

# Supine Cephalometric Analyses of an Adjustable Oral Appliance Used in the Treatment of Obstructive Sleep Apnea

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**ABSTRACT** *Objective:* To investigate the effects of the Klearway™ appliance on the upper airway in patients with obstructive sleep apnea (OSA) in the supine position. *Methods:* Sixteen subjects (12 males and 4 females) were recruited on the basis of baseline polysomnography with a documented Apnea and Hypopnea Index (AHI) >15 per hour. A second overnight sleep study was performed for each subject with the appliance in place. Baseline supine cephalometry was performed for each subject before the initial insertion of the appliance, and follow-up supine cephalometry was undertaken with the appliance in place. *Results:* The polysomnographic variables improved significantly, and the mean changes in overbite and overjet were 5.15 mm and 6.26 mm after insertion of the Klearway™ appliance. The supine sagittal cross-sectional areas of the pharynx and the tongue significantly increased, while the linear distance from the hyoid position to the mandibular plane or the RGN-C3 line significantly decreased after insertion of the appliance. The ratio of the vertical pharyngeal length to the sagittal cross-sectional area of nasopharynx or tongue decreased significantly. When the subjects were evaluated on the basis of the after-insertion AHI, the group with good response ( $n = 11$ ) was found to be significantly younger than the group with the poor response ( $n = 5$ ). Similarly, the good responders revealed less prominent chins, larger tongue heights, and an increase in hypopharyngeal sagittal cross-sectional area after insertion of the appliance. There was a significant correlation between the improvement in AHI (%) and the supine middle airway space ( $r = -0.52, p < 0.05$ ). *Conclusion:* The mechanical effect of the Klearway™ appliance on the upper airway and the stabilization of jaw posture may be important determinants of the efficacy of the appliance.

**KEYWORDS:** obstructive sleep apnea (OSA), oral appliance (OA), supine cephalometry

Obstructive sleep apnea (OSA) is a common disease characterized by repetitive nocturnal cessation of airflow and disturbed sleep.<sup>1,2</sup> In the last decade, a number of studies have used upright cephalometric radiographs to evaluate airway size and predict severity of disease or effects of oral appliances on OSA.<sup>3–11</sup> However, OSA may become worse or only occur during sleep in the supine position.<sup>12,13</sup> Several studies have investigated the change of upper airway size in healthy, snoring, and OSA subjects from the upright to the

supine position. Acoustic reflection studies have demonstrated that the cross-sectional area of the upper airway is narrower in the supine position.<sup>14,15</sup> Cephalometric studies have also shown that the superoposterior (retropalatal) airway space is reduced in the supine position in both patients with OSA and control subjects.<sup>16–19</sup> Martin et al.<sup>19</sup> have recently reported that patients with OSA in the upright position had smaller upper airway cross-sectional areas than either snorers or normal subjects, but there were no differences between subject groups in the supine position. Patients with OSA showed smaller decreases in the cross-sectional area of the upper airway from the upright to the supine position because they have to maintain their upper airway size in order to prevent their upper airways from becoming compromised. Miyamoto et al.<sup>20</sup> undertook detailed measurements of tongue postures from upright to supine lateral cephalograms in OSA male patients and males with non-apneic snoring matched for age, body mass index (BMI), and craniofacial skeletal pattern. In the non-apneic snorers, the tongue depth measurements for the

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superior-posterior portion of the tongue were larger in the supine than in the upright position. There was no significant difference in tongue depth measurements between the upright and the supine positions in the patients with OSA. It is suggested that when awake patients with OSA move from the upright to the supine positions they maintain their upright tongue posture, which tends to protect against upper airway collapse secondary to the increased gravitational load on the tongue.

Marklund et al.<sup>21</sup> evaluated the effect of a mandibular advancement device in patients with supine-dependent sleep apnea and patients with non-supine-dependent sleep apnea, and found that successful apnea reduction with a mandibular advancement device best correlated with supine-dependent sleep apnea. L'Es-trange et al.<sup>22</sup> used fluoroscopic recordings to investigate the effects of mandibular advancement on oropharyngeal airway dimensions in the sagittal plane in conscious, supine patients. They suggested that where mandibular advancement is considered beneficial, jaw opening should be kept to a minimum. Ryan et al.<sup>23</sup> used videoendoscopy to examine the changes in supine pharyngeal dimensions produced by the Klearway™ appliance and found that the oral appliance (OA) reduced the severity of OSA by maintaining patency of the velopharynx, particularly in its lateral dimension. The median cross-sectional area of the airway increased in the hypopharynx and velopharynx but not in the oropharynx.

The purpose of the current study was to use supine cephalometric measurements to investigate the effect of the Klearway™ appliance on the upper airway and its surrounding structures in patients with OSA and the correlation between the efficacy of the appliance on OSA and cephalometric variables.

## METHODS

### Subjects

Sixteen adult patients (12 males and 4 females) with symptomatic mild to severe OSA (AHI range 16.8 to 57.3 per hour) were evaluated in this study. The mean age of the patients was 45.1 years (range 25 to 69); the mean BMI was 26.7 kg/m<sup>2</sup> (range 21.3 to 34.6). Patients with OSA were recruited if they had a Apnea and Hypopnea Index (AHI) of >15 per hour as diagnosed by a baseline overnight polysomnographic study, had at least 10 healthy teeth in each of the maxillary and mandibular arches, had no evidence or past history of TMJ disease, revealed no limitation in mandibular movement, and lived in the metropolitan Vancouver area. All patients were seen in the Sleep Apnea Specialty Clinic at the

UBC Faculty of Dentistry after receiving a diagnosis of OSA from the referring sleep physician of the Sleep Disorders Clinic at the Vancouver Hospital. Each patient gave informed written consent, and the study was approved by the clinical screening committee for research involving human subjects at the University of British Columbia.

### Diagnostic Polysomnography

To diagnose OSA, an overnight polysomnogram monitoring was performed on each patient. Ryan and Love<sup>24</sup> have previously described the detailed overnight polysomnographic monitoring technique. A second overnight polysomnographic study was undertaken for every patient with the Klearway™ appliance in place after finishing titration of the appliance. Demographic data for OSA patients in this study are provided in Table 1. The severity of OSA was determined by AHI, defined as the total number of apneas and hypopneas divided by the total sleep time in minutes.

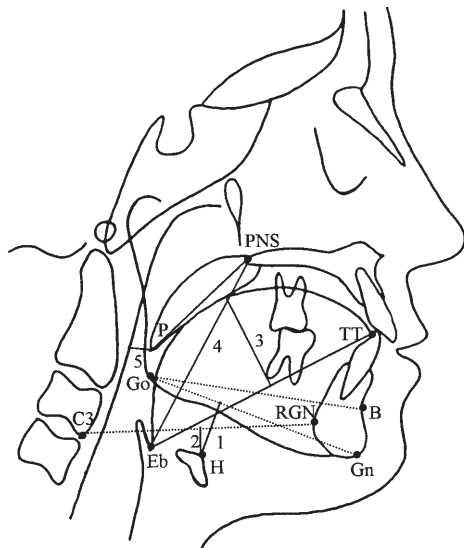
### Cephalometry

Two cephalometric radiographs were undertaken for each patient in the supine position, one before and the other after insertion of the appliance. To obtain the supine radiographs, the subject was instructed to lie down on a stretcher, mimic his or her usual sleeping position and position on the pillow, and maintain his or her teeth slightly apart in the rest position. Cephalograms were taken at the end of expiration after three tidal breaths. The non-well-known landmarks and variables on the cephalograms are shown in Figures 1 and 2. All cephalograms were traced and digitized twice by the same investigator.

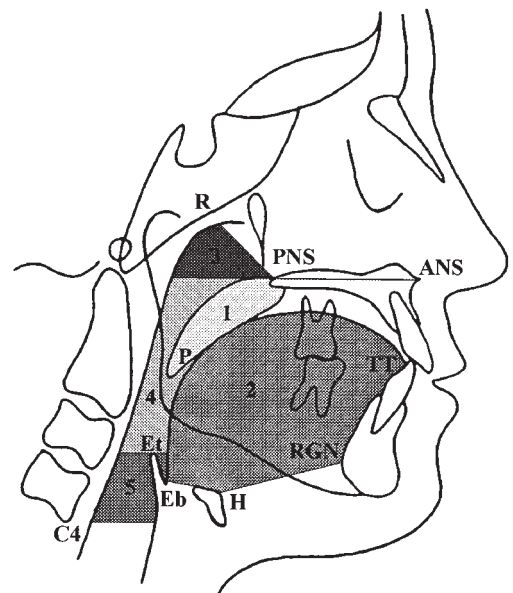
**TABLE 1. Patient Demographics before and after Appliance Insertion**

Variable	Before Insertion		After Insertion		P
	Mean	SD	Mean	SD	
AGE	45.06	12.06	46.39	12.16	***
BMI (kg/m <sup>2</sup> )	26.68	4.29	26.47	3.72	NS
AHI (events/hr)	33.44	12.46	11.16	7.65	***
AI (events/hr)	11.96	9.56	0.88	1.68	***
HI (events/hr)	21.48	12.36	10.28	7.06	**
Minimum SaO <sub>2</sub> (%)	77.03	9.64	82.40	6.65	*

Level of significance: \*p < 0.05; \*\*p < 0.01; \*\*\*p < 0.001; NS = not significant.



**FIG. 1.** Diagrammatic representation of landmarks and variables. B = superamentale; Go = gonion; Gn = gnathion; H = hyoidale; RGN = retrognathion; TT = tongue tip; Eb = base of epiglottis; PNS = posterior nasal spine; P = most inferior tip of soft palate; C3 = anterior-inferior limit of the third cervical vertebra. 1 MPH. 2 HH1. 3 TGH. 4 VAL. 5 MAS.



**FIG. 2.** Diagrammatic representation of landmarks and contours used to identify tongue, soft palate, nasopharynx, oropharynx, and hypopharynx sagittal cross-sectional areas. Et = tip of epiglottis; ANS = anterior nasal spine; C4 = anterior-inferior limit of the fourth cervical vertebra; R = roof of pharynx (point on posterior pharyngeal wall constructed by line PNS to cross-sectional point of cranial base and lateral pterygoid plate). 1. SPXA. 2. TGXA. 3. NASOXA. 4. OROXA. 5. HYPOXA.



**FIG. 3.** Anterior (A), lateral (B), posterior (C), and palatal (D) views of Klearway<sup>®</sup>. The palatal screw is designed not to encroach on tongue space, to permit a total of 44 separate 0.25 mm anterior positions of the mandible and to allow for vertical and horizontal jaw movement during sleep.

## Klearway™ Oral Appliance

The Klearway™ appliance used in this study is an appliance with several design advantages over other appliances available on the market (Figure 3). It is constructed of a temperature-sensitive acrylic resin that is slightly soft at body temperature and very compliant at higher temperatures. This not only decreases tooth discomfort but also considerably increases retention even in those patients who have experienced significant tooth loss. The Klearway™ also permits lateral and vertical jaw movement during sleep to reduce the risk of TMJ and jaw muscle discomfort and to facilitate all kinds of oral functions. Full tooth surface coverage may reduce the possibility of any occlusal change. Forty-four adjustable mandibular positions provided by turning the anteroposteriorly-oriented screw of the appliance make it possible to optimize such a mandibular advancement device without remaking the appliance. An initial bite registration was taken at the two-thirds maximum protrusive position. Minimum vertical separation between upper and lower incisors was obtained. An adjustment period followed the insertion of the appliance during which the advancement was continued until the subjective signs and symptoms of OSA such as witnessed apneas, snoring, and excessive daytime sleepiness were reduced or disappeared. Some subjects required no advancement beyond the two-thirds maximum protrusion position.

### Statistical Analysis

Data were expressed as mean  $\pm$  standard deviation (SD). A paired *t* test was used for the comparison be-

**TABLE 2. Cephalometric Analysis before and after Appliance Insertion**

Variable	Before Insertion		After Insertion		P
	Mean	SD	Mean	SD	
PHYNXA	1049.0	318.6	1155.1	324.9	*
TNGXA	3748.2	475.5	3962.8	514.1	**
MPH	22.70	5.75	19.65	4.78	*
HH1	13.33	4.64	9.41	5.07	*
VAL	79.49	7.69	79.14	8.25	NS
NASOXA	261.59	67.75	296.30	67.52	NS
VAL/NASOXA	0.327	0.103	0.279	0.064	*
VAL/TNGXA	0.021	0.002	0.020	0.002	*
SNB	77.34	3.42	79.87	3.59	***
OB	-0.35	4.56	-5.50	1.91	***
OJ	4.82	2.86	-1.44	2.38	***
LFH	76.61	7.68	81.83	6.49	***
PFH	87.18	6.88	91.69	7.26	***

Level of significance: \**p* < 0.05; \*\**p* < 0.01; \*\*\**p* < 0.001; NS = not significant.

For cephalometric abbreviations, see legends for Figures 2 and 3.

tween the baseline versus after-insertion values. A Pearson correlation analysis was used to determine if any baseline cephalometric or physiological variables are associated with the change in AHI (%). On the basis of the after-insertion value in AHI, the sixteen patients were divided into two groups, one (*n* = 11) with the after-insertion AHI  $\leq$  15, the other one (*n* = 5) with the AHI > 15. A unpaired *t* test was used to evaluate the cephalometric and polysomnographic variables between the two groups.

## RESULTS

The demographic data for the subjects in this study are shown in Table 1. The mean interval between the two polysomnographic studies for those patients was 15.9 months. During this period of time, there was no significant change in the mean BMI. The values of the polysomnographic variables listed in Table 1 were significantly improved after insertion of the Klearway™ appliance. Highly significant (*p* < 0.001) improvements in AHI and AI were seen, and the HI (*p* < 0.01) and minimum SaO<sub>2</sub> (*p* < 0.05) also improved. The results of supine cephalometric comparisons before and after appliance insertion are summarized in Table 2. The sagittal cross-sectional areas of tongue and pharynx increased significantly (*p* < 0.05), and the linear distance from the hyoid bone to the mandibular plane or the RGN-C3 line significantly decreased after insertion of the appliance (*p* < 0.01, 0.05). The ratio of the vertical airway length (VAL) to the sagittal cross-sectional area of the nasopharynx or tongue decreased significantly (*p* < 0.05). After the insertion of the appliance, the mean overbite and overjet significantly decreased by 5.15 mm and 6.26 mm, respectively. The mean SNB, anterior lower facial height (LFH), and posterior facial height (PFH) increased significantly (*p* < 0.001).

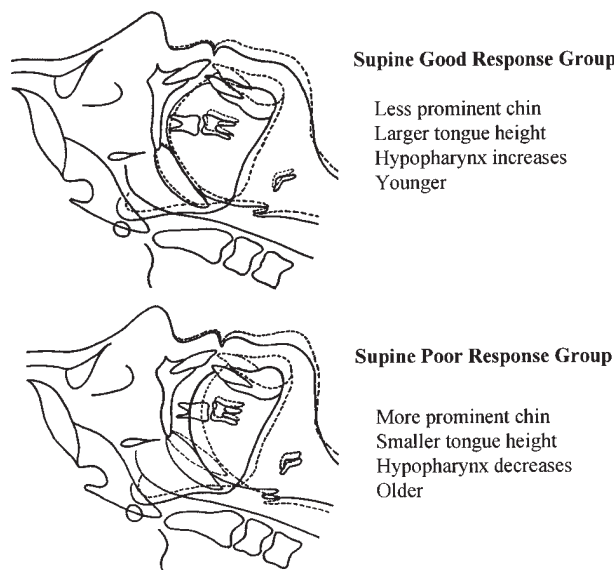
On the basis of the after-insertion AHI value, the patients were divided into two groups, a good response group (*n* = 11) with after-insertion AHI  $\leq$  15 per hour, and a poor response group (*n* = 5) with after-insertion AHI > 15 (see Table 3 and Figure 4). It was shown that the good response group was significantly younger than the poor response group (*p* < 0.05). There was less baseline and after-insertion protrusion of the mandible in the good response group when compared to the poor response group (*p* < 0.05). The baseline tongue height was significantly higher, but the increase in tongue height was significantly smaller in the good response group when compared to the poor response group (*p* < 0.05). After insertion of the appliance, the sagittal cross-sectional area of the hypopharynx increased in the good response group but decreased in the poor response group; the change was significantly different between the two groups (*p* < 0.05). Moreover, there were signifi-

**TABLE 3. Comparison between the Two Groups Based on Before and After Insertion Variables**

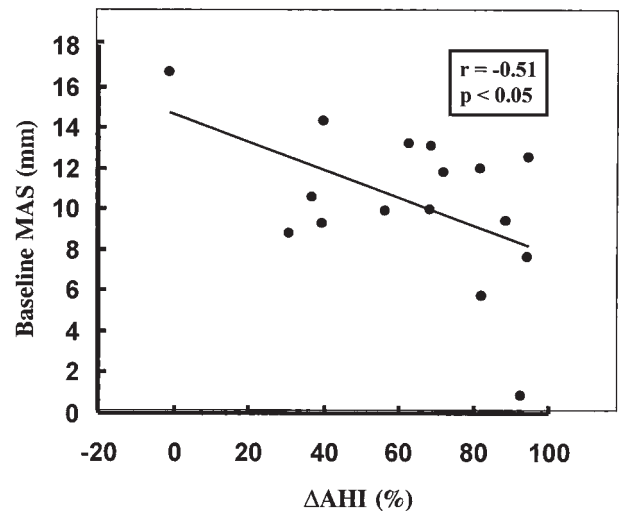
Variable	Good (n = 11) After Insertion AHI ≤ 15		Poor (n = 5) After insertion AHI > 15		P
	Mean	SD	Mean	SD	
AGE	40.73	10.10	54.60	11.22	*
BMI	26.66	4.52	26.71	4.23	NS
Baseline SNPG	77.79	2.83	81.21	3.10	*
After insertion SNPG	79.64	2.75	83.64	3.46	*
Baseline TGH	40.83	4.41	35.28	5.50	*
TGH change	0.82	4.05	6.50	5.59	*
HYPOXA change	63.58	76.89	-58.39	139.87	*
After insertion AHI	6.97	4.46	20.38	3.92	***
AHI change (%)	76.10	17.99	34.34	23.15	***
After insertion AI	0.30	0.39	2.16	2.70	*
After insertion HI	6.67	4.52	18.22	4.58	***

Level of significance: \*p < 0.05; \*\*\*p < 0.001; NS = not significant. For cephalometric abbreviations, see legends for Figures 2 and 3.

cantly lower after-insertion polysomnographic values (AHI, AI, and HI) (p < 0.001) and larger changes in AHI (p < 0.05) in the good response group than in the poor response group. In a simple correlation analysis, one significant correlation was found between the change in AHI (%) and the middle airway space (MAS, r = -0.521, p < 0.05). The decrease in AHI (%) following insertion of the OA was related to the size of the before-insertion MAS (r = -0.52, p < 0.05, Figure 5).



**FIG. 4.** Schematic summary of before-and-after-appliance-insertion supine cephalometric variables and demographic characteristics of OSA patients. The solid line represents the tracing before appliance insertion; the dotted line represents the tracing after appliance insertion.



**FIG. 5.** Relationship between the change in AHI (%) after insertion of the Klearway™ oral appliance and the baseline width (mm) of the Middle Airway Space (MAS).

## DISCUSSION

The current results demonstrate that there are substantial changes in the upper airway and its surrounding structures as measured in supine cephalometric radiographs secondary to the insertion of a Klearway™ appliance. The sagittal cross-sectional area of the pharynx increases significantly after the insertion of the appliance. The results confirm the mechanical effectiveness of the Klearway™ appliance even though the size and posture of the upper airway and its surrounding structures may be significantly influenced by gravitational forces. No significant changes in the anteroposterior airway space at different levels were found in this study, although significant effects of OAs on the upper airway were found in awake patients with upright cephalometric studies.<sup>25-31</sup> Klearway™ use may also play a role in the stabilization of mandibular posture during sleep. Miyamoto et al.<sup>32</sup> found that vertical mandibular posture was more open during sleep in OSA patients and that the amount of vertical opening increased during apneic events. L'Estrange et al.<sup>22</sup> suggested that mandibular opening should be kept to a minimum where a mandibular advancement device is considered beneficial. Body posture may also be an important determinant of the effects of the appliance on the upper airway. Yildirim et al.<sup>16</sup> suggested that body posture is an important determinant of upper airway dimensions, and Douglas et al.<sup>33</sup> demonstrated that both body posture and breathing route are important determinants of genioglossus EMG tone. In the supine body position, the effect of the appliance on the anteroposterior upper airway space may be compromised by the increased gravitational pull on the tongue and the soft palate and the decreased lung activity.

Several cephalometric studies of the pharynx in OSA subjects have previously been undertaken. Most of them have used a conventional cephalometric technique in the upright position. A supine cephalogram may provide more physiological data since it is observed in the sleeping position where upper airway obstruction of OSA patients usually occurs. Despite the evident two-dimensional limitations of cephalometric measurements, supine cephalometric techniques may be regarded as one of the most accessible clinical imaging tools. This study used supine cephalometric data obtained in wakeful subjects and thus cannot escape the limitations of a two-dimensional imaging technique in the wakeful state.<sup>31</sup> A small study sample is another obvious shortfall of this study.

The supine sagittal cross-sectional area of the tongue increased significantly, which implies that the shape and posture of the tongue has changed following the insertion of the Klearway™ appliance. Pae et al.<sup>17</sup> reveals an enlarged tongue sagittal cross-sectional area and an inferiorly positioned tongue in the supine position in the OSA group. In this study, the sagittal cross-sectional area of the tongue has been increased by the interaction of gravitational pull and the mechanical effectiveness of the appliance. Measurements of tongue area include suprahyoid structures because of the close anatomical relationship between the tongue and the suprahyoid structures.

Since the hyoid is positioned more closely to the mandibular plane after insertion of the appliance, it would seem that the reduction of the distance between the mandible and the hyoid bone may be an important factor in the search for improvement of OSA. An approximation of the mandible to the hyoid bone may result from the caudal and forward positioning of the mandible. This result is consistent with those found in upright cephalometric studies.<sup>9–11,25</sup>

On the basis of the after-insertion AHI, the sixteen subjects were divided into two groups. The good response group was significantly younger than the poor response group. The younger patients had a better response to the Klearway™ appliance. Age can be an important factor affecting the efficacy of oral appliances for the treatment of OSA. With aging of the upper airway, the dimension and compliance of the upper airway may deteriorate. Martin et al.<sup>34</sup> revealed that upper airway size decreases with increasing age in both men and women, and Burger et al.<sup>35</sup> reported increased compensatory upper airway dilator muscle activity in response to negative pressures in older patients.

Based on this supine cephalometric analysis, the prominence of the chin was less in the good response group than in the poor response group. The smaller the SNPG, the better the response to the appliance. This result is consistent with Mayer and Meier-Ewert.<sup>11</sup> Sub-

jects with a smaller or retruded chin may have a narrower upper airway, which in turn favors better efficacy with a mandibular advancement appliance. In the linear regression analysis, it was found that a narrower middle upper airway space (MAS) was associated with a larger improvement in AHI (%). Leither<sup>36</sup> suggested that the shape of the upper airway can play a crucial role in the efficacy of an oral appliance for OSA patients. Those with elliptical airways with the long axis oriented antero-posteriorly (A-P) would be particularly susceptible to airway collapse during sleep. In patients with OSA, the larger the absolute cross-sectional area or A-P space of the pharynx, the more likely it is that the pharyngeal orientation will be A-P. It might be more difficult to improve the cross-sectional area of the upper airway with an A-P orientation by a mandibular advancement device. Ryan et al.<sup>23</sup> documented that the shape of the pharynx did not change following the insertion of an oral appliance, and the lateral diameter of the velopharynx increased to a greater extent than the anteroposterior diameter.

Although the tongue height was larger in the good response group, the increase in the tongue height was significantly smaller. This suggests that the tongue height in the poor response group is more affected by the appliance in the supine position. Increased suprahyoid muscle activity might tend to protect against upper airway collapse secondary to the increased gravitational load on the tongue. Most interestingly, the sagittal cross-sectional area of hypopharynx was increased in the good response group, yet decreased in the poor response group. The change in the sagittal cross-sectional area of the hypopharynx may be associated with mandibular advancement. The latter in turn is associated with two factors. The first is the mandibular plane angle; the glenoid fossa in patients with a higher mandibular plane angle may result in more vertical than horizontal translation on the mandibular advancement, which tends to rotate the genioglossus and hyoid musculature closer to the oropharyngeal airway. The second is the dimension of the mandibular opening after insertion of the Klearway™ appliance. Excessive mandibular opening will camouflage the horizontal mandibular repositioning and cause clockwise rotation of the mandible. Thus, any benefit derived by increasing airway space or stabilization of the mandible and tongue by the appliance may very likely be overcome by deep encroachment of the soft tissue of the hypopharyngeal wall into the hypopharynx. In addition, as shown in Table 3, the standard deviation in the sagittal cross-sectional area of hypopharynx is very large, especially in the poor response group. This may be associated with its definition. The vertical levels of the fourth cervical vertebra and the tip of epiglottis affect the sagittal cross-sectional area of hypopharynx. This varies considerably from person to person.

## CONCLUSIONS

From supine cephalometric analyses, substantial changes in the upper airway were found before and after insertion of the Klearway™ appliance. The supine sagittal cross-sectional areas of the pharynx and tongue increased significantly, and the supine position of the hyoid bone was closer to the mandibular plane. When comparing the two different response groups, we found that the younger the patients and the less protrusive the chin, the better the response to the appliance. Also, the larger and more stable the baseline tongue height, the better the response. In addition, changes in the sagittal cross-sectional area of the hypopharynx were significantly different in the two groups in that it increased in the good response group but decreased in the poor response group. The mechanical effectiveness of the Klearway™ appliance and the stabilization of jaw posture may be important determinants of its efficacy.

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