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ORIGINAL ARTICLE

Systematic assessment of the impact of oral appliance therapy on the temporomandibular joint during treatment of obstructive sleep apnea: long-term evaluation

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Abstract
Objective The aim of the present study was to evaluate the symptoms of temporomandibular dysfunction (TMD) in patients with obstructive sleep apnea treated with long-term use of an oral appliance (OA) using a questionnaire based on the Helkimo Anamnestic Dysfunction Index. A further aim of the study was to evaluate the presence of daytime sleepiness using the Epworth Sleep Scale (ESS) and otologic symptoms.
Materials and methods Polysomnograms of 34 patients were performed at baseline and after 6 months of OA use. As follow-up, the patients were contacted by telephone interview to answer the same questionnaires after 36.0± 17.0 months.
Results and discussion The intensity of TMD symptoms decreased significantly throughout treatment ($p<0.01$). ESS values improved from 12.2±5.0 to 6.9±2.6 ($p\leq0.05$). Tinnitus was present in nine patients at baseline and decreased in intensity in seven patients by the final assessment while remaining at the same level in two patients.
Conclusions We conclude that long-term usage of an OA does not cause impairment to the temporomandibular joint. The Helkimo and otologic indexes are simple and useful in long-term patient follow-up. There was a long-term improvement in the ESS values over the years analyzed. A follow-up program could increase compliance by motivating patients to use the device regularly.

Keywords Oral appliance · Temporomandibular joint · Temporomandibular disorder · Sleepiness · Quality of life

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Introduction

An oral appliance (OA) is accepted as long-term therapy for obstructive sleep apnea (OSA) [1]. Patients should wear an OA for as long as they have sleep apnea, which is probably for the rest of their lives. An OA therapy is preferred because it is more comfortable than a continuous positive airway pressure (CPAP) as well as simpler to use and the efficacy of therapy, although lower than CPAP therapy, has been proven acceptable in the current literature [2–6]. There are studies assessing the long-term side effects of an adjustable mandibular repositioning appliance (OA) [7–18], but few have assessed the long-term impact of OA use [15–18].

It has been described that patients fitted with OA may develop symptoms such as excessive salivation, tooth discomfort, and pain in facial muscles or in the temporo-

mandibular joint (TMJ) during the first 6 months of treatment [7, 14, 19]. Long-term follow-up studies with OA are scarce, and there are a few studies addressing the correlation between OA usage and symptoms in the TMJ. To our knowledge, there has been only one study suggesting joint remodeling as a result of the forward displacement of the mandible [9]. In contrast to this study, Almeida and collaborators, using magnetic resonance and cephalometry, found that OA usage did not alter the position of the TMJ [15, 18]. Noises in the TMJ, tinnitus, and plugged ears often occur in individuals, and pain may sometimes occur as well. Temporomandibular disorder or dysfunction (TMD) refers to a group of disorders affecting the TMJ, masticatory muscles, and associated structures. These disorders share symptoms such as facial muscle pain, masticatory muscle fatigue, restricted jaw function, and joint noises [20–22]. Ear symptoms such as otalgia, tinnitus, vertigo, plugged ears, and hypo/hyperacusis may also occur due to the close anatomical relationship between the TMJ and ear structures [22, 23]. Epidemiological findings reveal that the prevalence of ear symptoms in the general population ranges from 10% to 31% but reaches as high as 85% in patients with TMD [23, 24]. McGown et al. found that even patients reporting symptoms related to the TMJ continued using an OA [25]. Petit and collaborators investigated contraindication factors in OA users, such as an insufficient number of teeth in each arch, untreated periodontal disease, substantial tooth mobility, or active TMJ conflict, and found that only two of every hundred patients who use an OA exhibited an active TMJ disorder [26]. Almeida and collaborators investigated the side effects among patients using an OA for more than 5 years and found that, compared to nonusers, the users experienced fewer side effects, such as morning headaches and jaw discomfort [27]. Thus, clinicians often question the impairment that an OA may cause to TMJ function due to the forward displacement of the mandible during OA usage. A detailed evaluation of the TMJ and related structures before OA treatment is necessary in order to record symptoms present at baseline. The aims of the present study were to assess the presence of TMD symptoms in patients with OSA treated with the long-term use of an adjustable mandibular repositioning appliance through a validated questionnaire based on the Helkimo Anamnestic Dysfunction Index, determine the presence of subjective symptoms using the Epworth Sleep Scale (ESS), and determine the presence of otologic symptoms using an additional questionnaire.

Materials and methods

A prospective consecutive study was carried out on 42 patients with sleep apnea and no co-morbidities, who were fitted with an OA between 2001 and 2008, with a minimum of 1 year of OA use. There were six patients who presented rhinitis in the baseline assessment. At their first appointment, dental/medical anamnesis and clinical evaluations were carried out. TMD symptoms were assessed using the Helkimo Anamnestic Dysfunction Index (Ai); otological symptoms and subjective symptoms were evaluated using questionnaires administered before treatment and at follow-up. The diagnosis and the degree of severity of OSA were established by a polysomnogram (PSG) before treatment, and the efficacy of OA therapy was confirmed through a PSG performed after 6 months of OA wear. The Univap Ethics Committee approved this study (protocol number H285/CEP/2001), and all patients gave their informed consent. Patients with diagnosed OSA were included in the study. OSA was defined by apnea/hypopnea index (AHI)≥5 associated with subjective daytime symptoms. Subjective daytime hypersomnolence was evaluated using the ESS [28]. Inclusion criteria consisted a minimum of eight to ten teeth in each arch for proper fitting of the OA. The appliance fitted on all patients was the adjustable PMPositioner®, which allows gradual protrusion of the mandible. A single dentist treated all patients, and a single dental technician was responsible for manufacturing the appliances. Patients who gave convincing assurance that the device had been used at least four nights per week over the previous year were included in the study. Patients were excluded if they presented active dental or periodontal disease and/or severe TMD or bruxism at the time of the baseline investigation [29]. Severe TMD symptoms were identified by pain in the TMJ region or during any mandible movements and difficulty to open the mouth wide, which do not allow the use of OA. Severe bruxism raises the probability of appliance damage, and therefore it was part of the exclusion criteria of the present study. Before treatment, all patients responded to a questionnaire based on the Helkimo Anamnestic Dysfunction Index, the ESS, and an otologic index questionnaire, which were administered by a single experienced sleep dentist. The PSG was performed in a single sleep laboratory performed using a Somnologica Studio-Embla A10, versão 3.1.2. (Islândia: Flaga hf. Medical devices) record device. A standard monitoring level 1 with ambulatorial system sleep study composed of 16 channels was utilized, and the results of the physiological variables were recorded. At follow-up, patients were contacted by telephone to answer the questionnaires in interview format carried out by the same dental sleep dentist who had administered the pre-treatment questionnaire. The interview approach was chosen because, if any patient had difficulty comprehending a question, the researcher could provide a detailed explanation, thereby avoiding misunderstandings. The questionnaires (the same set administered before treat-

ment) assessed the usage, the long-term impact of OA on the TMJ (Helkimo Anamnestic Dysfunction Index) [20], and the presence of tinnitus/plugged ears and subjective symptoms, such as excessive daytime sleepiness and memory lapses. The Helkimo Anamnestic Index classifies patients into three groups according to TMD symptoms. Patients were classified as follows: anamnestic index grade zero (Ai0) when there were no symptoms; anamnestic index grade I (AiI), representing mild TMD, when one or more symptoms were present, such as TMJ joint noises, jaw fatigue, and jaw stiffness upon awakening or in movements of the lower jaw; and anamnestic index grade II (AiII), moderate to severe TMD, when there were difficulties in opening the mouth wide, pain during movement of the mandible, and pain in the region of the TMJ or masticatory musculature. For each question, the answer was scored according to the intensity of the symptoms as never (0), rarely (1), sometimes (2), or often (3). The same proceeding was carried out for the questionnaire on tinnitus and plugged ears. To assess subjective sleepiness, the ESS was administered before treatment and at follow-up assessment. The Student's *t* test was used to assess statistically significant changes in measurements before and after long-term OA treatment. Correlations (*r*) were determined using either Pearson's correlation coefficient or Spearman's correlation coefficient for non-parametric variables. Data are expressed as mean ± standard deviation. A p value of <0.05 was considered significant.

Results

Initially, 42 patients were selected for the study. Three patients were excluded due to lack of OA compliance. One patient stopped using the OA due to muscle pain after more than 1 year of OA usage and therefore could not be included in the analysis. Patients included in the study were currently using their OA at four or more nights a week and had been doing so for more than 1 year. Five patients did not undergo a second PSG with the appliance in situ, stating that they were feeling well and there was no claim of snoring from their spouses. Since we could not evaluate if the amount of mandibular protrusion was effective, we have excluded them from this study. The final sample consisted of 34 consecutively selected patients (nine women and 25 men), with a mean age of 49.0±12.0 years and body mass index of 26.1±3.35 kg/m^2 (Table 1). All patients received the same device for OSA, and the titration reached the optimal anteroposterior mandibular position (9.6±0.3 mm). The greatest interincisal distance achieved was 6 mm. Twenty patients reported bruxism (51%), and its clinical characteristics were identified [29]. Among these, 50% had no TMD symptoms. The mean period of OA usage was 36.0±17.0 months (range, 12 to 72 months). All patients underwent PSG and responded to the ESS, Helkimo Anamnestic Dysfunction Index, and otologic questionnaires. All 34 subjects underwent a second sleep study to evaluate the efficacy of the OA therapy. The mean AHI of the 34 patients was 17.5±10.28 before treatment and 5.1±4.6 after 6 months of OA usage. According to the reports of the patients and their partners, snoring and subjective symptoms were significantly reduced. Thirty-one patients experienced short-term side effects, such as excessive salivation, occlusal changes, and tooth and TMJ discomforts, which lasted for the first 2 months. Only two patients reported TMJ discomfort lasting for the first 6 months. At follow-up assessment, all patients reported being satisfied with the therapy. One patient reported an occlusal change in the posterior region. No patient reported an increase in TMD symptoms and otological symptoms (present at baseline) throughout the study period. In fact, the patients reported that such symptoms had decreased. Due to the fact that the side effects had disappeared between 2 and 6 months, it was determined that there were no long-term symptoms and, therefore, no possibility to determine correlations between side effects and long-term usage.

Table 1 Demographic and PSG findings in all 34 patients at baseline and follow-up

	Baseline	Follow-up
Age	49±12	51.5±11.81
Gender	33 men/9 women	30 men/9 women
BMI	26.1±3.35	26.3±3.42
ESS	11.9±5.0	6.9±2.5*
AHI	17.5±10.28	5.1±4.66*
%REM	18.3±5.14	20.3±4.81*
$MinO_2$	81.1±7.90	88.0±5.28*

BMI body mass index, *ESS* Epworth Sleep Scale, *AHI* apnea/hypopnea index, *REM* rapid eye movement, *$MinO_2$* minimal oxyhemoglobin saturation

*$P<0.05$

Helkimo Anamnestic Dysfunction Index findings

The results of the Helkimo Anamnestic Dysfunction Index revealed significant differences in symptoms between evaluations. At baseline, index values were Ai0 in 19 patients (55.0%) and AiI in 15 patients (45.0%), and there was no patient with an AiII. Twelve patients exhibited joint noises, 12 had jaw fatigue, and none reported jaw stiffness upon awakening or during movements of lower jaw. At follow-up assessment, these index values were Ai0 in 24 patients (71.0%), AiI in ten (29.0%), and none with AiII

(Fig. 1). Three patients who had initiated OA therapy in 2004 and 2005 reported that the TMJ noises had disappeared; three patients exhibited decreased intensity in TMJ noises from "often" to "rarely," and only one reported often experiencing TMJ noises at the time of the follow-up assessment (Fig. 2). Two patients reported "rarely" experiencing jaw fatigue after long-term OA usage (Fig. 3). None reported jaw stiffness upon awakening or during movements of lower jaw. No patient reported TMJ pain. The paired Student's t test revealed statistically significant difference between evaluation times ($p \leq 0.05$) of TMJ noises and fatigue. This result was confirmed by the nonparametric Spearman correlation coefficient ($r = 0.7263$; $p < 0.0001$) for both TMJ noises and jaw fatigue.

ESS findings

The mean ESS of the 34 patients was reduced from 12.55±5.0 to 6.9±2.5 ($p \leq 0.05$). The patients reported that improvements in daytime somnolence, snoring, and witnessed apnea have prolonged over the years. This information was based on their partners' reports. There was, however, a weak correlation ($r = 0.3266$; $p < 0.05$) between changes in ESS scores and changes in the AHI post-treatment. The correlation between the amount of forward displacement of mandible and ESS at follow-up assessment was $r = -0.003$.

Otology index

A total of 52.0% experienced plugged ears before treatment, and only three patients (7%) still reported "rarely" experiencing plugged ears after treatment. The unpaired Student's t test revealed a statistically significant decrease in plugged ears in all 34 patients; this finding was confirmed by the Mann–Whitney test for nonparametric variables. Fifty percent of patients exhibited tinnitus in variable intensity before treatment, and at follow-up assessment only 30% reported "rarely" experiencing tinnitus. A significant decrease in tinnitus occurred between the pre-treatment and follow-up assessment, which was demonstrated by the paired Student's t test and confirmed by the Wilcoxon test ($p < 0.0001$). Concerning usage, 20 patients (59.0%) used the OA seven nights/week; three (8.0%) used it six nights/week; four (12.0%) used it five nights/week; and eight (21.0%) used it four nights/week. Table 2 displays the pre-treatment and long-term OA usage scores for all TMD and otologic symptoms in all 34 patients.

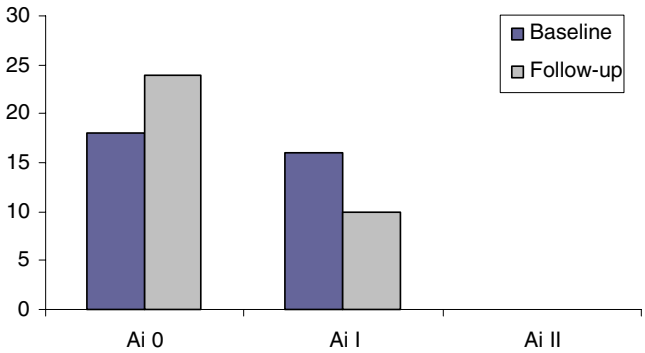

Fig. 1 Helkimo Anamnestic Dysfunction Index at baseline and follow-up: *Ai0* no TMD, *AiI* mild to moderate TMD, *AiII* severe TMD

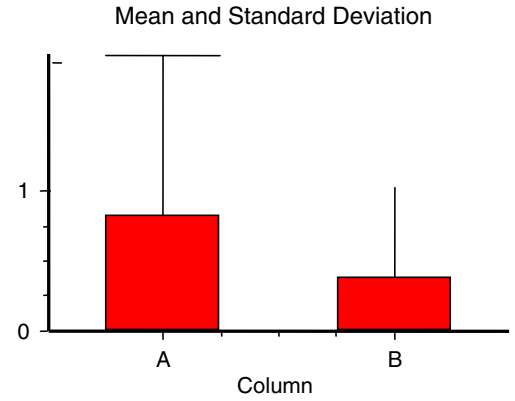

Fig. 2 Reduction in the intensity of TMJ noises over the years: **a** TMJ noises at pre-treatment=0.72±1.0; **b** TMJ noises at long-term evaluation=0.37±0.63 ($p < 0.05$)

Discussion

In this study, we demonstrated that the intensity of TMD symptoms decreased significantly during OA therapy ($p < 0.01$); in addition, tinnitus decreased in intensity in seven patients with the use of an OA. No patient needed occlusal splint therapy in order to reduce the TMJ symptoms due to OA use [30]. Long-term usage of an OA did not cause

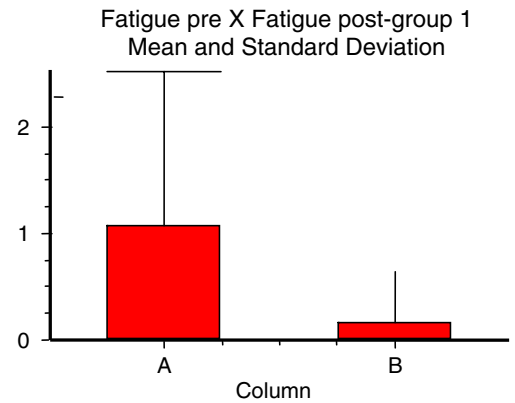

Fig. 3 Reduction in jaw fatigue over the years: **a** pre-treatment jaw fatigue=1.05±1.4; **b** jaw fatigue at long-term evaluation=0.10±0.4 ($p < 0.05$)

Table 2 TMD symptoms in all 34 patients before treatment and after long-term OA use

	Baseline				Follow-up			
TMD symptoms	N	R	ST	O	N	R	ST	O
TMJ noises	22	4	4	4	25	8	0	1
Jaw fatigue	22	0	1	11	32	2	0	0
TMD (stiffness, locking, luxation, pain)	0	0	0	0	0	0	0	0
Tinnitus	17	3	8	6	24	10	0	0
Plugged ears	17	4	12	1	31	3	0	0

TMD temporomandibular disorders, *TMJ* temporomandibular joint, *N* never, *R* rarely, *ST* sometimes, *O* often

impairment to the TMJ. Among studies on the long-term side effects of OA usage for the treatment of OSA, TMJ symptoms are usually cited (but not detailed) in terms of intensity before treatment and evolution over the years of OA usage. Only one study evaluated TMD symptoms but in a short-term period [19]. In a randomized 4-year follow-up study, OA usage was compared to upper airway surgery, and the results revealed that OA usage had few adverse effects on the TMJ [13]. In the present study, TMJ noises (clicking sounds) were present in 12 patients before treatment and decreased over the years; no patient reported TMJ crepitation. Jaw noises were only "rarely" experienced among the majority of individuals. Three patients reported that the clicking sounds present at baseline had disappeared. Fatigue at baseline was present in 12 patients (35%), and at final assessment only two exhibited this symptom. A previous study also found the disappearance of TMD symptoms in a patient that had used an OA for 6 months [13]. McGown et al. administered a questionnaire to evaluate the long-term use of OA in the treatment of OSA and found side effects presenting every night, including excessive salivation, altered bite, sleep disturbance, and TMJ pain, with the latter symptom present in nearly 50% of patients [25]. In contrast, the present study found that patients had no joint discomfort or pain after 6 months of PMPositionner® OA usage to the final assessment. Other studies agree that TMJ discomfort/pain is not common in long-term OA usage [13]. Rose et al. [14] analyzed dental casts and lateral cephalograms of 34 patients to evaluate occlusion and craniofacial changes during a period of 29.6±5.1 months [14]. The authors found important occlusal changes in various degrees, but OA did not cause impairment to the TMJ. Studies using cephalograms and magnetic resonance have shown no change in TMJ position and no observable remodeling of the TMJ during years of OA usage for the treatment of OSA [14, 15, 18]. It is, however, possible that the displacement of the mandible is too minor for detection. It remains speculative as to what extent changes occur in the glenoid fossa. Precise examination techniques are necessary in order to assess this possibility. When considering the treatment of OSA with OA, one must bear in mind that, in order to achieve treatment success, the mandible must be advanced, and this procedure may have a direct effect on the TMJ. Symptoms may appear in different degrees in different individuals. Due to this delicate TMJ/masticatory muscle proprioception, TMJ symptoms and tinnitus/plugged ears were classified and scored according to their intensity. Regarding the ear symptoms, plugged ears affected 17 patients (50.0%) before treatment, whereas only three patients (8%) still reported "rarely" experiencing this symptom at follow-up ($p \leq 0.05$). Tinnitus also decreased during the follow-up period ($p \leq 0.05$). Among the 17 patients who presented this symptom at baseline, ten patients reported in the follow-up assessment that it appeared "rarely", stating that it mostly occurred in stressful situations. Five patients who reported frequent tinnitus before OA usage indicated that the symptom had disappeared by the time of follow-up assessment. We hypothesize that the ear symptoms decreased due to condyle displacement caused by the minimal increase in the vertical dimension induced by the OA, thereby allowing decompression of TMJ region and related structures, as the muscles of the middle ear are closely related to the masticatory muscles [22]. Even though patients know about the possibility of such side effects, they prefer using an OA over a CPAP [13, 31, 32]. There are a large number of studies demonstrating that OAs are accepted as long-term therapy due to their efficacy [1, 33–36]. The present study corroborates the literature, as AHI was reduced from 17.5± 10.28 to 5.1±4.6 in our patients. Daytime sleepiness was measured using the ESS questionnaire. A significant decrease in the ESS score was found between baseline and final evaluation. At 3-year follow-up, patients were satisfied with the results of OA treatment regarding daytime somnolence, snoring, and witnessed apnea. These results are similar to those described in a paper published on ESS scores following CPAP usage [36]. There was, however, a weak correlation ($r=0.3266$; $p<0.05$) between changes in ESS score and changes in the AHI. Similar results were found in a previous study using a non-adjustable OA [19]. One shortcoming of that study and other related studies is the lack of an objective method for determining the amount of hours the OA was used by patients. Since compliance can be monitored only subjectively, we believe that further accurate evaluation methods for OA compliance should be

developed. The mean period of OA usage was 36.0± 17.0 months (range, 12 to 72 months). Patients reported wearing the appliance at least four nights a week; indeed, the majority of patients (61.7%) reported wearing the OA the entire night for seven nights a week. In a randomized study on a 4-year follow-up of treatment with OA, Walker-Engström et al. [13] found that all patients still regularly used their device at least five nights a week. Other papers have also found that most patients report the continued use of their OA following long-term treatment [14, 18]. The Helkimo index is widely used and accepted for the evaluation of articular/muscular status. Our results showed that TMD and otological symptoms have decreased in the period of the study, probably implying that the muscular/articular function was not impaired due to OA usage.

Conclusions

We conclude that the long-term OA usage did not aggravate the TMD symptoms. On the contrary, TMD symptoms lessened and use of OA most certainly did not cause impairment to the TMJ in patients with OSA presenting mild TMD symptoms. Otological symptoms have also reduced during the period of this study. According to reports of the patients and their partners, there was sustained improvement in subjective symptoms, such as excessive somnolence, over the years of OA usage. A follow-up program motivates patients to use the device regularly and allows evaluating the efficacy of treatment.

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