Effects of the Full Breath Solution Appliance for the Treatment of Obstructive Sleep Apnea: A Preliminary Study

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ABSTRACT: The aim of this study is to determine the effects of the Full Breath Solution (FBS) appliance in the management of obstructive sleep apnea (OSA) in 21 adults diagnosed with OSA. Oxygen saturation (SaO2) and apnea-hypopnea index (AHI) readings taken from polysomnographs (PSGs) indicated that the mean AHI fell by 73% (31.3±16.3 to 7.3±6.6, p<0.0001), and the mean SaO2 improved from 84.4%±6.7 to 88.91%±3.9 (p<0.05). While there was no change in total sleep time, the mean REM time during sleep increased from 22.0 min ± 22.3 to 47.0 min ± 29.1 (p<0.05). However, there was no change in non-REM time during sleep, or time spent in the supine position while asleep, but the arousal index decreased from 50.8±31.0 to 15.4±15.0 (p<0.001). Conclusions: The Full Breath Solution (FBS) appliance is a novel, effective approach in the management of OSA.

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Recent evidence suggests that obstructive sleep apnea (OSA) may be a heterogeneous disorder, involving pharyngeal soft tissue enlargement, including the tonsils, adenoids and tongue.[1] As a large tongue and a retrognathic mandible are recognized as etiological factors in the pathogenesis of OSA, careful examination of the oropharyngeal region is important in evaluating patients suspected of having OSA. In terms of treatment, however, nasal continuous positive airway pressure (CPAP) is commonly associated with reduced patient compliance, and oral appliances have been used to cope with this condition by forward and downward advancement of the mandible, which drags the tongue along with it, and thus opens the oropharyngeal airway.[2] Therefore, the significance of the tongue in OSA has long been noted. Alternative surgical procedures are aimed at reducing tongue volume and at repositioning the hyoid bone, by reducing the tongue base and enlarging the hypo-pharyngeal airway.[3] Indeed, in partial resection of the tongue, the oro- and nasopharyngeal spaces are widened by the surgical removal of a wedge of tissue from the body of the tongue.[4] In addition to the above, several other therapeutic alternatives have been proposed, including tracheostomy, palatopharyngoplasty,

mandibular advancement appliances,[5] pharmaceutical medications, positional alarms,[6] and tongue-retaining devices (TRD).

To increase upper airway patency, TRDs have been implemented,[7] as it is thought that atypical tongue muscle activity may contribute to OSA during sleep.[8] As well, the relationship between inspiratory effort and genioglossus (GG) activity may be of significance in the pathogenesis of OSA. Specifically, it is postulated that TRDs reduce the apnea-hypopnea index (AHI) by counteracting fluctuations in GG muscle (EMG) activity.[9] Recent studies have shown that neuromuscular stimulation of the GG muscle can modulate airflow during sleep in patients with OSA.[10] Indeed, electro-stimulation of the anterior sublingual and lateral surface of the tongue causes preferential contraction of the GG and tongue retractor muscles, which are thought to improve airflow dynamics during sleep.[11] In addition, the use of a TRD can help place the tongue in direct contact with the hard palate through the generation of negative inter-occlusal pressure.[12] Therefore, complex technology has been utilized to control tongue posture for the relief of tongue obstruction associated with OSA. However, topical receptor mechanisms in the pharynx are thought to influence dilator muscle activity,[13] and it is not unlikely that similar proprioceptive mechanisms exist for the tongue. If so, a mechanism of tongue-control based on proprioceptive information gained from receptors on the surface of the tongue could help patients maintain a tongue posture that prevents oropharyngeal obstruction, and hence alleviate OSA during sleep. Therefore, the aim of this study is to determine the effects of a simple, maxillary, tongue-restraining appliance in the treatment of OSA. The null hypothesis to be tested is that use of a Full Breath Solution (FBS) appliance in patients with OSA has no effect on the AHI levels post-treatment.

Materials and Methods

In this longitudinal, prospective study, the sample comprised 21 consecutive, adult patients (17 males, four females) with a history of OSA, defined as an AHI>5/h of sleep diagnosed with overnight polysomnography (PSG), who provided informed consent to participate in this study as part of their clinical management. As well, the principles of the Declaration of Helsinki were followed, and all identities were kept anonymous throughout the study. Exclusion criteria for the study sample included patients who were medically unstable, using oxygen, had a history of upper airway or nasal surgery, or who did not provide informed consent. The AHI readings were taken from all patients prior to treatment using a sleep lab PSG.

Dental impressions were taken of each patient's upper and lower dental arches by one clinician (BK) using standard dental impression materials, such as alginate or polyvinyl silicone. The bite registration was taken at about 25% of maximum protrusion, unlike the 70-80% protrusion that is typically employed in mandibular advancement appliances. The vertical opening was approximately edge to edge on the anterior teeth. Thus, the bite registration deployed represents a major difference for this appliance, which aims to maintain patient comfort with no jaw pain. Dental casts were then made from the impressions, and the casts along with the bite registration were sent to a laboratory to manufacture the device.

The appliance was constructed of a thermoplastic acrylic (ClearSplint, Astron Dental Corp., Lake Zurich, IL), which softens in hot water, and hardens within 10s, permitting easy seating of the appliance. The FBS appliance fits over only the upper teeth (**Figure 1a**), and represents a unique design for a small and comfortable single-arched appliance. Its shape is similar to a full coverage maxillary appliance that is used to treat bruxism, but the FBS appliance has a transpalatal bar that extends from the left to the right side of the maxillary arch (**Figure 1b**), and is located as far posteriorly as the patient can tolerate it to be placed. This horizontal transpalatal bar has an additional vertical extension or tail, called the posterior tongue restrainer (**Figure 1b**). The transpalatal bar and tail are positioned above the tongue and below the palatal mucosa, and not contacting it during wakefulness (**Figure 2**). Tissue contact occurs when the patient is in the supine position during sleep, when the tongue changes its position due to gravity inter alia. It is postulated that the narrow canopy formed by the transpalatal bar and tail over the tongue restrains and inhibits it from obstructing the upper airway. The FDA approval number for the FBS appliance is K061228 (2006).

In terms of treatment protocol, cone-beam imaging (ICAT, Imaging Sciences International Inc., Hatfield, PA,) is used to ascertain the position of the FBS appliance with respect to the patients' tissues. This clinical imaging is the protocol of choice. A barium paste (E-Z Paste, Barium Sulfate Esophageal Cream (60% w/w), Nanric, Inc., Lawrenceburg, NY) is used to coat the surface of the FBS appliance so that it is clearly visible on the cone-beam image (**Figure 3**). Adjustments are then made to custom fit the tail of the appliance in relation to the tongue as necessary (**Figure 4**). In addition, there is an acclimatization or titration phase after insertion and fitting. Specifically, the tail is added gradually, depending on the individual's level of tolerance, i.e., treatment con-

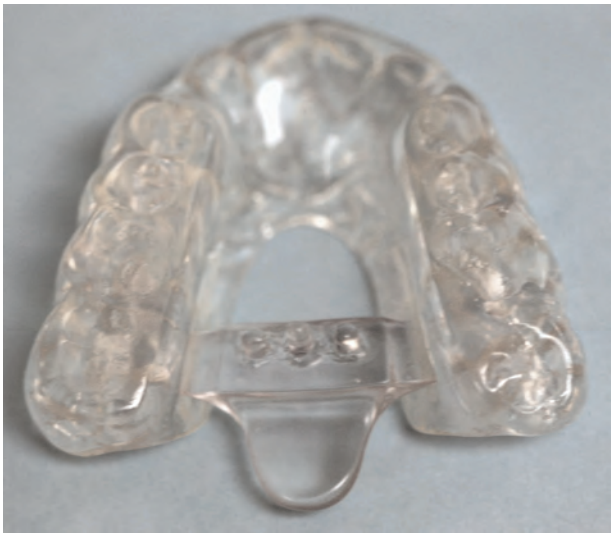
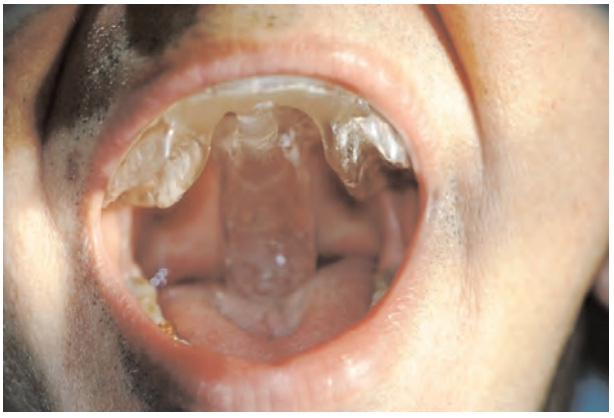


Figure 1(a and b)
a. (above) The FBS appliance has a transpalatal bar that extends from the left to the right side of the maxillary arch and is located as far posteriorly as the patient can tolerate it.
b. (below) The horizontal transpalatal bar has an additional vertical extension or tail, called the posterior tongue restrainer.



tinues with extension of the tail, which includes posterior and inferior additions of acrylic, so that the tail can be made longer and thicker. Once the patient's level of tolerance has been determined, patients are instructed to sleep in a supine position or on their side for best results, and referred for a sleep lab PSG.

In this study, the treatment time was calculated from the date of insertion of the appliance till the date that a post-treatment PSG sleep study was obtained. The AHI readings were thus repeated after treatment with the FBS appliance, using a sleep lab PSG. For statistical analysis, the mean pre- and post-treatment AHI and corresponding standard deviations were calculated. Differences between the mean variables were compared using two-tailed, paired t-tests at the 0.05 level of significance.

Results

The mean age of the patients was 66.7 yrs ± 9.4 with a mean BMI of 27.6 kg/m^2 ± 2.5. The mean treatment time was 3.9 months, calculated from the date of insertion of the appliance till the date that a post-treatment PSG sleep study was obtained. During treatment, patients who participated in this study reported minimal discomfort and no serious side effects from the appliance, except for increased salivation on appliance insertion. In addition, 5% of the patients had problems associated with discomfort from the transpalatal bar after initial insertion and fitting of the appliance. For these patients, the bar was initially moved forwards into the bicuspid region, and then moved posteriorly over a period of 2-3 weeks, allowing the patient to become habituated.

On insertion, 85% of patients comfortably tolerated a tail length of 1-3 cm (0.5-1.25 in) (**Figure 5**); 10% tolerated a tail >3 cm (1.25 in) (**Figure 6**) and 5% tolerated <1 cm (0.5 in) or no tail, initially. Also, 47.6% (ten out of 21 patients) had an AHI <5/h on the final PSG, while 80.1% (17 out of 21 patients) had an AHI <10/h on the final PSG. Four patients had an AHI >10/h on the final PSG. For these four patients, the mean pre-treatment AHI fell from 42.3/h to 18.5/h post-treatment. Thus, these four patients had a 56.4% improvement in AHI. Overall, all 21 patients showed a mean pre-treatment AHI of 30.2/h, which fell to 6.9/h post-treatment. The study sample of 21 patients showed >50% improvement in the AHI; therefore, the results from the sleep lab PSGs confirmed that the mean AHI fell 73% from 31.3/h±16.3 to 7.3/h±6.6 ($p<0.0001$), and the mean SaO_2 improved from 84.4%±6.7 to 88.91%±3.9 ($p<0.05$). The results are summarized in **Table 1**.

In addition, all patients subjectively reported better and more restful sleep with a reduction of snoring. Using PSG data, there was no change in total sleep time, but the mean REM time during sleep increased from 22.0 min ± 22.3 to 47.0 min ± 29.1 ($p<0.05$). However, there was no change in non-REM time during sleep, or time spent in the supine position while asleep. Nevertheless, the arousal index decreased from 50.8±31.0 to 15.4±15.0 ($p<0.001$). **Table 2** summarizes these findings.

Discussion

In this preliminary study, the sample consisted of typical sleep apnea patients whose primary reasons for seeking treatment were an inability to tolerate conventional CPAP and snoring; there were no particular oral/craniofacial characteristics that may have made them suitable for this treatment. Although no matched control group

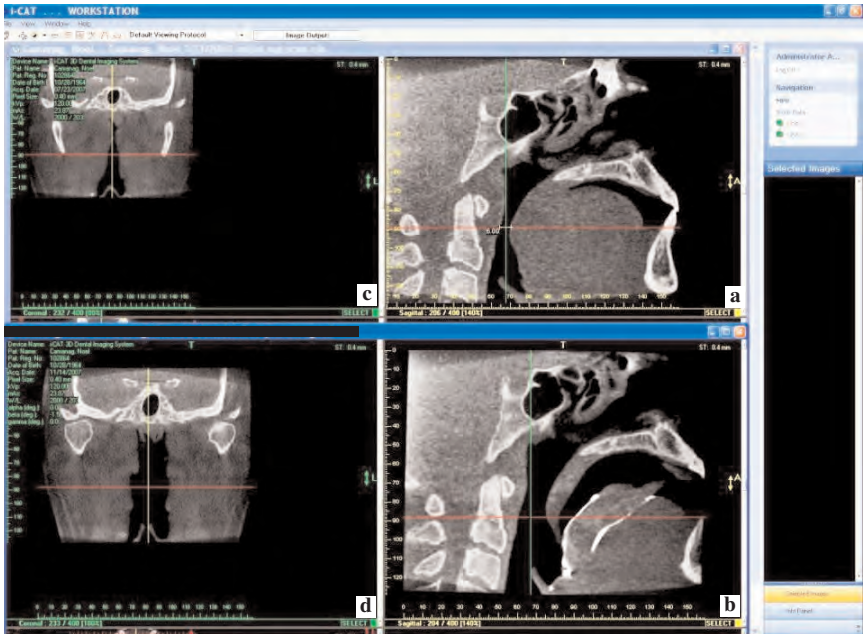


Figure 2
The sagittal plane (**a**) shows the relation of the soft palate and tongue. Note that the soft palate and the tongue are in contact, and the depth of the oropharyngeal airway space is narrow. The sagittal plane (**b**) shows the change in relation to the soft palate and the tongue **with** the FBS appliance in situ, which is clearly visible due to the coating of barium paste. The coronal plane (**c**) shows the width of the oropharyngeal airway space **without** the appliance. The coronal plane (**d**) shows the improvement in the caliber of the oropharyngeal airway space **with** the FBS appliance.

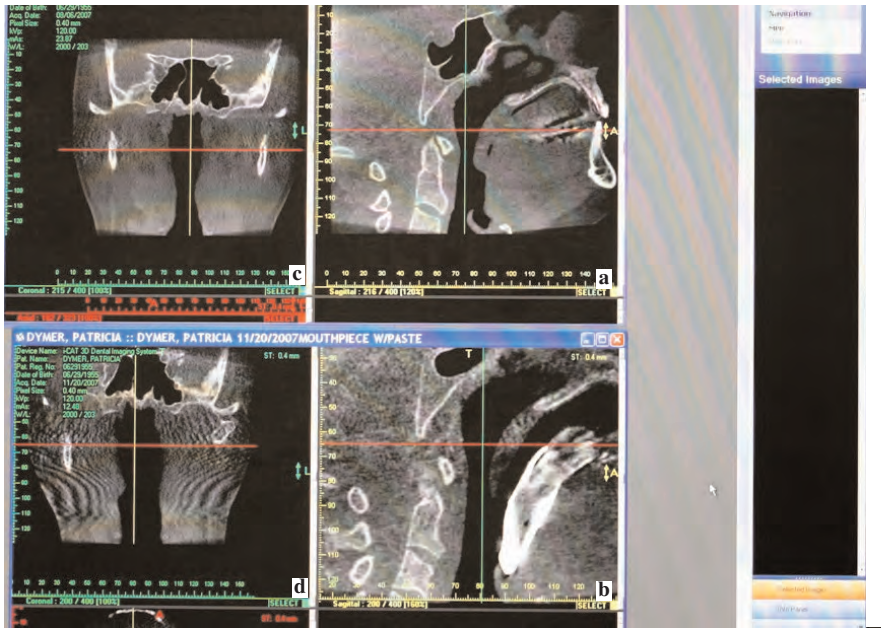


Figure 3
The sagittal plane (**a**) shows the relation of the soft palate and tongue with the appliance in situ, which is visible due to the coating of barium paste. Note that the soft palate and the FBS appliance are in contact, and the depth of the oropharyngeal airway is narrow. The sagittal plane (**b**) shows the change in relation to the soft palate and the FBS appliance after making the necessary adjustments. Note the increased depth of the oropharyngal airway space. The coronal plane (**c**) shows the width of the oropharyngeal airway space. The coronal plane (**d**) shows the improvement in the caliber of the oropharyngeal airway space.

was available for this particular study, and other data such as blood pressure, Epworth scale scores, and subjective satisfaction questionnaire assessments were not included, the improvement reported in this preliminary study appear to be based on the ability of the transpalatal bar to prevent the upward and backward displacement of the tongue, thereby maintaining patency of the oropharyngeal airway during sleep. While many treatments are advocated for the management OSA, the use of a single-arched, maxillary appliance is a novel approach to controlling tongue posture, which does not rely on >70% mandibular protrusion for clinical efficacy. Note that during bite registration for appliance construction, only 25% mandibular advancement was used, prior to inserting the FBS appliance. Thus, the appliance described here is not a mandibular advancement appliance per se.

In addition, although quantification of compliance was not gauged in this particular study, there were no reports of any significant discomfort or side effects, except for increased salivation when the FBS appliance was first

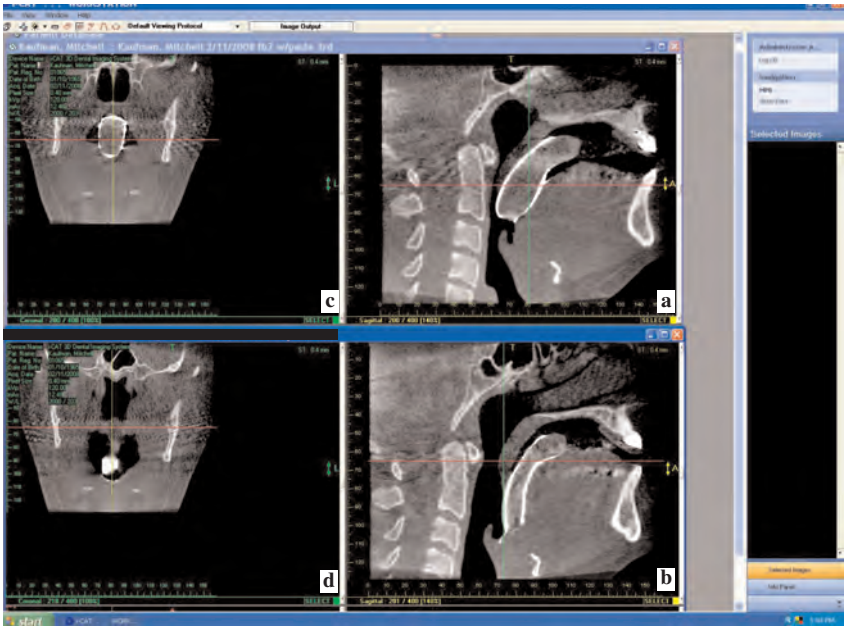


Figure 4
The sagittal plane (**a**) shows the relation of the soft palate and tongue with the FBS appliance in situ, which is clearly visible due to the coating of barium paste. Note the soft palate and the appliance are in contact, and the width of the oropharyngeal airway space is narrowed by the tail of the FBS appliance. The sagittal plane (**b**) shows the change in relation of the soft palate and the FBS appliance after making the necessary adjustments. Note that the tail of the appliance has been decreased in thickness, and the soft palate and FBS appliance are no longer in contact. The coronal plane (**c**) shows the tail of the FBS appliance occupying the oropharyngeal airway space. The coronal plane (**d**) shows the change in the tail of the FBS appliance after making the necessary adjustments. Note the improvement in the caliber of the oropharyngeal airway space.

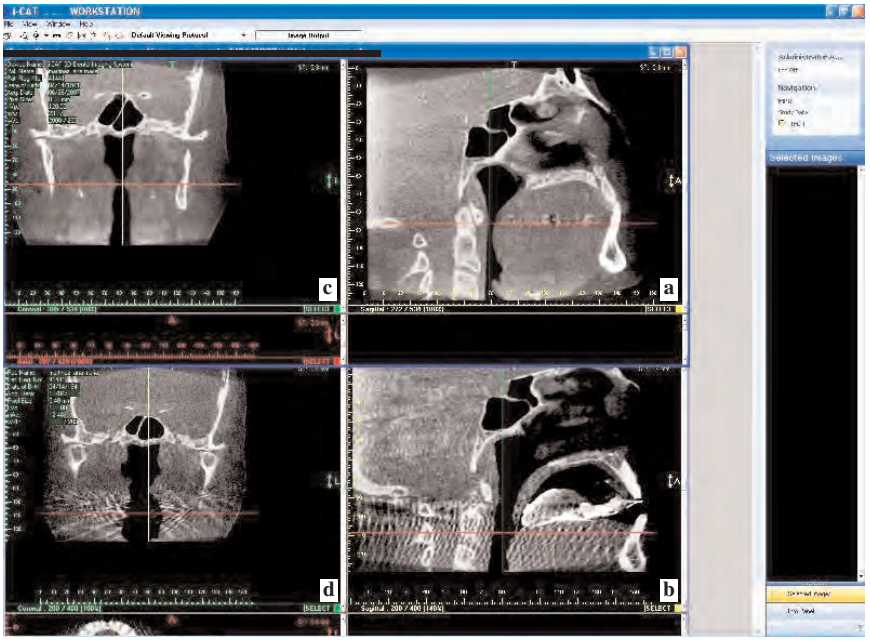


Figure 5
The sagittal plane (**a**) shows the relation of the soft palate and tongue with no appliance. Note the soft palate and the tongue are in contact, and the depth of the oropharyngeal airway space is narrow. The sagittal plane (**b**) shows the change in relation of the soft palate and the tongue with the FBS appliance in situ. Note the increased depth of the oropharyngeal airway space. The coronal plane (**c**) shows the width of the oropharyngeal airway space. The coronal plane (**d**) shows the improvement in the caliber of the oropharyngeal airway space.

inserted. Side effects were assessed on patients' complaints, and 5% of the patients reported problems associated with discomfort from the transpalatal bar after initial insertion and fitting of the FBS appliance. These problems included: the appliance being too tight on the teeth; the tail being too long; the tail being too low; the tail applying excessive pressure on the tongue; the tail being not low enough, and not exerting sufficient pressure on the tongue. All these issues were handled individually. Nevertheless, there were no special factors that affected the study, such as changes in weight or alcohol consumption, or differences in time spent sleeping in the supine position (**Table 2**) between the two PSG studies.

Gagnon, et al.[14] reported increased respiratory disturbances using a maxillary occlusal splint to manage OSA. In contrast in this preliminary study, we found that patients subjectively reported more restful sleep with a reduction of snoring. Indeed, the PSG data (**Table 2**) showed whilst there was no change in total sleep time, the mean REM time during sleep increased from 22.0 min ±

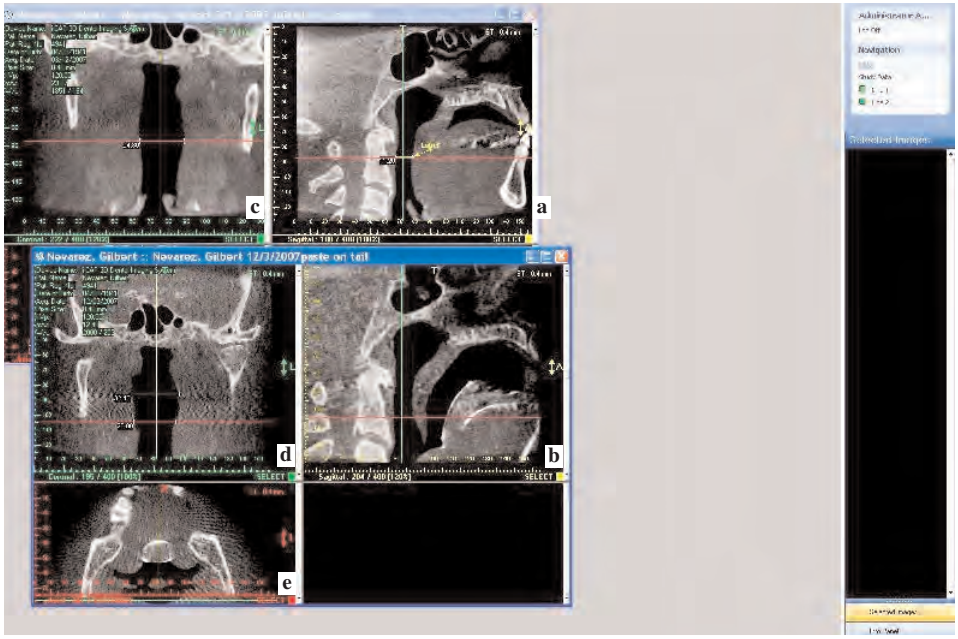


Figure 6
The sagittal plane (**a**) shows the relation of the soft palate and tongue with the FBS appliance on insertion. Note that the soft palate and the tongue are still in contact, and the depth of the oropharyngeal airway space is narrow. The sagittal plane (**b**) shows the change in relation of the soft palate and the tongue after making the necessary adjustments to the FBS appliance. Note the increased depth of the oropharyngeal airway space. The coronal plane (**c**) shows the width of the oropharyngeal airway space. The coronal plane (**d**) shows the changes in the caliber of the oropharyngeal airway space. The transverse plane (**e**) shows the extent of the changes in the caliber of the oropharyngeal airway space.

22.3 to 47.0 min ± 29.1 ($p<0.05$). In addition, while there was no change in non-REM time during sleep, or time spent in the supine position while asleep, the arousal index decreased from 50.8±31.0 to 15.4±15.0 ($p<0.001$). Thus, it can be surmised that both appliance design and clinical protocol are factors that affect the successful management of patients with OSA when using maxillary appliances.

Table 1
Data Values for the Subjects Who Participated in the Study

Gender	Age	BMI	Pre-Tx AHI	Post-Tx AHI	Pre-Tx SaO_2	Post-Tx SaO_2	Tx Time
M	65	32.8	54.0	24.7	80	83	2.3
F	77	26.0	18.0	1.1	87	91	3.0
M	66	24.0	13.0	0	90	93	8.0
M	75	27.0	23.6	1.0	88	95	6.8
M	76	31.0	49.2	19.4	81	90	3.5
M	67	25.0	18.6	4.9	83	90	10.0
M	65	26.0	38.5	8.2	85	86	1.5
F	74	32.0	7.1	3.6	85	88	7.0
F	75	26.0	25.3	6.0	84	88	3.3
M	69	28.5	27.0	4.6	86	88	4.8
M	78	29.6	32.0	12.0	88	80	1.3
M	68	27.5	10.0	6.0	90	92	3.5
M	52	30.5	49.5	3.0	60	87	3.8
M	77	26.2	34.3	17.9	86	89	0.8
M	55	26.0	29.8	8.6	87	89	1.8
F	42	28.0	17.7	5.3	89	96	4.3
M	66	25.8	65.8	1.2	91	94	4.8
M	56	29.4	27.5	7.5	87	87	4.3
M	57	26.2	21.0	9.1	80	89	1.0
M	74	25.0	39.0	7.8	77	84	2.8
M	67	29.0	58.0	0.3	89	88	2.8

BMI: body mass index; Tx: treatment; AHI: apnea-hypopnea index; SaO_2: minimum oxygen saturation

In fact, customized oral devices have been shown to be effective in many cases.[15] In a review of oral devices in the treatment of OSA, however, Lindman and Bondemark[16] found insufficient evidence for the clinician to determine which appliance is most likely to improve symptoms for a given patient. Nevertheless, it is recognized that side effects occur in a significant proportion of patients using mandibular advancement devices. In addition, the therapeutic effect of TRDs is variable and some cases have been reported in which snoring is resolved but the OSA persists.[17] In contrast, in some cases central sleep apnea can be successfully treated with a TRD.[18] Therefore, the use of a single-arched, maxillary appliance with a transpalatal bar investigated in this present study provides a viable alternative to conventional CPAP or surgery, presumably by restraining the tongue during sleep, which relieves oropharyngeal obstruction.

In support of the above contention, in this study we found that the pre- and post-treatment mean minimum SaO_2 levels improved from 84.4%±6.72 to 88.9%±3.9 ($p<0.05$) using the results from the sleep lab PSGs (**Table 2**). Therefore, an overall 9% improvement in minimum mean SaO_2 levels in pre- and post-treatment sleep studies was noted. This improvement appears to be related to the ability of the transpalatal bar to prevent the upward and backward displacement of the tongue, thereby maintaining the patency of the airway during sleep. Similarly, Higurashi, et al.[19] reported that the oxygen desaturation levels improved with a TRD in patients with mild to moderate OSA, and patients with more severe OSA may also benefit from the use of a TRD. We surmise that the effect of the transpalatal bar restrains the tongue and inhibits it from obstructing the oropharynx through a proprioceptive mechanism, thus preventing the SaO_2 levels from falling to lower levels than might otherwise occur. Of note, in a recent study it has been shown that even with less improvement and greater residual sleep disorder breathing than present in the current study, endothelial function may dramatically improve, and reduce the risk of cardiovascular complications.[5]

In one study, an oral appliance was designed to relieve upper airway obstruction during sleep by pulling the tongue forward using a truss pad positioned in its posterior region.[20] The majority of cases (75%) did not respond well due to side effects of the appliance with insufficient acceptability. Similarly, Katsantonis, et al.[21] found compliance to a TRD to be poor, although two of the six subjects in that study had significant improvement in their OSA symptoms. In addition, in a comparison of three oral appliances, Barthlen, et al.[22] found five of eight patients tolerated the TRD with the AHI decreasing from 50.3/h to 43.5/h, but the change was not statistically significant. In contrast, while only two out of the eight patients monitored in that study could sleep with a soft palate lift device in place, all eight patients tolerated the mandibular advancement device. Another study[23] compared the efficacy of somnoplasty and a TRD. It found no significant differences between the two groups when the percentage of sleep time spent in loud snoring was tested. Therefore, factors other than efficacy, such as compliance and

Table 2
Descriptive Statistics of Sleep Parameters Assessed Using Polysomnography
Mean Pre-Treatment Value Is Compared to Mean Post-Treatment Value (Last Column)

Parameter	Pre-treatment mean ± SD	Post-treatment mean±SD	Significance
AHI	31.3±16.3	7.3±6.6	p<0.001
SaO2 (%)	84.4±6.7	89.0±3.9	p<0.05
Total sleep time (mins.)	227.6±101.9	289.2±87.5	NS
Total REM time (mins.)	22.0±22.3	47.0±29.1	p<0.05
Total NREM time (mins.)	185.8±87.1	237.4±73.1	NS
Arousal index	50.8±31.0	15.4±15.0	p<0.001
Supine sleep time (mins.)	103.8±124.0	91.0±114.1	NS

AHI: apnea-hypopnea index
SaO_2: minimum oxygen saturation
REM: rapid eye movement
NREM: non-rapid eye movement
SD: standard deviation
NS: not significant

patient comfort, must be used when an appliance is chosen to control snoring. In this present study, none of the patients reported significant discomfort or intolerance of the FBS appliance and, although no subjective data were obtained, compliance was found to be excellent with the transpalatal bar design investigated. Indeed, all patients demonstrated a quantifiable decrease in the post-treatment AHI, and none showed any deterioration. Consequently, the overall results of treatment using the FBS appliance showed a decrease in the AHI of 73% from 31.3/h±16.3 to 7.3/h±6.6 ($p<0.0001$), as measured by sleep lab PSGs. Therefore, we surmise that a single-arched, maxillary appliance design that incorporates a transpalatal bar may induce a different corrective mechanism (based on proprioception) when compared to conventional TRDs, which rely on relative negative pressure.

Oral appliances recommended for the treatment of snoring and OSA modify the position of the mandible, tongue and other structures in the oral cavity. Piorunek, et al.[24] found all device designs can decrease snoring significantly, but the best results are obtained with the use of devices that correct the position of soft palate and uvula. Similarly, TRDs are designed to prevent airway obstruction and increase the dimension of the oropharynx during sleep, by holding the tongue in a forward position[25] but are associated with long-term, appliance-induced dental changes, such as anterior and/or unilateral posterior open bites and reduced anterior overjets.[26] Ferguson, et al.[27] used videoendoscopy to measure upper airway cross-sectional area (CSA) and shape in the hypo-, oro- and velopharyngeal regions during active mandibular and tongue protrusion during wakefulness. They reported that tongue protrusion caused a greater increased CSA in the velopharynx and oropharynx than mandibular protrusion, resulting in a more circularly-shaped upper airway. Therefore, control of tongue posture is one factor of significant importance in the prevention of OSA. Indeed, Ono, et al.[28] defined the effect of a TRD on GG muscle activity in adults during wakefulness. The TRD was designed to pull the tongue forward to enlarge the volume of the upper airway and to reduce upper airway resistance. The GG EMG activity was reduced with the TRD in subjects with OSA. Note that the afferent proprioceptive nerve supply to the anterior two-thirds of the tongue is thought to be mediated via C2-C3,[29] although some believe it to be via a complex communication of nerve trunks and nuclei at extra- and intra medullary levels.[30] Thus, the proprioceptive capability of the tongue may not be abolished during bilateral local anesthesia or presumably during sleep. In summary, while there is a need for a controlled study to verify the preliminary findings of this study, we suggest that the use of a single-arched, maxillary appliance with a transpalatal bar design utilizes a proprioceptive mechanism of tongue-control, based on information gained from tongue surface receptors, which helps patients attain a tongue-restraining posture for the amelioration and/or prevention of OSA.

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