

Comparative evaluation of buccal pad of fat with and without bovine collagen membrane in the management of oral submucous fibrosis: A prospective clinical study

ABSTRACT

Background: Oral submucous fibrosis (OSMF) is a chronic, debilitating disease characterized by juxtaepithelial fibrosis. The present study evaluates the efficacy of buccal fat pad (BFP) and bovine collagen membrane as reconstruction options.

Materials and Methods: The sample size includes 22 patients between 20 and 60 years, randomly distributed in two groups: Group I in which BFP was used and Group II where BFP with bovine collagen membrane was used after surgical resection of fibrotic bands. The clinical evaluation on postoperative 1st, 3rd, and 5th days and 1st, 2nd, 3rd, 4th, 12th, and 24th weeks subsequently.

Results: The mean age in Group I was 27.17 ± 3.157 years and Group II was 37.90 ± 6.657 years. The mean preoperative mouth opening was 9.75 ± 6.717 and 8.90 ± 3.784 mm in Groups I and II, respectively. The mean duration of presenting illness in Group I was 9.75 ± 2.598 years and in Group II was 8.80 ± 1.989 years. There was no significant difference observed between Groups I and II in relation to reduced mouth opening and duration of symptoms ($P > 0.05$) except for age. No significant difference was observed between both the groups in relation to preoperative pain, burning sensation, cheek stiffness, mucosal suppleness, postoperative infection, and postoperative pain at days 1 and 5 and 1st week. There was a significant difference observed in postoperative pain among both the groups on the 3rd day and 2nd week.

Conclusion: In the present study, both the groups have proved to give better results, as BFP in the form of interposition material showed rapid epithelization and minimum wound contracture.

Keywords: Bovine collagen membrane, buccal pad of fat, mouth opening, oral submucous fibrosis

INTRODUCTION

Oral submucous fibrosis (OSMF) is a chronic, debilitating disease characterized by juxtaepithelial fibrosis of the oral cavity. It is regarded as a precancerous and potentially malignant condition, an insidious, chronic disease that affects any part of the oral cavity including pharynx.^[1-3] Although occasionally preceded by formation of vesicles, it is always associated with a juxtaepithelial inflammatory reaction followed by fibroelastic change of the lamina propria and epithelial atrophy that leads to stiffness of the oral mucosa, causing trismus and inability to eat. According to the World Health Organization, a precancerous oral condition is defined as “a generalized pathological state of the oral mucosa associated with a significantly increased risk of cancer” that fits well with the characteristics of OSMF.^[4]

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Joshi in 1953 subsequently termed the condition as OSMF.^[5] Other names suggested include “diffuse oral submucous fibrosis,” “idiopathic scleroderma of the mouth,” “idiopathic palatal fibrosis,” and “sclerosing stomatitis.” Pindborg and Sirsat in 1966^[2] suggested that a more appropriate name would be “juxtaepithelial fibrosis.” Its premalignant nature was first described by Paymaster in 1956.^[6]

Geographically, OSMF has a specific distribution and affects predominantly Asians (particularly Indians from the southern states) and Taiwanese. An estimate from 1996 indicated that over 5 million people are affected in India alone (0.5% of the Indian population).^[7] It is predominantly seen in the second or third decade, and recent data suggested a male predominance; however, both sexes are equally at risk.^[7] The most commonly involved site is buccal mucosa, followed by palate, retromolar region, faucial pillars, and pharynx.^[8]

Clinically, OSMF is characterized by burning sensation in mouth on eating spicy food, blisters, recurrent stomatitis, defective gustatory sensation, and dryness of mouth initially. A useful clinical sign is pain on palpation in the sites where submucosal fibrotic bands are developing, and trismus is caused mostly by fibrosis in the dense tissue around the pterygomandibular raphe. Fibrosis of the eustachian tube may lead to deafness. Late symptoms include stiffness of oral mucosa and difficulty in mouth opening. Progressive fibrosis reaches the pharynx in advanced cases, leading to difficulty in swallowing, shrunken uvula, pain in ears, and nasal intonation of voice. Petechiae in the absence of blood dyscrasias or systemic disorders are found in about 22% of the patients with OSMF and occur most often on the tongue, followed by the labial and buccal mucosa. The most obvious clinical signs include blanched, opaque oral mucosa with palpable fibrous bands.

Histopathologically, it is characterized by progressive submucosal fibrosis with epithelial changes ranging from atrophy to hyperplasia to dysplasia. The most disturbing part of the disease process is its malignant transformation rate. A significant malignant transformation rate (7%–30%) poses global problems for public health.^[7,9]

A variety of etiologic factors including capsaicin, areca nut alkaloids, hypersensitivity, autoimmunity, genetic predisposition and chronic iron, zinc, essential vitamins, and Vitamin B complex deficiency have been suggested by various authors, the most common of which is chewing areca nut. Areca nut is chewed in various forms such as raw, dried, scented supari, mawa, mainpuri, gutkha, pan masala, and in betel quid either with or without lime. The exact role of any

one of these in the development, severity, and extent of the disease is not clear till date, as the disease may still occur if none of these are present.^[10,11]

The current protocol for the management of OSMF includes surgical, physical, and medical treatments. However, Kerr *et al.* in 2011^[12] recently hypothesized that cessation of the habit alone may have a considerable effect – more on the symptoms of OSMF than on reversing fibrosis. The introduction of buccal pad of fat (BFP) for the surgical management of OSMF is proved to be very efficient. Collagen is a biological product and has advantage of being more nonantigenic, excellent tissue compatibility and easy availability. It has been extensively tried as temporary dressing material in another surgical field.^[13]

OSMF is a common potentially malignant condition prevalent in the South Asian population. Despite Having Various Medical and Surgical Treatment Modalities for Osmf there is Still Lack of an Ideal or Preferred Protocol. The present study was conducted with the aim of achieving results in terms of mouth opening after transecting the fibrous bands followed by grafting using BFP with and without collagen and comparing their roles in achieving the same. The hypothesis of the study was to assess whether the bovine collagen membrane graft over the BFP provides better healing and improvement in mucosal suppleness and mouth opening.

MATERIALS AND METHODS

Twenty-two patients aged between 20 and 60 years, including both males and females which were diagnosed clinically as OSMF, were randomly selected from the outpatient department of the oral and maxillofacial surgery department. Written consent was obtained from each patient, and institutional ethical committee approval ECR/526/Inst/UP/2014 was taken. The inclusion criteria included patients with good general health but clinically proven OSMF (Stages III and IV) with restricted mouth opening. The exclusion criteria included patients with systemic diseases, compromised immune system, allergy or hypersensitivity to drugs, or any other agents being used in the study. Patients who were pregnant, lactating, with poor prognosis, localized infections, and not willing for regular follow-up were also excluded.

The rationale behind the study was to compare the clinical efficacy of BFP along with bovine collagen membrane with BFP alone as an onlay graft in reconstruction of surgical defect created after excision of fibrotic bands. Various reconstruction methods are available but the BFP is most easily accessible, much reliable, and has minimal donor site

morbidity. Bovine collagen membrane is considered as a scaffold to promote epithelization.

A detailed history was obtained from each patient with special reference to their habits and duration. Routine hemogram, urine, and clinical examinations were done to rule out any associated systemic diseases. The local examination included distribution of fibrous bands and sites of involvement. Functional staging of OSMF was assessed by measuring the interincisal distance in millimeters, based on the classification system by More *et al.* (2012).^[14]

The patients were randomly divided into Groups I and II. Preoperative antibiotics (ceftriaxone + sulbactam 1.5 g) were given intravenously, and patients were operated under general anesthesia. Nasoendotracheal intubation was performed under direct laryngoscopy or using fiber-optic in case of severely reduced mouth opening. The operating region was infiltrated with local anesthesia, and after palpation of fibrous bands, horizontal incision was given using no. 15 Bard-Parker blade along buccal mucosa at the level of occlusal plane away from opening of Stenson's duct, extending from angle of mouth anteriorly till pterygomandibular raphe posteriorly up to depth of submucosal layer. Release of fibrous bands was done by blunt dissection through curved hemostat or fingers until no restriction was felt. Intraoperatively, forceful mouth opening was done using Heister's mouth gag as wide as possible. Extraction of bilateral maxillary and mandibular third molars and coronoidectomy were also performed in few cases where intraoperative mouth opening achieved was <25 mm. The defect was irrigated with normal saline and betadine solution.

In Group I, BFP was approached through the posterosuperior margin of the created buccal defect, i.e., posterior to zygomatic buttress. BFP was dissected out gently until a significant amount was obtained to cover the defect without tension. After achieving hemostasis, BFP was secured with peripheral suturing using 3-0, 3/8 round body 22 mm Vicryl sutures [Figure-1]. Among Group II patients, reconstruction was done by placing pedicled bfp graft over the defect and then securing bovine collagen membrane over bfp. The collagen sheath was washed in saline to remove preservative isopropyl alcohol and cut with scissors to required shape. After leaving a small overlap on the remaining mucous membrane, it was secured over BFP with peripheral suturing to attain close approximation with BFP and mucosa [Figure-2].

Regular postoperative instructions were given, along with postoperative antibiotics and analgesics. Intensive physiotherapy was started within 36 h postoperatively

using Heister's mouth gag. Patients were discharged after 1 week, following mouth opening measurement, with strict instructions regarding continuance of intense mouth opening exercises and Cessation of habits. The clinical evaluation of healing was done on the basis of selected parameters on postoperative 1st, 3rd, and 5th days and 1st, 2nd, 3rd, 4th, 12th, and 24th weeks subsequently.

1. Assessment of pain was done using the Visual Analog Scale (VAS)^[15] scoring system (none 0 is 0, mild [1–24] is 1, moderate [25–49] is 2, and severe [50–100] is 3) on postoperative 1st, 3rd, and 5th days
2. Assessment of swelling was done using the scoring criteria laid by Siddiqi *et al.*^[16] on postoperative 1st, 3rd, and 5th days
3. Assessment of epithelization was recorded as per criteria used by Arai *et al.*^[17] on postoperative 1st, 2nd, 3rd, and 4th weeks
4. Assessment of mouth opening was done on postoperative 1st, 4th, 12th, and 24th weeks
5. Assessment of mucosal suppleness was done using scoring system, i.e., poor (contracture) – 1, fair (slightly altered) – 2, and good (normal or almost near to normal) – 3.

Data obtained were analyzed using SPSS version 16.0 SPSS 16.0 software Windows version (Inc., Chicago, USA). at a significance level of 0.05. The level of significance between the groups at various time intervals was evaluated using Chi-square statistical analysis.

RESULTS

Among Group I, 83.3% of the patients were 21–30 years old and 16.7% were 31–40 years old, whereas among Group II, 10% were 21–30 years old and 50% were of 31–40 years. Four patients were above the age of 40 years. A statistically significant difference was observed between both the groups. The mean age in Group I was 27.17 ± 3.157 , and in Group II, it was 37.90 ± 6.657 years. Among Group I, 12 patients were male, whereas in Group II, 8 were male and 2 were female, showing no significant difference observed between both the groups. However, male dominance was noticed.

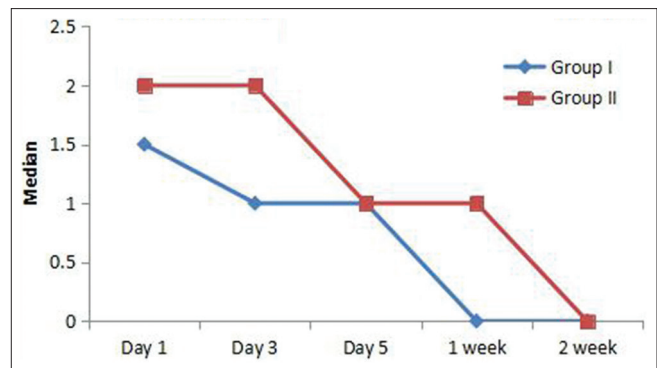
Among Group I, the duration of presenting illness was <10 years in 41.7% of the patients and >10 years in 58.3%. In Group II, it was <10 years in 20% and >10 years in 80% of the patients. The duration of presenting illness was more than 10 years in almost 60% of the patients in both the groups, but no significant difference was observed

between both the groups. The mean duration in Group I was 9.75 ± 2.598 , and in Group II, it was 8.80 ± 1.989 years. Among Group I patients, the mean preoperative mouth opening was 9.75 ± 6.717 , and in Group II, it was 8.90 ± 3.784 mm, with no significant difference. Among Group I, six patients presented with the chief complaint of mild pain on wide oral opening and six did not have any pain. In Group II, two patients reported with moderate pain, six have mild pain, and two have no history of pain. It showed that mild pain was associated with 50% of the cases, but no significant difference was observed between both the groups ($P > 0.05$). In Group I, 33.3% of the patients presented with burning sensation on taking spicy food and 66.7% did not experience it. In Group II, burning sensation was present in 50% and absent in 50% of the cases. No significant difference was observed between both the groups.

Among Group I, 83.3% reported with cheek stiffness and 16.7% did not suffer with it. In Group II, it was present in all 10 patients. It showed that palpable fibrous bands were associated in more than 80% of the cases but with no significant difference between the groups. In Group I, 16.7% of the patients were reported in M3 stage and 83.3% in M4 stage. Among Group II, only one patient was in M3 stage and 9 were having Stage 4 OSMF, but no significant difference was observed between both the groups.

Postoperative mucosal suppleness was assessed postoperatively. In Group I, 66.7% reported with good whereas 33.3% with fair mucosal suppleness over the operated side. In Group II, 20% reported good whereas 60% showed fair mucosal suppleness and 20% had poor status. None of the patients in Group I and one patient in Group II presented with postoperative infection, showing no statistically significant difference. Postoperative pain assessment was done at various time intervals [Table 1]. In both the groups, the median VAS score has significantly reduced at different time intervals [Graph-1]. Postoperative swelling assessment was done at various time intervals [Table 2]. In Group I and II patients, the median VAS score has significantly reduced at different time intervals.

The postoperative epithelization was observed in both the groups [Table 3]. In both Groups I and II, the median VAS score has significantly reduced at different time intervals except 2nd week in Group II. Intraoperatively, the mean mouth opening achieved in Groups I and II was 36.92 ± 4.92 and 31.60 ± 2.5 mm, respectively, with no statistically significant difference. On the 1st week after the surgery, the mean mouth opening of Group I and II patients was 27.83 ± 3.538 and 28.40 ± 2.271 , respectively. On the 4th week, it was 28.00 ± 4.472 mm in Group I and 27.00 ± 3.712 mm in



Graph 1: Graphical representation showing comparison of median Visual Analog Scale score between two groups at different time interval

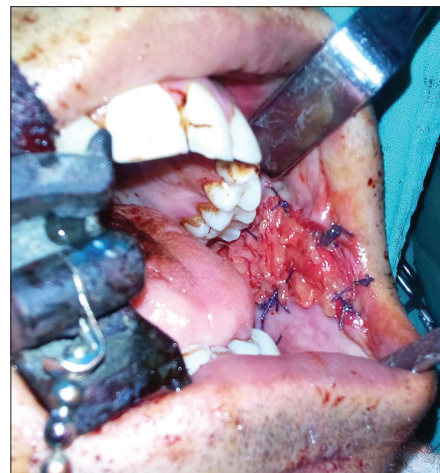


Figure 1: Photograph showing defect interpositioned with buccal fat pad graft alone



Figure 2: Photograph showing defect interpositioned with buccal fat pad graft covered with bovine collagen

Group II. On the 12th week, it was 27.50 ± 5.351 in Group I and 26.75 ± 3.327 in Group II. On the 24th week, it was 27.17 ± 5.508 in Group I and 26.00 ± 2.619 mm in Group II. There was no significant difference in Group I at different time intervals when compared with the 1st week. Among Group II,

Table 1: Postoperative pain assessment

Time interval	VAS score	Group I (n=12), n (%)	Group II (n=10), n (%)
Day 1	1	6 (50.0)	2 (20.0)
	2	6 (50.0)	6 (60.0)
	3	0 (0.0)	2 (20.0)
	Median (IQR)	1.50 (1.00-2.00)	2.00 (1.75-2.25)
	P	0.075*	
Day 3	1	8 (66.7)	2 (20.0)
	2	4 (33.3)	8 (80.0)
	Median (IQR)	1.00 (1.00-2.00)	2.00 (1.75-2.00)
	P	0.032**	
Day 5	0	4 (33.3)	2 (20.0)
	1	6 (50.0)	4 (40.0)
	2	2 (16.7)	4 (40.0)
	Median (IQR)	1.00 (0.00-1.00)	1.00 (0.75-2.00)
	P	0.257*	
1 week	0	8 (66.7)	4 (40.0)
	1	4 (33.3)	6 (60.0)
	Median (IQR)	0.00 (0.00-1.00)	1.00 (0.00-1.00)
	P	0.222*	
2 weeks	0	12 (100)	6 (60.0)
	1	0 (0.0)	4 (40.0)
	Median (IQR)	0.00 (0.00-0.00)	0.00 (0.00-1.00)
	P	0.018**	

*P>0.05 is insignificant; **P<0.05 is significant. IQR: Interquartile range, VAS: Visual Analog Scale

Table 2: Postoperative swelling

Time interval	Score	Group I (n=12), n (%)	Group II (n=10), n (%)
Day 1	1	10 (83.3)	6 (60.0)
	2	2 (16.7)	4 (40.0)
	Median (IQR)	1.00 (1.00-1.00)	1.00 (1.00-2.00)
	P	0.232	
Day 3	0	2 (16.7)	0 (0.0)
	1	10 (83.3)	8 (80.0)
	2	0 (0.0)	2 (20.0)
	Median (IQR)	1.00 (1.00-1.00)	1.00 (1.00-1.25)
	P	0.050	
Day 5	0	8 (66.7)	6 (60.0)
	1	4 (33.3)	4 (40.0)
	Median (IQR)	0.00 (0.00-1.00)	0.00 (0.00-1.00)
	P	0.752	
1 week	0	12 (100)	8 (80.0)
	1	0 (0.0)	2 (20.0)
	Median (IQR)	0.00 (0.00-0.00)	0.00 (0.00-0.25)
	P	0.112	
2 weeks	0	12 (100)	10 (100)
	Median (IQR)	0.00 (0.00-0.00)	0.00 (0.00-0.00)
	P	1.000	

IQR: Interquartile range

there was a significant difference on the 12th and 24th weeks compared to the 1st week, except on the 4th week [Table 4].

Table 3: Postoperative epithelization

Time interval	Epithelization	Group I (n=12), n (%)	Group II (n=10), n (%)
1 week	1	12 (100)	10 (100)
	Median (IQR)	1.00 (1.00-1.00)	1.00 (1.00-1.00)
	P	1.000	
2 weeks	1	6 (50.0)	10 (100)
	2	6 (50.0)	0 (0.0)
	Median (IQR)	1.50 (1.00-2.00)	1.00 (1.00-1.00)
	P	0.010	
3 weeks	1	0 (0.0)	2 (20.0)
	2	8 (66.7)	8 (80.0)
	3	4 (33.3)	0 (0.0)
	Median (IQR)	2.00 (2.00-3.00)	2.00 (1.75-2.00)
	P	0.018	
4 weeks	2	2 (16.7)	6 (60.0)
	3	10 (83.3)	4 (40.0)
	Median (IQR)	3.00 (3.00-3.00)	2.00 (2.00-3.00)
	P	0.040	

IQR: Interquartile range

Table 4: Postoperative mouth opening (mm)

Mouth opening	Mean±SD		t	P
	Group 1	Group 2		
Intraoperative mouth opening	36.92±4.92	31.60±2.5	3.069	0.006
Mouth opening (1 week)	27.83±3.538	28.40±2.271	-0.436	0.667
Mouth opening (4 weeks)	28.00±4.472	27.00±3.712	0.563	0.580
Mouth opening (12 weeks)	27.50±5.351	26.75±3.327	0.352	0.729
Mouth opening (24 weeks)	27.17±5.508	26.00±2.619	0.555	0.586

SD: Standard deviation

DISCUSSION

Oral submucous fibrous is a well-known clinical entity since the time of Sushruta as *vidari*. In modern literature, it was first described by Schwartz in 1952.^[18] It is a chronic, progressive precancerous condition of oral mucosa, predominantly seen in the South Asian subcontinent. Younger the age, more rapid is progression of condition with patients having burning sensation and presence of vesicles on the palate. Ulceration and dryness of the mouth are later followed by fibrosis of the oral mucosa, leading to rigidity of lips, tongue, palate, and trismus.

In the present study, palpable fibrous bands were mostly over posterior and anterior buccal mucosa, retromolar trigone, labial mucosa, and soft palate. In the present study, most of the patients were of younger age groups (20–40 years), and there was male predominance seen, as seen in a study by Arakeri and Brennan *et al.* in 2013.^[7] In the present study, all the patients had a history of areca nut chewing that generates free radicals and causes local immunosuppression. Similar etiology was observed by Seedat and van Wyk, 1988;^[19] Lal, 1953;^[20] and Cannif *et al.*, 1986.^[21] Aziz, 2008,^[22] reported that 7%–13% of the OSMF cases

transformed into squamous cell carcinoma, as seen in our study with one patient showing transformation into oral cancer.

The basic aim of any treatment modality is relieving fibrosis with surgical therapy to regain and retain its normal form and function. However, literature contains few references to the successful managements of OSMF. Relapse is a common complication that occurs after surgical release of the oral fibrosis caused by OSMF. Initially, surgeons aimed at surgical elimination of the fibrotic bands which showed further scar formation and recurrence of trismus, hence to prevent they started using various onlay graft and local flaps.^[23-25]

In the present study, we compared the clinical efficacy of using BFP with and without collagen in reconstruction of postsurgical defects in OSMF. The bulk of BFP in our series was found to be adequate in all cases, and it maintained its position as interposition material postoperatively, similar to the findings of Lai *et al.* (1955),^[26] Yeh,^[23] and Rapidis *et al.*^[27]

The clinical changes were evaluated by scoring various selected parameters in the postoperative periods: pain, swelling, epithelization, oral opening, mucosal suppleness, and postoperative infection. The pattern of reduction of pain along with the progression of time is indicative of proper healing in both the groups and consistent with the studies by Yeh^[23] and Rastogi *et al.*^[28] The pattern of reduction of swelling at different time intervals is consistent with the study of Pradhan *et al.*^[29] Healing of BFP was consistent in our study and comparable to studies done by Tideman *et al.*^[30] and Sharma *et al.*^[31] In patients with BFP along with collagen, at the end of the 4th week, 40% of the patients were having good epithelization. This is almost consistent with studies by Agrawal *et al.*^[32] and Pradhan *et al.*^[29] who advocated that collagen epithelizes in approximately 4–5 weeks. Improvement in the physiologic functions such as suppleness and elasticity of the buccal mucosa on clinical examination is similar to a study conducted by Yeh.^[23]

In the present study, prophylactic extraction of all third molars was done to avoid trauma to the flap in the retromolar region. In advanced disease, bilateral temporalis myotomy and coronoidectomy were done in few cases to achieve a mouth opening of more than 35 mm, as advocated by Chang *et al.*^[33] and Muhammad *et al.*^[34] The mean value of mouth opening was 31.2 mm and 37.4 mm, respectively, in a study conducted by Yeh. There was an increase of approximately 19.1 mm from the preoperative measurement in the study. The mean value of mouth opening of 27.17 mm at the end of the study and increase in the mouth opening of 17.4 mm was almost similar to various studies.^[29,31]

BFP + bovine collagen membrane (COLLOSKIN) was used following excision of fibrotic bands in Group II participants to cover the raw areas during initial phase of healing. The appearance of grafted area was restored to normal texture in about 4 weeks, in accordance with studies by Pradhan *et al.*^[29] and Agrawal *et al.*^[32]

CONCLUSION

The present study was conducted to assess the postsurgical improvement in pain, swelling, epithelization, mouth opening, and mucosal suppleness postoperatively up to 6 months following the use of BFP with and without collagen membrane in the management of OSMF. In the present study, both the groups proved to give better results as BFP in the form of interposition material showed rapid epithelization and minimum wound contracture. There was no extra or added advantage of placement of collagen over the BFP. Vigorous mouth opening exercises, cessation of habits, and improvement in the nutritional status are must for better results postoperatively. However, further studies should be conducted, to evaluate the efficacy of BFP with bovine collagen membrane in large sample size.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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