

**Original article:****COMPARATIVE STUDY OF ORAL SUBMUCOSAL FIBROSIS MANAGEMENT WITH TWO DRUG COMBINATION (TRIAMCINOLONE AND HYALURONIDASE) V/S THREE DRUG COMBINATION (TRIAMCINOLONE, HYALURONIDASE AND PLACENTAL EXTRACT)**

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**Abstract:**

**Background:** Oral submucosal fibrosis (OSMF) is a precancerous condition of the oral mucosa. It is exclusively occurring among Indians and South Asiatic people. It occurs due to areca nut consumption which leads to inflammation of oral and pharyngeal mucosa and impaired collagen metabolism. These leads to burning sensation in oral cavity, fibrosis of mucosal lining and trismus in OSMF.

**Aim:** Aim of the study is to know the effect of triamcinolone, hyaluronidase and placental extract in different combination in OSMF grade II and III patients.

**Material& Method:** A prospective study of 50 patients was done where they were divided in two groups. First group was treated with combination triamcinolone & hyaluronidase and second group was treated with triamcinolone, hyaluronidase and placental extract. Effectiveness of treatment was measured by visual analogue scale in pre and post treatment period. Mean score value for each symptoms was compared in two groups.

**Result:** At the end of study, burning sensation showed maximum improvement where mean score for first group was  $0.92 \pm 0.15$  and  $0.84 \pm 0.16$  in second group. For mouth opening, mean score of  $3.68 \pm 0.26$  was seen in first group and mean score of  $3.24 \pm 0.21$  was seen in second group. Both of these results show that second group can give better result compare to first group. Overall improvement was better in second group on comparing mean value score. Thus, OSMF patients show significant improvement ( $<0.05$ ) by medical treatment. in.

**Conclusion:** Maximal improvement seen in the burning sensation followed by other symptoms like colour of oral mucosa, fibrotic band and mouth opening in decreasing order in both the groups. Results were better with three drug combination group. Thus, corticosteroids, hyaluronidase and placental extract shows good improvement in OSMF patients in the form of relief of symptoms.

**Key words:** Oral submucosal fibrosis, areca nut, triamcinolone, hyaluronidase, placental extract.

**Introduction:** Oral submucous fibrosis (OSMF) is a chronic, insidious, generalized, and debilitating condition of the oral mucosa. It is a premalignant disorder associated with the

chewing of areca nut (betel nut). The habit is prevalent in South Asian populations but has been recognized nowadays also in Europe and North America. The incidence varies from 0.2 to 0.5% in India with a higher percentage being found in southern areas. Approximately 600 million persons are betel chewing, with a hot spot throughout the Western Pacific basin and South Asia. This makes betel the fourth most-consumed drug after nicotine, ethanol, and caffeine<sup>1, 2</sup>.

The earliest description of the disease was done by Schwartz in 1952<sup>3</sup>, who coined the term atrophica idiopathica mucosa oris to describe an oral fibrosing disease. Joshi subsequently termed the condition as oral sub mucous fibrosis (OSMF) in 1953, and Indian cases were reported from Bombay<sup>4</sup> and Hyderabad<sup>5</sup> for the first time. Pindborg et al. defined OSMF 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 juxtaepithelial inflammatory reaction followed by fibroelastic change of the lamina propria along with epithelial atrophy leading to stiffness of the oral mucosa and ultimately trismus and inability to eat<sup>6, 7</sup>".

OSMF shows a chronic and insidious change in fibroelasticity which is characterized by burning sensation in the oral cavity, blanching and stiffening of the oral mucosa and



oropharynx leading to trismus and inability to open the mouth. The symptoms and signs are depended on the progression of the lesions and the number

of affected sites. After transformation into squamous cell carcinoma (SCC), it is also responsible for mortality. Once the disease has developed, there is neither regression nor any effective treatment<sup>8</sup>. The combination of areca nut and tobacco has led to a sharp increase in the frequency of OSMF<sup>9</sup>. Other etiological factors are excessive consumption of spicy food, nutritional deficiencies like chronic iron and vitamin B complex deficiency.

Figure 1. Cases of OSMF showing pale white oral mucosa, fibrous bands, trismus respectively.

Dexamethasone in OSMF acts as an immune suppressive agent by its antagonistic activity on the soluble factors released by the sensitized lymphocytes succeeding the activation by nonspecific antigens<sup>10</sup>. It additionally muzzles the inflammatory reaction. Thus, fibrosis prevented by a decrease in fibroblastic proliferation and deposition of collagen. Hyaluronidase acts by breaking down hyaluronic acid (the ground substance in connective tissue) and lowers the viscosity of intercellular cement substance. Better results were observed with respect to trismus and fibrosis<sup>11</sup> in studies. Placental extract contains growth factors and anti-inflammatory agent and also has anti-platelet activity. It has biogenic stimulator action. It stimulates metabolism, increases the vascularity and promotes regeneration and recovery of the tissue upon inflammation into the body.

**Aim and objective:** To compare outcome of OSMF patients who were treated with medical therapy in two different groups, group A was treated with local injection of triamcinolone (40mg) and hyaluronidase (1500IU) and group B was treated with local injection of triamcinolone (40mg) , hyaluronidase (1500IU) and placental extract (2ml) in total 50 patients of OSMF (grade II and III).

**Material and method:** A prospective study of 50 patients of OSMF changes were taken in these study who came at L.G.Hospital, Ahmedabad. We took OSMF patients of grade II & III according to Khanna's OSMF classification for surgical management including both the sex. These patients were divided into two groups according as group A (triamcinolone & hyaluronidase) and group B (triamcinolone & hyaluronidase & placental extract). A detailed history of past and present complaints, detailed history of habits, nature of diet and other relevant factors were taken. Extraorally, the patient's mouth opening was measured with reference to interincisal points between upper and lower incisor teeth and it was assessed with geometric divider and metallic scale. Intraorally, the findings like blanching of oral mucosa, presence of vesicles and ulcers, palpable bands, limitation of tongue movement were observed.

The patient's age was noted according to age interval as 21-30 years, 31-40 years, 41-50 years and 51-60 years.

Group A patients were treated by intralesional injection of 40mg of triamcinolone and 1500IU hyaluronidase with 1ml 2% lignocaine HCL while Group B patients were treated by intralesional injection of 40mg of triamcinolone and 1500IU hyaluronidase with 1ml 2% lignocaine HCL and 2ml placental extract every 10 days for total 5 doses.

Outcome assessment was done by measuring following clinical parameters in post treatment period every 10 days and after 1 month of last dose.

The mouth opening was recorded at each assessment using a graded geometric divider and metallic scale by measuring the distance between the upper and lower central incisor edges at maximal unaided mouth opening, taking the mean of three readings. This method has been reported to have the accuracy of  $\pm 1$  mm. The different scores were assigned according to the patient's examination as 41 mm and above was considered as normal mouth opening score (0), 37-40 mm (1), 33-36 mm (2), 29-32 mm (3), 25- 28 mm (4), 21-24 mm (5), 17-20 mm (6) 13-16 mm (7), 9-12 mm (8), 5-8 mm (9) and 0-4 mm (10).

The colour of oral mucosa was assessed in natural light and was scored as normal pink Score (0), red or deep pink (1), pale white (2) and blanched white (3).

The fibrous bands were palpated and scored as no fibrous bands (0), one or two solitary fibrous bands (1), bands felt nearly in entire surface (2) and adherent fibrous band producing binding and rigidity of mucosa (3).

Protrusion of tongue was measured by asking patient to protrude the tongue as much as possible and then close the incisor teeth on it. The measurements were made from the incisor edge of maxillary central incisor to the tip of the tongue. The tongue protrusion was scored as 33 mm or above as normal score (0), 30-32 mm (2), 27-29 mm (2), 24-26 mm (3), 21-23 mm (4), 18-20 mm (5), 15-17mm (6), 12-14 mm (7), 9-11 mm (8), 5-8 mm (9) and 0-4 mm (10).

The patients were inquired about burning sensation while taking spicy food, paan, tobacco, hot beverages etc. and was scored as no burning sensation score (0), mild (1), moderate (2) and severe (3).

**Result:** In our study, out of 50 patients 40 male and 10 female of grade II and III of OSMF were included and they were equally divided into two groups according to treatment. Male: Female ratio is 4:1 which are showed in chat 1.

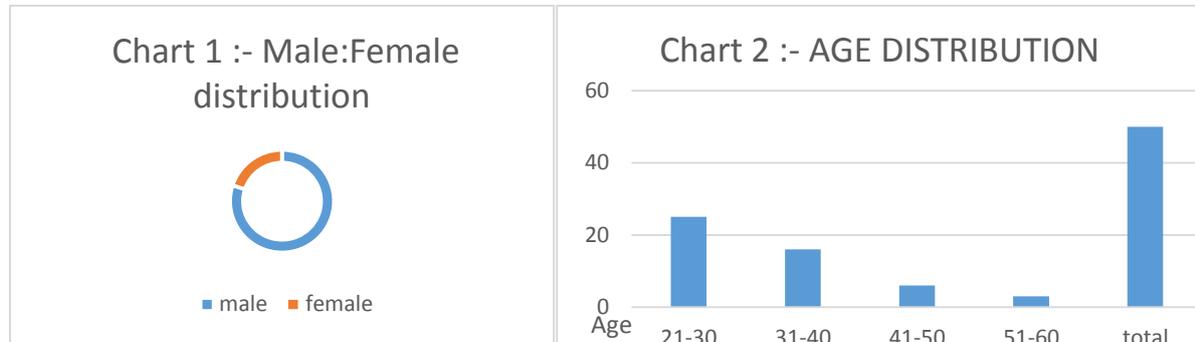


Chart 2 shows age distribution of OSMF patients according to different age groups. Maximum number of patients is belong to 21-30 years.

Table 1 shows result after treatment in the form of mean score in groups A. The difference of 2.8 between the pre-treatment ( $6.48 \pm 0.24$ ) and post-treatment ( $3.68 \pm 0.26$ ) mean score of mouth opening is shown in Table 1. The improvement in mouth opening is highly significant ( $P < 0.01$ ). The pre-treatment ( $2.28 \pm 0.1$ ) and post-treatment ( $1.24 \pm 0.11$ ) mean score of mucosal colour depicts a difference of 1.04 in improvement which is highly significant ( $P < 0.01$ ). There was an average reduction of 0.88 in fibrous bands where pre-treatment ( $1.96 \pm 0.13$ ) and post-treatment ( $1.08 \pm 0.11$ ) mean score values were compared ( $P < 0.01$ ). The improvement in burning sensation was observed where the pre-treatment ( $2 \pm 0.16$ ) and post-treatment ( $0.92 \pm 0.15$ ) mean score values were compared ( $P < 0.01$ ) and difference is 1.08. The pre-treatment ( $4.56 \pm 0.32$ ) and post-treatment ( $3.8 \pm 0.33$ ) mean score of protrusion of tongue and the difference is 0.56.

Table 1: Mean scores of clinical parameters in group A.

Clinical parameters	Maximal score	Pre-treatment score	Post-treatment score	Difference	Test of significance 't'
Trismus (mouth opening)	10	$6.48 \pm 0.24$	$3.68 \pm 0.26$	2.8	6.41
Colour of oral mucosa	3	$2.28 \pm 0.1$	$1.24 \pm 0.11$	1.04	2.16
Fibrous bands	3	$1.96 \pm 0.13$	$1.08 \pm 0.11$	0.88	2.16
Protrusion of tongue	10	$4.56 \pm 0.32$	$3.8 \pm 0.33$	0.56	1.09
Burning sensation	3	$2 \pm 0.16$	$0.92 \pm 0.15$	1.08	5.3

$P < 0.01$ ; values are Mean  $\pm$  SEM. n = 25

Table 2 shows result after treatment in the form of mean score in groups B. The difference of 3.08 between the pre-treatment (6.32±0.19) and post-treatment (3.24±0.21) mean score of mouth opening is shown in Table 2. The improvement in mouth opening is highly significant (P< 0.01). The pre-treatment (1.92 ±0.11) and post-treatment (0.96±0.13) mean score of mucosal colour depicts a difference of 0.96 in improvement, which is highly significant (P <0.01). There was an average reduction of 0.92 in fibrous bands where pre-treatment (1.64±0.14) and post-treatment (0.72 ±0.14) mean score values were compared (P < 0.01). The improvement in burning sensation was observed when the pre-treatment (2.04±0.16) and post-treatment (0.84 ±0.16) mean score values were compared (P < 0.01) and difference is 1.2. The pre-treatment (4.36 ±0.26) and post-treatment (3.28 ± 0.24) mean score of protrusion of tongue and the difference is 1.08.

Table 2: Mean scores of clinical parameters in group B.

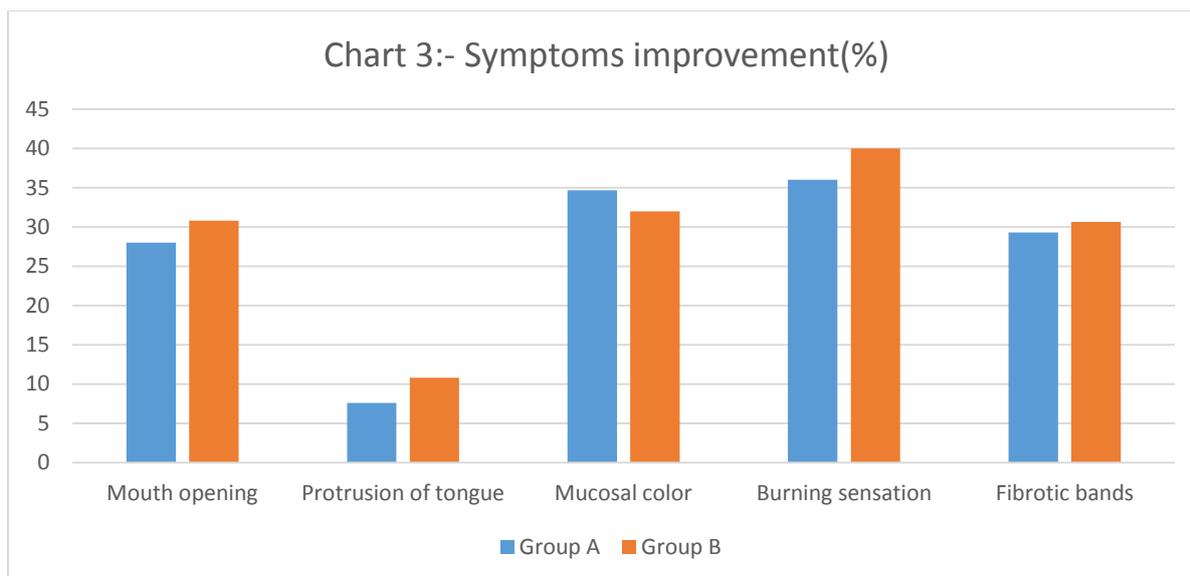
Clinical parameters	Maximal score	Pre-treatment score	Post-treatment score	Difference	Test of significance 't'
Trismus (mouth opening)	10	6.32±0.19	3.24±0.21	3.08	1.31
Colour of oral mucosa	3	1.92 ±0.11	0.96±0.13	0.96	2.17
Fibrous bands	3	1.64±0.14	0.72 ±0.14	0.92	4.49
Protrusion of tongue	10	4.36 ±0.26)	3.28 ± 0.24	1.08	1.97
Burning sensation	3	2.04±0.16	0.84 ±0.16	1.2	8.5

P < 0.01; values are Mean ± SEM. n = 25

Table 3 shows the overall improvement in both the groups in percentage with according to pre and post treatment mean scores in various clinical characteristic parameters. The maximum improvement 36% was observed in burning sensation followed by 34.66% in mucosal colour; 29.33% in fibrous bands; 28% in mouth opening and 7.6% in protrusion of tongue in group A. In the group B, the maximum improvement 40% was observed in burning sensation followed by 32% in mucosal colour; 30.8% in mouth opening; 30.66% in fibrous bands and 10.8% in protrusion of tongue. Chart 3 shows comparison between these two groups in the form of symptoms improvement.

Table 3:

Symptom improvement (%)	Symptom improvement	
	group A	group B
Mouth opening	28	30.8
Protrusion of tongue	7.6	10.8
Mucosal color	34.66	32
Burning sensation	36	40
Fibrotic bands	29.33	30.66



**Discussion:** OSMF is a peculiar disease which is considered to be a precancerous condition. OSMF is a chronic, progressive, and irreversible disease of unknown aetiology. The pathogenesis of the OSMF is not well established but the cause of OSMF is believed to be multifactorial. Caniff et al in 1986<sup>13</sup> and Pindborg in 1968<sup>14</sup> described the disease as a form of hypersensitivity to capsaicin, an irritant in chilies, but this was not totally substantiated in experimental work. A number of factors may trigger the disease process by causing a juxtaepithelial inflammatory reaction in the oral mucosa. Etiological factors which include areca nut chewing, ingestion of chilies, genetic and immunologic processes, nutritional deficiencies and other factors. OSMF is a premalignant disorder associated with the chewing of areca nut (betel nut).

Areca Nut (Betel Nut) chewing according to Liao in 2001 plays a major role in the pathogenesis of OSMF<sup>15</sup> which is a component of betel quid. Betel nut is frequently used as a psychotropic and antihelminthic agent and used as an after meal digestant which is taken to ease abdominal discomfort. Shear et al in 1967 and Caniff et al in 1987 evaluated correlation between betel nut chewing and the onset of oral sub mucous fibrosis<sup>13, 16</sup>.

According to Ranganathan in 2004 and Ariyawardana in 2006, smoking and alcohol consumption alone have been found to have no effect in the development of OSMF<sup>17, 18</sup> which are common habits in areca nut chewers. The strongest evidence regarding the etiology of OSMF is with the habit of areca nut chewing. In a study of over 1 lakh Indian subjects by Mehta F et al in 1968, areca nut was practiced by 52% of the patients with OSMF compared with 2.1 % amongst the total population<sup>19</sup>. A prospective study of 10 years on 10,000 individuals in India by Gupta PC et al in 1968, demonstrated an incidence of 0% OSMF amongst those who did not chew areca nut compared with an incidence of 35 % in 1 lakh per year among areca nut chewers<sup>20</sup>.

- Role of areca nut in pathogenesis of OSMF: - Arecoline is an active alkaloid found in betel nuts. It stimulates fibroblasts to increase production of collagen by 150% suggested by Canniff in 1981<sup>13</sup>. Chung-Hung in 2006, studied that arecoline was found to elevate the mRNA and protein expression of cystatin C (a non-glycosylated basic protein consistently up-regulated the variety of fibrotic diseases) in a dose-dependent manner in persons with OSMF<sup>21</sup>. Areca nuts has also been shown to have a high copper content

and chewing areca nuts for 5-30 minutes significantly increases soluble copper levels in oral fluids. This increased level of soluble copper supports the hypothesis as an initiating factor in individuals with OSMF<sup>22</sup>.

- Sex: The male: female ratio of OSF varies by region, but females tend to predominate. Seedat, Dec in 1988 studied that female predominance was reported in Durban, South Africa, a distinct demonstrated, with a male-to-female ratio of 1:13<sup>23</sup>. With the onset of new commercial betel nut preparations, trends in sex predominance and age of occurrence might shift. In our study, male : female ratio is 4:1 due to higher consumption of areca nut and its various form chewing more in male population in our country.
- Age: The mean age was 43 Years. The percentage of chewers increases with age and the frequency of chewing and type of betel nut may influence the individual's susceptibility. Ahmad in 2006 reported that patient age between 11-60 years. In our study, we noticed that maximum number of patient belong to 21-30 years of age due to dominance of this age group more towards starting areca nut chewing and 41-50 age group shows more severity of symptoms due to duration of habit which is increases along with the age. In our study, 25 patients belonged to age of 21-30 years where 22 were males and 3 were females, 16 patients belonged to age 31-40 years where 11 were males and 5 were females, 6 patients belonged to age 41-50 years where 4 were males and 2 were females and 3 patients belonged to age 51-60 years where all 3 were males. We compared our age distribution data with the study of Leena James et al (2015)<sup>28</sup> where 12 patients belonged to age 21-30 years where 8 were males and 4 were females, 7 patients belong to age 31-40 years where 4 were males and 3 were females, 6 patients belonged to age 41-50 years where 4 were males and 2 were females and 3 patients of age 51-60 years where 2 were males and 1 was female.
- According in 1995 Khanna<sup>24</sup> developed a group classification system for the surgical management of trismus which was taken in our study to see effect of conservative treatment in specifically in grade II & III.
  - ❖ Group I: This is the earliest stage and is not associated with mouth opening limitations. It refers to patients with an interincisal distance of greater than 35 mm.
  - ❖ Group II: This refers to patients with an interincisal distance of 26-35 mm.
  - ❖ Group III: These are moderately advanced cases. This stage refers to patients with an interincisal distance of 15-26 mm. Fibrotic bands are visible at the soft palate, and pterygomandibular raphe and anterior pillars of faucets are present.
  - ❖ Group IVA: Trismus is severe, with an interincisal distance of less than 15 mm and extensive fibrosis of all the oral mucosa.
  - ❖ Group IVB: Disease is most advanced, with premalignant and malignant changes throughout the mucosa.
- Few other classifications are as follow:
  - In 1989, Pindborg clinically divided OSMF is into 3 stages<sup>19</sup> and the physical findings vary accordingly to it which were also reported by Murti, in 1992; Cox, in 1996; Aziz, in 1997<sup>12</sup>:
    - Stage 1: Stomatitis includes erythematous mucosa, vesicles, mucosal ulcers, melanotic mucosal pigmentation, and mucosal petechia.

- Stage 2: Fibrosis occurs in ruptured vesicles and ulcers when they heal, which is the hallmark of this stage.
  - ❖ Early lesions demonstrate blanching of the oral mucosa.
  - ❖ Older lesions include vertical and circular palpable fibrous bands in the buccal mucosa and around the mouth opening or lips. This results in mottling and marble like appearance of the mucosa because of the vertical and thick fibrous bands running in a blanching mucosa. Specific findings include the following:
    - Reduction of the mouth opening (trismus)
    - Stiff and small tongue
    - Blanched and leathery floor of the mouth
    - Fibrotic and depigmented gingiva
    - Rubbery soft palate with decreased mobility
    - Blanched and atrophic tonsils
    - Shrunken bud like uvula
    - Sinking of the cheeks which is not commensurate with age or nutritional status
- Stage 3: Squeal of OSMF are as follows:
  - ❖ Leukoplakia is precancerous and is found in more than 25% of individuals with OSMF.
  - ❖ Speech and hearing deficits: may occur because of involvement of the tongue and the eustachian tubes.
- For the purpose of treatment, Kakkar and Puri graded OSMF patients on the basis of the clinical condition<sup>25</sup>.
  - ❖ Grade I: Only blanching of oral mucosa without symptoms
  - ❖ Grade II: Burning sensation, dryness of mouth, vesicles or ulcer in the mouth without tongue involvement
  - ❖ Grade III: In addition of Grade II with restriction of mouth opening
  - ❖ Grade IV: In addition to Grade III palpable bands all over the mouth without tongue involvement
  - ❖ Grade V: Grade IV and also tongue involvement
  - ❖ Grade VI: OSMF along with histopathologically proven cancer.

➤ Management and prevention: -

The treatment of patients with OSMF depends on the degree of clinical involvement. If the disease is detected at a very early stage, cessation of the habit is sufficient. Most patients with OSMF present with moderate to-severe staging. Moderate-to-severe staging of OSMF is irreversible. Medical treatment is symptomatic and aimed at improving mouth opening.

- Not to consume areca nut & other chronic irritant such as hot and spicy food.
- Advice green leafy vegetables.
- Administration of Vit. A, B complex & high protein diet.
- Administration of antioxidant OD for 6 – 8 weeks.
- Physiotherapy: - It increase mouth opening.

○ MEDICAL TREATMENT

According to Aziz (1997), treatment of OSMF includes the following<sup>12</sup>.

- Steroids: In patients with moderate OSMF, sub mucosal intralesional injections given. Topical application of steroids may help, prevent further damage. The recommended dose is 75 to 100 mg twice a week for 4 to 6 weeks.
- Hyaluronidase: The use of intralesional hyaluronidase shows significant improvement than steroids alone. The recommended dose is 1500 IU twice weekly for 4 to 6 weeks.

According to Karkar in 1985 the combination of steroids and hyaluronidase injection shows better long-term result than either using alone<sup>26</sup>. There was significant improvement in the OSMF symptoms like mouth opening, burning sensation, mucosal colour which is statistically highly significant ( $P < 0.01$ ) by using steroid and hyaluronidase<sup>27</sup>.

- Placental extracts: The action of placenta extract is essentially biogenic stimulation and its use is based on the tissue therapy method. The Inj. Placentex is an aqueous extract of human placenta which essentially acts on biogenic stimulation theory and contains the following ingredients: 1) Enzymes: alkaline and acid phosphatase, glutamic oxaloacetic acid transaminase, glutamic acid and pyruvic acid transaminase. 2) Nucleotides: RNA, DNA and ATP. 3) Vitamins: Vit. E, B1, B2, B6, pantothenic acid, biotin, PABA, folic acid, B12, choline, inositol. 4) Amino-acids: Alanin, asparagin, asparagenic acid, cysteine, glycine, histidine, leucine, lysine, phenylalanin, proline, serine, threonine, tryptophane, tyrosine, valine. 5) Steroids: 17 ketosteroids, cholesterol. 6) Fatty acids. 7) Trace elements, Sodium, K, Ca, Mg, Cu, Fe, P, Si. Sur in 2003 reported that the rationale for using placental extract in patients with OSMF derives from its proposed anti-inflammatory effect<sup>29</sup> prevents the mucosal damage<sup>28</sup>. Anil in 1993 reported that Sub mucosal administration of aqueous extract of healthy human Placental extract has shown marked improvement of the condition<sup>29</sup> and recommended dose of placental extract is 2ml twice weekly for 4 to 6 weeks.

There was significant improvement in the mouth opening which is statistically highly significant ( $P < 0.01$ ) by using placental extract<sup>30</sup>.

We compared our mean score parameters with the study of SK. Katharia et al (1992)<sup>31</sup> which saw that the difference of 1.45 between the pre-treatment ( $5.13 \pm 0.29$ ) and post treatment ( $3.68 \pm 0.25$ ) mean score of mouth opening. The difference of 0.91 was seen between the pre-treatment ( $2.36 \pm 0.15$ ) and post treatment ( $1.45 \pm 0.10$ ) mean score of mucosal colour. The difference of 0.82 was seen between the pre-treatment ( $2.68 \pm 0.12$ ) and post-treatment ( $1.86 \pm 0.10$ ) mean score of fibrous band. The highest improvement of 1.13 in burning sensation was observed where the pre-treatment mean score was  $2.81 \pm 0.10$  and post treatment mean score was  $1.68 \pm 0.13$ . The difference of 0.41 was seen between the pre-treatment ( $2.22 \pm 0.14$ ) and post-treatment ( $1.81 \pm 0.18$ ) mean score of protrusion of tongue. In that study, all the values were significant ( $P < 0.01$ ) except value for protrusion of tongue.

We also compared our symptomatic improvement value with the study of SK. Katharia et al (1992)<sup>31</sup> which saw that the maximum improvement (40.21%) was observed in burning sensation followed by 38.55% in mucosal colour; 30.59% in fibrous bands; 28.26% in mouth opening and 18.46% in protrusion of tongue.

#### ○ SURGICAL MANAGEMENT

Surgical treatment is indicated in patients with severe conditions. These include:-

- Simple excision of the fibrous bands: Excision can result in contracture of the tissue and exacerbation of the condition.
- Split-thickness skin grafting following bilateral temporalis myotomy or coronoidectomy: Trismus associated with OSMF may be due to changes in the temporalis tendon secondary to OSMF; therefore, skin grafts may relieve<sup>13</sup>.
- Nasolabial flaps and lingual pedicle flaps: Surgery performed only in patients with OSMF in whom the tongue is not involved<sup>31</sup>.

**Conclusion:** Thus in our study, OSMF treatment with local injection of corticosteroid, hyaluronidase and placental extract in combination shows great relief in symptoms than alone. We also noted that addition of placental extract shows great result. We noted 13-16 mm average mouth opening (mean score 6) before treatment and 25-28 mm average mouth opening (mean score 3) after treatment in both the groups along with marked reduction in burning sensation in oral cavity, fibrotic band and improvement in mucosal colour.

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