Management of obstructive sleep apnea using oral appliance with magnetic versus increase vertical dimension

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Abstract

Statement of Problem: Oral devices may be helpful in the management of obstructive sleep apnea by improving upper airway potency. Purpose: Management of obstructive sleep apnea using oral appliance with magnetic versus oral appliance with increased vertical dimension. Material and Methods: 12 patients with mild to moderate obstructive sleep apnea were evaluated in this study before and after wearing devices for six months. The patients randomly divided into two equal groups(A and B). Group A used oral appliances with magnetic for six month Patients in group B wear oral appliances with increased vertical dimension, Evaluation was done by Polysomnograph, clinical findings and cephalometric x-rays. Results: The results of this study revealed that improvement of clinical finding, symptoms and apnea index for patients wearing two types of oral appliance. Conclusions: It can be concluded that oral appliance, with magnetic and increase vertical dimension, make improvement for OSA patients oral appliances with magnets are more effective in management of mild and moderate obstructive sleep apnea in comparison to appliances with increased vertical dimension.

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Keywords: Management; obstructive; sleep; apnea; oral appliance; magnetic; dimension

Introduction

Obstructive sleep apnea (OSA) is repetitive episodes of upper air way obstruction during sleep, arterial oxygen desaturation, daytime hypersomnolence and snoring. [1] In addition, these patients are at increased risk for hypertension, heart failure myocardial infarction and stroke and road and traffic accidents when compared with general population.[2,3] The site of sleep dependent obstruction in OSA is usually in the retro palatal or the retroglossal region or both, the upper air way lumen.

Several studies demonstrate that oral appliances can be a useful alternative to positive air way pressure with mild to moderate sleep apnea . [4,5] There is also robust evidence of the efficacy of oral appliances for improving polysomnographic indices and modifying the health risk associated with OSA. [6]

Oral device may be helpful in the management of OSA by; improving upper air way potency, increasing the cross sectional area or decreasing the upper air way collapsibility by increasing the muscle tone . [7]

Orthodontists who get involved in this form of therapy are often surprised at how grateful their patients are after only a few nights of sleep without interruption and the subsequent restoration of adequate rapid eye movement (REM) sleep. [8]

The main advantages of oral devices are their relative simplicity of the treatment, reversibility , cost effectiveness and providing a genuine non surgical alternative to patients who can't tolerate continuous positive airway pressure devices (CPAP) or who represent a poor surgical risk . Also, they enhance craniofacial growth. [9]

The US FDA approved 16 devices for use in sleep apnea oral appliances as an alternative to CPAP therapy. They are designed to keep upper air way open. [10]

Although Mandibular Advancement Device (MAD) has positive effect in treatment of OSAS, it has multiple complications. These may include craniofacial change in maxillomandibular relationship and bony dimensions, overbite alteration, tooth pain and TMJ problems. [11]

In 2003, Iranhoe[12] suggested other devices claimed to increase vertical jaw separation. Frantz, 2001[13] mentioned that the effectiveness of such appliance improved when increasing vertical opening exceeding the rest position up to 5mm opening and

had comparable success to MADS. A magnetic appliance were used for treatment of obstructive sleep apnea. [14]

The aim of this study was to evaluate the effect of magnetic appliance versus increase vertical dimension on management of obstructive sleep apnea

Material and methods:-

This study was carried out on 12 patients selected from E.N.T clinic, Faculty of Medicine, Mansoura university. The patients suffered from mild or moderate OSA as evaluated by polysomnographic (PSG).

The following steps were done for each patient:

1) Apnea hypopnea index (AHI) (average number of apnea events per hour of sleep) was evaluated by PSG, clinical findings and symptoms were recorded. Any caries and perioral infection were also treated.
2) Lateral cephalogram was taken for each patient in centric occlusion, then traced and examined.
3) Upper and lower primary and secondary impression were made to obtain master cast. The patients were then classified into 2 groups; including 6 patients each, according to the appliance used:

Group A:

For this group, oral appliance with magnets was constructed as follows:

1) Mounting upper cast by using face bow and lower cast by centric occlusion record was done, undercuts and large diastema were blocked out with a thin mix of plaster.
2) The upper & lower teeth were waxed up occlussaly, buccally and lingually to the height of contour of teeth then packing, curing and finishing to obtain upper and lower acrylic appliance device.
3) Fixation of magnets, in each splint two parylene coated (poly-para-xylene 250µm) neody-mium-iron-boron magnets (Size 6.4mmØ x 2mm) (Ortho Organizers-Hanover- Germany) of the same pole in area of premolar & molar using self cure acrylic resin (to obtain repulsion force and prevent mouth closing) was done. Fig 1
4) A polysomnograph evaluation for one night and recording clinical findings and symptoms during insertion and after 4, 8 months of device insertion were done. Cephalometric radiograph was also taken after insertion, then after 8 months of appliance wear.

Group B:

For this group, oral appliance with increased vertical dimension of occlusion (about 5mm exceeding the rest dimension) was done as follows. [15]:

1) After adapting one layer of warm modeling wax over standing teeth, it was converted into clear acrylic resin templates.
2) Accurate adaptation of acrylic template inside the patient mouth after determing the vertical dimension of rest was done.
3) While the patient was closing, the upper and lower acrylic templates were sealed in his mouth at the vertical dimension of rest using soften compound.
4) Converting the modeling compound into chemical cured acrylic resin by using Heaper duplicate was followed.
5) After finishing and polishing, insertion in patient's mouth (Fig 2) and checking adaptation, instructions were given to the patient to use appliance during sleep and to have good home care.
A polysomnograph evaluation for one night, cephalometeric radiograph and clinical finding and symptoms were recorded.
6) After one month from appliance insertion, upper and lower templates were separated and reinserted into patient mouth with softened compound for recording the new increased vertical dimension (5mm from rest).
8) The modeling compound was again converted into chemical cured acrylic resin and steps 5 and 6 were made, then follow up after 2, 4 , 8 months as in group A.

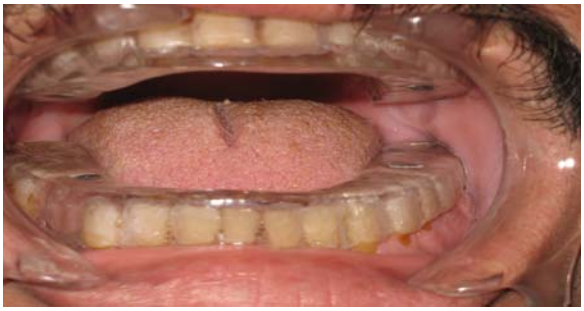

Fig 1**:** Oral appliance of group A with magnets.

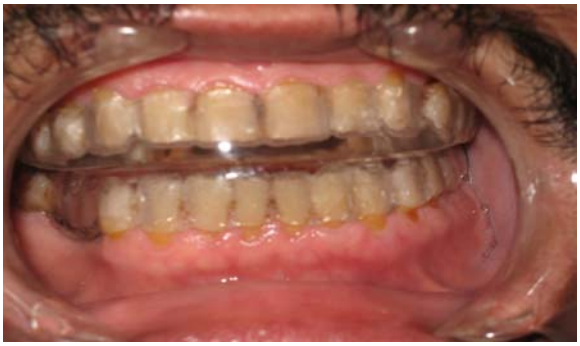

Fig **2:** Oral appliance with increased vertical dimension of group B.

Evaluation of patients:-

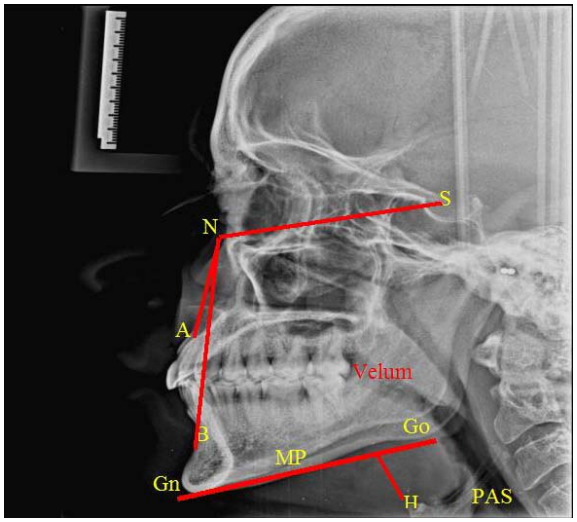

Figure **3**: Lateral cephalometric radiograph showing the Cervico-craniofacial skeletal reference points and lines used for linear and angular measurements. (A: subspinale : the most posterior midline point in the concavity between the anterior nasal spine and the lowest point on the alveolar bone overlying the maxillary incisors, B: Supramentale : the most posterior midline point on the anterior concavity of the mandibular symphysis, N: Nasion : the most anterior point of the frontonasal suture in the median plane, SNA: Maxilla protrusion angle, SNB: mandibular protrusion angle, ANB: maxilomandibular discrepancy, ANS-PNS: sagital length of maxilla, GN-GO: length of the body of the mandible , MP-H: mandibular plane hyoid distance , P: The most lower point of soft palate, PAS: posterior airway space retroglossal).

OSA is heterogeneous disorder rather than a single disease, therefore, evaluation by multi parametric procedure successively including a clinical findings items, resolution of symptoms and the course of a simple indicator of the quality of breathing sleep were done.

a) Cephalometric evaluations:

Lateral cephalometric radiographs with the teeth in occlusion were obtained for all subjects before the start of treatment and after 8 months. All cephalometric films were traced.

According to De Almeida et al. [16]; Cervico-craniofacial skeletal reference points and lines were used for linear and angular measurements as follow:

SNA angle measures the projection, anterior or posterior, of the maxilla. The reference range value is 82 ± 2°. SNB angle measures the position of the mandible. The reference range value is 80 ± 2°. Less than this is considered retrognathia. ANB angle measures the position of the maxilla with the mandible. The reference range value is 2°. This measures prognathism. PAS or retroglossal space; the reference range is 10-16 mm. MP-H is the distance between the mandibular plane (MP) and the hyoid bone (H). The reference range is 11-19 mm. The longer the distance, the higher the possibility of the patient having OSA (Fig. 3).

b) Clinical findings which help in the subjective assessments of OSA. Patients with high risk of sleep apnea were those who net two of the following three criteria :- Snoring(S), persistent day time sleepiness or drowsiness while driving(P) and obesity or hypertension(H) [17].

c) Frequency of sleep apnea- hypopnea index before and after treatment using polysomnograph. (AHI) Apnea hypopnea index: (the number of apnea and hypopneas average per hour of sleep; which is the total number of apnea during sleep divided by the total number of hours of sleep). This index measures the severity of the apnea.

Traditionally an AHI of 5 or more has been used to define the presence of OSA by dividing the sum of hours.

The American academy of sleep medicine [18] classified the severity of sleep apnea as follow :

Mild: RDI score between 5 and 15 apneas or hypopneas per hour of sleep.

Moderate: RDI score between 16 and30.

Severe: RDI score higher than 30.

Results:

Clinical finding & symptoms:-

The score of clinical finding ranged from 0 to 3: Score: 0= never, 1=slight chance, 2 = moderate chance, 3=high chance of clinical finding symptoms. The patients were evaluated during insertion of the devices, after 4months and after 8 months.

Table 1: Cephalometric parameters of group A and group B patients after appliance insertion and after 8 months of oral appliance wear.

Patients / group A		1	2	3	4	5	6
-SNA	1	85	80	82	82	85	81
	2	83	80	82	82	84	80
SNB	1	78	75	75	81	81	79
	2	81	79	79	82	83	83
-ANB	1	4	5	5	1	5	4
	2	2	2	1	0	2	3
-GoGN	1	6	6.2	7	5	5	6
	2	6.2	6.5	6.5	5.2	5	6.1
MPH	1	2	2.5	2.3	2.8	3	2.3
	2	1.5	2.2	1.5	1.8	1.6	1.7
-PAS	1	7	1.1	0.9	1.9	1.9	1.6
	2	11	1.8	1.1	2.4	2.3	1.8
group B							
-SNA	1	90	82	83	82	82	82
	2	87	82	82	82	82	81
SNB	1	88	78	77	81	80	75
	2	89	81	79	80	81	79
-ANB	1	2	4	6	2	2	7
	2	1	2	4	1	1	4
-GoGN	1	6.2	6.7	6	6.2	5	5.1
	2	6.5	6.5	6.1	6	5.5	5.5
MPH	1	3.1	2.2	3	3.2	2.6	3
	2	2.7	1.5	1.6	1.5	2	2.7
-PAS	1	1	1	1	2	1.5	1.3
	2	1.5	1.1	2	2.5	2.2	1.9

1-after appliance insertion. 2-after 8 months from appliance wear.

Table 1 Shows clinical findings and symptoms for group A,B during insertion. There were 3 patients with high chance of snoring and persistent sleep. 3 patients had moderate chance of snoring and persistent sleep. 2 patients had high chance of hypertension and 4 patients had moderate chance of hypertension.

Table 2 demonstrates also the result of apnea hypopnea index . It was found that for group A : during insertion 4 patients had moderate OSA, 2 patient had mild OSA. After 4 months, 2 patients had moderate OSA and 4 patients suffered from mild OSA. After 8 months, 3 patients had moderate OSA and 3 patients had no apnea.
For group B: during insertion 3 patients had moderate OSA and 3 patients had mild OSA. After 4 months, 2 patients had moderate OSA and 4 patients had mild OSA. After 8 month, only one patient did not suffer from OSA while the other 5 patients had mild OSA.

Table 2: Clinical findings and symptoms: Snoring (S), persistent day time sleepiness or drowsiness while driving (P), hypertension (H) and Apnea hypopnea index (AHI), for group A, B during insertion, after 4 months and after 8 months:

Clinical findinding / GroupA	S	S4	S8	P	P4	P8	H	H4	H8	AHI	AHI4	AHI8
	1	3	2	2	3	2	0	3	2	20	15	10
	2	2	1	1	2	1	0	2	1	25	20	9
	3	3	2	1	2	1	1	2	2	22	17	7
	4	3	1	1	3	1	0	3	2	10	7	2
	5	2	1	1	3	2	1	2	1	15	8	3
	6	2	1	1	2	1	0	2	1	18	9	4
GroupB												
	1	3	2	2	3	2	1	3	2	25	20	15
	2	2	1	1	2	1	2	2	2	15	12	10
	3	3	2	1	3	2	1	3	2	20	17	12
	4	2	2	1	3	2	2	2	2	12	10	7
	5	3	2	1	2	1	1	2	2	10	7	4
	6	2	2	2	2	1	1	2	2	17	10	7

Apnea hypopnea index (AHI):- Mild = 5-15, Moderate = 15 -30, Severe < 30.

Table (3) Mann Whitney U test for comparison between group A and B clinical finding and Cephalometric analysis (Snoring (S), persistent day time sleepiness or drowsiness while driving (P) , obesity or hypertension (H) and Apnea hypopnea index (AHI) , for group A , B during insertion, after 4 months and after 8 months:

variable	Mean± SD		Z	P
	Group A	GroupB		
S04	1.17±.41	.67±.52	-1.687	.092
S04p	47.22±12.55	25.00±20.41	- 1.950	.051
P04	1.17±.41	1.00±.00	- 1.000	.317
P04p	47.22±12.55	41.67±9.13	-.802	.423
H04	.83±.41	.33±.52	-1.682	.093
H04p	36.11±19.48	11.11±17.21	-2.047	.041*
AHI04	5.67±2.07	3.83±1.83	-1.580	.114
	After 8 months			
S08	1.33±.52	1.17±.75	-.365	.715
S08p	52.78±12.55	44.44±25.09	-.424	.672
P08	2.17±.75	1.17±.75	-1.950	.051
P08p	86.11±22.15	44.44±25.09	- 2.316	.021*
H08	.83±.41	.67±.52	-.638	.523
H08p	36.11±19.48	27.78±22.77	-.682	.495
AHI08	12.50±3.08	7.33±2.34	-2.347	.019*
	Cephalometric analysis			
SNAb	82.50±2.07	83.50±3.21	-.685	-.685*
SNAa	81.83±1.60	82.67±2.16	-.343	.732
SNAc	.67±.82	.83±1.17	-.087	.930
SNAcp	.81±.99	.98±1.35	-.085	.932
SNBb	78.17±2.71	79.83±4.54	-.407	.684
SNBa	81.17±1.83	81.50±3.78	-.494	.622
SNBc	-3.00±1.26	-1.67±1.75	-1.401	.161
SNBcp	-3.71±1.60	-2.07±2.21	-1.212	.226
ANBb	4.00±1.55	3.83±2.23	-.164	.870
ANBa	1.67±1.03	2.17±1.47	-.333	.739
ANBc	2.33±1.21	1.67±.82	-1.012	.312
ANBcp	138.89±141.68	87.50±20.92	-.665	.506
GoGnb	5.87±.77	5.87±.67	-.327	.744
G0Gna	5.92±.66	6.02±.45	-.082	.935
GoGnc	-.05±.29	-.15±.30	-.645	.519
Gogncp	-.94±4.54	-2.70±5.22	-.643	.520
MPHb	2.48±.37	2.85±.38	-1.615	.106
MPHa	1.72±.26	2.00±.57	-.573	.567
MPHc	.77±.39	.85±.57	-.080	.936
MPHcp	46.44±25.25	50.57±41.42	-.241	.810
PASb	2.40±2.29	1.30±.40	-.969	.332
PASa	3.40±3.75	1.87±.50	-.402	.688
PASc	-1.00±1.48	-.57±.29	-.405	.686
PAScp	-23.80±11.21	-29.30±13.79	-.480	.631

The statistical analysis of data obtained in the present study was done by using excel program and spss program statistical package for Social Sciences version 10. [19]. For all statistical analyses, the significance level was set at $P < .05$.

By using Mann Whitney U test, the polysomngraphic findings revealed that the mean percent changes in AHI values for the 2 groups before and after 4 and 8 months following the insertion of oral appliances. There was a significant (P=.041) in H04p in group A patients in comparison to group B patients. Also, P08 was significantly higher in group A patients in comparison to group B patients. Ah08 was significantly higher in group A patients compared to group B patients. On the other hand, SNAb was significantly higher in group B patients in comparison to group A patients.

Fig 4 shows improvement Apnea hypopnea index for group A more than group B.

Fig 5,6,7 show improvement hypertension (H), persistent day time sleepiness or drowsiness while driving (P) , Snoring (S) for group A more than group B.

Fig. 4

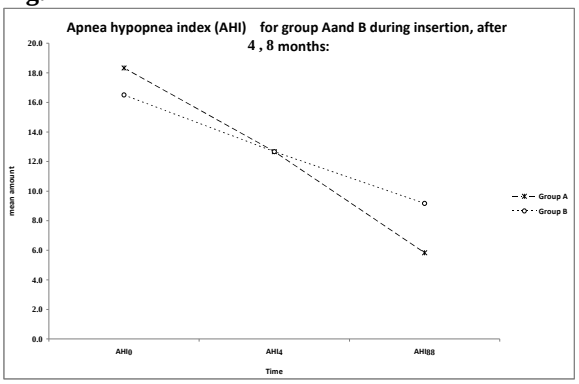

Fig 4. Improvement Apnea hypopnea index for group A more than group B

Fig 5

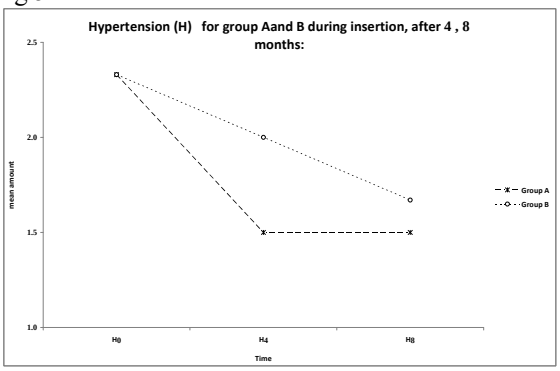

Fig. 6

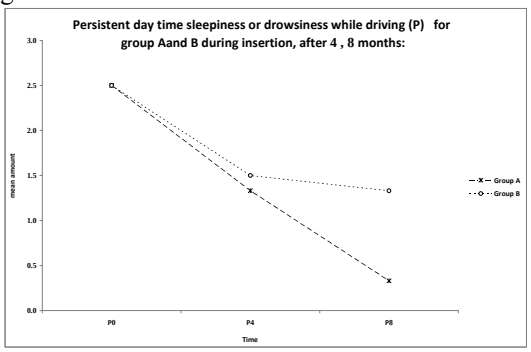

Fig. 7

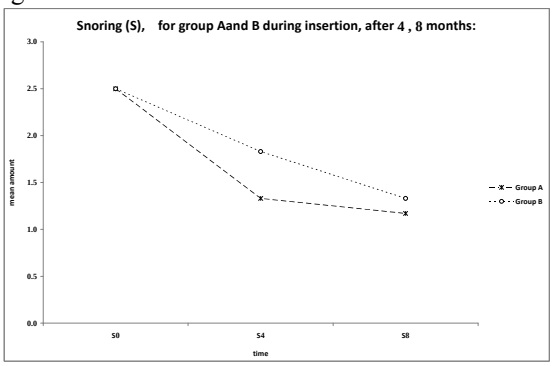

Fig 5,6,7. Improvement hypertension (H), persistent day time sleepiness or drowsiness while driving (P), Snoring (S) for group A more than group B.

Discussion:

OSA has been described as a public heath problem comparable to smoking in its effect upon society**.** [20]

Patients awareness regarding the problem is low especially in mild and moderate cases. An out line of the diagnostic approach to OSA is very important

The diagnosis of OSA is completed by two main:

1) Subjective assessments which involved focus sleep questioner clinical finding and classic symptoms

2) Objective assessment as physical examination sleep test polysomnograph and portable recording device**.** [21]

Chan A. et al**.** [22] mentioned that major advances in the field of oral appliances have provided a solid evidence for the use of oral appliances in the clinical management of OSA. OA are preferred by the patients; this has the potential of translating into better patient compliance and an equivalent health outcome.

Cephalometeric, studies have shown subtle retro positioning and shortening of the mandible and maxilla, even in the absence of distinct craniofacial abnormalities. In OSA patients compared with normal subjects [23,24,25] shorter and more posteriorly displaced mandible have been confirmed in up to tow third of OSA patients and correlated with decreased pharyngeal size. [26]

Neodymium-iron-boron alloy was selected as the magnetic material of choice because of its high energy product value (260 kJ/m³ as compared with 190 kJ/m³ for the often used samarium-cobalt alloy, Sm2Co17), and because the neodymium-iron-boron alloy shows even better biocompatibility than samarium-cobalt magnets. The high energy product implies a possibility of stronger attractive forces in the rest position for the same size and shape of magnetic units. In this study, two magnets were inserted in each splint, producing an inter jaw force of 2.5 to 3.0 N (250 to 3250g). One shortcoming of the rare earth magnets, particularly the neodymium-iron-boron alloy, is that the alloy is very susceptible to corrosion assault by the saliva. When a magnet corrodes, there is considerable risk of destroyed magnetic properties and loss of force. Furthermore, there is a risk of liberation of cytotoxic components. To avoid intera oral corrosion, the paryene coated magnets have to, as in this study, be further embedded in acrylic. [27,28]

Interestingly, in the present investigation, improvements in clinical, cephelometric and Apnea index record by polysomnographic parameters were observed for most patients of the two groups included. Consequently this could confirm that OA should be a satisfactory and an alternative treatment modality in large proportions of patients with mild and moderate OSA who could not get benefit from other treatment options. This observation appears to be in agreement with the findings of **Hoffstein**. [29] and **Jayan et al**. [30] who supported OA therapy for OSA patients.

This study can firms that OA can be a satisfactory treatment in a large proportion of patients with slight to moderate OSAS as this response consists of a reduction in AHI(<15 events per hour) combined improvement with clinical finding together with improvement in the quality of sleep. [31]

Also psychology behavior relative had improved. Another finding in the present work showed statistically significant decrease in daytime sleepiness. There was also an overall subjective improvement after the initial use of OAs.

This may be due to for group A and B made minimum upper air way space. This agree with george zoal. [32] who suggest that bite opening should be kept to minimum for improve at upper air way potency by stretching the palatoglassus and superior pharyngeal constrictor muscle.

An effective appliance for sleep apnea treatment should be able to move lower jaw horizontally to attempt to open the air way and rotate the lower jaw clock wise with a resultant further closing of pharyngeal space.

But more improvement for group A (magnetic appliance) than group B in spite of non significance occur. This can be explained by the fact that continuous repelling force from inherent magnetic forces which lead to improve at upper air way potency and allows freedom of function and, consequently, patient compliance is improved these agree with Bernhold M. et al . [14] who concluded that obstructive sleep apnea responded well to treatment with intra-oral magnetic appliance.

The most interesting point is decreased snoring, this may be due to the return of patients to normal state with continuous airflow; thus no vibration of soft Tissue occured. This agrees with Jayan et al[30] , who found that as a result of OSA, a reduction of the air flow occurs, so the patient increase the speed of the air flow in an attempt to maintain the required oxygen to the lungs. The increase in the air flow velocity causes vibration of soft tissues which is the sound of snoring.

Conclusion:

Oral appliance, with magnetic and increase vertical dimension, make improvement for OSA patients.

Oral appliance with magnetic more effective and help the management of patient with mild or moderate OSA patient in comparing with increase vertical separation of jaws

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