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# Clinical Effectiveness of Aloe Vera in the Treatment of Oral Mucosal

# **Diseases – A Double Blinded Randomized Clinical Trial**

Pazhanivel K<sup>1</sup>, \*Anuradha Ganesan<sup>2</sup>

<sup>1</sup>Senior lecturer, Thai Moogambigai Dental College and Hospital, Dr. M.G.R Educational and Research Institute University,

Maduravoyal, Chennai – 600095, Tamil Nadu, India.

<sup>\*2</sup> HOD & Professor, Department of Oral Medicine and Radiology, SRM Dental College, Ramapuram, Chennai – 600089, Tamil

Nadu, India.

# Abstract

Aloe vera, also called *Aloe barbadensis miller* has various pharmacological actions like immunomodulatory, antiinflammatory, antioxidant, wound healing, and antineoplastic activities. Studies have proved it to be effective in various medical and dental conditions with minimal side effects. The aim of the present study is to evaluate of efficacy of Aloe vera in the management of oral mucosal lesions. The objective was to compare the efficacy of topical Aloe vera gel and topical triamcinolone acetonide 0.1% in patients with recurrent Aphthous stomatitis, Oral Submucous Fibrosis (OSMF) and patients with symptomatic Oral Lichen Planus (OLP). Thirty-two participants were included in the study and were divided into 3 study groups, group I- Oral Submucous Fibrosis, group II- symptomatic Oral Lichen Planus and group III – Recurrent Aphthous Stomatitis. The patients were assessed for various parameters for a duration of 12 weeks for group I patients, 4 weeks for group II patients, 1 week for group III patients. All the groups were divided into subgroup A who received aloe vera gel 3 times a day and Subgroup B patients received topical triamcinolone acetonide 0.1% gel 3 times a day. All the groups showed significant improvement in both the subgroups in all the parameters, at the end of the study period. The clinical response and the efficacy were comparable to that of the topical triamcinolone acetonide 0.1% in all the groups. The study concludes that aloe vera can be an alternative, safe and effective treatment regime in the management of OSMF, Recurrent Aphthous Stomatitis and Oral Lichen Planus. Long term follows up studies with larger sample size are recommended.

Keywords: Aloevera, Triamcinolone acetonide, Oral Submucous fibrosis, Oral Lichen Planus, Recurrent Aphthous Stomatitis.

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#### 1. Introduction

Oral health is overall health, oral health is important for the better quality of life. Any disease related to oral cavity can cause pain, discomfort and alteration in the normal healthy living of an individual [1]. Oral mucosal lesions are any changes in oral mucosal surface that may present as a white, red, pigmented and the ulcerative lesions, any swelling or as variants of developmental defects [2]. A prompt and effective treatment protocol is mandatory in all these oral lesions and in today's scenario most of the oral diseases are treated with antimicrobials, immunomodulators and various other drugs which has numerous adverse effects. So numerous studies have been tried with various other alternative modalities with high efficacy and the lesser or no side effects. Ayurveda has extensively explored natural methods for improving the wellness of the body and mind for millennia. Ayurveda is traditional natural system of medicine in India which today, has become one of the emerging treatment modalities worldwide, for preventing and treating various oral and other diseases [3]. Ayurvedic medications holds good result in this perspective, among them aloe vera is one of the best choice with multiple pharmacological effect and least adverse effects and is used in various oral diseases as an alternative treatment modality. Aloe Vera (AV) is a cactus-like plant the parenchymatous cells in the fresh leaves secrete colourless mucilaginous gel (i.e., Aloe vera gel) that contains 98.599.5% water and remaining solids [4]. Aloe vera gel has pharmacological actions antifungal. various like antibacterial, antioxidant, anti-inflammatory, antitumor, hypoglycaemic properties and immune boosting properties and has been used as mouth rinses, dentifrices in treatment of gingivitis, periodontitis and as an endodontic medicament [5]. Studies have demonstrated that aloe vera has an important therapeutic use in the management of oral lesions such as Oral sub mucous Fibrosis, Oral Lichen Planus, Radiation Induced Mucositis, Burning Mouth Syndrome, Recurrent Aphthous Ulcer and Xerostomia. In literature various studies have been reported where aloe vera has been used to treat various medical and dental conditions and has proved to be effective with minimal side effects[6]. The aim of the present study is evaluation of efficacy of aloe vera in the management of oral mucosal lesions. The objective was to compare the efficacy of topical aloe vera gel and topical triamcinolone acetonide 0.1% in patients with Recurrent Aphthous Stomatitis, Oral sub mucous Fibrosis (OSMF) and patients with symptomatic Oral Lichen Planus.

#### 2. Materials and methods

The present study is a randomized clinical trial, single centered which was conducted in the outpatient Department of Oral Medicine and Radiology in a private college and hospital in Chennai. The study had received the approval by the Institutional research Ethical Committee (Ref No: MDCH/IEC/2018/11). All procedures followed were by the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1964. After screening many patients, 32 participants were included in the study and were divided into 3 study groups, depending on the history, signs and symptoms and also the clinical appearance of the lesion. The participants were divided into group I- Oral Sub mucous Fibrosis, group II- symptomatic Oral Lichen Planus and group III - Recurrent Aphthous Stomatitis. The clinical study design was adopted for a duration of 12 weeks for group I patients, 4 weeks for group II patients, 1 week for group III patients. The aim of the study, the methodology, the risks and benefits of the study were all explained very clearly to the participants following which an informed consent was obtained. It was a double blinded study and was conducted to evaluate the effectiveness of Aloe vera gel in the management of Recurrent Aphthous Stomatitis, Oral Submucous Fibrosis and patients with symptomatic Oral Lichen Planus. To compare the efficacy and reduction in the symptoms of by using Aloe vera gel and triamcinolone acetonide 0.1% in management of Recurrent Aphthous Stomatitis, Oral Submucous Fibrosis and symptomatic Oral Lichen Planus.

**GROUP I** study group consists of 11 participants presenting with clinical signs and symptoms of Oral Submucous Fibrosis and were graded according to Khanna and Andrade. <sup>[7]</sup> Patients who have not taken any treatment earlier for OSMF, patients who are ready to quit the associated habits and accept for regular follow ups and also with a mouth opening between 20 and 40 mm interincisally were included in the study. Patients with OSMF coexisting with other oral lesions, history of hypersensitivity to aloe vera, pregnant women and lactating mothers, history of associated systemic illness were excluded from the study. The entire sample were randomly allocated using computer generated sequence numbering into two subgroups, subgroup IA (n=6) and subgroup IB (n=5). Subgroup IA patients received aloe vera gel 3 times a day for 3 months and Subgroup IB patients received topical triamcinolone acetonide 0.1% gel 3 times a day for 3 months. Detailed instructions about the application of 5mg Aloe vera gel and triamcinolone acetonide 0.1% over the lesion were explained to the patient. Patient were instructed to avoid solid and liquid diet 15 minutes after application. Physiotherapy exercise was advised using ice cream sticks four times a day for 3 months. The following oral findings were recorded each time the patient visits the department [base line 1<sup>st</sup> visit] 3 weeks-6 weeks- 9weeks -12 weeks respectively. Clinical parameters like burning sensation, interincisal mouth opening tongue protrusion and cheek flexibility were recorded. The intensity of burning sensation was determined using a Numerical Rating Visual Analogue Scale (VAS) graded on a 10-point scale from 0 to 10, where 0 represented no burning sensation while 10 represented the worst burning sensation. The interincisal mouth opening was measured using a Vernier Calliper from the Mesio-incisal angle of upper central incisor to the Mesio-incisal angle of lower central incisor and was recorded in millimetres. Cheek flexibility was measured according to the method by Mathur and Jha [8].

**GROUP II** study group consists of 9 participants presenting with the chief complaint of burning sensation or pain and also were screened for the presence of clinical appearance of Oral Lichen Planus. Cases of symptomatic oral lichen planus and patients who have not taken any treatment earlier for oral lichen planus were included in the study. Patients with lichenoid reaction or with a known history of serious drug hypersensitivity, Pregnant women and lactating mothers, patients with oral lichen planus with any other systemic illness, hypersensitivity to aloe vera, patients with oral lichen planus with any other oral lesion were excluded from the study.

The entire sample was divided randomly in the same way as group 1 study group into two subgroups, subgroup IIA and subgroup IIB. Subgroup IIA patients received topical aloe vera gel 3 times a day for 4 weeks and subgroup IIB patients received topical triamcinolone acetonide 0.1% gel 3 times a day for 4 weeks. Clinical parameters like burning sensation or pain were assessed during every visit using visual analogue scale. The size of the lesion was recorded by the Thongprasom et al criteria[9].

**GROUP III** study group consists of 12 participants diagnosed with Recurrent Aphthous Stomatitis, the entire sample was divided into two subgroups using the same method of randomization followed in other groups. Subgroup IIIA patients (n=6) received topical aloe vera gel and Subgroup IIIB patients (n=6) received topical triamcinolone acetonide 0.1% for three times a day for 7 days. Instructions on the method of application was given in the similar way like the other two groups. Clinically diagnosed patients with Recurrent Aphthous Stomatitis (minor) in the oral cavity and also following the diagnostic criteria for Recurrent Aphthous Stomatitis proposed by Natah et al were included in the study [10]. Patients who gave a positive history of developing similar ulcers on the oral mucosa during a period of 3-4 months and ulcers less than 48 hours were included in the study. Patients with a history of associated systemic illness,

cases of Recurrent Aphthous Stomatitis (major), herpetic form lesions and smoking, history of hypersensitivity to aloe vera were excluded from the study. The following Clinical parameters were recorded. Size of ulcer was recorded using a calibrated dental probe with millimetre marking. The intensity of pain was determined using a Numerical rating visual analogue scale (0-10). The intensity of burning sensation was determined using Visual analogue scale (0-10). The Erythema grading by Greer et al (11) was followed, 0-no erythema, 1-light red/pink in colour, 2- red but not dark in colour 3- very red dark in colour. All the clinical parameters were recorded in a proforma for the (base line, first visit), 1<sup>st</sup> day, 3<sup>rd</sup> day and the 7<sup>th</sup> day.

# Statistical analysis

Statistical analysis was performed using Statistical package for Social Sciences software SPSS Version 23.0.Normality test was done using Shapiro-Wilk numerical test .The data was found to be normally distributed where p > 0.05. Descriptive statistics was done. Mean comparison between the groups was done using independent t test and within the groups was done using repeated measures ANOVA with different intervals. Tukey's post hoc test was done for pairwise comparison. A p value <0.05 was considered to be significant.

# 3. Results and Discussions

In the present study the mean distribution of burning sensation among subgroup IA and subgroup IB at baseline were 6.98±1.28 and 7.13±1.23 respectively. The burning sensation decreasing gradually through week 3, 6, 9 and 12 and there was a significant difference at week 12 between the two subgroups. The percentage reduction of burning sensation was 70.4% in subgroup IA and 91.6% in subgroup IB with a significant difference. The mean mouth opening and cheek flexibility also showed significant difference from baseline to 12 weeks and showed 6.1% improvement in subgroup IA and 10.2% in subgroup IB in mouth opening and 62.8% and 80.1% in subgroup IA and IB in cheek flexibility respectively. The tongue protrusion also showed improvement from baseline to week 12 and had 2.7% and 3.5% improvement in subgroup IA and IB (Table 1). In comparison with the topical aloe vera gel and topical triamcinolone acetonide 0.1% in cases of symptomatic oral lichen planus the mean burning sensation in subgroup IIA was 4±0.051 and in subgroup IIB was 4.5±2.121 at baseline. The burning sensation decreased gradually through week 2 & 4 with a percentage reduction of burning sensation of 50% in subgroup IIA and 69.9% in subgroup IIB. There was also significant difference in the mean pain score between baseline and week 4 within subgroup IIA and subgroup IIB .The lesion size between subgroup IIA and subgroup IIB does not show any statistically significant difference through baseline to week 2. However, there was a statistically significant difference in the mean lesion size between baseline and week 4 within subgroup IIA and subgroup IIB (Table 2).

In Group III study participants the mean burning sensation in subgroup IIIA was  $3.43\pm1.39$ and in subgroup IIIB was  $3.20\pm0.83$  at baseline. The burning sensation decreased gradually through Day 1, 3 and 7 and

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showed significant difference at Day 7 between two subgroups. The percentage reduction of burning sensation was more in subgroup IIIA with 62.8% and 56% in subgroup IIIB. There was significant difference in the mean pain score between baseline and Day 7 within the subgroups. The mean erythema in subgroup IIIA was 2±0.45 and in subgroup IIIB was 2±0.57 at baseline. The erythema decreased gradually through Day 1, 3 and 7. There was a significant difference in the mean erythema within the two subgroups (p=0.002 and 0.000). The percentage reduction of lesion size was 2.9% in subgroup IIIA and 4.5% in subgroup IIIB with a significant difference. There was significant difference in the mean lesion size between baseline and Day 7 within two subgroups (Table 3). The oral mucosal lesions can be potential indicators of an array of systemic conditions and can cause interference with speech, mastication, swallowing and alteration in normal functioning. Oral Submucous Fibrosis is a potentially malignant, precancerous condition of the oral cavity and oropharynx which is predominantly seen in the Indian subcontinent and Southeast Asian countries with an overall prevalence rate of 0.2-0.5%. The disease has a complex pathophysiology, and various etiological factors with burning sensation of the oral mucosa, ulceration, and pain as the initial oral manifestations [13].

The present study there was a significant difference in the mean burning sensation between the base line and week 12 in both the groups. The study by Nisha Singh et al showed significant improvement in patients receiving aloevera gel compared to antioxidants[18]. The study by Sudarshan et al showed an improvement of 80% reduction in burning sensation in patients with aloe vera group and 65.7% in the antioxidant group[15]. Many similar studies have showed significant reduction in the burning sensation in aloe vera group in comparison to non -aloe vera group. The non-aloe vera group comprises of anti-oxidants in the study conducted by Anuradha et al. [19]. Ramachandran et al. [5]. Santhosh Patil et al[20]. Recent data suggest that aloe vera also exerts anti-inflammatory effects through reduction of leukocyte adhesion and tumour necrosis factor (TNF) - alpha levels. It contains carboxypeptidase that inactivates bradykinins and produces an anti- inflammatory effect. During the inflammatory process, bradykinins produce pain associated with vasodilation and therefore, its hydrolysis reduces these two components and produces an analgesic effect. The gel containing a mannose – 6-phosphate has been credited with a wound healing effect. It also has soothing and cooling qualities. So, these could be the possible reasons for reducing pain and burning sensation in OSMF patients. Aloe vera is an antioxidant rich plant that contains vitamins such as A, C, and E along with minerals, beta carotene, Zinc iron, and selenium. Antioxidants help boost the immune system and combat free radicals in the body. So, these could be the possible reasons for reducing pain[18]. Aloe vera contains magnesium, lactate that inhibits histidine decarboxylase. This results in the inhibition of formation of histamine from histidine in mast cells[21].

Our study also aims to compare the efficacy of aloe vera gel with triamcinolone acetonide. Our results showed a more decrease in the burning sensation in the triamcinolone group compared to the aloe vera gel. Even though aloe vera gel had shown a considerable decrease triamcinolone proves to have a better efficacy in burning sensation in OSMF patients. In the present study there was a significant difference of mean mouth opening in both the groups from week 0 to week 12. Aloe vera has many constituents, which have varied actions, the mechanisms that can substantiate the improvement of mouth opening, cheek flexibility, and tongue protrusion like increased synthesis of hyaluronic acid, and dermatan sulfate in the granulation tissue of a healing wound and also aloe vera stimulates the fibroblasts which produce the collagen and elastin fibres that make the skin more elastic. Once the patients burning sensation is reduced, they try to open the mouth[19].

In the present study the cheek flexibility shows significant difference from week 6 to week 12 in both the participants treated with aloe vera gel and triamcinolone acetonide gel. Similar studies by Sudarshan et al[16] also shows an improvement in cheek flexibility in individuals with aloe vera gel. The shape of the uvula in all patients remained the same and did not show any changes in our study. There was clinical improvement in ulcer and vesicles in patients treated with aloe vera gel, similar study was also done by Patil et al [18] in the OSMF patients receiving spirulina compared with aloe vera. Oral Lichen Planus is a chronic inflammatory disease that commonly affects skin and oral mucosa. OLP is a T cell-mediated disease in which cytotoxic CD8+ T cells trigger apoptosis of oral epithelial cells. Upregulation of intercellular adhesion molecules and cytokines secreted by activated lymphocytes and keratinocytes such as interleukin (IL)-2, IL-4, IL-10 and tumour necrosis factor (TNF)-alpha can play a role in the pathogenesis of LP. Current treatments for OLP are aimed at alleviating pain and pain relief can be achieved in the majority of patients with topical treatment such as corticosteroids, cyclosporine, retinoic acid or tacrolimus. Various modalities are available in the treatment OLP, e.g. acitretin, azathioprine and systemic of corticosteroids. Recent data suggest that aloe vera also has anti-inflammatory effects by the reduction of leukocyte adhesion and TNF  $-\alpha$  level [22].

In the present study majority were females when compared to males, similar study with a female predominance have also been reported, because of inherent variation in the immune responses in females versus males which might account for the higher prevalence of autoimmune diseases among females[23]. In the present study the percentage reduction of burning sensation was 50% in Aloe vera gel and 69.9% reduction in triamcinolone gel. However, there was a significant difference at week 4 between two groups. Both the medicaments have potent anti- inflammatory actions. Significant improvement was seen in individual receiving aloe vera gel in the study conducted by Choonhakarn et al[22] showed burning sensation completely disappeared in 9 patients treated with aloevera gel (33%) and in 1 treated with placebo (4%). Many similar studies have showed significant reduction in the burning sensation in aloe vera group compared to non- aloe vera group. The non-aloe vera group comprises of placebo and topical triamcinolone acetonide [24]. In the present study showed the percentage reduction of pain was 75% in aloe vera group and 98% in triamcinolone group with a statically significant difference. However, there was a significant difference at week 4 between two groups. Significant improvement was seen in individual receiving aloe vera gel in the study conducted by Choonhakarn et al[22], Salazar-Sanchez N et al[25] and Sinha A et al[26] compared to non-aloe vera group.

However, there was a considerable and good reduction in the pain and burning sensation in the aloe vera group from baseline till the 4<sup>th</sup> week. Recent data suggest that aloe vera also exerts through reduction of leukocyte adhesion and tumour necrosis factor (TNF) - alpha levels. It also has soothing and cooling qualities, so these could be the possible reasons for reducing pain and burning sensation in OLP patients. Our study also aims to compare the efficacy of aloe vera gel with triamcinolone acetonide, our results showed a more decrease in the pain and burning sensation in the triamcinolone group compared to aloe vera gel. Even though aloe vera gel had shown a considerable decrease, triamcinolone proves to have a better efficacy in pain and burning sensation in OLP patients. In the present study the percentage reduction of burning sensation and pain in recurrent apthous stomatitis was 62.8% and 45.7% in aloe vera and 56% and 65% in triamcinolone group. However, there was a significant difference at day 7 between two groups similar to the studies by Mansour et al[27] and Babeeet al[28]. In the present study the percentage reduction of erythema was 22.8% in aloe vera and 36.4% reduction in triamcinolone. However, there was a significant difference in percentage reduction of Erythema also similar to study conducted by Mansour et al[27] showed aloe vera was more effective in the reduction of ulcer size, erythema, and exudation compared to myrrh. The percentage reduction of lesion size was 2.9% in aloe vera and 4.5% in triamcinolone group with a statistically significant difference. The reasons for the wound healing effect of aloe vera could be due to its ability to increase the epithelial cell migration. Glucomannan and gibberellin (present in the extract of aloe vera) promote the collagen synthesis. It has been found that the topical application of aloe vera increases the synthesis of hyaluronic acid and dermatan sulphate in the granulation tissue of the wound, promoting the wound healing. In addition, aloe vera increases the wound closure rate and the tensile strength of the wound. Aloe vera gel forms a protective coating on the affected areas and helps in healing wounds, fastens the healing rate.

Table 1. A comparison of effectiveness of aloe-vera and triamcinolone on OSMF

Outcome	Group	Mean ± SD						% Change
		Baseline	Week 3	Week 6	Week 9	Week 12	p value	
Burning Sensation	Aloe-vera	6.98 ± 1.28	$5.46 \pm 1.49$	$3.24 \pm 1.12$	$2.52 \pm 1.45$	2.11 ± 1.02	0.004	70.4%
	Triamcinolone	7.13 ± 1.23	4.65 ± 1.14	3.21 ± 1.06	2.56 ± 1.38	0.72 ± 1.52	0.000	91.6%
p value		0.452	0.216	0.204	0.156	0.001		
Mouth opening	Aloe-vera	29.4±1.14	30.2±1.09	30.6±1.14	30.8±0.83	31.2±1.07	0.000	6.1%
	Triamcinolone	30.1±0.75	30.5±0.83	31.3±0.51	32.8±0.75	33.0±0.63	0.000	10.2%
p value		0.213	0.618	0189	0.020	0.008		
Cheek flexibility	Aloe-vera	0.095±0.001	0.107±0.009	0.136±0.016	0.174±0.023	0.192±0.010	0.000	62.8%
	Triamcinolone	0.096±0.001	0.108±0.010	0.153±0.018	0.183±0.019	0.191±0.021	0.000	80.1%
p value		0.181	0.921	0.001	0.004	0.974		
Tongue Protrusion	Aloe-vera	43.1±0.44	43.5±0.37	43.9±0.40	44.4±0.31	44.7±0.18	0.000	2.7%
	Triamcinolone	42.8±0.42	43.1±0.49	43.9±0.26	44.1±0.27	44.9±0.35	0.000	3.5%
p value		0.387	0.193	0.974	0.098	0.827	1	

Table 2: A comparison of effectiveness of aloe-vera and triamcinolone in symptomatic oral Lichen planus

Outcome	Group		Mean ± SD	p value	% Change at week 4	
		Baseline	Week 2	Week 4		
Burning Sensation	Aloe-vera	4.00±0.05	2.50±0.071	2.00+0.00	0.001	50%
	Triamcinolone	4.50±2.12	3.00±1.41	1.05±0.71	0.000	69.9%
p value		0.149	0.543	0.013		
Pain score	Aloe-vera	5.00±0.02	3.00±0.08	2.00±0.06	0.004	75%
	Triamcinolone	5.00±1.41	2.50±0.71	0.09±0.80	0.000	98%
p value		0.845	0.459	0.002		
Lesion size	Aloe-vera	$2.75 \pm 0.95$	1.5 ± 0.57	$1.00 \pm 0.00$	0.006	43.7%
	Triamcinolone	3.6 ± 0.54	2.4 ± 0.89	0.07 ± 0.55	0.001	70.6%
p value		0.136	0.127	0.004		

Table 3: A comparison of effectiveness of aloe-vera and triamcinolone on recurrent aphthous stomatitis

Outcome	Group	Mean ± SD				p value	% Change
		Baseline	Day 1	Day 3	Day 7		
Burning Sensation	Aloe-vera	3.43±1.39	3.00±1.00	1.86±0.69	0.29±0.48	0.000	62.8%
	Triamcinolone	3.20±0.83	3.00±1.00	2.00±1.00	0.60±0.89	0.002	56.0%
p value		0.987	0.852	0.876	0.006		
Pain score	Aloe-vera	3.80±1.09	3.60±1.34	2.20±0.83	0.60±0.89	0.002	45.7%
	Triamcinolone	3.71±1.11	2.86±0.90	1.43±0.53	0.46±0.48	0.000	65.0%
p value		0.998	0.343	0.149	0.639		
Area of erythema	Aloe-vera	2.00±0.45	2.00±0.56	1.00±0.36	0.40±0.54	0.002	22.8%
	Triamcinolone	2.00±0.57	1.71±0.48	0.86±0.37	0.19±0.48	0.000	36.4%
p value		0.913	0.432	0.755	0.008	-	
Lesion size	Aloe-vera	0.300±0.070	0.280±0.083	0.220±0.044	0.094±0.089	0.007	2.9%
	Triamcinolone	0.357±0.127	0.314±0.106	0.214±0.069	0.023±0.095	0.000	4.5%
p value		0.431	0.606	0.922	0.021		

# 4. Conclusions

In conclusion the results of the present study showed that both aloe vera and triamcinolone acetonide 0.1% were found to be effective in the management of Oral Submucous Fibrosis, symptomatic Oral Lichen Planus and Recurrent Aphthous Ulcer(minor). Recent data suggest that aloe vera also exerts anti-inflammatory effects through reduction of leukocyte adhesion and tumour necrosis factor (TNF)- a levels. The gel containing a mannose – 6-phosphate has been credited with a wound healing effect. It also has soothing and cooling qualities. So, these could be the possible reasons for reducing pain and burning sensation in OSMF patients. It is a promising agent in treating oral lesions in the field of oral medicine and future research in various other oral diseases and different formulations can be tried.

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