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Original Article

Efficacy of two mandibular advancement appliances in the management of snoring and mild-moderate sleep apnea: A cross-over randomized study ☆

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Abstract

Background: Mandibular advancement appliances (MAA) are a recognized alternative treatment to continuous positive airway pressure (CPAP) for mild-moderate obstructive sleep apnea syndrome (OSAS). The aim of this study is to assess the efficacy of and subject satisfaction with two MAA in the management of OSAS.
Methods: Five women and 11 men (47.9 ± 1.6 years), previously untreated with CPAP, were recruited from a sleep disorders clinic following a polysomnographic diagnosis of mild-moderate OSAS with Respiratory Disturbance Index (RDI) of 9.4 ± 1.1. A randomized single blind cross-over study was completed with both Klearway and Silencer (three months for each study arm). Subjects completed standardized questionnaires on sleep quality, sleepiness and functional outcomes (Functional Outcome Sleep Questionnaire: FOSQ). MAA satisfaction (e.g., comfort) and efficacy (e.g., reduction of respiratory noises, headache) were assessed by subjects and sleep partner.
Results: The two MAA (Silencer 4.7 ± 0.9 and Klearway 6.5 ± 1.3) significantly reduced the RDI compared to the baseline night (10.0 ± 1.2, respectively $p < 0.001$ and $p < 0.01$). The RDI was slightly lower with the Silencer ($p \leqslant 0.05$) but subjects' preference for comfort was in favor of the Klearway (Klearway 7.0 ± 0.4 vs Silencer 5.8 ± 0.4, $p = 0.04$). The Epworth score, FOSQ, respiratory noise and morning headache were also improved following use of both appliances ($p \leqslant 0.05$ to 0.001).
Conclusion: Although both MAA decreased RDI and subjective daytime sleepiness in a *similar* manner, the choice between various types of MAA needs to be taken into account when considering the benefit of RDI reduction over the benefit of subject compliance. The long term benefit of increased RDI reduction vs. a better subject compliance needs to be assessed in prospective studies.

Abbreviations: AHI, apnea/hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; DBP, diastolic blood pressure; ECG, electrocardiogram; EEG, electroencephalogram; EMG, electromyogram; EOG, electrooculogram; ESS, Epworth sleepiness scale; FOSQ, functional outcomes of sleepiness questionnaire; FSS, fatigue severity scale; ICC, intra class correlation; LREM, latency to REM; LSO, latency to sleep onset; MAA, mandibular advancement appliance (named repositioning or device); N1, diagnosis night; N2, baseline night; N3–N4, assessment night, randomized Klearway or Silencer; OSAS, obstructive sleep apnea syndrome; RDI, respiratory disturbance index; REM, rapid eye movement; SaO_2, oxygen saturation; SBP, systolic blood pressure; SE, sleep efficiency; SLPR, sleep laboratory polygraphic recording; TST, total sleep time; TRT, total recording time; VAS, visual analog scale.

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Keywords: Sleep apnea; Snoring; Mandibular advancement appliance; Cross-over; Randomized; Headache; Apnea/hypopnea index; Respiratory disturbance index

1. Introduction

Mandibular advancement appliances (MAA) are indicated in the treatment of snoring and mild-moderate obstructive sleep apnea syndrome (OSAS) [1,2]. Although many studies have demonstrated the efficacy of MAA in the management of OSAS [3–7], Continuous Positive Airway Pressure (CPAP) is recognized as the "gold standard." Yet, MAA remain a valid alternative preferred by several subjects [7–9].

Surprisingly few studies have compared the efficiency of two MAA using the apnea/hypopnea index (AHI) or the respiratory disturbance index (RDI) or even patient or sleep partner satisfaction as outcomes [10–16]. Also, most of these studies include a large range of severity, from very mild to highly severe OSAS subjects.

The present study aimed to assess the efficacy and patient/sleep partner satisfaction with two MAA in subjects with mild-moderate RDI (apnea + hypopnea + respiratory effort-related arousal per hour of sleep, RERA). The null hypothesis is that the Klearway is *equivalent* to the Silencer for the management of OSAS patients. The alternative hypothesis is that one appliance is superior.

2. Material and methods

2.1. Study design, population and inclusion/exclusion criteria

In a prospective, single blind cross-over and randomized study comparing two MAA, sleep and respiratory data were collected over a total of four nights (Fig. 1). The four sleep laboratory polygraphic recording (SLPR) nights were for OSAS diagnosis (N1), baseline (N2) and MAA assessment (N3 and N4). Subjects were enrolled for a six-month period (three months for each MAA arm between June 2004 and October 2006) and a follow-up interview one to two years after N2.

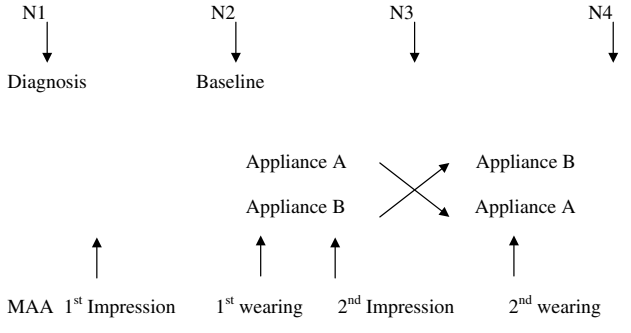

Fig. 1. Design.

The subjects were recruited from the sleep disorders clinic of a hospital in northeastern Quebec. Following one night of SLPR, subjects diagnosed with mild-moderate OSAS (RDI > 5 and RDI < 30) without any evidence of sleep disorders such as insomnia or REM (rapid eye movement) Behavior Disorder were invited to participate in the study. Subjects signed an informed consent form approved by our hospital's Institutional Ethics Review Board. Sample size estimation, conducted prior to the study based on values from literature [14], revealed that with 16 subjects, an 80% power to detect a clinically relevant difference of 30% in RDI between the two MAA (from an RDI of 8.5, SD of difference = 3.3, effect size = 0.76) would be present at the alpha level of 0.05.

The inclusion criteria included: a history of snoring, the presence of natural teeth on both dental arches and the ability to speak and read the French questionnaire. Exclusion criteria were previous treatment for OSAS, caries, periodontal disease, jaw pain or mandibular movement limitations (e.g., lack of protrusive jaw slide). Of the 23 subjects invited to participate in the study, four were excluded. Three subjects dropped out during the first study arm (after one and two months) due to intolerance to the MAA (excessive salivation, chronic sinusitis and jaw pain). Of these three, two wore the Klearway and one wore the Silencer.

2.2. Appliances

The two commercially produced MAA used in the study were the Klearway and the Silencer (Fig. 2). Both MAA offer an interincisal space of 9–12 mm. Random allocation to one of the two MAA study arms was generated by software (Systat software Inc., San Jose, California, USA) before MAA bite registration.

After an orodental examination, impressions of both dental arches were taken. A second dental impression and bite recording was made two months later for the second study arm. Two commercial dental laboratories fabricated the appliances: Klearway appliances were made at the Classic Dental Laboratory (Ottawa, Ontario, Canada) and the Silencer appliances were made at the Silencer laboratory (Burnaby, British Colombia, Canada).

As seen in Fig. 1, subjects received one of the two MAA the morning after N2 and N3. Subjects wore each MAA for two consecutive 12-week periods divided in

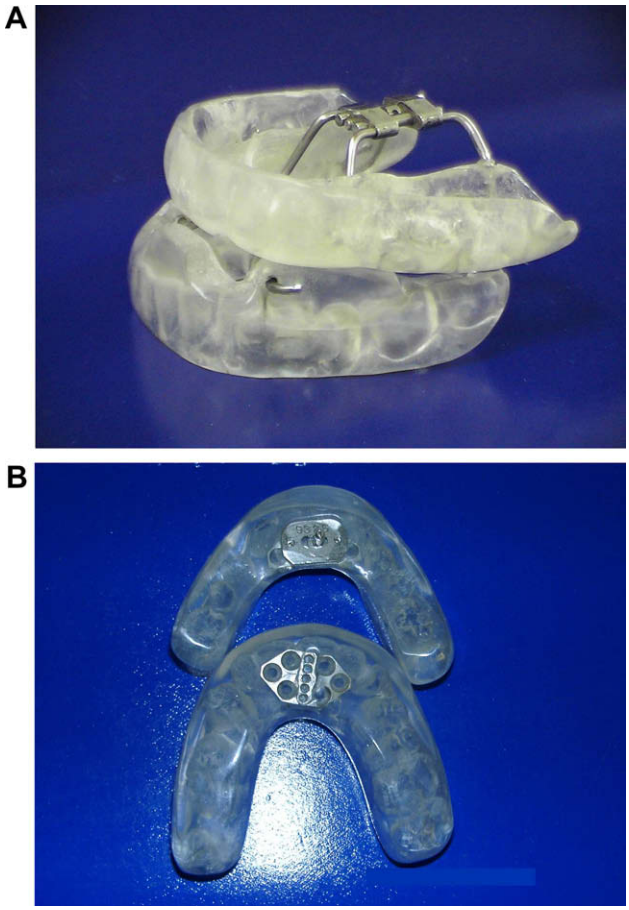

Fig. 2. (A) The Klearway advancement mechanism is located in the palatal area. (B) The Silencer advancement mechanism is situated in the incisor tooth area. (These MAA are formed with two trays that cover upper and lower teeth and offer free lateral mandibular movements.)

two blocks: (1) weeks 0–4 for adaptation and (b) weeks 4–12 for advancement, i.e., mandibular advancement of 4 mm (the 4 mm advancement was made after bite registration including an advancement of 50% of maximal protrusion for the Silencer and two-thirds of maximal protrusion for the Klearway). In our study the maximal protrusion had a mean of 13 mm. The bite was taken on average at 6.5 mm for the Silencer and at 8.5 mm for the Klearway, and the maximal advancement was on average 10.5/13 mm for the Silencer and 12.5/13 mm for the Klearway. The advancement was made by patients twice a week and verified by a dentist (LG) every four weeks for the Klearway, and two advancements of 2 mm were made by a dentist (LG) at four and eight weeks for the Silencer.

2.3. Sleep, respiratory and blood pressure measurements

SLPR and data acquisition were performed with LaMont Medical Inc. (Wisconsin, USA) amplifiers and Stellate software (Montreal, Canada). The polygraphic variables recorded were the Electromyogram (EMG) of chin/masseter and anterior tibialis muscles, the electrocardiogram (ECG derivations), the electrooculogram (EOG, LOC-A1, ROC-A2) and the electroencephalogram (EEG, C3-A2, C4-A1, O1-A2, O2-A1). Respiratory parameters were recorded using nasal cannula and a buccal thermistor. Respiratory movements were assessed with abdominal and thoracic belts. The oxygen saturation (SaO_2) was taken at the fingertip. Finally, a body sensor and video recorder were used to assess body position.

The following sleep and respiratory variables were considered: total sleep time (TST), total recording time (TRT), sleep efficiency (SE), latency to sleep onset (LSO), latency to REM (LREM), sleep stages (percentage and time in minutes), awakenings, micro-arousals, periodic limb movements, RDI (apnea + hypopnea with respiratory events associated with sleep microarousals [17,18]) and time in supine, prone and side position.

All SLPR were scored, blinded to treatment conditions, by two experienced technicians using the standard criteria [28]) under the supervision of a neurologist (MB) or a pneumologist (ML). The reliability of RDI scoring between technicians was excellent as measured with the intraclass correlation coefficient (ICC) (Fleiss, J.L.) of 0.93 (0.69–0.98). Furthermore, to be stringent, an independent sleep laboratory technician scored the same recordings, and the agreement between scorings from the two different sleep laboratories was excellent (ICC 0.97, 0.87–0.99).

The subject's blood pressure was measured each evening before N2–N3–N4 at 7:10 pm after a 10-minute rest.

2.4. Assessment of fatigue, sleepiness, treatment satisfaction

We used the fatigue severity scale (FSS) [19], the Epworth sleepiness scale (ESS) [20] and the functional outcomes of sleep questionnaire (FOSQ) [21].

A visual analog scale (VAS) of 10 cm was used for home questionnaires pertaining to activities of daily living and behaviors related to bedtime to evaluate the frequency and symptoms of sleepiness according to subjects and sleep partners [9,14,22]. Also, VAS was completed by subjects after wearing each MAA to evaluate their perception of the efficacy of and their satisfaction with the appliances.

2.5. Other variables

The subjects were mailed questionnaires concerning MAA efficacy and frequency of use up to March–April 2007. All 16 subjects responded; both the self evaluation questions used for assessments at N2, N3 and N4 and VAS were used to measure the subjects' levels of com-

fort, satisfaction and efficiency with the MAA at this time. The mean wearing time was reported in hours/night and nights/week.

In addition, we verified whether the subject shared his/her sleep environment with a sleep partner before/after the use of the MAA. Subjects answered questions about their relationships with sleep partners, e.g., "Was your personal relationship with your sleep partner influenced-improved by the use of one of the MAA treatments?" Subjects and sleep partners responded yes/no and estimated the percentage of improvement on VAS. Improvement in sleep quality was also estimated by subjects and sleep partners in comparison to the period before they wore the MAA.

2.6. Success criteria and statistical analysis

Sleep apnea treatment success criteria used were either the 50% RDI reduction and/or a RDI reduction below 10 and 5 [6,7].

ANOVAs for repeated measures were used to evaluate treatment effects. Paired comparisons were then used to assess differences between N2, Klearway and Silencer (N4 and N3). Moreover, to verify whether there was any sequence effects on treatment, we used ANOVA for repeated measures with sequence (Klearway → Silencer and Silencer → Klearway) as the between-subject factor and treatment effect as the within-subjects factor. No significant interaction between sequence and treatment was observed ($p = 0.60$ for RDI). A p value $\leqslant 0.05$ was used to assess the significance level. Data are presented as mean values ± standard error.

3. Results

The final sample of subjects who completed the full sequence comprised five women and 11 men aged 47.9 ± 1.6 years (range 37–60), with a body mass index (BMI) of 28.7 ± 0.8 kg/m^2 (range 24–35), and a neck circumference of 39.8 ± 0.8 cm (range 35–49) with a mean RDI at N1 of 9.4 ± 1.1 (range 5–21). It can be noted that there was no significant difference for the BMI and neck circumference from N2 to N3 to N4. Moreover, seven subjects had no medical problems. Of the nine others, six suffered from hypertension, two from asthma, two from cholesterol, one from periodic limb movement syndrome, one from digestive problems, and one from diabetes. Finally, one woman was undergoing menopause and taking estrogens to manage her symptoms.

3.1. RDI, oxymetry and blood pressure

In comparison to N2, both MAA with 4 mm advancement significantly reduced the RDI with a slight advantage in favor of the Silencer (Table 1, per protocol). Using a treatment success criteria of 50% reduction in the RDI, eight subjects (50%) with the Klearway and ten (63%) with the Silencer achieved success (data not shown). With criteria below 10 or 5 RDI, success was achieved respectively by 12 (75%) and 10 (63%) of subjects with Klearway and by 15 (94%) and 12 (75%) with Silencer. The RDI was also reduced by both MAA with no difference between appliances in the supine position or in non REM sleep. However, the Silencer had an advantage over the Klearway during REM sleep (Table 1, per protocol). The RDI was slightly increased (less than 4 events/h) in three subjects with Klearway and in one with Silencer. The marginal increase in SaO_2 from baseline is not considered clinically relevant. Both MAA reduced the systolic blood pressure (SBP) (no significant difference) and the reduction of diastolic blood pressure (DBP) was slightly more important for the Silencer (Table 1, per protocol). Also, to be cautious, we performed an intent-to-treat analysis of RDI results including the 19 subjects that were invited to participate in the study. The results are in line with the per protocol analysis (see Table 1, intent-to-treat analysis). Note that the baseline data from the three subjects who dropped out of the study were used for treatment nights.

Table 1
Respiratory and blood pressure variables

Variables	Baseline	Klearway	Silencer	K vs. S
Per protocol (16 subjects)				
RDI				
Total	10.0 ± 1.2	6.5 ± 1.3**	4.7 ± 0.9***	Silencer*
Supine	16.4 ± 2.7	10.5 ± 2.7*	7.7 ± 1.7**	NSD
REM	16.4 ± 2.0	13.9 ± 2.6	8.2 ± 1.5***	Silencer**
Non REM	8.4 ± 1.3	4.5 ± 1.0**	3.5 ± 0.9**	NSD
Intent-to-treat (19 subjects)				
RDI				
Total	10.7 ± 1.1	7.8 ± 1.3**	6.2 ± 1.2***	Silencer*
Supine	15.9 ± 2.4	10.9 ± 2.3*	8.6 ± 1.7**	NSD
REM	16.8 ± 1.9	14.7 ± 2.3	9.9 ± 1.7***	Silencer**
Non REM	9.1 ± 1.2	5.8 ± 1.2**	5.0 ± 1.2**	NSD
Oxymetry				
SaO_2%	95.2 ± 0.3	95.4 ± 0.2	95.6 ± 0.3*	NSD
Blood pressure				
SBP	127.3 ± 2.8	123.6 ± 1.7	123.0 ± 2.2	NSD
DBP	91.0 ± 2.7	85.0 ± 1.9	84.6 ± 2.3*	NSD

*$p \leqslant 0.05$, **$p \leqslant 0.01$, ***$p \leqslant 0.001$.
Column 1 to 3 from baseline.
Column 4 between MAA.
NSD, not statistically different between MAA, last column.

3.2. Sleep variables

In comparison to N2, the percentage of REM sleep was also marginally increased and the REM sleep latency was much more reduced with Silencer (Table 2). The percentage of stage 3–4 was slightly reduced by Klearway. Other sleep variables did not differ from baseline or between MAA.

Table 2
Sleep variables

Variables	Baseline	Klearway	Silencer	K vs. S
TST (min)	421.6 ± 10.7	438.7 ± 11.3	429.1 ± 10.5	NSD
SE (%)	83.1 ± 2.0	85.6 ± 2.1	83.9 ± 2.1	NSD
LSO (min)	12.1 ± 2.9	11.2 ± 1.6	13.7 ± 3.5	NSD
LREM (min)	123.5 ± 13.0	117.2 ± 17.7	88.3 ± 4.6**	S*
REM%	20.2 ± 0.9	22.0 ± 1.5	22.8 ± 1.2*	NSD
Stage 1%	6.2 ± 0.7	6.4 ± 1.3	6.1 ± 0.6	NSD
Stage 2%	54.1 ± 1.4	53.9 ± 1.5	52.9 ± 2.0	NSD
Stage 3-4%	19.5 ± 1.5	16.2 ± 1.9*	19.4 ± 2.0	K*

*$p \leqslant 0.05$, **$p \leqslant 0.01$, ***$p \leqslant 0.001$.
Column 1 to 3 from Baseline.
Column 4 between MAA.
NSD: not statistically different between MAA, last column.

3.3. ESS, FSS and FOSQ scores

In comparison to N2, both MAA significantly reduced the ESS score without any difference between MAA (Table 3). Both MAA tended to improve the FSS score ($p = 0.07$) without any difference between MAA. Both appliances were found to significantly improve the FOSQ total score and each subscale ($p \leqslant 0.05$ to 0.001) without any difference between MAA (Table 3).

3.4. Subjects' and sleep partners' self evaluation of MAA efficacy, comfort and compliance over time

The Klearway was reported by subjects to be significantly more comfortable at the end of N3 or N4 ($p < 0.05$; Table 4A) and similarly at the follow-up (no statistic; Table 4B).

As Table 5 shows, both subjects and sleep partners reported that the two MAA significantly reduced the frequency of snoring, choking, cessation of breathing, number of awakenings during the night, daytime sleepiness, frequency of morning headaches, daytime aggressive or irritable reactions, and decreased libido ($p \leqslant 0.05$ to 0.001). The subject's perception of choking and cessation of breathing during sleep showed a greater reduction with the Silencer in comparison to the Klearway ($p \leqslant 0.05$).

Table 4A
Patient self evaluation of MAA efficacy and preference

Subjects' evaluation (VAS)	Klearway	Silencer	K vs. S
Time to adapt (days)	4.7 ± 1.1	8.5 ± 2.4	NSD
Wearing time (h/by night)	7.1 ± 0.3	6.8 ± 0.2	NSD
Number of nights (by week)	6.6 ± 0.2	6.1 ± 0.4	NSD
Satisfaction (VAS)	7.4 ± 0.4	6.5 ± 0.5	NSD
Efficiency (VAS)	7.7 ± 0.4	7.4 ± 0.4	NSD
Comfort (VAS)	7.0 ± 0.4*	5.8 ± 0.4	Klearway*

Efficacy assessment after N3 and N4.
*$p \leqslant 0.05$, **$p \leqslant 0.01$; ***$p \leqslant 0.001$.
NSD, not statistically different between MAA, last column.

Table 4B
Number of patients expressing their preference for a given MAA at end of study

Variables	Klearway	Silencer	No difference
Efficiency	7	8	1
Comfort	11	5	0
Satisfaction	10	6	0
Preference	9	6	1

3.5. Other variables

Before wearing MAA, 9/16 subjects (56%) reported sharing the bed with their spouse; after they wore one of the MAA this number increased to 14/16 subjects (87.5%). Use of either one of the MAA treatments improved the subject's personal relationship with his/her sleep partner in 12 (75%) subjects and was judged better by 15 (94%) of sleep partners, an estimated improvement of 73.3% and 76.7% respectively. Both subjects and sleep partners reported that their sleep quality and quality of life were improved with two MAA ($p \leqslant 0{,}001$; data not shown) without any difference between them.

Table 3
Sleepiness, fatigue and Functional outcome scoring

Variables	Baseline	Klearway	Silencer	K vs. S
ESS	13.9 ± 1.3	9.3 ± 1.2***	9.9 ± 1.3**	NSD
FSS	45.4 ± 2.7	39.4 ± 3.6[1]	39.0 ± 2.6[1]	NSD
FOSQ				
Total	13.8 ± 0.7	17.2 ± 0.5***	16.8 ± 0.6***	NSD
General productivity	3.0 ± 0.2	3.5 ± 0.1**	3.5 ± 0.1**	NSD
Social outcome	3.0 ± 0.2	3.6 ± 0.1**	3.4 ± 0.1*	NSD
Activity level	2.7 ± 0.2	3.4 ± 0.2***	3.4 ± 0.2**	NSD
Vigilance	2.6 ± 0.2	3.3 ± 0.2***	3.3 ± 0.2***	NSD
Intimate relationships and sexual activity	2.6 ± 0.2	3.4 ± 0.1**	3.2 ± 0.2*	NSD

*$p \leqslant 0.05$, **$p \leqslant 0.01$, ***$p \leqslant 0.001$.
NSD, not statistically different between MAA, last column.
[1] Trend from baseline: $p = 0.07$.

Table 5
Self assessment questionnaire for subject and sleep partner

Questions	During study			After study
(0 = never, 10 = always) Subjects/sleep partners	Baseline	Klearway	Silencer	(Follow-up) May 2007
1 – Do you snore during the night?	9.3 ± 0.2	4.2 ± 1.0***	4.7 ± 1.0***	3.3 ± 0.8***
	/9.7 ± 0.1	/3.7 ± 0.9***	/3.3 ± 0.7***	/3.2 ± 0.8***
2 – Do you awake choking?	4.3 ± 0.9	2.4 ± 0.7*	0.9 ± 0.3***[1]	1.1 ± 0.5**
	/4.3 ± 1.0	/1.1 ± 0.4*	/1.4 ± 0.6**	/0.8 ± 0.3**
3 – Do you cease breathing during sleep?	4.7 ± 0.9	1.8 ± 0.5*	0.7 ± 0.2***[1]	1.2 ± 0.6**
	/4.5 ± 1.1	/0.7 ± 0.3**	/0.9 ± 0.5**	/0.8 ± 0.3**
4 – Do you awake during the night?	8.2 ± 0.5	4.2 ± 0.9***	4.5 ± 0.8***	3.7 ± 0.9***
	/8.2 ± 0.7	/3.3 ± 0.7***	/4.0 ± 0.9***	/2.9 ± 0.7***
5 – Do you suffer from daytime sleepiness?	5.3 ± 0.8	2.5 ± 0.8**	2.8 ± 0.7**	1.8 ± 0.7***
	/5.4 ± 0.9	/2.0 ± 0.6***	/1.4 ± 0.5***	/1.4 ± 0.5***
6 – Do you have morning headaches?	4.6 ± 1.1	1.6 ± 0.6**	1.9 ± 0.6**	1.6 ± 0.6**
	/4.1 ± 1.0	/2.0 ± 0.7*	/0.9 ± 0.3***	/1.9 ± 0.7**
7 – Do you feel aggressive or irritable during daytime?	5.7 ± 0.9	2.4 ± 0.6***	2.9 ± 0.6**	1.1 ± 0.4***
	/5.4 ± 0.8	/2.3 ± 0.8***	/2.3 ± 0.7***	/1.3 ± 0.4***
8 – Have you noticed a reduction in libido?	4.6 ± 0.8	2.2 ± 0.6**	2.1 ± 0.6**	1.9 ± 0.7***
	/3.6 ± 0.9	/1.9 ± 0.6*	/1.8 ± 0.8*	/1.8 ± 0.6*

*$p \leqslant 0.05$, **$p \leqslant 0.01$, ***$p \leqslant 0.001$, from baseline.
[1] Silencer > Klearway $p \leqslant 0.05$.

3.6. Follow-up

The follow-up questionnaires revealed that all 16 subjects wore one of the two appliances according to the subject's MAA preference at the end of the study (Table 4B). We calculated the compliance from right after N4 to the time when we received the last questionnaire (May 2007); all 16 subjects wore the appliance at this time: six from six to 11 months, four from 12 to 17 months, three from 18 to 23 months and three from 24 to 29 months. The mean wearing time was 7.0 ± 0.2 h/night and 5.7 nights/week. Moreover, we noted high estimations in self reports of MAA comfort (7.7 ± 0.4/10 cm), satisfaction (7.9 ± 0.5/10 cm) and efficiency (8.0 ± 0.4/10 cm). When the same questions as those asked after N3 or N4 were used at the follow-up, positive and significant effects persisted over time for all variables (Table 5, right column).

4. Discussion

The present study confirms that both the Klearway and Silencer are effective but *similar* in their capacity to reduce RDI in a population of subjects with mild-moderate OSAS, previously untreated with CPAP. Moreover, subjects' sleep quality and quality of life were significantly improved.

The slight but significant advantage of the Silencer needs to be interpreted with caution since the N2 mean RDI baseline index per hour of sleep is low (10 RDI) with a 12% standard error (Table 1). Both appliances had 4 mm advancement but the Silencer was statistically more efficient at reducing the RDI. While the Silencer is made with an advancement mechanism that provides more oral space for the tongue compared to the Klearway, it remains to be demonstrated whether the differences between efficacy of the appliances is related to tongue space. The clinical relevance of this effect needs to be reproduced. Moreover, the sample size of the present study is similar to that of several reports comparing two oral appliances [11–16].

Direct comparison of the present study data with data from previous studies using two sleep oral appliances is very difficult since various appliance designs were selected as active treatments or control conditions (e.g., Herbst, home made appliance, monobloc without mandible movement freedom, single dental arch appliance as a control) [10–16]. To the best of our knowledge, only two studies were conducted with SLPR [10,13]. Moreover, the inclusion of subjects with very high RDI or AHI in some of these studies (i.e., up to 127.7 RDI or 137 AHI) does not accord with actual guidelines. Use of MAA is recommended for mild to moderate OSAS subjects or in case of CPAP failure [1,2]. In the present report we excluded CPAP failure.

Another consideration that needs more comprehensive investigation in future studies comparing MAA and CPAP is long term compliance or adherence to treatment modality weighted with clinically relevant reduction of RDI or AHI overtime in relation to sleepiness, blood pressure, and cognitive and mood improvements. Regular CPAP use, for at least six days/week and 6.5 h/night, is high (>70%) in young and older patients initiating treatment [23], a result that is comparable with the present MAA comparative study in middle-aged subjects. It was reported that 31 of the 107 OSA subjects were intolerant to CPAP at three months [23]. Another study reported that six months afterwards less than 30% of patients were still undergoing CPAP treatment [24]. Conversely, at a one-year follow-up interview in the

present study all patients reported that they were still using the MAA. However, compliance can also be an issue with MAA; it is estimated that 50–90% of patients use the MAA on a regular basis depending on appliance design and study inclusion criteria but that the number of days/week or h/night of use is highly variable [6,7].

Importantly, not all subjects benefit from MAA. Follow-up recordings to assess RDI or AHI plus sleepiness are a necessary task for clinicians prescribing devices to manage respiratory sleep disorders. In the present study, as has been found previously in studies of MAA of a comparable design, three subjects with Klearway and one with Silencer experienced a transient but modest aggravation of RDI [4,12].

The slight reduction in blood pressure and the significant result obtained for the diastolic pressure is not surprising. Unlike this study, previous studies specifically planned to estimate changes in blood pressure with MAA ambulatory monitoring system and most included a large sample size [25–27].

The study has its limitations: we did not make morphological oropharyngeal measurements; the subjects were Caucasian and mainly French speaking, reducing applicability of findings to other ethnic groups; there was no one-year follow-up assessment of the RDI.

5. Conclusion

The present results confirm that both types of MAA are indicated in the management of mild-moderate OSAS. Since both MAA decreased RDI and subjective daytime sleepiness in a *similar* manner, the choice of an oral appliance needs to be weighted giving due consideration to the benefit of RDI reduction (in favor of the Silencer) over benefit of subject compliance (in favor of the Klearway). The long term benefit of a better RDI reduction vs. a better patient compliance needs to be assessed in prospective studies.

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