Economics of Oral Appliances



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CPAP has been the gold standard for treating obstructive sleep apnea, but custom oral appliances (OAs) are steadily gaining increased respect in the medical community. The problem is that while OAs lack the history of CPAP, the price of custom oral appliances is distinctly the gold standard, with most custom oral appliances in the \$2K to \$4K range. Sleep physicians who determine that CPAP is just not working for their patients want to help, but many are hesitant to recommend a pricey alternative that may, or may not, work. Dennis Hwang, MD, has seen the dilemma too many times during his 6-year tenure at Kaiser Permanente's Sleep Disorders Center in Fontana, Calif.

Less costly prefabricated devices have long been used as a "predictor", but formal peer reviewed studies are lacking. Hwang wanted to know: If patients have a good experience with prefab devices, is that truly a reliable predictor of success with the more expensive custom devices?

Hwang explored the question with his patients, eventually presenting the results at the 2014
Associated Professional Sleep Societies (SLEEP) convention in Minneapolis, in a poster titled,
"Feasibility Pilot Evaluating the Use of
Pre-Fabricated Titratable Mandibular
Advancement Device for Management of
Obstructive Sleep Apnea." Along with nine colleagues, Hwang used a simple-to-fit, pre-fabricated titratable OA device called
ApneaRx, made by the Aliso Viejo, Calif-based
Apnea Sciences Corp.

ApneaRx is a one-step boil-and-bite device where the lower tray can be advanced (relative to the upper tray) in 1 mm increments (up to 10 mm), which is similar to custom OAs. "The ApneaRx served as a predictor response mechanism," explains Hwang, a 42-year-old pulmonologist who was a sleep researcher at New York University prior to his arrival at Kaiser in 2009. "We believe that this mechanism accurately predicts whether patients are going to physiologically respond to a custom OA. It can also act as a transitional or temporary device while a patient is waiting for their custom OA."

In determining a "positive predictive value of virtually 100%," Hwang and his colleagues' sample size of (13 patients) showed that prefabricated devices are indeed a good predictor of custom success in patients with all degrees of OSA severity. "Just about every single patient who responded to a prefab OA also responded to a customized OA," reports Hwang. "However, because our clinical pilot did not look at custom OSA response rates in patients who did not respond to a prefab OA, we were not able to determine the negative predictive value of using an ApneaRx as a predictor response mechanism."

The apnea hypopnea index (AHI) of patients wearing the prefab OA was "very similar" to AHI calculated while wearing custom OAs. "Eleven of the 13 had virtually identical AHI readings with both devices," reports Hwang. "Patient #12 had a discrepancy, but the prefab AHI had improved significantly even with minimal mandibular advancement, and we anticipated that further advancement would result in greater effect. We concluded that this patient was a good candidate for OA therapy and was confirmed by more robust improvement in AHI with a properly advanced custom OA."

(Economics of Oral Appliances)

"The 13th patient did have a very significant decrease in the AHI although moderate OSA persisted "Even though the OA therapy did not produce as robust of a response as we hoped, we thought treating with an OA would be better than nothing."

A Policy Worth Pursuing?

Hwang and colleagues looked at a few different prefabricated devices before choosing the ApneaRx for its ease in fitting the patient. "There were some others where it would take 45 minutes to an hour for us to fit each patient," says Hwang. "With ApneaRx we were able to create a device and fit the patient in five to 10 minutes. These 'provider friendly' aspects, combined with easy calibrated advancement of the mandible, outweighed the occasional difficulty of fitting some patients with smaller jaws."

If a patient really loved the prefab OA (and responded well clinically), Hwang agrees that it could be used in a semi-permanent fashion, with some limitations. He points out, "The prefab does not last as long as the custom, so we would need to have one remade on an annual basis.

Another clinical use is for patients who are going camping and are not able to bring CPAP, they could use the prefab during their travels."

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As a predictor for custom success, or as a travel option, Hwang firmly believes that the prefabricated (or transitional) device can be incorporated into the modern sleep medicine practice. At the Fontana Sleep Center, the policy is a mainstay of the clinical workflow, but admittedly on a "patient-by-patient" basis.

Some patients with mild OSA—who want OA therapy—will sometimes be sent directly to the dentist for a custom OA. For those with moderate to severe OSA, Hwang is more likely to recommend the predictor response device.

"Most of the time we will use the ApneaRx as our predictor response mechanism," confirms Hwang. "We have another system called MATRx, which is a mechanism to titrate with a temporary OA during in-lab polysomnography. We generally prefer the ambulatory mechanism which we believe to be more cost-effective."

As a physician researcher, Hwang would ultimately like to explore the topic of negative predictive value (NPV), which he believes is just as important as positive predictive value. "We anticipate launching a formal prospective study where we would test patients with a custom OA in those that both respond and do not respond to a prefab OA. In this situation, we can calculate the NPV."



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