

## Five Years of Sleep Apnea Treatment with a Mandibular Advancement Device

### *Side Effects and Technical Complications*

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#### ABSTRACT

**Objective:** To determine the variation in prevalence of temporomandibular disorders (TMD), other side effects, and technical complications during 5 years of sleep apnea treatment with a mandibular advancement device.

**Materials and Methods:** Forty patients diagnosed with obstructive sleep apnea received an adjustable appliance at 70% of the maximum protrusion. The protrusion was then progressively increased. TMD (diagnosed according to the Research Diagnostic Criteria for TMD), overjet, overbite, occlusal contacts, subjective side effects, and technical complications were recorded before and a mean of 14, 21, and 58 months after treatment and analyzed by the Wilcoxon test ( $P < .05$ ).

**Results:** Fifteen patients still used the oral appliance at the 5-year follow-up, and no significant variation in TMD prevalence was observed. Subjective side effects were common, and a significant reduction was found in overjet, overbite, and in the number of occlusal contacts. Furthermore, the patients made a mean of 2.5 unscheduled dental visits per year and a mean of 0.8 appliance repairs/relines per year by a dental technician. The most frequent unscheduled visits were needed during the first year and were a result of acrylic breakage on the lateral telescopic attachment, poor retention, and other adjustments to improve comfort.

**Conclusions:** Five-year oral appliance treatment does not affect TMD prevalence but is associated with permanent occlusal changes in most sleep apnea patients during the first 2 years. Patients seek several unscheduled visits, mainly because of technical complications. (*Angle Orthod* 2010;80:30–36.)

**KEY WORDS:** Sleep-disordered breathing; Oral appliance; Craniomandibular disorders; Adverse effects; Device failure

#### INTRODUCTION

Obstructive sleep apnea (OSA) is a common respiratory disorder characterized by recurrent upper airway obstruction during sleep. Treatment options for

OSA include behavioral modification, continuous positive airway pressure (CPAP), surgery, and oral appliances. Although CPAP appears to be most effective in improving OSA, oral appliances may be a good alternative for patients with mild to moderate symptoms who prefer oral appliances to CPAP or for those who are unable to tolerate CPAP therapy.<sup>1</sup>

Mandibular advancement devices (MAD) are the most common class of oral appliance used to treat snoring and OSA. Although there are several MAD designs, all devices protrude the mandible and induce changes in the anterior position of the tongue, soft palate, lateral pharyngeal walls, and mandible, resulting in improved airway patency.<sup>2</sup> Increasing evidence suggests that MAD improves sleep-disordered breathing.<sup>1</sup> However, response to MAD is variable and normally depends on the MAD design and patient characteristics. The acceptance rate of MAD after 1 year ranged from 55% to 82%, and there was a declining trend over time.<sup>2</sup> The most common reasons

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for discontinuing MAD use are lack of efficacy, side effects, and complications.<sup>3</sup>

Subjective side effects are common, and the most frequently reported include temporomandibular joint (TMJ) pain, myofascial pain, tooth pain, salivation, TMJ sounds, dry mouth, gum irritation, and morning-after occlusal changes.<sup>4-7</sup> Most of these side effects are minor and well-tolerated and tend to be resolved in a short period. However, objective side effects such as tooth movement, skeletal changes, and occlusal alteration have also been reported.<sup>5,8-17</sup> Temporomandibular disorders (TMD) have been associated with the use of MAD, and this disorder is one of the exclusion criteria for many clinical studies. The majority of studies used the Helkimo Index or signs and symptoms to assess TMD.<sup>9,16,18</sup> TMD are a cluster of heterogeneous disorders of the masticatory muscles and TMJs. The myogenous and arthrogenous disorders may be further subclassified into myofascial and arthrogenous pain, disc displacements, and degenerative joint disease as the most common conditions. The Research Diagnostic Criteria for TMD (RDC/TMD) were developed for research use and are a successful diagnostic and classification system.<sup>19</sup>

Appliances are usually worn every night indefinitely for symptomatic relief. The type and frequency of technical complications of MADs should be considered before treatment. However, technical complications with MADs, such as clasp breakages, repeated adjustments to optimize retention, or replacement of the device, have been reported in only a few studies.<sup>4,11,18,20,21</sup> Technical complications may affect the cost for the patient and compliance with the treatment.<sup>22</sup>

The aim of this study was to evaluate variations in prevalence of TMD in OSA patients, as well as other side effects and technical failures, during 5 years of use of MADs.

## MATERIALS AND METHODS

Forty-one adult patients with mild to severe OSA were recruited from the Sleep Unit of the Bellvitge University Hospital, Barcelona, Spain, between April 2002 and May 2004. All patients were diagnosed with OSA, based on the presence of OSA symptoms (snoring, apnea, and sleepiness) and overnight polysomnography (Apnea-Hypopnea Index > 10/h). Polysomnography was scored manually according to standard criteria.<sup>23</sup> Patients were excluded if severe periodontal disease was present or if there were insufficient teeth to fit the MAD. All patients gave written informed consent to participate in the study, which was approved by the ethics committee of Bellvitge University Hospital. One patient was excluded because he did not have the minimum number of

healthy teeth needed to retain the oral appliance. Therefore, 40 OSA patients participated in this prospective case series.

The MAD consisted of two full-coverage acrylic splints connected by two lateral telescopic attachments (Herner Guiding Telescopes, Iserlohn, Germany), allowing mouth breathing and a degree of side-to-side, protrusive, and opening movements of the mandible. Polyvinylsiloxane impressions of the maxillary and mandibular arches were used to manufacture dental plaster casts. The George Gauge (Great Lakes Orthodontic Lab, Tonowanda, NY) was used to measure the maximum mandibular protrusion capacity and then to make an interocclusal record of the desired anteroposterior and vertical mandibular position to be achieved by the MAD. The amount of mandibular advancement was initially set at 70% of the maximum and was then progressively increased over the following weeks until the patient stopped snoring or side effects appeared. All MADs were fabricated by the same dental technician and fitted and adjusted by a specialist dentist. The patients were instructed to use the MAD every night during sleep.

Before treatment was initiated, one dental clinician examined all patients, applied the RDC/TMD, and recorded the occlusal characteristics. Following the RDC/TMD algorithms, all subjects were assigned to the non-TMD group or to one of the three main groups (group I, myofascial pain; group II, TMJ disc displacement; group III, TMJ arthralgia/osteoarthritis/osteoarthritis).<sup>19</sup> Multiple diagnoses per subject were also possible. Overjet and overbite were measured by means of a digital caliper (Absolute; Vogel Germany, Kevelaer, Germany). Intraoral tooth contact in the intercuspatal position was recorded using occlusal registration strips (Bausch Articulating Paper, Köln, Germany), and the recording was drawn on the protocol sheet.<sup>24</sup> The number of occlusal contacts and the number of teeth in contact were recorded in both the anterior and posterior regions.

The follow-up visits were planned to be performed 6 weeks after the last increase in mandibular advancement, 6 months later, and 5 years after starting the therapy. The first checkup visit was performed after an average of 14 months from the start of treatment, the second checkup was performed after an average of 21 months from the start of treatment, and the third checkup took place after 4.8 years (range, 3.6 to 5.8 years). Follow-up visits consisted of occlusal registration, application of the RDC/TMD protocol, and a questionnaire to record the side effects reported by the patients. When patients referred to TMD-related symptoms, the RDC/TMD protocol was performed again. To evaluate the MAD treatment outcome, polysomnography was repeated close to the time of

**Table 1.** Number (Percentage) of Patients Diagnosed with Temporomandibular Disorders (TMD) for Each Diagnosis Group According to RDC/TMD at Each Checkup

	Baseline			First Checkup (After 14 Mo)			Second Checkup (After 21 Mo)		Third Checkup (After 58 Mo)	
	All Patients	Users at First Checkup	Users at Second Checkup	Users at Third Checkup	Users at First Checkup	Users at Second Checkup	Users at Third Checkup	Users at Second Checkup	Users at Third Checkup	Users at Third Checkup
	N = 40	N = 35	N = 18	N = 15	N = 35	N = 18	N = 15	N = 18	N = 15	N = 15
TMD (any group)	10 (25%)	9 (26%)	3 (17%)	3 (20%)	7 (20%)	2 (11%)	2 (13%)	1 (6%)	1 (7%)	1 (7%)
Group I Myofascial pain	2 (5%)	1 (3%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Group II Disc displacement	7 (18%)	7 (20%)	3 (17%)	3 (20%)	5 (14%)	2 (11%)	2 (13%)	1 (6%)	1 (7%)	1 (7%)
Group III Arthralgia	3 (8%)	3 (9%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

the first checkup for patients wearing the oral appliance during the night. Patients whose polysomnographs showed a lack of response were advised to discontinue MAD use.

During the treatment, patients with technical complications of the MAD and side effects involving the masticatory system were seen by a dentist. The number of additional dental visits, the reason for each extra visit, and the number of MAD repairs in the dental laboratory were recorded. Routine checkups and visits to increase the amount of mandibular advancement were excluded from this analysis.

Occlusal characteristics, TMD prevalence, and subjective side effects data at baseline and at each follow-up were compared using the Wilcoxon test for paired samples.  $P < .05$  was regarded as statistically significant.

## RESULTS

Thirty-one men and nine women were included in the study. The mean age was 54.1 years (SD 8.7; range, 35 to 70). Of these 40 patients, five did not attend the first checkup, four were lost, and another patient was affected by repetitive acrylic breakages on the lateral telescopic attachment of the oral appliance. This patient was included in the technical complications analysis but not in the side effects analysis. Between the first and the second checkup, 17 patients stopped using the MAD, 11 of them because polysomnography showed that it was ineffective, three because of side effects (arthralgia, myofascial pain, or discomfort), and the other three because it was considered that the appliance was no longer necessary, oral cancer, or dental modifications. Between the second and third checkups, three more patients were excluded: one because of multiple breakages, the second because of discomfort, and the third because he lost weight and the MAD was no longer needed. Therefore, 15 patients still used the MAD at the 5-year checkup. The mean mandibular advancement at the

first checkup was 9.4 mm (83% of the maximum protrusion), and an increase in vertical dimension of 9.2 mm was observed at the incisal level.

At baseline, 10 patients were diagnosed with TMD according to the RDC/TMD (Table 1). Of these, three were classified as presenting myofascial pain (group I), seven presented disc displacement with reduction (group II), and two presented arthralgia (group III). Two patients diagnosed as belonging to group II were also diagnosed as belonging to either group I or group III, given that the diagnostic groups were not mutually exclusive. Three of the five patients initially diagnosed as disc displacement with reduction still used the MAD at the 5-year follow-up, and only one of these patients was still diagnosed as disc displacement. Two patients who were initially diagnosed as disc displacement and five initially diagnosed as myofascial pain or arthralgia stopped using the MAD because it was ineffective, rather than as a result of problems with the masticatory system. No significant differences were observed in the prevalence of any TMD diagnosis group before treatment and at each checkup. During advancement of MAD, four patients reported mandibular pain. Three of these cases were diagnosed as arthralgia and the other as myofascial pain. Two of these four patients had not been diagnosed with TMD at baseline.

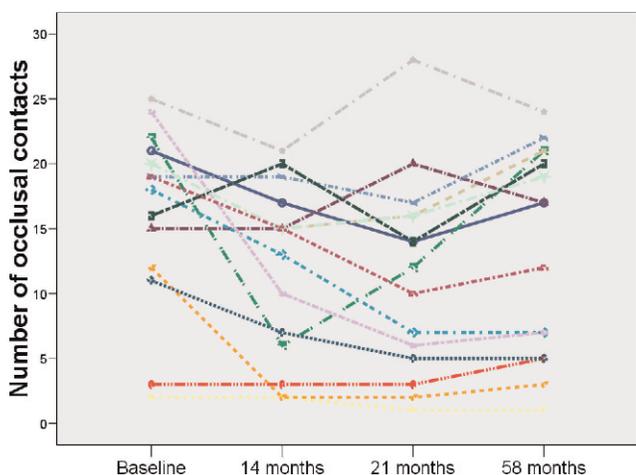
The number of occlusal contacts on the posterior teeth was reduced significantly during the 5 years of MAD treatment, and the greatest reduction was observed at the second checkup (Table 2). No significant differences in occlusal contacts or in the number of teeth in contact in the anterior region were observed during MAD treatment (Figure 1). Overbite and overjet were also significantly reduced during all treatments. Only 9%, 28%, and 33% of patients reported no side effects at the first, second, and last checkups, respectively (Table 3). Four patients stopped using the MAD because of side effects. The percentage of patients who reported tooth discomfort or mucosal irritations was significantly lower at the last checkup than at the first checkup.

**Table 2.** Variations in Occlusal Characteristics (Means ± SDs) in Patients Before Oral Appliance Treatment and at Each Checkup

	Baseline			First Checkup (After 14 Mo)			Second Checkup (After 21 Mo)		Third Checkup (After 58 Mo)	
	Users at First Checkup	Users at Second Checkup	Users at Third Checkup	Users at First Checkup	Users at Second Checkup	Users at Third Checkup	Users at Second Checkup	Users at Third Checkup	Users at Third Checkup	
	N = 40	N = 35	N = 18	N = 35	N = 18	N = 15	N = 18	N = 15	N = 15	
Posterior OC <sup>a</sup>	14.8 (6)	14.1 (6)	16.4 (6)	16.6 (6)	11.6 (7)**	13.1 (7)*	11.7 (7)**	11.5 (8)**	10.7 (8)**	12.7 (8)*
Anterior OC	6.4 (2)	6.5 (2)	6.3 (2)	6.5 (2)	6.5 (2)	6.3 (2)	6.1 (2)	6.8 (2)	6.6 (2)	6.9 (2)
Posterior TIC	6.4 (2)	6.4 (2)	7.1 (2)	7.0 (2)	5.6 (3)*	6.1 (3)*	5.5 (3)**	5.9 (3)*	5.5 (3)**	6.1 (2)
Anterior TIC	5.1 (1)	5.1 (1)	5.2 (1)	5.3 (1)	5.0 (1)	4.9 (1)	4.9 (1)	5.1 (1)	5.1 (1)	5.5 (1)
Overbite (mm)	2.69 (2)	2.71 (2)	3.40 (2)	3.35 (2)	2.20 (2)**	2.82 (2)*	2.77 (2)*	2.83 (2)*	2.63 (2)*	2.54 (3)*
Overjet (mm)	2.87 (2)	2.82 (2)	3.28 (2)	3.07 (2)	1.99 (2)***	2.53 (3)**	2.31 (2)*	2.54 (3)*	2.22 (2)*	1.97 (2)**

<sup>a</sup> OC indicates number of occlusal contacts; TIC, number of teeth in contact.

\**P* < .05; \*\**P* < .01; \*\*\**P* < .001, with respect to the baseline value (Wilcoxon test) for each group of patients.



**Figure 1.** Individual number of occlusal contacts in the posterior teeth (n = 15) at baseline and at each checkup.

Only eight patients did not request an extra visit to the dentist; four of these still used the MAD at the 5-year checkup. During the observational period, the patients made 160 extra visits to the dentist, and 54 appliance

modifications were performed by the dental technician (Table 4). This corresponds to a mean of 2.5 unscheduled dental visits per year and a mean of 0.8 appliance repairs/relines per year by a dental technician. The most frequent unscheduled visits were needed during the first year because of acrylic breakage on the lateral telescopic attachment (Figure 2), poor retention, and other adjustments to improve comfort. Forty appliance repairs (32 because of acrylic breakage and eight relines because of MAD loosening) were made by the dental technician during the first 14 months.

**DISCUSSION**

The results of the present study confirm the reduction of overbite and overjet associated with the use of MAD reported in other long-term follow-up studies.<sup>13,14</sup> Furthermore, the number of posterior occlusal contacts and number of posterior teeth in contact were significantly reduced during the first 2 years of MAD use. However, this tendency reversed during the period of 2 to 5 years of treatment, in

**Table 3.** Number of Patients (Percentage) Who Reported Side Effects Related to the Use of the Oral Appliance at Each Follow-Up

	First Checkup (after 14 Mo)			Second Checkup (after 21 Mo)		Third Checkup (after 58 Mo)
	Users at First Checkup	Users at Second Checkup	Users at Third Checkup	Users at Second Checkup	Users at Third Checkup	Users at Third Checkup
	N = 35	N = 18	N = 15	N = 18	N = 15	N = 15
At least 1 side effect	32 (91%)	16 (89%)	13 (87%)	13 (72%)	10 (67%)	10 (67%)
Dry mouth	15 (43%)	5 (28%)	3 (20%)	5 (28%)	3 (20%)	1 (7%)
Excessive salivation	17 (49%)	11 (61%)	10 (67%)	7 (39%)*	7 (47%)*	8 (53%)
TMJ discomfort or pain	9 (26%)	4 (22%)	4 (27%)	0 (0%)*	0 (0%)*	1 (7%)
Tooth discomfort or pain	16 (46%)	11 (61%)	10 (67%)	7 (39%)	6 (40%)	2 (13%)*
Muscular discomfort	4 (11%)	2 (11%)	2 (13%)	1 (6%)	1 (7%)	2 (13%)
TMJ sounds	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)
Mouth opening limitation	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Bite change	9 (26%)	3 (17%)	2 (13%)	3 (17%)	2 (13%)	1 (7%)
Mucosal irritations	12 (34%)	7 (39%)	6 (40%)	3 (17%)	1 (7%)*	1 (7%)*

\**P* < .05; with respect to the first checkup value (Wilcoxon test) for each group of patients.

**Table 4.** Number of Additional Visits with the Corresponding Reason and the Number of Appliance Repairs During Oral Appliance Treatment

Number of Extra Visits	From Baseline to Last Checkup	Baseline to First Checkup (0–14 Mo)	First to Second Checkup (14–21 Mo)	Second to Third Checkup (21–58 Mo)
	All Patients N = 36	Users at First Checkup N = 36	Users at Second Checkup N = 18	Users at Third Checkup N = 15
Mean time (mo)	34	13.6	10.1	35
Clinical adjustment	14	13	0	1
MAD breakages	96	71	10	15
MAD loosening	22	19	2	1
Side effects, other	28	20	0	8
Total clinical extra visits (extra visits/patient/year)	160 (2.5)	123 (3.0)	12 (0.7)	25 (0.6)
Number of repairs at laboratory (number/patient/year)	54 (0.8)	40 (0.9)	6 (0.4)	8 (0.2)

agreement with another long-term study.<sup>8</sup> It has been reported that the occlusal contact area and bite force of patients were reduced in the first months of wearing MAD.<sup>15</sup> This was also demonstrated in a long-term study.<sup>17</sup> Since bite force and occlusal contact area are the main factors that explain masticatory performance in dentate subjects,<sup>25</sup> and the asymmetry of these factors is related to masticatory laterality,<sup>26</sup> it appears that a reduction in masticatory performance can be expected in these patients. However, a direct relationship between the use of MAD and a worsening of masticatory efficiency is not demonstrated; this could be the subject of further research.

The results of this study suggest that 5 years of MAD treatment did not modify TMD prevalence in OSA patients. This is the first study in which TMD was diagnosed according to the RDC/TMD and classified as myofascial pain, disc displacement, and TMJ arthralgia/arthritis in OSA patients in long-term therapy with MAD. Furthermore, OSA patients initially diagnosed with TMD were not excluded from this study. Although it has been stated that active TMD is a

contraindication for MAD treatment,<sup>27</sup> the results of this study, in agreement with other studies,<sup>9,10,16</sup> suggest that the presence of disc displacement with reduction in the TMJ may not be a contraindication to treatment with a MAD. Furthermore, it has been found by means of magnetic resonance imaging that MAD appears to be innocuous to the TMJ in OSA patients, even in those with anterior disc displacement with or without reduction.<sup>28</sup> The onset of arthrogenous or myogenous pain during advancement of MAD does not seem to be related to the presence of TMD before treatment.

We observed that MAD breakages, mainly on the lateral telescopic attachment, were the most frequent reason for seeking an unscheduled visit to the dentist. Such complications could be explained by errors made by the technician, maladjustments made by the dentist, and functional overload caused by nocturnal bruxism. These complications not only led to discontinuation of the use of MAD in two patients but also increased the cost of treatment and delayed effective treatment for OSA. Therefore, technicians and dentists should make the maximum effort to give patients the most comfortable and robust appliance. Although many studies have been published about the efficacy and side effects of MAD therapy, only a few reports have dealt with technical failure and the maintenance costs of these devices.<sup>4,11,18,20–22</sup> In a previous study, 60% of subjects had experienced Herbst breakage and 40% received a replacement appliance after 3.6 years of treatment.<sup>11</sup> When a monoblock MAD was used, technical complications were reported infrequently during the first year of treatment.<sup>18</sup> However, six of nineteen patients had their monoblock device replaced by a new one in a 5-year follow-up study.<sup>20</sup> Monoblock devices could be more robust and cost effective, but an adjustable appliance allows the mandible to be protruded incrementally and permits a degree of side-to-side, protrusion, and opening movement of the mandible.

**Figure 2.** Acrylic breakage on the lateral telescopic attachment.

The present study has several limitations. First, no control group was used, and a cause-and-effect relationship between the results of the present study and the use of MAD should be assumed with caution. Furthermore, we cannot know whether some adverse effects were related to the use of an intraoral appliance and/or to fact that the jaw was protruded for 6 to 8 hours per day. Second, the sample size might not have been large enough to find significant comparisons or relationships, such as in the prevalence of TMD.

## CONCLUSIONS

- In most OSA patients, 5-year oral appliance treatment is associated with mild, temporary subjective side effects and permanent occlusal changes mainly during the first 2 years.
- The use of the oral appliance does not affect TMD prevalence.
- Patients often seek several unscheduled visits, mainly because of technical complications.

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