Sited Peer Reviewed Studies on Oral Sleep Appliance Effectiveness

The standard of care for treating obstructive sleep apnea is continuous positive airway pressure (CPAP). However, many patients are unable or unwilling to comply with long-term CPAP use. In addition, CPAP is difficult to use when traveling. The use of an oral appliance provides an effective treatment that many patients prefer to either CPAP or to the third alternative, surgical modification of the upper airway.

**Reviews of older studies**

An article [[1]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftn1) published in the *Journal of the American Dental Association* in 2003 reviewed a couple dozen studies done during the previous eighteen years and concluded that oral appliances have been shown to offer an alternative treatment to CPAP and surgery for treating sleep apnea patients. Of the two main types of oral appliances—tongue repositioning devices and mandibular repositioning appliances (MRAs)—only studies using MRAs are discussed. Tongue repositioning devices are, however, useful for patients with inadequate dentition to qualify for MRA therapy. Among the results reviewed, the use of an MRA was documented by upper airway imaging techniques to increase the openness of the upper airway and decrease the average number of respiratory events per hour from thirty-four (severe sleep apnea) to ten (mild sleep apnea). Another study found reductions from forty-eight to twelve, with 52 percent of the patients still successfully using the MRA at thirty-six months. Two randomized controlled trials (in which the control was a device that was not adjusted to reposition the mandible forward to open the airway) showed significant reductions in respiratory events and significant improvement in daytime sleepiness. Several trials comparing CPAP with MRA showed both to significantly reduce the number of respiratory events. While CPAP was more effective, patient compliance was better with MRA. Summarizing the studies reviewed, the authors conclude that the ideal MRA candidate has symptoms of daytime sleepiness, is not obese, has mild-to-moderate sleep apnea, has an adequate range of protrusion of the mandible, and has adequate dentition to anchor the MRA. In at least one study, however, even patients with severe sleep apnea achieved a 53 percent reduction in the number of respiratory events per hour. Complications of treatment were usually minor and transient, but the authors note the need for studies with longer duration follow-up.

Another systematic review published in 2004 also reviewed published studies using MRAs [[2]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftn2). Several studies are cited showing that MRA therapy decreases snoring and daytime sleepiness in a high proportion of patients, improves work performance, and improves sleep quality for both the patient and the bed partner. Numerous studies are cited to demonstrate effectiveness in different patient populations (such as greater effectiveness in leaner patients with less severe sleep apnea), side effects and complications (generally mild and transient) and patient compliance (generally good). In one study thirty-four of one-hundred consecutive sleep apnea patients were found ineligible for MRA therapy due to insufficient number of teeth, serious periodontal disease, active temporomandibular joint disorders, or restrictions in mandibular protrusion or opening. The recommendation is to consider oral appliance therapy in patients with simple snoring or mild sleep apnea who are not candidates for conservative treatments, like weight reduction, etc., and in patients with moderate to severe sleep apnea who do not tolerate or have refused CPAP, or who are not candidates for or who refuse surgery. A systematic search for studies on efficacy and complications of oral appliance therapy meeting detailed pre-specified criteria yielded, from 289 relevant articles, sixteen studies that were selected for appraisal of efficacy and thirteen for appraisal of comorbidities (side-effects or complications of treatment). Among the conclusions: compared to control devices that did not advance the mandible, MRA treatment was significantly more effective in reducing the number of respiratory events and daytime sleepiness in all trials studied. Compared to CPAP, MRA was less effective in reducing the number of respiratory events. Higher MRA success rates were observed with greater mandibular protrusion. Some adverse (but generally not serious) effects of oral appliance therapy were identified, and minor orthodontic side-effects and changes in dental occlusion were common. The authors recommend that follow-up be conducted on a regular basis to guarantee long-term efficacy and safety.

The Standards of Practice Committee of the American Academy of Sleep Medicine reviewed eighty-seven articles published from 1995-2006 [[3]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftn3). Comparing all of these studies was complicated by the variety of approaches used and variables studied. For example, some studies only considered treatment to be effective if the number of respiratory events was reduced to less than ten per hour, while others required only that the number of events be reduced from the pre-treatment baseline by 50 percent or more. Usually studies focused on patients with mild to moderate disease (thirty or less events per hour), but some included patients with more severe sleep apnea (forty or more events per hour). Most of the devices tested were designed to hold the mandible forward during sleep (MRAs), but a few studies used appliances that only held the tongue forward. Some MRAs were prefabricated while others were custom-made. Some appliances were single position while others were adjustable. Variables that emerged as important for the effectiveness of oral appliances include the severity of the sleep apnea, the amount of mandibular protrusion of the MRA, and the body mass index of the patient. Conclusions from all of these studies that the authors cite include, first of all, the observation that overall oral appliances are effective for treating obstructive sleep apnea. Defining successful treatment as no more than ten respiratory events per hour, successful treatment was achieved with in an average of 52 percent of patients. CPAP was more successful at lowering the number of respiratory events per hour, but many patients preferred oral appliances to CPAP for long-term use. Oral appliances were less effective than CPAP in patients with severe sleep apnea and in patients with higher body mass index (more obese). Therefore, oral appliances are not indicated as first line therapy for those with severe sleep apnea or severe daytime sleepiness, but may be indicated if these patients have failed other treatments. In a randomized study, oral appliances performed at least as well as surgery. In the small number of studies comparing MRAs with other oral appliances, MRAs were generally effective in reducing snoring and obstructive sleep apnea, and were more easily used and more effective than other oral appliances. No comparisons were done of different types of MRAs, but most studies were done with fixed position appliances that did not allow adjustment to optimize treatment. Thus the results of these studies, although positive overall, did not represent current best practices and so may underestimate the effectiveness of MRAs. Oral appliances are well-tolerated by most patients (a median appliance use of 77 percent of nights after one year). Side effects are common but minor, and usually improve with time, but tooth movement and malocclusion can occur in some patients and are frequently irreversible.

A study published in 2007 [[4]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftn4) reviewed eighty-nine oral appliance sleep studies focusing on reduction in respiratory events, reduction in snoring, effect on daytime function, comparison with other sleep apnea treatments, side effects, dental changes, and long-term compliance. The success of oral appliance therapy in reducing respiratory events to less than ten per hour was 54 percent; an additional 21 percent achieved at least 50 percent reduction in respiratory events, although they still remained above ten. Snoring was reduced by 45 percent and daytime function was improved somewhat. CPAP produced a greater reduction in the number of events than did oral appliances, but the majority of patients preferred using oral appliances over using CPAP. Follow-up studies at thirty months showed 56 to 68 percent of patients still using the oral appliance. The most common minor side effects encountered were excessive salivation and teeth discomfort.

**Fixed vs. adjustable devices**

A study published in 2011 [[5]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftn5) compared fixed with adjustable (the degree of mandibular advancement can be optimized) mandibular repositioning appliances. Both fixed and adjustable oral appliances were individually fabricated from impressions of the individual patient’s teeth. Fixed oral appliances are typically molded to advance the mandible by 50 to 80 percent of the patient’s maximal protrusion. Adjustable devices include a mechanism for the patient to increase or decrease protrusion to obtain the optimum balance between effectiveness and side effects. On the other hand, adjustable devices are more expensive. This paper presents the results of a review of consecutive adult patients treated with an oral appliance for obstructive sleep apnea between January 2003 and December of 2009 at the authors’ institution, and who underwent polysomnography before and after treatment. As military service members comprise a large fraction of the patients at this institution, many patients chose oral appliances because electricity to use CPAP is not reliably available during worldwide deployment. Choice of fixed or adjustable oral appliance was made according to resource availability—not by pre-established clinical criteria. Successful treatment was defined as less than five respiratory events per hour. A secondary endpoint for success was reduction of events to less than ten per hour with concurrent resolution of excessive daytime sleepiness. The sample cohort included 805 patients, of whom 74.8 percent used adjustable appliances and 25.2 percent used fixed appliances. Of the cohort, 86.7 percent were men and 38.8 percent were obese. Sleep apnea was mild in 34.1 percent, moderate in 29.2 percent and severe in 36.8 percent. Both devices provided a substantial decrease in events per hour, but the adjustable devices produced significantly greater reductions (74.4 percent versus 64.9 percent decrease) and more patients achieved successful therapy with adjustable devices (57.2 percent versus 46.9 percent).  In terms of whether sleep apnea at baseline was mild, moderate, or severe, adjustable devices produced a greater reduction in events for all three groups. Fixed devices were frequently successful in patients with mild disease, but adjustable devices performed better across all levels of disease severity. A multivariate statistical analysis showed that patients who were older, had a higher body mass index, or were using a fixed device were less likely to achieve less than five events per hour.

Adjustable oral appliances give superior results to fixed oral appliances; however, most of the older comparisons of CPAP to oral appliances compared CPAP titrated to optimally effective pressure with fixed oral appliances not adjusted to maximally effective mandibular advancement. A recent study compared CPAP and oral appliances that were both titrated to optimize settings [[6]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftn6). Sixty-four patients with mild to moderate sleep apnea were randomly assigned to therapy with an MRA, CPAP, or a placebo device. Polysomnography was obtained before treatment and after six months treatment to measure the number of respiratory events per hour. No differences were found between the MRA and CPAP groups in reductions in the number of events between baseline and after treatment. The reductions seen in the placebo group were much smaller. In terms of the number of patients who were successfully treated, statistical analysis indicates no difference between the MRA and CPAP groups.

**Conclusion:**

Oral appliances provide effective treatment for obstructive sleep apnea. Although a variety of oral appliances have been investigated, most studies have used mandibular repositioning appliances (MRAs), which position the mandible forward during sleep. These can either advance the mandible a fixed fraction of the maximum distance the patient can advance his or her mandible, or they can be adjustable to determine what advancement gives the greatest reduction in respiratory events per hour. Fixed MRAs are frequently optimal for patients with mild disease, but adjustable devices work better for moderate to severe disease. Comparisons with CPAP often show better results with CPAP for more severe disease, but even in this case, MRAs provide effective therapy for the many patients unwilling or unable to tolerate CPAP.

[[1]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftnref1) “The role of oral appliances in treating obstructive sleep apnea.” N Mohsenin, MT Mostofi, V Mohsenin. *J Am Dent Assoc.* **134:**442-9 (2003). http://www.ncbi.nlm.nih.gov/pubmed/12733777

[[2]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftnref2) “Efficacy and co-morbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systematic review.” A Hoekema, B Stegenga and LGM de Bont. *Critical Reviews in Oral Biology & Medicine* **15:** 137-155 (2004) DOI: 10.1177/154411130401500303. http://cro.sagepub.com/content/15/3/137

[[3]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftnref3) “Oral appliances for snoring and obstructive sleep apnea: a review.” KA Ferguson, R Cartwright, R Rogers, W Schmidt-Nowara.*SLEEP* **29:** 244-262 (2006). http://www.aasmnet.org/resources/practiceparameters/review\_oralapplianceosa.pdf

[[4]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftnref4) “Review of oral appliances for treatment of sleep-disordered breathing.” V Hoffstein. *Sleep Breath* **11:**1–22 (2007). DOI 10.1007/s11325-006-0084-8. http://www.ncbi.nlm.nih.gov/pubmed/17136406

[[5]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftnref5) “Comparison of adjustable and fixed oral appliances for the treatment of obstructive sleep apnea.” CJ Lettieri, N Paolino, AH Eliasson, AA Shah, AB Holley. J *Clin Sleep Med* **7:**439-445 (2011). DOI: 10.5664/JCSM.1300. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190841/review concept

[[6]](http://daghealth.com/2015/08/10/oral-appliance-therapy-a-review/" \l "_ftnref6) “Oral appliance therapy versus nasal continuous positive airway pressure in obstructive sleep apnea: a randomized, placebo-controlled trial.” G Aarab, F Lobbezoo, HL Hamburger, M Naeije. *Respiration* **81:**411-419 (2011). DOI: 10.1159/000319595.  http://www.karger.com/Article/Fulltext/319595