Original Article

Maximum tensile resistance of non-adjusted and adjusted expansion screws in the locking part of unassisted mandibular advancement splint

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Abstract

Objective: To test the vertical and horizontal tensile forces of the locking part of a novel Unassisted Mandibular Advancement (UMA) Splint.

Materials and methods: Twenty samples, each comprising a lower piece and an upper piece with an expansion screw, were prepared. The samples were divided into 4 groups (n=5): 1) non-expanded screw group for vertical force test (NEVT), 2) 5-mm-expanded screw group for vertical force test (5EVT), 3) non-expanded screw group for horizontal force test (NEHT), and 4) 5-mm-expanded screw group for horizontal force test (5EHT). NEVT and 5EVT groups received a vertical tensile force whereas NEHT and 5EHT groups received a horizontal tensile force. The pulling forces were continuously applied until the sample fractured or disconnected. The mode of failure for each sample was also evaluated.

Results: The mean maximum tensile force of NEVT group was 267.31 ± 13.26 N and 262.70 ± 11.68 N for 5EVT group. The mean maximum tensile force of NEHT group was 476.11 ± 100.08 N and 449.17 ± 95.87 N for 5EHT group. There was no significant difference between the mean maximum tensile forces of NEVT and 5EVT (p=0.576) as well as those of NEHT and 5EHT (p=0.675) analyzed by independent t-test. There were 3 modes of failure including upper piece distortion, upper piece fracture, and lower piece fracture.

Conclusion: The maximum tensile forces of the locking part in the UMA splint were not significantly affected by screw expansion. The maximum tensile forces were higher than that of the clinical maximum mouth opening force and mandibular retrusive force.

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Keywords: expansion screw; mandibular advancement; maximum tensile resistance; UMA splint

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Introduction

Obstructive sleep apnea (OSA) is a disorder that causes sleeping persons to partially or totally pause breathing due to upper airway obstruction (Sateia, 2014). This sleep disorder results from anatomical problems, airway collapse, or problems of motor neurons to control the airway (Chebbo et al., 2013, Dempsey et al., 2010). These problems are related to the orofacial soft tissue, such as the soft palate, uvula, oropharynx, hypopharynx, tongue, and muscles, obstructing the upper airway either directly or indirectly (Campana et al., 2010, Dempsey et al., 2010, Eckert and Malhotra, 2008). OSA treatments try to eliminate the upper airway obstruction by behavioural modification, using continuous positive airway pressure, surgery, or wearing an oral appliance (OA) (Hoffstein, 2007, Tsara et al., 2009). When treating sleep apnea, dentists often prescribe an OA for OSA patients. The main purpose of the OAs is to correct the tongue position, which drops backward and obstructs the airway while patients sleep (Sutherland et al., 2014). OAs can be divided into tongue retaining devices (TRDs) and mandibular advancement devices (MADs) (Hoffstein, 2007, Sutherland et al., 2014). Clinically, dentists prefer to use MADs rather than TRDs (Cistulli et al., 2004), because MADs simultaneously maintain the mandible and tongue in an anterior position, clearing the upper airway. Moreover, MADs have many designs to select from, and are more effective in reducing airway obstruction.

Although MADs are widely prescribed for OSA patients, they have many limitations in their use. Some MADs cannot be adjusted for the mandibular protrusive distance for individual patients. However, few MADs are designed for OSA patients who also have bruxism and/or sleep with their mouth open. Furthermore, there are few commercial brands of MADs available in developing countries. Most MADs are manufactured overseas with long shipping times and are expensive. These factors could limit the number of OSA patients able to receive this kind of treatment. Local-made MADs that are readily available at a lower cost would be beneficial for OSA patients in these countries.

It has been suggested that suitable MADs should be adjustable custom-made devices rather than non-adjustable prefabricated devices (Serra-Torres et al., 2015, Vanderveken et al., 2008). Titratable expansion screws in adjustable devices can change the mandibular position either forward or backward as required for an individual patient's treatment. In addition, a twin-block design can cause less side-effects compared with a monoblock design (Serra-Torres et al., 2015), because patients who wear a twin-block MAD can move their mandible more freely. Moreover, due to their flexibility and poor fitting with the teeth, thermoplastic prefabricated appliances can produce problems after using them for 6 months (Ballanti et al., 2015, Friedman et al., 2012). Such problems include jaw pain, tooth and/or gum discomfort, and device breakage (Friedman et al., 2012, Vanderveken et al., 2008). Therefore, a novel effective MAD should be an adjustable, twin-block, and rigid custom appliance (George, 2001, Scherr et al., 2014).

Based on the effective MAD recommendations for OSA patients, we have designed a novel local-made MAD, called the Unassisted Mandibular Advancement (UMA) splint (Figure 1). The UMA splint is composed of an upper piece and a lower piece. Both consist of the retention part on the occlusal surface of the teeth and two locking parts at the left and right sides above the retention part. The upper locking part has an expansion screw per side for titration the adjustable part. The active component is derived from the upper and lower locking parts. During UMA splint wearing, interlocking between the upper and lower locking parts helps OSA patients maintain their mandible in an anterior and jaw-closed position without other screws, elastic bands, or elements.

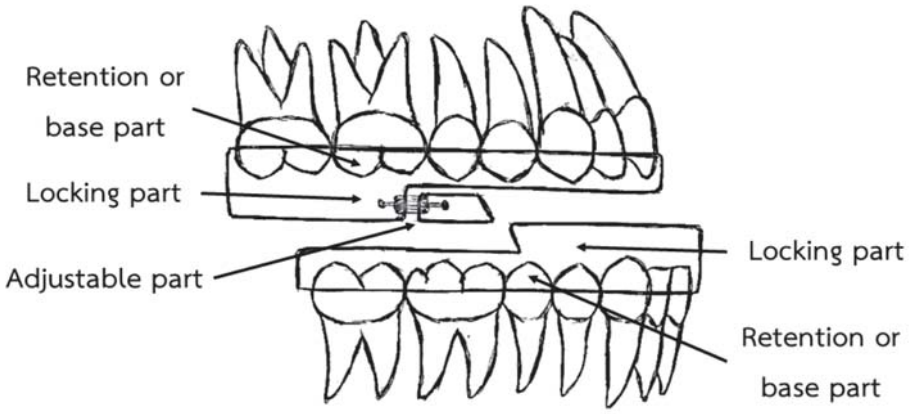

Figure 1: The concept and components of the UMA splint that fully covers the occlusal surfaces of the upper and lower teeth. The upper piece is composed of acrylic resin with left and right adjustable expansion screws, while the lower piece is composed of acrylic resin for interlocking with the upper piece.

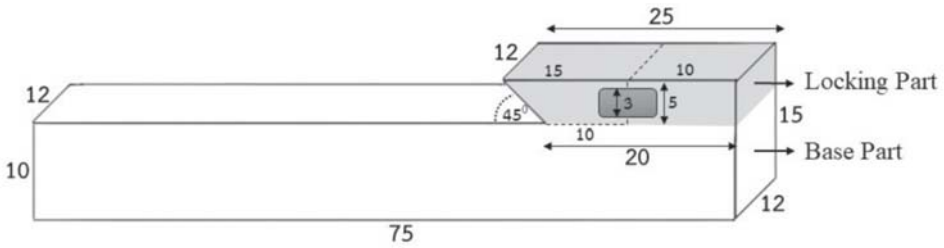

Figure 2: The sample dimension consisted of the base part (12 x 75 x 10 mm) and the locking part (12 x 25 mm at top surface and 12 x 20 mm at bottom surface connected to the base part). Each of twenty wax pieces was added an expansion screw (gray rectangle) at 15 mm from the free end of the locking part. The dashed line was the separated area providing the adjustable part.

Ideally, the UMA splint should withstand the forces generated while wearing it in the mouth. However, it is not known if the strength of the adjustable UMA splint is affected by expanding the adjustable screw. Therefore, the aim of this study was to test the vertical and horizontal tensile forces of the non-adjusted and adjusted locking parts of the UMA splint. The null hypothesis was that there was no difference in maximum tensile forces between non-expanded screw samples and 5-mm-expanded screw samples in both tensile testing directions.

Materials and Methods

Samples

Twenty samples were taken from forty wax pieces produced by dental modelling wax (Dentsply, Germany). The accuracy of the sample dimension was controlled by using a silicone mold. There were two components for each wax piece (Figure 2). The first component was a base part measuring 12 x 75 x 10 mm (W x L x H). The second component was a 5-mm thick trapezoid shaped locking part measuring 12 x 25 mm

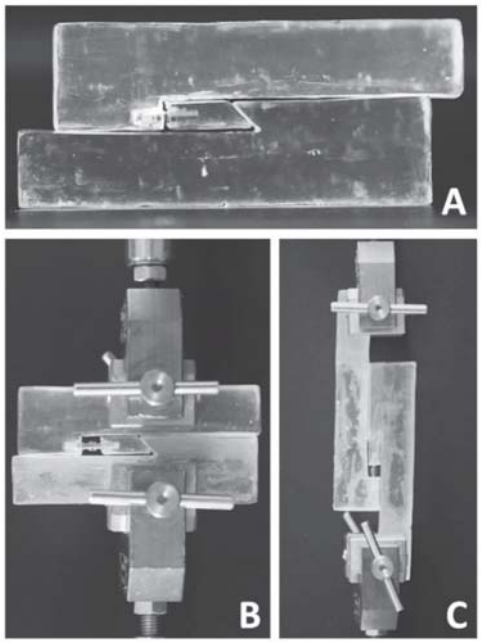

Figure 3: Acrylic resin samples; A) a sample combined an upper piece with a lower piece, B) a sample mounted by metal grips representing an upright head position for vertical force testing, and C) a sample mounted by metal grips representing a supine head position for horizontal force testing.

(W x L) at the top surface and 12 x 20 mm (W x L) at the bottom surface where it was connected to the base part. The result was a 45-degree angle. Each of the twenty wax pieces was added a stainless-steel expansion screw (Dentaurum, Germany) measuring 7.3 x 11.0 x 3.1 mm (W x L x H). This was placed 15 mm from the free end of the locking part (Figure 2).

All wax pieces with and without the expansion screws were replaced by clear heat-cured acrylic resin (Gnathopress, Rodex, SPD, Italy). After replacement, the twenty acrylic resin pieces with the expansion screws were manually separated by a file for the adjustable part (Figure 2). Twenty acrylic resin pieces with the expansion screws were defined as the upper pieces, while twenty acrylic resin pieces without the expansion screw were defined as the lower pieces. Forty acrylic resin pieces were randomly paired into twenty samples combined an upper piece with a lower piece (Figure 3A). Twenty paired samples were then divided into 4 groups (n=5); non-expanded screw group for vertical force test (NEVT), 5-mm-expanded screw group for vertical force test (5EVT), non-expanded screw group for horizontal force test (NEHT), and 5-mm-expanded screw group for horizontal force test (5EHT).

Tensile Force Test

The maximum tensile forces of twenty samples were tested by the universal testing machine (8872 Servohydraulic System, Instron, England). The samples were mounted on the machine by metal grips in two positions including horizontal and vertical mounting. The horizontal mounting represented an upright head position for vertical force testing in the NEVT and 5EVT groups (Figure 3B). The vertical mounting represented a supine head position for horizontal force testing in the NEHT and 5EHT groups (Figure 3C). All samples were vertically pulled by the upper metal grip at a pulling speed of 1 mm/min until either sample fracture or disconnection was found. The data were recorded as line graphs during testing by software (Merlin, Instron, England). At the end, the maximum tensile load or force (N) and the pulling distance (mm) were reported.

Mode of Failure

After tensile testing, the samples were visually observed and evaluated for their mode of failure. The samples were grouped by their physical features and the patterns on line graphs.

Data Analysis

The data were analysed by SPSS (version 22.0). Data normality was evaluated by the Shapiro Wilk test. The significant difference between groups was determined by the independent t-test with a 95% confidence interval and significance level (p-value) at 0.05.

Results

In the NEVT (Figure 4A) and 5EVT (Figure 4B) groups, the tensile force was rapidly increased to approximately 250 N, then turned to be the plateau with a serrated appearance indicating that the samples were being distorted to release the force. At the end, the force immediately disappeared because the pieces of samples slid past each other and were disconnected. In contrast, the tensile force of the NEHT (Figure 4C) and 5EHT (Figure 4D) groups demonstrated a steady increase in tensile loads, peaking at different levels in each sample. After achieving their peak, the samples fractured, and the tensile force suddenly dropped to 0 N.

When observing the physical features of samples after testing, each sample always showed a combination of an unaffected and an affected piece (Figure 5).

The samples were assigned to groups according to the visual observation of the changed pieces and the patterns of the continuous line graphs. There were 3 distinct groups; 1) the upper piece distortion group (Figure 5A) where the pieces of samples slid past each other and disconnected without any fracture, and the line graphs illustrated the serrated appearance, 2) the upper piece fracture group (Figure 5B) where the upper pieces were broken, and the line graphs dropped to zero, 3) the lower piece fracture group (Figure 5C) where the lower pieces were broken, and the line graphs dropped to zero.

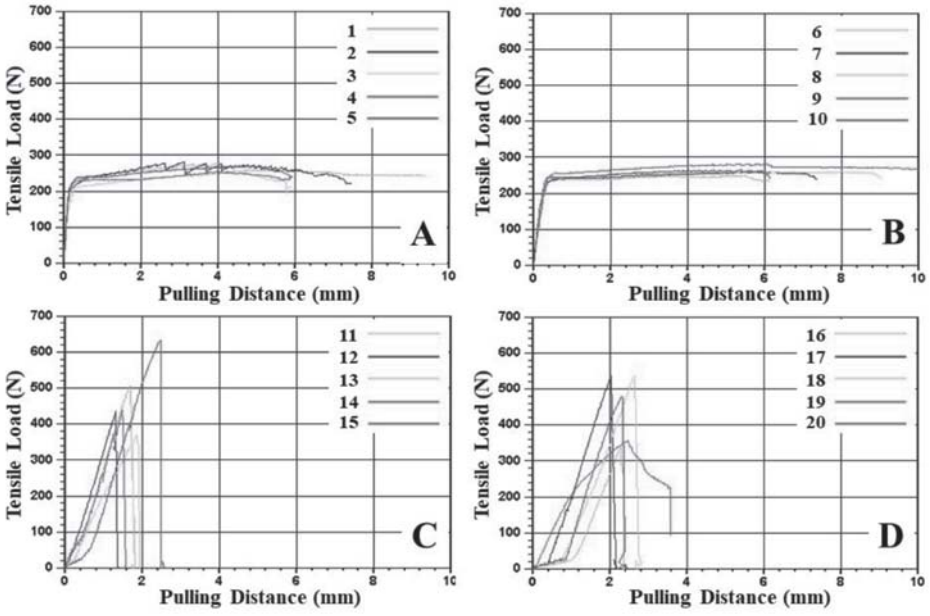

Figure 4: The continuous line graphs of four groups show the pulling distance (mm) (X-axis) along tensile testing at a pulling speed of 1 mm/min and the tensile load (N) (Y-axis); A) NEVT group (samples1-5), B) 5EVT group (samples 6-10), C) NEHT group (samples 11-15), and D) 5EHT group (samples 16-20).

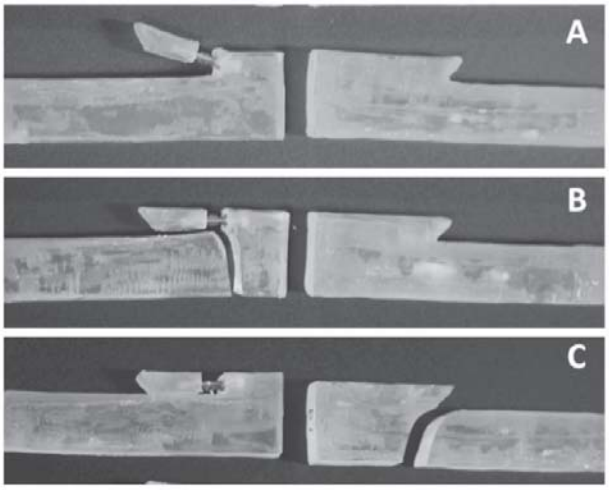

Figure 5: Representative acrylic resin samples demonstrating three different modes of failure; A) a distorted upper piece and an unchanged lower piece, B) a fractured upper piece and an unchanged lower piece, and C) a fractured lower piece and an unchanged upper piece.

Table 1: The mean maximum tensile forces and mode of failure after vertical and horizontal force testing.

Groups	Mean ± SD of Maximum Tensile Forces (N)	Independent t-test (p-value)	Mode of Failure (Number of Samples)		
			Upper Piece Distortion	Upper Piece Fracture	Lower Piece Fracture
NEVT	267.31 ± 13.26	0.576	5	-	-
5EVT	262.70 ± 11.68		5	-	-
NEHT	476.11 ± 100.08	0.675	-	2	3
5EHT	449.17 ± 95.87		1	3	1

NEVT = non-expanded screw group for vertical force test

5EVT = 5-mm-expanded screw group for vertical force test

NEHT = non-expanded screw group for horizontal force test

5EHT = 5-mm-expanded screw group for horizontal force test

The maximum tensile forces in each group were the normal distribution. The mean maximum tensile forces of the NEVT and 5EVT groups were 267.31 ± 13.26 N and 262.70 ± 11.68 N, respectively, which were not significantly different (p=0.576) (Table 1). The mode of failure for all samples in the NEVT and 5EVT groups was upper piece distortion. The mean maximum tensile forces of the NEHT and 5EHT groups were 476.11 ± 100.08 N and 449.17 ± 95.87N, respectively, which were also not significantly different (p=0.675) (Table 1).

Discussion

In the present study, we evaluated the maximum tensile forces of the adjustable component of the UMA splint in the vertical and horizontal force directions. We found that there was no significant difference in the mean maximum tensile forces between the NEVT and 5EVT groups after vertical force testing, and between the NEHT and 5EHT groups after horizontal force testing. Based on these results, the null hypothesis was not rejected.

This was our first study to evaluate the strength of the adjustable component of the UMA splint. The tensile tests we performed represent the natural forces that can occur on the UMA splint while patients are wearing it at night. The experimental setting for the vertical tensile testing simulated patients opening their mouths while wearing the UMA splint. In contrast, the horizontal tensile setting simulated that the UMA splint can withstand the backward forces from mandible, masticatory muscles, and ligaments. However, forces during other types of jaw movements, e.g. lateral forces during grinding, were not tested in this study because the UMA splint was designed to create less friction and would slip rather than break during lateral mandibular movements. Our MAD concept was designed based on the effective MAD criteria (Scherr et al., 2014) and the sleep bruxers who often have OSA (Jokubauskas and Baltrusaityte, 2017).

The UMA splint should be safe for OSA patients particularly when they open their mouths either unintentionally or intentionally. So, the maximum vertical tensile forces must be higher than the maximum mouth opening force (MMOF) of healthy people. The MMOFs were previously reported with both non-fixed head and fixed head measurements. According to Iida, et al., they found that MMOF was not affected by head movement (Iida et al., 2013). They also reported that fixed head MMOF was in the range of 43.15-95.12 N, higher in males, and reduced by age (Iida et al., 2013). The MMOF of healthy elderly males and females was 76.5 N and 48.1 N, respectively (Shinozaki et al., 2017). In addition, Hara, et al. measured MMOF in dysphagia patients which ranged from 39.81 to 48.54 N (Hara et al., 2014). In our study, the UMA splint exhibited maximum vertical tensile forces 2 to 4-fold higher than the MMOF. Thus, these findings provided the evidence that the UMA splint could withstand vertical forces in regular use.

Our results also demonstrated that the maximum horizontal tensile forces of the UMA splint are considerable higher than the mandibular retrusive force. Cohen-Levy, et al. measured the mandibular retrusive force on the adjustable part of a MAD after increasing the mandibular advancement distance (Cohen-Levy et al., 2013). They found a linear relation between the mandibular retrusive force and the mandibular advancement distance. For every 1 mm of mandibular advancement distance, the mandibular retrusive force increased 1.18 N. Therefore, greater mandibular advancement generates greater retrusive forces. However, the UMA splint samples tolerated horizontal tensile force much higher than this amount.

There were some limitations in the present study. Although the UMA splint tolerated the tensile forces applied in this study, there were other aspects that needed to be investigated. First, we tested the samples using increasing continuous tensile forces; however, MAD patients would be more likely to exert a sudden force specific to their own anatomy. Next, fatigue resistance or cyclic testing, which represents patients wearing the UMA splint over a long period of time, also needed to be evaluated. The force direction in this study did not exactly resemble jaw opening and mandibular retrusive directions since the tensile testing was limited by machine pulling which differs from human jaw movement. Moreover, using the UMA splint clinically would require two expansion screws at the left and right sides on the upper piece, thus our study did not entirely represent the exact strength of the actual UMA splint. The maximum tensile force of the UMA splint with two expansion screws may be higher. Finally, the tensile force is affected by sample width, height, and length. We fabricated samples that were 12-mm width, which is required for full occlusal coverage of Thai patients' teeth (Ruengdit et al., 2011). However, in a clinical setting, the length and width of the locking part could vary between patients depending on their tooth size. In addition, the 5-mm height of the locking part was designed for an expansion screw, whereas the 10-mm height of the base part was designed for metal grip fixation. All these factors could affect the strength of the locking part in clinical use.

This study used a very simple design with a 45-degree angle. Fracture lines manifested at this angle in both upper and lower pieces. The alteration of this angle could affect the fracture lines and the interlocking surface area. The use of a more acute angle produces a higher interlocking surface area, increasing the samples' ability to lock each other. This angle would result in reduced slipping and disconnection. Furthermore, if the sharp angles are blunted to reduce the wedge-like effect where the fracture lines developed, the samples may resist more force. The strength of samples with different angles, blunt angles, and full arch UMA splints with two expansion screws should be evaluated in future studies.

Conclusion

The UMA splint, a novel local-made MAD, was designed, and the mean maximum tensile forces of its locking part were evaluated. We found that the UMA splint locking parts' maximum tensile forces were not significantly affected by 5-mm screw expansion. Moreover, the UMA splint demonstrated that maximum tensile forces were higher than clinically generated vertical and horizontal forces. These results suggest that the UMA splint is safe for OSA patients.

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References

Ballanti F, Ranieri S, Baldini A, Cozza P. Long term therapeutic efficacy of a soft monobloc mandibular advancement device in adults with obstructive sleep apnea. Scientific World Journal. 2015:408469.

Campana L, Eckert DJ, Patel SR, Malhotra A. Pathophysiology & genetics of obstructive sleep apnoea. Indian J Med Res. 2010;131:176-87.

Chebbo A, Tfaili A, Ghamande S. Anatomy and physiology of obstructive sleep apnea. Sleep Med Clin. 2013;8:425-31.

Cistulli PA, Gotsopoulos H, Marklund M, Lowe AA. Treatment of snoring and obstructive sleep apnea with mandibular repositioning appliances. Sleep Med Rev. 2004;8:443-57.

Cohen-Levy J, Petelle B, Pinguet J, Limerat E, Fleury B. Forces created by mandibular advancement devices in OSAS patients: a pilot study during sleep. Sleep Breath. 2013;17:781-9.

Dempsey JA, Veasey SC, Morgan BJ, O'Donnell CP. Pathophysiology of sleep apnea. Physiol Rev. 2010;90:47-112.

Eckert DJ, Malhotra A. Pathophysiology of adult obstructive sleep apnea. Proc Am Thorac Soc. 2008;5:144-53.

Friedman M, Hamilton C, Samuelson CG, Kelley K, Pearson-Chauhan K, Taylor D, et al. Compliance and efficacy of titratable thermoplastic versus custom mandibular advancement devices. Otolaryngol Head Neck Surg. 2012;147:379-86.

George PT. Selecting sleep-disordered-breathing appliances. Biomechanical considerations. J Am Dent Assoc. 2001;132:339-47.

Hara K, Tohara H, Wada S, Iida T, Ueda K, Ansai T. Jaw-opening force test to screen for Dysphagia: preliminary results. Arch Phys Med Rehabil. 2014;95:867-74.

Hoffstein V. Review of oral appliances for treatment of sleep-disordered breathing. Sleep Breath. 2007;11:1-22.

Iida T, Tohara H, Wada S, Nakane A, Sanpei R, Ueda K. Aging decreases the strength of suprahyoid muscles involved in swallowing movements. Tohoku J Exp Med. 2013;231:223-8.

Jokubauskas L, Baltrusaityte A. Relationship between obstructive sleep apnoea syndrome and sleep bruxism: a systematic review. J Oral Rehabil. 2017;44:144-53.

Ruengdit S, Riengrojpitak S, Tiensuwan M, Santiwong P. Sex determination from teeth size in Thais. The 6th CIFS Academic Day 2011; 14-15 September 2011; Impact Muang Thong Thani, Thailand. 2011.

Sateia MJ. International classification of sleep disorders-third edition: highlights and modifications. Chest. 2014;146:1387-94.

Scherr SC, Dort LC, Almeida FR, Bennett KM, Blumenstock NT, Demko BG, et al. Definition of an effective oral appliance for the treatment of obstructive sleep apnea and snoring: a report of the American Academy of Dental Sleep Medicine. J Dent Sleep Med. 2014;1:39-50.

Serra-Torres S, Bellot-Arcis C, Montiel-Company JM, Marco-Algarra J, Almerich-Silla JM. Effectiveness of mandibular advancement appliances in treating obstructive sleep apnea syndrome: a systematic review. Laryngoscope. 2016;126:507-14.

Shinozaki H, Tohara H, Matsubara M, Inokuchi N, Yamazaki Y, Nakane A, et al. Relationship between jaw opening force and hyoid bone dynamics in healthy elderly subjects. Clin Interv Aging. 2017;12:629-34.

Sutherland K, Vanderveken OM, Tsuda H, Marklund M, Gagnadoux F, Kushida CA, et al. Oral appliance treatment for obstructive sleep apnea: an update. J Clin Sleep Med. 2014;10:215-27.

Tsara V, Amfilochiou A, Papagrigorakis MJ, Georgopoulos D, Liolios E, Alexopoulou C, et al. Guidelines for diagnosing and treating sleep related breathing disorders in adults and children (Part 2: treatment). Hippokratia. 2009; 13:247-52.

Vanderveken OM, Devolder A, Marklund M, Boudewyns AN, Braem MJ, Okkerse W, et al. Comparison of a custom-made and a thermo-plastic oral appliance for the treatment of mild sleep apnea. Am J Respir Crit Care Med. 2008; 178:197-202.