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Effect of the Pillar Implant on Snoring and Mild Obstructive Sleep Apnea: A Multicenter Study in Korea

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Objectives/Hypothesis: The effect of the Pillar implant on mild sleep-disordered breathing (SDB) has been assessed in various studies. However, most of these were conducted among a non-Asian population at a single institution. Therefore, the aim of this study was to prospectively evaluate the efficacy of the Pillar implant in Asian patients with simple snoring and mild obstructive sleep apnea (OSA) at multiple centers.

Study Design: Multicenter prospective clinical trials.

Methods: This study included consecutive subjects with simple snoring or mild OSA. We examined subjective symptoms (snoring intensity, frequency, witnessed apnea, and daytime sleepiness) and objective snoring and respiratory parameters (snoring duration [proportion of sleep while snoring louder than 50 dB], snoring loudness, apnea–hypopnea index, respiratory disturbance index, minimum arterial oxygen saturation, and oxygen desaturation index $\geq$ 4%) at 3 to 6 months after surgery. Adverse events were also investigated.

Results: Twenty-nine subjects with mild SDB completed the study. Whole group analysis found significant improvements in various subjective symptoms, but not in the objective snoring and respiratory parameters. A subgroup analysis of subjects with mild OSA (n = 11) found significant alleviation in various subjective symptoms, apnea–hypopnea index, respiratory disturbance index, and oxygen desaturation index $\geq$ 4%. No major complication related to surgery was observed, and most minor adverse effects were resolved without morbidity.

Conclusions: In selected Korean patients, the Pillar implant significantly improved not only subjective symptoms of mild SDB but also respiratory disturbances in mild OSA.

Key Words: Pillar implant, snoring, obstructive sleep apnea.

Level of Evidence: 2b.

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INTRODUCTION

Sleep-disordered breathing (SDB) describes a wide disease spectrum, encompassing everything from simple snoring to severe obstructive sleep apnea (OSA).[1] It is known to cause various problems such as somnolence, fatigue, headache, cardiovascular disease, deceased quality of life, and increased motor vehicle accidents.[2–5] Therefore, active treatment is recommended, including positive airway pressure, surgery, or an oral appliance.[6]

Significant comorbidities usually accompany moderate-to-severe OSA, however, and not simple snoring or mild OSA.[7] Several studies have indicated that simple snoring or mild OSA might also cause some comorbidities, but the chances are very low compared with moderate-to-severe OSA.[8,9] Treatment also focuses mainly on moderate-to-severe OSA and is often inappropriate for simple snoring or mild OSA when the inconvenience and aggressiveness of treatment are considered.[6] For patients with simple snoring or mild OSA, the alleviation of snoring is the main goal of treatment. Several trials have examined options for reducing snoring or mild OSA, such as laser-assisted uvuloplasty.[10,11] However, their results are relatively unsatisfactory; some treatments have even worsened snoring or apnea.[11]

The Pillar implant (Medtronic, Minneapolis, MN) was invented for the treatment of snoring or mild OSA in early 2000.[12] The three-piece implant is made of a woven polyester material and is inserted into the soft palate in a parallel orientation. It was designed to reduce vibration or narrowing of the soft palate by increasing its stiffness.

The effectiveness of the Pillar implant for simple snoring or mild OSA has been evaluated in various

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TABLE I.
General Characteristics at Baseline (N = 29).

Variable	Unit	Study Population
Demographic data		
Age	years	43.6 ± 12.3
Male/female	number	14/15
BMI	kg/m^2	22.3 ± 1.7
Medical history		
HTN/DM/Hepatitis/TB	number	2/0/1/0
Physical examination		
Tonsil size	grade (1–4)	1.1 ± 0.3
Palate–tongue level	grade (1–4)	1.8 ± 0.4

Data are mean ± SD.
All subjects were identified as Friedman stage II.
BMI = body mass index; HTN = hypertension; DM = diabetes mellitus; TB = tuberculosis.

studies.[13–17] However, most of these studies were conducted among a non-Asian population at a single center. Therefore, the purpose of this study was to investigate the efficacy of the Pillar implant in Asian patients with simple snoring and mild OSA prospectively at multiple centers.

MATERIALS AND METHODS

This study was conducted prospectively at five medical centers in Korea (Asan Medical Center, Konkuk University Hospital, Korea University Ansan Hospital, Kyung Hee University Hospital, and Seoul National University Bundang Hospital) and approved by the institutional review board of each center.

Subjects

Thirty patients (2–8 subjects per center) with simple snoring or mild OSA were enrolled consecutively. Each patient visited a participating center for the treatment of SDB-related symptoms (e.g., snoring, witnessed apnea, daytime drowsiness, etc.) and was found to have an apnea–hypopnea index (AHI; events/hour) < 15 following a sleep test, such as standard polysomnography or portable monitoring. Inclusion criteria were: 1) simple snoring or mild OSA (AHI < 15 in a sleep test); 2) body mass index (BMI; kg/m^2) < 25; 3) tonsil size grade 1 (tonsils hidden within the pillars) or grade 2 (tonsils extending to the pillars) and palate–tongue position 1 (the entire uvula and tonsils or pillars are clearly visible) or palate–tongue position 2 (the uvula but not the tonsils are visible); 4) suspected retropalatal obstruction; and 5) no response to or refusal of alternative (conservative or medical) treatment. Exclusion criteria were: 1) soft palate length < 25 mm; 2) medically unstable condition or pregnancy; 3) alcohol or drug abuse; 4) bleeding tendency or diabetes; and 5) patients expected to have difficulty in the study for other reasons.

Study Protocol

Before the Pillar implant procedure, we obtained informed consent from all patients and collected data on subjective symptoms, including snoring intensity (visual analogue scale [VAS] 0–10) and frequency (days/week), witnessed apnea (VAS 0–10) and daytime sleepiness (Epworth Sleepiness Scale [ESS] 0–24). Height and body weight were also measured. Patients underwent a sleep test using the Watch-PAT 200 device (Itamar Medical Ltd., Caesarea, Israel) for measuring objective snoring parameters (snoring duration [proportion of sleep while snoring louder than 50 dB], snoring loudness) and comparing objective treatment outcomes (AHI, respiratory disturbance index [RDI], minimum arterial oxygen saturation [minimum SaO_2], oxygen desaturation index ≥ 4% [ODI4]) before and after the Pillar implant procedure. The Pillar implant was inserted under local anesthesia. Three implants were placed in the midline and just off the midline, as previously described. At 7 to 14 days after surgery, we evaluated adverse events including pain, foreign body sensation, and swallowing difficulty using VAS (0–10) and the operation site for mucosal injury, infection, or extrusion of the implants. In addition, we asked patients about subjective symptoms, including snoring intensity, frequency, and witnessed apnea. Body weight was also measured. At 30 days after surgery, we repeated the same evaluation as on the previous visit, adding an evaluation of excessive daytime sleepiness. At 3 to 6 months after surgery, we repeated the same evaluation as on the previous visit, adding sleep examination (Watch-PAT 200) and questionnaires about bed partner satisfaction (VAS 0–10) and intention to recommend the Pillar implant to other patients (VAS 0–10).

Statistical Analysis

Intention-to-treat was analyzed. Continuous data are displayed as mean ± standard deviation (SD). Comparisons in variables before and after Pillar implant procedure were performed with the paired *t* test for parametric comparisons and the Wilcoxon signed-rank test for nonparametric comparisons. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) Version 20.0 (SPSS, Inc., Chicago, IL). Statistical significance was accepted when *P* value < .05.

RESULTS

Subjects

Out of 30 patients, 29 subjects with mild SDB completed the study (Table I). One patient dropped out due to extrusion of implant. Eighteen patients were simple snorers, and eleven had mild OSA.

Subjective Symptoms

All subjective symptoms changed significantly after the Pillar implant procedure (Table II). Intensity of snoring decreased significantly 3 to 6 months after surgery (from 6.3 ± 1.5 to 3.7 ± 2.3; $P < .001$). There was a significant reduction in frequency of snoring following Pillar implant insertion (from 5.5 ± 1.4 to 4.0 ± 2.0 days/week; $P < .001$). After surgery, witnessed apnea was alleviated significantly (from 2.3 ± 2.2 to 0.7 ± 1.2; $P < .001$). Significant change was also observed in daytime sleepiness after surgery (from 9.6 ± 4.0 to 7.7 ± 3.7 on ESS; $P = .001$).

Objective Test Results

There were no significant changes in objective findings, including snoring duration (from 18.2 ± 24.0 to 14.7 ± 20.4%; $P = .195$), snoring loudness (from 46.1 ± 6.1 to 45.5 ± 5.2 dB; $P = .419$), AHI (from 4.6 ± 3.9 to 5.3 ± 5.1; $P = .562$), RDI (from 13.3 ± 10.8 to

TABLE II.
Changes in Subjective Symptoms and Sleep Test Results in Patients With Mild Sleep-Disordered Breathing After Pillar Implant (N = 29).

	Before	After	*P* Value
BMI, kg/m^2	22.3 ± 1.7	22.5 ± 1.8	0.073
Subjective symptoms			
Snoring intensity, VAS (0–10)	6.3 ± 1.5	3.7 ± 2.3	< 0.001*
Snoring frequency, days/week	5.5 ± 1.4	4.0 ± 2.0	< 0.001*
Witnessed apnea, VAS (0–10)	2.3 ± 2.2	0.7 ± 1.2	< 0.001*
EDS, Epworth Sleepiness Scale (0–24)	9.6 ± 4.0	7.7 ± 3.7	0.001*
Objective sleep test results			
Snoring duration, % of sleep while snoring > 50 dB	18.2 ± 24.0	14.7 ± 20.4	0.195
Snoring loudness, mean dB	46.1 ± 6.1	45.5 ± 5.2	0.419
pAHI, events/hour	4.6 ± 3.9	5.3 ± 5.1	0.562
pRDI, events/hour	13.3 ± 10.8	11.1 ± 7.5	0.232
Minimum SaO_2, %	91.0 ± 3.7	92.5 ± 3.7	0.188
ODI4, events/hour	2.5 ± 2.4	2.5 ± 2.7	0.509

Data are mean ± SD.
**P* value < .05.
AHI = apnea-hypopnea index; BMI = body mass index; EDS = excessive daytime sleepiness; ODI4 = oxygen desaturation index ≥ 4%; p = PAT (peripheral arterial tonometry); RDI = respiratory disturbance index; SaO_2 = arterial oxygen saturation; VAS = visual analogue scale.

11.1 ± 7.5; P = .195), minimum SaO_2 (from 91.0 ± 3.7 to 92.5 ± 3.7%; P = .195), and ODI4 (from 2.5 ± 2.4 to 2.5 ± 2.7; P = .509) after the Pillar implant procedure (Table II).

Adverse Events

Two pieces of Pillar implant were extruded in one patient (who dropped out) 7 days after surgery. The mean scores for pain, foreign body sensation, swallowing, and speech difficulty were 2.0 ± 1.5, 2.4 ± 1.7, 1.8 ± 1.8, and 0.6 ± 1.0, respectively, 7 to 14 days after surgery. All of the scores became less than 1.0 at 30 days. No other specific adverse events occurred for 3 to 6 months after the surgery.

Bed Partner Satisfaction and Recommendation

The mean score of bed partner satisfaction was 5.0 ± 2.4 3 to 6 months after Pillar implant insertion. The mean score of intention to recommend the Pillar implant to other patients 3 to 6 months following surgery was 6.6 ± 2.5.

Subgroup Analysis With Mild OSA

Patients with mild OSA saw significant change in subjective symptoms, including snoring intensity (from 6.3 ± 1.4 to 3.0 ± 1.5; P < .001), snoring frequency (from 5.2 ± 1.3 to 3.0 ± 1.9 days/week; P < .001), witnessed apnea (from 3.3 ± 2.6 to 1.0 ± 1.7; P < .001), and daytime sleepiness (from 9.1 ± 3.4 to 7.1 ± 3.7; P = .001) (Table III).

The patients also experienced significant improvements in AHI (from 8.4 ± 3.6 to 6.3 ± 3.9; P = .018), RDI (from 19.2 ± 14.9 to 10.9 ± 5.5; P = .008), and ODI4 (from 4.8 ± 2.3 to 3.4 ± 2.5; P = .027), but not in snoring duration (from 26.4 ± 26.9 to 24.5 ± 24.4%; P = .802), snoring loudness (from 48.9 ± 7.4 to 48.5 ± 6.2 dB; P = .803), and minimum SaO_2 (from 88.6 ± 3.7 to 91.1 ± 4.6%; P = .176).

DISCUSSION

This study was designed to estimate the efficacy of the Pillar implant among Koreans with simple snoring and mild OSA prospectively at multiple institutions. Our results suggest that various subjective SDB symptoms were alleviated significantly after Pillar implant insertion. In addition, we confirmed that respiratory disturbances improved significantly following surgery in patients with mild OSA.

In the current study, significant improvement in subjective snoring intensity (from 6.3 ± 1.5 to 3.7 ± 2.3; P < .001) was found in subjects with mild SDB after the Pillar implant procedure. The Pillar implant decreased snoring intensity by 41.3%. These results are similar to those of the previous meta-analysis study evaluating the efficacy of the Pillar implant in snoring and mild-to-moderate OSA, which found that snoring decreased significantly after surgery (standardized mean difference [SMD], −0.591; 95% confidence interval [CI], −0.753 to −0.429; P < .001).[18]

To obtain objective data related to snoring in our study, we used the Watch-PAT 200, which uses a microphone to measure snoring duration (proportion of sleep while snoring louder than 50 dB) and snoring loudness (dB). Snoring duration (from 18.2 ± 24.0 to 14.7 ± 20.4 %; P = .195) and snoring loudness (from 46.1 ± 6.1 to 45.5 ± 5.2 dB; P = .419) decreased after surgery. However, the differences were not statistically significant. There are two considerations related to these results. First, the sample size was relatively small. To the best of our knowledge, the present study is the first clinical research or pilot investigation to compare objective

TABLE III.
Subgroup Analysis in Patients With Mild Obstructive Sleep Apnea Syndrome Before and After Pillar Implant (N = 11).

	Before	After	*P* Value
BMI, kg/m^2	22.3 ± 1.2	22.3 ± 1.2	0.993
Subjective data			
Snoring intensity, VAS (0–10)	6.3 ± 1.4	3.0 ± 1.5	0.001*
Snoring frequency, days/week	5.2 ± 1.3	3.0 ± 1.9	0.011*
Witnessed apnea, VAS (0–10)	3.3 ± 2.6	1.0 ± 1.7	0.010*
EDS, Epworth sleepiness scale (0–24)	9.1 ± 3.4	7.1 ± 3.7	0.031*
Objective data			
Snoring duration, % of sleep while snoring > 50 dB	26.4 ± 26.9	24.5 ± 24.4	0.802
Snoring loudness, mean dB	48.9 ± 7.4	48.5 ± 6.2	0.803
pAHI, events/hour	8.4 ± 3.6	6.3 ± 3.9	0.018*
pRDI, events/hour	19.2 ± 14.9	10.9 ± 5.5	0.008*
Minimum SaO_2, %	88.6 ± 3.7	91.1 ± 4.6	0.176
ODI4, events/hour	4.8 ± 2.3	3.4 ± 2.5	0.027*

Data are mean ± SD.
*P value < .05.
AHI = apnea-hypopnea index; BMI = body mass index; EDS = excessive daytime sleepiness; ODI4 = oxygen desaturation index ≥ 4%; p = PAT (peripheral arterial tonometry); RDI = respiratory disturbance index; SaO_2 = arterial oxygen saturation; VAS = visual analogue scale.

snoring information such as snoring duration and snoring loudness using the Watch-PAT 200 in SDB patients before and after Pillar implant insertion. Therefore, further study with a larger sample size is required to acquire more certain outcomes data. Second, environmental noise (e.g., sound associated with a bed partner, television, radio, outside, etc.) may be included because the Watch-PAT 200 was used at home in this study. To reduce this possibility, an in-laboratory sleep test is needed in a further clinical trial.

In a subgroup analysis of the patients with mild OSA, we found that the Pillar implant significantly changed not only all of the subjective symptoms but also respiratory disturbances. In particular, significant decreases were shown in daytime sleepiness (from 9.1 ± 3.4 to 7.1 ± 3.7; $P = .001$), AHI (from 8.4 ± 3.6 to 6.3 ± 3.9; $P = .018$), and RDI (from 19.2 ± 14.9 to 10.9 ± 5.5; $P = .008$). The Pillar implant reduced ESS, AHI, and RDI by 22.0%, 25.0%, and 43.2%, respectively. These outcomes correspond with the previous randomized controlled study, which reported that significant improvements in ESS (from 12.7 ± 2.7 to 10.2 ± 3.1) and AHI (from 23.8 ± 5.5 to 15.9 ± 7.6) were observed in the treatment group compared with the control group.[17] The previous meta-analysis also found that ESS (SMD, −0.481; 95% CI, −0.606 to −0.358; $P < .001$) and AHI (SMD, −0.378; 95% CI; −0.619 to −0.138; $P = .002$) significantly declined in patients with mild to moderate OSA after Pillar implant insertion.[18]

The Pillar implant procedure is a relatively safe, minimally invasive soft palate surgery. However, some postoperative adverse effects or complications are possible, such as extrusion, pain, speech problems, foreign body sensation, or swallowing discomfort. In this study, no critical or serious complications were found after Pillar implant insertion. Of 30 subjects, one experienced two extrusions of the Pillar implant 7 days postoperatively and dropped out of the study. Other complications, including pain, foreign body sensation, swallowing and speech difficulty, were temporary and were alleviated without morbidity within 3 to 6 months following the Pillar implant procedure.

In the present study, we investigated bed partner satisfaction and intention to recommend the Pillar implant to other patients at the final visit (3 to 6 months after surgery). Average bed partner satisfaction and intention to recommend to others 3 to 6 months after surgery was 5.0 ± 2.4 and 6.6 ± 2.5, respectively. These results indicate that following the Pillar implant surgery, bed partner satisfaction and intention to recommend to others were moderately positive.

There are a few limitations in the study. First, this clinical trial was not a randomized controlled study. Second, two considerations relevant to the objective measure of snoring sound, as previously described, could be addressed using in-laboratory sleep testing. Third, the discrepancy between subjective and objective snoring outcomes was found. The placebo effect may be associated with the subjective improvements. Fourth, this study was performed in Asian patients with mild SDB. Therefore, results of our study may be different from those of study for other ethnicities, including Caucasians.

CONCLUSION

The main findings of the current study are as follows: 1) The Pillar implant significantly improved various subjective symptoms such as snoring intensity and frequency in appropriately selected Korean patients with mild SDB; 2) The pillar implant also significantly alleviated respiratory disturbances such as AHI and RDI in patients with mild OSA; and 3) The Pillar implant is a relatively safe procedure and results in moderately positive bed partner satisfaction and intention to recommend to others.

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