Rapid review

Upper airway surgery for the treatment of adult obstructive sleep apnoea

ASERNIP-S REPORT NO. 67
Disclaimer

This is a rapid systematic review in which the methodology has been limited in one or more areas to shorten the timeline for its completion. Thus, modifications have been made in at least one of the following areas: search strategy, inclusion criteria, assessment of study quality and data analysis. It is considered that these amendments would not significantly alter the overall findings of the rapid review when compared to a full systematic review.

The methodology used for the rapid review is described in detail, including the limits made for this particular topic. These limitations have been made possible mainly by restricting the specific clinical questions asked. These limits were applied following the requirements of the specific review topic, together with clinical guidance from a protocol surgeon.

Therefore, this rapid review is a limited evidence-based assessment that is based on a simple systematic search of studies published in the peer reviewed literature. As a result, this rapid review may be used to inform certain questions on the specific review topic.
Executive summary

Aim and scope

This rapid review aimed to evaluate the safety and effectiveness of upper airway surgery for treating obstructive sleep apnoea (OSA) in adults in comparison with conservative therapy, treatment with devices (continuous positive airway pressure [CPAP] and oral appliances) and no treatment, through a rapid systematic review of the literature. Included for review were systematic reviews of primary studies and randomised controlled trials (RCTs) which reported on the use of upper airway surgery for treating diagnosed OSA in adults compared with conservative therapy, treatment with devices or no treatment/placebo. Effectiveness outcomes examined included polysomnography measures (for example, the apnoea–hypopnoea index [AHI]), symptom control, quality of life measures, patient satisfaction and survival. Safety outcomes examined perioperative, postoperative and long-term complications or adverse effects and postoperative pain. Studies were excluded if they included non-OSA snorers or patients <18 years, or had an unsuitable comparator (for example, comparison of different techniques within a particular procedure).

Methods

Studies were identified by searching BMJ Clinical Evidence, the York (UK) Centre for Reviews and Dissemination (CRD), the Cochrane Library, PubMed and EMBASE from inception to March 2008. Extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data or pearling references from retrieved articles was not undertaken. Literature considered eligible for critical appraisal and inclusion was restricted to English language publications. Data from the included studies was extracted by an ASERNIP-S researcher using standardised extraction tables developed a priori and checked by a second researcher.

Key results and conclusions

From the search strategy, 1016 potentially relevant articles were identified of which 35 articles were retrieved. Four systematic reviews, published between 1996 and 2007, were eligible for inclusion. The reviews evaluated a range of procedures, and included four relevant RCTs that examined the upper airway surgical procedures of uvulopalatopharyngoplasty (UPPP), laser assisted uvulopalatoplasty (LAUP) and temperature-controlled radiofrequency tissue ablation (TCRFTA). An additional RCT on another upper airway surgical procedure (palatal implants) which was published too recently to be included in any systematic review was also included in this rapid review. High-level evidence was not available for any other procedures. Conclusions based on the five included studies are summarised below.

1. There was insufficient evidence to determine the effect of upper airway surgery on polysomnography results. From limited short-term evidence, UPPP and TCRFTA do not present significant benefits in mean polysomnography outcomes compared with
conservative management or placebo, although one UPPP study reported a higher success rate in UPPP compared with conservative management. One RCT of LAUP and one RCT of palatal implants found some benefit in surgery compared with no treatment/placebo in the short-term. Use of devices (oral appliance therapy and CPAP) produced better polysomnographic outcomes than surgery in the short-term; however, unlike surgery, any device has the additional issue of compliance. Surgical success rates varied depending on the procedure, the patient population, and the definition of success. It is unclear from the evidence whether any surgical procedure is superior, and the long-term effectiveness of the procedures cannot be established.

2. There was insufficient evidence to determine the effect of upper airway surgery on daytime sleepiness, snoring or quality of life. When compared with conservative management or no treatment/placebo, two RCTs suggested some benefit for UPPP and palatal implants for daytime sleepiness and snoring, while two other RCTs found no benefit for LAUP and TCRFTA for daytime sleepiness. For quality of life measures, one RCT found no benefit for LAUP, while two others reported possible benefit after TCRFTA and palatal implant compared with no treatment/placebo. There was no difference between surgery and use of devices for these outcomes.

3. There was insufficient evidence to determine levels of patient satisfaction, or to make long-term survival comparisons between upper airway surgery and alternative treatments.

4. From limited safety evidence, it would appear that UPPP had more adverse effects than the less invasive procedures of TCRFTA and palatal implants. LAUP had similar adverse effects to UPPP, at similar rates of occurrence. Long-term safety data were not available from the included studies.

From the reviewed literature, upper airway surgery for OSA does not provide significant benefit over conservative treatment or treatment with devices. Following failed conservative treatment or treatment with devices, selected patient groups with specific anatomical features, body mass index and OSA severity may benefit from certain upper airway surgical techniques. However, at present, there is insufficient high-level evidence on the effectiveness of any surgical procedure, regardless of patient characteristics.
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Abbreviations and acronyms

AHI  apnoea–hypopnoea index
AI   apnoea index
ASDA American Sleep Disorders Association
CI   confidence interval
CPAP continuous positive airway pressure
CRD Centre for Reviews and Dissemination
ESS Epworth Sleepiness Score
FOSQ Functional Outcomes of Sleep Questionnaire
GA   genioglossus advancement
HM   hyoid myotomy and suspension
ISMO inferior sagittal mandibular osteotomy
LAUP laser-assisted uvulopalatoplasty
MMO maxillomandibular osteotomy and advancement
NHMRC National Health and Medical Research Council
ODI₄ oxygen desaturation index of 4% per hour in bed
ODI₁₀ oxygen desaturation index of 10% per hour in bed
OSA obstructive sleep apnoea
PICO population, intervention, comparator, outcome
RCT randomised controlled trial
RDI respiratory disturbance index
RERA respiratory effort related arousal
TCRFTA temperature-controlled radiofrequency tissue ablation
UPPP uvulopalatopharyngoplasty
UPPPGP uvulopalatopharyngoglossoplasty
Introduction

Objective
To evaluate the safety and effectiveness of upper airway surgery for treating obstructive sleep apnoea in adults in comparison with conservative therapy, treatment with devices (continuous positive airway pressure [CPAP] and oral appliances) and no treatment, through a rapid systematic review of the literature.

Background

Condition
Obstructive sleep apnoea (OSA) occurs due to repetitive pharyngeal narrowing or collapse, which results in periodic cessation of airflow during sleep (ASDA 1996). Symptoms include loud snoring, choking and gasping, disrupted sleep and daytime sleepiness (Young et al 2004; Sundaram et al 2005). Possible risk factors for OSA include overweight and obesity, male sex, age of 40–70 years, craniofacial and upper airway abnormalities, alcohol use before sleep, and night-time nasal congestion (Young et al 2004).

Severity of OSA is defined by two components: polysomnography (overnight monitoring of breathing abnormalities) and symptom severity (daytime sleepiness) (AASM Task Force 1999). A disordered breathing event measured during polysomnography may be an apnoea (airflow cessation for $\geq 10$ seconds), hypopnoea (airflow reduction for $\geq 10$ seconds in association with arousal or oxyhemoglobin desaturation), or the recently defined additional event of respiratory effort related arousal (RERA) (increased respiratory effort over $\geq 10$ seconds leading to arousal) (Patil et al 2007). Definitions of hypopnoeas and RERAs are controversial, with the current definition of an RERA comparable to a hypopnoea (Patil et al 2007). A common severity index of sleep disordered breathing is the apnoea–hypopnoea index (AHI), which is the number of apnoeas and hypopnoeas per hour of sleep. The respiratory disturbance index (RDI) is very similar but also includes RERAs in the calculation of disordered breathing events (Patil et al 2007). AHI (or occasionally RDI) scores of $\geq 5$, $\geq 15$ and $\geq 30$ are used to indicate mild, moderate and severe OSA, respectively, although these distinctions between severity levels remain unvalidated (AASM Task Force 1999).

Clinical need
In addition to the immediate symptoms, OSA has been associated with cognitive impairment, road traffic and industrial accidents, psychosocial problems, hypertension, cardiac morbidity and mortality, glucose intolerance and impaired quality of life (Young et al 2004; Elshaug et al 2007a). In the United States it is estimated that one in five adults have at least mild OSA and that one in 15 adults have moderate or severe OSA (Young et al 2004). An Australian survey of 2202 people between 35 and 69 years of age estimated that the incidence of OSA, based on an AHI of 15 or greater (moderate to severe OSA), was at least 3.6% (5.7% for men and 1.2% for women) (Olson et al 1995). The prevalence of OSA may be increasing, with hospital
separations for sleep apnoea (mainly overnight stays in sleep centres) in Australia between 2001–2002 and 2005–2006 increasing by 41.4% for private patients and by 7.5% for public patients (AIHW 2007).

**Treatment**

**Noninvasive therapy**

CPAP is the most commonly used and recommended treatment for OSA, and is often considered the gold standard treatment (Sundaram et al 2005; Elshaug et al 2007a). The CPAP machine delivers compressed air via a mask, which acts as a pneumatic splint to elevate and maintain a constant pressure along the upper airway, and prevent narrowing and collapse. Lack of compliance with CPAP is an issue in some patients (Fleisher and Krieger 2007). Other noninvasive treatments include weight loss, modification of sleep position, avoidance of evening alcohol, medications to relieve nasal obstruction and oral appliances that position the mandible and/or tongue to increase the airway space and reduce collapsibility (Sundaram et al 2005; Fleisher and Krieger 2007).

**Upper airway surgery**

The location of the pharyngeal narrowing or collapse associated with OSA varies between individuals and may occur in the retropalatal region, the retrolingual region or both. Surgical procedures are aimed at modifying either the retropalatal or the retrolingual region of the pharyngeal airway (ASDA 1996). The practice guidelines of the American Sleep Disorders Association (ASDA) state that surgery is indicated to treat patients who have an underlying specific surgically correctable abnormality that is causing the sleep apnoea, and may be indicated to treat patients for whom noninvasive treatments have been unsuccessful or have been rejected, provided they are medically stable enough to undergo the procedure (ASDA 1996).

The various upper airway surgical procedures are outlined below.

**Phase I procedures**

**Retropalatal:**

- **Uvulopalatopharyngoplasty (UPPP):** enlargement of the retropalatal airway by resection of the free edge of the uvula and soft palate. UPPP is performed as an inpatient procedure under general anaesthetic, and is one of the most common surgical treatments for OSA (Bailey et al 2006). The procedure may be combined with a tonsillectomy. In Australia, Medicare Benefits Schedule (MBS) claims for UPPP (item number 41786) have remained constant for the past four years at approximately 1300 claims each year (Medicare Australia 2007). The current MBS item descriptor does not place any restrictions on claims with regards to clinical indication, disease severity or patient group.

- **Laser-assisted uvulopalatoplasty (LAUP):** a modification of UPPP that can be performed under local anaesthetic as an outpatient procedure or under general anaesthetic in hospital (MBS item number 41787) (Medicare Australia 2007).
• Transpalatal advancement pharyngoplasty: advancement (pulling forward) of the soft palate that can be performed in conjunction with UPPP or after UPPP failure (MBS item numbers 45736 or 45731, or 45752 with the additional procedure of genioglossus advancement) (Bailey et al 2006; Medicare Australia 2007).

• Radiofrequency volume reduction of the soft palate: a less invasive procedure than UPPP that reduces excess tissue and decreases airway collapsibility via scarring. This procedure can be performed under local anaesthetic in an outpatient setting. Multiple treatment sessions are generally required (Bailey et al 2006).

• Palatal implants (for example, Pillar® Procedure [Restore Medical Inc., St Paul, MN, USA]): a minimally invasive outpatient procedure that stiffens the soft palate by inserting polyethylene terephthalate implants, which can be performed under local anaesthetic (Friedman et al 2008).

Retrolingual:

• Inferior sagittal mandibular osteotomy (ISMO) and genioglossus advancement (GA) with or without hyoid myotomy and suspension (HM): performed in hospital under general anaesthetic, the limited mandibular osteotomy with advancement (pulling forward) of the genioglossus muscles enlarges and stabilizes the retrolingual airway (Bailey et al 2006). The genioglossus advancement has two MBS item numbers (45732 or 45761) depending on the technique used (Medicare Australia 2007). An HM, which should only be performed in conjunction with other procedures, advances the hyoid bone, epiglottis and tongue base (MBS item number 41876) (Fleisher and Krieger 2007; Medicare Australia 2007)).

• Radiofrequency volume reduction of soft tissue and/or tongue: as described above. The MBS item number for a tongue procedure is 45675 (Medicare Australia 2007).

• Tongue base suspension suture (for example, Repose™ system [InfluENT Medical Inc, Concord, NH, USA]); a minimally invasive procedure to stabilise the tongue base, which can be performed under local anaesthetic as an outpatient procedure or under general anaesthetic in hospital (Bailey et al 2006).

Phase II procedures

Phase II procedures are more invasive and may be used if Phase I procedures are unsuccessful (Riley et al 1993).

Retropalatal:

• Maxillomandibular osteotomy and advancement (MMO): advancement of the maxilla and mandible to increase the dimensions of the retropalatal and retrolingual airway (several MBS item numbers, including 45744). The procedure is performed in hospital under general anaesthetic and often requires recovery time in intensive care (Elshaug et al 2007b).
• Mucosal sacrificing glossectomy techniques (for example, laser midline glossectomy and lingualplasty): performed in hospital under general anaesthetic; recent variations of submucosal glossectomy techniques cause little pain and may be considered Phase 1 (Robinson et al 2003). The MBS item number for these procedures is 45675 (Medicare Australia 2007).

Other surgical interventions
Anatomical abnormalities leading to nasal obstruction may also be corrected surgically by procedures such as septoplasty (correcting of malformed nose cartilage) or turbinectomy (removal of turbinate bone in the nose) (Bailey et al 2006). Bariatric surgery to initiate significant weight loss has been used to treat OSA in patients with morbid obesity (SIGN 2003). Tracheotomy can also successfully treat OSA by bypassing the portion of the airway that collapses or narrows, but is rarely performed due to its associated cosmetic effects and morbidity (ASDA 1996).

Issues regarding upper airway surgery
The use of upper airway surgery for treating adult OSA remains controversial (Elshaug et al 2007a). Guidelines from the Scottish Intercollegiate Guidelines Network state that use of UPPP or LAUP for treating OSA is not recommended based on a lack of evidence of their effectiveness (SIGN 2003). In contrast, the ASDA practice guidelines state that UPPP, with or without tonsillectomy, may be appropriate for patients who show narrowing or collapse in the retropalatal region, but should only be used when less invasive treatments, such as CPAP, have been considered (ASDA 1996). Other American guidelines state that LAUP is not recommended for treating OSA, but is comparable to UPPP for treating snoring (Littner et al 2001). Of the procedures directed at enlarging the retrolingual region, the ASDA guidelines state that ISMO and GA with or without HM is the most promising, and it is also noted that MMO may be successful when other surgeries have failed (ASDA 1996). The success of procedures such as UPPP is affected by anatomical factors (the site of pharyngeal narrowing or collapse, palate position, tonsil size), body mass index and OSA severity (Friedman et al 2002; Sher et al 1996). A widely used staging system identifies those patients who are most likely to have successful UPPP surgery (Friedman et al 2002). Many adults with OSA will have combined retropalatal and retrolingual collapse, and surgery to both regions may improve success rates (Sher et al 1996).

Among issues regarding the effectiveness of upper airway surgery are concerns that the effects of surgery may lessen over time, and that surgery may only mask symptoms of the disease, leaving OSA undertreated (Sundaram et al 2005). Most upper airway surgical procedures for OSA are also associated with considerable pain, and recovery takes several weeks. Immediate postoperative adverse effects of upper airway surgery can include haemorrhage, infection, hypertension and respiratory events (Riley et al 1997). The surgery can also be associated with longer-term complications. In UPPP, for example, longer-term complications include impaired function in the soft palate and throat muscles, altered pharyngeal sensation, dry mouth and changes to smell, taste and speech (Roosli et al 2006). One study reported that the majority of patients undergoing UPPP experienced severe pain...
and low overall satisfaction with the surgery; 61% would not have the operation again (Hicklin et al 2000).

**Issues regarding comparisons**

While the AHI or the RDI are commonly used to define OSA severity, they have a number of important limitations that may affect comparisons between studies and between interventions. These limitations are described below.

1) One limitation is that techniques for measuring airflow during polysomnography differ, making them difficult to compare. In Australian sleep laboratories, pressure transducers have been introduced in addition to thermistors to measure airflow, and are more sensitive than thermal sensors for detecting hypopneas (AASM Task Force 1999). Patients measured using the new technique will have more physiological, rather than pathological, hypopnoeas recorded, and have an RDI on average 40–50% higher than patients assessed using older equipment. Some sleep laboratories in Australia have adjusted for this by replacing the standard criteria of OSA severity (≥5 for mild, ≥15 for moderate, and ≥30 for severe) with 15–30 for mild, 31–45 for moderate, and >45 for severe, based on published normative data on asymptomatic controls using the new equipment (Banks et al 2004). However, the introduction of new technology and scoring techniques has not been uniform across the world, making comparisons between studies or interventions difficult.

2) Comparing treatment effects of surgery to a device such as CPAP is also difficult. CPAP gives good physiological control when worn, but only approximately half of patients will wear the device for a long enough duration (more than five hours per night) (Weaver et al 2007). In contrast, surgery is always applied 100% of the sleep time once performed, but incomplete physiological control is more common than complete control. Thus, when comparing the effect of a treatment, issues of compliance as well as efficacy need to be considered.

3) Recent discussion has focused on whether the traditional measure of surgical success (a ≥50% reduction in AHI or RDI, and a decrease in score to ≤20) represents clinically significant health outcomes (Elshaug et al 2007a). A recent study suggests that during CPAP treatment, a large reduction in AHI or RDI (that is, to near or below five events per hour of sleep) is required before improvements in some health outcomes, such as blood pressure, can be demonstrated (Becker et al 2003). As yet, there is no similar evidence to show that such a large reduction is necessary for important clinical outcomes after surgery.

Regardless, AHI and RDI scores correlate poorly with symptoms. A recent study found that these polysomnography indexes were not consistently associated with sleepiness, quality of life or reaction time at baseline or at outcome time points in patients with mild to moderate OSA (Weaver et al 2005). Thus polysomnography indexes may not quantify some important aspects of OSA disease burden or treatment outcome, and measurement of clinically relevant endpoints (for example, snoring control, sleepiness, reaction time and driving performance, other neurocognitive testing results and death) is also necessary when evaluating interventions for OSA (Weaver et al 2005).
Summary
In line with the ASDA guidelines, the role of upper airway surgery in adult OSA is generally accepted as appropriate only when less invasive treatments are ineffective, rejected or inappropriate (ASDA 1996). The critical issue is whether upper airway surgery should be offered in this context, or whether the patient should be left untreated. It is also important to compare surgery with other noninvasive options the patient may have rejected without due consideration.

Figure 1 shows a clinical decision pathway for treating OSA.
ASERNIP-S REVIEW OF UPPER AIRWAY SURGERY FOR TREATMENT OF ADULT OBSTRUCTIVE SLEEP APNOEA

INTRODUCTION

Figure 1: Clinical decision pathway for treating obstructive sleep apnoea
Research questions

This rapid review addressed the following specific research questions:

- Are upper airway surgical procedures safe for treating adult OSA?
- Are upper airway surgical procedures effective for treating adult OSA, and should they be offered after failed noninvasive treatment, such as conservative therapy or treatment with devices (CPAP and oral appliances)?
Methodology

Inclusion criteria
Studies were selected for inclusion in this rapid review on the basis of the criteria outlined below.

Population
Studies of adult human patients (men and women aged 18 years and over) with a diagnosis of OSA (AHI ≥5) were included.

Intervention
Included studies were related to the use of upper airway surgery for the treatment of OSA (including UPPP, LAUP, transpalatal advancement pharyngoplasty, palatal implants, inferior sagittal mandibular osteotomy and genioglossus advancement with or without hyoid myotomy and suspension, radiofrequency volume reduction of soft tissue and/or tongue, tongue base suspension suture [for example, Repose system], laser midline glossectomy and lingualplasty, maxillomandibular osteotomy and advancement).

Comparator interventions
The main comparators for upper airway surgery were conservative therapy (behaviour modification, weight loss, medications), treatment with devices (CPAP and oral appliances), and no treatment (including placebo).

Outcomes
Studies were included if they contained information on at least one of the following outcomes:

Effectiveness
- AHI/ RDI/ apnoea index (AI)/ oxygen desaturation index of 4% or 10% per hour in bed (ODI₄ and ODI₁₀)
- symptom control (for example, sleepiness scale)
- quality of life measures
- patient satisfaction
- survival.

Safety
- perioperative, postoperative and long-term complications or adverse effects
- postoperative pain
- mortality.
Study design
Recently published, well-conducted systematic reviews, rather than primary studies were selected preferentially for including in the review and critical appraisal. Systematic reviews were defined as those studies that met all the following criteria, as defined by Cook et al (1997):

1. Focused clinical question
2. Explicit search strategy
3. Use of explicit, reproducible and uniformly applied criteria for article selection
4. Critical appraisal of the included studies
5. Qualitative or quantitative data synthesis.

Where there were two or more systematic reviews with the same inclusion and exclusion criteria, the latest and most complete study was included. In addition, eligible randomised controlled trials (RCTs) published after the search date of the most recent systematic review were also included.

If no suitable systematic reviews on the topic were available, RCTs and pseudorandomised controlled trials were considered eligible for inclusion and critical appraisal. A study was deemed to be an RCT if the author(s) stated explicitly (usually by some variant of the term ‘random’ to describe the allocation procedure used) that the groups compared in the trial were established by random allocation (Higgins and Green 2005). Studies in which the method of allocation was known but was not considered strictly random (for example, alternation, date of birth and medical record number) were classified as pseudorandomised controlled trials (Higgins and Green 2005). Where no randomised and pseudorandomised controlled trials were identified, nonrandomised comparative studies were also included in the review.

When overlapping patient groups were reported in studies, only the paper quoting the most complete data set was used.

Publication date
No date restriction was applied.

Language of publication
Included studies were restricted to those published in English.

Literature search strategies
Databases searched
The following databases were searched from inception to 20 February 2008:

- BMJ Clinical Evidence
- The York (UK) Centre for Reviews and Dissemination (CRD)
- The Cochrane Library
The review did not include extended searching of internet websites and conference abstracts, handsearching of journals, contacting authors for unpublished data or pearling references from retrieved articles.

**Search terms**

Search terms used are listed in Table 1 below, and details of the full search strategy are provided in Appendix A.

<table>
<thead>
<tr>
<th>Area of inquiry</th>
<th>Search terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>MeSH headings (Cochrane, York CRD, PubMed)</td>
<td>Surgery OR Surgical Procedures, Operative Sleep Apnea Syndromes</td>
</tr>
<tr>
<td>EMBASE headings (EMBASE)</td>
<td>ear nose throat surgery/ OR major surgery/ OR nose surgery/ OR minor surgery/ OR dental surgery/ OR oral surgery/ OR head and neck surgery/ OR laser surgery/ OR surgery/ or general surgery/ or elective surgery/ OR maxillofacial surgery/ Sleep Apnea Syndromes</td>
</tr>
<tr>
<td>Text words (Cochrane, York CRD, EMBASE, PubMed)</td>
<td>surgery OR surg* OR operat* OR therapy OR therap* sleep apnea OR sleep apnoea</td>
</tr>
</tbody>
</table>

**Search Limits**

Subjects: Humans only
Studies: Systematic reviews, Meta-Analyses, Randomised/Randomized Controlled Trials
Limits: English language only

Note: * is a truncation character that retrieves all possible suffix variations of the root word; for example, surg* retrieves surgery, surgical, surgeon, etc. In databases accessed via the Ovid platform the truncation character is $.

**Selection of studies**

The reviewer (KH) applied the inclusion criteria to identify those studies potentially eligible for selection and appraisal based on their abstracts; these studies were retrieved as full text. The selection criteria were then applied fully to the retrieved studies to identify those to be appraised and included in the review. Full publications subsequently found not to meet the inclusion criteria were excluded and reasons for exclusion were documented.

**Data extraction and appraisal of study methodology**

Data from all included studies were extracted by one reviewer (KH) and checked by a second reviewer (PT) using standardised data extraction tables that were developed a priori. The studies included in the review were classified according to the National Health and Medical Research Council (NHMRC) hierarchy of evidence (see Table 2).
Table 2: National Health and Medical Research Council hierarchy of evidence

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case-series, either post-test or pre-test/post-test</td>
</tr>
</tbody>
</table>

Source: NHMRC 2000

Where systematic reviews were eligible for inclusion in the review, the methodology of these secondary studies was evaluated with respect to the following factors:

- Did the review ask a focused research question that incorporated the elements of the PICO (population, intervention, comparator, outcomes)?
- Were the inclusion and exclusion criteria of included studies clearly stated?
- Did the review use a clear and comprehensive search strategy?
- Did the review assess the validity of included studies, and if so which validity criteria were used?
- Was the analysis or synthesis of the results appropriate?
- Did the review include a summary of its main results, including a discussion of its strengths and limitations?

Where primary studies were eligible for inclusion in the review, the following criteria were used to appraise their methodology, where applicable:

- Were the objectives of the study clearly defined?
- Were the inclusion and exclusion criteria clearly described?
- Was there a clear description of the interventions used?
- Were the characteristics of patients included in the study clearly described?
- Were patients randomly assigned to intervention groups, and if so was the method of randomisation described?
- Was the randomised assignment of patients to intervention groups concealed from both patients and staff administering the study until recruitment was complete?
- Was there an attempt made to blind both patients, and staff responsible for measuring outcomes of the intervention, to the interventions patients received?
- ASERNIP-S REVIEW OF UPPER AIRWAY SURGERY FOR TREATMENT OF ADULT OBSTRUCTIVE SLEEP APNOEA -

- METHODOLOGY

• Were the number of patients who withdrew or dropped-out of the study reported, and the characteristics of these patients described?

• Were the main outcomes of interest adequately reported?

• Were point estimates and measures of variability presented for the primary outcome measures?

Non-randomised studies were also assessed for other features of study design or execution that may have introduced bias, such as comparability of patient groups at baseline, method of patient selection and comparability of timing of outcome assessment.

One reviewer (KH) appraised the studies, which were checked by the second reviewer (PT). Any differences were resolved through discussion.
Results

From the search strategy, 1016 potentially relevant articles were identified of which 35 articles were retrieved. Retrieved papers included systematic reviews and primary studies. In total, 30 retrieved articles were excluded and these are listed in Appendix B.

A total of five studies, including four systematic reviews (Sher et al 1996; Sundaram et al 2005; SBU 2007; Elshaug et al 2007a) and one RCT (Friedman et al 2008) were eligible for appraisal and inclusion in this rapid review. Table 3 lists the included systematic reviews, and evidence tables of the included systematic reviews and RCT are presented in Appendix C.

There was some overlap in the studies included in the systematic reviews by Sundaram et al (2005), SBU (2007) and Elshaug et al (2007a). The review by Sundaram et al (2005) included four RCTs of relevance to this rapid review (Lojander et al 1996; Ferguson et al 2003; Woodson et al 2003; Tegelberg et al 1999). Three of these RCTs were also included in the review by SBU et al (2007) (Ferguson et al 2003; Woodson et al 2003; Tegelberg et al 1999, although the latter was referred to as Wilhelmsson et al 1999 in this review, as several publications were produced from this trial). The review by Elshaug et al (2007a) only included the RCT by Ferguson et al (2003).
### Table 3: Summary of included systematic reviews relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
<thead>
<tr>
<th>Search details</th>
<th>Number and type of primary studies</th>
<th>Interventions (number of studies)</th>
<th>Number and type of primary patients</th>
<th>Outcome measures and follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sher et al (1996)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Time span</td>
<td>1966–1995</td>
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<td>Limits</td>
<td>English language, one database only</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Level II (n=0)</td>
<td></td>
<td></td>
<td>Outcomes measured Polysonography (Al, RDI), complications</td>
</tr>
<tr>
<td></td>
<td>Level III or IV (n=54)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(n=48 of relevance to this review)</td>
<td></td>
<td></td>
<td>Follow-up NR</td>
</tr>
<tr>
<td></td>
<td>Surgery</td>
<td>UPPP (37), UPPGP (2), laser midline glossectomy (1), lingualplasty (1), ISMO and GA with or without HM (3), MMO (4)</td>
<td>(n=1337 (992 UPPP, 39 UPPGP, 12 laser midline glossectomy, 22 lingualplasty, 137 ISMO and GA with or without HM, 135 MMO)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSA severity</td>
<td>For UPPP: RDI weighted average was 60.0 (range 25.8–82.1). For other surgeries: RDI ranged from 45 to 68.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*<em>Sundaram et al (2005)</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Time span</td>
<td>Up to 2007</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limits</td>
<td>RCTs</td>
<td></td>
<td></td>
<td>Outcomes measured Polysonography (ODI4, ODI10, AHI), symptoms (sleepiness, snoring, QoL), satisfaction, complications</td>
</tr>
<tr>
<td></td>
<td>Level II (n=8)</td>
<td></td>
<td></td>
<td>Follow-up</td>
</tr>
<tr>
<td></td>
<td>(n=4 of relevance to this review)</td>
<td></td>
<td></td>
<td>Lojander et al 1996 (1 year) and Tegelberg et al 1999 (4 years) had follow-up ≥1 year. All others had follow-up &lt;1 year.</td>
</tr>
<tr>
<td></td>
<td>Surgery versus conservative management or placebo</td>
<td>UPPP (1): Lojander et al 1996 (also performed ISMO and GA with HM on suitable patients) LAUP (1): Ferguson et al 2003 TCRFTA (1): Woodson et al 2003</td>
<td>n= 562 (range 17–150) (for all 8 RCTs)</td>
<td></td>
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<tr>
<td><strong>SBU et al (2007)</strong></td>
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<tr>
<td>Time span</td>
<td>Up to 2006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limits</td>
<td>RCTs (for efficacy section only), Danish, English, Finnish, French, German, Icelandic, Norwegian, Spanish or Swedish language</td>
<td></td>
<td></td>
<td>Outcomes measured Polysonography (AHI), symptoms (sleepiness, QoL), complications</td>
</tr>
<tr>
<td></td>
<td>Level II (n=30)</td>
<td></td>
<td></td>
<td>Follow-up</td>
</tr>
<tr>
<td></td>
<td>(n=4 of relevance to this review)</td>
<td></td>
<td></td>
<td>8 weeks to 1 year</td>
</tr>
<tr>
<td></td>
<td>OSA severity</td>
<td>For surgery versus conservative management or placebo: mean AHI 17 For surgery versus device: Wilhelmsson et al 1999: mean AHI 19±9, Woodson et al 2003: mean AHI 18±9</td>
<td></td>
<td></td>
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<tr>
<td><strong>Elshaug et al (2007a)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Time span</td>
<td>2001–2005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limits</td>
<td>English language, one database only</td>
<td></td>
<td></td>
<td>Outcomes measured Polysonography (AHI)</td>
</tr>
<tr>
<td></td>
<td>Level II (n=1)</td>
<td></td>
<td></td>
<td>Follow-up</td>
</tr>
<tr>
<td></td>
<td>Level IV (n=17)</td>
<td></td>
<td></td>
<td>6 weeks to 12.3 months</td>
</tr>
<tr>
<td></td>
<td>Surgery</td>
<td>Phase I procedures (14): included UPPP, LAUP, TCRFTA, RFTA, Repose system, GA, HM. (RCT was for LAUP: Ferguson et al 2003) Phase II procedures (4): included MMO</td>
<td>n= 385</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSA severity</td>
<td>NR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table notes: Al: apnoea index, AHI: apnoea–hypopnoea index, RDI: respiratory disturbance index, ISMO and GA with or without HM: inferior sagittal mandibular osteotomy and genioglossus advancement with or without hyoid myotomy and suspension, LAUP: laser-assisted uvulopalatoplasty, MMO: Maxillomandibular osteotomy and advancement, NR: not reported, ODI4 and ODI10: oxygen desaturation index of 4% or 10% per hour in bed, QoL: quality of life, RFTA: radiofrequency tissue ablation, TCRFTA: temperature-controlled radiofrequency tissue ablation, UPPGP: uvulopalatopharyngoglossoplasty, UPPP: uvulopalatopharyngoplasty

*In the review by Sundaram et al (2005) the results for the study termed Tegelberg et al 1999 included results from additional papers (Wilhelmsson et al 1999; Walker-Engstrom et al 2000; Walker-Engstrom et al 2002). The results for the study termed Lojander et al 1996 include results from an additional paper (Lojander et al 1999).
**Systematic review evidence**

Sher et al (1996)

**Appraisal of study methodology**

The aim of an early systematic review by Sher et al (1996) was to review the literature covering the surgical treatment of OSA and to determine the efficacy of various operations. The review only searched the MEDLINE database for English language publications from 1966 to 1993, with an update in 1995. The search strategy included broad search terms and did not include citation checking, handsearching of journals, or contact with authors. The selection criteria were reasonably extensive. Reviews, editorials or letters were excluded, as were primary studies that included fewer than nine patients. Papers were also excluded if they did not report a clear and unambiguous outcome measure, the patients had already been described in another included study, the paper included snorers who may not have had OSA, or if the study lacked appropriate baseline data.

Of the 54 articles that met the review’s selection criteria, 37 were on UPPP and the remainder were on other surgical techniques, including nasal, tongue, tracheotomy, mandibular and maxillomandibular procedures. Articles were appraised and quantitative data extracted and checked by two reviewers. However, the appraisal methodology was not reported. No RCTs were identified; therefore, all reported evidence was from lower-level studies. A meta-analysis was performed for the UPPP studies but homogeneity was not reported. Meta-analyses were not possible for other surgical techniques because of the limited number of studies.

**Efficacy**

For the combined polysomnography results for UPPP, the post-treatment weighted mean change in AI was −55.2% (range −84.3 to −17.2%) \( (P<0.0001) \) and in RDI was −38.2% (range −72.1 to 11.8%) \( (P<0.0001) \) compared with the baseline. The UPPP success rate, if defined as a 50% decrease in AI, was 229/353 patients (65%); if defined as a 50% decrease in RDI, the UPPP success rate was 197/375 patients (53%). In the UPPP studies, there was a significant correlation between mean baseline AI and percentage change in AI (−0.502; \( P=0.024 \)), suggesting that a high baseline AI is associated with a lower percentage decrease in this parameter. Following UPPP, the percentage change in AI was significantly larger in patients with retropalatal narrowing or collapse than in patients with retrolingual narrowing or collapse \( (P<0.0001) \). For uvulopalatopharyngoglossoplasty (UPPPGP), a modification of UPPP with limited resection of the tongue base, two case-series studies reported success rates of 50% (success defined as a 50% decrease in RDI) and 67% (defined as a 50% decrease in AI).

For laser midline glossectomy, one case-series study reported a success rate of 42% (defined as a 50% decrease in RDI), while for lingualplasty another study reported a success rate of 77% (defined as a 50% decrease in RDI and decrease in RDI to <20). Most of the patients in these two studies had undergone previous surgery, in particular UPPP. Three studies reported success rates for ISMO and GA with or without HM of 38–79% (defined as a 50% decrease in RDI). The procedure varied in these studies, because only two studies included hyoid suspension, and two included other procedures such as UPPP. One study reported MMO success rate to be as low as 20% (defined as RDI <10) if performed with no adjunctive
procedures, while another reported a success rate of MMO as the sole treatment of 100% (defined as RDI <10) in nonobese patients with skeletal deficiency. MMO success rates were reported in one study to be 78% (defined as RDI <10) if at least one adjunctive procedure was used and 100% with UPPP as one of the adjunctive procedures, while another study reported a success rate of 98% (defined as a 50% decrease in RDI and RDI <20) following unsuccessful Phase I surgery.

Safety

Nine papers reported no significant or long-term complications after UPPP. A further nine papers reported complications that included velopharyngeal insufficiency for longer than one month (n=14), postoperative bleeding (n=7), nasopharyngeal stenosis (n=5), voice change (n=4), successfully managed perioperative upper airway obstruction (n=3), vague foreign-body sensation (n=1), and death secondary to airway obstruction (n=1). Complications rates for UPPP were not clear, because the review did not report the sample sizes of these studies. One study reported no permanent complications but did report transient adverse effects, including postoperative bleeding, dysphagia and pain when swallowing following laser midline glossectomy. Another study reported that all patients (n=55) had transient anaesthesia of the lower teeth after ISMO and GA with or without HM. One study reported that, following MMO, there was no postoperative bleeding, motor nerve deficits or major skeletal relapse (movement of bone back to original position), but all patients (n=306) had transient anaesthesia of the cheek and chin, which resolved in 87% in 6–12 months.

Authors’ conclusions

The authors concluded that UPPP is effective in treating about 50% of patients with OSA, and that the probability of success is affected by the site of pharyngeal narrowing or collapse and the severity of OSA before surgery. Patients with pharyngeal narrowing or collapse limited to the retropalatal region, and patients with less severe OSA, had more favourable outcomes. The authors concluded that successful treatment of OSA requires careful selection from among the different surgical techniques that are available, that selecting the surgical technique should by guided by a region-by-region analysis of the individual’s pattern of airway compromise, and that the available surgical procedures, if applied in a logical fashion under a comprehensive protocol, may effectively treat the vast majority of patients with OSA. The review discussed the study limitations in detail, with mention of study design (only level III and IV evidence), biases related to small sample size, limited follow-up and patient selection, lack of uniformity in reporting polysomnography results, and lack of valid measures of sleep-related health status and quality of life.

Sundaram et al (2005)

Appraisal of study methodology

A Cochrane review by Sundaram et al (2005) assessed the effects of any type of surgery for treating the symptoms of OSA in adults. The review used a detailed search strategy, and searches were current as of July 2007. The reviewers searched multiple databases; respiratory journals and meeting abstracts were hand searched; reference lists were checked; and relevant research bodies were contacted to identify trials. No date or language restrictions were used.
Extensive selection criteria were used to identify RCTs of any specific surgical interventions for diagnosed OSA (AHI >5). Study controls could be other surgical or nonsurgical interventions, or no intervention. Primary outcomes were AHI and the Epworth Sleepiness Score (ESS) (where a higher score indicates more daytime sleepiness) or symptoms of sleepiness measured by other means. Children were excluded. Two independent assessors selected trials for inclusion and assessed the methodological quality of eligible trials based on the degree of allocation concealment and the likelihood of bias using the Jadad instrument (Jadad et al 1996). These reviewers also checked and extracted data.

Ten RCTs met the inclusion criteria, although two were subsequently excluded for using a combined sample of OSA and non-OSA snoring patients, and for not making any statistical comparisons between control and intervention groups. Each study used different comparisons, which meant that data could not be compared across all studies. However, the authors did report the meta-analysis methodology and heterogeneity testing that they would have used if sufficient data were available. The characteristics of included and excluded studies were presented in tabular form, while study results were reported narratively.

Sample sizes in the included RCTs ranged from 17–150 patients, and OSA severity ranged from mild to severe. Three studies compared surgery with conservative management (lifestyle advice), no treatment or placebo; two studies compared surgery with a device (CPAP or oral appliance therapy); and the remainder of the studies compared different surgical interventions. Study results from the latter group will not be discussed because they are outside the scope of this rapid review. Only two studies had a follow-up of longer than one year.

The RCTs in this systematic review were also located in the searches for this rapid review. Some of the results reported in the systematic review by Sundaram et al (2005) were unclear or appeared erroneous, prompting consultation with the primary study papers. It would appear that the systematic review contained several errors relating to data which didn’t correspond to that reported in the original paper. In these instances, the authors of this rapid review substituted results from the original paper. Corrections are noted in Table 3.

**Efficacy**

One study compared UPPP with conservative management and found no significant difference in ODI₄ and ODI₁₀ at 12 months between the groups. At one year, 7/16 UPPP patients and 1/10 conservative management patients had normal ODI₄ (defined as ≤10) \(P<0.02\). Another study compared UPPP with oral appliance therapy and found a significant difference in AHI in favour of oral appliance therapy at one \(P<0.01\) and four years \(P<0.01\). The success rate at one year (when defined as ≥50% reduction in AHI) was 26/43 patients (60%) in UPPP and 30/37 patients (81%) in oral appliance therapy \(P<0.05\). If the success rate was defined as AI<5 or AHI<10, 22/43 patients (51%) in the UPPP and 29/37 patients (78%) in the oral appliance therapy group were successful \(P<0.05\). The success rates were similar for different airway obstruction types. A study comparing LAUP with no treatment found a significant difference in final AHI in favour of LAUP \(P=0.04\), and a 21% reduction in mean AHI after LAUP \(P=0.03\). The success rate (defined as AHI≤10) was
5/21 patients (24%) in LAUP and 4/24 patients (16.7%) in the no treatment group. However, if the success rate was refined to an AHI ≤ 10 and satisfactory resolution of symptoms, 4/21 patients (19%) were successful in LAUP and 0/24 patients (0%) were successful in the no treatment group. The final included study compared temperature-controlled radiofrequency tissue ablation (TCRFTA) with placebo and CPAP. There was no significant difference in AHI between TCRFTA and placebo, whereas the AHI was lower in CPAP than TCRFTA, representing a significant difference in the change from baseline between the two groups in favour of CPAP (P=0.004). However, the average CPAP use was only 16.8 hours per week.

Several studies used obstruction criteria to ensure a patient’s suitability for the surgical technique to be used. The UPPP and conservative therapy study considered patients for UPPP if they had 50% obstruction at palatal level in the Mueller’s manoeuvre, but less than 50% obstruction at the epiglottic level. The UPPP and oral appliance therapy study excluded participants with significant nasal obstruction. The TCRFTA study excluded participants if they had tonsillar hypertrophy or nasal/supraglottic obstruction on examination, and the LAUP study only included participants with mild OSA.

The review also reported symptom outcome measures. The UPPP versus conservative management study reported a significant difference in symptoms of daytime sleepiness (visual analogue scale) in favour of UPPP at three (P<0.001) and 12 months (P<0.01), while the UPPP versus oral appliance therapy study found that there was no significant difference in vitality and sleep after one year (using the Minor Symptoms Evaluation Profile quality of life questionnaire) but a significant difference in favour of surgery for contentment (P<0.05). At four years 30/40 patients (75%) were satisfied with UPPP and 23/32 patients (72%) were satisfied with oral appliance therapy. The LAUP versus no treatment study found no significant difference in ESS or in the number of patients reporting unrefreshing sleep and excessive daytime sleepiness, or in quality of life (Calgary Sleep Apnoea Quality of Life Index). However, there was a significant improvement in frequency (P<0.005) and intensity (P<0.0001) of snoring in favour of LAUP. Eleven out of 21 patients were satisfied with LAUP. For the TCRFTA versus placebo study there was no significant difference between groups for change in ESS (P=0.12), but there was a significantly greater improvement in quality of life (Functional Outcomes of Sleep Questionnaire [FOSQ]) in favour of TCRFTA (P=0.04). When TCRFTA was compared with CPAP there was no significant difference in ESS or quality of life, although both groups improved significantly from baseline for both measures.

**Safety**

In terms of safety, the study that compared UPPP with conservative management identified a complication rate of 22% in the surgery group (4/18 patients), with complications that included removal of infected material (n=2), tracheostomy (n=1), and dysphagia (n=2). A myocardial infarction (n=1) and a transient ischaemic attack (n=1) also occurred in the surgery group. The UPPP versus oral appliance therapy study reported that in the surgical group fibrotic narrowing without symptoms (n=3), nasopharyngeal regurgitation of fluid (8%) and dysphagia (10%) occurred, while in the oral appliance group, one patient had aphthous ulcers caused by an allergic reaction to the acrylic polymer, and two patients reported discomfort.
The LAUP study identified adverse effects of LAUP treatment including moderate to severe pain (17/21 patients; 81%), dysphagia (4/21 patients; 19%), bleeding (9/21 patients; 43%), nasal regurgitation (5/21 patients; 24%), infection (4/21 patients; 19%), and temporary change in vocal quality (1/21 patients; 5%). The TCRFTA study found no significant difference between TCRFTA and placebo in frequency and severity of complications (three haematomas in each group and one ulceration in the TCRFTA group), postoperative pain, or swallowing difficulty. However, these safety data were from a limited number of the study participants. Twenty out of 21 CPAP participants had adverse effects (nasal symptoms, inconvenience, sleep interruption, problems with air mechanics, and skin or eye symptoms).

**Authors’ conclusions**

The authors concluded that surgical treatment was not consistently effective compared with different forms of active and inactive controls, that the evidence does not currently support the widespread use of surgical interventions for managing unselected patients with OSA, and that surgery cannot be recommended ahead of CPAP in patients with moderate and severe symptoms and significant sleep disordered breathing. Long-term follow-up comparing surgery with oral appliances suggested that the initial effect of surgery on airway obstruction lessened over time. All these conclusions still appear to be applicable despite the minor corrections from consultation with the primary studies. The authors recommended further studies to determine whether subgroups of patients would benefit from surgery, to provide long-term comparison between CPAP and surgical therapies, to assess the impact of UPPP on CPAP effectiveness and adherence, to assess cardiovascular outcomes such as blood pressure, and to assess and standardise techniques to identify the site of airway obstruction to allow more specific selection of surgical procedures.

**SBU (2007)**

**Appraisal of study methodology**

The systematic review included in the SBU (2007) report examined the benefits of treatment for OSA on daytime impairment and blood pressure in RCTs, and examined types and frequencies of adverse effects from treatment and compliance regardless of study design. This aim and review incorporated surgical treatment. Searches were current up to March 2006, with the search strategy including detailed search terms, searching of multiple databases, checking of reference lists, and contact with authors where needed. No handsearching of journals was reported and language was restricted to Danish, English, Finnish, French, German, Icelandic, Norwegian, Spanish or Swedish. There was no date restriction. Extensive selection criteria were used, and RCTs were included in the efficacy section of the review if they included ≥20 adults followed for a minimum of four weeks, OSA patients, any intervention aimed at reducing obstructive apnoeas/hypopnoeas, and primary outcomes of daytime sleepiness. For the safety section of the review, studies were included that reported any kind of clinical or patient-experienced adverse effect, including technical failures, regardless of trial design. Two independent reviewers reviewed the full reports of potentially relevant articles for inclusion. Studies were assessed for methodological quality using a modified Jadad rating scale, with data extracted independently by two reviewers. Study results
were combined where possible, using weighted mean difference or standard mean difference for comparison, and homogeneity was assessed. The review included extensive tabular data, including characteristics of included and excluded studies and results.

Thirty trials met the selection criteria for the efficacy section; however, only a small proportion of these were for surgical procedures. Three studies reported on surgery versus sham or conservative treatment (sample size of 134 patients, mean AHI of 17), two studies reported on surgery versus a device (CPAP: sample size of 80 patients, mean AHI of 19; or oral appliance therapy: sample size of 60 patients, mean AHI of 18), and one study compared two surgical interventions. Results from the latter study will not be reported in this rapid review. The follow-up period of all studies was one year or less.

**Efficacy**

The review presented the polysomnography results as a weighted mean difference between treatments. One study, which compared oral appliance therapy with UPPP, had a weighted mean difference in AHI of –4.5 (95% confidence interval [CI] –8.5 to –0.50) \((P=0.03)\). This significant difference was in favour of oral appliance therapy, but the review noted that the study did not investigate patients who did not comply with appliances at follow-up. For two studies that compared LAUP with placebo or no treatment, the weighted mean difference in AHI was –3.1 (95%CI –14.3 to 8.1) \((P=0.59)\). The review found conflicting evidence regarding LAUP, as one study found no effect of LAUP versus placebo or no treatment, while the other study found a reduction in AHI. Another study compared TCRFTA with placebo, with a weighted mean difference in AHI of 3.2 (95%CI –2.3 to 8.7) \((P=0.25)\). The same study compared CPAP and TCRFTA, with a weighted mean difference in AHI of –12.2 (95%CI –18.0 to –6.4) \((P<0.0001)\), significantly in favour of CPAP.

Symptom outcomes were also presented as weighted mean differences between treatments. For the study comparing oral appliance therapy with UPPP, ESS and quality of life results were not reported. For the two LAUP versus placebo or no treatment studies, the weighted mean difference in ESS was –1.2 (95%CI –3.9 to 1.6) \((P=0.40)\). The review did not report quality of life. For the TCRFTA versus placebo study, the weighted mean difference in ESS was –0.8 (95%CI –3.1 to 1.5) \((P=0.50)\), while the standardised mean difference in quality of life (FOSQ) was 0.24 (95%CI –0.33 to 0.81) \((P=0.41)\). The CPAP versus TCRFTA comparison produced a weighted mean difference in ESS of 0.5 (95%CI –2.3 to 3.3) \((P=0.72)\) and a standardised mean difference in quality of life of 0.09 (95%CI –0.69 to 0.52) \((P=0.78)\).

**Safety**

The safety section of the review incorporated all levels of primary study evidence, and included 28 UPPP studies, 20 UPP/LAUP studies, and nine TCRFTA studies. For UPPP, 30 deaths were reported in six studies, with a mean frequency of 0–1.5%. Serious perioperative and postoperative complications were reported in 0–16% of study participants. The persistent adverse effects of UPPP occurred at a rate of 14–62%, with these including difficulty in swallowing (28% [13–36%]), globus sensation (40%), voice changes (7–14%), persistent throat dryness (3–56%), smell disturbances (8%), taste disturbances (7%), velopharyngeal insufficiency (3%), and velopharyngeal stenosis (single cases)). For UPP/LAUP, one study
reported one death from septicaemia. Postoperative complications were reported in up to 5% of patients, while persistent adverse effects of UPP/LAUP were reported in 57% of patients (52–62%). These adverse effects included difficulty swallowing (26% (19–29%)), globus sensation (17–36%), voice changes (6–10%), smell disturbances (8%), taste disturbances (7%), increased vomiting reflexes (4%) and velopharyngeal stenosis (single cases)). For TCRFTA, perioperative and postoperative complications included palatal mucosal breakdown or mucosal ulcers (3–37%), palatal fistula (2%), uvula loss (2–7%), haemorrhage (5%), infections (% not reported), transient choking sensation (28%), difficulty swallowing (13%) and pain (19%). One study reported tongue base abscesses in 1 out of 18 patients and severe tongue swelling in 3 out of 18 patients, while another study reported tongue base abscesses in 2 out of 30 patients and mouth floor oedema in 2 out of 30 patients. The TCRFTA versus placebo RCT found no difference in adverse effects (pain and acute complications) within three weeks of surgery.

Authors’ conclusions

The authors concluded that the scientific evidence is contradictory regarding the effect of LAUP, and there is insufficient scientific evidence for the effect of any other surgery in reducing the frequency of obstructive sleep apnoeas. There is insufficient scientific evidence for the effect of any surgical modality on daytime sleepiness (ESS), quality of life measured with the FOSQ, or arterial blood pressure.

Elshaug et al (2007a)

Appraisal of study methodology

Using a focused research question, the review by Elshaug et al (2007a) conducted a meta-analysis to highlight how OSA surgical success rates decrease when contemporary, evidence-based criteria of effectiveness are applied. The search period of the review was restricted to 2001–2005 and the language was restricted to English. Detailed search terms were specified; however, the review only searched the MEDLINE database, and did not report citation checking, handsearching of journals, or contact with authors. Systematic reviews of RCTs, RCTs, cohort studies, case-control studies and case-series that reported AHI before and after surgery for individual cases were included. Exclusion criteria were not reported. The review assessed all papers for selection bias, allocation bias, confounders, blinding, and data-collection methods. However, the appraisal method was not reported in any detail. Meta-analyses were performed using lower-level evidence and one RCT, and homogeneity was assessed. The review included extensive tabular data of included study characteristics and results of meta-analyses.

Included in the review were 17 evidence level IV studies (case-series) and one RCT (LAUP versus no treatment). Fourteen articles were identified for Phase I procedures and four for Phase II. Of the Phase I studies, seven included use of UPPP, three included LAUP, two included TCRFTA, and two included varied procedures. Of the Phase II procedures, the majority were simultaneous mandible and maxilla advancements. The combined sample size was 347 patients for Phase I and 38 patients for Phase II procedures, and OSA severity was not reported. The follow-up period was one year or less.
Efficacy

The review pooled polysomnography results to present success rates for the different surgical procedures. When success was defined as a 50% reduction in AHI and/or AHI ≤20, the success rate was 52% for UPPP, 49% for LAUP, 61% for TCRFTA, 78% for varied procedures, 55% for all Phase I procedures, and 86% for Phase II procedures. If the success criterion was lowered to AHI ≤10, the success rate was reduced to 34% for UPPP, 19% for LAUP, 34% for TCRFTA, 56% for varied procedures, 32% for all Phase I procedures 32%, and 45% for Phase II procedures. A stricter success criterion defined as AHI ≤5 further reduced success rates to 16% in UPPP, 7% in LAUP, 6% in TCRFTA, 32% in varied procedures, 13% in all Phase I procedures and 43% in Phase II procedures.

Safety

Safety was not reported in this review.

Authors’ conclusions

The authors emphasised that surgical ‘success’ decreases when new evidence-based criteria of success are applied. They argue that a reduction in AHI to ≤20 still confers the status of at least mild to moderate OSA, and the number of recipients who achieve even this modest reduction varies substantially. Although many surgery publications report statistically significant improvements in AHI, a distinction must be drawn between statistical significance and clinical significance. The authors propose that in future surgical audits, in addition to reporting the statistical significance of findings, ‘objective cure’ rates should also be reported (that is, outcomes based on AHI of ≤5, ≤10, or both).

Randomised controlled trial evidence

Two RCTs on UPPP (Lojander et al 1996; Wilhelmsson et al 1999), one RCT on LAUP (Ferguson et al 2003), and one RCT on TCRFTA (Woodson et al 2003) were already reported in the systematic reviews that were included in this rapid review. One additional RCT on palatal implants by Friedman et al (2008) was included separately, because it was published after the search date for the most recent systematic review. No RCTs that met the inclusion criteria were identified for other Phase I surgical procedures, or for any Phase II surgical procedures.

Friedman et al (2008)

Appraisal of study methodology

This RCT compared palatal implants with placebo. Participants had mild or moderate OSA, a Friedman tongue position I, II or III, a soft palate ≥2cm and <3.5cm, and a body mass index (BMI) <32kg/m². Exclusion criteria were clearly defined, and included people with severe OSA and with unsuitable anatomical features (stage IV of the Friedman staging system [Friedman tongue position IV; tonsil size 3 or 4]). The palatal implant procedure and the placebo procedure used identical implant tools, except the hollow needle of the delivery tool did not contain an implant in the placebo group. With this method, both patients and
investigators, including those performing the procedure, were blinded to allocation. The physician interpreting the polysomnography test was unaware of the patient’s allocation. The RCT reported adequate methodological detail. Sample size was determined by a power calculation, and block randomisation to palatal implant or placebo was performed by the manufacturer of the implants. Patients were assigned to groups using sequential sealed envelopes with device lot number to be used for each patient. The lot numbers that corresponded to group assignments were not revealed until after study completion. Participant characteristics and primary and secondary outcomes for the study were clearly defined, as were the statistical methods used. Intention-to-treat analysis was undertaken, and losses to follow-up were documented. The study also discussed adverse events, study limitations and generalisability of results.

Thirty-one patients were randomly assigned to surgery and 31 patients were assigned to the placebo procedure. The duration of follow-up was three months. A statistical comparison of baseline demographic parameters revealed that the two groups were similar in BMI and airway anatomy, although the palatal implant patients were slightly older compared with placebo patients ($P=0.0034$).

**Efficacy**

In the implant group, the post-treatment change in AHI was greater than in the placebo group ($P<0.0001$), and the success rate (defined as $\geq 50\%$ reduction in AHI and AHI $<20$) was also significantly greater in the implant group (13/31 patients [41.9%]) than the placebo group (0/31 patients [0%]) ($P<0.001$). The implant group had a greater (more improved) post-treatment change than the placebo group for snoring (visual analogue scale) ($P<0.0001$), ESS ($P=0.0002$), and average quality of life score (average of eight domains of the Short Form-36 version 2) ($P<0.0001$). The symptom success rate defined as $\geq 50\%$ decrease in snoring was 21/31 patients (68%) in the implant group and 0/26 patients (0%) in the placebo group.

**Safety**

The only reported complications were partial extrusion of the implant, which occurred in two participants. The implants were removed and replaced, but the authors noted that these incidents lead to group assignment being prematurely revealed for the two patients.

**Authors’ conclusions**

The authors concluded that the study provided evidence that the palatal implant procedure can significantly decrease AHI, improve quality of life, reduce snoring intensity, and decrease daytime sleepiness. They propose that the palatal implant procedure is a low morbidity, simple to use palatal treatment option for mild to moderate OSA and snoring. However, the limited study population of nonobese mild to moderate OSA patients with predominate palatal obstruction makes it difficult to generalise the results to patient groups with different anatomy, multiple areas of airway obstruction, or more severe OSA.
Summary of review findings

Overview
Four systematic reviews met the rapid review inclusion criteria, as did one additional RCT, which was published too recently to be included in any of the systematic reviews.

The four systematic reviews were of mixed quality. Only two contained more than one RCT and had a comprehensive search strategy that included searching multiple databases. Three of the reviews described their appraisal techniques adequately. Each review had particular limitations. As the review by Sher et al (1996) was published more than 10 years ago the evidence presented is outdated, particularly because no RCT evidence was available at the time of publication. The review by Elshaug et al (2007a) was performed for a specific purpose and only included polysomnography results, with no symptom, quality of life or safety data. The Cochrane review by Sundaram et al (2005) contained numerous errors in the results section relating to incorrect reporting of data, while the SBU (2007) review included an RCT of questionable relevance, which used a study population of patients with simple snoring (that is, non-OSA snoring) as well as patients with OSA. In general, the reviews that used lower-level evidence (levels III or IV) may be less reliable.

All reviews were restricted by the lack of RCT evidence. The RCTs that were included used different upper airway surgical procedures; included specific patient groups selected by OSA severity, anatomy or BMI; and used different comparators, such as conservative therapy, no treatment, placebo, or a device (CPAP or oral appliance). Thus, any meaningful pooling of RCT results and any direct comparisons between studies were precluded.

The sections below summarise the results and conclusions that can be drawn from the included systematic reviews and RCT, in light of their limitations mentioned above.

Safety
Three of the systematic reviews reported safety data for various surgical procedures. For UPPP, adverse effects reported in three reviews included perioperative airway obstruction, postoperative bleeding, infection, dysphagia, velopharyngeal insufficiency, nasopharyngeal stenosis, voice changes, taste and smell disturbances, vague foreign-body sensation, and persistent throat dryness. The SBU (2007) review provided complication frequency rates from 28 UPPP studies, and reported a death rate of 0–1.5%, a rate of serious peri and postoperative complications of 0–16%, and a rate of persistent adverse effects of UPPP of 14–62%. For LAUP, the SBU (2007) review reported one death in one study, and found from 20 UPP/LAUP studies that postoperative complications were reported in up to 5% of patients and persistent adverse effects were reported in 52–62%. Adverse effects reported in the reviews were similar to UPPP, and included dysphagia, bleeding, infection, nasal regurgitation, globus sensation, velopharyngeal stenosis, voice changes, taste and smell disturbances, and increased vomiting reflexes. For TCRFTA, adverse effects reported in two reviews included haemorrhage, haematomas, infection, swelling, palatal mucosal breakdown or mucosal ulcers, palatal fistula, uvula loss, transient choking sensation, and dysphagia. One
RCT in the review by Sundaram et al (2005) performed statistical analyses on adverse effects data and found no significant difference in TCFRTA compared with placebo for pain and swallowing difficulty. All of the above procedures were associated with postoperative pain, which was reported to last for several weeks in the cases of UPPP and LAUP and up to one week in TCFRTA (SBU 2007). The only complication reported in the RCT on palatal implants was the partial extrusion of the implant in two participants, which was subsequently resolved in both cases. The systematic review by Sher et al (1996) was the only review to report on any other surgical procedures, with the main adverse effect following either MMO or ISMO and GA with or without HM reported as being transient anaesthesia of the cheek, chin, or lower teeth.

**Effectiveness**

**Polysomnography**

**UPPP**

All four systematic reviews reported UPPP polysomnography results. The early review by Sher et al (1996) concluded from case-series evidence that UPPP is effective in about 50% of patients, and patients with retropalatal collapse only and with less severe OSA are more likely to benefit. Sundaram et al (2005) reported evidence from two RCTs. One had a UPPP success rate of 44% (defined as ODI₁ <10), which was significantly better than conservative management ($P<0.02$), while the other RCT reported a UPPP success rate of 51% (defined as AI<5 or AHI<10), which was significantly lower than oral appliance therapy ($P<0.05$). UPPP mean polysomnography results were not significantly different from conservative therapy results, but were significantly different compared with oral appliance therapy ($P<0.01$), with oral appliance therapy showing the greater improvement. The same findings were reported in the SBU (2007) review. Elshaug et al (2007a) found a success rate from case-series data of 52% if success was defined as a 50% reduction in AHI and/or AHI ≤20. However, this rate dropped to 16% if the stricter criterion of AHI ≤5 was used.

**LAUP**

Three systematic reviews reported polysomnography results for LAUP. Sundaram et al (2005) reported results from one RCT which found a significant improvement in AHI after LAUP compared with no treatment ($P=0.04$), and reported a success rate (AHI≤10) of 24%. The SBU (2007) review used data from two RCTs (one of which included simple snoring patients) to conclude that the weighted mean difference in AHI was not significantly different between LAUP and placebo or no treatment. In the review by Elshaug et al (2007a), the success rate based on RCT and case-series evidence was 49% if defined as a 50% reduction in AHI and/or AHI ≤20, or only 7% if defined as AHI ≤5.

**Palatal implant**

While evidence for the palatal implant procedure was not available for inclusion in the systematic reviews, one recent RCT by Friedman et al (2008) found that AHI was significantly improved in an implant group compared with a placebo group ($P<0.0001$). The implant success rate defined as a ≥50% reduction in AHI and AHI <20 was 41.9%, which was significantly better than the placebo ($P<0.001$).
**TCRFTA**

In the three systematic reviews that reported on TCRFTA, two (Sundaram et al 2005; SBU 2007) reported on one RCT that found that AHI was not significantly different in TCRFTA compared with placebo, but was significantly lower during CPAP use compared with TCRFTA ($P=0.004$). Success rates were not reported in these reviews, but in the review by Elshaug et al (2007a) the success rate based on case-series evidence was 61% if defined as a 50% reduction in AHI and/or AHI $\leq 20$, or 6% if defined as AHI $\leq 5$.

**ISMO and GA with or without HM**

The only evidence for ISMO and GA with or without HM was case-series evidence. Sher et al (1996) reported that the success rates in three studies varied between 38–79% when defined as a 50% decrease in RDI.

**Laser midline glossectomy and lingualplasty**

From case-series evidence reported in the review by Sher et al (1996), one study reported a success rate of 42% for laser midline glossectomy, while another reported a success rate of 77% for lingualplasty. Both studies defined success as a 50% decrease in RDI.

**MMO**

Again, for this procedure, only case-series evidence was available. The review by Sher et al (1996) found that the success rates was between 78–100% when performed after Phase I procedures, or with adjunctive procedures (based on two studies). Elshaug et al (2007a) reported from case-series data that the success rate was 86% when defined as a 50% reduction in AHI and/or AHI $\leq 20$, or 43% when defined as AHI $\leq 5$.

**Further considerations regarding polysomnography results**

It should be noted that for all study results, the sample characteristics including anatomical factors, body mass index, and OSA severity may have influenced rates of surgical success. The RCT by Friedman et al (2008) only included nonobese, mild OSA sufferers, while the majority of the included RCTs specified airway obstruction selection criteria to increase the patients group’s suitability for surgery. Sher et al (1996) presented some analysis on the most suitable patient group to undergo UPPP, while Sundaram et al (2005) commented that more studies are required to further establish how the nature of airway obstruction relates to symptomatic response and to determine whether there are subgroups of patients who would benefit from each type of surgery. Further research is also needed to identify and standardise techniques to identify the site of airway obstruction, as localisation of the site of airway obstruction may allow more specific selection of surgical procedures (Sundaram et al 2005).

The difficulty with comparing the effectiveness of surgery with a device was highlighted in the RCT that compared TCRFTA with CPAP. In this RCT, CPAP compliance was potentially inadequate (mean of 16.8 hours of use per week), and the authors of this review noted that it is important to distinguish CPAP efficacy (effect when used) from effectiveness (effect in everyday life). While polysomnography outcome measures unfairly compare CPAP efficacy with surgical effectiveness, other measures, such as symptom control and quality of life, compare CPAP effectiveness and as such may be more useful (Woodson et al 2003). The same issue applies to the RCT that compared UPPP with oral appliance therapy. Only 62% of
patients in the oral appliance group were using the device at four years; however, in these patients the compliance was more likely to be adequate, with patients using their appliance on average 6.1 nights per week (Walker-Engstrom et al 2002).

As discussed in the Elshaug et al (2007a) systematic review, another issue regarding use of polysomnography measures relates to the definition of surgical success. As yet, there is no substantial body of evidence to indicate how large a reduction in AHI or RDI is necessary for important clinical outcomes following surgery. All the reviews and RCTs had different measures for success in terms of polysomnography results, which made comparisons between success rates difficult. Thus, other clinical outcome measures, such as change in symptoms and quality of life, need to be used in conjunction with polysomnography results to evaluate surgical effectiveness.

**Symptom control and quality of life**

As discussed, polysomnography alone is not an ideal measure of treatment success, because it is poorly correlated with health outcomes such as sleepiness, quality of life or reaction time (Weaver et al 2005). The direct measurement of symptom control and quality of life in studies is desirable, so treatment outcomes can be assessed. Two of the systematic reviews and the individual RCT provided symptom and/or quality of life outcome measures.

**UPPP**

From data from two RCTs, the review by Sundaram et al (2005) found a significant difference in daytime sleepiness in favour of UPPP compared with conservative management ($P<0.01$ at 12 months). There was no difference in vitality and sleep between UPPP and oral appliance therapy, but a significant difference in contentment in favour of UPPP ($P<0.05$). Symptom and quality of life results for UPPP were not reported in any other review.

**LAUP**

Sundaram et al (2005) reported that one RCT found no significant difference in ESS, daytime sleepiness, unrefreshing sleep or quality of life between LAUP and no treatment, but a significant improvement in frequency ($P<0.005$) and intensity ($P<0.0001$) of snoring in favour of LAUP. Using data from two RCTs, the SBU (2007) review came to the same conclusion that there was no significant difference in ESS between LAUP and placebo or no treatment.

**Palatal implant**

The one RCT by Friedman et al (2008) found that, compared with placebo, the implant group had significantly greater post-treatment changes for snoring ($P<0.0001$), ESS ($P=0.0002$), and average quality of life score ($P<0.0001$).

**TCRFTA**

The review by Sundaram et al (2005) reported data from one RCT, which found no significant difference in ESS between TCRFTA and placebo, and no significant difference in ESS or quality of life between TCRFTA and CPAP. There was a greater improvement in quality of life in TCRFTA compared with placebo ($P=0.04$). Using data from the same RCT to calculate the mean difference, the SBU (2007) review found no significant difference between TCRFTA and placebo or CPAP for ESS and quality of life.
Patient satisfaction
Two of the RCTs included in the review by Sundaram et al (2005) reported satisfaction as a patient-reported outcome measure. Eleven out of 21 patients were satisfied with LAUP, while the level of satisfaction for any comparative procedure was not reported. Thirty out of 40 patients were satisfied with UPPP, while 23 out of 32 patients were satisfied with the comparator, oral appliance therapy. The term ‘satisfaction’ was not clearly defined.

Long-term survival
From the included systematic reviews and RCT there was no study which compared the long-term survival rate of those who had upper airway surgery with those who had alternative treatment.
Conclusions

Four systematic reviews, published between 1996 and 2007, were eligible for inclusion in this rapid review. The reviews evaluated a range of upper airway surgical procedures for OSA, and included four relevant RCTs that compared UPPP, LAUP and TCRFTA with conservative therapy, treatment with devices, or no treatment/placebo. An additional RCT on palatal implants was included in this rapid review. Conclusions based on the included systematic reviews and RCT are summarised below; however, a lack of evidence made it difficult to make conclusive judgments regarding the safety and effectiveness of upper airway surgery for OSA.

1. There was insufficient evidence to determine the effect of upper airway surgery on polysomnography results. From limited short-term evidence (follow-up ≤1 year), it appears that UPPP and TCRFTA do not present significant benefits in mean polysomnography outcomes compared with conservative management or placebo, although one UPPP study reported a higher success rate in UPPP compared with conservative management. One RCT of LAUP and one RCT of palatal implants found some benefit in surgery compared with no treatment or placebo in the short-term (follow-up of three months). Use of oral appliance therapy and CPAP produced better polysomnographic outcomes than surgery in the short-term (follow-up of four years for oral appliances versus surgery and eight weeks for CPAP versus surgery); however, unlike surgery, any device has the additional issue of compliance. Higher-level evidence was not available for any other procedures. Surgical success rates varied depending on the procedure, the patient population, and the actual definition of success. Phase I procedures appear to be successful in approximately half of patients, if the traditional definition of success is used (a 50% reduction in AHI and/or AHI ≤20). It is unclear from the evidence whether any surgical procedure is superior, and the long-term effectiveness of the various surgical techniques cannot be established.

2. There was insufficient evidence to determine the effect of upper airway surgery on daytime sleepiness or snoring. When compared with conservative management or no treatment/placebo, two RCTs suggested some benefit for UPPP and palatal implants for daytime sleepiness and snoring, while two other RCTs found no benefit for LAUP and TCRFTA for daytime sleepiness. There was no difference between surgery and use of devices (CPAP or oral appliances).

3. There was insufficient evidence to determine the effect of upper airway surgery on quality of life. One RCT found no benefit for LAUP, while two others reported possible benefit after TCRFTA and palatal implant compared with no treatment or placebo. There was no difference between surgery and use of devices.

4. There was insufficient evidence to determine levels of patient satisfaction for upper airway surgical procedures.
5. Long-term survival comparisons between upper airway surgery and alternative treatments were not available from the reviewed literature.

6. From limited safety evidence, it would appear that the traditional surgical technique of UPPP had more adverse effects than the less invasive procedures of TCRFTA and palatal implants. Although LAUP is a less invasive procedure than UPPP, it had similar adverse effects, at similar rates of occurrence. There was insufficient evidence to definitively determine the safety profiles of other surgical procedures. Long-term safety data were not available from the reviewed literature.

There was a lack of high-level evidence on upper airway surgery for OSA, and RCT results were generally limited by small sample sizes, short follow-up periods, and the inability to generalise results. Upper airway surgery for OSA does not provide significant benefit over conservative treatment or treatment with devices. Following failed conservative treatment or treatment with devices, selected patient groups with specific anatomical features, BMI and OSA severity may benefit from certain upper airway surgical techniques. However, at present, there is insufficient high-level evidence on the effectiveness of any surgical procedure, regardless of patient characteristics.

**Acknowledgements**

The authors wish to acknowledge Dr Prema Thavaneswaran and Dr Ann Scott for their assistance during the preparation of this review.
References


National Health and Medical Research Council (NHMRC). How to use the evidence: assessment and application of scientific evidence, NHMRC, Canberra, Australia 2000.


Appendix A: Search strategy

Literature search strategy

**BMJ Clinical Evidence**

#1 sleep AND (apnoea OR apnea) Field: Text Word

**Cochrane and York CRD**

#1 surgery Field: MeSH Terms [no explode]
#2 surgical procedures, operative Field: MeSH Terms [no explode]
#3 surgery Field: Text Word
#4 surg* Field: Text Word
#5 operat* Field: Text Word
#6 therapy Field: Text Word
#7 therap* Field: Text Word
#8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
#9 sleep apnea syndromes Field: MeSH Terms [no explode]
#10 sleep apnea Field: Text Word
#11 sleep apnoea Field: Text Word
#12 #9 OR #10 OR #11
#13 #8 AND #12

**PubMed**

#1 surgery Field: MeSH Terms [no explode]
#2 surgical procedures, operative Field: MeSH Terms [no explode]
#3 surgery oral Field: MeSH Terms [no explode]
#4 laser therapy Field: MeSH Terms [no explode]
#5 surgical procedures, minor Field: MeSH Terms [no explode]
#6 surgery Field: Text Word
#7 surg* Field: Text Word
#8 operat* Field: Text Word
#9 therapy Field: Text Word
APPENDIX A
#18 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17

#19 sleep apnea syndromes Field: MeSH Terms [no explode]

#20 sleep apnea Field: Text Word

#21 sleep apnoea Field: Text Word

#22 #19 OR #20 OR #21

#23 #18 AND #22

#24 random* Field: Text Word

#25 systematic AND review Field: Text Word

#26 #23 AND #24

#27 #23 AND #25

#28 #26 OR #27
Appendix B: Excluded studies

Excluded reviews


Bridgman SA, Dunn KM. Systematic review of the surgical treatment of obstructive sleep apnoea. *Journal of Clinical Excellence* 2000; 1(4): 217–220. (Same authors performed original Cochrane review, which has since been updated, with more RCTs.)


Felder S, Schmitt H. *Diagnosis and treatment of sleep apnea: an economic evaluation – systematic review*. Köln: German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information 2001. (German language.)

Franklin KA, Rehnqvist N, Axelsson S. Obstructive sleep apnea syndrome – diagnosis and treatment. A systematic literature review from SBU. *Lakartidningen* 2007; 104(40): 2878–2881. (Swedish language)


Excluded randomised controlled trials

*Eligible but already reported in the included systematic reviews*


Lojander 1996 (RCT incorporates the following two papers):


Wilhelmsson 1999 (RCT incorporates the following four papers):


Surgery versus alternative surgery


**Excluded for other reasons**


Naya MJ, Vicente EA, Asin J, Gargallo P. Multi-level treatment for obstructive sleep apnea syndrome: comparative study of four different surgical techniques of palate. *Acta Otorrinolaringologica Espanola* 2002; 53(2): 110–120. (Non-English language, Cochrane excluded because there was no comparison between the groups.)


Appendix C: Evidence tables

Table C1: Evidence table of appraised secondary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
<thead>
<tr>
<th>Review details</th>
<th>Aim and search method</th>
<th>Study design and inclusion/exclusion criteria</th>
<th>Included studies</th>
<th>Results</th>
<th>Authors conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sher et al (1996)</td>
<td>To review the literature covering the surgical treatment of OSA and to determine the efficacy of the various operations. (Also, to evaluate all available information about the association between the site of pharyngeal narrowing or collapse and the success of UPPP.)</td>
<td>Level of evidence: systematic review of level III and IV evidence. Inclusion criteria: All articles written in English that included only adult subjects (age older than 18 years) and were published between the dates listed (1966–1995). Exclusion criteria: Reviews, editorials, and letter, patient population &lt;9, a clear and unambiguous outcome measure was not reported, the patients had already been described in another included study, paper included snorers who may not have had sleep apnoea, or study lacked appropriate baseline data (AI or RDI). Study selection and appraisal methods: All studies meeting inclusion criteria were retrieved, and grouped according to type of surgical procedure described. Articles were excluded according to above criteria. Articles reviewed in detail by two reviewers.</td>
<td>54 articles met inclusion criteria: Interventions: nasal (1 study), tongue (5), tracheotomy (3), mandibular and maxillomandibular (M4) (4), UPPP (37), uvulopalatopharyngoglosso-plasty (UPPGP) (2) 37 UPPP papers divided into: - Group 1: include mean AI or RDI data (all studies). - Group 2: subgroup of group 1 with sufficient information to determine response rate (29 studies). - Group 3: further subgroup with raw data on AI or RDI (17 studies, plus additional 2 not included in group 1 or 2).</td>
<td>Polysomnography: UPPP: - Significant decrease in AI, RDI, BMI following UPPP: Group 1 UPPP studies post-treatment change:</td>
<td>- UPPP is, at best, effective in treating less than 50% of patients with OSA. - The site of pharyngeal narrowing or collapse, although identified by different and unvalidated methods, has a marked effect on the probability of success of UPPP. The ideal patient for treatment with UPPP appears to be one who has pharyngeal narrowing or collapse limited to the retropalatal region. - Patients who have a favourable response with UPPP tend to have less severe OSA than those who do not have a favourable response. - For patients who have retrognathial narrowing or collapse, other surgical modifications have been described, such as palatalplasty, GAHM, and maxillomandibular osteotomy and enlargement. - It would appear from the data reviewed that successful treatment of OSA requires judicious selection from among currently available surgical techniques. Regional-by-region analysis of the individual's pattern of airway compromise should guide the selection process. - The available surgical procedures, if applied in a logical fashion under a comprehensive protocol, may effectively treat the vast</td>
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</table>
Table C1 continued: Evidence table of appraised secondary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Sample size</th>
<th>OSA severity</th>
<th>Sample size</th>
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<th>Sample size</th>
<th>OSA severity</th>
<th>OSA severity</th>
<th>Complications</th>
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<tbody>
<tr>
<td>Laser midline glossectomy: 1 study reported success rate of 41.7% (defined as 50% decrease in RDI).</td>
<td>1 study</td>
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<td>Linguoplasty: 1 study reported success rate of 77% (defined as 50% decrease in RDI and achievement of RDI &lt;20).</td>
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<td>ISMO and GA with or without HM: 3 studies report success rates of:</td>
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<td>- 67% (defined as 50% decrease in RDI and achievement of RDI &lt;20) (with hyoid myotomy and suspension, 49/55 patients also had UPPP).</td>
<td>3 studies</td>
<td>mean RDI 65.6±18.3 and 58.0±13.7 (responders only for 1 study: mean 58.7±23.4)</td>
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<tr>
<td>- 37.5% (defined as 50% decrease in RDI and achievement of RDI &lt;20) (without hyoid myotomy and suspension), 65.3% (with hyoid myotomy and suspension), 79.2% (with modified hyoid suspension).</td>
<td>3 studies</td>
<td>mean RDI 68.3±23 and 44.9±17.5</td>
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<td>MMO: 3 studies report success rates of:</td>
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<td>- 97.8% (defined as 50% decrease in RDI and achievement of RDI &lt;20) (84/91 had undergone unsuccessful stage 1 operations).</td>
<td>3 studies</td>
<td>mean RDI 65.6±18.3 and 58.0±13.7 (responders only for 1 study: mean 58.7±23.4)</td>
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<td>- 20% (defined as RDI &lt;10) (MMO with no adjunctive procedure), 77.8% (with at least one adjunctive procedure), 100% (with UPPP as one of the adjunctive procedures).</td>
<td>3 studies</td>
<td>mean RDI 68.3±23 and 44.9±17.5</td>
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<td>- 100% (defined as RDI &lt;10) (MMO as sole treatment).</td>
<td>3 studies</td>
<td>mean RDI 68.3±23 and 44.9±17.5</td>
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<td>Complications:</td>
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<tr>
<td>UPPP: 18 papers reported safety; 9 papers reported no significant or long-term complications. Complications reported in remaining 9 papers: velopharyngeal insufficiency for greater than 1 month (n=14), postoperative bleeding (n=7), nasopharyngeal stenosis (n=5), voice change (n=4), successfully managed perioperative upper-airway obstruction (n=3), vague foreign-body sensation (n=1), death secondary to upper-airway obstruction (n=1).</td>
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<td>Complications in additional UPPP studies: One study (n=135) reported: airway difficulty (n=14) (10%) (13 managed successfully, 1 death), postoperative hemorrhage requiring reoperation (n=3) (2%).</td>
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<td>Another study (n=101) reported: postoperative airway obstruction (n=11) (11%) (10 managed successfully, 1 death), postoperative haemorrhage requiring reoperation (n=5) (5%). At 1 year: persistent velopharyngeal insufficiency (n=22) (24%), dry throat (n=28) (31%), swallowing complaints (n=9) (10%), breathing difficulty (n=5) (5%).</td>
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<td>Laser midline glossectomy: no permanent complications reported. In 1 study (n=22), 3 patients required general anaesthesia for postoperative bleeding; moderate odynophagia and dysphagia were common for 2–3 weeks after the operation; and 1 patient required intravenous hydration for prolonged odynophagia.</td>
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<td>ISMO and GA with or without HM: In 1 study (n=55): 1 patient had a wound infection, all patients developed transient anaesthesia of the lower anterior teeth, and 2 patients sustained injury to an incisor as a result of osteotomy.</td>
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<tr>
<td>MMO: In 1 study (n=306): all patients had transient anaesthesia of the cheek and chin, which resolved in 87% in 6–12 months; no motor nerve deficits, postoperative bleeding, or major skeletal relapse occurred. In another study (n=23): 12% of patients developed cardiac arrhythmias, including cardiac arrest.</td>
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</table>
Each study undertook different comparisons, precluding summary estimates of data.

Polysonomography:

- UPPP: UPPP versus conservative management: No significant difference in ODI in favour of UPPP (P < 0.001). Success rate at 1 year (50% reduction in ODI): 26/43 (60%) in UPPP; 30/37 (81%) in oral appliance (P = 0.05). Success rate at 1 year in LAUP (AHis10): 5/21 (24%) in LAUP; 4/24 (17%) in conservative management. Success rate in favour of CPAP (P = 0.004). Average CPAP use only 16.8 hr/week.

- TCRFTA versus placebo: No significant difference in AHI (TLRFTA –4.5; placebo –1.8) (P = 0.34).

- TCRFTA versus CPAP: AHI lower in CPAP than TCRFTA (TLRFTA 4.6; CPAP 16.8) representing a significant difference in the change from baseline between the two groups (of 10.7 events/hour) in favour of CPAP (P < 0.001).

Symptoms:

- UPPP: UPPP versus conservative management: Significant difference in symptoms of daytime sleepiness (visual analogue scale) in favour of UPPP at 3 (<0.001) and 12 months (<0.001).

- UPPP versus oral appliance therapy: At 1 year, no significant difference in vitality and sleep (Minor Symptoms Evaluation Profile quality of life questionnaire), but significant difference in favour of surgery reported for contentment (P = 0.05). At 4 years 30/40 patients were satisfied with UPPP; 23/32 patients were satisfied with oral appliance therapy.

LAUP:

- LAUP versus conservative management: No significant difference in ESS or in number of patients reporting unrefreshing sleep and excessive daytime sleepiness, or in quality of life (Calgary Sleep Apnoea Quality of Life Index). Significant improvement in frequency (P < 0.005) and intensity (P < 0.001) of snoring in favour of LAUP. 11/21 patients satisfied with LAUP, 13/21 patients had little or no difficulty undergoing surgery.
### Table C1 continued: Evidence table of appraised secondary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

| Duration: Lojander et al 1996 (1 year) and Tegelberg et al 1999 (4 years) had follow-up ≥1 year. All others had follow-up <1 year.  |
| Outcomes: polysomnography, symptoms, quality of life  |
| Withdrawal: withdrawal rates recorded by all studies.  |

| Exclusion criteria:  |
| - Participants: children  |

| Study selection and appraisal methods:  |
| Two independent assessors selected trials for inclusion, and assessed the methodological quality of eligible trials (based on the degree of allocation concealment and the likelihood of bias, using the Jadad instrument).  |

| LAUP: Ferguson et al 2003  |
| TCRFTA: Woodson et al 2003  |
| Surgery versus device:  |
| UPPP: Tegelberg et al 1999  |
| TCRFTA: Woodson et al 2003  |

| Comparison of different surgical interventions: Not relevant to this rapid review.  |
| UPPP versus lateral PP: Cahali et al 2004  |
| LAUP versus BRVTR: Atef et al 2005  |
| Tongue advancement (mandibular osteotomy) with PPP versus tongue suspension with PPP: Thomas et al 2003  |
| RAUP versus submucosal channelling of the palate: Bassiony et al 2007  |

| Duration:  |
| Lojander et al 1996 (1 year) and Tegelberg et al 1999 (4 years) had follow-up ≥1 year. All others had follow-up <1 year.  |
| Outcomes: polysomnography, symptoms, quality of life  |
| Withdrawal: withdrawal rates recorded by all studies.  |

| TCRFTA:  |
| TCRFTA versus placebo: † No significant difference between groups for change in ESS (P=0.12). Significantly greater improvement in quality of life (Functional Outcomes of Sleep Questionnaire) in favour of TCRFTA † (P=0.04).  |
| TCRFTA versus CPAP: No significant difference in ESS or quality of life (FOSQ) (both groups improved significantly from baseline for both measures).  |

| Complications:  |
| UPPP:  |
| UPPP versus conservative management: 22% in surgery group † (4/18). Removal of infected material (2), tracheostomy (1), dysphagia (2). Myocardial infarction (1) and transient ischaemic attack (1) also in surgery group.  |
| UPPP versus oral appliance therapy: In surgical group: fibrotic narrowing without symptoms (3), nasopharyngeal regurgitation of fluid (8%), dysphagia (10%). In oral appliance group: recurrent aphthous ulcers due to allergic reaction to acrylic polymer (1), discomfort (2). Minor defects in 5 appliances, repair required in 7, repeated adjustments in 1.  |
| LAUP:  |
| LAUP versus conservative management: Moderate–severe pain (17/21; 81%), dysphagia (4/21; 19%), bleeding (9/21; 43%), nasal regurgitation (5/21; 24%), infections (4/21; 19%), temporary change in vocal quality (1/21; 5%) † Sample size (denominator) obtained from primary paper.  |

| TCRFTA:  |
| TCRFTA versus placebo: No significant difference in frequency and severity of complications (3 haematomas in each group, 1 ulceration in TCRFTA group), postoperative pain, or swallowing difficulty (increased in both groups after 1 week before abating to baseline levels). Data from limited number of participants.  |
| TCRFTA versus CPAP: As for TCRFTA versus placebo (above). In CPAP, 20/21 participants had side effects (nasal symptoms, inconvenience, sleep interruption, air mechanics, skin or eye symptoms).  |

### Review notes:

†corrections or ‡Additional important results or obtained from primary study paper(s).

The results for the study termed Tegelberg et al 1999 include results from additional papers (Wilhelmsson et al 1999; Walker-Engstrom et al 2000; Walker-Engstrom et al 2002). The results for the study termed Lojander 1996 include results from an additional paper (Lojander et al 1999).
Table C1 continued: Evidence table of appraised secondary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
<thead>
<tr>
<th>Review details</th>
<th>Aim and search method</th>
<th>Study design and inclusion/exclusion criteria</th>
<th>Included studies</th>
<th>Results</th>
<th>Authors conclusions</th>
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<tbody>
<tr>
<td>SBU (2007) Statens beredning för medicinsk utvärdering (SBU), Stockholm, Sweden</td>
<td><strong>Aim:</strong> To examine the benefits of treatment for OSA on daytime impairment and blood pressure in randomised controlled trials. To examine types and frequencies of adverse effects from treatment and compliance regardless of study design.</td>
<td><strong>Level of evidence:</strong> 1 (systematic review of level II evidence) <strong>Inclusion criteria:</strong> Efficacy section (benefits of treatment): - RCTs - Participants: Trials with ≥20 adults followed for a minimum of 4 weeks. Trials including patients investigated for suspicion of OSA and trials with patients with OSA. - Treatment: any intervention aimed at reducing obstructive apnoea/hypopnoea. - Primary outcome: daytime sleepiness ESS, multiple sleep latency test, maintenance of wakefulness test. - Secondary outcomes: standardised generic or disease-specific, self-reported measures of functioning and wellbeing, AHI or respiratory disturbances index, blood pressure (24 hour).</td>
<td><strong>Efficacy section:</strong> 30 trials met inclusion criteria. Surgery versus sham or conservative treatment: 3 parallel studies - <strong>Sample size:</strong> 134 - <strong>Mean age:</strong> 47 - <strong>OSA severity:</strong> Mean AHI 17, Mean ESS 11 - <strong>Intervention:</strong> LAUP in 2 studies (Ferguson et al 2003 [versus no treatment]; Larrosa et al 2004 [versus sham/placebo surgery]). TCRFTA in 1 (Woodson et al 2003) - <strong>Duration:</strong> 8 weeks to 7 months - <strong>Outcomes:</strong> AHI, ESS, quality of life (FOSQ) Surgery versus device: 1 study - <strong>Sample size:</strong> 80 - <strong>Mean age:</strong> 50 - <strong>OSA severity:</strong> Mean AHI 19±5 - <strong>Intervention:</strong> UPFF versus oral appliance therapy (mandibular repositioning appliance): Wilhelmson et al 1999 - <strong>Duration:</strong> 1 year - <strong>Outcomes:</strong> AHI (Data also reported elsewhere in review for additional study Woodson et al 2003: TCRFTA versus CPAP: - <strong>Sample size:</strong> 60 - <strong>Mean age:</strong> 49±5 - <strong>OSA severity:</strong> Mean AHI 19±5 - <strong>Intervention:</strong> TCRFTA versus CPAP - <strong>Duration:</strong> 8 weeks</td>
<td><strong>Polysomnography:</strong> UPPP: Oral appliance therapy versus UPPP (1 study): AHI weighted mean difference (95%CI): –4.5 (–8.5, –0.50) (P=0.03). Significant difference in favour of oral appliance therapy, but study did not investigate patients who did not comply with appliances at follow-up. LAUP: LAUP versus placebo/no treatment (2 studies): AHI weighted mean difference (95%CI): –3.1 (–14.3, 8.1) (P=0.59). Conflicting evidence as 1 study found no effect of LAUP versus placebo/no treatment while the other found a reduction in AHI. TCRFTA: TCRFTA versus placebo (1 study): AHI weighted mean difference (95%CI): 3.2 (–2.3, 8.7) (P=0.25). CPAP versus TCRFTA (1 study): AHI weighted mean difference (95%CI): –12.2 (–18.0, –6.4) (P=0.0001) in favour of CPAP. <strong>Symptoms (ESS, quality of life):</strong> UPPP: Oral appliance therapy versus UPPP (1 study): ESS: NR. Quality of life: NR. LAUP: LAUP versus placebo/no treatment (2 studies): ESS weighted mean difference (95%CI): –1.2 (–3.9, 1.6) (P=0.40) (Note: decrease in ESS denotes less sleepiness). Quality of life: NR. TCRFTA: TCRFTA versus placebo (1 study): ESS weighted mean difference (95%CI): –0.8 (–3.1, 1.5) (P=0.50). Quality of life (FOSQ) standardised mean difference (95%CI): 0.24 (–0.33, 0.81) (P=0.41). CPAP versus TCRFTA (1 study): ESS weighted mean difference (95%CI): 0.5 (–2.3, 3.3) (P=0.72). Quality of life (FOSQ) standardised mean difference (95%CI): 0.09 (–0.69, 0.52) (P=0.78). <strong>Complications:</strong> UPPP: - 30 deaths reported in 6 studies (causes of deaths: respiratory compromise, bleeding, intubation difficulties, infections, and cardiac arrest). Mean frequency of 0–1.5%. - Serious perioperative and postoperative complications reported in 0–16% (respiratory compromise, bleeding, intubation difficulties, reintubation, emergency tracheostomy, infections, and cardiovascular complications). - Postoperative pain reported for 12–14 days. - Persistent adverse effects of UPPP: 14–62% (including: difficulty swallowing (28%; 13–36%),...</td>
<td>- The scientific evidence is contradictory regarding the effect of LAUP, and there is insufficient scientific evidence for the effect of any other surgery in reducing the frequency of obstructive sleep apnoea. - There is insufficient scientific evidence for the effect of any surgical modality on daytime sleepiness (ESS), quality of life measured with the FOSQ, or arterial blood pressure. - The adverse effects of UPPP due to snoring or OSA include serious perioperative and postoperative complications, including death, bleeding and respiratory compromise. Persistent adverse effects are frequent, and difficulty in swallowing occurs in about 28% of patients. Voice changes are also common. - The adverse effects of UPP and LAUP due to snoring or OSA include serious postoperative complications. Persistent adverse effects occur in 50–80% of patients and difficulty swallowing in about 26%. Glottis sensation in the throat and voice changes are common.</td>
</tr>
</tbody>
</table>
### Table C1 continued: Evidence table of appraised secondary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
<thead>
<tr>
<th>Comparison group, observation time or indication of the treatment)</th>
<th>Outcomes: AHI, ESS, quality of life (FOSQ)</th>
<th>Different surgical interventions: Not relevant to this rapid review</th>
<th>UPPP versus lateral PP: Cahali et al 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclusion criteria:</td>
<td></td>
<td>Safety section:</td>
<td></td>
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<tr>
<td>- Studies aimed at reducing daytime sleepiness but not OSA.</td>
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<td>46 trials addressed the question concerning adverse effects of surgery due to snoring and sleep apnoea.</td>
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<tr>
<td>- Studies written in languages other than Danish, English, Finnish, French, German, Icelandic, Norwegian, Spanish or Swedish.</td>
<td></td>
<td>Sample size: NR.</td>
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<tr>
<td>Study selection and appraisal methods:</td>
<td></td>
<td>Mean age: 30–54.</td>
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<tr>
<td>Titles and abstracts screened for relevance, two independent readers went through full reports of potentially relevant articles for inclusion.</td>
<td></td>
<td>OSA severity: Mean AHI 5–59 (range 0–89)</td>
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<tr>
<td>RCTs assessed for methodological quality using Jadad rating scale. Data independently extracted by two reviewers.</td>
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<td>Intervention: 28 studies were on UPPP, 20 on uvulopalatoplasty (UPP) and LAUP, and 9 on TCRFTA.</td>
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<td>Duration: 18 hours to 8 years</td>
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<td>globus sensation (40%), voice changes (7–14%), persistent throat dryness (3–56%), smell disturbances (8%), taste disturbances (7%), velopharyngeal insufficiency (3%), velopharyngeal stenosis (single cases)).</td>
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<td>- 11% of patients regretted the surgery, according to one study.</td>
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<td>UPP and LAUP:</td>
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<td>- 1 death due to sepsicaemia reported in 1 study.</td>
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<td>- Postoperative complications reported in 5% (postoperative bleeding, local infections, temporal palatal incompetence).</td>
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<tr>
<td>- Postoperative pain reported for 10–18 days.</td>
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<tr>
<td>- Persistent adverse effects of UPP/LAUP: 57% (52–62%) (including: difficulty swallowing (26%; 19–29%), globus sensation (17–36%), voice changes (6–10%), smell disturbances (8%), taste disturbances (7%), increased vomiting reflexes (4%), velopharyngeal stenosis (single cases)).</td>
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<tr>
<td>- 13–22% of patients regretted the surgery.</td>
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<td>TCRFTA:</td>
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<tr>
<td>- Perioperative and postoperative complications reported: palatal mucosal breakdown or mucosal ulcers (3–37%), palatal fistula (2%), uvula loss (2–7%), haemorrhage (5%), infections (% NR), transient choking sensation (28%), difficulty swallowing (13%), pain (19%), 1 study reported tongue base abscess in 1/18 patients and severe tongue swelling in 3/18. Another reported tongue base abscess in 2/20 patients and mouth floor oedema in 2/30. The RCT (Woodson 2003) found no difference in adverse effects (pain and acute complications) within 3 weeks of surgery (active TCRFTA or placebo).</td>
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<tr>
<td>- Postoperative pain reported for 3–7 days.</td>
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<td>- No long-term follow-up studies on adverse effects of TCRFTA identified.</td>
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</table>
### Table C1 continued: Evidence table of appraised secondary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
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<tr>
<th>Review details</th>
<th>Study design and inclusion/exclusion criteria</th>
<th>Included studies</th>
<th>Results</th>
<th>Authors conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elshaug et al (2007a)</td>
<td><strong>Aims:</strong> To conduct a meta-analysis to highlight how OSA surgical success rates decrease when contemporary, evidence-based criteria of effectiveness are applied. <strong>Search period:</strong> 2001–2005 <strong>Databases searched:</strong> MEDLINE</td>
<td><strong>Level of evidence:</strong> systematic review of level II and IV evidence <strong>Inclusion criteria:</strong> - Systematic review of or individual randomised controlled trial or trials, cohort study, case-control study, case-series. - Report presurgical and postsurgical AHI for individual cases. <strong>Exclusion criteria:</strong> NR</td>
<td><strong>Polysonmography:</strong> Success defined as 50% reduction in AHI and/or AHI ≤20:</td>
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<td></td>
<td><strong>Outcome:</strong> polysomnography (AHI)</td>
<td><strong>UPPP</strong> 178 (7) 51.5 (44.3–58.7) 81.3% (56.6–89.2)</td>
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<td><strong>UPPP</strong> 178 (7) 51.5 (44.3–58.7) 81.3% (56.6–89.2)</td>
<td><strong>LAUP</strong> 72 (3) 48.6 (37.8–60) 82% (0–92.3)</td>
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<td><strong>TCRFTA</strong> 36 (2) 60.8 (45–75.5) Undefined</td>
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<td><strong>Varied</strong> 61 (2) 77.9 (66.9–87.2) Undefined</td>
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<td><strong>All Phase I</strong> 347 (14) 55 (43.6–68.2) 79.3% (64.1–86.3)</td>
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<td><strong>Phase II</strong> 38 (4) 86 (70–95) NR</td>
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<td><strong>Complications:</strong> NR</td>
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### Note:
- Surgical success decreases when new evidence-based criteria of success are applied.
- A reduction in AHI to ≤20 still confers the status of at least mild to moderate OSA, and the number of recipients/patients who achieve even this modest reduction varies substantially.
- This has implications for health outcomes of individuals with OSA and for what may be deemed clinically and cost-effective treatment.
- Although many surgery publications report statistically significant improvements in AHI, a distinction must be drawn between statistical significance and clinical significance.
- The authors propose that in future surgical audits, in addition to reporting the statistical significance of findings, objective cure rates are also reported (that is, outcomes achieved based on AHI of ≤5, ≤10, or both).
Table C2: Evidence table of appraised primary studies relating to upper airway surgery for treating adult obstructive sleep apnoea

<table>
<thead>
<tr>
<th>Study details</th>
<th>Aim and Intervention</th>
<th>Study design and inclusion/ exclusion criteria</th>
<th>Study population</th>
<th>Results</th>
</tr>
</thead>
</table>
| Friedman et al (2008) Department of Otolaryngology and Broncho-esophagology, Rush University Medical Centre, Chicago, Illinois | **Aim:** To compare palatal implants with placebo. Palatal implants Palatal implant (Restore Medical Inc, ST Paul, MN) using implant tools provided by manufacturer. Comparator (placebo) Palatal implant insertion tools identical, except hollow needle of delivery tool did not contain an implant. | **Level of evidence:** II **Method of randomisation:** Block randomisation to palatal implant or placebo performed by manufacturer. Patients assigned to groups using sequential sealed envelopes with device lot number to be used for each patient. The lot numbers that corresponded to group assignments were not revealed until after study completion. **Blinding:** Polysomnography interpreted by physician unaware of patient’s allocation. Patients and investigators blinded to allocation. **Duration of follow-up:** 3 months (median 96±17 days for surgery, 94±5 for placebo). **Losses to follow-up:** 7 (2 surgery, 5 placebo) (defined as unsuccessful in intention to treat analysis). **Study period:** 2005–2006 **Inclusion criteria:** History of OSA and/or symptoms of OSA (significant snoring and excessive daytime sleepiness), Friedman tongue position I, II or III, diagnosis of mild or moderate OSA (AHI ≥5 and <40), soft palate ≥2cm and <3.5cm, BMI <32 kg/m². **Exclusion criteria:** Severe OSA (ESS >20), frequent choking and gasping during sleep, and AHI ≥40), unwilling to be randomised to placebo group, Friedman tongue position IV, tonsil size 3 or 4, stage IV of the Friedman staging system. **Patients excluded:** NR | **Sample size:** Surgery: 31 Placebo: 31 **Age (mean years±SD):** Surgery: 48.1±11.2 Placebo: 39.0±9.9 **Sex mix (male/female):** Surgery: 18/13 Placebo: 15/16 **OSA severity:** Mild–moderate OSA Mean AHI±SD: Surgery: 23.8±5.5 Placebo: 20.1±4.0 **Previous medical treatment:** NR | **Polysomnography:** | Polyso...