

The Next Big Thing?

Establishing a novel and effective alternative to CPAP is no easy task, but the inventor of oral pressure therapy (OPT) believes he has the technology to do just that.

Matt Vaska is not your average garage tinkerer. As a Stanford-educated mechanical engineer with an affinity for medical solutions, the founder of ApniCure does not hesitate to focus his problem-solving skills on a host of vexing problems.

When his own dad could not cope with CPAP a few years ago, the 20-year medical technology veteran went looking for alternatives. "I was trying to figure out if there were other therapies," says Vaska, who founded and sold a cardiac-related company prior to starting ApniCure. "The more I learned, the more I realized this was a huge opportunity."

While acknowledging the clinical effectiveness of CPAP, Vaska believes the industry's "gold standard" leaves a lot to be desired. He ultimately attacked the problem from a mechanical perspective. "The tongue and soft palate are the bad actors," he says. "There must be a better way to move those things than putting a mask on your face every night. I started experimenting in my garage with a bunch of random ideas."

From those humble beginnings, Vaska developed The Winx™ Sleep Therapy System, which uses a proprietary platform technology called oral pressure therapy (OPT) to treat obstructive sleep apnea (OSA). The system is designed to offer a comfortable sleeping experience, allowing users to breathe naturally without a mask.

OPT is a light, oral vacuum delivered by a quiet console through a slim tube connected to a soft, flexible mouthpiece. The mouthpiece and vacuum work together to gently pull the soft palate forward and stabilize the tongue, increasing the size of the airway to allow for natural breathing during sleep.

Why Didn't I Think of That?

At this year's SLEEP show in Boston, curious physicians took a close look at the device, which is essentially a mouthpiece that fits completely inside the mouth. "It has a little bar that goes across the back that keeps your tongue from rising all the way to the roof of your mouth," explains Vaska. "That creates a little pocket between your tongue and the roof of your mouth in the back. You apply a light vacuum to that pocket—and the soft palate will move easily, almost like a sail—and pull itself up against the tongue.

"We also take advantage of a natural seal that occurs between the soft palate and the tongue so the negative pressure does not end up in the airway," he continues. "If that happened,

it would exacerbate the disease. We keep all the negative pressure in the oral cavity. There is a little shield on the front of the device to keep air from coming in the front of the mouth, so you have a completely sealed oral cavity with this device in place."

With need as the mother of invention, Vaska's idea to use negative pressure in the oral cavity proved to be the crucial lynch pin. "You don't need a mask because you breathe naturally through your nose," adds Vaska who has also developed medical devices in for cardiac surgery, electrophysiology, laparoscopy, and arthroscopy. "It's actually somewhat similar to CPAP in that there is a higher pressure in the airway and a lower pressure in the oral cavity—but we do it by lowering the pressure in the oral cavity instead of increasing the pressure in the airway."

There is currently no other FDA-approved technology available to treat sleep apnea that uses an oral vacuum, so Vaska contends that the Winx is truly something new under the sun. Along with the mouthpiece/facial interface, there is a pressure generator and a tubing set. Compliance monitoring is also available via an SD card and accompanying software.

Taken as a whole, docs at SLEEP came away intrigued, and even a bit envious. "When you explain pressure differential and how you can do it differently, a lot of physicians will say, 'Why didn't I think of that?'" says Vaska with a chucklesmile. "Once you see it, it makes a lot of sense, and that is gratifying for me. It uses something familiar, but avoids the problems of the mask."

Vaska contends that the Winx's effectiveness translates to severe apnea, in addition to mild and moderate. From a compliance standpoint, ApniCure tests show 6 hours on average per night and 90% nightly usage compliance.

All About Options

Oral appliances have made major inroads in recent years, but ApniCure officials believe their option may be more attractive—and less expensive. "Unlike with an oral appliance, where you must go to a dentist and spend months and thousands of dollars up front for fitting, we figured out how to do it in five minutes," says Vaska. "For the sleep physician, it is straight forward to provide the product, and we expect it is going to be a lot less of a hassle factor when dealing with patients."

Adding another viable treatment option to the medical world is a huge task, and ApniCure officials are not rushing the process. After securing FDA approval and increasing awareness at trade shows, the road to acceptance is still long.

Vaska has been there before with other ventures, so he has the patience for the long haul. Part of that patience stems from confidence, and a belief in the product and the market.

Benefits of the Winx system include

- soft, flexible mouthpiece allows breathing naturally through the nose without a mask or forced air;
- slim tubing that allows sleeping in any position;
- a quiet console that creates a peaceful sleeping environment for users and bed partners;
- discreet design that allows users to appear and feel natural while they sleep;
- a small, portable, and travel-friendly design;
- design that is simple to use, clean and maintain; and
- easy setup for patients to trial.

With massive demand, Vaska's colleague Steve Carlson, president and CEO of Redwood City, Calif.-based ApniCure, agrees that there is enough room for many options. "It is our goal to do it right with a careful, methodical, and controlled launch as we interface with managed care, other payors, and sales distribution," says Carlson. "In 2013, we plan to do a full United States launch."

Evidence Builds

Data presented as late-breaking abstracts at the 2012 American Thoracic Society (ATS) Conference helped build the case for oral pressure therapy (OPT).

In May 2012, ApniCure Inc, Redwood City, Calif, presented positive results from trials of the Winx™ Sleep Therapy System in patients with obstructive sleep apnea (OSA). Study results demonstrated significant improvements in apnea-hypopnea index (AHI); oxygen desaturation index (ODI); sleep architecture; and symptomatic measures of OSA; as well as high patient satisfaction with Winx.

These clinical data, as well as mechanism of action data, were presented as late-breaking abstracts during the "Diagnostic and Therapeutic Approaches in Sleep Apnea" session at the 2012 American Thoracic Society (ATS) Conference in San Francisco.

"In the ATLAST trial, Winx significantly improved the severity and symptoms of OSA, was shown to be safe and was associated with high nightly usage and patient satisfaction," said Richard K. Bogan, MD, chairman and chief medical officer of SleepMed Inc, and associate clinical professor of the University of South Carolina School of Medicine. "These are important

findings because continuous positive airway pressure (CPAP), the standard treatment for OSA, can be associated with physical and lifestyle challenges related to its forced air delivery through a mask. Winx, which allows users to breathe naturally without a mask, represents a new, non-invasive alternative for some patients with OSA, a serious disease that is associated with long-term medical and social consequences."

ATLAST Trial Design and Results

The multi-center, prospective ATLAST study examined the safety, effectiveness, and tolerability of the Winx system in 60 patients ages 32 to 80 with mild, moderate or severe OSA, with or without prior CPAP use.

Study participants underwent laboratory polysomnography at baseline with and without Winx treatment, and again following 28 nights of treatment with Winx to determine ODI and AHI, which was calculated using American Academy of Sleep Medicine criteria by a blinded scorer.

OSA symptoms were assessed with the Epworth Sleepiness Scale (ESS) and a modified Functional Outcomes of Sleep Questionnaire (mFOSQ). Nightly usage of Winx was assessed objectively by the system console which collected data on a standard data card.

The ATLAST study showed a significant reduction in AHI and ODI and was safe and durable. A substantial proportion of patients met the prospectively defined clinical success criteria, and these patients were easy to identify and included mild, moderate and severe OSA. Patients had significant improvement in sleep architecture and quality of life measures.

Patients showed high nightly compliance and preference over alternative therapies. Winx treatment was also shown to be compatible with current clinical practice due to features such as in-lab mouthpiece fitting, objective compliance monitoring, and compatibility with polysomnography systems.