ACTA SCIENTIAE

ISSN: 2178-7727

Impact of Mandibular Advancement Device or Maxillary Occlusal Splint on Bite Force in Sleep Bruxism Patients: A Randomized Controlled Trial

Punit Kumar Singha , Balendra P. Singhb , Habib A Alvib , Raghuwar D. Singhb , Kamleshwar Singhb, Sunit Jurelb, Deeksha Aryab , Suryakantc and Abhishek Dubeyd

aDepartment of Prosthodontics, Center for Dental Education, AIIMS, New Delhi, India.
bDepartment of Prosthodontics, King George's Medical University UP, Lucknow, India.
cDepartment of Pulmonary Medicine, King George's Medical University UP, Lucknow, India.
dIndian Council of Medical Research, New Delhi, India.

ABSTRACT

Aims: Sleep Bruxism (SB) is a condition that is usually present with increased bite force (BF) resulting in tooth wear, orofacial pain and fractured restoration. So, this study aimed to compare the BF in patients with SB before and after using a mandibular advancement device (MAD) and maxillary occlusal splint (MOS).
Methods: In this randomized controlled trial (RCT), 28 subjects were randomly intervened either MAD or MOS. Subjects BF was assessed with a digital Gnathodynamometer in the first molar region. This variable was evaluated at baseline, 1 month and 3 months follow-up
Results: Out of 32 participants, 28 participants were statistically analyzed as four subjects did not respond at the follow up period. Both MOS and MAD significantly reduced BF ($p<0.001$) after 3 months from baseline. However the average BF was similar at baseline, 1 and 3 months between the groups. Conclusion: The results suggest that both Mandibular advancement device and maxillary occlusal splint reduce bite forces in sleep bruxism.

Keywords- Sleep bruxism, mandibular advancement device, maxillary occlusal splint, gnathodynamometer, bite Force

INTRODUCTION

Bruxism is a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible. Bruxism has two distinct circadian manifestations: it can occur during sleep (indicated as sleep bruxism) or during wakefulness (indicated as awake bruxism).[1] Among these Sleep bruxism (SB) is a sleep related movement disorder characterized by clenching or grinding of the teeth.[2] Although the pathophysiology of SB has not been completely elucidated recent evidences suggest that SB is an excessive response to micro arousals.[3,4]

SB is usually presented with tooth wear and orofacial pain but even lead to teeth cracking or fracture, breakage of dental fillings or prosthesis in severe conditions.[5-7] These consequences of SB is mainly because sleep bruxers exercise their masticatory muscles beyond normal limits other than muscle activity resulting in stronger and more fatigue resistant masticatory muscles.[7,8] This abnormal muscle activity finally leads to muscular hypertrophy and increased BF. However, the magnitude of BF varies between subjects and depends on the methods used to measure the force.[9-12]

There is currently no specific or definitive treatment for SB. So, various preventive measures can be used such as: various occlusal devices; irreversible therapy involving occlusal treatment with occlusal adjustment; physiotherapy; emotional stress therapy; pharmacological therapy.[13]

Among these techniques, occlusal splint is considered as the most popular management strategies to prevent the consequences of SB. Several studies have reported significant reduction in the SB motor activity index (episodes per hour of sleep) after using the occlusal splint.[14-17] In present scenario several designs of occlusal splint are in use with the Maxillary Occlusal Splint (MOS) being one such type of occlusal splint. The Mandibular Advancement Device (MAD), which is an alternative for the treatment of obstructive sleep

DOI: 10.2563/acta.sci.2023.6.28

ISSN: 2178-7727

apnea (OSA), may also be used to reduce SB.[18-24] In addition to this certain studies had found that MAD and occlusal splint reduces BF in SB patients.[13,22,23]

However, certain studies have reported that there is no difference in BF in bruxers and non-bruxers and bite force is influenced by certain confounding variables such as pain, age, craniofacial morphology, and sex.[9-12] In addition to this, there is a lack of well designed randomized controlled trial to evaluate BF in SB patients. So, a well-designed randomized controlled trial was planned to evaluate BF in individuals with SB after random intervention with either a MAD or MOS controlling for potential confounders such as sex and body mass index (BMI).The null hypothesis was that MAD or MOS would have no effect on BF in SB individuals.

MATERIALS AND METHODS

A total of 50 individuals with self-reported SB were recruited for this randomized controlled trial from the general clinic of King George's Medical University (tertiary care hospital), Lucknow, India. These 50 individuals were then interviewed and clinically examined and thereafter 40 participants were selected based on the following inclusion criteria: self-reported SB, where tooth grinding sounds had occurred at least three times a week for the past 6 months; people of either sex aged between 18 and 40 years; and less than two missing teeth except for third molars. The exclusion criteria are as follows: strained or diurnal bruxers, physical and mental disability that would interfere with the study, and restricted mouth opening (less than 35 mm). The institutional ethical committee granted the ethical clearance (63rd ECM II-B/P11). All participants provided written informed consent after explanation of all aspects of the treatment. [24]

To confirm the diagnosis of intense and frequent SB the 40 participants spent 2 nights in a sleep laboratory. The data of the first night were excluded from statistical analysis as participants were permitted to acclimatize to the sleep-recording environment. So, the diagnosis of the SB and exclusion of other sleep disorders such as apnea, periodic limb movement, or epileptiform activity was based on the date of the second night. The polysomnographic SB research diagnostic criteria were used for diagnosis of intense SB: [25] more than four bruxism episodes per hour, more than six bruxism bursts per episode, and/or 25 bruxism bursts per hour of sleep and at least 2 episodes with grinding sounds. The polysomnographic recording was done by using laboratory-based polysomnography (S-7000 Cogent Technology; Embla System Inc, US). The data obtained were then analyzed using software(Somnologica Studio; Embla Systems Inc, US). After polysomnographic data analysis out of 40 participants, 36 participants meeting the SB research diagnostic criteria were enrolled into the study (Fig. 1). For this study Block randomization was planned. Computer generated chart was used for randomization in each block. One of the authors (B.P.S.) performed the allocation concealment, who handed over a sealed envelope containing the name of one of the devices to the patient. The other authors opened the sealed envelope and the device, either a MAD (MAD group) or MOS (MOS group), was given to the participants. However, because of discomfort four participants were unable to wear the appliance. In addition to this, four participants did not return for the follow-up examination, reducing the sample size to twenty-eight. [24] (Fig 1)

The MADs were fabricated with casts mounted on a semi adjustable articulator (Quickmount 8800; Whip Mix Corp, USA) at 50% to 75% of the maximum protrusion (depending on the participant's tolerance) with approximately 6 mm of inter-incisal opening.[26,27] On the maxillary and mandibular arch two sheets of base plate wax (Modelling Wax, MAARC, Shiva products, Thane, India) were adapted covering the occlusal surfaces of all the teeth, after which at the recommended protrusive position indentations were created on the wax pattern. The heat-polymerizing acrylic resin was used to process the wax pattern (DPI Heat Cure, Dental Products of India, Mumbai, India) and later on finished and polished (Fig 2). To fabricate the MOSs, the cast were articulated in centric relation with approximately 2.5 mm of inter-occlusal clearance in the first molar region.[12] On the maxillary arch two sheets of base plate wax (Modelling Wax, MAARC, Shiva products, Thane, India) were adapted, and an anterior ramp was created simultaneously to provide evenly distributed occlusal contact with the mandibular teeth. The pattern was processed by the heat-polymerizing acrylic resin (DPI Cure, Dental Products of India, Mumbai, India) and the processed MOS was then

DOI: 10.2563/acta.sci.2023.6.28

ISSN: 2178-7727

remounted on the articulator for occlusal adjustments until mutually protected occlusion was established. Later on the occlusal devices were finished and polished (Fig 3). The appliances, i.e. the MADs and MOSs were then adjusted to fit without discomfort. The MOS was adjusted such that there was mutually protected occlusion. The participants were instructed regarding the use of the device. For habituation the devices were worn for a period of 2 weeks. Participants were regularly followed throughout this period, to ensure their comfort with the appliance.[18]

The BF (Kgf) was measured unilaterally using a digital gnathodynamometer (Load Master, Model: BT 100, serial number 014831211, and Load Master Digital Indicator Model: LI450, Sl. No 014841. Bangalore, India) in the first molar region (Fig 4). The BF was measured in the first molar region this is because different regions of the oral cavity show different bite force and greater bite force is seen more posterior the transducer is placed in the dental arch, which has been explained by the mechanical lever system of the jaw.[28] The recordings were made with the participants sitting upright and the transducer placed between the upper and lower arch at first molar region and were instructed to bite as forcefully as possible for about 3 seconds as shown in (Fig 4). Three recordings were made with a rest period of 5 minutes for each side of each patient in each group and mean of the three recordings were taken as a final recording. The rest period was in agreement with the previous study.[13] The mean BF recording of each patient was then comparatively evaluated at baseline, and 1month and 3 months post rehabilitation with MOS and MAD.

Statistical analysis

The categorical variables were compared by the chi-square test, and continuous variables between the MAD and MOS were compared by an unpaired t test. Repeated measures ANOVA was used to compare the average change from baseline to follow-up (p=.05). The age and body mass index (BMI) were tested as covariates in the model. The analyses were carried out with statistical software (SPSS version 16.0; IBM Corp).

RESULTS

Table 1 shows the sociodemographic characteristic of all participants.[24] Assuming a 5% significance level and 14 participants as the sample size; the power of the study was found to be 99%. A significant decrease (P<0.001) in the right BF was observed in both the groups from baseline to 1 & 3 months. Similarly a significant decrease (P<0.001) in the left BF was observed in both the groups from baseline to 1 & 3 months However the average BF was similar at baseline, 1 and 3 months between the groups (Table 2 and 3). The addition of age and BMI as covariates in the model revealed no significant (P>.05) effect of age and BMI on the change in the BF.

DISCUSSION

A significant improvement (P<.001) in right and left bite force at 3 months compared to baseline was seen after using MAD and MOS. Therefore, the null hypothesis was rejected. Similar to other studies on bruxism, the study sample consisted of 28 participants, which supports its external validity.[23,29] T he mean age of the participants was 38.3 ±11.05 years in the MAD group and 31.31±9.4 years in the MOS group which was also similar to other recent studies.[22,23] The proportion of men was higher in both the MAD (71.4%) and MOS (57.1%) groups which is contrary to the other studies which reported the proportion of men to women with bruxism to be 50% (Table 1).[22,23]The sample was controlled for the possible confounding factors such as height, weight, or BMI values and further because of the short span of the study, there was unlikely any changes in the variables.

Similar to this study, Alkan*et al*[13] and Manieri*et al*[22,23] reported reduction in BF after using MOS and MAD respectively. The mechanism behind the positive effect of the MAD might be that the masticatory muscles have relaxed, and BF decreased.[22] But further studies are needed to clarify this as there are other hypothesis regarding its mechanism such as dimension and configuration of the appliance, presence of pain, restriction of movement or change in airway patency.[30]Other than MAD, MOS reduce hyperactivity and asymmetry in the activity of jaw elevator muscles by maintaining equal intensity contact on all of the teeth with immediate

DOI: 10.2563/acta.sci.2023.6.28

posterior disocclusion with anterior teeth in all excursive movements consequently leading to a stable and physiologically optimal occlusal force.[31,32] Despite this there is still no common consensus regarding the association between high BF and bruxism. Some authors reported higher bite force in subjects with bruxism while others did not found any association of higher bite force and bruxism .[9,10] Regarding MAD it has been seen that it is associated with discomfort, including tooth sensitivity and drooling which may have influenced BF measurement.

Despite all these, the study had certain limitations. Firstly eventhough sample size was sufficient to get a significant difference a larger sample size is required to reduce sample bias. Secondly the duration of the study was short as it has been reported that occlusal splint have short term effect on SB.[7]

So, in future long-term studies with a larger sample size oriented toward smaller, less cumbersome MADs are required to rule out sample bias and adverse effects of MAD.

CONCLUSION

Within the limitations of this short term study, both MAD and MOS improved the bite force of patients. However, a prolonged follow up study on a larger sample size must be performed in the future to assess the long-term effect of MAD and MOS.

CLINICAL IMPLICATIONS

The result of this study suggest use of MAD and MOS in sleep bruxism.

CONFLICT OF INTEREST STATEMENT/ACKNOWLEDGMENTS

No conflicts of interest.

REFERENCES

1. Lobbezoo F,Ahlberg J, Glaros AG, Kato T, KoyanoK, Lavigne G J, de Leeuw R, Manfredini D, Svensson P and Winocur E. Bruxism defined and graded: an international consensus. Journal of Oral Rehabilitation, 2013;40:2–4.
2. American Academy of Sleep Medicine. International classification of sleep disorders. 2nd ed. Westchester: American Academy of Sleep Medicine, 2005
3. Klasser GD, Rei N, Lavigne GJ Sleep Bruxism Etiology: The Evolution of a Changing Paradigm. *J Can Dent Assoc 2015;81:f2*
4. Castroflorio T[1], Bargellini A[2], Rossini G[3], Cugliari G[4], Deregibus A[3].Sleep bruxism in adolescents: a systematic literature review of related risk factors. Eur J Orthod. 2016 Feb 15. pii: cjw012. [Epub ahead of print]
5. Lavigne GJ, Manzini C, Kato T. Sleep bruxism. In: Kryger M, Roth T, Dement WC, Principles and Practice of Sleep Medicine. Philadelphia, PA: Elsevier Saunders, 2005:946–959.
6. Koyano K. Assessment of bruxism in the clinic. J Oral Rehabil. 2008;35:495–508.
7. Baba k, Haketa T, Sasaki Y, Ohyama T, Clark GT. Association between masseter muscle activity levels recorded during sleep and signs and symptoms of temporomandibular disorders in healthy young adults. J orofac Pain 2005;19:226-
8. Manfredini D, Lobbezoo F. Relationship between bruxism amd temporomandibular disorders: A systematic review of literature from 1998 to 2008. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2010;109:26-50
9. Nishigawa K, Bando E, Nakano M. Quantitative study of bite force during sleep associated bruxism. J Oral Rehabil 2001; 28:485-91.
10. Cosme DC, Baldisserotto SM, CanabarroSde A, Shinkai RS. Bruxism and voluntary maximal bite force in young dentate adults. Int J Prosthodont 2005; 18:328-32.
11. Narita N, Funato M, Ishii T, Kamiya K, Matsumoto T.Effects of jaw clenching while wearing an occlusal on awareness of tiredness, bite force, and EEG power spectrum. J Prosthodont Res 2009;53:120-125.

12. Ahlberg JP, Kovero OA, Hurmerinta KA, Zepa I, Nissinen MJ, Kononen MH, Maximal bite force and its association with signs and symptoms of TMD, occlusion, and body mass index in a cohort of young adults. Cranio 2003:21:248-252.
13. Alper Alkana, Emel Bulut, SelimAricic, Shuichi Satod. Evaluation of Treatments in Patients with Nocturnal Bruxism on Bite Force and Occlusal Contact Area: A preliminary report. Eur J Dent. 2008; 2:276-282.
14. Dube C, Rompre PH, Manzini C, Guitard F, de Grandmont P, Lavinge GJ. Quantitative polygraphic controlled study on efficacy and safety of oral splint devices in tooth grinding subjects. J. Dent Res. 2004; 83:398-403.
15. Okkerse W, Brebels A, De Deyn PP. et al. Influence of a bite-plane according to Jeanmonod on bruxism activity during sleep. J Oral Rehabil. 2002:29:980-985.
16. Van der Zaag J, Lobbezoo F, Wicks DJ, Visscher CM, Hamburger HL, Naeije M. Controlled assessment of the efficacy of occlusal stabilization splints on sleep bruxism. J Orofac Pain. 2005;19:151–158.
17. Harada T, Ichiki R, Tsukiyama Y, Koyano K. The effect of oral splint devices on sleep bruxism: a 6-week observation with an ambulatory electromyographic recording device. J Oral Rehabil. 2006;33:482–488.
18. Landry ML, Rompré PH, Manzini C, Guitard F, de Grandmont P, Lavigne GJ. Reduction of sleep bruxism using a mandibular advancement device: An experimental controlled study. Int J Prosthodont. 2006;19:549–556.
19. Huynh NT, Rompré PH, Montplaisir JY, Manzini C, Okura K, Lavigne GJ. Comparison of various treatments for sleep bruxism using determinants of number needed to treat and effect size. Int J Prosthodont 2006; 19:435–41
20. Aline C. Saueressig,Vivian C. Mainieri, Patricia K. Grossi, Simone C. Fagondes, Rosemary S.A. Shinkai, Eduardo M. Lima, Eduardo R. Teixeira, Márcio L. Grossi. Analysis of the Influence of a Mandibular Advancement Device on Sleep and Sleep Bruxism Scores by Means of the BiteStrip and the Sleep Assessment Questionnaire. Int J Prosthodont 2010;23:204–213.
21. Landry-Schönbeck A, de Grandmont P, Rompré PH, Lavigne GJ. Effect of an Adjustable Mandibular Advancement Appliance on Sleep Bruxism: A Crossover Sleep Laboratory Study. Int J Prosthodont. 2009;22:251-9.
22. Mainieri VC, Saueressig AC, Fagondes SC, Mainieri ET, Shinkal RSA, Grossi ML. Bite force and sleep quality in patients with bruxism before and after using a mandibular advancement device. Rev Odonto Ciênc. 2008; 23:229-233.
23. Mainieri VC, Saueressig AC, Fagondes SC, Teixeira ER, Rehm DD, Grossi ML. Analysis of the effects of a mandibular advancement device on sleep bruxism using polysomnography, the BiteStrip, the sleep assessment questionnaire, and occlusal force. Int J Prosthodont 2014;37:119-126
24. Punit Kumar Singh, Habib A. Alvi,Balendra Pratap Singh, Raghuwar D. Singh,Surya Kant, Sunit Jurel, Kamleshwar Singh, Deeksha Arya, and Abhishek Dubey. Evaluation of various treatment modalities in sleep bruxism.J Prosthet Dent 2015;114:426-431
25. Lavigne GJ, Rompre PH, Montplaisir JY. Sleep bruxism: validity of clinical research diagnostic criteria in a controlled polysomnographic study. J Dent Res 1996; 75:546-52.
26. Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman J Jr, et al. Practice parameters for the treatment of snoring and obstructive sleepapnea with oral appliances: an update for 2005. Sleep 2006; 29:240-3.
27. Prathibha BN, Jagger RG, Saunders M, Smith AP. Use of a mandibular advancement device in obstructive sleep apnoea. J Oral Rehabil 2003; 30:507-9.
28. Tortopidis D, Lyons MF, Baxendle RH, Gilmour WH. The variability of bite force measurements between sessions, in different positions within the dental arch. J Oral Rehabil 1998;25:681-686..
29. van der Zaag J, Lobbezoo F, Wicks DJ, Visscher CM, Hamburger HL, Naeije M. Controlled assessment of the efficacy of occlusal stabilizations plints on sleep bruxism. J Orofac Pain 2005; 19:151-8.

ISSN: 2178-7727

30. Klasser GD, Greene CS, Lavigne GJ. Oral appliances and the management of sleep bruxism in adults: A century of clinical applications and search for mechanisms. Int J Prosthodont 2010;23:453-462
31. Kurita H, Ikeda K, Kurashina K. Evaluation of the effect of stabilization splint on occlusal force in patients with masticatory muscle disorders. J Oral Rehabil 2000; 27:79.
32. Tim J. Dylina. A common-sense approach to splint therapy. J Prosthet Dent 2001; 86:539-45.

Tables

Table 1: Age wise Distribution of subjects in different groups

Group	Group A (MAD)	Group B (MOS)
Mean Age in years	38.13±11.05	31.31±9.4
Gender (%) Male Female	 71.4 28.6	 57.1 42.9
Weight	73.96±7.39	71.16±5.56
Height	167.6±6.62	172.62±5.90
Basal metabolic index (BMI)	26.45±4.24	23.94±2.31
SES (Total score)	%	%
Lower (<5)	0.0	0.0
Upper Lower (5-10)	21.4	0.0
Lower Middle (11-15)	21.4	71.4
Upper Middle (16-25)	57.1	28.6
Upper (26-29)	0.0	0.0

Table-2: Comparison of Right BF from baseline to 1 and 3 months

EMG BF Right	**Group A (MAD)**	**Group B (MOS)**	***P*-value**
Baseline	55.38±1.97	52.22±11.15	.29
1 month	44.77±2.39	45.59±5.25	.59
3 month	37.34±0.96	38.92±1.33	.07
p-value[2]			
Baseline vs 1 month	.0001*	.0001*	
Baseline vs 3 month	.0001*	.0001*	
1 month vs 3 month	.0001*	.0001*	

Table- 3: Comparison of Left BF from baseline to 1 and 3 months

EMG BF Left	**Group A (MAD)**	**Group B (MOS)**	***P*-value**
Baseline	52.59 ±2.45	50.73±12.65	.58
1 month	43.33±1.97	44.21±4.51	.59
3 month	36.76±1.13	37.72±1.72	.16
p-value[2]			
Baseline vs 1 month	.0001*	.0001*	
Baseline vs 3 month	.0001*	.0001*	
1 month vs 3 month	.0001*	.0001*	

DOI: 10.2563/acta.sci.2023.6.28

ISSN: 2178-7727

Legends

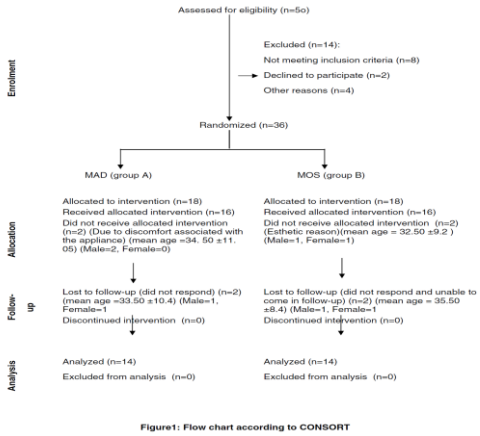

Figure1. Flowchart according to CONSORT

Figure2. Mandibular Advancement Device

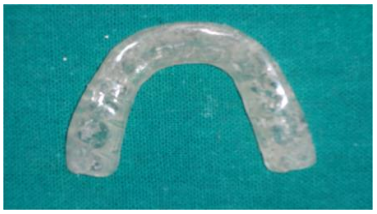

Figure3. Maxillary Occlusal Splint

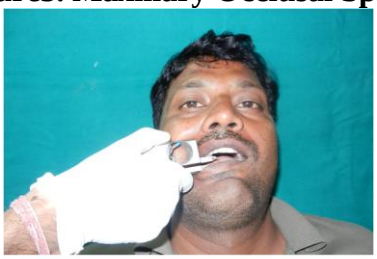

Figure 4.Measurement of Bite Force