

Collagen membrane: A new concept in surgical management for mucosal defect in oral sub mucous fibrosis



Sourav Kumar¹, Dipti Nayak², Shashank Kumar³, Musaab Khan⁴, Reshu Rastogi⁵, Vaishali Samant⁶

^{1,2}Private Practitioner, Rosera, Samastipur, Bihar, India, ³Post Graduate Trainee III year, Department of Orthopaedics, Narayan Medical College & Hospital, Sasaram, Bihar, India, ⁴Senior Lecturer, ⁵Post Graduate Trainee III year, ⁶Post Graduate Trainee II year, Department of Oral & Maxillofacial Surgery, Kothiwal Dental College & Research Centre, Moradabad, Uttar Pradesh, India

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ABSTRACT

Background: Oral submucous fibrosis (OSMF) is a doubtlessly malignant disorder of the oral cavity. The surgical control of this situation involves excision of the fibrotic bands and interpositional grafts to keep the elevated oral opening. Various strategies and graft had been utilized with differing achievement rates. **Aims and Objective:** Through this study, an attempt was made to evaluate the efficacy of collagen membrane as wound dressing material for mucosal defect in oral submucous fibrosis. **Materials and Methods:** The study include 30 patients in the age group of 15 to 60 years with stage III or IVa of oral sub mucous fibrosis all of which underwent operation under general anesthesia to enhance their mouth opening by fibrotomy of bands and placement of collagen membrane by same surgeon. After surgery all the patients were accessed under parameter like hemostatic effect, pain relief, granulation tissue formation, epithelization, contracture and reactivity. All patients were given similar prescriptions for pain killer, antibiotics and postoperative instructions. All patients were examined postoperatively. **Results:** In this study various parameter were accessing the efficacy of collagen membrane on wound defects were recorded. In this 1st parameter hemostatic 28 patients had a score of good (93.3%) with bleeding stopping within 5 minutes after application of membrane and only 2 patients had a score of fair (6.66%). In pain relief analgesics were stopped on the day of 3rd after procedure 16 patients had a good (53.3%) score, 12 patients had a fair (40%) score while only 2 patients had a poor (6.66%) score. All the patients had sufficient granulation tissue formation of entire wound therefore all the patients had score of good (100%) at the end of two weeks. Epithelization was noted in 28 patients who had score of good (93.3%) after 1 month. Contracture of the wound site at the end of 3 months were noted and rated as good in 20 patients (66.6%) while fair (33.3%) in 10 patients. No reactivity of any form was found in any of the subjects (100%). **Conclusion:** In our study we noticed that collagen membrane was found to be very effective in all the subjects and it provided us satisfactory results as intraoral wound dressing material.

Keywords: Collagen membrane; General anesthesia; Oral submucous fibrosis

INTRODUCTION

Oral submucous fibrosis (OSMF) is a chronic, progressive, precancerous condition of oral mucosa, oropharynx and rarely larynx, commonly seen in the Indian subcontinent.¹ The continuous involves irreversible fibrosis of the submucosa causes formation of fibrous band and leads to

trismus, a lack of inability to consume normal spicy food in the subcontinent area customary to, and carries a high risk of malignant transformation.² Malignant transformation rate of 3.7 to 6% is found in cases of oral submucous fibrosis.²

Various known etiological factors for this disease can be areca nut chewing, capsaicin in chillies, micronutrient

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Address for Correspondence:

Dr. Sourav Kumar, Rosera, Samastipur, Bihar, India, Pin-848210. Mobile: +91 7903558911. E-mail: kumarurbeyasaurav4@gmail.com

deficiency of iron, zinc and essential vitamins. A possible autoimmune basis to the disease with demonstration of various autoantibodies and an association with specific human leukocyte antigens has been reported, which increases the possibility of the genetic predisposition as well.³

There are numerous surgical procedures which include excision of fibrous bands with or without graft have been used. In surgical intervention masticator myotomy, coronoidectomy/coronoidotomy and surgical release of fibrotic bands are required. Reconstruction may be done with buccal fat pad (BFP) flap, skin grafts, tongue flap, greater palatine pedicled flap, placental graft, artificial dermis and anterolateral thigh flap, temporalis fascia flap and radial forearm flap and nasolabial flap.³

Khanna and Andrade proposed a comprehensive classification based on clinical and histological features: group I—maximum interincisal opening (MIO) >35 mm (early OSMF without trismus); group II—MIO range 26–35 mm (mild to moderate disease); group III—MIO range 15–25 mm (moderate to severe disease); group IVa—MIO < 15 mm (severe disease); group IVb—extremely severe premalignant/malignant intraoral lesions noted.⁴

Biological dressings like collagen create the most physiological interface among the wound surface, environment and impermeable to bacteria. Collagen, the most ample protein within the body, performs a crucial role in wound healing. Its deposition, maturation and remodelling are very important to maintain the integrity of the wound. Collagen is a biological product and has advantage of being more non-antigenic, excellent tissue compatibility and easy availability. It has been extensively tried as temporary dressing material in another surgical field. Wounds left uncovered are prone to infection, contraction, and scarring with other clinical complications.⁵

Raw wounds in the oral cavity behave similarly; a need therefore arises to use a biologic cover to prevent these complications. Thus collagen membrane can be one of the options for the surgical treatment of OSMF.

We used collagen membrane to cover the buccal defect after the excision of fibrous bands. Collagen membranes are enough sufficient to resist masticatory forces for a sufficient time, to permit granulation tissue to form, which seems uniformly.

Hence a study has been undertaken to establish the application of collagen membrane after fibrotic band excision for surgical management of oral sub mucous fibrosis.

Aims and objectives

Assess the efficacy of collagen membrane as wound dressing material for mucousal defect in oral submucous fibrosis in terms of haemostatic effect, pain relief, granulation tissue formation, epithelialization and contracture of wound.

MATERIALS AND METHODS

In this trial 30 patients underwent surgical management of OSMF as an application of collagen membrane after fibrotic band excision for oral submucous fibrosis. All of the subjects were evaluated preoperatively. Informed consent was obtained. Inclusion criteria were – 1. Patients with the age group of 15 to 60 years with a Mean age of 37.5+ years were Included in the study, 2. Patients falling under stage II & IVA (Khanna and Andrade) of Oral submucous fibrosis were included in the study.

Patients suffering from any renal or hepatic disease, blood dyscrasia, previous present gastric ulcers, heart disease, hypersensitivities, allergies, or idiosyncratic reactions to any study medications, Pregnant or lactating females and patients not consenting to participate in the study were excluded.

Surgical technique

The operations were accomplished under general anaesthesia with nasal intubation. The incisions had been made with an electrosurgical knife along each side of the buccal mucosa at the level of the occlusal plane away from the Stenson's orifice. Incision was turned out posteriorly to the pterygomandibular raphe or anterior pillar of the faces and anteriorly as far as the corner of the mouth, depending upon the location of the fibrotic bands which restricted mouth opening (Figure 1). These fibrotic bands had been constantly detectable by palpation. The wounds created had been similarly freed with the aid of using manipulation until no restrictions had been felt. The mouth was then compelled open with a mouth opener to an acceptable range of approximately 3.5cm. The reconstituted collagen membrane was placed on bilateral buccal defects and secured with quilt sutures (Figure 2).

Post-operative instruction:

All patients received Inj. Amoxicillin +Potassium Clavulanate 1.2gm and Inj. Metronidazole 500 mg, 8 hourly by the intravenous route for the first 4 days and then medication was turned switched directly to oral route for subsequent 4 days. Patients were put on Dexamethasone at the tapering doses for 3 consecutive days. Patients received analgesics, Injection Diclofenac sodium 12th hourly for the first two days. Analgesics had been stopped on the 3 postoperative days. All Patients had been told to stop chewing betel nuts or other addictive habits. Patients had

been taught mouth opening exercises with a Heister's mouth opener or the use of ice cream sticks and had been instructed to carry out this exercise 6 times per day.

RESULTS

Age of patients ranged from 21 to 52 years. A total of 12 (40%) patients each are in age group 15-30 years, 12 (40%) patients were in 46-60 years and 6 (20%) patients were in 46-60 years respectively.

According to Khanna and Andrade's group of staging OSMF based on clinical features 20 (66.66%) patients were in group of stage III While 10 (33.3%) patients belonged to group Iva (Table 1).

Haemostasis by the membrane was assessed 1 hour and 1 day postoperatively. It was considered to be good (2) when the bleeding stopped within 5 minutes, fair (1) when it was achieved after a more prolonged period, and poor (0) when intervention was required to stop bleeding. In our series of patients only 2 patients had a score of fair (6.66%) while rest 28 had a score of good (93.3%).

Pain being subjective, was categorized based on the patient's own words as good (none to mild), fair (moderate) and poor (severe). It was recorded on day 5 after the procedure when the patient was no longer taking analgesic medications. In our present study 16 patients had a good (53.3%) score, 12 patients had a fair (40%) score and 2 patients had a poor (6.66%) score.

The presence of granulation tissues was noted at the end of 2nd weeks and rated as good (entire wound), fair (nearly the entire wound), or poor (inadequate). In our series of patients, a score of good (100%) granulation tissue formation was seen in all the patients.

Epithelialization was noted at the end of the month and rated as good (entire wound), fair (nearly the entire wound), or poor (inadequate). In the present study only 2 patients had a score of fair (6.66%) while rest 28 had a score of good (93.3%).

Contracture of the wound site at the end of 3 months was noted and rated as good (25%), fair (50%) and poor or severe i.e. 50%. In our study 20 patients (66.6%) had a good score and 10 patients (33.3%) based on the contracture of wound.

Effectiveness was assessed by adding up the scores, and a value ranging from 8 to 10 was considered very effective; 5

Stage	No. of subjects	Percentage
III	20	66.6%
Iva	10	33.3%

to 7 was effective; and 0 to 4 considered as ineffective. In our present study 28 patients (93.3%) had a score of Very effective while only 2 patients (6.66%) had a score of effective.

Reactivity/allergenicity of the material was assessed depending on the reactions elicited and was graded as none when no reactions were seen, moderate when few reactions were noted but resolved without any intervention, and severe when intervention and treatment were required. In our present treatment no patients had any form of reactivity to the collagen membrane (Table 2).

Statistical analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical analysis Software. The values were represented in Number (%) and Mean \pm SD. The following Statistical formulas were used:

Mean: To obtain the mean, the individual observations were first added together and then divided by the number of observations. The operation of adding together or summation is denoted by the sign Σ .

The individual observation is denoted by the sign X, number of observations denoted by n, and the mean by \bar{X}

$$\bar{X} = \frac{\Sigma X}{\text{No. of observation}}$$

Number of observations (n)

DISCUSSION

Biomaterials derived from animal origin, especially the ones generally depend based totally on collagen, were utilized in various fields of surgery. Collagen is broadly to be had with advances in its technique of extraction, purification, and cross linkage. It has been viable to apply collagen in various forms in current times.⁶

Table 2: Distribution of patients

	No. of patients	Percentage	Score
Haemostatic effect			
1.	28	93.3	Good
2.	2	6.66	Fair
Pain relief			
1.	16	53.3	Good
2.	12	40	Fair
3.	2	6.66	Poor
Granulation			
1.	30	100	good
Epithelialization			
1.	28	93.3	Good
2.	2	6.66	Fair
Contracture			
1.	20	66.6	Good
2.	10	33.3	Fair
Reactivity			
1.	30	100	Good



Figure 1: Incision procedure



Figure 2: Reconstituted collagen membrane was placed

The aim of treatment for oral submucous fibrosis is firstly, to advise patient to stop habits and to provide good release of fibrosis with long term results in terms mouth opening.⁷ It is a well-established fact that in oral sub mucous fibrosis there is decreased vascularity to the affected region by fibrosis due to contraction and narrowing of blood vessel as a result of increased pressure on them by fibrosis tissue bands. The use of collagen membrane in treatment of OSMF is more suitable for juxtaposed defects of buccal mucosa, and is increasingly becoming popular. Collagen, a well-known protein, has been widely used in medical applications.²

In our series, all patients gave a positive history of chewing some form of betel nut or tobacco or a combination of the common form being roasted betel nuts. Diagnostic criteria in our study were burning sensation of mucosa, mucosal blanching, resulting in marbled appearance and stiffness of oral mucosa, stomatitis, sensation of dry mouth, alteration in taste, fibrosis of the oral mucosa followed by stiffness most commonly in the buccal mucosa, soft palate and faucial pillars. Fibrotic bands running vertically in the cheek and circumferentially in the lips. Majority of these diagnostic features were observed in all our patients with varying severity.

Regarding haemostasis in our series of patients only 2 patient had a score of fair (6.66%) while rest 28 had a score of good (93.3%) i.e., bleeding was stopped within 5 minutes after application of collagen membrane on the defect in all of the patients except two. Haemostasis by collagen is a result of its character, which includes being a specific activator of platelets, as well as their adhesion and aggregation. Collagen has chemo tactic effect to endothelial cells and fibroblasts, due to this inflammation and pain is significantly reduced.^{8,9}

The results of present study showed that collagen placement induced minimal pain, oedema and infection and wounds healed uneventfully. Typically the appearance of the areas of wound was found to be restored to normal texture within about 1 month of grafting, which was in accordance with the study conducted by Jasthi et al.¹⁰

In our series of patients a score of good (100%) granulation tissue formation was in accordance with the study of Rastogi et al.,¹¹ and Bandekeri et al.,¹² in which granulation tissue formation was seen in all his subjects after application of collagen as wound dressing material.

In the present study epithelialization was noted 1st month postoperatively in which 2 (6.66%) had fair and 28(93.3%) had a score of good epithelialisation, which was similar to study reported by Vastani et al.,³ and Singh et al.¹³

In our study contracture of the wound site at the end of 3 months was noted in which 20 patients (66.6%) had a good score and 10 patients (33.3%) fair based on the criteria noted for contracture of wound. Kothari et al.,¹⁴ found reduction of pain on maximal mouth opening with the advancement of time on both the sides of the patients suggestive of appropriate healing on both the sides suggesting similar results.

Reactivity/allergenicity of the material was assessed depending on the reactions elicited. In our present treatment no patients (100%) had any form of reactivity to the collagen membrane. Clinically, collagen is well tolerated with no adverse effects. These findings was similar to the study by Randhawa et al.¹⁵

Most crucial method for controlling scarring have been controlling infection and minimizing growth of granulation tissue. Collagen membrane appeared to satisfy these goals. Although it showed good biocompatibility as proven by Sowjanya et al.¹⁶

CONCLUSION

In our Study we noticed that surgical excision of fibrous bands and placement of collagen membrane provided us

with satisfactory results. However, it does not fulfil all the requirements of an ideal graft but is an alternative. Their application in the oral cavity is easy due to the simple chair side application and good tolerance of the membranes by the oral tissue.

Note

Collagen membrane can be used as simple chair side application. It is easily sterilised and stored at room temperature. Easily available for grafting and it is economical. Good haemostatic effect, sufficient granulation tissue formation, good wound contracture and epithelialization was noted in almost all patients.

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Author's Contribution:

SK- Concept and design of the study; prepared first draft of manuscript; **DN-** Interpreted the results; reviewed the literature and manuscript preparation; **MK-** Concept, coordination, review of literature; **RR-** manuscript preparation; **SK-** Statistically analyzed; **VS-** interpreted, preparation of manuscript and revision of the manuscript.

Work Attributed to:

Kothiwal Dental College & Research Centre, Moradabad, Uttar Pradesh, India.

Orcid ID:

Dr. Sourav Kumar- <https://orcid.org/0000-0003-2140-5886>
 Dr. Dipti Nayak- <https://orcid.org/0000-0003-0068-4126>
 Dr. Shashank Kumar- <https://orcid.org/0000-0001-9299-5006>
 Dr. Musaab Khan- <https://orcid.org/0000-0001-8194-7682>
 Dr. Reshu Rastogi- <https://orcid.org/0000-0003-3912-285X>
 Dr. Vaishali Samant- <https://orcid.org/0000-0001-8843-5313>

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