A review of effect of added vertical dimension in mandibular advancement device in treatment of obstructive sleep apnea

Sangwoo Kim

The Graduate School
Yonsei University
Department of Medical Device Engineering and Management

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Sangwoo Kim

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Sangwoo Kim is approved.

Thesis Supervisor: Jae-Sung Kwon

Thesis Committee Member #1: Seong Taek Kim

Thesis Committee Member #2: Sung-Hwan Choi

The Graduate School

Yonsei University

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Sangwoo Kim

Department of Medical Device Engineering and Management

The Graduate School, Yonsei University

(Directed by Professor Jae-Sung Kwon, M.D., Ph.D.)

Obstructive sleep apnea (OSA) is a serious sleep-related breathing disorder that partially disrupts or even completely halts the air flowing into the body, causing numerous direct and indirect discomforts and illnesses. It directly affects the human body by disrupting the healthy sleep process, thereby causing fragmented sleep and daytime sleepiness, and low levels of oxygen saturation due to blockage of airways. Such symptoms can lead to indirect yet far more serious threats of various health issues especially related to heart failures. Prevalence of OSA is observed in 24% of men and 9% of women have breathing symptoms of OSA; 80–90% of adults with OSA remain undiagnosed, unaware that their life may be in danger.

The standard of care for OSA is use of continuous positive airway pressure (CPAP), which can treat all severe OSA patients. However, many people consider CPAP treatment troublesome and even intolerable; thus, they are recommended an alternative treatment option of oral appliance therapy (OAT). Oral appliances utilize a wearable device (splint) to advance the lower jaw forward, avoiding the soft tissue and the tongue from collapsing and blocking the airways.

The OAT treatment mainly focuses on the design of the appliance, its efficacy, and possible side effects. Most of these rely heavily on the level of protrusion (mandibular advancement) and composition of the appliances. We aimed to determine and establish the relationship between mandibular advancement using the mandibular advancement device (MAD) and vertical dimension of occlusion in determining the optimal titration setting, which lead to improved efficacy of OAT.

Several keywords were selected and searched from four systems: Embase, Pubmed, RISS, and Google Scholar. In total, 3,232 references were retrieved as the initial database. After removing duplicate articles and references not relevant to the subject, 10 studies were selected that included clinical study outcomes of 188 patients.

In most cases, addition of vertical dimension in the titration enhanced the efficacy of the MAD. The limitation of such MAD included efficacy and minor side-effects such as patient discomfort or dryness of mouth in the morning.

In conclusion, the addition of vertical dimension in the titration may enhance the efficacy of the MAD, and is important in the advancement of the mandible. However, this could be a trade-off between efficacy and minor side-effects.

Key words; Obstructive Sleep Apnea, Oral Appliance Therapy, Vertical Dimension of Occlusion, Mandibular Advancement, Protrusion

A review of effect of added vertical dimension in mandibular advancement device in treatment of obstructive sleep apnea (OSA)

Sangwoo Kim

Department of Medical Device Engineering and Management
The Graduate School, Yonsei University

(Directed by Professor Jae-Sung Kwon, M.D, Ph.D.)

I. Introduction:

1.1 Obstructive sleep apnea

Studies show that sleep apnea is extremely common globally and patients suffering from sleep apnea have high risk of the resulting medical conditions; it may also become the root cause of sudden accidents that incur enormous social economic cost. Sleep apnea requires urgent attention because it can cause a serious illness that may become fatal. There are three types of sleep apnea, obstructive sleep apnea (OSA), central sleep apnea (CSA), and complex sleep apnea syndrome (CSAS); 90% of all sleep apneas diagnosed are in the category of OSA. OSA patients are increasing worldwide owing to increasing obesity, which is the most common cause of sleep disorders.

1.2 Definition

According to American Academy of Sleep Medicine (AASM), OSA is "a sleep-related breathing disorder that decreases or stops airflow despite an ongoing effort to breathe. It occurs when the muscles relax during sleep, causing soft tissue in the back of the throat to collapse and block the upper airway. This causes partial reduction (hypopneas) and pauses (apneas) breathing that last for at least 10 seconds during sleep. Most pauses last between 10 and 30 seconds, but some may persist for ≥1 minute. This can lead to abrupt reductions in blood oxygen saturation, with oxygen levels falling as much as ≥40% in severe cases."

Lack of oxygen intake triggers the human brain to alert the body through short arousal from sleep; this allows the body to restore normal breathing and adequate oxygen flow. Such an event can occur rather frequently throughout the night, resulting in fragmented, low quality sleep patterns that often lead to constant state of fatigue and daytime sleepiness, which in turn reduced concentration levels and daily productivity.

1.3 Prevalence and degree of OSA

Factsheet on OSA written by the AASM claims that OSA can occur in any age group, but higher prevalence was observed in middle and older ages. It also claims that about 24% of men and 90% of women have breathing symptoms of OSA with or without daytime sleepiness; however, 80–90% of adults with OSA remain undiagnosed. OSA can also occur in younger ages; it occurs in about 2% of children and is most common in preschool age-groups (AASM2008, American Academy of Sleep Medicine website, https://aasm.org/resources/factsheets/sleepapnea.pdf).

Common symptom of OSA is snoring loudly during sleep, accompanied by frequent periods of silence when airflow is reduced or blocked. When the body is briefly aroused due to low oxygen levels, their airway reopens, often make choking, snorting, or gasping sounds. A common measurement of sleep apnea is the apnea-hypopnea index (AHI), which implies the average number of apneas and hypopneas that occur per hour of sleep (AASM2008, American Academy of Sleep Medicine website, https://aasm.org/resources/factsheets/sleepapnea.pdf).

Classification of OSA severity is usually determined by the level of AHI obtained through sleep tests including overnight polysomnography or home sleep test. The range of AHI figures categorizing the OSA patients into three degrees of severity is as follows.

(AASM2008, American Academy of Sleep Medicine website, https://aasm.org/resources/factsheets/sleepapnea.pdf)

Table 1. OSA classification

Degree of severity	AHI range	Description
Mild	5–15	Involuntary sleepiness during activities that require little attention such as watching TV or reading
Moderate	15–30	Involuntary sleepiness during activities that require some attention such as meeting or presentations
Severe	30+	Involuntary sleepiness during activities that require more active attention such as talking or driving

Higher risk of OSA was observed in the following groups.

(AASM2008, American Academy of Sleep Medicine website, https://aasm.org/resources/factsheets/sleepapnea.pdf)

- People who are overweight (body mass index [BMI] of 25 to 29.9) and obese (BMI of ≥30)
- Men and women with large neck size: 17 inches or more for men, 16 inches or more for women
- Middle-aged and older men, and post-menopausal women
- Ethnic minorities
- People with abnormalities of the bony and soft tissue structure of the head and neck
- Adults and children with down syndrome

- Children with large tonsils and adenoids
- Anyone with a family member with OSA
- People with endocrine disorders such as acromegaly and hypothyroidism
- Smokers
- Those suffering from nocturnal nasal congestion due to abnormal morphology, rhinitis, or both

1.4 Treatment

Three ways to treat OSA is to use Mandibular Advancement Device (MAD), use Continuous Positive Airway Pressure (CPAP), or perform surgery to cut out the soft tissues that collapse to block the airway such as tonsils and adenoids. Studies show that most patients with sleep apnea does not need surgical treatment, and surgery may not be effective in all cases. Even if the surgery was affective, the condition may relapse if patients gain weight over time. Currently, the golden standard treatment method is CPAP as it is non-surgical and is able to address all severity level of OSA patients. The limitation of CPAP is the discomfort of wearing a full mask overnight, significant number of patients give up the CPAP treatment after failing to adjust to the device. MAD treatment is proven to be effective for patients with mild and moderate OSA conditions and for patients with CPAP intolerance. Latest technology allows manufacturers of such MAD device to create a smaller, lighter and more durable device by using 3D printers for fabrication. The major concern regarding the MAD treatment is its effectiveness, and potential side effect or adverse event arising as result of such treatment. Such event includes movement of the teeth, pain in the Temporo

Mandibular Joint (TMJ), permanent change of occlusion. Most of the concern relates to the occlusion relation of the patient. The side effect related to the occlusal change or TMJ pain or discomfort is mostly related to the level of titration, the amount of advancement of mandible and vertical opening is the factor that determines the effectiveness of the appliance, and the potential side-effects of the device. Hence, this paper will review ten studies of MAD oral appliance and evaluate the effectiveness of adding a vertical dimension in the titration of MAD in treatment of OSA.

1.5 Titration (mandibular advancement) protocol

The level of patient's mandibular advancement can be controlled by changing the connecting rod or adjusting the screws installed on the device. This procedure is called device titration.

Devices have different methods of adjusting the protrusion level; in general, all devices are capable of titration adjustments. The titration can usually be adjusted in increments of 0.5 mm or 1 mm. While there is no set titration protocol, most dentist will instruct the patient to use the device for a few nights before assessing the titration and making further changes, which also depends upon the patient's tolerance to titration.

According to Cistulli et al., "As a general rule of thumb, we often start patients at 60 percent of maximal protrusion allowed by the device, and then advance in 1 mm increments or less, every few weeks as tolerated, until they reach the maximum comfortable limit or device limit"

1.6 Vertical dimension of occlusion (VDO)

Vertical dimension of occlusion (VDO) is defined by Vinnakota et al., as “the lower facial height measured between two points when the maxillary and mandibular teeth are intercuspated. Thus, it is the vertical position of the mandible in relation to maxilla when the occluding members are in contact”. This definition refers to the degree of opening of the mouth.

If the design of the device can control the degree of mouth opening, or the level of vertical dimension of occlusion, it could help determine the optimal titration. As the VDO becomes a variable factor in oral appliance design, the efficacy of the appliance may change even if we hold the mandibular advancement level constant.

However, the importance of incorporating VDO into oral appliance treatment design is mostly ignored; there is insufficient data from existing studies showing clear evidence of correlation between efficacy of oral appliance therapy and titration combination of mandibular advancement and vertical dimension of occlusion.

1.7 Objectives of the review

As stated above, many people consider CPAP treatment troublesome and even intolerable; thus, the alternative treatment option of Oral Appliance Therapy (OAT) is often recommended.

Oral appliances employ a wearable device (splint) to advance the lower jaw forward and avoid the soft tissue and the tongue from collapsing and blocking the airways.

The OAT treatment mainly focuses on the design of the appliance, its efficacy, and possible side effects. Most of these rely heavily on the level of protrusion (mandibular advancement) and composition of the appliances.

We aimed to determine and establish a relationship between mandibular advancement using the MAD, and vertical dimension of occlusion in determining the optimal titration setting, which lead to improved efficacy of OAT.

II. Materials and methods

2.1 Selection of search engines

To identify relevant studies on MAD treatment of OSA, thorough database search was conducted using Pubmed, Embase, Google Scholar, and RISS. Four search engines were included comprising various scientific literatures, with different target users. For example, Pubmed contains medical and biological references with peer reviewed journals. Meanwhile, Embase and Google Scholar provide wider range of references. RISS can be used to search for studies published in Korea.

2.2 Search strategy and keywords

The search strategy including the MeSH and text words applied in the initial search were:

('sleep apnea, obstructive' OR (obstructive AND ('sleep' OR sleep) AND ('apnoea' OR apnoea OR 'apnea' OR apnea)) OR (('sleep' OR sleep) AND (('breathing' OR breathing) AND disorder* OR 'respiratory' OR respiratory) AND disorder*)) AND ('orthodontic appliances' OR 'orthodontic appliances' OR (oral AND (device* OR appliance* OR 'splint' OR splint)) OR (('dental' OR dental) AND (titration OR occlusion) AND (vertical or ‘vertical) AND (overjet or overbite) AND (device* OR appliance* OR 'splint' OR splint)) OR (('orthodontic' OR orthodontic) AND (device* OR appliance* OR 'splint' OR splint)) OR (mandib* AND advancement*))

The search was limited to case studies and clinical trials of MAD(s) and relevance of the subject matter was determined by study design and outcomes. Literature search results initially retrieved from various sources revealed 3,232 references. Duplicates and irrelevant studies were excluded, leaving 82 patient cases to be reviewed.

III. Results

3.1 Literature search

Initially, 3,232 references were retrieved after searching three systems, Embase, Pubmed, RISS, and Google Scholar. The initial database was exported in CSV format and reviewed; 1,187 duplicate articles were excluded from the compiled list and additional 2,035 cases were excluded because they were not relevant to the subject. Review articles and those lacking full text were excluded. Ten studies were finally selected, containing outcomes of clinical studies on 188 patients, which form the basis of this review.

3.2 Treatment eligibility

Standard criteria of undertaking OAT for treating sleep disorders, especially the OSA are usually limited to patients diagnosed with mild to moderate OSA or severe OSA patients who failed or refused the use of CPAP. Diagnosis of OSA and its degree of severity are commonly determined by the outcomes of Polysomnogram (PSG) and Home Sleep Test (HST), which monitor the signals detected in the sensors attached to patients' body overnight. One of the key features of PSG is the Apnea Hypopnea Index (AHI); depending on the AHI score, the patient is diagnosed No OSA (AHI < 5), Mild (AHI = 5-15), Moderate (AHI = 15-30), or Severe (AHI > 30). Treatment effectiveness can also be evaluated by measuring the AHI before and after the treatment.

Another subjective inclusion criteria include multiple signs and symptoms of OSA such as reports of snoring, and excessive daytime sleepiness (can be determined by Epworth sleepiness scale).

Usual exclusion criteria for OAT includes patients with evidence of central

sleep apnea, periodontal disease, or edentulism. Severe OSA patients with AHI >30 are often excluded from treatment unless they are CPAP intolerant.

All ten studies (Rawson 2018; Carollo 2018; Morgan 2018; Martı´nez-Gomisa et al. 2010; Aarab et al. 2010; Anitua et al. 2017; Pitsis et al., 2002; Choi, Kee, and Kang 1999; Lee 2018; Ra 2014) used the MAD device commercially available for 188 patients diagnosed with mild to severe OSA (Rawson 2018; Carollo 2018; Morgan 2018); three of these (Anitua et al. 2017; Aarab et al. 2010; Rawson 2018) studies comprised severe OSA patients with baseline AHI score ranging from 31 to 113. Thus, patients with severe OSA can also be treated with OAT and should not be excluded. The other studies were mostly on patients with mild to moderate OSA, but they focused on intolerance of the CPAP treatment protocol.

Active Temporomandibular Disorder (TMD) is a common contraindication of MAD treatment for OSA. However, in the study by Martı´nez-Gomisa et al. (2010), 'Five Years of Sleep Apnea Treatment with a Mandibular Advancement Device,' OSA patients initially diagnosed with TMD were not excluded; the use of oral appliances did not affect TMD prevalence. Despite the limited sample size, the study outcome suggests that not all TMD patients should be excluded from the population eligible for treatment.

3.3 Design of the Appliance

Design of the oral appliance or the MAD has various factors for the physician to examine and select. Most of these are determined case by case in relation to the patient's oral conditions including dental implants, supporting bone structure and its rigidity, any Temporomandibular joint (TMJ) issues, and other treatment plans or history. However, the critical design impacting the treatment is usually

related to occlusion.

The occlusion data of the patient must be considered when designing the OA to ensure treatment safety and patient comfort. Most OAT relies on advancement of the lower jaw or the mandible to avoid collapse of tissues that leads to blockage of airways. However, studies by Aarab et al. (2010) and Anitua et al. (2017) 'Effects of an oral appliance with different mandibular protrusion at a constant vertical dimension on obstructive sleep apnea' and 'Minimizing the mandibular advancement in an oral appliance for the treatment of obstructive sleep apnea' respectively, involved studies with 0% protrusion. In the Anitua et al. study, patients fitted with oral appliance at titration of zero advancement displayed reduction of AHI, which could indicate that in some patients, the zero-advancement position of MAD can maintain patency of the upper airways and stabilize the pharyngeal tissues.

In contrast, Aarab et al. (2010) applied four different mandible advancements to patients at 0%, 25%, 50%, and 75% the result of the study showed favorable effectiveness of AHI reduction at the protrusion of 50% and 75% compared to 0% and 25%. Greater protrusion yielded better outcomes following the OSA treatment. However, excessively protruded bite applied on the oral appliance also causes discomfort and deters use of the appliance, causes pain, or triggers permanent change of occlusion.

Three studies use different methods of bite registration (Rawson 2018; Carollo 2018; Morgan 2018). Dr. Rawson established the 'Phonetic Bite (PB),' "The goal of the PB Technique is to understand and respect the normal function of the bilateral TMJs and design an appliance, which "houses" the condyle inside the fossa rather than stretching it past a healthy range and holding it semi rigidly for a full night of sleep." The article also states that "The PB technique allows the patient's own neurology to guide us to a three dimensionally (3D) balanced

mandibular position as it relates the maxilla while repeating the series of “S” sounds by counting from “66” to “75”. This technique brings the upper and lower incisal edges into a vertical plane (edge to edge) to create the whistle aspect of the “S” sound.”

Dr. Carollo evaluated the patient with multiple Airway metrics bite jigs, while using the Eccovision acoustic pharyngometer for quick and easy measurement of the patient’s pharyngeal airway size and stability of the oral pharyngeal junction to the glottis. The pharyngometer graphically displays the relationship between the cross-sectional area of the airway and the distance down the airway in centimeters.

Dr. Morgan used “Routine clinical protocols… using the George Gauge (Great Lakes Dental Technology) to determine a starting jaw position at 60% of the maximum mandibular protrusive range of motion. By design, the George Gauge incorporates an incisal separation of 2 mm or 5 mm separation when mounted on a dental articulator for fabrication of a custom oral appliance. All of the 20 patients had bite recordings made using the 5 mm size fork.”

A study by Ra (2014) on “Effect of MAD Snoring Design on Pharyngeal Airway Dimension” explores the difference in commercially available oral appliances from its materials such as thermoplastic and acrylic devices, design of the appliance including soft and hard type monobloc and twin block, existence of titration wires and screw, and Herbst type appliance. The study uses four different types of appliances on the patient, Microimplant to custom-make facemask, MAD with tongue resistance measure, MAD from Somnomed, and self-made twin-block device. The study examined the airways and change in their surface areas as result of OSA treatment with different types of oral appliances. Upper airways such as parapharyngeal fat tissue, lateral pharyngeal wall, nasopharynx airway, soft palate airway, lingual airway, and hypopharynx airway

were viewed using different means such as, cephalographs and computed tomography (CT). The result of this study showed the importance of oral appliance designs; the patient's tongue position greatly influences the effectiveness of the entire study design. The thickness of the oral appliance differs; it influences the vertical dimensions along with the available space in the mouth for the patient's tongue. The size and thickness of the patient's tongue should also be considered for OSA treatment via oral appliance use.

3.4 Effect of added vertical dimension on the oral appliance

Three studies (Rawson 2018; Carollo 2018; Morgan 2018) added a vertical dimension into the design of the oral appliance to understand its effect on OSA treatment shown by the changes in AHI scores of patients.

Dr. Rawson's phonetic bite registration allowed for the oral appliance to have "10 mm vertical component divided approximately 30% on the maxillary member and 70% on the mandibular member." Dr. Rawson conducted the study on 32 patients divided into two groups.

Group 1 included six patients who met the inclusion requirements of Clinical diagnosis of Sleep Apnea with untreated moderate AHI of 15 to 30; Group 2 included 26 patients who met the inclusion requirements of Clinical diagnosis of Sleep Apnea with untreated moderate AHI of > 30 (Table 2).

Table 2. AHI reduction from baseline to post treatment

	Group 1	Group 2
Number of patients	6	26
Minimum AHI Baseline	14.9	30.3
Maximum AHI Baseline	29.1	113.1
Average AHI baseline	25.7	55.9
AHI post Treatment range	3.5-9.7	2.1–34.2
Minimum AHI reduction rate post treatment	62.3%	46.8%
Maximum AHI reduction rate post treatment	83.0%	96.5%
Average AHI reduction rate post treatment	74.8%	76.9%

For Group 1, the moderate AHI group, there was an average improvement of 74.8% in AHI ranging from 62.3% to 83.0%. For Group 2, the severe AHI group, there was an average improvement of 76.9% in AHI ranging from 51.2% to 96.5%

Dr. Carollo was presented with a case of a 77-year-old male patient, with moderate OSA, AHI of 19, and Respiratory Disturbance Index (RID) of 28. The patient attempted CPAP therapy, which was proven effective; however the patient became CPAP intolerant and opted for OAT. The patient's first oral appliance was ineffective due to incorrect design and positioning of titration. This was discovered by monitoring and comparing the data produced by the Pharyngometer.

The following table shows that new OA, fabricated with 10 mm vertical dimension in its design had a 94.7% improvement on AHI and an 85.7% improvement on RID (Table 3).

Table 3. Result of pre-treatment, CPAP, incorrect OAT, and corrected OAT

	Baseline	CPAP	OAT	OAT corrected
AHI	19	0.3	17.3	1
RDI	28	0.6	29.6	4
SpO_2 Nadir	81%	n/a	88%	89%
Notes		Intolerant	Lack efficacy	Significant improvement

Dr. Morgan's study was conducted on 20 patients, all of whom previously failed a trial of CPAP therapy and underwent the alternative treatment of oral appliance. Ten patients were fitted with Narval oral appliance (Res Med Corp.). Ten additional patients were fitted with a Panthera D-SAD device (Panthera Sleep). Both Narval and Panthera appliances are similar in manufacturing their process, using a sintering technique of fusing nylon polymer "beads" into shapes guided by digital files of scanned dental models.

Upon delivery of the custom appliance, patients were instructed to make further protrusive adjustments of 1 mm every 1–2 weeks to their appliance over 30 days until subjective symptoms of snoring, nocturnal arousals, and observed apneas improved, or they reached their maximum tolerance to further advancements.

At their return appointment, a progress home sleep test (HST) was administered. If the goal of an AHI<10/h was not reached, a novel “vertical tab” was added at the molar or bicuspid region to increase the inter-incisal distance by 2 mm, for a total of 7 mm. The tabs allow for a change in the vertical dimension while the holding protrusion-setting constant. No further adjustments to protrusion were made and a second HST was dispensed to examine the effect of vertical change on AHI and oxygen desaturation index (ODI) in isolation.

Figure 1. Example of 2 mm vertical tabs

Table 4. Result of Patients' Baseline AHI and AHI with or without Vertical tab (Mean values 24.6000 / 13.6500 / 12.6300, standard deviation 10.2347 / 4.4684 / 17.8541, *p*= 0.0029)

	Group 1	Group 2
Device used	Narval	Panthera D-SAD
Number of patients	10	10
Baseline AHI range	14–52.3	12.5–41
Average Baseline AHI	26.8	22.4
AHI post treatment range without VDO	10.2–21.7	4–16.4
Average AHI post treatment without VDO	16.06	11.24
AHI post treatment range with VDO	2.3–12.8	3.4–21.9
Average AHI post treatment with VDO	8.06	9.64
AHI reduction rate range post treatment without VDO	6%–63%	1%–76%
Average AHI reduction rate post treatment without VDO	0.35%	0.43%
AHI reduction rate range post treatment with VDO	36%–88%	-9%–87%
Average AHI reduction rate post treatment with VDO	67%	50%

This study did not show improvement of AHI scores in all patients with added vertical dimension of 2 mm; however, as per a satisfaction questionnaire, most patients reported that they were more comfortable with the increased vertical

dimension, which could because of “cushioning” between trays or improved outcomes.

In the study conducted by Pitsis et al. (2002), 24 patients were recruited for a randomized clinical trial with crossover study design. The aim of this study was to assess the effect of vertical dimension of occlusion induced by a mandibular advancement splint (MAS) on efficacy and side effects in the treatment of OSA. All patients in this study were recruited from a Sleep Disorders Clinic at a University Teaching Hospital, with inclusion criteria comprising the presence of symptoms of OSA such as snoring, fragmented sleep, and daytime sleepiness, and evidence of OSA on PSG shown by AHI > 5/hour. Patients with evidence of central sleep apnea, periodontal disease, or edentulism were excluded from the study. Dental impressions and bite registrations were considered for each patient to fabricate two different version of oral appliance, MAS-1 and MAS-2. Both MAS-1 and MAS-2 are custom-made for each patient with the same level of mandibular protrusion so that the patient feels comfortable; however, the vertical dimension was set different. MAS-1 had an interincisal opening of 4 mm, whereas MAS-2 was configured to have interincisal distance of 14 mm. All patients answered two questionnaires at baseline, assessing OSA symptoms and also undertook overnight PSG. To compare MAS-1 and MAS-2 appliances, patients were acclimatized to MAS-1 for up to 6 weeks; during this time, there was incremental advancement of the mandible until the maximum comfortable limit was reached. ‘The absolute amount of protrusion was measured with a stainless ruler as the horizontal distance from the lower central incisors in the maximum intercuspation to the maximum comfortable protrusion position.’ Next, patients were allocated randomly to Group I or Group II. All patients had 1 week of washout period when they did not wear dental appliances; they were subsequently treated with MAS-1 or MAS-2 for 2 weeks followed by the other

device for another 2 weeks; there was 1 week of washout period in between the application of two appliances. Outcomes were assessed at the end of each treatment period. The outcome was recorded through self-administered questionnaires filled by the patients to assess the frequency, severity, and duration of side effects along with treatment compliance and satisfaction with each appliance. Other outcomes such as Epworth sleepiness scale and regular PSG results were also collected to obtain and compare AHI levels after the treatment compared to pre-treatment baseline figures. In total, 23 of 24 recruited patients (21 men, three women) completed the study; one male patient withdrew due to personal time constraints. Outcome observation shows insignificant change in BMI; the mean mandibular protrusion for MAS-1 was 7.3 ± 0.5 mm, which represented 87 ±4% of the maximal protrusion. All patients tolerated both of oral appliances. There was no significant difference in the proportion of patients reporting excessive salivation (48 versus 57%, p=0.55), dry mouth (26 versus 22%, p=0.73), tooth grinding (22 versus 13%, p=0.43), and gum irritation (22 versus 13%, p=0.43) between MAS-1 and MAS-2; more patients reported jaw discomfort with MAS-2 (48 versus 70%, p=0.13). There was no significant difference in the reported severity, frequency, or duration of side effects between appliances.

Significant and equal reduction of Epworth sleepiness scale score was observed from baseline values with each MAS (18 ±1 versus 12 ±1, p<0.0001). ‘Significantly high proportion of patients preferred to use MAS-1 in comparison with MAS-2 (78 versus 22%, p=0.007)’ More quantitative outcomes such as Polysomnographic outcomes were reviewed; most outcomes showed insignificant differences between the two oral appliances, MAS-1 and MAS-2. Reduction in AHI compared to baseline values was 62% for MAS-1 and 52% for MAS-2. Arousal index decreased significantly with MAS-1 (28% reduction) and MAS-2 (33% reduction).

3.5 Level of protrusion titration

Four of the 10 selected studies focused on finding the optimal level of protrusion or mandibular advancement when setting up the oral appliance therapy for treatment of OSA. Aarab et al. (2010); Anitua et al. (2017); Choi, Kee, and Kang 1999; and Lee 2018 focused on the effects of oral appliance at different mandibular protrusion positions on 68 patients.

Aarab et al. (2010) conducted a clinical study involving 17 patients to assess the influence of four mandibular advancement positions on OSA treatment using MAD to hold the vertical dimension of occlusion constant at 6 mm, measured between the first incisors with the MAD in the mouth. We initially recruited 20 OSA patients to participate (13 men, seven women) with average age of 49.5 ± 8.1 SD. Three patients who did not complete the entire study were excluded from the final data resulting in 17 patients (12 men, five women). This study consisted of six PSG recordings per patient: a baseline recording at the hospital, four ambulatory recordings at home, and a follow-up recording at the hospital. The patients received the MAD on average 5 weeks before the first ambulatory recording at home. The patients were instructed to wear the MAD every night upon delivery. Like most studies, a complete response to the MAD treatment was defined as a reduction in AHI to less than five events per hour, and a partial response was defined as a reduction of at least 50% in AHI in comparison to baseline values, but with AHI remaining at five or more events per hour. During the ambulatory PSG tests at home, recordings were taken with the oral appliance in situ at 0%, 25%, 50%, and 75% of the maximum protrusion in random order, with average interval duration of 3 weeks between subsequent recordings. The study also collected and analyzed other outcomes from the patients such as BMI changes and Epworth Sleepiness Scale. The participants were interviewed considering compliance, i.e., the frequency of usage/wearing per week, and the

possible side-effects were also noted; finally, information regarding snoring intensity was collected from the participants' bed partners. Respiration and sleep variables from the baseline and follow-up PSG were analyzed for the 17 participants. Of the 17 patients, mandibular advancement of 25% was most effective for one patient, advancement of 50% was the most effective for sic patients, and the other 10 patients showed the most effective advancement of 75% for the MAD device. Furthermore, 12 of the 17 patients showed complete response to the MAD at its most effective protrusion setting, and one other patient had a partial response to the treatment. Considering compliance, percentage of nights per week of wearing the MAD varied according to the level of protrusion. For 0%, the compliance rate was 80.1%, for 25%, compliance rate was 94.4%, for 50%, compliance rate was 96.4%, and for 75%, compliance rate was 90.5%. Reasons for non-compliance included simple factors such as forgetting to wear the appliance before going to bed, illnesses including common cold, and transient side effects such as hypersalivation and dry mouth. Finally, a decrease in self-reported snoring intensity was found more frequently with in situ MAD set at the 50% and 75% protrusion positions.

Unlike the study conducted by Aarab et al. (2010), which shows evidence of better effectiveness at ≥50% mandibular advancement position, the study by Anitua et al.'s (2017) "Minimizing the mandibular advancement in an oral appliance for the treatment of obstructive sleep apnea" suggests that, for some patients, even zero advancement position will have positive effects on the OSA treatment. In total, 36 patients (22 men, 14 women) were recruited and treated for OSA using oral appliances. Commercially available oral appliance was selected and fabricated with thermoforming plastic sheet of 1.5 mm thickness for mandible, and 1 mm for maxilla; the necessary increase was incorporated in the

vertical dimension to avoid occlusion of the active inferior cusps and incisal edges onto a flat upper splint during protrusion. All patients were fitted with MAD without any mandibular advancement. AHI was recorded with a respiratory polygraphy two weeks after initiating the OAT. If necessary, the mandibular advancement was incorporated with step size of 1 mm. Optimal protrusion position was determined by the level of protrusion that yielded the most reduction of AHI compared to baseline. While determining the optimal titration, if the incremental advancement worsened the AHI result, the treatment was stopped at the previous level of advancement. The outcomes of sleep study were recorded using validated respiratory polygraphy comprising five channels: respiratory flow, oxygen saturation, cardiac frequency, corporal position, and snoring sensors; the device corresponded to classification III of the AASM. The outcomes of sleep study were controlled by a blinded sleep technician and supervised by a sleep medicine specialist. A respiratory event was recorded as apnea if it had duration of ≥10 s and drop in respiratory signal was >90% of the amplitude of the respiratory air flow. The characteristics of patients were predominated by overweight among men; 15 patients had mild OSA, 14 patients had moderate OSA, and seven patients had severe OSA with intolerance of CPAP treatment. The outcomes of the study showed that average decrease in AHI was 12.4 units and in the CT 90 (cumulative time spent below an oxygen saturation of 90%) was 7.6 minutes. The improvement in the respiratory events and blood oxygen saturation was statistically significant. The most effective mandibular advancement position found for the 36 patients participating in the study was as follows. 11 patients at zero protrusion, six patients at 1 mm advancement, nine patients at 2 mm advancement, five patients at 3 mm advancement, four patients at 4 mm advancement, and one patient at 5 mm advancement. In contrast, some previous studies claim that effectiveness of oral appliance is only valid with some level of mandibular advancement positioning, typically at least 50% of maximum

protrusion; even at zero protrusion, OAT can be effective in treating OSA patients.

Choi, Kee, and Kang (1999) recruited 14 participants; seven of these visited the University hospital for snoring but did not report any other disease or serious health concern. The control group included seven healthy participants without any serious illness, health-related concern, or snoring. Both groups had no evidence of Temporomandibular joint disorders and the participants could perform the regular range of mandibular motion. Unlike other studies, this study did not use a conventional oral appliance such as MAD for treatment of OSA; we used silicone mouth positioners to stabilize the jaw position; CT was performed for the normal jaw position and protrusive jaw position of all participants. Such mouth positioners were fabricated for each participant; both positioners set the vertical dimension of 7 mm as interincisal distance, one positioner included zero protrusion of mandible; the other positioner was set to two thirds (66.7%) of maximum protrusion range. All participants underwent computerized tomograms with two different mouth positioners in place, and resulting figures were compared between normal position of the mandible and the protrusion mandibular positioning, both for test group and control group. The main outcomes included change of minimal cross-sectional area of nasopharynx, oropharynx, and hypopharynx along with the change of volume of nasopharynx, oropharynx, and hypopharynx. The characteristics of the snoring (test) group were different from that of non-snoring (control) group, Average age was 41.6±13.2 compared to 23.6±1.5 for control group and the weight in test group was 70±11.8 versus 55.9±4.9 in control group; thus, overweight and obese population showed higher probability of snoring and OSA occurrence. The mean minimal cross-sectional area of nasopharynx and oropharynx was 190.3±28.5 mm^2 and 57.1±21.8 mm^2 for test group and 232.3±50.4 mm^2 and 72.7±18.2 mm^2 for control group, respectively. The cross-sectional area was smaller in the test

group, but it was not statistically significant. In contrast, the cross-sectional area of hypopharynx was larger in the test group than in the control group with outcome of 242.3±73.9 mm² for test group and 183.4±63.2 mm² for the control group; however, it was not statistically significant. The average volume of nasopharynx was almost same in the two groups; 5.21±0.86 cc for test group and 5.67±1.60 cc for the control group; for oropharynx, the average volume was 6.48±2.10 cc for test group and 4.60±1.51 cc showing slightly larger numbers for the test group but it was not statistically significant. The average volume of hypopharynx was 8.86±2.10 cc for test group and 11.71±2.09 cc for control group, i.e., test group had smaller volume ($P<0.05$). The effect of mandibular advancement position was determined by repeating the CT scans with the other mouth positioner at the protruded mandibular position and calculating the change in the two outcomes. As a result of mandibular advancement, average cross-sectional area of nasopharynx and oropharynx increased by 10.3% and 48.7%, respectively in the test group, but the average minimal cross-sectional area of nasopharynx reduced by 16.8% ($P<0.05$). For the control group, mandibular advancement was shown by 10.2% increase in average nasopharynx minimal cross-sectional area and 83.5% increase in oropharynx but without any change in cross-sectional areas of the hypopharynx. Lastly, the volume of nasopharynx, oropharynx, and hypopharynx increased by 5%, 25.8%, and 14.1% in test group, and 9.5%, 35.6%, and 1.4% in control group, respectively, but all data were statistically insignificant.

3.6 Side effect considerations

Side-effects or adverse events during the OAT are often related to simple discomfort of patients, dryness of the mouth, hypersalivation or more seriously related to occlusal change or pain in temporomandibular joint. Martı´nez-Gomisa et al. (2010) conducted the study “Five years of sleep apnea treatment with

mandibular advancement device; side effects and technical complications" involving 40 OSA patients for 5 years. Initially, 41 adult patients with mild to severe OSA were recruited from a university hospital in Barcelona, but one patient was excluded owing to less teeth; thus, oral appliance usage was not possible. Other patients were recruited between 2002 and 2004, all 40 patients (31 men, nine women) were diagnosed with OSA; the evidence was supported by overnight polysomnography with resulting AHI>10/h. Exclusion criteria were patients with severe periodontal disease or with insufficient teeth to fit the MAD. Twin block acrylic splint type MAD was used, and the George Gauge (Great Lakes Orthodontic Lab, Tonowanda, NY) was used to measure the maximum mandibular advancement and for the interocclusal record of the desired vertical dimension of occlusion of the oral appliance. The mandibular advancement setting started at 70% of maximum capacity; it was then progressively increased over the following weeks until the device efficacy was apparent (patient stopped snoring), or side effects started to appear. The initial baseline was created for all patients with information such as occlusal characteristics, allocation to non-TMD groups or one of the three main groups of TMD, overjet and overbite was measured by digital calipers (Absolute; Vogel Germany, Kevelaer, Germany), number of occlusal contacts and number of teeth in contact were recorded in both the anterior and posterior regions. Visits to the hospital was made in the beginning, follow-up visit was 6 weeks after the last increase in protrusion, 6 months later, and 5 years after starting the therapy. MAD efficacy and OSA treatment outcomes were evaluated regularly by conducting polysomnography; patients lacking response on the PSG were advised to stop oral appliance usage. 'Of the 40 patients, five patients 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.' Between the first and third checkup, 20 patients stopped using the MAD device; 11 patients stopped using the device as the PSG showed insufficient

efficacy, four stopped due to side effects such as arthralgia, myofascial pain, or discomfort, four patients believed that they did not need the appliance, and one patient stopped because of multiple breakages of the appliance. After 5 years of checkup, 15 still used the MAD device. '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.' Five participants initially diagnosed with myofascial pain or arthralgia stopped using the oral appliance because it was ineffective. The number of occlusal contacts on the posterior teeth was reduced significantly during the 5 years of OAT, and the greatest reduction was observed at the second checkup. Overbite and overjet were also significantly reduced during treatments. Only eight out of 40 patients did not request an extra visit to the dental clinics, and four of these patients still used the oral appliance 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. 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, 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. Thus, most OSA patients undergoing OAT may experience mild, temporary subjective side effects, and permanent occlusal changes mainly during the first 2 years; however, the use of oral appliance such as MAD does not affect TMD prevalence and some TMD patients should stop using the appliance because of its insufficient efficacy.

Lee et al. (2018) wrote "Effect of mandibular advancement device of different protrusion positions for treatment of obstructive sleep apnea on tooth and facial

bone: A Finite Element Study". Many OSA patients are treated with OAT and suffer from side effects associated with long-term usage of MAD appliance, such as permanent occlusion changes and discomfort or pain in the TMJ area; however, most studies mainly outline the analysis of data obtained from subjective questionnaires, clinical studies, and analysis of CT or cephalogram; they lack quantitative data on change in the teeth and facial bone from the use of MAD. The study used finite element analysis (FEA) to measure and analyze the stress on the teeth, alveolar bone, periodontal ligament, and facial bone in a non-invasive way. There was only one patient participating in this study who was a 27-year-old female, with no history of temporomandibular joint disorders or other dental conditions. The subject had a 2 mm of overbite and overjet at centric relation occlusion, and maximum protrusion capacity of the patient was 10 mm. The study analyzes various forces associated with MAD usage such as the 'Posterior restorative force of mandible,' which was at its lowest during 40% protrusion position of the maximum capacity, and statistical significance only applies to restorative force increasing at a 60% protrusion position of the maximum capacity; the maximum value of restorative force was at 70% of the protrusion position. The study also notes changes in mandibular arch due to OAT; different magnitudes of force are applied to different parts and directions of the arch. Excessive mandibular advancement set by the MAD appliance can change the shape of the mandibular arch, making it narrower in width, causing malocclusion, and other side-effects.

IV. Discussion

There is increasing research on sleep disorders and their treatment. OSA is a common sleep disorder that is investigated by many medical disciplines and clinical faculties. The standard of care for OSA patients is CPAP, and only the mild to moderately severe patients or those who fail to cope with CPAP treatment undergo OAT. However, the case studies reviewed in this paper suggest that OAT can be applied to broader audiences using the correct technique and design of the appliance.

Although OAT has relatively mild and temporary side-effects compared to other therapies such as surgery or CPAP treatment, OAT has adverse events as per a study by Martı´nez-Gomisa et al (2010). However, response to MAD is variable and generally 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. The most common reason for discontinuing MAD use is insufficient efficacy, side effects, and complications. However, Martı´nez-Gomisa et al. (2010) also suggested that TMD prevalence is not correlated with the statistically significant use of MAD; thus, it should not always be considered a contraindication or exclusion criterion for OSA treatment employing an oral appliance.

There are various limitations to each of the studies reviewed; only one participant was studied in some studies or they were conducted for a short time duration. However, the major limitation of the studies is that amount of data accumulated for studies defining the effect of vertical opening on the OAT therapy is lacking, and insufficient to produce a healthy guideline on how much interincisal distance should be maintained. Some previous studies suggest that this does not affect the end result, and we should focus on achieving the target

distance on the mandibular advancement position; this has more effective treatment outcomes and it increases the treatment adherence of the patient owing to increased comfort. The anatomical, physical, and structural characteristics of each patient should be carefully evaluated by examining their cephalograms, CT, scans, pharyngometer, and other diagnostic tools and customizing the appliance titration for the most effective treatment results. Most studies suggest frequent visit to the clinics in the first year to configure the protrusion position incrementally, usually starting at 50% of the maximum advancement capacity and progressively advancing the mandible by 1 mm per week until the optimal position is achieved.

The case study outlined in “A more effective Bite Registration technique for Dental Sleep Appliances” (Rawson 2018; Carollo 2018; Morgan 2018) demonstrated an overall average reduction in AHI of approximately 75% in 32 cases, of which 81.3% were in the severe category with pre-treatment AHI scores ranging from 33.2 to 113.1

Dr. Carollo’s case study demonstrated the importance of OA design, and showed how correctly fitted appliance can be as effective as CPAP treatment for moderately severe OSA patients. The case also pointed out that OAT can be very ineffective if it is not precisely designed to resolve the structural issue faced by the patient. Thus, OAT should always be custom-made following diagnosis by the dentist because generic splints are unlikely to have any significant medical benefit on the patient.

Finally, Dr. Morgan presented the case study with 20 patients, demonstrating the effect of increased vertical dimension on the OA. The appliance used by Dr. Morgan was both 3D printed, using digital CAD/CAM technology, and nylon-based substance. Notably, OAT is an alternative treatment for patients who failed to comply with CPAP treatment mainly because of discomfort while sleeping.

OAT application is more comfortable for patients in bed; with the new 3D printed nylon appliances, it is possible to upgrade the patient's experience by making the device smaller, lighter, thinner, yet more durable and prone to wear and tear when compared with the traditional appliances from dental laboratories. Dr. Morgan specifically used the 3D printed nylon appliances because he was aware of the downside of this latest technology, i.e., physicians cannot modify the appliance once it is fabricated. The traditional MAD device allowed modifications by adding acrylics to the device; owing to chemical differences in the polymer, this last-minute modification is not possible with the nylon MAD device. However, Dr. Morgan offered an alternative solution of adding a vertical dimension in the appliance, i.e., a 'vertical TAB' that also acts as cushion between the maxilla and mandible and improves user comfort even if the AHI is not reduced dramatically.

V. Conclusion

We reviewed 10 studies conducted on 188 patients to identify the effect of vertical dimension in oral appliances in treating OSA patients. All the studies adopted different number of patients and methodology, but reached a similar conclusion that in most cases. Addition of vertical dimension in the titration may enhance the efficacy of MAD, and is just as important, if not more important, as the level of advancement of the mandible as some suggests titration of zero protrusion position could also work with well-designed MAD that has enough vertical opening built into it. However, this could be a trade-off between efficacy and minor side-effects such as patient discomfort or dryness of the mouth in the morning.

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ABSTRACT (IN KOREAN)

폐쇄성수면무호흡증 환자의 하악전방디동장치(MAD) 제작 시 수직고경 추가가 미치는 치료 효과 확인

< 지도교수 권 재 성 >

연세대학교 대학원 의료기기산업학과

김 상 우

폐쇄성수면무호흡증은 심각한 수면 관련 호흡기 장애로, 수면 시 호흡을 방해하거나 완전히 중단하여 수면 중 공기 유입을 차단하게 된다. 이는 각종 직접적, 간접적인 증상을 초래하게 된다. 직접적인 증상으로는 온전한 숙면을 취하지 못하고 분절 수면을 하게 되며 주간 졸림 증상을 일으킬 수 있다. 또한 기도가 막혀 호흡이 차단됨에 따라 산소포화도가 일정 수준 이하로 떨어지게 되면 뇌 손상 혹은 심장 질환 등 더 위험한 합병증이 발병할 수 있다. 폐쇄성수면무호흡증의 유병률은 남성 24퍼센트, 여성 9퍼센트에 달할 정도로 높은 편이지만 성인 폐쇄성수면무호흡증 환자의 약 80에서 90퍼센트는 진단을 받지 못한 상태이며, 본인이 처한 위험에 대해 인지하고 있지 않을 가능성이 높다.

폐쇄성수면무호흡증의 표준 치료는 현재 지속기도양압기(CPAP)이며, 이는 양압

기 치료는 수면무호흡증의 정도와 관계 없이 모두 치료가 가능하기 때문이다. 다만, 많은 환자들은 양압기 착용을 불편해하며 수면 중 착용하지 않거나 적응에 실패할 가능성이 있으며, 이때 구강내장치 치료를 대안으로 사용할 수 있다. 구강내장치의 작용 원리는 치아에 착용하는 스플린트 형태의 장치를 사용하여 하악을 전방으로 고정시키고 수면 시 연조직이나 혀 등이 쳐져서 기도를 막지 못하도록 하는 것이다.

구강내장치를 사용한 폐쇄성수면무호흡증의 치료는 주로 장치의 디자인, 치료 효과, 그리고 부작용등에 대해 연구가 이루어졌다. 이는 대부분 하악이 얼만큼 전방으로 돌출되게 설계할 것인지, 어떤 재료로 장치를 만들지 등에 대한 내용이 대부분이다. 이 연구는 하악의 전방 이동과 더불어 수직고경의 변동을 고려했을 때 적합한 장치 titration 설계가 이루어질 수 있을지, 그로 인해 구강내장치의 치료효과를 개선 시킬 수 있을지 확인하고자 한다.

핵심 되는 말: 폐쇄성수면무호흡증, 구강내장치치료, 수직고경, 하악전방이동