

## ORIGINAL RESEARCH

# Role of laser fibrotomy with diode laser in oral submucous fibrosis

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Received: 26 March, 2023

Accepted: 29 April, 2023

### ABSTRACT

**Background:** Oral submucous fibrosis is one of the common oral potentially malignant disorders and also a crippling disease leading to severe morbidity. There are numerous medical, conservative and surgical treatments available but till date, no effective treatment is available. Surgical treatments are limited to advanced stages of OSMF but there is increased fibrosis post-operatively. Thus to reduce the post operative complications, laser fibrotomy has been introduced and studied as a non-invasive technique to treat oral submucous fibrosis. As there are only a few studies on laser, this study aims to show the effectiveness of laser treatment on OSMF. **Materials and methods:** A hospital based prospective and comparative study, conducted on 30 patients divided in two randomised groups. One group receiving the intralesional steroid treatment and another group receiving laser treatment. **Results:** Although both the groups showed improvement in symptoms, the patients treated with laser showed significantly better results. Also the compliance of the patients was good in this group as there was no repeated painful injections were given. **Conclusion:** With this study, it can be concluded that laser might be used as a potential non-invasive approach in the management of OSMF; however, large scale studies are required to investigate the efficacy and other effects of this technology. **Keywords:** oral submucous fibrosis, laser fibrotomy, diode laser, treatment, management, precancerous.

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### INTRODUCTION

Oral submucous fibrosis has been well established in Indian medical literature since the time of Sushruta, a renowned Indian physician who lived in the era 600 B.C and was termed as "Vidari". This condition was first described in the modern literature by Schwartz in 1953, who coined the term "Atrophic idiopathic mucosa oris"<sup>1</sup>. Joshi subsequently coined the term oral submucous fibrosis for the condition in 1953<sup>2</sup>. However, there are various synonyms proposed by different authors such as "Diffuse oral submucous fibrosis", "Idiopathic scleroderma of the mouth", "Idiopathic palatal fibrosis", "Sclerosing stomatitis" and "Juxta-epithelial fibrosis"<sup>3</sup>. Pindborg (1966) defined oral submucous fibrosis as, "An insidious, chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with juxta-epithelial inflammatory reaction followed by fibroelastic change of the lamina propria, with epithelial atrophy leading to stiffness of the oral

mucosa and causing trismus and inability to eat"<sup>3</sup>. More and Rao (2019) defined Oral Submucous Fibrosis (OSMF) as 'a debilitating, progressive, irreversible collagen metabolic disorder induced by chronic chewing of areca nut and its commercial preparations; affecting the oral mucosa and occasionally the pharynx and oesophagus; leading to mucosal stiffness and functional morbidity; and has a potential risk of malignant transformation'<sup>4</sup>.

WHO statistics states that there are >5 million oral submucous fibrosis with maximum number of patients seen in India worldwide. Hence it is known as 'India's disease'. Male to female ratio 2.36:1. The cases have also been reported from countries like Kenya, china, UK, Saudi Arabia and other parts of the world.<sup>1</sup>

The malignant potential was first described by Paymaster in 1956. A malignant transformation rate between 3% and 7.6% has been reported followed for a period of 17 years. Studies showed malignant transformation rate of 2.3% in 10 years, 4.5% in 15 years and 7.6% in 17 years during follow-up period.<sup>5-10</sup>

Various treatment modalities are available for treating this condition which includes medical and surgical treatment. Medical management is indicated in early stage of OSMF with mouth opening more than 25 mm. Surgical treatment is indicated in the advanced cases with reduced mouth opening. Local drug delivery are useful in alleviating symptoms such as local injections of steroids, hyaluronidase, chymotrypsin, and placental extract; physiotherapy; heat therapy in the form of hot rinses, lukewarm water<sup>11</sup>, or selective deep heating therapies; and surgical management such as submucosal resection of fibrotic bands, myotomy, laser fibrotomy<sup>12</sup>.

Lasers are a good alternative for surgical fibrotomy as it provides bloodless field, less post operative fibrosis, minimal scarring and minimally invasive. As it is a chronic disease, no single medical management can lead to complete reversal of symptoms<sup>13-16</sup>. Long term usage of medical treatments leads to increased expense, non-compliance, and systemic adverse effects<sup>17</sup>. In such situations, lasers are proved to be good alternative being safe and cost-effective treatment modality with minimal side effects.

## MATERIALS AND METHODS

A prospective randomized study was carried out to assess the efficacy of intralesional injection of steroid and laser treatment for the management of Oral Submucous Fibrosis in RIMS, Ranchi.

And was approved by the Institutional Ethics committee, RIMS Ranchi vide memo no .331 dated 11 – 08 – 2021.

## SAMPLE SELECTION

Hospital based study (RAJENDRA INSTITUTE OF MEDICAL SCIENCES) – Department of ENT and Dental College

## INCLUSION CRITERIA

1. Patient aged 20-60yrs of age.
2. Patients with current or previous use of any form of smokeless tobacco and/or areca nut (any duration and frequency).
3. Only Patients having stage 2 of Oral submucous fibrosis according to the Clinical staging by khanna et al. (i.e. presence of palpable fibrous bands in buccal mucosa and/or oropharynx, with/without stomatitis).
4. Patients willing to quit the habit of smokeless tobacco and/or areca nut.
5. Patients willing to accept regular follow-up protocol.

## EXCLUSION CRITERIA

1. Patient below 20yrs and above 60 yrs of age.
2. Any significant medical condition such as scleroderma, anemic stomatitis and diabetes that would interfere with the safety, treatment or compliance with the protocol. Known diabetics or those with altered blood sugar values at the

baseline assessment (assuming the normal random blood sugar ranging 70-140mg/dL), or any patient developing diabetes during the study will be excluded from the study.

3. Patients with known allergy or contra-indication to any of the ingredients of the test drugs.
4. Patients already undergoing treatment for Oral Submucous Fibrosis.
5. Pregnant and lactating females.
6. Patients having any other conditions leading to trismus.
7. Patients not willing to participate in the study.

## STATISTICAL ANALYSIS

All the data is entered in MS excel sheet and subjected to statistical analysis. Quantitative data measured in terms of Mean and Standard deviation (S.D.). Qualitative data measured in terms of percentages. Pre-op and Post-op data analyzed and compared using Paired 't' test using statistical package for social sciences (SPSS) version 20. P-value <0.05 was considered as statistical significance.

## PROCEDURE

Total of 30 patients with clinically diagnosed OSMF patients with an age ranging from 20-60 years were selected according to the mentioned inclusion and exclusion criteria and informed consent were taken from every individuals. A thorough case history along with a detailed clinical examination was performed for all individuals. Patient's detailed history was taken about their addictive habits. The mouth opening was recorded between the upper and lower incisors at initial visit, tongue protrusion, cheek flexibility, burning sensation and pain on opening mouth on VAS scale will be noted. The 50 patients were randomly divided into 2 groups, containing 15 patients each. One group received medical treatment, viz. Intralesional triamcinolone 40mg and hyaluronidase 1500 IU weekly injections for 12 weeks. Another group received the laser treatment in which the fibrotic bands was incised using diode laser and followed up for 12 weeks. Laser fibrotomy was done under local anesthesia (2% w/v lignocaine and adrenaline in ratio 1:2,00,000) using a 980-nm solid-state diode laser for oral soft tissues. The laser was used according to the manufacture's manual instructions. A metal hand-piece with disposable cutting fibre of width 400 µm diameter was used in continuous wave emission mode at 2-W power in contact mode. The total energy was calculated as 4 J and the fluence was 50 J/cm<sup>2</sup>. Complete epithelialisation of the mucosal defects took place in approximately 2–3weeks in all cases. The patients were advised to practice mouth-opening exercises rigorously, and topical corticosteroid (triamcinolone acetonide gel 0.1% as topical application thrice daily) was given for burning sensation and pain for 3 months. Regular follow-up of the patients was done every 2 weekly for 3 months. Improvement of symptoms and mouth opening was

measured during regular follow-up of patients and the effectiveness of both the modalities, i.e. medical and laser treatment was compared.

**OUTCOMES**

Regular follow-up of the patients was done every 2 weekly for 3 months. Improvement of symptoms and mouth opening will be measured during regular follow-up of patients and the effectiveness of both the modalities, i.e. medical and laser treatment will be compared.

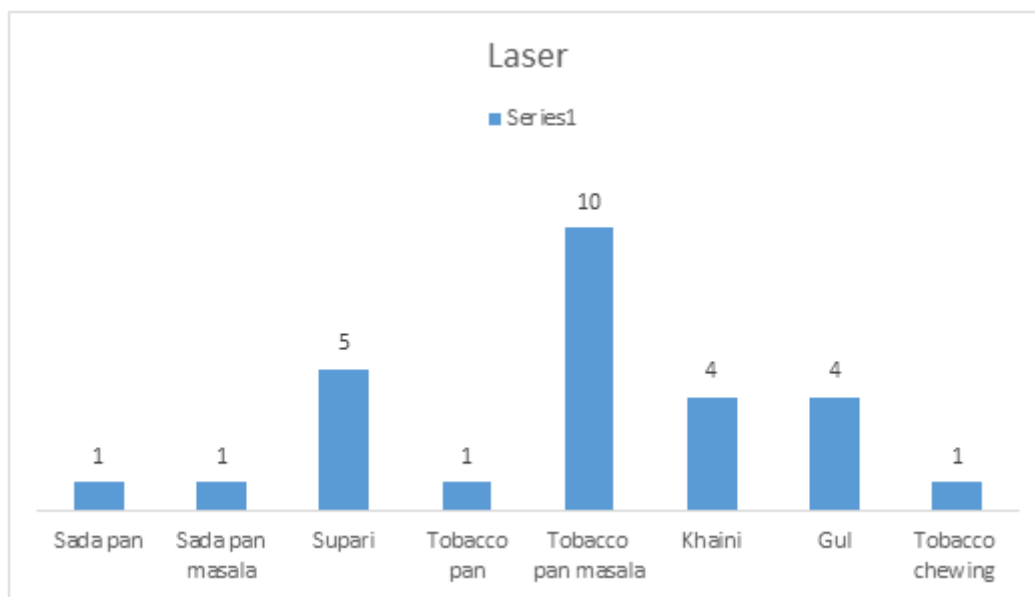
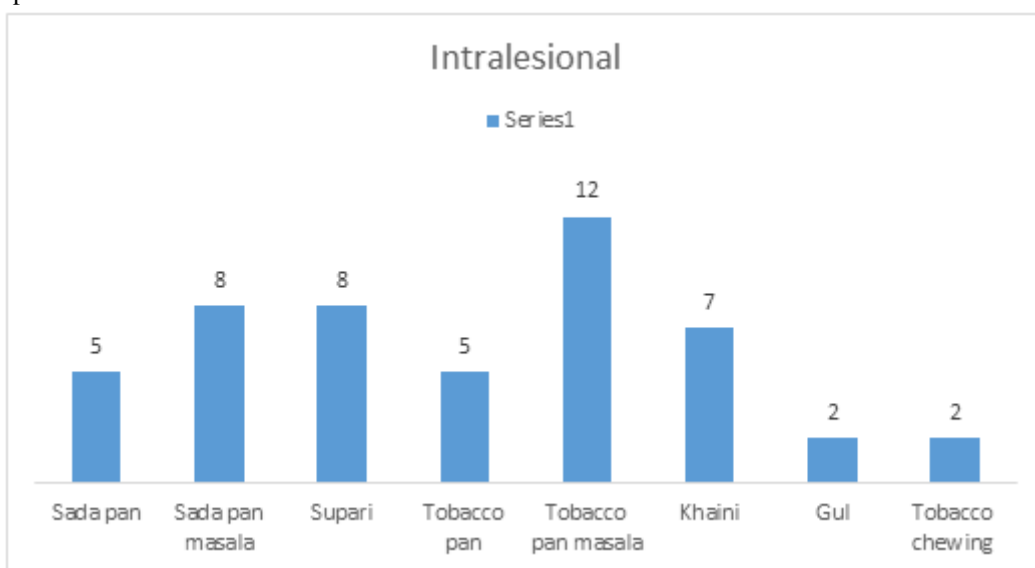
**PARAMETERS TO ASSESS THE OUTCOMES**

1. Inter-incisal mouth opening
2. Tongue protrusion

3. Cheek flexibility
  4. Burning sensation on consumption of hot/spicy foods
  5. Pain on opening the mouth
- These will be measured at 0 and 12 weeks.

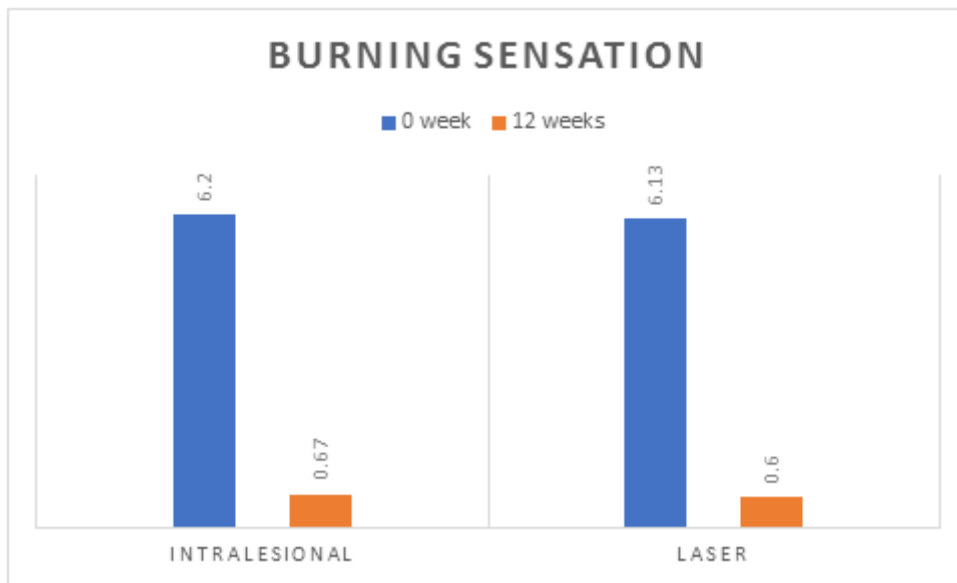
**RESULTS**

The age of the patients participating in the study ranged from 20-60 years with mean age being 34.9. Out of the 30 patients, a maximum patients belonged to the age group 31-40 years of life. The study comprised of 29 males and 1 female. The addictive habits were seen and Gutkha was seen to be most commonly used addictive habits followed by supari, khaini, sada pan masala, tobacco pan, sada pan, gul and tobacco chewing.



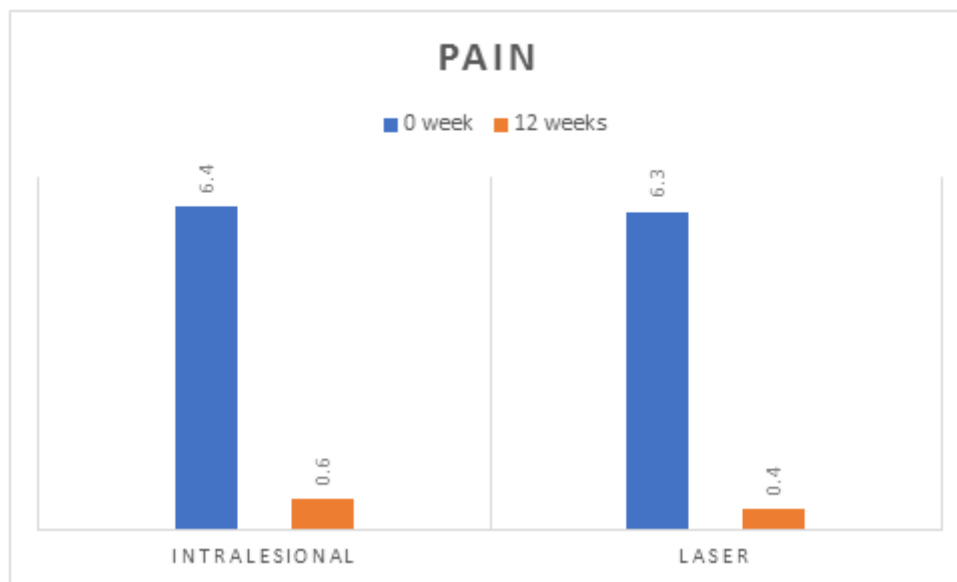
Out of the total study participants (n=30), patients receiving intralesional treatment shown mean burning sensation of 6.2 at 0 week, which got reduced to 0.67 at 12 weeks as per the VAS scale with mean difference of 5.53; and patients receiving laser treatment shown a mean burning sensation of 6.13 at 0 week, which got reduced to 0.6 at 12 weeks with mean difference of 5.53.

Burning sensation	0 wk	12 wks	P-value	Significance
Intralesional	6.2 ± 2.305	0.67 ± 0.9	<0.0001	Significant
Laser	6.13 ± 2.615	0.6±0.91		



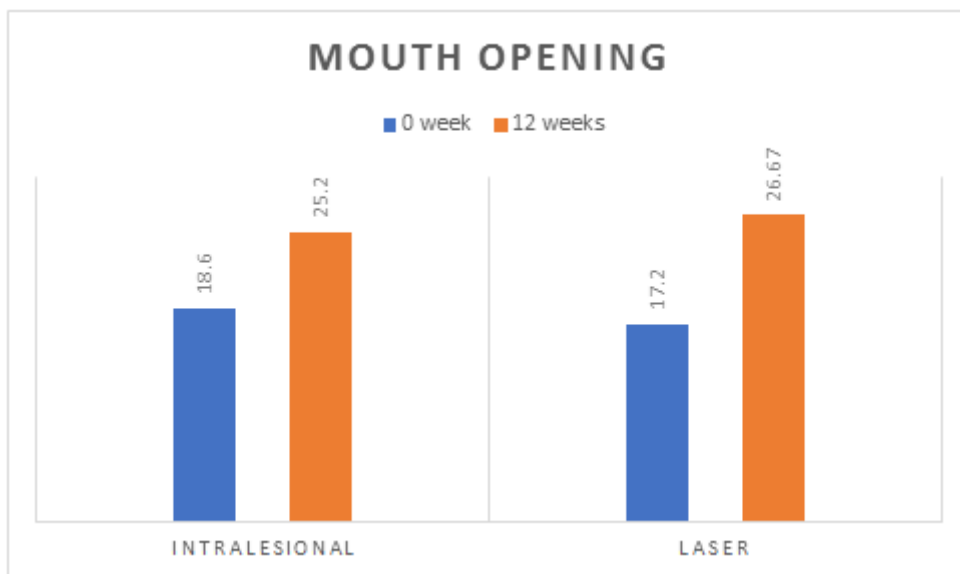
Out of the total study participants (n=30), patients receiving intralesional treatment shown pain on opening mouth with a mean value of 6.4 at 0 week, which got reduced to 0.6 at 12 weeks as per the VAS scale with mean difference of 5.8; and patients receiving laser treatment shown a mean value of 6.33 at 0 week, which got reduced to 0.4 at 12 weeks with mean difference of 5.93.

Pain	0 wk	12 wks	P-value	Significance
Intralesional	6.4±2.293	0.6±1.056	<0.0001	Significant
Laser	6.33±1.839	0.4±0.507		



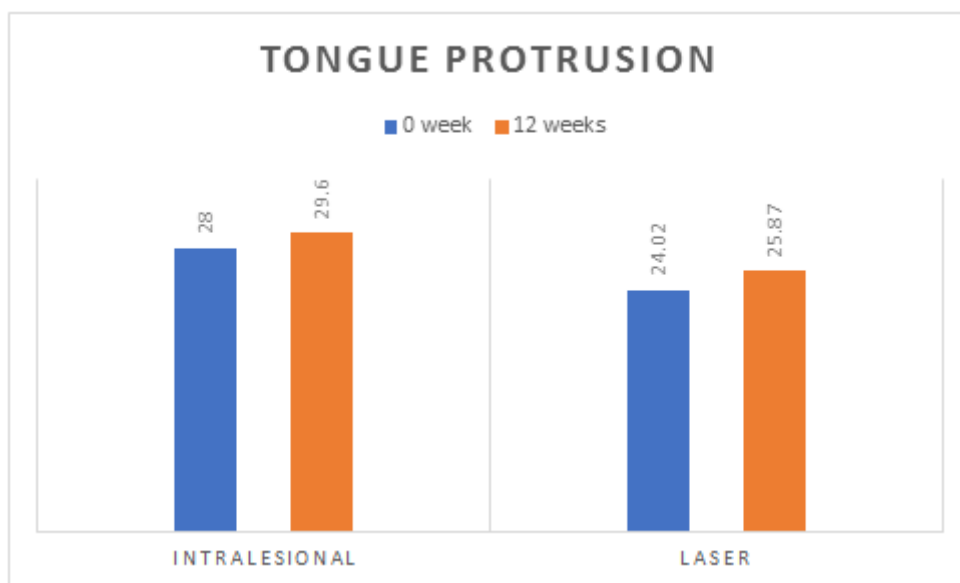
Out of the total study participants (n=30), inter-incisal mouth opening in the patients receiving intralesional treatment was seen to a mean value of 18.6 at 0 week and 25.20 at 12 weeks with a mean difference of 6.6. The inter-incisal mouth opening in the patients receiving laser treatment was noted with a mean value of 17.20 at 0 week and 26.27 at 12 weeks with a mean difference of 9.07

Mouth Opening	0 wk	12 wks	P-value	Significance
Intralesional	18.6±6.139	25.20±6.073	<0.0001	Significant
Laser	17.20±5.967	26.27±6.216		



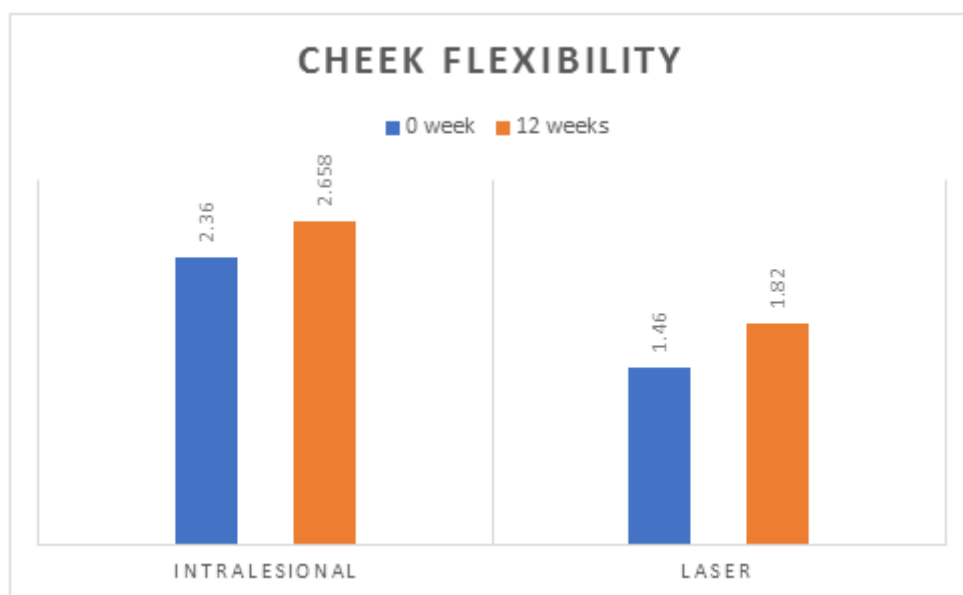
Out of the total study participants (n=30), tongue protrusion in the patients receiving intralesional treatment was measured and a mean value of 28 mm at 0 week and 29.8 mm at 12 weeks with a mean difference of 1.8. The tongue protrusion in the patients receiving laser treatment was noted with a mean value of 24 at 0 week and 25.93 at 12 weeks with a mean difference of 1.93.

Tongue Protrusion	0 wk	12 wks	P-value	Significance
Intralesional	28±7.387	29.8±7.636	<0.0001	Significant
Laser	24±5.451	25.93±5.405		



Out of the total study participants (n=30), cheek flexibility in the patients receiving intralesional treatment was seen to a mean value of 2.27mm at 0 week and 2.53mm at 12 weeks with a mean difference of 0.26. The cheek flexibility in the patients receiving laser treatment was noted with a mean value of 1.47 at 0 week and 1.87 at 12 weeks with a mean difference of 0.4.

Cheek Flexibility	0 wk	12 wks	P-value	Significance
Intralesional	2.27±0.884	2.53±0.915	<0.0001	Significant
Laser	1.47±0.516	1.87±0.640		



## DISCUSSION

There are 30 patients in this study belonging to 20-60 years, with majority of them in 31-40 years of life. This is consistent with the earlier studies by Sirsat and Khanolkaret al<sup>18</sup>, Sinor PN et al<sup>19</sup>, Ahmad et al<sup>20</sup> and Shah et al<sup>21</sup>. Mean age in our study is consistent with 29.04 years by Katharia et al<sup>22</sup>, 30 years by Maher et al.<sup>23</sup> and 30.7 years by Gupta et al<sup>24</sup>. This observation is different from that of Pindborg et al.<sup>3</sup> who reported the maximum number of OSMF cases in the age group of 40-49 years in their study. Higher male prevalence as shown in our study was consistent with the following studies with male: female ratio ranging from 2.4:1 to 40:1, namely Vinay K Hazarey et al, Pindborg and Kalapesi et al, Pindborg and Chawla et al, Pindborg and Bhat et al, Kiran et al, Pindborg and Mehta et al, Srivastava et al, Biradar SB et al<sup>26-33</sup>. However, few studies have reported female preponderance namely, Sinor PN et al., Seedat HA et al, Hazarey VK et al<sup>34-36</sup>. Such male predominance was also reported in earlier studies by Rawson et al.<sup>37</sup> who reported a 80% male patients and Apala Baduni et al<sup>38</sup> has reported a 95% male predominance. In the following study, Gutkha was seen to be most commonly used addictive followed by Areca nut (supari), sada pan masala, khaini, gul, tobacco pan, sada pan and tobacco. These findings were consistent with Babuet al.<sup>39</sup>, Nigam et al<sup>25</sup>, mehrotra et al<sup>40</sup>, shah et al<sup>41</sup>, Ali et al<sup>42</sup>, seedat and Van Wyk from South Africa<sup>43</sup> and Hazare et al<sup>44</sup> from India had similar observations in their studies.

The diode laser has a wavelength ranging from 805 nm to 980 nm that can be well absorbed by melanin and hemoglobin<sup>45</sup> and poorly absorbed by the HA and H<sub>2</sub>O present in the enamel. It is a portable device that transmits energy in gated or continuous pulse mode delivering rays through a flexible fiber optic cable and hence can be reached even to poorly accessible areas<sup>46</sup>. Its cutting depth is <0.01 mm. It gives a

precise controlled cutting without damaging deeper structures; hence ensuring satisfactory and rapid wound healing. The active material used is a semi-conducting crystal, usually GaAs (Gallium Arsenide) or similar compounds<sup>47</sup>. It has a good coagulation property which seals the blood vessels spontaneously while cutting. This allows excellent visibility and precision while dissecting. The operating time is less and the entire procedure is carried out intraorally without leaving any extraoral scar<sup>48</sup>. There is better compliance as there is low morbidity associated with the procedure. The limitation of laser is its high cost. In the present study, the patients showed a significant reduction in their symptoms post treatment. Literature research revealed that the diode laser has been used in the maximum number of studies (13 out of 20) to treat OSMF. In ten studies, diode laser was used for treating fibrotomy. Two studies used diode lasers for photo bio stimulation (Chandra et al., 2019; Singh et al., 2017)<sup>49,50</sup>. It is the application of laser at a low speed for a short specific interval of time affecting only the target area. This procedure is being used as an alternative to laser fibrotomy and has been proved to be a less invasive method as compared to fibrotomy. In one study, diode laser was applied for treating fibrotomy followed by LLLT (low level laser therapy) (Farista et al., 2018)<sup>51</sup>. In all the cases, patients showed improvement in the symptoms of the disease such as trismus, burning sensation and cheek flexibility with good wound healing and no scar formation. And in most of the cases, the treatment was followed by physiotherapy.

## CONCLUSION

Oral Submucous fibrosis is a crippling disease of the oral cavity due to its path physiology and its unsatisfactory management techniques. Within the limitations of the study, we conclude that laser fibrotomy and intralesional injection, both shows a

significant improvement in the symptoms of the patients; and laser fibrotomy is comparatively better when compared with Intralesional steroid. Gutkha and tobacco are the precipitating factors. Therefore, preventive measures to be taken at various levels; i.e. at national, state and individual level. It should involve education of the public regarding the ill effects of areca nut and tobacco along laws and punishments to restrict the sale of gutkha and similar products. Primary healthcare professionals including dentists should be knowledgeable and familiar with the etiopathogenesis, clinical presentation, diagnosis, and management of these lesions. With the above suggested significant results, there is no doubt that lasers can provide as an alternative and better means for surgical fibrotomy and relieving trismus in intermediate-late stages of OSMF cases as they are minimally invasive, cause less hemorrhage, and have short operating time, faster healing, less morbidity, and minimal surgical site scarring and relapse. Moreover, in review of predominance of this disease in our subcontinent, standardized protocols and procedures for surgical intervention have to be clearly outlined and established based on controlled trials and large sample size. In the modern era, the main concern for a surgeon remains the bloodless surgical field, minimum operating time, least morbidity. Thus usage and studies regarding the usage of laser in the treatment of OSMF should be encouraged, so as to know the efficacy and unknown side effects of lasers.

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