



# Comparative analysis of two custom-made mandibular advancement devices with varied designs for treating moderate to severe obstructive sleep apnea

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## ABSTRACT

**Introduction:** Custom-made titratable mandibular advancement device (MAD) treatment can nowadays be considered a promising first-line treatment in patients with mild to severe obstructive sleep apnea (OSA). Specific manufacturing designs and titration mechanisms of MAD are on the market, characterized by their titration approach, vertical opening, and materials selection.

The wing-designed MAD (SomnoDent® Flex™, SomnoMed Ltd, Sydney, Australia) has a lateral screw mechanism to advance the lower jaw in incremental steps of 0.1 up to 6.0 mm. The newer uniquely designed custom-made MAD with passive mouth closing (SomnoDent® Avant™ SomnoMed Ltd, Sydney, Australia) has a frontal exchangeable advancement strap of fixed lengths as a specific titration mechanism, all supporting freedom of lateral movement.

We aimed to assess the associations between the type of MAD prescribed and OSA treatment outcome.

**Methods:** Data from 209 patients (165 male, mean age 53.9 (±10.9) years, median baseline BMI and AHI 27.02 [24.8; 29.7] kg/m<sup>2</sup> and 22.8 [17.7; 31.6]/hour sleep, respectively) were collected.

Of this cohort, 91 patients with the traditional, wing-based SomnoDent® Flex™ and 118 patients with SomnoDent® Avant™. All patients were diagnosed with a type 1 polysomnography demonstrating moderate to severe OSA (15 ≤ AHI ≤ 65 per hour sleep). The selected MAD was fitted in the so-called maximal comfortable protrusion.

After 3 months of subjective titration until resolution of subjective symptoms and/or achieving physical limits, a checkup with validated home sleep monitoring was conducted. Treatment success was defined as “AHI reduction ≥50% with MAD compared to baseline AHI and AHI with MAD <10 events per hour”.

**Results:** These real-world data set showed that 67% of patients achieved treatment success, with a statistically significant reduction in AHI from 22.8 [17.7; 31.6] to 7.45 [3.4; 15.0]/h sleep. The SomnoDent® Avant™ achieved 75% treatment success versus 56% for the traditional, wing-based SomnoDent® Flex™ (P < 0.05). Overall, AHI reduction was 70% for SomnoDent® Avant™ (P < 0.05) vs. 63% for SomnoDent® Flex™ (P < 0.05).

**Conclusions:** This study shows that choice of MAD design can impact the treatment outcome and could become an important consideration in selecting the type of MAD for personalized treatment for OSA patients. While the results of the traditional wing-based MAD design were comparable to the therapeutic outcome with other titratable, custom-made MADs, the MAD with the passive mouth closing feature showed significantly greater reduction in total AHI potentially due to encouraged nasal breathing, reduced mouth breathing and lesser vertical opening thereby decreasing the probability of tongue base collapse.

## 1. Introduction

Recent data suggest that up to half of patients using continuous positive airway pressure (CPAP) therapy discontinue this treatment after three years [1]. The most prescribed non-CPAP therapy then for obstructive sleep apnea (OSA) is mandibular advancement device (MAD) treatment [2]. Custom-made titratable MADs have been

recommended, based on higher patients' comfort and superior retention over boil-and-bite and non-custom MAD devices, providing superior effectiveness [3–8]. Peer-reviewed literature indeed emphasizes that design of MAD can significantly influence its therapeutic effectiveness [7].

The effects of MAD design could well be related to a multifactorial mix of aspects such as the stability and steadfastness of the therapeutic

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degree of mandibular advancement, the bulkiness of the appliance, the sustainability of the overnight retention, the degree of mouth closure and subsequent nasal breathing and vertical opening induced by the MAD, among others [6,7,9–11]. For the attainment of therapeutic effectiveness, it is crucial to engage in the titration of the MAD, as it serves as an essential prerequisite for its efficacy. However, up till now, there is a lack of consensus regarding titration protocols, as well as the influence of various titration designs and rates of therapeutic mandibular protrusion [12]. Evidently, all these factors will interact with each other, and their sum will decide on the robustness of the specific MAD capability for OSA treatment.

The present study aims at comparing two custom-made titratable MADs with a different design and titration mechanism, in terms of their efficacy in reducing AHI in patients with moderate to severe OSA.

## 2. Material and methods

The present study is a single-center, retrospective clinical trial including adult patients eligible for MAD therapy with an established diagnosis of moderate to severe OSA ( $15 \leq$  apnea/hypopnea-index (AHI)  $\leq 50$ /h) on a recent type 1 PSG. Typically, patients were referred to the in-hospital accredited Dental Sleep Professional for screening for eligibility for OSA therapy with a titratable custom-made MAD. This study was approved by the ethical committee at Antwerp University Hospital, and written informed consent was obtained from each participant.

Two titratable custom-made MAD with different design were compared in this study. The first MAD was the SomnoDent Flex (SomnoDent® Flex™, SomnoMed Ltd, Sydney, Australia); this winged designed MAD is depicted on the Fig. 1, left panel, and consists of two separate splints allowing free vertical opening. This MAD has a lateral screw mechanism on the upper splint which is used to advance the lower jaw in incremental steps of 0.1 mm up to 6 mm for titration purposes. The second MAD evaluated in this study is the newer uniquely designed custom-made SomnoDent Avant MAD (SomnoDent® Avant™ SomnoMed Ltd, Sydney, Australia; see Fig. 1, middle panel) with passive mouth closing feature due to a supposed counter clock mechanism upon mouth opening. This MAD has a frontal exchangeable advancement strap of fixed lengths as its specific titration mechanism, that supports lateral movement. This mechanism claims to include a passive mouth closing design that encourages nasal breathing, with a maximal advancement of up to 9 mm in 1 mm steps. This mechanism claims to maintain mandibular advancement on vertical opening of the mouth.

MAD therapy started in maximal comfortable protrusion (MCP), measured in each individual patient as described before [13]. Patients were instructed about the details of daily MAD use as well as the titration process. For the first 3 months of MAD therapy, participants were

requested to titrate until resolution of subjective symptoms and/or achieving physical limits. A checkup with a validated home sleep monitoring test was conducted afterwards.

In the present study, we investigate the impact of design and each titration mechanism on the clinical efficacy using these custom-made titratable MAD's. Treatment success was defined as "AHI reduction  $\geq 50\%$  with MAD compared to baseline AHI and a decrease in AHI with MAD to fewer than 10 events per hour".

JMP software (Statistical Discovery LLC, Cary, NC, USA) was used for statistical analysis. Normality of distribution was assessed using Shapiro-Wilk Goodness of Fit test. Quantitative variables were expressed as mean  $\pm$  standard deviation (SD) or median (quartile 1, quartile 3). Treatment effects were compared by Student's t-test and Wilcoxon's matched-pairs test, depending on the distribution of the variables.

## 3. Results

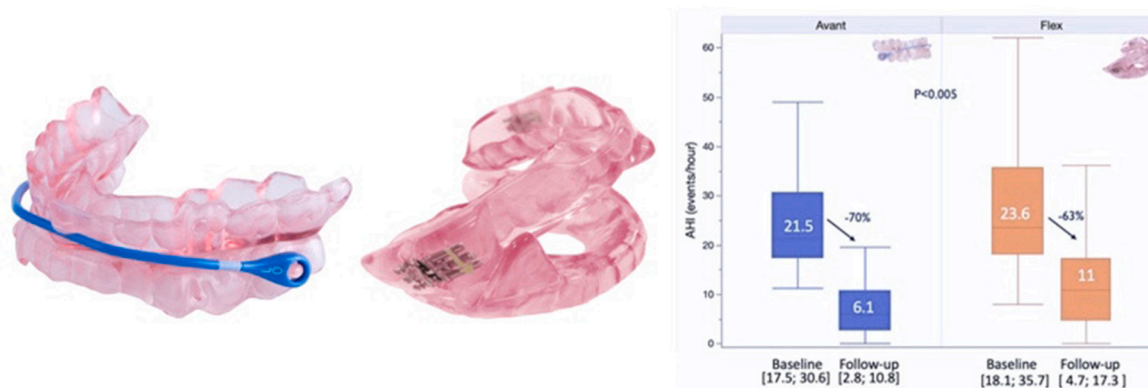
Data from a total of 209 patients with moderate to severe OSA were retrospectively collected. The patients' baseline characteristics are outlined in the Table 1. No significant differences were noted in terms of age and BMI among both treated MAD subgroups.

With all results pooled, a statistically significant reduction in AHI was noted from 22.8 [17.7; 31.6] to 7.45 [3.4; 15.0]/h (Fig. 1, right panel). This reduction in the overall group corresponds with a 68% reduction in AHI with MAD compared to baseline and a treatment success rate with MAD of 67%.

**Table 1**  
Overview of results.

	Total	Flex	Avant
<b>N moderate to severe OSA</b>	209	91	118
<b>N Male (% of total group)</b>	165 (79%)	69 (76%)	96 (81%)
<b>Age (years)</b>	53.9 ( $\pm 10.9$ )	53.8 ( $\pm 9.7$ )	52.6 ( $\pm 10.2$ )
<b>BMI (kg/m<sup>2</sup>)</b>	27.02 [24.8; 29.7]	27.4 [25.9; 29.7]	26.9 [24.7; 29.9]
<b>AHI baseline (moderate to severe OSA)</b>	22.8 [17.7; 31.6]	23.6 [18.1; 35.7]	21.45 [17.5; 30.6]
<b>AHI MAD (moderate to severe OSA)</b>	7.45 [3.4; 15.0] **	11 [4.7; 17.3]	6.1 [2.8; 10.8] **
<b>N severe OSA</b>	58	28	30
<b>AHI baseline (severe OSA)</b>	40.0 [33.8; 48.4]	41.6 [35.8; 50.3]	38.6 [32.5; 48.4]
<b>AHI MAD (severe OSA)</b>	14.8 [6.5; 24.2] **	13.1 [4.8; 24.2] **	15.4 [8.4; 24.8] **

Baseline anthropometrics and treatment characteristics of the overall group and the two separate treatment groups. \*\*:  $p < 0.05$ . Data are presented as mean ( $\pm$  standard deviation) or median [Q1, Q3], depending on the distribution of data.



**Fig. 1** The SomnoDent® Avant™ with passive mouth closing feature depicted in the left panel; the winged designed SomnoDent® Flex™ MAD shown in the middle panel; a boxplot with the AHI reduction with the two MAD illustrated in the right panel, being significantly better with each device compared to baseline but also illustrating a statistically significant difference between the two compared MAD favouring SomnoDent® Avant™.

In the subgroup of the 91 OSA patients treated with the winged design SomnoDent Flex MAD the significant reduction in AHI accounted for 63% with a treatment success of 56%.

The results with the passive mouth closing SomnoDent Avant MAD indicated a statistically significant reduction in AHI of 70% with treatment compared to baseline with a corresponding treatment success rate of 75%.

Further statistical analysis revealed that all three of these outcomes, (1) AHI with MAD compared to baseline, (2) delta AHI, and (3) treatment success, are statistically significantly higher ( $p < 0.05$ ) with SomnoDent Avant MAD when compared to SomnoDent Flex MAD.

A total of 58 out of 209 included patients had an initial diagnosis of severe OSA. The results with MAD are reassuring in this overall severe OSA group with a significant decrease in AHI from 43.0 at baseline to 16.2/h with MAD, a decrease in AHI with 61% and a treatment success of 50%.

Similar results are revealed with decreases in AHI and treatment success being 63 and 59%, and 55 and 45%, for the SomnoDent Avant and SomnoDent Flex, respectively. In contrast to the overall analysis including both moderate and severe OSA patients, for the severe AHI group no significant difference in the reduction of the AHI between both MADs was seen.

#### 4. Discussion

Custom-made titratable MAD therapy is a first-line treatment equivalent to CPAP in terms of reduction in AHI for patients with mild to moderate OSA, whereas recent evidence illustrates that MAD therapy is also able to reduce OSA severity and related symptoms and showing high adherence in patients with severe OSA [2,14–16].

As many different designs of MAD for OSA exist, selecting the MAD design of preference when prescribing this treatment is key but often arbitrary and non-patient specific. A recent review pointed out that the following principal characteristics should ideally be present when using custom-made MAD treatment for OSA in order to ensure maximum therapeutic benefit: optimal retention on the dentition, ability for gradual and incremental titration of mandibular protrusion, full occlusal coverage and, last but not least, a minimal anterior vertical opening [16].

In the present study the therapeutic efficacy of two titratable, custom-made MADs was compared (Figure). The results indicate that both MADs are highly efficacious in the treatment of patients with moderate to severe OSA (Table 1). The magnitude of overall decrease in AHI with MAD corresponds to the results with custom-made titratable MAD treatment of OSA in other clinical trials [17–19]. When comparing MADs with the more traditional wing-based design, such as incorporated into the SomnoDent Flex, two recent studies did not find significant differences between different designs of MADs [18,19].

While in the present study the reduction in AHI is statistically significant with both SomnoDent Flex and the SomnoDent Avant MAD, the latter device, the newer designed SomnoDent Avant also shows a significantly better AHI reduction compared with the traditional wing-based design.

In contrast to the more traditional designed MAD that are currently the ‘gold standard’ the SomnoDent Avant has a counterclockwise (CCW) rotation which could induce less tongue base collapse, in particular in supine position. Indeed, as depicted in the Figure, the strap that covers both separate parts of the SomnoDent Avant MAD encourages mouth closure, lip seal and nasal breathing. Nasal breathing is more efficacious than mouth breathing: as the mouth opens, the jaw moves inferiorly and posteriorly - positioning the tongue closer to the posterior pharyngeal wall and narrowing the airway significantly, and reducing the effectiveness of the MAD.

It could be argued that the more traditional custom-made MAD designs induce more vertical mouth opening as compared to the SomnoDent Avant’s unique design, where it has been shown that an increased

vertical opening will induce a tongue base collapse in the majority of OSA patients [9]. In addition, the sleep state induces a muscle relaxation that will typically permit the mandible to rotate downwards and backwards, with an accompanying reduction in tongue space leading to a more narrow upper airway [16]. The ability of keeping the vertical opening to a minimum is therefore a key design feature of MAD in order to achieve optimal effectiveness of MAD treatment for OSA [16,20]. If nasal breathing, rather than mouth breathing, can be promoted, this could indeed increase the effectiveness of a specific MAD design versus others. With oral breathing, as the mouth opens, the jaw moves inferiorly and posteriorly - positioning the tongue closer to the posterior pharyngeal wall and narrowing the airway significantly, and reducing the effectiveness of the MAD. In addition, reduced mouth breathing has been linked to dry mouth, increased snoring, and lower MAD efficacy.

Based on the results of this trial, and in contrast to recent statements that there is no evidence to support superiority in MAD designs used in OSA treatment, the passive mouth closing feature design of the SomnoDent Avant MAD, that encourages nasal breathing and potentially limits the vertical opening to the minimum, more than the traditional MAD design is capable of, might offer an overall higher efficacy. Regarding vertical opening the data in the literature indeed suggest indeed that the amount of bite opening induced by MAS could have a significant impact on MAD treatment effectiveness and that vertical opening should therefore be kept to the minimum [9,10].

Additionally, in the era where first-line indications for MAD maybe expanding to patients with severe OSA [14,15], in this study, significant and important AHI reductions were found with both MAD designs (Table 1) with an overall AHI reduction of 61%. These findings lend further credibility towards the selection of custom-made titratable MAD therapy as first-line therapy also in patients with severe OSA.

#### 5. Conclusions

The present study offers evidence that MAD design influences the overall reduction of AHI in patients with moderate to severe OSA.

Evidently, more detailed exploration of the results of this study, and further clinical trials addressing similar research questions need to continue to identify the factors contributing to the differences among the newer generations of titratable, custom-made MADs for OSA treatment.

#### CRedit authorship contribution statement

**Olivier M. Vanderveken:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Margot Van Daele:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Johan Verbraecken:** Writing – review & editing. **Marc J. Braem:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Marijke Dieltjens:** Writing – review & editing, Visualization, Methodology, Investigation, Formal analysis, Data curation.

#### Declaration of competing interest

These authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Olivier M. VANDERVEKEN reports a relationship with SomnoMed that includes: board membership and funding grants. Olivier M VANDERVEKEN reports a relationship with ProSomnus that includes: funding grants and speaking and lecture fees. Olivier M VANDERVEKEN reports a relationship with Inspire Medical Systems Inc that includes: consulting or advisory and funding grants. Olivier M VANDERVEKEN reports a relationship with Nyxoah SA that includes: funding grants. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Verbraecken Johan reports financial support was provided by Somnomed. Verbraecken Johan reports financial support was provided by Air Liquide SA. Verbraecken Johan reports financial support was provided by Atos Medical AB. Verbraecken Johan reports financial support was provided by Vivisol NL. Verbraecken Johan reports financial support was provided by Mediq BV. Verbraecken Johan reports financial support was provided by Medidis. Verbraecken Johan reports financial support was provided by Micromed OSG. Verbraecken Johan reports financial support was provided by Bioprojet. Verbraecken Johan reports financial support was provided by Desitin Pharmaceuticals. Verbraecken Johan reports financial support was provided by Epilog. Verbraecken Johan reports financial support was provided by Idorsia Pharmaceuticals Ltd. Verbraecken Johan reports financial support was provided by Koninklijke Philips. Verbraecken Johan reports financial support was provided by ResMed. Verbraecken Johan reports financial support was provided by Inspire Medical Systems Inc. Verbraecken Johan reports financial support was provided by Lowenstein Medical Technology LLP. Verbraecken Johan reports financial support was provided by Ectosense. Verbraecken Johan reports financial support was provided by ProSomnus. Verbraecken Johan reports financial support was provided by Sefam. Verbraecken Johan reports was provided by SD Worx. Verbraecken Johan reports financial support was provided by DEME. Verbraecken Johan reports financial support was provided by SOS Oxygène. Verbraecken Johan reports financial support was provided by Tilman S.A. Verbraecken Johan reports financial support was provided by Total Care. Verbraecken Johan reports financial support was provided by Ministry of the Flemish Community. Verbraecken Johan reports financial support was provided by Vlerick Business School. Verbraecken Johan reports financial support was provided by Itamar-Medical Inc. Verbraecken Johan reports a relationship with Bioprojet that includes: board membership, consulting or advisory, speaking and lecture fees, and travel reimbursement. Verbraecken reports a relationship with Epilog that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Margot VAN DAELE declares that she has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Marc BRAEM declares that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Marijke DIELTJENS declares that she has no known competing financial interests or personal relationships that could have appeared to

influence the work reported in this paper.

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