Aveo Tongue Stabilizing Device For Treatment of Obstructive Sleep Apnea

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Abstract

Introduction: Oral appliances are a simpler alternative to CPAP for the treatment of obstructive sleep apnea (OSA) as they are quiet, portable and don not require a power source.

Aim of the work: The aims of this work were to evaluate the efficacy and complications of Aveo tongue stabilizing device in the treatment of OSA and to determine the predictors of success.

Results: There were significant improvement of symptoms of OSA (snoring, daytime sleepiness, morning headache, nocturnal choking and witnessed apnea) while wearing the device in comparison to before wearing the device ($P = 0.002$, 0.003, 0.005, 0.025 and 0.046 respectively), The AHI and arousal index were significantly decreased while wearing the device in comparison to without wearing the device (23.67 ± 4.03 vs 9.93 ± 6.52, $P < 0.001$ and 31.07 ± 4.06 vs 20.67 ± 4.68, $P < 0.001$ respectively). Success was achieved in(9 cases out of 15) 60%, 40% with complete success and 20% with partial success while 40% showed treatment failure. Side effects of use of TRD were as follow: 80% excessive salivation, 66.67% dry mouth, 60% tongue abrasion and 6% jaw pain. The succeeded cases in comparison to failed cases showed significantly smaller neck circumference, lower BMI, lower AHI, lower % total slept time $SaO2 < 90\%$ and predominant supine AHI ($P < 0.001$, 0.002, 0.001, 0.002and 0.003 respectively)

Conclusion: we can conclude that Aveo TRD was effective in treatment of 60% of mild to moderate OSA and side effects occurred frequently to the extent to prevent 40% of patients to stop use of the device. The predictors of success were cases with low BMI, small neck circumference, low AHI and less hypoxemia and predominant supine AHI.

Introduction:

Although continuous positive airway pressure (CPAP) provides the most widely used method to treat sleep disordered breathing today, it is also the most cumbersome one. Many patients find it unappealing, difficult to tolerate and unacceptable, the only other non invasive alternative which can produce favorable results within a short time is oral appliance (1). Oral appliances are a simpler alternative to CPAP for the treatment of obstructive sleep apnea (OSA) as they are quiet, portable and don not require a power source (2).

In broad terms, oral appliance can be regarded as being either mandibular advancement splint (MAS) or tongue retaing device (TRD). MAS generally attach to the dental arches and mechanically protrude the mandible. TRD use suction pressure to maintain the tongue in a protruded position during sleep. MAS therefore require the patient to have sufficient teeth whereas TRD can be used by edentulous patients (3).

The American Academy of Sleep Medicine recommended the use of oral appliances for mild to moderate OSA or patients with severe OSA who are unable to tolerate CPAP or refuse treatment with CPAP. There is reboust evidence of the efficacy of oral appliances both in regard to improvement of polysomnography (PSG)

indexes as well as modifying the health risk associated with OSA (3).

Aims of the work:

The aims of this work are to evaluate the efficacy and complications of Aveo tongue stabilizing device in the treatment of OSA and to determine the predictors of success.

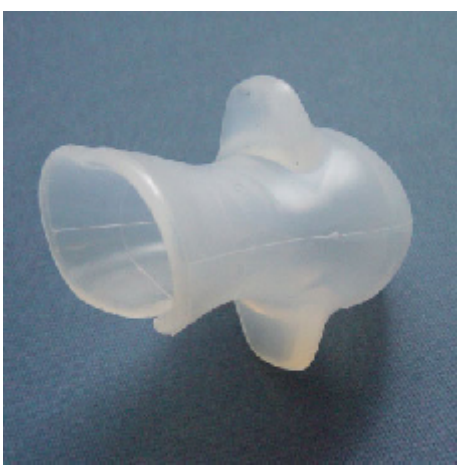
Subjects and methods:

This prospective study was done in Thoracic Medicine Department, Mansoura University Hospitals in collaboration with Radiology Department, Mansoura Faculty of Medicine and Prosthodontic department Mansoura Faculty of Dentistry in the period from January 2008 to May 2009.

The inclusion criteria of the cases of this study were at least two symptoms of OSA (snoring, fragmented sleep, witnessed apneas, morning headache and daytime sleepiness) and evidence of OSA on PSG (apnea hypopnea index (AHI) ≥ 5/hour), but cases with severe OSA (AHI > 30/hour) were excluded. Other exclusion criteria include bruxism, central apneas, regular use of sedatives, exaggerated gag reflex and standard contraindications for magnetic resonance imaging (MRI) such as cardiac defibrillators and metallic prothesis.

From twenty patients who commenced the trial, 15 patients completed the study (2 patients refused the device and 3 patients dropped during follow up). For the remaining fifteen patients, the following were done:

1) Thorough history taking with stress on symptoms of OSA.
2) Physical examination with stress on neck circumference, body mass index (BMI), and upper airway examination to exclude space occupying lesions in the nose and mouth and dental examination (teeth and gum).
3) Full night PSG(Jaeger sleep screen) for objective diagnosis of OSA and repeated later on after 1 month of acclimatization of the patients on the device for assessment of response to appliance. Positional OSA means >50% of AHI occur in supine position .
4) Consultation with the Prosthodontic Department, Mansoura Faculty of Dentistry, was done for proper insertion of the TRD device intraorally.
   The TRD used in this study was a preformed ,non adjustable appliance. Aveo tongue stabilizing device (Aveo) made by Innovative Health Technology PO Box 17572 Chritchurch, New Zeland.



   It consist of a narrowed isthmus which only extend intraorally to incorporate the incisor teeth or in edentulous patients, the alveolar ridge. This isthmus is joined anteriorly to a bulbous compartment. The tip of the tongue is inserted into the bulbous compartment, which contain vertical supports to hold the tongue in a forward position by negative pressure.
5) Intraoral examination was made to exclude any local inflammatory causes which prevent placement of the device, so thorough scalling and tongue examination was performed and the prosthodontist exclude the patients with parafunctional habits after examination of the existing occlusion. He also learned the patients how to insert and remove the device intraorally and instruct the patient for the way for maintaining the proper oral hygiene measures and hygiene measures of the device. Follow up program for all the

patients was performed during the period of study every week.

6) MRI (Siemens, Symphony 1.5 Tesla) was done on the upper airways with assessment of the shortest retropalatal and retroglossal dimensions (Antero-posterior and lateral) with and without wearing the device while the patients were awake in supine position. A mid saggital slice was done first and from which the shortest retropalatal and retroglossal transaxial slices were chosen for calculation of antero-posterior and lateral dimensions.
7) Response to the device (symptoms of OSA especially Epworth sleepiness scale (ESS) and results of PSG while wearing the device were assessed after 1 month of use of the device. Complete success means reduction of AHI to a level of normal (< 5 events / hour). Partial success means > 50% reduction in AHI but the residual AHI > 5 events / hours. Treatment failure means < 50% reduction in AHI (3).
8) Assessment of complications and compliance were done after 1 month of wearing the device.

Statistics: Data was analyzed using SPSS (Statistical Package for Social Sciences) version 10. Qualitative data were presented as number and percent. Comparison between groups was done by Z-test and Chi-square test. Normally distributed data was presented as mean ± SD. Student t-test was used to compare between two groups. $P < 0.05$ was considered to be statistically significant.

Results:

This prospective study comprised 15 patients with OSA. The mean age was 36 ± 3.3 years, 60% (9 of 15) were males and 40% (6 of 15) were females, the mean BMI was 29.8 ± 1.9 and mean neck circumference was 40.2 ± 2.8 cm.

Table (1): Symptoms of studied cases of OSA without and with use of the oral appliance.

Symptoms	Without oral appliance		With oral appliance		Statistics	
	No	%	No	%	Z	P value
1) Snoring	15	100	5	33.3	3.16	0.002
2) Daytime sleepiness	15	100	6	40	3.0	0.003
3) Morning headache	11	73.3	3	20	2.83	0.005
4) Nocturnal choking	9	60	4	26.7	2.24	0.025
5) Witnessed apnea	8	53.3	4	26.7	2.0	0.046

Table (2): ESS of studied cases of OSA without and With use of oral appliance.

	Mean ± SD	Statistics
ESS without oral appliance	13.33 ± 1.29	t = 10.84
ESS with oral appliance	9.6 ± 1.84	P < 0.001

ESS Epworth sleepiness scale

Table (3): PSG parameters in studied cases of OSA without and with oral appliance.

PSG parameters	Without oral appliance Mean ± SD	With oral appliance Mean ± SD	Statistics
(1) Desaturation index (events/hour)	17.6 ± 2.35	14.1 ± 3.5	t = 10.09 P < 0.001
(2) Average duration SaO2 < 90% (second)	23 ± 3.89	18.67 ± 5.77	t = 6.96 P < 0.001
(3) Minimum SaO2 %	81.47 ± 30.4	85.6 ± 4.05	t = 6.63 P < 0.001
(4) % Total sleep time SaO2 < 90%	2.85 ± 0.82	1.89 ± 0.95	t = 16.42 P < 0.001
(5) AHI (events/hour)	23.67 ± 4.03	9.93 ± 6.52	t = 15.69 P < 0.001
(6) Arousal index (events/hour)	31.07 ± 4.06	20.67 ± 4.68	t = 13.34 P < 0.001
(7) % Total sleep time of snoring	15.76 ± 5.99	4.2 ± 4.14	t = 10.033 P < 0.001

Sao2 Arterial oxygen saturation AHI Apnea hypopnea index

Table (4): MRI of the upper airways of studied cases of OSA without and with oral appliance.

	Without oral appliance Mean ± SD	With oral appliance Mean ± SD	Statistics
Retropalatal			
(a) Anteroposterior dimension (millimeter)	4.53 ± 0.52	6.60 ± 0.51	t = 9.025 P < 0.001
(b) Lateral dimension (mm)	8 ± 0.76	11.1 ± 1.6	t = 16.16 P < 0.001
(c) Anteroposterior / Lateral ratio	0.57 ± 0.10	0.59 ± 0.10	t = 7.485 P < 0.001
Retroglossal			
(a) Anteroposterior dimension (mm)	10.5 ± 0.52	13.7 ± 1.03	t = 14.4 P < 0.001
(b) Lateral dimension (mm)	19.7 ± 0.45	23.7 ± 1.5	t = 11.8 P < 0.001
(c) Anteroposterior / Lateral ratio	0.53 ± 0.02	0.58 ± 0.02	t = 6.537 P < 0.001

Table (5): Outcome of aveo-tongue stabilizing device in patients with OSA.

	No	%
Complete success	6	40
Partial success	3	20
Treatment failure	6	40
Total	15	100

Table (6): predictors of success in studied cases of OSA with oral appliance.

	Success (9) Mean ± SD	Failure (6) Mean ± SD	Statistics
Age	35.67 ± 3.39	36.50 ± 3.51	t = 0.460 P = 0.653
Neck circumference	38.11 ± 1.05	43.33 ± 1.03	t = 9.473 P < 0.001
BMI	29.11 ± 1.36	32.83 ± 2.23	t = 3.869 P = 0.002
ESS	12.78 ± 0.67	14.17 ± 1.60	t = 2.347 P = 0.035
Basal SaO2	90.89 ± 0.93	91.17 ± 0.75	t = 0.609 P = 0.553
% Total sleep time SaO2 < 90%	2.37 ± 0.61	3.57 ± 0.51	t = 3.955 P = 0.002
AHI	20.67 ± 1.73	28.17 ± 0.41	t = 12.481 P < 0.001
Arousal index	30.89 ± 3.48	31.33 ± 5.16	t = 0.200 P = 0.844
% Total sleep time snoring	13.82 ± 7.05	18.17 ± 2.07	t = 1.942 P = 0.081

Table (7): Effect of positional OSA on outcome of oral appliance

	Predominant Side AHI (8)	Predominant supine AHI (7)	Statistics
Success (9)	2 (25%)	7 (100%)	$\chi^2 = 8.750$
Failure (6)	6 (75%)	0 (0%)	P = 0.003

Table (8): Compliance of use of aveo tongue stabilizing device in patients with OSA.

	No	%
Compliant	9	60
Non compliant	6	40
Total	15	100

Table (9): Complications of Aveo tongue stabilizing device in patients with OSA.

	No	%
Excessive salivation	12	80
Oral dryness	10	66.7
Tongue abrasion	9	60
Jaw pain	1	6

Discussion:

Although continuous positive airway pressure (CPAP) provides the most widely used method to treat sleep disordered breathing today, it is also the most combersome one. Many patients find it unappealing, difficult to tolerate and unacceptable, the only other non invasive, alternative which can produce favorable results within a short time is oral appliance (1). The growing literatures regarding the benefits of oral appliances in the treatment of OSA has a growing enthusiasm for their use in clinical practice. There is now an increasing evidence base to support the use of oral appliances in clinical practice (4).

The aims of this work were to evaluate the efficacy and complications of Aveo tongue stabilizing device in the treatment of OSA and to determine the predictors of success.

There were significant improvement of symptoms of OSA (snoring, daytime sleepiness, morning headache, nocturnal choking and witnessed apnea) while wearing the device in comparison to before wearing the device ($P = 0.002$, 0.003, 0.005, 0.025 and 0.046 respectively), and the percentage of total sleep time spent in snoring was significantly decreased with wearing the device compared to before wearing the device ($15.76 \pm 5.99\%$ vs $4.2 \pm 4.14\%$, $P < 0.001$). Also the ESS was significantly decreased from 13.33 ± 1.29 before appliance to 9.6 ± 1.84 after appliance ($P < 0.001$). This was in accordance to schohofer et al (5) who reported on using TRD an improvement of snoring and ESS ($P < 0.05$). Dort and Hussein (6) reported a reduced snoring by more than 70% with the use of TRD. Hoffstein (1) on surveying different investigations found on use of different oral appliances an improvement of snoring by a mean of 45% by using different methods for assessment of snoring (visual analogue scale, number of snores/hour, amount of time spent with loud snoring/hour, number of night/week spent with snoring) also found that ESS dropped from mean of 11.2 to 7.8 which was statistically significant. Dean et al (7) reported that TRD stopped snoring in 33.3% and stopped and reduced it in 55.5% while the ESS was reduced significantly from 8.72 ± 4.52 to 3.78 ± 2.53 ($P = 0.009$). This illustrate that our results and the previously mentioned studies documented the improvement of OSA symptoms with the use of TRD.

The AHI and arousal index were significantly decreased while wearing the device in comparison to without wearing the device (23.67 ± 4.03 vs 9.93 ± 6.52, $P < 0.001$ and 31.07 ± 4.06 vs 20.67 ± 4.68, $P < 0.001$ respectively). This was in accordance to compilation of data from four peer reviewed studies (57 patients using TRD) which showed a mean decrease of AHI from 44 to 22 (Cartwright and Samuelson (8), Cartwright (9), Cartwright et al (10), and Cartwright et al (11). Ferguson et al (12) on use of TRD reported significant decrease in AHI from 45/hour to 19/hour ($P < 0.001$). Ferguson et al (4) on reviewing ten studies of different oral appliances reported a reduction of baseline by 50%. Dean et al. (7) with the use of Aveo TRD reported that the AHI decreased from 28.66 ± 4.39 to 13.01 ± 2.65 $P = 0.002$ and the arousal index decreased from 34.6 ± 4.04 to 21.93 ± 2.47 $P = 0.003$, while Barthlen et al (13) reported that AHI do not change significantly from 50.3 ± 18.9 at baseline to 43.5 ± 32.5 with the device ($P = 0.64$). This insignificant result can be explained by small number of studied cases (only 5 patients). Also Kingshott et al (14) reported a non

significant decrease of AHI from 20 ± 17 to 15 ± 13 P = 0.06 while the arousal index was significantly decreased from 34 ± 16 to 22 ± 14 P = 0.004. The explanation here for this non significant AHI also was the small number of studied cases (6 patients).

The parameters of SaO2 in our study showed significant improvement with the use of the device in comparison without use of the device. For desaturation index was 17.6 ± 2.35 vs 14.1 ± 3.5 events/hour P = 0.001, for average duration of SaO2 < 90% was 23 ± 3.89 seconds vs 18.67 ± 5.77 seconds P < 0.001, for % total sleep time (TST) SaO2 < 90% 2.85 ± 0.82% vs 1.89 ± 0.95% P < 0.001, and for minimum SaO2 was 81.47% ± 30.4 vs 85.6% ± 4.05 P < 0.001. This was in accordance to Higurashi et al (15) who reported significant increase in minimum SaO2 P < 0.05 and significant decrease % of TST spent with SaO2 < 90% P < 0.05, also in accordance to Deane et al (7) who reported that the minimum SaO2 was significantly increased from 83.3 ± 1.54% to 88 ± 1.24 %P = 0.003.Our results and the previously mentioned studies documented improvement of objective parameters of OSA (AHI, Arousal index, Desaturation indexes) with the use of TRD.

The antiroposterior (AP) and lateral (L) dimensions in the retropalatal and retroglossal areas were significantly increased with the wearing of the device in comparison to without wearing of the device. They were in retropalatal area 4.53 ± 0.52 mm vs 5.6 ± 0.51 mm (P < 0.001) for AP dimension and 8 ± 0.76 vs 12.1 ± 1.6 mm (P < 0.001) for (L) dimension, and in retroglossal area, 10.5 ± 0.52 mm vs 13.7 ± 1.03 mm P < 0.001 for (AP) dimension and 19.7 ± 0.45 mm vs 23.7 ± 1.5 mm (P < 0.001) for (L) dimension. This was in accordance to Ferguson et al (12) who reported that maximal protrusion of the tongue significantly increased the cross sectional area of the oropharynx and velopharynx P < 0.001. A lesser degree of the tongue protrusion also significantly increase the oropharynx cross sectional area P < 0.05 but not the velopharynx cross sectional area. Also our results are in accordance to Deane et al (7) who reported that the (AP) dimension significantly increased with the use of Aveo-TRD in the oropharynx (10.87 ± 1.12 mm vs 13.24 ± 0.83 mm P = 0.033) and also significantly increased the (L) dimension in velopharynx and oropharynx (15.43 ± 2.26 mm vs 20.05 ± 2.17 mm P = 0.044 and 19.85 ± 1.58 mm vs 24.57 ± 1.88 mm P = 0.034 while no significant differences of the (AP) dimension in the velopharnx (9.01 ± 1.08 mm vs 9.95 ± 1.02 mm P = 0.26). The difference between our result and that of Deane et al (7) can be explained by the difference in the degree of protrusion of the tongue during imaging which will be significant on maximal protrusion as in study of Ferguson et al (12). Our results and the previous studies document the increase in AP and L dimensions of velopharynx and oropharynx which illustrate the mechanism by which TRD improve OSA. Another possible mechanism is the change in muscle tone of pharyngeal muscles which need further investigation.

In our study, the AP/L ratio increased while wearing the device (from 0.57 to 0.59 in the palatopharyngeal area and from 0.53 to 0.58 in the glossopharyngeal area.this was statistically significant (p<0.001 for both). This was in accordance to Ferguson et al (12) who reported that AP/L diameter ratio increased with maximal tongue protrusion in oropharynx and velopharynx P < 0.001. The tongue protrusion resulted in a change in shape of the upper airway

from laterally oriented ellipse to a some what more circular contour. This change in shape was achieved through ventral displacement of the epiglottis, tongue and soft palate.

In our study, success was achieved in 9 cases out of 15 (60%), 40% (6 out of 15) with complete success and 20%(3 out of 15) with partial success while 40% (6 out of 15) showed treatment failure. Schonhofer et al (16) on use of snore Ex oral appliance reported significant decrease in AHI in compliant patients to the apparatus (6 patients) (32.7 ± 11.5 vs 16.7 ± 4.3, $P < 0.05$). Moses and Alvarez (17) reported that TRD make a comeback and prove their validity through a plethora of scientific researches. Hoffstein (1) on surveying 73 studies with a total of 2729 patients using different oral appliances achieved complete success in 54% and partial success in 21%. Yow (18) reported overall success rate of oral appliances in mild to moderate OSA to be in the range 57 – 81%. Deane et al. (7) on using Aveo TRD reported success rate of 6 out of 14 (42.81%), 28.5% for complete success and 14.3% for partial success in cases with mild to moderate OSA, and 75% (3 out of 4) with partial success in cases with severe OSA. The total success rate was 50% (9 out of 14). Our results documented that TRD achieved success in the lower range reported by Hoffstein (1) and Yow (18) by using different oral appliances mostly mandibular advancement device (MAD). This was in accordance to Deane et al (7) who reported a higher success rate with the use of MAD in comparison to Aveo TRD (67.7% vs 50%) but with no significant difference ($p=0.38$). On the reverse of our results and previous studies, Barthlen et al (13) reported slight decrease in AHI from 50.3 ± 18.9 to 43.5 ± 32.5) and Kingshott et al (14) reported a non significant trend for reduction in AHI with use of TRD. The mean reduction in AHI was 11/hour slept ± 10 SD. The non significant decrease in the AHI in the previous two studies can be explained by small number of studied cases (5 cases in the first study and 6 cases in the second study).

In our study, the succeeded cases in comparison to failed cases showed significantly smaller neck circumference, lower BMI, lower AHI, lower % total slept time $SaO2 < 90\%$ and predominant supine AHI ($P < 0.001$, 0.002, 0.001, 0.002and 0.003 respectively). These were in accordance to Ferguson et al (4), Chan et al (3), Yow (18) who reported that success of oral appliance occurred more in cases with lower AHI, lower BMI, smaller neck circumference and supine dependent OSA. These factors can be used in the future as predictors of success of use of Aveo TRD.

In our study, side effects of use of TRD were as follow: 80% excessive salivation, 66.67% dry mouth, 60% tongue abrasion and 6% jaw pain. These side effects leads to non compliance (discontinuation of use of the device) in 6 cases out of 15 (40%). This was in accordance to Ferguson et al. (4) who reported that tongue pain prevented the use of TRD in 3 out of 8 cases (37.5%, also was in accordance to Deane et al. (7) who reported that TRD side effects were as follow: excessive salivation in 85%, dryness of mouth in 68%, soft tissue irritation in 61.1%, jaw discomfort in 11.5%. These side effects prevented 50% of patients from using TRD.

The limitations of this study include that the MRI imaging of the upper airway of awake patients which differ from the physiologic state of sleep, relatively small number of studied cases and short duration of follow up. So further studies are needed to support the results of our study.

From this study, we can conclude that Aveo TRD was effective in treatment of 60% of mild to moderate OSA and side effects occurred frequently to the extent to prevent 40% of patients to stop use of the device. The predictors of success were cases with low BMI, small neck circumference, low AHI and less hypoxemia and predominant supine AHI.

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