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# A Mandibular Advancement Appliance Reduces Pain and Rhythmic Masticatory Muscle Activity in Patients with Morning Headache

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**Aims:** To evaluate the influence of an oral appliance on morning headache and orofacial pain in subjects without reported sleep-disordered breathing (SDB). **Methods:** Twelve subjects aged  $27.6 \pm 2.1$  (mean  $\pm$  SE) years and suffering from frequent morning headache participated in this study. Each subject was individually fitted with a mandibular advancement appliance (MAA). The first two sleep laboratory polygraphic recording (SLPR) nights were for habituation (N1) and baseline (N2). Subjects then slept five nights without the MAA (period 1: P1), followed by eight nights with the MAA in neutral position (P2), ending with SLPR night 3 (N3). Subjects then slept five nights without the MAA (P3), followed by eight nights with the MAA in 50% advanced position (P4), ending with SLPR night 4 (N4). Finally, subjects slept 5 nights without the MAA (P5). Morning headache and orofacial pain intensity were assessed each morning with a 100-mm visual analog scale. Repeated measures ANOVAs and Friedman tests were used to evaluate treatment effects. **Results:** Compared to the baseline period (P1), the use of an MAA in both neutral and advanced position was associated with a  $\geq 70\%$  reduction in morning headache and  $\geq 42\%$  reduction in orofacial pain intensity ( $P \leq .001$ ). During the washout periods (P3 and P5), morning headache and orofacial pain intensity returned to close to baseline levels. Compared to N2, both MAA positions significantly reduced ( $P < .05$ ) rhythmic masticatory muscle activity (RMMA). **Conclusion:** Short-term use of an MAA is associated with a significant reduction in morning headache and orofacial pain intensity. Part of this reduction may be linked to the concomitant reduction in RMMA. J OROFAC PAIN 2011;25:240–249

**Key words:** mandibular advancement appliance, morning headache, oral appliance, orofacial pain, rhythmic masticatory muscle activity

Headaches, sleep-disordered breathing (SDB) such as snoring and sleep apnea, and sleep bruxism are commonly reported health problems in clinical practice. Headaches can be classified as primary or secondary, depending on the presence of close temporal relation to another disorder known to cause headache.<sup>1</sup> Approximately 7.6% of the general population report morning headache.<sup>2</sup> Although the literature contains controversial reports, the causes of morning headache may include jaw clenching, poor oxygenation related to obstructive sleep apnea syndrome (OSAS), or other respiratory disturbances.<sup>3–5</sup> Studies have shown that more than 40% of subjects with sleep bruxism report morning headache.<sup>6,7</sup> Sleep bruxism is characterized mainly by rhythmic masticatory mus-

cle activity (RMMA) and occasional tooth grinding sounds.<sup>8,9</sup> A significant association between sleep bruxism and headache or orofacial pain has been suggested.<sup>6,7,10</sup> Several studies have suggested that morning headache is more common in patients with SDB than in normal subjects and that about three out of four patients with OSAS report morning headache.<sup>5,11-14</sup>

Headache management can be divided into pharmacological and nonpharmacological therapies. Pharmacological therapy gives rise to two problems: medication overuse and non-adherence. In a study of 1,160 patients suffering from headache, 71% reported not using or delaying medication therapy.<sup>15</sup> In an earlier study, 87% of chronic headache patients seen in headache clinics over a 3-year period consumed at least 14 analgesic tablets per week.<sup>16</sup> The non-pharmacological management of headache involves mainly behavioral therapy and oral appliances (OAs). Behavioral therapy involves an array of techniques such as biofeedback, relaxation, and cognitive-behavioral therapy.<sup>17</sup> OAs include the acrylic splint, the mouth guard, the occlusal splint, and the mandibular advancement appliance (MAA).<sup>18,19</sup> An OA is also the short-term treatment of choice for sleep bruxism.<sup>20</sup> Use of an OA has been shown to reduce tooth grinding and significantly reduce headache in patients with sleep bruxism.<sup>21</sup> SDB treatment involves continuous positive airway pressure (CPAP) therapy as well as an OA. Although CPAP is recognized as the "gold standard" treatment to date,<sup>22,23</sup> several studies in the last decade have demonstrated the positive effect of an MAA to manage mild-to-moderate OSAS.<sup>24-28</sup> Once the SDB is successfully treated, headaches often disappear or are significantly reduced in intensity.<sup>29</sup>

Because sleep disorder treatment in chronic headache patients may be followed by a reduction in headache complaints, and because the MAA is an acceptable therapy to manage SDB and sleep bruxism, it would be useful to test the efficacy of the MAA as an alternative to pharmacological therapy for morning headache patients without SDB.

The objective of the present study was to evaluate the influence of an oral appliance on morning headache and orofacial pain in subjects without reported SDB.

## Materials and Methods

### Study Design

In this controlled crossover study, subjects were individually fitted with a MAA and tested. Polygraphy was used to collect sleep and respiratory data over a

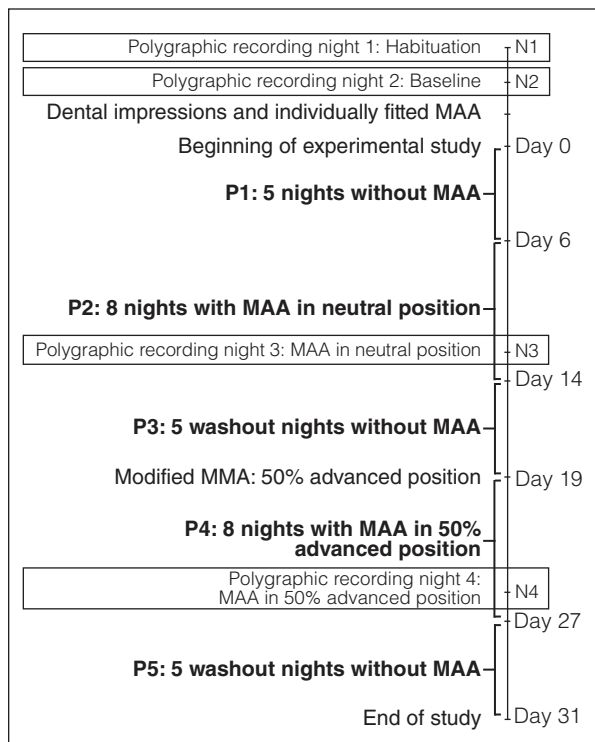
total of four nights (Fig 1). The first two sleep laboratory polygraphic recording (SLPR) nights were for habituation (N1) and baseline (N2). Subjects then slept five nights without the MAA (period 1: P1), followed by eight nights with the MAA in neutral position (P2), ending with SLPR night 3 (N3). Subjects then slept five nights without the MAA (P3), followed by eight nights with the MAA in 50% advanced position (P4), ending with SLPR night 4 (N4). Finally, subjects slept five nights without the MAA (P5).

### Morning Headache and Orofacial Pain Intensity

A 100 mm visual analog scale (VAS) was used to score self reports of morning headache and orofacial pain intensity that was recorded in daily questionnaires filled out by subjects from P1 to P5. Subjects also filled out questionnaires evaluating the MAA in both neutral and advanced position on SLPR N3 and N4 mornings. Questions covered the duration of the adaptation period (days), comfort (VAS), satisfaction (VAS), MAA efficacy (VAS), perceived sleep quality (VAS), wearing period (nights), feeling of dry mouth (yes or no), and perception of decreased morning headache intensity (yes or no). Questionnaires on awareness of tooth clenching and grinding were also filled out.

### Study Population and Inclusion/Exclusion Criteria

Subjects were recruited by advertisements (approved by the hospital's Ethics Review Board) posted on the university/college campus from February 2006 to April 2008. Subjects with a history of frequent morning headache contacted the research staff for a telephone interview. Depending on the interview results, subjects were selected for a clinical examination to screen the history behind the morning headache. Subjects were asked to complete several questionnaires about their general health, sleep habits, and headache complaints. Each tooth was scored for wear.<sup>30</sup> Subjects were then scheduled for one night of SLPR. Subjects with no evidence of SDB were invited to participate in the study. Subjects were asked to inform the research staff of any medication or treatment that could interfere with the study. All subjects signed an informed consent approved by the Sacré-Coeur Hospital Ethics Review Board. A prestudy sample size estimation determined that 12 subjects would be sufficient to detect with 80% power a clinically relevant decrease in morning headache of 40% on a VAS, based on a standard deviation (SD) of 20 and at .05 significance level.



**Fig 1** Schematic representation of the study design showing polygraphic recording nights and self-report data collection periods (P).

The inclusion criteria were reported frequent morning headache with signs and symptoms of migraine without aura or tension-type headache,<sup>1,5</sup> with or without concomitant orofacial pain, and presence of both dental arches. Exclusion criteria were signs or symptoms of migraine with aura, cluster or hypnic headaches,<sup>1,5,31</sup> medical disorders (psychiatric, psychological, and neurological), regular drug or alcohol intake, history of trauma or tumor, and unstable dental condition. Other exclusion criteria were the following: reported SDB, primary complaint of sleep bruxism, absence of two or more posterior teeth (third molars not considered), excessive tooth wear, gross dentoskeletal malocclusion, or previous treatment for any type of OA in the past 6 months. Subjects with an apnea/hypopnea index (AHI) > 10 events per hour of sleep during the habituation night (N1) were also excluded.

Twenty-five subjects with a history of frequent morning headache contacted the research staff, and 20 subjects were selected for a clinical examination after the telephone interview. After applying the inclusion and exclusion criteria, 14 subjects were retained to undergo a habituation night (N1). Two

subjects were excluded because they had AHI > 10 events per hour of sleep. The final sample that met the criteria and completed the full study comprised 7 women and 5 men aged  $27.6 \pm 2.1$  years (mean  $\pm$  standard error [SE], range 21 to 44 years).

### Appliances

The MAA used was an optimized mandibular retention device (ORM Technology) (Fig 2). The ORM is an adjustable, traction-based, individually fitted MAA designed to avoid dentoskeletal side effects.<sup>32-36</sup> It consists of two custom-made semi-rigid splints that are vacuum-pressed on the patient's teeth moldings and linked by a traction-based articulation to allow setting and adjusting the protrusion on a metric scale based on the patient's mandibular advancement capacity. The traction-based articulation and connector enable mandibular advancement parallel to the occlusion plane. This vector respects the physiology and reduces the force exerted on the muscles (masseter and posterior temporalis) as well as temporomandibular joint contact force compared to traditional MAAs.<sup>36,37</sup>

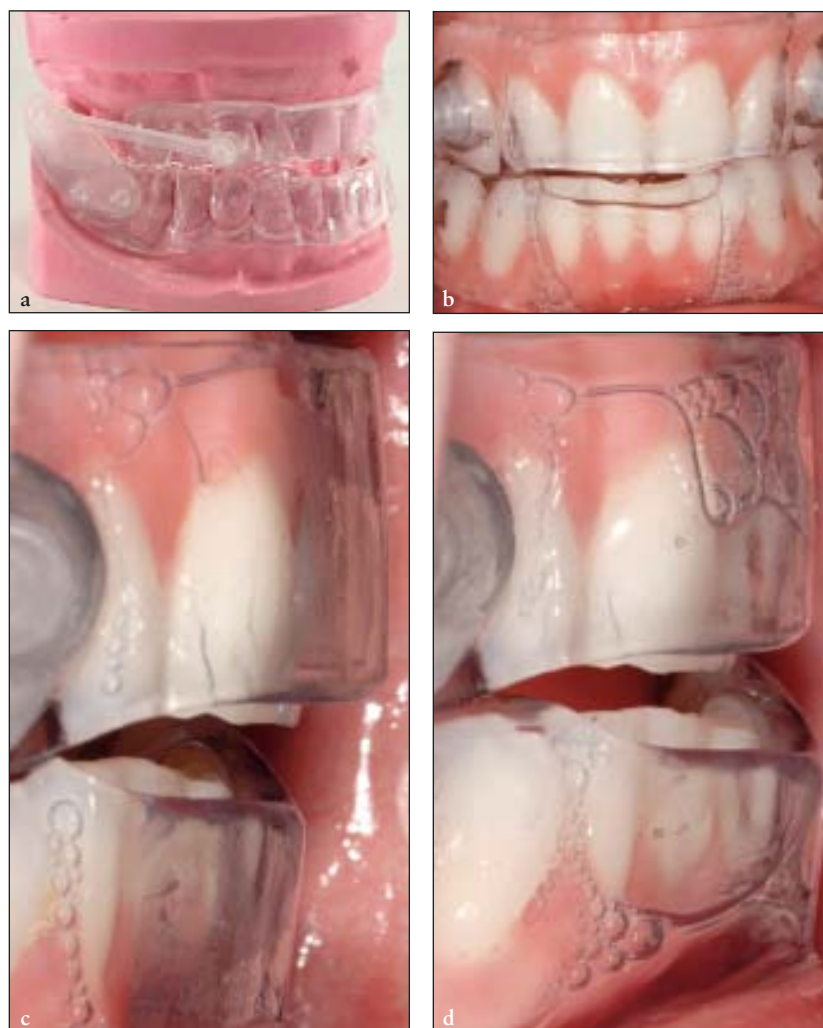
Dental x-rays and impressions were taken and maximum protrusion was measured. The devices were manufactured by a dental laboratory (Dentec). Patients received the MAA on day 0 of the study (Fig 1) and were asked to wear it only at night. The devices were set in neutral position (maximum intercuspatation) during P2 (Fig 2c) until N3 was completed. The appliance was then adjusted to advanced position (50% protrusion advancement) for P4 (Fig 2d) until N4 was completed.

### Sleep Measurements

SLPRs were made in a sound-attenuated temperature-controlled room from approximately 10:30 pm to 7:30 am or until the subject awoke. Patients were asked to avoid caffeine for at least 1 day before recording.

Surface electrodes were used for the SLPR and analysis according to a standardized protocol used in previous studies.<sup>9,38,39</sup> A nasal cannula (Oral and Nasal Luer Lock Cannula, Breadon Medical Corporation) and thoracic and abdominal belts were used to evaluate respiratory function. Physiological sleep variables were recorded using commercial software (Harmonie, Stellate) at an acquisition rate of 128 Hz. The following variables were quantitatively assessed: sleep efficiency (% time asleep/time in bed), sleep duration, arousals, awakenings, oxygen saturation, apnea, hypopnea, periodic leg movements during sleep, and RMMA. RMMA indexes were also

**Fig 2** Photographs of the MAA. (a) Lateral view on dental cast, (b) frontal view, (c) view in neutral position, (d) view in 50% advanced position.



calculated for each third of the night. All SLPR and associated events were scored using standard criteria<sup>40,41</sup> by experienced technicians blinded to treatment night and MAA position (neutral or advanced).

For the electroencephalographic (EEG) analysis, at least 4-second sections of stable EEG signals were selected from the C<sub>3</sub>A<sub>2</sub> derivation in rapid eye movement (REM) and non-REM sleep for compressed band array analysis according to Achermann's method.<sup>42</sup> Twenty non-REM and five REM sections were selected from each non-REM and REM cycle. Each sleep cycle was averaged into four non-REM sections and one REM section. The first three sleep cycles were analyzed. For EEG power spectral analysis, a cosine window was used to minimize activity leakage or spillover at a given frequency range, followed by a fast Fourier transform. EEG signals were quantified to estimate the power spectrum of the following bands: delta (0.50–4.00 Hz), theta (4.00–8.00 Hz), alpha (8.00–13.00 Hz),

sigma-spindle activity (12.75–15.00 Hz), low beta (13.00–22.00 Hz), and high beta (22.00–32.00 Hz).

Based on the predictive model for OSAS,<sup>43</sup> dental impressions were morphometrically measured to determine mandibular width, depth, length, overjet, overbite, area, and space.

### Statistical Analysis

Data are presented as mean  $\pm$  SE or median (min–max). Morning headache and orofacial pain values were averaged over each of the five periods. Repeated measures ANOVAs were used to assess the overall difference between periods. Paired comparisons were then used to compare periods. Repeated measures ANOVAs were used to evaluate treatment effects on sleep, respiratory, and bruxism variables. The baseline night (N2) was then compared to N3 and N4 by using paired comparisons. The Friedman followed by the Wilcoxon test was used for non-

normally distributed data. Correlations between RMMA and AHI with headache and orofacial pain were assessed with Pearson's correlations. Repeated measures ANOVAs with night, cycle, and section as within subject variables were used to separately evaluate treatment effects on EEG signals for non-REM and REM sleep. Questionnaires evaluating MAA in both neutral and advanced position were analyzed with paired *t* tests, the Wilcoxon test, and McNemar's chi-square test. A *P* value  $\geq .05$  was considered statistically significant.

## Results

### Study Sample

At the clinical evaluation, each subject reported a positive history of morning headache averaging  $7.4 \pm 1.8$  years duration (0.3 to 20.0 years). All subjects reported morning headache at a frequency of three times a week or more. Pulsative symptoms and band-like complaints associated with the morning headache were reported by 33% and 92% of subjects, respectively. Most subjects (83%) experienced bilateral pain. Photophobia or phonophobia during morning headache was reported by 25% of subjects. No subject reported nausea or vomiting associated with morning headache in the last three months. Subjects did not report either tooth clenching or grinding as the primary complaint. However, nine subjects (75%) reported tooth clenching, and seven of these nine subjects reported clenching during the night. Three subjects reported tooth grinding during the day and night. The mean tooth wear score was  $0.23 \pm 0.05$  (min 0, max 0.46). Eleven of the 12 subjects (92%) had previously consulted a physician or dentist for morning headache. Concomitant muscle tenderness and orofacial pain was reported by 66% and 42% of subjects, respectively. Use of pain medication in the past year (analgesics, nonsteroidal anti-inflammatory drugs) for morning headache was reported by nine subjects (75%). One subject reported taking Sominex (diphenhydramine), an over-the-counter sleep aid, every night of the study.

### Morning Headache and Orofacial Pain Intensity

Compared to baseline data (P1), the use of an MAA in neutral position was associated with a 70.2% ( $P < .0001$ ) decrease in morning headache intensity and 42.8% ( $P = .001$ ) decrease in orofacial pain intensity during P2 (Fig 3). During the washout period (P3), morning headache and orofacial pain inten-

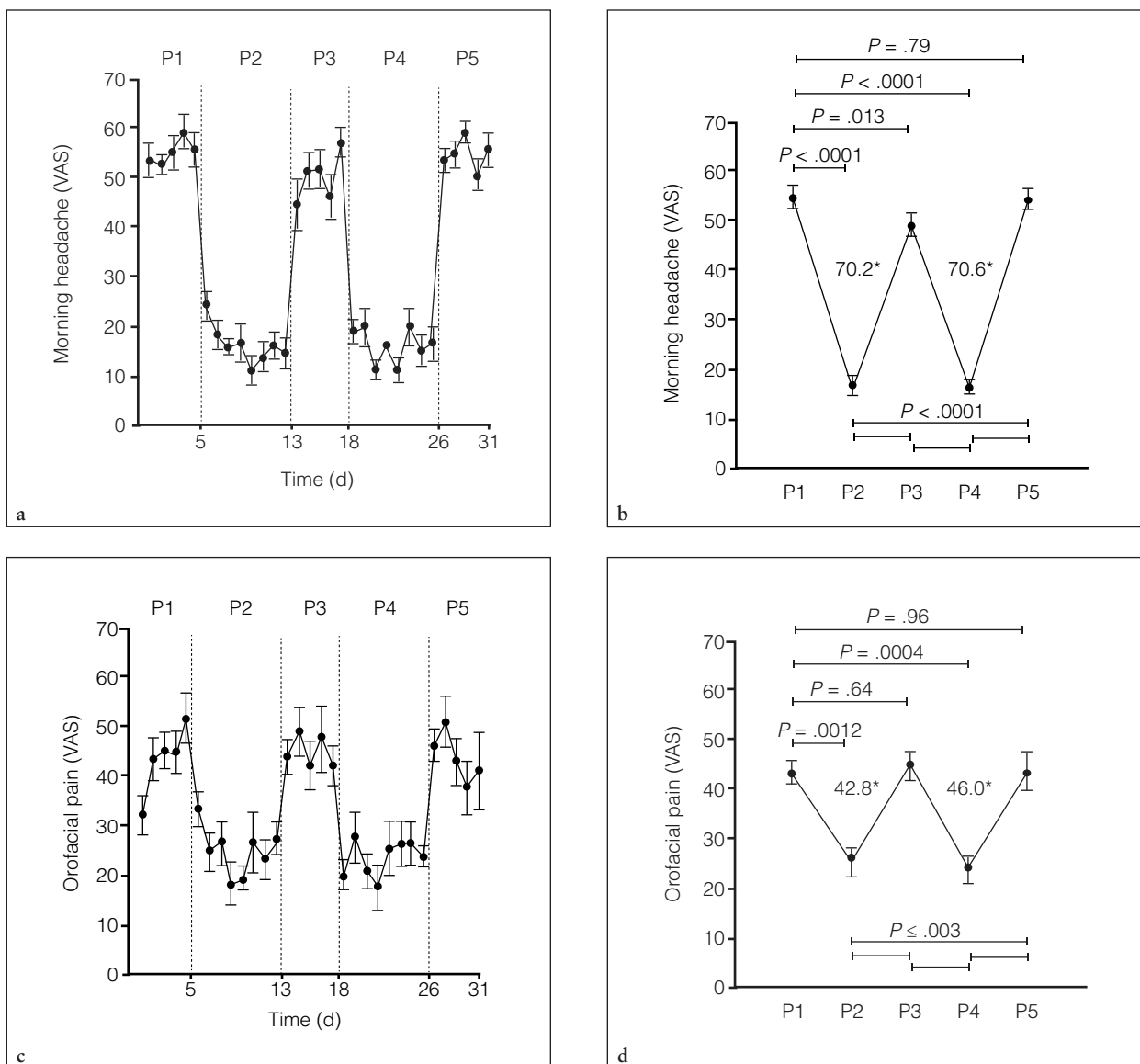
sity returned to close to baseline levels. Moreover, with the MAA in advanced position (P4), morning headache intensity decreased by 70.6% ( $P < .0001$ ) and orofacial pain intensity by 46.0% ( $P = .0004$ ) compared to baseline. At the end of testing, both variables returned to close to baseline levels. No statistical difference was noted between neutral and advanced position ( $P > .50$ ). Overall, there were no gender differences for morning headache ( $P = .98$ ) or orofacial pain ( $P = .71$ ).

### Sleep and Respiratory Variables

No significant difference between nights was seen for sleep stage distribution, sleep latency, total sleep time, or arousal index (Table 1). Compared to N2, both MAA positions slightly reduced sleep efficacy ( $P < .10$ ), with no difference between N3 and N4. Respiratory variables showed no significant differences over the three SLPR nights. However, two subjects had an AHI higher than 5 AH per hour during the baseline night (5.3 and 10.9). The subject with 5.3 AH per hour scored less than 2 for both nights with the MAA. The subject with 10.9 AH per hour still displayed high AHI with the MAA in neutral position (6.8) but lower AHI in advanced position (1.7). Morphometric measurements on dental impressions revealed no association between these measurements and AHI intensity for the baseline night (Pearson correlation, *P* values  $> .1$ , not shown). Periodic leg movements during sleep showed no significant variation over the three SLPR nights (Table 1). One subject with AHI below 3 AH per hour for the 3 study nights had more than 10 periodic leg movements per hour for the three study nights.

### RMMA

Compared to N2, both MAA positions significantly reduced RMMA ( $P < .05$ ), but with no difference between N3 and N4 (Table 1). The vast majority of RMMA episodes observed during the three nights were phasic (93%). During the baseline night, four subjects exceeded the diagnostic criteria for moderate to high frequency RMMA classification<sup>9,44</sup> for both RMMA episodes per hour ( $> 4$  episodes per hour) and RMMA bursts per hour ( $> 25$  bursts per hour). Of these four subjects, only two reported clenching during the night in the questionnaires, and tooth wear scores for the four subjects ( $0.22 \pm 0.11$ ) were not significantly higher than for other subjects ( $0.24 \pm 0.05$ ,  $P = .85$ ). Seven subjects had two or more episodes with grinding noise during the same night. Moreover, eight subjects had two or more episodes with grinding noise during the night, or more than



**Fig 3** Subjects self reports of morning headache and orofacial pain intensity. (a) Variation in morning headache over the study period, (b) average morning headache with statistical results for each study period, (c) variation in orofacial pain over the study period, (d) average orofacial pain with statistical results for each study period. \*% reduction from P1.

two RMMA episodes per hour. Of these eight subjects, five reported clenching during the night and three reported grinding during the night. At N2, no significant correlations were observed between reported pain (morning headache and orofacial pain) and either RMMA index or AHI ( $P > .20$ ). There were no correlations between changes in reported pain (morning headache and orofacial pain) and changes in either RMMA index or AHI when comparing nights with the MAA in either position to N2 ( $P > .30$ ). No significant correlation between the number of RMMA episodes with grinding noise and reported pain (morning headache and orofacial pain)

was observed ( $P \leq .80$ ) when only subjects with two or more RMMA episodes with grinding noise were considered. During the baseline night, the number of RMMA episodes per hour varied between thirds of the night ( $P = .006$ ), with the second third of the night showing higher RMMA frequency (median 2.81 episodes per hour, min-max 0–10.67) than the last third (1.22 episodes per hour, 0–8.53) ( $P = .007$ ). The number of RMMA episodes per hour in N3 and N4 was lower than in N2, but no statistically significant differences between thirds of nights were noted ( $P = .13$  for N3 and  $.16$  for N4).

Sleep variable	Baseline N2	MAA Neutral N3	MAA Advanced N4	P
% Sleep efficacy*	96.6 (78.7–97.6)	92.1 (53.3–98.0)	94.9 (60.6–97.2)	.046 N2–N3: .08 N2–N4: .008
Sleep latency (min)*	11.8 (2.7–104.0)	8.8 (1.3–33.7)	11.7 (0.7–142.7)	.17
Total sleep time (min)	447.1 ± 15.0	424.6 ± 20.0	426.5 ± 14.4	.42
% Stage 3+4	21.0 ± 2.1	20.7 ± 1.4	19.6 ± 1.8	.79
% REM	23.0 ± 1.4	20.7 ± 1.1	20.3 ± 2.2	.30
% REM efficacy	84.6 ± 2.8	87.1 ± 2.4	87.3 ± 2.8	.51
Arousal index (nb/hr)	8.4 ± 1.0	10.7 ± 1.3	9.2 ± 0.9	.12
% O <sub>2</sub> saturation	96.6 ± 0.2	96.3 ± 0.3	96.5 ± 0.2	.32
AHI (nb/hr)*	1.8 (0.1–10.9)	1.0 (0–6.8)	0.9 (0.1–2.7)	.26
Upper airway resistance (nb/hr)*	0	0 (0–0.13)	0 (0–0.33)	.37
Flow limitation (nb/hr)*	0	0 (0–0.5)	0 (0–0.8)	.27
% snoring time asleep*	1.4 (0.0–12.7)	1.8 (0.0–19.7)	0 (0–19.5)	.25
Periodic leg movements during sleep index (nb/hr)*	6.9 (0–41.9)	8.6 (0–21.4)	3.6 (0.5–21.1)	.10
RMMA episode index (nb/hr) **†	2.1 (0–8.7)	0.5 (0–3.7)	0.9 (0–3.5)	.049 N2–N3: .007 N2–N4: .04
RMMA burst index (nb/hr)*†	10.7 (0–43.6)	1.3 (0–17.4)	1.5 (0–14.2)	.017 N2–N3: .007 N2–N4: .03
RMMA tonic burst (nb)*†	0 (0–3)	1 (0–2)	0 (0–9)	.78
RMMA episodes with noise (nb)*†	2 (0–29)	0	0	< .001 N2–N3: .018 N2–N4: .018

\* = Median (min–max); otherwise, mean ± SE are presented; † = one subject could not be scored for RMMA during N3 and N4 since the head was covered by a blanket (n = 11). nb = number.

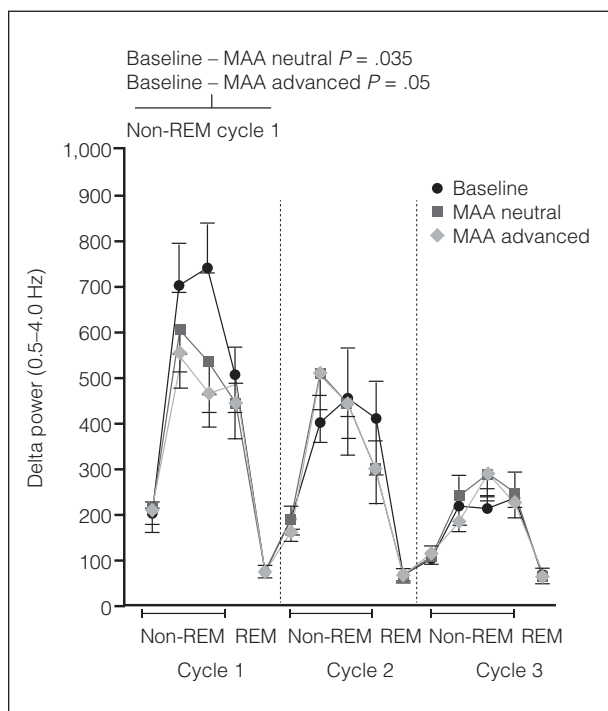


Fig 4 EEG delta power over the first three non-REM to REM ultradian sleep cycles. Data for baseline night and MAA nights in neutral and advanced position are shown.

### EEG Quantification

The comparison between study nights over consecutive non-REM sleep cycles showed no significant overall difference in delta power ( $P = .20$ , Fig 4). However, when analyses were performed separately for each non-REM cycle, a significant difference was observed between study nights for the first cycle ( $P = .039$ ). Subjects had higher delta power during the first cycle in baseline than MAA nights in both neutral and advanced position ( $P \leq .05$ , Fig 4). Delta power during REM showed no significant difference between nights ( $P = .31$ ). Statistical analyses



Table 2 Self-reported Results on Appliance Questionnaires (n = 11)

Appliance variable	MAA neutral	MAA advanced	P
Duration of MAA use per night (hours)	7.4 ± 0.3	7.3 ± 0.3	.68
Wearing periods (nights)	6.8 ± 0.3	6.7 ± 0.3	.72
Adaptation period (days)	4.5 ± 0.7 (1–9)	5.5 ± 0.8 (2–10)	.35
Comfort (100 mm VAS)	39.0 ± 5.1	36.6 ± 5.4	.76
Feeling of dry mouth*	54.5% (6/11)	54.5% (6/11)	.99
Satisfaction (100 mm VAS)	44.4 ± 8.2	41.6 ± 5.9	.71
Efficacy (100 mm VAS)	47.1 ± 8.2	44.3 ± 5.0	.73
Perception of decreased morning headache intensity*	54.5% (6/11)	63.6% (7/11)	.71

\* = Proportion of subjects, otherwise mean ± SE are presented.

of other frequency bands showed no overall significant difference between study nights for both non-REM and REM sleep (all  $P \geq .15$ , data not shown). Interestingly, sleep questionnaires revealed a linear decrease ( $P = .05$ ) in sleep quality as reported by subjects (VAS scale), from N2 ( $54.5 \pm 8.9$ ), N3 ( $44.1 \pm 7.9$ ) to N4 ( $34.3 \pm 6.8$ ).

### Appliance Questionnaires

Treatment compliance was high: all patients reported having worn their MAA every night, for approximately 7 hours per night for both positions (Table 2). Patients' complaints were mostly minor and transitory. Subjects reported that it took more time to adapt to the MAA in advanced (5.5 days) than neutral position (4.5 days), although this was not statistically significant ( $P = .35$ ). More than half the subjects (54.5%) reported mouth dryness. There were no statistically significant differences in perceived comfort, satisfaction, or efficacy between the two MAA positions. At the end of the study, 7 of the 12 subjects expressed a willingness to continue using the MAA.

### Discussion

The present study suggests that the MAA is an effective device for managing morning headache in the absence of SDB. Consistent with previous findings in SDB subjects, the results suggest that the use of an MAA reduces the intensity of morning headache.<sup>45</sup> To the authors' knowledge, this is the first experimental polygraphic study to report such results. Throughout the study, respiratory disturbances (apnea-hypopnea) remained below pathological level (< 10 episodes per hour of sleep) for most subjects.

Although sleep bruxism was not the primary complaint of the subjects in the present study,

RMMA indexes were significantly reduced with the MAA, which may have contributed to the decrease in morning headache. This result supports a previously published study in which an oral appliance was shown to reduce tooth grinding and headache in patients with sleep bruxism.<sup>21</sup>

A decrease in delta activity with the MAA was observed during the first non-REM cycle compared to the baseline night. Decreases in sleep efficacy and reported sleep quality with the MAA were also observed. These results cannot be entirely attributed to adaptation to the MAA because subjects reported on average an adaptation period of five nights and polygraphic recordings were performed during night eight for MAA either in neutral or advanced position.

The MAA is designed to position the jaw forward, which opens the upper airway and helps maintain good oxygenation. It both protects the teeth and prevents tooth grinding. The most common drawbacks reported by patients in the literature<sup>46</sup> are adaptation time and mouth dryness. In the present study, the adaptation period was less than a week, and more than 50% of subjects reported a feeling of dry mouth. There were no complaints of bulkiness of the device, in contrast to reports in the literature with other MAA designs.<sup>39,46</sup> This may be due to the innovative concept of the individually fitted ORM device. Some studies have also reported oro-dento-skeletal changes with long-term use of an MAA.<sup>32,33,47</sup> The ORM is designed to allow traction-based articulation, with vectors that respect the physiology and reduce the force exerted on the muscles as well as temporomandibular joint (TMJ) contact force and tooth displacement compared to traditional MAAs.<sup>36,37</sup> Although the severity of the drawbacks is questionable, they must be considered in long-term therapy, and the management protocol should include regular clinical follow-up.<sup>48</sup>

Due to a number of limitations of this study, the results should be interpreted and extrapolated with

caution. First, although the present sample was sufficient to obtain a significant difference in the main outcome (morning headache intensity), the results need to be confirmed in a controlled study with a larger sample. Second, the study did not make morphological oropharyngeal measurements to confirm the actual mechanism of the MAA. Third, it did not have a control group to test for the effect of time on the main outcome (morning headache intensity). Fourth, the upper airway resistance may have been inadequately scored, as it would have been more reliable to use an esophageal monitoring probe.<sup>49,50</sup> Finally, because the study sample consisted of relatively young subjects, several comorbid factors that are generally prevalent in a larger population were absent.

The causes of morning headache have been reported to include jaw clenching, poor oxygenation related to OSAS, or other respiratory disturbances.<sup>3-5</sup> The present results suggest that an MAA is an effective way to treat morning headache in the short term, despite a decrease in sleep efficacy. MAAs are already used by SDB patients, but they could also be used as a safe alternative for managing morning headache in the general population. The results showed no difference between the two positions, suggesting the prevention of jaw retrusion and collapsibility of the upper airway as an action mechanism. The significant decrease in RMMA index with the MAA may also have contributed to its efficacy in lowering morning headache, despite the lack of correlation between headache and RMMA reduction. OAs have also been associated with a decrease in headache and RMMA index in patients with sleep bruxism.<sup>21</sup> Therefore, a future study could test subjects with the same MAA in neutral position with and without the connector between the two splints, as in Landry et al.<sup>39</sup> Since an MAA without the connector between the two splints is equivalent to a standard appliance, such a study would help to distinguish whether the reduction in morning headache was due to the prevention of jaw retrusion or to a decrease in RMMA activity. Future studies should also consider longer-term use of the MAA.

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