NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of soft-palate implants for obstructive sleep apnoea

Obstructive sleep apnoea (OSA) is a breathing disorder in which the airway is blocked intermittently and repeatedly during sleep as the muscles of the mouth and throat relax. Patients with OSA usually snore and experience severe sleep disturbance and serious daytime sleepiness. The soft palate, a region of the roof of the mouth, is involved in OSA in some patients. Small pieces of synthetic fibre can be implanted into the soft palate, with the aim of making it stiffer and less likely to collapse and block the airway during sleep.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in March 2007.

Procedure name

- Soft-palate implants for obstructive sleep apnoea

Specialty societies

- British Society of Otorhinolaryngologists, Head and Neck Surgeons (ENT-UK)
- British Association of Oral and Maxillofacial Surgeons
- British Thoracic Society
- Association of Anaesthetists of Great Britain and Ireland
- Royal College of Anaesthetists
- British Sleep Society

Description

Indications

OSA or obstructive sleep apnoea/hypopnoea syndrome

OSA is characterised by repeated, reversible episodes of apnoea and hypopnoea during sleep, loud snoring and excessive daytime sleepiness.

A degree of relaxation of the soft structures of the mouth and throat during sleep is normal, but in most people the airway remains open. Patients with OSA have particular anatomical characteristics (sometimes including a long or floppy soft palate) that make the soft pharyngeal structures liable to collapse when the patient is asleep, blocking the airway. In adults, an apnoea episode is defined as a pause in breathing that lasts 10 seconds or more. In a hypopnoea episode, breathing continues but ventilation is reduced by at least 50% for 10 seconds or more. In response to an apnoea/hypopnoea episode, the patient will spontaneously arouse, either fully or to a lighter phase of sleep, in order to reopen the airway. The cycle can be repeated many times during the night. The patient's bed partner may witness them gagging or waking with a snort, but patients themselves may be unaware of the condition. OSA is more common in obese individuals, and can be exacerbated by alcohol consumption and sedative medication.

Daytime sleepiness associated with OSA can be extreme, and is associated with poor academic or work performance and an increased risk of accidents. Snoring and gagging episodes may disturb the sleep of bed partners or household members, and affect relationships. OSA has also been linked with the development of hypertension, though this association may not be causal.

The diagnosis and severity of OSA can be confirmed by sleep studies, which may involve one or more of measurement of inspiratory airflow, pulse oximetry, recording of snoring, EEG recording of sleep patterns and video recording. The apnoea-hypopnoea index (AHI) is the combined number of apnoea and hypopnoea episodes experienced on average per hour of sleep, although there is nightly variation. An AHI score of 5–14 events per hour is defined as mild OSA, 15–30 as moderate OSA, and a score above 30 as severe OSA. The Epworth sleepiness scale (ESS), with patient-reported scores ranging from 0 (best) to 24 (worst), is a tool used to assess daytime tiredness. Excessive daytime sleepiness is generally defined as a score of 8–10 or more.

Current treatment and alternatives

OSA may be improved by lifestyle changes such as avoidance of alcohol or sedative medication, weight loss and change of sleeping position.The treatment most commonly used for patients with more severe OSA is continuous positive airway pressure (CPAP), applied through a face mask during sleep. Other physical interventions include use of mandibular advancement devices during sleep. Surgical interventions for OSA that involves the soft palate include injection of a sclerosant into the soft palate

(injection snoreplasty), radiofrequency ablation of the soft palate, laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty and cautery-assisted palatal stiffening.

What the procedure involves

The procedure is usually performed under local anaesthesia. The soft palate may be measured to ensure that it is long enough to accommodate the implants, synthetic fibres typically less than 2 cm in length. A hollow introducer needle containing the implant is used to pierce the soft palate, close to the junction with the hard palate, reaching into the muscle layer. The needle is then withdrawn, leaving the implant in position. A mirror examination or nasal endoscopy may be used to check that the implant has not penetrated the nasal surface of the soft palate. Typically two or three implants are inserted in a single procedure, at the midline of the soft palate or parallel to it. The aim of the procedure is to stiffen the soft palate over subsequent weeks as a result of fibrosis. The implants may be removed with forceps if necessary.

Efficacy

Frequency of apnoea and hypopnoea episodes

Four case series of patients who received soft-palate implants for mild-to-moderate OSA reported decreases in mean AHI from preoperative baseline to final postoperative follow-up, although not all changes were significant.[1–4] Mean AHI (events per hour) decreased from 25.0 (standard deviation [SD] 13.9) to 22.0 (SD 14.8) in one study (n = 53, 90 days follow-up, p = 0.05),[1] from 16.2 (SD 4.6) to 12.1 (SD 9.1) in a second study (n = 25, mean follow-up 87 days, p = 0.033),[2] from 33 to 25 in a third study including patients with a history of palatal surgery for snoring or OSA (n = 23, 6 months' follow-up, p < 0.05),[3] and from 12.7 to 11.5 in a fourth study (n = 29, 3–6 months' follow-up, decrease not significant).[4]

Daytime sleepiness

The first three case series described above reported significant reductions (p < 0.001) in mean ESS scores from baseline to final follow-up. Mean scores decreased from 11.0 (SD 5.1) to 6.9 (SD 4.5),[1] from 9.7 (SD 3.6) to 5.5 (SD 3.5),[2] and from 13.2 (SD 2.9) to 8.7 (SD 1.8)[3] in the three studies. The fourth case series reported a reduction in ESS score in 52% (15/29) of patients (4–6 months' follow-up).[4] In two further case series that combined patients with mild OSA or simple snoring, ESS score decreased from 9.3 (SD 4.1) to 5.6 (SD 3.8) (n = 34, 1 year's follow-up, p < 0.001)[5] and from 8.9 (SD 5.6) to 5.7 (SD 5.6) (n = 9, 3 months' follow-up, p = 0.007).[6]

Snoring intensity

The first three case series reported significant reductions in snoring intensity (p < 0.001), assessed by the patient's bed partner using a scale from 0 (no snoring) to 10 (extreme snoring causing the partner to leave the room).[1–3] Mean scores decreased from 7.9 (SD 2.1) to 4.0 (SD 3.0),[1] from 8.4 (SD 1.2) to 4.3 (SD 2.6),[2] and from 8.7 (SD 1.8) to 3.4 (SD 1.8).[3] The fourth case series reported that snoring intensity had reduced by 50% (assessed by bed

partner) in 79% (23/29) of patients.[4] In the two case series that combined patients with mild OSA or simple snoring, mean scores for snoring intensity decreased from 7.1 (SD 2.1) to 4.8 (SD 3.1) at 1 year's follow-up ($p < 0.001$)[5] and, using a 0–100 loudness scale, from 79 (SD 17.2) to 48 (SD 20.4), ($p = 0.008$).[6]

Blood oxygen saturation

Two studies reported small increases in the minimum arterial oxygen saturation between preoperative baseline and final postoperative follow-up.[1,3] In the case series of 53 patients, lowest oxygen saturation during sleep was 81.8% (SD 10.6) at baseline and 83.2% (SD 6.2) ($n = 53$, 90 days' follow-up, difference not significant).[1] In the other case series, these values (estimated from a graph) were approximately 87% and 89%, respectively ($n = 23$, 6 months' follow-up, $p < 0.05$).[3]

Safety

Partial extrusion of the implant

Extrusion of the implant was reported in 8% (2/25) of patients (74–100 days' follow-up),[2] none of 23 patients (6 months' follow-up),[3] 2.7% (10/372) of implants ($n = 125$ patients, 4–6 months' follow-up),[4] and 9.9% (20/202) of implants ($n = 63$ patients, 90 days' follow-up).[1] Most studies reported that extruded implants were removed easily; however, in one study "considerable force" was required to remove a partially extruded implant that had meshed with surrounding tissue, and the patient required local anaesthesia.[4]

The two case series that combined patients with mild OSA or simple snoring reported partial extrusion of implants in 18% (6/34)[5] and 17% (2/12)[6] of patients – 9% (9/102)[5] and 9% (3/34)[6] of implants, respectively.

Infection and inflammation

Mucosal irritation or ulceration at the site of implantation occurred in 6% (4/63) of patients in one case series and resolved within 2 weeks.[1] One patient required antibiotics. Two case series (35 patients in total) reported that no patients experienced infection at the implantation site,[3,6] and one case series ($n = 34$) reported that no patients experienced mucosal breakdown, palatal swelling, discomfort or fistulae.[5] In three case series (69 patients in total) there were no occurrences of infection or inflammation at the implantation site.[3,5,6] No other adverse effects were reported in any of the studies.

Palatal perforation

In the case series of 25 patients, in one patient the posterior (nasal) palatal surface was perforated twice during the procedure before the third implant was placed properly.[2]

Pain

Four of the case series reported pain related to the procedure, using a scale from 0 (no pain) to 10 (extreme pain). In the first case series ($n = 53$), the mean pain score was 3.1 24–72 hours after the procedure, 1.4 after 2 weeks and 0.4 after 30 days.[1] In the second study ($n = 25$) the mean pain score was 0.5 before the procedure and 90 days after.[2] In two further case series, scores were 3–6 and 3–5 in the 24 hours after the procedure.[3,4]

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to soft-palate implants for OSA. Searches were conducted via the following databases, covering the period from their commencement to 17 March 2007: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See Appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with OSA. Studies that included patients with either OSA or simple snoring were also included.
Intervention/test	Soft palate implants
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy of the procedure.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on four case series of patients with OSA[1–4] and two case series that combined patients with OSA and patients with simple snoring.[5,6] No other studies were identified.

Existing reviews on this procedure

A number of evidence-based clinical guidelines for the treatment of OSA were identified but none of these discussed soft-palate implants.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures

'Radiofrequency ablation of the soft palate for snoring.' NICE interventional procedure guidance 124 (2005). Available from http://guidance.nice.org.uk/IPG124 ..

NICE is developing interventional procedures guidance on soft-palate implants for simple snoring (IP388) which is due to be published in Winter 2007.
http://guidance.nice.org.uk/ipcat.aspx?o=IP_388

Technology appraisals

NICE is developing quidance on 'Sleep apnoea – continuous positive airways pressure', which is due to be published in January 2008.
(http://guidance.nice.org.uk/page.aspx?o=350198)

Clinical guidelines

None

Public health

None

Table 2 Summary of key efficacy and safety findings on soft-palate implants for obstructive sleep apnoea

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Walker RP et al (2006)[1]

Case series

USA

Study period: Not stated

n = 63 for safety outcomes
(mean age: 50 years)

Inclusion criteria: Primary palatal contribution to OSA, determined by investigator, AHI 10–30, BMI ≤ 32 kg/m^2, age ≥ 18 years, soft palate long enough to accommodate 18 mm implant

Exclusion criteria:
Significant nasal obstruction, no bed partner, previous history of palatal surgery other than tonsillectomy, surgery outside the study during follow-up, did not receive follow-up polysomnography evaluation

Technique:
3 ‘Pillar’ implants, 18 mm × 1.8 mm, were used. Local anaesthesia, 3 of the 5 study centres gave patients antibiotics before surgery; all 5 centres gave postoperative antibiotics; anti-inflammatory medication was given before and after surgery; narcotic analgesia was used as required</td>
<td>n = 53 for all efficacy outcomes

Mean AHI
Pre-op: 25.0 (SD 13.9)
90 days’ follow-up: 22.0 (SD 14.8)
p = 0.05

Mean lowest oxygen saturation during sleep
Pre-op: mean 81.8 (SD 10.6)
90 days follow-up: 83.2 (SD 6.2)
No significant difference (p value not stated)

Mean ESS score
Pre-op: 11.0 (SD 5.1)
90 days’ follow-up: 6.9 (SD 4.5)
p < 0.001

Snoring intensity assessed by bed partner
Mean score using a visual analogue scale from 0 (no snoring) to 10 (extreme snoring causing partner to leave the room)
Pre-op: 7.9 (SD 2.1)
90 days’ follow-up 4.0 (SD 3.0)
p < 0.001

Percentage of bed partners who reported witnessing apnoea episodes
Pre-op: 69% of partners
90 days’ follow-up: 26%

Would recommend procedure to others?
77% of patients</td>
<td>Self-reported difficulties with swallowing or speech, or pain

Mean scores using a scale from 0 (no pain or difficulty) to 10 (extreme pain or difficulty
<table>
<tr><td>n = 53</td><td colspan="3">Time since procedure</td></tr>
<tr><td></td><td>24–72 hours</td><td>2 weeks</td><td>30 days</td></tr>
<tr><td>Swallowing</td><td>1.8</td><td>0.6</td><td>0.7</td></tr>
<tr><td>Speech</td><td>3.3</td><td>1.3</td><td>0.6</td></tr>
<tr><td>Pain</td><td>3.1</td><td>1.4</td><td>0.4</td></tr>
</table>
No baseline data were presented.

Serious adverse events
0/63 patients

Partial extrusion of the implant through soft–palate mucosa
9.9% (20/202) of implants
All were removed easily and most were replaced.

Other adverse events
Mucosal irritation or ulceration at the implantation site occurred in 4 patients (6%). This resolved within 2 weeks; 1 patient received antibiotics.</td>
<td>10 of the 63 patients were excluded from the efficacy analysis and from analysis of some safety outcomes; 7 of these did not comply with follow-up, 1 had alternative treatment during follow-up, and 2 had AHI < 10 at baseline. This may have caused bias in the results.</td>
</tr>
</table>

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Follow-up: **90 days** Conflict of interest: The study was partly supported by a grant from the manufacturer of the implant system. One author was a consultant for the manufacturer.	74% of bed partners		

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Nordgård S et al (2006)[2] **Case series** Norway Study period: not stated **n = 25** Consecutive patients who met the inclusion criteria were enrolled. Inclusion criteria: AHI 10–30, age ≥ 18 years, soft palate length > 25 mm, tonsil size < 50% of airway, no significant nasal stenosis, bed partner present, BMI ≤ 30 kg/m^2; > 50% of patients' obstructed breathing events were defined as high in origin (i.e. with retropalatal involvement). Location of airway obstruction was determined using a microtransducer system along a thin oesophageal tube during night-time polysomnography. Technique: Apnoeic events defined as a decrease in respiratory flow > 90%; hypopnoeic events defined as > 50% decrease, both combined with a 3% decrease in oxygen saturation. 3 'Pillar' implants (18 mm × 1.5 mm) were used; two doctors performed all the procedures; local anaesthesia was used; antibiotics were given after the procedure; diclofenac, 50 mg 3 times per day, was prescribed; duration of analgesic medication not stated.	**Mean AHI** Pre-op: 16.2 (SD 4.6) 90 days' follow-up: 12.1 (SD 9.1) p = 0.033 In 8% (2/25) of patients, AHI decreased to below 10.0 at 90 days' follow-up. In 24% (6/25) of patients AHI increased between baseline and 90 days' follow-up. Among patients identified as having breathing obstruction at the palatal level, 79% (15/19) experienced an improvement in AHI during follow-up (from 16.3 to 11.1). **Mean ESS score** Pre-op: 9.7 (SD 3.6) 90 days' follow-up: 5.5 (SD 3.5) p < 0.001 **Snoring intensity assessed by bed partner** (Mean score, using a scale from 0 to10, as for Walker 2006 above[1]) Pre-op: 8.4 (SD 1.2) 90 days' follow-up: 4.3 (SD 2.6) p < 0.001	**Pain** Mean score using scale of 0 (best) to 10 (worst) Pre-op: 0.5 (SD 1.1) 90 days' follow-up: 0.5 (SD 1.1) No significant difference **Partial extrusion of implant** 8% (2/25) of patients **Perforation / improper placement of implant** In 1 patient the posterior palatal surface was perforated twice before the third implant was placed properly. Another patient had one implant that had been placed superficially replaced during the procedure.	

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Follow-up: **mean 87 days (range 74–100)** Conflict of interest: The study was funded by the manufacturer of the implant system.			

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Friedman M et al (2006)[3] **Case series** USA Study period: Not stated **n = 23** (mean age 49 years) Inclusion criteria: Presented with snoring with or without daytime sleepiness, history of OSAHS 'successfully' treated previously with uvuluopalatopharyngoplasty or laser-assisted uvulopalatoplasty; AHI 5–40 demonstrated by polysomnography, retropalatal obstruction (seen on physical examination, Mueller manoeuvre and sleep endoscopy) identified as cause of symptoms; no evidence of obstruction by the tongue contributing to OSAHS; residual soft-palate segment ≥ 2 cm long, no nasopharyngeal stenosis, BMI < 40 kg/m^2 Technique: Pillar implants (18 mm long) were used; patients used over-the-counter analgesics for up to 48 hours; all-night sleep studies were conducted at follow-up. **Follow-up: 6 months** Conflict of interest: None stated	**AHI** (mean values estimated from a bar chart) Pre-op: 33 6 months' follow-up: 25; $p < 0.05$ **Minimum recorded arterial oxygen saturation during polysomnography** (mean values estimated from a bar chart) Pre-op: 87% 6 months' follow-up: 89%; $p < 0.05$ **Mean ESS score** Pre-op: 13.2 (SD 2.9) 6 months' follow-up: 8.7 (SD 1.8); $p < 0.001$ **Snoring intensity assessed by bed partner** (Mean score using a scale from 0 to 10, as for Walker 2006[1]) Pre-op: 8.7 (SD 1.8) 6 months' follow-up: 3.4 (SD 1.8); $p < 0.001$ **Quality of life** Assessed using the short-form-36v2 questionnaire, which covers 8 domains. Significant improvements ($p < 0.05$) were seen at 6 months' follow-up compared with preoperative scores for 'physical role', 'bodily pain', 'general health', vitality/energy', 'social functioning', 'emotional role' and 'mental health', but not for 'physical function', where the improvement was slight. Absolute numbers and p values were not presented. **Snoring level** Proportion of patients reporting a 50% reduction in snoring level (assessed by bed partner), with a postoperative level ≤ 5 out of 10, plus any reduction in ESS score 73.9% (17/23) of patients	**Pain** Using a scale from 0 (best) to 10 (worst) First 24 hours post-op: range 3– 6 **Extrusion of implant** 0/23 patients **Infection** 0/23 patients **Dysphagia (painful swallowing)** 0/23 patients All patients resumed normal activities and eating immediately after the procedure.	26 patients met the entry criteria, but 3 of these were not followed up for 6 months and were excluded from analyses, potentially creating bias. The authors commented that "the possibility of a placebo effect should always be considered, and this concern has been previously expressed by several groups working with Pillar implants."

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Friedman M et al (2006)[4] **Case series** USA Study period: 2003–2004 **n = 29 (out of 125 patients in total – see comment*)** Inclusion criteria: Palatal obstruction only (see comment), AHI < 40 (a lower cut-off appears not to have been defined a priori, but all patients had AHI in the range 6–37 per hour), BMI < 40 kg/m^2, soft palate length < 4 cm; uvula < 0.5 cm in length (estimated, not measured) Technique: Apnoea defined as cessation of breathing for at least 10 seconds; hypopnoea defined as "decreased effort to breathe at least 50% less than the baseline and with at least a 4% decrease in oxygen saturation". 3 Pillar implants used per patient; antibiotics used for 5 days after the procedure **Follow-up: 4–6 months** Conflict of interest: None stated. "The study was financially supported by the principal investigators using funds that were not derived from any outside source."	NB Timing of follow-up not clear. **50% reduction in snoring assessed by bed partner** 79% (23/29) of patients **Subjective improvement in ESS score** 52% (15/29) of patients **Mean AHI** Pre-op: 12.7 (SD 8.2) 3–6 months' follow-up: 11.5 (SD 12.9 – appears to be an error in the paper) Change is not significant **Patients with a reduction of > 50% in AHI and post-operative AHI < 20** 24% (7/29) of patients	**Pain** Mean score using a scale from 1 (best) to 10 (worst) 24 hours after procedure: range 3–5 3% (1/29) of patients had pain lasting more than 3 days **Dysphagia** 0/29 patients **Partial extrusion of implant** 2.7% (10/372) of implants in 125 patients (see comment*) These were removed after injection of a small amount of local anaesthetic and replaced at a later date. The authors noted that "considerable force" was required to remove a partially extruded implant, because it had attached to the surrounding tissue; local anaesthetic was required.	*The paper describes 125 consecutive patients who received soft-palate implants. Most patients had palatal obstruction as well as nasal, tonsillar, uvular or tongue-base obstruction, and were selected to receive implants in combination with other surgical procedures. Only the 29 patients with palatal obstruction alone and who received just palatal implants are described in this table. These are therefore a highly selected group. Patients who were not followed up for at least 4 months were excluded from this retrospective case review. This may have led to bias in the assessment of the procedure. The authors noted that extrusion occurred more frequently early in the study, when surgeons were less experienced, and may have occurred because of incorrect insertion. The authors suggest that subjective assessment may be better than objective measures of reduction in AHI for patients with mild OSAHS, because of night-to-night variability in AHI.

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Nordgård S et al (2006)[5]

Case series

Norway

Study period: not stated

n = 34

Consecutive patients who met inclusion criteria

Inclusion criteria:
Referred for habitual snoring, age > 18 years, AHI < 10, BMI < 30 kg/m^2, soft palate length > 25 mm, tonsil size < 50% of airway, no significant nasal stenosis, has a bed partner, no tonsillectomy during the study

Technique:
Apnoea defined as airflow < 10% baseline, hypopnoea as > 50% reduction in airflow, both lasting > 10 seconds and with a 3% decrease in oxygen saturation.

Pillar implants were used; patients received antibiotics for 7 days after the procedure; analgesics were given if necessary (duration not stated)

Follow-up: 1 year

Conflict of interest:
The study was funded by the manufacturer of the implant system.</td>
<td>Snoring intensity assessed by bed partner
(mean score, as assessed by Walker 2006 above[1])
Pre-op: 7.1 (SD 2.1)
30 days' follow-up: 4.5 (SD not stated)
90 days' follow-up: 3.4 (SD not stated)
1 year's follow-up: 4.8 (SD 3.1)

p < 0.001 baseline vs 1 year

Mean ESS score
Pre-op: 9.3 (SD 4.1)
1 year's follow-up: 5.6 (SD 3.8)

p < 0.001 1 year vs baseline

Patients satisfied with results
1 year's follow-up: 79% (27/34) of patients</td>
<td>Self-reported difficulties with swallowing or speech, or pain

Mean score, using a scale from 0 (no pain or difficulty) to 10 (extreme pain or difficulty
<table>
<tr><th></th><th colspan="3">Time since procedure</th></tr>
<tr><th></th><th>Pre-op</th><th>2 days</th><th>14 days</th></tr>
<tr><td>Swallowing</td><td>0.8</td><td>3.0</td><td>0.6</td></tr>
<tr><td>Speech</td><td>0.3</td><td>0.9</td><td>0.4</td></tr>
<tr><td>Pain</td><td>0.5</td><td>2.1</td><td>0.9</td></tr>
</table>
Partial extrusion of implant
18% (6/34) of patients
9% (9/102) of implants

One implant was removed under local anaesthesia; the other 8 were easily pulled out using forceps, without anaesthesia.

Other complications
None, including no mucosal breakdown, palatal swelling, discomfort or fistulae.</td>
<td>This study combines patients with OSA and patients with simple snoring only in the same analyses.

Three surgeons performed all the procedures.</td>
</tr>
</table>

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ho W-K et al (2004)[6]

Case series

Hong Kong

Study period: not stated

n = 12
(mean age 38 years)

Inclusion criteria:
“Presenting with disturbing snoring as the chief complaint”, AHI < 15 , BMI ≤ 30 kg/m^2

Exclusion criteria:
Known cardiovascular disease, previous history of pharyngeal surgery, history of swallowing or speech disorders, “pathologic conditions causing upper airway obstruction during sleep”

Technique:
‘AntiSnoring Device’ implants were used (predecessor to Pillar implants); the first 2 patients had 2 implants inserted under general anaesthesia; the rest had 3 implants inserted under local anaesthesia without sedation; fibreoptic nasopharyngoscopy was performed immediately after implantation to check that the</td>
<td>Efficacy was reported for the 9 patients whose implants did not extrude during follow-up.

<table>
<tr><th></th><th colspan="2">Time since procedure</th><th rowspan="2">p</th></tr>
<tr><th></th><th>Pre-op</th><th>3 months’ follow-up</th></tr>
<tr><td>Mean (SD) loudness of snoring (scale 0–100)</td><td>79 (17.2)</td><td>48 (20.4)</td><td>0.008</td></tr>
<tr><td>Mean (SD) AHI</td><td>4.8 (5.7)</td><td>8.3 (11.5)</td><td>0.33</td></tr>
<tr><td>Mean (SD) ESS score</td><td>8.9 (5.6)</td><td>5.7 (5.6)</td><td>0.007</td></tr>
</table>

<table>
<tr><th></th><th colspan="2">Number of patients</th></tr>
<tr><th>Effect of snoring on sleep of family members</th><th>Pre-op</th><th>3 months’ follow-up</th></tr>
<tr><td>No snoring</td><td>0</td><td>0</td></tr>
<tr><td>Mild snoring only</td><td>0</td><td>5</td></tr>
<tr><td>Affects spouse only</td><td>6</td><td>4</td></tr>
<tr><td>Affects whole family</td><td>0</td><td>0</td></tr>
<tr><td>Heard outside house</td><td>3</td><td>0</td></tr>
</table>

<table>
<tr><th></th><th colspan="2">Number of patients</th></tr>
<tr><th>No. nights per week that bed partner has to leave room</th><th>Pre-op</th><th>3 months’ follow-up</th></tr>
<tr><td>0</td><td>3</td><td>6</td></tr>
<tr><td>1–2</td><td>3</td><td>1</td></tr>
<tr><td>3–4</td><td>1</td><td>2</td></tr>
<tr><td>5–6</td><td>1</td><td>0</td></tr>
<tr><td>7</td><td>1</td><td>0</td></tr>
</table>
</td>
<td>Partial extrusion of implants
17% (2/12) of patients
9% (3/34) of implants

Delayed bleeding
0/12 patients

Infection
0/12 patients</td>
<td>This study combines patients with OSA and patients with simple snoring only in the same analyses.

The number of implants varied between patients: 2 patients had 2 implants inserted; 10 patients had 3 implants.

Patients who had an extruded implant were excluded from reporting of efficacy outcomes, potentially biasing the results.</td>
</tr>
</table>

Abbreviations used: AHI: apnoea–hypopnoea index (events per hour); BMI: body mass index; ESS, Epworth sleepiness scale; OSA: obstructive sleep apnoea; OSAHS, obstructive sleep apnoea / hypopnea syndrome; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
implant had not punctured the full thickness of the soft palate or the nasal aspect of the soft palate. Analgesia was prescribed as necessary. **Follow-up:** **3 months** Conflict of interest: None stated. “The authors have no relevant financial interest in this article”.			

Validity and generalisability of the studies

- No controlled trials of soft-palate implants for OSA have been published outside of conference proceedings.
- Two studies stated that only patients who had not previously undergone pharyngeal surgery were included.[1,6] One study included patients only if they had been 'successfully treated' with uvuluopalatopharyngoplasty or laser-assisted uvulopalatoplasty in the past.[3]
- No studies reported whether patients used CPAP or any other device before or during the study.
- Four of the six studies did not report outcomes for all patients. Three studies excluded patients who were not fully followed up.[1,3,4] One study excluded patients who experienced implant extrusion from reporting of efficacy outcomes.[6]
- Two of the six studies combined patients with OSA and patients with simple snoring without apnoea.[5,6]
- All the studies made some attempt to exclude patients whose condition was judged not likely to be caused by palatal obstruction.

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr Liam Flood, Mr Ian Ormiston, Mr Michael Timms, Dr Andrew Hartle, Professor Chris Dodds

- Three Specialist Advisers considered this procedure to be novel and one considered it to be a minor variation of an existing procedure. One Specialist Adviser did not comment on whether the procedure was established.
- None of the Specialist Advisers had performed the procedure. One said that he had watched surgical training videos about the procedure.
- Comparator interventions include CPAP, laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, radio-frequency ablation of the soft palate, and lifestyle modifications including weight loss.
- Key efficacy outcomes were considered to be change in AHI, sleep quality, oximetry (all evaluated during polysomnography), snoring intensity and quality of life. One Specialist Adviser commented that change in BMI is an important confounding variable and so should be monitored simultaneously, and that studies should collect follow-up data for at least 6 months.
- One Specialist Adviser believed that palatal surgery of any sort is inappropriate for patients with true OSA, with lifestyle modification and CPAP being appropriate treatments. He remarked that OSA is multilevel in origin, and is mostly hypopharyngeal, so that soft-palate interventions might not be expected to be efficacious. Another Specialist Adviser also commented that this procedure is unlikely to be of significant benefit to the great majority of patients with OSA, who can be effectively and safely treated with CPAP. Two Specialist Advisers commented that this procedure would be less effective for OSA than for simple snoring.

- One Specialist Adviser believed that the published studies were of small, highly-selected and non-representative groups of patients. One Specialist Adviser commented that the evidence supporting any treatment for snoring or OSA (other than weight loss or CPAP) is very limited. One Specialist Adviser commented that he was aware of small case series describing the procedure which indicated some improvement in patients' OSA symptoms.
- The Specialist Advisers considered that potential adverse effects include sepsis (potentially serious), local infection, migration or extrusion of the implant, failure of the implant, 'foreign-body' reaction, minor scarring of the soft palate and compromise of CPAP. One Specialist Adviser knew anecdotally of a patient whose palate had been severely scarred, affecting their speech.
- One Specialist Adviser believed that implants would inevitably extrude in time because of the mobility of the soft palate.
- One Specialist Adviser commented that the procedure avoids the need for general anaesthesia, but has the potential to fail. He said that it is not clear what options are available to patients whose symptoms have not improved following the procedure or whose implants have extruded.
- Two Specialist Advisers considered that training should include attending demonstrations or watching training videos. Another commented that surgeons should be supervised initially. One Specialist Adviser commented that this is a relatively simple procedure to perform.

Issues for consideration by IPAC

- All studies identified used one implant system manufactured by Restore Medical Inc, Minnesota. This was initially called the AntiSnoring Device and was later renamed the 'Pillar Procedure' after a modification to the delivery system.
- Conference abstracts published in summer 2006 of four small randomised controlled trials were identified. None expressed safety concerns and so have not been described here.

References

1. Walker RP, Levine HL, Hopp ML et al. (2006) Palatal implants: A new approach for the treatment of obstructive sleep apnea. *Otolaryngology – Head & Neck Surgery* 135: 549–54.
2. Nordgård S, Stene BK, Skjostad KW. (2006) Soft palate implants for the treatment of mild to moderate obstructive sleep apnea. *Otolaryngology – Head and Neck Surgery* 134: 565–70.
3. Friedman M, Schalch P, Joseph NJ. (2006) Palatal stiffening after failed uvulopalatopharyngoplasty with the pillar implant system. *Laryngoscope* 116: 1956–61.
4. Friedman M, Vidyasagar R, Bliznikas D et al. (2006) Patient selection and efficacy of pillar implant technique for treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngology – Head & Neck Surgery* 134: 187–96.
5. Nordgård S, Stene BK, Skjostad KW et al. (2006) Palatal implants for the treatment of snoring: long-term results. *Otolaryngology – Head and Neck Surgery* 134: 558–64.
6. Ho W, Wei WI, Chung K. (2004) Managing disturbing snoring with palatal implants: a pilot study. *Archives of Otolaryngology – Head & Neck Surgery* 130: 753–8.

Appendix A: Additional papers on soft-palate implants for obstructive sleep apnoea not included in summary Table 2

<table>
<tr><th>Article title</th><th>No. patients/ follow-up</th><th>Direction of conclusions</th><th>Reasons for non-inclusion in Table 2</th></tr>
<tr><td>Maurer JT, Hein G, Verse T, Hormann K, Stuck BA. (2005) Long-term results of palatal implants for primary snoring. Otolaryngology – Head and Neck Surgery 133: 573–8.</td><td>n = 40

1 year's follow-up</td><td>Mean AHI
Pre-op: 3.7 (SD 2.3)
90 days' follow-up: 5.5 (SD 5.4); p < 0.05.
One patient's AHI increased from 5.9 per hour to 17.7 per hour between the pre-op and 90-day follow-up.

Mean snoring intensity assessed by bed partner
Pre-op: 7.1
90 days' follow-up: 4.2
1 year's follow-up 4.8
p < 0.05 1 year vs pre-op
(SD not stated in text)

Mean ESS score
Pre-op: 6.1 (SD 3.2)
90 days' follow-up: 4.3 (SD 3.3)
1 year's follow-up: 4.9 (SD 3.1)
p < 0.05 post-op vs pre-op & 1 year vs baseline

Mean pain score, using a scale from 0 (no pain or difficulty) to 10 (extreme pain or difficulty:
<table><tr><td></td><td colspan="2">Time since procedure</td></tr><tr><td></td><td>2 days</td><td>90 days</td></tr><tr><td>Swallowing</td><td>0.4</td><td>0.1</td></tr><tr><td>Speech</td><td>0.7</td><td>0.1*</td></tr><tr><td>Pain</td><td>4.9</td><td>0.2*</td></tr></table>*p < 0.05

Partial extrusion of implant
25% (10/40) patients
11% (13/120) implants

No other complications</td><td>Selection criteria for this study are ambiguous. The authors state that patients with OSA or upper airway resistance syndrome were excluded, but do not describe how this was assessed. However, some patients did have AHI values > 5, which could be defined as OSA. The paper has not been included in Table 2 because of this ambiguity, and because it appears that the majority of patients in the study had AHI values < 5.</td></tr>
<tr><td>Maurer JT, Verse T, Stuck BA, Hormann K, Hein G. (2005) Palatal implants for primary snoring: short-term results of a new minimally invasive surgical technique. Otolaryngology – Head and Neck Surgery 132: 125–31.</td><td>n = 15

3 months' follow-up</td><td></td><td>Patients in this paper are included in the paper above.</td></tr>
</table>

Appendix B: Related published NICE guidance for soft-palate implants for obstructive sleep apnoea

Guidance programme	Recommendation
Interventional procedures	**IPG124 Radiofrequency ablation of the soft palate for snoring** 1.1 Current evidence suggests that there are no major safety concerns associated with radiofrequency ablation (RFA) of the soft palate for snoring. However, evidence on the short-term efficacy is limited and long-term outcomes are uncertain. Therefore, this procedure should not be used without special arrangements for audit, consent and research. 1.2 Clinicians wishing to undertake radiofrequency ablation of the soft palate for snoring should take the following actions. ▪ Inform the clinical governance leads in their Trusts. ▪ Ensure that patients understand the uncertainty about the procedure's efficacy and that they are fully informed about alternative treatment options, including lifestyle changes. Patients should also be provided with clear written information, and use of the Institute's *Information for the public* is recommended. ▪ Audit and review clinical outcomes of all patients having radiofrequency ablation of the soft palate for snoring. 1.3 Publication of efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for soft-palate implants for obstructive sleep apnoea

The search strategy covered both OSA and simple snoring. Literature relevant to OSA was then selected by hand from the abstracts identified.

IP404: Soft palate implants for snoring and obstructive sleep apnoea		
Database	**Date searched**	**Version searched**
Cochrane Library	19/03/2007	Issue 1, 2007
CRD databases (DARE & HTA)	19/03/2007	Issue 1, 2007
Embase	17/03/2007	1980 to 2007 Week 11
Medline	17/03/2007	1950 to March Week 1 2007
Premedline	19/03/2007	March 16, 2007
CINAHL	17/03/2007	1982 to March Week 2 2007
British Library Inside Conferences	19/03/2007	-
NRR	19/03/2007	Issue 1 2007
Controlled Trials Registry	19/03/2007	-

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1 exp Sleep Apnea Syndromes/
2 (Sleep adj3 apn$).tw.
3 hypopne$.tw.
4 hypopno$.tw
5 (obstruct$ adj3 apn$).tw.
6 OSAHS.tw.
7 obstructive sleep apnea hypopnea syndrome.tw.

8 (pickwick$ adj3 syndrom$).tw.
9 Snoring/
10 Snor$.tw.
11 (upper airway adj3 resist$ syndrom$).tw.
12 Obesity Hypoventilation Syndrome/
13 or/1-12
14 (Pill$ adj3 (implant$ or pet$ or stiffen$)).tw.
15 (palat$ adj3 implant$).tw.
16 (palat$ adj3 (stiffen$ or soft$)).tw.
17 or/14-16
18 13 and 17
19 Animals/
20 Humans/
21 19 not (19 and 20)
22 18 not 21
23 limit 22 to english language
24 limit 23 to yr="1997 - 2007"
25 from 24 keep 1-204