CASE SERIES

Management and Long-term Follow-up of Severe Obstructive Sleep Apnea with Oral/Nasal Airway Dilator System—An “OASYS” of Possibilities

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ABSTRACT

Aim and objective: This article aims to highlight the use of OAT (oral appliance therapy) with an oral/nasal airway dilator system in the treatment of patients with severe OSA, exhibiting non-tolerance with CPAP therapy.

Background: CPAP is the gold standard for the treatment of OSA. CPAP treatment for OSA is only effective if the patient is cooperative and willing for the therapy. Unfortunately, due to the often uncomfortable and invasive nature of this treatment method, CPAP has a relatively low compliance rate, ranging from 40 to 70%. This is because CPAP has drawbacks, including discomfort from the mask, a dry or stuffy nose, and eye irritation.

Case description: This article reports an interesting case of a 61-year-old female with severe OSA and non-tolerance/non-compliance with the CPAP therapy, who was referred by the sleep physician to the orthodontic clinic for evaluation and advice concerning OAT for her OSA.

Conclusion: Oral/Nasal Airway Dilator System (OASYS) works both as a nasal dilator and mandibular repositioner and acts by targeting multiple areas of the upper airway from the tip of the nose to the back of the throat.

Clinical significance: OASYS stands out from the crowd of oral appliances by adding additional actions and targeting multiple areas of the airway with one convenient appliance and thus offers an effective means of treating severe OSA patients who are non-compliant with the CPAP therapy.

Keywords: Continuous positive airway pressure (CPAP), Mandibular repositioner, Nasal airway dilator, non-compliance, OASYS, Retrognathic profile.

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BACKGROUND

Obstructive sleep apnea (OSA) is becoming an increasingly prevalent condition with a negative impact on the quality of life. The prevalence of OSA in India as ascertained from community-based epidemiological studies is 2.4–5% in males and 1 to 2% in females. Continuous positive airway pressure (CPAP) is recognized as the gold standard for the treatment of moderate and severe forms of OSA. However, CPAP treatment is only effective if the patient is willing to it. Unfortunately, due to the often uncomfortable and invasive nature of CPAP, it has a relatively low compliance rate, ranging from 40 to 70%. Also, CPAP is not without its drawbacks, including discomfort from the mask, a dry or stuffy nose, and eye irritation. Indian initiative on OSA (INOSA) guidelines recommend the use of adjustable oral appliances in patients with mild-to-moderate OSA. Although adjustable oral appliances have also shown significant clinical improvement in severe OSA cases, oral appliance therapy is not the first choice, and the posttreatment apnea–hypopnea index (AHI) and Epworth sleepiness scale (ESS) are still high, pre-empting their use in cases with severe OSA not compatible with CPAP therapy, thus necessitating surgery as the last life-saving option. Studies have concluded that it is essential to investigate adherence to oral appliances in addition to improvement in OSA symptoms, typified by the AHI as also the long-term dental and skeletal side effects, for oral appliance therapy to be considered as a success.

CASE DESCRIPTION

A 61-year-old female was referred by a sleep physician to the dental surgeon trained in sleep dentistry for evaluation and advice concerning oral appliance therapy for her OSA. The patient was diagnosed by a baseline polysomnography (PSG) 4 years back as a case of severe OSA with an AHI of 65 events/hour. The patient was offered CPAP therapy for her condition, but the patient withdrew from the therapy after 6 months due to a repeated feeling of claustrophobia and an inability to sleep with the constant buzzing noise of the CPAP. The patient reported to various sleep clinics over a period of 3 years with complaints of disturbed night-time sleep, repeated arousals from sleep due to gasping for air, early morning headaches, and severe daytime fatigue and, when the patient was hospitalized for the same, she was referred to the dental center for the possibility of oral appliance therapy.

Medical and sleep history of the patient including an ESS were recorded at the sleep clinic. The patient had an ESS score of 21. Clinical examination revealed that the patient was obese with a height of 150 cm, weight of 100 kg, and a body mass index (BMI) of 44.4 kg/m². Her vital signs revealed an average pulse rate of

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69 beats/minute and a respiratory rate of 18/minute. The arterial blood gas analysis revealed a PaO₂ of 90 mm Hg, PaCO₂ 42 mm Hg, HCO₃⁻ 27 mmol/L, and pH 7.32 at room temperature. Complete blood count, organ functions, BP, chest X-ray, ECG, thyroid function tests, and serum cortisol levels were ordered, which revealed that the patient had hypothyroidism, for which she was on daily medication with tab thyroxine 100 µg. Average ambulatory blood pressure monitor readings revealed that the patient was hypertensive, for which the patient was on a medication with Tab Metoprolol extended release 25 mg. Based on the treatment history elicited from the patient, the clinical presentation, evaluation by the sleep physician, and findings of the baseline PSG, the patient was diagnosed as a case of severe OSA who was non-compliant/non-tolerant with CPAP therapy.

An intraoral evaluation was carried out for the patient in the dental center. She had an overbite of 5 mm and overjet of 6 mm, with moderate occlusal wear of posterior teeth. There were no diastemas. Her skeletal profile was retrognathic (class II), and occlusal relation was Angle’s class II bilaterally and she had a preexisting mouth-breathing habit. A lateral cephalogram was recorded for the patient which revealed that the patient had a skeletal class II relation due to the posteriorly placed mandible. The cephalogram also revealed a steep mandibular plane and narrowing of the nasopharynx and posterior airway space. Evaluation of the position of the hyoid bone revealed an inferior and posterior position of the hyoid bone relative to the mandibular plane with an increased hyoid angle. The pretreatment lateral cephalogram and baseline PSG report are shown in Figures 1 and 2, respectively.

All the above findings made the patient a possible candidate for treatment using oral appliances. In view of the severity of OSA, conventional mandibular repositioning appliances were not considered. Two further procedures were used to assess the suitability of the patient for treatment with the OASYS (oral/nasal airway system) appliance. The patient was first evaluated with Cottle’s maneuver to determine if there was any improvement in the nasal airflow. This involves using the index and middle fingers to determine the amount of nasal dilation and to determine if the airflow can be improved with the use of nasal dilators. One or two fingertips were placed on the cheeks on either side of the nose. Then, it was gently pressed and pulled outward with the intention to temporarily open the nasal valve. Doing this helped the patient inhale more easily through the nose, which meant that the nasal obstruction was likely to be in the nasal valve, in the front part of the nose. For the next evaluation procedure, the patient was asked to close her lips and bite with the teeth together while breathing slowly through the nose for several breaths. The patient found it exceedingly difficult to breathe. The patient was then asked to allow air to fill the upper lip and try to breathe again, simulating the placement of nasal dilators. The patient reported that she found it much easier to inhale. She was thus found to be a suitable candidate for the OASYS appliance.

**Construction of the Appliance**

Upper and lower dental arch impressions of the patient were recorded, and multiple sets of casts were made. A George bite guage was used to determine the maximum protrusion afforded by the patient. To give maximum benefit while also aiming to achieve a lip seal, the extent of mandibular advancement and vertical opening required was determined. Using heavy-body rubber base impression material, bite recording was done at 40% of maximum protrusion and 6 mm vertical opening. The bite was then mounted onto the articulator. The OASYS appliance was fabricated in the dental laboratory. Figure 3A shows the fully customized lower active device with anterior labial shield, nasal dilators and tongue repositioners and Figure 3B shows the standard full-coverage upper arch 1.5-mm splint. Figure 3C shows the patient with the appliance.

At the time of appliance delivery, the patient was instructed regarding proper insertion and removal, care, and possible adverse effects which may occur with the use of the appliance. The appliance was placed in the mouth in this baseline position, and the patient was seen every 15 days to check for its fit, lip seal, and ability to breathe through the nose with the appliance in situ. The spouse of the patient was also regularly interviewed to record the quality of sleep and the presence of snoring. Initially, the patient had difficulty in breathing with the appliance, and so the nasal dilators were adjusted inward and no titration of the appliance was done for 1 month. The patient was seen every 3 days till the patient was comfortable with the use of the appliance. The patient reported improvement in subjective symptoms within a period of 1 month, with the added benefit of sealing the mouth and keeping the lips closed. The appliance was sequentially titrated by 3 mm over 3 months at the rate of 0.5 mm/month. A follow-up overnight PSG was repeated after 4 months with the patient wearing the appliance, and the AHI showed significant improvement with a recorded AHI of 28 events/hour. The appliance was sequentially titrated by another 3 mm over the next 9 months till she reached a point where the placement of the oral appliance became a challenge for her. Further titration was stopped, and a repeat PSG at 18 months’ time duration since the start of the oral appliance therapy was carried out, with the oral appliance in situ. AHI reduced further to 7 events/hour with a blood oxygen desaturation nadir of 96% at the most optimal oral appliance setting. The patient was reviewed every 6 months and any required changes in the extent of titration and fit of the appliance were addressed. The patient was asked to get in telephonic touch with the dental surgeon on facing any difficulties with the appliance.

The patient reported after 46 months with a crack in the upper splint and a complaint of loose fit of the lower device. The patient also complained of frequent removal of the appliance and desired that the appliance be tightened. Keeping in view the wear of the appliance and the extent of the crack of the upper splint, a new

![Fig. 1: Pretreatment lateral cephalogram](Image)
Fig. 2: Pretreatment baseline PSG report
Management of Severe OSA with Oral/Nasal Airway Dilator

The OASYS oral/nasal airway system is the only dental appliance for sleep-disordered breathing that is FDA approved by the ENT and dental divisions for the treatment of snoring and OSA. The appliance has two parts: a thin maxillary splint and a fully customized lower-active device. The main body of the appliance fits onto the mandibular posterior teeth and strengthens the area of pharynx by pulling the mandible and tongue forward to prevent the tongue from blocking the airflow. It is made up of a thermosensitive base material that is placed in warm water to soften it, making the fit over the mandibular posterior teeth easier. The lower splint consists of teardrop-shaped nasal dilators/buttons for improved nasal breathing, anterior labial shield for mandibular positioning, two locks on each side for easy adjustment of mandibular position, and lingual buttons/extensions to establish a better tongue posture and swallowing pattern (Figure 3A and 3B). The appliance has two screws on either side which permits easy sliding adjustment, both forward and backward. The screw has a range from 8 to 15 mm and is operated by an OASYS wrench. The OASYS is thus one appliance with multiple functions and targets multiple areas of the airway, all at the same time. This adjustable appliance is comfortable to wear and extremely patient-friendly. Another added benefit is lip closure, which is a desired and essential feature for patients with chronic mouth breathing. No case reports/studies on this appliance have been reported in India and even those reported worldwide have evaluated this appliance only for short periods.

A few studies have reported favorable effects of oral appliances on blood pressure. However, all these studies had a limitation of having a short follow-up period of only 3 months, which was considered too short. This case report indicates that application of careful selection criteria pertaining to craniofacial anatomy and dental factors, while offering oral appliance therapy to patients with severe/very severe OSA who are non-compliant with CPAP therapy, can have beneficial effects like improvement in blood pressure and reduction of AHI, observable from as early as 9 months. This shows that faithful compliance to oral appliance therapy can possibly lower blood pressure levels by increasing blood oxygen during sleep. Various studies have also reported morphological changes with oral appliances in the teeth and skeleton in long-term and time-related dental and skeletal side effects. In this case, regular persistent follow-up monitoring by the treating dental surgeon and long-term adherence by the patient resulted in no dental or skeletal side effects. Making the patient aware of the possibility of occurrence of such problems and asking the patient to report at the first instance of masticatory and/or cosmetic disturbances is thus important while prescribing oral appliance therapy to such patients. The case report also demonstrates that there is little or no relationship between device efficacy and variables...
### Fig. 4A: PSG report at 4 months with oral appliance

**ApneaLink - Report of 30-10-2014 11:50**

**Treating physician**
Dr Paban Tyagi

**Patient data**
- First name: Meena
- Last Name: Baksli
- Street:
- City, ST, Zip:
- Phone:

**Recording**
- Date: 29-10-2014
- Start: 23:07
- End: 05:35
- Duration: 5 h 28 min

**Evaluation**
- Start: 22:17
- End: 06:32
- Duration: 6 h 16 min

**AHI**

| Indices | Normal | Result |
|---------|--------|--------|
| Apnea index | 9 < 5 / h | 15.20 |
| ODI Oxygen Desaturation Index* | 28 < 5 / h | 178 |
| Average saturation | 95 94% - 95% | |
| Lowest saturation | 62 90% - 95% | |
| Baseline saturation | 97 % | |
| Minimum pulse | 46 > 40 bpm | |
| Maximum pulse | 113 < 90 bpm | |
| Average pulse | 64 bpm | |

**Analysis status:** Analyzed automatically

**Analysis parameters used (Default)**
- Apnea [0.0%; 10%; 85%; 1.0%; 20%; 60%; 8%; Hypopnea [70%; 10%; 100%; 1.0%; Snoring [8.0%; 0.0%; 3.5%; 0.5%; Desaturation [4.0%; CSR [5.50]]

**Suspected pathological breathing disorder**

**Normal range**

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*See Clinical Guide for abbreviations and ResMed standard parameters"
Fig. 4B: PSG report at 18 months with oral appliance
Fig. 4C: PSG report at 30 months with oral appliance
Fig. 4D: PSG report at the end of 4 years with oral appliance
Fig. 4E: Evaluation and summary of the sleep physician after 4 years of the use of the oral appliance.
like age and BMI, which were earlier reported to be important factors for the success of oral appliance therapy.

**CONCLUSION**

The OASYS oral appliance offers a ray of hope in the treatment of carefully selected patients with disorders of craniofacial anatomy having severe/very severe OSA not tolerant of CPAP therapy since it works both as a nasal dilator and mandibular repositioner. The appliance has demonstrated not only improvement in clinical symptoms but also a significant improvement in AHI.

**CLINICAL SIGNIFICANCE**

- OASYS appliance offers a viable long-term solution for patients with severe OSA who are CPAP non-compliant.
- This is the first reported study in India with long-term follow-up of 4 years for the treatment of a case of very severe OSA not tolerating CPAP in the first phase and treated with oral appliance alone with recorded improvements in AHI.
- OASYS appliance acts by targeting multiple areas of upper airway from the tip of the nose to the back of the throat and can serve to avoid surgery at later stages in carefully selected patients with severe OSA.

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