Original Article / Çalışma - Araştırma

Palatal Pillar implants for the treatment of simple snoring

Basit horlama tedavisinde palatal Pillar implantlar

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Objectives: In this study the efficacy of palatal implants for treatment of snoring was evaluated.

Patients and Methods: Seventeen patients (10 males, 7 females; mean age 49.2±7.8 years; range 31 to 66 years) with primary snoring and an apnea-hypopnea index of less than 15 were treated with palatal implants after clinical and endoscopic examination. Snoring-related symptoms were evaluated at baseline and 90 days after surgery and polysomnography was performed. Patients and their spouses completed questionnaires and visual analog scales (VAS) evaluating snoring, apneas, and the intensity, duration, and social effects of daytime sleepiness at baseline and 90 days after surgery. Pre- and postoperative assesment results were compared.

Results: Epworth sleepiness scale score was significantly decreased in the postoperative period ($p<0.05$). Postoperative mean VAS snoring, apnea, and daytime sleepiness scores were also significantly improved ($p<0.01$). No patients reported worsening of apnea, 5.9% of patients reported no change in apnea, and 94.1% of patients reported a marked decrease in apneas. In the postoperative period, 76.4% of patients reported reduced snoring, and 88.3% of patients reported reduced daytime sleepiness.

Conclusion: Palatal implants have been demonstrated to be a safe and effective treatment for snoring with minimal patient discomfort. Establishing realistic pretreatment expectations can maximize patient satisfaction.

Key Words: Palatal implant; sleep apnea syndrome; snoring; snoring treatment.

Amaç: Bu çalışmada horlama tedavisinde palatal implantların etkinliği değerlendirildi.

Hastalar ve Yöntemler: Basit horlaması olan ve apne hipopne indeksi 15'in altında bulunan 17 hastaya (10 erkek, 7 kadın; ort yaş 49.2±7.8 yıl; dağılım 31-66 yıl) klinik ve endoskopik değerlendirmelerin ardından palatal implant uygulandı. Tedavi başlangıcında ve 90 gün sonrasında horlama ile ilişkili semptomlar değerlendirildi ve hastalara polisomnografi uygulandı. Hastalar ve eşleri, horlamayı, apneyi, gündüz uykululuğunun yoğunluğunu ve süresini değerlendiren formları ve görsel analog skalalarını (GAS) tedavi başlangıcında ve implant uygulandıktan 90 gün sonra doldurdular. Ameliyat öncesi ve sonrası değerlendirme sonuçları karşılaştırıldı.

Bulgular: Hastalarda ameliyat sonrasında Epworth uykululuk skalası skorundaki düşme belirgindi ($p<0.05$). Ameliyat sonrası ortalama GAS horlama, apne ve gündüz uykululuk değerlerinde de istatistiksel olarak belirgin düzelme görüldü ($p<0.01$). Hiçbir hasta apnesinde kötüleşme bildirmedi, hastaların %5.9'u apnesinde değişme olmadığını, %94.1'i ise apnesinde belirgin azalma olduğunu bildirdi. Hastaların %76.4'ü ameliyat sonrasında horlamalarının, %88.3'ü ise gündüz uykululuklarının azaldığını bildirdi.

Sonuç: Palatal implantlar, horlama tedavisinde, hastaya fazla rahatsızlık vermeden uygulanabilen güvenli ve etkili bir tedavidir. Tedavi öncesinde hastada gerçekçi beklentilerin oluşturulması, hastanın bu tedaviden memnuniyetini artıracaktır.

Anahtar Sözcükler: Damak implantları; uyku apne sendromu horlama; horlama tedavisi.

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Snoring is generally caused by the vibration of the soft palate during the sleep, and approximately 20% of the adult population snores habitually.[1,2] The definition of snoring is the production of sound by the upper aerodigestive tract during sleeping due to airway collapse. A partial narrowing of the airway causes airflow turbulence, which in turn results in the vibration of the upper airway soft tissues. Vibration of the soft tissues can occur at the palatal level (the velopharynx) or at the tongue. Collapse and vibration of the velopharynx is found in most patients with sleep-related disorders.[3] Primary snoring appears to have no long-term effects on the coronary, the systemic or the cerebral circulation. However, it can cause difficulties, poor sleep quality and disturbances of others' sleep.[1]

Various treatment strategies have been used to counteract upper airway collapse in snoring and sleep apnea. Fujita et al.[4] introduced uvulopalatopharyngoplasty (UPPP), for the treatment of sleep apnea syndrome. A later modification to reduce the morbidity of UPPP, laser-assisted uvuloplasty (LAUP), was developed by Kamami[5] in 1990 as an outpatient-based treatment for both snoring and obstructive sleep apnea (OSA). Powell et al.[6] introduced radiofrequency tissue ablation (RFTA) surgery in 1997 to harden the soft palate with fibrosis. The swelling caused by tissue ablation, the unpredictable relapse of snoring over time due to scar remodeling and the necessity for more than one procedure have compelled physicians to seek alternative procedures. Injection of a sclerotic agent, namely sotradecol,[7] has been introduced as an alternative modality, but this procedure includes the risk of tissue necrosis or allergic reactions, and the extent of this tissue necrosis is unpredictable.[8]

Due to high postoperative morbidity in patients who undergo aggressive operative procedures such as UPPP and LAUP for simple snoring and mild OSA, patients and physicians prefer minimally invasive and less painful procedures as primary treatment options. Palatal implants were introduced in 2002 as a minimally invasive, single-stage treatment for snoring and sleep apnea with low morbidity and promising results.[9-11] In the Pillar procedure, three polyethylene terephthalate (PET) implants are inserted in the mucosal layer of the soft palate sagittally, parallel to each other, and spaced 2 mm apart in a simple office procedure. Research and clinical results demonstrate that PET material is safe to be used in humans. Polyethylene terephthalate has been used in surgical sutures, mesh, and vascular graft material for many years.[12-15] This material has biostability and creates a fibrotic reaction, which promotes tissue ingrowth.[16-18] Fibrotic capsule formation is mainly complete after 12 weeks following the procedure. The palatal implants increase the stiffness of the soft palate and also create a tissue reaction leading to fibrosis, which decreases the vibration of the soft palate due to airflow turbulence.[9]

The objective of this study was to evaluate the efficacy of palatal implants for the reduction of soft tissue vibration and snoring. We assessed subjective and objective data along with pre- and postoperative polysomnography (PSG) results in a sample of subjects with simple snoring.

PATIENTS AND METHODS

A prospective, nonrandomized clinical trial was performed on 17 patients (10 males, 7 females; mean age 49.2±7.8 years; range 31 to 66 years) in the Otolaryngology Department of the Tertiary health care from May 2005 to May 2006. In the sleep study center, pulmonary function tests (PFT) and prick tests for allergies were performed. Age, height and weight of the patients were recorded. The body mass index (BMI) was calculated as weight in kilograms divided by the height in meters squared. Patients and their bed partners were required to complete a questionnaire to evaluate the severity, intensity, duration, and social effects of snoring, apneas and daytime sleepiness. The intensity of snoring, apneas and daytime sleepiness were measured between 0 to 10 mm on a visual analog scale (VAS). On this snoring VAS, zero was taken as no snoring and 10 as snoring at maximum loudness causing the partner to leave the bedroom. Apnea VAS questionnaires were completed in a scale from zero to 10 by bed partners. Patients graded their day time sleepiness on a similar VAS scale. Patients and their bed partners were also asked how many nights or days per week they experienced disturbing snoring, apneas and severe daytime sleepiness. An Epworth sleepiness scale (ESS) was also used to assess daytime sleepiness.

Formal overnight PSG was performed on all patients. The PSG included electroencephalography, electrooculography, electrocardiography, submental electromyography, oximetry, airflow monitoring with nasal thermister, heart rate monitoring, body position monitoring, chest and abdominal movement monitoring, and leg movement

monitoring. A committee consisting of otolaryngologists from the otolaryngology clinic and chest disease specialists from two separate sleep laboratories discussed all the patients separately, together with their results.

Patients with an apnea-hypopnea index (AHI) score below 15 with a BMI less than 32 kg/m^2 were selected as candidates to enter the study. The exclusion criteria from this study included a soft palate length less than 25 mm, previous palatal or

Table 1. Pre- and postoperative patient datas

Age/ sex	ESS	BMI	AHI	ODI	Apnea	Snoring	DTS	Apnea day/week	Snoring day/week	DTS day/week	Apnea imp.	Snoring imp.	DTS imp.	Sugges-tion
49/F														
Preop.	8	27.6	13	9	8	8	8	4	5	4				
Postop.	8	27.6	13.3	9	4	4	5	2	3	2	Moderate	Moderate	Moderate	2
41/F														
Preop.	9	32	14.2	4	6	8	6	5	5	5				
Postop.	4	32	13	4	1	4	1	0	4	3	Good	Moderate	Moderate	1
46/F														
Preop.	11	26.4	6.2	1	4	6	6	5	5	3				
Postop.	5	26.4	13.9	4	0	1	0	2	3	0	Moderate	Good	Good	2
47/M														
Preop.	17	30	14.2	8	8	7	6	4	5	4				
Postop.	4	31	18.4	10	3	8	0	2	2	0	Same	Moderate	Moderate	3
59/M														
Preop.	9	29.3	4.5	4	7	8	4	3	5	3				
Postop.	9	29.3	5	5	4	4	1	2	5	3	Good	Good	Good	1
55/M														
Preop.	4	24.1	7.7	4	7	8	7	5	5	5				
Postop.	2	24.1	10.2	8	2	4	2	3	5	2	Moderate	Moderate	Moderate	2
58/M														
Preop.	4	32	12.7	6	8	8	7	5	5	4				
Postop.	2	32	14.6	3	4	6	2	3	3	3	Moderate	Moderate	Moderate	2
31/M														
Preop.	7	28	6.2	19	7	8	6	4	5	4				
Postop.	5	28.4	10.9	7	2	4	0	2	2	0	Moderate	Good	Good	2
46/F														
Preop.	16	32	14.6	12	7	8	9	4	5	5				
Postop.	10	32	17.7	6	4	6	6	2	3	3	Moderate	Moderate	Moderate	2
48/M														
Preop.	2	24.4	11.4	4	7	8	4	4	4	3				
Postop.	1	23	13.2	5	3	3	0	2	3	0	Moderate	Good	Good	2
45/F														
Preop.	4	24.2	4	1	9	7	7	5	5	3				
Postop.	5	22	5.5	2	0	4	2	0	3	2	Moderate	Good	Good	2
66/M														
Preop.	5	28.7	14.9	8	7	5	4	4	4	4				
Postop.	5	28.7	13.2	8	4	4	3	3	3	3	Moderate	Moderate	Moderate	2
45/F														
Preop.	1	31.8	15	17	6	8	7	4	5	3				
Postop.	1	31.8	18.7	17	3	9	2	1	4	2	Worse	Moderate	Good	4
49/M														
Preop.	2	26.6	12.9	5	6	8	5	3	5	4				
Postop.	2	26.6	12	10	4	5	0	1	3	1	Moderate	Moderate	Moderate	2
52/M														
Preop.	4	29	11.5	10	8	6	6	5	5	5				
Postop.	4	29	21.3	5	3	3	3	3	2	2	Good	Good	Good	1
52/F														
Preop.	1	28	8.4	6	7	7	2	4	4	2				
Postop.	1	26.7	13.3	15	3	4	0	4	3	1	Same	Same	Same	3
48/M														
Preop.	11	28	8.8	5	7	6	6	3	3	4				
Postop.	8	26.7	15.2	10	3	6	6	1	1	1	Same	Good	Same	3

ESS: Epworth sleepiness scale; BMI: Body mass index; AHI: Apnea hypopnea index; ODI: Oxygene desaturation index; DTS: Daytime sleepiness; imp: Improvement; F: Female; M: Male; Preop.: Preoperative; Postop.: Postoperative.

pharyngeal surgery (except for previous tonsillectomy or adenoidectomy), nasal polyposis, significant symptomatic septal deviation and severe cardiovascular or pulmonary disease. Additionally, patients without a regular adult observer of their sleep were excluded from this study.

Informed consent was obtained from all subjects. Consent forms, protocol, data sheets and questionnaire forms were approved by the hospital ethics committee.

The Pillar Implant System (Restore Medical Inc, St. Paul, MN, USA) consists of a delivery tool preloaded with a palatal implant. This system allows for positioning the placement of three implants within the soft palate. Once the appropriate depth is reached, a thumb slider on the handle is pulled down to retract the needle tip while the obturator housed within the needle maintains the position of the implant, leaving the implant in place when the delivery tool is withdrawn from the tissue. The office procedure was done under local anesthesia without sedation with all the patients in a sitting position. Lidocaine 10% spray was administered as a topical anesthetic to the oral mucosa, and lidocaine (1%) and adrenalin (1:100.000 dilution) was locally injected on the soft palate. The surgeon depressed the tongue with a spatula for optimal access to the field. Three implants were placed in each patient. The first implant was inserted at the median position sagittally in the intramuscular layer of the soft palate, entering just below the posterior end of the hard palate. The procedure was repeated to place the second and third implants 2 mm laterally on each side of the midline sagittally. Fiberoptic nasopharyngoscopy was performed immediately afterwards to ensure there is no exposure of the implant on the nasopharyngeal aspect of the soft palate. The patients were observed 30 minutes postprocedurally, and then discharged from hospital with a prescription of naproxen sodium 275 mg to be used as needed.

Follow-up was performed by means of office visits at 2, 7, and 30 days after surgery, but the final outcome was assessed 90 days after surgery by PSG, a complete physical examination and completion of questionnaires by patients and their bed partners. Patients were also asked if they would recommend the procedure to a friend.

Analysis was done using a SPSS (Statistical Package for Social Sciences) for Windows 10.0 version program (SPSS Inc., Chicago, Illinois, USA). Statistical significance was determined with the Wilcoxon signed-rank test for related samples and the Mann Whitney U-test for independent samples. $P<0.05$ values were considered to indicate significance. The results are expressed as mean ± standard deviation.

RESULTS

Pre- and postoperative results of sleep studies and patient datas are shown in Table 1.

There was no significant difference between the mean pre- and postoperative patient BMI ($p>0.05$; Table 2). The Epworth sleepiness scale score at the time of the surgery was 6.8±4.9 and it significantly decreased to 4.5±2.9 in the postoperative period ($p<0.05$; Table 2). The apnea-hypopnea index scores were 10.6±4.7 preoperatively and 13.5±4.8 postoperatively ($p<0.01$; Table 3); and they remained in the mild range. The mean oxygen desaturation index (ODI) remained statistically unchanged at 7.2±5.0 preoperatively and 7.5±4.1 in the postoperative period ($p>0.05$; Table 3).

The visual analog scale scores for snoring, apnea and daytime sleepiness indicate subjective improvement in these areas. The preoperative mean snoring VAS score decreased significantly

Table 2. Comparison of pre- and postoperative Epworth sleepiness scale and body mass index

	Mean±SD	Test statistic; *p*
Epworth sleepiness scale		
Preoperative	6.8±4.9	t:2.679;
Postoperative	4.5±2.9	p:0.016*
Body mass index		
Preoperative	28.4±4.3	t:1.691;
Postoperative	28.1±4.5	p:0.110

t: Paired sample t-test; *: Statistically significant; Mean±SD: Standard deviation.

Table 3. Comparison of pre- and postoperative apnea hypopnea index, and oxygen desaturation index

	Mean±SD	Test statistic; *p*
Apnea hypopnea index		
Preoperative	10.6±4.7	t:-3.498;
Postoperative	13.5±4.8	p:0.003**
Oxygen desaturation index		
Preoperative	7.2±5.0	t:-0.250;
Postoperative	7.5±4.1	p:0.806

t: Paired sample t-test; *: Statistically significant; Mean±SD: Standard deviation.

Table 4. Comparison of apnea, snoring, and daytime sleepiness scores

	Mean±SD	Median	Test statistic; *p*
Apnea			
Preoperative	7.0±1.1	7	Z:-3.648;
Postoperative	2.9±1.5	3	p:0.001**
Snoring			
Preoperative	7.3±1.0	8	Z:-3.329;
Postoperative	4.7±1.9	4	p:0.001**
Daytime sleepiness			
Preoperative	5.9±1.7	6	Z:-3.545;
Postoperative	1.9±2.1	2	p:0.001**

Z: Wilcoxon test; **: Statistically significant; Mean±SD: Standard deviation.

Table 5. Mean days in a week disturbed from apnea, snoring, and daytime sleepiness

	Mean±SD	Median	Test statistic; *p*
Apnea			
Preoperative	5.6±1.5	6	Z:-3.645;
Postoperative	1.7±1.5	2	p:0.001**
Snoring			
Preoperative	6.5±1.1	7	Z:-3.432;
Postoperative	3.5±1.8	3	p:0.001**
Daytime sleepiness			
Preoperative	5.0±1.6	5	Z:-3.648;
Postoperative	1.7±1. 5	2	p:0.001**

Z: Wilcoxon test; **: Statistically significant; Mean±SD: Standard deviation.

from 7.3±1.0 to 4.7±1.9 postoperatively (p<0.01). The mean apnea VAS score also decreased significantly from 7.0±1.1 to 2.9±1.5 postoperatively (p<0.01). Mean daytime sleepiness score also decreased significantly from 5.9±1.7 to 1.9±2.1 in the postoperative period (p<0.01; Table 4).

Bed partners were asked how many days of the week they felt uncomfortable because of the patients' apnea and snoring and their daytime sleepiness. For apnea, the mean number of days decreased significantly from 5.6±1.5 in the preoperative period to 1.7±1.5 in the postoperative period (p<0.01). For patients' disturbing snoring, the number of mean days decreased significantly from 6.5±1.1 in the preoperative period to 3.5±1.8 in the postoperative period (p<0.01). Mean days of disturbance from daytime sleepiness decreased significantly from 5.0±1.6 days to 1.7±1.5 days postoperatively (p<0.01; Table 5).

Patients were also asked for their subjective feelings about their apneas, snoring, and daytime sleepiness after the Pillar implant procedure. None of the patients mentioned worsening in apnea, 5.9% of the patients reported no change in apnea, 52.9% of the patients mentioned that their apnea were less and they felt moderately better than the preoperative period, and 41.2% of the patients said there was a marked decrease in apnea. As for snoring, 5.9% of the patients complained about a worsening of their snoring, 17.6% felt no change, 58.8% reported they had less snoring, and 17.6% of the patients mentioned that they felt great improvement in the postoperative period. None of the patients mentioned any worsening in daytime sleepiness, 11.8% reported no change, 47.1% mentioned their daytime sleepiness decreased moderately and they felt better, and 41.2% reported a marked decrease in daytime sleepiness (Table 6).

Table 6. Patient ratings of apnea, snoring, and daytime sleepiness after Pillar implant procedure

Measure	n	%
Apnea		
Bad	–	–
Same	1	5.9
Good	9	52.9
Very good	7	41.2
Snoring		
Bad	1	5.9
Same	3	17.6
Good	10	58.8
Very good	3	17.6
Daytime sleepiness		
Bad	–	–
Same	2	11.8
Good	8	47.1
Very good	7	41.2

Table 7. Patient satisfaction with the Pillar procedure

Suggestion	n	%
I'm really satisfied and I would recommend it to others	3	17.6
The results are moderately good and I could recommend it	10	58.8
It didn't reach my expectations so I would not recommend it	3	17.6
I felt uncomfortable during and after the procedure and would not recommend it to others	1	5.9

Regarding the Pillar implant procedure, 17.6% of patients indicated that they were really satisfied and would recommend it to others, 58.8% said the results were moderately good and they could recommend it, 17.6% said it did not fulfill their expectations and so they would not recommend it, and 5.9% said that they felt uncomfortable during and after the procedure and would not recommend it to others. (Table 7).

During the trial, a total of 51 implants were placed and three (5.9%) implants became visible under the mucosa of the soft palate. They were removed during the procedure and new implants were placed without any complication. There were no reports of postoperative pain or any other complication for the first 24 hours, and all patients were able to return to their normal daily activities. No other complications (e.g. extrusion of the implant, bleeding, infection, or mucosal lesions) were reported. There were no reports of chronic pain, dysphagia, or change in the taste sensation after the Pillar implantation.

DISCUSSION

Previous publications have reported positive results on the efficacy of palatal implants for the treatment of snoring. Kühnel et al.[11] reported that palatal implants were an effective treatment for snoring based on objective and subjective data from 106 patients. Ho et al.[9] reported on palatal implants for the treatment of snoring in 12 patients with improvement in the VAS scores from 79 (0-100) to 48 and also improvement in the ESS from 8.9 to 5.7. There were no changes observed in the patients' BMI and AHI in this trial. Nordgard et al.[10] reported a decrease in the snoring intensity VAS value from 7.3 to 3.6 and a decrease in ESS from 9.3 to 4.6, with 89% patient satisfaction. The one-year follow-up results for this group reported a decrease in the snoring intensity VAS from 7.1 to 4.1 with 70.6% patient partner satisfaction.[19] Maurer et al.[20] also reported on 40 patients after a one-year follow-up, period, and in this report, the snoring VAS value was reduced from 7.1 to 4.8 and the ESS was reduced from 6.1 to 4.9. Eryılmaz et al.[21] reported decreased AHI six months after the procedure. The visual analog scale of sleepiness, ESS, the intensity of snoring and the VAS of snoring according to the bed partner were also decreased in this study.

This investigation reports similar successful results as the previously published studies investigating palatal implants for the treatment of snoring. In our study, none of the patients reported any worsening in their apnea after three months; 5.9% of patients suggested no change and 94.1% mentioned a reduction in the apnea subjectively. Despite these subjective improvements, the AHI increases from 10.6±4.7 to 13.5±4.8 in the PSG results three months after Pillar procedure. Although this increase was found to be statistically significant, the postoperative mean AHI score remained in a mild range. Also, no change was observed on the ODI. These results may be due to the inflammation and edema caused by the implants. The results concerning the oxygen desaturation show us that a mild increase in the AHI might not be so serious. The postoperative PSG studies were performed at the 90th day postoperatively and this short term follow-up may have affected the end results. In another study, the investigators found the AHI and ODI values unchanged after the same follow-up period.[9]

The Pillar palatal implant procedure can be performed in the office and under local anesthesia. Patients do not need to be prescribed postoperative antibiotics or narcotic pain relief medication after the procedure. Regarding the implantation technique, the insertion point must be at the junction of the soft and hard palates. Additionally, it is important to not insert the implant while the patient is gagging and to remove the implant if it is visible through the oropharyngeal or nasopharyngeal mucosa in order to replace it with another implant.[22] In our study, there were no partial extrusions. We paid extra attention not to inject too much infiltration anesthesia material, and palpated the palate before the insertion of the implant as advised by previous authors.[22]

In conclusion, we reported the preliminary data on 17 patients receiving palatal implants to relieve snoring. The procedure was successful in the reduction of snoring in this 90-day follow-up study. Palatal implants represent an option for ENT surgeons for the single-stage treatment of simple snoring with minimal discomfort and minimal risk. The procedure is easy to perform and establishing realistic pretreatment expectations maximizes patient satisfaction. The patients should be informed that only minimal improvement might be obtained in the complaint of apnea. They should also be informed that the snoring problem is more prone to treatment than the apnea problem.

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