

ApneaRx "Predictor Appliance"

Low Cost – High Value Predictor Device for Oral Appliance Therapy

Randy Clare Respiratory Diagnostics

2015



Treatment Options for OSA

- CPAP is the gold standard of care.
- Oral Appliances (OA's) are gaining popularity and credibility with the medical community.
- Cost of dental appliances are a major hurdle Custom appliances cost between \$2 and \$4K.
- Patients with difficulty complying with CPAP want options to help manage their condition.
- Physician can be hesitant to suggest OA's because they may or may not work.



Kaiser Permanente Study

Investigator: Dennis Hwang, MD. Kaiser sleep lab Fontana, CA.

- Can Success with a Prefabricated Appliance predict success with a Custom appliance?
- Feasibility Pilot Evaluating the Use of Pre-Fabricated Titratable Mandibular Advancement Device for Management of Obstructive Sleep Apnea.







- ApneaRx
 - Simple-to-fit, pre-fabricated titratable OA.
 - 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.





"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."

- Dennis Hwang MD

Economics of Oral Appliances



ApneaRx

- Dr. Hwang's research indicates a positive predictive value of virtually 100%.
- Just about every single patient who responded to a prefab OA also responded to a customized OA.
- Pilot did not look at custom OSA response rates in patients who did not respond to a prefab OA – not able to determine the negative predictive value of using an ApneaRx as a predictor response mechanism.
- Eleven of the 13 patients had virtually identical AHI readings with custom and ApneaRx appliances.



ApneaRx

- One Patient 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.
- 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.
- One Patient did have a very significant decrease in the AHI although moderate OSA persisted Oral appliance therapy was initiated



Appliance selection

Investigators looked at several prefab appliances...

- Fabrication time, fit and function were all considered.
- Some appliances took as much as 45min to fabricate.



ApneaRx is ready for patients in less than 5 minutes!



© 2015 CareFusion Corporation or one of its subsidiaries. All rights reserved.

Appliance selection

- Dr. 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.



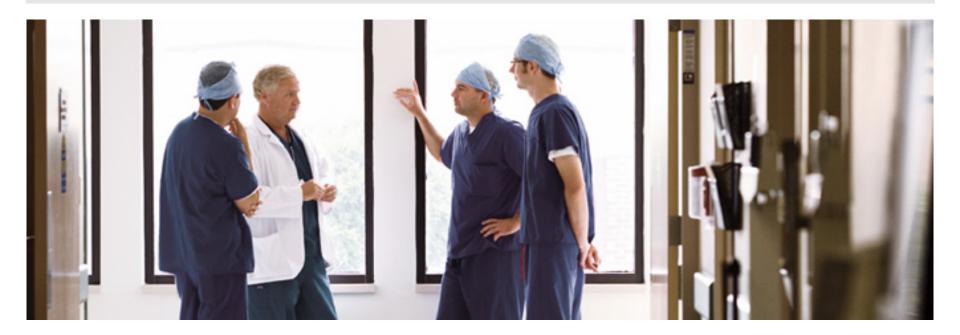




- Poster presentation is available at <u>http://goo.gl/37tSrZ</u>
- For more information and to order <u>http://bit.ly/1pQHXrs</u>
- ApneaRx fitting video <u>http://bit.ly/1Ca47PO</u>
- Economics of Oral Appliances



Questions



Thank you

