# Analysis of the Effects of a Mandibular Advancement Device on Sleep Bruxism Using Polysomnography, the BiteStrip, the Sleep Assessment Questionnaire, and Occlusal Force

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> Purpose: This before and after study evaluated the effects of a mandibular advancement device (MAD) on sleep bruxism (SB) activity and its associated signs and symptoms. *Materials and Methods:* Nineteen young adults (39.9 ± 12.9 years, 58% women) with a clinical history of SB without sleep or neurologic disorders and no spontaneous temporomandibular disorder pain were selected. SB activity was assessed after a habituation period of 2 weeks. The results of a 3-month treatment with a thermoplastic monoblock MAD were compared to baseline using electromyogram polysomnography and the BiteStrip, a portable EMG device. Sleep disorders were assessed and validated against the polysomnography sleep assessment questionnaire (SAQ). Additionally, common signs and symptoms of SB were evaluated with the research diagnostic criteria for temporomandibular disorders. Occlusal force was compared to baseline using a cross-arch force transducer. Results: There was a significant improvement in both SB activity and sleep scores (including SB episodes per hour) according to the BiteStrip and the SAQ, respectively. There was also a significant reduction in the signs and symptoms of SB, including grinding and/or clenching, temporomandibular joint (TMJ) sounds, muscle pain, and occlusal force. None of the SB subjects experienced MAD breakage, but in 24% of patients, the MAD treatment had to be interrupted due to TMJ/muscle pain and/or discomfort. Conclusion: The MAD treatment resulted in the reduction of SB activity, SB signs and symptoms, sleep disorders, and occlusal force. Int J Prosthodont 2014;37:119-126. doi: 10.11607/ijp.3675

Scharacterized by tooth clenching and/or grinding. The common signs and symptoms of SB are dental

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abrasions, tooth and restoration fractures, hypertrophic masseter and temporalis muscles, locking and limitation of temporomandibular joint (TMJ) movements, joint sounds, masticatory muscle fatigue, headaches, and periodontal and endodontic implications.<sup>1</sup> SB affects from 3% to 8% of the adult population, with a higher prevalence in younger populations (14%) than in older populations (3%), but without any gender preference in patients with SB without temporomandibular disorders (TMDs).<sup>2,3</sup>

SB has been previously associated with exogenous (peripheral) factors, such as occlusal interferences or anxiety.<sup>1,2</sup> More recently, endogenous (central) factors involving brain neurotransmitters of the basal ganglia have been given greater importance, including sleep disturbances.<sup>4–6</sup> The management of SB with occlusal splints is the standard approach, but this is considered a palliative treatment for grinding protection and pain relief because as it does not result in sleep muscle relaxation or the reduction of SB in the long term.<sup>3,7</sup>

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Some authors have reported that the presence of SB leads to increased occlusal force, which in turn leads to hypertrophy.<sup>7-9</sup> However, the relationship between high levels of occlusal force and the presence of both sleep and awake bruxism is controversial due to confounding variables such as pain, age, craniofacial morphology, sex, and others.<sup>10–13</sup> In addition, masseter activity levels do not correlate well with the signs and symptoms of TMD.<sup>3,7–9</sup>

Studies have examined whether there is an association between respiratory sleep disorders (eg, snoring and sleep apnea/hypopnea obstructive syndrome [SAHOS]) and SB, considering that SB may or may not happen concomitantly with SAHOS; and whether it may be more related to sleep disturbances rather than with apnea events in SAHOS.<sup>1,14,15</sup> The use of a mandibular advancement device (MAD) is well known as a treatment of mild to moderate SAHOS due to its effects in the oropharynx (eg, the increase in the airway pathway).<sup>15</sup> However, only four studies have reported a marked reduction (85% to 96.4%) in SB patients without sleep disorders who used either a soft thermoplastic or hard acrylic MAD, both far superior to occlusal splints (42%).<sup>16-19</sup> Additional studies are needed to determine the effectiveness of MAD treatment in SB activity and sleep quality using polysomnography, which is the current gold standard to assess SB.<sup>20-22</sup>

Therefore, the objective of this study was to evaluate the effects of MAD treatment on SB, sleep quality, signs and symptoms of SB, and occlusal force measurements using both electromyogram (EMG) polysomnography and the BiteStrip (portable EMG) as valid diagnostic tools.

## **Materials and Methods**

## **Patient Population**

Thirty consecutive patients with a chief complaint of SB without known sleep or neurologic disorders or following the use of medication were initially selected from the Faculty of Dentistry Orofacial Pain Clinic at the Pontifical Catholic University of Rio Grande do Sul (PUCRS), Brazil.<sup>1,2</sup> The inclusion criteria were confirmed based on a clinical history questionnaire for SB as follows: *(1)* tooth-grinding during sleep more than three times a week over the last 3 months confirmed by the bed partner, *(2)* presence of abnormal tooth wear, and *(3)* masseter muscle hypertrophy due to voluntary clenching.<sup>19,20-23</sup> Only patients between the ages of 20 to 45 years were selected to reduce age as a confounding factor in both the electroencephalography (EEG) and EMG activities.<sup>24</sup>

The exclusion criteria were based on a clinical history questionnaire and a brief clinical examination as follows: (1) self-reported presence of spontaneous orofacial pain (TMJ and masticatory muscles) aggravated by function in the morning, (2) absence of more than one tooth per quadrant, (3) severe limitation of maximum mouth opening (less than 35 mm), (4) pregnancy, (5) severe skeletal alterations, (6) orthodontic treatment in the last 2 years, (7) active periodontal disease and mobile teeth, (8) clinical history of psychiatric (eg, depression or anxiety), neurologic (eg, trigeminal neuralgia or Parkinson's disease), and/ or sleep (eg, snoring, apnea/hypopnea, periodic leg movement syndrome, or insomnia) disorders, and (9) use of systemic medications affecting the central nervous system.<sup>19,20-23,25</sup>

The selection was made by a single trained examiner who did not participate in the clinical examination, thereby preventing selection and examination biases.<sup>26,27</sup> The project was approved by the PUCRS Research Ethics Committee of the São Lucas Hospital (CEP/HSL, process no. 532/10) and the Clinical Hospital of Porto Alegre (HCPA, project 06-597), affiliated with the Federal University of Rio Grande do Sul (UFRGS).

# **Study Protocol**

Selected patients underwent assessments at baseline and after 3 months of treatment with the MAD using the following evaluation methods: (1) sociodemographic variables using a self-assessment questionnaire (baseline only), (2) traditional signs and symptoms of SB using the research diagnostic criteria for TMD (RDC/TMD), (3) sleep disorders using the sleep assessment questionnaire (SAQ), (4) SB activity assessment using both polysomnography EMG recordings and BiteStrip scores, and (5) occlusal force measurements using a cross-arch force transducer. Patients wore the MAD during the SB activity assessments at baseline and 3-month follow-up.

## **RDC/TMD** and the SAQ

Specific items of the RDC/TMD Axes I and II for the reported signs and symptoms of TMD in sleep bruxers were collected the day before the polysomnographic analysis to prevent interference with the sleep, EMG, and SB assessments and with occlusal force measurements.<sup>22,28,29</sup> The clinical examination was performed by a single trained clinician based on the RDC/TMD guidelines.<sup>28</sup> The chosen items of the RDC/TMD Axis I were collapsed into dichotomous outcomes to increase reproducibility.<sup>9,19,30,31</sup>

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The SAQ is a 17-item validated against polysomnography questionnaire that is used to screen for sleep disorders in epidemiologic studies (Cronbach's alpha correlation = 0.7).<sup>32</sup> The five factors that were identified in the SAQ were the following: (1) nonrestorative sleep, (2) insomnia, (3) sleep apnea, (4) daytime sleepiness, and (5) restlessness. The SAQ is scored in the following manner: never = 0 points, rarely = 1 point, sometimes = 2 points, frequently = 3 points, always = 4 points, and don't know = 0 points. The higher the sum of the scores (scores 0 to 68), the worse the sleep quality.<sup>32,33</sup>

# Sleep Disorders and SB Assessments Using Polysomnography

The polysomnography was performed in the sleep laboratory service at the Clinical Hospital of Porto Alegre by a single trained technician. The data were analyzed by a sleep medicine specialist. Both professionals were blinded to the RDC/TMD and SAQ results, which were scored by two postgraduate students who were involved in the study. The patients spent 1 night in the sleep laboratory for adaptation, and underwent 1 night of noninduced sleep for the polysomnographic assessment of SB on the following night. The second night was also used to detect sleep disorders that were not identified during the screening process. An EEG machine (Neurofax EEG 9100, Nihon Kohden) with electrode placement according to the 10/20 system was used. It used the following assembly: C3/ A1; C4/A2; O1/A2, right and left; electrooculography (EOG); and EMG of right and left masseter muscles.<sup>34</sup>

For the SB polysomnography EMG assessment, the total number of SB episodes, EMG bursts, and grinding episodes (using audio/video recordings) were registered for 8 hours. To be diagnosed with SB, the polysomnography had to show > 4.0 bruxism episodes per hour of sleep, > 25 bruxism bursts per hour of sleep, or > 1 episode of tooth grinding sounds per hour of sleep. The SB episodes were scored as phasic (ie,  $\ge 3$  EMG bursts, each lasting between 0.25 and 2.0 seconds), tonic (ie, 1 EMG burst lasting > 2.0 seconds), or mixed (ie, both types of bursts) episodes.<sup>3,20-22,34-37</sup>

## SB Assessment Criteria Using the BiteStrip

The BiteStrip, which is a portable surface EMG device, has a computer chip that registers the number of contractions of the masseter muscle during 5 hours of sleep time. The BiteStrip was placed on the left masseter only. Contractions that exceeded 30% of the maximum voluntary clenching muscle activity were considered an SB episode. After the test was completed, the display showed a four-scale ordinal categoric score representing the number of bruxism episodes (0 = no bruxism,  $\leq$  39 episodes; 1 = mild bruxism, 40 to 74 episodes; 2 = moderate bruxism, 75 to 124 episodes; 3 = severe bruxism,  $\geq$  125 episodes; and E = error message).<sup>38</sup>

#### MAD

Patients with a diagnosis of SB used a custom-made monoblock MAD for 3 months after an habituation period of 2 weeks. Maxillary and mandibular casts of the patient were mounted in a Whip-Mix semiadjustable articulator (Bio-art Dental Equipments) in a protrusive position (50% to 75% of maximum protrusive position, depending on patient's tolerance) with a 6-mm interincisal opening, according to a bite registration performed with a silicone-base material (3M Express, 3M ESPE).17-19 Then, two soft, 3-mm-thick, translucent thermoplastic bite splints were made in the thermo-vacuum device (Plastvac P7, Bio-art Dental Equipments). The splints were fused in the articulator in the preregistered position using a micro torch (Piezo Electronic Micro Torch-GB 2001, Micro Torch-Blazer). Patients were asked to fill out a reminder sheet to assure compliance during the study period.

#### Maximum Occlusal Force Measurement

The maximum occlusal force was measured using a cross-arch force transducer (Sensotec 13/2445-02) placed in first molar regions on the same day that the polysomnography was performed (baseline and after 3 months). The force transducer was covered with a layer of extradural rubber for protection of teeth. The measurements were performed three times with a rest interval of 5 minutes between them. The patient was asked to bite as hard as possible for a period of 2 to 3 seconds. The displayed values were converted to Newtons.<sup>8,9</sup>

#### Statistical Analysis

A before and after study design was selected that used a similar sample size from the authors' previous study, which disclosed significant differences.<sup>19</sup> The Kolmogorov-Smirnov test was used for the normality distribution of the continuous variables, using logarithmic transformation when needed.<sup>26,27</sup> The Student *t* test was used for evaluation of the continuous variables, and the McNemar test was used for the ordinal and dichotomous variables.<sup>39,40</sup>

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 Table 1
 Patient Characteristics

Independent variables	(n = 19)
Age (y): mean $\pm$ SD	39.9 ± 12.98
Educational level (%)	
Incomplete elementary school $= 1$	0.0
Completed elementary school $= 2$	0.0
Incomplete high school $= 3$	0.0
Completed high school $= 4$	21.0
Incomplete undergraduate degree = 5	5.3
Completed undergraduate degree = 6	47.4
Postgraduate education $=$ 7	26.3
Sex (%)	
Female = 0	58.0
Male = 1	42.0

#### Results

#### Population

Of the 30 subjects attending the first polysomnography, 11 missed the second polysomnography (36.7% dropout rate) due to the following reasons: (1) six patients did not adapt to the MAD due to TMJ/muscle pain and/or discomfort, (2) two patients had health problems that appeared after the initial screening, and (3) three felt discomfort during the first polysomnography. The final sample (n = 19) was composed predominantly of young adults and women, and most had a postsecondary high school education (Table 1). The social demographic characteristics of the excluded patients were similar to those of the included patients (mean age: 37.6 years, 71.4% with postsecondary education, and 85% women).

## **Before and After MAD Treatment**

The distribution of continuous variables was tested for normality, and only the SAQ showed a normal distribution. In Table 2, the polysomnographic tests showed a decrease in all variables but one after the use of the MAD. A reduction of 33.7% in the episodes per hour of sleep was observed and considered statistically significant. A decrease of 29.9% in the bursts per hour of sleep was also noted but was nonsignificant. Regarding sleep, the SAQ showed a highly significant reduction of 22.9% in sleep scores, suggesting an improvement in the sleep quality with the use of the MAD. A highly significant reduction of 35% was also noted in the maximum occlusal force.

In Table 3, all SB signs, symptoms, and activity showed significant reduction after the use of the MAD. Regarding the BiteStrip, a reduction of 75% was observed in the prevalence of patients with moderate to severe SB. A reduction of 59.8% was noted in the prevalence of patients with a self-reported presence of joint sounds. An increase in 66.4% was also observed in the prevalence of patients with no TMJ sounds. In addition, before using the MAD, all patients reported often/always grinding and/or clenching of teeth. Afterwards, these patients either showed no grinding or began to grind and/or clench only rarely/ sometimes. Almost all patients had pain upon palpation of the masseter muscles before using the MAD but not afterwards.

### Discussion

### **Population and Study Design**

Similar to four previous studies, this study was intended to assess the effect of the MAD on SB without sleep disorders using two valid methodologies.<sup>16–19</sup> SB patients with concomitant sleep disorders could have acted as modifying factors by increasing SB and reducing the therapeutic effect of the MAD; therefore, they were excluded as in previous literature.<sup>16-19</sup> Only 19 of 30 patients (63.3% response rate) were included in the final analysis. However, the present convenience sample was equivalent (12 to 30 subjects) to the population reported in similar studies.<sup>3,8-11,16-22</sup> The male/female ratio was close to 50%, confirming that there is no sex difference in pain-free bruxers.<sup>1,2,6,25,41</sup> Additionally, the mean age (39.9 years) was also very similar to that reported in the literature.<sup>1,2,6,16,25,41</sup> However, this similarity with the literature must be analyzed with care, because only patients from 20 to 45 years of age were included to control age as a confounder for EEG and EMG.<sup>24</sup> A before and after study design was selected because the patients were the controls. This was particularly important when assessing SB, TMD, and occlusal force, which are influenced by many confounders.<sup>9,19,30,31,39,40</sup> However, this study was not controlled, which is a threat to internal validity; therefore, the findings must be further confirmed by controlled studies using polysomnography.

#### SB Activity and Sleep Disorders

According to both the EMG polysomnography and BiteStrip readings, there was a sharp and significant reduction in SB episodes after the use of the MAD. Both methods were used at two time points; therefore, it would have been interesting to increase both the measurements and follow-up time to determine whether the reduction had remained stable over

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Table 2	Before and A	fter Results in	Continuous	Variables	Assessing Sleep	Disorders, SE	3 Activity, and	Occlusal Force
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Independent variables	Before (n = 19): mean $\pm$ SD	After (n = 19): mean $\pm$ SD	Р
EMG polysomnography episodes of SB/h	7.0 (0.11)	4.64 (0.13)	< .05*
EMG polysomnography bursts/h	15.73 (0.18)	11.02 (0.15)	NS*
SAQ (scores, 0 to 68)	26.21 (0.5)	20.21 (0.2)	< .001**
Maximum occlusal force (N)	$828.55 \pm 0.09$	$538.59 \pm 0.09$	< .001*

\*Paired Student t test with logarithmic transformation.

\*\*Paired Student t test.

Table 3	Before and After Resu	lts in Ordinal Variable	s Assessing SB Si	igns, Symptoms	, and Activity
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Independent variables	Before (n = 19)	After (n = 19)	P*
BiteStrip episodes of SB/5 h (%)			
No bruxism ( $\leq$ 39) = 0	5.3	52.6	< .05
Mild bruxism $(40-74) = 1$	10.5	26.3	
Moderate bruxism $(75-124) = 2$	47.4	10.5	
Severe bruxism ( $\geq$ 125) = 3	36.8	10.5	
Self-reported TMJ sounds (%)			
Absent $= 0$	47.4	78.9	≤ .001
Present = 1	52.6	21.1	
TMJ sounds (unilateral or bilateral palpation sensitivity) (%)			
Absent $= 1$	47.4	78.9	≤ .001
Crepitation $= 2$	15.8	5.3	
Click = 3	36.8	15.8	
Self-reported grinding and/or clenching of teeth (%)			
Never $= 1$	0.0	10.5	≤ .001
Rarely $= 2$	0.0	78.9	
Sometimes $=$ 3	0.0	10.5	
Often = 4	21.1	0.0	
Always = 5	78.9	0.0	
Masseter (unilateral or bilateral palpation sensitivity) (%)			
Absent $= 0$	5.3	100.0	≤ .001
Present = 1	94.7	0.0	

\*McNemar test.

time. In this study, there was a 33.7% reduction in SB episodes per hour of sleep and a 29.9% reduction in bursts per hour of sleep, which are higher than the reported SB individual fluctuation (up to 25%).<sup>42</sup> In addition, the majority of patients had an improvement in SB activity, which appears to reduce the possibility of incidental findings.<sup>26,27</sup> This study also found a mean of 7 SB episodes per hour, confirming that the current proposed EMG polysomnography criteria for the diagnosis of SB is reproducible.<sup>22</sup>

This study also confirms that portable EMG devices, including the BiteStrip, can be used only as screening tools for assessing SB activity.<sup>22,34,36,43</sup> This is based on the fact that the reduction in episodes of SB found in the BiteStrip was 2.2 times greater than the reduction in the EMG polysomnography (75% versus 33.7%, respectively). These findings confirm previous results

that the BiteStrip is better, compared with polysomnography, in diagnosing the presence of SB (kappa = 0.71) than the SB intensity (kappa = 0.51).<sup>34</sup> The literature shows a correlation from 0.79 to 0.81 between the BiteStrip and polysomnography EMG readings, which demonstrates its ability to measure muscle activity, but not the ability to distinguish SB episodes from other oral motor activities.<sup>22,34,36</sup> Despite the differences between the two methodologies, both confirmed the MAD treatment effects on reducing SB.

This study is also in agreement with recent literature, in which the MAD showed a greater reduction in SB activity than other intraoral appliances.<sup>16-19,29</sup> However, the MAD cannot replace the traditional Michigan-type occlusal splint in patients with SB without obstructive sleep apnea (OSA), only in those with both conditions because it can produce short-term discomfort/pain and/or long-term undesirable irreversible alterations in both the dentition and TMJ.<sup>44-46</sup> In contrast, the Michigan-type occlusal splint should not be used in patients with both SB and OSA, because a previous study reported that it might aggravate sleep apnea.<sup>47</sup> The mechanism by which this improvement takes place seems to be the forward movement of the mandible, which results in increased airway space.44,48 However, further studies should clarify the relationship between the amount of advancement and the amount of improvement in SB activity, as only one study has shown that a 75% advancement does not differ significantly from a 25% advancement, but that both differed from no advancement.<sup>18</sup> The MAD was originally designed to treat mild to moderate OSA; however, there might be a relationship between SB and OSA, which is discussed in more detail in the literature.14,15,49

After the use of the MAD, there was a reduction in both sleep scores (SAQ) and in SB episodes (EMG polysomnography and BiteStrip). The underlying mechanism might be that SB is related to microarousals and/or awakenings, which prevent deep sleep, thereby leaving the individuals in a light sleep stage, during which 80% of SB episodes take place.<sup>1,2,6,25,37,49</sup> Despite having a moderate to good correlation with polysomnography, the SAQ is a screening questionnaire, and only the global score was assessed.<sup>32,33</sup> In addition, the SAQ attributes the value "0" to more than one answer (ie, never and don't know), which might have influenced the results in an unpredictable manner, considering that never is always a negative response, but don't know might be a positive or a negative response.

# Signs and Symptoms of TMD, Occlusal Changes, Grinding Activity, and Maximum Occlusal Force

Very significant reductions in self-reported joint sounds, in unilateral or bilateral TMJ sounds upon palpation, and in unilateral or bilateral pain upon palpation of the masseter muscles were found. The results agreed with a previous study that showed an improvement in some classic signs and symptoms of TMD.<sup>19</sup> These data are also in agreement with one study that found that severe SB increases the risk of developing clicking in the TMJ (3.4-fold) in women.<sup>50</sup> This reduction in TMD signs and symptoms might be explained by either a reduction in SB activity or by the resilient MAD material, which may reduce the load transmitted to the TMJs; however, both theories are highly speculative.<sup>3,29</sup> In most studies, the correlation between TMD signs and symptoms versus masseter activity yielded negative results, but the impact of SB

on the TMJs must be further studied because most studies have focused on the masticatory muscles, which are more adaptable to pain and increased SB activity.<sup>78,21</sup>

Short-term side effects after the use of the MAD were present in 6 of 25 sleep bruxers (24%), who were excluded from the study due to TMJ/muscle pain and/or discomfort. This is in agreement with previous studies that reported increased salivation and jaw and teeth discomfort by a few patients.44,51 The MAD should not be used in patients with spontaneous TMD pain, particularly from the TMJ.<sup>16-19,29</sup> However, the following occlusal and skeletal long-term side effects in some patients may present 6 months after the use of the MAD and become evident after 30 months: (1) increase in face height due to downward relocation of the condyle, (2) reductions in overbite and overjet, (3) overeruption of the maxillary first premolars and mandibular first molars, (4) retroclination of the maxillary and proclination of the mandibular incisors, (5) anterior or posterior open bites, (6) increase in the width in both maxillary and mandibular arches, (7) decrease in crowding in both the maxilla and mandible, (8) flattening of the Spee curve in the premolar area, and (9) forward movement from the mandibular canine to second molar segment in relation to the maxilla.<sup>44-46</sup> These long-term side effects vary from patient to patient and may be reduced by 50% with elastomeric appliances.<sup>44</sup> However, in this study, this hypothesis was true for 76% of the initial sample, showing a high degree of individual variation. The patients showed no occlusal alterations, which was most likely due to the very short follow-up time.

In self-reported grinding and/or clenching, a very significant reduction was found; however, grinding is not higher in bruxers than other adults (3% to 7%).<sup>1,2,6</sup> There is also a week association between the tooth grinding pattern and bruxism behavior,<sup>11</sup> and grinding varies based on age, sex, tooth location, awake versus SB, and so on.<sup>8,9,12,13</sup> In addition, self-reported muscle tension/grinding is not reliable for bruxism diagnosis.<sup>1,2</sup> A very significant reduction in maximum occlusal force was also found, which is in agreement with the authors' previous study.<sup>9</sup> Similar studies have found increased maximum occlusal force levels in bruxism and reduced maximum occlusal force levels in TMD.<sup>52–54</sup> However, this remains controversial in the literature.<sup>7,9,10,52–54</sup>

Regarding the MAD, the adaptation period of 2 weeks and treatment protocol and appliance construction were in agreement with the literature and had no effect on the results.<sup>17–19,55–62</sup> In addition, the choice of the monoblock type over the split type has been shown to be equally effective with no difference

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in short-term side effects.<sup>56–60</sup> Finally, the choice of a 3-mm-thick soft thermoplastic material was reported to be easily adaptable and as effective as rigid materials.<sup>19,57,58</sup> However, the rigidity and integrity of this soft appliance must be assured to prevent the aspiration of broken parts.<sup>29,63–65</sup>

## Conclusions

The data indicated that the use of the MAD in sleep bruxers with no sleep/neurologic disorders or TMD spontaneous pain produced a very significant reduction in SB activity, TMJ sounds, masseter muscle palpation sensitivity, maximum occlusal force, and sleep scores, demonstrating an overall improvement in SB and sleep quality. However, in 24% of patients, the MAD treatment had to be stopped due to TMJ/ muscle pain and/or discomfort.

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