บทวิทยาการ
Original Article

ประสิทธิผลของเครื่องมือเคลื่อนตำแหน่งขากรรไกรล่างไปด้านหน้าแบบปรับไม่ได้ด้วยแม่เหล็ก ในผู้ป่วยที่มีภาวะหยุดหายใจขณะหลับจากการอุดกั้นระดับน้อย: การศึกษาติดตามผลเบื้องต้นในระยะสั้น

Efficacy of Non-adjustable Magnetic Mandibular Advancement Appliances (2M2A) in Patients with Mild Obstructive Sleep Apnea: a Preliminary Short-term Study

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บทคัดย่อ

วัตถุประสงค์: 1) ศึกษาประสิทธิผลของเครื่องมือในช่องปากชนิดยื่นขากรรไกรล่างไปด้านหน้าแบบปรับไม่ได้ด้วยแม่เหล็ก (2M2A) ในผู้ป่วยที่มีภาวะหยุดหายใจขณะหลับจากการอุดกั้นระดับน้อยต่อดัชนีการหยุดหายใจและหายใจแผ่ว (AHI) และระดับความอิ่มตัวของออกซิเจน

Abstract

Objectives: 1) to assess the efficacy of the non-adjustable mandibular advancement device, namely Magnetic Mandibular Advancement Appliances (2M2A) in patients with mild obstructive sleep apnea (OSA), compared between

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ในเลือดแดง ติดตามผลการรักษา 3 เดือน 2) ศึกษาการเปลี่ยนแปลงของโครงสร้างกระดูกกะโหลกศีรษะและใบหน้าและทางเดินหายใจส่วนบน ขณะใส่เครื่องมือ 2M2A ในผู้ป่วยที่มีภาวะหยุดหายใจขณะหลับจากการอุดกั้นระดับน้อย

วัสดุและวิธีการ: ผู้ป่วยไทยอายุ 20-69 ปี ที่ถูกส่งมาจากแพทย์ จำนวน 15 ราย ได้รับการวินิจฉัยภาวะหยุดหายใจขณะหลับจากการอุดกั้นระดับน้อยจากการตรวจด้วยพอลิซอมโนกราฟและล้มเหลวจากการรักษาโดยการจี้เพดานปากด้วยคลื่นความถี่วิทยุ การประเมินโครงสร้างกระดูกกะโหลกศีรษะใบหน้าและทางเดินหายใจด้วยภาพรังสีศีรษะด้านข้างโดยการเปรียบเทียบก่อนและหลังจากใส่เครื่องมือ 2M2A และประเมินดัชนีหยุดหายใจและหายใจแผ่วและระดับความอิ่มตัวของออกซิเจนในเลือดแดงด้วยพอลิซอมโนกราฟอีกครั้งภายหลังการใส่เครื่องมือ 3 เดือน

ผลการศึกษา: เมื่อประเมินหลังการรักษา 3 เดือน พบการลดลงของค่า AHI อย่างมีนัยสำคัญ ขณะที่ระดับความอิ่มตัวของออกซิเจนในเลือดแดงมีการเพิ่มขึ้นอย่างมีนัยสำคัญ ขณะผู้ป่วยใส่เครื่องมือ 2M2A พบการยื่นไปทางด้านหน้าและหมุนตามเข็มนาฬิกาของขากรรไกรล่าง ใบหน้าส่วนล่างยาวมากขึ้น การลดลงของค่ามุม ANB และระยะความเหลื่อมกันในแนวระนาบและแนวดิ่งของฟันหน้าบนและล่าง และการเพิ่มขึ้นอย่างมีนัยสำคัญของความกว้างของทางเดินหายใจส่วนบน

บทสรุป: ขณะใส่เครื่องมือ 2M2A จะเกิดการเปลี่ยนแปลงตำแหน่งของขากรรไกรล่าง การขยายขนาดของทางเดินหายใจส่วนบน และการปรับปรุงคุณภาพของการหลับให้ดีขึ้นอย่างมีนัยสำคัญในผู้ป่วยที่มีโรคหยุดหายใจขณะหลับจากการอุดกั้นระดับน้อย

คำสำคัญ: โรคหยุดหายใจขณะหลับจากการอุดกั้น การวัดภาพรังสีศีรษะด้านข้าง เครื่องมือเคลื่อนตำแหน่งขากรรไกรล่างไปด้านหน้า ทางเดินหายใจส่วนบน การจี้ด้วยคลื่นความถี่วิทยุ

pretreatment and 3-month after the insertion of the 2M2A, using apnea hypopnea index (AHI) and minimum oxygen saturation 2) to determine changes in craniofacial and upper airway structures in patients with mild OSA, treated with 2M2A by means of lateral cephalometric analysis.

Materials and Methods: Fifteen Thai subjects aged between 20 and 69 year-old with mild OSA who have failed to previous radiofrequency ablation treatment were recruited. Lateral cephalometric radiographs were taken twice; prior to and after the 2M2A inserted in place. Polysomnography was performed 3-month posttreatment.

Results: Three-month after insertion of the 2M2A, average AHI was significantly decreased, whereas minimum oxygen saturation was significantly increased. When the 2M2A inserted in place, forward position and clockwise rotation of the mandible, an increase in lower facial height and decreases in ANB, overjet and overbite were significantly observed. Significant increase of upper airway width was also found after the 2M2A inserted in place.

Conclusion: After the 2M2A inserted in place, changes of mandibular position, enlargement of upper airway, and improvement of AHI and minimum oxygen saturation was significantly observed in mild OSA patients.

Keywords: obstructive sleep apnea, lateral cephalometry, mandibular advancement device, upper airway, radiofrequency ablation

Introduction

Sleep-related breathing disorders (SRBD), characterized by disordered respiration during sleep, was estimated to be found 9% for women and 24% for men in Western population.(1) Among Thai population, the estimated prevalence of SRBD has been reported to be 6.1% in patients aged over 45 years old in both males and females.(2)

Obstructive sleep apnea (OSA) is the most common subgroup of SRBD according to a second edition of the International Classification of Sleep Disorders.(3) The OSA syndromes include those who have temporary repetitive upper airway obstruction, subsequent to increased breathing attempt but insufficient ventilation. At present, polysomnography has been used as a standard diagnostic test for OSA, based upon AHI (Apnea Hypopnea Index). AHI is the number of apneas and hypopneas that occur per hour of sleep. It can be categorized the severity as mild (5-14.9 episodes/ h), moderate (15-29.9 episodes/ h) and severe (≥ 30 episodes/ h), according to the Apnea Hypopnea Index (AHI).(4) Patients with OSA are associated with increased likelihood of cardiovascular disease, hypertension, ischemic heart disease, daytime sleepiness, motor vehicle accidents and reduced quality of life.(5)

It is suggested that upper airway soft tissue may aggravate the severity of OSA. Although obstruction of the upper airway may occur in different anatomical sites, abnormal closure of the upper airway is most often located in the retropalatal and retroglossal areas.(6) Furthermore, abnormal structure of craniofacial skeleton together with neuromuscular activity has been revealed to be the important factors for determining upper airway patency during sleep.(7) Accumulating studies, using lateral cephalometry, have pointed out possible risks for OSA including long and thick soft palate and tongue, inferior and anterior position of hyoid bone and decreased antero-posterior size of oropharynx.(8,9)

Several treatment modalities have been demonstrated to be effective for OSA treatment, e.g. weight loss, oral appliances (OAs), continuous positive airway pressure (CPAP), radiofrequency ablation, and surgical procedures.(11) CPAP and OAs are the two most common methods used for OSA treatment.(12) Typically, CPAP is the treatment of choice for OSA treatment, as it is effective for AHI reduction.(13) However, with the cumbersome, it can be discomfort in some patients. For those who non-adherent to CPAP, OAs appear to be an attractive treatment option and be advantageous over CPAP in terms of comfort design, minor side effects, and better treatment adherence compared to CPAP use.(13,14) Treatment with mandibular advancement devices are supposed to advance position of the mandible with different methods, including use of magnets, and assumed widening of the upper airway space during sleep. Uses of magnets for guiding the mandibular forward have been documented in OSA patients.(15,16)

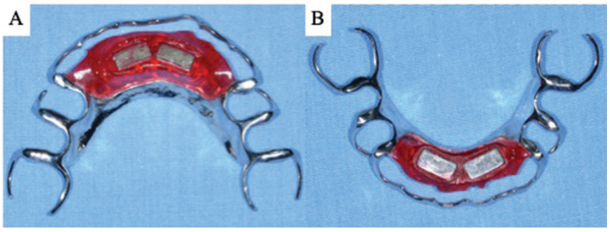
Radiofrequency ablation (RFA) of the soft palate is one of the treatment modalities which have been demonstrated its effectiveness for reducing simple snoring and treating mild to moderate OSA.(11) It is used to stiffen structure of the soft palate. The main advantage of RFA is that it can be performed in one or more sessions under local anesthesia. Although RFA of the soft palate is generally recommended as a second-line treatment for mild to moderate OSA if CPAP therapy is not adhered to or tolerated, it may be utilized as a first-line treatment alternative with the fruitful results.(11) Patients whom the RFA treatment do not provide successful results, either CPAP or OAs are other treatment options in this circumstance. In the present study, Magnetic Mandibular Advancement Appliances (2M2A) was used to improve OSA condition in patients who have previously received RFA treatment of the soft palate at least one session as the first-line treatment with remaining unpleasant results. The aims of the present study were 1) to assess the efficacy of the 2M2A in patients with mild OSA, compared between pretreatment and 3-month after the insertion of the 2M2A, using AHI and minimum oxygen saturation 2) to determine changes in craniofacial and upper airway structures in patients with mild OSA, treated with 2M2A, by means of lateral cephalometric analysis.

Materials and Methods

Fifteen Thai patients (male 8, female 7) aged between 20 and 69 year-old with snoring complaint and diagnosed as mild OSA, were referred from the Department of Otolaryngology, Faculty of Medicine, Chiang Mai University. The study protocol was approved by the Human Experimentation Committee of the Faculty of Dentistry, Chiang Mai University. The diagnosis of OSA was performed by overnight portable polysomnography using SOMNOCHECK V2.04 (data not shown).[17]

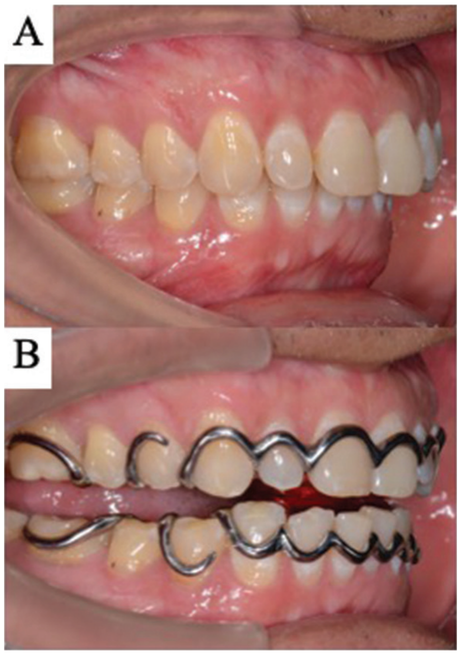
All participants have previously received RFA treatment of the soft palate at least one session as the first-line treatment with remaining unpleasant results, and thereafter were acquired 2M2A at the Department of Orthodontics and Pediatric Dentistry, Faculty of Dentistry, Chiang Mai University, in order to improve OSA condition. Polysomnography was performed prior to 2M2A insertion and two variables: AHI and minimum oxygen saturation were recorded as "pretreatment". The RFA was performed according to the previously described method.[11] Patients were excluded if one of the following condition present: inadequate number of healthy teeth, poor oral hygiene, ongoing periodontal diseases, significant limitation of mandibular protrusion (≤ 6 mm) and mouth opening, and acute temporomandibular disorders with pain conditions.

Magnetic Mandibular Advancement Appliances or 2M2A (patent no. 1501006198) are removable non-adjustable custom-made dental alloy frameworks, made of Cobalt-Chromium alloys (ADA specification No.14), with two pairs of Neodymium-Iron-Boron magnets (4.0 mm diameter x 1.5 mm



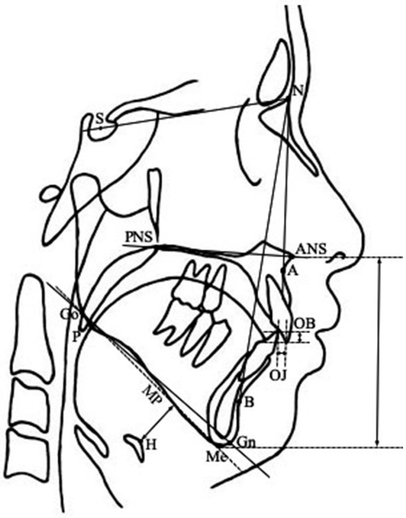
รูปที่ 1 *ลักษณะของเครื่องมือเคลื่อนตำแหน่งขากรรไกรล่างไปด้านหน้าโดยแม่เหล็ก (2M2A) ชิ้นส่วนบน (A) ชิ้นส่วนล่าง (B)*

Figure 1 *Design of the Mandibular Advancement Appliances (2M2A). Upper part (A), Lower part (B)*



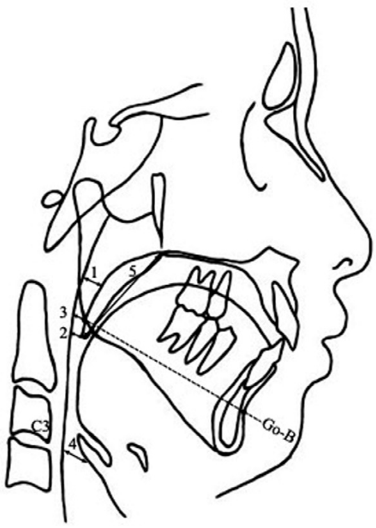
รูปที่ 2 *ภาพเครื่องมือ 2M2A ที่ออกแบบให้มีการเคลื่อนของขากรรไกรล่างไปทางด้านหน้าร้อยละ 50-75 ของการเคลื่อนไปด้านหน้ามากที่สุด ขณะไม่ได้ใส่เครื่องมือ 2M2A (A) ขณะใส่เครื่องมือ 2M2A (B)*

Figure 2 *View on 2M2A designed to move mandible anteriorly in 50-75 % range of maximum protrusion. Without 2M2A (A), With 2M2A (B)*



รูปที่ 3 *จุดที่ใช้วิเคราะห์ภาพรังสีศีรษะ*

Figure 3 *Cephalometric landmarks*



รูปที่ 4 *การวัดขนาดของทางเดินหายใจส่วนบน*

Figure 4 *Upper airway measurement*

ตารางที่ 1 *จุดและเส้นอ้างอิงที่ใช้วิเคราะห์ภาพรังสีศีรษะ*

Table 1 *Cephalometric landmarks and reference lines used*

Landmarks	Interpretation
S	Sella; midpoint of the fossa hypophysealis.
N	Nasion; anterior point at the frontonasal suture.
A	A point; the deepest anterior point in concavity of the maxilla.
B	B point; the deepest anterior point in concavity of the mandible.
ANS	Anterior nasal spine; the most anterior point of the anterior nasal spine.
PNS	Posterior nasal spine; the most posterior point of the hard palate.
Go	Gonion; mid-plane point at the gonial located by bisecting the posterior border lines of the mandible.
Gn	Gnathion; midpoint between the most anterior and inferior point on the bony chin.
Me	Menton; the most inferior point of the mandible.
H	Hyoidale; the most antero-superior point of the hyoid bone.
C3	The most antero-inferior point of the third vertebral corpus.
P	Tip of the soft palate
SN	Anterior cranial base; a line connecting S to N
PP	Palatal plane; a line connecting ANS to PNS
GoGn	A line connecting Go to Gn
MP	Mandibular plane; a line connecting Go to Me

ตารางที่ 2 *การวัดภาพรังสีศีรษะ*

Table 2 *Cephalometric measurements*

Measurements	Interpretation
SNA	Angle from sella to nasion to A point
SNB	Angle from sella to nasion to B point
ANB	Angle from A point to nasion to B point
SN-PP (°)	Angle between anterior cranial base and palatal plane
SN-GoGn (°)	Angle between anterior cranial base and GoGn plane
ANS-Me (mm)	Linear distance from ANS to Me which represents the lower anterior face height
Overjet (mm)	Linear distance between the incisal tip of maxillary central incisor and the labial surface of the mandibular central incisor on a line parallel to the occlusal plane
Overbite (mm)	Linear distance between the incisal tip of maxillary central incisor and the labial surface of the mandibular central incisor on a line perpendicular to the occlusal plane
MP-H (mm)	Linear distance between mandibular plane and Hyoidale
PNS-P (mm)	Linear distance between posterior nasal spine and tip of the soft palate

ตารางที่ 3 *การวัดทางเดินหายใจส่วนบน*

Table 3 *Upper airway measurements*

No.	Measurements (mm)	Interpretation
1	SPAS	Width of the airway behind the soft palate along parallel line to Go-B line.
2	MAS	Width of the airway along parallel line to Go-B line through the soft palate tip.
3	IAS1	Width of the airway along Go-B line.
4	IAS2	Width of the airway along parallel line to Go-B line through C3.
5	PNS-P	Linear distance from PNS to the soft palate tip.

thickness) covered with plastic caps and then embedded in acrylic, located in the anterior part of both in upper and lower frameworks (Figure 1A, B). The 2M2As were designed to guide the mandible in the 50-75% range of maximum protrusion in the present study (Figure 2A, B).

Polysomnography was performed again at 3-month after insertion of the appliances to determine treatment outcome and recorded as "posttreatment". The index collected after patients receiving RFA treatment were recorded as pretreatment.

All lateral cephalographic images were taken with Kodak 9000 Extraoral imaging system (Eastman Kodak, Rochester, NY, USA) with a standardized fashion for each patient. All subjects were positioned in the cephalostat with the Frankfort horizontal plane paralleled to the floor, the sagittal plane perpendicular to the path of the X-rays. Patients were trained to bite their molars in maximum intercuspation and to inhale through their nose. Each patient was assigned to take lateral cephalographs twice, prior to and after 2M2A inserted in place. To determine changes of mandibular position after 2M2A inserted in place, the digital radiographs were analyzed using cephalometric landmarks (Figure 3, Table 1) and measurements (Figure 3, Table 2). Dolphin Image

Software 11.8 (Dolphin Imaging and Management Solutions, Los Angeles, California, USA) was used for angular measurements including SNA, SNB, ANB, SN-PP and SN-GoGn, and a linear measurement: ANS-Me (Figure 3, Table 2). ImageJ 1.49v software (National institutes of health, USA) was used to determine changes of the distance between MP and H (Figure 3, Table 2), and the upper airway width (Figure 4, Table 3) after 2M2A inserted in place.

All statistical analyses were performed using the SigmaPlot software, version 12.5 (Systat Software Inc, San Jose, CA, USA). The data were analyzed using the Wilcoxon Signed Rank Test for between-groups comparison. Results were considered significant at $p < 0.05$.

To determine intra-examiner reliability, radiographs were re-measured by the same operator with a two weeks interval. The results of both readings were compared using kappa statistics. Statistical analysis showed that there were no significant differences between the first and the second measurements ($p < 0.05$).

Results

Craniofacial skeleton (Table 4)

Use of 2M2A significantly enhanced mandibular prognathism ($p < 0.05$), clockwise rotation of

ตารางที่ 4 *การเปรียบเทียบค่าตัวแปรบนโครงกระดูกขณะที่ไม่ใส่และขณะที่ใส่เครื่องมือ 2M2A*

Table 4 *Comparisons of skeletal variables between "without 2M2A" and "with 2M2A" in place*

Parameters	Without 2M2A	With 2M2A
SNA (°)	84.7 ± 1.1 84.6 (79.1-91.3)	85.3 ± 0.8 85.2 (80.8-91.5)
SNB (°)	79.1 ± 1.2 79.4 (71.4-87.4)	80.6 ± 1.0 79.3 (73.9-87.6)*
ANB (°)	5.5 ± 0.6 5.8 (2.3-9.8)	4.4 ± 0.6 4.5 (-0.5-7.7)**
SN-PP (°)	1.5 ± 1.0 0.7 (-7.8-7.0)	2.0 ± 0.8 1.6 (-4.1-5.4)
SN-GoGn (°)	32.7 ± 2.2 32.4 (17.2-50.0)	33.8 ± 2.1 32.3 (19.9-49.4)*
ANS-Me (mm)	64.8 ± 1.5 66.0 (55.9-74.2)	69.6 ± 1.3 71.6 (60.6-75.4)**
Overjet (mm)	4.9 ± 0.8 3.9 (2.5-11.3)	0.9 ± 1.0 -0.2 (-3.1-10.3)**
Overbite (mm)	1.7 ± 0.5 1.5 (-0.4-5.9)	-3.2 ± 0.3 -2.9 (-5.0-(-1.5))**
MP-H (mm)	16.2 ± 2.5 14.4 (5.7-43.1)	15.7 ± 2.5 12.4 (3.1-34.3)
PNS-P (mm)	36.1 ± 1.0 35.0 (31.2-43.2)	34.4 ± 0.9 34.9 (29.6-40.5)

*ผลแสดงเป็นค่าเฉลี่ย ± ค่าความคลาดเคลื่อนมาตรฐานของค่าเฉลี่ย (SEM) และค่ามัธยฐาน (พิสัย) จำนวน 15 ราย * $p < 0.05$; ** $p < 0.01$*

*Results are shown as mean ± standard error of the mean (SEM) and as median (range). n = 15 for all groups. * $p < 0.05$; ** $p < 0.01$*

ตารางที่ 5 *การเปรียบเทียบขนาดของทางเดินหายใจส่วนบนระหว่างขณะที่ไม่ใส่เครื่องมือและขณะใส่เครื่องมือ 2M2A*

Table 5 *Comparisons of upper airway dimension between "without 2M2A" and "with 2M2A" in place.*

Parameters	Without 2M2A	With 2M2A
SPAS (mm)	7.5 ± 0.8 8.3 (0-11.8)	9.7 ± 1.0 10.6 (2.8-17.8)**
MAS (mm)	6.7 ± 0.9 7.0 (0.0-12.0)	8.7 ± 0.9 8.9 (3.6-13.4)**
IAS1 (mm)	10.0 ± 1.4 9.3 (0-19.4)	12.4 ± 1.1 11.0 (7.9-20.2)**
IAS2 (mm)	10.3 ± 1.5 10.6 (3.2-22.6)	11.9 ± 1.6 10.3 (3.8-23.5)*

*ผลแสดงเป็นค่าเฉลี่ย ± ค่าความคลาดเคลื่อนมาตรฐานของค่าเฉลี่ย (SEM) และค่ามัธยฐาน (พิสัย) จำนวน 15 ราย * p < 0.05; ** p < 0.01*

*Results are shown as mean ± standard error of the mean (SEM) and as median (range). n = 15 for all groups. * p < 0.05; ** p < 0.01*

ตารางที่ 6 *การเปรียบเทียบค่า AHI และระดับความอิ่มตัวของออกซิเจนค่าต่ำที่สุดระหว่างก่อนและหลังการใช้เครื่องมือเป็นระยะเวลา 3 เดือน*

Table 6 *Comparisons of AHI and minimum oxygen saturation before and after having used 2M2A for 3 months.*

Parameters	Pretreatment	Posttreatment
AHI	4.3 ± 1.3 3.0 (1.0-10.0)	1.4 ± 0.7 1.0 (0-5.0)*
Minimum oxygen saturation	83.7 ± 1.5 84.0 (79.0-89.0)	89.3 ± 0.6 90.0 (87.0-91.0)*

*ผลแสดงเป็นค่าเฉลี่ย ± ค่าความคลาดเคลื่อนมาตรฐานของค่าเฉลี่ย (SEM) และค่ามัธยฐาน (พิสัย) จำนวน 7 ราย * p < 0.05*

*Results are shown as mean ± standard error of the mean (SEM) and as median (range). n = 7 for all groups. * p < 0.05*

the mandible ($p < 0.05$), an increase of lower anterior facial height ($p < 0.01$) and decreases of the ANB angle ($p < 0.01$), overjet ($p < 0.01$) and overbite ($p < 0.01$), when compared to the pretreatment. However, use of the 2M2A did not change the maxilla in relative to the cranial base, observed from the SNA angle and the SN-PP angle. Use of the 2M2A reduced the distances of MP-H and PNS-P, but it was not significantly changed when compared to the pretreatment.

Upper airway (Table 5)

After 2M2A inserted in place, significant enlargement of upper airway was observed from the SPAS ($p < 0.01$), MAS ($p < 0.01$), IAS1 ($p < 0.01$) and IAS2 ($p < 0.05$), when compared to the pretreatment.

Polysomnography (Table 6)

Three-month after insertion of the 2M2A, AHI was significantly decreased, whereas minimum oxygen saturation was significantly increased when compared to the pretreatment

Discussion

Use of the 2M2A in mild OSA patients resulted in enlargement of upper airway and improvement of AHI and minimum oxygen saturation in patients with mild OSA. It was demonstrated that the subjects, while using 2M2A, had forward position and clockwise rotation of the mandible, an increase in lower facial height and decreases in ANB, overjet and overbite. Use of 2M2A resulted in not only improving upper airway patency, but also contributing sleep wellness in mild OSA patients.

Typically, CPAP is the treatment of choice for mild to moderate OSA treatment,(13) but it has been reported that 5% to 50% of the patients discontinue CPAP use within the first week due to its bulky, inconvenient and uncomfortable to wear.(18) Alternatively, it is known that RFA treatment of the soft palate is effective to reduce snoring and generally accepted as the second-line treatment for mild to moderate OSA. The main mechanism of RFA is to enlarge upper airways by shrinking and stiffening the soft palate. Recently, the RFA has been performed as the first-line treatment with the successful rate of 31.37% among patients with mild to moderate OSA.(11) In the present study, the 2M2As were used as a second-line treatment option for the management of mild OSA after unsuccessful attempts with RFA treatment.

It is generally accepted that OAs can be used as an alternative method in those who are unable to tolerate CPAP or have failed surgery due to its convenient, reasonable cost, lifelong treatment and conservative approach. Accumulating studies have demonstrated that use of OAs could deteriorate the severity of OSA in patients with mild to moderate OSA.(19,20) At present, there are a number of OA designs for OSA patients to select and the majority of them are custom-fabricated. The 2M2A is a type of non-adjustable custom-made, composed of two separate splints connected by the Neodymium-Iron-Boron magnets. It is less bulky and improves comfort of the use of OAs by allowing patients for mandibular movement whenever needed. Furthermore, the appliances allow for normal function, e.g. swallowing and licking the lips.

A previous study has shown that improvement of OSA was dependent on the position of the mandible advanced by OAs in dose-dependent manner.(21) However, it was revealed that use of OAs in patients with mild to moderate OSA improved objective indicators comparably at both 50% and 75% of maximum mandibular protrusion positions.(22,23) As such, the 2M2As were fabricated in the 50-75% range of maximum protrusion in the present study.

In addition to the evaluation of changes in craniofacial skeleton parameters, it is suggested that the treatment success should be assessed with different objective measurement; e.g. AHI, oxygenation and upper airway dimensions, together with subjective symptoms; e.g. use of visual analogue scale.(22) Polysomnography is an objective-based sleep study, recognized as the gold standard in sleep medicine. The definition of successful treatment is varied from study to study. The most stringent definition of success was characterized as a reduction to less than five respiratory events per hour of sleep while the most liberal definition was described as a reduction of 50% or more from the baseline AHI.(10) In the present study, the mean AHI was significantly declined, after the use of 2M2A at night, from 4.3 to 1.3, which was reduced more than 50% of the baseline AHI, indicative of treatment success with OSA in these subjects.

A number of methods, e.g. lateral cephalometry, computed tomography and magnetic resonance imaging, have been utilized for assessment of the efficacy of oral appliances in OSA patients. Among these, lateral cephalometry has been considered to be the most accessible, economical, minimal radiation and reliable method to determine an impact of use of OAs on the upper airway. Furthermore, it is the most common radiological technique used in Orthodontics and Anthropology for the study of craniofacial features. Therefore, lateral cephalometry was used in the present study. However, one should be addressed is that use of lateral cephalometry, producing a two-dimension image, is limited and does not visualize the area of interest in three-dimension. In addition, lateral cephalogram was taken in an upright position, which does not imitate supine sleeping position.

OSA has often been observed in association with patients with micrognathia. A previous study demonstrated that Japanese patients with OSA had less SNB when compared with the control subjects and concluded that micrognathia is one of the crucial risk factors among Japanese.(24) In the present study, forward position of the mandible was observed while using 2M2A, according to the increase of SNB.

A low position of the hyoid bone is one of the distinctive cephalometric characteristics of OSA and it is considered to be a poor prognostic indicator for the successful use of OAs in patients with OSA.(8) From the present study, although the mean distance of MP-H was decreased after the 2M2A inserted, but it is not statistically significant difference. However, it should be pointed out that alteration of hyoid position in relative to the mandibular plane could be due to the mandibular configuration alone rather than the hyoid position that is responsible for the less than ideal response observed.

The length of the soft palate was measured from the linear distance between the posterior nasal spine and tip of the soft palate (PNS-P) according to a previously described method.(17) Although there was no correlation between PNS-P and AHI, a number of previous studies have shown that PNS-P was longer in OSA patients, when compared to non-OSA subjects.(17,25) In the present study, PNS-P was slightly decreased after the 2M2A had been warn. This implies that use of the 2M2A may not affect the length of the soft palate.

Previous studies have demonstrated that a greater mandibular plane in relation to the anterior cranial base (SN-MP) was correlated to a larger retropalatal airway space and a lower AHI.(26) It could be speculated that, when the OAs is worn, additional increases in SN-MP are expected to occur, thus improving the upper airway patency. This was observed in the present study that uses of the 2M2A resulted in a significant increase of SN-GoGn, lower anterior face height and concomitantly with a remarkable enlargement of the upper airway.

Decreased oropharyngeal airway appear common both in snoring and in OSA subjects. Furthermore, a previous study have found that the upper airway of OSA patients was more narrowed during sleep, when compared to those who did not have OSA.(27) Accumulating studies have demonstrated that anterior repositioning of the mandible and tongue increases the size and volume of the upper airway, in particular, at the retropalatal and retroglossal areas.(28,29) With the mandible advanced, the musculature of the pharynx and the tongue become stable, thus preventing these structures from collapsing during sleep, thus improving snoring or OSA. In the present study the upper airway was measured behind the soft palate through the C3 level. It was observed that, the width of upper airway, measured at different levels (SPAS, MAS, IAS1 and IAS2), was greater during the 2M2A inserted. It implies that anterior reposition of the mandible using the 2M2A directly increases the sizes of upper airway, resulted in significant increase of minimum oxygen saturation and reduction of AHI three-month posttreatment in mild OSA patients.

The limitations of the present study were restricted its sample size and treatment duration. More study is required to assess long-term uses of 2M2A on skeletal and dental changes with a larger sample size. Furthermore, lateral cephalometry provides limited data and poorly locates the upper airway structures, further study using cone-beam computed tomography is needed to visualize the upper airway soft tissue structures in three-dimension.

In summary, the present study has demonstrated that uses of the 2M2A in mild OSA patients alter the mandibular position, which results in the improvement in the AHI and minimum oxygen saturation. Lateral cephalogram; however, provides limited data and poorly locates the upper airway structures. Further studies using cone-beam computed tomography are needed to visualize the upper airway soft tissue structures in three-dimension.

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