

Long Term Effects of Palatal Implant Method in Adult Patients with Simple Snoring and Obstructive Sleep-Apnea Syndrome

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Abstract

Objective. To investigate the long term effect and reliability of palatal implant surgery, which is a minimally invasive technique, used in simple snoring and obstructive sleep-apnea syndrome types based on objective and subjective data.

Materials and Methods. Seventy-eight patients were included prospectively in this study. It has been possible to obtain preoperative and postoperative polysomnography results in 59 patients. The cases were followed-up for 8 months on average. Considering the apnea index and AHI values, the patients were divided into 5 groups, namely simple snoring (n=13), mild OSAS (n=21), moderate OSAS (n=17), severe OSAS (n=8), and the group on which polysomnography could not be performed, the no-polysomnography group (n=19). The cases were evaluated based on polysomnography and the Epworth Sleepiness Scale and visual analog scale filled by relatives or friends of the patients.

Results. The AHI of 46 patients diagnosed with OSAS decreased from 14.9 to 10.14 (31% decline) (p=0.279). The AHI of 13 patients with simple snoring diagnosis reduced from 3.09 to 2.02 (p=0.033). A 40% improvement was observed in VAS of all cases. Implant rejection occurred in 7 of our cases and 3 patients experienced ecchymosis.

Conclusion. It is concluded that palatal implant procedure is a good option for appropriate cases, it is equivalent to other methods in terms of treatment efficacy and that is more advantageous than other techniques in that it can be applied in office settings with low morbidity, is minimally invasive and brings about higher patient compliance. *Clin Ter 2015; 166(1):16-20. doi: 10.7417/CT.2015.1795*

Key words: snoring, obstructive sleep-apnea syndrome, palatal implant, OSA

Introduction

Snoring is recurrent and typically high-frequency respiratory sounds that originate from changes in shape and contents of the upper respiratory tract (1). The actual sound produced during snoring basically results from vibration of soft tissues in the upper respiratory tract. These tissues include soft palate, pharynx, and uvula (1, 2). Snoring is the most prominent complaint in obstructive sleep-apnea

syndrome (OSAS) and is seen in all the patients suffering from this disorder. **However, not all snoring is due to obstructive sleep apnea syndrome.** Snoring is a complaint that is usually noticed by family and/or household members rather than the patient. Snoring alone (simple snoring), is a much more common complaint than the obstructive sleep-apnea syndrome in the community (3). In order to call a clinical picture as OSAS, a physical examination and laboratory findings are also required in addition to the symptoms. The gold standard method for diagnosis is polysomnography (PSG). Apnea Hypopnea Index (AHI) values of 5/hours and above are considered as limits for OSAS, however, whether this is sufficiently in direct proportion with daytime symptoms and long term complications of the disease has not been clarified yet (4).

Various alternatives have been discussed for the treatment of simple snoring and OSAS. These treatment alternatives include losing weight, avoiding alcohol and sedatives, using intraoral apparatus and surgery [uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), tracheostomy, maxillofacial surgery, etc.] (5). Gold standard treatment for OSAS, yet adherence rates to continuous positive airway pressure (CPAP) are low. Comparing success rates and tolerability of the treatment modalities, no appropriate surgical method for treatment has been discovered yet. One of the recent surgical techniques that is performed in the soft palate is the palatal implant method. First experiences on Pillar[®] palatal implant (Restore Medical, Inc., St. Paul, MN, USA) started in 2004 and its use has become widespread as it is less invasive and its efficiency has been proved (6). Pillar palatal implant consists of linear, aromatic polyesters called "Polyethylene Terephthalate", each sized 2 mm in diameter and 18 mm in length. Although it is a synthetic material, it has been used in surgical procedures since 1950's. It forms stiffness by creating fibrosis in the soft palate. This, in turn, decreases apnea attacks and snoring by preventing vibration in the soft palate.

Our purpose in this study was to investigate the effect and dependability of the palatal implant technique on simple snoring and on the severity of OSAS in the long term.

Materials and Methods

Seventyeight cases who admitted to our clinic for snoring problems or with accompanying diagnosis of obstructive sleep-apnea syndrome were included for evaluation in this prospective study. The study was approved by the clinical research ethics committee of the Istanbul Medipol University (protocol number B.30.2.İMÜ.0.05.05-02). The study consists of cases who had continuous snoring and day and nighttime complaints of OSAS stated by the patient and his/her spouse. Patients with these complaints along with those who were considered to have only palatal pathology in their examinations and found to have simple snoring in polysomnography or OSAS and who were eager to fill survey forms regularly before and after the treatment were included in this study. Cases were excluded from the study if they showed nasal, nasopharyngeal, tongue root, body of tongue, epiglottal or skeletal system pathology whereas patients who had a soft palate shorter than 25 mm were also excluded. Also, pregnant or lactating patients, patients with swallowing and/or speech disorder, patients who had previous palatal or pharyngeal operations other than adenoidectomy, cases who had a previous diagnosis and treatment of respiratory tract cancer, patients with uncontrollable psychiatric problems, cases with serious respiratory and/or cardiovascular disorder, patients with active respiratory tract infection, patients with additional serious disease, cases who had no adult relative or friend to regularly observe the patient's sleep, patients who are younger than 18, cases who received CPAP therapy, patients with a Body Mass Index (BMI) >35 kg/m² and cases with central apnea were excluded from the study. Patients were asked to sign an "informed consent form" before the study. All of the patients underwent a detailed physical and endoscopic examination. Subjective data from the patient and his/her spouse were recorded. Objective data such as Apnea Index, Apnea-Hypopnea Index related to the disorder were obtained by polysomnography performed in the sleep laboratory before the treatment. **As subjective data concerning the patient, Epworth Sleepiness Scale (ESS) was used.** As for the spouse, visual analog scale (VAS) was used to evaluate subjective snoring data. **Snoring was graded preoperatively and postoperatively using a VAS score of between 0 to 10 by the spouse or a relative.** Snoring and apnea of the patient was evaluated preoperatively and decrease in these measures as percentages were reevaluated after 8 months. AI and AHI were taken into account as objective measures. Patients were classified according to apnea-hypopnea indices as simple snoring disease or mild-moderate-severe OSAS. The procedures were performed with local anesthesia in the ambulatory ENT clinic. Prophylactic antibiotics in amoxicillin/clavulanic acid form was given to patients in 2x1 g doses, starting with the procedure. Prior to surgery, the patient was asked to gargle with an antiseptic solution (*benzylamine HCl – chlorhexidine gluconat*). After that, topical anesthesia was performed by spraying lidocaine (Xylocaine) onto soft palate. A submucosal infiltration with 5 ml of solution containing lidocaine and adrenaline was administered to the regions where implant to be placed and vasoconstriction was provided by local anesthesia. Three *Pillar*[®] palatal implants were placed inside the muscles of the soft palate at the nearest place to the junction of the soft

palate and hard palate; one in the midline and two on both sides (2 mm from the midline) with the help of its own applicator in three stages. Special attention was given not to extrude implants from the soft palate mucosa and not to place them superficially. Besides, an analgesic (*paracetamol*) was recommended in case of pain. The patients were reevaluated approximately 8 months (6 to 15 months) after the procedure and subjective evaluation scores from the patient and his/her spouse and objective data from control polysomnography were obtained. **ESS was evaluated as the patients' subjective data;** as for subjective data from his/her spouse, analog snoring scale (VAS), severity and frequency of snoring and witnessed frequency of apnea were taken into account and these findings were compared with pretreatment values. As objective data, AI and AHI were statistically compared. Mann-Whitney *U*-test and ANOVA tests were used for statistical evaluation. The level of statistical significance was determined by a *p*-value ≤ 0.05 .

Results

A total of 78 patients, 59 with polysomnography and 19 without it were included in the study. The mean age of the patients was 45.07 (19-61) and 47 were males and 31 were females. The mean BMI of the cases was 27.0 (18.3-3.1) kg/m². In our patient group, 5 cases had hypertension, one had overlap syndrome, 2 cases used nasal topical corticosteroids, 6 cases had septum surgery, and 5 cases had a history of tonsillectomy.

The mean AHI was 14.9 (0.7-49.1) in polysomnography performed prior to treatment. In this assessment, 13 patients were diagnosed with simple snoring disease, 21 cases had mild OSAS, 17 patients had moderate OSAS and 8 patients had severe OSAS. A control polysomnography could be performed in 59 of the 78 patients within 8 months on average (6-15) after the treatment. Postoperative AHI was 10.14 on average (0.0-30.6), there were no significant change for AHI in three cases ($p=0.112$). **When considering the 46 cases with OSAS only, the mean AHI decreased from 14.9 to 10.14 (31% decline was noted) in the pre- and post-treatment polysomnography results ($p=0.279$).** The change in the AHI was not statistically significant ($p=0.207$). After the treatment, 19 patients were diagnosed with simple snoring, 37 cases had mild OSAS, 11 patients had moderate OSAS and 3 cases had severe OSAS while it was noted that ratio of the patients with simple snoring increased from 22% to 32.2%. Six of the 21 patients who had been diagnosed as mild OSAS prior to surgery were found to have simple snoring after the treatment.

No statistically significant difference was found when the preoperative and postoperative AI values were compared in the simple snoring group ($p=0.110$). **When the AHI comparison was done in the same group, a significant difference was seen ($p=0.033$);** as for subjective criteria, no statistically significant difference was noted in terms of ESS values in the same group ($p=0.79$) (Table 1).

No statistically significant difference was found when the preoperative and postoperative AI values were compared in the mild OSAS group ($p=0.129$). When the AHI comparison was done in the same group, a significant difference was seen

Table 1. Comparison of preoperative and postoperative AI, AHI and ESS in Simple Snoring Group.

	Groups	n	mean	SD	SEM
AI	Preop	13	.3769	.64699	.17944
	Postop	13	.1154	.33627	.09326
AHI	Preop	13	3.0923	1.06024	.29406
	Postop	13	2.0231	1.22621	.34009
SS	Preop	13	9.3846	4.42603	1.22756
	Postop	13	6.9231	3.06761	.85080

Simple Snoring Group Mann-Whitney U-Test

AI	AHI	ESS
p=0.110	p=0.033	p=0.79

AI: Apnea Index, AHI: Apnea-Hypopnea Index, ESS: Epworth Sleepiness Scale. SD: Standard deviation, SEM: Standard error of the mean. OSAS: Obstructive Sleep-Apnea Syndrome

Table 2. Comparison of preoperative and postoperative AI, AHI and ESS in the mild OSAS.

	Groups	n	mean	SD	SEM
AI	Preop	20	1.5100	1.64697	.36827
	Postop	20	.7050	1.09807	.24554
AHI	Preop	21	9.9381	2.91264	.63559
	Postop	21	6.3524	2.02549	.44200
ESS	Preop	21	8.5714	4.83292	1.05463
	Postop	21	5.9048	2.96487	.64699

Mild OSAS Group Mann-Whitney U-test

AI	AHI	ESS
p=0.129	p=0.000	p=0.045

AI: Apnea Index, AHI: Apnea-Hypopnea Index, ESS: Epworth Sleepiness Scale. SD: Standard deviation, SEM: Standard error of the mean. OSAS: Obstructive Sleep-Apnea Syndrome

($p < 0.005$); as for subjective criteria, a statistically significant difference was noted in terms of ESS values in the same group ($p = 0.045$) (Table 2).

A statistically significant difference was found when the preoperative and postoperative AI values were compared ($p = 0.042$) in the moderate OSAS group. When the AHI comparison was done in the same group, a significant difference was seen ($p < 0.005$); as for subjective criteria, a statistically significant difference was noted in terms of ESS values in the same group ($p = 0.026$) (Table 3).

No statistically significant difference was found when the preoperative and postoperative AI values were compared ($p = 0.115$) in the severe OSAS cases. When the AHI comparison was done in the same group, a significant difference was seen ($p = 0.001$); as for subjective criteria, no statistically significant difference was noted in terms of ESS values in the same group ($p = 0.065$) (Table 4).

When we consider subjective data of the patients, a comparison of preoperative and postoperative ESS values is provided in Figure 1.

Table 3. Comparison of preoperative and postoperative AI, AHI and ESS in the moderate OSAS.

	Groups	n	mean	SD	SEM
AI	Preop	16	4.6438	3.69486	.92371
	Postop	16	2.5938	2.39819	.59955
AHI	Preop	17	19.1176	3.05128	.74004
	Postop	17	12.8176	3.88237	.94161
ESS	Preop	17	10.7647	4.65738	1.12958
	Postop	17	7.4118	3.02198	.73294

Moderate OSAS Group Mann-Whitney U-Test

AI	AHI	ESS
p=0.042	p=0.000	p=0.026

AI: Apnea Index, AHI: Apnea-Hypopnea Index, ESS: Epworth Sleepiness Scale. SD: Standard deviation, SEM: Standard error of the mean. OSAS: Obstructive Sleep-Apnea Syndrome

Table 4. Comparison of preoperative and postoperative AI, AHI and ESS in the severe OSAS.

	Groups	n	mean	SD	SEM
AI	Preop	8	14.8125	8.13694	2.87684
	Postop	8	9.6000	5.62240	1.98782
AHI	Preop	8	38.7000	5.63002	1.99051
	Postop	8	27.6875	3.41528	1.20748
ESS	Preop	8	12.0000	4.86973	1.72171
	Postop	8	8.1250	4.45413	1.57477

Severe OSAS Group Mann-Whitney U-Test

AI	AHI	ESS
p=0.115	p=0.001	p=0.065

AI: Apnea Index, AHI: Apnea-Hypopnea Index, ESS: Epworth Sleepiness Scale. SD: Standard deviation, SEM: Standard error of the mean. OSAS: Obstructive Sleep-Apnea Syndrome

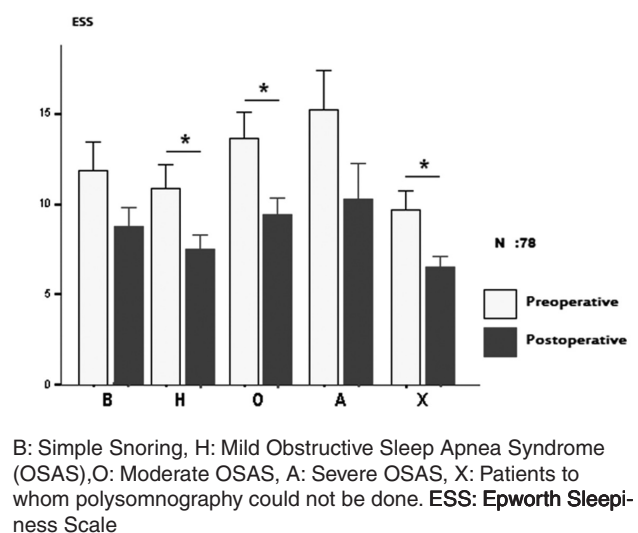


Fig. 1. Comparison of preoperative and postoperative ESS values.

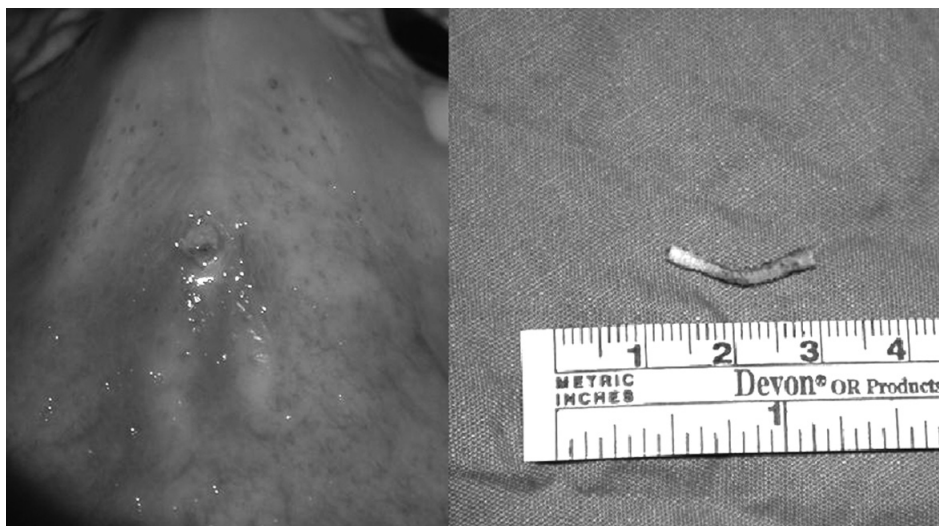


Fig. 2. The implant was rejected in the second week.

When VAS values were compared in the four groups, average preoperative scale was 10 and average postoperative scale was 6. A 40% of improvement was noted. However, the improvement was approximately 27% in cases with severe OSAS.

Implant rejection occurred in seven cases (8.9%), and the total number of implants that were rejected was 9 (Fig. 2). Four implants were rejected in the first hour, and new ones were placed. One implant was rejected in the second week, 3 implants were rejected in the 4th and 5th weeks and one implant was partially rejected in the postoperative first year. A new implant replacement was not considered to be necessary in these patients. **Three patients (3.8%) experienced ecchymosis on their palates.** Pain occurred in 7 cases (8.9%) in early stages as a complication. None of our cases suffered pain in the late stages.

Discussion

Purpose of treatment in simple snoring and OSAS is if possible, to relieve or at least diminish the complaints related to the disease, mainly snoring, day time sleepiness, and to eliminate the morbidity risk which may arise due to disease.

UPPP, which was first described by Ikematsu and popularised by Fujita, is an effective surgical procedure in treatment of moderate and severe OSAS (7). However, it has lost its popularity because it is an invasive and destructive type of surgery. Success rates in the treatment of OSAS which reach to 80% at the beginning, drops to 40% in the long term (8). Postoperative bleeding (2%), moderate nasal regurgitation (20-60%), velopharyngeal insufficiency (5%) and nasopharyngeal stenosis can be seen. Late complications include resonance changes in voice and foreign body-like feeling in the oropharynx due to increase in mucus secretion (9, 10).

LAUP is a technique that was started to be used in snoring and OSAS after UPPP in the early 1990's. It has many advantages over UPPP. It is performed in ambulatory setting in sessions of 15-20 minutes with local anesthesia. In their

study, Wareing et al. reported lower complication rates in LAUP as compared with UPPP. Besides, severe pain which may continue for 5-10 days after the operation and necessitate use of narcotic analgesics is the most important problem. Disadvantages include high price of laser equipment that is necessary for the procedure and possible requirement of successive implementations which may take few sessions. Postoperative pain causes the patients to be suspicious if any need for repeating LAUP arises (11).

Madani et al. accomplished the UPPP technique with the assistance of laser in order to minimize complications arising from traditional UPPP technique. Thanks to Laser Assisted-UPPP, which is a modified method, lesser amount of tissue can be resected from soft palate. It is also stated that voice changes and food reflux that are seen in UPPP do not occur in this technique. Its only disadvantage is intense throat pain that may last for 2 weeks (12).

CAPSO (Cautery Assisted Palatal Stiffening Operation) is an economical method that is specially applied in primary snoring and in some of the cases with OSAS. It is a bloodless technique that may be performed with limited anesthesia or IV sedation in office setting. Its success rate is high in primary snoring, but lower in OSAS. A pain that prolongs recovery period for a couple of days accompanies.

Gnuchtel et al. found no significant difference between CAPSO and LAUP techniques and mentioned about the huge disparity in costs between these two equipments (13). Uvulopalatal flap and transpalatal advancement palatoplasty are the techniques that involve uvula and soft palate and performed in some selected cases in recent years. **The uvulopalatal flap method can be performed in a single session has a low velopharyngeal insufficiency rate due to minimal excision of the tissue and is a reversible and less painful technique.** Transpalatal advancement palatoplasty, on the other hand, is a technique that is recommended for selected cases who did not respond previous UPPP and do not prefer maxillomandibular surgery (14).

Morbidity is significantly reduced by the radiofrequency thermal ablation (RFA) technique. Powell et al. used the RFA technique in the tongue root for the first time in ENT. Later, same authors used this technique in the soft palate for snoring

and published the results in 1998. Like LAUP, RFA can be done under local anesthesia and the severity and duration of pain are less. The advantage of this technique is that it can accomplish tissue ablation at a very low temperature. Mucosal integrity is not disrupted because it is done submucosally (15).

First developed by Ho et al. in 2004, palatal implant placement is a minimally invasive technique. Three implants are placed near the midline in the soft palate under local anesthesia. It is reported to be a safe and effective method that is easily tolerated by patients (6).

Romanow et al. reported no serious complications during 90 days of follow up in their 21 cases, only two implant rejections were seen in a patient (2/75); and partial rejection rate was 4%, patient satisfaction was 75% and patient's relative or spouse satisfaction was 90% (16).

Nordgard et al. reported a total of 9 rejections in 6 patients whom they followed for 1 year; a 51% decrease in snoring and patient's relative or spouse satisfaction of 86% in 36 cases (17).

Walker et al. reported no serious complications in 24 cases after a follow up of 30 days and apnea observation done by patient's relative or spouse that was evaluated by VAS reduced from 71% to an average value of 20% (18).

In a study, Friedman et al. placed palatal implant in 125 cases and they followed the cases for 4-6 months. No serious complications were reported as a result of the study. Partial rejection was evident in 10 cases, PSG and VAS were used as evaluation methods and recovery rate was 88% subjectively and 34% objectively (19).

Implant rejection occurred in seven cases (8.9%), and the total number of implants that were rejected was 9. Four implants were rejected in the first hour, and new ones were placed. **In our opinion, possible reasons for these early rejections** are that they were our first patients, local anesthesia was imperfect and the implant might have been placed too superficially. One implant was rejected in the second week, 3 implants were rejected in the 4th and 5th weeks and one implant was partially rejected in the postoperative first year. Sting-like and/or blocked-like feelings in throat that occurred in the early stages disappeared spontaneously. A new implant replacement was not considered to be necessary in these patients. The implant rejection rate in our study was lower comparing literature. **Three patients (3.8%) experienced ecchymosis on their palates.** This was due to use of antiaggregant. Other complications that we encountered included pain in 7 cases (8.9%) during the early stages. None of our cases suffered pain in the late stages. Sting-like and/or blocked-like feelings in throat that occurred in the early stages disappeared spontaneously. They were seen in 3 cases (3.8%) in the late period. **It was found out that these complaints were due to partial rejection.** No problems occurred involving functions of speech or swallowing in our cases.

In conclusion, under the light of these findings, we asserted that this procedure has advantages such as being minimally invasive, not causing complications like mucosal ulceration and velopharyngeal insufficiency, single-session-applicability and providing possibility to all other treatment modalities after the procedure. Sometimes, although rare some cases suffered pain in the early stages. In conclusion, we found that palatal implant procedure is a good option in simple snoring and mild to moderate OSAS. Considering the efficiency of treatment;

it can be performed in office settings with low morbidity; it is minimally invasive comparing other surgical methods, and it has advantages over other methods for patient compliance.

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