

Soft Palate Implants: A New Treatment for Obstructive Sleep Apnea?

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Introduction

Pillar® soft palate implants are a new and effective treatment for snoring. Patient and bed partner satisfaction remain high one year following implant.^{1,2} The effects of the implants in the treatment of obstructive sleep apnea have recently been studied in Europe. Clinically significant decreases in AHI and daytime somnolence have been reported.³ This study was designed to study the morbidity and efficacy of the palatal implants in mild to moderate sleep apneics in the US population.

Materials & Methods

This study is an on-going prospective, non-randomized trial that is being conducted at two sites (Hinsdale, Illinois and Cleveland, Ohio). Patients are screened according to the inclusion/exclusion criteria shown in Table 1.

Table 1. Inclusion Criteria

Patients were included if:

- Age > 18 years
- Apnea-hypopnea index (AHI) 10-30 episodes/hour
- Body mass index (BMI) ≤ 32 kg/m²
- Soft palate length > 25 mm
- No significant nasal obstruction
- No previous history of pharyngeal surgery

To date, 28 patients who met the criteria were chosen for implantation on an "intent to treat" basis. There are 4 females and 24 males enrolled in the study with a mean age of 48 years (range of 32-76) and a mean body mass index of 28.3 kg/m². Subjective quality of life data measured at baseline and 30 days post-procedure include excessive daytime sleepiness, the number of observed apneas by bed partners, snoring intensity, pain, speech changes and swallowing difficulties. Follow-up polysomnography is scheduled for 90 days post-procedure at which time optimal tissue response to the implant is expected. In addition, for the purpose of refining patient selection criteria, tonsil size, laryngoscopy grade, tongue position, level of nasal obstruction, and uvula size at baseline were recorded.

For each patient, three (3) implants were placed in the patient's soft palate under local anesthesia during a single-stage, office procedure.

Results & Discussion

The initial results on 24 patients followed for 30 days in this ongoing study are encouraging. No significant complications were observed during the procedure or at any of the follow-up periods.

Speech issues, swallowing difficulties, and pain associated with the procedure are shown in Figure 1. Minimal pain and swallowing difficulty was noted at 24-72 hours, but diminished quickly. Speech was unchanged by the procedure.

Mean daytime somnolence, as measured by the Epworth Sleepiness Scale (ESS), improved from 11.3 ± 4.5 to 7.6 ± 3.6 ($p < 0.001$). (Figure 2)

Snoring intensity, as measured by a visual analog scale (VAS), was significantly reduced from 8.4 ± 1.5 to 5.2 ± 2.7 ($p = 0.001$) as shown in Figure 3. Eighty-two percent (82%) of bed partners noted improvement in the patient's snoring at 30 days.

At 30 days post-procedure, only 20% of the bed partners observed apneas, compared to 71% at baseline. (Figure 4)

A partial extrusion of the implant was seen in a small number of patients. The partially extruded implants were removed without incident and replaced. The investigators feel extrusions may result from superficial placement. Implants need to be placed deep within the palatal muscle to minimize the potential for partial extrusions.

Conclusion

Early experience, though limited, suggests that the new Pillar® Palatal Implant System is associated with minimal morbidity and provides improvements in quality of life measures including daytime somnolence, snoring intensity, and number of observed apneas. Ninety day polysomnography is intended for all patients to evaluate the treatment's effectiveness on AHI reduction and future data will be evaluated to optimize patient selection criteria. Active recruitment for this study is ongoing.

Figure 1 - Pain, Speech and Swallowing

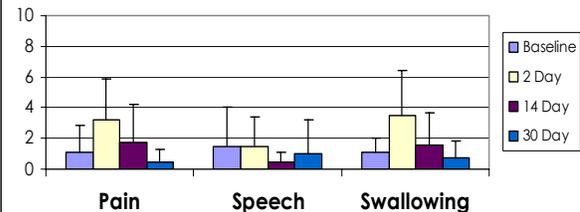


Figure 2 - Daytime Sleepiness

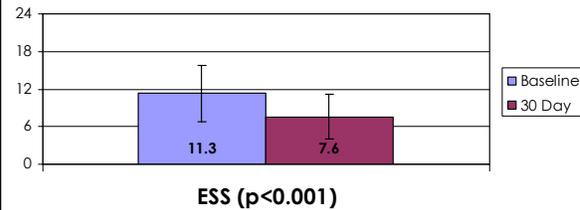


Figure 3 - Snoring Intensity

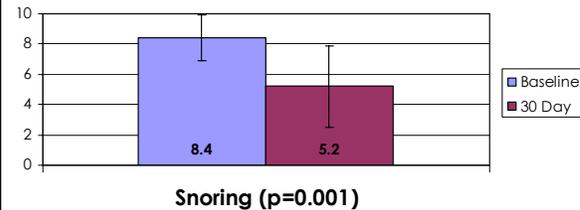
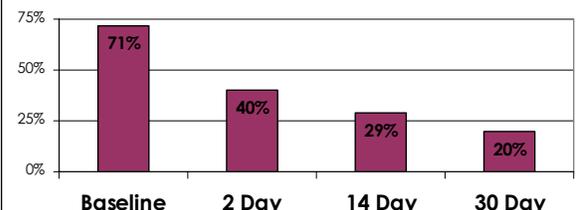


Figure 4 - Observed Apneas



Acknowledgments

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