

## Options and Evidence

### SomnoMed MATRx™ and SomnoDent G2 head a rapidly evolving class of oral appliances and overnight study systems that bolster compliance and verify effectiveness.

Executives at Dallas-based SomnoMed (Somnomed.com) are not afraid of evidence. On the contrary, they are making it easier to objectively measure effectiveness of the company's oral sleep appliance portfolio. The result is a measure of certainty for sleep physicians who want the best therapy for their patients.

The vehicle that fuels this elusive certainty is the SomnoMed MATRx™ (pending FDA approval). Ralf Barschow, Global CEO of SomnoMed, touts the device as nothing less than a revolutionary breakthrough in the prediction of efficacy for the SomnoDent Mandibular Advancement Splint (MAS).

#### Responder or Non-Responder?

A typical MATRx scenario usually starts with a SomnoMed dentist taking an oral impression of the patient and fabricating a customized overnight oral appliance. From there, patients take the overnight appliance to a sleep lab where it is used with SomnoMed MATRx.

To conduct a study with SomnoMed MATRx, the overnight appliance is attached to a small motor (50 grams) that is remotely controlled by a sleep technician. "Using this process, sleep technicians can clearly see whether the patient is a responder or non-responder to SomnoDent therapy," says Barschow, who also serves as president of SomnoMed North America. "The MATRx is analogous to a CPAP titration. For the first time, we are providing a means of predicting whether patients are suitable for an oral appliance. If they are, we can help determine optimal protrusive distance for their SomnoDent once they are returned to their SomnoMed dentist for further titrations."

#### MAS Fosters Compliance

Loyal customers are already familiar with SomnoMed's MAS treatments, each with different clinical indications aimed at OSA sufferers. These include the SomnoDent® Classic, SomnoDent® Flex, and SomnoDent® Edent for the Edentulous patient.

The SomnoDent® MAS is a custom-designed oral device that has been the subject of numerous stringent, independent, evidence-based studies that satisfy the need for safe and effective OSA treatment. The SomnoDent® MAS has a number of design features such as a streamlined design with minimal bulk, which maximizes lingual space, reduces gagging, and offers a comfortable treatment with a compliance rate of over 87% all night (*Am J Respir Crit Care Med* Vol 163. Pg 1457-1461, 2001).

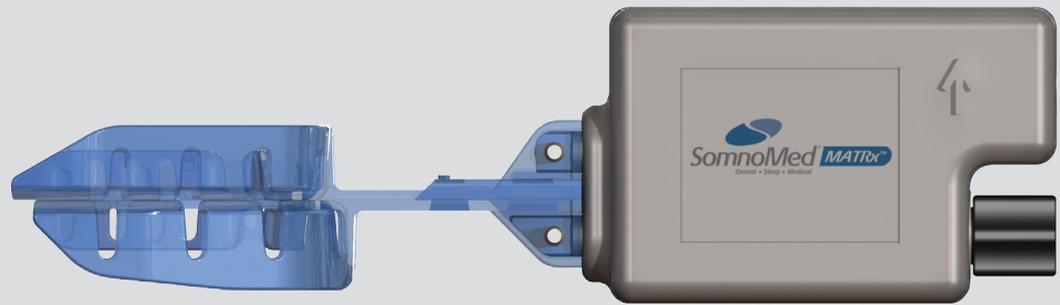
The company touts an excellent fit in both upper and lower arches with anterior and posterior contact for a stable occlusion, which prevents tooth movement and minimizes temporomandibular joint (TMJ) discomfort and injuries.

The SomnoDent MAS is constructed in two separate pieces that allow patients to open and close their mouth. This allows clear speech, yawning, and drinking without requiring patients to remove the appliance. The ability to communicate clearly while wearing the device is particularly appreciated by patients and their partners.

#### G2 Builds on Legacy

Building on the considerable legacy of the SomnoDent MAS, Barschow and White introduced the SomnoDent G2 (pending FDA approval) oral appliance at this year's American Professional Sleep Societies' (APSS) show in Minneapolis. Like other SomnoDent products, the G2 is made with a proprietary SMH BFlex polymer lining material, which enhances comfort, stability, and durability. "When we launched SomnoDent Flex 2.5 years ago, it was a big surprise in the dental sleep medicine community and raised the quality standard considerably, hence a 3-year manufacturer's warranty," says Barschow. "I compare this to our feedback on the next SomnoDent generation G2, which has taken everyone by storm—whether it is the controlled forward protrusion mechanism or the smaller metal-free design."

"Now for the first time, G2's proprietary click-on, click-off technology provides certainty and standardization around the titration of an oral appliance," adds Anthony White, vice president, SomnoMed Marketing & Academy. "This objective measure offers sleep physician's certainty in prescribing SomnoDent therapy."



MATRx Mandibular Positioner is a new device that will help sleep physicians measure effectiveness of SomnoMed's Oral Sleep Appliances.

### Oral Appliances Here to Stay

Respect for oral appliance therapy remained high at this year's APSS meeting in Minneapolis, echoing an inevitable trend that only seems to get stronger. Along with greater acceptance, foot traffic around the booth remained high, with serious inquiries outnumbering casual fact finders. "After Seattle and San Antonio, this is the third time we have had a strong presence at APSS," says White. "The response has been overwhelming. Sleep lab managers and sleep physicians came and said, 'The MATRx is the missing link here. The ability to prospectively predict which patients would be appropriate for SomnoDent therapy in a polysomnographic environment means we can, with confidence, provide patients that cannot tolerate or adhere to CPAP a second chance at therapy.'"

### Bright Future

In many ways, the APSS meeting in Minnesota reflected an industry on the cusp of change. Despite huge patient potential, lesser companies are falling by the wayside.

White believes clinicians will continue to embrace oral appliance sleep apnea therapies, but only patient-focused and evidence-based ideas will succeed. "Our products are backed by independent clinical studies validating their use," says White. "Once our new products are available, they will all have the necessary medical device approvals and meet all regulatory standards."

Viewed together, the MATRx (launch expected in Fall of this year) and G2 (release planned for beginning of 2012) are part of SomnoMed's effort to be viewed as the evidence-based medical device company that provides more than just therapy. Instead, the company is looking for a way to determine efficacy and compliance—all while spreading knowledge. An educational arm called the SomnoMed Academy fosters this mission by generating continuing education credits for the dental and medical fraternity.

Dentists, physicians' or sleep laboratory officials who wish to get involved can contact the company and purchase a starter program with collateral materials and sample devices. Participating dental professionals may choose to register for a Fundamentals Seminar, which is a 2-day continuing education event. The event is jointly presented by a physician and SomnoMed dentist that teaches dentists how to integrate dental sleep medicine and the SomnoDent therapy in their daily practice. "In accordance with the AASM guidelines, interested dentists learn why and how they need to interact with the medical community to get a proper diagnosis," says Barschow. "However, we have always maintained, and will continue to maintain, that it is the physician's role to treat and diagnose the patient. Once the SomnoDent therapy is deemed appropriate treatment, it goes to the dental arena for fitting. Patient care is for the physician, and diagnosis is for the physician."

Demand for education figures to be high, considering that dental therapy has gained firm acceptance among many segments of the market. It was not too long ago that full PSGs were considered infinitely superior to home tests, just as it was once considered unthinkable that oral appliances could be an equal, or in some cases an even better choice, than CPAP.

### Building Confidence

Ultimately, Barschow and White contend that all new products within dental sleep medicine must focus on gaining the support and confidence of the patients, dentists, and physicians that will in turn improve crucial compliance rates. "The MATRx and G2 boost confidence among patients and clinicians," says Barschow, who has more than two decades of experience with dental/medical materials and technology. "Patients are confident they are receiving the highest quality oral appliance treatment out there. That confidence brings them back into treatment, which improves compliance—and improves their lives."

For more information, visit [www.somnomed.com](http://www.somnomed.com)