



Key Research Findings

Influence of Nasal Resistance on Oral Appliance Treatment Outcome in Obstructive Sleep Apnea

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It has been recognized that nasal airway resistance (NAR) is elevated in patients with OSA. However, little is known regarding the influence of nasal resistance on mandibular advancement splint (MAS) treatment outcome in OSA patient. We hypothesized that nasal resistance differs between MAS responders and nonresponders and therefore may influence treatment outcome. Thirty-eight patients with known OSA underwent polysomnography while wearing a custom-made MAS. Treatment outcome was defined as follows: Responders (R) $\geq 50\%$ reduction in AHI, and Nonresponders (NR) as $< 50\%$ reduction in AHI. NAR was measured using posterior rhinomanometry in both sitting and supine positions, with and without MAS. The mean AHI in 26 responders was significantly reduced from $29.0 \pm 2.9/h$ to $6.7 \pm 1.2/h$; $P < 0.01$). In 12 nonresponders there was no significant change in AHI ($23.9 \pm 3.0/h$ vs $22.0 \pm 4.3/h$; $P = ns$). Baseline NAR was significantly lower in responders in the sitting position compared to nonresponders (6.5 ± 0.5 vs 9.4 ± 1.0 cm H₂O; $P < 0.01$). There was no significant change in NAR (from baseline) with MAS in either response group while in the sitting position, but in the supine position NAR increased significantly with MAS in the nonresponder group (11.8 ± 1.5 vs 13.8 ± 1.6 cm H₂O/L/s; $P < 0.01$). Logistic regression analysis revealed that NAR and BMI were the most important predictive factors for MAS treatment outcome. **These data suggest that higher levels of NAR may negatively impact on treatment outcome with MAS.**

This study suggests the need for an interdisciplinary approach between ENT Surgeons and Sleep Physicians in treating OSA – a condition demonstrating a multifactorial pathophysiology.

Dental appliance treatment for obstructive sleep apnea

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CHEST. 2007 Aug; 132(2): 693-9.

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Oral appliances for the treatment of obstructive sleep apnea (OSA) are worn during sleep to maintain the patency of the upper airway by increasing its dimensions and reducing its collapsibility. Oral appliances are a simpler alternative to continuous positive airway pressure (CPAP). Over the last decade, there has been a significant expansion of the evidence base to support the use of oral appliances, with robust studies demonstrating their efficacy. This work has been underpinned by the recognition of the importance of upper airway anatomy in the pathophysiology of OSA. The updated practice parameters of the American Academy of Sleep Medicine now recommend their use for mild-to-moderate OSA, or for patients with severe OSA who are unable to tolerate CPAP or refuse treatment with CPAP. Oral appliances have been shown to have a beneficial impact on a number of important clinical end points, including the polysomnographic indexes of OSA, subjective and objective measures of sleepiness, BP, aspects of neuropsychological functioning, and quality of life. Elucidation of the mechanism of action of oral appliances has provided insight into the factors that predict treatment response and may improve the selection of patients for this treatment modality.

Longitudinal studies to characterize the long-term adverse effects of oral appliance use are now beginning to emerge. Although less efficacious than CPAP for improving the polysomnographic indexes of OSA, **oral appliances are generally preferred by patients. This has the potential to translate to better patient adherence and may provide an equivalent health outcome.**

Use of flow-volume curves to predict oral appliance treatment outcome in obstructive sleep apnea

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Am J Respir Crit Care Med. 2007 Apr 1;175(7):726-30.

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Background: It has been recognized that mandibular advancement splint (MAS) treatment is effective in some, but not all, patients with obstructive sleep apnea (OSA). Hence there is a need for a simple and reliable clinical tool to assist in the differentiation of treatment responses. We hypothesized that abnormalities of flow-volume curves, together with other clinical variables, may have clinical utility in the prediction of MAS treatment outcome.

Methods: Fifty-four patients with known OSA underwent MAS treatment. Expiratory and inspiratory flow-volume curves were measured in the erect and supine positions to derive midinspiratory flow (MIF(50)) and the ratio of expiratory to inspiratory flow at 50% of vital capacity (MEF(50):MIF(50)). Multivariable logistic regression was performed to identify additional significant clinical variables in the prediction of treatment outcome.

Results: The mean (\pm SD) apnea-hypopnea index (AHI) in 35 responders was significantly reduced from 28.9 \pm 13.7 to 6.7 \pm 5.8/hour ($p < 0.001$). In 19 nonresponders there was no significant change in AHI. MIF(50) was lower (6.04 \pm 1.80 vs. 6.88 \pm 1.08 L/second; $p = 0.035$) and the MEF(50):MIF(50) ratio was higher (0.82 \pm 0.23 vs. 0.61 \pm 0.15; $p = 0.001$) in responders than nonresponders. Logistic regression analysis revealed that the MEF(50):MIF(50) ratio was the most important predictive factor for MAS treatment outcome, but that body mass index, age, and baseline AHI were also contributory.

Conclusions: **These data suggest that flow-volume curves, in combination with other factors such as body mass index, age, and baseline AHI, may have a useful clinical role in the prediction of treatment outcome with MAS.**

Position paper on the use of mandibular advancement devices in adults with sleep-related breathing disorders

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A position paper of the German Society of Dental Sleep Medicine (Deutsche Gesellschaft Zahnärztliche

Schlafmedizin, DGZS)

Abstract Custom-made mandibular advancement devices are an effective treatment option for snoring, upper airway resistance syndrome, and obstructive sleep apnea (OSA). Evidence-based data indicates their efficacy, and international sleep societies recommend oral appliance (OA) therapy for patients with sleep-related breathing disorders. The following position paper by the German Society of Dental Sleep Medicine (DGZS) is to guide the interdisciplinary team (sleep physician and sleep disorder dentist) in detail when to prescribe oral appliances. This position paper supports the responsible use of OA as an effective treatment option for patients with sleep-related breathing disorders. The paper advises of proper indication regarding OSA severity, body mass index (BMI), and dentition. **It emphasizes the interdisciplinary approach of oral appliance therapy and suggests treatment under the guidance of dentists trained in dental sleep medicine.**

Treatment of snoring and obstructive sleep apnea with mandibular repositioning appliances

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Snoring and obstructive sleep apnea form part of a spectrum of sleep disordered breathing affecting a significant proportion of the general population and particularly the middle aged. The consequences can be severe and even life threatening for both the individual directly affected and those more remotely involved. Adverse sequelae can manifest themselves acutely or in the longer term as a result of obstructive breathing induced hypersomnolence, neurocognitive deficits and cardiovascular abnormalities. The combination of anatomical and neuromuscular risk factors in the pathogenesis of OSA has resulted in a varied approach to its management. One such treatment option is mandibular repositioning appliances (MRA), which mechanically stabilize the airway. Whilst the efficacy of this simple intervention has been rigorously proven quite recently in a significant proportion of patients with varying disease severity, individual patient selection in its application remains uncertain. **Short-term side-effects are common but usually transient**, whilst in the long-term minor permanent adverse developments on the dentition and occlusion have been reported. Considering both the medicolegal implications of snoring and OSA and the increasing popularity of MRA, it is recommended that skilled multidisciplinary respiratory and dental personnel form the primary care team.

Oral appliance therapy reduces blood pressure in obstructive sleep apnea: a randomized, controlled trial

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Sleep. 2004 Aug 1;27(5):934-41.

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Study objective: To investigate the short-term effect (4 weeks) of oral appliance therapy for obstructive sleep apnea on blood pressure.

Setting: Multidisciplinary sleep disorders clinic in a university teaching hospital. **PATIENTS:** Sixty-one patients diagnosed with obstructive sleep apnea on polysomnography (apnea hypopnea index ≥ 10 per hour and at least 2 of the following symptoms--daytime sleepiness, snoring, witnessed apneas, fragmented sleep; age > 20 years; and minimum mandibular protrusion of 3 mm).

Intervention: A mandibular advancement splint (MAS) and control oral appliance for 4 weeks each.

Measurements and results: Polysomnography and 24-hour ambulatory blood pressure monitoring were carried out at baseline and following each 4-week intervention period. Patients showed a 50% reduction in mean apnea hypopnea index with MAS compared with the control and a significant improvement in both minimum oxygen saturation and arousal index. There was a significant reduction with the MAS in mean (\pm SEM) 24-hour diastolic blood pressure (1.8 ± 0.5 mmHg) compared with the control ($P = .001$) but not in 24-hour systolic blood pressure. Awake blood-pressure variables were reduced with the MAS by an estimated mean (\pm SEM) of 3.3 ± 1.1 mmHg for systolic blood pressure ($P = .003$) and 3.4 ± 0.9 mmHg for diastolic blood pressure ($P < .0001$). There was no significant difference in blood pressure measured asleep.

Conclusion: Oral appliance therapy for obstructive sleep apnea over 4 weeks results in a reduction in blood pressure, similar to that reported with continuous positive airway pressure therapy.

Effect of oral appliance therapy on upper airway collapsibility in obstructive sleep apnea.

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Am J Respir Crit Care Med. 2003 Jul 15;168(2):238-41

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Oral appliance therapy is emerging as an alternative to continuous positive airway pressure for the treatment of obstructive sleep apnea (OSA). However, its precise mechanisms of action are yet to be defined. We examined the effect of a mandibular advancement splint (MAS) on upper airway collapsibility during sleep in OSA. Ten patients with proven OSA had a custom-made MAS incrementally adjusted during an acclimatization period until the maximum comfortable limit of mandibular advancement was reached. Polysomnography with the splint was then performed. After a 1-week washout period, upper airway closing pressures during sleep (with and without MAS) were determined. Significant improvements with MAS therapy were seen in the apnea/hypopnea index (25.0 ± 3.1 vs. 13.2 ± 4.5 /hour, $p < 0.03$) and upper airway closing pressure in Stage 2 sleep (-1.6 ± 0.4 vs. -3.9 ± 0.6 cm H₂O, $p < 0.01$) and in slow wave sleep (-2.5 ± 0.7 vs. -4.7 ± 0.6 cm H₂O, $p < 0.02$) compared with no therapy. **These preliminary data indicate that MAS therapy is associated with improved upper airway collapsibility during sleep.** The mediators of this effect remain to be determined.

Effect of vertical dimension on efficacy of oral appliance therapy in obstructive sleep apnea

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Am. J. Respir. Crit. Care Med. 2002 Sep 15;166 (6): 860-4

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The aim of this study was to assess the effect of bite opening induced by a mandibular advancement splint (MAS) on efficacy and side effects in the treatment of obstructive sleep apnea. In a randomized crossover fashion, 23 adult patients received either MAS-1 (4 mm of interincisal opening) or MAS-2 (14 mm of interincisal opening) for 2 weeks, followed by the alternate treatment for 2 weeks, with an intervening 1-week washout. Complete response was defined as a resolution of symptoms and a reduction in apnea/hypopnea index (AHI) to less than 5 per hour. Partial response was defined as improved symptoms and a reduction in AHI of 50% or more, with the AHI remaining at a value of 5 or more per hour. Both MAS-1 and MAS-2 produced similar reductions in mean (\pm SEM) AHI from baseline: 21 ± 2 versus 8 ± 1 /hour and 21 ± 2 versus 10 ± 2 /hour, respectively ($p < 0.001$). Either complete response or partial response occurred in 74 and 61% of patients with MAS-1 and MAS-2, respectively. Subjective improvements were reported with both appliances by the majority of patients. Patients preferred MAS-1 (78 versus 22%, $p = 0.007$). **This study suggests that the amount of bite opening induced by MAS does not have a significant impact on treatment efficacy but does have an impact on patient acceptance.**

Oral appliance therapy improves symptoms in obstructive sleep apnea: A randomized, controlled trial

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The aim of this study was to evaluate the effect of a mandibular advancement splint (MAS) on daytime sleepiness and a range of other symptoms in obstructive sleep apnea (OSA). Using a randomized crossover design, patients received 4 weeks of treatment with MAS and a control device (inactive oral appliance), with an intervening 1-week washout. At the end of each treatment period, patients were reassessed by questionnaire, polysomnography, and multiple sleep latency test. Fifty-nine men and 14 women with a mean (\pm SD) age of 48 ± 11 years and proven OSA experienced a significantly improved mean (\pm SEM) sleep latency on the multiple sleep latency test (10.3 ± 0.5 versus 9.1 ± 0.5 minutes, $p = 0.01$) and Epworth sleepiness scale score (7 ± 1 versus 9 ± 1 , $p < 0.0001$) with the MAS compared with the control device after 4 weeks. The proportion of patients with normal subjective sleepiness was significantly higher with the MAS than with the control device (82 versus 62%, $p < 0.01$), but this was not so for objective sleepiness (48 versus 34%, $p = 0.08$). Other OSA symptoms were controlled in significantly more patients with the MAS than with the control device. **MAS therapy improves a range of symptoms associated with OSA.**

A randomized, controlled study of a mandibular advancement splint for obstructive sleep apnea

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Am. J. Respir. Crit. Care Med., Volume 163, Number 6, May 2001, 1457-1461

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Although there is increasing interest in the use of oral appliances to treat obstructive sleep apnea (OSA), the evidence base for this is weak. Furthermore, the precise mechanisms of action are uncertain. We aimed to systematically investigate the efficacy of a novel mandibular advancement splint (MAS) in patients with OSA. The sample consisted of 28 patients with proven OSA. A randomized, controlled three-period (ABB/BAA) crossover study design was used. After an acclimatization period, patients underwent three polysomnographs with either a control oral plate, which did not advance the mandible (A), or MAS (B), 1 wk apart, in either the ABB or BAA sequence. Complete response (CR) was defined as a resolution of symptoms and a reduction in Apnea/Hypopnea Index (AHI) to $< 5/h$, and partial response (PR) as a 50% reduction in AHI, but remaining $\geq 5/h$. Twenty-four patients (19 men, 5 women) completed the protocol. Subjective improvements with the MAS were reported by the majority of patients (96%). There were significant improvements in AHI ($30 \pm 2/h$ versus $14 \pm 2/h$, $p < 0.0001$), MinSaO₂ ($87 \pm 1\%$ versus $91 \pm 1\%$, $p < 0.0001$), and arousal index ($41 \pm 2/h$ versus $27 \pm 2/h$, $p < 0.0001$) with MAS, compared with the control. The control plate had no significant effect on AHI and MinSaO₂. CR (n = 9) or PR (n = 6) was achieved in 62.5% of patients. **The MAS is an effective treatment in some patients with OSA, including those patients with moderate or severe OSA.**

Effect of oral appliance therapy on neurobehavioral functioning in obstructive sleep apnea: a randomized controlled trial

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J Clin Sleep Med., 2005; 1(4): 278-284

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Study Objectives: This study aimed to assess the efficacy of a custom-made mandibular advancement splint for the treatment of obstructive sleep apnea with respect to neuropsychological functioning and mood state.

Methods: A randomized controlled crossover design was used in which 73 participants (mean age = 48.4, SD = 11.0, % men = 80.8) with at least 2 symptoms of obstructive sleep apnea and an apnea hypopnea index $> \text{or} = 10$ per hour underwent treatment with both mandibular advancement splint and an interactive oral device. Polysomnographic, neuropsychological and self-report measures were conducted at baseline and repeated after each of the two 4-week treatment phases.

Results: MAS treatment was associated with improvements on the somatic component of the Beck Depression Inventory and the Vigor-Activity and Fatigue- Inertia scales of the Profile of Mood States. While there were no improvements within the neuropsychological domains of attention/working memory, verbal memory,

visuospatial or executive functioning, treatment with the mandibular advancement splint was associated with faster performance on a test of vigilance/psychomotor speed. These changes, however, did not correspond to the improved subjective sleepiness or apnea-hypopnea index during treatment.

Conclusions: Treatment with the mandibular advancement splint results in improvements in self-reported sleepiness, fatigue/energy levels and vigilance/psychomotor speed in patients with obstructive sleep apnea.

Oropharyngeal Collapse Predicts Treatment Response With Oral Appliance Therapy in Obstructive Sleep Apnea

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Sleep 2006; 29(5): 666-671

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Study Objectives: To examine whether primary oropharyngeal collapse of the upper airway during sleep predicts treatment success with oral appliance therapy in patients with obstructive sleep apnea.

Design: Prospective physiologic study.

Setting: Multidisciplinary sleep disorders clinic in a university teaching hospital.

Patients: Twelve treatment-naïve adult patients with obstructive sleep apnea (apnea-hypopnea index ≥ 10 /h and at least 2 of the following symptoms: snoring, fragmented sleep, witnessed apneas, or daytime sleepiness).

Intervention: Custom-made mandibular advancement splint (MAS).

Measurements and Results: A baseline diagnostic polysomnogram confirmed AHI ≥ 10 per hour. During the following acclimatization period, a custom-made adjustable MAS was incrementally advanced until maximum comfortable mandibular protrusion was reached. A second polysomnogram with MAS in situ determined efficacy. Following a 1-week washout period, a final sleep study was performed using multisensor catheters (with and without MAS, in random order during the same night) to determine upper-airway closing pressures and the site or sites of upper-airway collapse. MAS resulted in significant improvements, mean \pm SEM, in AHI (22.0 ± 2.6 vs 9.2 ± 1.9 /h, $p < .01$) and upper-airway closing pressures during stage 2 non-rapid eye movement sleep (-1.1 ± 0.3 vs -2.8 ± 0.5 cm H₂O, $p < .01$). All 4 patients with primary oropharyngeal collapse achieved an AHI < 5 per hour. Only 1 of the 8 patients with primary velopharyngeal collapse achieved an AHI < 5 per hour. Oropharyngeal collapse, compared with velopharyngeal collapse, predicted treatment success with MAS ($p < .02$).

Conclusions: These preliminary data suggest that primary oropharyngeal collapse of the upper airway during sleep is an important predictor of treatment outcome with MAS therapy.

Comparison of Mandibular Advancement Splint and Tongue Stabilizing Device in Obstructive Sleep Apnea: A Randomized Controlled Trial

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Sleep 2009; 32(5): 648-653

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Study Objectives: To compare the efficacy of a mandibular advancement splint (MAS) and a novel tongue stabilizing device (TSD) in the treatment of obstructive sleep apnea (OSA).

Design: A randomized crossover design was used.

Patients: Twenty-seven patients (20 male, 7 female), recruited from a tertiary hospital sleep clinic.

Intervention: Custom-made mandibular advancement splint (MAS).

Measurements and Results: The apnea-hypopnea index (AHI) was reduced with MAS (11.68 ± 8.94 , $P = 0.000$) and TSD (13.15 ± 10.77 , $P = 0.002$) compared with baseline (26.96 ± 17.17). The arousal index decreased for MAS (21.09 ± 9.27 , $P = 0.004$) and TSD (21.9 ± 10.56 , $P = 0.001$) compared with baseline (33.23 ± 16.41). Sixty-eight percent of patients achieved a complete or partial response with MAS, compared with 45% with TSD. The Epworth Sleepiness Scale (ESS) score was decreased with MAS ($P = <0.001$) and TSD ($P = 0.002$). Subjective improvements in snoring and quality of sleep were reported, with a better response for MAS than TSD. Compliance was poorer for TSD, and the side effect profiles of the 2 modalities were different. All patients were satisfied with MAS compared to TSD, and 91% of patients preferred the MAS.

Conclusions: Objective testing showed the MAS and TSD had similar efficacy in terms of AHI reduction. Patients reported improvements with both devices; however, better compliance and a clear preference for MAS was apparent when both devices were offered. Longer term studies are needed to clarify the role of TSD.

Nasopharyngoscopic evaluation of oral appliance therapy for obstructive sleep apnea

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European Respiratory Journal, 2010; 35: 836-84

Abstract: This study aimed to explore the effect of mandibular advancement splints (MAS) on upper airway anatomy during wakefulness in obstructive sleep apnea (OSA). Patients commencing treatment for OSA with MAS were recruited. Response to treatment was defined by a $\geq 50\%$ reduction in the apnea/hypopnea index. Nasopharyngoscopy was performed in the supine position. Nasopharyngoscopy was performed in 18 responders and 17 nonresponders. Mandibular advancement caused an increase in the calibre of the velopharynx (mean;SEM $+40$;10%), with relatively minor changes occurring in the oropharynx and hypopharynx. An increase in cross-sectional area of the velopharynx with mandibular advancement occurred to a greater extent in responders than nonresponders ($+56$;16% versus $+22$;13%; $p,0.05$). Upper airway collapse

during the Müller maneuver, relative to the baseline cross-sectional area, was greater in nonresponders than responders in the velopharynx (-94;4% versus -69;9%; p,0.01) and oropharynx (-37;6% versus -16;3%; p,0.01). When the Müller manoeuvre was performed with mandibular advancement, airway collapse was greater in nonresponders than responders in the velopharynx (-80;11% versus +9;37%; p,0.001), oropharynx (-36;6% versus -20;5%; p,0.05) and hypopharynx (-64;6% versus -42;6%; p,0.05). These results indicate that velopharyngeal caliber is modified by MAS treatment and this may be useful for predicting treatment response.

The effect of mandibular advancement on upper airway structure in obstructive sleep apnea

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Thorax 2010 65: 726-732; doi: 10.1136/thx.2009.131094

Background: The mechanisms by which mandibular advancement splints (MAS) improve obstructive sleep apnoea (OSA) are not well understood. This study aimed to evaluate the mechanism of action of MAS by assessing their effect on upper airway structure in patients with OSA.

Methods: Patients were recruited from a sleep disorders clinic for treatment with a custom-made MAS. MRI of the upper airway was performed during wakefulness in the supine position, with and without the MAS.

Results: Sixty-nine patients with OSA were recruited. Treatment with the MAS reduced the apnea/hypopnea index (AHI) from 27.06 to 12.26 events/h ($p < 0.001$). There was an increase in the total airway volume with mandibular advancement (16.56 to 18.16 cm³; $p < 0.01$) that occurred predominantly because of an increase in the volume of the velopharynx (5.76 to 6.56 cm³; $p < 0.001$). This increase in airway calibre was associated with an increase in the lower anterior facial height (6.86 to 7.56 cm; $p < 0.001$), reduction in the distance between the hyoid and posterior nasal spine (7.46 to 7.26 cm; $p < 0.001$), lateral displacement of the parapharyngeal fat pads away from the airway (right parapharyngeal fat pad 0.17 to 0.22 cm; left parapharyngeal fat pad 0.22 to 0.26 cm) and anterior movement of the tongue base muscles (0.33 to 0.36 cm). Subanalyses in responders and non-responders to MAS treatment showed that the increase in upper airway calibre with mandibular advancement occurred only in responders.

Conclusion: These results suggest that the mechanism of action of MAS is to increase the volume of the upper airway, predominantly by increasing the volume of the velopharynx, and this increased volume is associated with changes in the surrounding bony and soft tissue structures.



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