

Obstructive Sleep Apnea: A Palatable Treatment Option?

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Summary

- ✓ **The Pillar® Palatal Implant System consists of three polyester threads that are permanently implanted in the palate (the roof of the mouth) to reduce airway obstruction in individuals with mild to moderate obstructive sleep apnea (OSA) and snoring.**
- ✓ **Three small, non-randomized uncontrolled trials reported a moderate reduction in the number of breathing interruptions during sleep, three to six months following palatal implant insertion. Statistically significant improvements in daytime sleepiness and snoring intensity were also reported.**
- ✓ **The minimally invasive surgical procedure causes mild, transient discomfort. A potential complication is partial extrusion of the implant, requiring removal and replacement.**
- ✓ **Currently, there is insufficient published evidence to determine whether palatal implants are an effective treatment option for patients with mild to moderate OSA due to palatal obstruction.**
- ✓ **Larger, randomized controlled studies are needed to determine the long-term safety and efficacy of the implants in a more diverse patient population, including those who are obese or those with comorbid medical conditions. Comparisons with existing treatments for OSA are also needed.**

The Technology

The Pillar® Palatal Implant System is a set of three tiny, braided, polyester threads that are permanently implanted in the soft palate. The procedure, which takes about 10 minutes, is done under local anesthesia by an ear, nose, and throat (ENT) specialist during a single office visit. This minimally invasive treatment is intended to reduce airway obstruction in patients with mild to moderate obstructive sleep apnea (OSA) and snoring. In the weeks following insertion, firm tissue grows around the implant, adding to the structural support of the soft palate and making it less likely to collapse into the airway during

sleep, or to vibrate, causing snoring.¹ The Pillar implant is manufactured by Restore Medical, Inc. (St. Paul, MN) and distributed in Canada by Southmedic Inc. (Barrie, ON).

Regulatory Status

The Pillar Palatal Implant System was licensed by Health Canada in August 2006,² and by the US Food and Drug Administration (FDA) in February 2004.³

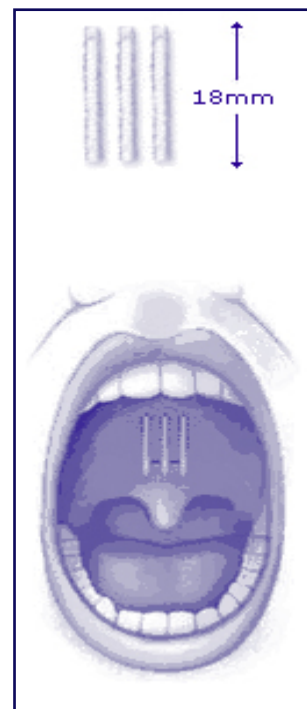


Image courtesy of Restore Medical, Inc.

During the Pillar® Procedure, three 18 mm polyester threads are implanted in the soft palate.

Patient Group

OSA affects about 4% of men and 2% of women between the ages of 30 to 60.^{4,5} Patients with OSA stop breathing repeatedly, up to hundreds of times during the night, which causes a transient arousal from deep sleep to wakefulness or a lighter sleep phase.⁶ This sleep disruption leads to excessive daytime sleepiness, impaired cognitive performance, disturbed mood, reduced quality of life, and

increased risk of traffic accidents due to sleepiness.⁷ About two-thirds of individuals with OSA are obese [defined as a body mass index (BMI) ≥ 30 kg/m²]. OSA is strongly associated with large neck circumference⁸ and snoring.⁹ OSA is also associated with an increased risk of hypertension, myocardial infarction, and stroke.^{7,10}

OSA is diagnosed in a sleep laboratory using polysomnography to measure the depth of breathing during sleep, the number of breathing cessations per hour, blood oxygen levels, and movement.⁴

An objective measure of the severity of OSA is the apnea-hypopnea index (AHI) or the number of hourly episodes of sleep arousal caused by apnea (temporary pauses in breathing) and hypopnea (decreased rate and depth of breathing). Mild OSA has been defined as an AHI of five to 14 episodes per hour; moderate as an AHI of 15 to 30, and severe as an AHI >30 .⁶ Although it may not be the best measure for OSA, AHI is the one most commonly used.⁶ There is some variation in the AHI values used to diagnose OSA severity.⁹

Current Practice

Lifestyle modifications such as losing weight, quitting smoking, abstaining from alcohol or sedatives near bedtime, and avoiding sleeping in a supine position may help resolve symptoms of OSA, but most patients require additional treatment.^{8,11}

The mainstay of therapy for OSA is life-long use of continuous positive airway pressure (CPAP) through a snug-fitting nasal mask during sleep.^{7,8,11,12} CPAP decreases sleepiness and improves quality of life, mood, and alertness in most patients.^{4,10} There is also evidence that CPAP reduces blood pressure and cardiovascular events in patients with moderate to severe OSA.⁷ However, some patients find the therapy cumbersome and obtrusive and complain of mask discomfort, frequent leaks, nasal congestion, and skin irritation.^{4,7} Long-term compliance with CPAP therapy is estimated to be 60% to 70%.¹³

Custom-fitted oral appliances that alter the position of the jaw and tongue may help patients with mild OSA who have not responded to lifestyle modifications or CPAP.^{6,11}

Uvulopalatopharyngoplasty (UPPP) is a surgical procedure to remove tissue in the soft palate or uvula in carefully selected patients with OSA who fail treatment with nasal CPAP and/or oral appliances. UPPP has been shown to reduce the AHI by 38%,⁵ but general anesthesia is required, and postoperative pain and morbidity are significant.^{6,8,14} Other surgical options for OSA include the

removal of the tonsils and adenoids, nasal or lower jaw surgery, tongue reduction procedures, or tracheostomy.¹¹

The Evidence

Several trials have assessed palatal implants for the treatment of snoring without OSA; this review, however, is limited to studies assessing the treatment for OSA.

A prospective non-randomized trial of 25 non-obese patients (BMI ≤ 30 kg/m²) with mild to moderate OSA reported a statistically significant reduction in the AHI from a mean of 16.2 events per hour to a mean of 12.1 events per hour ($p < 0.05$), 90 days after palatal implant insertion. Nineteen patients (76%) experienced a decrease in AHI, 12 of whom (48%) had an AHI ≤ 10 . Six patients (24%) had an increase in AHI. Subjective measures of daytime sleepiness (using the Epworth Sleepiness Scale) decreased from a mean of 9.7 to a mean of 5.5 ($p < 0.001$), and the degree of snoring intensity (reported by bed partners using a 10-point Visual Analog Scale) decreased from a mean of 8.4 to a mean of 4.3 ($p < 0.001$).¹⁴

A prospective non-randomized trial evaluating 53 patients (mean BMI = 28.4 kg/m²) with mild to moderate OSA reported a statistically significant reduction in AHI, from a mean of 25 events per hour to a mean of 22 events per hour ($p = 0.05$), 90 days after insertion of palatal implants.¹⁵ Daytime sleepiness decreased from a mean of 11 to a mean of 6.9 ($p < 0.001$), and the degree of snoring intensity decreased from a mean of 7.9 to a mean of 4.0 ($p < 0.001$).¹⁵

A retrospective review of 125 patients (BMI between 19.5 kg/m² and 39 kg/m²) who received palatal implants for the treatment of snoring included 22 patients with mild OSA and 15 patients with moderate OSA, who were evaluated three to six months post-procedure. Patients with OSA also received an adjunctive nasal procedure to correct obstruction. Only in the patients with mild OSA was there a statistically significant reduction in AHI from a mean of 12.9 events per hour to a mean of 9.3 events per hour (21.3% decrease, $p = 0.017$). Twenty-eight of the 37 patients with OSA (75.7%) reported a subjective improvement in snoring intensity and daytime sleepiness.¹⁶

These three trials reported moderate reductions in the number of breathing interruptions during sleep three to six months after patients received palatal implants for the treatment of mild to moderate OSA.¹⁴⁻¹⁶ However, in one study, one-quarter of the patients had an increase in the number of breathing interruptions.¹⁴

Patients recruited to these studies did not represent the general population with OSA; two studies excluded patients with large tonsils, nasal stenosis, significant or morbid obesity, or no bed partner.^{14,15} The third trial excluded patients with morbid obesity (BMI >40 kg/m²).¹⁶

A double-blind trial that is underway will randomize patients with mild to moderate OSA to receive either palatal implants or a sham procedure.¹⁷ Another randomized placebo-controlled study is evaluating the combined effectiveness of palatal implants with CPAP treatment for mild to moderate OSA.¹⁸ Results of further trials, reported at the 2006 annual meeting of the American Academy of Otolaryngology, have been submitted for publication.¹⁹

Adverse Effects

Palatal implant insertion causes minimal bleeding or discomfort, and patients usually return to normal diet and activities within 24 hours.¹

Partial extrusion of the implant can occur (where the tip of the insert can be felt through the surface of the palate tissue). Removal and re-insertion of a new implant requires another office-based procedure and local anesthesia.¹⁶ The manufacturer reports fewer than 1% partial extrusions since the product was launched in the US in 2004 for the treatment of OSA.¹ In published clinical trials, extrusion rates were reported in two of 25 patients (8%),¹⁴ 10 of 125 patients (8%),¹⁶ and 20 of 202 implants (9.9%) inserted in 63 patients.¹⁵ In one multi-centre trial,¹⁵ the majority of extrusions occurred at one site, which could be attributed to a “learning curve” effect as physicians gained experience with the new technique.

Administration and Cost

An ENT specialist inserts the implants during a single, brief office visit. After a local anesthetic is injected, a small, disposable delivery tool is used to insert the implants in the soft palate. Although the implants are intended to remain in the palate permanently, they can be removed, leaving the palate intact.¹⁴

In Canada, patients pay between C\$1,500 and C\$2,000 to have the implants inserted in a private clinic (Ryan Barnes, Southmedic Inc., Barrie, ON: personal communication, 2006 Oct 27). Additional costs include a short prophylactic course of oral antibiotics.

Cost-effectiveness studies that compare palatal implants to other OSA treatments are needed. For example, CPAP therapy costs approximately C\$2,700, including the

device (C\$1,200), with diagnosis and airflow titration in an overnight sleep laboratory.²⁰ Masks are an additional cost and require replacement every six to eight months. The amount of government assistance to cover the cost of the CPAP device varies from province to province, as does coverage from private medical insurance plans.²¹

Concurrent Developments

Various other technologies are being investigated for the treatment of OSA, including new types of oral appliances and upper airway exercise therapies.^{22,23} New treatments for obesity may also have an effect on OSA.

Rate of Technology Diffusion

ENT specialists require minimal training to perform the surgical procedure, however perfect placement requires practice.¹⁶ According to the Canadian distributor, the first palatal implants used in Canada were inserted in Ontario, in October 2006. To date, five Canadian ENT specialists have received palatal implant training (Ryan Barnes, Southmedic Inc., Barrie, ON: personal communication, 2006 Nov 20).

Implementation Issues

At present, there is insufficient published evidence to determine whether palatal implants are an effective treatment option for patients with mild to moderate OSA due to palatal obstruction. Randomized controlled studies are needed to determine the long-term safety, efficacy, and cost-effectiveness of palatal implants in a more diverse patient population, including those with obesity and/or comorbid medical conditions. Comparisons with existing treatments for OSA are also needed. From such studies, a clearer picture should emerge about which patients are likely to benefit from palatal implants.

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