
MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

MONDAY, JUNE 15, 2009

VOL. 13, No. 113

Special Reprint PAGE 1 OF 2

Compliance, PEEP are benefits of Provent sleep therapy device

With 'poster child' CEO...

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Every "gold standard" therapy has its challengers, in the form of alternative treatments promising safer/cheaper/more effective results.

And the primary therapy for sleep-disordered breathing, known as CPAP – though generally acknowledged even by its challengers to be highly effective, if not entirely "gold standard" –worthy – seems to have more than the usual contenders claiming patient attention.

CPAP (for continuous positive airway pressure) attracts a whole range of competitors because of its major drawback: It's neither aesthetically nor psychologically pleasant to wear a mask over your face, to force air in and out, while sleeping. So while CPAP is an important part of sleep clinic work and decreases the symptoms of sleep apnea and other sleep-disordered problems, it's estimated that it garners only about 50% compliance in outside-the-clinic use by those it could help.

A therapy frequently not used attracts competition—from multiple methods promising to reduce snoring (both drugs and devices), to surgery and surgical implants for the throat and mouth, to a range of oral appliances.

Enter **Ventus Medical** (Belmont, California) with its Provent Sleep Apnea Therapy, and its CEO, John McCutcheon, who told *Medical Device Daily* that he represents "the poster child" for a variety of sleep therapies, since he's tried several of them and is one of those non-compliant with CPAP.

He says that he recently joined the company only after he had used Provent for several weeks and found that it significantly improved his sleep, thus becoming an experienced advocate (but saying he's not quite yet infomercial-ready).

Highlighted by three poster sessions at last week's SLEEP 2009, the 23rd annual meeting of the **Associated Professional Sleep Societies** (Westchester, Illinois) in Seattle, Provent is deceptively simple: essentially a valve, a pair of them taped over the nostrils with a hypoallergenic adhesive while sleeping.

The valves – combining medical-grade silicone film and polypropylene materials – facilitate the in/out movement of air and have been shown to improve the breathing during

sleep of many patients and offers – perhaps it's most important benefit – simplicity of use and thus greater compliance.

Disposable after each night's use, the valve devices are offered 30 to a box. McCutcheon says a price point has not been set yet, but likely will be comparable to CPAP and significantly less than any surgical strategies.

Various therapies for sleep apnea and disordered breathing "have come and gone," McCutcheon says, largely perhaps because of the range of disorders, a whole flock between simple snoring to apnea leading to heart disease, and a whole variety of causes. Provent was FDA-cleared last year, but has been used mostly at trial centers rather than being aggressively marketed.

The reason, McCutcheon acknowledges, is that, like many 510(k)-cleared products, the company has to build confidence, and a payor foundation, by developing clinical evidence, with the posters at SLEEP 2009 being one such effort.

One of the posters, described as a "physiologic mechanism of action" study, found that Provent produced sleep improvements in eight of 11 patients. Of the eight patients, five demonstrated a "complete response" and in three what was described as a "partial response."

David Rapoport, associate professor of medicine at **New York University School of Medicine**, poster presenter, said that the findings "were associated with positive and prolonged intranasal pressure when the patient exhales."

He described this pressure as auto-positive end-expiratory pressure (autoPEEP) and said that it "keeps the airway open until the patient inhales, may increase the end-expiratory lung volume, and thus creates a pull on the trachea and upper airway. This is how Provent Therapy prevents apneic episodes and helps patients with sleep-disordered breathing."

In the eight responsive patients, "end-expiratory intranasal pressure" increased to a range between 11 cm and 26 cm H₂O during periods of complete success, whereas the non-responders' intranasal pressure ranged from 3 cm to 10 cm H₂O, with lowest pressures at the time of failure of treatment.

The researchers said that this indicates "that the increased pressure could have been the mechanism of action that keeps the airway open until the patient inhales."

Philip Westbrook, MD, emeritus professor of medicine at **UCLA** and chief medical officer for Ventus, said Provent offers a therapeutic alternative "that is discreet . . . dispos-

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able and comfortable to use throughout the night, regardless of a patient's sleep position."

In a second poster, Westbrook and colleagues showed success rates and a significant change in Apnea-Hypopnea Index (AHI) in 58 patients with sleep apnea using Provent via "expiratory resistive loading."

Provent Therapy reduced AHI from 26.6 ± 24.8 to 13.7 ± 20.1 , a 49% reduction. During the treatment night, 72% of subjects met either the $AHI < 10$ or AHI improved by at least 50% criteria; 36% met the success criteria of $AHI < 5$; 59% met $AHI < 10$; and 66% had an $AHI < 50\%$ of their baseline value. Further, 50% of subjects met both the $AHI < 10$ and AHI improved by at least 50% criteria.

Westbrook said the results indicated Provent effectiveness that is comparable to mandibular advancement, an oral device therapy, and surgical approaches, with essentially no adverse events. He noted the greater ease of use, and that Provent thus "could be an early consideration for the treatment of OSA."

The third poster used a model that built in two key considerations: that Provent therapy doesn't solve all sleep

problems but also the significant patient resistance to CPAP and its non-use.

Anne Abreu, director of reimbursement and business development at Ventus, and colleagues, in their presentation, showed that Provent may prevent a similar or greater number of abnormal breathing events as compared to CPAP.

"This model demonstrates the importance of factoring in compliance rates when choosing a therapy for treating obstructive sleep apnea," she said.

McCutcheon told *MDD* that the company is looking for "broad commercialization" of Provent sometime next year and is still working to develop the exact valve structure, or structures – chiefly whether a single-valve architecture is best or if these need to be customized to individual problems and patients.

Further out, he sees opportunities for broadening the applications, for instance, for COPD, but that the company for now will focus on the use for sleep apnea. And a key milestone could come next year with the successful pursuit of the CE mark. ■