

## Trial Appliances: Are We There Yet?

Jean-François Masse, DMD, MSc, Diplomate, ABDSM

Editor-in-Chief *Journal of Dental Sleep Medicine*  
Universite Laval, Quebec City, Quebec, Canada

During the last 27 years, I have witnessed many changes in our field: the criteria defining OSA have changed a few times<sup>1-4</sup>, the indications for oral appliances have moved from the treatment of primary snoring<sup>5</sup> to the treatment of moderate apnea as a first line therapy<sup>6</sup>, and diagnosis went from hospital-based facilities to the use of ambulatory devices often combined with telemedicine to improve access to treatment for patients. Because of the obesity epidemic and the more stringent diagnostic criteria for OSA<sup>4</sup> among other things, the prevalence of OSA has greatly increased during that time.<sup>7</sup> As years have gone by and research supporting the use of oral appliances has steadily increased, I have remained hopeful that our field would grow and we would find as many apneics using oral appliances as the ones using CPAP. Am I too optimistic? Just look at the evidence: there is not a month during which one cannot read new studies on oral appliances published, often in high impact journals. The scientific community, the educators are interested in oral appliances. The scientific community sees the value - the oral appliance is just as good as the CPAP for quality of life, cognitive and functional outcome.<sup>8</sup> We now know that the CPAP, despite being an excellent treatment for OSA, is not tolerated by a great number of patients.<sup>9,10</sup> Despite this, it is estimated that many of those who unsuccessfully use CPAP are not even offered an alternative treatment after the failure.<sup>11</sup> That concept is beyond me... A great number of people suffering from OSA could be treated with oral appliances and yet, they are not.<sup>12</sup>

This frustration is shared by many and is also recognized by physicians, some of whom have tried to address it by coming up with solutions<sup>13</sup> or writing what a lot of sleep doctors have been thinking<sup>14-16</sup>: many medical colleagues are hesitant to prescribe an oral appliance due to the uncertain prognosis combined with the high cost of the device. David White suggested in an editorial<sup>14</sup> that things would be simpler if dentist could use a “relatively inexpensive boil-and-bite device” to predict oral appliance success.

The best study I could think of comparing custom to prefabricated oral appliances is the one by Vanderveken<sup>17</sup> in 2008. The results were unequivocal: a

boil and bite appliance could improve snoring but was not good at correcting the apnea-hypopnea index. In that perspective, it was potentially useless for the sleep dentist to use a boil and bite appliance to predict the result of oral appliance therapy with patients.

Time has passed, techniques and materials have improved and new trial appliances have been introduced to the market. We have recently seen good, relatively large studies with some favorably comparing temporary to regular appliances.<sup>18-20</sup> These studies not only come up with excellent results, but were also done with sound titration protocols. In addition to the successful use of trial appliances to predict compliance success, the increased use of trial appliances could also open the door to evaluation for OAT treatment that had previously been cost-prohibitive: evaluation of combined (CPAP-OA) therapy, emergency therapy for symptomatic patients, evaluation of mandibular advancement in future orthognatic surgery cases, evaluation of oral appliance treatment on specific morning headache patients and the list goes on.

Of course, the trial appliance has its limitations and will not be able to evaluate the effect of some oral appliance adjuncts like the Tongue Tamer<sup>21</sup>, the tongue lifter and the nasal dilators<sup>22</sup> we find on some models. Neither will it predict the success of different systems like the one on the Oventus<sup>23</sup> appliance with and without positive airway pressure valves. However, if the use of trial appliances becomes mainstream, we can hope that these adjuncts will someday be incorporated on newer trial models.

So, are we there yet? Only time will tell but it seems we are closer from regularly using trial appliances than ever.

### CITATION

Masse, JF. Trial appliances: Are we there yet?. *J Dent Sleep Med.* 2019;6(3)

### REFERENCES

1. Rechtschaffen A, Kales A. A manual of standardized terminology.

- techniques and scoring system for sleep stages of human subjects. Bethesda, MD: U. S. National Institute of Neurological Diseases and Blindness, Neurological Information Network. 1968.
2. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The report of an American Academy of Sleep Medicine Task Force. *Sleep* 1999;22:667-89
  3. Iber C, Ancoli-Israel S, Chesson AL Jr., Quan SF. *The AASM manual for the scoring of sleep and associated events: rules, terminology and technical specifications*. 1st ed. Westchester, IL: American Academy of Sleep Medicine, 2007.
  4. Berry, Richard B., et al. Rules for scoring respiratory events in sleep: update of the 2007 AASM manual for the scoring of sleep and associated events. *J of Clin Sleep Med*. 2012; 597-619.
  5. Schmidt-Nowara W, Lowe A, Wiegand L, Cartwright R, Perez-Guerra F, Menn S. Oral appliances for the treatment of snoring and obstructive sleep apnea: a review. *Sleep*. 1995;18(6):501-10.
  6. Ferguson KA, Cartwright R, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep*. 2006;29(2):244-62.
  7. Peppard PE, Young T, Barnett JH, Palta M, Hagen EW, Hla KM. Increased prevalence of sleep-disordered breathing in adults. *Am J Epidemiol*. 2013;177(9):1006-1014.
  8. Schwartz M, Acosta L, Hung YL, Padilla M, Enciso R. Effects of CPAP and mandibular advancement device treatment in obstructive sleep apnea patients: a systematic review and meta-analysis. *Sleep Breath*. 2018 Sep;22(3):555-568. doi: 10.1007/s11325-017-1590-6.
  9. McEvoy RD, Antic NA, Heeley E, et al. CPAP for prevention of cardiovascular events in obstructive sleep apnea. *N Engl J Med*. 2016;375(10):919-931.
  10. Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. *Proc Am Thor Soc*. 2008;5(2):173-178.
  11. Russell JO, Gales J, Bae C, Kominsky A. Referral patterns and positive airway pressure adherence upon diagnosis of obstructive sleep apnea. *Otolaryngol Head Neck Surg*. 2015 ;153(5):881-7. doi: 10.1177/0194599815596169.
  12. Carberry JC, Amatoury J, Eckert DJ. Personalized management approach for OSA. *Chest*. 2018;153(3):744-755.
  13. Remmers J, Charkhandeh S, Grosse J, Topor Z, Brant R, Santosham P, Bruehlmann S. Remotely controlled mandibular protrusion during sleep predicts therapeutic success with oral appliances in patients with obstructive sleep apnea. *Sleep*. 2013; 1;36(10):1517-25, 1525A. doi: 10.5665/sleep.3048.
  14. White DP. Continuous positive airway pressure versus the mandibular advancing splint: are they equally effective in obstructive sleep apnea management? *Am J Respir Crit Care Med*. 2013 Apr 15;187(8):795-7. doi: 10.1164/rccm.201302-0318ED.
  15. Eckert DJ. Phenotypic approaches to positional therapy for obstructive sleep apnoea. *Sleep Med Rev*. 2018;37:175-176. doi: 10.1016/j.smrv.2017.06.007.
  16. Schmidt-Nowara W.J Preferred treatment. *Clin Sleep Med*. Apr 15;9(4):325-6. doi: 10.5664/jcsm.2578.
  17. Vanderveken OM, Devolder A, Marklund M et al. Comparison of a custom-made and a thermoplastic oral appliance for the treatment of mild sleep apnea. *Am J Respir Crit Care Med*. 2008 15;178(2):197-202
  18. Gagnadoux F, Nguyen XL, Le Vaillant M, et al. Comparison of titrable thermoplastic versus custom-made mandibular advancement device for the treatment of obstructive sleep apnoea. *Respir Med*. 2017;131:35-42. doi: 10.1016/j.rmed.2017.08.004.
  19. Pépin JL, Raymond N, Lacaze O, et al. Heat-moulded versus custom-made mandibular advancement devices for obstructive sleep apnoea: a randomised non-inferiority trial. *Thorax*. 2019;74(7):667-674. doi: 10.1136/thoraxjnl-2018-212726
  20. Levendowski D, Munafo D, Clark SJ, Hevener B, Arista DC, Morgan T. Distributions of OSA Therapy Outcomes Based on a Trial Oral Appliance and/or Supine Avoidance. In: 2th Annual Meeting of the American Academy of Dental Sleep Medicine; June 1-3, 2018; Baltimore, MD. Abstract 16.
  21. Turek, G. A novel device for passive restraint of the tongue as an adjunct to mandibular advancement therapy in incomplete responders. *J Dent Sleep Med*. 2019;6(2)
  22. Singh GD, Abramson M. Effect of an intra-oral nasal dilation appliance on 3-D nasal airway morphology in adults. *Sleep Breath*. 2008;12(1):69-75.
  23. Lai V, Tong BK, Tran C, et al. Combination therapy with mandibular advancement and expiratory positive airway pressure valves reduces obstructive sleep apnea severity. *Sleep*. 2019. pii: zsz119. doi: 10.1093/sleep/zsz119.

## SUBMISSION AND CORRESPONDENCE INFORMATION

**Submitted in final revised form June 30, 2019**

Address correspondence to: Jean-François Masse,  
Professor, Université Laval, 2780 Masson #200, Quebec  
City, QC, G1P 1J6, Canada; Tel: 418871-1447; Fax:  
418-871-4983; Email: jean-francois.masse@fmd.ulaval.ca