Original Article

Airway and Craniofacial Changes With Mandibular Advancement Device in Chinese With Obstructive Sleep Apnoea

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Abstract

Introduction: The objective of this study was to investigate whether a reduction of obstructive sleep apnoea (OSA) severity is associated with significant airway and craniofacial changes with mandibular advancement device (MAD) in Chinese subjects. Materials and Methods: A total of 14 Chinese subjects (8 males, 6 females) diagnosed with OSA by overnight polysomnography (PSG), were fitted with the MAD. The mean ± standard deviation baseline apnoea-hypopnoea index (AHI) was 38.4 ± 17.2 and minimum arterial oxygen saturation (SaO_2) was 75.5 ± 11.1%. The second lateral cephalogram was taken (wearing the MAD) after the second PSG. The second PSG was indicated when symptoms have improved as shown by the Epworth Sleepiness Score and sleep questionnaire after wearing the MAD for 1 month. Comparison of cephalometric variables was done to evaluate the effects of the MAD on the upper airway and anatomical variables. Pre-treatment versus post-treatment variables were compared using Wilcoxon signed-rank test to determine the statistical significance at the 5% levels. The changes in airway variables were correlated with the changes in AHI using the Spearman correlation test. Results: At the second polysomnogram, AHI was significantly reduced to 10.9 ± 14.7. Minimum SaO_2 was significantly increased to 86 ± 8.4%. Mean airway dimension was significantly increased at the nasopharyngeal area from 22.7 ± 3.0 mm to 24.8 ± 2.1 mm. The distance of the hyoid bone to the mandibular plane was significantly reduced with the MAD from a mean of 21.2 ± 5.7 mm to 13.9 ± 7.0 mm (P <0.05). This reduction of the distance of the hyoid bone to the mandibular plane was significantly correlated with the reduction in the AHI. Conclusion: An increase in the nasopharyngeal airway and reduction of the distance of the hyoid bone to the mandibular plane was observed for this sample of Chinese OSA subjects. This study forms the baseline for future studies on the effects of MAD on the airway and craniofacial structures in a larger sample.

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Key words: Lateral cephalogram, Mandibular advancement splint, Mandibular advancement device, Obstructive sleep apnoea, Polysomnogram

Introduction

The mandibular advancement device (MAD) consists of upper and lower splints attached to the teeth and postures the mandible forward. The rationale for use of the MAD is that the forward movement of the mandible moves the tongue forward since the tongue is attached to the genial tubercles of the mandible.[1] The mandibular advancement may also move the hyoid bone position forward, thereby modifying and increasing the airway space below the level of the base of the tongue.[2,3] With the use of MAD, significant improvement in respiratory parameters such as apnoea-hypopnoea index (AHI), arousals and oxygen saturation has been reported.[4-6] The increasing popularity of the MAD is due to its non-invasiveness, improved comfort, quietness and portability.

Upper airway imaging has been used to visualise the pathogenesis and biomechanical basis of treatment of obstructive sleep apnoea (OSA). A number of imaging modalities have been used, including fluoroscopy, nasopharyngoscopy, cephalometry, magnetic resonance imaging (MRI) and both conventional and electron beam computerised tomography (CT) scanning. The limitation

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of lateral cephalometry in the examination of the oropharyngeal airway is that that it presents a 2-dimensional, static image of a 3-dimensional, dynamic structure. The rationale of using lateral cephalograms in this study is that they provide a simple, inexpensive, readily accessible method of screening and are associated with low radiation exposure.[2,7] Advanced techniques may be too time-consuming and expensive for routine clinical use and may require relatively high doses of radiation. The findings of studies using lateral cephalometry compared to studies that used more sophisticated techniques indicate that cephalometry can be used to accurately evaluate the craniofacial soft and hard tissue structures.[8] The American Academy of Sleep Medicine report in 2005 recommended that cephalometric evaluation should be performed when they are deemed necessary.[9]

Ethnicity was identified as a risk factor for OSA. This difference in prevalence and severity on OSA could be explained by the difference in craniofacial anatomy among different racial groups. Chinese, when compared with Caucasians (matched by age, gender, skeletal pattern, body mass index and AHI), revealed more severe underlying craniofacial skeletal discrepancies. Chinese OSA subjects had significantly smaller maxillae and mandibles, more severe mandibular retrognathism, proclined lower incisors, increased total and upper face height, steeper and shorter anterior cranial bases.[10] By contrast, soft tissue and upper airway measurements did not differ except for a larger superior-posterior airway space, larger nasopharynx and shorter tongue height in Chinese.[10] In a study by Li et al,[11] Caucasians had smaller posterior airway space and increased distance from the mandibular plane to the hyoid bone compared to Asian men with OSA.

In Asia, the prevalence of symptomatic OSA in middle-aged men and women was 4.1-7.5% and 2.1-3.2%, respectively.[12] In Singapore, the prevalence of OSA and sleep related breathing disorders of Chinese, Malays and Indians was 6.2%, 8.1% and 10.9%, respectively.[13] The prevalence of OSA detected in snorers was 19.7%, 30% and 12% among the Chinese, Malays and Indians, respectively.[14] Singapore is a multi-racial society, therefore this study was limited to Chinese to eliminate racial differences. As most studies of the effects of MAD on airway were conducted on Caucasians, a prospective study was done with the aim to investigate whether a reduction of OSA severity was associated with significant airway and craniofacial changes with MAD in Chinese subjects.

Materials and Methods

Subjects

Ethical approval on the use of subjects' data was obtained from the Institutional Review Board (IRB). The whole protocol of the clinical study was explained to the subjects and they were asked to sign a consent form when they agreed to enter the study.

Subjects diagnosed with OSA by 2 major hospitals in Singapore were referred between 2001 and 2004. All were Chinese. There was no gender preference and the accepted age ranged from 20 to 60 years old. All subjects were examined by a multi-disciplinary team consisting of sleep physicians, ENT surgeons and an Orthodontist who explained the various treatment options.

Subjects with the following conditions were excluded from the MAD treatment option:

1. Less than 8 teeth in each jaw
2. Limitations in jaw movement (minimum forward movement of 5 mm and minimum vertical opening of 25 mm)
3. Severe periodontitis
4. High caries susceptibility (e.g. low salivary flow)
5. Temporomandibular disorders
6. Gross ENT problems (e.g. enlarged tonsils, nasal polyps, cysts, haemangiomas)

A total of 14 Chinese subjects (8 males, 6 females) diagnosed with OSA by overnight polysomnography (PSG), were fitted with the MAD. The MAD (Intraoral Snoring Therapy-appliance, (IST); Scheu Dental, Germany) consists of 2 thin thermoplastic splints held together by a bilateral telescopic assembly. These adjustable telescopic guides are used to protrude the mandible anteriorly. The MAD advances the mandible and tongue while imparting a slight vertical clockwise rotation (Fig. 1). The bite registration was recorded using a George gauge (American Orthodontics serial no. 852-899, Winconsin, USA) with the mandible protruded at 75% of the maximum protrusion and the occlusion vertically separated by 5 mm.

The mean ± standard deviation baseline AHI was 38.4 ± 17.2 and minimum arterial oxygen saturation (SaO_2) was 75.5 ± 11.1%. The classification of severity of OSA was based on the AHI:

Mild OSA	:	5 to 20 events per hour
Moderate OSA	:	21 to 50 events per hour
Severe OSA	:	More than 50 events per hour

Based on this classification, 2 subjects had mild OSA (mean AHI of 8.9), 9 subjects had moderate OSA (mean AHI of 37.0) and 3 subjects had severe OSA (mean AHI of 71.3).

Lateral Cephalometric Evaluation

All lateral cephalograms for this study were taken by 1 operator using the same X-ray machine. The lateral cephalograms were taken using a standardised procedure in the natural head posture. The subject's tongue was

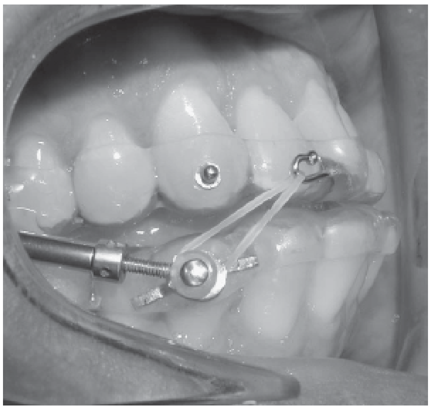

Fig. 1. The MAD in the subject's mouth.

Fig. 2. The lateral cephalogram.

Fig. 3. The lateral cephalogram with MAED.

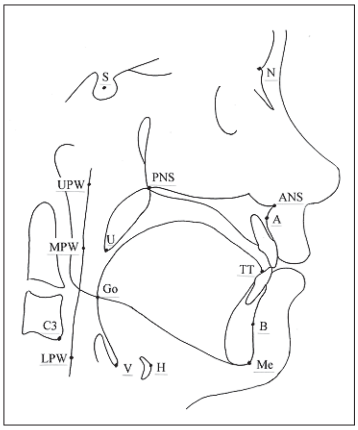

Fig. 4. The cephalomatic landmarks (Adapted from Liu et al[18]).

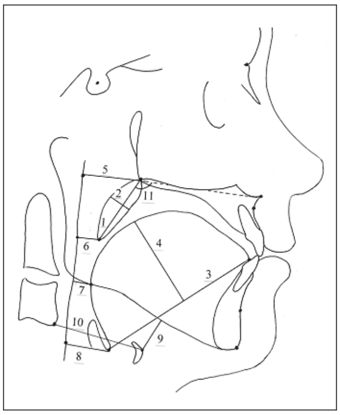

Fig. 5. Cephalometric variables. (Adapted from Liu et al[18])

1: SPL
2: SPT
3: TGL
4: TGH
5: PNS-UPW
6: U-MPW
7: PAS
8: V-LPW
9: H-MP
10: H-C3
11: PNS-U/PNS-ANS

coated with barium sulphate to visualise its position in relation to the airway space (Fig. 2). The cephalometric landmarks and points were based on the methods previously described by Lowe et al[15] and Tangugsorn et al[16,17] (Table 1, Table 2, Fig. 4). An orthopantomogram was taken for each subject to rule out TMJ pathology and for dental assessment.

The second lateral cephalogram was taken (wearing MAD) after the second PSG (Fig. 3). The second PSG was indicated when symptoms have improved as shown by the Epworth Sleepiness Score and sleep questionnaire (Appendix) after wearing the MAD for 1 month. Comparison of cephalometric variables (Table 3, Fig. 5) was done to evaluate the effects of the MAD on the upper airway and anatomical variables. The lateral cephalograms and tracing procedure was carried out by 1 operator to eliminate inter-operator variability.

Statistical Analysis

To reduce intra-operator variability, all pre-treatment and post-treatment lateral cephalograms were traced and re-traced by the same operator on 2 separate sessions held 1 month apart. The Bland Altman test was used to check for significant differences between the 2 sets of measurements.

Statistical analyses were carried out using the software, Statistical Package for Social Sciences (SPSS version 12; SPSS Inc, Chicago IL). The mean and standard deviation of cephalometric measurements were recorded. Pre-treatment versus post-treatment variables were compared using Wilcoxon signed-rank test to determine the statistical significance at the 5% level. The changes in airway variables were correlated with the changes in AHI using the Spearman correlation test.

Results

Three subjects (21%) dropped out of the study. At the second polysomnogram, AHI was significantly reduced to 10.9 ± 14.7. Minimum SaO_2 was significantly increased to 86 ± 8.4%. Baseline lateral cephalograms were taken for all 11 subjects. Lateral cephalograms with the MAD in the mouth were taken for 10 subjects as 1 subject refused to take the second cephalogram. The final sample consisted

Table 1. Cephalometric Landmarks Used in this Study

Landmark	Name	Definition
A	Subspinale	The most posterior point on the profile of the maxilla between the anterior nasal spine and the alveolar crest
H	Anterior Hyoid	The most anterior and superior point on the body of the hyoid bone
ANS	Anterior Nasal Spine	Tip of the anterior nasal spine
B	Supramentale	The most posterior point on the profile of the mandible between the chin point and the alveolar crest
C3	Cervical Vertebra 3	The most antero-inferior point on the cervical vertebral body
Go	Gonion	Most postero-inferior point on the mandible
LPW	Lower Pharyngeal Wall	A point on the posterior pharyngeal wall intersecting with a perpendicular line from V
Me	Menton	Lowermost point on the mandibular symphysis in the midline
MPW	Middle Pharyngeal Wall	A point on the posterior pharyngeal wall intersecting with a perpendicular line from U
N	Nasion	Anterior point of the intersection between the nasal and frontal bones
PNS	Posterior Nasal Spine	Tip of the posterior spine of the palatine bone, at the junction of the hard and soft palate
S	Sella	Centre of sella turcica
TT	Tongue Tip	The tip of the tongue
U	Tip of the Uvula	The most postero-inferior point of the uvula
UPW	Upper Pharyngeal Wall	A point on the posterior pharyngeal wall identified by the extension of the palatal (ANS-PNS) plane
V	Vallecula	Intersection of epiglottis and the base of the tongue

Table 2. Cephalometric Planes Used in this Study

Plane	Name	Definition
NL	Nasal Plane	The line between the anterior nasal spine and posterior nasal spine representing the maxillary plane
MP	Mandibular Plane	The line between Go and Me

of 10 subjects who went through the whole protocol. The Bland Altman tests showed intra-examiner agreement for all cephalometric variables.

With the MAD in the mouth, the airway was increased at the nasopharyngeal (PNS-UPW), oropharyngeal (U-MPW), retroglossal (PAS) and hypopharyngeal spaces (V-LPW). Mean airway dimension was significantly increased at the nasopharyngeal area from 22.7 ± 3 mm to 24.8 ± 2.1 mm (Table 4).

The soft palate length, thickness and inclination did not change significantly with the appliance in place. The tongue length and height also did not change significantly with the appliance. The hyoid bone was significantly raised to the mandibular plane with the MAD from a mean of 21.2 ± 5.7 mm to 13.9 ± 7.0 mm (P <0.05). The hyoid bone came forwards (H-C3) from a mean of 36.7 ± 4.9 mm to 37.3 ± 4.4 mm but this was not statistically significant (Table 4).

The MAD significantly increased the mean anterior total face height (ATFH) by 9.7 mm, posterior total face height (PTFH) by 6.3 mm and the mandible was significantly lowered to the maxillary plane by 5 degrees (P <0.05). However, the ANB angle did not change significantly.

As significant changes were noted for the variable PNS-UPW and distance of hyoid to mandibular plane (H-MP), correlation analysis was done on these 2 variables with changes in AHI. There was a moderately strong correlation (r = 0.703) for the variable H-MP with changes in AHI and this was significant (P = 0.023). A greater reduction in the distance of the hyoid to mandibular plane with the MAD correlated with a greater reduction in the AHI. There was an insignificant (P = 0.603) correlation (r = 0.188) with changes in PNS-UPW with changes in AHI.

Discussion

Three subjects discontinued treatment. Two subjects (1 moderate and 1 severe OSA) who dropped out did not find the appliance effective and discontinued wearing the MAD. One subject who had mild OSA found the appliance beneficial in reducing the loudness of snoring and daytime sleepiness. This subject who had mild OSA continued to wear the MAD but was unable to go for the second PSG. It is possible that the 3 subjects who dropped out may have reduced the improvement in respiratory and airway parameters.

Table 3. Cephalometric Variables Used in this Study

Mm,Variable	Name	Definition
PNS-UPW	Nasopharyngeal Airway Space	Distance from PNS to UPW along an extension of the nasal plane
U-MPW	Velopharyngeal Airway Space	Distance from U to MPW
PAS	Oropharyngeal Airway Space; Posterior Airway Space	Distance between a point on the base of the tongue and another point on the posterior pharyngeal wall both determined by an extension of a line from point B through Go
V-LPW	Hypopharyngeal Airway Space	The distance from V to LPW
SPL	Soft Palate Length	Distance from PNS to U
SPT	Soft Palate Thickness	The maximal thickness of the soft palate measured perpendicular to PNS to U
TGL	Tongue Length	Distance between V and T
TGH	Tongue Height	Distance along the perpendicular bisector of the V-TT line
H-MP	Hyoid To Mandibular Plane	Vertical position of hyoid. Distance along a perpendicular line from AH
H-C3	Hyoid to 3rd Cervical Vertebra	Anteroposterior position of hyoid. Distance between C3 and AH
ATFH	Anterior Total Face Height	Distance from N-Me
PTFH	Posterior Total Face Height	Distance from S to Go

Degrees, Variable	Definition
PNS-U/NL	Inclination of the long axis of the soft palate relative to the nasal plane
ANB	Anteroposterior maxilla/mandible discrepancy
MP-SN	Mandibular plane to cranial base angulation

Table 4. Cephalometric Variables at Baseline and with the Mandibular Advancement Device (MAD)

Cephalometric Variable	Baseline Range	Baseline Mean ± SD	MAD Range	MAD Mean ± SD	*P* value
Airway					
PNS-UPW	17.25 - 27.25	22.67 ± 2.99	21.00 - 28.25	24.78 ± 2.08	0.01*
U-MPW	3.00 - 11.00	6.72 ± 2.27	5.00 - 19.00	8.77 ± 4.19	0.13
PAS	5.00 - 14.00	8.75 ± 2.54	6.00 - 15.50	10.34 ± 3.66	0.17
V-LPW	8.00 - 21.00	14.80 ± 4.22	9.75 - 22.00	16.57 ± 3.53	0.18
Soft tissue					
SPL	31.75 - 44.00	39.33 ± 3.55	28.00 - 46.75	39.86 ± 5.66	0.92
SPT	7.50 - 16.50	11.77 ± 2.67	7.00 - 16.00	10.55 ± 2.47	0.06
PNS-U/NL	119.75 - 136.50	126.20 ± 4.80	114.00 - 135.0	124.55 ± 7.56	0.20
TGL	76.50 - 100.50	88.04 ± 7.10	78.00 - 97.50	87.45 ± 6.73	0.24
TGH	32.50 - 42.00	37.63 ± 3.07	32.50 - 47.50	40.13 ± 4.72	0.19
Skeletal					
H-MP	11.00 - 28.50	21.17 ± 5.74	2.50 - 25.00	13.93 ± 7.03	0.03*
H-C3	30.00 - 46.00	36.71 ± 4.93	29.97 - 44.00	37.32 ± 4.45	0.82
ATFH	117.50 - 144.50	133.31 ± 8.85	125.00 - 153.5	142.95 ± 8.53	0.03*
PTFH	75.25 - 101.00	87.48 ± 8.92	78.75 - 105.50	93.80 ± 9.91	0.03*
ANB	1.75 - 11.00	5.69 ± 2.90	1.00 - 14.25	5.13 ± 3.56	0.14
MP-SN	18.00 - 38.00	27.13 ± 6.38	17.50 - 44.00	29.34 ± 8.03	0.01*

*Statistically significant $P < 0.05$

The nasopharyngeal airway space at the palatal plane (PNS-UPW) was significantly increased with MAD wear (P <0.05) in the present study. An increase in nasopharyngeal airway space was also noted by Tsuiki et al[18] in a cephalometric study of 18 OSA subjects with the MAD, but the increase in airway was not significantly different. Both these studies are in contrast with Liu et al[19] who found that the nasopharyngeal airway was unchanged in patients from Beijing. It seems surprising that the airway at the palatal plane should increase. A possible mechanism for widening of the airway at the palatal plane is through tension transmitted along the palatoglossus muscles to the soft palate. As the soft palate comes forward, tension is transmitted along the palatopharyngeus muscle to the back wall of the pharynx. [20] This tension of the back wall of the pharynx may have altered the size of the airway in this region. Future studies with 3-dimensional imaging could be used to confirm this.

The velopharyngeal airway space at the tip of the soft palate (U-MPW) was increased with the MAD, but this was not significantly different from baseline values. Some studies have found significant increase in velopharyngeal airway.[18,19,21] Two mechanisms were suggested by Liu et al[19] to explain the increase in airway. Firstly, the anterior movement of the tongue may decrease the gravitational effect on the soft palate on the assumption that the base of the tongue opposes the anterior wall of the soft palate. Secondly, the forward displacement of the mandible may decrease the collapsibility of the velopharynx because the lateral wall of the soft palate connects to the base of the tongue through the palatoglossal arch. Mandibular advancement possibly stretches the soft palate forward, stiffening the velopharyngeal segment. However, Isono et al[22] indicated that the gravitational influence of the tongue on the soft palate was rather weak. Additional studies with larger sample sizes are needed to examine this force-anatomy dynamic relationship.

In the present study, the oropharyngeal airway space (posterior airway space) was increased, but this was insignificant. This was in agreement with Liu et al,[19] Bonham et al[21] and Eveloff et al.[23] By contrast, Schmidt et al[24] found a significant increase in the posterior airway space in the majority of subjects. Subjects in the present study who did not show an increase in posterior airway space had improvement in AHI. Furthermore, the hypopharyngeal (V-LPW) airway space was not significantly changed. This latter finding was also reported by Liu et al.[19] Computed tomographic measurements of the velopharynx and hypopharynx cross sectional area with the MAD in OSA patients from Hong Kong showed no significant increase.[25] The improvement in OSA severity despite no significant increase in the velopharynx, oropharynx and hypopharynx dimensions in this study could be that the MAD resulted in a less collapsible airway as other studies have reported.[18,25]

The soft palate length, thickness and inclination to the palatal plane were not changed significantly with the MAD used in this study. Similarly, tongue length and tongue height were not changed significantly with the MAD. This result concurred with Eveloff et al[23] who found no significant differences in soft palate length with the MAD but differed from Liu et al[19] who found that the soft palate length increased significantly and the tongue dorsum was lowered.

The distance of the hyoid to mandibular plane was significantly reduced by an average of 7.24 mm (P <0.05). This cephalometric observation concurred with Liu et al[19] and Eveloff et al[23] whereby the hyoid to mandibular plane distance was reduced by an average of 5 and 9 mm, respectively. There was also a significant correlation (P <0.05) between changes in the hyoid bone to the mandibular plane and changes in the AHI. In a recent cephalometric study on Chinese patients, the distance of mandibular plane to hyoid bone was significantly correlated with the severity of OSA.[26] Two mechanisms are suggested to explain the reduction in hyoid to mandibular plane distance and the significant correlation with the reduction in AHI. Firstly, the MAD that postured the mandible forwards also pulled forwards the muscles attached to the hyoid. This reduced the distance of the hyoid bone to the mandibular plane and also improved the pharyngeal airway patency. Secondly, the mandibular advancement with the MAD altered the compliance of the muscles and reduced its collapsibility.

The differences in the cephalometric results between the present study and other studies on OSA could be due to (i) the smaller sample size in this study of 10 subjects, (ii) the MAD action; the MAD could have enlarged the airway more laterally instead of antero-posteriorly. Such a change could not have been detected with a 2-dimensional lateral cephalometric representation of the pharyngeal airway; (iii) the varied but unpredictable individual response of OSA subjects towards mandibular advancement as suggested by Gale et al[3] and (iv) ethnicity. Due to a lack of studies done on Chinese subjects, the comparison made here are mainly to Caucasian subjects. A larger superior-posterior airway space, larger nasopharynx, shorter tongue height[10] and reduced distance from the mandibular plane to the hyoid bone in the Chinese[11] compared to Caucasians could have accounted for the difference in the cephalometric results between the present study and other studies on OSA.

There are several limitations to this study. The results of this study are applicable only to this sample of Chinese subjects with OSA and may not be extrapolated to the larger Chinese population. The sample size, while small to start with, was further reduced as 3 subjects dropped out of the study before the second evaluation and one did not take the second lateral cephalogram, leaving a final sample of 10 subjects who completed the study. It was also difficult to compare the results of airway and craniofacial changes with the Chinese as most studies did not state the race. The lateral cephalometric evaluation used in this study is a 2-dimensional analysis of the pharyngeal airway, which has its limitations in assessing changes in the lateral dimension.

With the introduction of the less expensive and low-radiation conebeam computerised tomography of the craniofacial complex, 3-dimensional studies to assess the changes in pharyngeal airway in response to the MAD can be carried out on Chinese subjects in major healthcare institutions which have the cone beam CT scanner.

Conclusion

An increase in the nasopharyngeal airway and reduction of the distance of hyoid bone towards the mandibular plane was observed for this sample of Chinese OSA subjects. This study forms the baseline for future studies on the effects of mandibular advancement device on the airway and craniofacial structures in a larger sample.

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Appendix

Sleep Hygiene (1) Baseline

1. Do you have excessive salivation?
   ☐ No ☐ Yes
2. Do you have reduced salivation or dry mouth?
   ☐ No ☐ Yes
3. Do you snore?
   ☐ No ☐ Yes
   How many times per week ______
4. Do you appear to stop breathing at any time?
   ☐ No ☐ Yes
   How frequent per night ____ per week
5. Do you wake up often?
   ☐ No ☐ Yes
   How frequent per night ____ per week _______
6. Do you have frequent headaches?
   ☐ No ☐ Yes
   How frequent per week ____ per month _______
7. What is the usual number of hours you sleep per night?
   _____ Hours
8. Do you have any other comments or concerns?

Sleep Hygiene/Effects of MAD (2)_____ month

1. Are you able to sleep with the appliance?
   ☐ Yes ☐ No ________________________
2. Is it comfortable?
   ☐ Yes ☐ No ________________________
3. Are your teeth sore in the morning? If so, for how long?
   ☐ No ☐ Yes ________________________
4. Is your bite different from normal in the morning?
   ☐ No ☐ Yes ________________________
5. Does your jaw hurt? When? For how long?
   ☐ No ☐ Yes ________________________
6. Does your jaw muscle hurt? When? For how long?
   ☐ No ☐ Yes ________________________
7. Do you have excessive salivation using the appliance?
   ☐ No ☐ Yes ________________________
8. Do you have reduced salivation or dry mouth using the appliance?
   ☐ No ☐ Yes
9. Do you snore? Is it as loud as usual? ________________________
   ☐ No ☐ Yes
   How many days per week ______ ?
10. Do you appear to stop breathing at any time?
    ☐ No ☐ Yes
    How frequent per night ____ per week _______
11. Is your breathing any different from prior to the appliance placement?
    ☐ No ☐ Yes________________________
12. Do you wake up often?
    ☐ No ☐ Yes
    How frequent per night ____ per week _____
13. Do you feel more refreshed in the morning?
    ☐ No ☐ Yes________________________
14. Do you have headaches after wearing the appliance?
    ☐ No ☐ Yes

How frequent per night _______ per week _________

15. Do you have any other comments or concerns?