Clinical efficacy of mouth exercising devices in oral submucous fibrosis: A systematic review

Shailesh M. Gondivkar^{a,*}, Amol R. Gadgail^b, Sachin C. Sarode^c, Rima S. Gondivkar^d,
Shankargouda Patil^e, Rahul N. Gaikwad^f, Monal Yuwanati^g

^a Department of Oral Medicine & Radiology, Government Dental College & Hospital, Nagpur, Maharashtra, India

^b Department of Dentistry, Indira Gandhi Government Medical College & Hospital, Nagpur, Maharashtra State, India

^c Department of Oral Pathology & Microbiology, Dr. D.Y. Patil Dental College & Hospital, Dr. D.Y. Patil Vidyapeeth, Pune, Maharashtra State, India

^d # 301, Aarti Regency, Mahalakshmi Nagar, Manewada Road, Nagpur, Maharashtra State, India

^e Department of Diagnostic Sciences, Division of Oral Pathology, College of Dentistry, Jazan University, Jazan, Saudi Arabia

^f Department of Community Dentistry and Oral Epidemiology, College of Dentistry, Qassim University, Buraydah, Saudi Arabia

^g Department of Oral Pathology & Microbiology, People's College of Dental Sciences & Research Centre, Bhopal, Madhya Pradesh, India

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ABSTRACT

Background: The management of oral submucous fibrosis (OSF) is primarily focused towards minimizing patient's symptoms and to prevent cancer development. Mouth exercise physiotherapy independently or in combination with other modalities is considered to be a mainstay for increasing the mouth opening (MO). The present systematic review was performed to identify different mouth exercising devices (MEDs) used and to provide detailed information on the fabrication and clinical efficacy of these devices among OSF patients.

Methods: PubMed, Scopus, Web of Science, Google Scholar and CINAHL were searched for relevant literature until February 2019 and the information was extracted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. All full text papers describing use of MED in OSF patients were considered eligible.

Results: Initial search resulted in 88 hits. After removing duplicates and screening of titles and abstracts, five papers that met the inclusion criteria were included. We identified five MEDs used for increasing the MO in OSF patients. Only one study administered additional treatment with topical steroids, oral antioxidants and ice-cream stick regime. The follow-up across studies ranged from 8 weeks to 6 months. Majority of the studies reported significant improvement in the MO without any relapse and side effects.

Conclusions: MED could play an important role in the management of OSF. Limited researches in this area suggest a dire need for the further investigations using randomized controlled trials.

1. Introduction

The progressive limitation in the normal mouth opening (MO) is one of the most common manifestations reported by patients with oral submucous fibrosis (OSF).¹ Depending on the severity of the disease, OSF patients may experience limited MO from few millimeters to even several centimeters. Limited MO usually restrains normal daily functions including mastication, deglutition and speech. Patients with limited MO always have difficulties in oral hygiene care; subsequently leading to caries and periodontal diseases. In addition, the limited access makes dental treatments strenuous in these patients. This can result

in impaired health-related quality of life (HRQoL) including physical and psychological disabilities.^{2–4} Furthermore, past studies demonstrated poor nutritional status and depression in patients with reduced mouth opening.⁵

OSF is a chronic progressive debilitating disease of the oral mucosa with a malignant transformation risk of 1.9% to 9%.⁶ Although highly predominant in Indian subcontinent and other Asians,⁷ OSF is gradually spreading all over the world including Europe and America due to Southern Asian immigrants population.^{8,9} As per the latest clinical definition, OSF is a debilitating, progressive, irreversible collagen metabolic disorder induced by chronic chewing of areca nut and its

* Corresponding author. Department of Oral Medicine & Radiology, Government Dental College & Hospital, Medical College Campus, Medical Square, Nagpur, Maharashtra State, 440003, India.

E-mail addresses: shailesh_gondivkar@yahoo.com (S.M. Gondivkar), gadgail@yahoo.co.in (A.R. Gadgail), drsachinsarode@gmail.com (S.C. Sarode), rsongdivkar@gmail.com (R.S. Gondivkar), dr.ravipatil@gmail.com (S. Patil), dr.rahul1415@gmail.com (R.N. Gaikwad), monal9817@gmail.com (M. Yuwanati).

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Fig. 1. PRISMA flowchart showing flow of information.

commercial preparations; affecting the oral mucosa and occasionally the pharynx and esophagus; leading to mucosal stiffness and functional morbidity; and has a potential risk of malignant transformation.¹⁰ In contrast to probable causative factors in other conditions, limited MO in OSF is the result of progressive sub-epithelial fibrosis of the oral mucosa resulting in loss of elasticity and stiffness.

OSF may be resolved with cessation of areca nut/betel quid chewing habits if it is noticed before initiation of limitation of MO.¹¹ Once initiated, it is difficult to control the progression of reduction in MO. At present, there is no consensus on treating OSF-related limited MO. Although variety of conservative therapeutic options has been tried in past, no promising treatment modality is available for complete relief of OSF symptoms.¹² Surgical treatments have also been advocated depending upon severity of the difficulties in MO. Unfortunately, all these modalities have limitations, compliance issues and relapse.¹³ Past literature supports mouth exercising as an adjunctive physiotherapy to help improve MO and prevent post-surgical relapse.^{11,13–16} Physiotherapy alone has also been documented to increase oral opening in OSF by tissue remodeling.¹⁵ Various mouth exercising devices (MEDs) have been described in the literature for the treatment of OSF.^{14–17}

Since, no comprehensive review is available till date about MEDs in OSF patients, the present review was designed with the aim to identify different MEDs used and to provide detailed information on the fabrication and clinical efficacy of these devices among OSF patients.

2. Material and methods

2.1. Study design

The present systematic review was carried out using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement as a reporting guide.¹⁸

2.2. Search strategy

The PubMed, Scopus, CINAHL, Web of Science and Google Scholar were searched for all the publications describing MED in OSF on 15th February 2019. As per the search strategy (Supplementary material 1& 2), all the relevant papers were identified. In addition, the reference lists of all relevant articles were also hand-searched.

2.3. Eligibility criteria

All full text papers using MED in OSF patients were considered eligible. Review articles, editorial and correspondence were excluded. No restriction was applied on date and papers published in any language if they were available with the English translation. The outcome measure used was MO.

2.4. Study selection

Two reviewers (SG and AG) independently screened titles and abstracts of the relevant articles for their eligibility. Full texts of all potentially eligible papers were then retrieved and assessed again independently by the same reviewers (SG and AG). Any discrepancies were resolved by discussion with third reviewer (SS) and a list of the articles to be included in this review was finalized.

2.5. Data extraction

Two reviewers (SG and AG) independently assessed all the included studies. Any disagreements were resolved by discussion with third reviewer (SS).

2.6. Data analysis

Data extraction revealed considerable heterogeneity of the included studies so that a meta-analysis could not be carried out. Instead of that, data were pooled into a table and a descriptive summary was generated to report on study characteristics and outcomes.

3. Results

3.1. Search results

The initial search resulted in a total of 87 hits (PubMed: 29, Scopus: 39, CINAHL: 2, Google Scholar: 16 and Web of Science: 1). We identified one additional paper after reference checking of relevant articles. After removal of duplicates and screening of titles and abstracts, 8 full texts were agreed for further evaluation, of which 5 met the inclusion criteria. Fig. 1 demonstrates an overview of the search process.

3.2. Study characteristics

Thorough literature search identified three original research^{15,19,21} and two case reports^{17,20} describing MEDs for treatment in OSF patients and published between 1996¹⁷ and 2019.²¹ The target population in all the papers was OSF patients. However, Li et al.²¹ included head & neck (H & N) cancer patients additionally. The number of patients was in the range of 1–117. In addition to use of MED, Patil et al.¹⁹ administered topical steroids, oral antioxidants and ice-cream stick regime to OSF patients. Cox et al.,¹⁵ Chaitanya et al.²⁰ and Li et al.²¹ did not provide any associated treatment. However, Le et al.¹⁷ used oral stent post-surgical treatment to prevent relapse. The follow-up across studies ranged from 8 weeks to 6 months. Majority of the studies reported significant improvement in MO without any relapse and side effects (Table 1).

EZBite: This MO training device is developed by Li et al.²¹ in 2019 and is made up of polyvinyl chloride plastic and stainless steel. The size of EZBite is 6.1 × 5.8 × 10 cm and weights around 78 gm. The device is helpful in patients with MO of > 5 mm as the minimum width of open-mouth is 5 mm. The device can be used at 20–60 °C and can bear occlusal stress of 25 kg/cm². The upper and lower mouthpieces of EZBite are placed between maxillary and mandibular teeth and the handle is squeezed with a stretching range of 5 mm. The device can be easily controlled by the patients.

Nallan C-H appliance: This device is developed by Nallan et al.²⁰ in

Table 1
An overview of characteristics of the studies.

Sr. no.	Author	Type of article	Name of MED	Type	Year	Country	Target population	Total no. of patients	Associated treatment	Follow-up	Outcome (average increase in MO)	Relapse
1.	Le et al. ¹⁷	Case report	Oral stent	Tooth-borne	1996	Canada	OSF	01	Daily physiotherapy exercises	6 months	Maintained Mouth opening range	None
2.	Cox and Zollettner ¹⁵	Original research	Tongue spatula	Tooth-borne	2009	Nepal	OSF	Physiotherapy group: 23 Hyaluronidase & steroid injection group: 15	Cessation of areca nut use and advised bland diet avoiding spicy foods. Haematinic and anti-helminthic supplements in anaemic patients	4 months	Significant improvement in MO (p < 0.0005) in physiotherapy group as compared to other groups	NR
3.	Patil et al. ¹⁹	Original research	MED	Non-tooth-borne	2016	India	OSF	Control group: 16 Group A1: 53 Group A2: 46 Group A3: 18	Topical steroids, oral antioxidants & ice-cream stick regime intervened to all patients in addition Group A1: No additional treatment Group A2: Injectable Depomedrol Group A3: Band removal surgery	6 months	Significant improvement in MO in MED users (8.4 mm) as compared to non-users (5.5 mm)	NR
4.	Chaitanya et al. ²⁰	Case report	Nallan C-H	Tooth-borne	2018	India	OSF	03	None	8 weeks	Significant improvement in MO (2–8 mm)	None
5.	Li et al. ²¹	Original research	EZBite	Tooth-borne	2019	Taiwan	H&N cancer, OSF	20	None	12 weeks	Significant improvement in MO (10.5 mm)	NR

Note: MED: Mouth exercising device, MO: Mouth opening, OSF: Oral submucous fibrosis, H&N: Head and neck, NR: Not reported.

Fig. 2. Schematic diagrams of the mouth exercising devices.

2018 by using self-cure acrylic resin. It is designed for individual patient as acrylic plate which covers labial/buccal surfaces of all mandibular teeth and maxillary molars with extended occlusal plates in maxillary and mandibular molars. The labial extension helps the device to stay fit in position and prevents breakage and accidental slip into the adjacent mucosa and esophagus. The 12 mm gauge hyrax screws are adapted bilaterally on buccal aspects of molars during fabrication. Patients are instructed to use the appliance overnight for 8 weeks and followed every week. At each visit, hyrax screws are release 1 mm on each side.

MED: This appliance is prepared by Patilet al.¹⁹ in 2012 with the help of two hemispherical acrylic resin plates and orthodontic wire coil. For use, smaller plate of MED is placed intraorally and bigger one extraorally and then orthodontic wire coil is adjusted by opening and closing it to accommodate the intermediate cheek. The patient is then instructed to squeeze the intermediate cheek mucosa. Similar procedure is followed for other affected areas of buccal mucosa.

Oral stent: Oral stent was used by Le et al.¹⁷ in 1996 to prevent post-surgical relapse in OSF patients. They have inserted oral stents in place immediately after surgical procedure 24 h a day for 2 weeks; patient was fed by using nasogastric tube during this time. This oral stent was made of orthodontic acrylic and has posterior vertical stops bilaterally.

Tongue spatula: Cox et al.¹⁵ used tongue spatulas for jaw exercises in 2009 wherein, tongue spatulas were placed passively between anterior teeth and held for 1 min on each occasion. The jaws were opened five times in each session and this physiotherapeutic exercise was advised for five times a day. The number of spatulas were determined according to comfortable maximal MO. Cox et al. added an additional spatula every fifth day unless this caused pain, in which case the additional spatula was added on the tenth day. To alleviate painful events, they advised aspirin (200 mg) or paracetamol (250 mg) 30 min prior to jaw exercise.

4. Discussion

The present systematic review identified three prefabricated (EZBite, tongue spatulas & MED) and other two custom-made (Nallan C-H & oral stent) MEDs used in OSF patients. Even though the appliances presented herein were diverse in their design, application and mode of action, majority were found to be effective in improving MO in OSF patients. However, the oral stent used by Le et al.¹⁷ successfully maintained the range of MO after surgical procedure. Looking at the magnitude of the problem, the number of papers published on this topic is very limited. Equally important is percolation of this knowledge to the clinicians for the betterment of the patients. We believe that present paper will be important source of information for the clinicians and researchers for future clinical trials and new designs.

In addition to other consequences, limited MO in OSF patients particularly may increase the chances of malignant transformation. This could be due to lack of self-cleansing activity of stiff oral tissues; thereby increasing the contact of betel nut and tobacco carcinogens with the tissues. Moreover, stiffness and rigidity has been identified as independent factor, which can initiate and promote carcinogenesis.²² Therefore, the management of OSF patients should primarily be focused towards improving the MO and increasing flexibility of the oral mucosa to halt the possibility of malignant changes. This may enhance the chewing ability, oral hygiene care, speech and thus further helps in achieving better HRQoL of this population. World workshop on Oral Medicine V summarized that mouth exercise physical therapy independently or in combination with other modalities may be useful to improve MO in OSF.²³ In addition, past literature demonstrates significant positive association between jaw exercises and improved MO range in head and neck cancer patients. Therabite device and Dynasplint system have also shown effectiveness for improving MO.^{24–26} Despite of increasing prevalence of OSF worldwide, the literature on MEDs in OSF patients is lacking. Therefore, there was a dire need of evaluating the influence of MEDs in these patients.

The MEDs can be tooth-borne or non-tooth-borne. Four of the 5 appliances presented herein were tooth-borne.^{15,17,20,21} Fig. 2

Table 2
Comparative analyses of different mouth exercising devices.

Sr. no.	MED	Pros	Cons
1.	Oral stent	<ul style="list-style-type: none"> ● Simple to fabricate ● Biocompatible ● Non-invasive ● Cost-effective ● Good tensile strength 	<ul style="list-style-type: none"> ● Tooth-borne ● Uncomfortable to wear and during eating ● Need to modify as per requirement ● Need to wear for prolonged period
2.	Tongue spatula	<ul style="list-style-type: none"> ● Easy application ● Biocompatible ● Non-invasive ● Cost-effective 	<ul style="list-style-type: none"> ● Patient non-compliance ● Tooth-borne ● Painful ● Need to advice analgesic agents prior to begin physiotherapy ● Contraindicated in patients with missing anterior teeth, carious teeth or periodontitis ● Patient non-compliance ● Need to use for longer period ● Patient non-compliance
3.	MED	<ul style="list-style-type: none"> ● Non-tooth borne, handy, easy to use ● Simple to fabricate ● Can be used in patients with poor dental conditions ● Comfortable ● Biocompatible ● Non-invasive ● Cost-effective ● Good tensile strength 	
4.	Nallan C-H	<ul style="list-style-type: none"> ● Simple to fabricate ● Biocompatible ● Non-invasive ● Cost-effective 	<ul style="list-style-type: none"> ● Tooth-borne ● Difficult to insert in oral cavity ● Excessive salivation ● Need to use with caution in patients with compromised periodontal conditions, mobile teeth ● Reduced tensile strength after prolonged use ● Need to use for longer period ● Patient non-compliance
5.	EZBite	<ul style="list-style-type: none"> ● Comfortable ● Biocompatible ● Non-invasive ● Cost-effective ● Good tensile strength 	<ul style="list-style-type: none"> ● Tooth-borne ● Contraindicated in patients with missing anterior teeth, carious teeth or periodontitis. ● Short-arm force of appliance causes difficulty in hand manipulation ● Need to use for longer period ● Patient non-compliance

MED: Mouth exercising device.

demonstrates the schematic diagrams of the MEDs reported in the present review. In tooth-born appliances, opening force can be applied with the help of the devices or stents placed/fixed between the maxillary and mandibular arches or teeth to keep the dental arches apart.^{15,17} Due to limited access for oral hygiene care, dental caries and periodontal diseases are commonly seen in patients with severe limited MO. Therefore, it is very difficult to use tooth-borne appliances in patients with carious teeth or periodontal diseases. In addition, partially or completely edentulous patients do not allow operating such appliances easily. This may results in limited successful outcomes due to patients' non-compliance for longer term. However, MED developed by Patil et al.¹⁹ was non-tooth-borne, handy and easy to use for patients. This appliance is simple to fabricate, can be used in patients with poor dental conditions and can allow rehabilitation to start immediately after surgical procedures.¹⁹ We believe that thorough oral examination should be carried out for determining the status of the dentition and accordingly decision should be taken for the use of type of the device.

The mode of action of all the appliances is diverse in nature. The MED designed by Patil et al.¹⁹ works by local squeezing and stretching of the cheek mucosa. The authors explained that the biokinetics in OSF is partially correlated with the therapeutic ultrasound. The device may cause loosening of the adherent fibrous tissue due to separation of collagen fibers and softening of cement substances; subsequently increasing the elasticity of the tissues. They further proposed that the separated collagen fibers and increased subcutaneous matrix may improve the blood circulation in the area.¹⁹ The mechanical action of the EZBite involves passive mouth-opening exercises.²¹ The probable mechanism behind Nallan C-H appliance is physiotherapeutic effect, which causes tissue remodeling to improve MO.²⁰ The mechanical force of the Nallan C-H appliance induces stretching of the elevator and depressor muscles. This further strengthens musculature, avoids fibrosis, and improves flexibility, tissue elasticity & blood circulation.²⁰ The physical therapy by tongue spatulas also modify tissue remodeling

through promotion of physical movements.¹⁵ The oral stent acts by preventing scar tissue contracture and microstomia after surgical removal of fibrous bands.¹⁷ All these devices have been investigated individually in OSF patients. Since the mechanism of actions are diversified in nature, a combination of two or more devices could bring synergistic action and probably will be more efficient than use of single device. However, further studies are needed in this direction to come up with appropriate algorithm of the MED for effective MO.

For better outcomes with minimum side effects, MED should be biocompatible, non-invasive, simple to fabricate, cost-effective, comfortable to wear and should have good tensile strength. Table 2 describes the comparative analyses of the various MEDs reported in this review. Nallan C-H is biocompatible as it is made of acrylic resin and hyrax screws which are routinely used in the fabrication of partial or complete dentures and for palatal expansion in orthodontic treatment respectively and have been proven to be biocompatible in the patients.²⁰ Similarly, MED described by Patil et al.¹⁹ is also biocompatible as made of acrylic resin material and orthodontic wires. Oral stent was prepared by using orthodontic resin and thus, is biocompatible.¹⁷ However, EZBite, is made of plastic material and stainless steel.²¹ All the five appliances are non-invasive, simple to fabricate and cost-effective as compared to popular Therabite and Dynasplint devices. The ergonomic design of the device is considered to be the important factor in relation to the patient compliance as they need to wear these devices for longer duration to achieve successful outcomes. Among five, the MED by Patil et al.¹⁹ was reported to be most comfortable and handy to the patients. As it is designed as non-tooth-borne, this appliance can be used in both dentate and edentulous patients easily. In addition, its use is not limited in patients with carious teeth or periodontal diseases.¹⁹ However, the Nallan C-H appliance was noted to be difficult to insert intra-orally during initial phases of treatment.²⁰ Oral stent has also caused discomfort to the patient to wear and during eating. Le et al.¹⁷ provided nasogastric tube to the patient during this phase for feeding.

Mouth exercise physiotherapy by using tongue spatulas may results in pain which is considered as a sign of inflammation and potential exacerbation. Therefore advising analgesic medications prior to begin physiotherapy is essential. The EZBite has short-arm force, which causes difficulties in hand manipulation of the appliance. Moreover, it is not suitable to use in patients with periodontal diseases and partially edentulous anterior arches due to risk of trauma to the teeth and soft tissues.²¹ All the appliances presented in this review reported to have sufficient tensile strength for long-term use. However, Chaitanya et al.²⁰ reported reduced strength of Nallan C–H appliance after weeks of usage. This might be due to the fabrication errors; as explained by the authors.

The present systematic review has certain strengths and limitations. The relevant articles were searched in multiple electronic databases without any restrictions of time and language; minimizing chances of missing any relevant papers. Although we have used broad search strategy, we could find only five relevant papers, demonstrating a lack of literature on this topic. There is a possibility of publication bias as in all systematic reviews. There are chances of gray literature which may not have published. Due to lack of randomized controlled trials on this topic, we could not able to perform the meta-analysis.

5. Conclusions

The present systematic review identified five different MEDs used for improvement of MO in OSF patients. This review will bring awareness among the clinicians about various MEDs and probably also will be part of their practice. Regular use of MEDs appeared to be effective in increasing MO in these patients. Although these appliances are biocompatible and cost-effective, patients co-operation is the primary requirement for successful outcomes. We recommend future studies to implement these appliances for improving MO and HRQoL in OSF patients. Newer appliances such as Therabite and Dynasplint system should also be given due consideration for the management of limited MO in OSF.

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Declaration of competing interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jobcr.2020.06.010>.

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