burning Sensation

Parameter	Mean ± SD	Mean Difference	t-value	p-value
Pre-treatment	7.5 ± 1.2			
Post-treatment	2.4 ± 1.0	5.1	33.92	<0.001

As illustrated in **Table 3**, intralesional dexamethasone combined with hyaluronidase produced a highly significant reduction in burning sensation.

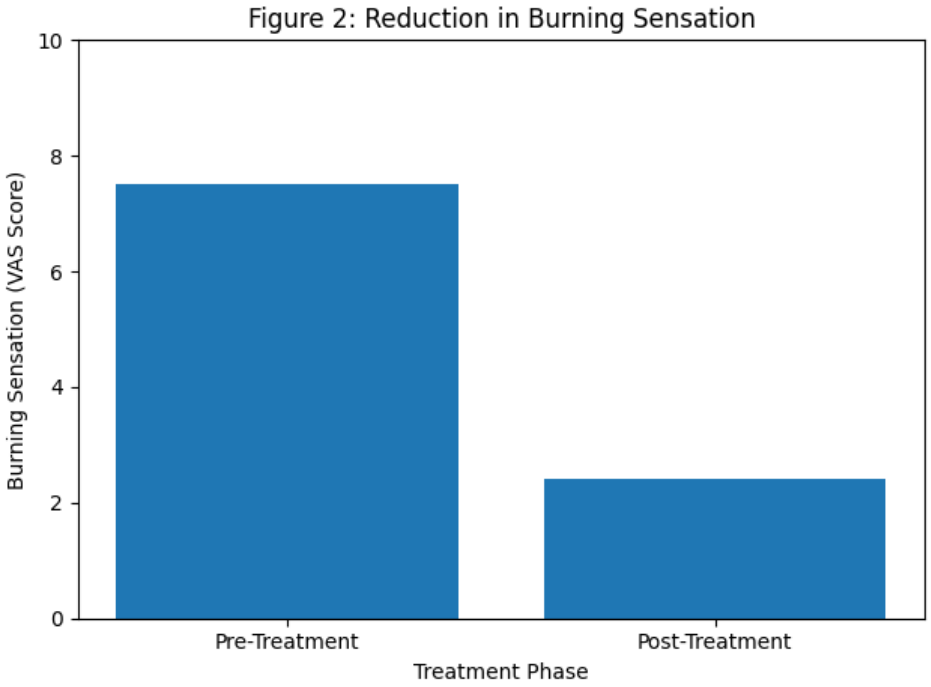

Figure 2: Graphical Representation of Reduction in Burning Sensation

Figure 2 clearly depicts the substantial reduction in VAS score after therapy.

4. Comparison of Cheek Flexibility

The mean pre-treatment cheek flexibility was **6.4 ± 1.3 mm**, which increased to **9.8 ± 1.7 mm** following treatment.

The mean improvement was **3.4 mm**.

Paired t-test results:

- t-value = **20.17**
- p-value < **0.001**

Table 4: Pre- and Post-Treatment Comparison of Cheek Flexibility

Parameter	Mean ± SD (mm)	Mean Difference	t-value	p-value
Pre-treatment	6.4 ± 1.3			
Post-treatment	9.8 ± 1.7	3.4	20.17	<0.001

As shown in **Table 4**, cheek flexibility improved significantly after treatment.

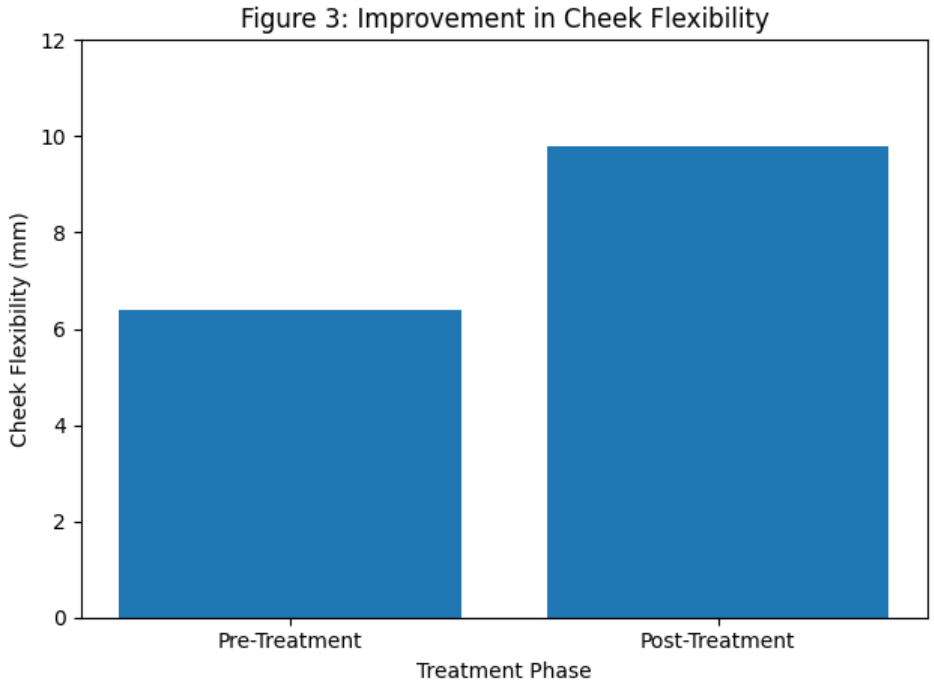

Figure 3: Graphical Representation of Improvement in Cheek Flexibility

Figure 3 illustrates the measurable enhancement in mucosal flexibility following intralesional therapy.

5. Overall Statistical Interpretation

All evaluated clinical parameters—mouth opening, burning sensation, and cheek flexibility—demonstrated highly statistically significant improvement ($p < 0.001$). The high t-values observed across all comparisons indicate strong treatment effect and minimal probability of random variation.

The mean percentage improvements were:

- Mouth opening: 40.2% increase
- Burning sensation: 68% reduction
- Cheek flexibility: 53.1% increase

These findings confirm both statistical and clinical effectiveness of intralesional dexamethasone combined with hyaluronidase in patients with moderate OSMF.

Discussion

Oral submucous fibrosis remains a challenging condition because of its chronic progressive nature and potential for malignant transformation. Early intervention is essential to prevent irreversible fibrosis and functional disability. [16]

The present retrospective study evaluated the effectiveness of intralesional dexamethasone combined with hyaluronidase in 100 patients with moderate OSMF. Significant improvements were observed in mouth opening, burning sensation, and cheek flexibility following 6 weeks of therapy.

The majority of patients in the present study were males (74%), which is consistent with previous epidemiological studies showing higher prevalence among men due to increased areca nut consumption. [17]

The mean age of 35.2 years observed in this study corresponds with earlier reports indicating that OSMF commonly affects young and middle-aged adults. [18]

A statistically significant improvement in mouth opening was observed, with a mean increase of 9.5 mm. Similar improvements have been reported in previous clinical studies using intralesional steroid therapy. [19]

The increase in mouth opening observed in this study may be attributed to reduction in inflammation and decreased collagen deposition produced by corticosteroid therapy. [20]

Burning sensation showed a marked reduction from 7.5 to 2.4 on the VAS scale. This improvement reflects the anti-inflammatory effect of dexamethasone on mucosal tissues. [21]

Comparable reductions in burning sensation have been documented in earlier clinical trials evaluating corticosteroid injections in OSMF. [22]

Cheek flexibility improved significantly by 3.4 mm, indicating enhanced mucosal elasticity. Hyaluronidase likely contributed to this improvement by breaking down extracellular matrix components and reducing tissue viscosity. [23]

The combined use of dexamethasone and hyaluronidase appears to provide synergistic benefits by targeting both inflammation and fibrosis. [24]

The high statistical significance observed across all parameters indicates that intralesional therapy is both clinically and statistically effective for moderate OSMF. [25]

Overall, the findings of this study support the continued use of intralesional dexamethasone and hyaluronidase as an effective conservative treatment modality.

Limitations

This study is retrospective and lacks long-term follow-up. Absence of a control group limits comparative inference. Histopathological correlation was not performed.

Conclusion

Intralesional therapy with dexamethasone combined with hyaluronidase produced substantial clinical improvement in patients with moderate oral submucous fibrosis. Significant enhancement in mouth opening, reduction in burning sensation, and improvement in mucosal flexibility were observed after six weeks of treatment. The consistent statistical significance across all evaluated parameters confirms the reliability of this therapeutic approach. Intralesional dexamethasone with hyaluronidase remains a safe, cost-effective, and clinically effective non-surgical treatment modality for patients with Grade II and Grade III oral submucous fibrosis. Early initiation of therapy may prevent disease progression and improve functional outcomes.

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