Efficacy of the Pillar Implant in the Treatment of Snoring and Mild-to-Moderate Obstructive Sleep Apnea: A Meta-Analysis

Ji Ho Choi, MD, PhD; Soo-Nyung Kim, MD, PhD; Jae Hoon Cho, MD, PhD

Objectives/Hypothesis: The Pillar implant is one of the surgical options for snoring and obstructive sleep apnea (OSA). It is designed to be inserted into the soft palate to reduce vibration and collapsibility. The efficacy of the Pillar implant has been evaluated in various studies. However, only one study conducted a meta-analysis of the findings, and was based on only three studies. We tried to get a more definite conclusion on the efficacy of the Pillar implant.
Study Design: Meta-analysis.
Methods: Efficacies were analyzed separately, one for snoring and the other for mild-to-moderate OSA. We searched MEDLINE, LILACS, SCOPUS, and the Cochrane Library. The key words "snoring AND implants" were used for snoring, and "apnea AND implants" for OSA. Seven studies for snoring and seven studies for mild-to-moderate OSA were finally included for meta-analysis. For snoring patients, a visual analogue scale that is scored by the bed partner was used to evaluate the loudness of the snoring sound.
Results: The Pillar implant reduced snoring sound significantly (standardized mean difference [SMD], -0.591; 95% confidence interval [CI], -0.753 to -0.429, $P < .001$). For mild-to-moderate OSA patients, the Pillar implant significantly reduced the Epworth Sleepiness Scale (SMD, -0.481; 95% CI, -0.606 to -0.358, $P < .001$), and apnea-hypopnea index (SMD, -0.378; 95% CI, -0.619 to -0.138, $P = .002$). Mean extrusion rate was 9.3% (95% CI, 7.0 to 12.2%).
Conclusions: The present results indicate that the Pillar implant has a moderate effect on snoring and mild-to-moderate OSA. However, we need more studies with high level of evidence to arrive at a definite conclusion.
Key Words: Pillar implant, snoring, obstructive sleep apnea, meta-analysis.
Laryngoscope, 123:269–276, 2013

INTRODUCTION

For patients with snoring or obstructive sleep apnea (OSA), various treatment modalities have been introduced and their efficacies have been evaluated.[1–8] The efficacy of positive airway pressure therapy in reducing symptoms, such as daytime sleepiness and cardiovascular complications, has been repeatedly proven through numerous studies.[5,6] However, low adherence to this therapy has spurred people to seek alternative treatments including upper airway surgery. Various surgical procedures on the upper airway have been attempted for snoring and OSA.[2,8] Yet, their efficacy remains equivocal.[2] This is mainly because of a shortage of high-level evidence on the surgical results and the absence of definite criteria about surgical success. From ethical and practical standpoints, sham surgery for snoring or OSA is not easily accepted, unlike sham positive airway pressure, which makes it impossible to conduct a controlled study to yield high-level evidence, as for positive airway pressure. Moreover, the definition of surgical success varies between studies and the clinical validity on each definition remains unproven.[9-13] For example, success criteria such as an apnea-hypopnea index (AHI) score <5 or <20 is quite artificial and lacks evidence-based grounding.

In spite of all these limitations, a few systematic reviews of surgical treatment have been published.[2,4,8,9,11,13] Most of them have dealt with laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, and maxillomandibular advancement. Relatively clear conclusions for each procedure have been reached. Laser-assisted uvulopalatoplasty failed to show any clinical efficacy on sleep-related breathing disorder, and so is no longer recommended as a treatment for snoring or OSA.[9,12,13] Uvulopalatopharyngoplasty, which has been the most frequently used surgical method, does not reliably normalize AHI when treating moderate-to-severe OSA.[9,12,13] Although rather aggressive, maxillomandibular advancement is considered to be the only surgical procedure except for tracheotomy to reduce AHI significantly and consistently.[8–10,12,13]

In addition to above procedures, the Pillar implant (Medtronic, Minneapolis, MN) has been used since early 2000.[14,15] The Pillar implant was designed to reduce vibration or narrowing of the soft palate by increasing its stiffness.[14] The implant is made of a woven polyester

material, and three pieces of implant are inserted into the soft palate in a parallel orientation. It was approved in 2002 by the US Food and Drug Administration for treatment of snoring and in 2004 for mild-to-moderate OSA. The efficacy of the Pillar implant has been evaluated in various studies. However, only one of these was a meta-analysis, and was based on only three studies, all published before June 2008.[13]

The aforementioned meta-analysis was insufficient to draw any definite conclusion about the efficacy of the Pillar implant due to the small number of studies. To address this, we searched studies published from January 2002 to March 2011 and meta-analyzed not only the change of daytime sleepiness and AHI, but also snoring loudness after the instillation of the Pillar implant.

MATERIALS AND METHODS

Literature Sources and Study Identification

We searched MEDLINE, LILACS, SCOPUS, and the Cochrane Library from January 2002 to March 2011 to identify interventional studies of the Pillar implant. Separate searches were conducted for snoring and for OSA. To identify eligible studies for snoring, the key words "snoring AND implants" were used. For OSA studies, the key words were "apnea AND implants." Two reviewers, working independently, screened all abstracts and titles for candidate studies and discarded studies that were not related to the Pillar implant. After the initial screening, they reviewed the full text publications for eligibility, and disagreements were resolved by consensus. Only studies written in English were selected.

Study Selection

All of the studies were included in which the Pillar implant was used as a single surgical procedure for the treatment of snoring or mild-to-moderate OSA. We did not consider any further specific criteria for inclusion. However, studies involving the Pillar implant used as a salvage procedure after failure of previous upper airway surgery or a combined surgery with other ones were excluded. The efficacy of the Pillar implant on snoring and OSA was also separately analyzed. For snoring, we included studies that provided both a pre- and postprocedure visual analogue scale (VAS) of snoring sound loudness. The VAS score, which was usually reported by the bed partner, ranged from 0 to 10, with 0 being no snoring sound and 10 being the loudest sound imaginable. It was not mandatory to perform polysomnography to rule out OSA. For OSA, we included studies that provided both pre- and postprocedure Epworth Sleepiness Scale (ESS) and AHI. The ESS was estimated by a questionnaire soliciting each subject to rate his/her probability of falling asleep on a 0 to 3 scale of increasing probability for eight different situations. The scores for the eight questions were added together to obtain a single number. A number in the 0 to 9 range was considered to be normal, whereas a number ranging from 10 to 24 indicated daytime sleepiness. The AHI is a measure of the means average number of apnea and hypopnea episodes per hour during sleep. OSA was defined as an AHI or respiratory disturbance index $\geq$5/hour. Implantation of the Pillar implant is typically done under local anesthesia.

Data Abstraction

If two or more studies presented the same data from a single patient population, we included these data only once in our analyses. From the studies about the effect of pillar implant on snoring, we abstracted data regarding patient number, follow-up duration, pre- and postprocedure VAS, P value in comparison between pre- and postprocedure VAS, and the extrusion rate of the implant after the procedure. From the OSA studies, we abstracted data regarding patient number, follow-up duration, pre- and postprocedure ESS, P value in comparison between pre- and postprocedure ESS, pre- and postprocedure AHI, P value in comparison between pre- and postprocedure AHI, and the extrusion rate of the implant after the procedure.

Statistical Analyses

VAS, ESS, AHI, and extrusion rate were statistically analyzed. Mean values of pre- and postprocedure VAS, ESS, and AHI were provided in all studies, whereas standard deviation values were not. Heterogeneity was calculated with the Cochran Q statistic test and the I^2 test. The I^2 test describes the rate of variation across studies because of heterogeneity rather than chance and ranges from 0 (no heterogeneity) to 100 (maximum heterogeneity). All results are reported with 95% confidence intervals (95% CI), and all P values were two-tailed. When a significant heterogeneity among the outcomes was found ($I^2 > 50$), the random-effects model according to DerSimonian-Laird was used. This model assumes that the true treatment effects in the individual studies may be different from one another and that these are normally distributed. In this study, the random-effects model was used only for analysis of AHI ($I^2 = 69.5\%$). Those outcomes that did not present with heterogeneity ($I^2 < 50$) were analyzed with the fixed-effects model. The fixed-effects model uses the inverse variance approach, and it is assumed that all studies come from a common population. VAS ($I^2 = 0.0\%$), ESS ($I^2 = 0.0\%$), and extrusion rate ($I^2 = 21.0\%$) were analyzed by the fixed-effects model. Because of the small number of studies in each subgroup, we used a funnel plot, Begg's test, and Egger's test simultaneously to detect publication bias. Analysis was performed using Comprehensive Meta-Analysis version 2.0 (Biostat, Englewood, NJ).

RESULTS

Search Results and Characteristics

The primary search for the effect of the Pillar implant on snoring identified 40 relevant studies. Among them, 26 studies were discarded after screening of the title and abstract. Seven studies were additionally excluded: five for lack of primary outcome measure (VAS) and two for duplicate subjects with other studies. Finally, seven studies were included for meta-analysis. They were all case-controlled studies, and the total number of enrolled subjects was 174. Mean follow-up duration ranged from 3 to 12 months (Table I, Fig. 1).

The primary search for the effect of the Pillar implant on OSA identified 59 relevant studies. Among them, 50 studies were discarded after screening of the title and abstract. Two studies were additionally excluded, one for lack of primary outcome measure (ESS and AHI) and the other for duplicate subjects with other study. Finally, seven studies were included for meta-analysis. Five studies were case series and two were placebo-controlled trials. The total number of enrolled subjects was 363. Among them, 76 subjects participated

Published Year	Author	No. of Patients	Follow-up (mo)	Visual Analogue Scale			P Value	Level of Evidence
				Before Procedure	After Procedure	Reduction Rate		
2004	Ho et al.[14]	12	3	79	48	39	.008	Level II-2
2004	Nordgård et al.[15]	35	3	7.3	3.6	51	<.001	Level II-2
2005	Maurer et al.[18]	40	12	7.1	4.8	32	<.05	Level II-2
2006	Skjøstad et al.[19]	10 (regular type)	6	7.7	4.7	39	<.01	Level I
		10 (stiffer type)		8.1	6.1	25		
2006	Romanow et al.[20]	21	3	8.5	4.4	48	<.001	Level II-2
2009	Saylam et al.[21]	21	12	9.1	5.1	44	<.05	Level II-2
2010	Rotenberg et al.[22]	25	12	9.5	5.0	47	<.001	Level II-2

as a placebo-control group. Mean follow-up duration ranged from 3 to 29 months (Table II, Fig. 2).

For the calculation of extrusion rate, we analyzed the aforementioned 14 studies together because the extrusion rate between the two groups would not differ.

Outcomes

Snoring sound loudness (VAS). Seven studies assessed the efficacy of the Pillar implant on reduction of snoring sound. The Pillar implant reduced snoring sound significantly compared to preprocedure values (standardized mean difference [SMD], -0.591; 95% CI, -0.753 to -0.429; $P < .001$) (Fig. 3). A significant interstudy heterogeneity was not found ($\chi^2 = 5.32$, $P = .503$, $I^2 = 0.0\%$). Begg's test ($P = .05$) and Egger's test ($P = .03$) suggested that some bias source might be included in this sample of studies. However, classic fail-safe N was 92. Moreover, Duval and Tweedie's trim and fill showed there was no difference between observed and adjusted values. Therefore, we concluded that the selective studies were not biased. Funnel plot analysis was also provided (Fig. 4A). We also did a subgroup analysis based on the study types and metaregression on body mass index (BMI) but did not find any significant results.

Epworth Sleepiness Scale. Seven studies assessed the efficacy of the Pillar implant on reduction of daytime sleepiness. The Pillar implant reduced ESS significantly compared to preprocedure values (SMD, -0.481; 95% CI, -0.606 to -0.358, $P < .001$) (Fig. 5). A significant interstudy heterogeneity was not found ($\chi^2 = 5.72$, $P = .455$, $I^2 = 0.0\%$). Begg's test ($P = .05$) and Egger's test ($P = .01$) suggested that some bias source might be included in this sample of studies. However, classic fail-safe N was 105. Moreover, Duval and Tweedie's trim and fill showed there was no difference between observed and adjusted values. Therefore, we concluded that the selective studies were not biased. Funnel plot analysis was also provided (Fig. 4B). We also did subgroup-analysis based on the study types and metaregression on BMI but did not find any significant result.

Apnea-Hypopnea Index. Seven studies assessed the efficacy of the Pillar implant on reduction of AHI. The Pillar implant reduced AHI significantly compared

to preprocedure values (SMD, -0.378; 95% CI, -0.619 to -0.138; $P = .002$) (Fig. 6). A significant interstudy heterogeneity was found ($\chi^2 = 19.64$, $P = .003$, $I^2 = 69.5\%$). Egger's test ($P = .27$) showed that a bias source was not evident in this sample of studies, but Begg's test ($P = .10$) did not. However, Duval and Tweedie's trim and fill showed there was no difference between observed and adjusted values and classic fail-safe N was 47. Therefore, we concluded that the selective studies were not biased. Funnel plot analysis was also provided (Fig. 4C). We also did a subgroup-analysis based on the study types and metaregression on BMI, but did not find any significant results. Only noticeable thing was that the SMD of AHI was -0.376 (95% CI, -0.520 to -0.232, $P < .001$) for five case-controlled studies and -0.332 (95% CI, -1.318 to 0.654, $P = .509$) for two randomized controlled studies. Standardized mean difference for the two groups were nearly the same; however, the SMD for two randomized controlled studies was not statistically significant ($P = .509$).

Extrusion rate. Fourteen studies assessed the extrusion rate of the Pillar implant. The standardized mean of extrusion rate was 9.3% (95% CI, 7.0 to 12.2%) (Fig. 7). A significant interstudy heterogeneity was not
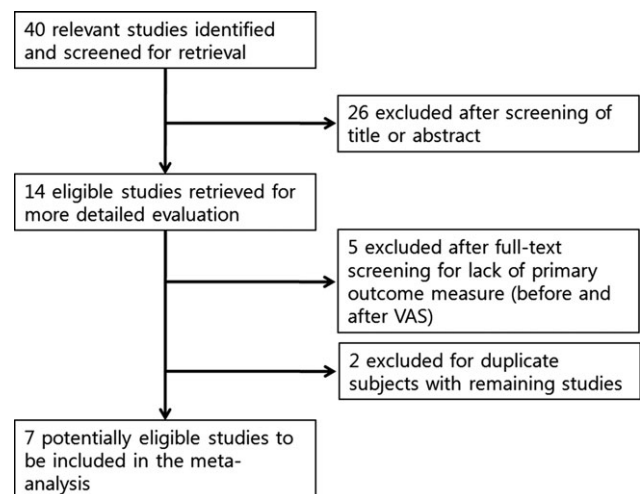

Fig. 1. Study selection to evaluate the effect of the Pillar implant on snoring. VAS = visual analog scale.

Published Year	Author	No. of Patients	Follow-up (mo)	Epworth Sleepiness Scale				Apnea-Hypopnea Index				Level of Evidence
				Before Procedure	After Procedure	Reduction Rate	P Value	Before Procedure	After Procedure	Reduction Rate	P Value	
2006	Nordgård et al.[29]	25	3	9.7	5.5	43	<.001	16.2	12.1	25	<.05	Level II-2
2006	Walker et al.[30]	53	3	11.0	6.9	37	<.001	25.0	22.0	12	<.05	Level II-2
2007	Goessler et al.[31]	16	3	7.2	4.6	36	<.05	16.5	11.8	29	<.05	Level II-2
2007	Walker et al.[32]	13 (responder)	14.6	12.0	6.8	43	<.01	19.5	12.8	34	<.05	Level II-2
		9 (nonresponder)		11.3	10.7	5		19.9	26.2	32		
2008	Friedman et al.[33]	29 (treatment)	3	12.7	10.2	20	<.001	23.8	15.9	33	<.0001	Level I
		26 (placebo)		11.7	11.1	5		20.1	21.0	−5		
2008	Steward et al.[34]	50 (treatment)	3	10.7	9.2	18	<.01	17.2	20.1	−17	.27	Level I
		50 (placebo)		10.6	8.7	14	<.01	16.7	25.7	35	.0005	
2011	Neruntarat[35]	92	29	12.3	7.9	36	<.001	21.7	10.8	50	<.001	Level II-2

found ($\chi^2 = 16.46$, $P = .225$, $I^2 = 21.0\%$). Funnel plot analysis (Fig. 4D), Begg's test ($P = .58$), and Egger's test ($P = .43$) showed that a bias source was not evident in this sample of studies.

DISCUSSION

Both snoring and OSA are considered to be a spectrum of sleep-related breathing disorders.[3] Theoretically, laminar airflow passing through the upper airway becomes turbulent and vibrates surrounding structures such as the soft palate, tongue base, or pharyngeal wall when the upper airway narrows to a certain degree, which produces the sound identified as snoring.[16] If the narrowing progresses beyond snoring, the upper airway closes at some point and airflow stops (i.e., OSA).[16] We need to differentiate those two disorders because the medical consequences differ between them. This is why we analyzed the efficacy of the Pillar implant on snoring and OSA separately.

Pillar Implant on Snoring

Even though snoring is not defined as one disease entity in the category of sleep-related breathing disorder by the International Classification of Sleep Disorder (Second Edition), it causes many social and lifestyle problems.[3] Moreover, snoring may progress to obstructive sleep apnea.[16] A number of surgical techniques have been tried for the treatment of snoring. Most surgical procedures attempt to stop the fluttering of the soft palate by resection of redundant tissue and/or stiffening of palate by flaps, because the soft palate is thought to be the part that vibrates the most.[14,15,17] Uvulopalatopharyngoplasty and laser-assisted uvulopalatoplasty diminish snoring by reducing the palate and surrounding tissue volume and increasing stiffness through postoperative scarring.[9] There are other techniques, such as radiofrequency ablation, which produces selective scar tissue in the soft palate to induce stiffness.[9] However, significant complications like pain, dryness, and foreign-body sensation, or frequent recurrence of snoring after preexisting surgical procedures have made many clinicians eager for

new method.[9] The Pillar implant is a new alternative. It has long-lasting effects due to its biologically compatible structure, a leads to chronic inflammatory response and fibrous capsule formation.[14,15] It is presumed that the soft palate is stiffened through not only the direct effects of the implant but also because of the surrounding fibrosis. This effect is expected to persist as long as the implants are retained.

When analyzing the results of the Pillar implant on the treatment of snoring, the biggest problem is that there is no standard definition for the evaluation of the treatment results. Usually, the VAS score obtained from the bed partners have been used. For meta-analysis of the efficacy of the Pillar implant on reduction of snoring sound, seven studies were presently included.[14,15,18–22] The meta-analysis indicated that the Pillar implant reduces snoring sound significantly compared to preprocedure values. In all studies, VAS score improved in a statistically significant manner.[14,15,18–22] The SMD was −0.591 and 95% CI ranged from −0.753 to −0.429 ($P < .001$).
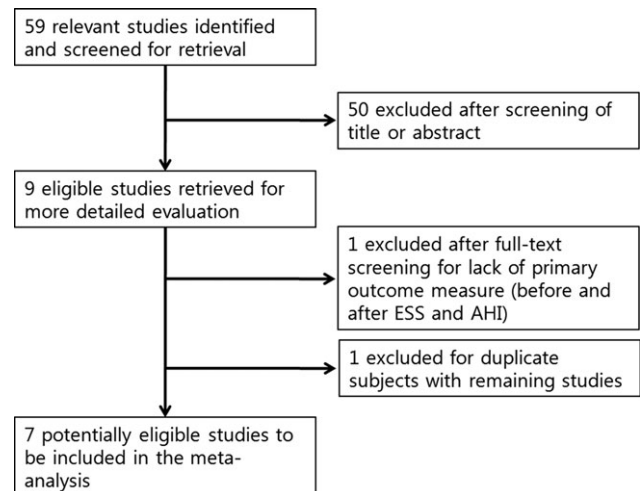
Fig. 2. Study selection to evaluate the effect of the Pillar implant on mild-to-moderate OSA. ESS = Epworth Sleepiness Scale; AHI = Apnea-Hypopnea Index.

First author	Time point	Std diff in means and 95% CI	Std diff in means	SE	Variance	Lower limit	Upper limit	Z-value	p-value
Ho	2004		-0.933	0.346	0.120	-1.610	-0.255	-2.697	0.007
Nordgård	2004		-0.615	0.184	0.034	-0.976	-0.254	-3.337	0.001
Maurer	2005		-0.336	0.163	0.026	-0.654	-0.017	-2.067	0.039
Skjøstad	2006		-0.650	0.246	0.061	-1.133	-0.168	-2.643	0.008
Romanow	2006		-0.850	0.255	0.065	-1.349	-0.351	-3.338	0.001
Saylam	2009		-0.479	0.230	0.053	-0.931	-0.028	-2.080	0.037
Rotenberg	2010		-0.757	0.227	0.051	-1.202	-0.313	-3.339	0.001
			-0.591	0.083	0.007	-0.753	-0.429	-7.139	0.000

Fig. 3. Effect of the Pillar implant on snoring sound intensity. Std diff = standard difference; CI = confidence interval.

There were some limitations to this study. Most of the relevant studies were not placebo-controlled, but were usually case-controlled studies.[14,15,18,20–22] Without considering a placebo effect, we could not evaluate the efficacy of surgical procedure correctively. VAS is very subjective score, which might be influenced greatly by a placebo effect. Patients and their family members typically tend to exaggerate the surgical effect. However, ethically and technically, placebo-controlled trials for surgical issues are very difficult. Patients could not accept easily the possibility that they might have the sham implant inside their body. Moreover, it is not so

simple to install a placebo implant as it is to administer a placebo drug. Only one study explored this in a randomized controlled study.[19] The studies compared the regular implant to a rigid one that was stiffer; the authors concluded that the regular implant was more effective than the rigid one. However, the rigid implant was not a pure placebo, so we are unable to ascertain the true efficacy of the Pillar implant. A second limitation concerns the short follow-up period. The average follow-up duration of three studies was only 3 months, 6 months for one study, and 12 months for three studies.[14,15,18,20–22] Fibrosis induced by surgery initially only
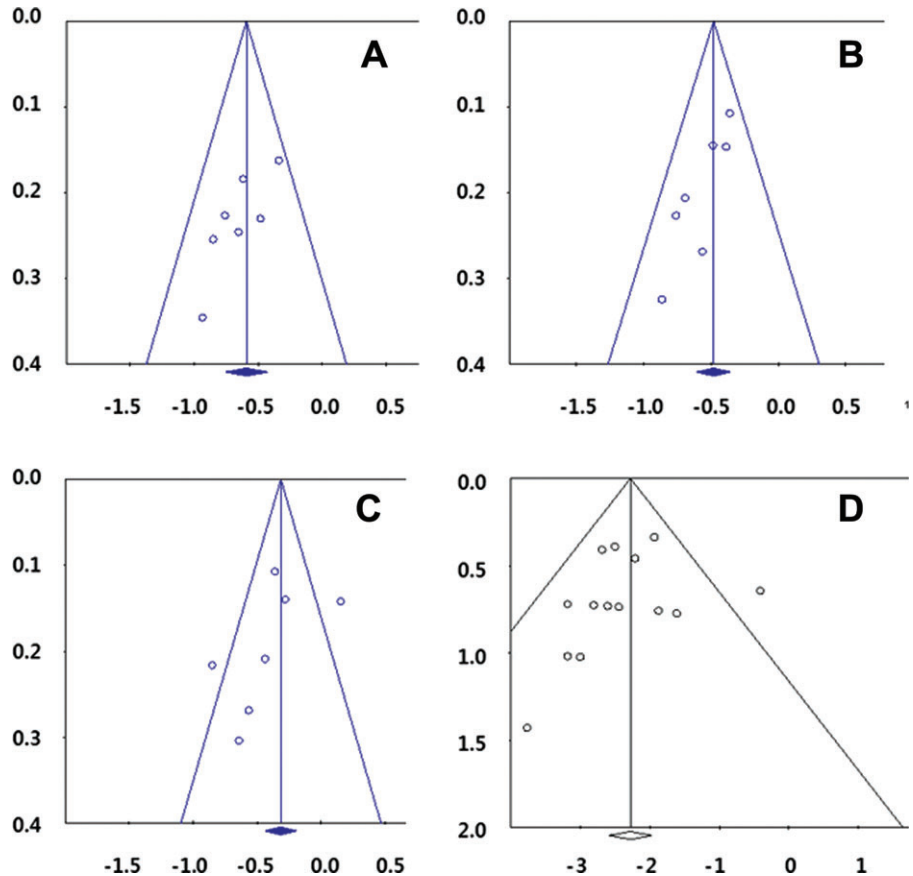
Fig. 4. Funnel plots for visual analogue scale (A), Epworth Sleepiness Scale (B), Apnea-Hypopnea Index (C), and extrusion rate (D). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

First author	Time point	Std diff in means and 95% CI	Std diff in means	SE	Variance	Lower limit	Upper limit	Z-value	p-value
Nordgård	2006		-0.757	0.227	0.051	-1.202	-0.313	-3.339	0.001
Walker	2006		-0.484	0.145	0.021	-0.768	-0.199	-3.333	0.001
Goessler	2007		-0.562	0.269	0.072	-1.089	-0.035	-2.090	0.037
Walker	2007		-0.863	0.325	0.106	-1.500	-0.226	-2.656	0.008
Friedman	2008		-0.690	0.207	0.043	-1.095	-0.285	-3.338	0.001
Steward	2008		-0.385	0.147	0.021	-0.672	-0.097	-2.625	0.009
Neruntarat	2011		-0.358	0.108	0.012	-0.569	-0.147	-3.328	0.001
			-0.481	0.064	0.004	-0.606	-0.356	-7.564	0.000

-1.00 -0.50 0.00 0.50 1.00
Decrease   Increase

Fig. 5. Effect of the Pillar implant on daytime sleepiness. Std diff = standard difference; CI = confidence interval.

makes surrounding tissue rigid but usually loosens at a later time, which might be one of the reasons why snoring or obstructive sleep apnea can recur after surgery. Pillar implantation can theoretically maintain a stiffened soft palate for a long time. However, data are lacking, and long-term follow-up studies are needed. The last limitation is that we could not rule out the coexisting OSA because polysomnography was not mandatory for diagnosis of snoring in the recent studies. Only one study among seven applied to polysomnography to d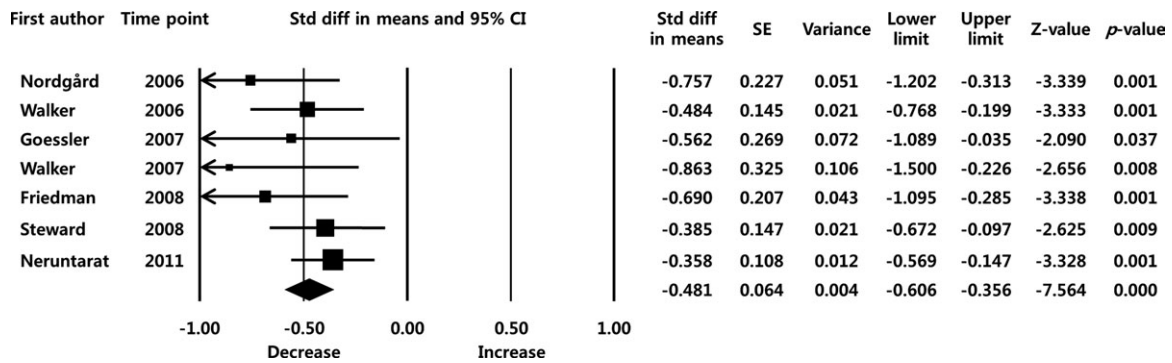iagnose simple snoring and rule out OSA.[18] Our meta-analysis shows that the snoring sound reduced considerably after Pillar implantation; however, coexisting OSA could be persistent or even worse. To prevent or cure the remnant OSA, polysomnography is essential for the treatment of snoring, but frequently skipped due to the high cost and inconvenience.

Pillar Implant on Mild-to-Moderate OSA

OSA is accompanied by many medical problems and ultimately increases death rate, which is why OSA patients should be treated aggressively.[1,3] Generally, the result of surgical treatment on severe OSA is not satisfactory.[9,13] Therefore, surgical trials have focused on mild-to-moderate OSA. The kind and method of surgery for OSA is not different from those for snoring. However, the main purpose is somewhat different. Snoring surgery is intended only to reduce or stop vibration of relevant structures, whereas the aim of OSA surgery is to enlarge the airway or to prevent airway collapse. Uvulopalatopharyngoplasty is thought to both enlarge the airway by removing tonsils or redundant tissue and prevent airway collapse by making scar tissue, whereas the Pillar implant is designed only to decrease collapsibility of the airway.[9,13] Although conservation of tissue is the main merit of the Pillar implant, it might impose a limitation on surgical effect. To meta-analyze the efficacy of the Pillar implant on mild-to-moderate OSA, ESS and AHI were used. ESS is a tool to evaluate a subjective daytime sleepiness.[23–25] Even though ESS could not reflect the severity of OSA directly, daytime sleepiness is one of the main symptoms of OSA patients and affects their quality of life deeply.[23,24] Therefore, improvement of daytime sleepiness should be a very important goal of treatment.[23] This is why we evaluated pre- and postprocedure ESS in this study. AHI is a parameter that so far most precisely reflects the severity of OSA. Moreover, AHI is an objective score measured by polysomnography, therefore it is not as influenced by the placebo effect.[26–28]

Seven studies assessed the efficacy of the Pillar implant on reduction of daytime sleepiness and AHI. The Pillar implant reduced ESS significantly compared to preprocedure values.[29–35] The SMD was -0.481 and the 95% CI ranged from -0.606 to -0.358 ($P < .001$). AHI was also reduced significantly. The SMD was 0.378

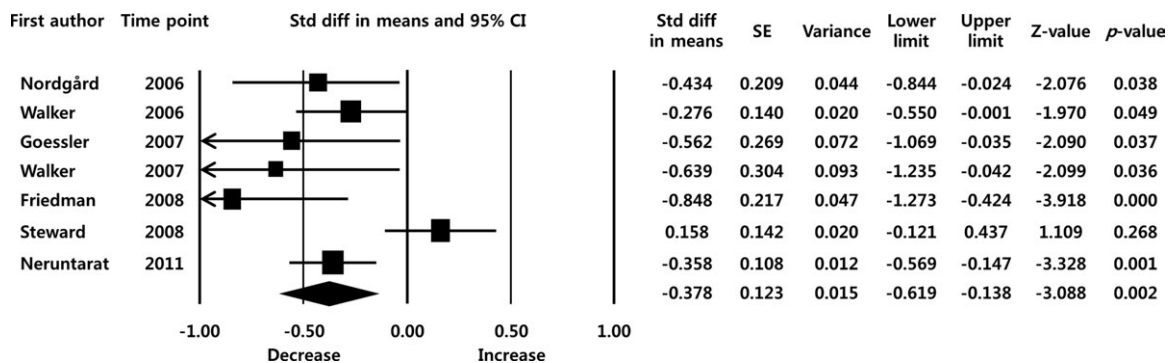| First author	Time point	Std diff in means and 95% CI	Std diff in means	SE	Variance	Lower limit	Upper limit	Z-value	p-value
Nordgård	2006		-0.434	0.209	0.044	-0.844	-0.024	-2.076	0.038
Walker	2006		-0.276	0.140	0.020	-0.550	-0.001	-1.970	0.049
Goessler	2007		-0.562	0.269	0.072	-1.069	-0.035	-2.090	0.037
Walker	2007		-0.639	0.304	0.093	-1.235	-0.042	-2.099	0.036
Friedman	2008		-0.848	0.217	0.047	-1.273	-0.424	-3.918	0.000
Steward	2008		0.158	0.142	0.020	-0.121	0.437	1.109	0.268
Neruntarat	2011		-0.358	0.108	0.012	-0.569	-0.147	-3.328	0.001
			-0.378	0.123	0.015	-0.619	-0.138	-3.088	0.002

-1.00 -0.50 0.00 0.50 1.00
Decrease   Increase

Fig. 6. Effect of the Pillar implant on Apnea-Hypopnea Index. Std diff = standard difference; CI = confidence interval.

First author	Time point	Event rate and 95% CI	Event rate	Lower limit	Upper limit	Z-value	p-value
Ho et al.	2004		0.617	0.042	0.477	−2.078	0.038
Nordgård	2004		0.057	0.014	0.202	−3.850	0.000
Maurer	2005		0.133	0.034	0.405	−2.464	0.014
Skjøstad	2006		0.400	0.158	0.703	−0.628	0.530
Romanow	2006		0.048	0.007	0.271	−2.924	0.003
Saylam	2009		0.023	0.001	0.277	−2.629	0.009
Rotenberg	2010		0.040	0.006	0.235	−3.114	0.002
Nordgård	2006		0.080	0.020	0.269	−3.313	0.001
Walker	2006		0.099	0.043	0.213	−4.802	0.000
Goessler	2007		0.064	0.030	0.133	−6.533	0.000
Walker	2007		0.127	0.069	0.220	−5.708	0.000
Friedman	2008		0.069	0.017	0.238	−3.552	0.000
Steward	2008		0.040	0.010	0.146	−4.404	0.000
Neruntarat	2011		0.076	0.037	0.151	−6.349	0.000
			0.093	0.070	0.122	−14.694	0.000

−1.00   −0.50   0.00   0.50   1.00
Absent   Present

Fig. 7. Extrusion rate of the Pillar implant. CI = confidence interval.

and the 95% CI ranged from −0.619 to −0.138 (P = .002). In conclusion, the Pillar implant improves the daytime sleepiness and reduces AHI in mild-to-moderate OSA patients.

However, this conclusion is not definitive. Out of seven relevant studies, only two were placebo-controlled studies and the others were case-controlled studies.[29–35] ESS is a subjective score, which is very likely to be influenced by a placebo effect. AHI is an objective measurement and so might be less influenced by a placebo effect, but a placebo group is also required to get a clear conclusion. ESS was significantly improved in all seven studies.[29–35] An interesting finding was that the ESS score was improved significantly even in the placebo group ($P < .01$) in one placebo-controlled study.[34] However, the AHI also increased significantly in the same placebo group after procedure ($P = .0005$).[34] However, other placebo-controlled studies and the case-controlled studies did not show such an extraordinary result.[29–33,35] The authors did not have a clear answer for such an unexpected result.[34] The follow-up periods in the studies were short; 3 months for five studies, 14.6 months for one, and 29 months for another.[29–35]

Extrusion Rate of Pillar Implant

The most noticeable merit of the Pillar implant is trivial accompanying complications.[14,15,18–22,29–35] Pain and foreign body sensation disappear, usually within the first week, and symptoms are self-limited. Mucosal ulcerations, fistulas, or infections have been rarely reported. The most bothering aspect is the extrusion of the Pillar implant. Once a Pillar implant is extruded, it should be removed and a new one should be implanted beside the previous one. To calculate the average extrusion rate, we included all 14 studies together, because the extrusion rate would not be different between snoring and OSA patients.[14,15,18–22,29–35] The extrusion rate ranged from 0% to 25%. The standardized mean of extrusion rate was 9.3%, and the 95% CI ranged from 7.0% to 12.2%.

Clinical Significance of Pillar Implant

We could calculate the results that transformed into the SMD. The value was statistically meaningful. However, it is not possible to infer the real value of VAS, ESS, or AHI from the SMD because we do not know the standard deviation of the whole population. What we try to inform is that we cannot answer this questions: How much does VAS or AHI improve after the Pillar implant? We can say that it does to a Statistically significant extent. There is also the dilemma that statistical improvement and clinical improvement might be different. The common representation of the SMD is Cohen's d, which suggests that bigger size is more effective in clinically meaningful terms.[36] An effect size (SMD) between two means within a range closely encompassing 0.20± is considered small (possibly clinically nonsignificant), 0.50± is a medium effect, and 0.80± or greater is considered large (and clinically significant).[36] According to Cohen's assumption, we can say that the Pillar implant reduces VAS (SMD, −0.591), ESS (SMD, −0.481), and AHI (SMD, −0.378; closer to −0.50 than to −0.20) only moderately even though those reductions are statistically significant. Therefore, we should consider that some patients could still have loud snoring, daytime sleepiness, or a high AHI after receiving the Pillar implant.

CONCLUSION

Although case-controlled studies were mainly included for meta-analysis on this subject, the Pillar implant seems to have a considerable efficacy on snoring and mild-to-moderate OSA patients.

BIBLIOGRAPHY

1. Norman D, Haberman PB, Valladares EM, Michaelson PG. Medical consequences and associations with untreated sleep-related breathing disorders and outcomes of treatments. *J Calif Dent Assoc* 2012;40:141–149.
2. Powers DB, Allan PF, Hayes CJ, Michaelson PG. A review of the surgical treatment options for the obstructive sleep apnea/hypopnea syndrome patient. *Mil Med* 2010;175:676–685.
3. Flemons WW. Clinical practice. Obstructive sleep apnea. *N Engl J Med* 2002;347:498–504.
4. Friedman M, Wilson M, Lin HC, Chang HW. Updated systematic review of tonsillectomy and adenoidectomy for treatment of pediatric obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg* 2009;140:800–808.
5. Rao M, Rajda G, Uppuluri S, Beck GR, Liu L, Bisognano JD. The role of continuous positive airway pressure in the treatment of hypertension in patients with obstructive sleep apnea-hypopnea syndrome: a review of randomized trials. *Rev Recent Clin Trials* 2010;5:35–42.
6. Berry RB, Parish JM, Hartse KM. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. An American Academy of Sleep Medicine review. *Sleep* 2002;25:148–173.
7. Hoekema A. Efficacy and comorbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systematic review and preliminary results of a randomized trial. *Sleep Breath* 2006;10:102–103.
8. Holty JE, Guilleminault C. Maxillomandibular advancement for the treatment of obstructive sleep apnea: a systematic review and meta-analysis. *Sleep Med Rev* 2010;14:287–297.
9. Franklin KA, Anttila H, Axelsson S, et al. Effects and side-effects of surgery for snoring and obstructive sleep apnea—a systematic review. *Sleep* 2009;32:27–36.
10. Dekeister C, Lacassagne L, Tiberge M, Montemayor T, Migueres M, Paoli JR. Mandibular advancement surgery in patients with severe obstructive sleep apnea uncontrolled by continuous positive airway pressure. A retrospective review of 25 patients between 1998 and 2004. *Rev Mal Respir* 2006;23:430–437.
11. Kezirian EJ, Goldberg AN. Hypopharyngeal surgery in obstructive sleep apnea: an evidence-based medicine review. *Arch Otolaryngol Head Neck Surg* 2006;132:206–213.
12. Aurora RN, Casey KR, Kristo D, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. *Sleep* 2010;33:1408–1413.
13. Caples SM, Rowley JA, Prinsell JR, et al. Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis. *Sleep* 2010;33:1396–1407.
14. Ho WK, Wei WI, Chung KF. Managing disturbing snoring with palatal implants: a pilot study. *Arch Otolaryngol Head Neck Surg* 2004;130:753–758.
15. Nordgard S, Wormdal K, Bugten V, Stene BK, Skjostad KW. Palatal implants: a new method for the treatment of snoring. *Acta Otolaryngol* 2004;124:970–975.
16. Susarla SM, Thomas RJ, Abramson ZR, Kaban LB. Biomechanics of the upper airway: Changing concepts in the pathogenesis of obstructive sleep apnea. *Int J Oral Maxillofac Surg* 2010;39:1149–1159.
17. Kuhnel TS, Hein G, Hohenhorst W, Maurer JT. Soft palate implants: a new option for treating habitual snoring. *Eur Arch Otorhinolaryngol* 2005;262:277–280.
18. Maurer JT, Hein G, Verse T, Hormann K, Stuck BA. Long-term results of palatal implants for primary snoring. *Otolaryngol Head Neck Surg* 2005;133:573–578.
19. Skjostad KW, Stene BK, Norgard S. Consequences of increased rigidity in palatal implants for snoring: a randomized controlled study. *Otolaryngol Head Neck Surg* 2006;134:63–66.
20. Romanow JH, Catalano PJ. Initial U.S. pilot study: palatal implants for the treatment of snoring. *Otolaryngol Head Neck Surg* 2006;134:551–557.
21. Saylam G, Korkmaz H, Firat H, Tatar EC, Ozdek A, Ardic S. Do palatal implants really reduce snoring in long-term follow-up? *Laryngoscope* 2009;119:1000–1004.
22. Rotenberg BW, Alsaffar H, Kandessamy T. Patient outcomes after soft palate implant placement for treatment of snoring. *J Otolaryngol Head Neck Surg* 2010;39:323–328.
23. Yaremchuk K, Tacia B, Peterson E, Roth T. Change in Epworth Sleepiness Scale after surgical treatment of obstructive sleep apnea. *Laryngoscope* 2011;121:1590–1593.
24. Rosenthal LD, Dolan DC. The Epworth sleepiness scale in the identification of obstructive sleep apnea. *J Nerv Ment Dis* 2008;196:429–431.
25. Johns MW. Daytime sleepiness, snoring, and obstructive sleep apnea. The Epworth Sleepiness Scale. *Chest* 1993;103:30–36.
26. Tschopp K, Zumbrunn T, Knaus C, Thomaser E, Fabbro T. Statistical model for postoperative apnea-hypopnea index after multilevel surgery for sleep-disordered breathing. *Eur Arch Otorhinolaryngol* 2011;268:1679–1685.
27. Ruehland WR, Rochford PD, O'Donoghue FJ, Pierce RJ, Singh P, Thornton AT. The new AASM criteria for scoring hypopneas: impact on the apnea hypopnea index. *Sleep* 2009;32:150–157.
28. Cherniack NS. The sleep apnea number game: counting the apnea-hypopnea index. *Respiration* 2009;77:21–22.
29. Nordgard S, Stene BK, Skjostad KW. Soft palate implants for the treatment of mild to moderate obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2006;134:565–570.
30. Walker RP, Levine HL, Hopp ML, Greene D, Pang K. Palatal implants: a new approach for the treatment of obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2006;135:549–554.
31. Goessler UR, Hein G, Verse T, Stuck BA, Hormann K, Maurer JT. Soft palate implants as a minimally invasive treatment for mild to moderate obstructive sleep apnea. *Acta Otolaryngol* 2007;127:527–531.
32. Walker RP, Levine HL, Hopp ML, Greene D. Extended follow-up of palatal implants for OSA treatment. *Otolaryngol Head Neck Surg* 2007;137:822–827.
33. Friedman M, Schalch P, Lin HC, Kakodkar KA, Joseph NJ, Mazloom N. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg* 2008;138:209–216.
34. Steward DL, Huntley TC, Woodson BT, Surdulescu V. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. *Otolaryngol Head Neck Surg* 2008;139:506–510.
35. Neruntarat C. Long-term results of palatal implants for obstructive sleep apnea. *Eur Arch Otorhinolaryngol* 2011;268:1077–1080.
36. Acion L, Peterson JJ, Temple S, Arndt S. Probabilistic index: an intuitive non-parametric approach to measuring the size of treatment effects. *Stat Med* 2006;25:591–602.