



A randomized control trial measuring the effectiveness of a mouth-exercising device for mucosal burning in oral submucous fibrosis

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Objectives. To evaluate effect of ice-cream stick exercise regimen with or without a mouth-exercising device (MED) on mucosal burning sensation in oral submucous fibrosis.

Study Design. In total, 282 patients with oral submucous fibrosis were treated with topical corticosteroid and oral antioxidant and the ice-cream stick exercise regimen. Patients in subgroups A1, A2, and A3 were additionally given a new MED. Patients in subgroups A1 and B1 patients with interdental distance (IID) of 20 to 35 mm were managed without any additional therapy; patients in subgroups A2 and B2 with IID of 20 to 35 mm were additionally managed with intralesional injections; and those in subgroups A3 and B3 with IID less than 20 mm were managed surgically. Subjective evaluation of decrease in the oral mucosal burning was measured on a visual analogue scale (VAS). Analysis of variance and Tukey's multiple post hoc analysis were carried out to present the results.

Results. Patients using the MED, that is, subgroups A1, A2, and A3, showed reduction in burning sensation in the range of 64.8% to 71.1% and 27.8% to 30.9%, whereas in subgroups B1, B2, and B3, reduction in burning sensation ranged from 64.7% to 69.9% and from 29.3% to 38.6% after 6 months. The wo-way analysis of variance indicated statistically significant results in changes in initial VAS scores to 6-monthly VAS scores between MED users and non-MED users.

Conclusions. The MED helps to enhance the rate of reduction of mucosal burning sensation, in addition to the conventional ice-cream stick regimen, as an adjunct to local and surgical treatment. (Oral Surg Oral Med Oral Pathol Oral Radiol 2016;122:713-718)

Oral submucous fibrosis (OSMF) is a chronic oral mucosal precancerous condition that predominantly affects Asians.¹ The disease is slowly spreading all over the world, including Europe and America, because of increased immigration of South Asians to these parts of the world.^{2,3} The hallmark of the disease is progressive juxtaepithelial fibrosis of oral soft tissues, resulting in restricted mouth opening and burning sensation.^{4,5} The main etiology of the disease is chewing of betel quid and/or areca nut.⁵ The treatment of OSMF is principally focused on cessation of the betel nut chewing habit, restoration of the mandibular range of motion, oral cancer surveillance, and

improvement in mouth opening. Local and surgical treatments have been advocated, depending on the severity of difficulty in mouth opening. Treatment based on a presumed inflammatory basis supports the use of steroids, interferon gamma, or anti-inflammatory placental extracts, dietary supplementation, and injection of derivative enzymes to facilitate removal of fibrous tissue.^{6,7} Oral physiotherapy or exercise is a well-established supportive treatment for OSMF to improve the range of mouth opening and to prevent postsurgical relapse.⁶⁻¹¹ Cox and Zoellner⁸ tested the hypothesis that physiotherapy alone can modify tissue remodeling in OSMF to increase mouth opening. A new mouth-exercising device (MED) that is non-tooth-borne, convenient, and easy to use by patients has been designed.¹¹ This MED causes local squeezing and stretching of the mucosa, which ultimately results in an increase in the elasticity of the mucosal tissues, which, in turn, leads to increase in mouth opening.^{11,12}

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Statement of Clinical Relevance

Burning mucosal sensation is one of classic sign of oral submucous fibrosis. Reduction of burning sensation is one of the treatment goals for this condition. New mouth-exercising devices help enhancing the rate of reduction of mucosal burning sensation.

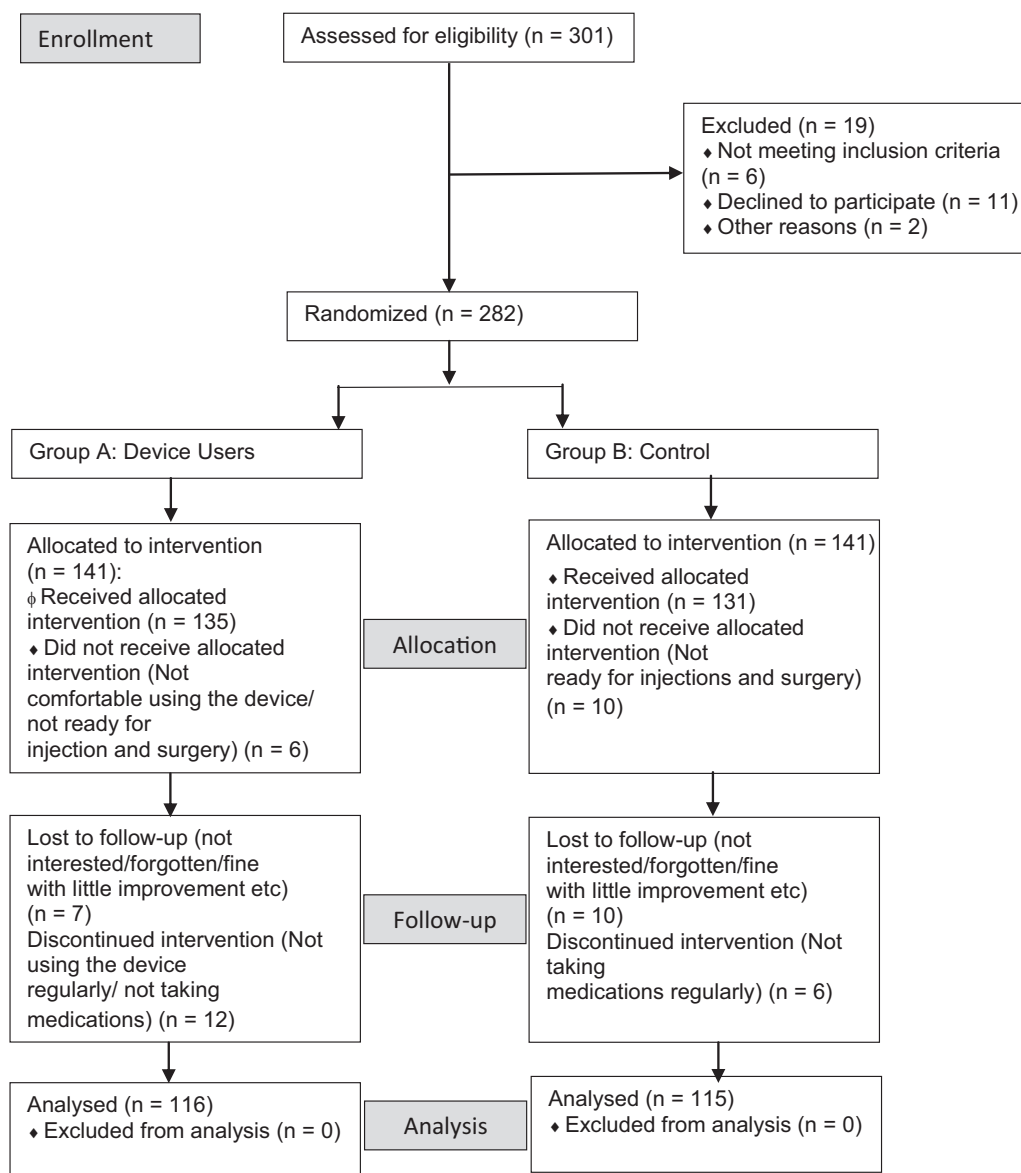


Fig. 1. Patient dropout flowchart.

Although mucosal burning sensation is one of the hallmarks of OSMF, little information is available in the literature indicating its existence in patients with OSMF and the existing treatment modalities to reduce it. Oral mucosal burning sensation is one of the key symptoms of these patients, as it restricts the intake of spicy foods, subsequently leading to unmet nutritional needs. Severity of burning sensation of the oral cavity was reported to be correlated with the degree of minor salivary glands fibrosis.¹³ Moreover, burning sensation was more pronounced in some areas, such as the buccal, labial, and palatal regions.¹³ Previous reports on OSMF predominantly discussed reduced mouth opening, including treatment modalities for it, but hardly mentioned mucosal burning sensation in specific terms.

The purpose of this study was to evaluate the efficacy of oral physiotherapy, in comparison with the conventional ice-cream stick regimen, with or without additional MED exercise, and its effect on reduction in mucosal burning sensation in association with local ointment application, intralesional drug administration, and surgical treatment.

MATERIALS AND METHODS

Trial design

This study was designed as a randomized controlled clinical trial. The trial design and the study protocol were approved by the Institutional Ethical Committee of the Government Dental College and Hospital, Nagpur, India. The trial was registered at

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