

# Influence on the masticatory system in treatment of obstructive sleep apnea and snoring with a mandibular protruding device: A 2-year follow-up

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The aim was to identify the incidence and types of possible adverse events in the masticatory system after treatment with a mandibular protruding device (MPD) during a 2-year period in patients with obstructive sleep apnea (OSA) or snoring. The subjects comprised 65 middle-aged patients (44 OSA patients, 21 snorers). A clinical examination and a questionnaire concerning signs and symptoms from the masticatory system were performed before, after 6 months, and after 2 years of MPD use. The frequencies of registered signs from the masticatory system, such as muscle and joint tenderness, palpation, and pain during mandibular movement, decreased significantly between baseline and the 2-year follow-up. There were significant changes in the mandibular range of protrusion (+0.7 mm,  $P < .001$ ), overjet (-0.5 mm,  $P < .001$ ), and overbite (-0.6 mm,  $P < .001$ ) compared with the initial examination. Nine patients developed a lateral open bite during treatment, and 2 of them experienced subjective symptoms related to the altered occlusion but still used the MPD every night. No patient reported pain on opening the mouth wide or during jaw movements. Two reported tiredness on jaw function. The reported frequency of headaches was also significantly reduced ( $P < .01$ ). The high compliance rate in MPD use showed that the therapy is well tolerated, but there is a risk of minor alterations in the occlusion during MPD treatment. (*Am J Orthod Dentofacial Orthop* 2004;126:687-93)

**T**he general aim of all treatment modalities in sleep-breathing disorders is to facilitate breathing and thereby reduce the risk of increased morbidity. Protruding the mandible with an oral appliance during sleep will open the airway<sup>1</sup> from a lateral view and activate the muscles, thereby making breathing easier in patients with obstructive sleep apnea (OSA) or snoring. The somnographic 2-year follow-up

results have previously been reported elsewhere.<sup>2</sup> The main results of treatment with a mandibular protruding device (MPD) were that more than 80% of the OSA patients normalized their oxygen desaturation index values (reduced 50% or more from baseline values), and the snorers maintained their initial healthy values. Ninety percent of the patients reported subjective reductions of snoring and apnea (reduced 50% or more from baseline values).

Up to 2 years, the proportion of patients with occlusal changes increased with the time of use of the oral appliance, according to Pantin et al.<sup>3</sup> Tegelberg et al<sup>4</sup> reported few adverse events affecting the masticatory system and dental occlusion after 1 year of treatment with a dental appliance. Cephalometric reports of long-term consequences, such as proclination of the mandibular incisors and a mandibular posterior rotation, have previously been reported on this material,<sup>5</sup> and the results agreed with another recently published study.<sup>6</sup>

A few reports have also appeared on the long-term consequences related to the dental occlusion, the masticatory muscles, and the temporomandibular joints (TMJ).<sup>3,7,8</sup>

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This study was supported by grants from Örebro County Council and the Swedish Dental Society.

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Submitted, June 2003; revised and accepted, October 2003.

0889-5406/\$30.00

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doi:10.1016/j.ajodo.2003.10.040

The design of the MPD resembles in part Herbst appliances or activators, used for orthodontic treatment of Class II malocclusions. With a Herbst appliance, the mandible is held continuously in an anterior position for 3 to 6 months, in contrast to the MPD, which holds the mandible in the protruded position only during sleep. No adverse long-term effects in the TMJ have been recorded with Herbst appliances in young orthodontic patients,<sup>9,10</sup> but the appliance can alter the occlusion, primarily a dentoalveolar effect. Activators are often open laterally in the lower part to allow the mandibular teeth to move anteriorly in contrast to the MPD, which has a full occlusal cover of the teeth to prevent tooth movements.

Our hypothesis is that MPD treatment will be successful and the first choice of treatment for a wider set of patients.<sup>2,11</sup> One reason that this has not been fully implemented is the fear of side effects (occlusal changes, joint pain, joint locking).<sup>12,13</sup>

The aim of this study was to identify the incidence and types of adverse events in the masticatory system after treatment with MPDs in patients with OSA and snoring.

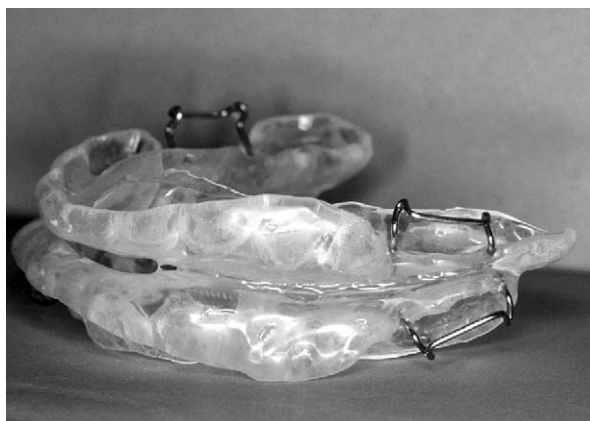
#### MATERIAL AND METHODS

The study sample comprised 77 consecutive patients (63 men, 14 women) referred to the Department of Stomatognathic Physiology at the Postgraduate Dental Education Center from the University Hospital, Örebro, Sweden, with a diagnosis of OSA ( $n = 50$ ) or snoring without apnea ( $n = 27$ ). The inclusion criteria were complaints of snoring or a medical diagnosis of OSA and enough teeth to retain the MPD. The exclusion criteria were a severely compromised dentition and a maximum mandibular protrusion capacity of less than 6 mm, measured with a George gauge (Peter T. George, Honolulu, Hawaii).<sup>14</sup>

All patients signed informed consent forms and agreed to participate in the study. Approval for the study was obtained from the Medical Ethics Committee at Örebro University Hospital. Before the MPD intervention, all patients underwent a 1-night somnographic registration at a hospital, previously described in detail.<sup>11</sup> In addition, clinical examinations of the masticatory system were performed, and each patient answered a questionnaire.

Follow-ups were made 6 months and 2 years after the MPD treatment by using the same clinical examination protocols and questionnaires.

The MPD was made as a monobloc with a heat-cured methyl methacrylate resin (Microdent, Forshaga, Sweden) (Fig). The maxillary and mandibular segments of the MPD provided full occlusal coverage of the teeth and



**Fig.** Mandibular protruding device (MPD).

were designed to prevent tooth movement and minimize tongue pressure to the teeth. To increase the retention of the device, 4 Adams clasps gripped the maxillary and mandibular first molars bilaterally. A vertical opening between the maxillary and mandibular portions of the device in the anterior region allowed the patient to breathe through the mouth. The vertical height of the MPD was made as low as possible so that the mandibular incisors could just pass the maxillary incisors.

The MPD was constructed with the mandible in an intended advanced position of 75% of the maximum protrusive capacity, as measured with the George gauge, which was used to make an interocclusal record of the anterior and vertical positions of the mandible.<sup>15</sup> After the MPD was fabricated, the actual amount of mandibular advancement with the MPD was measured with a ruler, and overjet and overbite were also rechecked.<sup>15</sup> The patients were instructed to use the MPD every night during sleep.

During the examination, the following parameters were assessed: mandibular mobility, tenderness to palpation of the TMJ and the masticatory muscles, TMJ function, and pain on mandibular movement; the examination included a morphological functional assessment of the dental occlusion comprising classification of the mandibular-maxillary sagittal (Angle Class I, II, or III) and frontal relationships (normal, open, edge-to-edge, or deep bite [where the mandibular incisal edges had to make contact in the fourth quarter of the palatal surface of the maxillary central incisors as a minimum]).

Lateral open bite was recorded with a 12- $\mu$ m occlusion foil (Hanel, Roekeo, Langenau, Germany). A lateral open bite was defined as no occlusal contact with the foil in the premolar and molar regions in the intercuspatal position.

Overjet was determined with a steel ruler as the distance from the buccal surface of the mandibular right incisor to the buccal side of the maxillary right incisor edge. Overbite was measured in the right incisor region as the distance from the incisal edge of the maxillary incisor marked on the buccal surface of the mandibular incisor to the incisal edge of the mandibular incisor. The measurement was determined to the nearest half millimeter.<sup>15</sup>

The mandibular range of mobility was recorded as follows: the patient was asked to move his or her jaw into positions of maximum opening, protrusion, and laterotrusion (right/left) and to report any pain during the movements. The maximum mandibular movement capacities were registered with a steel ruler (in millimeters), and further assessment of the TMJ included sounds (crepitation and clicking). Tenderness to bilateral digital palpation of the TMJ and the masticatory muscles (temporal, masseter, insertion of the temporal, and complex of the pterygoid) were assessed as present or not.

At baseline, a masticatory-function questionnaire of 10 questions was given to the participants, in which the frequency of the functional disturbances of the masticatory system was noted. The follow-up questionnaire comprised 9 of the initial 10 questions, permitting evaluation of changes in symptoms after nocturnal use of the MPD and recording of adverse events. A question about the frequency of MPD usage was added. This was estimated by the question "how often did you use the appliance?" with the following predefined reply alternatives: never, once or twice a month, once a week, several times a week, or every night.

At the 2 follow-ups, the patients ranked their experiences of the MPD on a 0-10 graded Likert scale as "a foreign object in the mouth" where 0 was "no problem" and 10 was "worst problem imaginable."

Three questions concerning headache, jaw tiredness, and locking of the jaw had 6 predefined reply alternatives about the frequency of symptoms: never, once or twice a month, once a week, several times a week, every day/night, and don't know. Seven questions about functional disturbances of the TMJ, the masticatory muscles, and the dental occlusion had 3 predefined reply alternatives: yes, no, and don't know.

All patients ( $n = 65$ ) answered the question about their own feelings of occlusion at baseline and at the 2-year follow-up ( $n = 64$ ).

### Statistics

The arithmetic mean and standard deviation (SD) were calculated for each continuous variable. For the questionnaire responses, except the question ranked on

the Likert scale, only the frequencies were reported. Tests for statistical significance were performed with a paired-sample Student *t* test. The McNemar test was used when the data was dichotomous. The Wilcoxon signed rank test was used to evaluate the long-term follow-ups on signs and symptoms from the masticatory system, with and without the MPD. *P* values less than .05 were considered significant.

The replies with 6 predefined alternatives were dichotomized into 2 groups, a group consisting of the alternatives "never," "once or twice a month," and "once a week," and another group consisting of the alternatives "several times a week" and "every day/night." Answers of "don't know" were classified as missing data.

The MPD advancement of the mandible was, at the 2-year follow-up, divided into 3 advancement groups: less than 5 mm, greater than or equal to 5 and less than 7 mm, and greater than or equal to 7 mm, to classify each patient and permit comparing the differences between the outcome of adverse events in relation to the amount of advancement.

### RESULTS

Twelve patients did not attend the 2-year follow-up and were excluded in the analysis<sup>5</sup>; 65 patients (44 OSA, 21 snorers) remained for clinical assessment (mean age, 55 years; range, 31-73 years), and 52 of them answered the masticatory-function questionnaire. There were no significant differences between the 13 patients who did not answer the questionnaire and the 52 patients who did regarding age, body mass index, or muscle tenderness. According to the protocol, 65 patients had at baseline a body mass index (weight/height<sup>2</sup>) of on average 29.2 (range, 21-38, SD 3.6) and a neck circumference of 41.7 cm (range, 34-51.5 cm, SD 3.3).

Fifty-five patients (85%) used the MPD every night at the 2-year follow-up; another 5 (8%) used it several times a week; 1 used it once a week and 4 less often. The patients' feelings of the MPD as a "foreign object in the mouth" were that it was a small problem. The average value was 1.9 (range, 0-8) on a 0-10 Likert scale. More than 84% graded it 3 or lower.

### Clinical protocol

At baseline according to Angle's classification, 50 patients had Class I relationships, 11 were Class II Division 1, 1 was Class II Division 2, and 3 were Class III. The frontal relationships were normal in 52 patients; 3 had open bites, 5 had deep bites, and 5 had edge-to-edge bites.

There were significant changes between baseline

**Table I.** Mandibular range of mobility, overjet, and overbite (mm) measured at baseline and 6-month (n = 64) and 2-year follow-ups (n = 65)

	Baseline	6-month follow-up		2-year follow-up	
	Mean (SD)	Mean (SD)	Difference from baseline P*	Mean (SD)	Difference from baseline P*
Maximum mouth opening	48.5 (7.2)	49.3 (7.6)	.010	49.7 (6.9)	.003
Maximum protrusion	9.6 (2.1)	10.4 (2.1)	<.001	10.3 (2.1)	<.001
Overjet	3.7 (2.4)	3.3 (2.3)	<.001	3.2 (2.5)	<.001
Overbite	3.2 (2.0)	3.0 (2.0)	.040	2.6 (2.1)	<.001

\*Paired samples *t* test; SD, standard deviation.

**Table II.** Clinical signs in masticatory system at baseline and 6-month and 2-year follow-ups (n = 65)

Clinical signs	Baseline	6-month follow-up		2-year follow-up	
	n (%)	n (%)	Difference from baseline P*	n (%)	Difference from baseline P*
Pain during mandibular movement	10 (15%)	10 (15%)	1.000 (ns)	2 (3%)	.011
TMJ and masticatory muscles (1 or several) tenderness	12 (18.5%)	10 (15%)	.564 (ns)	1 (1.5%)	.002
TMJ crepitation	6 (9%)	6 (9%)	1.000 (ns)	5 (7.5%)	.655 (ns)
TMJ clicking	13 (20%)	9 (14%)	.206 (ns)	7 (11%)	.058 (ns)

\*Wilcoxon signed rank test; TMJ, temporomandibular joint; ns, not significant.

and the 6-month and 2-year follow-ups in the maximum range of protrusion and mouth opening, but the range of laterotrusion remained unchanged. Overjet and overbite gradually decreased significantly between baseline and the 2-year follow-up (Table I).

None of the 65 patients had a lateral open bite before treatment; 2 patients (3%) (not significant) at the 6-month follow-up and 9 (14%) regular users of the MPD (8 OSA, 1 snorer; 6 men, 3 women) at the 2-year follow-up ( $P = .003$ ) were found to have such a bite (unilateral [ $n = 5$ ] or bilateral [ $n = 4$ ]). Of these patients, 8 had Class I occlusions, and 1 had a Class II Division 1 occlusion before treatment; 7 patients had normal frontal relationships, 1 had an open bite, and 1 had a deep bite.

On average ( $n = 65$ ), the mandibular advancement with the MPD in place was 6.6 mm (SD 1.6; range, 3.5-11.0).<sup>15</sup> At the 2-year follow-up, five patients had lateral open bites after creating mandibular advancements of  $\geq 5$  to  $< 7$  mm with the MPD, and 4 patients had lateral open bites after creating an advancement of greater than or equal to 7 mm, but no patients with a smaller advancement ( $< 5$  mm) experienced this adverse event. All 9 patients who had established lateral open bites at the 2-year follow-up used their MPDs every night. Their mandibular advancement with the MPD, on average, was no greater than that of the others.

At baseline, 22 of the 65 participants (34%) clinically had at least 1 TMJ sign, such as clicking or crepitation (17), or tenderness to palpation (12). At the 2-year follow-up, a significant reduction in pain during mandibular movements ( $P < .02$ ) was found, and the TMJ status was stable compared with the baseline (Table II). No patient had locking at the baseline examination or during the 2-year period studied. This was verified in the clinical examinations.

#### Masticatory-function questionnaire

At baseline, 59 patients answered the masticatory-function questionnaire, and, of these, 52 (88%) attended the 2-year follow-up (43 men, 9 women). One patient did not answer the questionnaire at the 6-month follow-up, and another did not at the 2-year follow-up. The questionnaire results are shown in Table III.

Headache frequency of several times a week or every day/night was significantly reduced ( $P < .01$ ) at the 2-year follow-up. Initially, 9 patients reported headache every day/night or several times a week. A decrease was seen at 6 months, when 4 patients reported headaches at the same frequency. At the 2-year follow-up, 48 patients had no headaches or only once or twice a month, and only 1 patient still had headaches several times a week ( $P < .01$ ).

Three patients (6%) reported tiredness on jaw function at baseline several times a week or every

**Table III.** Frequency distribution from masticatory function questionnaire regarding reported symptoms at baseline and 6-month and 2-year follow-ups

Question:	Baseline (n = 52)	6-month follow-up (n = 51)		2-year follow-up (n = 51)	
	n (%)	n (%)	Difference from baseline P*	n (%)	Difference from baseline P*
Own feeling of . . . .(symptoms)					
TMJ sounds (clicking/crepitations)	9 (17%)	12 (23.5%)	.808 (ns)	6 (12%)	.030
Difficulty in opening mouth wide	1 (2%)	0	.317 (ns)	0	.317 (ns)
Facial pain in relation to food intake	1 (2%)	5 (10%)	.046	1 (2%)	1.000 (ns)
Pain on opening mouth wide (activity)	6 (11.5%)	5 (10%)	.705 (ns)	0	.014
Pain between meals (rest)	1 (2%)	4 (8%)	.083 (ns)	0	.317 (ns)
Pain in cheeks	1 (2%)	5 (10%)	.046	1 (2%)	1.000 (ns)

\*Wilcoxon signed rank test; *TMJ*, temporomandibular joint; *ns*, not significant.

day/night; at the 6-month follow-up, this had increased to 8 patients (16%), but, at the 2-year follow-up, only 2 patients (4%) experienced such tiredness. These patients, however, were not the same patients as at baseline. None had TMJ locking several times a week or every day/night at baseline, but 1 had experienced TMJ locking at the 6-month follow-up and another at the 2-year follow-up. The reported symptoms were not verified at the clinical examinations.

Three of the 52 patients answered at baseline that they were aware of tooth grinding or clenching (bruxism), 36 were not aware, and 13 answered that they did not know. Despite the significant decrease measured in overjet and overbite (Table I), only 2 patients reported a permanent sense of altered occlusion. Two of the 9 patients who had established a lateral open bite also felt that the occlusion had changed for the worse. Seven felt no negative change in the occlusion. Agreement was found between the clinical examination of the occlusion and the answer to “own feeling of occlusion” in 50 of 64 patients. Six patients replied “don’t know” at the 2-year follow-up, but none had a lateral open bite.

**DISCUSSION**

In general terms, the frequencies of signs and symptoms of the masticatory system—TMJ sounds, TMJ or masticatory muscles tender to palpation, muscle and joint pain, and headache—decreased between baseline and the 2-year follow-up. At the 6-month follow-up, there was an increase in pain during both function and rest; pain diminished at the 2-year follow-up, similar to the finding of Bondemark and Lindman.<sup>7</sup> Zamburlini and Austin<sup>16</sup> found that an anterior repositioning splint seemed to be superior to a flat-plane occlusal splint in eliminating reciprocal clicking and palpatory tenderness of the TMJ. Lowe<sup>17</sup> stated that mild joint problems might be lessened by the forward position. Davies and Gray<sup>18</sup> concluded that a stabiliza-

tion splint used nightly could help relieve the pain in patients with TMJ pain dysfunction syndrome. The MPD probably also acted as a kind of occlusal splint, which is known to reduce signs and symptoms of temporomandibular disorders (TMD) (for a review, see Kreiner et al<sup>19</sup>), and we suggest that the MPD generates the same positive effect on the TMJ system.

Therefore, it can confidently be stated that the risk for developing signs and symptoms in the masticatory system because of treatment with an MPD seems to be low in a long-term perspective. In the short term (6 months), however, such a risk could be present. Apparently, the masticatory system has a good capacity for adaptation if MPD use continues. A slight increase in mandibular mobility was recorded at the 2-year follow-up.

We conclude that MPD treatment has many advantages and should be considered the first choice of treatment on a wider set of patients, including severe OSA patients, if an optimal amount of MPD advancement is used.<sup>20</sup> One reason that this has not been fully implemented previously has been the fear of side effects (occlusal changes, muscle and joint pain),<sup>12,13</sup> but, in this study, the adverse events were minor compared with the positive effects on sleep.<sup>2</sup>

The reported prevalence of TMD differs depending on whether it is based on a clinical evaluation of signs or on reported symptoms. We found at baseline a frequency of TMD clinical signs (TMJ clicking/crepitation or tenderness to palpation of the TMJ and masticatory muscles) of 34% in our study group. Twenty-three percent of those who answered the questionnaire reported at least 1 symptom of TMD. Österberg and Carlsson<sup>21</sup> found, in a geriatric population, that 86% had some sign of TMD objectively, and 59% reported subjective symptoms of TMD. Agerberg and Carlsson<sup>22</sup> stated that a clinical examination showed that only 14% had no signs of pain and dysfunction,

and 41% had some symptoms of TMD as reported in a questionnaire.

Ulfberg et al<sup>23</sup> reported that, without treatment, headache among heavy snorers and OSA patients was more prevalent than among the controls. Headache is a consequence of untreated sleep-disordered breathing that was reduced significantly with an MPD in our study ( $P < .01$ ); this is similar to findings in other studies.<sup>4,7,11</sup> The finding of a drastic decrease in headache frequency at the follow-up might also be an important factor for the positive outcome of the patient's experience of the treatment with the MPD. The most likely explanation for the reduction of headache frequency is probably improved oxygen saturation when breathing is normalized.

The dropout rate at the 2-year follow-up was 16%; this means that at least 65 of 77 patients still used their MPDs. The compliance rates reported in follow-up studies on oral appliances for OSA and snoring vary between 51% and 100%.<sup>4,24,25</sup> During the 2-year period studied, the relative absence of TMD symptoms, and even the decrease of symptoms in some patients, can explain part of the good compliance rate of the 85% of patients who reported still using the appliance every night after 2 years. This also agrees with Pancer et al<sup>26</sup> and Mehta et al.<sup>27</sup> Neill et al<sup>28</sup> reported side effects in 79% of the patients, and, in 26%, side effects prevented regular use of their appliances. This was more frequent than in our study.

A monobloc device in hard acrylic, as our MPD, has been reported to reduce overjet and overbite.<sup>5-7,29</sup> Appliances of this type might transmit forces to the maxilla and mandible via the teeth causing the adverse events (reduced overjet and overbite). Marklund et al<sup>30</sup> stated that occlusal side effects were more pronounced in subjects using hard acrylic devices than in patients with soft elastomeric devices. We used only hard acrylic and found that the mean reduction in overjet and overbite was similar to what Marklund et al reported with hard acrylic. We also found that, during the 2-year treatment period, 9 of 65 patients (14%) developed lateral open bites, unilaterally or bilaterally, indicating an alteration of the occlusion. Those affected were patients who previously had normal occlusions and had used their MPDs every night. The changes in the occlusion, however, did not influence the compliance rate, and very few patients noticed an alteration in their occlusions.

Cephalometric studies have shown a slightly posterior rotation of the mandible,<sup>5,6</sup> but researchers have not been able to fully explain why this occurs. Remodeling of the TMJ has been suggested,<sup>25</sup> but no conclusive evidence for this assumption has yet been pre-

sented. Our MPD efficiently locked the teeth in a fixed position that did not change at the 2-year follow-up. Our assumption is supported by the observation that the occlusions in other patients, who for various reasons temporarily stopped using their MPDs, were normalized after several weeks without treatment. We believe that the most likely explanation for the occlusal changes after MPD treatment is alterations of the soft tissues of the TMJ. Whether the position of the mandible is permanently changed or whether the mandibular incisors become proclined warrants further investigation. In this regard, it has been speculated that the inferior lateral pterygoid muscle is shortened when a MPD is used, and if the mandible is not retruded to the normal position during daytime, the muscle will be permanently shortened, and the condyle cannot attain its normal position.<sup>31</sup>

Patients are generally unaware of changes in their occlusions, and that emphasizes the need for regular follow-ups.<sup>30</sup> Early morning, nonpersisting discomfort in the mouth and TMJ are reported by Randerath et al<sup>32</sup> in 40% of the patients. Ferguson et al<sup>33</sup> reported a preference for oral appliances despite the effectiveness of continuous positive airway pressure. This can explain what we found—that subjective benefits outweighed the minor inconveniences of MPD treatment. It can consequently be concluded that the risk of minor occlusal changes in some patients who undergo MPD treatment can be accepted in light of its many positive benefits from the point of view of general medicine and quality of life. An MPD is today the first choice of treatment in patients with mild and moderate OSA at Örebro University Hospital, and even patients with severe OSA, for whom the main treatment modality is nasal continuous positive airway pressure, can benefit from this alternative.

## CONCLUSIONS

The signs and symptoms from the masticatory system were reduced and the mean range of mandibular mobility increased slightly in patients who underwent long-term treatment with MPDs. The high compliance rate after 2 years of MPD use is a good indication that the therapy is well tolerated. A risk of minor alterations in the occlusion with MPD therapy is obvious, but very few patients experienced problems.

We thank Associate Professor Göran Isacson, AstraZeneca, Södertälje, Sweden, and initiator of this study, for advice and fruitful discussions, and statistical consultant Anders Magnuson, Örebro University Hospital, for statistical expertise, advice, and fruitful discussions.

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