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Timothy J. Walter, M.D.
Uma Marar, M.D.

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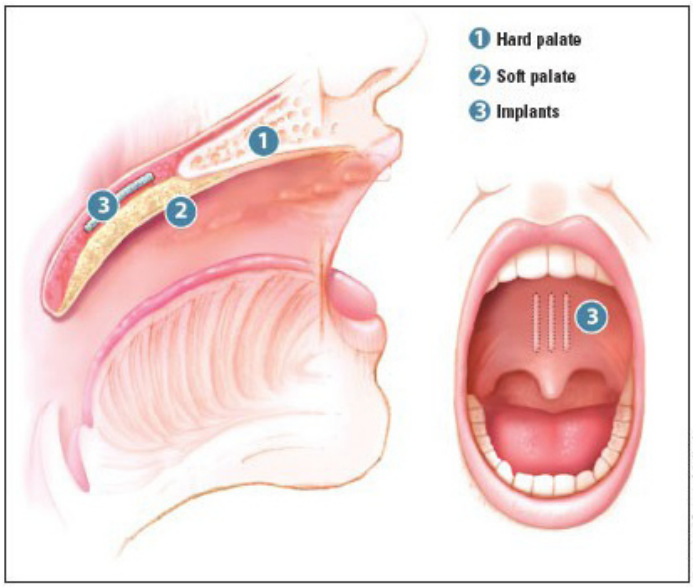
The Pillar Implant Procedure for OSA



Courtesy of Restore Medical.

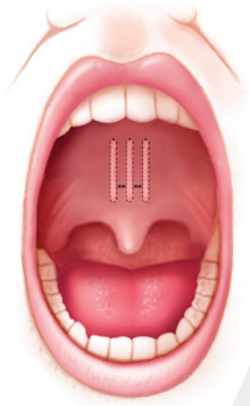
Three tiny implants add structural support to the soft palate, to eliminate the airflow obstruction that causes OSA.

Continuous Positive Airway Pressure (CPAP) therapy is the gold standard and most efficacious commonly utilized treatment in patients with Obstructive Sleep Apnea (OSA). Other treatment modalities for OSA include mandibular advancement devices and oropharyngeal surgery. A comprehensive review of 89 publications performed between 1982 and 2006 therapy involving a total of 3,027 patients with OSA comparing these treatment modalities demonstrated that CPAP therapy is effective in reducing the initial apnea-hypopnea index (AHI) by 75%, mandibular advancement devices by 42%, and uvulopalatopharyngealplasty (UPPP) by 30%.[1]

An OSA treatment option that has recently received a significant amount of publicity in the central Ohio area via television commercials is the Pillar Implant procedure. This is a form of oropharyngeal surgery involving the placement of three polyester implants in the soft palate under local anesthesia during a single-stage office procedure. The implants are placed into tissue that spans both the soft and hard palate, thus bridging the two and providing increased support of the soft palate, much like battens in a sail prevent the sail from luffing in times when the wind is low. The procedure is logical in the sense that it is minimally invasive in comparison to a UPPP or other oropharyngeal surgery utilized in the treatment of OSA, but what is the true efficacy of the pillar procedure?

Until 2006 very little data regarding the Pillar Implant procedure was available. One prospective, non-randomized study of 53 patients with OSA conducted at 5 clinical sites demonstrated a small decrease in the AHI from 25.0 +/- 13.9 to 22.0 +/- 14.8 events/hour (P = 0.05) following the Pillar Implant procedure.[2] The largest study looking at the efficacy of the palatal pillar procedure involved 62 non-obese adults with history of snoring, daytime sleepiness, and mild/moderate OSA that were randomized to receive palatal implants (n = 31) or placebo procedure (n = 31). Although the authors concluded that the treatment group was significantly improved compared with the placebo group, improvement in the AHI was negligible at 0.9 +/- 4.3.[3]

Uvulopalatopharyngoplasty (UPPP) is the most commonly performed type of oropharyngeal surgery in regards to the treatment of OSA. As the success rate of UPPP is relatively low, some interest has arisen as to whether or not there may be a role for the placement of palatal pillars in the soft palatal tissue remaining following a failed UPPP. One prospective, nonrandomized study of 26 patients with failed UPPP who underwent the Pillar Implant procedure as a revision procedure was performed in patients with mild to moderate OSA, and presented with recurrence or persistence of snoring after UPPP. Although postoperative snoring levels (3.4 +/- 1.8) and ESS (8.7 +/- 1.8) significantly improved (P < .0001), subjective cure was only achieved in 21.7% of patients.[4] A



similar more recent prospective, nonrandomized study involving 16 patients with failed UPPP after a 6-month follow-up period also demonstrated a very modest improvement in the AHI from 18.08 +/- 6.02 to 16.8 +/- 5.05 events/h (P = 0.03).[5]

These studies performed over the past several years have demonstrated that the Pillar Implant procedure may at best provide marginal improvement in the patients with mild to moderate obstructive sleep apnea.

Currently there is no practice parameter paper in regards to the use of the Pillar Implant procedure in patients with OSA. Likewise, no published studies are available in regards to the efficacy of the Pillar Implant procedure in patients with moderate to severe OSA, patients with OSA with significant oxygen desaturations, or patients with OSA with significant commonly associated co-morbidities such as hypertension, diabetes, congestive heart failure, myocardial infarction, or stroke.

It is not clear why studies involving these patient groups have not been performed. Until such data becomes available, it may be advisable to limit the use of this procedure to patients with mild OSA, without significant oxygen desaturations or other co-morbidities, who fail or are non compliant with CPAP therapy, and who are not good candidates for or who do not wish to pursue treatment with mandibular advancement devices or other forms of oropharyngeal surgery.

[1] Sleep Breath. 2007 Mar;11(1):1-22.
[2] Otolaryngol Head Neck Surg. 2006 Oct;135(4):549-54.
[3] Otolaryngol Head Neck Surg. 2008 Feb;138(2):209-16.
[4] Laryngoscope. 2006 Nov;116(11):1956-61.
[5] Eur Arch Otorhinolaryngol. 2008 Jun;265(6):687-93.