NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of soft palate implants for simple snoring

Snoring is a breathing disturbance that occurs during sleep. Although not always problematic, it can disturb sleep and affect relationships with others. The noise of snoring is produced by vibration of soft tissues in the mouth or throat and in some people involves the soft palate, a region of the roof of the mouth. Small pieces of synthetic fibre can be implanted into the soft palate, with the aim of making it stiffer and less likely to vibrate.

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 simple snoring

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

Simple snoring

Snoring can occur without other clinical features, may be associated with increased upper airway resistance (which can cause sleep disturbance, but does not include episodes of apnoea or hypopnoea), or be part of obstructive sleep apnoea (OSA). These three conditions form a spectrum of breathing disturbance during sleep, of increasing severity. This overview relates only to patients who snore but do not experience apnoea or hypopnoea episodes, although they may experience a degree of sleep disturbance. NICE is preparing separate interventional procedures guidance on the use of soft-palate implants for OSA.

The muscles around the upper airway relax during sleep. A narrowed airway can lead to air turbulence, which causes vibration in soft tissues of the oropharynx, generating the snoring sound during inspiration. The specific origin of the noise varies between individuals, and may include the soft palate. Snoring may disturb the sleep of the patient and their bed partner, and affect relationships.

This procedure may be used for patients with problematic snoring where the soft palate is implicated, and when snoring has not been improved by conservative treatment.

Current treatment and alternatives

Conservative management includes weight loss for obese patients, avoidance of alcohol or sedative medication, smoking cessation and changing the sleeping position. Physical appliances have also been used to maintain normal airflow dynamics during sleep, including mandibular advancement devices. Surgical interventions 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

The studies described below included only patients with simple snoring, unless stated otherwise.

Snoring intensity

Snoring intensity was assessed by the patient's bed partner, using a scale (usually 0–10) ranging from no snoring to snoring that caused the partner to leave the room. Mean scores at preoperative baseline and at 90 days' and 1 year's follow-up were 7.6, 3.7 and 4.0, respectively, in one case series (values estimated from a diagram, n = 99, p value not reported),[1] and 8.5, 5.0 and 4.4, respectively, in a second case series (n = 25, $p < 0.001$ vs baseline).[2]

Three case series combined patients with simple snoring and those with OSA in their analyses.[4–6] Mean scores at the time points listed above were 7.1, 4.2 and 4.8, respectively (n = 32, $p < 0.05$ vs baseline) in the first cases series[4] and 7.1, 3.4 and 4.8, respectively, (n = 34, $p < 0.001$ vs baseline) in the second case series.[5] Mean loudness scores in the third case series, which were measured on a scale from 0 to 100, were 79 at baseline and 48 at 90 days' follow-up (n = 9 p = 0.008).[6]

A randomised controlled trial (RCT) found that mean scores (on a scale from 0 to 10) decreased from 7.7 at baseline to 4.7 at 90 days' follow-up in 10 patients with standard implants ($p < 0.01$) compared with a decrease from 8.1 to 6.1 (not significant) in 10 patients with more rigid implants.[3]

Daytime sleepiness

Daytime sleepiness is a dominant symptom of OSA, which is covered by separate guidance. However, patients may have increased upper airway resistance in the absence of apnoea or hypopnoea which may cause sleep disturbance and hence daytime tiredness. Bed partners of snorers may also wake patients. The Epworth sleepiness scale (ESS), which uses patient-reported scores ranging from 0 (best) to 24 (worst), was used in five studies to assess daytime tiredness.

Two case series found significant reductions in ESS scores after the procedure.[1,2] In the first case series mean scores were 8.0 at baseline and 4.0 and 5.2, respectively at 90 days' and 1 year's follow-up (values estimated from a diagram, n = 99, $p < 0.0001$ although it is not clear which comparison this refers to).[1] In the second, mean scores were 8.3 at baseline (n = 24), 7.4 at 30 days' follow-up (n = 25, p = 0.024), and 7.3 at 90 days' follow-up (n = 21, no longer significant).[2]

The three case series that combined patients with OSA and simple snoring found significant reductions in mean sleepiness scores.[4–6] In the first case series, mean scores were 6.1 at baseline, compared with 4.3 and 4.9 at 90 days' and 1 year's follow-up, respectively (n = 40, $p < 0.05$ vs baseline).[4] In the second, mean scores decreased from 9.3 at baseline to 5.6 at 1 year's

follow-up (n = 34, p < 0.001).[5] In the third case series mean scores decreased from 8.9 at baseline to 5.7 at 3 months' follow-up (n = 9 p = 0.007).[6]

Satisfaction and willingness to recommend the procedure to others
Five studies reported these outcomes.[1-5] The proportion of patients willing to recommend the procedure to other people with snoring problems ranged from 75% (a case series of 25 patients at 90 days' follow-up)[2] to 83% (a case series of 99 patients at 6 months' follow-up).[1] In the case series of 34 patients, 80% of patients said they were satisfied with the procedure, at 1 year's follow-up.[5] The proportion of bed partners willing to recommend the procedure ranged from 50%, of 10 patients who received standard implants in the RCT,[3] to 90% in a case series of 25 patients at 90 days' follow-up.[2] A study of 40 patients reported that 90% of 'patients and bed partners' would recommend this procedure at 1 year's follow-up, but it is not clear how this figure was calculated.[4]

Safety

The studies described below included only patients with simple snoring, unless stated otherwise.

Serious adverse effects
Three studies (159 patients in total) specifically reported that no severe adverse events occurred following the procedure.[1,3,4] The three remaining studies did not mention any serious adverse events.

Infection or inflammation
Four studies (176 patients in total), reported that no patient experienced infection as a result of the procedure,[1,2,4,6] and one study (n = 34) reported that no patients experienced mucosal breakdown, palatal swelling, discomfort or fistulae.[5]

Partial extrusion of the implant
Three studies of patients with simple snoring reported the proportion who experienced extrusion of at least one implant (standard rigidity),[1–3] ranging from 0 of 10 patients in the RCT (6 months' follow-up)[3] to 6.4% in one case series (actual number not stated, total n = 99, up to 1 year's follow-up)[1]. In the RCT, 40% (4/10) of patients who received more rigid implants experienced extrusion within 6 months of surgery.[3] In the three case series that combined patients with simple snoring or OSA, the proportions of patients who experienced implant extrusion were 25% (10/40, within 1 year),[4] 18% (6/34, within 1 year)[5] and 17% (2/12, within 3 months).[6]

Difficulty swallowing
Studies presented patient-reported scores for difficulty swallowing after the procedure, using a scale from 0 (no difficulty) to 10 (extreme difficulty). The case series of 25 patients reported that the mean score was 0.3 at 90 days' follow-up.[2] The case series of 40 patients with OSA or simple snoring reported that the mean score was 0.4 after 2 days and 0.1 after 90 days' follow-up.[4] The case series of 34 patients with OSA or simple snoring reported that mean scores were 3.0 and 0.6 at 2 and 14 days' follow-up, respectively.[5]

Speech difficulties
Studies reported difficulty speaking after the procedure as a mean score using a scale from 0 (no difficulty) to 10 (extreme difficulty). In the case series of 25 patients, mean score at 90 days' follow-up was 0.5.[2] The RCT noted that 1 of 20 patients reported changes in their voice on the first postoperative day (not described further).[3] The case series of 40 patients with OSA or simple snoring reported that mean scores were 0.7 and 0.1 at 2 and 90 days' follow-up, respectively.[4] The case series of 34 patients with OSA or simple snoring reported that the mean score was 0.9 and 0.4 at 2 and 14 days' follow-up, respectively.[5]

Pain
Studies reported scores for pain, using a scale from 0 (no pain) to 10 (extreme pain). The case series of 25 patients reported that the mean score was 0.5 at 90 days' follow-up.[2] The case series of 40 patients with OSA or simple snoring reported that mean scores were 4.9 and 0.2 at 2 and 90 days' follow-up, respectively.[4] In the case series of 34 patients with simple snoring or OSA, mean scores were 2.1 and 0.9 at 2 and 14 days' follow-up, respectively.[5]

'Foreign–body' sensation
Two studies mentioned that some patients experienced 'foreign–body' sensation after the procedure;[1,4] this was reported by 4.1% of 99 patients in one of the studies.[1]

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to soft-palate implants for simple snoring. 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 simple snoring. 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 two case series[1 2] of patients with simple snoring and one randomised controlled trial that compared implants of differing rigidity.[3] Three case series that combined patients with OSA and patients with simple snoring were also included.[4-6]

Existing reviews on this procedure

No published systematic reviews with meta-analysis or evidence-based guidelines were identified at the time of the literature search.

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 procedures guidance 124 (May 2005). Available from http://guidance.nice.org.uk/IPG124 .

NICE is developing interventional procedures guidance on soft-palate implants for obstructive sleep apnoea (IP404) which is due to be published in Winter 2007.
http://guidance.nice.org.uk/ipcat.aspx?o=IP_404

Technology appraisals

None

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; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Kuhnel TS et al (2005)[1] **Case series** Germany, Hong Kong, Norway Study period: not stated **n = 99** Inclusion criteria: Habitual snoring, soft palate length ≥ 25 mm, "absence of significant nasal obstruction and/or other anatomical contributions to snoring", has a bed partner, BMI < 30 kg/m^2 Exclusion criteria: OSA (determined by sleep study), "Impairment of nasal breathing and space requirements in the vicinity of the upper respiratory tract" (determined by endoscopy and mirror examination), BMI ≤ 30 kg/m^2, emotional problems, neoplastic diseases, significant cardiovascular problems, drug or alcohol abuse Technique: "AntiSnoring Device" (Restore Medical); 3 implants per patient **Follow-up: Up to 1 year** Conflict of interests: Not stated	**Mean ESS scores** (Estimated from box-plot diagram) Pre-op: 8.0 90 days' follow-up: 4.0 1 year's follow-up: 5.2 p < 0.0001 (but not stated which comparison this corresponds to) **Mean snoring intensity assessed by bed partner** (Estimated from box-plot diagram) Pre-op: mean 7.6 90 days' follow up: 3.7 180 days' follow up: 4.0 Significant reduction from pre-op baseline to 180 days (p value not stated) **Proportion of patients snoring at least 5 nights a week (assessed by bed partner)** Pre-op: 93% 180 days' follow-up: 42% **Proportion of patients whose snoring could be heard outside the bedroom (assessed by bed partner)** Pre-op: 90% 180 days' follow-up: 46% **Would recommend procedure to other snorers?** 6 months' follow-up: 83% of patients, 72% of bed partners	**Pain** "No problems were seen." **'Foreign-body' sensation** 4.1% of patients (number not stated) **Partial extrusion of implant** 6.4% of patients (number not stated) Removed under local anaesthesia for some patients. No infections, abcesses or velopharyngeal insufficiency occurred. No serious adverse events were reported.	Five centres participated in the study. At one centre patients were given a sedative before the procedure. At one centre patients were given antibiotics after the procedure. 106 patients underwent the procedure but 7 of these were not included in the report or analyses because of "protocol deviations" (not further described). This may have biased the results. Duration of follow-up may have varied between centres. This is not clear in the paper, and numbers of patients at each time point were not stated.

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Romanow JH et al (2006)[2] **Case series** USA Study period: not stated **n = 25** (mean age 50 years) Inclusion criteria: Socially unacceptable snoring without witnessed apnoeas or daytime sleepiness; snoring due to palatal flutter determined by examination, no clinical diagnosis of OSA. Patients deemed at risk of OSA were included only if polysomnography demonstrated absence of OSA; age > 18 years: soft palate length ≥ 25 mm; has a bed partner Exclusion criteria: Previous pharyngeal surgery (excluding tonsils, adenoids), nasal polyposis or significant nasal septal deflection, pregnant or breastfeeding, dysphagia or speech disorder, unstable psychiatric disorder Technique: Three 'Pillar' implants were used	**p values are for comparison with the pre-operative value; n = 24 for pre-op assessment, n= 25 at 30 days' follow-up, n = 21 at 90 days' follow-up** **Mean snoring intensity assessed by bed partner** ▪ Pre-op: 8.5 (SD 1.4) ▪ 30 days' follow-up: 5.0 (SD 2.1), p < 0.001 ▪ 90 days' follow-up: 4.4 (SD 2.5), p < 0.001 **Daytime sleepiness** Mean values, assessed using a scale from 0 (no daytime sleepiness) to 10 (constant sleepiness throughout the day) ▪ Pre-op: 3.7 (SD 2.8) ▪ 30 days' follow-up: 2.3 (SD 2.2), p = 0.006 ▪ 90 days' follow-up: 2.3 (SD 2.1), p = 0.016 **Mean ESS scores** ▪ Pre-op: 8.3 (SD 3.7) ▪ 30 days' follow-up: 7.4 (SD 3.7), p = 0.024 ▪ 90 days' follow-up: 7.3 (SD 4.5) p = 0.095 **Would recommend procedure to other snorers at 90 days' follow-up?** 75% of patients 90% of bed partners	**p values are for comparison with the pre-operative value; n = 24 for pre-op assessment, n= 25 at 30 days' follow-up, n = 21 at 90 days' follow-up** Values are mean scores, assessed using scales from 0 (no pain or difficulty) to 10 (excruciating pain or extreme difficulty) **Speech** Preop: 0.7 (SD 1.5) 30 days' follow-up: 0.6 (SD 1.1), p = 0.520 90 days' follow-up: 0.5 (SD 1.3), p = 0.027 **Swallowing** Preop: 0.7 (SD 1.0) 30 days' follow-up: 0.6 (SD 21.0), p = 0.643 90 days' follow-up: 0.3 (SD 0.3), p = 0.077 **Pain** Preop: mean 0.7 (SD 1.1) 30 days' follow-up: 0.5 (SD 0.9), p = 0.134 90 days' follow-up: 0.5 (SD 1.6), p = 0.046 **Partial extrusion of implant** 3% (2/75) of implants 4% (1/25) of patients Implants were reported as extruded at	Follow-up data were not complete for all patients but all data were included in analyses.

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
per patient, patients received antibiotics for 5 days after the procedure and analgesics as needed **Follow-up:** **90 days** Conflict of interest: The study was supported by a grant from the manufacturer of the device.		71 days follow-up **Other complications** There were no other complications, including no infection, bleeding or airway difficulties.	

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
Skjøstad KW et al (2006)[3] **Randomised controlled trial** The study compared two implants of different stiffness. Norway Study period: **n = 20** (mean age 44 years) Inclusion criteria: Socially problematic snoring due to palatal flutter, soft palate length ≥ 25 mm, age > 18 years, AHI ≤ 5, BMI < 30 kg/m^2, tonsil hypertrophy < 50% of airway, no significant nasal obstruction, no previous history of pharyngeal surgery, patient has a bed partner Exclusion criteria: OSA or upper airway resistance syndrome Technique: 10 patients received the standard commercially-available implant; 10 received a more rigid implant ("80% increased rigidity"). Polysomnography were conducted before surgery and at 90 days'	**Snoring intensity assessed by bed partner** Values are mean scores, assessed using a visual analogue scale from 0 (best) to 10 (snoring causes partner to leave room). (Timing of measurement of efficacy is not stated clearly in the paper. See comment *.) Standard implants: Pre-op: 7.7 Post-op: 4.7 p < 0.01 More rigid implants: Pre-op: 8.1 Post-op: 6.1 Difference not significant **Patient would recommend to other snorers? (6 months' follow-up)** Standard implants: 80% (8/10) of patients would, 2/10 undecided More rigid implants: 20% (2/10) patients would, 6/10 undecided, 2 would not. **Bed partner would recommend to other snorers? (6 months' follow-up)** Standard implants: 50% (5/10) of partners would, 4/10 undecided, 1 would not More rigid implants: 20% (2/10) patients would, 3/10 undecided, 5 would not	**Pain** "Mild, often compared with a mild infection of the throat that resolved in a couple of days." Patients used analgesics for 1 day on average; 55% (11/20) did not require any analgesic medication. **Voice** One patient reported altered voice on the first day after the procedure. **Partial extrusion of the implant** Standard implants: 0/10 patients More rigid implants: 40% (4/10) of patients 17% (5/30) of implants (4 extruded orally; 1 extruded toward the epipharynx) "No other adverse events were observed."	Participants were consecutive patients at one hospital. "One patient needed 5 mg diazepam intravenously [when the implant was inserted] because of mild mental stress." The method of randomisation was not described. Blinding appears to have been adequate. *Questionnaires were completed by patients and partners at several points during follow-up, but the authors did not state which time point they are reporting on.

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
follow-up. All patients were examined by fibreoptic nasopharyngolaryngoscopy. Patients received penicillin for 1 week after surgery. Analgesics were used as required. **Follow-up:** **6 months** Conflict of interests: The study was supported by a grant from the manufacturer of the device.			

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; 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>Maurer JT et al (2005)[4]

Case series

Germany

Study period: 2001–2002

n = 40
(mean age 42 years)

Inclusion criteria:
Primary snoring due to palatal flutter (diagnosed by clinical examination and both rigid and fibreroptic endoscopy while patient was awake), soft palate length ≥ 25 mm, age 18–80 years, AHI ≤ 15, BMI < 30 kg/m^2

Exclusion criteria:
OSA or upper airway resistance syndrome (see comment *), nasal polyps or symptomatic septal deviation, dysphagia, speech disorder, history of pharyngeal surgery for snoring or radiation therapy for upper respiratory tract, acute infection of respiratory tract, pregnancy, breastfeeding, drug abuse

Technique:
Polysomnography and “SNAP” recordings (see comment **) were</td>
<td>Mean AHI, n = 40
Pre-op: 3.7 (SD 2.3)
90 days’ follow-up: 5.5 (SD 5.4) p < 0.05
AHI increased in 1 patient from 5.9 at baseline to 17.7 at 90 days’ follow-up.

Oxygen saturation
<table>
<tr><th></th><th colspan="2">Time since procedure</th></tr>
<tr><th></th><th>2 days</th><th>90 days</th></tr>
<tr><td>Mean (%)</td><td>94.6 (SD 1.8)</td><td>94.3 (SD 1.7)</td></tr>
<tr><td>Minimum (%)</td><td>89.8 (SD 4.1)</td><td>87.1 (SD 5.8)</td></tr>
</table>
“SNAP”** recording of snoring characteristics
<table>
<tr><th></th><th colspan="2">Time since procedure</th></tr>
<tr><th></th><th>2 days</th><th>90 days</th></tr>
<tr><td>Snores per hour</td><td>273 (SD 178)</td><td>276 (SD 172)</td></tr>
<tr><td>Loudness of loudest 10% of snoring events [dB]</td><td>15 (SD 7)</td><td>16 (SD 6)</td></tr>
</table>
There was no significant change (and mostly a small increase) in parameters assessed by “SNAP” recording before the procedure and at 90 days’ follow-up, including in the number of snores per hour and the loudness of the loudest 10% of snores.

Snoring intensity assessed by bed partner
Values are means, assessed using a visual analogue scale from 0 (best) to 10 (worst)
n = 32 (8 patients did not have a bed partner or partner did not participate)

Pre-op: 7.1
90 days’ follow-up: 4.2</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><th></th><th colspan="2">Time since procedure</th></tr>
<tr><th></th><th>2 days</th><th>90 days</th></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 the implant
25% (10/40) patients
11% (13/120) implants
Mean time to partial extrusion: 53 days (range 21–299)
Extrusion caused “mild pain or a foreign-body sensation”. All extruded implants were removed, under local anaesthesia if necessary.
One patient lost all three implants.

Perforation
No implants (0/120) perforated the oral or pharyngeal surface of the soft palate.

Other complications
No complications during surgery or within 2 weeks afterwards, including no infection. None of the patients took days off work. No severe adverse events during follow-up.</td>
<td>*The authors state that patients with OSA or upper airway resistance syndrome were excluded. However, the maximum AHI threshold was set at 15 per hour and mean pre-operative AHI values also indicate that some patients had AHI values above 5 and would therefore be defined as having mild OSA in other studies. Because of this ambiguity, this study has been classified as combining patients with simple snoring and OSA.

**The “SNAP” system is a portable device that enables recording of oximetry, snoring sounds and airflow during a sleep study.</td>
</tr>
</table>

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; SD: standard deviation

Study details	Key efficacy findings	Key safety findings	Comments
performed at baseline and at 90 days' follow-up. The 'Anti Snoring Device' was used for the first 19 patients and the 'Pillar procedure' for the next 21 patients (both made by the same manufacturer). The implants were identical but the delivery tool was modified in the later version. Three implants were used per patient. Patients took paracetamol for 1–4 days after the procedure. **Follow-up:** **1 year** Conflict of interest: The study was supported in part by the manufacturer of the device.	1 year's follow-up: 4.8 (SD not stated) Both $p < 0.05$ vs pre-op **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) Both $p < 0.05$ vs Pre-op **Would recommend to other snorers?** 90 days' follow-up: 38/40 patients and bed partners (95%) At 1 year's follow-up: 36/40 patients and bed partners (90%)		

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; 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

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% of baseline, hypopnoea as > 50% reduction in airflow, both lasting > 10 seconds and with a 3% drop in oxygen saturation.
Pillar implants were used. Patients took antibiotics for 7 days after the procedure; analgesics were used 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>Mean snoring intensity assessed by bed partner
(as assessed by Walker 2006 above[1])
Pre-op: 7.1 (SD 2.1)
30 days' follow-up: 4.5
90 days' follow-up: 3.4
1 year's follow-up: 4.8 (SD 3.1)
All p < 0.001 vs pre-op

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

p < 0.001 1 year vs pre-op

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 the 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 by forceps without anaesthesia.

Other complications
None, including no mucosal breakdown, palatal swelling, discomfort or fistulae.</td>
<td>This study combines patients with mild 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; 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:
“Presented 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, pathological 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; 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>p</th></tr>
<tr><th></th><th>Pre-op</th><th>3 months post-op</th><th></th></tr>
<tr><td>Mean loudness of snoring on scale 0–100 (SD)</td><td>79 (17.2)</td><td>48 (20.4)</td><td>0.008</td></tr>
<tr><td>Mean AHI (SD)</td><td>4.8 (5.7)</td><td>8.3 (11.5)</td><td>0.33</td></tr>
<tr><td>Mean ESS score (SD)</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 post-op</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 bed partner 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 post-op</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; 10 patients had 3 implants.

Patients who had an extruded implant were excluded from reporting of efficacy outcomes, potentially causing biased results. One further patient was lost to follow-up.</td>
</tr>
</table>

Abbreviations used: AHI: apnoea-hypopnoea index (events per hour); BMI: body mass index; ESS: Epworth sleepiness scale; OSA: obstructive sleep apnoea; 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: "The authors have no relevant financial interest in this article".			

Validity and generalisability of the studies

- This overview summarises evidence on a total of 230 patients, 184 of whom definitely had no diagnosis of OSA. The largest case series included 99 patients.[1]
- One study excluded seven patients who underwent the procedure[1] from their report because of non-adherence to the study protocol; another study excluded from their analysis of efficacy patients whose implants extruded.[6] If these patients differed from the rest of the sample in terms of frequency of adverse events or efficacy outcomes, results would have been biased.
- Three of the six studies combined patients with OSA and those with simple snoring without apnoea or hypopnoea.[4–6]
- Five of the six studies made some attempt to identify the origin of patients' snoring, either by examining the palate for flutter or by ruling out nasal obstruction as a cause.[1–5]
- All studies excluded patients with a soft palate shorter than 25 mm (to allow space for insertion of the implant).
- Four of the six studies excluded patients who had undergone previous pharyngeal surgery.[2–4,6]
- Follow-up for some safety outcomes was limited. Three studies reported scores for pain or difficulty with speech or swallowing within the first 2 days after surgery.[3–5] One study reported these outcomes at 30 days' follow-up at the earliest.[2]

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, with little literature available on safety or long-term efficacy. One Specialist Adviser considered it to be a minor variation on 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 procedures include laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty and radio-frequency ablation of the soft palate.
- Key efficacy outcomes were considered to be snoring intensity (with various measures available), satisfaction and quality of life of the patient and their bed partner, and daytime sleepiness (assessed using the Epworth scale).
- Efficacy concerns included extrusion of the implant, which one Specialist considered inevitable in time because of the mobility of the soft palate. He also commented that weight gain and increasing age would also inevitably lead to recurrence of snoring.

- Four Specialist Advisers commented that there are limited published data about the procedure, two of whom remarked on the lack of data on long-term follow-up at present. One Specialist Adviser commented that the short-term data that are available suggests that the procedure is reasonably safe and effective, and another commented that he was aware of small case series which indicated some improvement in symptoms.
- It was noted that this procedure would only be efficacious for palatal snoring.
- 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, bleeding, pain, minor scarring of the soft palate and compromise of continuous positive airway pressure. One Specialist Adviser knew anecdotally of a patient whose palate was severely scarred, affecting their speech.
- 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.
- One Specialist Adviser commented that there are concerns about the efficacy of this procedure rather than about its safety.
- One Specialist Adviser commented that the evidence supporting any treatment for snoring or OSA (other than weight loss or continuous positive airways pressure) is very limited
- Two Specialist Advisers considered that training should include attending demonstrations or watching training videos, another said that surgeons should be supervised initially, and another said that ENT or maxillofacial surgical training was necessary. Two Specialist Advisers commented that this is a relatively simple procedure.
- One Specialist Adviser commented that the procedure should be undertaken in a properly staffed and equipped theatre with a recovery area.

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 but was later renamed the ‘Pillar Procedure’ after a modification to the delivery system.
- No controlled trials comparing soft-palate implants with other procedures for simple snoring have been published outside of conference proceedings. Two conference abstracts (published August 2006) of randomised controlled trials were identified, but these raised no particular safety concerns and so have not been included in the overview.

References

1. Kuhnel, T. S., Hein, G., Hohenhorst, W., Maurer, J. T. (2005) Soft palate implants: A new option for treating habitual snoring. *European Archives of Oto-Rhino-Laryngology* 262: 277–280.
2. Romanow, J. H., Catalano, P. J. (2006) Initial U.S. pilot study: Palatal implants for the treatment of snoring. *Otolaryngology – Head & Neck Surgery* 134: 551–557.
3. Skjøstad, K. W., Stene, B. K., Norgård, S. (2006); Consequences of increased rigidity in palatal implants for snoring: a randomized controlled study. *Otolaryngology– Head and Neck Surgery* 134: 63–66.
4. Maurer, J. T., Hein, G., Verse, T., Hormann, K., Stuck, B. A. (2005) Long-term results of palatal implants for primary snoring. *Otolaryngology – Head and Neck Surgery* 133: 573–578.
5. Nordgard S, Stene BK, Skjostad KW et al. (2006) Palatal implants for the treatment of snoring: long-term results. *Otolaryngology – Head and Neck Surgery* 134: 558–564.
6. Ho W, Wei WI, Chung K. (2004) Managing disturbing snoring with palatal implants: a pilot study. *Archives of Otolaryngology – Head & Neck Surgery* 130: 753–758.

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

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Maurer, J. T., Verse, T., Stuck, B. A., 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: 125–131.	99	This paper presents the short-term results of the study. Longer-term results (including the data presented in this paper) have subsequently been published, and that paper is included in Table 2.[4]	

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 simple snoring

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

IP 388: 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