

# Aggravation of Respiratory Disturbances by the Use of an Occlusal Splint in Apneic Patients: A Pilot Study

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**Purpose:** This pilot study was designed to test the hypothesis that the use of a single oral splint may aggravate respiratory disturbance in sleep apneic patients. **Materials and Methods:** A group of 10 patients with a history of snoring and a recording night confirming a diagnosis of sleep apnea were included. Patients were then invited to spend 2 nights in the sleep laboratory: night 2 to establish baseline data (baseline night) and night 3, 1 week later, to assess the influence of an occlusal maxillary splint on sleep (splint night). The following variables were analyzed under blind conditions: total sleep time, sleep efficiency and number of awakenings, microarousals, apnea-hypopnea index per hour of sleep (AHI), respiratory disturbances index per hour of sleep (RDI), and percentage of sleeping time with snoring. **Results:** No statistically significant difference in AHI was noted between baseline and splint nights. However, four patients experienced an aggravation in apnea diagnosis category on the night they used the splint. The AHI was increased by more than 50% in 5 of the 10 patients. The RDI showed a 30% increase from baseline to splint nights. The percentage of sleeping time with snoring also increased by 40% with the splint. **Conclusion:** This open study suggested that the use of an occlusal splint is associated with a risk of aggravation of respiratory disturbances. It may therefore be relevant for clinicians to question patients about snoring and sleep apnea when recommending an occlusal splint. *Int J Prosthodont 2004;17:447-453.*

In clinical dentistry and sleep medicine, the use of mandibular advancement devices (MAD) is a recognized management strategy for two respiratory disturbances during sleep: snoring and sleep apnea.<sup>1,2</sup> In

sleep medicine, snoring and sleep apnea are classified under “obstructive sleep apnea and hypopnea syndrome” (OSAHS).<sup>3</sup> Although snoring is found in 25% of the adult population, the prevalence of OSAHS, when estimated with sleep polygraphic recordings, is around 2% to 4%. However, clinicians should be aware that patients who complain about snoring may suffer from undiagnosed sleep apnea, a medical condition that carries risks of hypertension and daytime sleepiness (with increased risk of transportation or work accidents), altered memory, enuresis, and periodic limb movement during sleep.<sup>4</sup>

In the present study, patients with OSAHS were selected based on complaints of respiratory disturbance or snoring during sleep and excessive daytime sleepiness not explained by other factors. OSAHS diagnosis, ie, partial or complete cessation of breathing, was confirmed using polygraphic recordings.<sup>3,5</sup> The severity of sleep-related obstructive breathing events is classified into three categories according to the number of

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In partial fulfillment of the requirements for the MSc degree of Y. Gagnon.

apnea-hypopnea events observed per hour of sleep (AHI): mild when AHI is between 5 and 15, moderate between 15 and 30, and severe when greater than 30.<sup>3,6</sup> A criterion of 50% reduction in AHI is frequently cited to assess whether this respiratory condition is being successfully managed using a continuous positive airway pressure device or MAD, although a reduction in AHI below 10 or 20 has also been considered a necessity for success.<sup>1,7-9</sup>

In the general population, the estimated prevalence of tooth grinding–sleep bruxism is 8%.<sup>10</sup> The prevalence of pain caused by temporomandibular disorders (TMD) is 8% to 15% for women and 3% to 10% for men.<sup>11-13</sup> It has been estimated that more than 3,000,000 oral splints (also called occlusal splints) are fabricated each year in the United States to manage sleep bruxism and TMD.<sup>14</sup>

Although the mechanism of action of the splint is unknown, it is possible that splints modify the space between the dental arches; the mandible is then slightly lowered and could be retruded, and the space for the tongue may also be reduced. Consequently, the authors wondered whether using such a device might alter airway patency, especially during sleep. This conjecture is based on the observation that in the sleep of normal subjects, the tongue and hyoid bone tend to move backward and airway patency is reduced in the supine position.<sup>15-17</sup> Moreover, in apneic patients, the rationale behind using an MAD is that functional airway patency may be recovered by causing the mandible to protrude.<sup>1,2</sup> Taking this information into account, as well as the possibility that sleep apnea/OSAHS may be under-recognized in patients treated with an oral splint for bruxism or pain caused by TMD, the authors hypothesized that the use of a single maxillary oral splint may aggravate respiratory disturbance in sleep apneic patients.

## Materials and Methods

Data from 10 sleep apnea patients (3 women and 7 men) were collected in this prospective, single blind (the technician who assessed sleep outcomes) comparative study. The mean age of the patients was 49 years (range 31 to 59 years). The mean body mass index was 29.7 kg/m<sup>2</sup> (range 19.5 to 48.8 kg/m<sup>2</sup>). Patients were included in the study following clinical recognition of snoring and a night of sleep diagnosis for apnea. The mean Epworth value for all subjects was 10.8 (range 3 to 18).<sup>18</sup> All patients presented snoring and an AHI greater than 5 (mean 20, range 7 to 30) during the diagnosis night. None of the subjects had an AHI greater than 30 on that night (night 1).

Six of the 10 patients were taking various medications: three were taking antidepressive or anxiolytic

medications, two were undergoing hormone therapy, two were taking a gastric reflux agent, and one was taking an antihypertensive agent. The use of any of these medications was not interrupted. Although the oral examination did not reveal any carious or periodontal lesions or temporomandibular dysfunction or pain, two patients had a history of occasional tooth grinding (reported 1 night/week). To prevent any potential bias created by patients' expectations about receiving an MAD, they were instructed that the oral splint is commonly used in dentistry and that the study objective was to assess its influence on respiratory variables (eg, snoring, apnea) in a sleep apnea population. All participants were informed about their right to withdraw from the study, and all signed an informed consent form in accordance with the ethics of the institution.

## Procedures and Analysis

Polygraphic recordings from the first night (diagnosis night) were used for sleep apnea assessment. The first night was followed by a minimum of 2 weeks of adaptation to the oral splint. Then, patients were invited to participate in 2 experimental nights in a nonrandom order. After a minimum of 3 weeks without using any oral splint, the night 2 (baseline night) laboratory sleep data were collected without the oral splint. One week later, after having used the oral splint for 7 nights, the night 3 (splint night) laboratory sleep data were collected with the oral splint in mouth. The following variables were selected to distinguish between sleep stages: electroencephalogram (EEG), C<sub>3</sub>A<sub>2</sub>, O<sub>2</sub>A<sub>1</sub>, electrooculogram (EOG), and electromyogram (EMG) for chin/suprahyoid and tibialis muscles. Respiratory activity and snoring were assessed using a nasal pressure transducer, pulse oxymetry at fingertip, and electrocardiogram (ECG). Respiratory movements were assessed with thoracic and abdominal belts. Body position was assessed using the belt position sensor and video recordings.

After baseline and splint nights, an electrophysiology technician scored the traces according to standard criteria<sup>19</sup> while blind to study objectives and use of the splint. The following measurements were made: total sleep time, sleep latency, sleep efficiency (% time asleep/total time in bed), sleep stages expressed in %, number of awakenings (> 15 seconds), microarousals (3- to 15-second changes on EEG, EMG), periodic limb movements, apnea events (10 seconds of complete cessation in respiration), hypopnea events (50% reduction in airflow > 10 seconds or < 50% reduction in airflow in the presence of a microarousal or 3% O<sub>2</sub> desaturation), upper airway resistance (< 30% reduction in airflow with snoring and the presence of a microarousal), % sleeping time with snoring sounds, and

**Table 1** Sleep and Respiratory Variables During Baseline and Splint Nights

Variable	Baseline	Splint	<i>P</i>
<b>Sleep</b>			
Total sleep time (min)	399.4 ± 12.6	402.5 ± 17.0	.90
Sleep time spent supine (%)*	27 (3–66)	29 (11–71)	.72
Sleep latency (min)*	6.2 (1.4–18.8)	6.1 (2.9–28.5)	.72
Sleep efficiency (%)	83 ± 2	84 ± 3	.64
% of sleep in:			
Stage 1	11 ± 2	12 ± 2	.41
Stage 2	65 ± 3	66 ± 4	.84
Stage 3	5 ± 1	4 ± 1	.38
Stage 4	4 ± 1	4 ± 2	.95
REM	15 ± 2	14 ± 2	.61
Awakenings/night	32.2 ± 4.5	34.8 ± 5.2	.44
Microarousals/hour	20.8 ± 3.0	20.9 ± 3.9	.96
Periodic limb movements/hour	16.6 ± 4.9	14.5 ± 4.0	.41
<b>Respiratory</b>			
AHI (apnea + hypopnea events/hour)*	20.1 (10.5–43.1)	20.9 (11.8–85.0)	.22
RDI (apnea + hypopnea + resistance events/hour)*	21.5 (13.0–59.2)	27.5 (13.1–85.7)	.06
RDI sleeping on side or stomach/hour*	4.3 (1.5–58.4)	18.3 (4.2–81.3)	.01
RDI sleeping in supine position/hour	47.0 ± 8.1	45.8 ± 8.8	.86
Sleeping time with snoring sound (%)*	23 (0–69)	32 (5–90)	.04
Saturation O <sub>2</sub>	93.4 ± 0.9	93.6 ± 0.8	.54
Minimum saturation O <sub>2</sub>	83.3 ± 2.2	81.4 ± 2.6	.33

\*Median (range) shown, and Wilcoxon signed ranks test used to compare groups; otherwise, mean ± standard error of the mean shown, and paired *t* test used.

% time in the supine position.<sup>3,19</sup> The sleep and respiratory variables were expressed in an index per hour of sleep. Apnea and hypopnea were counted together as an index, AHI.<sup>6,20</sup> The respiratory disturbance index (RDI) represents the number of upper airway resistance events plus apnea and hypopnea events observed per hour. Moreover, RDI was subclassified into side or stomach position and supine position. One author, a pneumologist, reviewed all sleep scores to confirm the diagnosis of sleep apnea and OSAHS.

As described above, patients were categorized as experiencing mild sleep-related obstructive breathing events if AHI was between 5 and 15, as moderate if AHI was between 15 and 30, and as severe if AHI was greater than 30.<sup>3,6</sup> Any change from the mild to moderate category, or moderate to severe, was rated “more severe,” and any change in the opposite direction was rated “less severe.” Furthermore, changes in AHI from baseline to splint nights were categorized as greater or less than 20% (night-to-night variability) or 50% (treatment effect).<sup>1,7–9,21–23</sup>

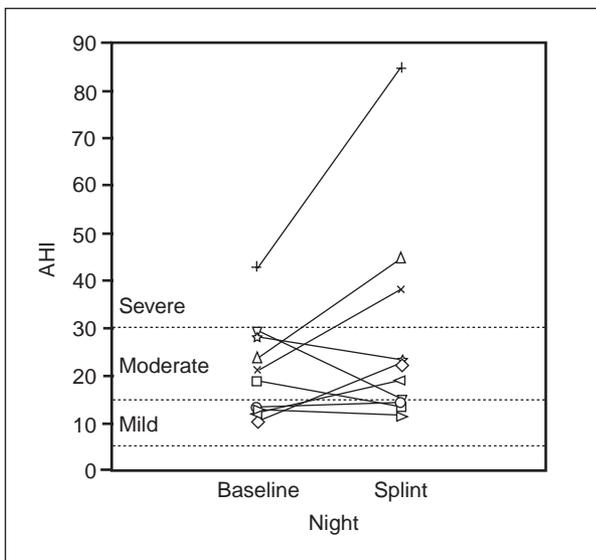
The oral splint for the maxillary arch was made of hard acrylic resin. It was approximately 1.5 mm thick at the molar level and covered all teeth and the anterior midpalatal area. The palate was approximately 4 mm thick at the lingual aspect of the incisors, tapering to 1 mm at the palatal area. The dental casts were mounted on a semiadjustable articulator, in centric relation, to allow lateral canine guidance and protrusive

anterior guidance without any corresponding interference. The splints were adjusted in the mouth for patient comfort and occlusal function. After study, use of the splint was interrupted.

Statistical differences between the 2 nights were assessed using paired *t* tests and Wilcoxon signed ranks tests in the case of non-normal distribution (Systat, version 10, SPSS). *P* ≤ .050 was considered statistically significant.

## Results

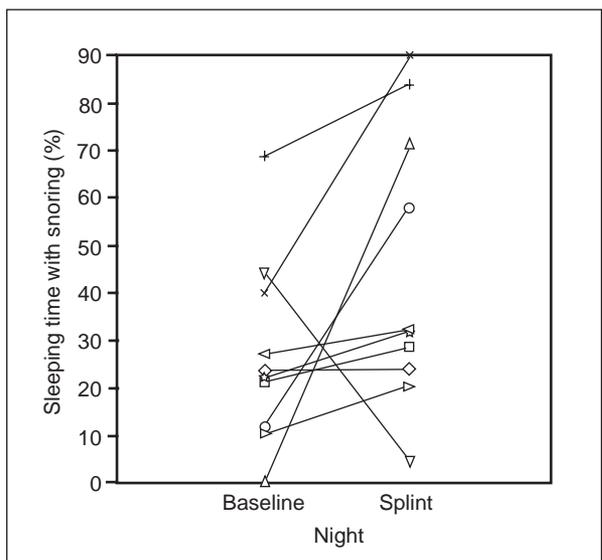
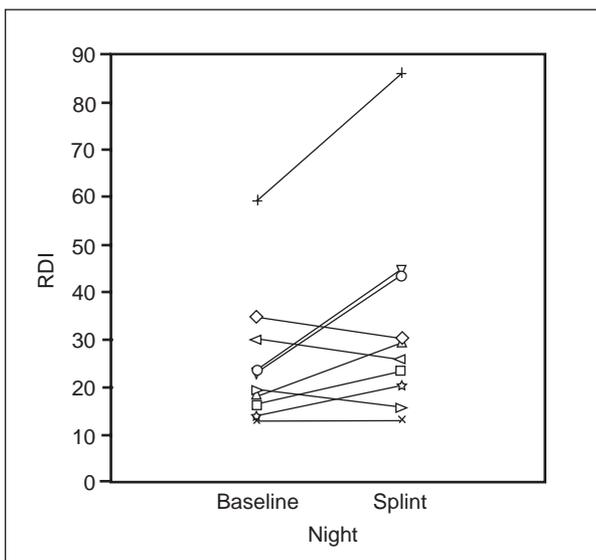
There was no statistically significant difference in any of the sleep variables between the baseline and splint nights (Table 1). The % of sleeping time spent supine was not changed with the splint (*P* = .720). The median AHI remained similar during baseline and splint nights (Table 1). However, a graph of individual variation (Fig 1) revealed that six subjects experienced an increase in AHI with the splint. The splint induced slightly more respiratory events (RDI) associated with upper airway resistance (*P* = .060). The RDI was increased in six patients with the splint (Fig 2). Moreover, approximately 4 times (*P* = .005; Table 1) more respiratory events were noted when patients slept on their sides or on their stomachs with the splint. The percentage of sleeping time with snoring was also 40% higher during the night with the splint (*P* = .040). Individual variation showed that eight subjects had a



**Fig 1 (left)** Distribution of apnea-hypopnea index per hour of sleep (AHI) for baseline and splint nights. AHI values for each patient for baseline and splint nights are connected. Dashed lines = AHI severity classification limits.

**Fig 2 (below left)** Distribution of respiratory disturbances index per hour of sleep (RDI) for baseline and splint nights. RDI values for each patient for baseline and splint nights are connected.

**Fig 3 (below)** Distribution of sleeping time with snoring for baseline and splint nights. Measurements for each patient for baseline and splint nights are connected.



clear increase in % of sleeping time with snoring with the splint (Fig 3).

The changes in diagnostic classification of sleep apnea severity criteria described above revealed that one patient got better (changed from moderate to mild), but four patients got worse (two went from mild to moderate, and two went from moderate to severe). Using a quantitative 20% change criterion (eg, over AHI variability index),<sup>22</sup> two patients showed improvement in AHI, whereas five got worse. Using the 50% treatment effect criterion for change in AHI, none of the patients improved, and the same five as above got worse. Among the five patients with a 50% increase in AHI, three spent a higher % sleeping time

in a supine position (mean increase of 16%), and two spent a lower % sleeping time (mean decrease of 10%). Those five patients who got worse (with the 50% criterion) were then compared with the other five for body mass index, age, and severity of AHI. There was no statistically significant difference between the two groups. When these criteria were used for the RDI, no patients showed improvement, whereas six got worse with the 20% criterion; three were worse according to the 50% criterion. For the change in % of sleeping time with snoring, one patient improved and seven got worse using the 20% criterion, and four got worse with the 50% criterion.

## Discussion

The use of maxillary occlusal devices in patients with a diagnosis of sleep apnea is associated with a risk of aggravated respiratory disturbance, as seen in at least 40% of our patients. However, these results need to be further tested in larger population and over a longer observation period.

For future controlled studies, a sample size of 26 subjects would allow an 80% chance of detecting a difference in AHI as large as the one found in the present study, at the usual level of statistical significance ( $\alpha = .05$ ). Moreover, the study design could be strengthened by using blind conditions for patients, eg, a palatal or lingual (Hawley) control splint without occlusal tooth coverage.<sup>24</sup> This would protect against potential bias such as patients expecting that they are receiving treatment for their condition, although the placebo effect in sleep studies using respiratory devices (eg, low continuous positive airway pressure) does not seem to be strong.<sup>25,26</sup> Longer observation periods (eg, > 4 to 6 months) could also show different results. This is unlikely, however, since the variation in RDI in older sleep apnea patients over a 4- to 6-month period is low (6 to 8/hour of sleep).<sup>27</sup> Similarly, comparison of AHI after 1 and 5 years of using an MAD revealed little difference.<sup>28</sup> Despite this apparent low variability, it is interesting to note that in the latter study, an aggravation of the AHI was observed in 5 of 19 patients.

Moreover, no difference in RDI or AHI outcome measures was reported in studies designed to assess the efficacy of various MADs and in which patients wore maxillary or mandibular devices.<sup>7,8,29-31</sup> Only one of the above studies provided data that allowed us to analyze shifts in respiratory variables according to American Academy of Sleep Medicine (AASM) severity criteria<sup>3</sup>; two of eight patients got worse with the maxillary device (no advancement), and six showed no obvious change.<sup>29</sup> The design of the device was different from the one we used; it was a thick thermoplastic block (Snore Guard, Inventive Resources), fitted to the maxillary teeth, that opened the bite without an obvious relationship to the mandibular teeth. The controlled studies that used one arch device (maxillary or mandibular) as a placebo-control condition had different study designs (eg, randomized, blind to study objective), methods for scoring respiratory disturbances (eg, AHI, RDI, oxymetry), and oral device designs that preclude any direct comparison with the present study.<sup>7,8,29-31</sup>

It could also be argued that night-to-night variability may have modified the values of respiratory outcomes used in this study (eg, RDI, AHI). We recognize that the night-to-night variability in the apnea index could have influenced the classification of our patients. This is supported by one study using 20 light to severe

apneic patients. Recordings over 4 nights revealed that 50% of subjects moved to a different category.<sup>21</sup> In fact, six shifted to a lighter category, and four moved to a more severe one. In our study, using the AASM criteria,<sup>3</sup> one subject improved and four got worse. When we used the 20% variability criterion,<sup>20,21</sup> we noted that two patients improved and five got worse.

Despite these limits to methodology, the present pilot study raised some questions regarding the effect of an oral splint on respiratory variables in relation to mandible and tongue positions. In normal sleepers, airway patency is reduced during sleep, particularly in the supine position; the jaw is more open, and posterior placement of the tongue and hyoid bone tends to be more pronounced.<sup>15,32</sup> Similar findings have been reported in sleep apneic patients with larger tongues.<sup>17,33,34</sup> Thus, oral devices (eg, occlusal splint, MAD) that open up the vertical intermaxillary dimension and may alter tongue position may also modify airway patency. The vertical opening in the anterior teeth area is between 1.5 and 4.5 mm (depending on the design of the device) and 1.5 mm in the molar area.<sup>8,29-31</sup> It could therefore be possible that, following an increase in the vertical intermaxillary dimension and palatal thickness, the mandible rotates posteriorly, reducing airway patency.<sup>35,36</sup> Moreover, since sleep apneic patients have an altered responsiveness to sensory mechanical or chemical inputs and different timing in the onset of activation of the inspiratory muscles (eg, genioglossus),<sup>5,37-41</sup> it could be hypothesized that the presence of a foreign body (eg, an oral device) causes the reflexes that maintain airway patency to become dysfunctional. This hypothesis will need to be assessed in normal subjects and in OSAHS patients wearing oral devices.

A surprising finding of this pilot study was the four-fold increase in respiratory event frequency while patients were sleeping on their sides or stomachs with the splint despite the fact that the indices and total sleep time were not different in the supine position. The palatal device may further reduce the airway space over the tongue and change mandibular position, which may contribute to an aggravation of respiratory disturbances when patients sleep on their sides or stomachs. Consequently, in future studies on oral device efficacy for respiratory disturbance assessment, it may be important to control for dominant sleep apnea-hypopnea position, since supine respiratory disturbances are more likely to be reduced by an MAD than are lateral ones.<sup>34</sup>

A randomized and controlled study showed that a mandibular oral splint, used as a control device, did not increase the AHI compared with the baseline night.<sup>7</sup> If the latter results are confirmed in other studies, a mandibular oral splint may be an alternative for patients with mild sleep apnea and severe/frequent tooth grinding related to sleep bruxism.

Clinicians should be aware that manipulating the oral airway space (eg, by using an occlusal device that fills the distance between the maxilla and mandible, reducing tongue space) might have consequences for patients with respiratory sleep disturbances (eg, apnea, snoring). The relevance of these preliminary findings needs to be validated in a randomized and controlled study using a larger sample size before any final recommendations can be made concerning treatment plans (eg, the use of splints, implants, fixed prosthodontics) for patients suffering from OSAHS.

### Acknowledgments

The research was supported by a CHUM Research Center grant and partly by a CIHR grant. The collaboration of Anne-Marie Laurin, Catherine Dubé, Francine Bélanger, Christiane Manzini, and Alice Petersen was greatly appreciated.

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*Literature Abstract*

### **Dentists' molar restoration choices and longevity: A web-based survey**

The purpose of this article was to investigate restorative choices of dentists for their own molars and the estimated time since the restorations were placed. Information of dentists' molars was obtained from a Web-based survey (<http://www.dent.ohio-state.edu/restsurvey/dentistsurvey/>). The survey was designed to receive dentists' demographic data and charting of their eight molar teeth with estimated time the restorations were placed. Seven hundred fifty-seven valid replies provided information for 6,034 teeth. Restorations reported included amalgam restoration (36%), gold inlay/onlay (13%), full crown (CVC) (10%), metal-ceramic crown (MCC) (8%), and resin composite (7%). Other esthetic options were below 3%. Restorations that were placed more than 20 years ago included amalgam restorations (58%), gold inlays/onlays (48%), and crowns (23%). In the last 5 years, 56% of esthetic restorations and 5% of amalgams were placed. Significant differences were noted for dentist's gender, year of graduation, and location of practice. The authors concluded that: (a) web-based survey allowed fast response to questions by dentists; (b) most respondents have not replaced traditional metallic restorations with esthetic alternatives; (c) dentists still choose nonesthetic options for significant numbers of their own restorations. This survey recorded the existing dental restoration on eight molars of the participating dentists. The existing dental restorations simply may not be prescribed by the responding dentist himself/herself. This study assumed "the way dentists treat their own teeth may be a good indication of the accumulated wisdom of the profession, knowledge of dentists' own restorative choices may provide guidance in selecting the most appropriate restorations." This is questionable because dentists may not have participated in the treatment planning of their own teeth.

**Rosenstiel SF, Land MF, Rashid RG.** *J Prosthet Dent* 2004;91:363-368. **References:** 4. **Reprints:** Dr Stephen Rosenstiel, The Ohio State University, College of Dentistry, 305 W 12th Avenue, Columbus, OH 43218-2357. e-mail: [rosenstiel.l@osu.edu](mailto:rosenstiel.l@osu.edu)—*Ansgar C. Cheng, Singapore*

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