Title: Sleep Quality and Comfort Reported by Sleep Bruxism Individuals Wearing the Occlusal Splint and Mandibular Advancement Splint: Revisiting Two Crossover Studies

Running title: Oral Device Comfort in Sleep Bruxism Individuals

Authors:

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Abstract

Purpose: To assess (1) whether the occlusal splint (OS) or mandibular advancement splint (MAS) allowed the best quality of sleep and was most comfortable; and (2) the relationship of sleep quality and comfort with the reduction in rhythmic masticatory muscle activity (RMMA) related to sleep bruxism (SB). Materials and Methods: Polysomnographic data of 21 SB subjects (25.6 ± 4.5 years), collected in two previous studies, were compared. Morning
self-report data on sleep quality and comfort of the oral device, polysomnographic data, and RMMA index data from no-device nights were compared to data from nights using an OS or MAS. The reduction ratio of the RMMA index was calculated with the OS and the MAS. A responder to the oral device was identified when the RMMA index was less than 2, and when there was a reduction of at least 50% from the no-device night. Results: Sleep quality reports on comfort of the oral device showed a mild advantage to the OS when compared to the MAS ($r^2 = 0.47$, $r^2 = 0.32$: $P \leq .01$, respectively). The MAS induced a greater reduction on the RMMA index ($P = .03$) than the OS in responders. Conclusion: In the short term, the comfort of an oral device seemed to influence sleep quality in SB individuals. Despite the slightly higher degree of comfort offered by the OS, the MAS induced a greater effect on RMMA index. Int J Prosthodont 2022. hoi: 10.11607/ijp.7525

1. Introduction

Sleep bruxism (SB) is the repetitive muscle activity during sleep which closes and opens the jaw, producing tooth clenching or grinding (1, 2), observed in dentulous and edentulous individuals. Although SB is a common oral behavior (3, 4), it can progress to a disorder when its consequences (e.g., tooth damage, pain), or comorbidities such as sleep-disordered
breathing or neurological conditions (e.g., REM behavior disorder, epilepsy), become severe (3, 5, 6) (7).

Occlusal splint (OS) therapy is a standard approach to prevent tooth wear and damage (8), and to manage temporomandibular disorders (9). When worn during sleep, the OS helps to reduce jaw muscle activity, including that associated with SB (10-13). Its effect, however, appears to be mainly transient or short-term although one study showed a marginal effect at one month, and a significant one at three months (10, 13, 14). In patients with SB and obstructive sleep apnea (OSA), OS use is questionable and requires caution, as it can aggravate apnea/hypopnea incidence (15, 16).

Many studies have assessed the effectiveness of the mandibular advancement splint (MAS; alternatively referred to as the mandibular advancement appliance (MAA) and mandibular advancement device (MAD)) as a treatment for snoring and mild to moderate OSA; very few, however, have tested its efficacy in managing SB alone or in the presence of comorbid transient morning headache and/or OSA (13, 17-22). In a case report on the MAS, used by a patient presenting concomitant OSA and SB, reductions in the apnea/hypopnea and the rhythmic masticatory muscle activity (RMMA) indices (events/hour) were observed on polysomnographic sleep recordings (PSG) performed after 60 days of use (23). MAS use by
patients presenting concomitant OSA and SB needs further documentation before reliable recommendations can be made (3) (24) (7).

Comfort can be an issue for the design of any oral device whether it is used to manage SB alone or with comorbid OSA (19, 20, 25-29). Oral device comfort is assessed through self-reports, generally using a 100 mm visual analogue scale. This is clearly subjective, however, and can influence treatment adherence (19, 20, 25). Further, sleep quality has a strong influence on people’s general health (30). The effect of oral device design on sleep quality has been assessed in a previous report that considered both the OS and the MAS (13). The parallel sleep laboratory study showed sleep quality to have been improved and RMMA related to SB during the night, reduced, by both the OS and the MAS; this seems to have been observed after only three months of use. However, the report did not address oral device comfort during the night.

What is needed is the simultaneous evaluation of treatment comfort, sleep quality, and RMMA reduction, with the OS and the MAS in SB subjects. The aims of this retrospective study were to assess 1) which of the occlusal splint (OS) or mandibular advancement splint (MAS) allowed the best quality of sleep and was most comfortable; 2) the relationship between the quality of sleep and comfort with the reduction in RMMA related to SB.
1. Materials and Methods

1.1. Study design and subjects

This retrospective crossover study is based on data collected in two previous studies conducted at our sleep research laboratory (19, 20). The experimental design included one night for sleep laboratory habituation and a second night (labeled no-device night) to be used as a reference. Subjects then wore an OS or MAS while sleeping for two weeks in each crossover study arm, to optimize habituation, prior to sleep recording nights, as described below.

A total of 24 Caucasian subjects participated in the studies. They were recruited through advertisements posted at a university and a college in Montreal, and then selected following interviews and clinical examinations. Three main criteria led the selection process; 1) a history of tooth grinding, heard at least 3 times a week in the past 6 months by a sleep partner or family member; 2) observation of tooth wear; and 3) anamnesis of masseter or temporalis muscle fatigue in the morning. Criteria for exclusion were the presence of the following sleep disorders, verified by PSG at our sleep laboratory: OSA (>5 apnea and hypopnea events per hour of sleep), restless leg syndrome (>10 periodic limb movement events per hour of sleep),
and epileptiform brain activity. Participants presenting a history of medical disorders (psychiatric, physiological, neurological, sleep-disordered breathing) or any medication, drug, or alcohol use were also excluded. Other exclusion criteria were absence of two or more posterior teeth, use of a dental prosthesis, and major dental-skeletal malocclusion. One participant was excluded before data collection because he could not tolerate either oral device (OS or MAS) and two others failed to meet the inclusion criteria, leaving 21 participants (overall 25.6 ± 4.5 y.o.; 15 females: 25.5 ± 5.0 y.o., 6 males: 26.0 ± 3.6 y.o.).

Both studies were approved by the Research Ethics Board of the Hôpital du Sacré-Coeur de Montréal, and all subjects signed an informed consent form.

1.2. Oral Devices

In the first study, a single maxillary OS and a boil-and-bite custom-fit, also called thermoplastic or prefabricated, MAS were used (19, 31). In the second study, a single mandibular OS and an adjustable, called custom-made, MAS were used (20). All oral devices were adjusted for maximum patient comfort. The devices were worn for two weeks before PSG recording to allow habituation. The OS and MAS manufacturing processes have been described in previous reports (19, 20). Either an OS or a MAS was randomly chosen and
worn for two weeks, after which all subjects slept without an oral device for a second two weeks as a wash-out period. Then subjects wore the other oral device for a third two-week period.

2.2.1 Occlusal splint (OS)

Impressions of mandibular and maxillary teeth were taken with irreversible hydrocolloid dental material, and the working cast model was then poured with artificial dental stone. The dental cast model was mounted on a semi-adjustable articulator. To create the OS, all of the mandibular or maxillary teeth were covered with a hard acrylic resin to a thickness of 1.5 to 2.5 mm in the first molar region. The contacts of the OS to the opposite jaw were adjusted equally to achieve bilateral symmetry in the supine position. The oral device was then able to give participants full freedom of mandibular movement during sleep.

2.2.2 Mandibular advancement splint (MAS)

Two kinds of MAS device were used, each with a double arch. The first was constructed from thermoplastic and heat-molded foam, and was easily fitted at chairside; then the amount of mandibular advancement was measured by George Gage (Great Lakes Orthodontics). The second was constructed from a hard acrylic resin; then the amount
of mandibular advancement was measured by Gothic arch tracing record (Gothic Arch Tracer GAT). Both devices had a similar fixed vertical retention pin positioned on the upper arch and a slot in the lower arch to keep its maximum position at 75% of maximum protrusion. In terms of width, the MAS devices were about twice as thick as the OS device in first molar region.

1.3. Sleep questionnaires

In the sleep laboratory, in the first hour after waking, participants were asked to grade five items on a “Morning Questionnaire”: “Sleep Quality”, “Oral Device Comfort”, “Bruxism as a sleep disturbance factor”, “Anxiety”, and “Fatigue”. These were rated on a visual analog scale (VAS), a 100 mm straight horizontal line anchored by descriptors at each end (19, 20, 25). For “Sleep Quality” and “Oral Device Comfort”, the descriptors were “bad quality” and “no comfort” on the left and “good quality” and “good comfort” on the right. For “Bruxism as a sleep disturbance factor”, “Anxiety”, and “Fatigue”, which measured painful experiences, they were “not at all” on the left, and “extremely” on the right.

1.4. Polysomnographic recording
PSG sleep laboratory recordings were performed from approximately 22:30 to 7:30 in a sound-attenuated, temperature-controlled room. Recordings included surface electrocardiograms (ECG), electroencephalograms (EEG: C3-A2 and O2-A1), bilateral electro-oculograms, and electromyograms (EMG). EMG recordings covered the bilateral masseter, temporalis, anterior tibialis, and unilateral chin/suprahyoid muscles.

The reference points were the earlobe and the middle of the forehead. Chest movements and respiratory parameters were measured using a chest and an abdominal belt, a thermistor placed beneath the nostrils to assess airflow, a standard pulse oximetry (O2 saturation) and a nasal cannula. Audio/video monitoring was performed to identify body movements, SB with tooth-grinding, and other orofacial movements. All signals were sampled at 128Hz for offline analysis using Harmonie software (formerly Stellate Corp., Canada, now Natus, USA) at 16-bit resolution (National Instruments, PCI-6033E, USA).

Baseline data were recorded for two consecutive nights without an oral device. For the analysis, data recorded during the second night as the reference, labeled the no-device night, were compared to data collected after two weeks of oral device use with a PSG sleep laboratory recording as described above. To capture the maximum effect on RMMA, only data from the MAS mandibular position adjusted to 75% of the maximum mandibular
protrusion were compared to the no-device night (19, 20). Data from the 40% and 25% positions, as presented in the original studies, were excluded.

1.5. *Scored variables and EMG quantification*

Sleep architecture and variables were visually scored offline according to Rechtschaffen and Kales standard criteria (32) using modified 20-s epochs. All scoring was performed by the same sleep technician blind to patient status (no device, with the OS, or with the MAS).

Polysomnographic sleep variables of interest included sleep duration and percentage of each sleep stage. In addition, sleep apnea-hypopneas and O₂ saturation were scored according to standard criteria (33, 34).

RMMA related to SB episodes was scored according to the International Classification of Sleep Disorders of 2014 (35) by another trained research technician using right and left masseter electromyograms (36-39). The RMMA index related to SB was expressed as the number of RMMA episodes per hour, bursts per hour, and bursts per episode, as per SB research diagnostic criteria (SB-RDC) (37). We also adapted pragmatic criteria to further separate responders from non-responders. First, responders would be those for whom the oral device reduced RMMA episodes to two or less per hour (40). Second, the following reduction
ratio would also be calculated to evaluate the changes made by the oral device as against a no-device night. In responders, that reduction ratio would be at least 50%, using a formula presented in the literature (41):

$$\frac{\text{RMMA episodes/hour (no-device night)} - \text{RMMA episodes/hour (OS or MAS night)}}{\text{RMMA episodes/hour (no-device night)}} \times 100.$$

The relative therapeutic effectiveness of the OS and MAS was calculated on the basis of morning self-reports (sleep quality) and the RMMA reduction ratio. This novel method was derived from the mean disease alleviation (MDA) calculations used initially to compare relative adherence with treatment efficacy, recently applied in the field of obstructive sleep apnea (42, 43). It is an intuitive method to assess and compare treatment efficacy and effectiveness, suggested by Vanderveken, Sutherland and colleagues (42, 44, 45). Hence, sleep quality and RMMA reduction ratio respectively were turned to, rather than treatment adherence and efficacy of the oral appliance, in order to calculate MDA in this study. Sleep quality, especially, was utilized as a marker for treatment adherence through its impact on quality of life (46-48). The MDA modified for SB was calculated as the area under the curve, where the horizontal axis was the RMMA reduction ratio, calculated as described above, and the vertical axis was the sleep quality (100 mm converted into 100%).
1.6. Statistical analysis

Normality of data distribution for sleep and RMMA parameters was assessed with Shapiro–Wilk’s test and box plot readings using SPSS 22 (IBM Inc., NY, USA). All normally distributed data were pooled and averaged for each subject (mean ± SEM), and a linear mixed model for repeated measures analysis was performed, followed by Bonferroni-corrected pairwise mean comparisons. Non-normally distributed data were subjected (median (interquartile range (IQR): first quartile – third quartile)) to the non-parametric Friedman test followed by Wilcoxon’s signed ranks test with Bonferroni correction.

Since both oral device types (i.e., the OS and MAS) from two previous studies were combined, student-t tests or Mann-Whitney U tests were done to ensure that there were no treatment-specific differences in RMMA and self-reports (i.e., maxillary vs mandibular OS; between both MAS used).

Linear regression analysis was conducted with sleep quality as a dependent variable, and each question in the morning self-report following OS and MAS nights, as an independent variable. As described above, a responder to an oral device was identified when the RMMA
index was less than 2, and a reduction of at least 50% from the RMMA index of a no-device night was observed; McNemar’s test was used to compare the proportion of responders between the OS and MAS groups. The RMMA reduction ratio was also compared between the OS and MAS groups, in responders and non-responders, using the Mann–Whitney U test. Statistical significance was set at p<0.05.

A post-hoc power analysis was carried out on sleep questionnaires to calculate the observed power and the effect size (Pass version 12).

2. Results

2.1. Sleep quality and oral device comfort

The OS and MAS data from both studies were combined, as none of the morning self-reports revealed significant differences when we compared them within both OS groups, nor when we compared them within both MAS groups.

Morning reports of sleep quality and comfort related to oral device use were significantly better for the OS than for the MAS (P = 0.05 and P < 0.001, respectively; Table 1). Further, the relationship between sleep quality and oral device comfort with the OS and the MAS showed an overall positive correlation (P < 0.001, r² = 0.421 for both devices together), with
a higher correlation for OS than for MAS nights ($P = 0.001, r^2 = 0.473$ OS; $P = 0.010, r^2 = 0.316$ MAS; Figure 1). However, a comparison of the two correlation coefficients did not show a significant difference using Fisher r to z transformation ($P = 0.549$). Further, although the slope of sleep quality vs that of oral device comfort was compared between OS and MAS users using mixed model analysis, this also showed no significant difference. No differences between oral device designs were found either for the self-reported items “Bruxism as a sleep disturbance factor,” “Anxiety,” or “Fatigue.” Post-hoc power analysis on the difference between OS and MAS revealed that sleep quality had a medium effect size (0.49) and a power of 0.51, while oral device comfort had a very large effect size (1.27) and a power of 0.99.

Compared to the no-device nights, sleep efficiency and percentage of sleep stage 2 duration were significantly higher for the OS nights ($P = 0.007$ and $P = 0.006$, respectively; see Table 2). Moreover, the number of awakenings and the percentage of slow wave sleep were significantly lower with OS use compared to no-device nights ($P = 0.025$ and $P = 0.008$, respectively). No statistically significant differences were found between MAS nights and those with OS use or no device (Table 2).
2.2. **RMMA-SB variables**

Maxillary and mandibular OS data were combined as there was no significant difference between OS types for all RMMA variables \( (P \geq 0.345) \) nor in the self-report questionnaires \( (P \geq 0.201) \). However, even though there was no significant difference between the two types of MAS for RMMA variables, except the RMMA index \( (P \geq 0.169) \) and in all questionnaire data \( (P \geq 0.095) \), only the RMMA index with the custom-made MAS was significantly higher than that with the boil-and-bite/thermoplastic MAS \( (P = 0.028) \).

For both OS and MAS use, the RMMA episodes per hour were significantly fewer, about 45 and 85% reduction in the short term based on the no-device nights \( (P = 0.026 \) and \( P < 0.001 \), further details in Table 2). RMMA bursts had almost same trend as the RMMA episodes (Table 2). Further, the MAS nights \( (83.44 \text{ (interquartile range (IQR): } 61.57 – 90.41)) \) had a significantly higher reduction ratio of RMMA episodes, based on no-device nights, than did the OS nights \( (47.38 \text{ (IQR: } 24.09 – 70.73)) \) \( (P < 0.001) \).

Based on the RMMA results shown above, 9 participants were classified as OS responders and 12 participants, as OS non-responders. For MAS wear, 15 participants were classified as responders and 6 participants as non-responders \( (P = 0.031, \text{ Table 3}). \) The MAS responders had a significantly higher RMMA reduction ratio than the OS responders \( (P = 0.030, \text{ Figure} \)
2), and the non-responders showed no difference between oral devices ($P = 0.250$, Figure 2).

The non-responders were equally distributed between OS and MAS wear.

Figure 3 shows the relative therapeutic efficiency (based on MDA calculations modified for SB) of the OS and the MAS. The SB MDA is 39.21% for the OS and 47.98% for the MAS, showing no significant difference between the two ($P = 0.136$). Yet, the oral devices exhibited different sleep quality reports and RMMA reductions. More specifically, a lower RMMA index reduction ratio (47.38 %) was observed with use of the OS, although it was associated with better self-reported sleep quality (82.75 %). In contrast, the MAS showed much better efficacy in reducing the RMMA index (83.44%) but lower sleep quality (57.50 %).

3. Discussion

The major finding of this study is the positive correlation between sleep quality and comfort related to oral device design. In the short term (2 weeks), the OS was much more comfortable than the MAS, based on morning self-reports. The MAS resulted in a greater reduction in the RMMA index than did the OS when worn at night; however, therapeutic effectiveness, a new
concept added between sleep quality and RMMA reduction ratio, was no different in the MAS than in the OS.

3.1. *Oral Device Comfort*

The comfort of an oral device could be a critical issue in treatment adherence for some SB patients. It appears that comfort may be related to device size, although it is possible that the MAS protrusive displacement, dry mouth, and the retention mechanisms (maintaining the displacement) also contribute to discontinued or perceived discomfort including tooth pain (49, 50). This supposition is supported by our previous work, which showed that while only a marginal difference in comfort was noted between intermediate and nearly full MAS protrusion, the greater thickness of the MAS was a predominant complaint. Moreover, because both studies addressed short-term use (2 weeks), the habituation window for the device (i.e., the MAS) may not have been sufficient. This is indirectly supported by a crossover randomized clinical trial in OSA patients over the longer term (6–27 months of MAS use), where we compared two MAS designs: a thicker one, as was used in the second SB study (Silencer, Canada), and a thinner one (Klearway, Canada) (25). In the short term, the thinner device was reported to be significantly more comfortable (Klearway 70/100 mm
vs. Silencer 58 mm), but after six months, no reported difference in oral device comfort was found (both devices at 77/100 mm). In a European crossover MAS study, a higher failure rate was obtained with a boil-and-bite/thermoplastic than with a custom-made MAS, mainly due to retention issues, another variable of interest related to comfort (31).

3.2. Sleep quality

Sleep quality is associated with quality of life in populations (30) and could play an important role in treatment adherence in SB. In this study, OS overnight use showed significantly higher subjective sleep quality than did MAS use. Since a similar study reported that both the OS and MAS improved sleep quality as well as reduced RMMA episodes after three months (13), the quantity of RMMA episodes might be linked to sleep quality in SB patients (21). On the other hand, a previous study reported sleep quality not to have been associated with SB (51).

3.3. Reduction in RMMA related to SB
In the present study, the RMMA index during sleep decreased with both the OS and MAS compared to no-device nights. This was expected and is in agreement with several previous studies (12, 13, 52-54).

When comparing the percentage of responders to non-responders, 72% of MAS users were responders versus just 43% of OS users. The MAS thus appears to be more effective in reducing RMMA than the OS. This is unlikely to be attributable to the MAS’s double arch design or its restriction of mandibular movement alone, as shown in a randomized study of one week’s use of three oral device types (55). Whereas the three devices (a regular full upper arch OS, an MAS in free mode between upper and lower arch, and an MAS with restriction of mandibular movement but no protrusion) significantly reduced RMMA episodes/hour and bursts/hour from reference nights (no oral device), no differences in these RMMA outcome variables were observed between the three device designs. Further, in that study, no difference was noted between the OS and MAS in the non-responder group (55).

In the present study, the number of non-responders using the MAS was smaller than that using the OS, but the reduction ratio of the RMMA had a similar distribution for the two oral device designs. The MAS, therefore, might not be sufficient to reduce RMMA episodes entirely. Several previous studies have demonstrated that while masseter muscle activity is
controlled by the central nerve system, oral peripheral sensory input can override the central nerve control and inhibit time-related oro-functional activity (52, 56, 57). Oral peripheral sensory input, via periodontal mechanoreceptors, affects oral motor function (58): the restriction of mandibular movement thus stimulates upper and lower peripheral sensory input. The inhibitory effect of the MAS was therefore probably activated both by upper and lower additive peripheral sensory input and by the restriction of mandibular movement (55). While the OS may also activate an inhibitory effect through the upper or lower sensory input, it may have been weaker than that for the MAS. However, the present short-term study cannot explain the reason why the distribution of non-responders to the MAS, and to the OS, was similar. We suggest that the reduction cannot be fully explained by the restriction of mandibular movement but that the novelty/habituation window may also play an important role, and that oral device comfort in the initial habituation phase may be critical to an explanation of the benefits of a much less comfortable MAS.

3.4. Clinical implications

The therapeutic effectiveness of the two appliances (the OS at 39% and the MAS at 48%) was not statistically different even though the OS was characterized by higher oral device
comfort reports, and the MAS, by stronger efficacy as a treatment for SB. As suggested in a previous study on the impact of device thickness on SB reduction (59), the thicker MAS was more efficient in reducing SB activity. On the other hand, the thinner OS was associated with higher sleep quality which can impact treatment adherence. This suggests that by taking into account both treatment efficacy and treatment adherence (with sleep quality used as a proxy), the disease alleviation outcome should be similar with the use of either. Clinicians should thus use their own judgment and patient preference to assess the balance between oral device comfort and efficacy in reducing the RMMA index.

3.5. Limitations in the results interpretation

Some limitations in the interpretation of these results must be considered. First, data were collected from two studies. These data were combined, however, as no difference was found in self reports or in RMMA variables between the two types of OS, nor between the two types of MAS. Although the OS was worn over either upper or lower teeth, we also found positioning to result in no difference in comfort, sleep or RMMA variables. The sample may have been too small to assess differences in the outcomes of interest. Further, the materials
used for MAS manufacture differed greatly. The boil-and-bite material used for the 2006 study (19) was bulkier than that for the 2009 study (20), where we used a custom-fitted device requiring dental impressions. Although we found differences in outcomes between the studies, the small sample size may again have been a limitation, in addition to the appliance design and manufacturing method. Further, since the median of RMMA indices for each MAS was less than 2, the difference in episodes per hour between the two types of MAS was less than 1, and the morning self-administered questionnaires showed no significant differences in the two MAS nights, it was thought that combining both MAS data sets would not affect our study. Smaller orthodontic devices custom made with CAD/CAM technologies, for example, appear to be more comfortable (29).

Second, this study assessed short term changes in outcomes, over just two weeks, thus a validated sleep quality questionnaire such as the Pittsburgh Sleep Quality Index covering one month could not be used in the present study design. Clearly, longer-term assessments are needed to effectively compare device designs (10, 11, 13, 14).

Third, for the modified MDA calculations, sleep quality was used as a proxy for treatment adherence. Future studies should use microchips embedded in the oral devices to record objective treatment adherence.
Fourth, the MAS advancement was set at 75% of maximum protrusion, which may have biased the oral device comfort reports. It is now accepted that shorter advancement is more appropriate for some individuals with transient morning pain or OSA (18, 60, 61). Future studies with larger samples including SB and OSA subjects are needed to compare appliance comfort across advanced oral device designs and related technologies.

4. Conclusion

In the short term, the comfort of an oral device seems to influence sleep quality in SB individuals. Despite the OS being slightly more comfortable, the MAS induced a greater effect on the SB-RMMA index. Since device size and jaw protrusion may matter in some individuals, future studies are needed to assess their long-term use, taking into account patient preference and effectiveness with SB, in the absence and presence of sleep comorbidities.

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Conflicts of Interest (COI): The authors have no conflicts of interest related to this study to disclose.
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Table 1: Morning Self-report using Occlusal splint (OS) and Mandibular advancement splint (MAS)

<table>
<thead>
<tr>
<th></th>
<th>OS</th>
<th>MAS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sleep Quality (mm)</strong></td>
<td>82.75 (38.50 – 98.75)</td>
<td>57.50 (35.25 – 70.50)</td>
<td>0.050</td>
</tr>
<tr>
<td><strong>Oral Device Comfort (mm)</strong></td>
<td>79.25 (55.63 – 90.75)</td>
<td>16.50 (0.00 – 44.50)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bruxism perturb your sleep (mm)</td>
<td>0.00 (0.00 – 3.00)</td>
<td>3.00 (0.00 – 9.00)</td>
<td>0.167</td>
</tr>
<tr>
<td>Anxiety presently (mm)</td>
<td>0.00 (0.00 – 10.75)</td>
<td>0.00 (0.00 – 4.75)</td>
<td>0.123</td>
</tr>
<tr>
<td>Fatigue presently (mm)</td>
<td>7.00 (0.00 – 24.50)</td>
<td>11.50 (0.00 – 24.50)</td>
<td>0.348</td>
</tr>
</tbody>
</table>

Since each item of self-report questionnaire was used by VAS which was straight line of 100 mm scales, these units are millimeter.

Median (first quartile – third quartile). Wilcoxon signed rank tests were used.

In bold: Variables with significant difference
Table 2: Sleep parameters for No-Device night vs. Occlusal splint (OS) and Mandibular advancement splint (MAS) nights.

<table>
<thead>
<tr>
<th></th>
<th>No-Device (reference night)</th>
<th>OS</th>
<th>MAS</th>
<th>P-value</th>
<th>Overall Post-hoc test**</th>
<th>a vs b</th>
<th>a vs c</th>
<th>b vs c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep duration (min)</td>
<td>440.44 ± 8.32</td>
<td>451.75 ± 10.52</td>
<td>434.63 ± 6.69</td>
<td>0.268</td>
<td>0.870 1.000 0.337</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep efficiency (%)</td>
<td>95.39 ± 0.54</td>
<td>97.10 ± 0.50</td>
<td>96.18 ± 0.57</td>
<td>0.009</td>
<td>0.007 0.428 0.257</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REM efficiency (%)</td>
<td>89.82 ± 1.94</td>
<td>89.75 ± 1.78</td>
<td>89.63 ± 1.48</td>
<td>0.988</td>
<td>1.000 1.000 1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep latency (min)*</td>
<td>7.00 (5.00 – 14.33)</td>
<td>4.00 (2.83 – 11.00)</td>
<td>6.00 (2.83 – 11.33)</td>
<td>0.112</td>
<td>0.161 0.368 1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REM latency (min)*</td>
<td>79.33 (67.17 – 111.83)</td>
<td>77.00 (64.67 – 96.67)</td>
<td>72.67 (61.83 – 88.00)</td>
<td>0.867</td>
<td>1.000 1.000 1.000</td>
<td></td>
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<tr>
<td>Stage 1 (%) *</td>
<td>4.41 (3.55 – 7.83)</td>
<td>4.33 (3.31 – 6.59)</td>
<td>4.92 (3.48 – 7.45)</td>
<td>0.229</td>
<td>0.269 1.000 0.840</td>
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<tr>
<td>Stage 2 (%)</td>
<td>58.03 ± 1.95</td>
<td>64.42 ± 1.45</td>
<td>61.95 ± 1.41</td>
<td>0.008</td>
<td>0.006 0.152 0.635</td>
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<tr>
<td>Stage 3+4 (%)</td>
<td>14.74 ± 1.84</td>
<td>10.65 ± 1.40</td>
<td>11.39 ± 1.64</td>
<td>0.020</td>
<td>0.025 0.105 1.000</td>
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<td>Stage REM (%)</td>
<td>21.52 ± 0.81</td>
<td>21.10 ± 0.84</td>
<td>21.59 ± 0.73</td>
<td>0.866</td>
<td>1.000 1.000 1.000</td>
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<tr>
<td>Awakenings (%)</td>
<td>4.55 ± 0.54</td>
<td>2.87 ± 0.48</td>
<td>3.80 ± 0.56</td>
<td>0.010</td>
<td>0.008 0.489 0.245</td>
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<td>Sleep stage shift (times)</td>
<td>167.52 ± 8.68</td>
<td>143.86 ± 10.45</td>
<td>154.29 ± 8.56</td>
<td>0.089</td>
<td>0.087 0.638 0.974</td>
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<tr>
<td>Micro-arousals index (/hr)</td>
<td>6.32 ± 0.69</td>
<td>5.58 ± 0.50</td>
<td>5.56 ± 0.60</td>
<td>0.364</td>
<td>0.677 0.643 1.000</td>
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<tr>
<td>RMMA episodes</td>
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<tr>
<td>Episodes/hr</td>
<td>4.31 (2.88 – 6.10)</td>
<td>2.42 (0.96 – 4.40)</td>
<td>0.63 (0.35 – 2.16)</td>
<td>&lt;0.001</td>
<td>0.026 &lt;0.001 0.026</td>
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<td>RMMA bursts</td>
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</table>

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Mean ± SEM shown for normal data distribution. Linear mixed models for repeated measures followed by pairwise mean comparisons were used.

*; Median (first quartile – third quartile) shown when data distribution was not normal. Friedman and Wilcoxon signed rank tests were used.

In bold: Variables with significant difference;

RMMA; rhythmic masticatory muscle activity.

**; Bonferroni corrected p values.
Table 3: Responders and non-responders in each oral device treatment.

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<th>MAS</th>
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<tr>
<td></td>
<td>Responders</td>
<td>Non-Responders</td>
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<td>0</td>
</tr>
<tr>
<td>Responders</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Non-Responders</td>
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<td>6</td>
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<tr>
<td>Sum</td>
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<td>6</td>
</tr>
</tbody>
</table>

McNemar’s test (P = 0.031)

OS; occlusal splint

MAS; mandibular advancement splint

Note: Responder meant less than 2 RMMA episodes per hour and greater than and equal 50% RMMA deduction ratio using oral device night, and non-Responder meant greater than or equal to 2 RMMA episodes per hour or less than 50% RMMA reduction ratio.
Legends to Figures

Figure 1: Multiple regression showing morning self-reports of sleep quality and oral device comfort using the occlusal splint (OS) and mandibular advancement splint (MAS).

Figure 2: The difference of RMMA reduction ratios between the occlusal splint (OS) and mandibular advancement splint (MAS) for classification of users as responders or non-responders. The Mann-Whitney test was used.

(Note: Responders meant less than or equal to 2 MMA episodes per hour and greater than or equal to a 50% RMMA reduction ratio, for nights when oral devices were used; and non-responders meant greater than 2 RMMA episodes per hour and less than a 50% RMMA reduction ratio.)

Figure 3: The therapeutic effectiveness for occlusal splint (OS) or mandibular advancement splint (MAS) using results of morning self-report (sleep quality) and RMMA reduction ratio.

(Note: Gray area represented the therapeutic utilities for each oral device. OS indicated good sleep quality but low RMMA reduction ratio, while MAS showed mild sleep quality but high RMMA reduction ratio.)
Figure 1
Figure 2
Figure 3

Therapeutic efficacy

OS

Reduction ratio in RMMA episodes/hour

Sleep Quality

80

60

40

20

0

0 20 40 60 80 100

MAS

Reduction ratio in RMMA episodes/hour

Sleep Quality

60

40

20

0

0 20 40 60 80 100